Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in obesity management

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Doctor of Professional Studies

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Abstract

This project focused on evaluating, constructing and integrating standardised clinical data-collection tools for obesity management in personalised nutrition practice. A mixed methods research design including surveys and interviews was used. A collaborative Delphi survey method was undertaken with purposefully selected stakeholder participants, who then contributed to the construction of four new tools.

The project comprised of two research questions:

1. Is it possible and ethical to standardise a personalised approach to nutrition practice?
2. If so, what tools can be constructed and validated to help individual health history data collection, clinical decision making and clinical outcome analysis to enable the development of a case-by-case evidence base for personalised nutrition practice in the management of obesity?

Theoretical frameworks that influenced the project include: the functional medicine approach, clinical psychoneuroimmunology (cPNI), the interdisciplinary approach of systems science, pathophysiological mechanistic reasoning and translational bioinformatics. The project focused on personalised nutrition practice, which is primarily centred on nutritional therapy but also draws on the practice of dietitians, nutritionists, functional medicine and cPNI practitioners.

The research project had five stages included in the overall design. The first was a literature review undertaken to inform the project approach and tool development. The second stage involved gathering, categorising and evaluating existing tools. Surveys and interviews assessed practitioner experiences of using tools, while interviews with statisticians and academics evaluated their experiences and views on tool development to inform the development of new tools. The third stage was the Delphi method: a multi-staged, collaborative survey resulting in the development of four new clinical tools. The fourth stage was a pilot trial which aimed to achieve face validity and measure feasibility and utility for each of the four tools. The final stage included a survey and interviews which aimed to evaluate ways standardised tools could be successfully embedded into personalised nutrition practice.

The findings showed that there were few ethical concerns with utilising standardised data-collection tools in nutrition practice, but there were numerous ethical considerations in relation to the development of a case-by-case evidence base for personalised nutrition practice. It was possible to construct new tools aimed at standardising individual health

history data collection and clinical outcome analysis in order to support clinical decision making, but it was not possible to validate these tools.

This project has been the first of its kind: a synthesis of different nutritional practice approaches to support the development of robust translational bioinformatics tools using pathophysiological reasoning. The results have created new knowledge in terms of understanding, defining and developing an evidence-based personalised nutrition practice approach. This could lead to major change initiatives and enhance and strengthen the nutrition profession.

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Abbreviations and Acronyms

AfN	Association for Nutrition
BANT	British Association of Applied Nutrition and Nutritional Therapy
BDA	British Dietetics Association
BMI	Body mass index
BMJ	British Medical Journal
BSE	Bovine spongiform encephalopathy
CER	Comparative effectiveness research
CNELM	Centre for Nutrition Education and Lifestyle Management
CNHC	Complementary and Natural Healthcare Council
CPD	Continued professional development
cPNI	Clinical psychoneuroimmunology
DProf	Doctorate of Professional Studies
EBM	Evidence-based medicine
EEQ	Emotional eater questionnaire
FHH	Family health history
FM	Functional medicine
GDPR	General data protection regulation
GP	General practitioner
HEE	Health Education England
HPC	Health Professions Council
HRA	Health risk assessment
HRT	Hormone replacement therapy
IFM	Institute of Functional Medicine
IPA	Interpretive phenomenological analysis
IPAQ	International physical activity questionnaire
MU	Middlesex University
MYMOP	Measure yourself medical outcomes profile
NCOR	National Council for Osteopathic Research
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NOS	National occupational standards
NT	Nutritional therapist
NTEC	Nutritional Therapy Education Commission
OSN	Organisation Studies Network
PCA	Principal component analysis

PM	Personalised Medicine
PNI	Psychoneuroimmunology
PPGR	Post-prandial glycaemic response
PSA	Professional Standards Agency
QOL	Quality of life
QOLOD	Quality of life, obesity and dietetics
QQ10	10-item self-completed validity questionnaire
RCT	Randomised control trial
RSM	Royal Society of Medicine
SML	Statistical machine learning
UKVRN	UK Voluntary Register of Nutritionists
WHO	World Health Organization

Chapter 1: Introduction

This DProf research has been a five-year project to evaluate, construct and integrate standardised clinical data-collection tools for obesity management in personalised nutrition practice. Four new clinical tools have been constructed for individual health data collection and clinical outcome analysis, which aim to support clinical decision making. Numerous complex considerations which have impacted on the development and use of standardised data-collection tools in personalised nutrition practice were analysed. The practical, professional, institutional and ethical implications of what it would take to develop a viable and successful personalised nutrition practice model were explored.

This chapter outlines the objectives of this project, its theoretical underpinnings and terms of reference. It explores the context of this project within my doctoral studies, my background, and how my own ethical and personal philosophies impact upon this project. It also sets out the contents of each chapter.

1.1 Background

This project stems from the observation that nutrition and health care practitioners do not routinely assess data on the outcomes of their patients and even less frequently compare the outcomes of similar patients (Kurtin and Stucky, 2009) in any meaningful, robust or standardised way.

As a nutritional therapist, I am keen to understand the efficacy of interventions that my clients experience in order to inform my own clinical decision making. Tools that pool health data from an obese population and statistically analyse the effect of changing variables (diet, supplements, sleep, stress, etc.) on signs, symptoms and biomarkers of health could provide a robust assessment of patient outcomes. This may also enable the development of a new, case-by-case evidence base, which could provide evidence on the efficacy of interventions and further support clinical decision making, thereby increasing positive health outcomes for patients. Such an evidence base could then utilise statistical machine learning to make probabilistic predictions for the management of obesity.

There are numerous limitations to using clinical trials to develop an evidence base for personalised nutrition practice (Gibson et al., 2010a), not least because research for nutrition and health cannot be modelled on a linear cause-and-effect relationship between one nutrient and one physiological effect (Fardet & Rock, 2014). Foods and the human body are both multivariable complex systems and our response to nutrients appears to be an individual and personal attribute (Whelan et al., 2010). Both deductive and inductive reasoning are required to make clinical decisions (Kyriacou, 2004). The development of a

case-by-case evidence base may better enable us to understand the impact of diet and nutrition on complex health issues such as obesity, diabetes mellitus, cancer, hypertension and other chronic diseases.

Dietetics is currently the only nutrition practice available via the NHS. Making nutritional therapy accessible through mainstream health care provision (i.e. to offer equality of access) is important to me. Nutritional therapy claims to be a client-focused, evidence-based, bioscience complementary therapy (Benbow et al., 2017), however nutrition therapy is not one of the 'big five' complementary therapies provided in mainstream health care. Assessing the effectiveness of nutrition interventions and enabling the development of its evidence base appears essential if nutritional therapy practice is going to be accepted (or integrated) into mainstream health care provisions.

Standardised data-collection tools would provide opportunities to:

- make audit tools available to help practitioners understand the efficacy of their own practice outcomes (Johnston et al., 2000);
- support therapists' clinical decision making and improve their practice outcomes (Paul, 1993);
- create a new, case-by-case, evidence base for nutritional practitioners, using Bayesian Networks, Bayesian Statistics and Statistical Machine Learning to make probabilistic predictions from empirical data;
- create roles for practitioner researchers within the profession; and
- move towards integration or acceptance of nutritional therapy in mainstream clinical medicine.

1.2 Aims and objectives of the project

This research project aimed to:

- evaluate the ethics, limitations and opportunities of standardising data-collection methods in personalised nutrition practice;
- construct new clinical tools for health data collection, clinical decision making and clinical outcome analysis that standardise case data-collection methods and enable assessment of the efficacy of interventions; and
- enable the development of a new, case-by-case, evidence base for personalised nutrition practice in obesity management.

The overarching objectives were to:

- use a mixed methods collaborative research approach to achieve these aims;

- gather and evaluate existing clinical tools and review implications for standardising data-collection methods;
- collaboratively construct and trial new tools; and
- evaluate how these tools can be successfully integrated into practice.

1.3 Research questions

The main questions that the project is designed to answer are:

1. Is it possible and ethical to standardise a personalised approach to nutrition practice?
2. If so, what tools can be constructed and validated to help individual health history data collection, clinical decision making and clinical outcome analysis to enable the development of a case-by-case evidence base for personalised nutrition practice in the management of obesity?

1.4 Terminology used

Some of the terminology used in this project is explained in this section to provide further clarity. These terms may be specific to my professional background or have various meanings.

Abductive, inductive and deductive reasoning – reasoning uses existing knowledge to draw conclusions, make prediction or provide explanations. Abductive reasoning begins with an incomplete set of observations and proceeds to the most likely explanation. Inductive reasoning makes broad generalisations from specific observations. Deductive reasoning starts with a broad generalisation and moves towards specific conclusions.

Adiposity - a condition of being severely overweight, or obese.

Biomedical - relating to both biology and medicine.

Body mass index (BMI) - a person's weight in kilograms (kg) divided by his or her height in meters squared. A measure used to work out if an individual's weight is healthy.

Client – an individual who has sought nutrition intervention through a professional nutrition practitioner. Some nutrition practitioners, such as dietitians, use the word 'patient', so this appears in some of the surveys and interview discussions. The terms 'client' and 'patient' can be used interchangeably.

Clinical psychoneuroimmunology (cPNI) – is a systems biology-based clinical reasoning method which incorporates nutritional interventions. "Psychoneuroimmunology is the study of the interactions among behavioural, neural, endocrine, and immune processes" (Daruna and Daruna, 2012, p. 9).

Dietetics – the science or art of applying the principles of nutrition to the diet.

Functional medicine – “is a systems biology-based clinical approach that focuses on identifying and addressing the root cause of disease” (IFM, 2018). Functional medicine incorporates nutritional interventions.

Informatics - the science of processing data for storage and mining; information science.

Mechanism – refers to a physiological or pathophysiological process. A pathophysiological mechanism seeks to explain pathology as a deviation from the normal physiological function of a process or mechanism of disease. Mechanistic reasoning aims to provide a pathophysiological rationale.

Nutrition practice – clinical practice by nutrition practitioners. Chapter 2 explores various approaches to clinical nutrition practice.

Nutrition practitioner – this means dietitians, nutritionists, nutritional therapists (NTs). The use of ‘nutrition practitioner’ aims to be more inclusive and overcome any issues related to collaboration.

Obesity – a complex health disorder in which excess body fat accumulated, where an individual has a BMI (Body Mass Index) of 30 and above.

Ontological - the branch of metaphysics dealing with the nature of being.

Pathophysiological reasoning – Pathophysiological reasoning is an approach to clinical decision making through the understanding of pathophysiological mechanisms of disease.

Pathophysiology – the application of a convergence of pathology with physiology as a means to understand disease processes.

Personalised – Nardini et al. (2012) recognise various meanings of ‘personalised’: one referring to tailoring to an individual’s needs and another referring to interventions based on the genetic profile of the individual. The terms ‘personalised’, ‘tailored’ and ‘individualised’ can be used interchangeably. Currently, personalised nutrition includes tailored or individualised dietary counselling, which may include nutritional interventions based on the client’s genetic profile. This report further explores the meaning of ‘personalised’ and ‘personalised nutrition practice’.

Precision medicine – “an innovative approach to tailoring disease prevention and treatment that takes into account differences in people’s genes, environments, and lifestyles” (US FDA, 2017).

Reductionism - the practice of analysing and describing a complex phenomenon in terms of its simple or fundamental constituents, especially when this is said to provide a sufficient explanation.

Stratification – the arrangement or classification of something into different groups.

Stratified medicine – "is based on identifying subgroups of patients with distinct mechanisms of disease, or particular responses to treatments" (Medical Research Council, 2017).

Systems biology – is the study of complex biological networks. It frequently utilises mathematical and computational modelling to study the complex interactions within biological systems (Yan, 2012).

Tool(s) – this refers to clinical instruments used by nutrition practitioners to record client data. It includes both paper tools, like questionnaires, and online applications such as diet and exercise trackers.

Translational – "the process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease. The philosophy of 'bench to bedside' underpins the concept of translational medicine, i.e. basic research (bench) to patient care (bedside)." (Office for Translational Research, 2017).

1.5 Scope of the project

The scope of the project is important to define in order to ensure both depth and breadth of analysis could be achieved and to clearly delineate boundaries (Baxter, 2008). This project focuses on personalised nutrition practice – which mainly centres on nutritional therapy practice – but also draws on the knowledge of other nutritional practitioners such as dietitians, nutritionists, functional medicine and cPNI practitioners. The purpose of this was the development of collaborative relationships and the insight of various approaches to nutrition practice.

The decision to limit the project by focusing on one health condition, obesity, had strengths in that it provided a more targeted research scope and a definable target population. Obesity has a complex aetiology, it is linked to many other health conditions and comorbidities, so this choice allowed for the consideration of numerous complex health issues that individual clients present with. However, focusing on obesity did limit the number of practitioners and clients that could participate in pilot trialling the tools. Obesity is also a disease focused approach, which is problematic in a personalised approach. These limitations are explored further throughout the project. Obesity was chosen because it is a key research topic at the Centre for Nutrition Education and Lifestyle Management (CNELM), where I work.

1.6 The researcher and role within project

I am the Head of Education at CNELM, leading and directing educational courses in nutritional science and personalised nutrition. Although this project was funded by my

workplace, this research is not about my workplace. The majority of our students become student members of the professional body, the British Association for Nutrition and Lifestyle Medicine (BANT). Successful completion of our Nutrition Therapy Education Council (NTEC) accredited courses enables our graduates to apply to register with the Complementary and Natural Healthcare Council (CNHC) which is the UK voluntary regulator for complementary health care practitioners, including NTs. Graduates may then also choose to become full BANT members. My roles at CNELM include, but are not limited to:

- leading, directing and developing programmes;
- senior management and senior academic team member;
- module leading and teaching;
- undertaking staff development;
- clinical supervision; and
- research supervision.

I was a student at CNELM and graduated with a BSc (Hons) Nutritional Therapy in 2006; then graduated in 2007 with an MSc in Evidence-Based Nutrition in collaboration with CNELM and Middlesex University Work-Based Learning. I am a Fellow member of BANT and I am registered with the CNHC. I am also a member of: the Nutrition Society, the Royal Society of Biology, the Institute of Learning, and the Royal Society of Medicine. As well as working part-time at CNELM, I run a private nutritional therapy practice called Health Generation.

I started studying nutrition while I was ill, at the age of 24, with rheumatoid arthritis. After trying several approaches to improve my health following my own research, it was changing my diet that had the most profound effect. This has driven me to explore and educate others about the importance of individual human physiology, pathology and the role of diet on health outcomes.

I value fairness, equality, justice, empowerment and freedom; widening access to personalised nutrition support is important to me. I believe nutrition education is key to empowering individuals to support their own health needs. Patient empowerment and the rejection of medical paternalism are moral themes which drive my support for the development of personalised nutrition (Juengst et al., 2012). My own values align well with my organisation's values and vision. CNELM's strategic vision includes

> steering the integration of personalised nutrition and nutritional therapy to becoming a widely accessible and accepted healthcare option within mainstream and complementary healthcare.
>
> (CNELM, 2017)

My role within the project has been one of research facilitator, data gatherer and data interpreter. As a practitioner-researcher I have brought my knowledge and skills to this project, which have influenced it in numerous ways. I have aimed to give the different views and approaches of the participants equal weighting, to limit the inevitable subjectivity my position in the project brings (Costley, Elliott and Gibbs, 2010 p. 33) and to overcome the drawbacks of collaborative research. The extent to which I have succeeded in these endeavours is discussed throughout this thesis.

Throughout the project, I was both an insider- and outsider-researcher. I may be an NT, but I am an outsider in dietetics and other nutrition practices. As anticipated, my dual role as practitioner-researcher allowed me to collectively bring together insiders and outsiders, resulting in a broad range of diverse views. This helped to limit bias, epistemological problems and ethical issues (Elliott, 1984 pp. 19–25) but also led to complexity and conflicts in findings, which are explored in chapters 4, 5 and 6.

It has been my responsibility to undertake and complete the research project within the timeframe and to the best of my capabilities, to ensure integrity, rigour and ethical competence. It has been the role of my academic advisers to oversee the entire project and guide its approach to a successful conclusion. They provided substantial support over the term of the doctorate which developed my knowledge and thinking in relation to the project and more broadly in terms of leadership and academia.

I am ideally placed, as Head of Education at CNELM and as an NT with professional and regulatory body connections, to disseminate the learnings and insights achieved in this project and influence change. As well as implementing the recommendations given in Chapter 8, I now wish to be instrumental in facilitating the provision of doctoral research supervision at CNELM, in collaboration with an awarding institution. This would be a significant advancement for both CNELM and the nutritional therapy profession.

The IPL4013 Review of Learning module at the outset of the DProf allowed for a reflective exploration of how my learning to date prepared me to undertake doctoral research. I concluded that due to my access to resources, personal traits, work experience, professional contacts and knowledge, I was in a unique position to undertake this research.

1.7 Theoretical underpinnings

Research is conducted within the context of existing ideas, literature and evidence. There are a number of key theoretical underpinnings within the project which shaped the research questions and approaches (Petre and Rugg, 2010, p. 7).

The overarching aim of personalised medicine is to optimise health care and health outcomes for individual patients (Ginsburg and Willard, 2009). Zenker et al. (2007) argue

that the current evidence-based medicine paradigm limits the potential to provide truly individualised validated care because it focuses on validating interventions for statistically identifiable subgroups (Zenker et al., 2007). I agree with Miles, Loughlin and Polychronis (2008) that personalised medicine that uses a plurality of evidence should form the basis of modern health care practice.

Theoretical frameworks that influence the way the tools are constructed include: the functional medicine approach (Nicolle and Woodriff Bierne, 2010, p. 33), clinical psychoneuroimmunology (cPNI), the interdisciplinary approach of systems science, pathophysiological mechanistic reasoning and translational bioinformatics.

The extent to which the tools developed as part of this research have embedded the concepts of functional medicine, cPNI, medical data and pathophysiological reasoning was guided by the expert professionals who participated in the collaborative approach. Standardised data-collection tools must be meaningful from different nutritional perspectives and practice approaches, but they must also be tools that would be deemed suitable and interpretable by any mainstream health care practitioner. This may enable nutritional therapy to be accepted as a mainstream primary care option.

The use of standardised data-collection methods in personalised nutrition practice may allow for the development of a new evidence base which can further bridge theory and practice. By creating a feedback loop where clinical evidence is used to refine clinical practice we are aspiring to be translational – this has shaped the way the tools were constructed. Collaboration, data integration and practical applications are important in translational research, and this is also reflected in the collaborative mixed methods approach undertaken in this research project.

Zenker et al. (2007) recognise that using computer-based algorithmic support is important for clinical decision making, especially when the data is complex. Mapping clinical observations to quantitative hypotheses about the outcomes of health conditions as a result of interventions can lead to improved insight and the ability to predict responses to interventions (Zenker et al., 2007). Zeevi et al. (2015) demonstrated that machine learning algorithms can integrate and compare individual, multi-dimensional data and enable evidence-based validation of decision-making algorithms. However, it is beyond the scope of this project to develop mathematical or computerised data models. This project is focused on designing the questionnaires and tools that can enable the development of a case-by-case evidence base for personalised nutrition practice in obesity management. These tools could, in time, provide the validated and standardised data which would facilitate the compilation of the case-by-case evidence base into a data set on which machine learning algorithms could be applied.

A collaborative Delphi approach was considered to be the optimal method to develop the tools, and a pilot trial was utilised to evaluate the successful integration of standardised tools into clinical nutrition practice. It is also recognised that the translation of research discoveries into clinical practice is slow and difficult, but the proper management of translational research could enable the delivery of reliable and clinically relevant outcomes (Kumar, 2007) that would transform personalised nutrition practice.

1.8 Timeframe

The structure of the project was formed around the following five stages, which all built towards meeting the overall aims and objectives: literature reviews, data gathering, collaborative tool development, tool pilot trials and evaluation.

The estimated schedule, including the project write-up, was 45 months – from October 2013 to June 2017 – part-time, during term time only. The project exceeded the schedule by 15 months. It took longer than anticipated to analyse the results of the surveys, interviews and Delphi rounds. The pilot trial duration was also extended by six months to promote engagement, and a portion of this extra time was focused on producing papers for publication. This has so far been successful for two papers (Barrow et al., 2017; Miles and Barrow, 2018).

1.9 Aim and structure of report

This report sets out the aims and objectives of the project as well as a critical and reflective evaluation of its methodology and findings. It aims to critically discuss the project activity, research findings, conclusion and recommendations. It aims to demonstrate evidence of achievement and lays out the original contributions made to the development of organisational and professional knowledge. The design of this report follows the Middlesex University Project module handbooks, which were provided throughout this project (between 2013 and 2018).

This chapter aims to put my project into context and explains why the project area is important.

Chapter 2, the literature review, explains how the literature shaped and influenced the study from the outset. It has eight sections (and a chapter summary): the first explores approaches to undertaking the literature reviews; the second explores the meaning of personalised nutrition; the third considers evidence-based personalised nutrition practice approaches; the fourth explores pathophysiological mechanisms in obesity and pathophysiological reasoning; the fifth reviews a range of existing tools for nutrition practice in the management of obesity; the sixth discusses a range of considerations for developing a standardised personalised

approach; the seventh evaluates ethical considerations for standardising a personalised approach; and the eighth explores a vision for transforming personalised nutrition practice.

Chapter 3 critically describes and justifies the choice of the research approach and data-collection methods for the research project. The overall reliability of the methodological approach is evaluated, and ethical issues are explored. My role as a work-based researcher is also evaluated.

Chapter 4 describes and analyses the project activity and discusses the activity undertaken to develop and complete the research methods, surveys and interviews used throughout the research.

Chapter 5 presents the analysis of research findings for each of the research methods undertaken to construct new clinical tools.

Chapter 6 presents the analysis of research findings for each of the research methods undertaken to explore how standardised data-collection methods could be integrated into nutrition practice.

Chapter 7 is a reflective account which also explores my own developmental transformation throughout the project.

Chapter 8 summarises the project, draws conclusions and recommendations from the findings and evaluates project outputs and their impact on the profession. The dissemination of research findings is discussed, and recommendations for further research are made.

Each chapter starts with an introduction to describe the scope of the chapter and ends with a chapter summary to emphasise the key material and provide a conclusion.

1.10 Chapter summary

Personalised nutrition practice and the importance of gathering robust clinical data to support intervention decision making and the development of a case-by-case evidence base are the main themes of the project. My own background, position and personal philosophy (and how these have impacted the project) have been explored at a preliminary level and will be discussed further in my role as an insider-researcher (section 3.6).

The expectations of the content for each chapter have been laid out. This project has given me a number of opportunities to exemplify “leading transformation in personalised nutrition practice” which is the proposed title for the DProf award. It is anticipated that the project meets the overall aims and objectives of the doctoral programme.

Chapter 2: Literature Review

This chapter describes the literature reviews undertaken and explores how the literature shaped and influenced study from the outset of this project.

2.1 Approach to literature review

An extensive search of Summon, Google Scholar, PubMed, Cochrane Library, Science Direct, Allied and Complementary Medicine, DH-DATA, Embase and Medline using the following keyword searches of the title (or title and abstract) was conducted at the start of the project, during October and November 2013. Throughout the project more research and literature was utilised to inform the project. This chapter draws on the literature review results and wider literature identified throughout the project.

Search description forms tracked the primary review results, as well as: review title, search dates, search terms, inclusion and exclusion criteria and the numbers of papers identified and included for each search (see appendices 1 and 2). Across each search, foreign language papers, papers published prior to 2003 and unrelated topic papers were excluded. Each paper included for full review was then listed in the literature and tool search results tracker spreadsheet (see appendix 3). Papers unavailable online were located via the British Library and the Royal Society of Medicine. Included papers were analysed in detail to assess: type of study, methodology, why the study was done and their relevance to the search topic.

The overarching aim was to critically review a range of relevant ideas and theories and explore how personalised nutrition practice could be transformed with the development of a new case-by-case evidence base. The objectives for the literature review include:

- defining ‘personalised nutrition’;
- comparing personalised nutrition practice, evidence-based practice and various approaches to nutritional practice;
- identifying a range of pathophysiological mechanisms associated with obesity and exploring the value of mechanistic reasoning;
- exploring a range of existing tools relevant for obesity management and nutrition practice and considered their utility in supporting a personalised nutrition practice approach;
- exploring a range of considerations for robust standardised data collection tool development and their integration with nutrition practice;
- evaluating ethical considerations of standardising a personalised approach to nutrition practice; and

- exploring a vision for transforming personalised nutrition practice.

The review allowed for a thorough search of the literature in a manner that aimed to limit researcher bias; the approach was informed by Aveyard's (2010) book, *Doing a Literature Review in Health and Social Care*. Literature reviews are always limited by the search terms used and rely on previously published research.

The results from various searches are presented under the following headings: personalised nutrition, evidence-based personalised nutrition practice, pathophysiological mechanisms in obesity and mechanistic reasoning, existing tools for nutrition practice in the management of obesity, developing a standardised personalised approach and ethical consideration for standardising a personalised approach. The results from all searches are then considered to explore a vision for transforming personalised nutrition practice.

2.2 Personalised nutrition

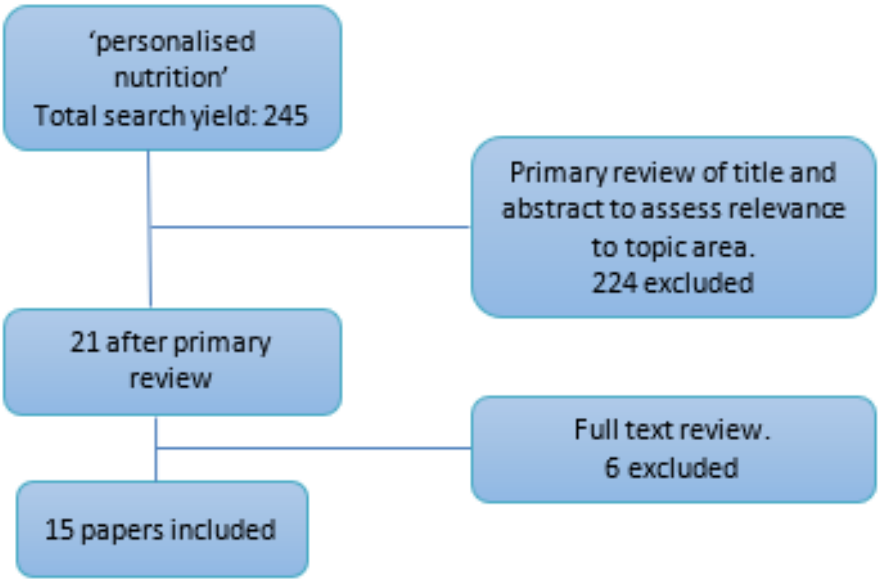

Figure 1 *Numbers of papers reviewed for personalised nutrition keyword searches at the outset of the project*

This review aims to define 'personalised nutrition'. The majority of the 245 papers located by searching for the term 'personalised nutrition' were review papers of how advances in nutrigenomics and nutrigenetics could contribute to the development of personalised nutrition. Primary research assessing the effects of nutrigenomics and nutrigenetics in obesity and other health conditions is developing rapidly and gaining importance in nutrition practice (Joffe and Houghton, 2016). However, the majority of these papers were excluded because they were not relevant to obesity or the research aims.

Of the 15 papers that were included, all except 2 were reviews papers on what personalised nutrition means, how it can be developed or delivered, or were analysing related ethical or

legal issues. The two primary studies included a focus group analysis on the factors that influence consumer uptake of personalised nutrition (Stewart-Knox et al., 2013) and a qualitative study which interviewed General Practitioners (GPs) to gather their views on barriers and opportunities in relation to gene-based nutrition advice (Bouwman, Molder and Hiddink, 2008).

The term ‘personalised nutrition’ is derived from ‘personalised medicine’ (PM). Historically, the main driver for PM has been pharmacogenetics, and the term ‘personalised medicine’ does not appear in the heading of articles until after the use of the term ‘pharmacogenomics’ (Fierz, 2004). Genomic medicine is defined as:

> The use of information from genomes and their derivatives to guide medical decision making.
>
> (Ginsburg and Willard, 2009)

Explanations for understanding the numerous meanings of PM have been presented in review papers by various authors (Ken Redekop and Mladsi, 2013; Pokorska-Bocci et al., 2014; Siest, 2014; Patel et al., 2015), but there is no single definition. PM may or may not include genetics and/or genomics and is also known as ‘precision medicine’. It may be tailored to the individual (also known as person-centred care) and it may also be termed stratified medicine, which targets particular groups of patients. Nardini et al. (2012) recognise the various meanings of ‘personalised’ with one being personalised to the individual’s preferences and needs and another which refers to interventions based on the genetic profile of the individual. Day et al. (2017) consider ‘personalised’ to mean biological stratification and person-centred care. Day et al. (2017) claim that this dual approach, incorporating biological and social aspects of health care, is supported by the UK government through funding, as well as within the National Health Service (NHS).

The term ‘personalised nutrition’ also has various meanings, with one being the use of dietary counselling to tailor interventions to the individual’s preferences and needs, and another which refers to the adjustment of diet based on results of genetic tests. Görman (2006) argues personalised nutrition should also include the notion that people should take greater responsibility for their own health. Personalised nutrition practice has not yet been defined in the literature.

Of the review studies included, the most notable (Joost et al., 2007; Görman et al., 2013) occurred as a result of the Food4Me project (Gibney and Walsh, 2015), an EU-funded programme which undertook a number of multi-centre studies to explore personalised diet, genotype and phenotype analysis and how this data could be used to deliver personalised online dietary advice. It highlighted that diet-gene-health relationships are poorly understood, and that tools for genetic assessment and evidence to support therapeutic interventions are

still some time off being meaningfully integrated into nutrition practice (Görman et al., 2013). This approach is an emerging, novel concept with numerous challenges (Gibney & Walsh, 2015).

More recently, and also of significant interest, has been a flagship study undertaken by Zeevi et al. (2015) to predict outcomes of personalised dietary interventions aimed at managing post-prandial glycaemic response (PPGR). Management of blood glucose plays a key role in obesity and diabetes management, yet predicting PPGR has been difficult, with the numerous confounding factors involved. Some 800 individuals (aged 18–70) underwent comprehensive profiling, including food frequency assessment, lifestyle and medical background questionnaires, anthropometric measures and biomarkers including microbiota profiling and metagenomic sequencing. They also had their PPGR monitored for seven days, along with their daily activities, including real-time physical activity, sleep and food intake measures (using smartphone applications). Zeevi et al. (2015) used machine learning algorithms to integrate and compare the individual, multi-dimensional data. Their results demonstrated interpersonal variability in PPGR to the same foods, and researchers were able to accurately predict individual PPGRs to standardised meals – a finding that was then validated in a separate, independent, 100-person cohort study. They then used a blinded randomised controlled dietary intervention study to determine if personally tailored dietary interventions, based on the same comprehensive profiling of participants, could improve PPGRs, which, it was found, they could. Further work needs to be done to understand how individuals will respond to standardised meals over longer periods of time, but this was the first example of how a systems biology approach can be used to predict the efficacy of personalised nutrition interventions.

As described in Chapter 1, systems biology is the study of complex biological networks. It is an interdisciplinary field including genomics, genetics, physiology, pathology, toxicology and clinical medicine that uses computational modelling to study the interactions among biological elements for a thorough understanding of disease (Yan, 2012). The broader considerations of health and disease should also include social, cultural, lifestyle, environmental and economic factors. Nutritional science is a systems science (BANT, 2017a). Systems biology is based on the understanding that the whole is greater than the sum of its parts (Noble, 2012). Personalised nutrition needs to extend beyond the idea of dietary interventions based on genetic tests, because this view is limited.

2.3 Evidence-based personalised nutrition practice

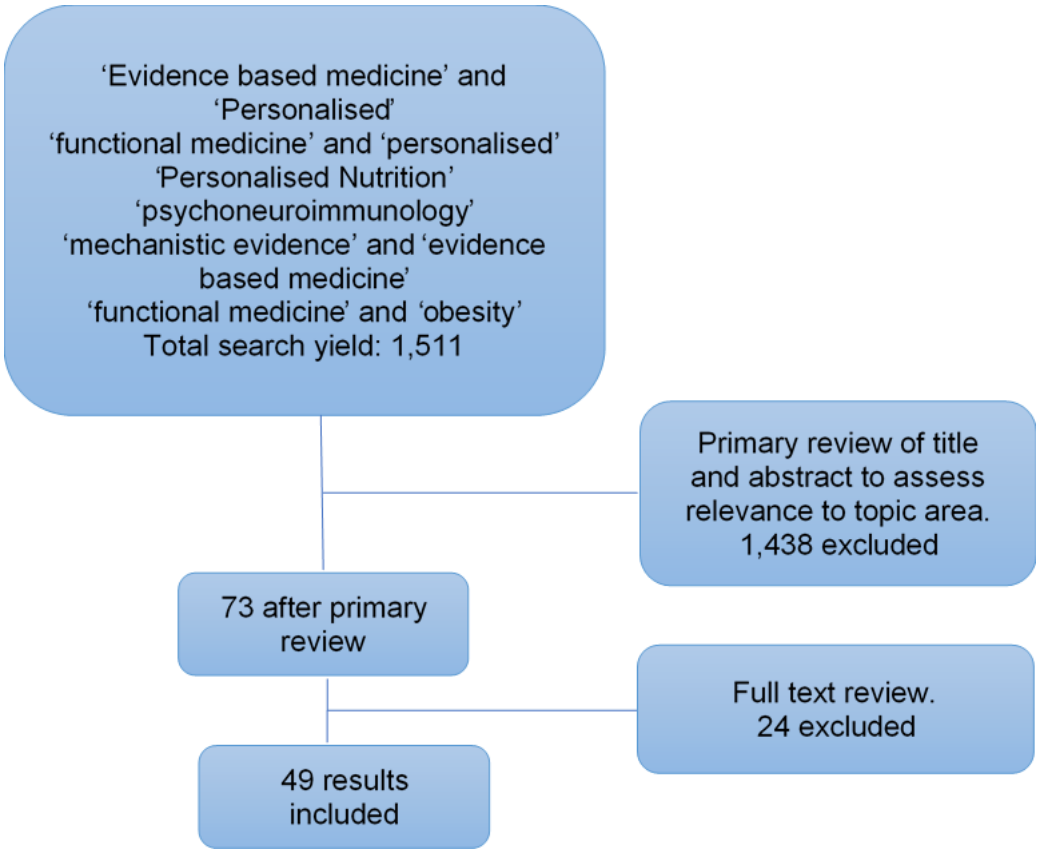

Figure 2 *Numbers of papers reviewed for evidence-based personalised nutrition practice keyword searches at the outset of the project*

This review aims to explore and compare 'personalised nutrition practice', 'evidence-based practice' and other approaches to nutritional practice. The search for 'evidence based medicine' and 'personalised' initially yielded 364 papers. The majority were excluded because they discussed specific health conditions or interventions which were unrelated to this project. The papers included were mostly review papers which reflected upon, or directly relate to, current thinking on evidence-based medicine (EBM) and PM. Other searches were undertaken to consider various approaches to personalised nutrition practice, including "functional medicine" and "psychoneuroimmunology".

Of the 19 included studies from the search 'evidence based medicine' and 'personalised', at least 5 (Fierz, 2004; Kumar, 2007; Miles, Loughlin and Polychronis, 2008; Bereczki, 2012; Greenfield and Kaplan, 2012; Nardini, Annoni and Schiavone, 2012) explore various critiques of EBM from its epistemological positioning to its empirical issues. The complex range of debates is beyond the scope of this review and have already been comprehensively described by Howick's (2011) *The Philosophy of Evidence Based Medicine*. Succinctly, one of the main issues is that it is limited to narrow and frequently unrepresentative groups of patients and the extrapolation of this data to individual patients with individual health

considerations is fraught with limitations (Greenfield & Kaplan, 2012; Fierz, 2004). Sackett describes EBM as:

> a process of lifelong, self-directed learning aimed at providing the best possible patient case using the clinically important available information about diagnosis, prognosis, therapy and other clinical and health care issues.
>
> (Sackett, 1997, p. 2)

The overarching aim of PM is to optimise health care and health outcomes for individual patients (Ginsburg and Willard, 2009) but it could be argued that this is also an aim of EBM. The evolution of EBM and PM are described in review papers by de Leon (2012) and Bereczki (2012).

EBM and PM are two different approaches to making and reasoning evidence, with EBM grounded on statistical notions and epidemiological data gathered through systematic meta-analysis and randomised controlled trials (RCTs), whereas PM considers mechanistic explanations of molecular interactions, pathways and biomarkers (Nardini et al., 2012). RCT do enable causal inference, but they limit the potential to provide truly individualised validated care because their focus is on validating interventions for statistically identifiable subgroups (Zenker, Rubin and Clermont, 2007). Mechanistic explanations are considered to be a low form of evidence in EBM because mechanistic explanations and predictions come apart in various ways (Andersen, 2012). Mechanisms can explain what is happening in a system while failing to provide the basis for prediction when interventions are applied (Andersen, 2012). Bereczki (2012) argues that PM is an upgrade of EBM, because PM allows for the use of a range of sources of evidence, including patient preferences and individual expertise. However, it is not one approach or the other; it is plurality of evidence that should form the basis of modern day health care practice (Miles et al., 2008).

Of the 7 included studies from the search ‘functional medicine’ and ‘personalised’, 3 reviewed the application of functional medicine in clinical practice (Macdonald Baker et al., 2005; Galland, 2006; DeBusk, Sierpina and Kreitzer, 2011). 2 papers reviewed the role of functional medicine in relation to dietetics practice (Ford et al., 2011; Swift, 2012) while Jones et al. (2009) reviewed functional medicine educational programmes and Ehrlich, Callender and Gaster (2013) undertook a survey (n=136) to characterise clinicians utilising integrative medicine in practice.

The functional medicine model was first proposed by Jeff Bland in the 1980s and is being led by the Institute of Functional Medicine. According to Ford et al. (2011), integrative and functional medicine represents a broader paradigm of medicine that is person-centred, appreciates that individuals have unique metabolic patterns, and encompasses actions such as decision making. Functional medicine focuses on the mechanisms of biochemical pathways that are the basis for metabolic networks and how these are affected by a person’s

unique diet, genetic and environmental interactions throughout their lifespan (Ford et al., 2011). Functional medicine is a clinical approach to personalised health care which has been evolving over the past four decades.

According to Jones et al., functional medicine is a:

> Systems-orientated personalized medicine that recognises common underlying mechanisms of complex and chronic diseases and cuts across multiple organ systems to shape a patient's trajectory toward health and disease
>
> (Jones et al. 2009)

Of the 452 papers that resulted from searching "clinical psychoneuroimmunology", the majority were excluded for either focusing on specific health conditions or not related to the project. The two results that were included came from two chapters of the same book (Yan, 2008) which explored the complex interactions between psychological and behavioural factors and functions of the nervous, immune and endocrine systems that help to explain the mechanisms underlying health and disease.

As defined in Chapter 1, cPNI studies the interactions among behavioural, neural and endocrine, and immune processes. Physical and psychological conditions have a close impact on each other, with attitudes and social support impacting on disease and life expectancy, while physical illness is known to alter mood, behaviour and memory and behavioural and lifestyle interventions can improve clinical outcomes (Yan, 2012). Yan (2012) considers that PNI research will also help to identify the correlations between genotype and phenotype, which is a key issue in PM. A systems biology approach, based on the understanding that the whole is greater than the sum of its parts, has been used to develop understanding of this complex biopsychosocial paradigm.

Historically, reductionism (which takes the view that the whole can be explained by its component parts), has been the dominant scientific paradigm (Porta, 2008, p. 154) and the dominant epistemological approach in nutrition research (Hoffmann, 2003). Epidemiological research and associative studies are used to inform public health policy development and clinical guidelines. Clinical guidelines support an evidence-based differential diagnosis practice approach.

Differential diagnosis is a hypothetico-deductive clinical reasoning method where the patient's signs and symptoms are used to identify the possible causes and diagnoses of illness and disease and derive a testable hypothesis. In the model and process for dietetics practice, once a diagnosis has been established clinical guidelines are utilised to form a person-centred intervention approach (BDA, 2015). Such health care models have been criticised for being disease-based, i.e. that they treat diseases rather than patients (Wade and Halligan, 2004). However, great strides have been made to develop and support

person-centred care in mainstream health care systems. According to Health Education England (HEE):

> Person centred care is about focusing care on the needs of individual. Ensuring that people's preferences, needs and values guide clinical decisions, and providing care that is respectful of and responsive to them.
>
> (HEE, 2018)

BANT (2017) state:

> Practitioners consider each individual to be unique and recommend personalised nutrition and lifestyle programmes rather than a 'one size fits all' approach.
>
> (BANT, 2017a)

However, BANT (2017) do not define what 'personalised nutrition' means. In this context, it appears this term may mean 'person-centred care'.

Nutrition practitioners use clinical guidelines, such as the National Institute for Health and Care Excellence (NICE) guidelines on obesity prevention and management, to make evidence-based recommendations (AfN, 2012; BANT, 2018; BDA, 2015). These guidelines use an EBM hierarchical approach to determine the value of research, where systematic reviews of clinical trials used to determine the efficacy of particular interventions in a given population are the gold standard (NICE, 2014b). However, clinical decision making based on this approach has inadvertently excluded pathophysiological reasoning because EBM is lacking mechanistic explanations (Sharma and Minhas, 2012).

Extrapolation of clinical guidelines to evidence-based personalised nutrition practice is problematic for numerous reasons (Maher et al., 2016); the complexity of individuals, foods and individual intake, as well as confounding factors and the limitations of measuring these variables robustly (Willett, 1987; Michels, 2003; Gibson et al., 2010b; Jacobs, 2012). Disease expression is an individual and complex mix of genetics, environmental, lifestyle and dietary interactions. Individual responses to food intake are also a complex mix of genetics, environment, lifestyle and dietary interactions (Zeevi et al., 2015). The current evidence base provides answers on the average efficacy of an intervention, yet the clinical question is whether an intervention works for a specific individual (Lutz et al., 2006).

Comparative effectiveness research (CER) is becoming a more prominent approach to health care data analysis and identifying what works (Khoury et al., 2013). Rather than the traditional efficacy and effectiveness research, CER aims to answer three questions: what works, for whom, and in whose hands? Answering these will require fundamental changes to clinical research, including the direct comparison of interventions (Greenfield and Kaplan, 2012). The World Health Organization (WHO) explores the meaning of 'health' and the various approaches to comparing individual health measures (Chatterji et al., 2002). A number of patient-centred outcomes will need to be compared to assess the impact of

interventions on symptoms, quality of life and biomarker changes (Greenfield & Kaplan, 2012). Although CER has its critics, it does provide an approach to determine the best interventions for individuals (Garber and Tunis, 2009; Kaats, Preuss and Leckie, 2009).

Some nutrition practitioners may also use research that extends beyond the guidelines to inform their clinical decision making and develop a personalised practice approach (NTEC, 2015). This method has also received numerous criticisms. Distilling a vast amount of published disease-oriented and population-based evidence in order to make appropriate evidence-based recommendations for individuals is problematic, time-consuming (Spicker, 2013), and gives sufficient room to make inaccurate inference from the data (Pizzorno, 2012).

Some nutrition practitioners use a functional medicine clinical approach (Benbow et al., 2017). As described in Chapter 1, functional medicine is a systems-based clinical reasoning method. It takes the patient's signs and symptoms, as well as health history, family history, environment and lifestyle factors across a lifespan, and categorises them under physiological mechanism and functional headings on a matrix map (see Figure 3). Individual signs, symptoms, health, diet, lifestyle factors and family history are also viewed as antecedents, triggers and mediators of disease and illness.

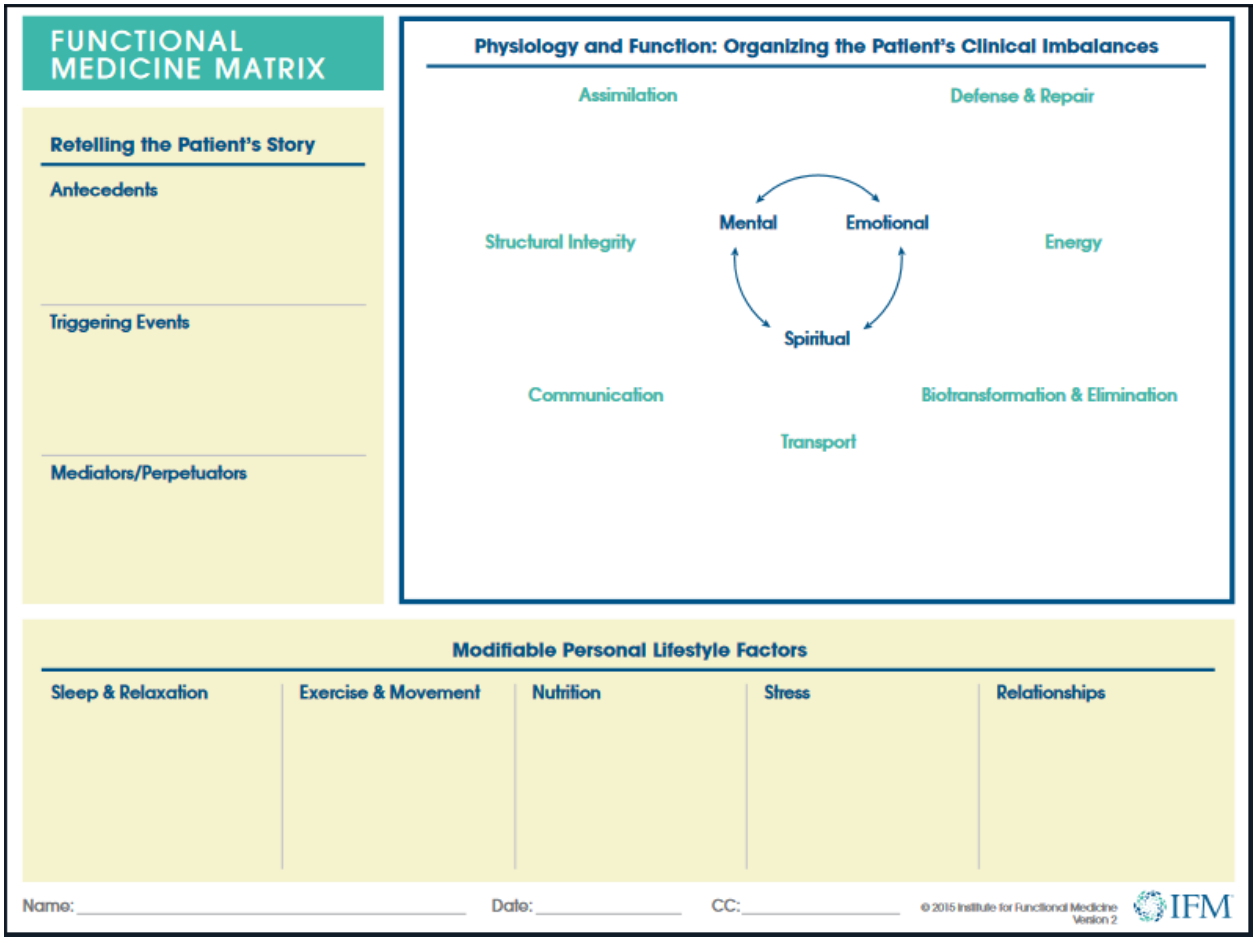

Figure 3 *Functional Medicine Matrix to enable practitioners to organise and prioritise individual health issues under functional headings (IFM, 2018)*

By organising the patient's signs, symptoms, health history etc. into this map, the practitioner may be able to identify potential physiological and functional imbalances. When there are numerous signs, symptoms and health issues clustered under the headings, this indicates pathophysiology. Practitioners can then prioritise interventions whose mechanisms of action ameliorate mechanisms of pathophysiology function. Although this approach is open to interpretation and inaccurate inference by practitioners, it provides a more personalised practice approach than the use of clinical guidelines alone because it supports pathophysiological reasoning and targets interventions at an individual's physiological function.

A literature search did not identify research to validate the matrix tools or the headings incorporated within the matrix. It is unlikely that these headings cover the breadth of pathophysiological mechanism in disease. It appears from Figure 4 that although the functional medicine matrix headings span a range of factors at various systems levels, it does not differentiate them. In my opinion, the functional medicine model does not yet provide a solution that fully incorporates the social, psychological and behavioural

dimensions of disease. The call for a biopsychosocial model in health care goes back as far as the late 1970s (Engel, 1977).

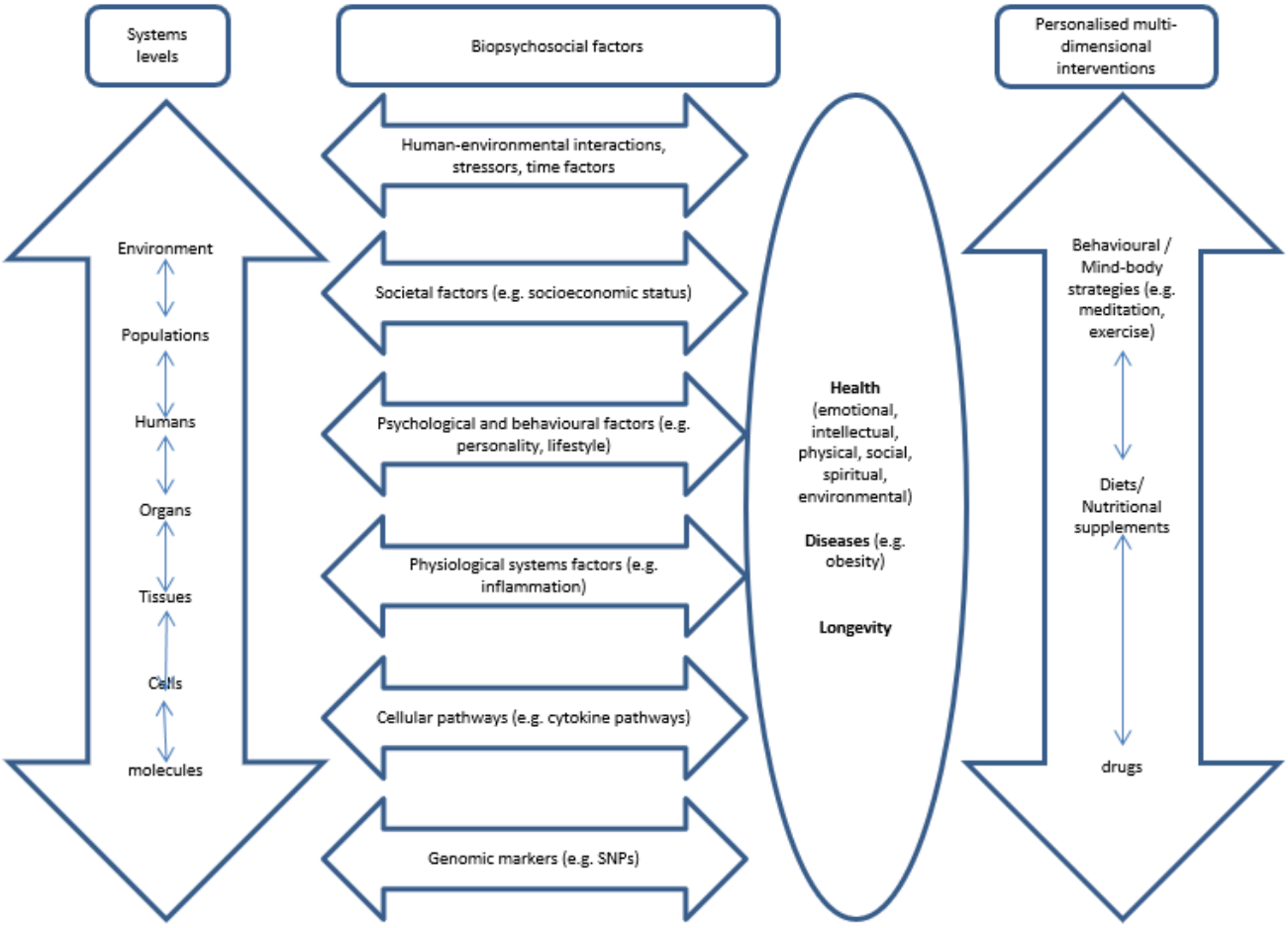

Figure 4 *Biopsychosocial factors at various systems levels and potential personalised interventions in multiple dimensions (Yan, 2012)*

Functional medicine has received numerous critiques (Gorski, 2014; Sampson, 2014) which are primarily about validity and semantics. These criticisms appear to misunderstand the limitations of EBM and of applying pharmacological research methods, which frequently considers one input (drug intervention) and one output (biomarker) in complex multivariate systems such as food, nutrients and the human body, which work through multiple complex mechanisms (Wade and Halligan, 2004; Ahn et al., 2006; Fardet and Rock, 2015). Although the functional medicine model does have limitations and does encompass a number of unproven methods, including the use of matrix tools, it does also appear to be trying to overcome the limitations of the disease-led and reductionist biomedical model. The functional medicine clinical process does extend beyond the matrix: by taking the client history and retelling the client story re-conceptualised within the functional matrix framework, it aims to promote client understanding, autonomy and reciprocity. However, without robust

validation of its tools and clinical approach, the functional medicine model will continue to be criticised.

Nutrition practitioners may utilise laboratory assessments to determine biochemical and physiological function as well as markers of disease (BDA, 2015; NTEC, 2015). More recently, this has included nutrigenetic assessment (NTEC, 2015). Through the use of test results practitioners are able to consider pathophysiological mechanisms contributing to disease. This approach also enables practitioners to target interventions more directly to individual biochemical and physiological needs, rather than interventions based on assumptions or guidelines. However, many laboratory assessments are diagnostic rather than functionally oriented, and laboratory assessments are not available to assess the wide range of pathophysiological mechanistic functions. Testing, when available, does allow practitioners to measure the outcomes of interventions by retesting, which enables practitioners to corroborate the efficacy of nutrition intervention against the outcomes of test results.

Traditionally, prospective cohort studies are used to determine the efficacy of nutrition interventions (Maher et al., 2016), but this is also considered problematic because the research relies on participants retrospectively remembering their dietary intake at the time of diagnosis (Michels, 2003). Real-time assessment of diet intake – through the use of repetitious and ongoing analysis undertaken over long time periods – is helping to overcome this issue (Michels, 2003; Gibson et al., 2010b).

The competence and ability of the practitioner has a significant influence over the effectiveness of interventions (Greenfield & Kaplan, 2012). One of the limitations is the variation in practitioners' ability to think abductively. Kumar (2007) recognises that one of the major difficulties for practitioners is selecting the best available evidence. The data used to inform clinical decision making is often conflicting and too large to manage or organise by using tools such as the functional matrix. This creates variability in patient outcomes between the best abductive reasoner and the worst abductive reasoner. When clinical decisions are widely divergent, clinical outcomes suffer and patient safety may be compromised (Rozich et al., 2004). Historically, clinical guidelines are used to overcome this issue.

There are other influences over the effectiveness of interventions which result from the therapeutic relationship. A recent phenomenological analysis (Miles and Barrow, 2018), undertaken at CNELM and supervised by myself, demonstrated that the relationship with the nutrition practitioner influences client engagement, confidence and compliance with a personalised weight loss programme. There are measures for the therapeutic alliance in psychology practice (Ardito and Rabellino, 2011) but there appear to be none for nutrition

practice. Studies investigating this in nutrition practice have utilised interviews and focus groups (Endevelt and Gesser-Edelsburg, 2014). Several studies highlight the value of incorporating coaching strategies alongside nutrition interventions to support behavioural change (Cecil, 2016; Martin et al., 2018; Miles and Barrow, 2018). Lifestyle coaching, teaching cooking skills, developing self-awareness, practising mindfulness and stress management skills, should all form part of personalised nutrition practice. Behaviour modification is a cornerstone of effective health care (DeBusk et al., 2011) and is already embedded in models of nutrition practice (AfN, 2018; BDA, 2015; NTEC, 2015).

To summarise; some nutrition practitioners utilise health assessment and laboratory tests to determine a nutritional diagnosis and use disease-oriented clinical guidelines to make person-centred intervention recommendations (BDA, 2015). However, this does not constitute a personalised practice approach. Practitioners may also use health assessment and laboratory tests to assess physiological function (AfN, 2012; BDA, 2015; NTEC, 2015), which allows for interventions to be directly targeted to individual biochemical and physiological needs. DeBusk et al. (2011) state that molecular nutrition will become the foundation for modern nutrition and that interventions should target underlying pathophysiological mechanisms. The current EBM paradigm makes pathophysiological reasoning without appropriate test results problematic because of the need to extrapolate disease-oriented evidence or utilise low-forms of evidence (mechanistic, observational, case studies etc.) to support intervention decisions for individuals. Further mechanistic evidence is required to support an evidence-based personalised nutrition practice approach. The definition, model and process for personalised nutrition practice has not yet been defined, even though ‘personalised nutrition’ is a term used in nutrition practice (BANT, 2017a) and more widely in the industry.

Functional medicine offers a non-validated clinical model to undertaking a mechanistic pathophysiological reasoning approach to support clinical decision making. EBM and PM are also methods for supporting clinical decision making (Bereczki, 2012) and they provide types of evidence, with EBM including epidemiological data and PM including a range of evidence (mechanistic, observational etc.). Psychoneuroimmunology (PNI) contributes biopsychosocial insight, while systems biology offers an approach to analysing and comparing complex health data, including the outcomes of interventions which can translate findings to inform clinical practice, hence making it translational (Feldman, 2015). Systems biology is also better able to consider the complexity than the use of a reductionist approach (Ahn et al., 2006; Mazzocchi, 2008a; Fardet and Rock, 2015).

If the strengths of each nutrition practice approach were combined into an evidence-based personalised practice approach, it would include the use of robust, standardised and

validated tools that gather patients' signs and symptoms, health history, family history, environment, lifestyle, social, diet, behavioural and other factors which have an impact on physiological processes across a lifespan. The personalised nutrition practice approach would then analyse them along with anthropometric measures, laboratory assessments and biomarkers for pathophysiological mechanisms. Such tools would pool data into a case-by-case evidence base which utilises computational network modelling to predict the efficacy of personalised nutrition interventions. Prediction on the efficacy of interventions should be validated using blinded randomised controlled stratified intervention studies as demonstrated by Zeevi et al (2015). This model would provide practitioners with data that supports evidence-based pathophysiological reasoning. It would enable clinicians to prioritise interventions based on mechanisms of their actions which ameliorate whichever mechanisms of pathophysiology are a priority for that individual. Interventions may then be applied in a person-centred practice approach. This would transform evidence-based personalised nutrition practice into P4 medicine: a personalised, preventative, predictive and participatory approach (Hood and Flores, 2012).

2.4 Pathophysiological mechanisms in obesity and mechanistic reasoning

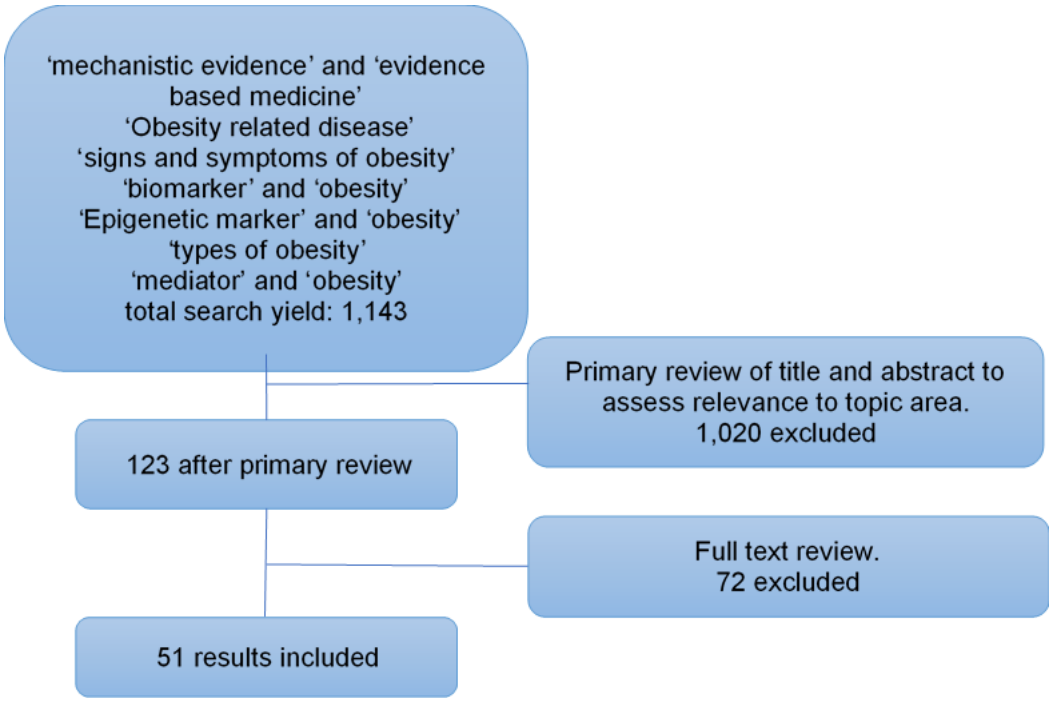

Figure 5 *Numbers of papers reviewed for pathophysiological mechanisms in obesity keyword searches at the outset of the project*

This review aims to identify a range of pathophysiological mechanisms associated with obesity, as well as explore the value of a mechanistic reasoning approach. The 49 results from the initial searches gave insight into the clinical assessment of obesity which informed

the tool development, however many studies were excluded because their main focus was not obesity. Numerous additional resources were also utilised to develop a comprehensive list of pathophysiological mechanisms, other diseases, health conditions and red flags for tool development (Bowling, 1995a, 2005; Kypreos, 2009; Stern and Kazaks, 2009; Nahikian-Nelms, 2011; NTEC, 2015).

From the 51 results, the following 16 pathophysiological mechanisms in obesity were identified:

- infection origin (Pasarica and Dhurandhar, 2007; Bassols et al., 2010);
- inflammation (Eder et al., 2009; Clària et al., 2010; Fain, 2010; Fuentes, Roszer and Ricote, 2010; Tai and Ding, 2010; Yang et al., 2010; Kim et al., 2011; Benozzi, Perruzza and Pennacchiotti, 2012; Choi et al., 2013; Deepali, Thomas and Gupte, 2013);
- leptin resistance and satiety issues (Erez et al., 2011; Orbetzova et al., 2012);
- insulin resistance (Lu et al., 2008; Fuentes, Roszer and Ricote, 2010; Yang et al., 2010; Kurpad and Aeberli, 2012);
- dyslipidaemia (Eder et al., 2009; Piva et al., 2011);
- oxidative stress (Piva et al., 2011; Choi et al., 2013);
- epigenetics (Campión, Milagro and Martínez, 2009, 2010; Tammen, Friso and Choi, 2013);
- addiction (Kenny and Shaw, 2011);
- genetics (Guo et al., 2006; Bouchard and Drake, 2010; Herrera, Keildson and Lindgren, 2011);
- hormonal imbalance (Kushner, 2012);
- pregnancy (Kushner, 2012);
- medication related mechanisms (Aronne, 2002; Benozzi, Perruzza and Pennacchiotti, 2012);
- psychological factors (Grossniklaus et al., 2012; Karasu, 2012; Kushner, 2012); and
- diet intake and energy expenditure.

Some of these results have been corroborated by a recent review study (Longo, Heymsfield and Wadden, 2017) which highlighted lifestyle and environment, genetics and energy balance dysregulation as the main pathophysiological mechanisms of obesity. However, this study failed to consider a range of other mechanisms, which led to criticism (Calkins, 2017). Mechanisms of pathophysiology for adiposity increase risk of comorbidities, such as diabetes and sleep apnoea, were presented in a mechanistic map in this review (see Figure 6), but the pathophysiological mechanisms contributing to obesity were not mapped out.

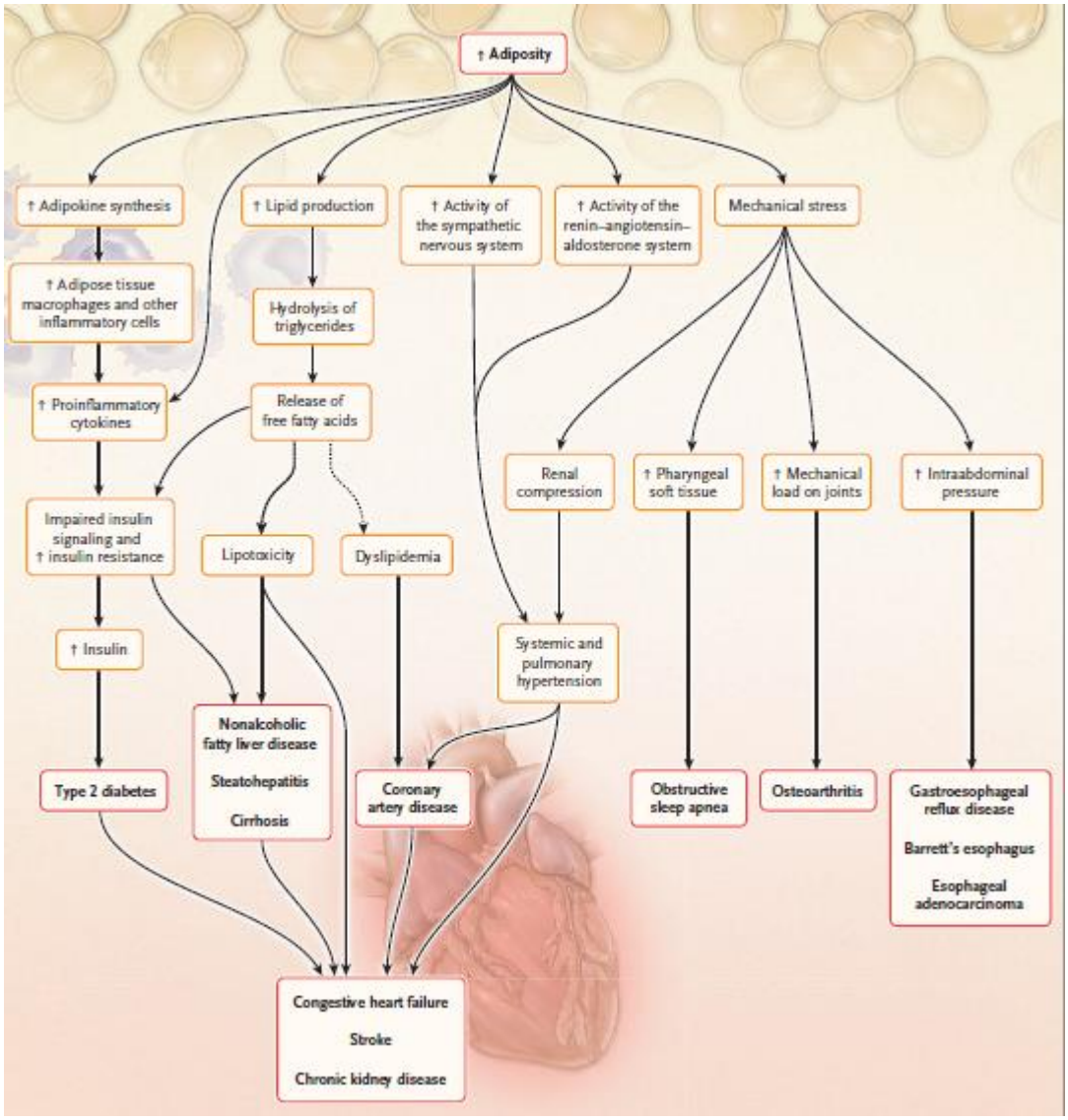

Figure 6 *Some pathways through which excess adiposity leads to major risk factors and common chronic diseases (Longo et al., 2017)*

Of the 15 included studies which resulted from searching “obesity related diseases”, 44 other diseases and health conditions were identified (Browning, 2003a; Martin, Qasim and Reilly, 2008; Michael I. Goran, 2008; O’Rourke, 2009; Horng and Hotamisligil, 2011; Mathew, Okada and Sharma, 2011; Na et al., 2011; Yamauchi and Kadowaki, 2013a; Doron et al., 2013; Ohashi et al., 2014; Reilly T Enos, Velázquez and Murphy, 2014; Nigro et al., 2014; Choi and Snider, 2015; Sarah C Ferrante et al., 2015; Zhang et al., 2015; Lee et al., 2015) see Table 7 for the full list of conditions. Health conditions included were associated with obesity and/or correlated to the mechanisms of pathophysiology.

As demonstrated in Figure 6, mechanisms correlate certain inputs with certain outputs. Mechanistic reasoning is the ability to make inferences from the knowledge to inform clinical decision making (Nardini et al., 2012). One critique of using this type of reasoning approach are that the system may be too complex to allow inference about causal interactions (Nardini

et al., 2012). This issue may be overcome with stratification, where patients are grouped according to genetic variants, characteristics or biomarkers to determine the optimal interventions for each subgroup (Smith, 2012; Siest, 2014; Day et al., 2017).

Overall, the results highlight the complexity of pathophysiological mechanisms in obesity. All pathophysiological mechanisms interrelate, and some pathophysiological mechanisms – such as inflammation – are at the root of numerous diseases (Hunter, 2012; Ruiz-Núñez et al., 2013). Understanding of pathophysiological mechanisms is often incomplete, which may be a result of the EBM model prioritising other forms of research. Mechanisms behave paradoxically, with more than one mechanism likely to be involved in producing a patient-relevant effect (Howick, Glasziou and Aronson, 2013). Mechanisms are primarily theoretical, and this is supported by examples of treatments based on mechanism of action which have subsequently been found to be ineffective (Nardini et al., 2012). Mechanisms like dyslipidaemia and oxidative stress do not have defined signs and symptoms; they require laboratory assessment to determine their influence in individual disease progression, and not all pathophysiological mechanisms have laboratory assessments.

Broader social, environmental, cultural and ethical influences also contribute to obesity. Stress, trauma and adverse events have been shown to be positively associated with adult obesity (Palmisano, Innamorati and Vanderlinden, 2016). Social roles and relationships in relation to obesity have primarily focused on marital status, but ethnicity, cultural factors and social relationships also play a role (Crawford et al., 2010 p106). However, the mechanisms by which sociocultural factors are associated with obesity are not well understood (Crawford et al., 2010 p107).

It is beyond the scope of this review to define the complexity of how pathophysiological mechanisms contribute to obesity. However, this research is ongoing at CNELM, where research students are asked to undertake a systematic literature review of how pathophysiological mechanisms contribute to obesity. The students then synthesise research from a range of studies, describe and draw pathophysiological mechanistic maps from findings, and consider how this mechanistic insight can be used to inform evidence-based clinical practice.

In terms of nutrition practice, the British Dietetics Association (BDA 2015) process gathers information utilising an ‘ABCDEF’ structure: **A**nthropometry, **B**iochemistry, **C**linical/physical, **D**ietary, **E**nvironmental/behavioural/social, patient **F**ocused. A literature search did not identify research to validate this approach and it does not appear to enable pathophysiological reasoning, unless functional (rather than diagnostic) laboratory test results are available. The functional medicine approach to organising health data under functional headings was explained in section 2.3. The BANT (2017b) consultation process

uses: environmental inputs, gut function, defence and repair, mind and spirit, hormone and neurotransmitter regulation, detoxification, energy production/oxidative stress and structural integrity as a model for supporting mechanistic reasoning. These headings are likely derived from the IFM matrix and warrant similar criticism in relation to semantics, lack of validity, limitations in relation to the breadth of pathophysiological mechanisms, and potential for inaccurate inference. These approaches do demonstrate that some nutrition practitioners already collate and interpret information that supports mechanistic pathophysiological reasoning. However, these approaches are not yet fully developed and are limited in terms of providing an evidence based personalised nutrition practice approach because pathophysiological mechanisms are complex and mechanistic evidence has numerous limitations.

As discussed, systems biology and advances in computational technology provide a framework and method for generating comprehensive and complex network maps of the physiological and functional interactions which provide mechanistic insight (Mast, Ratushny and Aitchison, 2014). Zenker et al. (2007) recognise that using mathematical models of physiological mechanisms to map clinical observations to quantitative hypotheses about physiological conditions would lead to improved insight and the ability to predict responses to interventions. In essence, this is what Zeevi et al. (2015) achieved – the ability to predict outcomes of personalised dietary interventions aimed at managing PPGR as a result of monitoring multiple physiological mechanisms which affect PPGR.

Further developing an evidential framework for mechanistic knowledge, as well as processes and tools which support mechanistic reasoning, are required to support and develop an evidence-based personalised nutrition practice approach. Developing pathophysiological mechanistic understanding may also provide opportunities for developing new biomarkers and laboratory assessments. Goodman and Gerson (2013) state that, for it to be maximally useful, an evidential framework must be applicable to all forms of disease intervention. This requires a high degree of generality for the overall structure, but with elements that are customisable for particular intervention contexts.

2.5 Existing tools for nutrition practice in the management of obesity

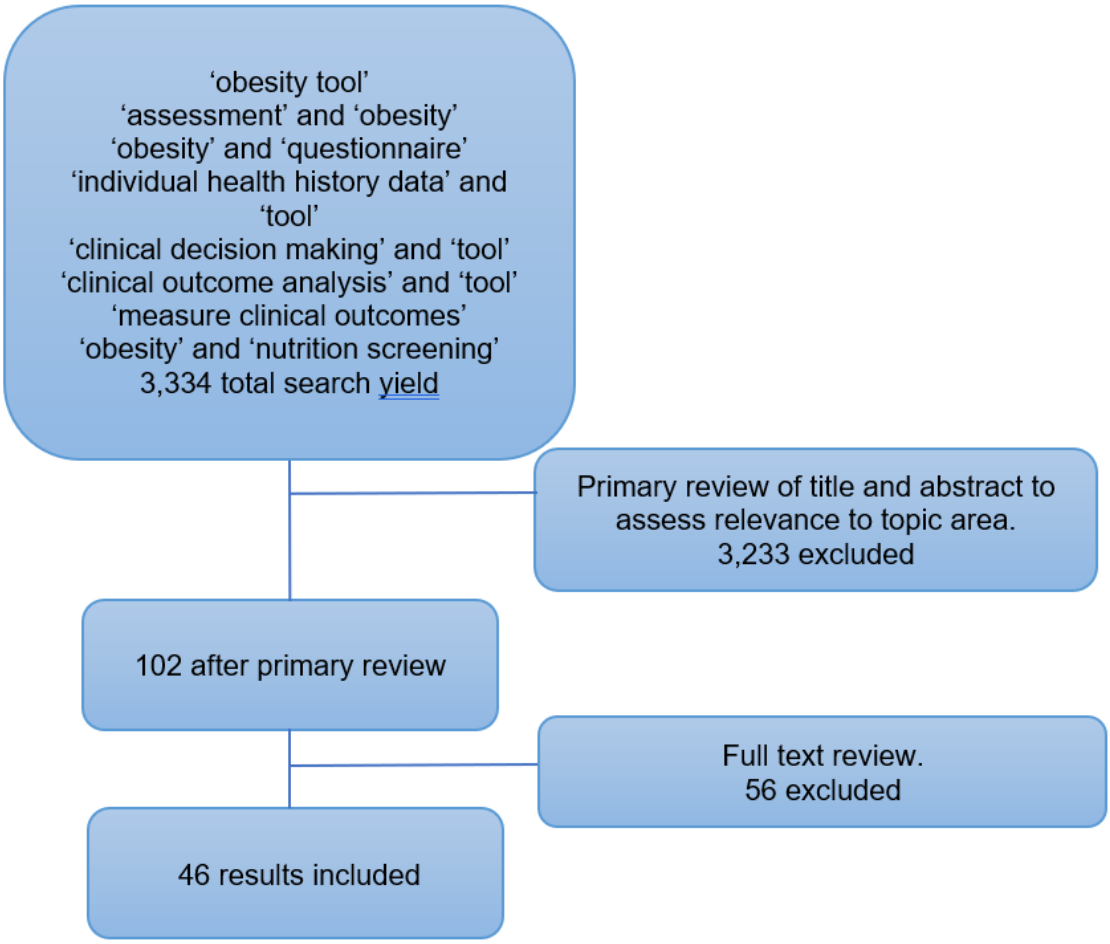

Figure 7 *Online searches to identify existing tools for nutrition practice in the management of obesity resulting from keyword searches at the outset of the project*

A total of 3,334 papers were considered for inclusion and a total of 46 papers met the final inclusion criteria; those excluded were papers on tools deemed not suitable for clinical nutrition practice. The results were used to inform tool development as part of this project, which is described in Chapter 3 and Chapter 5. This review explores a range of existing tools relevant for obesity management and nutrition practice and considers their utility in supporting a personalised nutrition practice approach.

The final 46 papers selected included a broad range of primary and secondary research papers including: review papers which highlighting the strengths and limitations of tools and questionnaires used in obesity assessment and management (Han, Sattar and Lean, 2006; Koopman and Mainous, 2008; Sharma and Padwal, 2010; Beechy et al., 2012; Levy and Heyes, 2012; Lindsay et al., 2013), validity research papers which highlighted numerous validity approaches undertaken in tool development (Ziegler et al., 2005; Müller, Bosy-Westphal and Krawczak, 2010; Therrien et al., 2011; Garaulet et al., 2012), comparative

studies (Heinz, Ko and Peterson, 2005; Al-Sultan, 2008; Wee, Davis and Hamel, 2008; Jenkins et al., 2013), cross-sectional studies (Ledikwe et al., 2003; Finelli et al., 2006; Otsuka et al., 2006; Ozier et al., 2008; Chambers and Swanson, 2010; Martínez-González et al., 2012; Hajian-Tilaki and Heidari, 2013) and pilot and trial studies of new tools (Chambers and Swanson, 2006; Greenwood et al., 2008).

Assessments identified included:

- body mass index (BMI), body composition and anthropometric measures (Heinz, Ko and Peterson, 2005; Han, Sattar and Lean, 2006; Al-Sultan, 2008; Müller, Bosy-Westphal and Krawczak, 2010; Beechy et al., 2012; Martínez-González et al., 2012; Hajian-Tilaki and Heidari, 2013);
- obesity risk factors such as diet and exercise or activity behaviour (Chambers and Swanson, 2006; Finelli et al., 2006; Koopman and Mainous, 2008; Beechy et al., 2012; Lindsay et al., 2013);
- quality of life assessments (Ziegler et al., 2005; Wee, Davis and Hamel, 2008; Therrien et al., 2011; Beechy et al., 2012);
- weight history assessment (Jenkins et al., 2013);
- hunger assessments (Beechy et al., 2012);
- sleep assessments (Beechy et al., 2012);
- nutritional risks (Ledikwe et al., 2003);
- psychological influences, eating behaviours and perceived body image assessment (Greenwood et al., 2008; Ozier et al., 2008; Beechy et al., 2012; Garaulet et al., 2012; Ogawa et al., 2012);
- measure yourself medical outcomes profile (MYMOP) (Paterson, 1996); and
- patient and clinical decision aids (Levy and Heyes, 2012; Campos, 2013; Reilly-Harrington et al., 2013).

Other tools were identified throughout the project, including:

- the Stanford health assessment (Pecoraro et al., 1979; Bruce and Fries, 2003);
- quality of life assessments (WHO, 1998; Mannucci et al., 1999; Chambers and Swanson, 2010; Forhan, Vrkljan and MacDermid, 2010);
- medical outcomes surveys (SF12 and SF36) (Wee, Davis and Hamel, 2008);
- the Rotterdam checklist (Hardy et al., 1999);
- the Edmonton symptom assessment system (Richardson and Jones, 2009);
- stress assessment (Cohen et al., 1983; Cohen, Janicki-Deverts and Miller, 2007; Torres and Nowson, 2007; Ozier et al., 2008; Greenfield and Marks, 2009; Stewart-Knox et al., 2012);

- food addiction scale (Gearhardt, Corbin and Brownell, 2009; Pursey et al., 2014);
- motivation assessment tools (Ceccarini et al., 2015); and
- signs and symptoms analysis (Weatherby, 2004).

Sharma and Padwal (2010) provide an aetiological framework for the assessment and management of obesity. They provide a wide range of considerations regarding the underlying pathology and complexity of obesity development including: genetics, gender, age, medication, sociocultural factors, physiological and psychological factors. They do not provide a health data-collection or assessment tool. The framework is theoretical and lacks a practical application. This paper was key for identifying categories/headings of pathophysiological mechanisms in the development of the project's tools. Sharma and Padwal (2010) state that although their framework is time-consuming in terms of systematically assessing the range of individual factors contributing to obesity, it would save costs by allowing practitioners to target interventions to an individual's underlying pathology rather than a one-size-fits-all approach.

Beechy et al. (2012) undertook a review to provide researchers and clinicians with a guide to the current and emerging measurement tools for assessing body composition. They review a number of tools used to measure: psychological health, diet intake, physical exercise and hunger assessment in obese populations. This helped to identify a range of existing tools within these categories to support new tool development. Some of the tools reviewed in this study are utilised in clinical trials of anti-obesity drugs or after bariatric surgery. Use of these same tools in nutrition practice may allow for a comparison of nutrition intervention to drugs and surgery.

Chambers & Swanson (2006) undertook a pilot trial of a 100 item self-reported health assessment questionnaire for multiple risk factors for obesity and related health behaviour findings, as well as measures such as BMI. The risk factor categories include food, physical activity and inactivity as well as other considerations such as sleep, smoking and current weight control behaviours. The tool mainly assesses individual eating and exercise behaviour, which allows interventions to be targeted to support individual behaviour change. Sleep, childhood, maturity and family background were included as risk factors. A risk factor is an attribute which increases the chance of disease, whereas pathophysiology seeks to explain the mechanisms by which a disease develops and progresses. Gathering data on risk factors may not support clinical decision making, for example: knowing there is a family background of obesity suggests a genetic and/or environmental influence (van der Sande et al., 2001) but does not provide further insight. A clearer understanding of individual pathophysiological mechanisms involved in genetic and environmental influences would better support a personalised nutrition practice approach.

NICE (2014a) guidelines on obesity assessment, identification and management state that the following should be assessed in a nutrition consultation: presenting symptoms, underlying causes, comorbidities, risk factors, lifestyle, psychosocial distress, psychological problems, medication, family history, the individual's view of their weight and possible reasons for weight gain, eating and physical activity patterns, unhelpful beliefs about eating, physical activity or weight gain, ethnic and socioeconomic background information and environmental factors, what has been successful for the individual before, their readiness to change and confidence in making change. This highlights the need to consider a wide range of influences on obesity development beyond pathophysiological mechanisms and beyond the range of biopsychosocial factors at various systems levels as presented in Figure 4 (Yan, 2012a). The NICE guidelines (NICE, 2014a) do not recommend which tools should be used for assessing presenting symptoms, underlying causes, comorbidities, risk factors etc. It is assumed that the choice of assessment method is left to the practitioner or health practice for which the practitioner works. Interestingly, the NICE guidelines (NICE, 2014a) do make recommendations for laboratory tests which determine pathophysiological function in obesity, such as fasting insulin, lipid profile, endocrine function and liver function assessments.

Ginsburg and Willard (2009) reviewed important steps in the advancement of personalised health care. They consider that health risk assessment (HRA) and risk stratification should form the basis for prediction and personalisation. They consider HRA in combination with family health history (FHH) assessment is critical because it enables the complex combination of genetics, environment and lifestyle factors to be assessed. Historically FHH has not been well utilised because it lacks validity, standard collection methods, usable access and clinical guidance for interpretation and decision making (Ginsburg & Willard, 2009).

Tickle-Degnen and Bedell (2003) argue that all relevant, valid and available research evidence should be used when making clinical decisions. They critically appraise the standard levels of the evidence model and justify a flexible multifaceted approach to assessing, selecting and using research evidence for clinical decision making. Making all data available for consideration in clinical decision making is arguably appropriate, but it would not necessarily support timely decision making without a value-based hierarchy. Ginsburg and Willard (2009) also reviewed clinical decision support and the issue of the average 17-year duration for clinical research to feed into clinical practice. They state the most effective method for providing clinical decision support is to deliver the right, person-specific data at the most appropriate time (Ginsburg & Willard, 2009). To achieve this would

require an online data system, whereas the data-collection tools identified in numerous searches undertaken by this project are mainly paper-based.

In terms of assessing clinical outcomes, Donabedian (2005) undertook a review to evaluate current methods for assessing the outcomes and quality of medical care, included clinical records and direct observation. Donabedian (2005) acknowledges outcomes are difficult to measure. According to MacDermid, Grewal and MacIntyre (2009), the first step in choosing an outcome measure is deciding which attributes are of clinical interest. Tools currently in use in nutrition practice include the MYMOP, which is a patient generated and individualised outcomes assessment. In a comparative study between the MYMOP, the medical outcomes short form-36 (SF36) health survey, and a 5-point health change score, the MYMOP showed itself to be more sensitive to change than the SF36 (Paterson, 1996).

Greenhalgh et al. (2005) state that patient-reported outcome and health-related quality of life measures have little influence on clinical decision making and that studies which measure these outcomes are concerned only with whether the intervention works, rather than *how* the intervention works. Greenhalgh et al. (2005) agrees that insight into pathophysiological mechanisms would support clinical decision making as long as the tools used are patient-centred and the data is fed back to clinicians in a way that it can be integrated with clinical information throughout the clinical decision-making process. However, measuring outcomes of interventions is still required to determine the efficacy of interventions.

A task force report on 'Developing Obesity Outcomes and Learning Standards' (Wolf, 2002) discuss measures such as sleep, quality of life, physical exercise etc. in terms of assessing health outcomes in obesity management. They concur that long-term assessment of these outcomes may allow for more robust data analysis.

Vo et al. (2016) undertook a systematic review of tools used to assess the outcomes of pharmacist interventions. They managed to identify 82 distinct tools with various structures from implicit mono-dimensional to explicit multi-dimensional tools. They concluded that most tools focused on clinical assessment, not a range of potential impacts to outcomes as a result of intervention. Vo et al. (2016) state that a comprehensive tool for assessing clinical outcomes is not yet available. They suggest that this was most likely to be due to the fact that tools are constructed on theoretical models and therefore may not be suitable for clinical practice.

The BDA (2015) model and process for nutrition practice provides a list of indicators that can measure outcomes when compared against reference standards or baseline measures. These include anthropometry, biochemical laboratory markers, clinical and physical measures such as nutritional status, complications and symptoms, dietary assessment as

well as environmental, behavioural, social and psychological assessment. However, other than anthropometry and laboratory assessment, no specific tools are recommended or named by the BDA to undertake these assessments.

The Institute of Functional Medicine (2018) do provide a range of tools including medical symptoms questionnaire, female and male health assessment questionnaires, sleep questionnaire, activity questionnaire and numerous other non-validated clinical data assessment tools. None of the tools seem to enable robust evaluation of the outcomes of interventions. Interestingly, the health assessment tools gather individual medical history and symptoms data under headings of pathophysiological function including gastrointestinal, respiratory, urinary/genital, musculoskeletal, skin, cardiovascular, neurological/emotional and inflammatory/immune categories. Further research is required to establish whether these tools or this form of data collection is valid and supports clinical decision making.

Overall, this review has highlighted that although numerous validated tools for obesity assessment exist, the majority assess only some risks, measures or mechanisms, such as hunger assessment, sleep assessment, quality of life, wellbeing assessment, behaviour and addiction (Beechy et al., 2012). Most of these tools were also developed from a research perspective rather than a clinical perspective and may therefore not support clinical decision making in personalised nutrition practice. There appears to be no comprehensive validated tool to assess the range of complex mechanisms involved in obesity. Sources which did explore the complexity of obesity (Beechy et al., 2012; NICE, 2014a) did not provide tools for use in clinical assessment. Other than anthropometric measurements and laboratory assessments, there currently appear to be no standardised data-collection methods to gather individual health data or assess the outcomes of interventions utilised in nutrition practice (AfN, 2018; BDA, 2015; NTEC, 2015).

2.6 Developing a standardised personalised approach

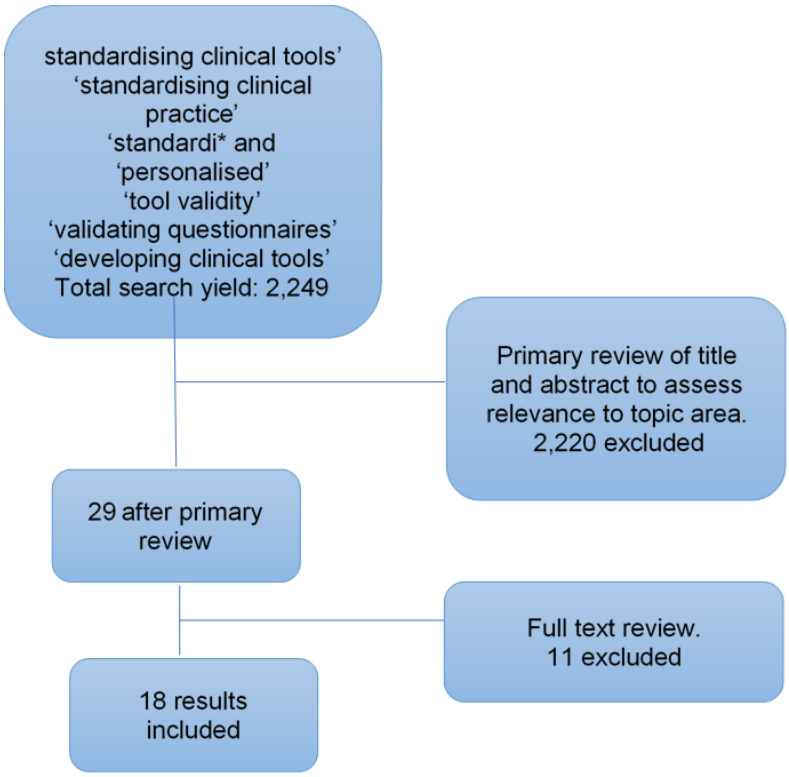

Figure 8 *Numbers of papers reviewed for standardising, developing and validating personalised nutrition practice tools resulting from keyword searches at the outset of the project*

This review explores a range of considerations for robust standardised data collection tool development and their integration with nutrition practice. Of the 2,249 papers initially yielded by this search, the majority were excluded because they discussed specific health conditions, or standardising clinical practice recommendations, which are unrelated to this project. This project does not seek to standardise personalised nutrition practice through the development of clinical guidelines. It seeks to standardise health data-collection methods from individual clients, so the data can be statistically analysed and compared.

Of the 9 included studies which utilised "standardised" or "standardi*" in the search term, there were 5 reviews which looked at: the experiences of implementing standardised electronic health records for Canadian Nurses (Hannah et al., 2009), the clinical utility of adopting PM (van Rooij, Wilson and Marsh, 2012), the value of consensus-driven evidence-based clinical pathways (Kurtin and Stucky, 2009), key factors for the development of new tools for personalised health data collection (Harvey et al., 2012) and the data management and informatics challenges of integrating and managing individual's health data (Sheldon and Ou, 2013).

Of the primary studies included, Wood and Nelson (2013) analysed nursing records to identify how nurses had historically pursued best practice, and their study identified that their

approach to improvement was the standardisation of procedures. Bruner et al. (2012) analysed nursing literature to explore the concept of clinical significance in relation to evidence-based practice and whether clinical significance can exist when it depends on individual patient values. Collins et al. (2013) undertook a survey (n=6) to evaluate a collaborative project which developed standardised electronic health records. Thiru et al. (2003) also utilised a collaborative technique to develop a framework, which aimed to facilitate standardised data collection in primary care.

The major reasons to standardise aspects of the personalised approach are to ensure parity of care among practitioners, that the data collected has the most value from a research point of view, and that data outcomes are able to inform intervention decisions (van Rooij et al., 2012). Computerised data interpretation and decision support tools could make better data available to practitioners and enable evidence-based validation of decision-making algorithms (Zenker, Rubin and Clermont, 2007). The benefits of standardised clinical outcomes data are also described by Hannah et al. (2009) as allowing practitioners to see the impact of their efforts on patient health outcomes, the benefit to patients as their health outcomes improve, improved continuity and quality of patient care and giving decision and policy makers more detailed analysis data on effective or ineffective practice.

Sheldon and Ou (2013) discuss the importance of high quality standardised clinical data which also assesses intervention outcomes and analyses information from multiple, disparate and heterogeneous sources such as lifestyle, laboratory data, family history, clinical trials and clinical practice for the purposes of clinical research. However, clinical data is often inconsistent and incomplete, so any data integration approach must have a method for separating non-validated or poor-quality data from accurate, complete and standardised data (Sheldon & Ou, 2013). This highlights the need for continued quality control and re-analysis of the validity of data gathered by new tools (Sheldon & Ou, 2013).

Of the 8 studies included from searching “tool validity”, “validating questionnaires” and “developing clinical tools”; 4 undertook validation of health tools: Brisbois-Clarkson et al. (2009) validated a micronutrient preference checklist for a specific population. Sharma et al. (2004) assessed the feasibility of a global mental health assessment computerised tool which standardises the assessment of mental health problems; Cohn et al. (2010) developed and evaluated the usability and analytic validity of an online FHH assessment tool and Spook et al. (2013) examined the feasibility, utility and economic validity of a smartphone application (app) which monitors dietary intake and physical activity levels. What is interesting about this last paper is that it discusses the advantages and disadvantages of collecting real-time data using smartphone and online apps. They reported that it is possible to gather complex health behaviours and related influences through smartphone

applications, but that varying compliance comes from the monitoring burden of having to constantly input diet and physical activity, which affects the validity of the data.

Two included studies reviewed commonly used statistical methods to evaluate reliability and validity (Jones, 2004; White and van den Broek, 2004). Although types of validity are frequently described in the literature, there is no gold standard method for achieving validity. Elia and Stratton (2011) critically examined the relevance of validity – specifically concurrent and predictive validity for nutrition screening tools. They provide a framework for screening clinical tools by assessing the tool's aims, its application in various care settings and its processes for user implementation, as well as the evidence-based principles supporting the tool, such as reliability, validity and ease of use. Elia and Stratton (2011) acknowledge that there are many dimensions to validity, including content, construct, concurrent, criterion and predictive. Jones (2004) makes it clear that a number of studies are required to assess validity (as it is an ongoing process) and that numerous validation assessments will have to be undertaken on an ongoing basis.

Thiru et al. (2003) recognise that ruthless standardisation may undermine itself and alienate practitioners. In order to successfully engage practitioners in the use of standardised information and to achieve successful transformation of clinical practice processes, then managing cultural change and highlighting the benefits to practitioners and patients is key (Hannah et al., 2009). A collaborative approach may facilitate these changes culturally. Bruner et al. (2012) also recognises that standardising definitions, measures and methodology is essential to being able to disseminate best practices.

Bouwman et al. (2008) interviewed 15 GPs, as "gatekeepers of health" who are instrumental to influencing the views and perspectives of patients on personalised nutrition. These interviews were qualitatively analysed to assess their perceived barriers and opportunities towards involvement in gene-based nutrition advice. Only one participant had heard of nutrigenomics and nutrigenetics and he perceived it relevant to nutritionists and not general practice (Bouwman et al., 2008). Education and involvement of individual consumers and a range of health care practitioners, including GPs, is therefore essential to the success of future personalised nutrition approaches.

Harvey et al. (2012) states that the development of new tools for personalised health data collection need to not only be standardised but also integrated and harmonised in order to collate and analyse data in an integrated and dynamic rather than linear way.

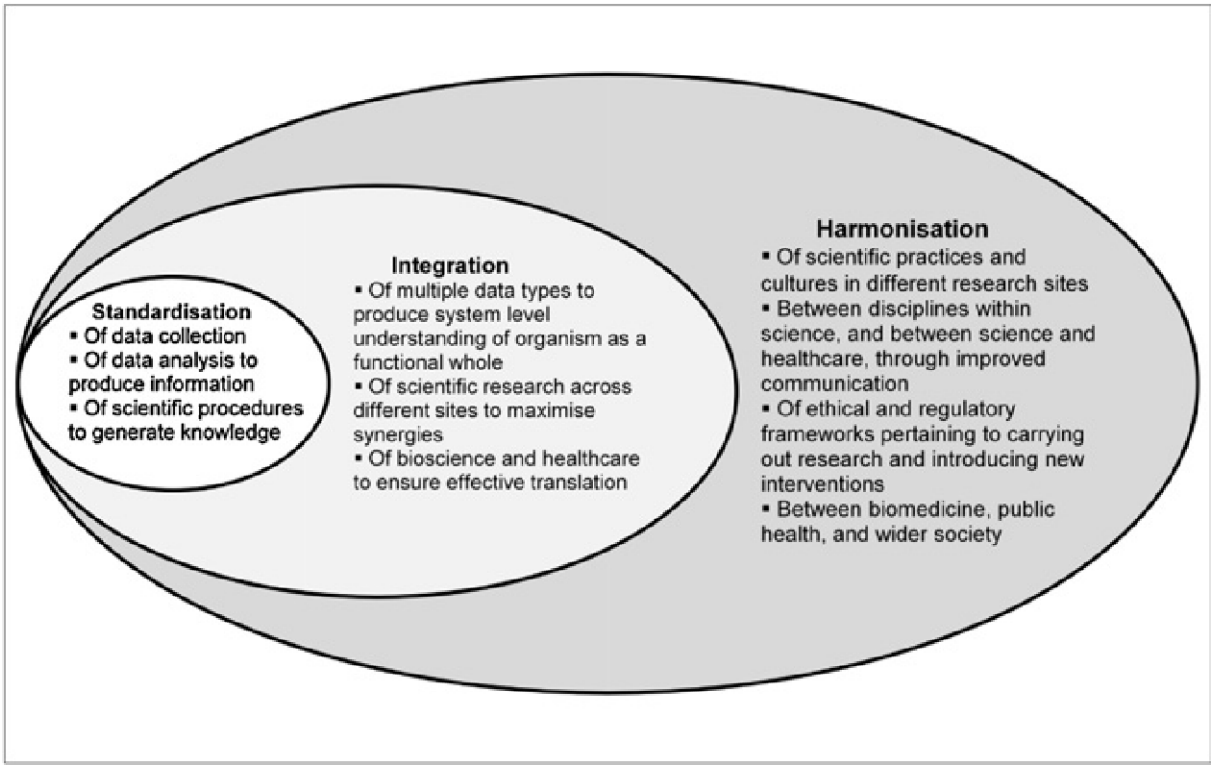

Figure 9 *Standardisation, integration and harmonisation in personalised medicine taken from Harvey et al. (2012)*

Hannah et al. (2009) recognise that in order to successfully engage practitioners in the use of standardised health records and to achieve successful transformation of clinical practice processes, managing cultural change and highlighting the benefits to the patient and their own practice are key. Bruner et al. (2012) states that standardising definitions, measures and methodology is essential to being able to disseminate examples of best practice. Clinicians should use standardised, validated and reliable measures to evaluate their intervention decisions and clinical outcomes (MacDermid, Grewal and MacIntyre, 2009) but the ethical considerations of standardising data-collection methods in personalised nutrition practice should be fully considered first.

In 2009 the National Council for Osteopathic Research (NCOR) introduced standardised data-collection tools for osteopaths in private practice. Standard data collection is also undertaken by members of the Chartered Society of Physiotherapy (2018). Aside from anonymised data-collection methods, there were no other ethical issues raised in their documentation. Interestingly, the primary motivations for NCOR (2009) standardising data-collection methods were to enable profiling of professional activities including clinical practice, protecting the scope of practice in the face of increasing regulation, increasing professional visibility and raising standards of care by focusing on management practices and outcomes.

2.7 Ethical considerations for standardising a personalised approach

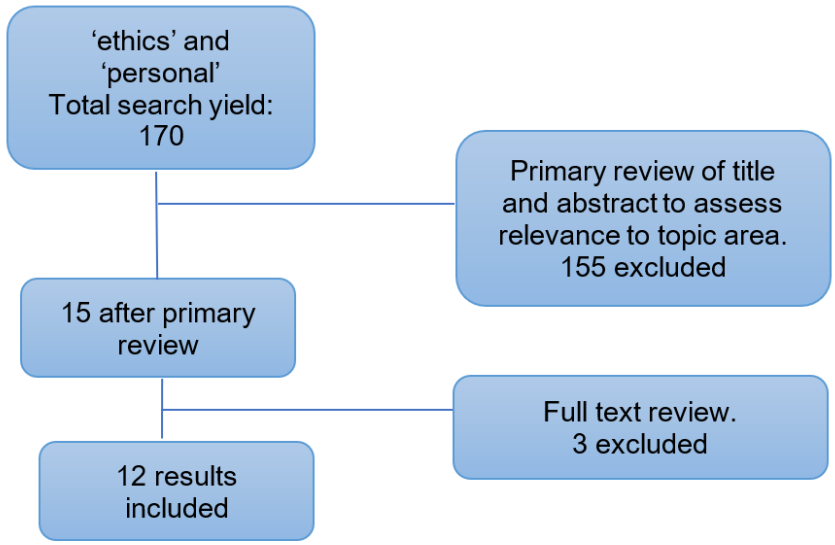

Figure 10 *Numbers of papers reviewed on ethical considerations for standardising a personalised approach resulting from keyword searches at the outset of the project*

This review aims to evaluate ethical considerations for standardising a personalised approach to nutrition practice. The search for "ethics" and "personalised" initially yielded 170 papers. The majority were excluded because they were unrelated to this project. Of the 12 included studies, 11 were review studies and 1 was a Nuffield Health consultation paper (Finnegan, 2009) which provided a comprehensive exploration of bioethical concerns relating to PM. Of the included review studies, two resulted from the Food4me study (Görman, 2007; Görman et al., 2013) and explored the meanings of ethics, health and welfare as well as the role food plays in social, cultural and personal identity.

Three of the included studies, (Burke and Psaty, 2007; Lévesque et al., 2008; Chalmers et al., 2013) review ethics in particular relation to genetic and genomic data. Chalmers et al. (2013) points out the blurred lines between research and providing clinical care as well as issues including privacy and sharing/pooling of data, consent, management of 'incidental' findings, comprehensiveness of reporting and the question of return of results to participants, in relation to genetic and genomic test results and clinical practice. Also included was a study by Shoenbill et al., (2013) which addresses the ethical, logistical and technological issues involved in incorporating genetic data into electronic health records.

Pooling electronic health data into a case-by-case evidence base does present numerous issues with informed consent, privacy, transparency, confidentiality and data protection. Kaplan (2016) explores the issues around electronic health data, data sharing, big data and data mining, including the balance between individual privacy versus the aggregate public interest. Solutions for overcoming key issues for data mining electronic health records are

discussed in the literature (Blumenthal and Tavenner, 2010; Jensen, Jensen and Brunak, 2012; Ross, Wei and Ohno-Machado, 2014). Some of these issues of privacy, confidentiality and data protection can be overcome by collating anonymised data (Graham, 2012). Clarity and transparency related to ownership, trustworthy intermediaries and legal protection are also essential (Harvey et al., 2012).

Gefenas et al. (2011) explored ethics issues of personalised, predictive and preventative health care as well as the human rights influences which shifted modern medical ethics from paternalism to autonomy-based therapeutic relationships. One potential concern is whether the increase in data to support clinical decision making through the increased power of prediction will lead to an increase in the authority of the practitioner, lead to a more directive type of relationship and the promotion of paternalism (Gefenas et al., 2011). There is a shift in the doctor-patient relationship from paternalism to the ethical principle of patient's autonomy, where patients are customers and want to take an active role in decisions that affect them (Sacristán, 2013). Sacristán (2013) claims that person-centred health medicine is broader than PM as it includes the psychological, social and cultural considerations of the patient. I disagree; comprehensive personalised approaches should also include psychological, social and cultural considerations. Miles (2013) also discusses ethical issues related to person-centred health care and the need to consider individual psychological, emotional and social necessities. Individual values and views regarding their health outcomes are also important.

A personalised approach could strengthen patient autonomy and enhance individual health control (Nordström et al., 2013). However, owing to the complexity of nutritional information, one has to consider autonomy in relation to responsibility and trust. Nordström et al. (2013) reviewed autonomy and responsibility and the dilemma of individualisation, such as: the conflicts between individual and societal expectations, the rights and capabilities of individuals, the complexity of individual health behaviour and trust in companies or institutions offering personalised nutrition services. Acceptance of personalised nutrition therefore depends on consumers' understanding of its benefits and implications (de Roos, 2013).

As a result of the development of PM, Meslin and Cho (2010) consider the need for updating the social contract between science and society, while Corrigan (2014) explores the concept and potential inequality, of the consumer of personalised health care. Enabling the development of a new case-by-case evidence base for personalised nutrition practice may be ethically essential to support therapists' ability to think abductively and improve their practice outcomes (Paul, 1993; Koehn, 1994).

The stigma of obesity is another ethical issue (Puhl and Brownell, 2001; Puhl and Heuer, 2009, 2010; Karasu, 2012), including stigma from nutrition practitioners (Berryman et al., 2006). Discrimination is another issue raised by Chalmers et al. (2013). If this new personalised nutrition practice service is paid for by the consumer and is effective at supporting clinical decision making and therefore improving health outcomes, are those who cannot afford to pay for this approach being discriminated against? Currently nutritional therapy is privately funded by individual clients. Dietetics is offered through the NHS, but only if a patient has been 'diagnosed' with ill-health. If nutritional therapy is going to be accepted into mainstream health care, then who pays for it? Finnegan (2009) points out that the NHS is founded on the principle that everyone has the right to treatment, but nutrition intervention is not currently considered a primary treatment approach – rather a preventative one. If the development of a case-by-case evidence base allows for further identification of the validity and efficacy of personalised intervention approaches for obesity or other disease, and even allows for cost comparisons against conventional treatment approaches, then it may become appropriate to integrate nutritional therapy into mainstream health care provision.

Ethical issues raised by Penders et al. (2007) consider whether nutritional categorisation /stratification will be a stigma and if certain categories receive more interest from food manufacturing companies or for health insurance purposes. Fierz (2004) agrees there is an ethical risk that there will be subgroups of minority patients who will be negatively impacted by such an approach. Görman (2007) has explored the meanings of ethics, health and welfare as well as the role food plays in social, cultural and personal identity. He raises interesting ethical questions when using food as an instrument for health and asks:

> Will personalised nutrition contribute to a good life? Or will personalised nutrition instead limit the role of some or all food to medicine and transform eating into lifelong medication?
>
> (Görman, 2007)

This is also explored by Lévesque et al. (2008) who states that "healthism" may raise excessively narrowly-focused expectations about one's health, as well as alter social norms about food choices and lead to the medicalisation of food.

According to the Nuffield Council on Bioethics consultation paper (Finnegan, 2009) there is strong commercial pressure to move to a more consumer-driven approach to health care because, rather than offering preventative health care, this is expected to expand health care markets. Finnegan (2009) quotes the former chair of GlaxoSmithKline who proposed that by 2020 there will be more emphasis on "pre-symptomatic" treatment because including healthy people would provide a bigger 'treatment' market; gaining commercial control of diagnostic and prognostic tests are key to achieving this as they would allow for target

marketing of health care products and services. Pre-symptomatic treatment is different to a preventative approach to health care. Finnegan (2009) goes on to say that a health care approach based on marketing products can lead to the neglect of public health. This does not explore where the line is between marketing health care products and making patients aware of a range of health care choices. The government has policies for reducing obesity and improving health by “helping people make healthier choices” (Department of Health 2015) which are clearly aimed at prevention rather than cure.

Chalmers et al. (2013) raise valid considerations for obtaining broad consent, stating that as much information as possible should be provided and that a strong framework of governance needs to be put in place to help safeguard participants’/clients’ rights as well as facilitate responsible research. They state that gauging public opinion is essential to the process of determining best-practice regulation and governance.

2.8 Transforming personalised nutrition practice

By pulling together the results from all the searches so far, and from wider sources, it is possible to consider the development of personalised nutrition practice and what it would take to achieve the vision of developing a case-by-case evidence base to support it. It is not the aim of this project to develop a new case-by-case evidence base. Indeed, it does not even seek to build new electronic health record tools for personalised nutrition practice, rather, this project has constructed new clinical tools which aim to standardise clinical data-collection methods and support pathophysiological mechanistic reasoning. Standardised tools provide the opportunity to develop a case-by-case database that can both improve the quality of care and provide opportunities to undertake translational nutrition research (Khoury et al., 2009). Ginsburg and Willard (2009) agree that a personalised approach requires the development of robust, standardised and validated tools, including health risk assessment, family health history and clinical decision support tools. It also requires integration of these tools into health systems and workflows. The development of any health information system relies on the quality of the data gathered. The completeness, reliability and validity of each tool are key.

As discussed, it is the plurality of evidence and statistical machine learning that could enable us to produce complex statistical models from computer readable clinical descriptions and provide weighted predictions, therefore supporting clinical decision making (Carmeli et al., 2012). Systems biology offers an approach to analysing and comparing complex health data, including the outcomes of interventions, which would make this data and research translational. cPNI may help to rebuild the philosophical connection between holism and reductionism in biomedical health care by establishing integrative models of systemic interactions (Yan, 2012a).

Person-centred nutrition is currently being provided by nutrition practitioners by tailoring nutrition and lifestyle interventions to individual consumers under the name ‘personalised’. Bio-molecular laboratory data is required to inform personalised nutrition intervention decisions, but that data itself does not constitute ‘personalised nutrition practice’. Although genetic testing supports personalised nutrition practice, this data is currently not available for most individuals and the evidence to support clinical decision making based on research is not yet sufficient (Görman et al., 2013). However, new personalised nutrition tools should be able to integrate laboratory data, genetic and genomic data. Molecular nutrition will become the foundation for future nutrition practice (DeBusk et al., 2011).

Biological data is interrelated, and therefore the data gathered is not independent, but an interrelated and connected source (Sheldon & Ou, 2013). The issues with using a mechanistic approach are that mechanisms are primarily theoretical, and systems may be too complex to allow inference about causal interactions (Nardini et al., 2012). Data can therefore be gathered using a mechanistic approach to support pathophysiological reasoning, but intervention decisions should be based on robust evidence, including clinical trials and CER.

CER should give a rigorous evaluation of the impact of different therapeutic options and the extent to which, under normal conditions, they perform as intended (Khoury et al., 2009). Randomised control trials (RCTs) are more focused on efficacy – the extent to which an intervention produces a beneficial result under ideal conditions, whereas CER use a diverse population (typically recruited from a variety of settings) and measures a broad range of clinical and health outcomes (Khoury et al., 2009). However, both RCTs and CER give no indication of how an intervention caused the outcome, which mechanistic reasoning does consider. Howick (2011, p. 154) explores the need for combining mechanistic reasoning with CER to bolster the strength of evidence and support clinical decision making. Rather than choosing the treatment with the best scientific evidence, we should use the scientific evidence to create the best treatment interventions for the individual. This constitutes an evidence-based personalised practice approach.

The use of individual biochemistry, physiology, pathology, psychological, social and cultural data to create a unique intervention also constitutes personalised nutrition practice. Tracking individual responses to changes in diet, nutrient intake and lifestyle (also known as the N = 1 approach) can utilise statistical machine learning to produce a comprehensive analysis of the impact of dietary interventions. Collating this data for numerous individuals amounts to developing a case-by-case evidence base which may be utilised to make probable predictions on the outcomes of dietary interventions. This could better support evidence-based clinical decision making than the current paradigm.

However, the number of combinations and permutations of genetic, lifestyle, diet and environmental factors is so large it may never be possible to evaluate all such interactions (Penders et al., 2007). A solution to this is stratification. An analogy is drawn by Penders et al. (2007) who compare stratification with clothing sizes; although a size 10, 12 or 14 is not tailored, they are more suitable for individuals. When health and intervention data from numerous individuals is stratified into subgroups, where it can be analysed and compared, it may then it may be possible to validate interventions for various subgroups, make probabilistic predictions on the outcome of interventions and deliver a P4 approach.

Fierz (2004) reviewed the challenges for delivering personalised health care and agrees that the ultimate goal of personal information is robust, comparable, lifelong, comprehensive electronic health records. The development of tools that connect personal information, including health data and test results, to the existing evidence base would better inform clinical decision making. With the advent of the 'internet of things', personal health and activity data can now be collated from a range of sources, including wearable devices (Chiauzzi, Rodarte and DasMahapatra, 2015) which are considered to be a cornerstone in the field of health informatics (Zheng et al., 2014). The use of information technology to improve dietary assessment and tackle obesity has been assessed by Carter et al. (2012). Online applications would allow real-time, long-term data collection by enabling individuals to track their own diet intake and other measures such as weight, food intake, exercise, health outcomes etc.

Shklovsky-Kordi et al. (2005) developed a computerised case history data-collection system for monitoring patient information and clinical outcomes. They aimed for their system to be patient-centred and permit easy communication between different specialities of health practitioners, which meant it had to accommodate different documents including test results, text files and images. Villa et al. (2012) have also designed a tool that translates ontological patient data into visual concept and mind maps to help users understand the clinical case and visualise the interrelated medical concepts. This gives an insight into how clinical data from new tools may be analysed and interpreted to support clinical decision making. As well as visual representations, compressing clinical data to highlight the most important or urgent information could add value. Villa et al. (2012) matched the data entered with stored protocols for diagnostic procedures and treatment. Although, as previously discussed, in personalised nutrition practice, it is not appropriate to use established intervention protocols, but rather present a range of evidence-based practice options. This can then can be discussed with patients and considered in terms of their individual needs, as well as social, cultural and financial implications.

Kawamoto et al. (2005) undertook a systematic review of RCT to identify which functions in clinical decision support systems helped to improve clinical outcomes. Kawamoto et al. (2005) identified that the provision of actionable recommendations, delivered automatically and at the time of decision making, have significantly improved patient care. There should also be a system which alerts practitioners to relevant updates as a result of new knowledge (Sheldon & Ou, 2013). Clinical decision support tools will therefore need to be able to deliver data via various systems of working, including updating health records and interactive technology (Sheldon & Ou, 2013).

Bouwman et al. (2005) discusses personalised nutrition communication through interactive computer technology and highlights that online approaches can provide individualised nutrition advice to a larger reach of people, but that web-based interventions do not necessarily tackle behaviour change. Bouwman et al. (2005) presents a framework for research on social acceptance of personalised nutrition communication through interactive computer technology, which can be used to assess the advantages of any new tools developed as online applications. Technology should allow individuals to gain access to personally relevant information but also to interact with support groups and health professionals (Bouwman et al., 2005).

The provision of 'broad consent' has been implemented in the UK for population-based genome projects and 'tiered consent' could also be considered. Although Chalmers et al. (2013) discussed genetic research, they raise valid considerations for the development of a case-by-case evidence base, and suggest that as much information as possible should be provided to participants. A strong governance framework needs to be put in place to help safeguard participants' rights, as well as facilitate responsible research. Ginsburg and Willard (2009) predict that regulatory and legislative policy will also change to support the emerging practice of personalised health care.

Ethical behaviour and good practice in undertaking and reporting on data is a key consideration. Petersen (2009) states that clinical expectations not supported by 'strong' evidence are unrealistic, misleading and may potentially affect the health and wellbeing of individuals and communities. Petersen (2009) goes on to state that modest, qualified claims are essential, which seems obvious, but examples of the Bovine Spongiform Encephalopathy (BSE) fiasco, the genetic modification controversy and other medical scandals given by Peterson (2009) make it clear that this approach has not always been taken. It could increase risk of rejection of innovative approaches such as personalised nutrition practice and its tools. Meslin and Cho (2010) also highlight the need for reciprocity: articulation of what constitutes benefit without overstatement, commitment to greater

transparency, involvement of the public in the scientific process and a commitment to achieving these goals over the pursuit of personal interest.

The development of personalised nutrition practice has yet another significant barrier: adherence (de Abreu et al., 2013; Grass et al., 2015). Personalised nutrition practice will only achieve improved quality of life if the end-users are motivated to change their behaviour and act on personalised dietary intervention recommendations (Ronteltap and van Trijp, 2007). Behaviour, engagement and adherence play a huge role in the success of client outcomes in nutrition practice. The benefit of personalised nutrition depends on the motivation of the individuals to change their dietary behaviours (Fallaize et al., 2013). A client's beliefs about their health and illnesses are also critically important, as these may be influencing the behavioural and physiological response to illness (Galland, 2006).

If individuals are not willing to change their eating routines, how can personalised nutrition practice help to prevent nutrition-associated diseases like obesity? Görman et al. (2013) demonstrate that the results of genetic tests may help to improve individual compliance to dietary changes, but this could be true of any test results which demonstrate the potential efficacy of the intervention. It may be education around the benefits of the intervention that positively influences compliance rather than the test result itself. Therefore, if practitioners are able to make probabilistic predictions on the efficacy of interventions, will that yield the same motivation? Implementing appropriate and sustained dietary change requires person-centred behavioural counselling (DeBusk et al., 2011). Developing effective evidence-based personalised nutrition practice tools may also enable practitioners to have more time to spend with clients to work on behaviour modification and education by spending less time on research and data gathering.

Problems with the feasibility of the mission of the project

Problems with the feasibility of fulfilling the long term aims (the mission) of the project firstly lie in the limitations of the numerous gaps in the data collected, ranging from reporting bias to tacit and unique variables of the therapeutic relationship. Secondly, the impact of standardising data collection methods may not be desirable if it limits practice flexibility. The art of the therapeutic consultation should aim to improve the client experience and enhance the therapeutic relationship. Any developments in the standardisation of data collection should support and not impinge negatively on this.

2.9 Chapter summary

This chapter has reviewed a wide range of literature pertinent to the work undertaken in this project and related directly to the project aims and research questions. The background of evidence-based and personalised nutrition practice has been explored along with a vision and potential scope for the development of a case-by-case evidence base for obesity

management which could transform personalised nutrition practice. Such a vision cannot be realised without underpinning tools which are robust and valid. The next chapter will further explore the methods undertaken for the construction of new clinical tools which aim to standardise case data-collection methods and enable assessment on the efficacy of nutrition interventions in obesity management.

Chapter 3 Project Design and Methodology

This chapter critically describes and justifies the choice of the research approach and data-collection methods. The overall reliability of the methodological approach is evaluated and ethical issues are explored. The author's role as an insider-researcher is also evaluated.

3.3 Project aims and objectives

As described in Chapter 1, the overarching project aims were to:

- evaluate the ethics, limitations and opportunities of standardising data-collection methods in personalised nutrition practice;
- construct new clinical tools for health data collection, clinical decision making and clinical outcome analysis that standardise case data-collection methods and enable assessment of the efficacy of interventions; and
- enable the development of a new, case-by-case, evidence base for personalised nutrition practice in obesity management.

The objectives were to:

- use a mixed methods collaborative research approach to achieve these aims;
- gather and evaluate existing clinical tools and review implications for standardising data-collection methods;
- collaboratively construct and trial new tools; and
- evaluate how these tools can be successfully integrated into practice.

3.4 Research questions

The main questions that the project is designed to answer are:

1. Is it possible and ethical to standardise a personalised approach to nutrition practice?
2. If so, what tools can be constructed and validated to help individual health history data collection, clinical decision making and clinical outcome analysis to enable the development of a case-by-case evidence base for personalised nutrition practice in the management of obesity?

Further questions raised by the main questions include:

- What are the implications and ethical considerations of standardising a personalised approach to nutrition practice?
- Is it possible to have a standardised tool that does not detract from personalised nutrition practice?
- What are the practitioner's views on the ethics and implications of standardising approaches to personalised nutrition practice?

- What tools currently support individual health history data collection, clinical decision making and clinical outcome analysis in nutrition practice for the management of obesity?
- What are the practitioner's experiences and views on using these tools?
- Do these tools measure a comprehensive range of pathophysiological mechanisms affecting individual aetiology of obesity?
- What are the strengths and weaknesses of these tools?
- What new tools could be constructed to enable individual health history data collection, clinical decision making and clinical outcome analysis in nutrition practice to support the management of obesity?
- Do these new tools measure a comprehensive range of pathophysiological mechanisms affecting individual aetiology of obesity?
- What are the clients' and practitioners' views and experiences of using these new tools?
- What is the impact of these tools on practice processes?
- What reliable and valid data do these new tools provide?
- How can standardised tools be integrated into personalised nutrition practice?
- How can standardised tools be used to build a case-by-case evidence base for personalised nutrition practice?

3.5 Ontological and epistemological considerations

The ontological and epistemological positioning of this project is complex for a number of reasons: the transdisciplinary positioning of the project (personalised health care, nutrition, obesity, health and wellbeing, translational bioinformatics, complexity, systems science etc.), the use of qualitative research methods to develop tools that require statistically measurable and comparable outcomes, and the subjective nature of self-reported health issues.

Clinical biomedical research has been shifting towards integrative and translational methodologies and frameworks (Zerhouni, 2006; Payne, Embi and Sen, 2009). Personalised nutrition practice aspires to be a predictive, translational systems science by creating a feedback loop where clinical evidence is used to refine clinical practice. It has been proposed that approaches such as emergence in complex systems and systems biology are better able to consider complexity than the reductionist approach (Ahn et al., 2006; Mazzocchi, 2008b; Fardet and Rock, 2014), on the basis that the 'rules' that exist in biochemistry and pathology are subject to modification by environmental and evolutionary forces.

Mixed method research does not necessarily mean “better” research (Brannen, 2005), however, in the context of this study it allowed for abductive, inductive and deductive reasoning and incorporated the ‘intersubjectivity’ of the researcher to conceive and produce robust measures for new tools by using multiple paths to explain meaning (Jupp, 2006, p. 116). Research methods reflect the complexities of the outcomes sought and were chosen to help achieve sustainable change. The Delphi survey method allowed for collaboration with representatives from diverse backgrounds and aimed to enhance the quality of the research, shape its products and help to limit researcher bias (Costley et al., 2010, p. 108). Collaboration sits within an interactionist research paradigm (Costley et al., 2010, p. 107).

The Delphi survey method is considered to favour a positivist paradigm with a realist ontology and representational epistemology (Hanafin, 2004). However, the approach taken for this project is qualitative and subjective; it gathered the participant’s opinions of the tools throughout iterative tool development using a series of Delphi survey rounds. Although it aimed to gain group consensus, this was rarely achieved. The results of the survey rounds were used to refine tool development, and therefore this element of the project sits within the constructivist paradigm.

The structured and standardised tools that resulted from the Delphi survey method sit within a positivist paradigm. These tools gather a mix of both objective and subjective health data and are designed to be statistically analysed and robust.

Concepts of health, wellbeing and quality of life are social and individual constructs. The WHO (Chatterji et al., 2002) has explored some of the issues relating the measuring concepts of health and disease. Chatterji et al. (2002) describe the necessity for a set of core health-measuring domains to facilitate valid, reliable and comparable tool development. The health-measuring domains for this project have emerged from key physiological mechanisms, which appear to contribute to obesity development, as identified during the research process.

3.6 Overall design

The research was designed to meet the research aims and objectives as well as the professional doctorate learning outcomes, which included making “a significant contribution to practice” (Coghlan, 2007). The project employed a mixed methods research design, including the Delphi survey method, to structure the group communication process so that the collaborative process was as effective as possible (Linstone and Turoff, 2002, p. 3).

The strengths of the approach include the collaborative, mixed methods design to consider this broad and complex problem with representatives from diverse backgrounds. Schon (1983) argues that professional knowledge has a wide scope of dynamic and complex

knowledge which was essential to explore. Collaborative research can benefit and enhance the quality of research (Costley, Elliott and Gibbs, 2010, p. 108).

There were five stages included in the overall design (see figure 11):

1. Literature review – to inform the project approach, tool development and answer research questions. The literature review was presented in Chapter 2.
2. Data gathering – to gather, categorise and evaluate existing tools and assess experiences of using tools, or tool development, to inform new tool construction.
3. Collaborative tool development – a multi-staged, Delphi survey method which aimed to achieve consensus for new tool development (Keeney, Hasson & McKenna, 2011).
4. Pilot trial – to trial new tools in practitioner's clinical setting.
5. Evaluation – to evaluate ways in which standardised tools can be embedded into personalised nutrition practice and enable the development of a new evidence base for personalised nutrition practice.

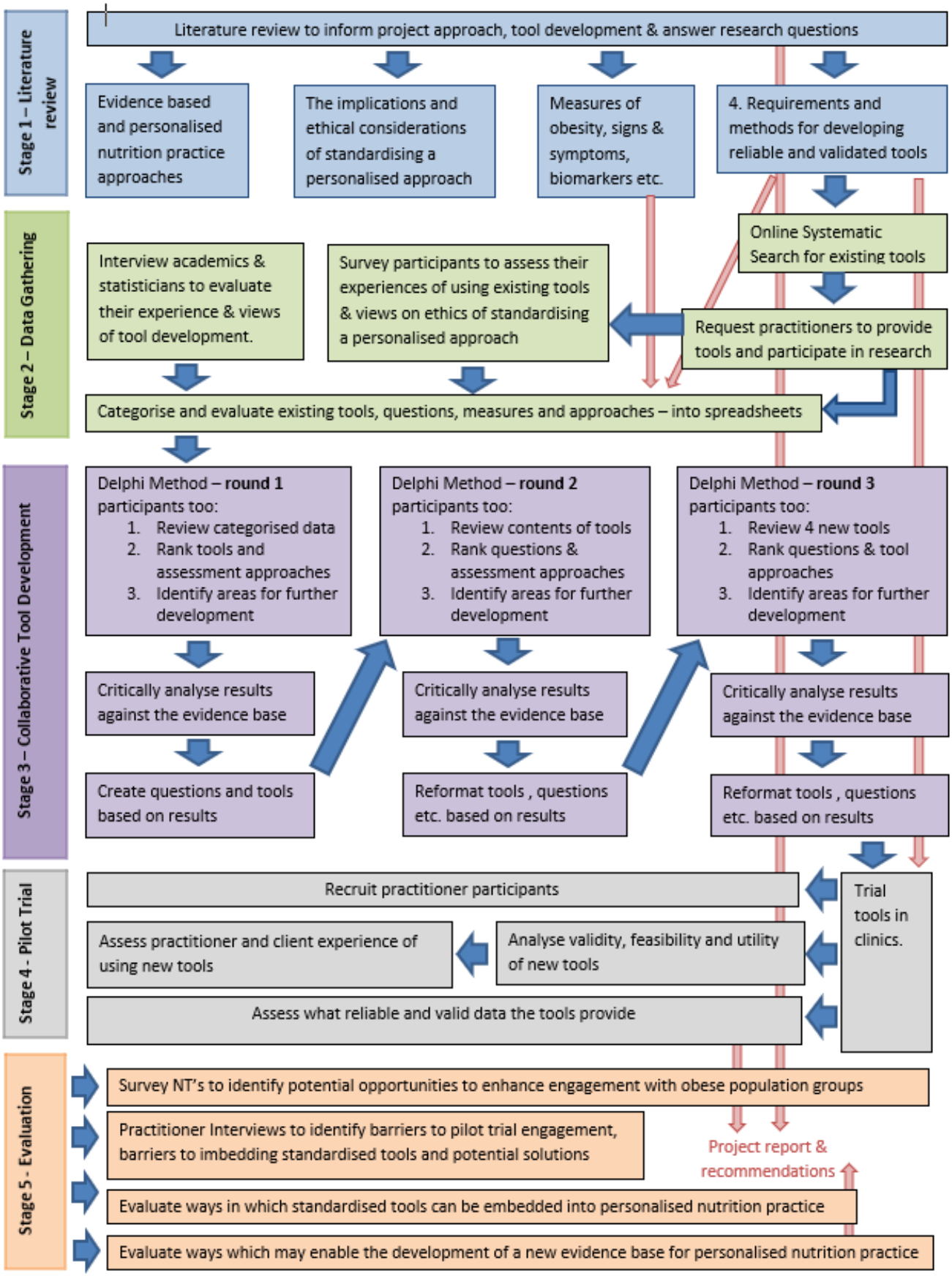

Figure 11 *Flow chart of the five stages of the research project*

Reflective practice took place throughout and between each of the stages to assess reflexivity and project progression through the use of a reflective journal. Reflective discussions with research supervisors, peers and participants were also recorded in the journal. The value of reflection for enhancing learning at doctoral level has been explored by Klenowski and Lunt (2008). Reflecting on my reflective journal entries was undertaken regularly to explore my personal development, subjectivity and reflexivity. Reflexivity is an essential component of research (Finlay, 1998) and is explored at length in Chapter 7. Positionality and my roles within the research project, as research facilitator, data gatherer and data interpreter, were briefly discussed in section 1.5. This is discussed again in the next section, as I aim to explore the impact of my role as an insider researcher on the project design, methodology and the potential bias that my position brings.

3.7 My role as an insider-researcher

Coghlan (2007) has explored some of the opportunities and challenges of insider research. Being within the nutritional therapy profession places me outside traditional dietetics or medical models, which influences my perception of the limitations of the current health care research model, but may also limit my understanding of what it would take to make the new proposed model work in mainstream health care. Drawing in a range of participants was therefore intended to support professional development and limit bias (Mitchell, Reilly and Logue, 2009). The benefits and tensions of collaborative research have been well explored in the literature (Hague and Snyder, 1991; Godin and Gingras, 2000; Macduff and Netting, 2000; Cummings and Kiesler, 2005; Li and Qiu, 2006; Cook, Learning and Hempstead, 2010; Hettiger, 2010; Paulson, Wajdi and Manz, 2012; Collins et al., 2013; Cheruvelil et al., 2014).

The complexities of the politics within the various nutrition professions have also impacted on the project outcomes. Dietitians and nutritionists appeared more reluctant to participate in the project than NTs. This observation may stem from my own perception and concerns as an outsider to these professions and stronger professional connections with NTs. This may also be due to the fact that my relationships with NTs are stronger, and, because of my insider position, which is why NTs were more willing participate in the project.

It is my belief that nutritional therapy is perceived to be less ‘legitimate’ than other nutritional professions because it is positioned as a complementary therapy. This drives my desire to be able to demonstrate the efficacy of nutritional therapy interventions and help to place it squarely within mainstream health care. Achieving this goal may lead to unintended consequences. For example, could the integration of NTs into mainstream health care actually spell the end of nutritional therapy due to the constraints of government guidelines

and nutrition policy? Some consequences are likely, but as well as the drawbacks there may also be unintended benefits.

Mercer (2009) states that as an insider-researcher I would enjoy freer access, stronger rapport and a deeper, more readily available frame of shared references with which to interpret the data I collected. However, I also had to limit the bias of my own preconceptions throughout the project – particularly during data analysis. Reflection allowed me to regularly question my approach, assumptions and role dynamics, as well as appraise ethical dilemmas as they arose. Collaborative enquiry has allowed me to more deeply explore and theorise my own areas of practice.

The following table represents how I envisage my position within the context of the participants and approaches to nutrition practice. The middle column represents where I am both an insider and outsider: for example, I teach and understand elements of functional medicine and clinical psychoneuroimmunology, but I am not registered as a practitioner at the IFM and I have not undertaken certified cPNI training. Although I am not a medical practitioner, I perceive myself to be part of teaching and developing a PM approach to health care. I have been a client of nutritional therapy and dietetics practitioners in the past but because of my training I am now an outsider as a client.

Table 1 *My insider/outsider positioning within the context of the participants and approaches to nutrition practice*

Insider	**Insider & outsider**	**Outsider**
Nutritional therapist	Functional medicine	Dietetics
Researcher	Clinical psychoneuroimmunology	Nutritionist
Academic	Personalised medicine	Obese
Personalised nutrition	Nutrition practitioner client	Statistician

3.7.1 Roles and responsibilities

Throughout the project, I have had a number of roles including: research co-ordinator, researcher, Head of Education at CNELM, nutritional therapist (in my own private practice), clinic supervisor and research supervisor.

Being an insider-researcher has had an impact on the research process and activities. The project has included a range and number of research participants, without whom this project would not have been possible. During the research process, there was a need to adapt the research activities based on participant feedback in order to gain participation. This is discussed further in Chapter 4.

It has been the responsibility of the nutrition practitioner participants to manage their clients as per the client information sheet (appendix 4). They tested the developed tools in their consultation process and were asked to ensure the client is provided with nutrition interventions that met their needs. It was also their responsibility to ensure they follow the guidelines and procedures set out for the research and undertaking the pilot trial (appendices 5 and 6). This approach ensured client confidentiality, but it also placed me outside of managing the client participants in the pilot trial phase, which made that process difficult to manage.

Overall, the positionality of insider research did impact on the research outcomes in that it was those participants who saw me as an insider that were easier to engage. It may have been better to focus solely on building tools for nutritional therapy practitioners, but the concern was that this could move nutritional therapy practice further away from mainstream acceptance rather than towards it.

3.8 Research methods

The mixed methods approach included:

1. Online searches for existing tools in obesity management and personalised nutrition practice, as well as the categorisation and evaluation of these tools.
2. A survey of nutrition practitioners to identify which tools they use in clinical practice and why.
3. Interviews with some of the survey participants to gather their views on clinical assessment and clinical decision making, as well as their views on ethics and standardising approaches to personalised nutrition practice.
4. Interviews with academics and statisticians to evaluate their views on and experience in how to undertake robust tool development for this project.
5. A Delphi survey to construct new robust clinical tools which assess the efficacy of personalised nutrition practice in obesity management.
6. A pilot trial of new tools with practitioners in clinical practice to achieve face validity and measure feasibility and utility for each of the four tools.
7. A survey of NTs to explore their engagement with an obese (BMI>30) population.
8. Interviews with nutrition practitioners to identify ways to embed standardised tools in personalised nutrition practice and explore potential approaches to overcome barriers.

3.9 Ethics and ethics approval

Ethics approval was obtained from the Middlesex University Ethics Committee in December 2013 (appendix 7), including approval for the data-collection procedures utilised in this study,

participant information sheets and consent forms. The research undertaken has complied with the Health and Social Care Research Ethics Sub-Committee guides. Two amendments were made to the ethics application. In May 2015, approval was obtained to include individuals from an obese population in Delphi group surveys (appendix 8). Sensitivity around seeking obese individuals was considered when recruiting participants. Then, in January 2017 approval was obtained to remove the word 'obesity' from the client participation sheet (appendix 10), as practitioner feedback during the pilot trial raised that practitioners may not be able to ascertain if their client met the obese (BMI >30) inclusion criteria before the consultation, and the client may not yet be aware that they are obese prior to the nutrition consultation.

The word 'obese' has numerous social stigmas (Puhl & Heuer, 2010). It was felt that this could be a barrier in engaging practitioners and their clients with the pilot trial process. Bias, stigma and discrimination towards obese individuals is unfortunately still pervasive (Puhl & Brownell, 2001). I therefore aimed to be as sensitive and supportive as possible, changing the wording as the project developed to exclude the use of the term 'obese' and instead referring to "clients seeking to lose weight".

Overall, the guiding principles of the Code of Human Research Ethics from the British Psychological Society (BPS, 2010) were followed: to obtain informed consent from potential research participants, to minimise the risk of harm to participants and protect their anonymity and confidentiality, to avoid using deceptive practices and to give participants the right to withdraw from the research.

It has been my role to ensure the relationship with these participants is based on principles of honesty and empowerment. The roles of the participants were made explicit in the participant information sheets (see appendices 4 and 5). Signed consent forms were sought from interview participants (see Appendix 10). To make the process easier and to encourage engagement, the data from the consent forms was transferred to the surveys, making it clear that their participation was entirely voluntary, that they could withdraw at any time and were free to omit any answers. They were also made aware that the data provided may be used for analysis and subsequent publication.

Procedures were implemented to maintain the confidentiality of the participant data. Personal information was stored in locked cabinets and computer files were secured by means of passwords. Only the researcher and authorised supervisors were able to access the information.

Silverman's (2006, p. 323) ethical safeguards model informed the relationship with participants. Participants were volunteers whose involvement was kept confidential. All those

involved were protected from harm and I aimed to build a mutual trust between the research and participants. Honesty was central to the relationship between the researcher, participants and institutional representatives (Walliman, 2005). Appropriate interpretation and translation of findings was conducted and I ensured that research results were fed back to participants where possible (Lienert, 2002).

Ethical considerations were reviewed at every stage. During the Delphi stage it became apparent from practitioner feedback that one of the questions relating to trauma on the newly developed tools could be a trigger for some clients. Stress and trauma is positively associated with adult obesity. A systematic review by Palmisano et al. (2016) which reviewed 70 studies (N=306,583 participants) concluded that 87% of those studies reported adverse events as a risk factor for developing obesity. Regardless of the association, in the final review of the tools, post-pilot trial, this one question relating to trauma was removed as in order to minimise risk of harm this question should not be asked via an online tool.

The ethical dimensions of complex research are themselves complex. One key area that I explored throughout the project was that of professionalism and ethics in complementary medicine, as nutritional therapy describes itself as a client-focused, evidence-based, complementary therapy (Benbow et al., 2017). Koehn's (1994) book on professional ethics was particularly thought-provoking in terms of professional expertise and authority. This seemed to reinforce the idea that enabling the development of new case-by-case evidence base for personalised nutrition practice was ethically essential to support therapists' ability to think abductively and improve their practice outcomes (Paul, 1993).

Another key area that I explored throughout the project were the differences in health care paradigms and practice approaches between complementary therapists and mainstream health care. I believe that nutritional therapy should be accessible through mainstream health care provision to offer equality of access. The Professional Standards Agency (PSA) are encouraging mainstream health care practices to create broader disciplinarily teams which include NTs (Professional Standards Authority, 2015). However, the stigma and perception that all complementary therapies are 'anti-science' is still pervasive (Crellin & Ania, 2002).

3.10 Data collection, analysis and evaluation

3.10.1 Identification, categorisation and evaluation of existing tools

An extensive search of Summon, Google Scholar, PubMed, Cochrane Library, Science Direct, Allied and Complementary Medicine, DH-DATA, Embase and Medline using the following keywords (see Table 2) in the title or title and abstract was conducted to identify

existing tools which support individual health history data collection, clinical decision making and clinical outcome analysis suitable for nutrition practice in the management of obesity.

Online searches were broken down into the following stages:

1. Broad search to identify tools
2. Categorisation of tools identified
3. Searches for tools related to each category
4. Evaluation of final results

Eight broad searches for existing tools were undertaken and tracked.

Table 2 *Search terms used for broad online searches to identify existing tools*

1	'obesity tool'
2	'assessment' AND 'obesity'
3	'obesity' AND 'questionnaire'
4	'individual health history data' AND 'tool'
5	'clinical decision making' AND 'tool'
6	'clinical outcome analysis' AND 'tool'
7	'measure clinical outcomes'
8	'obesity' AND 'nutrition screening'

The terms 'obesity' and 'tool' helped to focus the search results, as terms like 'individual health history data' and 'nutrition screening' were too broad. A search description form was completed for each of the search terms used (see example in appendix 1). Results were recorded with a brief critical summary in a "literature and tool search results tracker spreadsheet" (see appendix 3). The purpose of the results tracker spreadsheet was to make the search methodology both transparent and replicable. Any tools not deemed relevant for clinical nutrition practice to gather individual health history data, support clinical decision making or analyse clinical outcomes for adults in personalised nutrition practice obesity management were excluded.

Papers were reviewed and coded into themes via Nvivo. Specific tools or measures identified were then listed in the tool categorisation spreadsheet (see appendix 11). These results allowed for the identification of broad categories and some specific measures. When reviewing the results, the categories in the spreadsheet were emergently developed and notes about measures and tools were made within each of the eleven subject categories. The following categories were identified:

1. General
2. Diet and nutrition
3. Psychology
4. Physical activity
5. Genetics and family history
6. Physiological
7. Sociocultural
8. Body composition
9. Test results
10. Goals and outcomes
11. Intervention tracking

Once all papers identified from the first round of searches had been reviewed and the categorisation spreadsheet developed, it became clear that this initial broad search had not identified all relevant tools. Further searches were therefore conducted to identify tools relevant to each category before final evaluation of the results.

The benefits of this broad approach resulted in the identification of research papers highlighting the strengths and limitations of specific tools and research papers reviewing how to develop clinical tools.

A second search was therefore undertaken, utilising the same methodology as before, to identify tools related to each category.

Table 3 *Search terms used for online searches to identify existing tools for categories*

General category:	‘assessment’ AND ‘obesity’
	‘obesity’ AND ‘questionnaire’
Diet and nutrition category:	‘obesity’ AND ‘nutrition screening’
	‘nutrition’ AND ‘obesity’ AND ‘assessment’ OR ‘questionnaire’ OR ‘measure’
	‘Diet’ AND ‘obesity’ AND ‘assessment’ OR ‘questionnaire’ OR ‘measure’
Psychology:	‘psychology’ AND ‘obesity’ AND ‘assessment’ OR ‘questionnaire’ OR ‘measure’

Physical activity[1]	'physical activity' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'
Genetic predisposition	'genetics tool' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'
	'family history' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'
Physiological	'physiol*' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'
Sociocultural	Socio AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'
Body composition	'composition' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'
Test results	'blood' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure' No specific tools for this, just specific markers such as blood tests.
Goals and outcomes	'goals' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure' 'outcome' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure' (measuring outcomes of obesity interventions only)
Intervention tracking	'intervention' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'

Again, a search description form was completed for each of the search terms used (see appendix 1); see appendix 2 for inclusion and exclusion criteria and numbers of results. Results were also recorded in the literature and tool search results tracker spreadsheet (appendix 3). The tool categorisation spreadsheet (appendix 11) was updated to include further categories and measures. Quality assessment of the tools was undertaken. Tools and measures that were shown to be unreliable or invalid were excluded. Tools not suitable for an obese population or for nutrition practice were excluded. Tools where modification and distribution were prohibited were also excluded. Permission was sought to utilise tools identified as a part of this research project, where required. If permission was unobtainable then tools were excluded. Reasons for other exclusions were captured in the tool categorisation spreadsheet (appendix 11) under the following headings:

- aim of the tool's measurements;

[1] Physical activity was compared to exercise as a search term and physical activity provided more salient results.

- target population;
- permission to use tool;
- content;
- application e.g. self-reported or expert required;
- outcome measures;
- feasibility (cost, time burden);
- reliability, validity, interpretability, readability;
- comparative studies; and
- inclusion and exclusion criteria.

Resources were utilised to develop the above headings and formulate a robust quality assessment method (Bowling, 2005; Nahm et al., 2007; Beechy et al., 2012).

See Table 4 for a list of online literature searches conducted to inform new tool development and enable categorisation of questions according to pathophysiological mechanisms for obesity.

Table 4 *Search terms used for online searches to identify a range of pathophysiological mechanisms, 'other diseases', health conditions and red flags associated with obesity and tools and tests/measures assessing those mechanisms*

5.1	'signs and symptoms of obesity'
5.2	'biomarker' AND 'obesity'
5.3	'genetic marker' AND 'obesity'
5.4	'epigenetic marker' AND 'obesity'
5.5	'types of obesity'
5.6	'mediator' AND 'obesity'
5.1	'obesity related disease'

Again, a search description form was completed for each of the search terms used (see appendix 1). See appendix 2 for inclusion and exclusion criteria and numbers of results, and results were also recorded in the literature and tool search results tracker spreadsheet (appendix 3). Numerous other resources were also utilised to develop a comprehensive list of pathophysiological mechanisms, other diseases, health conditions and red flags (Bowling, 1995a, 2005; Kypreos, 2009; Stern and Kazaks, 2009; Nahikian-Nelms, 2011; NTEC, 2015).

3.10.2 Survey of nutrition practitioners

Results from the identification, categorisation and evaluation of existing tools were used to create a survey for nutrition practitioners which aimed to determine which of the tools

identified were being utilised in clinical nutrition practice, as well as gather practitioners' views on the strengths and weaknesses of these tools and identify other tools and data-collection methods practitioners utilise to gather client data.

The survey was conducted via the online tool SurveyMonkey (Finley, 1999). Thematising and designing of the survey was supported by review of the tailored design method guidelines in the 2009 book on surveys by Dillman et al. The survey was pilot tested twice with two nutrition practitioners before the link to the online survey was distributed via email to nutrition practitioners between October and December 2014. Recipients included: contacts generated from the online searches for tools, BANT members, my own contact list and the CNELM contact list.

A survey search and send tracker spreadsheet tracked the dates of the emails sent and holds the contact data for practitioners who had been emailed the survey (appendix 12). A total of 98 practitioners were emailed to complete the survey. When the survey closed on 1 January 2015 a total of 32 questionnaires had been completed. The response rate was 32%, which is considered to be average (Sheehan, 2006). Reminder emails were sent to increase response rates.

A mix of multiple-choice and open-ended questions in the surveys gathered quantitative and qualitative data. SurveyMonkey has a number of data analysis features. All response data was downloaded so the results could be analysed and evaluated. Quantitative data analysis was measured to identify the numbers of respondents using the tools or assessment methods and the most perceived strengths and weaknesses of the assessment methods.

Qualitative data analysis is not traditionally measured, but analysis allowed the identification of themes and informed new tool development. All participants who stated they were willing to allow the researcher to view the clinical tools forms and/or questionnaires they used or created were asked to provide them with written consent for use within the research project. These tools were reviewed to inform new tool development. The analysis of results also supported the formulation of interview questions for the interviews of participants, which allowed for triangulation of the data.

3.10.3 Interviews of survey participants

Results of the practitioner survey informed interview questions. All participants who stated in the survey that they were willing to participate in interviews were invited for interview. Interviews aimed to gather views on clinical tools, assessment and decision making, as well as evaluate views on the ethics and implications of standardising approaches to personalised nutrition. The objectives were to:

- evaluate practitioner views on standardising approaches to personalised practice;

- identify ways in which practitioners use clinical assessment to make clinical decisions;
- identify ways in which practitioners engage with the evidence base;
- evaluate implications for building new tools; and
- discuss potential ethical issues of building a case-by-case evidence base.

Interview techniques, ethics and strategies for improving quality were gleaned from Kval's (1996, p. 87) book titled *Interviews*, and its seven-step interview approach was utilised:

Step 1 – Thematising: Pulled together a list of potential participants and thoughts about the aims and questions.

Step 2 – Designing: interview aims and objectives and the interview guide were developed. A mix of open-ended, semi-structured questions were included to facilitate conversational dialogue.

Step 3 – Pilot testing questions: - feedback from my research supervisors was gathered on the interview guide, which led to a reordering of questions and eliminating any repetition for similar questions. Once completed, the interview guide (appendix 13) was sent to interviewees at least 5 days in advance to ensure that they had time to prepare.

Step 4 – Undertaking the interviews: Between 18 March and 9 April 2015, six interviews with nutrition practitioners were conducted. The interviewees included:

- two specialist obesity dietitians;
- two NTs who run group weight loss programmes;
- one NT and lecturer; and
- one naturopath and weight loss coach.

The interviews were held via an online conference facility (gotomeeting.com) at times convenient for the interviewees. The interviews were recorded for transcription purposes.

Step 5 – Transcribing: the audio recording was transcribed verbatim, uploaded to Nvivo and then coded under the following themes:

- standardised approaches;
- ethical issues;
- practitioner views on using tools;
- patient/client-centredness;
- health history assessment;
- clinical decision making;
- engagement with the evidence base;
- linking new tools to the evidence base;

- case studies;
- clinical outcome analysis.

Step 6 - Analysing: Kvale (1996, p. 192) describes a five-step interview analysis method that was utilised, including:

1. meaning condensation – summarising large interviewee statements into briefer ones
2. meaning categorisation – coding into categories
3. narrative structuring - structuring narratives in categories
4. meaning interpretation – interpreting the meaning of the texts
5. generating meaning through ad hoc methods – adding more context.

Step 7 – Verification: results were triangulated with literature during the writing up of results.

3.10.4 Interviews of academics and statisticians

The aim of the interviews with academics and statisticians was to evaluate their experience and views on tool development and validation and/or data set management to inform new tool development.

Objectives were to:

- evaluate ways in which new tools can provide reliable and statistically validated data;
- identify ways in which new tools can relate to the existing evidence base;
- evaluate ways in which tools can best be pilot tested or trialled; and
- identify implications and ethical issues of building a case-by-case evidence base.

Kvale's (1996, p. 87) seven-step interview approach was utilised, as with previous interviews. Participants were selectively sampled based on their experience of tools development, research skills or potential knowledge contribution. They were identified via LinkedIn and personal contacts. A mix of open-ended and semi-structured questions were included to facilitate conversational dialogue. The interview guides (see appendix 14) included the aims and objectives as well as the main questions. This was sent to interviewees at least five days in advance to ensure that they had time to prepare. The interviews were held via online gotomeeting.com at times convenient to the interviewees. Between 17 February 2015 and 9 April 2015 six interviews were conducted with the following participants:

- senior principal statistician for a clinical research institute with a PhD in Organic Chemistry and an MSc in Medical Statistics;
- director of research at CNELM with a PhD in computer science;
- senior lecturer in nutrition and public health with a PhD in Nutritional Epidemiology;

- senior lecturer and module leader for methods of nutritional assessment and dietitian;
- chartered psychologist and director of a research organisation with a PhD in Health and medical psychology; and
- senior lecturer, health psychologist and programme director for NHS education who developed a self-reported tool for multiple risk factors in obesity.

The contents of the interviews were transcribed verbatim, uploaded to Nvivo and then coded under the following themes:

- developing new tools;
- desired from new tools;
- tool validation;
- data sets;
- database research;
- online applications;
- Delphi groups; and
- tools identified from interviews.

Kvale's (1996, p. 187) five-step analysis method, within the seven-step interview approach, was then utilised as per the previous interviews and the results were verified by triangulation with literature.

3.10.5 Delphi project

The aim of the Delphi survey was to construct new clinical tools for health data collection and clinical outcome analysis that standardise case data-collection methods and enable assessment of the efficacy of interventions. Objectives were to:

- gain opinion on which tools should be developed;
- gain opinion and consensus on content for tools;
- construct tools so that they can provide reliable and statistically validated data;
- evaluate ways in which these new tools can relate to existing evidence base; and
- measure feasibility, utility and achieve face validity for each new tool.

Participants were purposefully identified and selected to include a range of stakeholders, including: nutrition practitioners working with obese individuals, representatives from educational establishments, representatives from professional bodies, information systems experts and statisticians, experienced tool developers, academics and obesity researchers, as well as nutrition patients seeking to manage obesity and/or weight loss.

Procedure undertaken for selecting participants:

1. Identify relevant disciplines and organisations.

2. Identify individuals in relevant disciplines and organisations.
3. Contact experts.
4. Categorise experts within each panel and rank according to their qualifications, knowledge and potential contribution.
5. Invite experts for each panel. Target size 15–20.

The participant panels were divided into three perspectives: clinical utility, research utility and client/patient acceptance.

The final panel of participants was 17 including:

- five nutrition patients who were seeking to manage obesity/weight loss;
- seven nutrition practitioners (one dietitian, two weight management consultants, one nutritionist, one NT, one deputy head of care, one GP reviewing from a clinical perspective);
- two academics and/or obesity researchers;
- two statisticians and/or information systems management experts; and
- one other reviewing from a research perspective.

Participants were asked to complete three rounds of structured questionnaires anonymously. At the start of each round, there was a brief introduction video explaining the developments in tool construction to date, a summary of participant responses from the previous round (except for Round 1), as well as the aims and objectives of the round and requirements for feedback via the questionnaire.

The Delphi method is a flexible but structured way to gain opinion and consensus from a group of experts and stakeholders. No definitive guidelines exist for undertaking this research methodology, but the following resources were reviewed as a guide: Keeney et al. (2011), Linstone and Turoff (2002), Albert (1999), Hasson et al. (2000), Trevelyan and Robinson (2015).

Aims of Round 1

The aims of the first survey were to review a range of tools and assessment approaches and rank them according to which were perceived to be most important for new tool development. The objectives were to gather consensus from: nutrition practitioners on which assessments provided the most clinical utility, from academics and researchers on which assessments were most useful for research purposes and from nutrition clients on which assessments they would be willing to provide personal data.

Round 1 survey questions were developed based on the categorisation of tools, as well as responses to a survey of practitioners, and interviews of practitioners and experts, which were previously undertaken as part of this research project. For example, all assessments

used by the majority of practitioners who responded to the survey were included in the first Delphi survey.

Practitioner and research questionnaires collated in previous stages of the research, as well as Jeor, (1997), Allison (1995), Bowling (1995) and Bowling (2005), were also reviewed for additional assessment methods. SurveyMonkey software was used to develop and undertake the online surveys. Each Delphi survey was pilot trialled and reviewed by the research supervisors, then updated as a result of feedback. Each survey round was online for two weeks and reminder emails were sent to participants after one week and again before the deadline. Round 1 was completed in October 2015.

After analysis of Round 1 and a review of existing tools, obesity literature was reviewed to identify: a range of pathophysiological mechanisms, other diseases, health conditions and red flags associated with obesity and tools and tests/measures assessing those mechanisms. These mechanisms provided headings so that tools could be restructured in Round 2. The aim of structuring questions under mechanisms of pathophysiology (such as hormone imbalance, inflammation and dyslipidaemia) was to enable nutrition practitioners to more easily identify which mechanisms of pathophysiology may be a priority for the management of their client. This therefore supports pathophysiological reasoning as well as clinical decision making.

Aims of Round 2

The aims of Round 2 were to review the content of tools and approaches which were structured under headings of mechanisms of pathophysiology relating to obesity, rank satisfaction with the questions/approaches or their wording and identify areas for further development.

Objectives were:

- *To gather consensus from nutrition practitioners on their satisfaction*, specifically: that the questions/approaches correlate with mechanism and question aim and that the questions/approaches may help practitioners identify contributing obesity mechanisms for individuals' clients/patients – and therefore support clinical decision making.
- *To gather consensus from academics and researchers* on whether the questions were appropriately phrased to limit bias and support statistical analysis, the questions/approaches correlated with question aims, and assessment and reassessment at six months, one year, two years etc. would allow for meaningful statistical analysis.

- *To gather consensus from nutrition clients* on whether they were satisfied the wording of the questions/approaches was clear and enabled them to give a suitable answer, they were satisfied the wording of the questions/approaches was appropriate and free of emotional charge, and that they would be willing to answer the questions.

SurveyMonkey software was used to develop and undertake the online survey. Each Delphi survey was pilot trialled and reviewed by the research supervisors, then updated as a result of feedback. Each survey round was online for two weeks, and reminder emails were sent to participants after one week and before the deadline. Round 2 was completed in March 2016.

Following Round 2 analysis, four new tools were constructed:

1. **Personalised health history questionnaire** – this aims to collect health history and family history data around mechanisms of obesity, as well as collect a range of baseline health measurements. This questionnaire is for the client to complete before the first consultation.
2. **Intervention record** – this aims to capture which interventions were recommended by the nutrition practitioner at the end of each consultation. This tool is designed to be completed by the nutrition practitioner at the end of each consultation.
3. **Personalised health follow-up questionnaire** – this aims to measure any changes to the client's health after intervention. This questionnaire is for the client to complete before their return consultation.
4. **Achievement record** – this aims to capture which interventions the client complied with. This tool is designed to be completed by the nutrition practitioner at the outset of each return consultation.

Aims of Round 3

The aims of Round 3 were to:

- review the health questionnaire to see which questions can be eliminated in order to reduce its overall size;
- review a follow-up questionnaire to see which questions should be repeated in order to capture changes to the client's health and weight;
- review the intervention record to gather consensus on questions/approaches and wording;
- review the achievement record to see which questions from the intervention record should be repeated in order to capture client compliance to intervention recommendations; and
- identify areas for further development.

Objectives were for nutrition practitioners to review these tools from a clinical perspective: that the questions are appropriately phrased, that the questions/approaches correlate with question aims, and that the questions/approaches support clinical decision making. This round also asked nutrition practitioners if they would be willing to participate in the pilot trail of these tools.

Objectives for academics and researchers were to review these tools from a research perspective, i.e. that the questions are appropriately phrased to limit bias and support statistical analysis; that the questions/approaches correlate with question aims and that assessment and reassessment at six months, one year, two years etc. would allow for meaningful statistical analysis.

Objectives for clients were to review tools from the client perspective and determine if they were satisfied the wording of the questions/approaches was clear and enabled them to give a suitable answer; that they were satisfied the wording of the questions/approaches was appropriate and free of emotional charge, and that they would, as clients seeking weight loss support, be willing to provide this information.

Qualtrics (2012) software was used to develop and undertake the online survey. Each Delphi survey was pilot trialled and reviewed by the research supervisors, then updated as a result of feedback. Each survey round was online for two weeks and reminder emails were sent to participants after one week and before the deadline. Round 3 was completed in September 2016.

Keeney et al. (2011, p. 72) suggest Burnard's (1991) 14-stage process method of content analysis, but this approach seemed overly complex and Keeney et al. (2011, p. 72) also states that a simple approach to content analysis works well. A simpler approach was therefore undertaken by recording the results in spreadsheets so that group collective opinion and consensus could be more easily analysed. Results from each round were used to construct new tools as well as formulate the objectives and requirements for feedback for the next round. Informal literature reviews were used to support tool construction. Responses were summarised between rounds and fed back to the participants through a process of controlled feedback (Hasson, Keeney and McKenna, 2000).

The spreadsheet data was manually analysed. Infrequently occurring development suggestions/statements may have been omitted to keep new tool construction manageable. Consensus was equated at the majority (51%) agreement among respondents, e.g. if the majority of nutrition clients were willing to provide information, then consensus on whether an assessment should be included was equated at the majority stating yes, as opposed to

no. The ‘maybe’ responses were not counted in the overall weighting as to whether an assessment should be included in the construction of new tools.

3.10.6 Pilot trial

A pilot study of the newly developed tools was undertaken between 11 October 2016 and 30 September 2017. Tool pilot testing aimed to achieve face validity and measure feasibility and utility for each of the four tools. Objectives were:

- practitioner and client completion of face validity surveys;
- assessment on practitioner and client experience of using these tools; and
- assessment on what reliable and valid data the tools provide.

Nutrition practitioners were invited to participate. This invitation was disseminated via email targeting, CNELM and BANT social media, networking and word-of-mouth. The aim was for the invitation to reach as many practitioners as possible, and practitioners were asked to get in contact should they be willing to participate. Strategies for enhancing participation in the pilot trial, such as personalised email contact, were also undertaken from the outset. Nutrition practitioners listed on LinkedIn, the freelance dietitian website, the nutritionist resource website, the BANT website and the Zest4Life website were personally emailed and invited to participate. Two follow-up emails were sent to these practitioners in an effort to increase engagement. Participation invitations and responses were tracked on a spreadsheet (see appendix 15).

Sample size was based on the number of practitioners willing to trial tools multiplied by the number of obese patients in their clinic willing to participate. In total, 51 practitioners responded to the invitation as willing to participate. They were sent the pilot trial protocol (see appendix 6) and participation sheets (see appendices 4 and 5). These practitioners received an initial phone call to address any queries and discuss participation. During participation they were provided with email and telephone support to address any queries and they were sent copies of all completed documentation and guided through each stage.

The inclusion criteria stated that: each practitioner must trial all four tools on a minimum of two clients, all tools and review surveys must be completed by 31 July 2017, and clients should be seeking nutrition intervention for weight loss. Practitioners who had agreed to participate but were not engaging were contacted to promote engagement and offer support. The following adaptations and activities were undertaken based on practitioner feedback and guidance provided by Prescott et al. (1999), to support engagement:

- PDF versions of the tools were disseminated to practitioners so they could review them;
- the pilot trial protocol was simplified;

- consent procedures were embedded so this was not a separate additional activity;
- a seven-minute video was recorded and disseminated to explain the process, importance and purpose of the pilot trial[2];
- the client information sheet was reworded to remove references to obesity and to change the inclusion criteria from ‘clients with BMI >30’ to ‘clients seeking to lose weight’;
- telephone meetings were offered and arranged to address any questions and help overcome any barriers to engagement;
- deadline dates for pilot trial completion were extended by three months and then another three months;
- reassurance around confidentiality was provided; and
- reassurance that the impact to the practitioner’s normal practice would be limited was provided.

A considerable amount of effort was invested over the course of 11 months to ensure practitioners were able to engage with the pilot trial. A total of three practitioners did finally participate. The importance of pilot and feasibility studies has been explored by Van Teijlingen and Hundley (2001). Identifying if the proposed tools are appropriate or too complicated was important. Insight into the fidelity and usability of the tools was essential for further tool development. Pilot trialling also intended to determine whether the tools were adequate for larger studies, which could have, for example, assessed the impact of different layouts and construction to response sets. If participation numbers had been much higher, it may have been possible to utilise common factor analysis and principal component analysis to help reduce the number of questions on the tools and simplify them.

For those that did engage, data was collected via the online survey software, Qualtrics. Practitioners were asked to send their clients the participant information sheet for clients to establish if they were happy to participate. If so, the practitioner was able to send them the link to complete Tool 1 – the health history questionnaire – via the online research software Tool, Qualtrics. Each client had to be given a unique identification number to maintain their confidentiality.

Practitioners were able to undertake client consultations at a time that suited them. When the client had completed Tool 1, the practitioner was sent a copy and prompted to ask their client to complete the QQ-10 face validity survey (Moores, Jones and Radley, 2012). At the end of the first consultation practitioners were requested to complete Tool 2 – the

[2] https://www.youtube.com/watch?v=CCXmh7sJXfc&t=3s

interventions record (via the online link) – which aimed to capture all the recommended interventions.

Once enough time had elapsed to allow the client to implement the recommendations, practitioners were requested to send their client the online link to Tool 3, the follow-up questionnaire. Again, the practitioner was sent a copy of the completed questionnaire and prompted to ask the client to complete the QQ-10 face validity survey. At the end of a follow-up consultation practitioners were requested to complete Tool 4, the achievement record, with the aim of capturing which interventions the patient had complied with.

Once a practitioner had gone through this process with a minimum of two clients they were asked to complete adapted versions of the QQ-10 face validity survey for each of the tools. The pilot trial protocol explained the process for practitioners (see appendix 6).

Analysis focused on the validity of survey responses rather than questionnaire responses. It was not necessary to analyse the health issues and interventions undertaken by the few clients who responded. Rather, practitioner and client feedback on the use of the tools was assessed to determine issues with the tools and/or pilot trial that may have presented barriers to engagement.

A mix of multiple-choice and open-ended questions in the face validity surveys gathered quantitative and qualitative data. Results of the validity surveys were exported to a spreadsheet for analysis. The small number of responses meant that statistical analysis was unachievable.

3.10.7 Survey of NTs

This survey was conducted by a group of undergraduate students at CNELM and supervised by myself and the programme leader for the BSc (Hons) Nutritional Science programme. These students were required to create and administer social research within a community, analyse the data and justify a strategy for implementing a sustainable health culture within the given community. These students were presented with two important queries that arose as a result of the pilot trial:

1. Do obese (BMI>30) individuals seek out nutritional therapy support?
2. Do NTs have the resources to reach or adequately engage with the growing obese population?

With supervision, these students conducted a survey titled:

> Do nutritional therapists have the resources to reach or adequately engage with the growing obese population within various locations?
>
> (Gordon et al., 2017)

The aim of this survey was to identify potential opportunities to enhance engagement between obese population groups and NTs. The survey was conducted via the online tool SurveyMonkey (Finley, 1999). The survey was pilot tested with both supervisors before the link to the online survey was distributed to NTs in August 2017 via the BANT members' Facebook page and the CNELM Facebook page.

When the survey closed on 14 August 2017, a total of 49 NTs had completed the survey. Social media reminders were sent to increase response rates. A mix of multiple-choice and open-ended questions in the surveys gathered quantitative and qualitative data. Survey Monkey has a number of data analysis features; all response data was downloaded so the results could be analysed and evaluated.

3.10.8 Interview nutrition practitioners

The aim of the interview was to gather practitioner views on the barriers that may prevent nutrition practitioners from embedding standardised tools in personalised nutrition practice and exploring potential approaches to overcoming these barriers. Objectives included to:

- evaluate barriers which may have prevented them (or other practitioners) from being able to participate with the pilot trail;
- evaluate barriers which may prevent other practitioners from embedding standardised tools into personalised nutrition practice;
- identify barriers of engagement with tools provided by clinic clients;
- discuss potential ethical issues which may contribute as barriers to using standardised tools;
- explore strengths and limitations of the NT profession which may impact on the utilisation of standardised tools; and
- evaluate approaches to overcoming any barriers.

Kvale's (1996) seven-step interview approach was utilised, as with previous interviews. Participants were selectively sampled from the pilot trial process: they were nutrition practitioners who had been willing to participate in the pilot trial stage but did not engage. A mix of open-ended, semi-structured questions were included to facilitate conversational dialogue. The interview guide (see appendix 16) included the aims and objectives as well as the main questions. This was sent to interviewees at least five days in advance to ensure that they had time to prepare. The interviews were held via online Zoom meeting at a time convenient to the interviewee. Between 25 April 2017 and 23 May 2017 six interviews with nutrition practitioners were conducted, with:

- three NTs who specialise in weight loss programmes;
- one Bariatric nutritionist;

- one NTs and MSc Personalised Nutrition Programme Leader;
- one naturopath and weight loss coach.

The contents of the interviews were transcribed verbatim, uploaded to Nvivo and then a word frequency query was conducted to identify the following themes: tools, questionnaire/questions/question, standardised, clients/people, consultation, practitioner/practitioners/practice and profession.

Figure 122 *Nvivo word frequency cloud diagram*

Transcripts were then analysed and coded using these themes. Kvale's (1996, p. 187) five-step interview analysis methods was then utilised as per the previous interviews and the results were verified by triangulation with literature.

3.11 Advantages, disadvantages and critical analysis of the methodology

The tool-gathering approach was informed by MacDermid et al. (2009), who highlight the complications in searching the literature for outcome measures and difficulties obtaining and getting permission to use tools. Broad search terms were used in order to capture a wide range of potential papers and tools for inclusion. Bias could have been introduced when the results from the first search were used to frame the second search, which may have limited the breadth of the results. This data-collection approach also involved a degree of subjective judgement regarding the extent to which any study or tool met the inclusion criteria and was deemed relevant for clinical nutrition practice to gather individual health history data, support

clinical decision making or analyse clinical outcomes. However, requesting further tools for inclusion through practitioner surveys and interviews helped overcome these limitations. The search description forms, search results tracker spreadsheet and tool categorisation spreadsheet were designed to make the methodology transparent and replicable.

Conducting surveys via online survey applications was low in cost and provided functionality which eased data analysis. Anonymity meant that when reminding potential participants to complete the survey, they could not be targeted because it was impossible to tell who had already done it. Survey development was difficult due to the limited number of features in the online survey software, which meant that a number of the surveys were quite lengthy. Biemer (2010, p. 28) highlights a range of strengths and limitations relating to survey quality. Surveys were designed with multiple objectives and were therefore complex and multi-dimensional. The advantage of using and developing surveys within the project's methodology meant that I was able to experiment with design and layout as well as learn from the analysis of surveys conducted which then influenced new tool development. An increased awareness of the issues affecting design, reliability, validity and analysis was achieved through this process.

The use of CNELM's and my own contacts for interview sampling introduced selection bias in terms of the target population. However, a minimum of three interview participants did allow for triangulation of the data. The semi-structured approach was advantageous in terms of gathering specific data, increasing comparability of the results, and being able to have a flexible and open discussion. The issue with the open discussion element was that I found it difficult not to become engaged with the conversation, and therefore I may have unwittingly influenced responses by expressing agreement or my own views as part of the conversation.

Again, the use of CNELM and my own contacts, and identifying "who is an expert" will have introduced a level of selection bias for the Delphi participants (Keeney et al., 2011). The Delphi method has had a number of criticisms, which are explored by Keeney et al. (2011, p. 20), including a lack of universal guidelines (and therefore a single definition of the approach), with no guidance on the number of participants required for a representative sample. Due to the sample size for each of the three perspectives (clinical utility, research utility and client acceptance), it was not possible to gain consensus. Although the results were aggregated and that informed new tool development, there was a level of subjective interpretation for tool development.

It was clear from the surveys and interviews that tools should be simple and easy to use. However, the Delphi process did not allow for the tools to be narrowed down or simplified. With each survey round there was more feedback to incorporate, and although the feedback included calls to simplify the tools, participants were unable to sufficiently eliminate

questions in Round 3 in order to reduce the overall length of the tools. The length of the final tools was likely too large and complex, which may have added to the lack of practitioners willing to engage in the pilot trial.

Failure to achieve recruitment targets for the pilot trial is a well-known issue among researchers. Treweek (2015) highlights that more than 50% of clinical trials fail to achieve their recruitment targets. Barriers to clinician and patient participation in clinical trials were thoroughly explored by (Prescott et al., 1999), as well as the length and complexity, barriers that appeared to be an issue in this pilot trial include: lack of time (for both practitioners and patients); stigma associated with obesity; perceived lack of importance of the trial; the difficulty of practitioners admitting to patients/clients they did not know the relevance of some of the questions in the tools; incompatibility of the trial protocol with “normal” clinical practice, lack of suitable patients and lack of practitioner research experience.

Bias is an issue when recruitment numbers are low. Selection bias is problematic because the majority of practitioners that did engage were more likely to have been associated with CNELM, either as students or staff. This pre-existing relationship would likely mean they were more willing to put the time and effort into engaging with the research. Severity of illness or case complexity was also an issue that led practitioners to exclude certain clients from participating. So, when practitioners were considering which of their clients to ask to participate they were making a subjective choice based on whether they thought the client was likely to be willing and able to engage with the process and documentation.

The fact that the tools are designed to measure the efficacy of nutritional interventions could be interpreted by practitioners as tools which measure how effective they personally are in practice, which may have also been a barrier to participation.

Tool questions had initially been developed on paper and questions were then transferred to the online survey software Qualtrics to be able to undertake the pilot trial with online versions of the tools. During the transfer of questions from paper to the online software it was not possible to keep the same format of all questions – some had to be adapted to work in the software. Although using online survey software has advantages over paper tools, the reality is that the software is cumbersome. The vision for these tools is to develop them as online platforms which can be accessed via multimedia methods. The advantages for developing a bespoke application for these tools would mean that the access, design and flow of the tools could be enhanced. It would also give practitioners more control; they would be able to check if their clients had completed the tools and print off the documents for themselves, and that may provide more practitioner ownership and engagement. It is beyond the remit of this project to develop the tools via a bespoke online application.

The decision-making process within this project has aimed to be transparent, replicable and rigorous to ensure research quality as well as facilitate ease of participation. Although the universal definition of quality has not been clearly defined (Reeves & Bednar 1994, Jacobson 1998) it is recognised that different research paradigms and research stakeholders may interpret quality differently. Conventional research values were applied to this project including: rigour, verisimilitude, an objective research approach and transparent, systematic and reproducible research methods.

3.12 Chapter summary

This chapter has outlined the project's ontological and epistemological position, research design and methodology, and it explores how the research methods may produce results that address the research questions. The processes for data collection and analysis were described and critically analysed. My own role as an insider and outsider researcher was also explored and will be reviewed again as part of the reflexive account in Chapter 7. The next chapter builds on this account of the overall methodology and various methods used in the project to explore the practical aspects of the project's activities.

Chapter 4: Project Activity

This chapter aims to describe and analyse the project activities undertaken for the methodologies described in Chapter 3. It explores the practical activities undertaken to develop and complete the research methods, surveys and interviews used throughout the project and draws significantly on my research journal.

4.1 Overall activity

Although the project was funded by my workplace, this research was not *about* my workplace and did not take place within my workplace. This project does however support strategic vision of my workplace:

> steering the integration of personalised nutrition and nutritional therapy to become an accepted mainstream healthcare option, and contributing meaningfully to the development of an evidenced-based approach to support personalised nutrition interventions by using advanced statistical techniques known as statistical machine learning (SML) to overcome the limitations of randomised controlled trials (RCTs)
>
> (CNELM, 2017)

As Head of Education, investing in my professional development is also advantageous to my workplace as their business culture aims to:

> Engender commitment, accountability, integrity and partnership among staff and students in line with our Vision and Mission. Promote excellence, consistency and commitment in our teaching.
>
> (CNELM, 2017)

My workplace provided me with access to use their resources, such as email and online conference call facilities and access to clients coming through the supervised student clinic. They gave me time off from work to focus on writing this report and they continue to be supportive of my professional development. Factors which determined the project activities included: access to resources, time constraints and access to research participants. The positive professional reputation of my workplace may have helped gain participants from the nutritional therapy profession, but it may also meant that participant self-selection was biased, it is likely that NTs would wish to support the development of the profession by supporting researchers wishing to demonstrate the efficacy of nutritional therapy practice.

4.2 Data collection and analysis

The first activity undertaken was to complete several literature reviews which aimed to critically review, prior to undertaking data collection, a range of ideas and theories relevant to the project, as well as explore how personalised nutrition practice could be transformed with the development of a new case-by-case evidence base. As described in Chapters 2 and 3, an extensive online search was conducted to identify, categorise and evaluate existing tools

which support individual health history data collection, clinical decision making and clinical outcome analysis suitable for nutrition practice in the management of obesity.

In February 2014, during the literature reviews and gathering of existing tools, I progressed from using folders and a highlighter pen to undertake manual coding, to using Nvivo 10 software. Nvivo 10 is a data handling software package that enables storage, organisation and analysis of qualitative research data. Loading the documentation into Nvivo felt, at the time, like a major change in the project's activities. It was not just the analysis capabilities of the software, but the fact that I was checking again during data entry, that allowed me to be confident in the robustness of the data. The ease of coding using the software was helpful. It is interesting to note that before using Nvivo I wanted to go back and check my work manually. However, moving to the Nvivo package had a significant impact on time constraints. The time it took me to learn the software and input the data seemed worthwhile for the ease of analysis.

Before completing the searches and undertaking the analysis I compared the tool categorisation spreadsheet with the nodes of categorised data in Nvivo. I updated the categorisation spreadsheet so that the categories and Nvivo nodes corresponded. This highlighted a number of tools that I had not identified through the manual paper method. Nvivo therefore appears to have provided more rigour in data collection and analysis.

The large volume of existing tools identified that were suitable for nutrition practice in the management of obesity impacted on the development of the practitioner survey. I was aware that participants could become overwhelmed by the time commitment required to complete a long survey. My concern was that participant overwhelm could impact on participation later in the project as well as directly affect participant withdrawal and/or provide incomplete survey results. On the other hand, I also felt I had to include all the tools identified because that would be a direct reflection of the data gathered and if I excluded any that would be adding my subjective bias. I aimed to be rigorous and transparent. Finally, it was the quality analysis of each tool that allowed for exclusion of some tools, which reduced the volume and size of the survey. Different approaches to developing the survey were considered and piloted with practitioners to help analyse how to best cut the survey down to an appropriate size before it was conducted.

Integrating a number of valid, robust and reliable tools into an online format and then establishing validity may have presented a solution for meeting the research outcomes. However, the majority of the tools identified were developed purely for research purposes and appeared to provide minimal clinical utility. Initially it was also difficult to determine how the data provided by these tools could inform clinical decision making. Consideration was given to developing a clinician's guide so that the aim and purpose of each question could

be understood, but that was not possible because of the complexity of potential responses to questions. The idea to group questions under pathophysiological mechanisms to support clinical decision making did not emerge until after Round 1 of the Delphi surveys. I kept good records throughout the project, and this certainly helped my analysis and project report writing.

Over the whole project, 18 semi-structured interviews were undertaken. Towards the final few interviews I became concerned that I was leading the interviewees. I had made a concerted effort not to lead when I was asking questions, but in some cases I did consider the need to explain my thinking about the research. I thought that because participants had given their time to do the interviews with me, and because pilot trial participation was minimal, I should explain my views and findings around that. Once I had this realisation, I aimed to explain my view after participants had answered interview questions in a bid not the lead them.

At the time of starting to transcribe my interviews I had just attended a Middlesex University seminar on qualitative interviews which highlighted the importance of transcription for analysis purposes. However, my project is not about gathering depth of meaning, as in social research, so I reviewed the value of self-transcription versus the time it takes to transcribe and outsourced transcription via a professional and confidential service. I was then able to review the transcription and start the coding process, which was significantly more efficient.

Data analysis for all activities took considerably longer than anticipated in my proposal. My research journal was also extensive, and I added entries regularly. I am motivated by robustness and spent a lot of time checking and rechecking my work, which was time-consuming. I also wanted to triangulate data where possible, for example between interviews and surveys.

4.3 Tool development

Delphi Round 1 reviewed a range of tools and approaches, and questions for inclusion in new tool development, as per the methodology described in Chapter 3. Where possible, questions for inclusion in new tools were based on questions already included in validated tools from the following sources. The identification/development of questions for each category was therefore based on the following approach:

1. Search for suitable question in Jeor (1997); if none identified
2. Search Allison (1995); then
3. Search Bowling (1995); then
4. Search Bowling (2005); then

5. Search Weatherby (2004); then
6. Search validated tools identified in categorisation spreadsheet; then
7. Search practitioner tools provided after the survey with permission to use in this research project; then
8. Search online for relevant questions and approaches.

Round 2 aimed to gain feedback and consensus on satisfaction with the included questions.

The decision for developing tools before Round 2 of the Delphi surveys was discussed with my research supervisors and it was felt that it would be better to have a visual representation and choices of questions for participants to give their opinion on, rather than have them imagine tools and make recommendations. I used the Round 1 Delphi survey results to develop the Round 2 survey questions. If the Round 1 survey results highlighted that practitioners did not use an assessment method then I excluded the assessment. This started to cut back on the size of the new tool. The need to keep the tool concise outweighed the value of including assessments that the majority of practitioners did not use.

It was clear from the interview results that I had to further simplify tools and assessment. It was therefore decided to exclude already well established and validated tools for dietary intake and physical activity assessment as part of this project. Although these assessments are clearly important, they did not need to be newly constructed; the existing validated approaches could be integrated with new tools. I therefore focused on developing the tools that had not yet been robustly developed or validated: the health history and family history tools.

What was useful in using existing validated tools to develop new tools for Round 2 was that the questions included in existing tools had already been validated. I therefore used the following hierarchy for formulating the new tools questions:

- first choice: question was taken verbatim from one of the validated tools;
- second choice: question was researched for any consensus about the best way to formulate the question;
- third choice: the majority of tools (across those listed) that pose the question in the same way; and then
- fourth choice: question from non-validated tools – these were highlighted for further consideration by the Delphi group.

After a review of existing tools it appeared that questions grouped under headings such as “health issues” “symptoms” “hormone health”, appeared helpful for practitioners to be able to undertake clinical decision making and prioritise intervention strategies. A literature review was then undertaken to identify pathophysiological mechanisms of obesity, signs and

symptoms of those mechanisms and tools and tests assessing those mechanisms, so that questions could be grouped under headings of pathophysiological mechanisms.

During the development of questions related to mechanisms there were numerous problems. For example, all mechanisms interrelate: mechanisms like dyslipidaemia and oxidative stress do not necessarily have clinical signs and symptoms. This led me to search, review and understand that validating clinical tools which explicitly enable pathophysiological mechanistic reasoning for personalised nutrition practice has not been done before. Although it was possible to find tools which had clustered questions around physiological functions, none of them were validated and validated tools identified during this search did not provided a pathophysiological reasoning approach.

I had to make some educated guesses about signs and symptoms of mechanisms so that I could develop relevant questions. Many of the signs and symptoms which formed questions related to mechanisms were therefore created, but they are not evidenced. There were mechanisms, such as oxidative stress, that were not explicitly included in new tool development because of this issue. It would therefore be essential that the results from these mechanism questions are validated against laboratory test data on oxidative stress, inflammation, dyslipidaemia and other proposed mechanisms.

Mechanism question development:

1. Mechanisms and diseases identified from online literature searches; then
2. Mechanisms and disease questions identified from existing tools; then
3. Brainstorming questions with colleagues; and then
4. Ask practitioners at next Delphi round if:
    - the range of obesity mechanisms, proposed for inclusion in new tools, is appropriate and comprehensive; and if
    - the questions and approaches for each mechanism correlates with it, and/or if further questions are required.

After Round 2 and before Round 3, the new tool questions were entered into an online survey application called Qualtrics, so they could be pilot trialled via an online system rather than on paper. However, the Qualtrics software does not have the functionality to present the questions in the same way as the format the Delphi group agreed on (appendices 17 and 18). Other software packages such as SurveyMonkey and Google Tools were reviewed at length, but Qualtrics possessed the best functionality. It was therefore decided to carry on developing the tools in Qualtrics.

Moving the questions from the paper formats to an online format meant that the formatting of the tools changed, and it also meant some of the questions had to be adapted. Any

questions that were adapted were changed as little as possible, staying true to original question. Any changes that were made also prioritised reducing the overall size or length if the tool and increasing clarity.

During this development, I realised tool development had focused on health data collection which supported clinical decision making, but there was a lack of intervention tracking to enable clinical outcome analysis. This led me to develop Tool 2 (the intervention tracking tool) (appendix 19), which aims to capture the interventions that were recommended by the nutrition practitioner; Tool 3 (the follow-up questionnaire) (appendix 20), which aims to measure any changes to the client's health after intervention; and Tool 4 (the achievement record) (appendix 21), which aims to capture the interventions the client complied with. These were developed based on existing tool analysis and on the results of Delphi Round 1 and practitioner surveys. This meant that tools 2, 3 and 4 only went through one Delphi round before being pilot trialled. However, it was anticipated that feedback would be received during the pilot trial and a final Delphi round would be conducted after further changes had been made based on feedback from the pilot trial.

4.4 Pilot testing

The methodological approach and the activities undertaken for the pilot trial are described in Chapter 3. After several months of promoting the pilot trial I managed to get 52 practitioners willing to participate, but only 3 of them actually engaged with the pilot trial process. I undertook various activities to promote engagement, which are discussed in section 3.9. Changing the inclusion criteria from obese clients (BMI>30) to clients seeking weight loss broadened the number of clients who could participate in the pilot trial. At this point I thought that would help increase engagement, but it did not. The adapted QQ10 validation survey questions were about the client and practitioner views of using the tools, whether the tools were too long, too complex and easy enough to use, and allowed them to express their health concerns, so changing the inclusion criteria did not affect the validation data gathered for the tools.

I discussed the pilot trial with BANT (the Nutritional Therapy Professional Body) and they agreed if I recorded a request for participation on camera that I could disseminate the participation request on the BANT website and social media. I did this, and also recorded a video for those practitioners who had already agreed to participate in order to explain the changes, the purpose and value of the study in an effort to increase engagement.

I had feedback from practitioners that the barrier was in recruiting clients – that the clients did not understand the purpose and the value of the research, even though the purpose was outlined in the participant information sheet (appendix 4). Asking practitioners, who may also not have fully understood the purpose and value of the research, to explain this quite

complex research study to their clients was problematic. On reflection, it may have been easier to organise a group of obese participants myself, then validate the tools directly with the group, and then present the validated tools to the practitioners for use.

The pilot trial outcome led to a change of focus for the project: to explore the barriers that may have contributed to this outcome, to explore obstacles that may prevent practitioners from embedding standardised tools in personalised nutrition practice and to identify potential approaches to overcoming these barriers.

I also started to wonder what numbers of obese individuals engaged with nutritional therapy. There was a dearth of research available on this theme. In January 2017 a group of students at my workplace were seeking a research project. I met with them and discussed my concerns. The students conducted a survey of nutritional therapy practitioners which I supervised. The survey aimed to identify the number of obese individuals' practitioners were seeing in nutritional therapy practice, how those therapists engaged with the obese population and identify any barriers with a view to identifying potential opportunities to enhancing engagement between obese population groups and NTs.

I was always aware that this project was complex, however it emerged that each of the following had depths of complexity which were not anticipated:

- obesity – all individuals come to obesity through their own unique set of circumstances, beliefs, genetics, lifestyle and environment;
- nutrition practice – all practitioners approach practice individually, based on their own unique set of values, approaches to the therapeutic relationship, personality and experience; and
- clinical tools – the range and variety as well as how integral they are to the process of clinical practice.

4.5 Professional development activities

In addition to the described methodological activities I undertook numerous professional development activities throughout the project, including:

- attending lectures and seminars;
- attending BANT AGMs and keeping track of professional body updates;
- presenting at:
    - Middlesex University Research conferences;
    - the Nutrition Society Postgraduate Conference;
    - the University of West London Research Conference;
    - an Organisation Studies Network (OSN) seminar; and
    - the 20th Dilemmas in Human Services International Research Conference.

- having a paper published on leadership[3];
- supporting student research and publication.[4]

Some of these influenced my approach to the project more than others. For example, I went to an inspirational event at Oxford University called Big Data Science in Medicine. It raised a number of questions that I had already been thinking about and had included in my interview questions, e.g. how can existing online tools be integrated with newly developed paper tools? There is now a plethora of data-gathering applications measuring daily diet intake, exercise, sleep etc. that people use through their smartphones. These tools may be the best way to track compliance and outcomes of nutrition interventions because of ease of use and real-time tracking. This event highlighted the future moves towards data tracking and analysis which enabled me to probe deeper on these considerations via practitioner interviews.

It has been critically important that I remained engaged with professional development activities. The insights gained from other researchers has been particularly useful in helping to identify opportunities to enhance the project's activities.

4.6 Chapter summary

This chapter reviewed the key activities undertaken as part of this project and presented some of the numerous considerations and reflections that presented themselves through undertaking these activities. Managing the range of complexities, as well as time constraints, impacted on all aspects of the project's outcomes. The next chapter will report on and discuss the project's results and findings.

[3] Michelle Barrow, BSc, MSc, QTLS. Dr. Gordon Weller. Dr. Celia Bell, PhD. Dr Linda Bell, PhD. (2017) Leadership Development: reflective insights from a female Head of Education. Work Based Learning e-Journal International.
[4] Miles, H., & Barrow, M. (2018). Committed to Weight Loss: an IPA Analysis Into the Experiences of Individuals Who Lost Weight Through Nutritional Intervention. Current Research in Food and Nutrition, 6(1).

Chapter 5: New Tool Construction Findings

This chapter presents the analysis of research findings for each of the research methods undertaken to construct new clinical tools for individual health data collection and clinical outcome analysis which support clinical decision making. The approach for undertaking the interviews, surveys, the Delphi method, and pilot trial are described in chapters 3 and 4. This chapter critically analyses the results from each research method in turn. The overall discussion of findings assimilates and summarises the results, and aims to interpret the findings within the context of existing literature, the scope of the project and construction of new tools.

5.1 Findings from online search for existing tools

A broad and extensive online search to identify existing tools which support individual health history data collection, clinical decision making and clinical outcome analysis was conducted between November 2013 and January 2014. A total of 3,334 papers were considered for inclusion, and a total of 46 papers met the final inclusion criteria (appendix 2). These papers have already been discussed in the literature review (section 2.5).

Reviewing these results and the tools provided by participants of the survey and interviews allowed for the identification of broad categories of assessments related to the development and management of obesity and the identification of some specific obesity-related measures and tools. This enabled the development of the tools categorisation spreadsheet (appendix 11). Categories included: general, diet and nutrition, psychology, physical activity, genetics and family history, physiological, sociocultural, body composition, test results, goals and outcomes and intervention tracking.

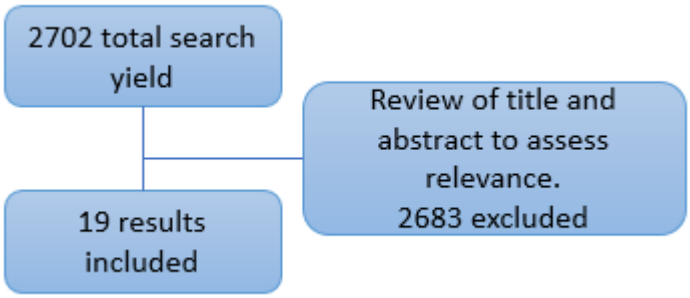

Figure 133 *Results of searches for tools related to each category*

As discussed in section 3.9, further searches were then conducted to identify tools related to each of these categories. These results allowed for the tool categorisation spreadsheet (appendix 11) to be updated with tools and measures that were identified in this second

round of searches. In total, as a result of both sets of searches, 11 categories, 65 measures and 34 tools were recorded.

The results highlighted a gap between tools identified via online searches and tools used in clinical practice, such as online dietary assessment applications. Five online applications (*Dietplan6*, *Nutritics*, *CRON-O-Meter*, *SELFnutritiondata* and *myfitnesspal*) as well as three clinical tools (Measure Your Medical Outcome Profile – MYMOP, pedigree chart and functional matrix) were therefore added to the tool categorisation spreadsheet. MYMOP is a validated tool (Hourigan et al., 2014) which measures health outcomes the patient considers most important, but it does not correlate changes of health outcomes to interventions.

After quality assessment, a final total of 11 categories, 44 measures and 29 tools were included.

Table 5 *Final categorisation of tools identified which support individual health history data collection, clinical decision making and clinical outcome analysis suitable for nutrition practice in the management of obesity*

Category	**Measures**	**Tools**
Diet and Nutrition	diet intake	food frequency questionnaire
	eating habits	food diary/record
	eating styles, behaviours and habits	24-hour recall
	diet history	14-item Mediterranean assessment tool
		three-factor eating questionnaire (TFEQ)
		eating habit questionnaire (EHQ)
		Dietplan6
		Nutritics
		CRON-O-Meter
		SELFnutritiondata
		myfitnesspal
Health History	medication	
	medical conditions	

	weight history	
	health history	
Risk Factors	obesity risk factors	
Psychology	psychological wellbeing assessment	general wellbeing schedule
	perceived body image	EEQ emotional eating questionnaire
	emotional eating	emotions and stress questionnaire
	emotions and stress	Larocque obesity questionnaire
	eating behaviour	eating disorders in obesity questionnaire
	eating disorder	
	addiction	
	motivation	
	depression	
Physical activity	physical activity undertaken	activity recall
	barriers to physical activity	Baecke questionnaire
	sedentary behaviour	IPAQ (sort 7-day)
Body Composition	BMI	
	anthropometrics	
	Basal metabolic rate	
	resting heart rate/pulse	
	blood pressure	
	waist circumference	
	waist-hip ratio	
Family History	family history	pedigree chart

Quality of life		IWQOL lite
		Moorhead-Ardelt quality of life questionnaire
		obesity-related wellbeing (ORWELL 97)
		obesity and weight loss quality of life instrument (OWLQOL)
		short form – 12
		short form – 36
		World Health Organization Quality of Life questionnaire
Sleep	quantity, patterns, quality	
Sociocultural	self-efficacy	self-efficacy questionnaire
	personal or social pressures	
	patient perspectives /beliefs	
	self-care	
	relationships	
Goals and Outcomes	patient goals	MYMOP
	patient's expected outcomes	
	patient-defined outcomes	
	satisfaction with intervention programme	
	self-reported weight loss	
	clinical decision making	
	intervention compliance, dietary habits, physical activity and health-related life quality	
	user satisfaction of using tool to enable ongoing review	

	interventions recommended	

The next stage of the research was to identify which tools clinicians used for data collection. This was undertaken through an online survey.

5.2 Findings from survey of nutrition practitioners

A total of 98 practitioners were emailed to complete a survey about the data they gather in clinical practice with an obese population and how they gather the data. When the survey closed on 1 January 2015 a total of 32 questionnaires had been completed. Of the 32 respondents 29 were practitioners with experience of working with obese (BMI +30) adults. It was these 29 practitioners who met the inclusion criteria; those excluded did not have experience of working with obese (BMI +30) adults.

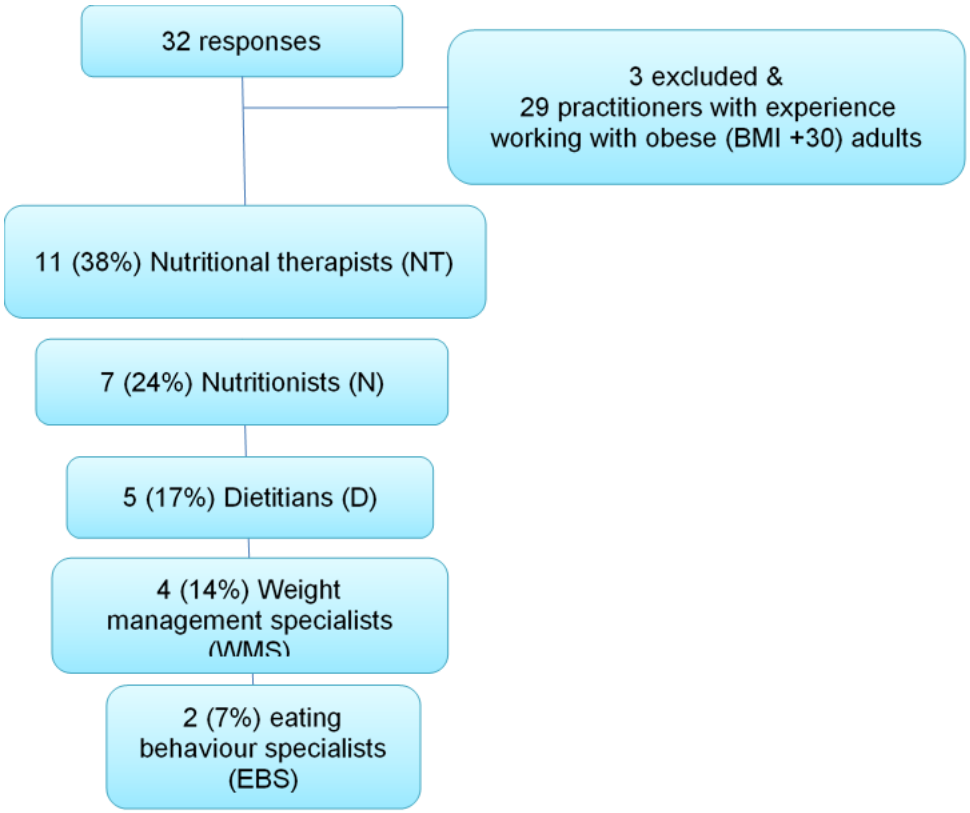

Figure 144 *Quantity of nutrition practitioners who participated with the survey and their professions*

5.2.1 Diet and nutrition

Across the tools used to assess diet intake, the most frequently used assessments were eating style, behaviour and habits (19 out of 27 = 70.39%), with food frequency assessments and food diaries coming joint second. Sixteen out of 28 (57.14%) respondents always use food frequency assessment and 16 out of 27 (59.26%) always use food diaries in clinical practice, while only 5 out of 27 (18.52%) always use 24-hour diet recall. Eating styles, behaviour and habit assessment as well as food diaries were perceived to identify factors that may contribute to the client's obesity, while the most frequently mentioned strength of

food frequency assessment, 24-hour diet recall and dietary analysis software was ease of use. The most frequently given weakness was that the client did not always give accurate information.

The online application *myfitnesspal* was the most frequently used dietary analysis software (8 out of 21 = 38%). This application lets the client enter food diary data as opposed to the other programmes, which require the practitioner to enter the data on behalf of the client. Just over half of respondents (14) always, or sometimes, used dietary analysis software while many never (10) or rarely (3) used it. The limited use of online software applications for dietary analysis may be due to the lack of user friendly applications, and that their use 'takes too long' was cited as the main weakness.

Practitioners mostly utilised their own questionnaires and food diaries. Only two respondents stated they used validated food assessment questionnaires. Three practitioners solely gathered data through interview in consultation and three had their clients enter data online, while one gave their client the option to track dietary intake online.

Food diaries and follow-up consultations and interviews with the client were the most frequently cited methods of assessing diary compliance. Dietary assessment tools not used in clinical practice, such as the Mediterranean diet assessment, were excluded from consideration for new tool development.

5.2.2 Health history and risk factors

Twenty out of 27 respondents (74.07%) always assessed weight in obese (BMI 30+) clients, 4 sometimes assessed it (17.81%) and 3 never assessed weight (11.11%). The majority of practitioners collected weight data through interview in consultation (22 out of 23 = 95.65%). Responses highlight that weight history analysis is useful to assess weight throughout the client's lifespan because it:

"gives rich clinical information about aetiology and current behaviour and its origins" (EBS)

Tracking weight loss was also considered essential to track compliance and/or the efficacy of interventions by 10 out of 20 respondents (50%).

Twenty out of 26 respondents (76.92%) assessed both health history and obesity risk factors while 5 (19.23%) assessed health history only and 1 (3.85%) assessed obesity risk factors only. The majority of practitioners (16 = 66.67%) assessed these throughout the lifespan, 5 (20.83%) since childhood, 2 (8.33%) since adulthood and 1 (4.17%) since adolescence. Most practitioners (22 = 85%) gathered this data through interview at the consultation and asked clients to complete a non-validated questionnaire (9 = 34%).

The most commonly perceived strength of assessing individual health history and risk factors was that it identifies factors that may have contributed to the client's obesity (15 = 68.18%) while the most perceived weakness was that clients do not always give accurate information (13 = 86.67%).

5.2.3 Psychology

Twenty-one of 26 (80.77%) respondents assess perceived stress, addiction and motivation of their obese clients. One dietitian and one nutritionist only assessed motivation. One weight loss specialist and one NT only assessed motivation and perceived stress. The majority (12) gathered this data through interview at consultation only. Eight respondents gathered this data via interview in consultation and had the client complete a questionnaire. Six respondents just have the client complete a non-validated questionnaire. When asked how respondents assess or measure changes to the client's stress, addiction and/or motivation, the majority (9) responded that this was done through questioning and interview. Other answers included:

- *"through observed behaviour and changes in coping and management skills, eating and weight change"* (EBS)
- *"online diaries or journals"* (NT)
- *"goal setting"* (D)
- *"food diary, weight change and self-reported changes."* (N)
- *"repeat completion of the questionnaire at intervals: start, then at 6 months, then at 12 months"* (D)
- *"changes not measured"* (WMS)
- *"careful and continuous monitoring"* (EBS).

When asked if participants assess perceived body image in nutrition practice with obese clients, of the 22 respondents 9 always or sometimes assessed body image and 8 (3.33%) never assessed it. Out of 24 who answered, the majority (18 = 75%) did not use any of the psychology tools identified in online searches. Four had used the emotional eater questionnaire and 2 had used the general wellbeing schedule.

Of 24 respondents, 8 always (33.33%) and 7 (29.17%) sometimes assessed eating disorders in obesity, compared to 3 (12.50%) who rarely assessed it and 6 (25.00%) who never assessed it. Of 17 responses, 12 gathered the data through questioning at interview. Individual respondents stated that they assess for signs of eating disorders by:

"talking to [the] client in consultation" (NT)

"look for red flags which may indicate an eating disorder" (N)

"careful questioning at the consultation" (N)

One stated they only assessed for eating disorders if it was raised as an issue by the referrer. Of the 24 who answered the question, 7 always (29.17%) and 6 (25.00%) sometimes assessed depression in obesity clients compared to 4 (16.67%) who rarely assessed it and 7 (29.17%) who never assessed it. Of 16 responses, 10 gathered the data through questioning at interview. Individual respondents stated they used:

"a mixture of questionnaire and face-to-face questions" (NT)

"consultation and medical history" (WMS)

"[if signs of depression are observed then] a referral [would be made]" (N)

When asked if respondents used any other method or tools for psychological assessment in obese individuals, 25 respondents skipped the question, suggesting they do not. Three specifically stated 'no', with 1 adding:

"as am not qualified" (NT)

Other responses include:

"Not specifically. I am trained in assessing obese patients multi-dimensionally including possible night-eating syndrome" (EBS)

"I am piloting our own pre-intervention questionnaire to assess readiness and expectations of weight management intervention" (D)

When asked how they assessed or measured changes to depression, emotional eating, disordered eating or perceived body image, practitioners responded:

"[It] varies from client to client… [the] client and I will work out a programme that works for client." (NT)

"talking to the client during consultation" (NT)

"in-person questioning" (N)

"through discussion, client compliance" (NT)

"questioning" (EBS)

"careful monitoring" (EBS)

5.2.4 Physical activity

Twenty responded when asked if they use physical activity recall in nutrition practice with obese individuals. Thirteen (65.00%) stated always, 5 (25.00%) stated sometimes and 2 (10.00%) stated never. Of 16 responses, the most frequently highlighted strength was ease of use (10 = 62.50%), while out of 13 responses the most frequently highlighted weakness is

that the client does not always give accurate information (11 = 84.62%). When asked which tool they used most frequently to assess physical activity (the international physical activity questionnaire [IPAQ] or the Beacke questionnaire), 21 stated neither, 10 skipped the question and 1 weight management specialist responded that they used the IPAQ questionnaire.

Out of the 21 who responded, 18 (85.71%) assessed both barriers to physical exercise and sedentary behaviour. None just assessed sedentary behaviour, 2 (9.52%) – one NT and one weight management specialist – just assessed barriers to physical exercise and one (4.76%) NT stated neither. Fifteen stated that the data was gathered through questioning and interview at the consultation, 1 of whom used this in combination with a questionnaire.

Physical activity recall, barriers to physical exercise and sedentary behaviour appear to be frequently assessed. The survey failed to assess data-collection methods for these. It is likely that physical activity recall data is gathered via interview in consultation, as this was the most frequent method for assessing barriers to physical exercise and sedentary behaviour. Questionnaires, online journal and applications such as *myfitnesspal* also allow for exercise tracking, but these data-collection methods were not mentioned.

5.2.5 Body composition

Twenty-two responded on the use of BMI in the assessment of obese clients. Thirteen (59.09%) responded that BMI is always taken into account, 5 (22.73%) responded sometimes, 2 (9.09%) responded rarely and 2 (9.09%) responded that they never assess BMI. One NT response stated they used:

“fat percentages using [the] Tanita scale and clothes size.” (NT)

When asked how height and weight data was gathered, 14 (70.00%) responded that they measured the client for height and weight and 6 (30%) responded the client reports their own height and weight.

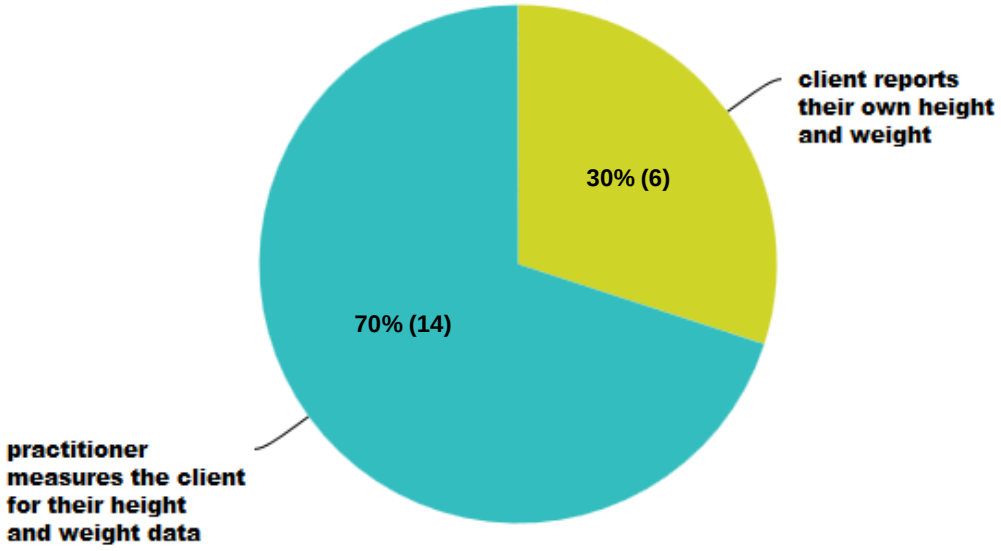

Figure 155 *Gathering height and weight data chart*

Of the 22 that responded to whether they use waist circumference or waist-to-hip ratio, 9 (40.91%) stated they used both, 5 (22.73%) stated they used waist circumference only, 1 (4.55%) stated waist-to-hip ratio only and 7 (31.82%) stated they used neither. Twenty (90.91%) respondents never use callipers. One NT stated rarely and one nutritionist stated sometimes. One stated:

"During my training as a nutritional therapist I pinched a volunteer's nerve with callipers so I know that it can cause problems. Also, I assume clients may not want this type of physical contact." (NT)

Seventeen (77.27%) respondents never assess the basal metabolic rate or resting heart rate. Two (9.09%) practitioners, one eating behaviour specialist and one weight management specialist assessed resting heart rate only. Ten (45.45%) did not assess blood pressure or pulse. Six (27.27%) assessed just blood pressure and 6 (27.27%) assessed both, while no respondents assessed only pulse. Nine (75%) collected the data by measuring the client while 3 (25%) have the clients report their own measurements.

5.2.6 Family history

Twelve (57.14%) out of 21 who responded stated they always ask obese clients about the health of family members. Five (23.81%) said they sometimes ask, 2 (9.52%) said they rarely ask and 2 (9.52%) stated they never ask about the health of family members. Fifteen (78.95%) gather this data through interview at consultation. Seven (36.84%) have the client complete a form or questionnaire. One (5.26%) practitioner completes a pedigree chart and none ask the client to enter the data online.

5.2.7 Quality of life

Eighteen responded to the use of validated clinical tools in quality of life assessment. Sixteen used none of the tools named. One eating behaviour specialist uses the ORWELL 97 obesity-related wellbeing tool and the WHO Quality of Life questionnaire. One Weight management specialist also uses the WHO Quality of Life questionnaire.

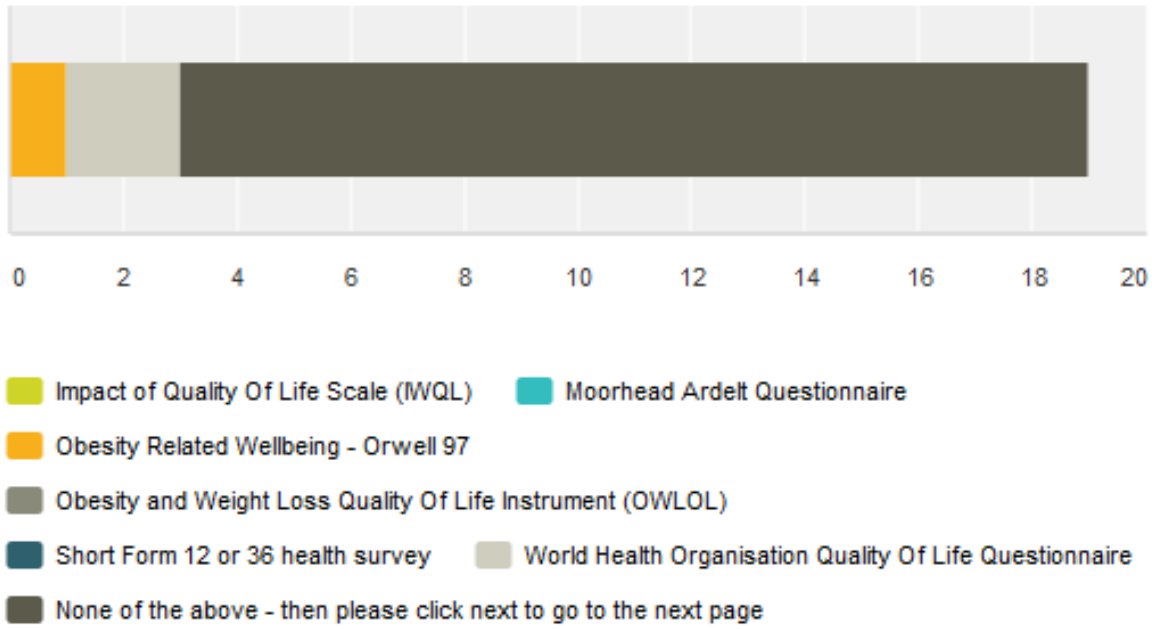

Figure 166 *Results for use of validated quality of life assessments*

5.2.8 Sleep

Twelve out of 19 respondents assessed sleep quantity, patterns and sleep quality. One nutritionist, 1 dietitian and 1 weight management specialist did not assess any of these. One NT assessed sleep quantity and patterns only, 1 dietitian assessed quality only, 1 dietitian assessed quantity only and 1 nutritionist assessed sleep patterns only. One dietitian stated:

"We discuss how inadequate sleep can impact obesity in group and one-to-one sessions." (D)

5.2.9 Sociocultural

In the management of obese clients, 7 practitioners assess all of the sociocultural influences named in the chart below.

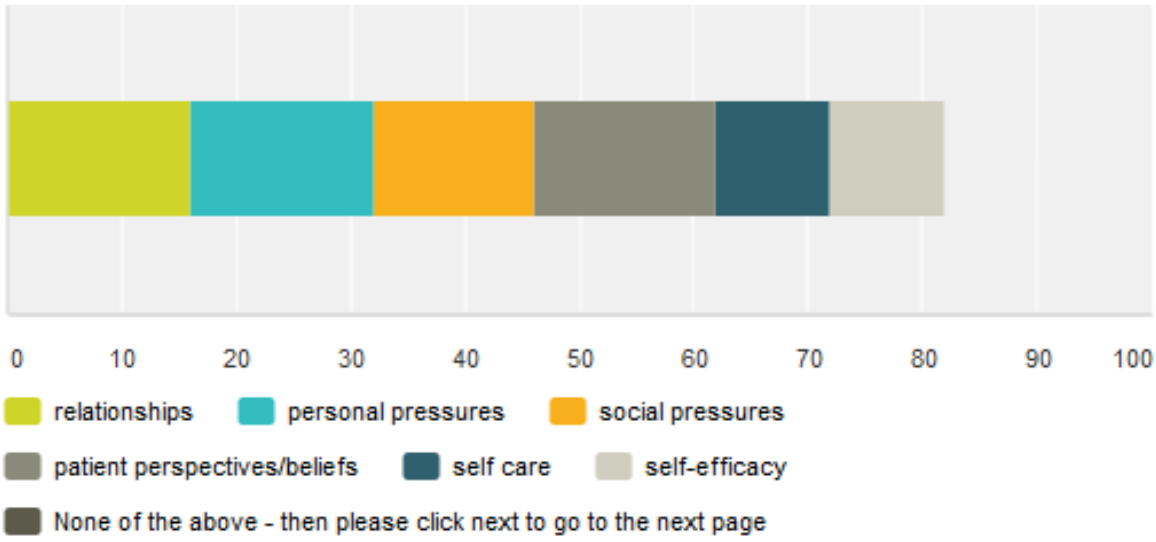

Figure 177 *Results for assessment of sociocultural influences*

One eating behaviour specialist who assessed all of these stated:

"I am trained to assess all of these and work with all of these." (EBS)

No other comments were given, suggesting other sociocultural factors should be assessed.

When asked how the data was collected, 6 (31.58%) gathered the data through interview at consultation and have the client complete a questionnaire. Twelve gather the data through interview at consultation only and none ask the client to complete only a questionnaire.

5.2.10 Goals and outcomes

Out of 20 respondents, only 1 nutritionist did not assess whether the client met their expected outcomes/goals as a result of nutritional intervention and did not assess the client's satisfaction with the intervention programme. The majority (16 = 80%) assessed both of these. Two NTs and 1 dietitian only assessed whether the client met their expectations, while 1 NT only assessed the client's satisfaction with the intervention programme. When asked how the data was collected, 12 stated they gather the data through interview at consultation, 2 had the client complete a questionnaire or feedback form while 5 stated they used both methods.

Nineteen responded when asked if they use the MYMOP to assess the outcomes of nutritional interventions in obesity management. Of the 19, 14 responded 'never' and 5 responded 'sometimes'. An open-ended text option was given for respondents to comment on whether and how they measure or assess any other outcomes of nutritional interventions in obesity management:

"clinical interview [because it] fosters rapport and wellbeing of patient [without] just [focusing on] weight" (EBS)

"progress reports in clinic journals/diaries from client, whatever reporting log we have elected to use in clinic" (NT)

"overall improvements in health [assessed through] interview" (D)

"sometimes functional tests…allow reassessments and helps in clinical decision making" (N)

"Reviewing lab data, GP-patient summaries, self-reported feedback from individuals or carers" (D)

"Improvements in these areas can be very powerful: they demonstrate the worth of intervention to GPs, carers, patients and remind participants that their commitment and actions have made a tangible difference to their health" (D)

However, *"Sometimes the differences are not significant enough at that point in the process to make an impact."* (D)

5.2.11 Discussion of survey results

Results highlight varying and inconsistent clinical assessment and data-collection approaches in nutrition practice. The majority of nutrition practitioners used their own approach to gather data through the use of their own non-validated questionnaires or through interview within the consultation setting. Only a few practitioners used a few validated tools. It is assumed that this is due to a lack of validated tools and applications to support clinical nutrition practice. There is also a variation in data gathered by practitioners, on sleep for example, which is likely due to: the individual approaches used to gather data, the varying levels of clinical skill, training and knowledge of practitioners, and varied understanding of the clinical relevance of contributing factors, such as sleep.

The strength 'ease of use' was the most frequently cited across all assessments, and was the most significant strength in at least 20 different assessments. It may be that 'ease of use' plays a role in the choice of assessment methods for practitioners. 'Ease of use' was followed by 'identifies factors that may be contributing to the client's obesity', which was the main strength across 9 different assessments, except in the use of MYMOP and blood pressure and pulse assessment. The assessment 'allows you to re-assess and monitor client progress' was also considered to be a strength across all assessment methods except for family history assessment, and it was the most significant strength of the MYMOP assessment. The 'data informs clinical decision making' was considered a strength across all assessment methods, while "accuracy of data gathered" was considered a strength in all assessments except sleep and the MYMOP assessment. "Reliability and validity of assessment" scored the lowest in terms of strengths suggesting a need for reliable and validated tools in nutrition practice.

This is supported by an assessment of the weaknesses which highlights “the assessment lacks reliability and validity” was frequently cited as a weakness across most assessment methods. Although, “the client does not always give accurate information” was the highest scoring, most frequently cited weakness. It is not clear in the literature whether client/patient-reported data may be more accurate when recorded electronically or when a practitioner gathers the data via interview. It seems logical that certain body composition assessments may be more accurate when measured by the practitioner, especially where “difficulty getting accurate measure” is cited as the main weakness. “Takes too long” was cited as a weakness across numerous assessment methods, highlighting practitioner time constraints. The majority (23 = 73%) of participants, irrespective of their profession, were self-employed in private practice, which may impact these findings. Independent practice may contribute to time pressures, economic uncertainty, case load uncertainty and excessive workload issues (Nash, Norcross and Prochaska, 1984).

It is more time effective for the client to enter diet data directly into software rather than have the client give the data to the practitioner to enter. Currently, there appears to be a lack of client facing diet applications for professional use. *Nutritics* are developing an application in order to provide a shared client and practitioner tool which can provide detailed dietary analysis to support professional clinical decision making. A new application, *CheckYourNutrition*, came to market in 2017. *CheckYourNutrition* assesses food frequency via food diaries, but does not appear to include explicit information about eating style, behaviour and habits. It would be beneficial if food diary/journal applications allowed clients to upload food photographs, enabling practitioners (or a software application) to undertake nutrient analysis directly.

Health history and obesity risk factors are essential to help identify pathophysiological mechanisms that may be contributing to client obesity and to identify further red flags and comorbidities, such as Type 2 diabetes, sleep apnoea and other conditions or medications that may contribute to or result from obesity (Aronne, 2002). There appears to be a lack of standardised clinical tools to gather and assess this type of data in an obese population. Overcoming the limitations of accurate client information is difficult when the information relates to other people (Ginsburg & Willard, 2009). A family history questionnaire or checklist is a tool used in research or general practice, while the pedigree chart is more likely used by geneticists.

With regards to clinical outcome analysis, many of the body composition measures, such as BMI and waist-to-hip ratio, can be used as outcome measures to evaluate the effectiveness of a weight loss programme, even though there are a number of strengths and limitations to

each of the assessment methods, which are clearly described in the literature (Beechy et al., 2012; Silva et al., 2013; Switzer, Mangat and Karmali, 2013; Lindsay et al., 2014).

Outcome analysis is also about keeping in touch regularly with the patient (Velentgas et al., 2013). However, there was a lack of outcomes analysis which correlates to actions or interventions the clients may have implemented.

The meaning and purpose of measuring quality of life has broad considerations (Bowling, 1995, p. 1). The measurement of health outcomes is essential to researching effectiveness of clinical interventions and disease-specific scales are considered more clinically and socially significant than generic quality of life (QOL) scales (Bowling, 1995, p. 16). QOL measures frequently overlap with measuring psychological wellbeing, exercise ability and sociocultural support. It would be important to limit repetition but also capture red flags, potential comorbidities and broader health status. Measurement of health outcomes should be tied to measures for exercise, sedentary behaviour, diet intake and psychological mood (Wolf, 2002).

There are a number of tools available for measuring social networks and support. Social roles and relationships in relation to obesity have primarily focused on marital status, but ethnicity, cultural factors and relationships also play a role (Crawford, Jeffery, Ball, & Brug, 2010 p. 106). The mechanisms by which sociocultural factors are associated with obesity are not well understood (Crawford et al., 2010, p. 107) probably because they are numerous and complex (Crawford & Jeffery, 2005 p. 37–53). Developing a case-by-case evidence database may allow for correlation analysis which further explores the influence of sociocultural factors in obesity. This data could also help to highlight or limit the number of confounding factors when data mining such a database.

A number of outcome analysis methods are used in clinical practice but each practitioner uses their own approach. Standardisation of intervention and outcome analysis tracking may allow for CER. The MYMOP (Paterson, 1996) is a validated and frequently used tool that allows for reassessment and monitoring of client progress. However, it is limited because it utilises client-reported outcomes and therefore has limited comparative capacity. Tracking of obesity-specific outcomes alongside client-reported outcomes provides more robust clinical outcome analysis (Wolf, 2002).

What has not been assessed by the survey, and was not reported by the respondents, was the identification of potential pathophysiological contributors to obesity, such as inflammation, insulin resistance and hormone imbalance, to support clinical decision making. New tools which link data on sleep patterns to eating habits may also be able to identify associations between sleep and eating for individuals and stratified cohorts. This could help

to personalise intervention decisions and potentially motivate change of lifestyle and behaviour in individuals.

Some respondents shared their own clinical tools as a result of this survey. These were reviewed and compared to validated tools to inform new tool development. A number of the practitioner's self-developed health history questionnaires do gather health data where questions are clustered in physiology groupings e.g. cardiovascular system questions, nervous system questions, circulatory questions etc.

Signs and Symptoms Analysis from a Functional Perspective by Weatherby (2004) includes a nutritional assessment questionnaire that takes this grouping approach. It also provides a guide to the significance of the question, what responses may indicate and potential clinical recommendations for consideration. The questionnaire and approach by Weatherby (2004) is not validated, and the connections made from the questions to the clinical recommendations made in the book are not referenced or linked to research, but the approach appears useful for clinical practice. Analysing health data when it is grouped in this way may support practitioners' pathophysiological reasoning and clinical decision making.

Although the survey was useful for gathering information to inform new tool development, results did not identify frequently used validated tools that could be integrated into an online format. These results highlighted that there are currently no standardised data-collection methods in clinical nutrition practice, and each practitioner is gathering data in their own unique way. Therefore, enabling robust, standardised data-collection methods could transform personalised nutrition practice.

5.3 Findings from interviews

Twelve interviews with nutrition practitioners (6), academics (5) and a statistician (1) were conducted and transcribed between February and June 2015. Their comments below are coded with their initials and P for practitioner, A for academic and S for statistician. The interviews with practitioners aimed to gather views on clinical tools, assessment and decision making, as well as evaluate views on the ethics and implications of standardising approaches to personalised nutrition. The aim of the interviews with academics and statistician was to evaluate their experience and views on tool development and validation and/or data set management to inform new tool development.

Results from all 12 interviews are presented under 14 headings, which were the themes identified from the data during transcription and analysis. The following combines both practitioner and academic results, as a number of academics also have clinical experience and some practitioners were in academia. They also discussed a number of overlapping

themes; therefore analysis enables a comparison of the differences and similarities between practitioner and research responses.

5.3.1 Standardised approaches

All six practitioners responded positively when asked about their views on the use of standardised data collection approaches or questionnaires in personalised nutrition practice. Consistency, structure, reliability and getting comparable information were seen as benefits:

"They provide a structure really, a practice for all kinds of practitioner whether they be dietitian, public health therapist, or GP, other health profession, to gather basic data, that is consistent." (CC-P).

Practitioners also highlighted potential limitations:

"I'm unconvinced that some of the questionnaires don't just distort the information as much as they give [sic]*." "It's very, very hard to get somebody to tell you the truth about what they really eat," and "what becomes reported on a piece of paper becomes an instrument for being judged." "It becomes some kind of interrogation around food." "My way of getting around that is a very unstructured, very relaxed sort of interview."* (RJ-P)

"There is a small risk of putting the practitioner's agenda over and above the patient's agenda, which means that before a patient comes to you, you already know the set of questions you are going to ask so from that point of view the practitioner's agenda becomes more of the priority and there is a risk of losing the patient-centred approach." (DT-P)

A way to overcome these concerns was also proposed:

"So long as the practitioner is using the tool alongside the consultation the tool will not replace the individualised conversation." (DT-P)

5.3.2 Ethical issues

When practitioners were asked about ethical issues arising from using standardised approaches to personalised nutrition practice, there were some concerns, including:

"…maintaining and protecting the patient's autonomy." (DT-P)

"Legal and ethical implications of storing personal data is probably one of the biggest challenges." (AJ-S)

Inclusivity and tool validity were also raised as ethical considerations:

"people who can't read or write can't go away to a complete questionnaire in their own time." (AJ-S)

"Patients for whom English is not their first language [may be excluded]" (JS-A).

"Because we live in a multiple society [sic] *and you know, you wouldn't want your [tools] to put people off who come from slightly different cultural backgrounds."* (MA-A)

"You will also want to see how non-obese people respond." (JN-A)

Another important issue was identified:

"From an ethical perspective we can't demand questions to be answered." (CR-A)

5.3.3 Patient/client-centredness

Patient- and client-centredness was a recurring theme throughout the interviews, for example:

"What's important with a professional is when they get to speak to somebody kind of face-to-face about the issue, is to be able to be patient, patient-led and patient- kind of directed". (JS-A)

"I think a lot of achieving weight loss is about wanting to do it in a way that suits you." "Every case is very, very different, so I think a lot of it is very much linked to recognition in the individual of what's caused the problems and their engagement with addressing it." (CR-A)

"Let them lead the way in terms of them deciding what the priorities are and what the strategies will then be." "The key thing is helping them unpick their relationship with food, what have you tried in the past, what's worked well and what doesn't work well." (RJ-P)

"A lot of it is very much about getting people involved in their own self-help." (CR-A)

5.3.4 Health history collection

Practitioners were asked how they determine the main issues contributing to obesity for their individual clients:

"Looking at the diet, looking at the family history and looking at certain factors that are going to be influencing things such as sleep and stress and hormones." "From a tool point of view I guess by the time I'm meeting with them it's all verbal." (HL-P)

"[This information] comes more from speaking to the client and understanding at that initial appointment how we're going to get them on the right track as quick as possible". "The reality is the majority of us don't know who is going to walk through the door… so you need to know everything about everything." (NM-P)

This also highlights that gathering health details before consultation is useful:

"Dietitians will have access to people's medical records, and so you don't actually need to get the patient to spend a lot of time actually telling you about their medical history because you know a lot of it." (JS-A)

"Initially before I see anyone usually, I get a GP-patient summary, which will tell me all of their current active problems and any recent blood test they have had. And then the rest of it really comes directly from the patients, when they sit in front of me." (CC-P)

The importance of triangulating data was also discussed:

"If they say that they are a gym member can we go back and see how often they have scanned into their local suite of their local gym." However, *"rather than challenge them about it, just try to sort of understand the reasons why they're misreporting in those ways or question them in different ways so that we get more precise data."* (CR-A)

5.3.5 Clinical decision making

Practitioners were asked in which ways the questionnaires and tools help them make clinical decisions:

"The tools that we are currently using are not able to help practitioners decide what intervention is better for patients." (DT-P)

"You make clinical decisions on the day… based on the evidence that you have." (NM-P)

From the questionnaires and *tools "you are able to get some baseline data, be it physical activity levels, their eating pattern, and things like that. You can use that information as a basis to discuss where they may be struggling. For instance, if you realise that a patient is not eating regularly and the problem is that they don't apportion time to have breakfast, then you can fill up the conversation around time management. So from that standpoint, if you have a tool that can identify the difficulties then you can use that as a basis to, to direct your conversation with the patient."* (DT-P)

"It's about really just understanding what, what's getting in the way for them and helping them through the often practical ways of overcoming that". (AG-P)

Results highlight that clinical decisions can also be patient-led:

"When I say 'how can I help?' that question is nearly always answered with a key clinical outcome." (RJ-P)

5.3.6 Clinical outcomes analysis

Although the interviews failed to ask specific questions about clinical outcomes analysis, it was discussed, and results were closely related to patient-centredness:

"[It is a] tool to capture the baseline data, like these how much fruits and vegetables they were eating, how much physical activity they were doing, how often they were eating breakfast and things like that," and then assess *"the data [again in] six months' time."* (DT-P)

"I have more touch points with that client on obesity management. So it might be that I have a weekly touchpoint, it might be that if they are local I will see them each week and the follow ups might only be 15 minutes, 30 minutes but there will be an allowance probably once a month for a longer session. I'll do the intervening touch points by Skype or by phone and then as I progress with a client then the gaps between having contact with me will probably get longer, assuming it's all going well, (obese clients) definitely need more care and hand-holding and more support and most of that is around motivation." (AG-P)

"What's really missing at the moment is before and after interventions [analysis]" (RJ-A)

"You need to [understand] from one consultation to the next as to what's working, what isn't working, what progress is being made" (HL-P)

"Capturing data now and then we will follow up and see the trend of that data maybe six months' time. I think that is the missing link the fact that the tool that we are using was not able to help practitioners decide what intervention is better for patients." (DT-P)

5.3.7 Engagement with the evidence base

Practitioners were asked 'In what ways do you use the scientific literature to support your clinical decision making?' As well as, 'In what ways do you analyse the client data you have gathered against scientific literature?'

"Within the NHS most people will base the decision making on existing guidelines more so than individual pieces of evidence and the hope is that these guidelines are based on evidence, so most people use that as useful clinical decisions rather than sourcing evidence and all." (DT-P)

"I'll look at guidelines for particular illnesses"; "pinning down the guidelines"; "we've got too many guidelines"; "I would look at NICE quite a lot" (RJ-P)

The dietitian and the naturopath referred to guidelines when asked about engagement with the evidence base. Other practitioners engaged with the evidence base to explore their client's health condition if it was complex or beyond their clinical experience. They also engaged with the evidence to:

- *"check drug, nutrient interactions"* (RJ-P);
- *"research about medications"* (NM-P); and
- *"look at the mechanism or action of the pathophysiology of the disease"; "mechanism of action of interventions"* (JN-A).

Time constraints were also frequently cited as a barrier to engaging with the evidence base.

5.3.8 Linking new tools to the evidence base

Practitioners were asked 'if a tool or questionnaire was devised that that linked to supporting research literature, how would that be useful for your clinical practice?'

"Fabulously useful. It would, it would make the difference between using it and not using it". (RJ-P)

Unfortunately, there were no solutions offered by practitioners in terms of how that could work. Academics responded cautiously to the idea of linking new tools to the evidence base:

"That is a huge amount of work, I mean that is a lot of work. I think if you can, make that recommendation" (MA-A)

"I guess that's quite a long way down the road in terms of tool development, isn't it? Because you wouldn't really want to do that, until you have got your own substantive database. Because you know, if you – for example if you develop a tool and you use that tool, and say, hundred people who are obese, you don't know how representative your sampling is, of the general population or about clinical population. So, actually linking that to evidence in terms to improve clinical decision making, I think you will probably need to be fairly far down the road in terms of your tool development before you can actually do that. Because, you know, making these kind of links on the basis of a limited evidence base. I am not sure how helpful that would be." (VS-A)

5.3.9 Case studies

Three practitioners highlighted the value of case studies when discussing engagement with the evidence base:

"What I respond to the most is reading other case studies." (HL-P)

"[Research data] kind of has to be case study-based really because it's the practical clinical side that we are looking at not the research theory. It's not the theory of what happens when rats are fed with something, it's actually what happens with real people"; "It's a great way of keeping up to date." (AG-P)

Practitioners were also asked 'what are the advantages and disadvantages of sharing case data with researchers to create an evidence database for nutrition practice?' The advantages for sharing case data include:

"It makes you look at yourself a bit when you listened to other people's ways of doing things." (CC-P)

The considerations or limitations for sharing case data:

"At the moment [sharing case data is] not that useful because I think it's so individual and it's so out of any format, I think that's the problem. I think giving a format that could be followed so there could be some level of uniformity, I think would be essential." "I absolutely would [share case data] if I completely trusted them, I knew how it was going to be used and how they were asking you to submit the information wasn't too time-consuming." "[What's required is] a repository that is a bit more structured, if you were uploading a case that you would be forced to put it into a certain format, so that you collected all of the essential stuff that was important for clinical decision making." (HL-P)

5.3.10 Priority considerations for developing new tools

Practitioners and academics were asked what they thought were the most important considerations for the use or development of questionnaires/tools in clinical practice. There appears to be a conflict of views between practitioners and academics on using tools. The practitioners were interested in narrative medicine:

"I don't think it's appropriate to tick a box about 'do you feel anxious often?' I think that that comes out in the narrative." (RJ-P)

"Sometimes the best thing you can do is actually put the pen down and… just let people's feelings and thoughts and anxieties about doing this come to the fore, just a series of flexible and open questions to keep the dialogue going is sometimes all you need." (JS-A)

"You can look through a questionnaire and really get a good understanding what you think you are going to want to work on with that client, but often, it's actually when you speak to them, you uncover a lot more information." (NM-P)

The academic view is:

"Free text answers are deeply problematic [from the point of view of statistical analysis], you've got to code them up. If we are going to develop a tool that is useful and statistically validated then the free text answers may be of clinical utility but they are not really given statistical utility." (JN-A)

"So tools need to be developed so that they are useful for research purposes"; "proper statistical analysis"; "to be able to pull that (data) out (into a spreadsheet) and then we can analyse it in a standard piece of software… like SPSS." "[and to be able to] look for before and after efficacy, do time series analysis, see how people on different diets are responding similarly or differently." (JN-A)

Tools also need to be useful for clinical purposes:

"Usability, practicability, striking the balance between getting as much information as possible but doing it within a context of it not being demotivating." (AG-P)

"You need [the tool] to be flexible: not all people come to obesity via the same route." (JS-A)

"[There are] very different kind of histories and so any tool needs to be able to capture the sort of richness and depth" (JS-A)

"Anything that's sort of relatively easy to do is not going to capture the complexity" (HL-P)

"Your main concern is if this tool going to be an add-on or is it going to help me save or manage time"; "Time is the huge factor." (DT-P)

It was felt by one practitioner that tools are about:

"Making sure that we are showing a degree of competency as a profession so, we are using the questionnaire to help us make sure we've covered red flags, family history, the medications are the client is taking, the GP details, consent from the client… it covers quite a lot of admin and important clinical audit aspects, as well as giving us some basic information around their physiology" (NM-P)

Having a client without a questionnaire: *"[is] like a comfort blanket taken away from me, but also it, it does, prevent me from being able to make sure I've covered all the, the major areas that might not necessarily come up in a general chit chat conversation style of, of questioning."* (NM-P)

Clinical tools appear to have numerous applications, one (as above) is in providing security, but practitioners also thought it was about:

- *"getting as much background information as possible"* (AG-P); and
- *"[getting] a client thinking because what we offer is quite a different sort of approach that they've probably had before. A lot of people have forgotten their whole health history and if you just go in without a questionnaire or anything, asking them some of the questions we ask, - they wouldn't remember. So by having the health questionnaire it gets them thinking, it gets them talking to family members to jog their memories and that enables us to get much more complete information on the day."* (HL-P)

5.3.11 Desired from new tools

A number of suggestions were made throughout the interviews for the desired functionality of newly developed tools:

"Electronic data capture is vital"; "Combine these tools with mechanistic information"; "To have questions that are clearly tied to pathophysiology"; "Linking each question to a particular mechanism." (JN-A)

"Objective evidence-based measures that are quick"; "Probabilistic flowcharts for clinical decision making that were evidence-based"; "I want to be able to keep electronic records in the clouds for all my clients"; "Easy to use." (RJ-P)

"Really easy to use and not easy to misinterpret" (NM-P)

"Evidence-based so it gets us more accepted in mainstream medicine" (HL-P)

"Wouldn't it be great if you had, if there was a fabulous easy access repository of data" (AG-P)

5.3.12 Tool validation

Academics were asked about their views on validating tools:

"The tool needs to be statistically validated" (JN-A)

"We [have] got to [be able] to pool our data, especially in the UK, it's ridiculous, how everyone is doing something slightly different and it's not comparable and then all that information is completely waste." (MA-A)

Validation techniques discussed include:

"Face validity is one of the most important things" (MA-A)

"The advantage of using the existing ones [questionnaires] is that you're hopefully at least starting with questions that make sense and pass the face validity test." (AJ-S)

"Go back to people with obesity, go back to your patients and make sure that what you are asking them is, what you think you are asking them because we often think, we are asking something, and people respond differently because they don't quite understand what we are trying to get at." (MA-A)

"Things like reading age are important. So, readability, using lay language, a lot of psychological tools are pretty awful in terms of the questions they ask and tend to ask the same questions." (VS-A)

"Very standard techniques [as well as more complex analysis]"; "principle component analysis or PCA which is very typically used to validate questionnaires or understand the responses that particular groups of people have to questionnaires" (JN-A)

It was thought that the pilot trials would provide an opportunity to undertake validity assessment.

5.3.13 Data sets

Academics were also asked about the management of data sets:

"Possibly some of the best data you could get is if you are getting good quality longitudinal data, so you are following up the same subjects over a period of time, and if they are changing their diet patterns during that time, then you are starting to get some potentially useful data on the physiological parameters at any rate, that's not going to help you so much with the long-term outcomes"; "That's a lot more reliable than looking at between person facts as you have got cross-sectional data, all you can do is compare the person who eats 12 sausages with the person who eats tofu burgers"; "Missing data is always a big problem. Well, I say it's always a big problem often in questionnaires if people filling the questionnaire tools, they often do fill in all the questions"; "You will usually get a small amount of missing data... if you are unlucky, you might get lots of missing data and statistically that can be quite tricky to handle." (AJ-S)

"You always going to get some people who report good and some who report bad deliberately, if you like, and I think it's just a question being aware of that. I mean, there are other biases." (VS-A)

"The more important thing is how you get people to honestly complete the measures." (MA-A)

5.3.14 Database research

The implications and ethical issues of building a case-by-case evidence base was discussed with both practitioners and academics:

"There is the challenge of knowing what you are going to do with the data before you start building your database for research purposes, you want to be really clear about what your research hypothesis is and making sure that the data is going to be able to answer that"; "Even if you think really carefully about that build of wonderful database and get a great sample size and everything, it may still not be completely convincing"; "That's why potentially using longitudinal data could be beneficial because that cuts out a lot of the confounding [factors], but it certainly won't cut out all of it." (AJ-S)

"Even in the general population sample, you can't assume that that is representative because it may be that the kind of people who consult nutritional therapists, they are not representative in a general population. I think when you get into the stage of building up a clinical database, within that you are going to have lots of subsets of people, with different characteristics, and I think it might be dangerous to make to draw inferences on the basis of a database, of say a thousand people but where those thousand people have vastly different characteristics. So, for example, maybe different health conditions or different age group or different socioeconomic groups. So, I think you have to be very careful, not to draw inferences that are not representative, of the population you are working with." (VS-A)

"I think, it's very difficult thing when you think about data mining because people can't give that consent to things that they don't, you know, you might not know what purpose you want to use your database for. So you can't ask people to give consent." "People may be happy to give general consent but they don't know who's going to be using the data. Can you guarantee for example, it's not going to be used for commercial purposes? People may not want that, they may be happy to give it to the health consultant but not for commercial reasons. So, I think the ethics of this is really important. And then of course, it's the whole data protection issues as well. You have to be really careful of that." (VS-A)

5.3.15 Discussion of interview results

One of the main research questions this project is designed to answer was "is it possible and ethical to standardise a personalised approach to nutrition practice?" It appears from the interviews results that standardised data-collection approaches, such as questionnaires, are important and beneficial, and could contribute to the development and dissemination of best-practice case reports. The perceived benefits included enabling the development of a repository of data and evidence development for personalised nutrition practice. There were limited ethical concerns relating to standardising data-collection methods, although ensuring patient-centredness and inclusivity were key, as was ensuring tools do not replace the consultation process because of the value placed on client narrative and centredness. The results do highlight that ethically, the use of tools and questions cannot be made compulsory in practice and the value of undertaking ongoing population and cross-cultural validity assessments is necessary to address the ethical concerns raised (Beaton et al., 2000; Zumbo and Chan, 2014).

The ethical concerns and validity of data mining from a case-by-case evidence base are more problematic, and highlight the importance of data storage, consent and the issues of gaining consent for data mining when it may not be possible to be exact about its purposes. Solutions for overcoming key issues for data mining electronic health records are discussed in the literature (Blumenthal and Tavenner, 2010; Jensen, Jensen and Brunak, 2012; Ross, Wei and Ohno-Machado, 2014). The value of knowing the purpose of the evidence base before building it was seen as key. The primary purpose of building a case-by-case evidence base for nutrition practice is to allow for the probabilistic prediction of the outcomes of interventions. This is the key goal. Missing data was also identified as an issue, although there are statistical methods for overcoming this.

The results highlighted the value of ongoing feedback from the users of the tools in order to further shape them and ensure compliance. Trialling tools with diverse representation groups may also help identify sensitivity to cultural differences as well as around questioning of obesity, to avoid questions becoming an interrogation of food intake or an instrument of

judgement (Hannah et al., 2009). As a result, obese individuals were invited to engage with the development of new tools via the Delphi process, as well as provide feedback on completing new tools after pilot trialling.

The results support the perception that practitioners engage with the evidence base in different ways. Some practitioners are using public health guidelines such as NICE, as discussed in Chapter 2. Other practitioners are using the primary literature in order to explore the client's health history when it is complex, unique or is something they have not experienced in clinic before. Whether this allows for a more personalised approach than the use of public health guidelines is debatable. Clinical decisions can be patient-led, and this may help with client engagement and compliance. Case studies were cited as more helpful for practitioners in terms of insight than other research studies, but it was felt case studies could be improved if the information was presented in a standardised format.

Flexibility of new tools is required to suit individualised approaches to practice by a range of practitioners including dietitians, nutritionists and NTs. Electronic data capture would provide a more flexible approach than paper tools. Online tools are considered important for a number of reasons, not just for practitioner ease but also as a tool for clients to self-monitor their real-time food intake and behaviour. The use of information technology to improve dietary assessment and tackle obesity has been assessed by Carter et al. (2012). The development of online applications is beyond the remit of this project; instead the project will seek opportunities for online tool development with existing online tool providers.

Relating new tools to the existing evidence base was met positively by practitioners, but the volume of work required to achieve something meaningful to inform clinical practice was highlighted by academics as something to approach cautiously and is in any case beyond the remit of this research project. This will instead become a recommendation for postdoctoral development.

The development of new tools needs to consider both clinical and research approaches. Considering the results from the survey and these interviews, new tools are needed to:

- highlight obesity risk factors and red flags;
- ensure tools stay in the remit of nutrition practice;
- offer a choice of assessment measures but not make tracking all of them compulsory;
- relate questions to pathophysiological mechanisms of disease to support pathophysiological reasoning;
- enable analysis to identify associations between intervention compliance and health and weight outcomes;

- gather data which may help to limit the number of confounding factors when data mining;
- track obesity-specific outcomes alongside client-reported outcomes; and
- allow for frequent measuring of outcomes measures at regular intervals.

The ways in which new tools could provide reliable and statistically validated data were discussed with academics. The conflict between the academics' responses and the practitioners' value of narrative medicine highlighted that more than one data-collection approach is required to meet each of these needs. New tools therefore aimed to include:

- statistically analysable baseline and follow-up measures – e.g. physical activity levels, food intake, measuring before and after interventions;
- recommended interventions and compliance tracking;
- administrative data such as GP details and consent; and
- free text but structured case study forms providing a uniformed format.

Structured case study development is not an aim for this project but was considered during tool development. Only the first two points above are required for development to meet the aims of this project. Ideally, individual health data gathered by the tools should be anonymised to manage data protection risks (Graham, 2012). Practitioners could continue to use their methods for administrative data gathering, such as GP details, which are not required for analysis and add to the complexity of ethical issues including confidentiality, privacy and data protection.

5.4 Findings from Delphi Survey

Three rounds of Delphi surveys were conducted between October 2015 and June 2016.

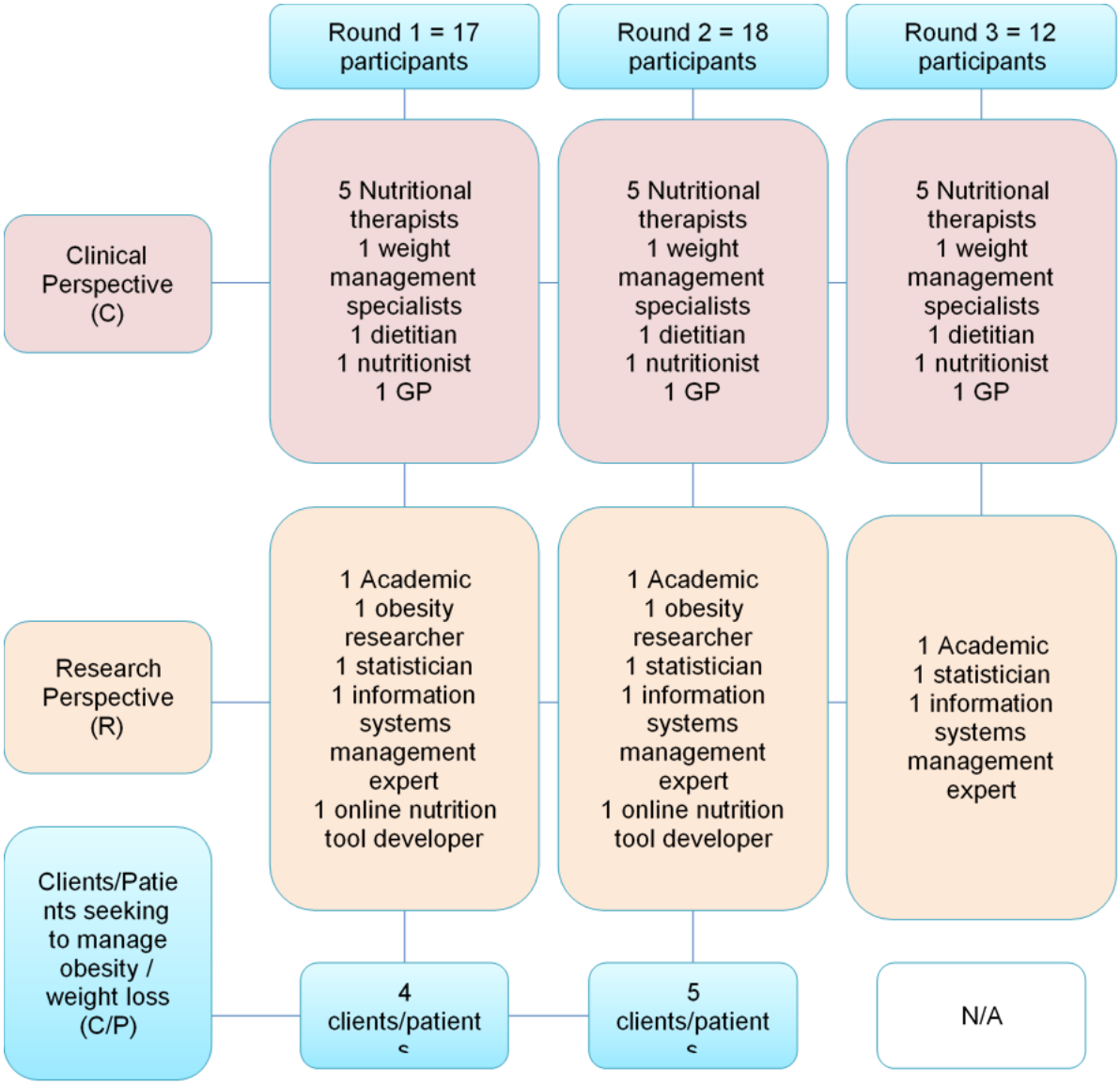

Figure 188 *Delphi survey participants, and their perspective and profession*

The overall aim of the Delphi method is to collaboratively construct new clinical tools which assess the efficacy of personalised nutrition practice in obesity management. Due to the word count restrictions of this report it is not possible to present an in-depth analysis of each round, although this was conducted. The following discussion provides an overview of the Delphi survey results, feedback and research utilised for the development of four new clinical tools.

The majority of nutrition client/patient (C/P) participants were willing to provide information for the various assessments. Therefore, it can be assumed in the discussions below that nutrition clients/patients are happy to provide the information unless otherwise stated. Comments followed with (R) were from participants from the research perspective. Comments followed with (C) were from participants from a clinical perspective.

In Round 1 participants reviewed and ranked a range of tools and assessment methods, as described in Chapter 3. The results of Round 1 helped to develop new tool categories and questions for tool development. Round 2 aimed to gain feedback and consensus on satisfaction with the included questions. The results from Round 2 were used to construct four new tools:

1. **Tool 1: Personalised health history questionnaire** (https://mdxl.eu.qualtrics.com/SE/?SID=SV_78MODoa9LvgWDKB) – this aims to collect health history and family history data around mechanisms of obesity, as well as collect a range of baseline health measurements. This questionnaire is for the patient to complete before the first consultation.
2. **Tool 2: Intervention record** (https://mdxl.eu.qualtrics.com/SE/?SID=SV_2rdbdwQkaKAMqTX) – this aims to capture which interventions were recommended by the nutrition practitioner. The practitioner should complete this at the end of each consultation.
3. **Tool 3: Personalised health follow-up questionnaire** (https://mdxl.eu.qualtrics.com/SE/?SID=SV_8IxX3qhW1nUQb0p) – this aims to measure any changes to the client's health measurements after intervention. This questionnaire is for the patient to complete before their return consultation.
4. **Tool 4: Achievement record** (https://mdxl.eu.qualtrics.com/SE/?SID=SV_eDvG2CfybY4hMrP) – this aims to capture which interventions the patient complied with. This tool is completed by the nutrition practitioner at the outset of each return consultation.

Feedback at the end of Round 2 highlighted the health questionnaire was:

"much too long" (R)

"length / detail required likely to affect compliance" (R)

Round 3 of the Delphi surveys aimed to review the content and reduce the overall size and complexity of the health history questionnaire as well as gain feedback and consensus on satisfaction with the questions proposed for inclusion in Tool 2, the intervention record and Tool 4, the achievement record. Tool 4 was originally named the 'compliance record' but, based on Round 3 feedback it was renamed the 'achievement record'.

5.4.1 Diet and nutrition

The first round of the Delphi survey reviewed the use of various dietary assessments including food frequency tracking, food diaries, 24-hour diet recall and online dietary assessment tools.

The results of the previous survey, together with the results of the Delphi Round 1 highlight that practitioners engage with numerous validated food frequency questionnaires as well as numerous online applications for assessing food frequency, eating styles and dietary habits. These existing tools can be utilised and there was no need to develop new diet and nutrition intake assessment tools as part of this project. Diet and nutrition assessment does however need to be tracked before, during and after intervention so that changes to food intake can be measured against health and weight outcomes. This was therefore included in tools 2 and 4.

5.4.2 Health history and risk factors

In Round 1, 10 participants' considered health and family history should be gathered by a questionnaire/tool before the consultation. One clinician stated it should be gathered in the consultation setting. Multiple-choice questioning was the preferred data-collection method, with seven participants highlighting multiple-choice and four highlighting free text as a data-collection method. Seven participants stated that a symptoms checklist should also be included.

No validated health history tools were identified, but practitioner questionnaires included a range of approaches to gathering this data. Validated tools such as the Stanford health assessment (Pecoraro et al., 1979; Bruce and Fries, 2003) exist, and although they are not focused on obesity, their content and approaches did inform new tool development. Medical health history questionnaires were also reviewed and considered.

Seven participants stated that a symptoms checklist should also be included in the tool/questionnaire and that it should include red flag symptoms. Some validated symptom checklists do exist, such as the Rotterdam checklist (Hardy et al., 1999) and the Edmonton symptom assessment system (Richardson and Jones, 2009), but these were designed for use in palliative care. There do not appear to be any similar validated symptom checklists for use in obesity, although numerous measures of QOL in obesity do exist (Chambers & Swanson, 2010; Forhan, Vrkljan, & MacDermid, 2010; Mannucci et al., 1999). There are also generic health-related QOL assessments such as the medical outcomes study (SF12 and SF36) (Wee, Davis and Hamel, 2008), which informed the development of new tools.

New health questionnaires (tools 1 and 3) aim to relate symptoms and health history questions to pathophysiological mechanisms of obesity. This should support a pathophysiological reasoning practice paradigm. A literature review was undertaken to identify a range of pathophysiological mechanisms, 'other diseases', health conditions and red flags associated with obesity and tools and tests/measures assessing those mechanisms, as described in Chapter 3. The results identified a range of pathophysiological

mechanisms (see Table 6), and results were used to inform categories and questions for tool development.

Table 6 *Pathophysiological mechanisms contributing to obesity*

Mechanism	**Reference**
Addiction	Kenny and Shaw (2011)
Dietary intake	
Dysbiosis	Dimitrov (2011)
Dyslipaemia	Eder, Baffy, Falus, and Fulop, (2009); Piva et al., (2011)
Energy expenditure	
Epigenetics	Campión, Milagro, and Martínez, (2009); Javier Campión, Milagro, and Martínez, (2010); Tammen, Friso, and Choi (2013)
Early onset obesity	Lillycrop and Burdge, (2011); Martínez, (2012); Rhee, Phelan, and McCaffery, (2012)
Genetics	Bouchard and Drake (2010); Guo et al., (2006); Herrera, Keildson, and Lindgren, (2011)
Hormonal imbalance	Kushner (2012)
Hyperglycaemia	Choi et al., (2013); Fuentes, Roszer, and Ricote, (2010); Kurpad and Aeberli, (2012); Lu et al., (2008); Yang et al., (2010)
Infections origin	Bassols, Moreno, Ortega, Ricart, and Fernandez-Real, (2010); Pasarica and Dhurandhar, (2007)

Inflammation	Benozzi, Perruzza, and Pennacchiotti, (2012); Choi et al., (2013); Clària, Titos, López-Vicario, and González-Périz, (2010); Deepali, Thomas, and Gupte, (2013); Eder et al., (2009); Fain, (2010); Fuentes et al., (2010); Kim, Shin, Moon, and Chung, (2011); Tai and Ding, (2010); Yang et al., (2010)
Insulin resistance	Fuentes et al., (2010); Lu et al., (2008)
Medication related mechanisms	Benozzi et al., (2012)
Other diseases (diabetes, cancer etc)	Kishida, Funahashi, and Shimomura, (2013)
Oxidative stress	Choi et al., (2013); Piva et al., (2011)
Pregnancy	Kushner, (2012)
Psychological factors (e.g. depression, beliefs, motivation)	Grossniklaus et al., (2012); Karasu, (2012); Kushner, (2012)
Satiety disruption/leptin resistance	Erez et al., (2011); Orbetzova et al., (2012)
Sleep disturbance	Clària et al., (2010)
Smoking cessation	Fuentes et al., (2010)
Socio economic factors	

Stress/adrenal dysfunction	Bloomgarden, (2009); Greenfield and Marks, (2009); Grossniklaus et al., (2012); Karasu, (2012); Kushner, (2012)

During Delphi Round 2 clinicians were asked if they considered the proposed range of mechanisms (listed in Table 6) to be comprehensive. Six participants said yes and two were unsure.

In Round 3 of the Delphi survey, participants were asked which of the mechanism headings should be deleted, included or adapted. Out of the 12 respondents who completed the Delphi survey, if at least half of them (6 or more) stated the heading should be deleted or adapted then this change was made, for example: dysbiosis was changed to digestive issues, while insulin resistance and hyperglycaemia were changed to blood sugar regulation.

A list of 'other diseases', health conditions and red flags associated with obesity was also developed based on a literature review utilising the term "obesity-related diseases" (see appendix 2) (Browning, 2003b; Martin, Qasim and Reilly, 2008; Michael I Goran, 2008; O'Rourke, 2009; Horng and Hotamisligil, 2011; Mathew, Okada and Sharma, 2011; Na et al., 2011; Yamauchi and Kadowaki, 2013b; Doron et al., 2013; Ohashi et al., 2014; Reilly T. Enos, Velázquez and Murphy, 2014; Nigro et al., 2014; Choi and Snider, 2015; Sarah C. Ferrante et al., 2015; Zhang et al., 2015; Lee et al., 2015). Health conditions included were associated with obesity and/or correlated to the above mechanisms of pathophysiology. Results were used to develop a table of health conditions for health history analysis (see Table 7), which was presented to the Delphi group for inclusion in Round 2.

Table 7 *Health history question on new tool*

	Question 1		**Question 2**
	Please Tick		please provide more details e.g. type of condition
Condition	Current	Past	
Alzheimer's disease			
Asthma			
Atherosclerosis			

Attention deficit hyperactivity disorder (ADHD)			
Autism spectrum disorder			
Binge-eating disorder			
Bulimia			
Cancer			
Cardiovascular / heart disease			
Celiac disease			
Chronic fatigue syndrome			
Chronic venous disease			
Chronic viral condition			
Depression			
Eating disorder			
Epstein Barr virus			
Fibromyalgia			
Gallbladder disease			
Glaucoma			
Gout			
Hepatitis (A, B or C)			
Herpes virus			
High blood pressure			
Hypertension			
Insomnia			
Kidney disease			
Mononucleosis (mono)			
Mood or anxiety disorder			

Night-eating syndrome			
Non-alcoholic fatty liver disease			
Osteoarthritis			
Peripheral vascular disease			
Polycystic ovarian syndrome (PCOS)			
Post-traumatic stress			
Respiratory disorders			
Shingles			
Sleep apnoea			
Steatohepatitis			
Thyroid disease			
Thyroiditis			
Type 1 diabetes			
Type 2 diabetes			

Practitioners and clients were asked to rate their satisfaction with the list of conditions proposed for inclusion. All who answered were satisfied except one practitioner who stated there are:

"too many conditions and many clients would not know what they all mean. Could they be reduced to a smaller list of higher level conditions, using names that clients would understand?" (C)

Another stated:

"terminology quite medical" (C)

Numerous changes were made based on feedback, for example: insomnia was swapped to disturbed sleep, thyroiditis was deleted and thyroid disease was changed to thyroid disease or condition, to support use client-focused language.

In Round 2, all clinicians were satisfied or moderately satisfied these questions would support clinical decision making. All academics who responded were satisfied or moderately satisfied these questions would support meaningful statistical analysis.

5.4.3 Medication

A medication category was added after Round 1. The questions aim to identify if the medication has side effects which may be contributing to obesity and to enable checking of drug nutrient interactions. Three approaches to collecting this data were elucidated from practitioner questionnaires. Participants were asked to rate their preferred choice.

Approach 1:

4. Are you taking any medications, non-prescription drugs or herbal supplements of any kind? If yes, please list.
❑ YES ❑ NO ❑ NOT SURE/MAYBE

Approach 2:

MEDICATIONS and SUPPLEMENTS. *Please use a separate sheet if necessary.*

Please list below any prescribed drugs – current or in the past

Medication	Dose	Condition being treated	Frequency	Duration	current	past
					☐	☐
					☐	☐
					☐	☐

Please list below any Over the Counter Medicines – current or in the past

Medication	Dose	Condition being treated	Frequency	Duration	current	past
					☐	☐
					☐	☐
					☐	☐

Please list below any vitamins, minerals, herbs and other Supplements – current or in the past

Supplement	Dose	Reason for taking	Frequency	Duration	current	past
					☐	☐
					☐	☐
					☐	☐

Approach 3:

1. Please list below all of the medications you took in the PAST WEEK. For each medication you list, please answer each of the questions in the box below.

	IN THE PAST WEEK:					
a. Medication name and strength	b. How many days did you take it?	c. How many times per day did you take it?	d. How many pills did you take each time?	e. How many times did you miss taking a pill?	f. For what reason were you taking it?	g. How well does the medicine work for you? 1 = well 2 = okay 3 = not well

Figure 199 *Proposed approaches to gather data on medication intake*

Each of the approaches was the preferred choice of six different of respondents. Overall, Approach 1 had a marginally higher preference score. Approach 1 had the least number of participants scoring it as their least preferred choice. Approach 3 overall came out with the highest score in terms of satisfaction that the approach assesses current use of medication and Approach 1 had the worst score. Therefore, Approach 3 has been included in new tools and updates based on feedback provided. For example, supplements were included, instructions included examples, and some of the questions were altered.

5.4.4 Smoking history

A smoking history category was added after Round 1. The aim of the questions is to identify if smoking cessation, or history of smoking cessation, is a potential contributing mechanism of obesity and to consider if smoking indicates other mechanisms of obesity such as oxidative stress and addiction. Questions on smoking were based on Jeor (1997 p. 662 and p. 811). During Round 2 all clinicians were satisfied or moderately satisfied these questions would support clinical decision making. All academics who responded were satisfied or moderately satisfied that these questions would support meaningful statistical analysis. Individual feedback helped to improve clarity of the final questions:

"I like the approach, but I think that more formatting and direction will be needed to make sure people answer the questions correctly" (R)

5.4.5 Pregnancy

A pregnancy category was added to identify if pregnancy had been a contributing factor to individual obesity. On the questionnaire, clients are asked to describe their weight, before, during and after pregnancy. All practitioners and academics who responded, except 1 academic, were satisfied with the questions which assess pregnancy as a contributing factor to individual obesity. All clinicians were satisfied or moderately satisfied that these questions would support clinical decision making. All academics who responded were satisfied or moderately satisfied that these questions would support meaningful statistical analysis. All clients were willing or moderately willing to answer these questions, except the male client who did not respond to this question. The tool was updated to clarify these questions were for females only.

5.4.6 Hormone balance

A hormone balance category for females was added. Questions aim to identify if: length of cycle is an indicator of hormone imbalance, and if the menopause, hormone replacement therapy (HRT), contraceptive intake or other female sex hormone imbalances and conditions may be potential contributors to obesity. All clinicians and academics except one academic were satisfied the questions assess length of hormone cycle, menopause and hormone imbalance. Overall, three academics were unsatisfied the questions assess use of HRT and

the contraceptive pill and three were unsatisfied the questions assess if female hormone balance may be a contributor to obesity in an individual. Feedback helped to further develop the clarity of the questions for the final tool:

"should include other forms of contraception" (NT)

5.4.7 Inflammation

An inflammation category was added after Round 1 to identify if it is a potential contributing mechanism to obesity. Results of Round 2 highlighted all clinicians and two academics were satisfied that the questions correlate to the mechanism and aims. However, feedback highlighted the:

"Question [was] not sufficiently sensitive or specific for inflammation" (R)

The literature was reviewed to overcome this issue, but no clear solution was found. No validated tools exist for inflammatory assessment, the original questions had been derived from the WHO QOL assessment (WHO, 1998). Further research on inflammatory conditions led to rosacea and psoriasis also being included as part of this assessment. The language was considered too technical, so adaptations were made based on feedback to simplify the questions and reduce any replication with questions in health history category. Suggestions question for inclusion were added:

"Non-coeliac gluten sensitivity, inflammatory skin conditions" (C)

"iritis, eczema" (C)

An example box was also added for clarity. All clinicians were satisfied or moderately satisfied these questions would support clinical decision making. All academics who responded, except one, were satisfied or moderately satisfied these questions would support meaningful statistical analysis. All clients were willing or moderately willing to answer these questions.

5.4.8 Behaviour and food

This category was added to assess if satiety hormone disruption, such as leptin resistance, may be a potential contributing mechanism to obesity and, if in combination with dietary assessment, food addiction may be a potential contributing mechanism to obesity and the potential need to include the validated food addiction scale. Feedback highlighted:

"This is impossible by the nature of the questions, unless you have biomarkers and/or validation tools in place" (R)

This raises an important point: the aim of the project is to develop and validate news tools. Undertaking laboratory testing and gathering data on biomarkers of clients could be used to corroborate the validity of responses related to mechanisms such as satiety hormones.

5.4.9 Digestive issues

This category was added after Round 1 to identify if dysbiosis is a potential contributing mechanism to obesity. Questions relate to gastrointestinal function. Overall satisfaction the questions correlate to the mechanism and question aim was achieved. An academic suggested:

"Give some likely tick-box options for question 3 and also an 'other' option. This would make analysis easier." (R)

This was implemented. All clinicians were satisfied or moderately satisfied these questions would support clinical decision making. All academics who responded were satisfied or moderately satisfied these questions would support meaningful statistical analysis. All clients were willing or moderately willing to answer these questions.

5.4.10 Blood sugar regulation

The aim of this category was to identify if insulin resistance or hyperglycaemia are potential contributing mechanisms for obesity and to assess potential red flags for diabetes. All academics and clinicians except one were satisfied or moderately satisfied that the questions correlate to the mechanism and aim. Overall satisfaction was achieved in relation to clinical decision making and statistical analysis and all clients were willing or moderately willing to answer these questions. Changes were made based on feedback.

5.4.11 Blood fats

The aim of this category was to identify if dyslipidaemia is a potential contributing mechanism to obesity for the individual patient. All academics and clinicians, except one clinician and one academic were satisfied or moderately satisfied that the questions assess dyslipidaemia as a potential contributing mechanism to obesity. One clinician stated:

"Dyslipidemia is a metabolic consequence of obesity, not the other way round, so [it is] difficult to see how it would be a potential mechanism to obesity" (C)

Although this is a valid point, questions which help to identify dyslipidaemia may help to guide clinical decision making. This section was included in Round 3, which asked participants to eliminate sections in order to reduce the overall size of the tool. The results highlight this section should continue to be included.

5.4.12 Psychology

Clinicians highlighted that self-perceived stress (five participants), addiction (four participants), motivation (four participants), eating disorders (five participants), depression (five participants) should be data gathered by new tools. Feedback highlights:

"There are several validated questionnaires available to choose from but [a] free text option also needed if [the] client wants to expand on anything" (C)

Stress assessment for obesity management is important (Cohen, Janicki-Deverts and Miller, 2007; Torres and Nowson, 2007; Ozier et al., 2008; Greenfield and Marks, 2009) and the perceived stress scale is a validated tool (Cohen, Kamarck, & Mermelstein, 1983) that has been used to assess the relationship between stress and obesity (Stewart-Knox et al., 2012). Several versions of the perceived stress scale have been validated. The four-item version appears to be the shortest version and therefore easiest to complete, so this was included in new tool construction.

A food addiction scale has been validated (Gearhardt, Corbin and Brownell, 2009; Pursey et al., 2014) and was considered for inclusion, however it is a 25-item questionnaire and this may need to be shortened to be of clinical utility. As well as food addiction, determining other addictions would be important for clinical decision. Feedback highlights:

"The client may be more likely to admit their addictions in a questionnaire; however, if the practitioner has the right skills to get the truth from the client then asking them in the consultation may be more accurate". (C)

"Suggest asking both in the tool pre-consultation and also in the face-to-face. Depending on the person, they may respond more honestly in one situation or the other, so this covers all bases" (R)

"This can be sensitive" (R)

so questions on addiction:

"need to be phrased in a way so the client does not feel judged or ashamed" (C)

Motivation assessment tools were reviewed (Ceccarini et al., 2015). The National Obesity Forum provides a four-item patient motivation and readiness to change tool which was included in new tool development which was included in new tool development.

By Round 2, the aims of psychological assessment had developed to include:

- epigenetic changes as a potential contributing mechanism to obesity;
- psychological factors as a potential contributing mechanism to obesity;
- QOL;
- sleep disturbance as a potential contributing mechanism in obesity;
- self-perceived stress as a potential contributing mechanism to obesity;
- individual motivation and readiness to change;
- the need to undertake further assessment using validated tools e.g. sleep disorder scale, depression scale; and

- the need to refer individuals for psychological support.

Two practitioners and two academics were unsatisfied with questions which assess epigenetic changes as a potential contributing mechanism to obesity. Feedback stated:

"a more in-depth questioning needed to tease out the epigenetic contribution" (C)

This was not possible because the literature does not link epigenetic change to signs and symptoms.

One practitioner and one academic were unsatisfied with questions assessing psychological factors as a potential contributing mechanism to obesity. One academic was unsatisfied with questions assessing QOL and sleep disturbance as a potential contributing mechanism in obesity and self-perceived stress as a potential contributing mechanism to obesity. All who responded were satisfied with questions which assessed individual motivation and readiness to change. One academic was unsatisfied with questions which assess the need to undertake further assessment using existing validated tools e.g. the sleep disorder scale and the depression scale, and two academics were unsatisfied with the questions which assessed the need to refer individuals for psychological support. The feedback stated:

"Psychological questions are not diagnostic just indicators" (R)

All clinicians who responded were satisfied or moderately satisfied these questions would support clinical decision making. All academics were satisfied or moderately satisfied these questions would support meaningful statistical analysis. All clients were willing or moderately willing to answer these questions. This section was developed as a result of feedback and presented for elimination or inclusion in the final tools at Round 3 of the Delphi survey which resulted in this section being included in the final questionnaire.

5.4.13 Physical activity

As with diet and nutrition intake, there are numerous validated physical activity assessments, questionnaires and online applications that nutrition practitioners had already engaged with. Physical activity data-collection methods therefore do not require new tool development. Changes to physical activity levels should be tracked before, during and after intervention, so that change can be measured against health and weight outcomes, this was therefore included in tools 2 and 4.

5.4.14 Body composition

Although the limitations of BMI have been thoroughly explored in the literature (Kok, Seidell and Meinders, 2004; Daniels, 2009; Shah and Braverman, 2012), it is the most frequently used assessment of body size and it provides nationally recognised parameters of overweight and obesity (Lindsay et al., 2014). Assessments will need to ask clients for their

weight and height in order to calculate BMI. Six clinicians stated it should be measured by the practitioner using scales in the consultation setting. Researchers felt this measure was important to ensure an accurate baseline. However, clinicians feedback highlighted that this was a sensitive subject and should be a patient dependant decision:

"Excess body weight is a sensitive subject, this information should be collected face-to-face" (C)

"Many clients do not want to weigh themselves so asking them to do so could be upsetting for them" (C)

"Some clients estimate their weight" (C)

Checking accuracy during the consultation is therefore important:

"The initial consultation could be used to teach them best practice so future 'weigh ins' could be recorded in the tool" (R)

Clinician feedback stated waist circumference was:

"needed only in rare cases and can be measured at the consultation" and "is easy to give the answer but someone would wonder about the accuracy and consistency in methodology" (C)

This was therefore excluded in new tool development. Proposed questions for gathering data on individual weight history across lifespans where there have been weight changes, were presented in Delphi Round 2. The questions were developed based on a weight history questionnaire from the University of Iowa. Early onset obesity as a contributing mechanism for obesity (Lillycrop and Burdge, 2011; Martínez, 2012; Rhee, Phelan and McCaffery, 2012). Feedback highlighted retrospective weight assessment over a lifetime *"will be incredibly difficult for people to recall"* (C).

Two academics and one practitioner were unsatisfied that the questions meet their aim. The reasons given are:

"You are putting a lot of reliance on participants' memor[ies]" (R)

However, all clinicians were satisfied or moderately satisfied these questions would support clinical decision making and all academics who responded were satisfied or moderately satisfied these questions would support meaningful statistical analysis. This assessment was therefore included but adjusted to enhance clarity based on the feedback provided.

5.4.15 Family history

Ten clinicians considered health history and family history should be gathered by the questionnaire/tool before the consultation. Multiple-choice was the preferred data-collection method, however research feedback highlighted:

“There might be an argument for using free text while developing such a tool, as that might help determine what terms are commonly used. But ultimately a categorical assessment will be much easier to analyse” (R)

Seven clinicians considered family history should be recorded via a pedigree chart before the consultation, however a pedigree chart is not a specific assessment but an approach to collating FHH data.

No validated family history tools were identified, but practitioner questionnaires did include a range of approaches to gathering this data. Validated tools such as the Stanford health assessment (Pecoraro et al., 1979; Bruce and Fries, 2003) do exist and their content and approaches were reviewed for new tool development. Three approaches to collecting this data were taken from clinical tools and suggested for inclusion in Delphi Round 2. Participants were asked to rate their preferred choice:

Approach 1:

FAMILY HISTORY – (Please X all appropriate boxes)

	Severe Obesity	Heavy	Normal Weight	Bariatric Surgery	Diabetes	Heart Problems
Father						
Paternal Grandfather						
Paternal Grandmother						
Father's brothers						
Father's sisters						
Mother						
Maternal Grandfather						
Maternal Grandmother						
Mother's brothers						
Mother's sisters						
Your brothers						
Your sisters						
Your sons						
Your daughters						

Approach 2: Is there any history of obesity, disease or health problems in your family?

	tick for yes	Comments
Grandfathers	☐	.....
Grandmothers	☐	.....
Father	☐	.....
Mother	☐	.....
Brothers	☐	.....
Sisters	☐	.....
Sons	☐	.....
Daughters	☐	.....

Approach 3:

Family History

Overweight Family Members _____
Family History of Heart Disease _____
Family History of Diabetes/Endocrine Disease _____
Family History of High Blood Pressure _____
Family History of Cancer _____
Family History of Arthritis _____
Family History of Early Death _____
Family History of Asthma _____
Family History of Stroke _____
Family History of Depression _____
Other Family Disease History _____

Figure 20*Proposed approaches to gather data on family health history*

Approach 1 was the most preferred choice by twelve respondents. Two academics stated that this approach was *"easier for optical mark recognition and hence analysis"* (R).

Feedback also highlighted:

"perhaps numbers would be more useful than X's as there may be more than one sister/brother/daughter with the same diseases" (R)

"It's not clear if the lack of an X means that the family member definitely didn't have the condition or if the participant doesn't know. Perhaps instruct participants to put a Y in the box if the family member had the condition, N if they didn't, and leave it blank if they don't know" (R)

These suggestions were incorporated into the final tool. Feedback also highlighted that:

"other weight categories need to be added (underweight and anorexia in particular) and disease will be added, and the examples are just for instruction" (R)

An underweight column was added, although anorexia is quite specific, so an additional column of "Other health condition: Please insert name or description" was included instead.

Three practitioners and two academics were satisfied that Approach 1 assessed family history of obesity and disease. Two clinicians were somewhat dissatisfied these questions would support clinical decision making while one academic was somewhat dissatisfied these questions would support meaningful statistical analysis. Although clients were willing to provide this information, it relies on recall and is about family members, so their perception is likely inaccurate. One respondent stated:

"people need simple questions" (C)

Further analysis is required to determine the validity of this assessment.

5.4.16 Sociocultural

Sociocultural factors aim to assess baseline gender, date of birth, marital status and occupation data, as well as potential sociocultural factors contributing to obesity in individual patients, including socioeconomic status, ethnicity, changes in marital status, changes in occupation and history of food insecurity. Feedback from an academic suggested using census questions on marital status. Question were therefore updated to replicate the census. Proposed questions for each of these were presented in Delphi Round 2.

One academic was unsatisfied that the questions measured a range of sociocultural mechanisms which may have contributed to obesity or weight gain in individual clients. Feedback from the research perspective highlights:

"I'd be surprised if the questions you ask are the only relevant sociocultural mechanisms that could contribute to weight gain" (R)

"exclude some life event factors – e.g. moved house and childbirth" (R)

Childbirth is assessed later in the questionnaire. Moving house was not included to keep the questionnaire brief, although it could be relevant as a major life event and should therefore be explored in the consultation.

All but one practitioner was satisfied or moderately satisfied these questions would support clinical decision making. All academics who responded were satisfied or moderately satisfied these questions would support meaningful statistical analysis. All clients were willing or moderately willing to answer these questions.

Practitioners suggested the following questions should be included:

- **household income**
- mobility / disability
- distance to shops
- migrant status
- how many people in household
- **highest level of education**
- amount (of money) available to spend on food
- location
- social class
- social isolation
- job seniority

Household income and highest level of education were suggested by more than two respondents and are therefore to be included in new tool development. The 'highest level of education question' was taken from the UK census. The other questions were not included in an effort to keep the questionnaire short and easy.

5.4.17 Goals and outcomes

The interventions record (Tool 2) and the achievement record (Tool 4) were introduced to the Delphi group in Round 3. These tools were created based on a review of stage three Round 1 Delphi results and a review of applications such as *myfitnesspal* and *MBODY360*. Dietary approaches were developed from Wills' (2008) book *The Diet Bible*, and my own ideas. Exercise approaches were developed from *myfitnesspal* application. The laboratory assessments section was developed from a review of various laboratory websites.

In Round 3, practitioners were asked to rate their overall satisfaction with the wording/phrasing of each of the questions in the interventions record (Tool 2) and the achievement record (Tool 4). Academics were asked to "rate their satisfaction that the wording/phrasing of each of the questions limits potential bias and statistical analysis" and clients were asked to "rate their satisfaction that the wording/phrasing of each of the questions is clear and enables you to give a suitable answer" and whether questions are "appropriate and free of emotional charge". Most respondents were either satisfied or

somewhat satisfied with the wording/phrasing of each of the questions. Changes were made as a result of feedback. For example, one practitioner commented:

"I would like an option to put quantities into the Q2 table i.e. increase by x amount."

It is agreed that the quantification of responses would enhance the tool and analysis, so quantities were included.

In Round 3 clients, practitioners and academics were asked about which of the Tool 1 health questionnaire questions should be repeated at follow-up consultations to assess changes to the client's health and weight after nutrition intervention. This method was used to create Tool 4, the follow-up questionnaire. There were a number of questions that did not need to be repeated (e.g. sex) and that was apparent from the outset. It has been worthwhile to get consensus on which questions should not be repeated on the follow-up questionnaire. A recurring comment was that questions can be asked at the consultation and although this is true, free text in a consultation setting is difficult data to analyse and measure. The benefit of keeping the questions on an initial and follow-up tool is that they are all asked in the same way. If a client does not wholly complete the questionnaire tool then the questions should be asked in the consultation setting in order to close any data gaps.

Based on the feedback in Round 3 on Tool 1, the health questionnaire, changes were implemented to reduce the overall size or length of the tool. Most respondents indicated all questions should be kept. Some sections were combined to reduce overall size and increase simplicity. At the end of Round 3 participants were asked if they had any other comments or suggestions, practitioners responded:

"looks like it will be a very useful tool - still concerned about how long it will take to complete though" (C)

"I feel almost all of the questions are relevant if you want to obtain a true picture of the client, their current health situation, thoughts, feelings, contributory factors etc. As long as this is explained to the client and they understand that this is the best way to help them then I don't think they would have a problem filling it in" (C)

"I think some of this depends on the term your client has been with you for example woman's bodies change fast and you could have a woman who start with you in January of 2016 who is still menstruating however, it could have all changed by June therefore it's probably a good idea to repeat some of the questions from time to time but not weekly or monthly. You could also have someone in full time employment when they start and they could be made redundant while they are with you" (C)

In response to the above comments it is good feedback that a practitioner felt the tool will be very useful. It is agreed that a practitioner can explain the value of these tools to the client

and that should increase the comprehensiveness of data the client provides in the tools. The follow-up tool should be completed regularly so that the practitioner can assess any changes before meeting the client at the consultation.

5.4.18 Discussion of Delphi survey

This Delphi survey approach did succeed in the development of new tools which aim to enable individual health history data collection and clinical outcome analysis in nutrition practice which may support clinical decision making for the management of obesity. They include statistically analysable baseline and follow-up measures. The health questionnaires should enable clients to effectively communicate their health issues and support practitioner clinical decision making by enabling pathophysiological reasoning because questions relate to, and are clustered in, pathophysiological mechanisms of obesity. The tracking of recommended interventions and client compliance/achievement should enable practitioners to analyse the impact of interventions in relation to the client's weight and health outcomes as a result of compliance behaviour. These will be assessed in the pilot trial.

New tools allowing frequent measuring of outcomes measures at regular intervals and gather data which allow for the assessment of confounding factors when data mining. New tools do not make any question or measure compulsory, as highlighted with psychological assessment, the willingness of clients to provide this data, or the ability of clients to provide data, may vary from client to client. This may prove problematic however as it is not possible to analyse the impact of this until sufficient data has been gathered to undertake statistical analysis.

What had not been anticipated during tool development was that the tools would themselves determine the consultation process, for example that tools 1 and 3 should be completed by the client before the consultation and tools 2 and 4 should be completed by the practitioner after the consultation. It may be that my own clinical approach biased tool development towards this process. However, it appeared to emerge from developing the tools. It would have helped to gain consensus on the tools being used in this way, or gain opinion on how the tools could more flexibly fit with a range of practitioner approaches clinical practice and data collection.

The Delphi survey method did not succeed in reducing the size or complexity of these tools. This may be a consequence of individual practice approaches where practitioners have varied views on what data should be gathered to inform clinical decision making, hence adding more questions, rather than reducing them. However, it was anticipated that the pilot trial feedback may lead to further adaptations based on feedback which would help to simplify the tools.

5.5 Findings from pilot trial

The pilot trial with practitioners in clinical practice aimed to achieve face validity and measure feasibility and utility for each of the four tools. Fifty-one practitioners responded to the invitation willing to participate, however only 3 practitioners engaged with the full pilot trial process.

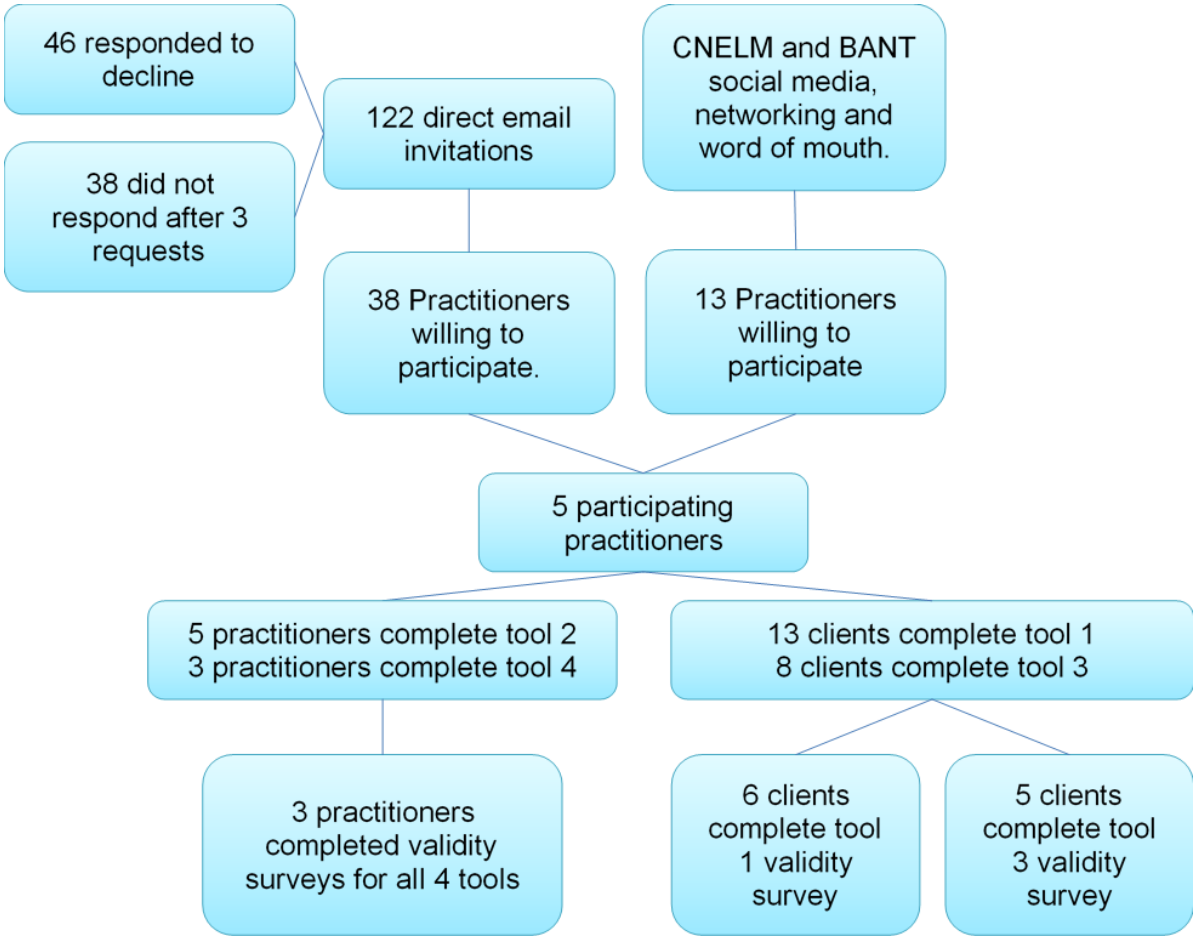

Figure 21*Pilot trial participant recruitment and number of completed new tools during the pilot trial process*

Lack of engagement with the pilot trial is analysed and discussed in Chapter 6. This chapter is focused on new tool construction and this section therefore reports on the results and feedback from participants who did engage with the pilot trial.

Table 8 *Number of completed pilot trial tools and validity surveys*

Tool/Survey	**Number completed**
Tool 1 – health questionnaire	13 client records
Tool 1 – validity survey for clients	6 client records

Tool 1 – validity survey for practitioners	3 practitioner records
Tool 2 – intervention record	10 records completed by 5 practitioners
Tool 2 – validity survey for practitioners	3 practitioner records
Tool 3 – follow-up questionnaire	8 client records
Tool 3 – validity survey for clients	4 client records
Tool 3 – validity survey for practitioners	3 practitioner records
Tool 4 – achievement record	6 records completed by 3 practitioners
Tool 4 – validity survey for practitioners	3 practitioner records

The following analysis focuses on validity survey responses rather than data gathered by new tools. It was not necessary at this point to analyse the individual health history and interventions recommended, or other data reported in new tools, because that does not meet with the purpose of this project. It would have been useful to undertake an analysis of which questions were completed by participants, but due to the low response numbers it was also not possible to conduct any statistical analysis on questionnaire responses. Due to the low number of respondents it was also not possible to assess face validity or measure feasibility or utility for any of the tools. Rather, an analysis of practitioner and client feedback on the use of the tools was undertaken to determine further changes that could enhance the development new tools.

5.5.1 Tools 1 and 3 – health questionnaires

Tool 1, the personalised health questionnaire, aims to collect health history and family history data around mechanisms of obesity, as well as a range of baseline health measurements. Tool 3, the follow-up questionnaire, aims to measure any changes to the client's health measurements after intervention. This questionnaire is a repeat of the majority of questions from Tool 1, in the same format. Therefore, this analysis reviews the feedback on both of these tools simultaneously. Tabled results of the validity surveys can be seen below (tables 9 and 10).

All practitioners and clients felt the new tools allowed clients to effectively communicate their health issues. All practitioners felt the language was appropriately client-centred. One client

disagreed that Tool 1 was easy to complete but all clients agreed Tool 3 was easy to complete. Only two clients enjoyed filling in the health questionnaires, three did not agree or disagree, and one did not enjoy filling in the first health questionnaire. Client feedback stated:

"As the English is not my mother language it was a little bit more difficult to understand it"; "I found some of the instructions difficult to follow and could be simplified" (C/P)

"The section on medication is difficult to complete as you have to keep scrolling back up to see the headings and then back down to the condition. otherwise I thought it was ok." (C/P)

The issue with scrolling was due the Qualtrics software functionality. Feedback from one practitioner stated:

"The layout was visually confusing and too restrictive" (C)

All practitioners felt tools 1 and 3 were easy to interpret, with two out of three stating "strongly agree". This may be due to the arrangement of questions in categories of pathophysiological mechanisms. All respondents felt the questionnaire was relevant to the health issues of the client, and that it included all aspects of health issues that concerned them, except one for the follow-up questionnaire who did not agree or disagree. Client feedback highlighted:

"remembering history of ailments of grandparents quite difficult" (C/P)

Table 9 *Results of validity assessments on Tool 1 – The health questionnaire*

PRACTITIONER RESPONSES TO VALIDITY ASSESSMENT ON TOOL 1										
The questionnaire allowed my clients to effectively communicate their health issues	The questionnaire was easy to interpret	The questionnaire was relevant to the health issues of my clients	The questionnaire included all the aspects of my client's health issues that I am concerned about	This questionnaire is an improvement on the questionnaires I have previously used in practice	I would be happy to use this questionnaire in my routine clinical practice	The questionnaire improved my clinical decision making	The questionnaire could be shortened	There were aspects of the questionnaire which were inappropriate	The questionnaire could be simplified	The language of the questionnaire was appropriately patient-centred
Mostly agree	Mostly agree	Mostly agree	Mostly disagree	Strongly disagree	Strongly disagree	Mostly disagree	Mostly disagree	Neither agree or disagree	Mostly disagree	Mostly agree
Strongly agree	Strongly agree	Strongly agree	Strongly agree	Strongly agree	Mostly agree	Mostly agree	Strongly agree	Strongly disagree	Mostly agree	Strongly agree
Strongly agree	Strongly agree	Strongly agree	Mostly agree	Mostly agree	Mostly agree	Mostly disagree	Mostly disagree	Mostly agree	Mostly disagree	Strongly agree

CLIENT RESPONSES TO VALIDITY ASSESSMENT ON TOOL 1										
The questionnaire helped me to communicate about my health issues	The questionnaire was easy to complete	The questionnaire was relevant to my health issues	The questionnaire included all the aspects of my health issues that I am concerned about	I enjoyed filling in the questionnaire	I would be happy to complete the questionnaire again in the future as part of my routine care	The questionnaire was too long	The questionnaire was too embarrassing	The questionnaire was too complicated	The questionnaire upset me	
Mostly agree	Mostly agree	Mostly agree	Mostly agree	Neither agree or disagree	Mostly agree	Mostly disagree	Strongly disagree	Strongly disagree	Strongly disagree	
Mostly agree	Mostly agree	Mostly agree	Mostly agree	Neither agree or disagree	Mostly agree	Mostly agree	Strongly disagree	Neither agree or disagree	Strongly disagree	
Mostly agree	Mostly disagree	Mostly agree	Mostly agree	Mostly disagree	Neither agree or disagree	Mostly agree	Mostly disagree	Mostly agree	Mostly disagree	
Mostly agree	Mostly agree	Mostly agree	Mostly agree	Strongly agree	Strongly agree	Mostly agree	Strongly disagree	Neither agree or disagree	Strongly disagree	
Mostly agree	Mostly agree	Strongly agree	Strongly agree	Mostly agree	Mostly agree	Mostly agree	Strongly disagree	Strongly disagree	Strongly disagree	
Mostly agree	Mostly agree	Mostly agree	Mostly agree	Neither agree or disagree	Strongly agree	Neither agree or disagree	Mostly disagree	Mostly disagree	Strongly disagree	

Table 10 *Results of validity assessments on Tool 3 – The follow-up questionnaire*

PRACTITIONER RESPONSES TO VALIDITY ASSSESSMENT ON TOOL 3									
The questionnaire allowed my clients to effectively communicate their health issues	The questionnaire was easy to interpret	The questionnaire was relevant to the health issues of my clients	The questionnaire included all the aspects of my client's health issues that I am concerned about	This questionnaire is an improvement on the questionnaires I have previously used in practice	I would be happy to use this questionnaire in my routine clinical practice	The questionnaire improved my clinical decision making	The questionnaire could be shortened	There were aspects of the questionnaire which were inappropriate	The questionnaire could be simplified	The language of the questionnaire was appropriately patient-centred
Mostly agree	Mostly agree	Neither agree or disagree	Neither agree or disagree	Mostly disagree	Mostly disagree	Mostly disagree	Mostly disagree	Strongly disagree	Mostly disagree	Mostly agree
Strongly agree	Strongly agree	Strongly agree	Strongly agree	Mostly agree	Mostly agree	Mostly agree	Strongly agree	Strongly disagree	Mostly disagree	Strongly agree
Mostly agree	Strongly agree	Mostly agree	Mostly agree	Neither agree or disagree	Mostly disagree	Neither agree or disagree	Strongly agree	Mostly agree	Mostly agree	Strongly agree

CLIENT RESPONSES TO VALIDITY ASSESSMENT ON TOOL 3									
The questionnaire helped me to communicate about my health issues	The questionnaire was easy to complete	The questionnaire was relevant to my health issues	The questionnaire included all the aspects of my health issues that I am concerned about	I enjoyed filling in the questionnaire	I would be happy to complete the questionnaire again in the future as part of my routine care	The questionnaire was too long	The questionnaire was too embarrassing	The questionnaire was too complicated	The questionnaire upset me
Mostly agree	Mostly agree	Mostly agree	Mostly agree	Neither agree or disagree	Mostly disagree	Mostly disagree	Strongly disagree	Neither agree or disagree	Strongly disagree
Mostly agree	Strongly agree	Strongly agree	Strongly agree	Mostly agree	Strongly agree	Neither agree or disagree	Strongly disagree	Neither agree or disagree	Strongly disagree
Neither agree or disagree	Mostly agree	Mostly agree	Mostly agree	Neither agree or disagree	Neither agree or disagree	Strongly agree	Neither agree or disagree	Strongly disagree	Strongly disagree
Mostly agree	Strongly agree	Strongly agree	Mostly agree	Mostly agree	Mostly agree	Mostly disagree	Strongly disagree	Strongly disagree	Strongly disagree
	Mostly agree	Mostly agree	Strongly agree	Neither agree or disagree	Mostly agree	Neither agree or disagree	Strongly disagree	Strongly disagree	Strongly disagree

One practitioner felt tools 1 and 3 were not an improvement on the questionnaires they had previously used in their own practice. Two agreed that Tool 1 was an improvement although one did not agree or disagree that Tool 3 was an improvement. One practitioner stated:

"I would like to see a question such as: What is the main reason you are seeking nutritional support? And, what is most important for you to achieve from your consultation? I would also like to see more questions relating to social network to get an understanding about loneliness, friendships, available support etc. I think the question on "How often do you experience negative feelings" should have been left entirely open and not exemplified with...'such as depression, despair and anxiety' which may lose some clients, who are none of those, but feel negative in their thinking" (C)

This is useful feedback which should be implemented to enhance the questionnaire. Another practitioner stated:

"I did not see any questions on exercise? Or sexual health? Or diet?" (C)

The exclusion of dietary and exercise analysis was explained to participants in the pilot trial introduction video. No sexual health category was included because this was not identified as a contributing factor to individual obesity development. There were specific questions on the herpes virus in the health history section, birth control in the hormone section, as well as pelvic inflammatory disease and the prostate gland in the inflammation section.

Four out of six clients felt the first health questionnaire was too long, two out of three practitioners felt it could be shortened. Only one client agreed Tool 3 was too long and two out of three practitioners felt the follow-up could be shortened. Practitioner feedback stated:

"There were too many questions at the beginning on ethnicity, marital status and education and income brackets. It could feel rather intruding and such questions may be better left to the end once the person has settled into answering questions about themselves. I personally would never ask about income brackets. I do understand that for research purposes such questions are very relevant." (C)

All clients agreed they would be happy to complete the questionnaires again as part of their routine care, except one who neither agreed or disagreed. Two practitioners were also happy to use Tool 1 in their routine clinical practice, but one strongly disagreed. By the return questionnaire only one practitioner was happy to use it in their practice. Not one client found the questionnaires embarrassing but one practitioner stated there were aspects which were inappropriate. One practitioner also stated:

"I would never make decisions based on a questionnaire and I aim to use a questionnaire only to guide my questions in the consultation where appropriate. In my view a questionnaire runs the risk of preconceived ideas prior to meeting the client, which may drive the questions

and consultation in an unfavourable way for the client. It can however be an aid in exploring certain areas and as a tool for monitoring progress if partially repeated at a later stage in the process." (C)

New tools are not meant to replace the consultation process but are used as a tool for tracking progress robustly.

5.5.2 Tools 2 and 4 – intervention tracking

Tool 2, the intervention record, aimed to capture which interventions were recommended by the nutrition practitioner. Tool 4, the achievement record, aimed to capture which interventions the client/patient complied with. Tool 4 is almost a replicate of Tool 2 and therefore this analysis reviews the feedback on these tools simultaneously. The practitioner completes these tools, therefore only practitioners were invited to complete the validity surveys and provide feedback on this tool. The results of the validity surveys can be seen in tables 11 and 12 below.

Two practitioners agreed, and one did not agree or disagree, that Tool 2 enabled them to capture all the recommended interventions and that it was easy to complete. Two practitioners agreed, and one disagreed that Tool 4 enabled them to capture whether their clients complied with the recommendations and the extent to which their clients complied with the recommendations.

One agreed, one disagreed, and one neither agreed or disagreed that Tool 2 could be shortened and simplified. The same responses were received for Tool 4 being shortened but two also agreed it could be simplified. Two disagreed and one agreed the intervention tool was an improvement on their previous approach to recording prescribed interventions, while one agreed, one disagreed and one did not agree or disagree, that Tool 4 was an improvement on their previous approach. Feedback stated:

"This tool did not quite capture my interventions of cPNI as the psychological and social and coaching aspect was missing in the reporting, use of questionnaires for say ACEs (adverse childhood events) and some other interventions I often use – intermittent living, so the tool could be developed." (C)

The achievement tool could be updated with a 'reasons' free text box as feedback highlighted:

"My client suffered emotional trauma between the two consultations and there was nowhere to record why she was non-compliant." (C)

Feedback also stated:

“It was too time-consuming to complete the supplements with names and brands etc. It would have been great to simply leave space to paste say the supplement prescription that the client has received.” (C)

Another aspect of feedback was:

“psychological and social steps taken - I do a lot of coaching and the tool lacks ways of monitoring steps taken to implement ideas from the coaching and progress/perceived progress.” (C)

Only one practitioner would be happy to use these tools in their clinical practice, feedback stated they are:

“not user friendly and quite restrictive.” (C)

Only one agreed the intervention tool improved their clinical decision making, however two felt the achievement tool improved their clinical decision making. Only one agreed (one disagreed and one neither agreed or disagreed) that these tools are useful in clinical practice.

Table 11 *Results of validity assessments on Tool 2 – The intervention record*

PRACTITIONER RESPONSES TO VALIDITY ASSSESSMENT ON TOOL 2								
The Interventions Record tool enabled me to capture all the recommended interventions	The Interventions Record tool was easy to complete	The Interventions Record tool was easy to interpret	The Interventions Record tool is useful in my clinical practice	This Interventions Record tool is an improvement on my previous approach to recording prescribed interventions	I would be happy to use the Interventions Record tool in my routine clinical practice	In conjunction with the questionnaire, the Interventions Record tool improves my clinical decision making	The Interventions Record tool could be shortened	There were aspects of the Interventions Record tool which were inappropriate	The Interventions Record tool could be simplified
Neither agree or disagree	Neither agree or disagree	Mostly disagree	Mostly disagree	Mostly disagree	Mostly disagree	Mostly disagree	Strongly disagree	Neither agree or disagree	Mostly disagree
Strongly agree	Strongly agree	Strongly agree	Mostly agree	Mostly agree	Mostly agree	Mostly agree	Strongly agree	Strongly disagree	Mostly agree
Mostly agree	Mostly agree	Strongly agree	Neither agree or disagree	Mostly disagree	Mostly disagree	Mostly disagree	Neither agree or disagree	Mostly disagree	Neither agree or disagree

Table 12 *Results of validity assessments on Tool 4 – The achievement record*

PRACTITIONER RESPONSES TO VALIDITY ASSESSMENT ON TOOL 4											
The Achievement Record tool enabled me to capture whether my client complied with the recommended interventions	The Achievement Record tool enabled me to capture the extent to which my client complied with the recommended interventions	The Achievement Record tool was easy to complete	The Achievement Record tool was easy to interpret	The Achievement Record tool is useful in my clinical practice	The Achievement Record tool is an improvement on my previous approach to recording client compliance	I would be happy to use the Achievement Record tool in my routine clinical practice	In conjunction with the follow-up questionnaire, the Achievement Record tool improves my clinical decision making	In conjunction with the other questionnaires /tools used in this pilot trial, I am able to analyse the impact of intervention compliance on my client's health and weight	The Achievement Record tool could be shortened	There were aspects of the Achievement Record tool which were inappropriate	The Achievement Record tool could be simplified
Mostly disagree	Mostly disagree	Mostly agree	Mostly agree	Mostly disagree	Strongly disagree	Strongly disagree	Mostly disagree	Neither agree or disagree	Mostly disagree	Mostly disagree	Mostly disagree
Strongly agree	Mostly agree	Strongly agree	Strongly agree	Mostly agree	Mostly agree	Mostly agree	Mostly agree	Mostly agree	Strongly agree	Strongly disagree	Mostly agree
Mostly agree	Mostly agree	Mostly agree	Strongly agree	Neither agree or disagree	Neither agree or disagree	Neither agree or disagree	Mostly agree	Mostly agree	Neither agree or disagree	Neither agree or disagree	Mostly agree

5.5.3 Discussion of pilot trial

There is insufficient data provided by the pilot trial to undertake meaningful or statistical analysis. However, the feedback further corroborated some of the earlier findings, such as the value of undertaking population and cross-cultural validity assessments for new tools and not making questions compulsory. The restriction of the online software also highlights the need to develop a tailored online assessment which can provide the appropriate functionality, which can also positively impact on increasing the simplicity of assessment and therefore save time.

Data on patient income sources was not meant to support clinical decision making, but rather allow for an analysis of confounding factors when data mining. The clarity of the purpose of each question needs to be made clear so practitioners can differentiate between the research and clinical perspectives of the tools.

Data on the clinical utility of these tools was lacking. There were still further suggestions being made on what else the tools needed to be included by various practitioners, which would further grow the tools, rather than simplify them. It may better to break the tools down into smaller tools so that they are less time-consuming to complete. Questions which gather more intrusive data can then be gathered later during the consultation process, on a separate tool or in person, once the practitioner and client have built up rapport and trust. For example, there could be one tool for health history assessment, another for family history assessment, another for tracking progress. Having numerous, small, quick to complete validated tools may give practitioners an opportunity to pick and choose when clients complete tools, this could also be client-led and may enable a more personalised data collection approach using numerous standardised tools.

Feedback on the need to include coaching measures not only raises a valid point for adding therapeutic interventions to these tools but also supports the idea that the outcomes of nutritional interventions are not just due to dietary, supplement and exercise interventions (Karasu, 2012; Miles and Barrow, 2018). New tools lack appropriate therapeutic relationship measures which should have been evaluated for inclusion. There is, without doubt, the practitioner element and therapeutic intervention. This raises some important questions:

1. How can the benefits of nutrition intervention be teased out from the practitioner's therapeutic intervention?
2. Can we measure the therapeutic alliance in nutrition practice?
3. Is nutritional therapy more about the therapy than the nutrition?

These are further addressed in the chapters 6 and 8.

5.6 Overall discussion of findings

This project aimed to evaluate the ethics of standardising data-collection methods in personalised nutrition practice, and although patient autonomy, inclusivity, data management and data mining consent concerns were raised there was overall support for standardising data-collection methods as long as that does not impact on the practitioner being able to make personalised intervention decisions and recommendations. Standardised data-collection methods do not need to limit the scope of personalised nutrition practice but could support clinical decision making, as well as enabling practitioners to pool data and develop a case-by-case evidence base that allows for analysis and comparison on the efficacy of interventions that further supports clinical decision making.

The online search for tools identified numerous validated tools for assessing dietary intake, physical activity levels, body composition, QOL and psychological factors in obesity. Many of these tools were developed for research rather than clinical purposes and the survey of nutrition practitioners highlighted that only a few practitioners use validated tools. Although some of these tools may lack clinical utility, others are well established and useful and could be utilised by all nutrition practitioners to standardise data-collection methods.

There is a gap in tools which gather data on individual health history, family history, sociocultural influences on obesity as well as goals and outcomes. The survey of nutrition practitioners and the interviews highlighted that the majority of practitioners are developing and using their own questionnaires to gather this data. In a review paper, Snyder et al. (2012) compare the advantages and disadvantages of methods for gathering data, including paper questionnaires, interviews and via computer technology. Snyder et al. (2012) highlight the advantages of interviews and the potential requirement to train clients on how to use both paper questionnaires and internet applications. The consultation interview should not be replaced by internet applications but rather be used in conjunction with them to enhance efficient data collection (Snyder et al., 2012).

Another finding is that none of the current outcome assessments used in practice, including the validated MYMOP tool, appear to robustly consider or enable those outcomes to be measured against the client's compliance to implementing dietary and nutritional interventions. Findings of the survey results highlight measurements on health outcomes that can be tied to measures for exercise, sedentary behaviour, diet intake and psychological mood. The new tools created for this project specifically aim to enable the analysis of intervention compliance on the client's health and weight outcomes.

Practitioners are currently using their own tools for clinical practice and there is currently no standardised clinical approach to data collection. The results of the survey also demonstrate

that, through the use of their own tools, there is a large variation in data gathered by practitioners – on sleep for example. Nutrition practitioners are currently undertaking clinical reasoning and making intervention decisions based on varied data sets. It could therefore be assumed that, even when using clinical guidelines to make recommendations, if one patient saw two nutrition practitioners independently, the interventions given to that patient from each practitioner could vary because the intervention decisions have been made on different data sets from the same individual.

Current tools do not appear to enable the identification of contributing pathophysiological mechanisms of obesity. Clustering questions in groups of pathophysiological mechanisms associated with obesity may enable mechanistic reasoning. This new approach is not without its limitations (Pizzorno and Jr, 2012), but practitioner feedback on new tools does suggest this approach could help to improve clinical decision making.

Practitioners value tools which are easy to use and that help them to identify factors that contribute to the client's obesity. A number of other developmental considerations were identified from the survey and interviews, and the Delphi method allowed for collaborative development of four new clinical tools for health data collection and clinical outcome analysis, which aim to support clinical decision making and can be used to standardise case data-collection methods in personalised nutrition practice.

The pilot trial of the four new collaboratively developed clinical tools gained interest from practitioners but was unsuccessful in engaging and retaining them. The reasons for the lack of engagement and retention are explored in the next chapter. The feedback from practitioners and clients that did engage in the pilot trial process highlight the need to re-evaluate the construction of the tools and further consider the impact of the therapeutic relationship on the outcomes of nutritional practice. There was a conflict of feedback across the research methods, between keeping tools streamlined, easy and user-friendly as well as comprehensive, thorough and robust.

5.7 Chapter summary

This chapter has explored the results for each of the research methods undertaken to construct new clinical tools for health data collection and clinical outcome analysis. The findings were summarised in the overall discussion. The conclusions and recommendations that arise from these results are discussed further in Chapter 8.

Chapter 6: Integrating Standardised Data-Collection Methods Findings

This chapter presents the analysis of research findings for each of the research methods undertaken to evaluate the limitations and opportunities for integrating standardised data-collection methods in personalised nutrition practice. The approach for undertaking the pilot trial, survey and interviews were described in Chapters 3 and 4. The overall discussion of findings assimilates and summarises the results, and aims to interpret the findings within the context of existing literature, the scope of the project and standardising data-collection methods in personalised nutrition practice.

6.1 Findings from pilot trial – lack of engagement

Results from participants who did engage with the pilot trial were reported in the previous chapter. These findings explore the lack of engagement with the pilot trial. Of the 46 practitioners who responded to emails invitations to participate with the pilot trial the following reasons were cited for declining to participate:

Table 13 *Reasons nutrition practitioners gave for declining to participate in the pilot trial*

Reasons for declining to participate:	**Number of practitioners**
No reason stated	15
Not working with obese population	11
Too busy	7
Works with children or adolescents	3
Not seeing clients at this time	2
Would need to apply for ethics approval at their clinic	1
Withdrew after seeing information	1
New practitioner - just starting out	1
Not comfortable asking client to give more info	1
Practitioner does not have enough clients	1
Concern about confidentiality	1

Cannot find suitable clients	1
Has not yet qualified	1

The most frequently cited reason to decline from participation with the pilot trial was that nutrition practitioners were not engaged with an obese population. Of the 11 practitioner that stated they were not working with an obese population, 10 were NT and 1 was a naturopath.

Of the 51 practitioners who responded willing to participate 44 were nutritional therapy practitioners, 6 were dietitians and 1 was a naturopath. This is likely due to the request to engage reaching more NTs than other practitioner groups, like dietitians. Practitioners engaged with BANT and CNELM social media are more likely to be NTs. Direct emailing also targeted more NTs than dietitians or other practitioners.

6.1.1 Discussion of pilot trial – lack of engagement and retention

These results raise at least two important queries:

1. Do obese (BMI>30) individuals seek out nutritional therapy support?
2. Do NTs have the resources to reach or adequately engage with the growing obese population?

A review of the literature was undertaken to address these questions, however there was no data available and research to assess these questions should be undertaken. These questions were therefore raised with a group of CNELM undergraduate students seeking to undertake a research project, who went on to survey NTs (Gordon et al., 2017). These results are reported in Chapter 6.3.

Initial recruitment of 51 practitioners for this pilot trial suggests retention was a bigger issue than recruitment. The biggest barrier from my perspective was asking practitioners to recruit their clients to engage with the tools. Many practitioners may have struggled to explain the purpose of the trial to their clients and therefore disengaged. Engaging directly with the target population to undertake research to validate tools may be one way to overcome this barrier.

It may have also been a concern for practitioners to have the outcomes of their interventions recorded and assessed. These tools not only record the outcomes of interventions but directly report the intervention decisions and outcomes successes of practitioners. This level of reporting may have provided another barrier to engagement, if practitioners have self-doubt about their ability they may not wish to report on the outcomes of the interventions they recommended.

In a 6-month mixed methods study of GP's (n=11) which assessed GP confidence and self-efficacy before and after implementing weight management programmes found that those

who engaged with the pilot intervention had an increase in confidence and self-efficacy when managing obesity (Sturgiss et al., 2017). They concluded that a structured obesity management tool can improve practitioner self-efficacy and confidence in managing obesity (Sturgiss et al., 2017). Further highlighting the benefits of this research projects to practitioners and limiting any concerns may help to overcome this barrier.

To identify and explore these concerns, and any other barriers, interviews were conducted with practitioners who had been willing to participate in the pilot trial stage, but did not engage, to evaluate barriers which may have prevented them, or other practitioners from being able to participate with the pilot trail or embed standardised tools into their own practice. These results are reported in Chapter 6.4.

6.2 Findings from survey of nutritional therapists

This survey, conducted by CNELM research students (Gordon et al., 2017) under my supervision, aimed to identify potential opportunities to enhance engagement between obese population groups and NTs. A total of 49 nutritional therapy practitioners had completed the survey. The survey was conducted to meet the aims of these student's research projects. Not all results of the survey are reported here. Only the results which are directly relevant to this project are reported here.

In response to the question "What percentage of your total number of clients per month are obese (BMI >30)"? 69% (34) stated less than 25% and 8% (4) stated more than 50%.

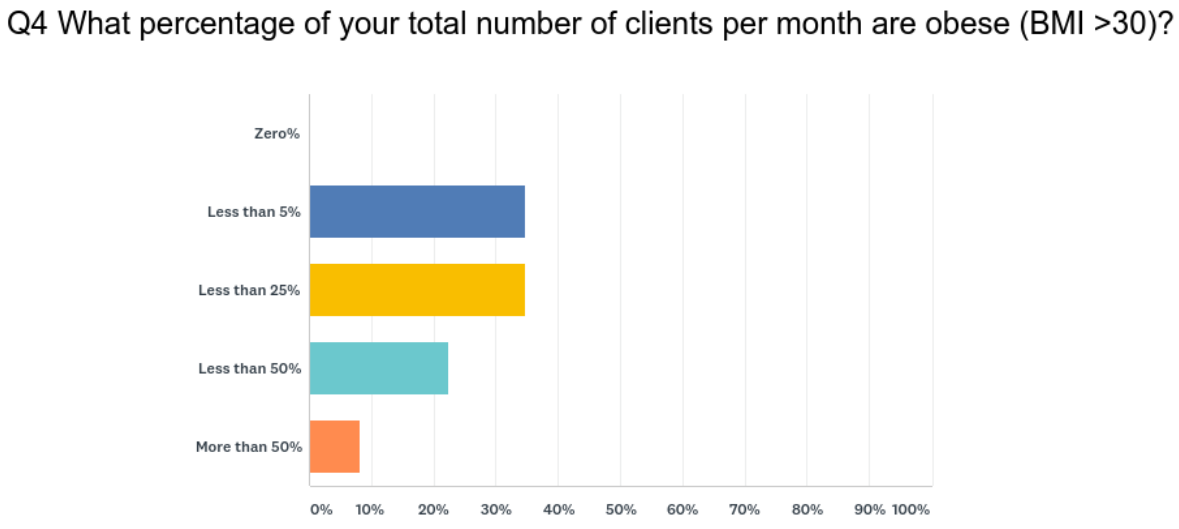

Figure 22*Survey results chart of the percentage of total number of obese nutritional therapy clients per month*

When asked "Within your marketing do you specifically state weight loss management is part of your practice?" 61% (30) responded they did not and 31% (15) responded they did.

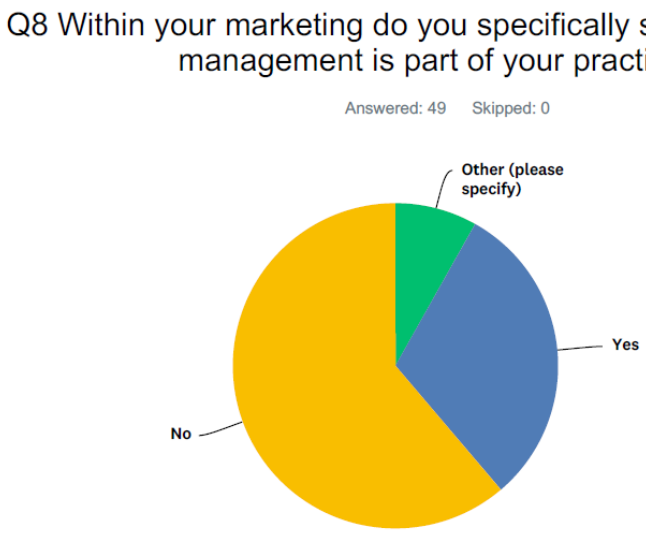

Figure 23*Survey results pie chart of NT"s who do and do not have marketing which specifically states weight loss management*

The survey also asked, "do you experience any barriers engaging with an obese population?" 53% (26) stated they did not and 47% stated they did experience barriers. When asked to specify these barriers, 12 cited barriers for individual clients such as:

"embarrassment, shame, denial, perception of friends/relatives/others"

"difficulties committing to change".

[They are] "*very focused upon how others perceive them and believe others think they are constantly eating".*

"they are not commonly the demographic that seeks nutrition advice".

Interesting, there were also responses such as:

"they are entrenched in slimming world and Weight Watchers ethos", "so many people want to follow high street clubs"

"I feel the likes of Weight Watchers and Slimming World have convinced the obese and overweight population that their programmes are the only ones likely to help clients achieve their weight loss goals" because "group type initiatives more aggressively market to this audience".

In response to the question "What strategies do you use for marketing your practice? Tick all that apply" 90% (44) stated via their own website and 88% (43) stated by word-of-mouth. Other responses included:

"networking meetings, referrals, and newsletters".

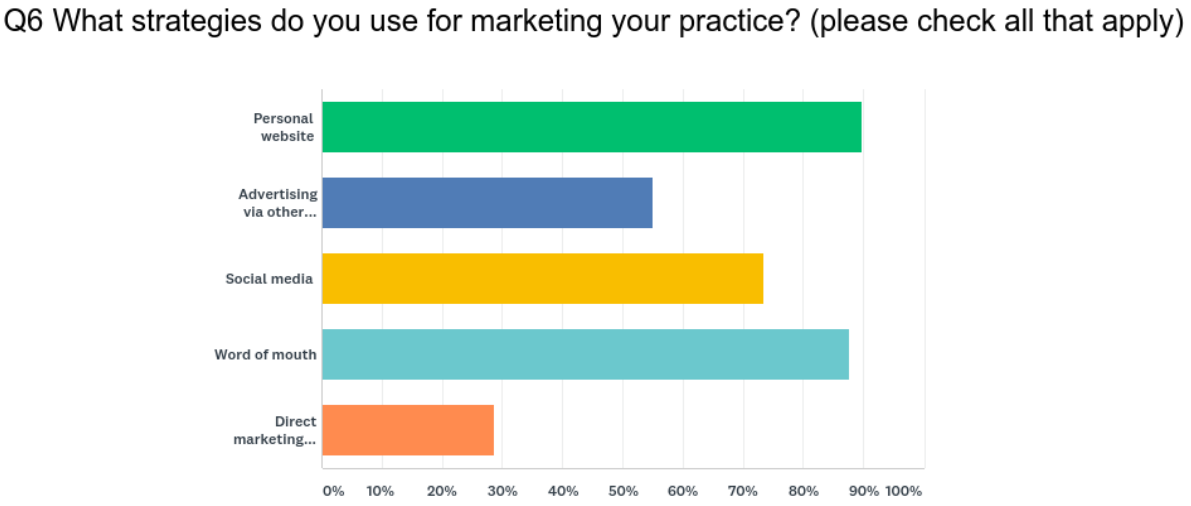

Figure 24*Survey results bar chart of strategies used by NT''s to market their practice*

When asked "Do you have any suggestions on how NTs might improve their engagement with an obese population?" numerous responses gave actions for individual practitioners, such as:

"run talks and classes"

"volunteer at a local community event"

undertake "further training in counselling"

"get more involved in group programmes"

"work as part of a multi-disciplinary team"

A number of other suggestions should also be considered at a professional level:

"it's about awareness of NT more than anything."

"by describing how nutritional therapy supports each individual to achieve wellness"

"group formats, Facebook/email support advertising the personalised approach"

"online programmes with regular NT contact"

"getting GPs on board to refer to NTs"

"contact GP's, bariatric consultants, counsellors etc."

"Integrated education with GPs who would be willing to work with us" and "more promotion from GP's".

6.2.1 Discussion of the survey

This survey was targeted directly to NTs. Whereas the surveys and interview participants results reported earlier in this research project (see Chapter 5) engaged a range of nutritional practitioners already working with an obese population. It was therefore not until the lack of engagement with the pilot trial that concerns were raised about the broader engagement of obese populations with nutritional therapy.

The survey results suggest the stigma related to obesity is a challenge for clients wanting to engage with nutritional intervention. The impact of the stigma of obesity has been well explored in the literature (Karasu, 2012; Puhl & Brownell, 2001; Puhl & Heuer, 2009, 2010). This research did not explore the potential stigma of nutritional therapy practitioners working with obese individuals. A comparative analysis of dietetic and non-dietetic students using a validated fat-phobia scale highlighted that dietitians exhibit moderate negative attitudes towards obesity (Berryman et al., 2006). Although the authors acknowledge numerous limitations with this research, they concluded that educational programmes which explored bias towards obesity helped to reduce negative attitudes (Berryman et al., 2006). It may therefore be worthwhile to undertake similar research with NTs to raise awareness and minimise barriers to engagement.

The results also highlight the limitations of NTs marketing themselves individually when compared to weight loss brands like Weight Watchers and Slimming World who have a global reach and engage with numerous marketing activities including TV advertising. The comments on how NTs may improve engagement with an obese population varies from individual activities which NTs can undertake and activities which can be undertaken at the level of the professional body. Some of these responses point to actions that are already undertaken by the nutritional therapy professional body, BANT, for example in 2013 BANT launches a programme to inform GPs about nutritional therapy (BANT, 2013).

There are also other actions which could be considered by the NT's professional body, BANT: large scale advertising to raise awareness of NTs, nationwide online nutritional therapy group and individual consultations, developing collaborative relationships with other professional bodies e.g. bariatric surgeons, counsellors and other health care professions, and integrated education and CPD events for other health professionals.

6.3 Findings from interviews

Six interviews were conducted with nutrition practitioners who had been willing to participate in the pilot trial, but did not engage, to further explore practitioner views on the barriers that may prevent them and other nutrition practitioner from embedding standardised tools in personalised nutrition practice. This included strengths and limitations of the profession

which may impact on the utilisation of standardised tools, and approaches to overcoming barriers. Results are presented under these nine headings which are themes that emerged from analysis: engagement barriers, time constraints, invasiveness, compliance, flexibility, health complexity, tools guide practice, practice approach and potential solutions.

6.3.1 Engagement barriers

Participants were asked "what are the barriers engaging clients with standardised tools? Either for this pilot trial or more generally." Each participant described different barriers to engagement and it was therefore not possible to identify any single issue affecting all participants.

"One has to come, come across so professional as a, as a nutritional therapist because, because we aren't [yet accepted] … if I was sitting there in a GP practice, I've already won the respect of those people. But as a nutritional therapist, it's my responsibility to win the respect of those people, so, I've got to be pretty sure about what I'm saying and, and coming across as, as professional"; "so, if I'm then, getting somebody to take part in any study right at the outset, I suppose I have to be very clear" (CB)

"I wonder if the, the professional base isn't used to participating in research either. So they didn't" (RJ)

"I think the main barrier for me was, [clients] just weren't interested, you know, they just, they didn't get anything back from it… they were more concerned about their weight loss than helping to participate in some trial" (MC)

Asking practitioners to engage their clients on a pilot trial appears to have been a barrier to participation for at least two practitioners.

"I guess it was the fact that it was a sort of third-party sort of set-up I think possibly had something to do with it" (LO)

"It's probably easier to work on a practitioner-only side; than to get the practitioner and the patient to do it together" (RJ)

6.3.2 Time constraints

Time constraints were mentioned by all participants – either their own time constraints to engage with the process or the time constraints that prevented their clients from completing the tools:

"Time-consuming, I think that would be a major, major factor" (CS)

"If you're busy and you're rushed for time and you've got to take time aside to discuss it with the client; that might have been another hurdle." (RJ)

"There's a lot of sort of chasing up, often, to get these things back from people.. I know particularly the pilot trial... I remember looking at your questionnaire initially and I think it said.. this may take up to an hour to fill in... I will often look at that and go 'well I don't have an hour now, I won't, I can't do it now. I'll come back to it.' And then you just never come back to it. I think, sort of, time is a big thing for people and, you know, they think, 'I'll do that when I have a bit more time', and they never have a bit more time"; "and possibly… I wasn't as hot on following up with them to make sure that they did it? You know, it wasn't sort of a top priority for me to kind of follow up with them to make sure that they'd done it: If I'm honest, that was probably part of it." (LO)

Aside from the pilot trial, participants were asked: "Have you received any feedback from your clients on their experience of filling out questionnaires?"

"A lot of people have commented that the six page questionnaire that I give them is, is quite long and takes a long time to fill out." (CB)

[A client may say} *"Gosh, that's a big document to fill out… but [that's] not really [a barrier] most people seem to have been fairly happy to do that"* (CS)

"They want some streamlined… nowadays everyone's busy and people want to be given information in as simple and quick a form as possible" (CS)

There were opposing opinions on streamlining the tools:

"It's impossible to make your questionnaire shorter. If it's, if it's shorter then it doesn't collect all the data. So, you either make it proper, and long... or you don't make it at all. I mean, because you still have to ask these questions." (NG)

6.3.3 Invasiveness

One participant commented on the potential of obesity stigma being a barrier to engagement:

"I can imagine that stigma would be quite a big thing, where people wouldn't want to get too involved with being part of a trial because, I guess, it's the whole feeling like a bit like a guinea pig, might not appeal to them. So, it is quite a sensitive delicate area; I think people feel quite a lot of, self-blame, possibly for being overweight… it's not the same as some other health conditions that people might feel is out of their control. So I guess embarrassment and shame might be one of the reasons." (CS)

"I think weight loss is such a delicate area anyway, because there's so much stigma around it." (CS)

"It's very in-depth, it's very straightforward; it's very invasive… you're asking a lot of very pointed, very sharp questions. Sometimes some people don't want to answer…" (NG)

The invasive nature of the questionnaire may therefore have presented another barrier to some clients:

"If you don't know the practitioner and you don't sort of quite know what you're signing up for, I think maybe you, yes, would, there would be a little sort of barrier of sharing information with someone that you don't know anything about" (LO)

"If you give a questionnaire that's got quite a lot of personal, in-depth consultation, or you're going through somebody's life history in depth, then it can feel quite threatening in some ways" (CB)

"Until you've been working with somebody for a while, you have not achieved with them, this trusted adviser status, so any profession, whether you're talking about accountancy, law, has this concept of trusted adviser status that you build up with a client… So, we're almost on a back step for trusted adviser status because we're not part of the National Health Service, and at that point we haven't developed this trusted status, adviser status" (CB)

Building up a trusting therapeutic relationship is important for client engagement:

"I call my work coaching. I do. Because that's what it is; it, it's training and coaching... therapy... because that, that's the most important part in this thing… you have to kind of get a rapport; you have to get some understanding... he or she feels comfortable disclosing a lot of data to you." (NG)

"At first there's a little bit coldness in relationships... then there comes out a crisis; then that person feels like, okay, well, there's somebody who's finally listening, finally understanding, and then it runs for, this warmth of relationships, therapeutic relationships, runs for maybe a couple of consultations, and then... they come to some barrier, and very often... they despair, and they don't come back, because - it's not like something isn't working, it's because they can't overcome the psychological part of it." (NG)

The psychological and coaching element of nutritional therapy is an important part of supporting clients to make healthy changes to their lifestyle. Building a trusting relationship may also support client compliance which was another recurring theme.

6.3.4 Compliance

"In an ideal world, I'd love to be able to send a client a form that they fill in beforehand, and that gets sent back to me and I get to review it before I see the client and then we sort of, you know, that then leads you on to what happens in the consultation. But I just think – I've had so many troubles with getting people to do things before you've established a

relationship with them or something, you know? I think after the initial contact they'd be more willing to follow it through?" (LO)

"I've tried on various occasions to sort of send them through to a client for them to fill in beforehand and they either haven't read the instructions or they just don't get it and so they've filled it in wrong. And so, it's completely useless." (LO)

"I now will do those forms with someone sitting in front of me so I can guide them through [it]– It's a very simple form… but people still get it wrong." (LO)

"Overwhelmingly, the key issue that I'm gonna have to deal with is compliance. It doesn't matter what the information is; it's all about compliance and the better relationship I can build, the better my chances of compliance, the better my chances are that people will be honest with me around food." (RJ)

6.3.5 Flexibility

With a personalised approach there also has to be a willingness to meet individual needs:

"Some people love writing everything down and some people forget. I don't think they're opposed. It's just life gets in the way, and, you know, they're not as, possibly as organised as others." (MC).

"many people like hard copies" (NG)

"Some of them don't have computers because they have tablets; some of them don't have tablets or computers: they have telephones. It's impossible to fill in questionnaire" (NG)

"When you integrate Asian cultures; when you integrate Indian, Pakistani cultures, true, true cultures – I mean not, not people who are born here – they sometimes, they don't even know what that question means, whatever that question is, because they never actually thought about it." (NG)

Cultural validity analysis would need to be undertaken to meet various needs. However, in order to achieve a standardised data-collection approach, such as through an online application, it will not be possible to overcome some of these barriers:

"There's a lot of apps out now, with tools for weight loss now, all using the same tools. But, I think when you're seeing somebody personally every week, it's because you're not doing that – you want that personal intervention and you want that personal care." (MC)

An approach should incorporate both of these facets; it should include personalised coaching and care with the client, and data-gathering which can be done online.

6.3.6 Health complexity

"The biggest barrier to me, personally taking part in this was the fact that this [was] very much geared to obesity, and of course I wasn't having anyone saying, 'I want to deal with obesity' and 'not having enough flow of clients at this point in time.'" (CB)

"Lots of people come [for nutrition therapy] and they've got complex [health] issues, and they're not mentioning… obesity" (CB)

Clients come for nutritional therapy for health reasons, and weight loss may not the primary concern:

"Nutritional therapy's so complicated just because we're dealing with living, human people – every single one of them is different." (CS)

"The issue with that is that… somebody with high weight is not the only thing we look at… they have so many other issues… so, if you give them obesity questionnaire, you might… miss out things?" (NG)

"There are different questionnaires, like stress questionnaire, a weight loss questionnaire; I had thyroid questionnaire; I had a stress questionnaire; I had specific questionnaires for childhood obesity… but then I stopped using them because I thought… it's almost like going into very single track." (NG)

6.3.7 Tools guide practice

Participants were asked about methods they use when assessing their clients. Again, all participants were using their own tools and methods, but these results could also indicate that some practitioners may be adapting their data-collection methods depending on their patient and on their own clinical experience:

"The questionnaire was developed over time really. So I started off with a questionnaire… but edited it, so I added in bits, took away bits… so it's just been edited according to what use." (CS)

"I'm sort of following, loosely following a Zest4Life kind of intake form. But I've kind of adapted that to be my own intake form." (LO)

"I use timelines to help myself think, but in terms of, it's a very unstructured interview. I've got some standard questions, like where do you think this all began?" (RJ)

"I do have two questionnaires. One questionnaire is Dicken's questionnaire...The second questionnaire was developed by myself from some medical questionnaires... I created my questionnaire the way I think." (NG)

"I don't really have anything concrete… a food diary, emotional diary, and weigh-in: they're probably the main tools. And then I track that through a sheet that I have where it's – just looking at it now – it's in chronological order: they have their goals, what they want to achieve." (MC)

"I've sort of tried different questionnaires, we obviously had a questionnaire when I graduated, so that was the one I used for a number of years, and then there was an update and I tweaked it myself, and I've used the CNELM questionnaire as well to see how that panned out; when I was with Nuffield, then I used their questionnaire." (CB)

This highlights the fact that practitioners are also developing their own questionnaires to suit their practice approach:

"[A] questionnaire is not just a tool: [a] questionnaire is a way of thinking." (NG)

"The health questionnaire… dictates my thoughts before the consultation and, which sort of questions I want to ask the client - what additional information I want to get out of them. So that gives me clues as to what, you know, where I think needs probing further." (CS)

This highlights another barrier for the pilot trial:

"When they are faced with a new tool and it's perhaps structured in a way that they're not accustomed to using, that then they have to reconfigure their whole consultation to fit that tool into it. And they have to make a decision as to whether they abolish their existing tool or whether they use this tool as a replacement, and then they have to question whether the new tool includes all the other things that they had previously, and so there's quite a lot of complex thinking that someone has to engage in before including those tools." (CB)

"If you're asking questions on marital status, past pregnancies, this sort of thing, which can appear to be quite invasive sort of information, you have to feel comfortable that you can act on that information. And if you don't know whether you're going to do anything with that information, then you almost feel uncomfortable about asking it." (CB)

"When I look through a questionnaire that I made and the people filled it in, I don't need to read every line. I just see where these marks are on the page - I know what we're talking about. So I'm used to it, you see? It's my comfort zone. So we've basically have to retrain ourselves to use [the pilot trial tools] …" (NG)

6.3.8 Practice approach

"The process of nutritional therapy in itself is quite complex, because it can mean different things to different people." (CB)

The various approaches to gathering client data and the use of questionnaires to guide the consultation process highlights that nutritional therapy practitioners all take their own approach to practice. There were even opposing views about the impact of this:

"Every practitioner works very, very differently … and I think that is a strength" (LO)

"Lack of standardised practice is a massive weakness, I think, in the profession. So, I know that if I go to a doctor or a GP anywhere in the country, that at least I'm going to be assessed in, in a certain way and that if I'm at risk, for example, of getting diabetes that there's certain algorithms behind the analysis. And it doesn't matter if I go to this clinic or that clinic, that those things are in place to, to pick that up. And that gives me, as an individual, a certain amount of assurance." (CB)

"We do lots and lots of different things; we do them in lots and lots of different ways… the way that we apply evidence is really very… variable" (RJ)

"I think the trouble is everyone works so differently… we are so varied in the way that we are looking and working with clients, it, I think it's hard to standardise the process. But then on the flip side of that, I get that it would be really useful and in terms of being able to validate what we do –particularly if we are wanting to communicate with the medical profession – you know, I totally get that it would be [a] really useful thing to do, but how you come up with that sort of structured standard thing that people use, I don't know." (LO)

"The profession as it exists, is so very… atomised, I would say, in that each practitioner does things in their own way. So that... is one barrier and I think it's also a barrier to us developing perhaps a common language and... collaboration." (CB)

"I think [standardised practice] must happen, not just should happen, must happen. We all should have standardised approach – I mean personalised in terms of patients but standardised in terms of what, how we understand things"; "It has to happen. Because otherwise, if there, there's no standards in the industry, that's rubbish." (NG)

"I think historically we've been very bad at structuring our consultation process" even the "different [nutritional therapy] training providers [are] teaching students in different ways." (CB)

"Tools have to really be asking questions that are absolutely vital in terms of the way that the consultation goes." "If the tools really helped to guide practitioners to embed perhaps a more structured approach to their practice, then, perhaps they would start to use standardised tools a bit more." (CB)

There was discussion about the wider impact of various practice approaches on the profession:

"I work in a hospital up north... doctors… [have] asked, 'So you're a nutritional therapist? We used to have another nutritional therapist here… could you tell us about your profession, 'cos we're, we're not quite sure; are you all guys doing the same thing?' That question was asked." (LO)

"People don't necessarily know what... nutritional therapy's going to involve when they, when they rock up to see a nutritional therapist; it's still a sort of slightly unknown process, to a lot of people, 'cos it will be the first time that they've come across someone, and they're used to having that sort of seven minutes with their doctor, where they don't go into as much detail about their health, and past medical history, and lifestyle, and all that kind of stuff. So I think that the way we work is, is quite… novel, to most clients." (LO)

"[Clients] might not come back if they don't know why they're coming back or how that process is structured." (CB)

"I think the industry, with nutrition, functional medicine, naturopathy, is very confusing for lots of people and you could do a one-month qualification, a degree, a post-degree, a post-grad qualification, but at the moment it's dietetics, isn't it? That's the only kind of recognised… and nutritionists. But nutritional therapy, I think, has a, a still quite a slanted view." (MC)

"The training colleges aren't standardised either, you know, are they? There's such a huge variation in the training of nutritional therapists. So I mean, I guess it's got to sort, you know, really, that's where we need to start: is in terms of the kind of training, qualifications." (LO)

"There is such a varying degree of how the core curriculum is being interpreted." (CB)

"There's such a huge variation in the training of nutritional therapists. So I mean, I guess that's where we need to start." (LO)

6.3.9 Potential solutions

As well as highlighting barriers to the pilot trial and implementing standardised data-collection methods into personalised nutrition practice, participants were asked "What could be done to encourage the use of standardised tools (or standardised data collection) in personalised nutrition practice?"

"Structuring our consultation process… I think that's crucial to the success of the profession". "A more staged approach because they're dealing with the fundamentals of that first consultation allows them to really focus on, on fundamentals and diet, and it builds trust with the client so that they've found that they've got a much higher rate of, of clients returning as a consequence of that." (CB)

"I think there should be some process in place but I'm not sure whether it's the same tool that everyone should be using…I think there should be a system in place but I think… people are different." (MC)

"Maybe have something where the standardisation would be, there are certain areas that should be covered by every practitioner but then that can be built on, you know, those areas can then be extended on, rather than, you know, an exact standardised tool." (CS)

"If we had some tools which were centralised tools that everybody had available to them, I think that would be an excellent thing, and I think it would help to standardise nutritional therapy"; "a collective of standardised tools that you could apply in practice." (CB)

"I feel… nutritional practice that could be dealt in a fairly algorithmic way… So, it's about finding a way that standardises perhaps some certain core assessments, with a capacity to go deeper into certain other aspects, if you're perhaps a specialist in that area. For example, if you're a specialist in gut health, or, or obesity, then you would perhaps want additional tools on top of a, an overriding tool to, to, to dig further into those areas." "What are the really essential questions that they have to be in there? So, things about medication, things about red flags, things, the diet is obviously crucial… and certain symptoms. So, again, this comes back to how then one structures the process." (CB)

"New tools should not take not more than half an hour of somebody's time probably… otherwise it just becomes stressful and that's what you are trying to avoid in the first place." (CS)

"Raise awareness, or at least make people comfortable in terms of how to use the tools and things." (LO)

"Probably just general education on… what a positive outcome would be. So,.. what's the importance of it… and really sort of targeting thinking of how that… importance with clientele and also for practitioners … how would those outcomes improve their practice." (CS)

These comments give insight into some potential solutions for implementing standardised tools into personalised nutrition practice.

6.3.10 Discussion of interview findings

NTs and their participants may not have experience of participating in such research and they may not have felt, or considered themselves, sufficiently confident about explaining the purpose and value of the trial. If the purpose and benefits of the pilot trial were not adequately explained to the clients, it would be difficult to engage them. This is a complex project, therefore making the benefits of engaging with these tools clearer to both practitioners and their clients may have increased engagement with the pilot trial. In order to

validate clinical tools, they need to be used with the population group. These results support my concern that practitioners may have struggled to recruit participants for the pilot trial. It may have been better to work directly with an obese population only, rather than through practitioners.

When developing clinical tools there clearly needs to be a balance in terms of efficiency and completeness to support robust data gathering. Shorter but more frequent data collection approaches may allow further flexibility and help overcome barriers of time constraints, engagement and compliance. It may also be possible for practitioners to better support population groups who are unable to access or engage with online tools if the tools are shorter and quicker to complete.

It is also important to build the therapeutic relationship prior to requesting personal and invasive data. A consultation process may need to be developed alongside online tools, where data is collected in stages along with a staged consultation approach. The aims of each consultation and/or outcomes of data sets can determine which further tools are required for completion. Initially a smaller baseline questionnaire (medication, red flags, presenting issues) is required, then more invasive data could be collected personally during the consultation process. This could include trauma and adverse events that an individual might find it difficult to share until a much later stage in the consultation process. Then a questionnaire to assess pathophysiological mechanisms and laboratory data. Then assessment of barriers to compliance, motivation, food addition, behaviour or personality assessments could be undertaken, depending on the client's individual requirements at any given time. Meanwhile collecting ongoing dietary analysis, exercise and lifestyle data through real-time application would allow for compliance/achievement monitoring. Developing a range of short, validated, standardised tools may therefore help to overcome a number of the barriers presented and enable a more personalised data collection approach, which could be client-led.

These results also highlight the incongruence with creating tools for personalised nutrition practice that focuses on a condition such as obesity. Focusing on obesity is a disease-oriented approach rather than a personalised approach. The complexity of client health issues means clients rarely present with obesity or any other disease in isolation, meaning it may be better to have personalised health questionnaires that do not focus on obesity, but can be used for all clients.

Practitioners use their clinical tools to guide their consultation process. They have been trained to use their tools and have developed them over time to suit their needs within the consultation process. Engaging them with new clinical tools requires a significant time

commitment and this has likely impacted on engagement with the pilot trial, especially as the majority of nutrition practitioners who have engaged with this research are self-employed so time issues, case load uncertainty and excessive workload issues (Nash, Norcross and Prochaska, 1984) may have presented additional barriers to engagement. For any new approach to be successful it is clear that training practitioners to use new tools is necessary.

The variation of programmes delivering nutritional therapy across different training providers should be further investigated by the NTEC. The NTEC did undertake an online survey of NTs (n=408) exploring their working profiles to support the development of the core curriculum, which was insightful in terms of identifying the number of NTs trained at various academic levels and what sources of evidence informed their clinical practice, with continued professional development (89.2%), scientific journals (80.6%), industry events (67.2%) and internet forums (55.9%) coming out on top (Benbow et al., 2017). Interestingly, word-of-mouth marketing was identified as the most successful marketing method by 80.7% of respondents. Further research to identify how NTs can raise their profile through professional marketing strategies could be useful.

NTEC reported that 68.2% of participants suggested the medical professional has poor regard for NTs, although some reported that this was improving along with an overall improvement of the public perception of nutritional therapy (Benbow et al., 2017). The authors conclude that advances for professional development, and the perception of NTs by medical professionals and the public, could be improved by setting the qualification level at academic level 6, which is the same as nutritionists and dietitians (Benbow et al., 2017).

Further comparison of clinical training provided by nutritional therapy education providers, as well as a comparison of practice approaches as taught and practised, would be insightful. Benbow et al., (2017) explored clinical practice, with 66.9% of respondents stating they use functional medicine to inform clinical decisions and 73% using a systems biology approach, although the clinical approaches to these were not described. Performance criteria is specified in the National Occupational Standards (NOS) for nutritional therapy, but there is little guidance given in terms of practice approach other than:

> “Conduct a nutritional and overall health assessment and plan the therapy”
>
> (Skills for Health, 2010)

The NT core curriculum provides further description:

> “Nutritional therapy practitioners use a wide range of tools to assess and identify potential nutritional imbalances and understand how these may contribute to an individual’s symptoms and health concerns. This approach allows them to work with individuals to address nutritional balance and help support the body towards maintaining health”
>
> (NTEC, 2015)

NTEC and BANT also state:

> "Nutritional Therapy is the application of nutrition science in the promotion of health, peak performance and individual care. Health is defined by the World Health Organisation as "a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity". Nutritional therapy embraces this definition and professional practice is underpinned by a set of fundamental principles which support optimal health outcomes, i.e.
> • biochemical individuality: understanding and appreciating the importance of variations in metabolic function deriving from genetic, epigenetic and environmental differences among individuals.
> • person centred: emphasising individual care rather than disease care, following Sir William Osler's admonition that "It is more important to know what patient has the disease than to know what disease the patient has"
> • dynamic balance of internal and external factors: understanding that resilient homeostasis (the buffering capacity to respond to a perturbation) is important for physiological equilibrium;
> • web-like interactions: understanding that human physiology functions as an orchestrated network of interconnected systems, rather than individual systems functioning autonomously and without effect on each other; and
> • promotion of organ reserve: as the means to enhance health span by maintaining genomic stability and mitochondrial capacity so decreasing morbidity."
>
> (BANT, 2017a; NTEC, 2018)

These synthetically describe nutritional therapy and its underpinning philosophies to a degree but they do not analytically describe the process or practice approach. The BANT Professional Practice Handbook (2018) provides further description of the boundaries of NT practice but does not detail a practice approach.

The BDA (2015) on the other hand provides a model and process for dietetics practice which includes:

- the use of structured records to improve quality of care;
- structured reporting and communication of clinical reasoning;
- information sources for clinical data gathering using a systematic and standardised structure;
- methods for assessment and reassessment;
- approaches to clinical reasoning;
- definitions of what constitutes nutrition and dietetic interventions;
- implementation of intervention approaches as well as monitoring; and
- reviewing and evaluating intervention approaches.

These all provide clarity in terms of what can be expected from dietetic practitioners.

The BDA describes this process as:

> "an important step in the development of consistent high standards of dietetics practice"
>
> (BDA, 2015).

Although the BDA model and process are client-centred and include consideration of social, cultural, lifestyle and economic factors, they take a differential diagnosis approach where signs, symptoms and aetiology are used to determine a nutrition and dietetics diagnosis and then evidence-based guidelines are used to determine an intervention. This approach fits with the EBM paradigm but cannot be considered personalised nutrition practice because it does not allow for consideration of the broader complexities of health and disease, including genetics, genomics, epigenetics, physiology, pathology and toxicology, as explored in Chapter 2.

The interview results highlight that the varying practice approaches were a barrier to implementing standardised tools. Using a computer technology analogy: when the operating systems are different one cannot implement standard applications. In order to be able to implement standardised tools into clinical practice there may first need to be a more standardised practice approach. Further research should be conducted to understand the implications of developing a more structured process for undertaking personalised nutrition practice and how this can be achieved without limiting the scope of practice. Personalised nutrition practice may not need to be standardised, its process may just need to be better defined.

6.4 Overall discussion of findings

The pilot trial of the four new collaboratively developed clinical tools gained interest from practitioners but lacked engagement from practitioners during the pilot trial. The interviews with practitioners that followed identified some of the reasons why the pilot trial was unsuccessful and aimed to identify ways in which standardised tools could be integrated into personalised nutrition practice.

Rather than having one large health questionnaire, it seems smaller, more frequent data-collection points would better engage clients and enable a more flexible and less invasive practice approach. It could also allow for the development of a therapeutic relationship before whole life histories or invasive assessments are undertaken. Having a selection of short standardised tools and data-gathering techniques may also allow practitioners to consider which assessment methods are best suited to their clients, which could support a personalised nutrition practice approach.

The lack of clarity around the nutritional therapy process is likely contributing to the varying practice approaches undertaken by nutritional therapy practitioners. Variation of practice approaches has consequences for how clinical decisions are made and how clients are managed. Variation of practice approaches also seems to be impacting how the profession is perceived by other health professionals and how the profession is able to describe and

promote itself. Clarification of a personalised nutrition practice approach appears to be essential for developing standards in nutritional therapy and promoting its acceptance in mainstream health care. However, developing a clear message which describes nutritional therapy in a meaningful way which can be understood by other health care professionals and the general population, is challenging.

This project also aimed to evaluate the ethics of standardising data-collection methods in personalised nutrition practice, and although patient autonomy, inclusivity, data management and data mining consent concerns were raised, there was overall support in standardising data-collection methods as long as that does not impact on the practitioner being able to manage the consultation in their own way and making personalised intervention decisions and recommendations. Standardised data-collection methods do not need to limit the scope of personalised nutrition practice but could enable us to pool data and develop a case-by-case evidence base that allows for analysis and comparison on the efficacy of interventions which supports, rather than standardises, clinical decision making.

6.5 Chapter summary

This chapter has explored the results from each research method in turn to explore the implementation, analysis and outcomes of this project. The overall discussion of findings summarised the main results and project outcomes. The conclusions and recommendations that arise from these results are further discussed in Chapter 8.

Chapter 7: Reflexive Account

Continual reflection was undertaken throughout the project to assess the influence of my position within the research, as explored in Chapter 3. This chapter is a retrospective reflective account which draws on my reflective learning diary and explores my developmental transformation throughout the project as well as the impact of my self-development and the outcomes of this project on professional environments such as my workplace and the nutritional therapy profession. Theories of reflection, such as Johns' (2000) model of structured reflection, Brookfield's (1995) four critical lenses and Gibbs (1988) reflective cycle, were reviewed, and their approaches utilised to advance and deepen my reflective thinking.

7.1 Self-development

The DProf, and this project, were undertaken part-time over six years while I maintained a part-time (three days per week) working role as Head of Education at CNELM. My work is complex and encompasses a number of roles. I am a senior manager in a middle-leadership position (Bryman, 2007). Managing my workload alongside the project (two to three days per week) while also taking care of my family has developed my time management skills, especially the ability to compartmentalise: focused working on specific roles at one time, isolating issues, planning and moving forward in incremental steps, closing one compartment to focus on another (Blair, 2012). Compartmentalisation has been essential to be able to juggle numerous roles and responsibilities and this has also required a considerable amount of forward planning and organising to achieve successfully.

In essence there have been three selves: worker, student, parent/family member. Being a parent/family member meant that I had to take time away from working and studying, which impacted positively on my emotional health. I am fortunate that I did not experience any major personal or familial issues during the project. I have an incredibly supportive spouse, family and work environment. There were times over the course of the programme when I was deeply unhappy about the burden of the workload and the impact of that on my availability for my child. A number of qualitative research studies have explored the experience of female doctoral students and identified that being a mother has profound implications (Brown and Watson, 2010). Although I had anticipated the amount of work involved, I had not anticipated the level of emotional fluctuation that I experienced. Similar experiences are described by female doctoral students in the phenomenological study by Schmidt and Umans (2014). Being a mature student in a supportive environment meant I did not experience some of the stressors explored by Schmidt and Umans (2014), such as: financial difficulties, peer pressure and low status. Nonetheless, the times of stress and

emotional turbulence, whether created by my own expectations or by external influences, have deepened my empathy for students I work with. As a result, I am better placed to provide guidance and support to the students in my workplace who are also juggling many roles with families and finding that stressful. This empathy and support may have a positive impact on student retention (Lillis, 2011) in my workplace.

Setbacks with my project included an intense feeling of failure due to the lack of engagement with the pilot trial, and the barriers to publishing the leadership research paper were at times overwhelming, but I kept going. During setbacks I am quick to undertake self-assessment reflection. I consider that I responded appropriately to feedback and broke through the barriers that presented themselves. Overcoming these research barriers has made more resilient, reflexive and adaptable. I am proud of myself for keeping going in times of adversity and I am better able to manage and accept overwhelm as a result. I consider my strength throughout the project has been persistence. In a series of experiments described by McFarlin et al. (1984), it appears that self-esteem is key for increased persistence following initial failure. Although persistence is essential for goal attainment, numerous skills have been required at various stages of the project to achieve success.

Below is an extract from my reflective journal which demonstrates the changing of my perceptions about myself and reflective insights about potential research bias:

> I have been having a lot of thoughts about the value of the professional doctorate and the limitations of myself and my research. Clearly simplification is important, limiting complexity and making things easy, which I don't always do, could have been further applied in terms of the tools. I realise hindsight is a wonderful thing but if I had interpreted the initial interviews in another way could I have come to these answers about keeping forms simple earlier? Was my bias in terms of meeting the outcomes of the research aims and objectives preventing me from seeing that the tools are too complex and practitioners/the profession are not ready or is that the result of my research and I would never have come to that if it hadn't been for the lack of engagement with the pilot trial? A confusing time.
>
> Barrow (2016)

These types of reflexive insights occurred throughout the project. My learning was non-linear and heuristic. The learning from a professional doctorate cannot be designed or predicted. Hopwood's (2010) qualitative research highlights that my academic job role influences my self-development choices and my project activities are shaped by self-development intentions. On reflection, my self-development intentions were in response to the demands of both my research project and my work role. I am highly motivated in self-development activities and that is influenced by my work environment which encourages staff self-development and delivers student development opportunities (Ryan and Deci, 2000).

My writing has been prolific, not just about the project and the research outcomes but my reflective diary and my research journals are extensive. I have become highly reflective.

When I was unable to undertake project tasks I read academic and self-development study skills books and this further guided my writing. Self-development was one reason for undertaking professional doctoral studies; to me it is as meaningful as accomplishing the research. Reflective writing allowed me to develop academic self-regulation including self-motivation, self-monitoring and goal attainment (Siebert and Walsh, 2013). I have learnt that I am more determined, self-reliant and adaptable than expected. These attributes have not only brought me to the completion of this project but are essential for effective leadership.

As a result of completing the project I have found my confidence has grown, which has changed the perception I have of myself. I left school with few academic qualifications. During my 30s I achieved two degrees, a diploma to teach and numerous CPD awards; imminently this professional doctorate. Imposter syndrome, an internal feeling of academic and intellectual self-doubt (Clance and Imes, 1978), at the outset of the doctoral studies and the outset of my job role as Head of Education made me more determined to prove myself. Self-doubt has been replaced with resilience and confidence. Professional identity development has been achieved in numerous ways: enhanced understanding of workplace cultures, utilisation of theory in complex work environments, development of reflective and ethical practice, raised critical awareness and personal epistemological development (Hofer, 2008; Trede, Macklin and Bridges, 2012).

Certainly, knowledge and skills such as research skills, writing and getting published were achieved during the course of the project. The project was highly complex, and managing it developed my adaptability, collaboration, communication and leadership skills. The self-development aspects of undertaking the project were what I most enjoyed, because it felt like I was making progress. Most surprisingly, my feminist and broader political views also developed during the project, maybe from the insights and knowledge gained, maybe from the development of critical analysis, or maybe from the political developments that took place during the course of the project – including Brexit – as I am European, not British.

All of the self-developments discussed in this section have fed into my work and the contribution I make within my workplace and within the profession in ways I am now able to recognise and ways that I have yet to recognise. Self-development will continue as I reflect post-project, post-doctorate and as a part of lifelong learning.

7.2 Development in my work role

I have already explored some of the influences of my self-development on my work roles, such as drawing on my student status to empathise with the students at my workplace. Self-development has also enhanced my ability to think critically about problems, identify solutions and create new knowledge as well as my ability to plan, manage and deliver work

projects, which has benefitted my organisation. For example, I instigated a research-based approach to undertaking projects and surveys within my own organisation, which allows us to better measure the effects of change and make evidence informed decisions. Publishing research (Barrow et al., 2017) and contributing to academic conferences also helps to raise the profile of my institution and to meet the organisation's vision:

> …to be viewed as a centre of excellence
>
> (CNELM 2017)

I am very grateful that my institution has been supportive of my studies in a number of ways: funding, encouragement, time away from work to write, and much more. Working in an academic environment has positively influenced my research in numerous ways. Prior to undertaking the DProf, working at my institution had socialised me to academia and scholarly practice (Antony, 2002; Weidman and Stein, 2003). During the project I was surrounded by other academics who were available for ideas and support. This "developmental network" (Sweitzer, 2009) has been essential for doctoral progress and success. It has provided me with opportunities to reflect and self-appraise as well as enhance my understanding of my collaborative network and my position to undertake effective resource management.

My professional development also impacted on the professional development activities I provide as a part of my job role, positively affecting students, staff, my institution and indirectly, the professions into which graduates will move. I very much enjoy teaching and I have utilised my learning to enhance and broaden my teaching practice in numerous ways, including: the development of reflective practice, teaching ethics to enhance the student's ability to consider ethical issues and undertake ethical reasoning, as well as teaching research methods at my institution and another institution.

I have also fed my learning into staff development in numerous ways: I have given staff workshops on my learning, promoted the integration of reflection and ethical reasoning into teaching and learning activities across taught programmes, and supported the development of the CNELM research agenda. My job role has evolved during my time working on the project. I have been training other staff to take on the module leading which I used to manage. I have focused more on developing the Head of Education role as a consequence of the insights afforded to me by engagement with professional doctoral studies. The new module leaders under my leadership have made excellent progress and I consider this a result of my ability to communicate complex issues effectively, as these modules include complex nutritional topics.

My confidence grew with research supervision. I am now helping students to publish papers (Miles and Barrow, 2018), which has a positive effect on my institution, the students and the

nutritional therapy profession. My ideas for research projects, how to design them and manage the complexities of ethical issues that surround them have developed as a result of my studies, and that impacts positively on student research – both in scope and quality. I am now keen to support my institution in facilitating the provision of doctoral research supervision at CNELM in collaboration with an awarding institution. It is CNELM's mission to:

> Provide globally accessible high quality education and training in nutritional science and personalised nutrition" and to "promote lifelong learning and provide opportunities for continuing professional development
>
> (CNELM, 2017)

Although I enjoy a good level of autonomy in my working role, my research supervisors allowed me to work more independently, and although at times I craved more direction, the level of autonomy provided by the doctoral research has allowed for significant growth and self-development. Autonomy in work influences job satisfaction, self-esteem, work-related motivation, attitudes and behaviours (Schwalbe, 1985; Pierce and Gardner, 2004). Group autonomy also positively influences group cohesiveness and effectiveness (Langfred, 2000). This insight has led me to review and reconsider the management strategies within my workplace by seeking to support staff development, individual autonomy and group autonomy.

The overwhelm of managing the workload of work and studies, within time restrictions, led to feelings of not being able to do anything well; not my research, my job role or my family role. The project did take my time, and sometimes my focus, away from my work. Accepting the limitations of time resources was not always easy, but this has honed my time management skills and my research and project planning. Being realistic about expectations, breaking down tasks into manageable sizes, and understanding what I can achieve within time frames helped to take the stress out of feeling overwhelmed.

When pressured by time constraints I have a tendency to focus on task-orientation and I can lose focus on strategic oversight. I have learnt that I must make time in my working and research roles to consider wider contexts of the tasks at hand and that collaboration and reflection are good ways of providing the space required for enhancing strategic oversight and planning. Although there has been critical discourse of the use of reflection in workplace-based learning (Siebert and Walsh, 2013), development of reflection and academic self-regulation has also benefitted my organisation because it has allowed for a deeper analysis and evaluation of workplace issues, as well as the self (Siebert and Walsh, 2013).

Costley et al. (2010) undertook a grounded theory approach, utilising open-ended interviews, to study the impact of professional doctorates in the workplace of ten candidates who had

completed their studies and identified that personal attributes, skills, professional effectiveness are outcomes of undertaking a professional doctorate project, as well as enhanced credibility and status in their professional community, enhanced personal capability and that the process of undertaking a professional doctorate continues to make an impact after the project has been completed. Costley et al. (2010) conclude that the DProf programme offers many benefits for the individual, their workplace and their professional environment and, although time-consuming, the benefits hugely outweigh the impact of time and focus away from work to undertake it.

7.3 Project outcomes

The project's outcomes are highlighted throughout this report and expand beyond the construction of four new clinical tools for health data collection and clinical outcome analysis. The use of the term 'personalised nutrition practice' within the project aims and research questions, and the research methods outcomes led me to explore what personalised nutrition practice means. Uncovering the limitations of the descriptions and approaches to nutrition practice has been a significant finding. However, it cannot be claimed that all dietitians use only evidence-based guidelines and do not undertake pathophysiological reasoning, in the same way that it cannot be claimed all NTs undertake pathophysiological reasoning and do not make evidence-based recommendations, mainly because the results only represent a small sample of nutrition practitioners. By describing what constitutes personalised nutrition practice, a new model and approach for nutrition practice has emerged. Pathophysiological clinical reasoning is a model for personalised nutrition practice which has emerged from combining the personalised, person-centred, evidence-based and systems biology philosophies. Although similar to the functional medicine model, personalised nutrition practice should extend beyond it by: more explicitly taking a mechanistic approach, building validated and evidence-based tools that support pathophysiological reasoning, further encompassing cPNI and biopsychosocial model, collating and data mining case-by-case data sets, and by enabling the outcomes of interventions to be predicted.

Having come to these realisations as a result of the project, the benefit of hindsight has provided valuable insight into how standardised clinical tools can be developed to support pathophysiological reasoning and further develop a personalised practice approach. The vision for developing a case-by-case evidence for personalised nutrition practice remains. The need to develop standardised data collection tools for personalised nutrition practice also remains. However, because the research results pointed to a lack of process for personalised nutrition practice, one of the project outcomes has therefore been to propose a

definition of personalised nutrition practice, which has not previously been done by professional bodies or within existing research.

This project has therefore moved me into a position for leading transformation in personalised nutrition practice by further defining, developing and disseminating its approach. I am now ideally positioned to further develop standardised validated personalised practice tools to support a pathophysiological clinical reasoning approach, through my own postdoctoral research but also through my research supervision role. Development of a case-by-case evidence database is also achievable through postdoctoral research and collaboration with software developers.

7.4 Nutritional therapy profession

The nutritional therapy profession is in a state of flux. It is relatively new compared with dietetics practice. It was important that I kept abreast of changes in the profession to identify opportunities to influence change and to inform the project and its activities. I had invited the British Association of Nutrition and Lifestyle Medicine (BANT) to participate with the Delphi method, and was disappointed that directors and managers of BANT did not choose to participate as this could have been of benefit to the profession. I did however engage with BANT's Centre of Excellence. In this context I reviewed the Nutrition Evidence Database that BANT developed and gave feedback on how to enhance it, thinking about how it could feed into a case-by-case evidence base in the future.

In a members' newsletter dates November 2017, the BANT chair discussed the development of a "standard consultation questionnaire" (BANT 2017) which I have requested to be involved with. It is positive that the professional body recognise the value of developing standardised clinical tools and the need to share standardised case study reports in order to share practice approaches. Although the directors and managers of BANT were not directly involved in this research project, several BANT members were, and that provided an opportunity to hear their voices of how practitioners would like a standardised data-collection approach to develop. My concern with BANT implementing standardised tools to current practice is that it would likely have limited engagement and uptake by practitioners, as this project experienced. It is therefore my recommendation that any new tools are best embedded in the training of NTs, to develop a new wave of practitioners who can use them, and to offer existing practitioners CPD training on the use of standardised tools. It is also a recommendation that any newly developed tools undergo numerous validity assessments otherwise it could push the profession further away from acceptance and collaboration with mainstream health care.

I had preconceived issues with the nutritional therapy profession: about the varying approaches to practice, the lack of standardised data-collection methods and the lack of assessment methods to determine the efficacy of interventions. This project was borne out of these observations. I consider the lack of engagement with the pilot trial as a reflection of issues within the nutritional therapy profession: the lack of a clearly defined practice process, practitioners defining their own practice approach and how implementing standardised tools disrupts that approach, how obesity management is difficult, lack of engagement with these clients and lack of understanding of nutritional therapy relative to nutritionists and dietitians among the public. It seems that the research results support my observations, but the risk is: did my preconceived ideas lead to bias? With critical analysis and regular reflection throughout the project I am satisfied that sufficient bias limitation was undertaken during the research process and that the project outcomes could not have been predicted.

The results indicate that because practitioners earn income from their client work and word-of-mouth is their best advertisement, disrupting the consultation process could have a negative impact on their livelihoods. The results did not fully explore that practitioners may see the tools as a measure of their own efficacy rather than a measure of the efficacy of the interventions they recommended. This was my own interpretation. However, this led me to consider how these tools measure the therapeutic relationship and if that can be separated out from the nutritional interventions, which is an important and complex consideration.

Another insight regarding the lack of engagement with the pilot trial came from a discussion with a peer which made me reflect on the results of the practitioner survey and interviews. I had originally taken the results from the first round of surveys and interviews that practitioners were not using standardised tools, instead using their own tools, as a sign that developing a standardised tool was essential. What I had not fully considered was that one of the things that a questionnaire does is to set up the expectations of the consultation process both from the client and the practitioner perspective. As such I think that practitioners consider that they need to have an intimate understanding of a questionnaire and the directions in which each question can take them. I thought one of the reasons for the resistance in uptake from practitioners is that it deviates from their existing questionnaire and therefore influences and potentially changes the patterns and process of their consultation. This concern was therefore explored further with practitioners following the pilot trial.

In terms of my development, I had not anticipated the level of insight into professional nutrition practice that I have achieved over the course of the project. This insight was gained as a result of a lack of engagement with the pilot trial, which I had initially perceived as a failure. However, had the pilot trial succeeded and had I produced and analysed results of the new tools created I may not have gained insight into the complexities of engaging

practitioners with such tools. This outcome may have been found much later, increasing risk to the profession. This outcome also places me in an excellent position to be able to advise BANT on how to develop and integrate standardised tools into clinical practice. This outcome also resulted in the interviews which explored approaches to practice that led me to identify the limitations of the current descriptions of nutrition practice. It is this outcome that bought out many valuable outcomes and should therefore be perceived as a key result. Ultimately, undertaking the development of these tools and highlighting the value of building a case-by-case evidence base for personalised nutrition practice has been blazing a trail for other researchers, practitioners and the profession to transform personalised nutrition practice.

There are currently no opportunities to undertake PhD research with providers of nutritional therapy training. Facilitating the provision of doctoral research opportunities for the profession would be a significant enhancement. Few NTs have doctorates. As an NT myself, my DProf attainment may also contribute to raising the standards of the profession. Developing doctoral research opportunities within the profession could also support my own postdoctoral research opportunities.

The nutritional therapy profession as a whole does not market itself for weight loss. Individual practitioners may advertise themselves as such, but that does not compare to the marketing strategies of brands such as Weight Watchers, Slimming World or Lighter Life. The NHS does not refer obese individuals to seek out nutritional therapy. Nutritional therapy is paid for privately and can be costly in comparison to other weight loss programmes. There are so many reasons why I question whether obesity as a focus for this project had actually been a good choice, because of the stigma and complexity related to it. However, obesity is a growing epidemic which can hugely benefit from nutrition intervention at a personal level. Increasing the opportunities for this population group to engage with practitioners and increasing the evidence for the efficacy for interventions at a personal level continues to be a worthwhile pursuit.

7.5 Chapter summary

The value of reflection in and on action (Schon 1983, p. 68) throughout my doctoral development has highlighted numerous benefits to a range of stakeholders, most notably my work environment and my ability to identify areas for enhancement within my working role, within my organisation and development opportunities for staff.

Chapter 8: Conclusions and Recommendations

This chapter summarises the project and identifies the achievements of the project in relation to its aims. It evaluates the project outputs and their potential impact on the profession and further explores the vision for transforming personalised nutrition practice. Recommendations are recapped, and dissemination of the findings are discussed, followed by a conclusive discussion.

This research project aimed to evaluate, construct and validate standardised clinical data-collection tools for obesity management in personalised nutrition practice. The main questions the project was designed to answer are:

1. Is it possible and ethical to standardise a personalised approach to nutrition practice?
2. If so, what tools can be constructed and validated to help individual health history data collection, clinical decision making and clinical outcome analysis to enable the development of a case-by-case evidence base for personalised nutrition practice in the management of obesity?

A clear distinction was made in Chapter 2 that this project did not seek to standardise personalised nutrition practice through the development of clinical guidelines. It has sought to standardise health data-collection methods from individual clients', so the data can be statistically analysed and compared. Clinicians should use standardised, validated and reliable measures to evaluate their intervention decisions and clinical outcomes (MacDermid, Grewal, & MacIntyre, 2009). In order to provide a comprehensive personalised nutrition practice approach, data-collection methods should aim to capture as many influences on disease expression as possible, including: genetic, genomic, physiological, pathological, biochemical, dietary, behavioural, lifestyle, cultural and the social aspects of care, as well as the client's own values and views regarding their outcomes.

There were ethical concerns with utilising standardised data-collection methods related to issues of validity, inclusivity and non-compliance. However, standardising data-collection methods may enable better auditing and analysis of intervention efficacy and therefore help to minimise the risk of harm. There were also numerous ethical considerations in relation to the development of a case-by-case evidence base. Chalmers et al. (2013) pointed out the blurred lines between the benefits of research and providing clinical care, issues included: privacy and sharing/pooling of data, consent, discrimination and comprehensiveness of reporting. These issues need to be fully considered within a governance framework for the development of a case-by-case evidence base.

It has been possible to construct new tools which aim to standardise individual health history data collection and clinical outcome analysis to support clinical decision making, but it has not possible to validate these tools. This complex project has been the first of its kind in trying to pull together various nutritional practice approaches to support the development of robust translational bioinformatics tools using a pathophysiological reasoning approach, and it has been ambitious from the outset. Although there were setbacks in terms of pilot trialling and validating these tools, the learnings provided by these findings have been insightful for understanding what further work needs to be done in order to achieve standardisation of data-collection methods to enable the vision of transforming personalised nutrition practice and the development of a case-by-case evidence base.

8.1 Standardising data-collection methods in personalised nutrition practice

One of the aims of the project was to evaluate the ethics, limitations and opportunities of standardising data-collection methods in personalised nutrition practice. Results highlighted that participant practitioners were using their own methods to assess individual health data through interview at the consultation setting and through the use of health questionnaires they had developed themselves or adapted from other sources. Subsequent interviews highlight that practitioners developed their own clinical data-collection methods to support their own clinical practice approaches.

Variations in data gathering and practice approaches increases the variation of data available to support clinical decision making among practitioners. This is clearly problematic and undermines an evidence-based approach. When clinical decisions are widely divergent clinical outcomes suffer and patient safety may be compromised (Rozich et al., 2004). Standardisation of data-collection tools is therefore required to increase data quality and uniformity of practice, reduce practice variation and improve patient safety (Rozich et al., 2004).

Intervention effects are variable (Zeevi et al., 2015, Whelan, Hollar, Agatston, Dodson, & Tahal, 2010) so in order to make evidence-based personalised nutrition a reality we need to utilise standardise health data-collection methods which enable the data to be stratified into subgroups where it can be analysed and compared. Interventions can then be validated, and efficacy predicted for various subgroups. Limiting the ethical concerns associated with nutritional categorisation, including discrimination and ‘healthism’, needs to be further considered as a possible unintended consequence of developing this approach.

An unexpected outcome of the Delphi method was that, through the development of the tools, a consultation approach emerged. It was also clear from practitioner interviews that

clinical tools are utilised to support and guide the practice approach. There were barriers in trying to implement standardised tools into a range of practice approaches during the pilot trial. Varying practice approaches may be a consequence of various data-collection approaches. Structured data-collection methods may therefore help to develop a more uniform practice approach for personalised nutrition practice.

Interview results highlight that the range of practice approaches has far-reaching implications in terms of how the nutritional therapy profession is perceived and understood by mainstream health care and the public. Interview results suggest variations in practice approaches could be due to variations of training provision, which should be further investigated by NTEC. A review of the NOS and core curriculum on what constitutes a nutritional therapy practice did identify a lack of clarity in what constitutes a nutritional therapy model and process in comparison to dietetics practice, which may explain the variations in clinical training provision.

It is difficult to encapsulate a succinct description that gives clients and potential collaborative professionals a firm grasp of what can be expected from nutritional therapy. If this was achieved it may enable the profession to communicate more directly and succinctly with the public to build engagement and ease the ability to further undertake large scale advertising, nationwide intervention programmes, the development of collaborative relationships, integrated education and CPD events and help facilitate acceptance of nutritional therapy in mainstream health care. I plan to undertake postdoctoral research to develop the description, model and process for NT practice as this fits with my ambition to make nutritional therapy accessible through mainstream health care.

The therapy element of nutritional therapy is another consideration raised by feedback on the tools which highlighted that the therapeutic intervention element of practice has an impact on the outcome of any intervention programme. There is a lack of appropriate therapeutic relationship measures for nutrition practice and it may never be possible to completely tease out the benefits of nutrition intervention from the practitioner's therapeutic intervention. Nutrition practice is about both the interpersonal therapeutic intervention and the nutritional interventions themselves, and the influence of these are likely to be as unique as each individual practitioner and each individual client. Until we have appropriate tools and methods to measure them robustly, we cannot properly address questions which ask: what works, for whom, and in whose hands.

This project stemmed out of the observation that nutrition and health care practitioners do not routinely assess data on the outcomes of their patients, and even less frequently compare the outcomes of similar patients (Kurtin & Stucky, 2009) in any meaningful, robust

or standardised way. New tools appear to enable analysis on the outcomes of interventions, but the pilot trial was too small to draw any firm conclusions. Zeevi et al. (2015) demonstrated that robust analysis of numerous data outcomes can inform intervention decisions in personalised nutrition practice, leading to predictive, preventative, personalised and participatory (P4) practice.

It also appears possible to create the tools which enable standardised data-collection methods that do not detract from personalised nutrition practice. With further development, new clinical tools in personalised nutrition practice could enable a standardised personalised approach to nutrition practice and support the development of a new case-by-case evidence database. The results of the literature review and interviews highlight limited ethical concerns with the utilisation of standardised data-collection methods – in fact they may help to increase data quality and uniformity of practice, reduce practice variation and improve patient safety (Rozich et al., 2004).

As discussed, ethical issues in relation to the development of a case-by-case evidence base and data mining are broader and would need to be addressed with the collaborative development of a governance framework alongside the development of the evidence database. Some of the issues of privacy, confidentiality and data protection can be overcome by anonymised data collection and ensuring GDPR compliance. Clarity and transparency related to ownership, trustworthy intermediaries and legal protection are also essential (Harvey et al., 2012). There are also problems with larger scale data analysis, such as sampling bias, which would need to be further examined by statisticians and data analysts.

Addressing these does not help overcome the concern that the increase of data to support clinical decision making through the increased power of prediction may increase the authority of the practitioner and promote paternalism (Gefenas, Cekanauskaite, Tuzaite, Dranseika, & Characiejus, 2011). Nor does it address discrimination issues for those who cannot afford to pay for this approach, or how such an approach might successfully be integrated into NHS practice. Of course, acceptance of nutritional therapy into mainstream health care provision may help to address the issue of inequality of access. The issues of patient ability to access, read, complete and interact with complex tools are hurdles that can be overcome with practitioner support.

Making questions and tools non-compulsory was seen as an ethical requirement. Clinical data is often inconsistent, inaccurate and incomplete, so any data integration approach must have a method for separating non-validated or poor-quality data from accurate, complete and standardised data (Sheldon & Ou, 2013). Quality and completeness of data sets are

essential. Smaller, easier, more frequent questionnaires may aid client compliance and data completeness. However, there is a need for continued quality control and re-analysis of the validity of the data gathered by new tools (Sheldon & Ou, 2013).

Zeevi et al. (2015) demonstrated that it is possible to gather complex health behaviours and related influences through comprehensive, standardised profiling and smartphone applications. Real-time assessment of diet intake, through the use of repetitious and ongoing analysis over long time periods, is helping to overcome the issues associated with retrospective dietary analysis (Gibson, Ferrucci, Tangrea, & Schatzkin, 2010; Michels, 2003). However, the burden of having to constantly input diet and physical activity can affect the validity of the data. It would be beneficial if food diaries/journals allowed clients to upload food photographs rather than input data. It appears the development of applications and online assessments which allow for nutrient analysis of content from photos to be analysed has already begun (Martin, Kaya, & Gunturk, 2009).

In order to enable standardised data-collection methods in personalised nutrition practice there has to be training provided to students and practitioners on the use of tools and practice approaches. This training should be embedded into the NOS and core curriculum with clear recommendations, naming specific robust and validated data tools for use in practice. The results highlight that practitioners are not researchers and may not be clear about the purpose and value of the data being collated, further emphasising the need for training. Hannah et al. (2009) recognise that in order to successfully engage practitioners in the use of standardised health records and to achieve successful transformation of clinical practice processes, managing cultural change and highlighting the benefits to the patient and their own practice are key.

8.2 New tool construction

One of the aims of the project was to construct new clinical tools for health data collection, clinical decision making and clinical outcome analysis which standardises case data-collection methods and enables the assessment of the efficacy of interventions. Initially, it was thought, through collation and evaluation of existing tools and the practitioner survey on the use of tools in clinical practice, that the most frequently used validated tools could be integrated into an online format, and then validated. Instead the results highlighted that validated tools were not frequently used in nutrition practice and that there were no standardised data-collection methods; each practitioner who participated was gathering data in their own unique way.

Results from gathering and analysing existing tools highlighted the need to focus tool development on statistically analysable baseline and follow-up measures – before and after

interventions – and tracking of client interventions compliance. The tools should include the broader considerations of health and disease and should include social, cultural, lifestyle, environmental and economic factors. The tools should also enable the data to be stratified into subgroups where it can be analysed and compared, and then interventions can be validated for various subgroups. The Zeevi et al. (2015) flagship study was the first to use this systems biology, P4, personalised nutrition approach.

The literature reviews highlighted that a personalised approach needs to understand mechanisms of pathophysiology, that mechanistic reasoning has the ability to make inferences from the knowledge to inform clinical decision making (Nardini, Annoni, & Schiavone, 2012), and although mechanistic reasoning is not without limitations (DeBusk, Sierpina, & Kreitzer, 2011), mechanism of actions of interventions which target underlying pathophysiological mechanisms facilitate a personalised rather than disease-centred practice approach. Assessments and approaches for undertaking mechanistic reasoning in clinical practice are currently lacking. Results from the Delphi surveys highlight new tools created measure a comprehensive range of pathophysiological mechanisms affecting individual aetiology of obesity to enable mechanistic reasoning. Chapter 4 explored the issues with the development of questions related to pathophysiological mechanisms and the need to validate the questions against laboratory test data. Further research is required to fill the gaps in current mechanistic understanding of obesity which CNELM is currently undertaking. CNELM has developed a mechanism review research method which students undertake for their research projects. This is developing mechanistic insight and enhancing the understanding of its value to nutrition practice and clinical reasoning.

Results from the categorisation and evaluation of existing tools, practitioner survey and Delphi method highlighted that the only validated assessments frequently used in practice were those used to assess diet intake (e.g. 24-hour diet recall) and physical activity recall. However, the limitations of retrospectively remembering dietary intake and exercise activities (Michels, 2003) can be overcome with real-time, repetitious and ongoing assessment (Gibson et al., 2010; Michels, 2003), through the use of online real-time smartphone applications which already exist for dietary intake and physical activity assessment. There was therefore no need to construct these tools as part of this project.

The results also highlighted that there was a gap in tools which gather data on individual health history, family history and sociocultural influences on obesity and that, although some practitioners undertaking outcome analysis did use validated tools, such as the MYMOP, the assessment of clinical outcomes was not measured against intervention compliance. It has therefore not been possible to measure the outcomes in relation to interventions in any robust manner. To enable CER a number of patient-centred outcomes need to be compared

to assess the impact of interventions on symptoms, QOL and biomarker changes (Greenfield & Kaplan, 2012). Tool development focused on these areas, which led to the creation of four new clinical tools:

1. **Tool 1: Personalised health history questionnaire** – which aims to collect health history and family history data around mechanisms of obesity, as well as collect a range of baseline health measurements. This questionnaire is for the patient to complete before the first consultation.
2. **Tool 2: Intervention record** – which aims to capture which interventions were recommended by the nutrition practitioner. The practitioner should complete this at the end of each consultation.
3. **Tool 3: Personalised health follow-up questionnaire** – which aims to measure any changes to the client's health measurements after intervention. This questionnaire is for the patient to complete before their return consultation.
4. **Tool 4: Achievement record**– which aims to capture which interventions the patient complied with. This tool is completed by the nutrition practitioner at the outset of each return consultation.

Tools need to further include client values, preferences, abilities, objectives, values, self-expressed needs, economic resources and anthropometric data, biomarker and laboratory analysis (including genomic and genetic tests), real-time diet (food intake, quality, quantity, habits, preferences etc.) and lifestyle assessment (exercise/sleep quality and amount etc.), and social, psychological, personality and behavioural dimensions of disease, but this was beyond the capacity of this project at this time. There was conflict in participant feedback between keeping tools streamlined, easy and user-friendly as well as comprehensive, thorough and robust. It was clear from the Delphi responses that it is incredibly difficult to prioritise what health data should be collected in personalised nutrition practice, because it is all important due to the complex nature of factors influencing individual obesity development and clinical decision making. The ability to comprehensively capture all the influences on health outcomes over a lifetime is not achievable through these tools and may never be achievable due to the huge number of complex combinations and permutations of genetic, epigenetic, lifestyle, diet and environmental factors and, in reality from a clinical perspective, there are issues of invasiveness, ability, time constraints and compliance to manage. Yet, the tools constructed do provide a good start.

For example, health risk data in combination with FHH data to support clinical decision making is considered to be a critically important step in the advancement of personalised health care (Ginsburg & Willard, 2009). Historically FHH has not been well utilised because it has lacked standard and valid collection methods (Ginsburg & Willard, 2009). Numerous

assessments to establish the validity and reliability of these tools still need to be undertaken, including the validity of mechanistic clusters of questions. They should be undertaken directly with the target population to limit the barrier of engaging client participation through practitioners. Validity, quality and accuracy of data provided is clearly key to avoid misleading patients and practitioners (Finnegan, 2009). Inaccurate and unreliable data is not useful in guiding clinical decision making.

These tools assess a huge range of clinical outcomes, although the clarity of the purpose of each question needs to be made clear so practitioners can differentiate between the research and clinical perspectives of the tools. These tools appear to support analysis of the impact of interventions on clinical outcomes. However, like Zeevi et al., (2015) real-time physical activity, sleep and food intake measures using smartphone applications in combination with comprehensively profiling is required. It is recommended that practitioners use existing online and smartphone tools for dietary analysis and tracking. I have been working with one student on a research project which aims to evaluate and compare the functionality and validity of online dietary assessment applications in order to offer practitioners a comparative analysis of these tools. Relationships have been forged with software developers and it may be possible to work with existing online tool application organisations to develop a more robust method for assessing health changes as a result of nutritional intervention.

The results demonstrated an incongruence with creating tools for personalised nutrition practice that focused on a condition such as obesity. Focusing on obesity is a disease-oriented approach rather than a personalised approach. The complexity of client's health issues (clients rarely present with obesity or any other disease in isolation) means it would be better to have baseline tools that do not focus on obesity but can be used for all clients.

In terms of further developing comprehensive profiling that is suitable from a clinical perspective than the development of numerous, small, quick and easy to complete validated tools appear to provide a solution. For example, single tools for each of the following that should not take more than half an hour, preferably less, to complete:

- administrative data (address, GP address);
- patient goals and outcomes;
- presentation, risk factors and red flags;
- health history, health currently and ongoing real-time analysis;
- family history;
- food behaviour, dietary influences and intakes over a lifespan, currently and ongoing real-time analysis;

- lifestyle history, lifestyle currently and ongoing real-time analysis;
- exercise history, exercise currently and ongoing real-time analysis;
- weight history, weight currently and ongoing real-time analysis;
- history of medical interventions, current medical interventions and ongoing analysis;
- history of other interventions (e.g. supplements), currently and ongoing real-time analysis;
- patient/client values, preferences, abilities, motivation, objectives, self-expressed needs;
- history of economic resources and sociocultural influences, current influences and ongoing analysis;
- psychological, personality and behavioural assessments and ongoing behavioural analysis;
- self-perceived stress;
- QOL assessments;
- therapeutic alliance assessment;
- anthropometric assessments;
- smoking and addiction history, currently and ongoing analysis; and
- female pregnancy and contraception history.

These represent the categories and findings discussed in Chapter 5. Like health data, all tools should all interrelate. These tools already gather data on physiological mechanisms contributing to obesity including, addiction, pregnancy, medications, stress and smoking (see Table 6). There should also be tools which cluster questions to a range of evidence-based physiological functions involved in disease expression, such as:

- digestion, assimilation and elimination;
- immune system function;
- hormonal function;
- neuronal function;
- energy production;
- structural integrity;
- repair functions;
- detoxification function;
- psychological and emotional management; and
- transport and bioavailability.

Signs and symptoms clustered within each of these physiological functions suggest pathophysiological mechanisms such as: dysbiosis, dyslipidaemia, hormonal imbalance etc.

and the need for further investigation into their influence on disease expression with biomarker and laboratory analysis. Tool development requires further underpinning mechanistic insight. It may be possible to validate these tools against biomarker and laboratory analysis. Independent cohort studies are also required to validate the statistical prediction models of mechanisms of actions of intervention targeted to these mechanisms to support these physiological functions. This would help to provide an evidence-based approach to pathophysiological reasoning and personalised nutrition practice.

This approach would also support the pathophysiological reasoning paradigm. Numerous tools may enable practitioners to gather standardised health data for numerous individuals via a variety of practice approaches. Over time, it may be possible to develop long and short versions for some of these tools, similar to the SF-36 and short SF-12 health status survey tools, allowing practitioners to discuss, negotiate and agree with their clients which assessment methods are best suited to the client at any given time. It gives practitioners an opportunity to build rapport before requesting completion of more invasive questions or tools. This approach should also be client-led; clients determine which range of non-compulsory tools or ongoing analysis they engage with at different stages of the consultation process. This would enable a more personalised data-collection approach using numerous standardised tools and therefore support personalised nutrition practice. Clearly, only fully completed tools should be used for data mining and substantiating evidence to inform clinical practice.

Evidence-based personalised nutrition practice needs to be rooted in the use of validated tools in the same way other health professions accessible through mainstream health care do. Postdoctoral research will aim to develop and validate each of these tools. Evaluation of their impact on the practice process is also required, and the analysis of multiple tools by functional medicine practitioners could be insightful. Again, this research fits well with my ambitions. I believe this would provide an opportunity to make personalised nutrition practice a unique practice approach, which could attract a range of health care practitioners, including NTs, nutritionists and dietitians who are keen to develop their health care practice and professional development in this way.

8.3 Transforming personalised nutrition practice

One of the aims of the project was to enable the development of a new case-by-case, evidence base for personalised nutrition practice in obesity management. This discussion expands on the vision for transforming personalised nutrition practice through the development of an online application which gathers data via these bioinformatics tools and collates them to develop a case-by-case evidence base.

Bereczki (2012) argued that PM is an upgrade of EBM, because PM allows for the use of a range of sources of evidence, including patient preferences and individual expertise. It is not one approach, or the other, it is plurality of evidence that should form the basis of basis of modern day health care practice (A. Miles, Loughlin, & Polychronis, 2008). Systems biology offers the approach to analysing and comparing this complex health data, including the outcomes of interventions, which can translate findings to inform clinical practice, hence making it translational (Feldman, 2015). The risks of nutritional categorisation/stratification raised by Fierz (2004) and the issues of healthism and the medicalisation around food do require further exploration (Görman, 2007).

Zeevi et al. (2015) have led the way in demonstrating that machine learning algorithms can be used to integrate and compare complex data from a range of individual, multi-dimensional health influences in order to make predictions on the outcomes of interventions, and use independent cohort studies to validate the statistical prediction models, to achieve a personalised nutrition approach that extends beyond stratification based on genetic tests and beyond personalisation, meaning tailoring interventions to the individual's preferences and needs.

The literature review highlighted the value of developing bioinformatics tools in promoting the practice of personalised and systems medicine, because these tools can integrate clinical and laboratory data and also enable the development of case-by-case evidence base that would allow for data mining and knowledge discovery (Yan, 2012). The literature review justified why these tools should enable pathophysiological reasoning. As discussed, new tools should collate health data that helps to uncover individual functional imbalances in physiological mechanisms that underpin disease development. Physiological mechanism research is currently limited because the EBM paradigm ranks it as low value, however understanding pathophysiological mechanisms is essential for clinical decision making because it allows for consideration of mechanisms of action of interventions to be targeted to ameliorating mechanisms of pathophysiology. It was clear from tool development in this project that this approach to collecting health data has not previously been undertaken. Further research is required to fill the gaps in mechanistic understanding.

Developments in complex computational network analysis are enabling the modelling of genomic, genetic, epigenetic, biochemical, metabolic and proteomic pathways. Systems biology seeks to integrate this knowledge and study their interactions for a thorough understanding of disease (Yan, 2012). Modelling mechanisms of actions of therapeutic interventions, such as food and nutrients, could also be integrated to understand how they impact numerous physiological mechanisms both short- and long-term.

In the future, new tools could triangulate clinical data gathered with other sources, such as real-time food intake, supplement ordering, sleep and exercise tracking, supermarket loyalty card shopping data, social network data, gym membership data etc. It would be beneficial if the food diaries/journals allowed users to upload photographs. Numerous data-collection methods are important for improving the validity of data (Golafshani, 2003). The development of the internet of things (physical devices, home appliances, smartphones, vehicles etc.) and technologies for big data analysis may enable this. This data can be continually analysed and monitored against changes in biomarkers (cholesterol, PPGR, cholesterol etc) to determine how they affect individual physiological and pathophysiological mechanisms. SML is then utilised to predict the efficacy of lifestyle, dietary and exercise adaptations, as well as medications and nutritional supplements, which can be utilised to ameliorate underlying mechanisms of pathophysiology and promote optimal physiological function. It may even be able to provide data to a range of devices to inform real-time decisions on food intake, exercise and sleep and alert practitioners to contact individuals who have red flag issues.

Kawamoto et al. (2005) identified that clinical decision support which provides actionable recommendations that are delivered automatically, at the time of decision making, have significantly improved patient care. Therefore, a case-by-case evidence base which translates data to create personalised clinical decision support tools should deliver it at the time of decision making utilising interactive technology (Sheldon & Ou, 2013). The approach by Villa et al. (2012) suggests a system which presents a range of evidence-based practice options which can be discussed with patients in terms of their needs and preferences and therefore also enables person-centred tailoring to individual needs. This system should also alert practitioners to relevant updates as a result of new knowledge (Sheldon & Ou, 2013).

A case-by-case evidence base may enable the dissemination of personalised nutrition research, and not just structured case studies but longitudinal evidence for the outcomes of groups of stratified cases. Data collected from practitioners on their management approaches, for example, time spent on lifestyle coaching, teaching cooking skills, developing self-awareness, mindfulness, stress management skills etc. may allow further assessment of the influence of practice approach and determine what works, for whom and in whose hands.

Collaboration with laboratories may also allow for the integration of patient test results. Data from the database could not only inform patients and practitioners, it could potentially inform clinical pathology laboratories about the development of new tests and physiological functional assessment. Tools can link to the evidence-based literature in numerous ways, including interpretive guides on test results provided by laboratories.

An online data-collection and data provision system, accessible for a range of health practitioners and consumers, should save practitioner time in researching and evaluating evidence-based recommendations. Allowing time for incorporating coaching strategies alongside nutritional interventions to support behavioural change can positively influence client's engagement, confidence and compliance with personalised weight loss programmes (Miles & Barrow, 2018). The application could also host forums or communities where groups of patients can chat, and practitioners can post information. Social support with internet communities can play a pivotal role with compliance. The development of such an application is clearly ambitious, labour-intensive and costly.

8.4 Problems with the feasibility of the mission of the project

The mission of the project are its long terms aims: to centralise the data gathered by a range of short, standardised and validated clinical tools that have been created to enable the develop a case-by-case evidence base. It aims to apply statistical machine learning to these new data sets to facilitate probabilistic predictions on the outcomes of interventions; and to enable new research to be undertaken to determine the efficacy of a range of nutrition interventions for personalised nutrition practice.

Ogden (2016) highlights the gaps inherent in the translation process from protocol to individual behaviour as well as the issues with patient variability in terms of their adherence to interventions. The variability of the data reported and collated underpin the issues with measuring interventions (independent variable) and outcomes (dependent variable). Ultimately, it is the quality of the data input that determines the quality of the data output. Enforcing data standards and quality would be a significant challenge. Adjustment for differences in individual variables would be critical in the assessment and comparison of client's outcomes data to inform intervention decisions for future clients (Krousel-Wood 1999).

Nutrition interventions require behaviour change (diet, exercise supplements etc). Behaviour changes comes from the individual client not the intervention. The differences in practitioner approaches and their unique therapeutic relationship with each client can make a significant difference to the client's experience, their behaviour change and ultimately their health outcomes (Kelley at al 2014, Pan, Luie 2016). Although we may be able to identify these variables and potentially measure these experiences we cannot limit or solve the issue of patient variability, their behaviour or adherence to interventions, in future clients. Ogden (2016) highlights benefits of variability in practice, how practice variability offers flexibility and a richer professional environment than one that is standardised or systematised. The

variability of individual clients requires variability in practice approaches in order to support effective behaviour change but it is exactly these variations that provides issues with measuring and extrapolating data from case-by-case data sets.

The problems with the feasibility of the mission of the project lie in the limitations due to the numerous gaps and quality of the data collected. It may never be possible to measure the numerous gaps or the nuances of the therapeutic relationship. Variability in behaviour and compliance of clients exists and cannot be ignored. There lies value in variability of practice and the art of the therapeutic relationship which aims to enhance the consultation process and client experience. Developments in the standardisation of data collection in nutrition practice should therefore support freedom and flexibility in the consultation process and where possible adjust for differences in individual variables.

8.5 Recommendations

This section aims to recap all the recommendations made throughout the project. Dissemination of the project findings will include: teaching at my academic institution and other institutions, publication in peer-reviewed scientific journals, presentation at academic and industry events and conferences as well as research supervision. The results of this project highlighted the importance of publishing data on the validity and reliability of new tools across a range of journals as well as promoting them through professional bodies and CPD events.

CNELM is in the process of changing the name of the Nutritional Therapy Practice Diploma to the Personalised Nutrition Practice Diploma as a result of my recommendation. Pathophysiological reasoning to support clinical decision making will be further embedded into the syllabus and learning outcome content for this programme. The name change for the practice diploma may attract prospective, or already qualified, nutrition practitioners such a dietitians and nutritionists who wish to develop their professional skills with a personalised nutrition practice pathophysiological reasoning approach. This may, in time and with other developments, enable CNELM to pursue accreditation of its personalised nutrition programmes with the Health Professions Council (HPC) and/or the Association for Nutrition (AfN).

Postdoctoral research will aim to develop and validate numerous online tools as discussed, to support personalised nutrition practice and pathophysiological reasoning, and to enable the vision for developing a case-by-case evidence base. This may be achievable through my own research and research supervision within my role at CNELM. Fulfilling those goals also requires further research to develop valid clinical questions around mechanisms of

pathophysiology, develop mechanistic reviews and mapping, research to integrate and compare the complex data mechanistic insight provides, developing robust therapeutic relationship measures for nutrition practice, research to enable triangulation of health data with other sources such as real-time data tracking, studies to validate statistical prediction models and numerous ongoing validity assessments for tools.

Postdoctoral research will also focus on developing the description, model and process for personalised nutrition practice and nutritional therapy practice. I will continue to seek opportunities for acceptance of nutritional therapy practice in mainstream health care provision. Research should also be undertaken to identify how NTs can raise their professional profile through professional marketing strategies and successfully achieve nationwide online nutritional therapy consultations.

Further research is also required to explore the potential stigma of nutritional practitioners working with obese individuals and how nutrition practice can better engage with an obese population as well as identify actions to help limit wider social stigma for this population group.

Some of the tools reviewed as a part of this project were utilised in clinical trials of anti-obesity drugs or after bariatric surgery, so utilising those tools in clinical trials of nutrition interventions may allow for a comparison of nutrition intervention to drugs and surgery, which would provide valuable CER.

In terms of developments within my work and professional environments, I will continue to teach personalised nutrition and support CNELM with the development of its programmes to help provide integrated education and CPD events for a range of health professionals, as well as support their aim to:

> Build a Research Centre, with active postdoctoral, PhD and MSc researchers focusing on an integrated approach to evidence based personalised medicine… our aim is also to build bridges between academic communities: bringing together researchers in statistical machine learning and systems biology with practitioners in nutritional therapy and functional medicine.
>
> (CNELM 2017)

As discussed, I am keen to support CNELM with the development of a PhD research programme, in collaboration with an awarding institution, which would attract researchers to help undertake this research. There appears to be an interest among graduates and students. There is funding available for research into nutrition and obesity from the National Institute for Health, the Medical Research Council and the UK government for developing personalised health technologies that better target interventions to patients. With funding, CNELM may be able to build its research centre. PhD students can also support delivery of academic content to CNELM's undergraduate and postgraduate programmes.

I also aim to continue to develop my own teaching on: developing research methods for nutrition practice, ethical reasoning, robust clinical outcome analysis and the use of electronic health records and standardised tools to support practice, as well as undertaking supportive obesity analysis and management in practice. Teaching at other institutions would also help to raise awareness of my research findings and support a movement towards a personalised practice approach, as well as raise the profile of CNELM.

I aim to work with existing online tool application organisations to develop a more robust method for assessing health changes as a result of nutritional intervention for existing diet and exercise tracking applications. As discussed, research supervision is already underway to evaluate the functionality of existing applications, which may enable identification of the most suitable software organisations to collaborate with.

I aim to work directly with professional bodies to support the development of collaborative relationships with other professional bodies e.g. bariatric surgeons, counsellors and other health care professions. I aim to support NTEC with any investigation on the variation of clinical training education delivered across different training providers and any updates they may wish to make to the NOS and core curriculum to better define what constitutes a nutritional therapy practice approach. I also aim to help the development of clear recommendations for, and naming specific, robust and validated data tools for use in nutritional therapy practice.

I aim to work with BANT to continue the development of their centre of excellence, to support the development of large scale advertising to raise awareness of NTs and the development of nationwide online nutritional therapy consultation programmes. In order to achieve these, the development of a cohesive and succinct explanation of the nutritional therapy approach is essential.

8.6 Conclusions

This collaborative research project has been committed to enabling the development of a new, case-by-case, evidence base for personalised nutrition practice in obesity management. It has constructed four new clinical tools which: take a pathophysiological mechanism approach to data collection and analysis. These tools aim to be meaningful to different nutritional perspectives as well as suitable and interpretable by any mainstream health care practitioners. It has identified barriers and complexities for integrating standardised tools into clinical practice and provides recommendations for how standardised tools can be successfully integrated into practice.

This project met with its objectives, it: explored potential ethical issues relating to the use of standardised tools in nutritional therapy practice and collated, categorised and evaluated

existing tools which support individual health history data collection, clinical decision making and clinical outcome analysis in nutrition practice. It identified the practitioners' and clients' experience of using existing tools, their strengths and weaknesses, to inform new tool development and explored the views and experience of academics and statisticians on robust tool development to inform new tool development. It collaboratively constructed new tools and pilot trialled them with a small number of practitioners and their clients. The project then evaluated ways in which standardised tools could be implemented into nutritional therapy practice.

Key stakeholders have included CNELM, Middlesex University, professional nutrition bodies such as BANT and NTEC as well as research participants including a variety of nutrition practitioners, and their clients seeking who were seeking to lose weight. Feedback on the use of the new clinical tools highlighted, for those that engaged with it, experienced raised awareness and understanding of the factors contributing to obesity. Practitioners, academics, statisticians and researchers are stakeholders who were brought together to contribute to the development of new clinical tools. The results of the project have created new knowledge in terms of understanding, defining and developing an evidence-based personalised nutrition practice approach which can lead to major change initiatives and enhance and strengthen the nutrition profession, particularly the nutritional therapy profession.

This project has positively impacted on further research in terms of supervising student research projects and achieved publication of research, which raises the profile of CNELM. It has positively impacted staff development. Recommendations for further research and professional developments have been described. Research success is also important for Middlesex University in order to meet their aims and objectives as well as demonstrate it can fulfil the requirements and expectation for other doctoral candidates. The project meets the Level M and Level D descriptors as described in the projects module handbook.

My own skill development was explored in Chapter 7, my plans are to continue on the journey of lifelong learning, to enable other student's success on their journey, to continue to enhance the nutritional therapy profession and to strive for the development of a new, case-by-case, evidence base for personalised nutrition practice and the integration of nutritional therapy in mainstream health care provision.

8.7 Chapter summary

This chapter has summarised the project and drawn conclusions and recommendations from the project's findings. It has addressed the research questions the project was designed to answer and evaluated the project outputs and its impact on the profession.

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Appendix 1 Example literature review search description form

Review 1: Search Description Form 1	
Student Name: Michelle Barrow	Student Number: M00118142
SEARCH TERMS: **'Evidence based medicine'** **AND 'personalised'**	
INCLUSION CRITERIA: Topic related to evidence based practice in general Dates ranged from 2003 to present	
EXCLUSION CRITERIA: Topic related to specific disease/health condition or intervention Repeat findings Topic not related Foreign Language Papers	
OTHER INFO:	
SEARCH ENGINES USED: Summon	**SEARCH DATE:** 12th October 2013
SEARCH NUMBER: 1	in title and abstract Excluded newspaper articles and book reviews
NUMBER OF RESULTS: 0	**NUMBER OF RESULTS INCLUDED:** 0
Comments:	
SEARCH ENGINES USED: Google Scholar	**SEARCH DATE:** 12th October 2013
SEARCH NUMBER: 2	In the title

NUMBER OF RESULTS: 2	**NUMBER OF RESULTS INCLUDED:** 2
Comments:	
SEARCH ENGINES USED: PubMed	**SEARCH DATE:** 12th October 2013
SEARCH NUMBER: 3	Title and abstract
NUMBER OF RESULTS: 8	**NUMBER OF RESULTS INCLUDED:** 2
Comments: 3 excluded related to specific diseases or treatments, 1 was in Russian except for the abstract, 1 was in Italian except for abstract, 1 was repeat finding	
SEARCH ENGINES USED: Cochrane Library	**SEARCH DATE:** 12th October 2013
SEARCH NUMBER: 4	**abstract**
NUMBER OF RESULTS: 5	**NUMBER OF RESULTS INCLUDED:** 0
Comments: all related to specific conditions	
SEARCH ENGINES USED: Science Direct	**SEARCH DATE:** 12th October 2013
SEARCH NUMBER: 5	In the abstract

NUMBER OF RESULTS: 8	**NUMBER OF RESULTS INCLUDED:**
Comments: 7 on specific conditions, 1 in Spanish.	
SEARCH ENGINES USED: RSM all Databases	**SEARCH DATE:** 12th October 2013
SEARCH NUMBER: 6	In the abstract
NUMBER OF RESULTS: 341	**NUMBER OF RESULTS INCLUDED:** 24
Comments: most excluded due to not being related, discussing a specific treatment or condition or foreign language paper. A number of articles were on the pharmaceutical industry and how they were using pharmacogenetics in clinical medicine but that was deemed not relevant.	

Appendix 2 Literature reviews keywords, inclusion and exclusion criteria and number of results table.

Review and Search number	Keywords:	Number of initial results	Inclusion criteria	Exclusion criteria	Number of results included for full review	Papers excluded (see appendix 3)	Final papers included
1.1	'Evidence based medicine' and 'Personalised'	364	Topic related to evidence based practice in general. Dates ranged from 2003 to present	Topic related to specific disease/health condition or intervention. Repeat findings. Topic not related. Foreign Language Papers.	28	9	19
1.2	'functional medicine' and 'personalised'	356	Topic related to functional medicine practice in general. Dates ranged from 2003 to present.	Topic related to specific disease/health condition or intervention. Topic not related. Foreign Language Papers.	12	5	7
1.3	'Personalised Nutrition'	245	Topic related to evidence based and personalised practice in general. Dates ranged from 2003 to present.	Topic related to specific disease/health condition or intervention. Reviews of nutrigenomics, nutrigenetics and metabolomics. Topic not related Foreign Language Papers.	21	6	15
1.4	'Clinical psychoneuroimmunology'	452	Topic related to psychoneuroimmunology practice in general. Dates ranged from 2003 to present.	Topic related to specific disease/health condition or intervention. Topic not related. Foreign Language Papers.	2	0	2
1.5	'mechanistic evidence' and 'evidence based medicine'	66	Topic related to evidence based practice in general. Dates ranged from 2003 to present	Topic related to specific disease/health condition or intervention. Repeat findings. Topic not related. Foreign Language Papers.	8	2	6
1.6	'functional medicine' and 'obesity'	28	Topic related to functional medicine practice in general. Dates ranged from 2003 to present	Topic related to specific disease/health condition or intervention other than obesity. Repeat findings. Topic not related. Foreign Language Papers.	2	2	0
2.1	'ethics' and 'personalised'	170	Topic related to standardising a personalised approach Dates ranged from 2003 to present.	Articles on genetic testing, genome analysis and whole body scans. Articles relating to a specific condition other than obesity. Articles relating to a specific intervention, biobanks or pharmaceuticals. Topic not related. Foreign Language Papers.	15	3	12
2.2	'Standardising clinical tools'	104	Topic related to standardising a personalised approach Dates ranged from 2003 to present.	Topic not related. If related to a specific condition or treatment. Foreign Language Papers.	6	2	4

2.3	'standardising clinical practice'	564	Topic related to standardising a personalised approach Dates ranged from 2003 to present.	Topic not related. If related to a specific condition or treatment. Foreign Language Papers.	4	2	2
2.4	'standardi*' and 'personalised'	459	Topic related to standardising a personalised approach Dates ranged from 2003 to present.	Topic not related. If related to a specific condition or treatment. Foreign Language Papers.	5	2	3
3.1	'tool validity'	817	Focused on requirements and methods for developing, validating or evaluating tools. Dates ranged from 2003 to present.	Topic not related to developing, validating or evaluating tools. Tools not assessing health. Tools assessing a specific disease/conditions not related to obesity. Pediatric, geriatric or hospital based studies. Foreign Language Papers.	9	1	8
3.2	'validating questionnaires'	255	Topic related to validating questionnaires. Dates ranged from 2003 to present.	Topic not related to validating questionnaires. Tools not assessing health. Tools assessing a specific disease/conditions not related to obesity. Pediatric, geriatric or hospital based questionnaires. Foreign Language Papers.	2	1	1
3.3	'developing clinical tools'	50	Topic related to validating questionnaires.	Topic not related. Foreign Language Papers.	3	3	0

			Dates ranged from 2003 to present.				
4.1	'obesity tool'	827	Topic relating to assessment of obesity. Dates ranged from 2003 to present.	Topic not related. Focus on other health conditions. Pediatric tools. Treatment tools. Foreign Language Papers.	9	5	4
4.2	'assessment' and 'obesity'	1438	Topic relating to assessment of obesity. Dates ranged from 2003 to present.	Topic not related. Focus on other health conditions. Pediatric tools. Treatment tools. Foreign Language Papers.	35	22	13
4.3	'obesity' and 'questionnaire'	138	Topic relating to assessment of obesity. Dates ranged from 2003 to present.	Topic not related. Focus on other health conditions. Pediatric tools. Treatment tools. Foreign Language Papers.	23	10	13
4.4	'individual health history data' and 'tool'	242	Topic relating to assessment of health history. Dates ranged from 2003 to present.	Topic not related. Focus on other health conditions. Pediatric tools. Treatment tools. Foreign Language Papers.	7	4	3
4.5	'clinical decision making' and 'tool'	260	Topic relating to clinical decision making tools. Dates ranged from 2003 to present.	Topic not related. Focus on other health conditions. Pediatric tools. Treatment tools. Foreign Language Papers.	16	10	6

4.6	'clinical outcome analysis' and 'tool'	152	Topic relating to outcome analysis. Dates ranged from 2003 to present.	Topic not related. Focus on other health conditions. Pediatric tools. Treatment tools. Foreign Language Papers.	0		
4.7	'measure clinical outcomes'	260	Topic relating to clinical outcome assessment. Dates ranged from 2003 to present.	Topic not related. Focus on other health conditions. Pediatric tools. Treatment tools. Foreign Language Papers.	11	4	7
4.8	'obesity' and 'nutrition screening'	17	Topic relating to obesity and nutrition screening. Dates ranged from 2003 to present.	Topic not related. Focus on other health conditions. Pediatric tools. Treatment tools. Foreign Language Papers.	1	1	0
5.1	'signs and symptoms of obesity'	174	Topic related to obesity mechanisms, diseases, health conditions, red flags. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers.	9	4	5
5.2	'biomarker' and 'obesity'	345	Topic related to obesity mechanisms, diseases, health conditions, red flags. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers.	33	26	7
5.3	'genetic marker' and 'obesity'	110	Topic related to obesity mechanisms, diseases, health conditions, red flags. Dates ranged from 2003 to present.	Topic not related. Focused on other health conditions. Foreign Language Papers.	11	10	1
5.4	'epigenetic marker' and 'obesity'	89	Topic related to obesity mechanisms, diseases, health conditions, red flags. Dates ranged from 2003 to present.	Topic not related. Focused on other health conditions. Foreign Language Papers.	28	25	3
5.5	'Types of obesity'	176	Topic related to obesity mechanisms, diseases, health conditions, red flags. Dates ranged from 2003 to present.	Topic not related. Focused on other health conditions. Foreign Language Papers.	5	3	2
5.6	'mediator' and 'obesity'	105	Topic related to obesity mechanisms, diseases, health conditions, red flags. Dates ranged from 2003 to present.	Topic not related. Focused on other health conditions. Foreign Language Papers.	21	8	13
5.7	'obesity related disease'	188	Provides range of obesity related diseases, health conditions and red flags. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers.	19	4	15
6.1	'nutrition' AND 'obesity' AND 'assessment' OR	661	Provides obesity related tool. Dates ranged from 2003 to present.	Topic not related. Focused on other health conditions.	3	1	2

	'questionnaire' OR 'measure'			Foreign Language Papers. Only first 100 titles and abstracts reviewed for relevance.			
6.2	'diet' 'obesity 'assessment' OR 'questionnaire'	537	Provides obesity related tool. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers. Only first 100 titles and abstracts reviewed for relevance.	4	4	0
6.3	'psychol*' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'	190	Provides obesity related tool. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers. Only first 100 titles and abstracts reviewed for relevance.	5	2	3
6.4	'physical activity' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'	61	Provides obesity related tool. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers.	3	3	0
6.5	family history' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'	95	Provides obesity related tool. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers.	0	0	0
6.6	'physiol*' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'	48	Provides obesity related tool. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers.	1	0	1
6.7	Socio' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'	96	Provides obesity related tool. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers.	1	0	1
6.8	composition' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'	428	Provides obesity related tool. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers. Only first 100 titles and abstracts reviewed for relevance.	4	3	1
6.9	'blood' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'	125	Provides obesity related tool. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers. Only first 100 titles and	1	0	1

				abstracts reviewed for relevance.			
6.10	goals' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'	210	Provides obesity related tool. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers. Only first 100 titles and abstracts reviewed for relevance.	0		0
6.11	outcome' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'	111	Provides obesity related tool. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers. Only first 100 titles and abstracts reviewed for relevance.	0	0	1
6.12	'intervention' AND 'obesity' AND 'assessment' OR 'questionnaire' OR 'measure'	145	Provides obesity related tool. Dates ranged from 2003 to present	Topic not related. Focused on other health conditions. Foreign Language Papers. Only first 100 titles and abstracts reviewed for relevance.	0	0	0
TOTAL:		11,158			367	187	181

Appendix 3 Literature and tool search results tracker spreadsheet - example sheet.

Review 1 Search 1: 'Evidence based medicine' AND 'Personalised' in title and abstract AND 'personalised' in title and abstract													
Student Number: M00118142													
Search Engine/ source:	Search #	Result #	Citation:	available	Found in other searches:	year:	type of study:	methodology:	why the study was done:	Relevance to search topic:	Included/ Excluded:	Reason for exclusion:	Critical Summary:
Google scholar	2	1	Miles, A., Loughlin, M., & Polychronis, A. (2008). Evidence-based healthcare, clinical knowledge and the rise of personalised medicine. Journal of evaluation in clinical practice, 14(5), 621–49. doi:10.1111/j.1365-2753.2008.01094.x	got		2008	review & position statement on EBM	53 papers reviewed which reflect upon or directly relate to current thinking on EBM. No clear methodology provided. Data collection could be biased.	to meet the statement of intent of the thematic edition of the Journal of Evaluation in Clinical Practice	good	included		An EBM position statement in the 11th Thematic edition of the Journal of Evaluation in Clinical Practice. The paper is opinionated but does offer a range of considerations for the strengths and weaknesses of EBM and the evidence based hierarchy. Its conclusion states that EBM is the application of epidemiological data to clinical practice but that EBM and the clinical science are subordinate to the mechanisms of the consultation and provision of personalised healthcare services because the science is
													distinct from the clinical practice. The development of genomics and translational medicine has given rise to personalised medicine but the authors consider personalised medicine is currently marginalising EBM and highlights plurality of evidence should form the basis of basis of modern day health care practice.
Google scholar	2	2	Kumar, D. (2011). The personalised medicine . A paradigm of evidence-based medicine, 31–40. doi:10.4415/ANN	got	PubMed search 3 # 5. RSM search 6 # 196	2011	review	none described	to review the practice of EBM based in an individual's phenotype and genotype	ok	included		gives insight into the future of medicine using genome based evidence and bioinformatic tools and that tools should be person centred not disease centred. The conclusion highlights that clinicians and health professionals will need to be able to use genomic based diagnostic and therapeutic tools. Nutrigenomic is rapidly gaining

													importance in the nutrition practice. The tools for genetic assessment and evidence to support therapeutic interventions are still some time off being integrated into nutrition practice.
PubMed	3	3	Choong, M. K., & Tsafnat, G. (2012). The implications of biomarker evidence for systematic reviews. *BMC medical research methodology*, *12*(1), 176. doi:10.1186/1471-2288-12-176	got		2012	systematic review	PubMed was searched for systematic reviews, RCTs, case reports and non-systematic reviews with and without mentions of biomarkers between years 1990–2011. They compared the frequency and growth rate of biomarkers and non-biomarkers publications. They also compared the growth of the	demonstrate the growth and implications of biomarker evidence to inform those undertaking systematic reviews	good	Included		Biomarkers allow for the sub stratification of disease populations and therefore guide person centred interventions. They can also be used to measure responses to interventions. However they quote themselves on one of their previous papers which found that that only a limited number of biomarkers have been incorporated into clinical guidelines. They state biomarker assay development and limited industry support is considered a bottleneck for translating biomarker
								proportion of biomarker-based RCTs with the growth of the proportion of biomarker-based systematic reviews.					research into clinical practice. If diagnostic laboratories had other mechanisms by which they could evaluate and test assay development, and if biomarkers could be routinely integrated into nutrition practice, then this could support the advancement of personalised nutrition practice.
PubMed	3	7	Kumar, D. (2007). From evidence-based medicine to genomic medicine. *Genomic medicine*, *1*(3-4), 95–104. doi:10.1007/s11568-007-9013-6	got	RSM search 6 # 324	2007	review	none described	to review the rapid transformation of modern medicine from the evidence-based medicine to genomic medicine	good	included		recognises that the translation of research discoveries into clinical practice is slow and difficult and that the proper management of translational research would enable the delivery of reliable and clinically relevant outcomes. One of the major difficulties for clinicians is selecting the best available evidence. If clinical staff cannot be expected to undertake

													a comprehensive analysis of the evidence before making a clinical decision then how can they be supported? Are current databases and information systems impacting positively on clinical decision making and outcomes effects?
RSM	6	41	McClellan, K. a, Award, D., Simard, J., & Knoppers, B. M. (2013). Personalized medicine and access to health care: potential for inequitable access? *European journal of human genetics : EJHG*, *21*(2), 143–7. doi:10.1038/ejhg.2012.149	got		2013	review	none described			excluded	focuses solely on genetic information so has limited relevance to the aims	

RSM	6	45	Sacristán, J. a. (2013). Patient-centred medicine and patient-oriented research: improving health outcomes for individual patients. BMC medical informatics and decision making, 13, 6. doi:10.1186/1472-6947-13-6	got		2013	discussion	none described	to discuss the objectives and characteristics if PCM and the implications in research and medical practice	excellent	Included		Person centred health medicine is broader than personalised medicine as it includes the psychological, social and cultural considerations of the patient. PCM better reflects nutrition practice that medical practice at this time. Patient centred medicine, information exchange, patient's preferences individualisation. Clinical decision making tools should provide comparative effectiveness research (CER) which compares the benefits and harms of alternative methods of intervention Subgroup analysis advantages over analysis of the individual patient, for mechanism of disease as it may provide factors that determine differences in

													prognosis or response between subtypes. Patient orientated approach.
RSM	6	84	Nardini, C., Annoni, M., & Schiavone, G. (2012). Mechanistic understanding in clinical practice: complementing evidence-based medicine with personalized medicine. Journal of evaluation in clinical practice, 18(5), 1000–5. doi:10.1111/j.1365-2753.2012.01907.x	got		2012	review		compare visions of EBM and personalised medicine and how the impact clinical decision making	good	included		argue that evidence based medicine (EBM) and personalised medicine are driven by 2 diverse approaches to making and reasoning evidence with EBM grounded on statistical notions and epidemiological data gathered through systematic meta-analysis and randomized controlled trials whereas personalised medicine is grounded on mechanistic explanations of molecular interactions, pathways and biomarkers.

RSM	6	87	Di, S. P., Mauro, A., & Paola, G. (2012). When east meets west-person-centred medicine: A new paradigm beyond traditional, complementary, alternative and unconventional medicine. European Journal of Integrative Medicine, 4, 103. doi:http://dx.doi.org/10.1016/j.eujim.2012.07.714	printed		2012	abstract only from conference notes			ok	excluded	too little to provide any valuable input that has not already been provided by full papers	
RSM	6	93	Brand, A. (2012). The public health genomics challenge: Translating systems medicine into healthcare systems. Drug	printed		2012	abstract only from conference notes			ok	excluded	too little to provide any valuable input that has not already been	

			Metabolism and Drug Interactions, 27(3), A4-A5. doi:http://dx.doi.org/10.1515/dmdi-2012-0025									provided by full papers	
RSM	6	96	Rubin, D. B., & van der Laan, M.,J. (2012). Statistical issues and limitations in personalized medicine research with clinical trials. The International Journal of Biostatistics, 8(1), 18. doi:http://dx.doi.org/10.1515/1557-4679.1423	got		2012	review	none described		ok	included		considers the problems of constructing and evaluating personalisation 'rules' , the proposed statistical "rules2 may help to fo0rm an unbiased estimator of its performance using independent validation data. Discusses some of the difficulties confronting statistical research in personalised medicine and ideas for how our experimental set-up can explore solutions.

RSM	6	104	Khoury, M. J., Gwinn, M., Glasgow, R. E., & Barnett S. Kramer. (2013). A Population Perspective on How Personalized Medicine Can Improve Health. Am J Prev Med., 42(6), 639–645. doi:10.1016/j.amepre.2012.02.012.A	got		2012	review paper	none described	not clearly stated	good	included		This paper discussed how a population perspective should be integrated into the components of P4 medicine. The P4 components being predicative, preventive, personalised and participatory medicine. Systems biology approach allow us to measure the complex effects of environmental exposures, ultimately all approach needs to extend beyond genomic medicine because of the broader considerations to health and disease including social, cultural and economic factors. they caution that new applications with uncertain clinical utility can divert resources from effective interventions to minimally effective

													or infective interventions.
RSM	6	113	Greenfield, S., & Kaplan, S. H. (2012). Building useful evidence: Changing the clinical research paradigm to account for comparative effectiveness research. Journal of Comparative Effectiveness Research, 1(3), 263-270. doi:http://dx.doi.org/10.2217/cer.12.23	got		2012	review paper	none described	not clearly stated	good	included		Rather than the traditional efficacy and effectiveness research Comparative effectiveness research (CER) aims to answer 3 questions: what works? For whom? And in whose hands? Answering them will require fundamental changes to clinical research. A number of patient centred outcomes will need to be compared to assess interventions, including symptoms, quality of life and biomarker changes. The evidence for EBM is limited to narrow

													and frequently unrepresentative groups of patients and the extrapolation of this data to individual patients with individual health considerations is fraught with limitations. In who's hands? The quality of the practitioner may have a significant influence over the effectiveness of interventions
RSM	6	116	Lambin, P., Roelofs, E., & Dekker, A. (2012). Rapid learning health care & randomised trial: Are the two approaches antagonistic or complementary ? Radiotherapy and Oncology, 103, S35-S36. doi:http://dx.doi.org/10.1016/S0167-	printed		2012	symposium/conference notes	none described	not clearly stated	good	included		Without understanding the outcomes of different interventions it is not possible to decide which intervention is the best. The availability of data to inform clinical decision making is often conflicting and too large to manage. With the personalised approach adding significant complexity we need to find ways to assimilate the data

			8140(12)70427-9										to support decision making and provide quality, person centred healthcare. it highlights the CAT network in Maastricht which is a global data pooling network that allows data on every single patient to be automatically collected and analysed in a way that can accurately predict how decision affect the patient's health outcomes. They also recognises it is important to gather data on daily practices.
RSM	6	123	Van, D. G. (2012). Systems approaches to personalized wellness. Psychosomatic Medicine, 74(3) doi:http://dx.doi.org/10.1097/PSY.0b013e3182583b27	conference abstract available online		2012	conference notes				excluded	no information provided	
RSM	6	130	Bereczki, D. (2012). Personalized medicine: A competitor or an upgrade of evidence-based medicine? Personalized Medicine, 9(2), 211-221. doi:http://dx.doi.org/10.2217/pme.11.93	printed		2012	review paper	none described	not clearly stated	good	included		"Evidence based medicine is a method of healthcare decision making". The evolution of EBM and personalized medicine are described. This highlights that over the last 20 years it is the types and scale of evidence that have changed the interpretation of EBM. In most health conditions a combination of hundreds of variables, rather than a single metabolic or genetic biomarker, which decides clinical responsiveness . To improve intervention efficacy subgroup analysis, such as genetic response in Personalised medicine, allow for a more targeted approach. Argues that personalised medicine is an upgrade of EBM, because EBM allows

													for the use of a range of sources of evidence, including patient preferences and individual expertise. Personalised medicine add further sources of evidence but clinical decision making still needs to consider and combine the best available evidence with patient preferences in order to offer the most optimal intervention options.
RSM	6	131	Lambin, P., & Dekker, A. (2012). So you think you can decide which treatment is best for you? you can't. nor can your doctor! but help is underway. Radiotherapy and Oncology, 102, S176-S177. doi:http://dx.doi.org/10.1016/S0167-8140(12)70292-X	conference abstract		2012	conference notes abstract		write up of conference notes		excluded	too little to provide any valuable input that has not already been provided by full papers	
RSM	6	144	Yan, Q. (2012). The role of psychoneuroimmunology in personalized and systems medicine Humana Press, 999 Riverview Drive, Suite 208, NJ 07512-1165. doi:http://dx.doi.org/10.1007/978-1-62703-071-7_1	no		2012	chapter of a book	none described	not clearly stated	excellent	included		Psychoneuroimmunology (PNI) offers the scientific basis for personalised and systems medicine because it explores the complex interactions of the psychological and behavioural factors with the functions of the nervous, immune and endocrine systems that help to explain the mechanisms underlying health and disease. PNI studies the bidirectional interactions between physical and psychological influences on health. Physical and

													psychological conditions have a close impact on each other, with attitudes and social support impacting on disease and life expectance, physical illness is known to alter mood, behaviour and memory and behavioural and lifestyle interventions can improve clinical outcomes. A systems biology approach has been used to understand this complex biopsychosocial paradigm. It considers PNI may help to rebuild the philosophical connection between holism and reductionism in biomedical healthcare by establishing integrative models of systemic interactions. It considers PNI will help to identify the
													correlations between genotype and phenotype which is a key issue in personalised medicine.
RSM	6	146	Carmeli, B., Casali, P., Goldbraich, A., Goldsteen, A., Kent, C., Licitra, L., . . . Waks, Z. (2012). Evicase: An evidence-based case structuring approach for personalized healthcare. Studies in Health Technology and Informatics, 180, 604-608. Retrieved from http://search.proquest.com/professional/docview/1399840870?accountid=13835	got		2012	review	none described	suggest a framework and methodology for evicase construction and utilization	good	included		recognise dome of the challenges of developing clinical support systems, including the difficulty of applying clinical trial data to individuals and of keeping systems up to date with the rapidly increasing body of knowledge. They present an approach to integrate controlled clinical trial evidence with data driven clinical insights generated from a analysing patient-specific data in order to combine evidence based practice and personalised care-based reasoning. The 'Evicase' approach is 3 tiered: 1. Knowledge guided analysis – individual patient profiling to inform specific intervention options for the patient's current presentation.

													2. Descriptive analysis – insights generated from retrospective statistical analysis of patient records, where analysis of feature combinations and the weighting of their contributions may help support clinical decision making. 3. Predictive analysis – analysing the patient's clinical data in context of similar cases may allow for probabilistic prediction on the efficacy of interventions This approach is however disease and drug based and may not translate well to nutrition practice which is significantly more complex.

RSM	6	147	Windeler, J. (2012). Individualized medicine - our (lack of) understanding. Zeitschrift Für Evidenz, Fortbildung Und Qualität Im Gesundheitswesen, 106(1), 5-10. doi:http://dx.doi.org/10.1016/j.zefq.2011.08.001			2012					excluded	foreign language paper	
RSM	6	202	Hamet, P. (2011). Power and limits of large scale genomics as a tool for personalized medicine. Journal of Pharmacy and Pharmaceutical Sciences, 14(3) Retrieved from http://search.proquest.com/professional/docview/1013574395?			2011	conference notes abstract	none described	not clearly stated		excluded	too little to provide any valuable input that has not already been provided by full papers	

			accountid=138535										
RSM	6	221	Kussmann, M., Panchaud, A., & Affolter, M. (2010). Proteomics in nutrition: Status quo and outlook for biomarkers and bioactives. Journal of Proteome Research, 9(10), 4876-4887. doi:http://dx.doi.org/10.1021/pr1004339			2010	review	none described	review the current and future aspects of nutritional proteomics, focusing on two outputs: identification of health biomarkers and analysis of food bioactives.	ok	included		refers to personalised nutrition as a conceptual analogue to personalised medicine that means adapting food to individual needs.Food components interact with the body on a system, organ, cellular and molecular level. Nutrigenomics attempts to understand how our genome is expressed as a response to nutrition whereas nutrigenetics focuses genetic predisposition and susceptibility toward diets which allows for sub stratification of individuals.

													Proteomics in nutrition considers 3 different proteomic levels, the host, food and microbes, it provides data on biomarkers and bioactive components and aims to answer questions on nutritional bioavailability and bioefficiency).
RSM	6	223	Cascorbi, I. (2010). Safe and effective medicines for all: Is personalized medicine the answer? Expert Review of Clinical Pharmacology, 3(5), 627-637. doi:http://dx.doi.org/10.1586/ecp.10.36			2010	review	none described	outline the impact of pharmacogenetics and pharmacogenomics with regard to personalised medicine	poor	excluded	focuses solely on drugs and therefore does not relate to the aims	

RSM	6	262	Latoszek-Berendsen, a, Tange, H., van den Herik, H. J., & Hasman, a. (2010). From clinical practice guidelines to computer-interpretable guidelines. A literature overview. Methods of information in medicine, 49(6), 550–70. doi:10.3414/ME10-01-0056	got		2010	literature review	an extensive search of the scientific literature in PubMed was carried out with a focus on guideline characteristics, guideline development and implementation and guideline dissemination	to obtain an insight into factors that influence the design and implementation of guidelines	good	included		Clinical practice guidelines are meant to improve the process and outcome of healthcare as well as support clinical decision making, they have been used for over 30 years but they do present challenges in personalised healthcare for example they usually come from a population perspective. It defines characteristics of high quality guidelines including: validity, reliability, reproducibility, clinical applicability, clinical flexibility, clarity, development by a multi-disciplinary process and regular review. The process of creating and maintaining guidelines is time and resource consuming. Guideline appraisal instruments are reviewed by
													(Latoszek-Berendsen et al., 2010), it is important for the quality of guideline that the guideline as a whole and its recommendations are evaluated to ascertain if guidelines are 1. adequate for use in practice and 2. whether they can support clinical decision making.
RSM	6	271	Ginsburg, G. S., & Willard, H. F. (2009). Genomic and personalized medicine: foundations and applications. Translational research : the journal of laboratory and clinical medicine, 154(6), 277–87. doi:10.1016/j.trsl.2009.09.005	got		2009	review article	none described	not clearly stated	excellent	included		Health risk data in combination with family health history (FHH) data to support clinical decision making is considered to be a critically important step in the advancement of personalised health care. Benefits of tools should allow for the integration of genetic and genome data such as sequences and biomarker data, even if that data is currently not available.

RSM	6	272	Khoury, M. J., Rich, E. C., Randhawa, G., Teutsch, S. M., & Niederhuber, J. (2009). Comparative effectiveness research and genomic medicine: an evolving partnership for 21st century medicine. Genetics in medicine : official journal of the American College of Medical Genetics, 11(10), 707–11. doi:10.1097/GIM.0b013e3181b99b90	got		2009	review	none described	to argue that comparative effectiveness and genomic medicine should co-exist	good	included		argue that comparative effectiveness research and genomic medicine must co-exist by integrating genome based personalised perspectives into clinical decision making. Comparative effectiveness research (CER) should give a rigorous evaluation of the impact of different therapeutic options and the extent to which, under normal conditions, they perform as intended. RCT's are more focused on efficacy, the extent to which an intervention produces a beneficial result under ideal conditions whereas CER use a diverse population, typically recruited from a variety of setting and they measure a broad range of clinical and health outcomes

RSM	6	302	Confalonieri, M. (2008). Life sciences: A new area of action for the physician. Recenti Progressi in Medicina, 99(3), 129-133. Retrieved from http://search.proquest.com/professional/docview/700046307?accountid=138535			2008				excluded	foreign language paper	
RSM	6	308	Munshi, A., & Duvvuri, V. S. (2008). Nutrigenomics : Looking to DNA for nutrition advice, 7(January), 32–40.	got		2008	review	none described	not clearly stated	ok	included		reviews the development of nutrigenomics, the way in which foods and nutrients can influence gene expression, and nutrigenetics, the way individual genetics affect susceptibility to nutrient intake, as well as nutritional systems biology, which incorporates proteomics,

													transcriptomics and metabolomics
RSM	6	337	Fierz, W. (2004). Challenge of personalized health care: to what extent is medicine already individualized and what are the future trends? Medical science monitor : international medical journal of experimental and clinical research, 10(5), RA111–23. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/15114285	got		2004	review	none described	not clearly stated	good	included		Evidence based medicine takes statistical information about the general population and applies it to the individual Intervention effects are highly variable. The challenge is to make evidence based individualised medicine and in order to achieve that we need lab test biomarkers that identify subgroups and interventions tailored to the subgroups. There is a risk that there will be sub groups of minority patients who will be negatively impacted by such an approach. Argues that health care is an informational management endeavour including 2 types of information; patient specific and knowledge based and that the challenge is to link the two in a way that supports clinical decision making. The ultimate goal of personal information is lifelong, comprehensive electronic health records. Patient centeredness is about having quality of compassion, empathy and responsive to patient needs, values and expressed preferences of the individual. Discusses the ethical, legal and the social issues of personalised healthcare requiring informed consent, trusted intermediaries and legal protection.

Appendix 4 Participant information sheet for nutrition clients

PARTICIPANT INFORMATION SHEET FOR NUTRITION CLIENTS

Study title: Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in weight management.

Invitation Paragraph

You are invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Thank you for reading this.

What is the purpose of the study?

The aim of this pilot trial is to assess tools used for case history collection and clinical outcome analysis. You will be asked to complete a health history questionnaire online, by your nutrition practitioner, and a similar questionnaire after you have implemented the nutritional interventions. You will then be invited to complete a short 10 question survey to assess your experience of using these online tools.

Why have I been chosen?

You are someone who is seeking, nutritional intervention and have been asked to participate because you meet the selection criteria.

What will happen to me if I take part?

The aims, duration and outcome of the nutrition consultation will remain the same. The way we collect your health information and interpret it may be different from the way we collect data from other clients. You will continue to have the same support from your practitioner and receive personalised nutrition interventions to meet your needs. Nutrition and lifestyle interventions are determined by the nutrition practitioner and agreed and arranged between you.

What do I have to do?

Please book a consultation with your practitioner or clinic manager at a time that suits you. Please complete the online questionnaires and surveys when requested to do so.

What are the possible benefits of taking part?

We hope that participating in a nutrition consultation will benefit you. The study is focused on improving the ways in which your health information is collected and analysed. Your views on completing the questionnaires are extremely valuable and help to further develop the tools. The outcomes of this study may enable nutrition practitioners to collect and analyse client health information more effectively.

What are the possible disadvantaged and risks of taking part?

There are no known risks of participating in this study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you that is used will have your name and address removed so that you cannot be recognised from it.

All data will be stored, analysed and reported in compliance with the Data Protection Legislation.

What will happen to the results of the research study?

The results of the research will be published as part of the postgraduate dissertation which will be completed by the end of 2018 – you will not be identified in any report or publication.

You can contact michelle@cnelm.co.uk to request a copy of the published results.

Who has reviewed the study?

The Middlesex University, School of Health and Education, Health Studies Ethics sub-Committee.

Contact for further information

Michelle Barrow

Centre for Nutrition Education and Lifestyle Management

2 Edward Court

Wellington Road

Wokingham

Berks RG40 2AN

Tel: 0118 979 8686

Email: michelle@cnelm.co.uk

Dr. Celia Bell & Dr. Linda Bell

Middlesex University

The Boroughs

Hendon

London NW4 4BT

Tel: 0208 411 5555

Email: c.bell@mdx.ac.uk l.bell@mdx.ac.uk

Appendix 5 Participant information sheet for nutrition professionals

PARTICIPANT INFORMATION SHEET FOR NUTRITION PROFESSIONALS

Study title: Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in obesity management

Invitation Paragraph

You are invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please do ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

The aim of this research project is to assess whether it is possible and ethical to standardise a personalised approach to nutrition practice. It will assess current approaches to the nutritional management of obesity and tools used for case history collection, clinical decision making and clinical outcome analysis. It will assess participants' experience of using these tools and their views on the ethics and implications of standardising approaches to personalised nutrition practice. This project aims to integrate or improve existing tools in order to provide new, statistically validated tools which relate to the current evidence base. This is undertaken to assess the possibility for developing a new, case by case, personalised nutrition evidence base for the management of obesity.

Why have I been chosen?

This research project aims to incorporate knowledge and expertise from a variety of professionals. You have been selected as a potential participant because of your knowledge and skills. At least 30 other individual participants, including: practitioners, representatives of

educational establishments and professional bodies, students, academics and researchers have been asked to participate.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you do not wish to participate you do not have to do anything in response to this request.

What will happen to me if I take part?

There are number of different research methods to this study. You may be asked to take part in one or more of the following; surveys, interviews, workshops, focus groups, Delphi survey and tool testing trials. You will be asked after each contribution if that is your final contribution or if you are happy to contribute again.

Questionnaires will take between 5 and 20 minutes to complete and the deadline for completion will be two weeks from the date they are dispatched. You will be sent a form or an online link containing the survey or questionnaire which you can complete and submit in your own time.

Interviews will take between 30 minutes and 90 minutes. They will be semi structured and informal with the topics for discussion sent to you in advance. The actual date, time and duration you are available will be agreed with you in advance. Interviews will be audio recorded for ease of transcription unless you request otherwise.

Workshop or focus groups – This is when a few participants get together with the researcher in order to assess or develop ideas. Their duration varies from 1 to 4 hours. The dates and duration will be made available in advance.

New data collection tools will be trialled. This means you are a practitioner or student working with clients in a clinic setting and may use these tools during the consultation process. Consultations will be audio or video recorded. Written consent from the client will also be obtained before collecting data from them. The aims and duration of the nutrition consultation should remain the same. The way you collect and interpret health information from your client may be different from the way you have previously collected and assessed data. You will still determine, agree and arrange any appropriate personalised nutrition interventions with your client to meet their needs. A follow-up consultation will need to be arranged 6-8 weeks after the initial consultation where you will collect further data on your client’s progress.

Please note that in order to ensure quality assurance and equity this project may be selected for audit by a designated member of the committee. This means that the designated member can request to see signed consent forms. However, if this is the case your signed consent form will only be accessed by the designated auditor or member of the audit team.

What do I have to do?

Complete the consent forms and return to michelle@cnelm.co.uk

Michelle will then contact you with the relevant options for participation.

What are the possible disadvantaged and risks of taking part?

There are no known risks of participating in this study.

What are the possible benefits of taking part?

There is no intended benefit to the participants taking part in this study. The outcomes of this study may enable nutrition practitioners to collect and analyse client health information more effectively which could strengthen the evidence base for nutritional intervention and better inform the management of obesity in the future.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you which is used will have your name and address removed so that you cannot be recognised from it.

All data will be stored, analysed and reported in compliance with the Data Protection Legislation.

What will happen to the results of the research study?

The results of the research will be published as part of the postgraduate dissertation which will be completed by the end of 2017 – you will not be identified in any report or publication.

You can contact michelle@cnelm.co.uk to request a copy of the published results.

Who has reviewed the study?

The Middlesex University, School of Health and Education, Health Studies Ethics Sub-Committee.

Contact for further information

Michelle Barrow

Centre for Nutrition Education and Lifestyle Management

2 Edward Court

Wellington Road

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Berks RG40 2AN

Tel: 0118 979 8686

Email: michelle@cnelm.co.uk

Dr. Celia Bell & Dr. Linda Bell

Middlesex University

The Boroughs

Hendon

London NW4 4BT

Tel: 0208 411 5555

Email: c.bell@mdx.ac.uk l.bell@mdx.ac.uk

Appendix 6 Pilot Trial Protocol

Pilot Trial Protocol

Background:

Four new clinical tools have been developed through a series of expert panel reviews as part of a doctoral research project. The project aims to develop and validate robust clinical tools which can assess the efficacy of personalised nutrition practice in obesity management. The data from these tools may allow for the development of a new, case by case, evidence base for personalised nutrition practice. The tools have all been developed for online access using research software called Qualtrics. The 4 new tools include:

1. **Personalised health history questionnaire** – this aims to collect health history and family history data around mechanisms of obesity, as well as collect a range of baseline health measurements. This questionnaire is for the client/patient to complete before the first consultation.
2. **Intervention record** – this aims to capture which interventions were recommended by the nutrition practitioner. The practitioner should complete this at the end of each consultation.
3. **Personalised health follow-up questionnaire** – this aims to measure any changes to the client's health measurements after intervention. This questionnaire is for the client/patient to complete before their return consultation.
4. **Achievement record** – this aims to capture which interventions the client/patient complied with. This tool is completed by the nutrition practitioner at the outset of each return consultation.

Pilot Trial aims:

This pilot trial aims to achieve face validity and measure feasibility and utility for each of the 4 tools.

- Clients/Patients will be asked to completed a 10 question face validity survey (the QQ-10 instrument) after tool 1 (personalised health history questionnaire) and tool 3 (personalised health follow-up questionnaire) have been completed.
- Practitioners will be asked to complete adapted versions of the QQ-10 face validity survey for each of the tools after they have completed the pilot trial process.
- An analysis of face validity, feasibility and utility will be undertaken once all pilot trials have been completed.

Parameters:

- Each practitioner must trial all 4 tools on a minimum of 2 clients.
- All tools and review surveys must be completed by 31st July 2017.
- The clients are seeking nutrition intervention for weight loss. Please assess your client meets this parameter before sending them the online link to the personalised health history questionnaire to complete.
- All participants (clients and practitioners) are free to withdraw from participating in this research at any time and this must not affect the service or care the patient/client is given. If you or your client wish to withdraw please inform michelle@cnelm.co.uk.
- All information must be kept confidentially.
- If you have any queries or concerns, please contact Michelle Barrow on 07879 403321 or michelle@cnelm.co.uk

Method:

Please send your client the participant information sheet for clients an establish if they are happy to participate. If so, please send them the link to complete tool 1 (the health history questionnaire) via the online research software tool Qualtrics (the link to the questionnaire is given below). You will need to give the client a unique identification number to maintain their confidentiality, and inform michelle@cnelm.co.uk of the client identification numbers, so you can be sent a copy of the completed questionnaire before you conduct the initial consultation.

Each day (Monday to Fridays) Michelle Barrow will check to see if any new questionnaires have been completed and forward them to the relevant practitioners. When the client has completed tool 1, Michelle will send it to you and prompt you to ask the client/patient to complete the 10 question face validity survey to assess their views on tool 1. The survey's used to assess face validity are also online via the research software Qualtrics. The survey link will be sent to you with your client's completed questionnaire.

You can conduct the initial consultation at a time that suits you. At the end of the first consultation you should complete tool 2, the interventions record (via the online link below) which aims to capture all the recommended interventions.

Prior to the return consultation, please remind the client of their unique identification number and send them the link to tool 3, the follow-up questionnaire (see below for link). Again, you will be sent a copy of the completed questionnaire and prompted to ask the client/patient to complete the 10 question survey to assess their views on tool 3.

You can conduct the return consultation at a time that suits you. At the return consultation please complete tool 4, the achievement record (link below), so that you can assess which of the recommended interventions the client was compliant with. At the end of the return consultation you should complete tool 2, the interventions record again if further interventions were recommended.

Once you have conducted all of the pilot trials (a minimum of 2 clients are required) please inform michelle@cnelm.co.uk then you, the practitioner, will be asked to complete the face validity surveys for each of the 4 tools. Links to face validity surveys for completion will be sent to you via email. The pilot trial process is due to end on 1st May 2017.

The flow-chart below aims to visually clarify this process. If you have any queries, please do contact Michelle on 07879 403321 or michelle@ cnelm.co.uk

Links to tools:

Tool 1 FOR CLIENT COMPLETION - Personalised health history questionnaire:
https://mdxl.eu.qualtrics.com/SE/?SID=SV_78MODoa9LvgWDKB

Tool 2 FOR PRACTITIONER COMPLETION – Interventions record:
https://mdxl.eu.qualtrics.com/SE/?SID=SV_2rdbdwQkaKAMqTX

Tool 3 FOR CLIENT COMPLETION - Follow-Up Questionnaire:
https://mdxl.eu.qualtrics.com/SE/?SID=SV_8IxX3qhW1nUQb0p

Tool 4 FOR PRACTITIONER COMPLETION – Achievement record:
https://mdxl.eu.qualtrics.com/SE/?SID=SV_eDvG2CfybY4hMrP

Your participation in this research project and your feedback on these tools is much appreciated. Thank you.

Prior to initial consultation

- Send clients/participants (adults seeking weight loss) the client information sheet to establish if they are willing to participate.
- If so, please give your client a unique identification number and ask them to complete tool 1, personalised health questionnaire (link provided above)
- Please inform Michelle f your client's unique identification number.
- Michelle will send completed questionnaites to you and you will also be prompted to ask the client to complete the 10 question validity survey.
- If you have not received your client/patient questionnaire, or if you have a query, then please do contact michelle@cnelm.co.uk or call her on 07879 403321

Initial consultation

- Please undertake the initial consultation at a time that suits you.
- At the end of the initial consultation please complete tool 2, the interventions record (link provided above)

Prior to return consulation

- Please arrange a follow-up consultation with the client.
- Remind your client of their participant identification number and ask them to complete tool 3, follow-uphealth questionnaire (link provided above).
- Each day (Monday to Fridays) Michelle Barrow will check to see if any new questionnaires have been completed and forward them to the relevant practitioners, you will also be prompted to ask the client to complete the 10 question survey.
- If you have not received your client/patient questionnaire, or if you have a query, then please do contact michelle@cnelm.co.uk or call her on 07879 403321

Return consultation

- At the outset of each return consultation please complete tool 3- the achievement record (link provided above).
- Undertake the return consultation
- At the end of the consultation please complete a second tool 2, the interventions record, if more recommendations are given (link provided above)

After return consultation

- Once all tools have been completed and submitted, the clients have completed the survey's reviewing the tools, and the practitioner has completed a minimum of 2 clients the pilot trial is complete. Please do use this process for as many clients as possible.
- At the end, the practitioner will be prompted to complete the face validity survey's for each of the tools.
- Your participation and feedback on the tools is much appreciated. Thank you.

Appendix 7 Ethics committee permission

School of Health and Education
The Burroughs
London NW4 4BT

www.mdx.ac.uk
Main switchboard:
020 8411 5000

To: Michelle Barrow

Date: 29 August 2013

Dear Michelle

Re Application 999 "Constructing validated clinical tools to enable the development of new evidence base for personalised nutrition practice in obesity management" Supervisor: Celia Bell Category: A2, A3, A4, A5, A6

Thank you for the response which adequately answers the ethics committee's queries. On behalf of the Health Studies Ethics sub-Committee, I am pleased to give your project its final approval.

Please note that the committee must be informed if any changes in the protocol need to be made any stage.

I wish you all the very best with your project.

Yours sincerely

Prof. Gordon Weller
Chair of Ethics Sub-committee (Health Studies)

Appendix 8 Ethics committee change approval 2015

School of Health & Education
The Burroughs
Hendon
London NW4 4BT

Main Switchboard: 020 8411 5000

05th June 2015

HEESC APPLICATION NUMBER: 999 Michelle Barrow and Dr Celia Bell

Dear Michelle and Dr Bell

Re your application titled: "Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in obesity management"

Thank you for submitting your revised application. I can confirm that your application has been given approval from the date of this letter. The Committee would also like to make the following recommendations:

Consent forms:

- Include initial boxes
- Please include version number on the PIS and Consent forms.

Please can any amendment in light of recommendations be submitted to Leeann for our records.

Please ensure that you contact the ethics committee via Leeann Bradley l.f.bradley@mdx.ac.uk if there are any changes to the study to consider possible implications for ethics approval. The committee would be pleased to receive a copy of the summary of your research study when completed.Please quote the application number in any correspondence.

Good luck with your research.

Yours sincerely

Dr Gordon Weller
Chair of Health & Education Ethics Committee

Appendix 9 Ethics committee change approval 2017

Middlesex University London

School of Health & Education
The Burroughs

Hendon
London NW4 4BT

Main Switchboard: 020 8411 5000

HEESC APPLICATION NUMBER: 999 – Michele Barlow

Dear Researcher

Re your application titled " Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in obesity management "

The requested extension to December 2018 and the slight change to the PIS, removing the word 'obese'. These are approved and recorded.

Yours sincerely

Dr Gordon Weller
Chair of Health and Social Care Ethics Sub-Committee

Appendix 10 Participant consent form

Version Number 2 (June 15)

Participant Identification Number:

CONSENT FORM

Title of Project: Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in obesity management.

Name of Researcher: Michelle Barrow BSc (Hons), MSc, QTLS.

Please initial box

1 I confirm that I have read and understand the information sheet dated .....……..…for the above study and have had the opportunity to ask questions. [1]

2 I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. [2]

3 I agree that this form that bears my name and signature may be seen by a designated auditor. [3]

4 I agree that my non-identifiable research data may be stored in National Archives and be used anonymously by others for future research. I am assured that the confidentiality of my data will be upheld through the removal of any personal identifiers. [4]

5 **Delete 5 and or 6 if not applicable:**

I understand that sections of any of my medical notes may be looked at by [5]

responsible individuals from [company name] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

6 I understand that my interview may be taped and subsequently transcribed. 6

7. I agree to take part in the above study. 7

Name of participant	Date	Signature
Name of person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

1 copy for participant; 1 copy for researcher;

Appendix 11 Tool categorisation spreadsheet – example sheet

Category: diet and nutrition									
Measure	**tool**	**Identified in**	**aim of tool measurement**	**target popul-ation**	**permission to use tool**	**Content**	**Application e.g. self-reported, expert**	**outcome measures**	**feasibility (cost, time burden)**
diet intake	24 hour diet recall	Review 5 search 1 line 8	retrospective assessment of dietary intake	all	N/A`	subjects are asked to recall all foods and estimating portion sizes for a particular time period.	can be self-reported or taken by interviewer who can ask more probing questions	nutritional intake over 1 day	quick with minimal burden, simpler than keeping a diary but less accurate.
diet intake	multi pass method	Review 5 search 1 line 8	form of diet recall with a 3 or 5 stage approach	all	to be determined	1. quick list of foods eaten or drunk. 2. collection of detailed info OR forgotten food list (5 cycle). 3. a recall review (time and occasion when they were eaten). 4. detail cycle of foods and amounts 5. the final review	expert asks but can be automated	coding of food intake	3 steps is less work than 5 steps. Could the same be achieved with an online tool already in existence. Needs to be conducted by interviewer.
diet intake	food frequency questionnaire	review 5 search 9 line 7	checklist of foods consumed - usually used in conjunction with 24 hour diet recall and a 3 day food record	all	must use validated tool - e.g. 1999 EPIC. there is no standard FFQ. Each questionnaire should be judged for its ability to provide the information for which it was	list of foods and frequency of eating them, portion size also important	either	coding of food intake - good for assessing average log-term diet intake	inexpensive, quick and easy to standardise if not too many questions are included. Not all foods can be included. Validity

					intended. Tool for obesity is ideal. the online Food4Me FFQ has good agreement with the validated printed EPIC-Norfolk FFQ				must be established
diet intake	willett FFQ	Nvivo	as above - food frequency questionnaire with 153 items. Old from early 90's	all					
diet intake	Food dairy / record	Nvivo	diaries are meant to record all food ingestion after it has occurred.	all	N/A`	record of date and time, described food eaten, portion size, where eaten and estimated calories	self-reported	assessment of food intake	provide rich detail, subject to errors but better than food recall. Can be quire demanding in terms of time. deterioration of record quality occurs with lack of motivation
diet intake	visual estimation of dietary intake	Nvivo	using pictures to get a visual estimation	all	lots of work developing pictures	photos of foods	expert	assessment of food intake in conjunction with food recall or frequency	significant set-up burden
diet intake	eating styles questionnaire	Nvivo	stratify participants into eating style groups such as "emotional eater"' "food fretter", "social".						

diet intake	14 item Mediterranean assessment tool	review 5 search 1 line 9	assesses quality of food intake, Irrespective of calorie intake	all	not yet	14 food frequency questions related to healthy foods	either	food frequency of healthy foods	short questionnaire, easy
eating habit questionnaire	eating habit questionnaire (EHQ)	review 5 search 14 line 1	assesses food consumption patterns - another food frequency approach	all	not yet	includes food frequency questionnaires which stratify subjects into groups to support clinical decision making	either	food frequency	short questionnaire, easy
eating style	your personal eating style profile	review 5 search 9 line 6							
eating style & hunger assessment	three factors eating questionnaire TFEQ R18 or R21	review 5 search 9 line 7	assesses food intake behaviour	Obese population but has been validated for general population	not yet - need to request to look ta questionnaire - no example online	R18 is 51 questions that measure 3 dimension of eating behaviour including 1. cognitive restraint of eating, uncontrolled eating and hunger. Scored with Likert scale. R21is only 21 questions	self-reported	insight into cognitive, behavioural and emotional aspects of eating which may help direct NLP or behavioural support programmes	51 questions is long but the R21 is only 21 questions and has shown good reliability

diet history	Diet history questionnaire	Nvivo	assessment of food intake. can be combination of food intake and frequency	all	N/A`	interviewer questions respondent about usual eating patterns. Used to cross check against diaries and meals	expert interview but also self-administered tools available	elaborate picture of quality and quantity of food intake	more complete than food records or food recall, careful interviewing is required. Still retrospective analysis. Can be time consuming (Allison 1995)
eating behaviour		review 5 search 2, line 10	already assessed above						
software analysis	diet plan 6	my own knowledge							
software analysis	nutritics	my own knowledge	diet diary which links to food databases in order to provide dietary analysis		not yet	uses UK and Irish database data and compares intakes to national DRV's	expert enters details provided by client - it would be better if the client entered their details instead.		
software analysis	cron-o-meter	my own knowledge	diet diary analysis		not yet				free application
software analysis	Self-nutrition data	my own knowledge	diet diary analysis		not yet				
application	MyFitnessPal	my own knowledge	diet diary analysis	all	not yet		self-reported and can be shared		burden in client adding the info. We would need the info anyway so they would still have to provide it

Appendix 12: Survey of nutrition practitioners search and send tracker spreadsheet - anonymised

Date	Source searched	Search terms	Results	Included	job roles	Excluded	Contact Details	date chased	date chased
27/10/2014	linked in = my own contacts	obese	8	4	weight management specialist, dietician, prodimed director, nutritionist	working with children, not stated they practice nutrition with obese individuals on their profile	**ALL EMAIL ADDRESSES AND CONTACT DETAILS REMOVED TO KEEP PARTICIPANTS ANONYMOUS**	11/11/2014	
27/10/2014	linked in = my own contacts	obesity	49	31	specialist obesity dietician x 5, health improvement practitioner x 2, physician, dietician x 2, eating & behaviour specialist, ION nutritional therapist x 4, CNELM NT x2, nutritionist, UW NT, weight management specialist, nutrition consultant, clinical psychologist, NHC NT, obesity practitioner, addiction counsellor	journal publisher, non-practitioners, clinical nurses in obesity surgery.		11/11/2014	
27/10/2014	CNELM contacts, emailed top level management to ask for their contact recommendations		15	14	CB, RJ, Professor RT, HL (anonymised)	Professor Roy Taylor is a diabetes researcher and not an obesity practitioner		11/11/2014	
03/11/2014	BANT Members				emailed BANT admin and asked for contacts of practitioners specialising in obesity			11/11/2014	

03/11/2014	http://www.freelancedietitians.org/search/Search_profile_private.asp	area of interest: obesity. Profile description: DOM	5	4	DOM = dieticians working in obesity management. I emailed all dieticians listed as such on this website.	1 duplicate (susan@nutritionu.co.uk)		21/11/2014	01/12/2014
03/11/2014	http://www.domuk.org/viewpage.php?cat=7&page=45	DOM	3	3	DOM = dieticians working in obesity management. British Obesity and Metabolic Surgery Society (BOMSS) dietitians.			21/11/2014	01/12/2014
03/11/2014	google	UKVRN Obesity	5	5	included the first 5 nutrition practitioners who state they work in obesity or weight management			21/11/2014	01/12/2014
03/11/2014	google	nutritionist obesity	5	4	included the first 5 nutrition practitioners who state they work in obesity or weight management	mostly websites not practitioners		21/11/2014	01/12/2014
03/11/2014	google	nutrition practitioner weight loss	5	0	included the first 5 nutrition practitioners who state they work in obesity or weight management			21/11/2014	01/12/2014
03/11/2014	google	nutrition practitioner obesity	0	0	included the first 5 nutrition practitioners who state they work in obesity or weight management			21/11/2014	01/12/2014
03/11/2014	google	obesity weight loss nutrition London	5	5	included the first 5 nutrition practitioners who state they work in obesity or weight management			21/11/2014	01/12/2014
03/11/2014	nutrition society members				emailed office and asked for contacts of practitioners specialising in obesity			21/11/2014	01/12/2014
03/11/2014	Association for Nutrition				emailed chief executive rand asked for contacts of practitioners specialising in obesity			21/11/2014	01/12/2014

03/11/2014	dieticians in obesity management				emailed DOM UK and asked for contacts of dietitians			21/11/2014	01/12/2014
03/11/2014	Association for the Study of Obesity				emailed office manager and asked for contact details			21/11/2014	01/12/2014
10/11/2014	weight watchers		1	1				21/11/2014	01/12/2014
10/11/2014	Rosemary Connolly		1	1				21/11/2014	01/12/2014
10/11/2014	slimming world		1	1				21/11/2014	01/12/2014
10/11/2014	obesity society							21/11/2014	01/12/2014
10/11/2014	British nutrition foundation					told me to contact AfN		21/11/2014	01/12/2014
10/11/2014	nutritionist resource		126	15	aimed for dietitians 7 nutritionists to avoid weighting to nutritional therapy	those who had no easy to find email address		21/11/2014	01/12/2014
10/11/2014	IFM find a practitioner database	obesity	8	7		those who had no easy to find email address		21/11/2014	01/12/2014
10/11/2014	PNI practitioner	weight	6	3				21/11/2014	01/12/2014

Appendix 13 Example academic interview guide

Interview Guide Academics

Study title: Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in obesity management

Contact:
Email: michelle@cnelm.co.uk,
Tel: 07879 403321

Consent form:
You will have been sent a consent form to complete and participant information sheet. The information sheet states interviews will take between 30 minutes and 90 minutes. They will be semi structured and informal. The topics for discussion are below so you can see these in advance. The actual date, time and duration has been agreed and is stated below. Interviews will be audio recorded for ease of transcription unless you request otherwise. If you have not done so already please return the signed consent forms.

Aims & Objectives of Interview:

The aim of the interviews is to evaluate your experience/ views on tool development and validation and/or data set management. Objectives include:

1. Evaluate ways in which new tools can provide reliable and statistically validated data
2. Identify ways in which new tools can relate to the existing evidence base
- Evaluate ways in which tools can best be pilot tested/trialled
- Identify implications and ethical issues of building a case by case evidence base

Interview data sheet	
Participant name:	**AJ**
Job title/ speciality:	**Senior Principal Statistician**
Email:	ANON
Further contact details:	None provided
Date agreed to participate:	17th February 2015
Interview date, time & duration:	21st February 2015 11am to 12.15pm
Type of interview:	GoToMeeting
Audio Recording:	yes
Consent forms signed:	yes
Participant info sheet provided:	Yes on 15th February 2015
Transcription Date:	

Transcription source:	Nvivo
Circumstances booking interview:	
Circumstances during interview: My laptop crashed half way through the interview. I had to reboot and email Adam and send him new online meeting details but he did return to complete the interview. I was unable to take any motes during the interview because the sound volume was low and my typing would have meant I may not have been able to hear the responses.	
Interview questions:	**Interviewer observations:**
Welcome. Would you like me to quickly review the purpose of this interview and/or my research aims?	
There are 16 questions and we have up to ?? minutes to discuss each one.	
In your view, what are the most important considerations when developing a health questionnaire/tool to enable the creation of an individual case by case database on the health status and nutritional intakes of an obese population?	
If you had a mix of existing questionnaires (some validated, some	

not, some used for research, some used in practice). How would you use these existing questionnaires be used to develop new questionnaires or tools?	
How would you use existing online tools for data gathering, such as apps which measure food intake, exercise and sleep, to support the creation of new tools?	
What assessments of validity would you seek for new questionnaires and/or tools?	
Questions and scales in the newly constructed questionnaires/tools – in what ways would you assess their quality before the tool is piloted?	
Have you participated in a Delphi consensus before? What are your views on this methodology.	
Comparing the new tools with other similar tools- which method do you consider is the best approach? • Have 2 practitioners in a room completing the tools for the same client? • Have the client see two practitioners consecutively? • test-retest trial of the tool?	

What are the best ways to track individual responses and response sets? What are the best ways to identify response set answers to the questionnaire? If these are identified how should the questionnaire be adapted?	
What are the ways you manage incomplete data sets?	
Are there any other issues I should consider for the development of new tools? This would involve ranking questions, measures and tool approaches.	
I would like to relate specific questions on the tool (and their responses) to the existing evidence base to help inform clinical decision making. How could this be done?	
What do you consider to be the obstacles to clinical database research?	
What do you consider to be ethical issues when building clinical database for data mining?	
Would you be willing to participate in Delphi group surveys?	

Do you have any further comments?	
Interviewer reflections post interview: Many valuable insights were shared by the interviewee. Mainly that the purpose of what the tool should do and what data we want to elicit from it should be absolutely clear at the outset.	
Interviewee additions post interview:	

Appendix 14 Example practitioner interview guide

Interview Guide Practitioners

Study title: Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in obesity management

Contact:
Email: michelle@cnelm.co.uk
Tel: 07879 403321

Consent form:
You will have been sent a consent form to complete and participant information sheet. The information sheet states interviews will take between 30 minutes and 90 minutes. They will be semi structured and informal. The topics for discussion are below so you can see these in advance. The actual date, time and duration has been agreed and is stated below. Interviews will be audio recorded for ease of transcription unless you request otherwise. If you have not done so already please return the signed consent forms.

Aims & Objectives of Interview:

The aim of the interview is to gather your views on clinical assessment and decision making, as well as your views on standardising approaches to personalised nutrition practice. Objectives include:

3. Evaluate practitioner views on standardising approaches to personalised practice
4. Identify ways in which practitioners use clinical assessment to make clinical decisions
5. Identify ways in which practitioners engage with the evidence base

- Evaluate implications for building new tools
- Discuss potential ethical issues of building a case by case evidence base

Interview data sheet	
Participant name:	*DT*
Job title/ speciality:	Obesity Dietitian – clinical advisor at diabetes UK
Email:	ANON
Further contact details:	
Date agreed to participate:	13/3/15
Interview date, time & duration:	21/3/15
Type of interview:	GoToMeeting
Audio Recording:	yes
Consent forms signed:	yes

Participant info sheet provided:	yes
Transcription Date:	
Transcription source:	

Circumstances booking interview:

Booked over email.

Circumstances during interview:

Very quiet speaker, it was quite hard to hear what he was saying.

Interview questions:	**Interviewer observations:**
Welcome. Would you like me to quickly review the purpose of this interview and/or my research aims?	
What are your views (strengths and weaknesses) on standardising approaches to personalised nutrition practice? For example, using a standardised questionnaire.	Keeping the patient's agenda rather than having the practitioner as the priority. Alongside not replace conversation and consultation.
In your view, what ethical issues arise from using standardised approaches to personalised nutrition practice?	

What are the most important considerations when using a questionnaire/tool in clinical practice?	Time is the main factor, as dietician only gets 30 minutes. It needs to be web-based, user friendly and time saving
The questionnaires/tools you use - were they developed by yourself or someone else? *If self-developed* - how did you go about developing the tool? *If developed by someone else* - who developed it/where did you get it?	Used a tool that was developed across departments
Through clinical assessment, how do you determine which are the main issues contributing to obesity for that individual?	Depends on the patient, some can be patient led.
In which ways do the questionnaires and tools help you make clinical decisions?	Outcome and target focused and protocol driven.
What further data or questions could help support your clinical decision making?	
The client data you have gathered, in what ways do you analyse this against scientific literature?	

In what ways do you use the scientific literature to support your clinical decision making?	
If there were no time constraints, In what other ways could you use the scientific literature to support your nutrition practice?	
If a tool or questionnaire was devised that that linked to supporting research literature. How would that be useful for your clinical practice?	
Do you assess any of the following: • Case history questionnaire Life line? • Motivation questionnaire / motivational interviewing? • Exercise ability?	Uses motivational interviewing Assesses exercise ability by oxygen measure in researcher rather than clinical practice.
Under which circumstances would you ask clinical clients to use online data recording or mobile phone apps to measure their food intake, exercise, sleep etc?	
What are the advantages and disadvantages of sharing case data with researchers to create an evidence database for nutrition practice? Would this be something you are willing to do?	

Apart from having to gain client permission, what other considerations arise from creating a case by case evidence base for nutrition practice?	
Would you be willing to participate in Delphi group surveys?	
Do you have any further comments?	
Interviewer reflections post interview: I was conscious to take notes of thoughts that occurred to me but then realised that if something occurred in my head, a question, then I asked it. It was all audio captured.	
Interviewee additions post interview:	

Appendix 15 Pilot trial participation request tracker – anonymised

		nutrition practitioner											
Removed: ANON	Lesley	online search for obesity nutrition practitioner	11/10/2016	Dietitian			07/11/2016	21/11/2016	06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	Coleen	online search for obesity nutrition practitioner				no reason given							
Removed: ANON	Natalie	online search for obesity nutrition practitioner											
Removed: ANON	Perryn	online search for obesity nutrition practitioner	19/10/2016	Nutritional Therapist		would need to apply for ethics approval at her clinic	07/11/2016	21/11/2016					
Removed: ANON	Katy	online search for obesity nutrition practitioner											
Removed: ANON	Barbara	Colleague											
Removed: ANON	Ann	Participated in Delphi	12/10/2016	Nutritional Therapist		not seeing clients	07/11/2016	21/11/2016	06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	Natalie	Participated in Delphi	19/10/2016	Nutritional Therapist			07/11/2016	21/11/2016	06/01/2017	20/02/2017	13/3/17 has 1 client	06/03/2017	
Removed: ANON	Louise	Participated in Delphi				too busy							
Removed: ANON	Elizabeth	Participated in Delphi	19/10/2016	Nutritional Therapist			07/11/2016	21/11/2016	06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	Rhiannon	suggested by colleague											

Pilot Trial Participants requests						declined to participate	Protocol & client participant info sent		Date sent PDF tools	Date sent Updated client info sheet	Phone call response		
emails	name	Located via:	Date agreed to participate	Job title	Client 1 code			Date checked ok				sent video link	follow up to video
Removed: ANON	Vanessa	online search for obesity nutrition practitioner											
Removed: ANON	Laura	online search for obesity nutrition practitioner											
Removed: ANON	Lindsey	online search for obesity nutrition practitioner											
Removed: ANON	Alison	online search for obesity nutrition practitioner											
Removed: ANON	Frances	online search for obesity nutrition practitioner	14/11/2016	Nutritional therapist			14/11/2016	21/11/2016	06/01/2017	20/02/2017		06/03/2017	
Removed: ANON	Zara	online search for obesity nutrition practitioner				not working with obese							
Removed: ANON	Rita	online search for obesity											

Removed: ANON	Gemma	suggested by colleague				no reason stated							
Removed: ANON	Alice	suggested by colleague		Nutritional therapist		not seeing obese clients							
Removed: ANON	Pauline	suggested by colleague		Nutritional Therapist		not seeing obese clients							
Removed: ANON	Lisa	suggested by colleague	12/10/2016	Nutritional Therapist			07/11/2016	21/11/2016	06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	Claire	Met at UWL											
Removed: ANON	Nicola	Met at UWL	19/10/2016	Nutritional Therapist			07/11/2016	21/11/2016	06/01/2017	20/02/2017		06/03/2007	20/03/2017
Removed: ANON	all zest4life practitioners	Zest4Life	sent to all practitioners										
Removed: ANON	all CNELM graduates	GOOGLE GROUP											
Removed: ANON	Sarah	Linked in	07/11/2016	Nutritional Therapist			14/11/2016	06/01/2017	06/01/2017	20/02/2017	08/03/2017	06/03/2017	
Removed: ANON	Melissa	CNELM google group response	07/11/2016	Nutritional Therapist			07/11/2016	28/11/2014	06/01/2017	20/02/2017	22/2/17 - not many obese clients	06/03/2017	
Removed: ANON	Olga	Linked in	21/11/2016	Nutritional Therapist			21/11/2016						
Removed: ANON	Karina	Linked in	07/11/2016	Nutritional Therapist	HHH1001		07/11/2016	28/11/2016	06/01/2017	20/02/2017	23/2/17 has 3 clients just needed to understand the process better	03/03/2017	
Removed: ANON	Megan	Linked in											
Removed: ANON	Lorraine	Linked in				Too busy							
Removed: ANON	Catherine	Linked in	07/11/2016	Nutritional Therapist			07/11/2016		0	20/02/2017			
Removed: ANON													
Removed: ANON	carmen	CNELM google group response	07/11/2016	Nutritional Therapist	872848456		07/11/2016	28/11/2016	06/01/2017	20/02/2017	24/02/2017	03/03/2017	
Removed: ANON	Angharad	Freelance dietitian website				children's dietitian							
Removed: ANON	Patricia	Freelance dietitian website				seeing adolescents							
Removed: ANON	Katie	Freelance dietitian website	08/11/2016	Dietitian		withdrew after seeing info	08/11/2016						
Removed: ANON	Paula	Freelance dietitian website	22/11/2016	Dietitian			22/11/2016		06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	Claire	Freelance dietitian website											

Removed: ANON	Orla	CNELM google group response	07/11/2016	Nutritional Therapist			07/11/2016	28/11/2016	06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	OJ	CNELM google group response	09/11/2016	Nutritional Therapist			09/11/2016	28/11/2016	06/01/2017	20/02/2017	30/03/2017 said he would get me 2	06/03/2017	20/03/2017
Removed: ANON													
Removed: ANON	Maureen	CNELM google group response	10/11/2016	Nutritional Therapist			10/11/2016	28/11/2016	06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	Olivia	Zest4life practitioner	10/11/2016	Nutritional Therapist		withdrew	10/11/2016						
Removed: ANON	Janet	Freelance dietitian website				no reason given							
Removed: ANON	Debra	Freelance dietitian website											
Removed: ANON	Sharmain	Freelance dietitian website											
Removed: ANON	Dawn	Freelance dietitian website	28/11/2016	Dietitian		declined to participate	28/11/2016		06/01/2017	20/02/2017		06/03/2017	
Removed: ANON	Helen	Freelance dietitian website				no reason given							
Removed: ANON	Alix	Nutritionist Resource Website											
Removed: ANON	Alison	Nutritionist Resource Website											
Removed: ANON	Rebecca	Nutritionist Resource Website											

Removed: ANON	Amanda	Nutritionist Resource Website											
Removed: ANON	Ruth	Nutritionist Resource Website				no reason given							
Removed: ANON	Gemma	Nutritionist Resource Website											
Removed: ANON	All BANT practitioners												
Removed: ANON	Helen	?	14/11/2016	Nutritional Therapist		just starting out	14/11/2016	28/11/2016	06/01/2017	20/02/2017	28/02/2017	03/03/2017	
Removed: ANON	Jo	Online search for "weight loss nutritionist London"	18/11/2016	Dietitian		declined to participate	18/11/2016	28/11/2016	06/01/2017	20/02/2017		06/03/2017	
Removed: ANON	Hayley	Online search for "weight loss nutritionist London"		Nutritional Therapist		doesn't see obese clients							
Removed: ANON	Sue	Online search for "weight loss nutritionist London"							05/01/2017	20/02/2017	10/03/2017	06/03/2017	
Removed: ANON	Caroline	Online search for "weight loss nutritionist London"				not comfortable asking clients to give more info							
Removed: ANON	Laura	Online search for "weight loss	28/11/2016	Dietitian			28/11/2016		06/01/2017	20/02/2017			

		nutritionist London"											
Removed: ANON	Martin	Online search for "weight loss nutritionist London"											
Removed: ANON	Yvonne	Online search for "weight loss nutritionist London"	28/11/2016	Nutritional Therapist			28/11/2016		06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	all on LinkedIn												
Removed: ANON	Kerry	response to BANT social media	20/11/2016	Nutritional Therapist			20/11/2016	24/01/2017	06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	may	Nutritionist Resource Website		Nutritional Therapist		doesn't see obese clients							
Removed: ANON	Liz	Nutritionist Resource Website		Nutritional Therapist		doesn't see obese clients							
Removed: ANON	Rebecca	Nutritionist Resource Website											
Removed: ANON	Fiona	Nutritionist Resource Website		Nutritional Therapist		no obese clients							
Removed: ANON	Rebecca	Nutritionist Resource Website				declined to participate							
Removed: ANON	Sam	Nutritionist Resource Website	16/12/2016	Nutritional Therapist		ask again after April	11/01/2017		06/01/2017	20/02/2017			
Removed: ANON	Katie	Nutritionist Resource Website	10/01/2017	Nutritional Therapist			10/01/2017		11/01/2017	20/02/2017		06/03/2017	20/03/2017

Removed: ANON	Severine	Nutritionist Resource Website	06/01/2017	Nutritional Therapist		doesn't see obese clients							
Removed: ANON	Leo	Nutritionist Resource Website											
Removed: ANON	Anna-Karin	Nutritionist Resource Website	12/12/2016	Nutritional Therapist			12/12/2016		06/01/2017	20/02/2017	7/4/17 - will do their best	06/03/2017	20/03/2017
Removed: ANON	rose	BANT website											
Removed: ANON	Annabelle	BANT website											
Removed: ANON	Kelly	BANT website											
Removed: ANON	Alli	BANT website	05/12/2016	Nutritional Therapist			05/12/2016		06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	Avril	BANT website - got as far as 61st practitioner with keyword "weight"											
Removed: ANON	Andrea	Zest4Life website											
Removed: ANON	Monica	Zest4Life website											
Removed: ANON	Deb	Zest4Life website		Nutritional Therapist		no obese clients							
Removed: ANON	Richard	Zest4Life website											
Removed: ANON	Sandra	Zest4Life website											
Removed: ANON	Tracy	Zest4Life website	09/12/2016	Nutritional Therapist		over committed so withdrew	09/12/2016						

Removed: ANON	Ailsa	Zest4Life website											
Removed: ANON	Melanie	Zest4Life website				feels she cannot take it on							
Removed: ANON	Lianne	Zest4Life website											
Removed: ANON	Susie	Zest4Life website	12/12/2016	Nutritional Therapist			12/12/2016		06/01/2017	20/02/2017	arranging	06/03/2017	
Removed: ANON	Lucy	Zest4Life website	12/12/2016	Nutritional Therapist			12/12/2016		06/01/2017	20/02/2017	22/2/17 has someone tomorrow that could possibly work	06/03/2017	
Removed: ANON	Sharon	Zest4Life website											
Removed: ANON	Linda	Zest4Life website				declined to participate							
Removed: ANON	Nishta	Zest4Life website	06/01/2017	Nutritional Therapist			06/01/2017					07/04/2017	
Removed: ANON	Kathleen	Zest4Life website	16/12/2016	Nutritional Therapist	KFJH		16/12/2016		06/01/2017	20/02/2017	14/3/17 - will try	06/03/2017	
Removed: ANON	Giulietta	Zest4Life website											
Removed: ANON	Claire	Zest4Life website											
Removed: ANON	Rebecca	Zest4Life website				declined to participate							
Removed: ANON	Annabel	Zest4Life website				just moved but keep on mailing list							

Removed: ANON	Laura	Zest4Life website				not enough clients							
Removed: ANON	Jan	Zest4Life website											
Removed: ANON	Carolyn	Zest4Life website	16/12/2016	Nutritional Therapist			16/12/2016		06/01/2017	20/02/2017	07/03/2017 may potentially have clients	07/03/2017	
Removed: ANON	Vanessa	Zest4Life website				declined to participate							
Removed: ANON	Magda	Zest4Life website				seeing adolescents							
Removed: ANON	Helen	Zest4Life website	09/12/2016	Nutritional Therapist			12/12/2016		06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	Jane	Zest4Life website	09/12/2016	Nutritional Therapist			12/12/2016		06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	Anoushka	Zest4Life website				doesn't want to because of client confidentiality							
Removed: ANON	Sarah	Zest4Life website				doesn't wish to do							
Removed: ANON	Emily	Zest4Life website	09/01/2017	Nutritional Therapist			09/01/2017			20/02/2017		06/03/2017	20/03/2017
Removed: ANON	Anne	Zest4Life website				declined to participate							
Removed: ANON	Sune	Zest4Life website				too busy							
Removed: ANON	Aira	Zest4Life website											

Removed: ANON	Helen	Zest4Life website											
Removed: ANON	Jill	Zest4Life website											
Removed: ANON	Antonia	Zest4Life website											
Removed: ANON	Mary	Zest4Life website				no longer sees clients							
Removed: ANON	Marcelle	Zest4Life website											
Removed: ANON	Samantha	Zest4Life website				not seeing weight loss clients now							
Removed: ANON	Sarah	Zest4Life website											
Removed: ANON	Sarah	Zest4Life website											
Removed: ANON	Anne	Zest4Life website											
Removed: ANON	Kay	Zest4Life website											
Removed: ANON	Susan	Zest4Life website	09/12/2016	Nutritional Therapist			12/12/2016		06/01/2017	20/02/2017		06/03/2017	20/03/2017
Removed: ANON	Debbie	Zest4Life website											
Removed: ANON	Debs	Zest4Life website											
Removed: ANON	Aileen	Zest4Life website	13/12/2016	Nutritional Therapist		can't get the clients	13/12/2016		06/01/2017	20/02/2017	withdrawn	06/03/2017	
Removed: ANON	Linda	Zest4Life website				cannot take it on							
Removed: ANON	Rhaya	Colleague	06/01/2017	Naturopath		not seeing obese clients	06/01/2017	03/02/2017		20/02/2017		03/03/2017	

Removed: ANON	Zoe Macdonald	she contacted me after Facebook request	20/02/2017	Nutritional Therapist		cannot do it as still a student							
Removed: ANON	Bea	Colleague	21/02/2017	Nutritional Therapist							21/02/2017	03/03/2017	
Removed: ANON	coriander	Colleague	22/02/2017	Nutritional Therapist			16/03/2017				22/02/2017	03/03/2017	
Removed: ANON	Helen	BANT seminar	27/02/2017	Nutritional Therapist								03/03/2017	20/03/2017
Removed: ANON	Mary	Video response	13/03/2017	Nutritional therapist			13/03/2017						
Removed: ANON	Miranda	Video response	13/03/2017	Nutritional Therapist			13/03/2017						
Removed: ANON	Corrina	Video response	13/03/2017	Nutritional Therapist	HAF0102		13/03/2017		17/03/2017		17/03/2017		
Removed: ANON	Linda	liked video					14/03/2017						
Removed: ANON	Gloria	Video response					16/03/2017						
Removed: ANON	Debbie	word of mouth	03/05/2017	Nutritional Therapist			03/05/2017						

Appendix 16 Example post pilot trial practitioner interview guide

Post Pilot Trial Practitioner Interview Guide

Study title: Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in obesity management

Contact:

Email: michelle@cnelm.co.uk,

Tel: 07879 403321

Consent form:

You will have been sent a consent form to complete and participant information sheet. The information sheet states interviews will take between 30 minutes and 90 minutes. They will be semi structured and informal. The topics for discussion are below so you can see these in advance. The actual date, time and duration has been agreed and is stated below. Interviews will be audio recorded for ease of transcription unless you request otherwise. If you have not done so already please return the signed consent forms.

Background:

Four new clinical tools were developed through a series of expert panel reviews as part of this doctoral research project. Despite reaching out to hundreds or practitioners, and interest from numerous practitioners, there was unfortunately little to no engagement with the pilot trial of these tools. This project now wishes to explore the barriers that may have contributed to this outcome and explore idea for overcoming these barriers.

Aims & Objectives of Interview:

The aim of the interview is to gather your views on the barriers that may prevent practitioner from imbedding standardised tools in personalised nutrition practice and explore potential approaches to overcoming these barriers. Objectives include:

6. Evaluate barriers which may have prevented you, or other practitioners from being able to participate with the trail or embed standardised tools into your own practice.
7. Evaluate barriers which may prevent other practitioners from embedding standardised tools into personalised nutrition practice
8. Barriers of engagement with tools provided by clinic clients
9. Discuss potential ethical issues which may contribute as barriers to using standardised tools

10. Explore strengths and limitations of the Nutritional Therapy profession which may impact on the utilisation of standardised tools
11. Evaluate approaches to overcoming any barriers
12. Explore size/ duration/ approaches in which standardised tools could be easily imbedded into practice.

Interview data sheet	
Participant name:	**LO**
Job title/ speciality:	**Naturopath and nutritional therapist**
Email:	**Anonymised**
Further contact details:	
Date agreed to participate:	**4/5/17**
Interview date, time & duration:	**19/5/17 10.30am**
Type of interview:	Zoom online conference call
Audio Recording:	**yes**
Consent forms signed:	**yes**
Participant info sheet provided:	**yes**
Transcription Date:	
Transcription source:	
Circumstances booking interview: All communication by email	
Circumstances during interview: Nothing out of the ordinary	
Interview questions:	**Interviewer observations:**

Welcome. Would you like me to quickly review the purpose of this interview and/or my research aims?	
There are 10 questions.	
Please do tell me a little about yourself and your nutritional practice.	**naturopath**
Roughly, what percentage of your clients are obese or seeking weight loss? (less than 5 %, less 25%, less than 50%, more than 50%)	
What tools, or other methods, are you currently using when assessing your clinic clients? How were the tools developed?	**Bioimpedance machine** **Zest for life intake – adapted** **Health and blood sugar questionnaire** **MSQ for other clients – introduced through that via nutri seminars**
How does the content & structure/layout of your existing tools impact on your evaluation of the client and the process of the consultation?	Trained on using tools
Do you think nutritional therapy professionals should use standardised tools in clinical practice? *Prompt: Currently practitioners use their own tools. Standardised = all practitioner using the same tools.*	
Embedding standardised tools into your own practice, either for this pilot trial, or more generally: How do you think this would this impacts your evaluation of the client, or the process of the consultation?	

Prompt: How many questions, or how long, should a standardised tool be to make it easy to embed into practice?	
What are the barriers engaging clients with standardised tools? either for this pilot trial or more generally. *Prompt: Have you received any feedback from your clients on their experience of filling out questionnaires?*	**Do you think we need questionnaires?**
What facets, e.g. strengths and limitations, of the nutritional therapy profession may impact on the utilisation of standardised tools in practice?	
What could be done to encourage the use of standardised tools (or standardised data collection) in personalised nutrition practice?	
Do you have any further comments?	
Interviewer reflections post interview: I feel as though I have got to the nub of most issues at this point (4 interviews in) but I have another 2 interviews booked on Tuesday so will see it through to 6 and then stop this part of the data collection.	
Interviewee additions post interview: Participant followed up by sending me the tools she referred to in the interview	

Appendix 17 Tool 1 Questionnaire paper format

Personalised Nutrition Health Questionnaire

Client Identification: name/address/ID number/email address/ other contact details as appropriate.

Socio-cultural:

Q1. I identify my gender as (please select)
☐ Male
☐ Female
☐ Other _____ (please state)

Q2. Date of Birth:

_____(DD/MM/YY)

Q3. What is your legal marital or same-sex civil partnership status (please select):

☐ Never married and never registered a same-sex civil partnership (please skip to question 5)
☐ Married
☐ In a registered same-sex civil partnership
☐ Separated, but still legally married or in civil partnership
☐ Divorced or formerly in a same-sex civil partnership which is now legally dissolved
☐ Widowed or surviving partner from a same-sex civil partnership

Q4. Have there been any changes to your marital or same-sex civil partnership status in the following time periods? (please select)

Married or registered in same-sex civil partnership.	☐ N/A	☐ Within last 6 months	☐ Within last year	☐ Within last 2 years	☐ Over 2 years ago
Separated, but still legally married or in civil partnership	☐ N/A	☐ Within last 6 months	☐ Within last year	☐ Within last 2 years	☐ Over 2 years ago
Divorced or formerly in a same-sex civil partnership which is now legally dissolved	☐ N/A	☐ Within last 6 months	☐ Within last year	☐ Within last 2 years	☐ Over 2 years ago
Widowed or surviving partner from a same-sex civil partnership	☐ N/A	☐ Within last 6 months	☐ Within last year	☐ Within last 2 years	☐ Over 2 years ago

Q5. Last week, were you (tick all that apply)
☐ working as an employee
☐ working self-employed or freelance
☐ away from work ill, on maternity leave or temporarily laid off
☐ on a training scheme
☐ in full time or part time education
☐ retired
☐ looking after home or family
☐ long-term sick or disabled
☐ other (please state) _____

Q6. Have you changed jobs within the following time periods (select all that apply):

☐ N/A	☐ Within last 6 months	☐ Within last year	☐ Within last 2 years	☐ Over 2 years ago

Q7. Have you been made redundant or stopped working within the following time periods (select all that apply):

☐ N/A	☐ Within last 6 months	☐ Within last year	☐ Within last 2 years	☐ Over 2 years ago

Ethnicity: Q8. What is your ethnic group? Choose one section from A to E, then tick one box to best describe your ethic group or background:

- **White**

☐ English/Welsh/Scottish/N. Irish/British
☐ Irish
☐ Gypsy or Irish Traveller
☐ Any other white background
Please state _____

C. Asian/Asian British
☐ Indian
☐ Pakistani
☐ Bangladeshi
☐ Chinese
☐ Any other Asian background
Please state _____

B Mixed/multiple ethnic groups
☐ White and Black Caribbean
☐ White and Black African
☐ White and Asian
☐ Any other mixed/multiple ethic background

D. Black/African/Caribbean/Black British
☐ African
☐ Caribbean
☐ Any other Black/African/Caribbean background: Please state _____

E. Other ethnic group
☐ Arab
☐ Any other ethnic group:
Please state _____

Food Security:

Q9. Have you ever used food aid systems, such as food stamps, food banks or other food support initiatives? (please select)O

☐ N/A	☐ Within last 6 months	☐ Within last year	☐ Within last 2 years	☐ Over 2 years ago

Q10. if yes, how frequently have you used food aid systems during that period (please select)

☐ N/A	☐ 1-5 times	☐ 6-10 times	☐ 11-20 times	☐ More than 20 times

Education & Income: Q11. Which of these qualifications do you have? (tick every box that applies if you have any of the qualifications listed):
☐ 1-4 O levels/CSEs/GCSEs (any grades), Entry level, Foundation Diploma
☐ NVQ Level 1, Foundation GNVQ, Basic Skills
☐ 5+ O levels (passes)/CSEs (grade 1) GCSEs (grades A8-C), School certificate, 1 A level/2-3 AS levels/VCE's, Higher Diploma
☐ NVQ Level 2, Intermediate GNVQ, City and Guilds Craft, BTEC First/General Diploma, RSA Diploma
☐ Apprenticeship
☐ 2+ A levels/VCEs, 4+ AS levels, Higher School Certificate, Progression/Advanced Diploma
☐ NVQ Level 3, Advanced GNCQ, City and Guilds Advanced Craft, ONC, OND, BTEC National, RSA Advanced Dip.
☐ Degree (for example BA, BSc), Higher degree (for example MA, PhD, PGCE)
☐ NVQ Level 4-5, HNC, HND, RSA Higher Diploma, BTEC Higher Level
☐ Professional qualifications (for example teaching, nursing, accountancy)
☐ Other vocational/work-related qualifications
☐ Foreign qualifications
☐ No qualifications

Q12. Which category best describes your total annual household income before taxes (please select)

☐ Less than £25,000
☐ £25,000 to £34,999
☐ £35,000 to £49,999
☐ £50,000 to £74,999
☐ £75,000 to £99,999
☐ £100,000 to £149,999
☐ £150,000 to 199,999
☐ £200,000 or more

Weight Assessment:

Q13 what is your height?
In feet and Inches: _____ foot _____ inches
Or in meters: _____ m

Q14. What is your current weight?
In Stone and pounds:_____ stone_____ lbs

Q15. How would you best describe your weight during the following periods if your life? (please select)

Age 0-5	☐ Underweight	☐ Average weight	☐ Overweight	☐ Obese
Age 6-10	☐ Underweight	☐ Average weight	☐ Overweight	☐ Obese
Age 11-14	☐ Underweight	☐ Average weight	☐ Overweight	☐ Obese
Age 15-18	☐ Underweight	☐ Average weight	☐ Overweight	☐ Obese
Age 19-25	☐ Underweight	☐ Average weight	☐ Overweight	☐ Obese

Q16. What is the most and least you have weighed as an adult?

Most :
In Stone and pounds:_____ stone_____ lbs
Or in Kilogram: _____ kgs

Least:
In Stone and pounds:_____ stone_____ lbs
Or in Kilogram: _____ kgs

Q17. Describe how much your weight has fluctuated in the past year:

Highest weight:
In Stone and pounds:_____ stone_____ lbs
Or in Kilogram: _____ kgs

Lowest weight:
In Stone and pounds:_____ stone_____ lbs
Or in Kilogram: _____ kgs

Q 18 **Family health and weight history:**

Please **Y** to all appropriate boxes for the family members who **have,** or have had, each condition.
Please add numbers (1, 2, 3 etc.) if you have more than 1 sister, brother, daughter etc. with the same condition.
Please add **N** to all appropriate boxes for family members who **have not**, or have never had, each condition.
Please leave boxes blank for the instances where you do not know, are unsure or do not have such a relative.

	Example column	**Under-weight**	**Normal Weight**	**Over-weight**	**Obese**	**Bariatric surgery**	**Diabetes type 1**	**Diabetes type 2**	**Other health condition.** Please insert name or description (e.g. stroke, cancer, mental health issues, gout, arthritis):
Your Father	Y								

Paternal Grandfather	Y								
Paternal Grandmother	N								
Father's brothers	N								
Father's sisters	1								
Your Mother	N								
Maternal Grandfather									
Maternal Grandmother									
Mother's brothers									
Mother's sisters	2								
Your brothers	N								
Your sisters	N								
Your sons	1 and 2								
Your daughters	1								

Personal health history:

Q19. Please select if you are have experienced any of these in the last 3 months:

☐ unexplained pain	☐ blurred vision or dizziness	☐ difficulty swallowing	☐ paralysis	☐ unexplained bruising
☐ bleeding from nipple	☐ breast lumps	☐ discharge from vagina	☐ persistent cough	☐ unexplained rash

☐ blood in sputum	☐ calf swelling	☐ headaches	☐ persistent nose bleeds	☐ unexplained weight loss
☐ blood in urine	☐ change in nature of moles	☐ loss of appetite	☐ shortness of breath	☐ unexplained heavy periods
☐ blood in vomit	☐ chest pain	☐ numbness	☐ slurred speech	☐ unexplained loss of periods

If you are currently experiencing any of these conditions please make an appointment to see your primary health care provider such as your G.P.

Q20. The following table aims to identify your history of disease and other health conditions. Please complete providing as much information as possible. Please use another sheet of paper if necessary:

Condition:	**Please Tick** Leave blank if not applicable		please provide more details e.g. type of condition	When did this condition start? (date)	Duration (months or years, e.g. 6 months, 2 years)	How was/is it managed/treated? (medication, surgery, therapy etc.)
	Current	Past				
addiction						
arthritis: rheumatoid, osteoarthritis etc.						
attention deficit hyperactivity disorder (ADHD)						
autism						
cancer						
chronic fatigue						
Dementia e.g. Alzheimer's						
depression						
disturbed sleep or insomnia						
eating disorder e.g. binge eating disorder/bulimia						
eye disease e.g. glaucoma						
food allergy, e.g. celiac, peanut, dairy etc.						

gall bladder disease						
Gout						
heart disease or vascular disease						

Continued..	**Please Tick** Leave blank if not applicable		please provide more details e.g. type of condition	When did this condition start? (date)	Duration (months or years, e.g. 6 months, 2 years)	How was/is it managed/treated? (medication, surgery, therapy etc.)
	Current	Past				
hepatitis (A, B or C)						
herpes virus, including Epstein Barr or shingles						
high blood pressure						
kidney disease						
liver disease						
mood or anxiety disorder						
night eating syndrome						
Polycystic Ovarian Syndrome (PCOS)						
post-traumatic stress						
respiratory disorders e.g. asthma, sleep apnoea						
thyroid disease or condition						
type 1 diabetes						
type 2 diabetes						
Any other disease or condition:						

Medication and Supplementation

Q21.Please list below all the medications, drugs or supplements you took in the PAST MONTH. For each one you list please answer the questions below as best as you can. Medications include prescriptions, over the counter medicines, cold remedies, painkillers, contraceptives, creams, injections, eye drops etc. Supplements include vitamins, minerals, herbs, probiotics etc. Please use another sheet of paper if necessary:

Medication, drug or supplement name or type	Dose/strength e.g. mg, ml etc.	For what reason were you taking it?	How many days did you take it?	How many times did you take each day?	How many times did you miss taking it?	How well does it work for you? 1 = well 2 = okay 3= not well 4= unsure

Smoking history

Q22. Please answer 1 and 2. You only need to answer 3,4 and 5 if you have a history of smoking.

1. Do you currently smoke tobacco (e.g. cigarettes, cigars, pipes etc.) or e-cigarettes?	☐ No.	☐ Daily. How many cigarettes per day? _____	☐ Less than daily. How many cigarettes per month? _____	
2. Have you smoked tobacco or e-cigarettes in the past?	☐ No *please skip to Q23.*	☐ Yes. at what age:_____	For how long: _____	How many cigarettes per day? _____
3. How does smoking affect your weight?	☐ Keeps my weight down	☐ No effect	☐ Keeps my weight up	☐ I don't know

4. How many times have you stopped smoking for more than 3 months?	☐ 1-2 times	☐ 3-6 times	☐ 7-14 times	☐ 15-20 times	☐ More than 20 times
5. If you have smoked and stopped. Did you gain weight as a result of stopping smoking?	☐ No	☐ Yes	If yes, how much weight did you gain?	How many times did you gain weight as a result of stopping smoking?	

Pregnancy Men please skip to Q29. For females only:
Q23. Are you pregnant now? ☐ No. ☐ Maybe. ☐ Yes, How many weeks pregnant are you_____?

Q24. Have you ever been pregnant?
☐ Yes, how many times?_____ How many children have you given birth too?_____
☐ No, please skip to Q25.

If yes, please answer where possible:	Child 1	Child 2	Child 3	Child 4	Child 5
Sex of each child - M/F					
Date of birth for each child - DD/MM/YY					
Vaginal delivery for each child - Yes/No					
Did you experience gestational diabetes - Yes/No					
On average, how much weight did you put on during each pregnancy? - Lbs or Kgs					
How much pregnancy weight did you lose 6 months after each pregnancy? - Lbs or Kgs					

Q24. Please describe your weight, before, during and after pregnancy

Before pregnancy (1st)	☐ Underweight	☐ Normal weight	☐ Overweight	☐ Obese
During pregnancy (1st)	☐ Underweight	☐ Normal weight	☐ Overweight	☐ Obese
6 months after pregnancy (1st)	☐ Underweight	☐ Normal weight	☐ Overweight	☐ Obese
Before pregnancy ((2nd)	☐ Underweight	☐ Normal weight	☐ Overweight	☐ Obese

During pregnancy (2nd)	☐ Underweight	☐ Normal weight	☐ Overweight	☐ Obese
6 months after pregnancy (2nd)	☐ Underweight	☐ Normal weight	☐ Overweight	☐ Obese
Before pregnancy (3rd)	☐ Underweight	☐ Normal weight	☐ Overweight	☐ Obese
During pregnancy (3rd)	☐ Underweight	☐ Normal weight	☐ Overweight	☐ Obese
6 months after pregnancy (3rd)	☐ Underweight	☐ Normal weight	☐ Overweight	☐ Obese

Please use another sheet of paper if necessary.

Hormone Balance Men please skip to Q29. For females only:
Q25. Are you still menstruating?
☐ No, when did your periods cease and why?_____
(please skip to Q26.)
☐ Yes, are your periods regular? ☐ Yes. ☐ No, if no please give further details_____

On average, what is the length of time between periods?;

☐ Less than 20 days	☐ 20-30 days	☐ 30-40 days	☐ More than 40 days

Q26. Please highlight any of the following that apply to you and highlight if they apply currently or in the past:

Hot flushes (past/current)	Insomnia (past/current)	Night sweats (past/current)	Menopausal symptoms (past/current)	Ovarian Cysts (past/current)
PMT (past/current)	PCOS (past/current)	Endometriosis (past/current)	Fibroids (past/current)	Fertility problems (past/current)
Breast cysts (past/current)	Loss of libido (past/current)	Facial hair (past/current)	Swollen/tender breasts (past/current)	Mood swings (past/current)
Other:				

Q27. Are you, or have you ever been, on HRT or bio-identical hormones? ☐ No, ☐ Yes, please give further details:

_____

Q28. Have you ever taken:

Birth control pills? ☐Yes, ☐No
Birth control implants? ☐Yes,☐ No,
IUD coil? ☐Yes, ☐No.

How long did you use these contraception?
☐ 6 months-2 years
☐ 2-5 years
☐ more than 5 years

Inflammation

Q 29. Please rate:

How often do you feel aches and pains? Such as back pain, neck pain, headaches or general soreness.	☐ almost every day	☐ at least once a week	☐ once or twice a month	☐ a few times a year	☐ never
What are the most common causes of pain your experience? E.g. back ache, head ache, period pain etc.					
How often do you take anti-inflammatory or anti-pain medication such as ibuprofen, aspirin or prescription drugs?	☐ almost every day	☐ at least once a week	☐ once or twice a month	☐ a few times a year	☐ never

Q30. Please circle any of the following that apply to you and highlight if they apply currently or in the past:

Example: Acne, eczema, rosacea, psoriasis (past/current)	Allergies or Hypersensitivities e.g. hay fever, food allergies, rhinitis (past/current)	Asthma (past/current)	Autoimmune diseases e.g. systemic lupus, vitiligo, Hashimoto's Addison's disease. (past/current)	Please give further details of conditions you have circled:
Celiac Disease (past/current)	Cystitis (past/current)	Inflammation of the prostate gland (men only) (past/current)	Inflammatory kidney condition (past/current)	
Inflammatory skin conditions e.g. acne, eczema, rosacea, psoriasis (past/current)	Inflammatory bowel disease e.g. ulcerative colitis, Crohn's, (past/current)	Non-coeliac gluten sensitivity (past/current)	Pelvic inflammatory disease (past/current)	
Any other inflammatory condition?				

Satiety hormone disruption and food addiction

Q31. Please highlight which of the following best applies to you:

I frequently think about food	Not at all	Occasionally	Sometimes	Frequently	Always
I frequently crave food	Not at all	Occasionally	Sometimes	Frequently	Always
I continue to eat after I feel full	Not at all	Occasionally	Sometimes	Frequently	Always
I feel hungry no matter what I eat	Not at all	Occasionally	Sometimes	Frequently	Always
I cannot go long periods without eating	Not at all	Occasionally	Sometimes	Frequently	Always
I always feel hungry	Not at all	Occasionally	Sometimes	Frequently	Always

Dysbiosis

Q32. Please highlight any of the following that apply to you and indicate if they apply currently or in the past:

Example: Indigestion (past/current)	Indigestion (past/current)	Heartburn (past/current)	Bowel movements shortly after eating (past/current)	Frequent stomach upset or pain (past/current)
Nausea or vomiting (past/current)	Constipation or hard to pass stools (past/current)	Diarrhoea or urgency to go (past/current)	Blood in stools / black stools (past/current)	Undigested food in stools (past/current)
Stools are not well formed (loose) (past/current)	Excessive foul smelling gas (past/current)	Cramping in lower abdomen (past/current)	Mucus in stools (past/current)	Pain between shoulder or under the rib cage (past/current)
Irritable bowel syndrome (IBS) (past/current)	Offensive stool (past/current)	Pale, bulky stool (past/current)	Stools that float (past/current)	Stools that sink (past/current)
Haemorrhoids (past/current)	Anus itching (past/current)	Thrush (past/current)	Fungal or yeast infections e.g. athletes foot, ring	History of parasites (past/current)

			worm (past/current)	

Q33. How often do you have a bowel movement?
☐ More than once a day. ☐ Once a day. ☐ Once every few days. ☐ Other:-
_____

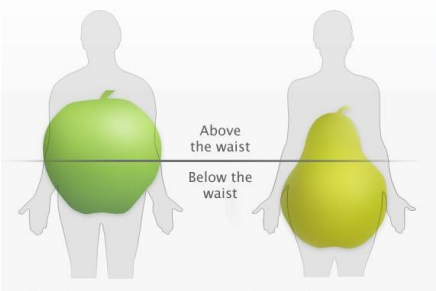
Q34. Have you noticed any recent changed in your in bowel habits
☐ No. ☐ Yes - please give details:-
_____
☐ Other
_____

Insulin resistance and hyperglycaemia
Q35. Please tick which of the following best applies to you:

I urinate more than I feel is normal	☐ Never	☐ Seldom	☐ Often	☐ Always
I feel I urinate at night more frequently than is normal	☐ Never	☐ Seldom	☐ Often	☐ Always
I feel very thirsty more frequently than normal	☐ Never	☐ Seldom	☐ Often	☐ Always
I feel very tired more frequently than normal	☐ Never	☐ Seldom	☐ Often	☐ Always
I have experienced unexplained weight loss	☐ Never	☐ Seldom	☐ Often	☐ Always
I have itching around the penis or vagina	☐ Never	☐ Seldom	☐ Often	☐ Always
I have episodes of thrush	☐ Never	☐ Seldom	☐ Often	☐ Always
I have skin tags	☐ Never	☐ Seldom	☐ Often	☐ Always
I experience cuts or wounds that heal slowly	☐ Never	☐ Seldom	☐ Often	☐ Always
I experience blurred vision	☐ Never	☐ Seldom	☐ Often	☐ Always
I experience weakness or dizziness after a period of fasting or with hunger	☐ Never	☐ Seldom	☐ Often	☐ Always
I can feel extreme hunger	☐ Never	☐ Seldom	☐ Often	☐ Always
I experience drowsiness	☐ Never	☐ Seldom	☐ Often	☐ Always
I experience nausea	☐ Never	☐ Seldom	☐ Often	☐ Always

Dyslipidaemia.
Q36. Do you have difficulty losing weight? ☐ not at all ☐ moderately difficult ☐ extremely difficult
Q37. Tick which applies to you :
☐ most of my weight is above the waist (apple)
☐ most of my weight is below the waist (pear)
☐ I am not sure
☐ other. Please describe: -
_____

Q.38 When did you last have your cholesterol tested:
☐ Never. ☐ In the last 6 months. ☐ In the last year. ☐ In the last 3 years.



Q 39. My cholesterol level is

☐ I don't know.

☐ Low.

☐Normal.

☐ Raised.

Please provide exact cholesterol measure:

Total Cholesterol: _____ Low Density Cholesterol (LDL):_____

Triglycerides:_____ High Density Cholesterol (HDL):

Oxidative stress

Q40. Please tick which of the following best applies to you:

I experience shortness of breath	☐ Never	☐ Seldom	☐ Weekly	☐ Every night
I snore	☐ Never	☐ Seldom	☐ Weekly	☐ Every night
I wake up in the night with a very dry and sore throat	☐ Never	☐ Seldom	☐ Weekly	☐ Every night
I wake up with a chocking or grasping sensation	☐ Never	☐ Seldom	☐ Weekly	☐ Every night

Q41. Have you ever been diagnosed with sleep apnoea?

☐ No - please skip to Q42. ☐ Yes – when were you diagnosed (dd/mm/yy)_____

Are you receiving treatment? ☐ No ☐ Yes – Please describe treatment _____

Epigenetic Changes

Q42. Please tick which of the following best applies to you:

Prior to the age of 17 I experienced stress or trauma (e.g. death of parent, separation, physical, emotional or sexual abuse, significant accident)	☐ No	☐ I cannot remember	☐ Yes	If yes: please provide further information on a separate sheet if you wish to.	
If yes, on a scale of 1 to 5, how traumatic was this?	☐ 1 Least traumatic	☐ 2	☐ 3 traumatic	☐ 4	☐ 5 Extremely traumatic

Psychological Factors

Q43. Please tick which of the following best applies to you:

How much do you enjoy life.	☐ Not at all	☐ A little	☐ A moderate amount	☐ Very much	☐ An extreme amount
To what extent do you feel your life to be meaningful?	☐ Not at all	☐ A little	☐ A moderate amount	☐ Very much	☐ An extreme amount
How often do you have negative feelings such as depression, despair, anxiety?	☐ Always	☐ Very often	☐ Quite often	☐ Seldom	☐ Never
I feel able to accept my bodily appearance	☐ Not at all	☐ A little	☐ A moderate amount	☐ Very much	☐ An extreme amount
On the whole I feel satisfied with myself	☐ Strongly disagree	☐ Disagree	☐ Neither agree or disagree	☐ Agree	☐ Strongly agree
I take a positive attitude towards myself	☐ Strongly disagree	☐ Disagree	☐ Neither agree or disagree	☐ Agree	☐ Strongly agree

Quality of life

Q44. Please tick which of the following best applies to you:

How would you rate your quality of life?	☐ Very poor	☐ Poor	☐ Neither good nor poor	☐ Good	☐ Very Good
How would you rate your physical functioning?	☐ Very poor	☐ Poor	☐ Neither good nor poor	☐ Good	☐ Very Good
How would you rate your general health	☐ Very poor	☐ Poor	☐ Neither good nor poor	☐ Good	☐ Very Good
How would you rate your emotional health?	☐ Very poor	☐ Poor	☐ Neither good nor poor	☐ Good	☐ Very Good

Sleep

Q45. Please tick which of the following best applies to you:

How would you rate the quality if your sleep?	☐ Poor		☐ Neither good nor poor	☐ Good
How frequently do you doze during the day?	☐ Always	☐ Often	☐ Seldom	☐ Never
How frequently do you wake in the night?	☐ Always	☐ Often	☐ Seldom	☐ Never
How frequently do you use over the counter or prescription sleep aids?	☐ Always	☐ Often	☐ Seldom	☐ Never
On average, how many hours sleep do you get per night	☐ 3 or less	☐ 4-5	☐ 6-8	☐ 9 or more

Stress

Q46. Please tick which of the following best applies to you:

In the last month, how often have you felt that you were unable to control the important things in your life?	☐ Never	☐ Almost never	☐ Sometimes	☐ Fairly often	☐ Very often
In the last month, how often have you felt confident about your ability to handle your personal problems?	☐ Never	☐ Almost never	☐ Sometimes	☐ Fairly often	☐ Very often
In the last month, how often have you felt that things were going your way?	☐ Never	☐ Almost never	☐ Sometimes	☐ Fairly often	☐ Very often
In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	☐ Never	☐ Almost never	☐ Sometimes	☐ Fairly often	☐ Very often

Motivation to change

Q47. Please tick which of the following best applies to you:

In the past month, have you been actively trying to lose weight?	☐ Yes	☐ No
In the past month, have you been actively trying to keep from weight gain?	☐ Yes	☐ No

Are you seriously considering trying to lose weight to reach your goals in the next 6 months?	☐ Yes	☐ No
Have you maintained you desired weight for more than 6 months?	☐ Yes	☐ No

Appendix 18 Tool 1 Questionnaire - download of online format

Personalised Nutrition Health Questionnaire

Start of Block: Socio Cultural:

Q113 **PERSONALISED HEALTH HISTORY QUESTIONNAIRE**

Please complete this questionnaire as comprehensively as possible. It may take up to 1 hour to complete the whole questionnaire.

On completion, the information will be sent to your nutrition practitioner. The aims, duration and outcome of the nutrition consultation will remain the same.

The aim of this pilot trial is to assess the way health information is collected and interpreted. After completion you will then be invited to complete a short 10 question survey to assess your experience of using this questionnaire.

Q118 Your participation in this study is entirely voluntary and you can withdraw at any time and you are free to omit any question. You should be aware that the data you provide may be used for analysis and subsequent publication. The researchers will implement procedures to maintain the confidentiality of the participant data. Personal information provided will be stored in computer files secured by means of passwords or in locked cabinets. Only the researcher and authorised supervisors will be able to access the information. Personal information will be destroyed once the research is completed.

Thank you very much and please do get in touch if you have any questions.

Researcher: Michelle Barrow; Centre for Nutrition Education and Lifestyle Management (CNELM) and Middlesex University
michelle@cnelm.co.uk
Research Supervisors: Dr L Bell (L.bell@mdx.ac.uk); Dr C. Bell (c.bell@mdx.ac.uk)

Study title: Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in weight management.

Academic Year: 2016/17

Q117 Name of your Nutritionist/Dietician/Nutritional Therapist/Practitioner:

_____

Q1 Your Participant Information Number:

_____

Q2 I identify my gender as:

- ☐ Male (1)
- ☐ Female (2)
- ☐ Other (please state in box below) (3)

_____

JS

Q115 Date of birth:

Month (1)	▼ January (1) ... (150)
Day (2)	▼ January (1) ... (150)
Year (3)	▼ January (1) ... (150)

Q3 What is your legal marital or same-sex civil partnership status:

▼ Never married and never registered a same-sex civil partnership (1) ... Widowed or surviving partner from a same-sex civil partnership (6)

Skip To: Q5 If What is your legal marital or same-sex civil partnership status: = Never married and never registered a same-sex civil partnership

Q4 Have there been any changes to your marital or same-sex civil partnership status in the following time periods?

- [ ] N/A (1)
- [ ] Within the last 6 months (2)
- [ ] Within the last year (3)
- [ ] Within the last 2 years (4)
- [ ] Over 2 years ago (5)
- [ ] Please provide further details if you wish: (6)

_____

Q5 Last week, you were (select all that apply):

- working as an employee (1)
- working self-employed or freelance (2)
- away from work ill, on maternity leave or temporarily laid off (3)
- on a training scheme (4)
- in full time or part time education (5)
- retired (6)
- looking after home or family (7)
- long-term sick or disabled (8)
- other (please state in box below) (9)

  _____

Q10 What is your ethnic group? Choose one section from A to E, then tick one box to best describe your ethic group or background:

▼ English/Welsh/Scottish/N. Irish/British (1) ... Any other ethnic group (please state) (18)

Q11 Have you ever used food aid systems, such as food stamps, food banks or other food support initiatives?

▼ N/A (1) ... Over 2 years ago (5)

Skip To: Q13 If Have you ever used food aid systems, such as food stamps, food banks or other food support initia... = N/A

Q12 If yes, how frequently have you used food aid systems during that period:

▼ 1-5 times (1) ... More than 20 times (4)

Q13 Which of these qualifications do you have? (tick every box that applies if you have any of the qualifications listed):

- 1-4 O levels/CSEs/GCSEs (any grades), Entry level, Foundation Diploma (1)
- NVQ Level 1, Foundation GNVQ, Basic Skills (2)
- 5+ O levels (passes)/CSEs (grade 1) GCSEs (grades A8-C), School certificate, 1 A level/2-3 AS levels/VCE's, Higher Diploma (3)
- NVQ Level 2, Intermediate GNVQ, City and Guilds Craft, BTEC First/General Diploma, RSA Diploma (4)
- Apprenticeship (5)
- 2+ A levels/VCEs, 4+ AS levels, Higher School Certificate, Progression/Advanced Diploma (6)
- NVQ Level 3, Advanced GNCQ, City and Guilds Advanced Craft, ONC, OND, BTEC National, RSA Advanced Dip. (7)
- Degree (for example BA, BSc), Higher degree (for example MA, PhD, PGCE) (8)
- NVQ Level 4-5, HNC, HND, RSA Higher Diploma, BTEC Higher Level (9)
- Professional qualifications (for example teaching, nursing, accountancy) (10)
- Other vocational/work-related qualifications (11)
- Foreign qualifications (12)
- No qualifications (13)

Q14 Which category best describes your total annual household income before taxes:

▼ Less than £25,000 (1) ... £200,000 or more (8)

End of Block: Socio Cultural:

Start of Block: Weight Assessment

Q15 **Weight Assessment**

What is your height in feet and inches?

Feet (1)

Inches (2)

▼ 1 (1) ... 7 ~ 11 (84)

Q16 What is your current weight in stone and pounds?

Stone (1)

Pounds (2)

▼ 1 (1) ... 65 ~ 13 (975)

Q17 How would you best describe your weight during the following periods if your life?

	Underweight (1)	Average weight (2)	Overweight (3)	Obese (4)
Age 0-5 (1)	☐	☐	☐	☐
Age 6-10 (2)	☐	☐	☐	☐
Age 11-14 (3)	☐	☐	☐	☐
Age 15-18 (4)	☐	☐	☐	☐
Age 19-25 (5)	☐	☐	☐	☐

Q18 What is the most you have weighed as an adult?

Stone (1)

Pounds (2)

▼ 1 (1) ... 65 ~ 13 (975)

Q19 What is the least you have weighed as an adult?

Stone (1)

Pounds (2)

▼ 1 (1) ... 65 ~ 13 (975)

Q20 Describe how much your weight has fluctuated in the past year: What is the most you have weighed in the past year?

Stone (1)

Pounds (2)

▼ 1 (1) ... 65 ~ 13 (975)

Q21 What is the least you have weighed in the past year?

Stone (1)

Pounds (2)

▼ 1 (1) ... 65 ~ 13 (975)

End of Block: Weight Assessment

Start of Block: Family health and weight history

Q112 On the table below: Please add **Y** to all appropriate boxes for the family members who have, or have had, each condition. Please add numbers (1Y, 2N, 3Y etc.) if you, or your parents, have more than 1 sister, brother, daughter etc. Please add **N** to all appropriate boxes for family members who have not, or have never had, each condition. Please leave boxes blank for the instances where you do not know, are unsure or do not have such a relative. Use the tab button to navigate to each box. Here is an example:

Q21 Click to write the question text	Underweight (1)	Normal Weight (2)	Over-weight (3)	Obese (4)	Bariatric surgery (5)	Diabetes Type 1 (6)	Diabetes Type 2 (7)	Other health condition. Please insert name or description (e.g. stroke, cancer, mental health issues, gout, arthritis etc.) (8)
Your Father (1)								
Paternal grandfather (2)								
Paternal grandmother (3)								
Father's brothers (4)								

Father's sisters (5)								
Your Mother (6)								
Maternal grandfather (7)								
Maternal grandmother (8)								
Mother's brothers (9)								
Mother's sisters (10)								
Your brothers (11)								

Your sisters (12)								
Your sons (13)								
Your daughters (14)								

Page Break

Q22 **Personal Health History**

Please select if you are have experienced any of these in the last 3 months:

- unexplained pain (1)
- bleeding from nipple (2)
- blood in sputum (3)
- blood in urine (4)
- blood in vomit (5)
- blurred vision or dizziness (6)
- breast lumps (7)
- calf swelling (8)
- changes in nature of moles (9)
- chest pain (10)
- difficulty swallowing (11)
- discharge from vagina (12)
- headaches (13)
- loss of appetite (14)
- numbness (15)
- paralysis (16)
- persistent cough (17)
- persistent nose bleeds (18)
- shortness of breath (19)
- slurred speech (20)
- unexplained bruising (21)
- unexplained rash (22)
- unexplained weight loss (23)
- unexplained heavy periods (24)
- unexplained loss of periods (25)

If you are currently experiencing any of these conditions please make an appointment to see your primary health care provider such as your G.P.

Q26 The following table aims to identify your history of disease and other health conditions. Please complete providing as much information as possible. Please use box on next question to provide more information if necessary:	Leave blank if not applicable. Write "current" if you are currently experiencing this condition. Write "past" if you have previously experienced this condition (1)	Please provide more details e.g. type of condition (2)	When did this condition start? (date) (3)	Duration (months or years, e.g. 6 months, 2 years) (4)	How was/is it managed/treated? (medication, surgery, therapy etc.) (5)
addiction (1)					
arthritis: rheumatoid or osteoarthritis etc. (2)					
autism (3)					
cancer (4)					

chronic fatigue (5)					
dementia e.g. Alzheimer's (6)					
depression (7)					
disturbed sleep or insomnia (8)					
eating disorder e.g. binge eating disorder/bulimia (9)					
eye disease e.g. glaucoma (10)					
food allergy e.g. celiac, peanut, dairy etc. (11)					

gall bladder disease (12)					
gout (13)					
heart disease or vascular disease (14)					
hepatitis (A,B or C) (15)					
herpes virus, including Epstein Barr or shingles (16)					
high blood pressure (17)					
kidney disease (18)					

liver disease (19)					
mood or anxiety disorder (20)					
night eating syndrome (21)					
polycystic ovarian syndrome (22)					
post-traumatic stress (23)					
respiratory disorders e.g. asthma, sleep apnoea (24)					
thyroid disease or condition (25)					

type 1 diabetes (26)					
type 2 diabetes (27)					
any other disease or condition (28)					

Q27 Please provide more information regarding the previous question if you wish:

_____

_____

_____

_____

_____

Page Break

Q28 **Medication and Supplementation**

Please list below all the medications, drugs or supplements you took in the PAST MONTH. For each one you list please answer the questions below as best as you can. Medications include prescriptions, over the counter medicines, cold remedies, painkillers, contraceptives, creams, injections, eye drops etc. Supplements include vitamins, minerals, herbs, probiotics etc.

	Medication, drug or supplement name or type (1)	dose/strength e.g. mg, ml etc. (2)	for what reason were you taking these (3)	How many days did you take it? (4)	How many times did you take each day? (5)	How many times did you miss taking it? (6)	How well does it work for you? well, okay, not well, unsure (7)
Medication/drug: (1)							
Medication/drug: (2)							
Medication/drug: (3)							
Medication/drug: (4)							
Medication/drug: (5)							

Medication/drug: (6)							
Supplement: (7)							
Supplement: (8)							
Supplement: (9)							
Supplement: (10)							

Q30 Please provide more information regarding the previous question if you wish:

_____

_____

_____

_____

_____

Page Break

Q29 **Smoking History**

Do you currently smoke tobacco (e.g. cigarettes, cigars, pipes etc.) or e-cigarettes?

▼ No (1) ... Less than daily (3)

Skip To: Q33 If Smoking History Do you currently smoke tobacco (e.g. cigarettes, cigars, pipes etc.) or e-cigarettes? = No

Skip To: Q31 If Smoking History Do you currently smoke tobacco (e.g. cigarettes, cigars, pipes etc.) or e-cigarettes? = Daily

Skip To: Q32 If Smoking History Do you currently smoke tobacco (e.g. cigarettes, cigars, pipes etc.) or e-cigarettes? = Less than daily

Q31 How many per day?

_____

Q32 How many per month?

_____

Q33 Have you smoked tobacco or e-cigarettes in the past?

▼ No (1) ... Yes (3)

Skip To: End of Block If Have you smoked tobacco or e-cigarettes in the past? = No

Q42 At what age did you start smoking?

▼ 16 (1) ... 75 (60)

Q43 For how long did you smoke:

_____

Q44 How many times per day did, or do, you smoke?

▼ 1-5 (1) ... more than 40 times per day (9)

Q34 How does smoking affect your weight?

▼ keeps my weight down (1) ... I don't know (4)

Q35 How many times have you stopped smoking for more than 3 months?

▼ Never (1) ... more than 20 times (6)

Q36 If you have smoked and stopped, did you gain weight as a result of stopping smoking?

▼ No (1) ... Yes (3)

Q37 How much weight did you gain as a result of stopping smoking?

_____

Q38 How many times did you gain weight as a result of stopping smoking?

_____

End of Block: Family health and weight history

Start of Block: Pregnancy

Q39 **Pregnancy**

Are you pregnant now?

- ☐ Yes (1)
- ☐ Maybe (2)
- ☐ No (3)
- ☐ I don't know (4)

Skip To: Q41 If Pregnancy Are you pregnant now? = No

Skip To: Q41 If Pregnancy Are you pregnant now? = I don't know

Q40 How many weeks pregnant are you?

_____

Q41 Have you ever been pregnant?

- [ ] Yes (1)
- [ ] No (2)
- [ ] I don't know (3)

Skip To: End of Block If Have you ever been pregnant? = No

Skip To: End of Block If Have you ever been pregnant? = I don't know

Q47 How many times have you been pregnant?

▼ once (1) ... more than seven times (8)

Q48 How many children have you given birth too?

▼ 1 (1) ... More than 6 (7)

Q49 Please answer where possible:	Child 1 (1)	Child 2 (2)	Child 3 (3)	Child 4 (4)	Child 5 (5)
Sex of each child: M/F (1)					
Date of birth for each child: DD/MM/YY (2)					
Vaginal delivery: Yes/No (3)					
Did you experience gestational diabetes: Yes/No (4)					

On average, how much weight did you put on during each pregnancy? please state estimated weight gain in pounds (Lbs) (5)					
How much pregnancy weight did you lose 6 months after each pregnancy? please state estimated weight loss in pounds (Lbs) (6)					

Q50 Click to write the question text

	Underweight (1)	Normal weight (2)	Overweight (3)	Obese (4)
Before pregnancy (1st) (1)	☐	☐	☐	☐
During pregnancy (1st) (2)	☐	☐	☐	☐
6 months after pregnancy (1st) (3)	☐	☐	☐	☐
Before pregnancy (2nd) (4)	☐	☐	☐	☐
During pregnancy (2nd) (5)	☐	☐	☐	☐
6 months after pregnancy (2nd) (6)	☐	☐	☐	☐
Before pregnancy (3rd) (7)	☐	☐	☐	☐
During pregnancy (3rd) (8)	☐	☐	☐	☐
6 months after pregnancy (3rd) (9)	☐	☐	☐	☐

Q51 Please use this box to provide details for further pregnancies if necessary

_____

_____

_____

_____

_____

End of Block: Pregnancy

Start of Block: Mechanisms of Pathophysiology

Q53 **Hormone Balance.** For females only:

Are you still menstruating?

- ☐ Yes (1)
- ☐ No (2)

Skip To: Q55 If Hormone Balance. For females only: Are you still menstruating? = Yes

Q54 When did your periods cease and why?

_____

Skip To: Q58 If When did your periods cease and why? Is Not Empty

Skip To: Q58 If When did your periods cease and why? Is Empty

Q55 Are your periods regular?

- [ ] Yes (1)
- [ ] No (2)

Skip To: Q57 If Are your periods regular? = Yes

Q56 If no, please give further details:

_____

_____

_____

_____

_____

Q57 On average, what is the length of time between periods?

▼ Less than 20 days (1) ... More than 40 days (4)

Q58 Please highlight any of the following that apply to you and indicate if they apply currently or in the past:	Currently (1)	In the past (2)	Unsure (3)
Hot flushes (1)	☐	☐	☐
Menopausal symptoms (2)	☐	☐	☐
PCOS (3)	☐	☐	☐
Fertility problems (4)	☐	☐	☐
Facial hair (5)	☐	☐	☐
Insomnia (6)	☐	☐	☐
Ovarian Cysts (7)	☐	☐	☐
Endometriosis (8)	☐	☐	☐
Breast cysts (9)	☐	☐	☐

Swollen/tender breasts (10)	☐	☐	☐
Night sweats (11)	☐	☐	☐
PMT (12)	☐	☐	☐
Fibroids (13)	☐	☐	☐
Loss of libido (14)	☐	☐	☐
Mood swings (15)	☐	☐	☐

Q59 Other:

_____

_____

_____

_____

_____

Q60 Are you, or have you ever been, on HRT or bio-identical hormones?

- ☐ Yes (1)
- ☐ No (2)

Skip To: Q62 If Are you, or have you ever been, on HRT or bio-identical hormones? = No

Q61 Please give further details:

_____

Q62 Have you ever had:

	Yes (1)	No (2)
Birth control pills (1)	☐	☐
Birth control implants (2)	☐	☐
IUD coil (3)	☐	☐

Q63 How long did you use these contraception's?

- ☐ 6 months - 2 years (1)
- ☐ 2 - 5 years (2)
- ☐ more than 5 years (3)

Q65 **Inflammation**

	almost every day (1)	at least once a week (2)	once or twice a month (3)	a few times a year (4)	never (5)
How often do you feel aches and pains? such as back pain, neck pain, headaches or general soreness. (1)	☐	☐	☐	☐	☐
How often do you take anti-inflammatory or anti-pain medication such as ibuprofen, aspirin or prescription drugs? (2)	☐	☐	☐	☐	☐

Q66 what are the most common causes of pain you experience? e.g. back ache, head ache, period pain etc.

_____

Q67 Please highlight any of the following that apply to you and indicate if they apply currently or in the past:	currently (1)	in the past (2)	Unsure (3)
Allergies or hypersensitivities e.g. hay-fever, food allergies, rhinitis (1)	☐	☐	☐
Asthma (2)	☐	☐	☐
Autoimmune diseases e.g. systemic lupus, vitiligo, Hashimoto's, Addisions disease (3)	☐	☐	☐
Celiac disease (4)	☐	☐	☐
Cystitis (5)	☐	☐	☐
Inflammation of the prostate gland (men only) (6)	☐	☐	☐
Inflammatory kidney condition (7)	☐	☐	☐
Inflammatory skin conditions e.g. acne, eczema, rosacea, psoriasis (8)	☐	☐	☐

Inflammatory bowel disease e.g. ulcerative colitis, Crohn's (9)	☐	☐	☐
Non-coeliac gluten sensitivity (10)	☐	☐	☐
Pelvic inflammatory disease (11)	☐	☐	☐

Q68 Any other inflammatory condition?

_____

Q69 Please give further details of inflammatory conditions you have experienced:

_____

_____

_____

_____

_____

Q71 **Behaviour and Food**

Please highlight which if the following best applies to you:

	not at all (1)	occasionally (2)	sometimes (3)	frequently (4)	always (5)
I frequently think about food (1)	☐	☐	☐	☐	☐
I frequently crave food (2)	☐	☐	☐	☐	☐
I continue to eat after I feel full (3)	☐	☐	☐	☐	☐
I feel hungry no matter what I eat (4)	☐	☐	☐	☐	☐
I cannot go long periods without eating (5)	☐	☐	☐	☐	☐
I always feel hungry (6)	☐	☐	☐	☐	☐

Q73 **Digestive Issues** Please highlight any of the following that apply to you and indicate if they apply currently or in the past:	currently (1)	in the past (2)	Unsure (3)
Indigestion (1)	☐	☐	☐
Heartburn (2)	☐	☐	☐
Bowel movements shortly after eating (3)	☐	☐	☐
Frequent stomach upsets or pain (4)	☐	☐	☐
Nausea or vomiting (5)	☐	☐	☐
Constipation or hard to pass stools (6)	☐	☐	☐
Diarrhoea or urgency to go (7)	☐	☐	☐
Blood in stools / black stools (8)	☐	☐	☐
Undigested food in stools (9)	☐	☐	☐

Stools are not well formed (loose) (10)	☐	☐	☐
Excessive foul smelling gas (11)	☐	☐	☐
Cramping in lower abdomen (12)	☐	☐	☐
Mucus in stools (13)	☐	☐	☐
Pain between shoulders or under the rib cage (14)	☐	☐	☐
Irritable bowel syndrome (IBS) (15)	☐	☐	☐
Offensive stools (16)	☐	☐	☐
Pale, bulky stools (17)	☐	☐	☐
Stools that float (18)	☐	☐	☐
Stools that sink (19)	☐	☐	☐
Haemorrhoids (20)	☐	☐	☐

Anus itching (21)	☐	☐	☐
Thrush (22)	☐	☐	☐
Fungal or yeast infections e.g. athletes foot, ring worm (23)	☐	☐	☐
Parasites (24)	☐	☐	☐

Q74 How often do you have a bowel movement?

▼ More than once a day (1) ... Once every few days (3)

Q75 Other:

_____

Q76 Have you noticed any recent changes in your bowel habits?

- ☐ no (1)
- ☐ yes (2)
- ☐ other (3)

Skip To: Q79 If Have you noticed any recent changes in your bowel habits? = no

Q77 Please give details:

_____

_____

_____

_____

_____

Q79 **Blood Sugar Regulation** Please tick which of the following best applies to you:	never (1)	seldom (2)	often (3)	always (4)
I urinate more than I feel is normal (1)	☐	☐	☐	☐
I feel I urinate at night more frequently than is normal (2)	☐	☐	☐	☐
I feel very thirsty more frequently than normal (3)	☐	☐	☐	☐
I feel tired more frequently than normal (4)	☐	☐	☐	☐
I have experienced unexplained weight loss (5)	☐	☐	☐	☐
I have itching around the penis or vagina (6)	☐	☐	☐	☐
I have episodes of thrush (7)	☐	☐	☐	☐
I have skin tags (8)	☐	☐	☐	☐

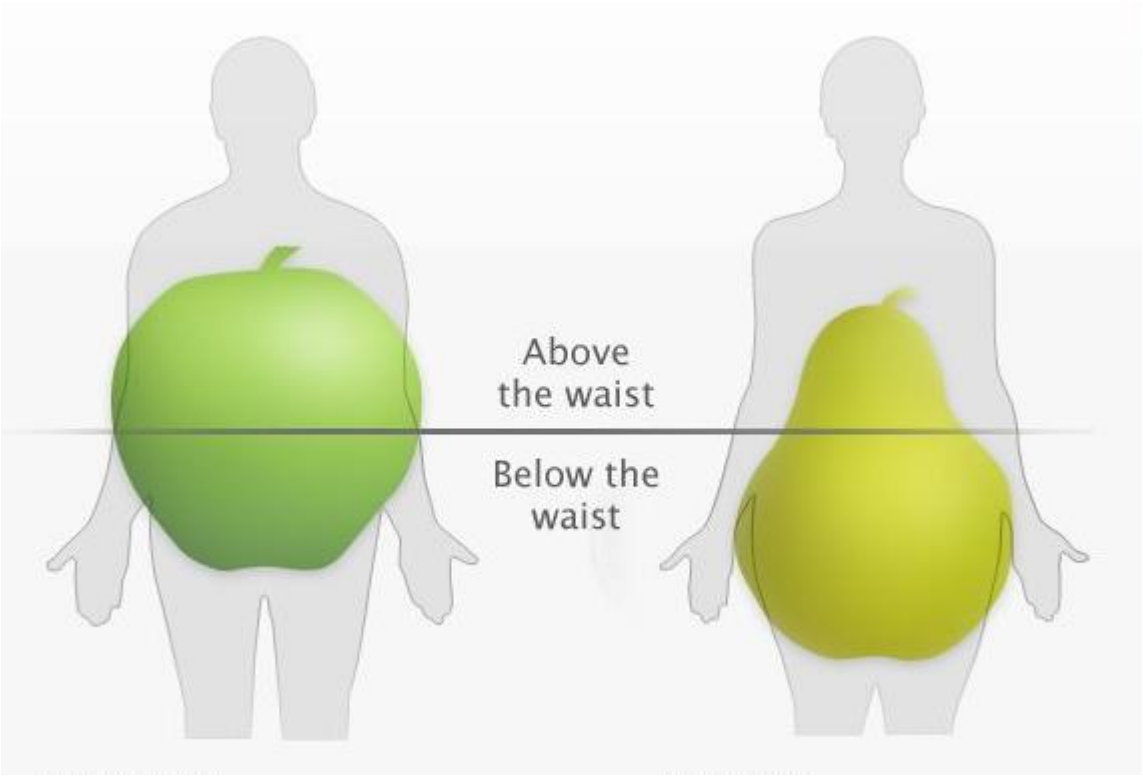
I experience cuts or wounds that heal slowly (9)	☐	☐	☐	☐
I experience blurred vision (10)	☐	☐	☐	☐
I experience weakness or dizziness after a period of fasting or with hunger (11)	☐	☐	☐	☐
I can feel extreme hunger (12)	☐	☐	☐	☐
I experience drowsiness (13)	☐	☐	☐	☐
I experience nausea (14)	☐	☐	☐	☐

Q81 **Blood Fats**

Do you have difficulty losing weight?

▼ not at all (1) ... extremely difficult (3)

Q82



Q83 Which apply to you?

- [ ] most of my weight is above the waist (apple) (1)
- [ ] most of my weight is below the waist (pear) (2)
- [ ] I am not sure (3)
- [ ] Other (4)

Skip To: Q85 If Which apply to you? = most of my weight is above the waist (apple)

Skip To: Q85 If Which apply to you? = most of my weight is below the waist (pear)

Skip To: Q85 If Which apply to you? = I am not sure

Skip To: Q84 If Which apply to you? = Other

Q84 Please describe your body weight:

_____

Q85 When did you last have your cholesterol tested:

▼ Never (1) ... In the last 5 years (5)

Skip To: Q102 If When did you last have your cholesterol tested: = Never

Q86 My cholesterol level is:

▼ Raised (1) ... I don't know (4)

Skip To: Q102 If My cholesterol level is: = Normal

Skip To: Q102 If My cholesterol level is: = I don't know

Q87 Click to write the question text

	Please provide exact cholesterol measure: (1)
Total Cholesterol: (1)	
Triglycerides: (2)	
Low Density Cholesterol (LDL): (3)	
High Density Cholesterol Level (HDL): (4)	

Q102 **Quality of Life**

Please select which of the following best applies to you:

	Very poor (1)	Poor (2)	Neither good nor poor (3)	Good (4)	Very good (5)
How would you rate your quality of life? (1)	☐	☐	☐	☐	☐
How would you rate your physical functioning? (2)	☐	☐	☐	☐	☐
How would you rate your general health? (3)	☐	☐	☐	☐	☐
How would you rate your emotional health? (4)	☐	☐	☐	☐	☐

Q99 Please select which of the following best apply to you:

	Not at all (1)	A little (2)	A moderate amount (3)	Very much (4)	An extreme amount (5)
How much do you enjoy life? (1)	☐	☐	☐	☐	☐
To what extent do you feel your life to be meaningful? (2)	☐	☐	☐	☐	☐
I feel able to accept my bodily appearance (3)	☐	☐	☐	☐	☐

Q100 Please select which of the following best apply to you:

	Strongly disagree (1)	Somewhat disagree (2)	Neither agree nor disagree (3)	Somewhat agree (4)	Strongly agree (5)
On the whole I feel satisfied with myself (1)	☐	☐	☐	☐	☐
I take a positive attitude towards myself (2)	☐	☐	☐	☐	☐

Q89 **Sleep**

Please highlight which of the following best applies to you:

	Never (1)	Seldom (2)	Weekly (3)	Every night (4)
I experience shortness of breath (1)	☐	☐	☐	☐
I snore (2)	☐	☐	☐	☐
I wake up in the night with a very dry and sore throat (3)	☐	☐	☐	☐
I wake up with a choking or gasping sensation (4)	☐	☐	☐	☐

Q90 Have you ever been diagnosed with sleep apnoea?

▼ No (1) ... Yes (2)

Skip To: Q105 If Have you ever been diagnosed with sleep apnoea? = No

Q91 When were you diagnosed with sleep apnoea? (DD/MM/YY)

_____

Q92 Are you receiving any treatment?

▼ Yes (1) ... No (2)

Q93 Please describe treatment

_____

Q105 How would you rate the quality of your sleep?

- ☐ Poor (1)
- ☐ Neither good nor poor (2)
- ☐ Good (3)

Q106 On average, how many hours sleep so you get per night?

- ☐ 3 or less (1)
- ☐ 4-5 (2)
- ☐ 6-8 (3)
- ☐ 9 or more (4)

Q104 Please select which if the following best applies to you:

	Always (1)	Often (2)	Seldom (3)	Never (4)
How frequently do you doze during the day? (1)	☐	☐	☐	☐
How frequently do you wake in the night? (2)	☐	☐	☐	☐
How frequently do you use over the counter or prescription sleep aids? (3)	☐	☐	☐	☐

Q108 **Stress** Please select which of the following best applies to you:	Never (1)	Almost never (2)	Sometimes (3)	Fairly often (4)	Very often (5)
In the last month, how often have you felt that you were unable to control the important things in your life? (1)	☐	☐	☐	☐	☐
In the last month, how often have you felt confident about your abilities to handle your personal problems? (2)	☐	☐	☐	☐	☐
In the last month, how often have you felt that things were going your way? (3)	☐	☐	☐	☐	☐

In the last month, how often have you felt difficulties were piling up so high that you could not overcome them? (4)	☐	☐	☐	☐	☐
How often do you have negative feelings such as depression, despair, anxiety? (5)	☐	☐	☐	☐	☐

Q94 Prior to the age of 17 I experienced stress or trauma (e.g. death of parent, separation, physical, emotional or sexual abuse, significant accident)

- ☐ No (1)
- ☐ I cannot remember (2)
- ☐ Yes (3)

Skip To: Q110 If Prior to the age of 17 I experienced stress or trauma (e.g. death of parent, separation, physical... = No

Skip To: Q110 If Prior to the age of 17 I experienced stress or trauma (e.g. death of parent, separation, physical... = I cannot remember

Q97 On a scale of 1 to 5 how traumatic was this?

- [ ] 1. least traumatic (1)
- [ ] 2. (2)
- [ ] 3. traumatic (3)
- [ ] 4. (4)
- [ ] 5. extremely traumatic (5)

Q96 Please provide further information if you wish to:

_____

_____

_____

_____

_____

Q110 **Motivation to change**

Please select which of the following best applies to you:

	Yes (1)	No (2)
In the past month, have you been actively trying to lose weight? (1)	☐	☐
In the past month, have you been actively trying to keep from weight gain? (2)	☐	☐
Are you seriously considering trying to lose weight to reach your goals in the next 6 months? (3)	☐	☐
Have you maintained your desired weight for more than 6 months? (4)	☐	☐

End of Block: Mechanisms of Pathophysiology

Start of Block: The end

Q114 Please **click save** to complete this questionnaire.
Thank you. Please do let your practitioner know you have completed it so they can get access your data. Your practitioner will arrange a consultation date and time with you.

Appendix 19 Tool 2 Intervention record - download of online format

Interventions Record

Start of Block: Dietary Recommendations

Q1 **INTERVENTIONS RECORD**

This tool should be completed by you, the practitioner, to record which interventions were recommended. Please complete it whenever new recommendations are made.

Q21 The aim of this pilot trial is to assess the way health information is collected and interpreted.

Your participation in this study is entirely voluntary and you can withdraw at any time and you are free to omit any question. You should be aware that the data you provide may be used for analysis and subsequent publication. The researchers will implement procedures to maintain the confidentiality of the participant data. Personal information provided will be stored in computer files secured by means of passwords or in locked cabinets. Only the researcher and authorised supervisors will be able to access the information. Personal information will be destroyed once the research is completed.

Thank you very much and please do get in touch if you have any questions.

Researcher: Michelle Barrow; Centre for Nutrition Education and Lifestyle Management (CNELM) and Middlesex University
michelle@cnelm.co.uk
Research Supervisors: Dr L Bell (L.bell@mdx.ac.uk); Dr C. Bell (c.bell@mdx.ac.uk)

Study title: Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in weight management.
Academic Year: 2016/17

Q23 Practitioner Name:

_____

Q17 Participant Information Number:

_____

JS

Q2 Date of record completion:

Month (1)	▼ January (1) ... (150)
Day (2)	▼ January (1) ... (150)
Year (3)	▼ January (1) ... (150)

Q3 **Dietary recommendations**

Please highlight which of the following dietary interventions are recommended:

- [ ] Anti-Candida (1)
- [ ] Fodmaps (2)
- [ ] Intermittent fasting (3)
- [ ] Low fat (4)
- [ ] Low salt (5)
- [ ] Meal replacement (6)
- [ ] Vegan (7)
- [ ] Other: (please state in box below) (8)

_____

- [ ] Balanced glycaemic load (9)
- [ ] Dairy Free (10)
- [ ] Juicing (11)
- [ ] Low glycaemic index (12)
- [ ] Low sugar (13)
- [ ] Nut free (14)
- [ ] Vegetarian (15)
- [ ] Calorie restriction (16)

- [ ] Gluten free (17)
- [ ] Ketogenic (18)
- [ ] Low histamine (19)
- [ ] Micro matching (20)
- [ ] Nutrient dense (21)
- [ ] Wheat free (22)

Q4 Please indicate which of the following food changes were recommended, giving an indication of portion size where possible:

	Increase intake (1)	Decrease intake (2)	Maintain art current levels (3)	Avoid (4)	Not applicable (5)
Alcohol (1)					
Caffeine (2)					
Complex carbohydrates (3)					
Essential fatty acids - Omega 3 (4)					
Essential fatty acids - Omega 6 (5)					
Fluid - water (6)					
Fluid -other (7)					

Fruit (8)					
Prebiotic foods (9)					
Probiotics foods (10)					
Protein (11)					
Raw foods (12)					
Salt (13)					
Saturated fat (14)					
Simple carbohydrates (15)					
Soy foods (16)					

Sugar (17)					
Vegetables (18)					
Wholegrains (19)					
Other (please state) (20)					
Other (please state) (21)					
Other (please state) (22)					

Q7 Please describe any other dietary recommendations: (e.g. timing of eating)

_____

_____

_____

_____

End of Block: Dietary Recommendations

Start of Block: Physical Activity

Q5 **Physical Activity**

was physical activity recommended?

- [ ] Yes (1)
- [ ] No (2)

Skip To: End of Block If Physical Activity was physical activity recommended? = No

Q6 Please indicate the type and duration of exercise, stating the number of recommended minutes per week	Minutes per week (1)	Further details: (2)
Aerobics (1)		
Cycling (2)		
Dancing (3)		
Gardening (4)		
Gym classes (state which) (5)		
Running (6)		
Strength Training (7)		
Swimming (8)		

Team sports (state which) (9)		
Other (please state) (10)		
Other (please state) (11)		

Q8 Please describe any other physical activity recommendations:

_____

_____

_____

_____

End of Block: Physical Activity

Start of Block: Supplement recommendations

Q9 **Supplement recommendations**

Were supplements recommended?

- ☐ Yes (1)
- ☐ No (2)

Skip To: End of Block If Supplement recommendations Were supplements recommended? = No

Q10 Please indicate which supplements were recommended and provide the product brand and name, recommended dose and duration of recommendation:	Product brand and name (1)	Recommended dose (2)	Duration of recommendation e.g. 1 week, 1 month, 6 months, ongoing. (3)
Multi vitamins and minerals (1)			
Fatty acids (2)			
Probiotics (3)			
Amino acids (4)			
Herbal products (5)			
Slimming aids (6)			
B vitamin formulas (7)			

Vitamin C formulas (8)			
Vitamin D formulas (9)			
Vitamin E formulas (10)			
Calcium formulas (11)			
Chromium formulas (12)			
Iron formulas (13)			
Magnesium formulas (14)			
Specific vitamins (15)			
Specific minerals (16)			

Brain and nervous system support (17)			
Cardiovascular products (18)			
Energy support (19)			
Female health products (20)			
Gastrointestinal support (21)			
Glandular formulas (22)			
Immune support (23)			
Inflammatory formulas (24)			
Joint support (25)			

Liver support (26)			
Male health products (27)			
Muscle support (28)			
Other (please state) (29)			
Other (please state) (30)			
Other (please state) (31)			

End of Block: Supplement recommendations

Start of Block: Test recommendations

Q11 **Test recommendations**

Were tests recommended?

- [ ] Yes (1)
- [ ] No (2)

Skip To: End of Block If Test recommendations Were tests recommended? = No

Q12 Please indicate which tests were recommended, provide the test name and from where the test was requested:	Test details e.g. name, biomarker (1)	Source of test e.g. GP, biolab, doctors data, Genova diagnostics etc. (2)
Allergy or intolerance testing (1)		
Amino acid analysis (2)		
Biochemistry / haematology profile (3)		
Cholesterol (4)		
Fasting sugar and haemogolbin A1c (5)		
Fasting lipid panel (6)		
Fatty acids profile (7)		
Gastrointestinal profile (8)		

Genetic or genomic assessment (9)		
Hormone analysis (10)		
Inflammatory markers (11)		
Liver function assessment (12)		
Nutritional profile (13)		
Oxidative stress profile (14)		
Specific minerals (15)		
Specific vitamins (16)		
Thyroid function test (17)		
Toxic metal screen (18)		

Other (please state): (19)		
Other (please state): (20)		

End of Block: Test recommendations

Start of Block: Referral recommendations

Q13 **Referral recommendations**

Were any recommendations made for further support?

- ☐ Yes (1)
- ☐ No (2)

Skip To: End of Survey If Referral recommendations Were any recommendations made for further support? = No

Q14 Please indicate which referrals were made

- Bariatric surgery (1)
- Other health care professional (please stat):e (2)

  _____

- Other (please state): (3) _____
- Counselling/psychological support (4)
- Personal trainer/gym (5)
- Eating disorder support (6)
- General practitioner (7)
- Life coaching (8)
- Sleep apnoea assessment (9)

End of Block: Referral recommendations

Start of Block: The end

Q17 Please **click save** to complete this form.
Thank you very much for your involvement in this research project.

Q22 Data may be inspected by the Chair of the Health Studies Ethics sub-committee and the Chair of the School of Social Sciences Ethics committee of Middlesex University, if required by institutional audits about the correctness of procedures. Although this would happen in strict confidentiality, please write NO if you do not wish this data to be included in audits.

_____

End of Block: The end

Appendix 20 Tool 3 Follow-up Questionnaire - download of online format

Follow-up Personalised Nutrition Health Questionnaire

Start of Block: Socio Cultural

Q113 **PERSONALISED FOLLOW-UP QUESTIONNAIRE**

Please complete this follow-up questionnaire as comprehensively as possible. Many of the questions are a repeat from the first questionnaire so that an assessment of changes to your health can be made. It may take up to 1 hour to complete the whole questionnaire.

On completion, the information will be sent to your nutrition practitioner. The aims, duration and outcome of the nutrition consultation will remain the same.

The aim of this pilot trial is to assess the way health information is collected and interpreted. After completion you will then be invited to complete a short 10 question survey to assess your experience of using this questionnaire.

Q118 Your participation in this study is entirely voluntary and you can withdraw at any time and you are free to omit any question. You should be aware that the data you provide may be used for analysis and subsequent publication. The researchers will implement procedures to maintain the confidentiality of the participant data. Personal information provided will be stored in computer files secured by means of passwords or in locked cabinets. Only the researcher and authorised supervisors will be able to access the information. Personal information will be destroyed once the research is completed.

Thank you very much and please do get in touch if you have any questions.

Researcher: Michelle Barrow; Centre for Nutrition Education and Lifestyle Management (CNELM) and Middlesex University
michelle@cnelm.co.uk

Research Supervisors: Dr L Bell (L.bell@mdx.ac.uk); Dr C. Bell (c.bell@mdx.ac.uk)
Study title: Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in weight management.
Academic Year: 2016/17

Q117 Name of your Nutritionist/Dietician/Nutritional Therapist/Practitioner:

_____

Q115 Your Participant Information Number:

_____

Q5 Last week, you were (select all that apply):

- working as an employee (1)
- working self-employed or freelance (2)
- away from work ill, on maternity leave or temporarily laid off (3)
- on a training scheme (4)
- in full time or part time education (5)
- retired (6)
- looking after home or family (7)
- long-term sick or disabled (8)
- other (please state in box below) (9)

  _____

Q11 Have you ever used food aid systems, such as food stamps, food banks or other food support initiatives?

▼ N/A (1) ... Over 2 years ago (5)

Skip To: Q14 If Have you ever used food aid systems, such as food stamps, food banks or other food support initia... = N/A

Q12 If yes, how frequently have you used food aid systems during that period:

▼ 1-5 times (1) ... More than 20 times (4)

Q14 Which category best describes your total annual household income before taxes:

▼ Less than £25,000 (1) ... £200,000 or more (8)

End of Block: Socio Cultural

Start of Block: Weight Assessment

Q16 What is your current weight in stone and pounds?

Stone (1)

Pounds (2)

▼ 1 (1) ... 65 ~ 13 (975)

End of Block: Weight Assessment

Start of Block: Family health and weight history

Page Break

Q22 **Personal Health History**

Please select if you are have experienced any of these since your last nutrition consultation:

- unexplained pain (1)
- bleeding from nipple (2)
- blood in sputum (3)
- blood in urine (4)
- blood in vomit (5)
- blurred vision or dizziness (6)
- breast lumps (7)
- calf swelling (8)
- changes in nature of moles (9)
- chest pain (10)
- difficulty swallowing (11)
- discharge from vagina (12)
- headaches (13)
- loss of appetite (14)
- numbness (15)
- paralysis (16)
- persistent cough (17)
- persistent nose bleeds (18)
- shortness of breath (19)
- slurred speech (20)
- unexplained bruising (21)
- unexplained rash (22)
- unexplained weight loss (23)
- unexplained heavy periods (24)
- unexplained loss of periods (25)

If you are currently experiencing any of these conditions please make an appointment to see your primary health care provider such as your G.P.

Q26 The following table aims to identify any changes to health conditions since your last consultation. Please complete providing as much information as possible. Please use box on next question to provide more information if necessary	Leave blank if not applicable. Write "current" if you are currently experiencing this condition. Write "past" if you have previously experienced this condition. Write “new” if you have developed this condition since your last nutrition consultation. (1)	Please provide more details e.g. type of condition (2)	Have there been any improvements or positive changes to this condition or its symptoms since your last nutrition consultation? (3)	Has there been any deterioration or negative changes to this condition or its symptoms since your last nutrition consultation? (4)	How is it currently being managed/treated? (medication, surgery, therapy etc.) (5)
addiction (1)					
arthritis: rheumatoid or osteoarthritis etc. (2)					
autism (3)					

cancer (4)					
chronic fatigue (5)					
dementia e.g. Alzheimer's (6)					
depression (7)					
disturbed sleep or insomnia (8)					
eating disorder e.g. binge eating disorder/bulimia (9)					
eye disease e.g. glaucoma (10)					

food allergy e.g. celiac, peanut, dairy etc. (11)					
gall bladder disease (12)					
gout (13)					
heart disease or vascular disease (14)					
hepatitis (A,B or C) (15)					
herpes virus, including Epstein Barr or shingles (16)					
high blood pressure (17)					

kidney disease (18)					
liver disease (19)					
mood or anxiety disorder (20)					
night eating syndrome (21)					
polycystic ovarian syndrome (22)					
post-traumatic stress (23)					
respiratory disorders e.g. asthma, sleep apnoea (24)					

thyroid disease or condition (25)					
type 1 diabetes (26)					
type 2 diabetes (27)					
any other disease or condition (28)					

Q27 Please provide more information regarding the previous question if you wish:

_____

_____

_____

_____

_____

Page Break

Q28 Please list below all the medications, drugs or supplements you took in the PAST MONTH. For each one you list please answer the questions below as best as you can. Medications include prescriptions, over the counter medicines, cold remedies, painkillers, contraceptives, creams, injections, eye drops etc. Supplements include vitamins, minerals, herbs, probiotics etc.	Medication, drug or supplement name or type (1)	dose/strength e.g. mg, ml etc. (2)	for what reason were you taking these (3)	How many days did you take it? (4)	How many times did you take each day? (5)	How many times did you miss taking it? (6)	How well does it work for you? well, okay, not well, unsure (7)
Medication/drug: (1)							
Medication/drug: (2)							

Medication/drug: (3)							
Medication/drug: (4)							
Medication/drug: (5)							
Medication/drug: (6)							
Supplement: (7)							
Supplement: (8)							
Supplement: (9)							
Supplement: (10)							

Q30 Please provide more information regarding the previous question if you wish:

_____

_____

_____

_____

_____

Page Break

Q29 Do you currently smoke tobacco (e.g. cigarettes, cigars, pipes etc.) or e-cigarettes?

▼ No (1) ... Less than daily (3)

Skip To: Q33 If Do you currently smoke tobacco (e.g. cigarettes, cigars, pipes etc.) or e-cigarettes? = No

Skip To: Q31 If Do you currently smoke tobacco (e.g. cigarettes, cigars, pipes etc.) or e-cigarettes? = Daily

Skip To: Q32 If Do you currently smoke tobacco (e.g. cigarettes, cigars, pipes etc.) or e-cigarettes? = Less than daily

Q31 How many per day?

_____

Q32 How many per month?

_____

Q33 Have you smoked tobacco or e-cigarettes in the past?

▼ No (1) ... Yes (3)

Skip To: End of Block If Have you smoked tobacco or e-cigarettes in the past? = No

Q42 At what age did you start smoking?

▼ 16 (1) ... 75 (60)

Q43 For how long did you smoke:

_____

Q44 How many times per day did, or do, you smoke?

▼ 1-5 (1) ... more than 40 times per day (9)

Q34 How does smoking affect your weight?

▼ keeps my weight down (1) ... I don't know (4)

Q35 How many times have you stopped smoking for more than 3 months?

▼ Never (1) ... more than 20 times (6)

Q36 If you have smoked and stopped, did you gain weight as a result of stopping smoking?

▼ No (1) ... Yes (3)

Q37 How much weight did you gain as a result of stopping smoking?

_____

Q38 How many times did you gain weight as a result of stopping smoking?

_____

End of Block: Family health and weight history

Start of Block: Pregnancy

Q39 **Pregnancy**

Are you pregnant now?

- ☐ Yes (1)
- ☐ Maybe (2)
- ☐ No (3)
- ☐ I don't know (4)

Skip To: Q41 If Pregnancy Are you pregnant now? = No

Skip To: Q41 If Pregnancy Are you pregnant now? = I don't know

Q40 How many weeks pregnant are you?

_____

Q41 Have you ever been pregnant?

- ☐ Yes (1)
- ☐ No (2)
- ☐ I don't know (3)

Skip To: End of Block If Have you ever been pregnant? = No

Skip To: End of Block If Have you ever been pregnant? = I don't know

Q47 How many times have you been pregnant?

▼ once (1) ... more than seven times (8)

Q48 How many children have you given birth too?

▼ 1 (1) ... More than 6 (7)

Q49 Please answer where possible:	Child 1 (1)	Child 2 (2)	Child 3 (3)	Child 4 (4)	Child 5 (5)
Sex of each child: M/F (1)					
Date of birth for each child: DD/MM/YY (2)					
Vaginal delivery: Yes/No (3)					
Did you experience gestational diabetes: Yes/No (4)					

On average, how much weight did you put on during each pregnancy? please state estimated weight gain in pounds (Lbs) (5)					
How much pregnancy weight did you lose 6 months after each pregnancy? please state estimated weight loss in pounds (Lbs) (6)					

End of Block: Pregnancy

Start of Block: Mechanisms of Pathophysiology

Q58 Hormone Balance. For females only: Please highlight any of the following that apply to you and indicate if they apply currently or in the past:	Currently (1)	In the past (2)	Unsure (3)
Hot flushes (1)	☐	☐	☐
Menopausal symptoms (2)	☐	☐	☐
PCOS (3)	☐	☐	☐
Fertility problems (4)	☐	☐	☐
Facial hair (5)	☐	☐	☐
Insomnia (6)	☐	☐	☐
Ovarian Cysts (7)	☐	☐	☐
Endometriosis (8)	☐	☐	☐

Breast cysts (9)	☐	☐	☐
Swollen/tender breasts (10)	☐	☐	☐
Night sweats (11)	☐	☐	☐
PMT (12)	☐	☐	☐
Fibroids (13)	☐	☐	☐
Loss of libido (14)	☐	☐	☐
Mood swings (15)	☐	☐	☐

Q59 Other:

_____

_____

_____

_____

_____

Q60 Are you, or have you ever been, on HRT or bio-identical hormones?

- ☐ Yes (1)
- ☐ No (2)

Skip To: Q62 If Are you, or have you ever been, on HRT or bio-identical hormones? = No

Q61 Please give further details:

_____

Q62 Have you ever had:

	Yes (1)	No (2)
Birth control pills (1)	☐	☐
Birth control implants (2)	☐	☐
IUD coil (3)	☐	☐

Q63 How long did you use these contraception’s?

- [ ] 6 months - 2 years (1)
- [ ] 2 - 5 years (2)
- [ ] more than 5 years (3)

Q65 **Inflammation**

	almost every day (1)	at least once a week (2)	once or twice a month (3)	a few times a year (4)	never (5)
How often do you feel aches and pains? such as back pain, neck pain, headaches or general soreness. (1)	☐	☐	☐	☐	☐
How often do you take anti-inflammatory or anti-pain medication such as ibuprofen, aspirin or prescription drugs? (2)	☐	☐	☐	☐	☐

Q66 what are the most common causes of pain you experience? e.g. back ache, head ache, period pain etc.

_____

Q67 Please highlight any of the following that apply to you and indicate if they apply currently or in the past:	currently (1)	in the past (2)	Unsure (3)
Allergies or hypersensitivities e.g. hay-fever, food allergies, rhinitis (1)	☐	☐	☐
Asthma (2)	☐	☐	☐
Autoimmune diseases e.g. systemic lupus, vitiligo, Hashimoto's, Addisions disease (3)	☐	☐	☐
Celiac disease (4)	☐	☐	☐
Cystitis (5)	☐	☐	☐
Inflammation of the prostate gland (men only) (6)	☐	☐	☐
Inflammatory kidney condition (7)	☐	☐	☐
Inflammatory skin conditions e.g. acne, eczema, rosacea, psoriasis (8)	☐	☐	☐

Inflammatory bowel disease e.g. ulcerative colitis, Crohn's (9)	☐	☐	☐
Non-coeliac gluten sensitivity (10)	☐	☐	☐
Pelvic inflammatory disease (11)	☐	☐	☐

Q68 Any other inflammatory condition?

_____

Q69 Please give further details of inflammatory conditions you have experienced:

_____

_____

_____

_____

_____

Q71 **Behaviour and Food**

Please highlight which if the following best applies to you:

	not at all (1)	occasionally (2)	sometimes (3)	frequently (4)	always (5)
I frequently think about food (1)	☐	☐	☐	☐	☐
I frequently crave food (2)	☐	☐	☐	☐	☐
I continue to eat after I feel full (3)	☐	☐	☐	☐	☐
I feel hungry no matter what I eat (4)	☐	☐	☐	☐	☐
I cannot go long periods without eating (5)	☐	☐	☐	☐	☐
I always feel hungry (6)	☐	☐	☐	☐	☐

Q73 **Digestive Issues** Please highlight any of the following that apply to you and indicate if they apply currently or in the past:	currently (1)	in the past (2)	Unsure (3)
Indigestion (1)	☐	☐	☐
Heartburn (2)	☐	☐	☐
Bowel movements shortly after eating (3)	☐	☐	☐
Frequent stomach upsets or pain (4)	☐	☐	☐
Nausea or vomiting (5)	☐	☐	☐
Constipation or hard to pass stools (6)	☐	☐	☐
Diarrhoea or urgency to go (7)	☐	☐	☐
Blood in stools / black stools (8)	☐	☐	☐
Undigested food in stools (9)	☐	☐	☐

Stools are not well formed (loose) (10)	☐	☐	☐
Excessive foul smelling gas (11)	☐	☐	☐
Cramping in lower abdomen (12)	☐	☐	☐
Mucus in stools (13)	☐	☐	☐
Pain between shoulders or under the rib cage (14)	☐	☐	☐
Irritable bowel syndrome (IBS) (15)	☐	☐	☐
Offensive stools (16)	☐	☐	☐
Pale, bulky stools (17)	☐	☐	☐
Stools that float (18)	☐	☐	☐
Stools that sink (19)	☐	☐	☐
Haemorrhoids (20)	☐	☐	☐

Anus itching (21)	☐	☐	☐
Thrush (22)	☐	☐	☐
Fungal or yeast infections e.g. athletes foot, ring worm (23)	☐	☐	☐
Parasites (24)	☐	☐	☐

Q74 How often do you have a bowel movement?

▼ More than once a day (1) ... Once every few days (3)

Q75 Other:

_____

Q76 Have you noticed any recent changes in your bowel habits?

- ☐ no (1)
- ☐ yes (2)
- ☐ other (3)

Skip To: Q79 If Have you noticed any recent changes in your bowel habits? = no

Q77 Please give details:

_____

_____

_____

_____

_____

Q79 **Blood Sugar Regulation** Please tick which of the following best applies to you:	never (1)	seldom (2)	often (3)	always (4)
I urinate more than I feel is normal (1)	☐	☐	☐	☐
I feel I urinate at night more frequently than is normal (2)	☐	☐	☐	☐
I feel very thirsty more frequently than normal (3)	☐	☐	☐	☐
I feel tired more frequently than normal (4)	☐	☐	☐	☐
I have experienced unexplained weight loss (5)	☐	☐	☐	☐
I have itching around the penis or vagina (6)	☐	☐	☐	☐
I have episodes of thrush (7)	☐	☐	☐	☐
I have skin tags (8)	☐	☐	☐	☐

I experience cuts or wounds that heal slowly (9)	☐	☐	☐	☐
I experience blurred vision (10)	☐	☐	☐	☐
I experience weakness or dizziness after a period of fasting or with hunger (11)	☐	☐	☐	☐
I can feel extreme hunger (12)	☐	☐	☐	☐
I experience drowsiness (13)	☐	☐	☐	☐
I experience nausea (14)	☐	☐	☐	☐

Q85

Blood Fats

When did you last have your cholesterol tested:

▼ Never (1) ... In the last 5 years (5)

Skip To: Q102 If Blood Fats When did you last have your cholesterol tested: = Never

Q86 My cholesterol level is:

▼ Raised (1) ... I don't know (4)

Skip To: Q102 If My cholesterol level is: = Normal

Skip To: Q102 If My cholesterol level is: = I don't know

Q87 Click to write the question text

	Please provide exact cholesterol measure: (1)
Total Cholesterol: (1)	
Triglycerides: (2)	
Low Density Cholesterol (LDL): (3)	
High Density Cholesterol Level (HDL): (4)	

Q102 **Quality of Life**

Please select which of the following best applies to you:

	Very poor (1)	Poor (2)	Neither good nor poor (3)	Good (4)	Very good (5)
How would you rate your quality of life? (1)	☐	☐	☐	☐	☐
How would you rate your physical functioning? (2)	☐	☐	☐	☐	☐
How would you rate your general health? (3)	☐	☐	☐	☐	☐
How would you rate your emotional health? (4)	☐	☐	☐	☐	☐

Q99 Please select which of the following best apply to you:

	Not at all (1)	A little (2)	A moderate amount (3)	Very much (4)	An extreme amount (5)
How much do you enjoy life? (1)	☐	☐	☐	☐	☐
To what extent do you feel your life to be meaningful? (2)	☐	☐	☐	☐	☐
I feel able to accept my bodily appearance (3)	☐	☐	☐	☐	☐

Q100 Please select which of the following best apply to you:

	Strongly disagree (1)	Somewhat disagree (2)	Neither agree nor disagree (3)	Somewhat agree (4)	Strongly agree (5)
On the whole I feel satisfied with myself (1)	☐	☐	☐	☐	☐
I take a positive attitude towards myself (2)	☐	☐	☐	☐	☐

Q89 **Sleep**

Please highlight which of the following best applies to you:

	Never (1)	Seldom (2)	Weekly (3)	Every night (4)
I experience shortness of breath (1)	☐	☐	☐	☐
I snore (2)	☐	☐	☐	☐
I wake up in the night with a very dry and sore throat (3)	☐	☐	☐	☐
I wake up with a choking or gasping sensation (4)	☐	☐	☐	☐

Q90 Have you ever been diagnosed with sleep apnoea?

▼ No (1) ... Yes (2)

Skip To: Q105 If Have you ever been diagnosed with sleep apnoea? = No

Q91 When were you diagnosed with sleep apnoea? (DD/MM/YY)

_____

Q92 Are you receiving any treatment?

▼ Yes (1) ... No (2)

Q93 Please describe treatment

_____

Q105 How would you rate the quality of your sleep?

- ☐ Poor (1)
- ☐ Neither good nor poor (2)
- ☐ Good (3)

Q106 On average, how many hours sleep so you get per night?

- ☐ 3 or less (1)
- ☐ 4-5 (2)
- ☐ 6-8 (3)
- ☐ 9 or more (4)

Q104 Please select which if the following best applies to you:

	Always (1)	Often (2)	Seldom (3)	Never (4)
How frequently do you doze during the day? (1)	☐	☐	☐	☐
How frequently do you wake in the night? (2)	☐	☐	☐	☐
How frequently do you use over the counter or prescription sleep aids? (3)	☐	☐	☐	☐

Q108 **Stress** Please select which of the following best applies to you:	Never (1)	Almost never (2)	Sometimes (3)	Fairly often (4)	Very often (5)
In the last month, how often have you felt that you were unable to control the important things in your life? (1)	☐	☐	☐	☐	☐
In the last month, how often have you felt confident about your abilities to handle your personal problems? (2)	☐	☐	☐	☐	☐
In the last month, how often have you felt that things were going your way? (3)	☐	☐	☐	☐	☐

In the last month, how often have you felt difficulties were piling up so high that you could not overcome them? (4)	☐	☐	☐	☐	☐
How often do you have negative feelings such as depression, despair, anxiety? (5)	☐	☐	☐	☐	☐

Q110 **Motivation to change**

Please select which of the following best applies to you:

	Yes (1)	No (2)
In the past month, have you been actively trying to lose weight? (1)	☐	☐
In the past month, have you been actively trying to keep from weight gain? (2)	☐	☐
Are you seriously considering trying to lose weight to reach your goals in the next 6 months? (3)	☐	☐
Have you maintained your desired weight for more than 6 months? (4)	☐	☐

End of Block: Mechanisms of Pathophysiology

Start of Block: The end

Q114 Please **click save** to complete this questionnaire.
Thank you. Please do let your practitioner know you have completed it so they can get access your data. Your practitioner will arrange a consultation date and time with you.

Q119 Data may be inspected by the Chair of the Health Studies Ethics sub-committee and the Chair of the School of Social Sciences Ethics committee of Middlesex University, if required by institutional audits about the correctness of procedures. Although this would happen in strict confidentiality, please write NO if you do not wish your data to be included in audits.

_____

End of Block: The end

Appendix 21 Tool 4 Achievement record - download of online format

Achievement Record

Start of Block: Dietary achievements

Q1 **ACHIEVEMENT RECORD**

This tool should be completed by practitioner to record which interventions that the client achieved. This record should be completed at the start of every follow-up appointment to assess which interventions the client achieved.

Q20 The aim of this pilot trial is to assess the way health information is collected and interpreted.

Your participation in this study is entirely voluntary and you can withdraw at any time and you are free to omit any question. You should be aware that the data you provide may be used for analysis and subsequent publication. The researchers will implement procedures to maintain the confidentiality of the participant data. Personal information provided will be stored in computer files secured by means of passwords or in locked cabinets. Only the researcher and authorised supervisors will be able to access the information. Personal information will be destroyed once the research is completed.

Thank you very much and please do get in touch if you have any questions.

Researcher: Michelle Barrow; Centre for Nutrition Education and Lifestyle Management (CNELM) and Middlesex University
michelle@cnelm.co.uk
Research Supervisors: Dr L Bell (L.bell@mdx.ac.uk); Dr C. Bell (c.bell@mdx.ac.uk)
Study title: Constructing validated clinical tools to enable the development of a new evidence base for personalised nutrition practice in weight management.
Academic Year: 2016/17

Q22 Practitioner Name:

_____

Q18 Participant Information Number:

_____

JS

Q2 Date of record completion:

Month (1)	▼ January (1) ... (150)
Day (2)	▼ January (1) ... (150)
Year (3)	▼ January (1) ... (150)

Q3 **Dietary recommendations**

Please tick which of the following dietary interventions were achieved:

- [ ] Anti-Candida (1)
- [ ] Fodmaps (2)
- [ ] Intermittent fasting (3)
- [ ] Low fat (4)
- [ ] Low salt (5)
- [ ] Meal replacement (6)
- [ ] Vegan (7)
- [ ] Other: (please state in box below) (8)

_____

- [ ] Balanced glycaemic load (9)
- [ ] Dairy Free (10)
- [ ] Juicing (11)
- [ ] Low glycaemic index (12)
- [ ] Low sugar (13)
- [ ] Nut free (14)
- [ ] Vegetarian (15)
- [ ] Calorie restriction (16)
- [ ] Gluten free (17)
- [ ] Ketogenic (18)
- [ ] Low histamine (19)

- [ ] Micro matching (20)
- [ ] Nutrient dense (21)
- [ ] Wheat free (22)

Q4 Please indicate which of the following food changes were achieved, giving an indication of portion size where possible:	Increase intake (1)	Decrease intake (2)	Maintain art current levels (3)	Avoid (4)	Not applicable (5)
Alcohol (1)					
Caffeine (2)					
Complex carbohydrates (3)					
Essential fatty acids - Omega 3 (4)					
Essential fatty acids - Omega 6 (5)					

Fluid - water (6)					
Fluid -other (7)					
Fruit (8)					
Prebiotic foods (9)					
Probiotics foods (10)					
Protein (11)					
Raw foods (12)					
Salt (13)					
Saturated fat (14)					

Simple carbohydrates (15)					
Soy foods (16)					
Sugar (17)					
Vegetables (18)					
Wholegrains (19)					
Other (please state) (20)					
Other (please state) (21)					
Other (please state) (22)					

Q7 Please describe any other dietary achievements:

_____

_____

_____

_____

_____

End of Block: Dietary achievements

Start of Block: Physical Activity

Q5 **Physical Activity**

was physical activity recommended?

- ○ Yes (1)
- ○ No (2)

Skip To: End of Block If Physical Activity was physical activity recommended? = No

Q6 Please indicate the type and duration of exercise, stating the number of minutes achieved per week:	Minutes per week (1)	Further details: (2)
Aerobics (1)		
Cycling (2)		
Dancing (3)		
Gardening (4)		
Gym classes (state which) (5)		
Running (6)		
Strength Training (7)		
Swimming (8)		

Team sports (state which) (9)		
Other (please state) (10)		
Other (please state) (11)		

Q8 Please describe any other physical activity achievements:_____

_____

_____

_____

_____

End of Block: Physical Activity

Start of Block: Supplement Recommendations

Q9 **Supplement recommendations**

Were supplements recommended?

- ○ Yes (1)
- ○ No (2)

Skip To: End of Block If Supplement recommendations Were supplements recommended? = No

Q10 Please indicate which supplements were taken and provide the product brand and name, recommended dose and duration of taking these supplements:	Product brand and name (1)	Recommended dose (2)	Duration of taking supplements e.g. 1 week, 1 month, 6 months, ongoing. (3)
Multi vitamins and minerals (1)			
Fatty acids (2)			
Probiotics (3)			
Amino acids (4)			
Herbal products (5)			
Slimming aids (6)			
B vitamin formulas (7)			

Vitamin C formulas (8)			
Vitamin D formulas (9)			
Vitamin E formulas (10)			
Calcium formulas (11)			
Chromium formulas (12)			
Iron formulas (13)			
Magnesium formulas (14)			
Specific vitamins (15)			
Specific minerals (16)			

Brain and nervous system support (17)			
Cardiovascular products (18)			
Energy support (19)			
Female health products (20)			
Gastrointestinal support (21)			
Glandular formulas (22)			
Immune support (23)			
Inflammatory formulas (24)			
Joint support (25)			

Liver support (26)			
Male health products (27)			
Muscle support (28)			
Other (please state) (29)			
Other (please state) (30)			
Other (please state) (31)			

End of Block: Supplement Recommendations

Start of Block: Test recommendations

Q11 **Test recommendations**

Were tests recommended?

- ○ Yes (1)
- ○ No (2)

Skip To: End of Block If Test recommendations Were tests recommended? = No

Q16 Please indicate which tests were undertaken, provide the test name, whom provided the test, test result and further information :	Test details e.g. name, biomarker (1)	Source of test e.g. GP, biolab, doctors data, Genova diagnostics etc. (2)	Test results (3)	Further information (4)
Allergy or intolerance testing (1)				
Amino acid analysis (2)				
Biochemistry / haematology profile (3)				
Cholesterol (4)				
Fasting sugar and haemogolbin A1c (5)				

Fasting lipid panel (6)				
Fatty acids profile (7)				
Gastrointestinal profile (8)				
Genetic or genomic assessment (9)				
Hormone analysis (10)				
Inflammatory markers (11)				
Liver function assessment (12)				
Nutritional profile (13)				

Oxidative stress profile (14)				
Specific minerals (15)				
Specific vitamins (16)				
Thyroid function test (17)				
Toxic metal screen (18)				
Other (please state): (19)				
Other (please state): (20)				

End of Block: Test recommendations

Start of Block: Referral Recommendations

Q13 **Referral recommendations**

Were any recommendations made for further support?

- ○ Yes (1)
- ○ No (2)

Skip To: End of Survey If Referral recommendations Were any recommendations made for further support? = No

Q14 Please indicate which referrals were followed-up:

- ☐ Bariatric surgery (1)
- ☐ Other health care professional (please stat):e (2) _____
- ☐ Other (please state): (3) _____
- ☐ Counselling/psychological support (4)
- ☐ Personal trainer/gym (5)
- ☐ Eating disorder support (6)
- ☐ General practitioner (7)
- ☐ Life coaching (8)
- ☐ Sleep apnoea assessment (9)

Q17 Please provide any further information as a result from referrals:

_____

_____

_____

_____

_____

End of Block: Referral Recommendations

Start of Block: The End

Q18 Please **click save** to complete this form.
Thank you very much for your involvement in this research project.
Please inform michelle@cnelm.com that you have completed this form so a PDF of this completed tool can be sent to you. If you have any queries please contact michelle@cnelm.co.uk or call 07879 403321.

Q21 Data may be inspected by the Chair of the Health Studies Ethics sub-committee and the Chair of the School of Social Sciences Ethics committee of Middlesex University, if required by institutional audits about the correctness of procedures. Although this would happen in strict confidentiality, please write NO if you do not wish your data to be included in audits.

_____

End of Block: The End