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Towards Individually Tailored Interventions for Weight Management in Children and Adolescents

Jennifer S. Cox

A dissertation submitted to the University of Bristol in accordance with the requirements for award of the degree of Doctor of Philosophy in the Faculty of Health Sciences.

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Abstract

The Care of Childhood Obesity (COCO) clinic offers the only Tier 3 paediatric weight management service in the country. The clinic is successful, with two-thirds of patients losing weight, however for the remaining one-third, the current approach does not result in a change in weight. The current care includes a multi-disciplinary approach, with patients having appointments every-other month with a dietitian, clinical nurse specialist, clinical psychologist and social worker, and meeting with a consultant endocrinologist every four months.

The aim of this PhD is to use insight from psychology to improve the care of the patients who attend the COCO clinic. To do this, this PhD has taken two approaches. First, I have considered interventions that have shown promising results in non-clinical, psychology laboratory settings and both trialled and reviewed how they have translated into paediatric clinical settings. Secondly, I have approached the problem from a patient-led perspective, conducting patient interviews and using tools from Health Psychology including the COM-B model to begin the co-design of a new intervention.

The thesis takes a mixed methods approach, with quantitative research, qualitative research and a systematic review contributing to the conclusions made. We see that interventions designed for adults do not necessarily translate directly to successful interventions in children. Whilst children are able to understand the concepts of portion size, eating speed and calorie dense foods; maintaining engagement with interventions that utilise these concepts to change behaviour is more difficult. Self-determination, the sense that a person can make their own choices and control their own outcomes, without external influence, is a key facet of motivation. From interviews I conducted with patients and their families, it was apparent that the children and adolescents lacked self-determination. Using COM-B and a person-centred approach, I have begun to develop an intervention using Acceptance and Commitment Therapy, that would aim to raise patients' sense of self-determination and improve their outcomes at the clinic. NIHR research for patient benefit funding has been successfully secured, meaning this co-design work will be continued as a post-doctoral project.

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Throughout my PhD I have been based at the Bristol Biomedical Research Centre Nutrition Theme. I would like to thank everyone there for creating a warm, supportive environment in which to conduct a PhD. I felt privileged to benefit from the expertise of the department, and the well-rounded research experience I feel I have gained. Beginning as part of a cohort of PhD students has been so beneficial, and I would like to thank the PhD girls for being such great, grounded support for my PhD work (and now also in raising our babies). Whilst at the BRC, I have been fortunate to be involved with several additional projects and research groups. In particular, I would like to thank the members of the Nutrition and Behaviour Unit (NBU) at the University of Bristol, the Network for Eating behaviour Research Discussion (NERD) at Exeter University, Health Psychology and interventions Group (HPIG) at the University of Bristol and the research team involved in the Weight maintenance in type 2 diabetes (WELMID) project. Each of these groups has offered different insights and thought-provoking discussions, and I am grateful to have been part of each of them.

I would like to thank the clinical team at the COCO clinic for their time and guidance, and for enabling me to be a part of so many of their busy clinics. During my PhD, I have been able to gain broad experience thanks to being able to observe/support/join in with projects and programmes working around food, food education and health across Bristol. I would like to thank the team at Square Food Foundation and at Alive and Kicking in particular.

I would like to thank Ingrid Wallace at Cardiff University, whom I trained in ACT with. Your infectious enthusiasm for all things ACT has had a transformative impact on how I see the world and has shaped the outcomes of my PhD and future career path. I would like to thank Dr Helen McCarthy for trusting me with helping to run her training courses, and in the process offering me huge insight into the clinical application of eating behaviour research. Thank you for sharing so openly with me and bringing to life this research area. I would like to thank Dr Caroline Limbert for encouraging me to take on a PhD in the first place, and her support with the process of both this PhD and my professional qualification.

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Author Declaration

I declare that the work in this dissertation was carried out in accordance with the requirements of the University's *Regulations and Code of Practice for Research Degree Programmes* and that it has not been submitted for any other academic award. Except where indicated by specific reference in the text, the work is the candidate's own work. Work done in collaboration with, or with the assistance of, others, is indicated as such. Any views expressed in the dissertation are those of the author.

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Common Acronyms

ACT = Acceptance and Commitment Therapy
AIM2Change = Helping **A**dolescents to increase their **I**ntrinsic **M**otivation to **c**hange weight
ADHD = Attention deficit hyperactivity disorder
ASD = Autism spectrum disorder
BMI = Body mass index
BMI SDS = Body mass index Standard deviation score
BP = Blood pressure
CAMHS = Child and adolescent mental health service
CBT = Cognitive behavioural therapy
CDC = Centre for Disease Control
CEBQ = Child Eating Behaviour Questionnaire
CEW = Complications from Excess Weight
COCO = Care of Childhood Obesity
COM-B = Capability, Opportunity, Motivation, Behaviour
HRQOL = Health related quality of life

MRC = Medical Research Council
NHS = National Health Service
NICE = National Institute for Health and Care Excellence
NIHR = National Institute for Health and Care Research
PHE = Public Health England.
PPI = Patient and Public Involvement
PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analysis
PROSPERO = Prospective Register of Systematic Reviews
QOL = Quality of life
RCTs = Randomised controlled trials
SD = Standard deviation
SDT = Self-Determination Theory
T2DM = Type two Diabetes Mellitus
WHO = World Health Organisation

Dissemination of works from this PhD

Inclusive and exclusive of the work included in this thesis

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Cox, J. S., Elsworth, R., Perry, R., Hamilton-Shield, J. P., & Hinton, E. C. (2020). The feasibility, acceptability and benefit of interventions that target eating speed in the clinical treatment of children and adolescents with overweight or obesity: A Protocol for a Systematic Review. https://doi.org/10.21203/RS.3.RS-41461/V1

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Cox, J. S., Hinton, E. C., Searle, A, Giri, D, Lawrence, N. S., Brunstrom, J. B., Hamilton Shield, J. P. (2020). Perspectives of parents of children attending a paediatric weight management clinic In the UK without clinically significant weight loss in: A qualitative thematic analysis. Obesity Review. EP-514. https://onlinelibrary.wiley.com/doi/full/10.1111/obr.13118

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Prader-Willi Syndrome. JCRPE Journal of Clinical Research in Pediatric Endocrinology, 13(4), 439–445. https://doi.org/10.4274/JCRPE.GALENOS.2021.2021.0010

Kinnear, F. J., Wainwright, E., Perry, R., Lithander, F. E., Bayly, G., Huntley, A., Cox, J., Shield, J. P., & Searle, A. (2019). Enablers and barriers to treatment adherence in heterozygous familial hypercholesterolaemia: a qualitative evidence synthesis. BMJ Open, 9(7), e030290. https://doi.org/10.1136/bmjopen-2019-030290

Sauchelli, S., Bradley, J., Cox, J., England, C., & Perry, R. (2020). Weight maintenance interventions for people with type 2 diabetes mellitus: A systematic review protocol. Systematic Reviews, 9(1), 1–7. https://doi.org/10.1186/S13643-020-01467-7/PEER-REVIEW

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Poster presented by L. Porter at BFDG 2021

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Poster presented by R. Treleven at ECO 2021

Treleaven, R., Cox, J.S., Easter, S., Shield, J.P.H. & Giri, D. (2021). Is skipping breakfast associated with increased weight loss in adolescents? A retrospective review of breakfast habits in adolescents from a single tertiary paediatric obesity clinic

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Cox, J. S., Khalil, N. H., Hinton, E. C., Hamilton-Shield, J. P., Brunstrom, J. M., & Lawrence, N. S. (2018). Development of a clinical tool for weight management using response inhibition training. Appetite, 130, 302. https://doi.org/10.1016/J.APPET.2018.05.175

Chapter 1. Introduction

1.1 Definition and prevalence of obesity

Obesity is a complex, chronic, often relapsing disease that is multifaceted in its expression and causation (Agarwal & Nadolsky, 2022; Burki, 2021; Jastreboff et al., 2019; World Health Organization., 1997). The Obesity Society have defined obesity as;

> *"A multi-causal chronic disease recognized across the life-span resulting from long-term positive energy balance with development of excess adiposity that over time leads to structural abnormalities, physiological derangements, and functional impairments. The disease of obesity increases the risk of developing other chronic diseases and is associated with premature mortality. As with other chronic diseases, obesity is distinguished by multiple phenotypes, clinical presentations, and treatment responses"* (Jastreboff et al., 2019).

Defining obesity as a disease has been highly contested, but currently many leading health organisations acknowledge that the condition meets disease criteria (Burki, 2021; Jastreboff et al., 2019; World Health Organization., 1997). This thesis takes the standpoint of obesity being a disease. This classification is an important step in reducing the stigma and discrimination faced by people with obesity, and a step towards ensuring investment in research, treatment and public health policy necessary to improve patient outcomes (Agarwal & Nadolsky, 2022; Jastreboff et al., 2019).

Obesity is often defined by body mass index (BMI), calculated by an individual's weight divided by the square of their height (BMI=kg/m2). A BMI of over 30 classifies an adult as having obesity, a BMI of 25 – 29.9 as having overweight (World Health Organization., 1997). In children and adolescents, BMI also needs to consider age and sex and therefore BMI standard deviation score (SDS) (also referred to as a BMI z-score) adjusts the BMI by age and sex, often using 1990 Growth Reference Data from the Child Growth Foundation (Cole et al., 1995) or the 2000 Centre for Disease Control (CDC) growth charts (Barlow, 2007). A child is considered to have overweight if they have a BMI greater than the 85th percentile, and obesity if they exceed the 95th percentile or have an absolute BMI greater than 30 (Gallager, 2020). Using anthropometric data has limitations in its ability to distinguish fat mass from other components of the body including muscle mass and bone density. Greater accuracy can be obtained using technological approaches such as bio-impedance scales, dual-energy x-ray absorptiometry (DXA) or magnetic resonance imaging (MRI)(Hunt et al., 2007; Thivel et al., 2018). However the cost and feasibility of such technology limits its ability to be used (Gallager, 2020). BMI and BMI SDS are the most common measure of overweight and obesity in both clinical and research settings and are recommended in National Institute for Health and Care Excellence (NICE) guidelines (NICE, 2020).

The number of children and young people experiencing obesity is increasing. In 2020/21, 14.4% of reception children (age 4/5) and 25% of year 6 pupils (age 10/11) were obese, an increase from 9.9% and 21% respectively in 2019/20 (NHS Digital, 2021). Rate of increase has been exacerbated in part, by the COVID-19 pandemic (NHS Digital, 2021). We see higher rates of obesity in boys than girls (NHS Digital, 2021). With a few exceptions (L. Daniels et al., 2022; Rudolf et al., 2019), globally, the prevalence of obesity is rising with 30% of the world's population thought to live with overweight or obesity (Dobbs et al., 2014), including 5.6% of girls and 7.8% of boys (NCD Risk Factor Collaboration (NCD-RisC) et al., 2017). Obesity is thought to contribute to 5% of all deaths and have the same economic impact as smoking or armed conflict (~$2 trillion per year)(Dobbs et al., 2014).

Those living in the most deprived areas of the UK are more than twice as likely to experience obesity as those living in the least deprived areas (NHS Digital, 2021). Those in the 10% of the population experiencing the greatest deprivation, experience more than double the rates of obesity than those in the lowest 10% of deprivation (Public Health England, 2021). Importantly, cases of severe obesity are four times higher in the most deprived 10% (Public Health England, 2021). Whilst on a population level, we are seeing some decreases in national obesity rates, these decreases are happening within our most affluent population. The more deprived areas are seeing an increase in cases, meaning that the inequality gap is widening (Public Health England, 2021). There is a greater frequency of excess weight amongst minority ethnic groups, however it is likely that these figures are impacted by both deprivation and inequality (Public Health England, 2021). However, in terms of obesity related complications such as Type 2 diabetes, these same ethnic minorities may be defined as overweight and obese at lower BMI thresholds.

For weight loss to have a clinically significant health impact, a BMI SDS reduction in children and adolescents of between 0.5 and 0.6 is required (Birch et al., 2019; Hunt et al., 2007). At the COCO clinic, a weight loss of 5% of body weight is often prescribed. Younger children without serious obesity related complications, may pursue weight maintenance, which when accompanied by growth has the impact of reducing BMI and is protective of development.

1.2 Overview of factors that cause and maintain the disease

To develop treatment, it is important to understand the aetiology of a disease to effectively target interventions (Michie et al., 2011). Obesity is complex in its aetiology with its cause and effect often being interconnected. Whilst common thinking has been that obesity is due to the energy imbalance caused by consuming too many calories and not burning enough through movement, it is becoming clearer that this view is oversimplified (Butland et al., 2007; Dobbs et al., 2014). The UK government's Foresight report depicts schematically the large number of interlinking contributors to overweight and obesity in a systems map, with the intention of better understanding where

intervention may be effective (Butland et al., 2007)(Figure 1.1). The model highlights seven key areas; individual psychology, social psychology, individual physical activity, the physical activity environment, food production, food consumption and physiology. Many of these factors are beyond the control of the individual, especially when the individual is a child (Obesity Health Alliance, 2021). It is therefore pertinent that obesity is considered as a disease like any other, with a medical aetiology, as opposed to a condition that the individual has brought upon themselves through lifestyle 'choices', and a lack of willpower (Jastreboff et al., 2019).

The foresight map centralises the concept of energy balance and, having evolved in times of food-scarcity, how we are biologically adapted to seek, consume and store food for survival (Butland et al., 2007, Higginson et al., 2016). These powerful drivers to retain energy are now juxtaposed with the obesogenic environment in which we live, driven by urban living, multinational food companies and political decisions. Areas of socioeconomic deprivation compound the problem with greater exposure to food cues, fast-food restaurants (Cetateanu & Jones, 2014; Fraser & Edwards, 2010; Hamano et al., 2017), an environment that does not support physical activity (Pirgon & Aslan, 2015), low levels of contact with the natural world (Mears et al., 2020) and high levels of environmental stress (Parasin et al., 2021). Living in homes experiencing socioeconomic deprivation increases childhood stress, food insecurity, and decreases sleep, all known contributors to obesity (Tester et al., 2020).

The biological implication of stress may be one of the most significant and interconnected contributors to the onset of obesity (Mietus-Snyder & Lustig, 2008). Stress triggers hormonal responses at the hypothalamus, pituitary, adrenal (HPA) axis and the sympathetic nervous system which can trigger food intake and insulin production (Dallman, 2010). The evolutionary rewarding qualities of food become reinforcing and maladaptive coping mechanisms can develop (Dallman, 2010; Tester et al., 2020). This means that chronic childhood stress can be a significant trigger for obesity and obesity-promoting coping mechanisms (Hemmingsson et al., 2014, Adjei et al., 2021).

Children's eating environment is key to their experiences of obesity. The foods they are exposed to and their nutritional experience during the first 1000 days from conception to age 2 life is shown to be a critical period for later BMI and health outcomes (Llewellyn & Syrad, 2018). Parents' position as role models of a healthy lifestyle is important, influencing child eating behaviour and consumption of vegetables (Pearson et al., 2009; Wirthlin et al., 2020). Modelling has been shown to be a more effective way of supporting a child's healthy diet, than an overly pressured or controlling methods that can evoke eating in the absence of hunger (Birch et al., 2003), eating disorder behaviours and obesity (Orlet Fisher & Birch, 1999; Scaglioni et al., 2022). Families with a low socioeconomic

background have been seen to implement more controlling parenting strategies around food, at least in part due to financial reasons (Loth et al., 2013). Family mealtimes are important for nutrient consumption (Chawner et al., 2021; Robson et al., 2020) and family functioning (Fruh et al., 2011; Robson et al., 2020).

Research to date demonstrates obesity to be highly heritable, child obesity rates are associated with both parents' BMI (Public Health England, 2021) and genetics are thought to be responsible for 50%, and sometimes as great as 90% of the expression of obesity (Elks et al., 2012). In twin studies where monozygotic twins are raised in separate families, little impact of environment is seen (Stunkard et al., 1990). Rare monogenic conditions have been identified through work such as the Human Genome Project (Rankinen et al., 2006, Hu, 2009), and much more commonly, polygenetic causes of obesity have been identified (Frayling et al., 2007; Loos & Janssens, 2017). The Fat Mass and Obesity Associated (FTO) gene of chromosome 16 is an example of a polygenetic cause of obesity, being shown to influence body weight slightly from age seven (Frayling et al., 2007). Often these polygenetic combinations are epigenetic, meaning that the expression of the gene is dependent on the environment, the diet or the makeup of the microbiome (Thaker, 2017). The prenatal period is an important time for epigenetic changes, but exposures throughout the lifetime can affect genetic programming, and these genetic changes can be heritable compounding problems of deprivation and stress (Golding et al., 2022; Thaker, 2017). A meta-analysis showed that whilst inactive people with the FTO gene were 23% more likely to have obesity, for those who were active there was no difference in BMI, in fact active people were 30% less likely to have obesity than inactive people without the FTO gene (Kilpeläinen et al., 2011; Qi & Cho, 2008).

The Foresight report acknowledges the power of the underlying evolutionary drivers that support weight gain, with this becoming part of the model's central 'core'. When we diet and our body identifies a lack of energy it makes subtle changes to metabolic rate and energy expenditure to compensate (Bacon, 2020; Maclean et al., 2015). These mechanisms utilise many systems within the body ensuring that the body has several layers of defence against starvation, making weight management difficult. These powerful evolutionary processes to retain energy now work within an obesogenic environment, whereby sedentary behaviour and over consumption of calories are the default. Here, self-regulation is required to prevent obesity (McClelland et al., 2017; Thaler & Sunstein, 2008; Butland et al., 2007). Self-regulation is the conscious ability to manage behaviour accordingly to adapt to environmental and social demands. It is core to flexible interactions, in guiding behaviour to align with personal values and in supporting emotional resilience.

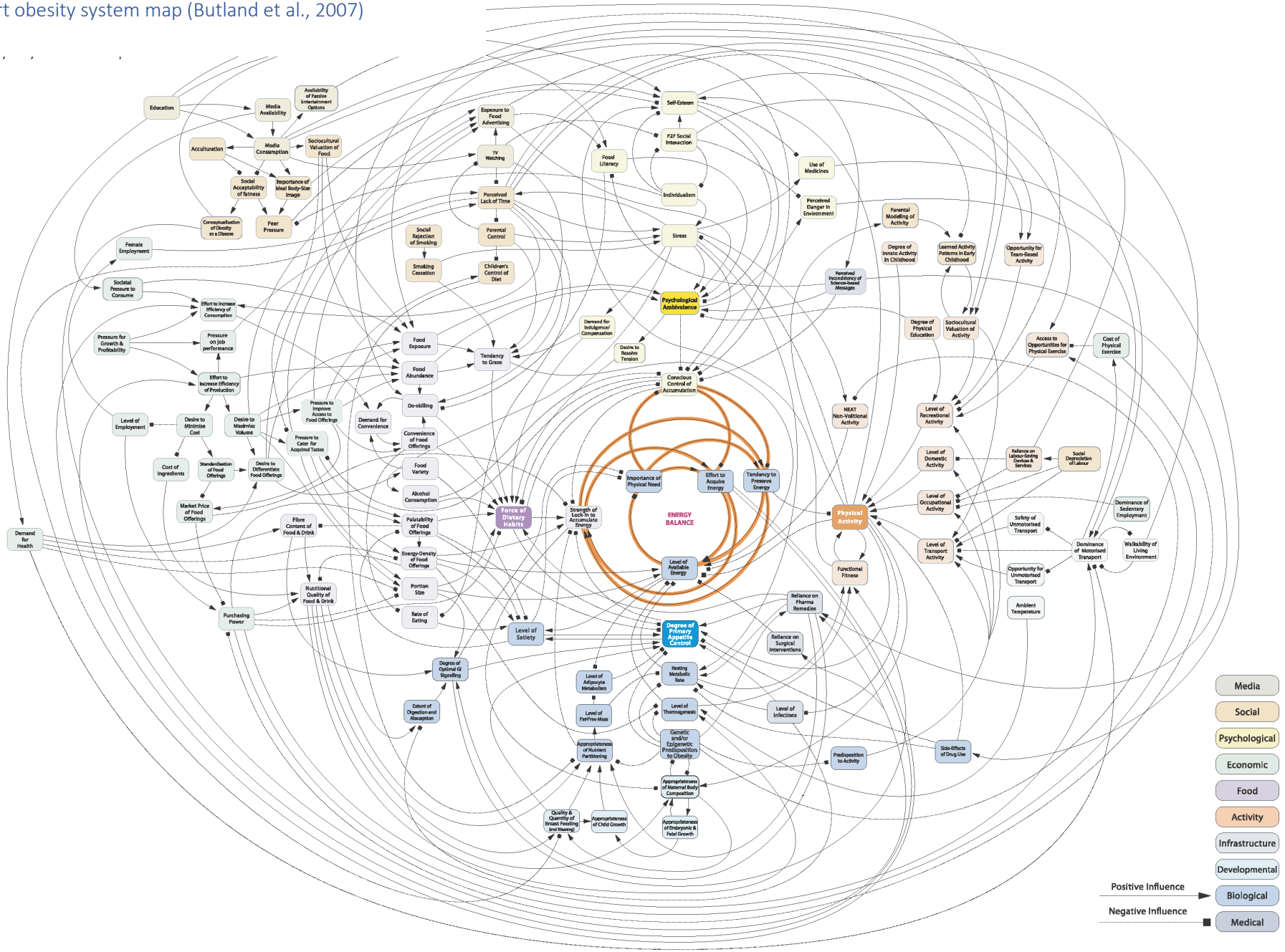
Forms of self-regulation including executive functioning and inhibitory control (Verbeken et al., 2013), delay of gratification (Mischel et al., 1989), self-regulation of eating (McCrickerd, 2018) and self-regulation of emotions . Self-regulation has been seen to interplay with genetic predisposition to food cue-responsiveness and has been demonstrated to affect how an individual interacts with the environment (Forman & Butryn, 2015). Self-regulation is thought to determine how responsive one is to food-cues (Lawrence et al., 2012), how willing they are to tolerate short-term discomfort for long-term gain, and how goal oriented their actions are (Forman & Butryn, 2015; McClelland et al., 2017). The development of self-regulation is thought to be significantly negatively impacted by chronic stress, whilst the presence of self-regulation helps individuals to navigate life stressors flexibly without becoming overwhelmed (McClelland et al., 2017).

Emotional eating, defined as an increase in eating due to negative emotional state, often in an attempt to regulate and reduce the impact of these negative emotions (Altheimer & Urry, 2019; Ganley, 1989) is a known risk factor for obesity, including in adolescents (Frayn & Knäuper, 2018; Lazarevich et al., 2016). Individual differences in adolescent emotional eating rates are seen to be connected to differences in stress levels, anxiety and tension (Nguyen-Rodriguez et al., 2009). Twin studies conclude that emotional eating is not an inherited trait, but is largely learned from the home environment and parental behaviour (Llewellyn et al., 2012). Disinhibited eating, is used interchangeably with emotional eating in some contexts (Frayn & Knäuper, 2018), being an umbrella term that incorporates a wide range of eating behaviours that result from low self-restraint around eating. Loss of control over eating (LOC), binge eating, eating in the absence of hunger are included within the term disinhibited eating (Shomaker et al., 2011). Disinhibited eating is a known risk factor for obesity, including in adolescents and is connected to executive functioning performance (Liang et al., 2014; Shomaker et al., 2011),.

Differences in cognitive control within the food environment have been demonstrated to explain how not everyone develops obesity in an obesogenic environment (Butland et al., 2007). Individual differences and psychological traits, including susceptibility to external cues, impulsivity and reward sensitivity have been demonstrated to link with the development and maintenance of obesity in both adults and children (Hetherington, 2007; Nederkoorn et al., 2006). Individual differences in ability to regulate based on appetite and satiety is seen to connect with children's increased intake and responsiveness to portion sizes (Mooreville et al., 2015). Individual differences to striatal dopamine (DA) D2 receptors, thought to be complicit in addictive behaviours have also been considered to contribute to differences in eating behaviour and obesity risk in adolescents and adults (Hetherington, 2007). These individual differences affect short term eating behaviour, for example food intake has been linked to individual differences within reward and motivation brain

regions when exposed to food cues (Lawrence et al., 2012). Across the longer term, there is evidence that weight is affected (Nederkoorn et al., 2010). Whether individual differences are considered traits or learnt patterns of eating varies, however interventions remain possible. Interestingly, those with high self-control seem protected from the presence of individual differences (Lawrence et al., 2012).

Figure 1.1. Foresight report obesity system map (Butland et al., 2007)



1.3 Impact of Covid-19

Both the rates of childhood obesity and the disparity in rates by socioeconomic background have been exacerbated due to the impact of Covid-19 (Loopstra, 2020; NHS Digital, 2021; Tester et al., 2020). The economic impact has hit those most at risk of food insecurity the greatest, with almost half of those eligible for free school meals not accessing an alternative source of meal support for their children (Loopstra, 2020; Parnham et al., 2020). During usual periods of time out of school such as the summer holidays, weight often rises. An effect considered to be due to elongated time without structure, boundary's around eating times, and regular physical activity (Franckle et al., 2014). A combination of social and economic factors throughout the pandemic has resulted in the greatest increase in childhood obesity rates in a year since the National Child Measurement Programme (NCMP) began 15 years ago (NHS Digital, 2021).

1.4 Consequences and impact of obesity throughout the life course

It is considered important to intervene to prevent and treat childhood obesity because of the significant implications for physical, psychological, and social outcomes (The King's Fund, 2021). Whilst we recognise obesity as a disease in its own right, it is also considered as a risk factor for other non-communicable diseases (Jastreboff et al., 2019; World Health Organization., 1997). Some outcomes of obesity are directly caused by obesity itself, such as sleep apnea (Jehan et al., 2017) and joint problems (Powell et al., 2005), other problems arise as associated co-morbidities such as cardiovascular disease, cancer and type two diabetes (Jastreboff et al., 2019). However, other complications are due to the social and psychological implications of being a higher weight and being exposed to the societal stigma that exists (Bacon, 2008). Poor psychological wellbeing is also a contributor to overweight and obesity making cause and effect difficult to determine (Blaine, 2008). For many of the factors the relationship is a complex loop, for example stress which is exacerbated by stigma and is both caused by obesity, and contributes to it (Dallman, 2010; Tester et al., 2020).

Biologically, obesity is considered a state of chronic inflammation, which can trigger immune system dysregulation (Hotamisligil, 2006; Zatterale et al., 2020), a mediator of cardiovascular disease (Inge et al., 2014) and metabolic syndrome. Systemic inflammation was seen in more than 75% of 242 young people who were classified as suitable for bariatric surgery (Inge et al., 2014). As weight status increases we see a much greater risk of metabolic syndrome, a cluster of conditions, classified by the presence of high blood pressure and blood sugar, high triglycerides and low high-density lipoprotein cholesterol, and a high percentage of abdominal fat (NHS, 2022). Together, these conditions increase the risk of atherosclerosis, diabetes, coronary heart disease and stroke. 0.3% of healthy weight young people had metabolic syndrome, whilst prevalence was 20.8% in those with obesity (Sharma et al., 2019). The onset of type 2 diabetes in childhood is one of the most problematic

medical consequences of obesity and chronic inflammation (Barlow, 2007; Hotamisligil, 2006; Weiss et al., 2005).

Other complications of childhood onset of obesity include gastrointestinal problems such as non-alcoholic fatty liver disease, reflux, gallstones and constipation (Barlow, 2007). Obstructive sleep apnea, is found at a prevalence of >50% in adolescents with obesity (Kalra et al., 2005), increasing the risk of pulmonary hypertension, reducing sleep and consequently affecting academic performance and attention (Barlow, 2007). Idiopathic intracranial hypertension is rare, but 82% of occurrences in 12-15 year olds were attributable to obesity (Matthews et al., 2017). There is compelling evidence that those with overweight and obesity in childhood, maintain these weight statuses into adulthood (Freedman et al., 2005, 2018). This puts them at risk of the increased mortality and morbidity of adult obesity and the 200+ comorbidities that are associated with it (Jastreboff et al., 2019). Links have been made between excess body fat and 13 different cancers, with body size in childhood also being associated with elevated risks of the same cancers (Secretan et al., 2016). There is also suggestion that childhood obesity can result in adult cardiovascular problems, regardless of the weight status in adulthood (Li et al., 2004).

For children and adolescents, the effects of experiencing overweight and obesity may have significant impacts on their social and psychological wellbeing. In a clinical population, social difficulties were common and psychological health and scores on a Health-Related Quality of Life (HRQOL) scale were worst in children with the highest BMI's (Harcourt et al., 2019). Stigma has been shown to generate disadvantage across multiple life domains, affecting treatment in health care settings (Flint, 2019), perceptions of employment suitability (Public Health England, 2016), and academic performance (Langford et al., 2022). Furthermore, a systematic review of the effects of weight stigma suggests that stigmatisation reduces health behaviours, including willingness to exercise, and increased weight-related health problems (R. Puhl & Suh, 2015). Stigma operates as a psychosocial contributor to the onset and maintenance of obesity (R. Puhl et al., 2020) creating a vicious circle of impact. Poorer life outcomes are demonstrated in those who have experienced stigma, including academic performance, income and relationships, thought to be mediated by onset of depression (French et al., 2018). Again, the impact of stigma is a likely moderator in this relationship and we see higher rates of self-harm, suicidal ideology and suicide attempts in those who have experienced discrimination for their larger bodies (Sutin et al., 2018). Interestingly, despite a strong link between negative affect and obesity in adults with obesity and clinical treatment-seeking adolescents, there is an indication that overweight and obesity in non-clinical samples is not cause for an increase in depression or decrease in self-esteem (Wardle & Cooke, 2005). This suggests

that it is not the obesity per se, but the societal experience and the state of dissatisfaction that would lead to treatment seeking that is causative of depression.

A consequence of overweight and obesity is often an increased association with restricted eating, dieting and control of food, which in turn are behaviours associated with increasing weight (Dulloo & Montani, 2015). Restrictive parenting practices have been shown to create patterns of disordered eating in children, particularly in girls, where restriction led to higher consumption levels (Birch & Fisher, 2000; Fisher & Birch, 1999) and negative self-evaluation of eating (Jennifer Orlet Fisher & Birch, 2000). Dieters have a 2-3 times higher risk (Goldschmidt et al., 2012; Haines et al., 2006) of experiencing bulimia with compensatory behaviour, or binge eating disorder, a diagnostic and statistical manual of mental disorders (DSM-5) recognised disorder characterised by impulsive consumption of perceived high quantities of food in a short period of time (American Psychiatric Association, 2013, Stice et al., 2017). Estimations of eating disorder prevalence within weight management services is vary, with prevalence of up to 45% reported (Giel et al., 2013). Many studies report a high-frequency of subclinical disordered eating behaviour (Glasofer et al., 2007). Interactions between dieting, pressure to be thin, internalization of a 'thin-ideal', body dissatisfaction, depression and negative affect, accumulate to mean that adolescents with obesity are at particular risk for BED and BN (Jebeile et al., 2021).

In summary, obesity is correlated with worse physical and psychological outcomes. Delivering interventions is considered cost-effective at both increasing quality adjusted life years for the individual (QALY) and when compared with the cost of treating the co-morbidities of obesity, which can be complex (Harrison et al., 2021). However, with so many of the outcomes of overweight being caused or exacerbated by the stigma associated with being in a heavier body, interventions must be extremely mindful to avoid stigmatising components.

1.5 Importance of maintaining weight loss

If weight loss is maintained, it can have marked improvements on health. Optimistically, the inflated cancer risks seen in those with obesity are reduced following weight loss (Secretan et al., 2016) and preventing weight-gain over two years reduced the chance of adolescents with obesity moving from impaired glucose tolerance to type 2 diabetes (Weiss et al., 2005). However, weight maintenance is arguably harder than weight loss (Dulloo & Montani, 2015) due to the biological changes that occur in the body during period of weight-loss. Weight loss reduces energy requirement, through requiring less energy to run a smaller body (A. M. Sharma & Padwal, 2010). Further to that, weight loss creates fundamental changes within the homeostatic system, including to the structure of adipose tissue (Maclean et al., 2015). Maclean et al. (2015) detail the level of challenge weight-maintenance creates;

> '*Weight loss awakens the body's defence system in a manner that is persistent, saturated with redundancies, and well-focused on the objective of restoring the body's depleted energy reserves. Successful, long term weight loss requires recognition of the strength and persistence of these biological pressures, and a better understanding of how they may be countered with environmental, behavioural, pharmaceutical or other interventions. To be effective, interventions aimed at preventing weight regain will likely need to be as comprehensive, persistent, and redundant as the biological adaptations they are attempting to counter*'.

However, around 20% of adults do maintain weight loss. The National Weight Control Registry is a database of adults who have successfully maintained weight (Wing, 1994; Wing & Phelan, 2005). Common behaviours in this weight maintaining adult group include self-monitoring, engaging in physical activity for at least an hour a day, maintaining a consistent diet without making dietary changes on the weekends, and eating a low calorie diet. Of note, weight-maintenance in this context is defined as maintaining a weight loss for at least a year (Wing & Phelan, 2005) which may not be sufficient to improve life-time health particularly in adolescent populations. Often adults who succeed in weight maintenance are those with low depression scores (Wing & Phelan, 2005), low life stressors and capacity for high motivation and engagement with continuing changes (Forman & Butryn, 2015). Importantly for our clinical population, having a medical prompt for the initiation of weight loss was a beneficial factor in maintaining weight loss (Wing & Phelan, 2005).

To support patients with sustainable approaches to weight maintenance, NICE guidelines recommend that;

> *"Small but realistic goals should be mutually agreed with the child or young person and their family. These should relate to goals that they value and that motivate them to attend… Stress the importance of maintaining changes, no matter how small, over the longer term*" (NICE, 2020).

Several other approaches also stress the importance of taking small, stepwise changes, building them into habitual behaviours before progressing onto new changes (Lou Atkins & Michie, 2014; McCarthy, 2019; Michie et al., 2014). The cycle of weight-loss, followed by weight-gain, known as weight-cycling, is both psychologically and physically damaging. Weight-cycling, independent of BMI, has been shown to cause cardiac problems and results in increasing BMI (Dulloo & Montani, 2015; Montani et al., 2015). Intensive diet programmes with inflexible rules are more likely to include high levels of dietary restriction, which may further contribute to obesity through pathways of disordered eating (Hall & Kahan, 2018; L. Thomas, 2019; Agüera et al., 2021). Consequently, there is compelling

evidence to suggest that weight control attempts that have not considered longevity may contribute to weight gain over the long-term (Bacon, 2020; Dulloo & Montani, 2015; Hall & Kahan, 2018). Within the COCO clinic some patients require timely reductions in weight to improve medical treatment outcomes. Conditions such as non-alcoholic fatty liver disease or severe sleep apnea that requires over-night ventilation require weight to be reduced and may result in patients being prescribed restrictive diets or meal replacement plans. In these patients it is essential that the intensive weight loss phases are accompanied by a focus on sustainable lifestyle changes that can be embedded to create a new, healthier lifestyle.

1.6 Clinical structure for the treatment of overweight and obesity in the UK

Currently, the UK offers a tiered approach to weight maintenance (NHS England, 2014). Tier 1 equates to population-wide initiatives often rolled out by organisations such as the former Public Health England. Campaigns such as the 5-a-day campaign to encourage the eating of more fruit and vegetables would be considered tier 1. Tier 2 includes community-based health and wellbeing courses, often organised in conjunction with leisure centres that are offered to those with overweight or obesity. In the Bristol area, where the work of this thesis is focused, the tier 2 services have been decommissioned due to difficulties with recruitment, retention and cost-effectiveness; meaning for many children entering the tier 3 clinic, this is their first experience of NHS weight management support (Bristol City Council, 2019).

Tier 3 services are offered as hospital outpatient clinics and provide a multi-disciplinary team approach to the treatment of overweight and obesity when it is causing significant co-morbidities or safeguarding concerns. This thesis focuses on developing interventions for use within Tier 3 services, specifically in the Care of Childhood Obesity (COCO) clinic, run in Bristol. The team is headed by two endocrinologists and following its restructure in 2017, offers patients a combination of psychological and practical support delivered by a multi-disciplinary team (MDT) consisting of a clinical psychologist, clinical nurse specialist, a social worker, and a dietician (NIHR Bristol BRC, 2021; University Hospitals Bristol NHS Trust, 2022). The clinic is the only fully funded paediatric weight management clinic in England and recently been used as the blueprint for another 14 new Complications of Excess Weight services (CEW) in England (NHS England, 2022; NIHR Bristol BRC, 2022).

Tier 4 services consist of surgical management of obesity. Currently, there is no dedicated tier 4 service however bariatric surgery is increasingly being offered to children and adolescents in the UK (NHS England, 2017). Adolescents need to meet criteria in order to be eligible, including having reached physiological maturity, and have significant comorbidities that are both likely to worsen, and will be improved via surgery, and decision to operate always involves a risk-benefit analysis. Whilst the surgery is definitely not suitable for all patients, for some it could be a life-changing, cost effective approach (Shield et al., 2008). Results are promising, with a systematic review suggesting a 28% decrease in BMI three years post operative, meaning that 26% of patients no longer met the classification of obesity (Inge et al., 2014).

With the absence of tier 2 services, some families may choose to engage with commercial diet programmes or programmes offered through magazines or social media. Whilst some of the more established programmes yield relative success (Jebb et al., 2011), many of these approaches appear unsuccessful, and contribute to the common phenomenon of weight-cycling (S. L. Thomas et al.,

2008). Many diets do not take into consideration the psychological and biological drivers to eat (Bailey et al., 2014; McCarthy, 2019). The predominant methodology used by many commercial diets is to inform people of the importance of eating less and moving more, which over-simplifies the myriad of complex causes and effects of obesity (Butland et al., 2007) and can leave people feeling demoralised (Fitch, 2020). Without integrating knowledge of our evolutionary psychology and the psychology of eating behaviours and behaviour change, these diet programmes often require a vast shift in lifestyle, cost and time that are unsustainable over the medium to long-term (McCarthy, 2019). Utilising the science and psychology of eating and behaviour change may improve commercial diet offerings (L. Atkins & Michie, 2013).

Early intervention is encouraged, with the reviews reporting that once children were older more complex interventions would be required, and less likely to be successful (Sabin et al., 2007). The most ideal approach would be early intervention that prevented obesity onset (Obesity Health Alliance, 2021). Programmes such as the Tier 1 programme HENRY (Health Exercise Nutrition for the Really Young) have worked with families of children aged 0-5 to prevent the onset of obesity. The programme has shown recent promising results in reversing trends by reducing childhood obesity prevalence, and is particularly of note as it is having the greatest impact in areas of the highest deprivation (Rudolf et al., 2019). HENRY is built upon the Family Partnership Model which takes the therapeutic stance of working together with parents to find solutions to their problems. The programme has positive results in terms of improving health via dietary content, engagement with physical activity and importantly, the programme has improved psychological well-being, parenting skills and parental self-efficacy which should offer children a more stable family environment and enable health-enhancing changes to be sustained long-term (Willis et al., 2013, 2016).

1.7 How the current structure targets factors that cause and maintain obesity

Within tier 3 services, the MDT is a key asset to the clinic, aiming to support the child's broad physical and psychological needs (NIHR Bristol BRC, 2022). For most patients, obesity may have occurred through a combination of biopsychosocial factors, and their treatment course will include support to make lifestyle changes, specialised dietetic guidance, psychological support and the services of a social worker who may be able to assist the family with support with their circumstances and finances.

In some cases, the endocrinologists may access diagnostic testing to identify biological underpinnings of obesity and in certain cases, pharmaco-therapy may be recommended. Endocrine disorders can sometimes be causal factors in obesity, and these will be tested for in patients at the clinic. These include hypothyroidism, a relatively common and treatable factor, caused by a lack of thyroxine (T4) within the body and Cushing's Syndrome; caused by too much of the hormone cortisol

within the body (Weaver, 2008). Polycystic ovary syndrome is another endocrine condition commonly linked to obesity, however its effects are both caused and exacerbated by a higher body weight through insulin resistance (Weaver, 2008). In other cases, such diagnosis may help to alleviate self-blame but may not modify treatment course, with diet and behavioural changes remaining the primary course of treatment (Barlow, 2007).

Occasionally, generalised pharmacotherapy to treat obesity are offered to patients, predominantly Orlistat, demonstrating a 0.86 reduction in BMI after one year (Chanoine et al., 2005), but this does not suit everyone and comes with side effects unpleasant and embarrassing for the adolescent. More recently, liraglutide has been licenced for use in patients (NICE, 2021), following evidence from a RCT (Kelly et al., 2020). The COCO clinic has seen patient benefit with its use, with 94% of patients improving their BMISDS between January 2021 and February 2022 (Unpublished communications, 2022).

The clinic will investigate cases whereby a monogenetic cause of obesity is considered to be a feature; for example, if the child is demonstrating signs of MC4R mutations. Cost can be a barrier to genetic testing, however the COCO clinic has access to screening via a European Consortium that has increased the detection of genetic cases in this population. However, even when genetic polymorphisms associated with higher BMI are identifies, treatment decisions are often not altered as it is considered that weight status remains a modifiable factor (Kilpeläinen et al., 2011; Qi & Cho, 2008).

Dieticians will work with the clinical patients to support them with all elements of the diet and food intake including reducing high calorie foods, making dietary swaps, managing portion sizes, and eating patterns. They will factor in meal timings, and context and work towards a tailored plan for each patient (British Dietetic Association, 2019). Dieticians will work with whole families, understanding the importance of parents in facilitating a healthy diet, selecting appropriate portion sizes (Potter et al., 2018) and role modelling appropriate eating habits (Pearson et al., 2009; Wirthlin et al., 2020). An understanding of behaviour change science can be integrated into practice to help families make adjustments to the eating environment to make healthy choices the easier choices (Dobbs et al., 2014).

Patients at the clinic have often experienced negative childhood experiences. Whilst childhood abuse was not shown to impact adolescent weight (Hawton et al., 2018) meta-analyses have demonstrated links between childhood abuse and adult obesity (Danese & Tan, 2013; Hemmingsson et al., 2014), moderated by the stress response, and psychosocial emotional dysregulation

(Hemmingsson et al., 2014, Adjei et al., 2021). NICE guidelines acknowledge the impact of trauma and psychological wellbeing on weight (NICE, 2020), and The COCO clinic has a social worker and a clinical psychologist who work with patients to understand the underlying problems.

In particular, binge eating disorder, has strong correlations to obesity (Agüera et al., 2021). The disorder is similar to that of Bulimia Nervosa, but without compensatory purging behaviours. The condition has recently been added to the DSM-5 (American Psychiatric Association, 2013), however currently very few people are able to access treatment, despite the condition being accompanied by high levels of mental suffering as well as the complications of obesity that may result (Mehler et al., 2016). In those that experience it, BED is a significant contributor to obesity onset and maintenance (Stice et al., 2005).

The COCO clinic has a dedicated social worker, part of their role is to support families to access resources that they need. Poverty is a key contributor for obesity, and the clinic data demonstrates that a high proportion of patients come from areas of low socioeconomic backgrounds. These patients typically also have poorer outcomes at the clinic (unpublished clinical data, 2022). The impact of COVID-19 has affected the most disenfranchised the hardest; the number of children being supported by food banks doubling between 2016/17 and 2020/21 (The Trussell Trust, 2021). The co-existence of obesity and child hunger is underpinned by stress and the relative accessibility and affordability of high-calorie, highly processed foods (Tester et al., 2020). For families with children, who earn less than £15,000, 42% of their after-housing disposable income would need to be spent on food to meet the recommendations of the NHS's Eatwell Guide. Estimates predict that fruit and vegetables have increased in price by 55–91% between the years 1990 to 2012, whilst many processed and high calorie foods have significantly reduced in cost in that time (Wiggins et al., 2017).

There are links between obesity and neurodiversity and learning difficulties in children and adolescents. Autism spectrum disorder (ASD) (Zuckerman et al., 2014), Attention Deficit Hyperactivity Disorder (ADHD) (Turan et al., 2021) and developmental delay (Emerson, 2009) have been connected to increased risk of obesity. The effects are thought to be mediated by unusual dietary habits and sensory differences, as well as factors affecting socioeconomic deprivation (Gatineau, 2014). For those with ADHD, cognitive processes factor in the relationship, including a reduced reward experience from food, emotional overeating and food responsiveness (Turan et al., 2021). The COCO clinic did pilot specialist outpatient clinics at local schools for children with special educational needs, lead by the clinical nurse specialist to improve access to services for this group. Unfortunately, changes to the role of school nurses, who had supported the clinics identifying and

measuring children within the schools, meant that the infrastructure was no longer in place to support the clinics.

Because of the complex aetiology of obesity, the medical model of treatment does not work alone. The MDT approach is gold standard (NICE, 2020), and enables the clinic to treat the patients holistically.

1.8 Theory of intervention development

In research laboratories all over the world, huge developments are being made to our understanding of obesity and eating behaviour, but a translational gap exists. Whilst these laboratories uncover insightful mechanisms and develop many promising interventions, very few of these become successful, clinically applicable tools that help patients in the long-term (Akers et al., 2010). It has been reported that whilst research uncovers many evidence-based interventions, they are rarely adopted by clinical practice, in part because of limitations with their real-world applicability (Johnston & Moreno, 2016). To bridge this gap, there is an increasing understanding that interventions need to be developed with greater connection to clinical practice.

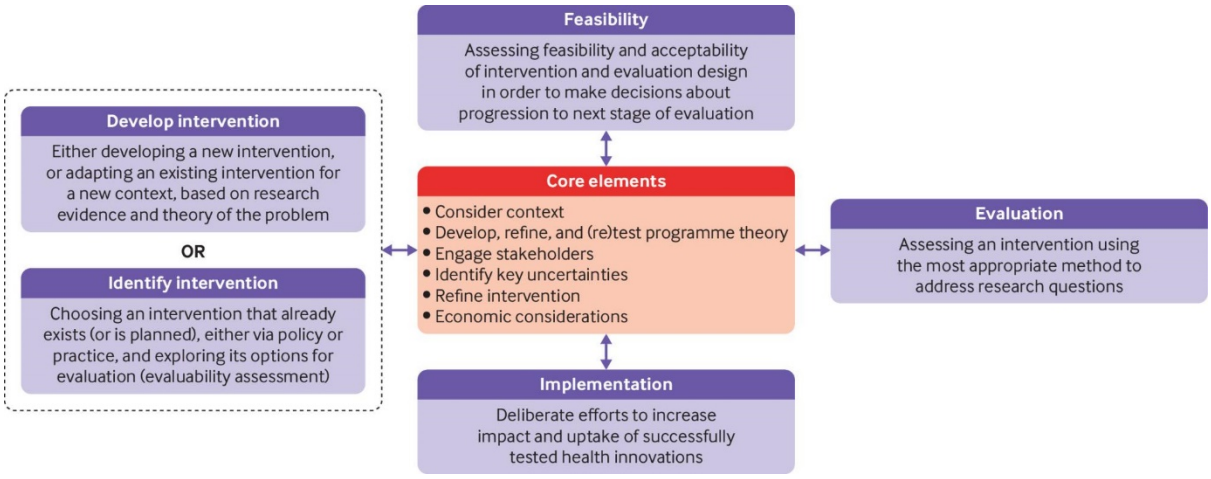
Consequently, the process of developing interventions is garnering increasing attention. When interventions do make the translation from laboratory to clinical trial, a vast amount of money, time and resources is used in running research trials (including feasibility and pilot work) that are deemed unsuccessful (Chalmers et al., 2014). Often, these failures are due to practical elements of the research, for example, high drop-out rates that may be avoidable with adaptions to logistical elements such as intervention location or timing (Ponzo et al., 2021). Problems with feasibility could be driven by errors within the design, including having unintended consequences of not having patient-centric outcomes (Michie et al., 2014). Such problems could be avoided if intervention development occurred in close contact with key stakeholders, including clinical teams and patients (Johnston & Moreno, 2016).

Considering the intricate web of factors that contribute to childhood obesity (Figure 1.1) (Butland et al., 2007), the interventions implemented in the treatment of childhood obesity are also typically complex, with many interwoven facets that need to be considered in order for the intervention to be acceptable, adhered to, and ultimately effective. Furthermore, developmental changes, impacts and outcome needs of children and adolescents with obesity are unique to those of adults with obesity, meaning it is not a simple case of taking an intervention that works in adults and trialling it in young people. There is increasing acknowledgement that interventions need to be specifically designed and tailored for paediatric populations(Anselma et al., 2019).

The Medical Research Council (MRC) have published recent guidelines for best practice when researching complex interventions (Skivington et al., 2021). The new guidelines, when compared to the original guidelines (Medical Research Council, 2006), have increased emphasis on understanding the context and the patient group and facilitating iterative improvements. Whilst the original MRC framework for complex interventions was designed for Randomised Control Trials (RCTs), the newest guidelines are broader in their design and encourage more of a co-design approach, involving service users at every stage. The guidelines lay out that six key phases of intervention development should occur (depicted in figure 1.2), however the stages are not linear and do not need to be explored sequentially, emphasising the importance of iteration in intervention development.

Whilst feasibility and pilot trials offer insight into the acceptability of the intervention, they typically offer this insight on the completed, static form of the intervention, where changes are difficult to implement (O'Cathain et al., 2019). Increasingly, research is including more iterative intervention development phases prior to feasibility trials that may integrate some feasibility work, alongside evaluation, PPI, in-depth understanding of the context and the barriers and facilitators present (Skivington et al., 2021). Often this work evolves continuously, with new knowledge and insight shaping the intervention over time. Investing the time and money right from the beginning of intervention development prior to pilot and feasibility trials may ensure the intervention is best answering the needs of the patient group, giving the best chance of a successful outcome (Hoddinott, 2015; Skivington et al., 2021).

Figure 1.2. The MRC phases of intervention development



With the increased focus on intervention development, has come a range of intervention development tools, theories and manuals (O'Cathain et al., 2019) – the MRC approach is just one of these. Also in recognition of the importance of this work, there is a trend to publish intervention development work, offering opportunity to share best practice and improving transparency of research processes (Hoddinott, 2015).

This thesis includes the development of interventions at varying stages of the MRC intervention development model, including a systematic review to identify interventions and development work of existing interventions. The knowledge and experience I have gained throughout my PhD results in Chapter 6, which details an intervention I have developed including learnings from throughout the course of my PhD. Chapter 6 integrates elements of two models of intervention development; the person-based approach (Yardley, Morrison, et al., 2015) and the behaviour change wheel COM-B framework (Michie et al., 2014).

Table 1.1. The intervention development stages within this PhD

Chapter	Intervention	Development Phase	Detail
2	Portion Size	'Develop an existing intervention'	Adapting and intervention that is used successfully in adults for use in children
3	Eating speed	'Identify intervention'	Exploring the evidence of the success of a range of interventions targeting the same behaviour to understand best practice
4	Response inhibition app	'Feasibility'	A feasibility trial, with built-in qualitative work to understand context and stakeholder feedback.
5	Qualitative service review	'Core elements' – context, stakeholders	Understanding context and stakeholders' perspective on an intervention in order to refine the intervention
6	Acceptance and commitment therapy	'Develop intervention'	Development of an intervention using research, evidence, and theory.

1.9 Choosing intervention targets

Considering the biopsychosocial aetiology of obesity, a wide range of intervention targets may reduce obesity. The McKinsey Institute has identified 78 different workable interventions that sit within three broad categories – environment, personal responsibility and education (Dobbs et al., 2014). Analysis suggests that no one targeted intervention will change the epidemic of obesity alone. Likely, a full range of large-scale, top-down, government, industry and policy changes would need to be accompanied by individual and community-based bottom-up interventions in order to completely reverse the global trend (Dobbs et al., 2014). Global, systemic changes to policy and our food environment require collaborative efforts from government with food and diet centred large corporations and buy-in from corporations (Mozaffarian et al., 2018). Whilst changes are underway, progress is costly and slow. Meanwhile, our target population require support now. Only focusing on whole-system and environmental interventions also suggests that humans have no self-regulatory capacity when faced with an obesogenic environment. The diversity in body-weights within a population suggests that the individual differences discussed above do affect how we respond to the environment (Blundell et al., 2010). Interventions to support individuals are an important factor in

the web of change and can have a faster impact on the individual that system and environmental change, which takes time to filter into practice (Butland et al., 2007).

With a background in Health Psychology and studying for registration as a chartered health psychologist, I examined potential interventions that focus on the psychology and social experience of eating to augment work in the clinical environment. Moving away from interventions that focus on the overly simplistic messaging to *'eat less and move more'*, we looked to psychological interventions to support weight management (Shaw et al., 2005; Vallis et al., 2020). We see from Cochrane reviews that modest weight loss in adolescents can be achieved through multicomponent weight management programmes (Ells et al., 2018). In adults, the addition of psychological interventions enhanced the outcome of diet and exercise interventions. With important insights coming out of the behavioural science field, urging consideration of how people eat as well as looking at what they eat, targeting eating behaviours may offer important new avenues to support change (L. Atkins & Michie, 2013; Vallis et al., 2020). Interventions that change how people eat may be easier to implement and sustain. For example, interventions that aid people in slowing eating or to eat smaller portions enable people to continue to eat the foods that they enjoy, and that they can afford whilst supporting weight loss. Consequently, portion size is recommended within seven key areas for intervention (Barlow, 2007). Both the University of Bristol and Exeter University, where my supervision team is based, have leading research laboratories that explore the psychology of eating. They test interventions on students and the public and have developed some promising concepts that may help reduce weight for individuals. The Nutrition and Behaviour Unit at the University of Bristol had designed computer software that demonstrated portion sizes of many meals and snacks (Hinton et al., 2013). The Nutrition theme of the NIHR Biomedical Research Centre had been working on reducing eating speed using a Mandometer®(Ford et al., 2010; Hamilton-Shield et al., 2014; Hinton et al., 2018).

A second key area recommended to support weight-management is the reduction in intake of sugar sweetened beverages and highly energy dense foods (Barlow, 2007). Professor Natalia Lawrence at Exeter University had developed an app that utilises inhibitory control training to reduce people's intake of high fat, salt and sugar containing foods, including sugar sweetened beverages (Lawrence, O'Sullivan, et al., 2015). The app works by supporting people to resists impulses to consume these foods, and by reducing peoples liking and wanting for the foods (Veling et al., 2017), using insight from the psychology of how we eat, to support changes in what we eat. I set out to try to translate these promising psychological interventions into workable clinical tools.

Alongside this work, I began a service review, interviewing patients about their current experience of the weight-management service they were attending. NICE guidelines highlight that when developing services for children and young people, all weight-management services must "have taken into account the views of children, young people and their families" (NICE, 2020). This work was insightful and helped to explain why some of the other interventions trialled at the clinic were not effective. As my understanding of patient-led research and the importance of context-driven intervention development increased, the remainder of my PhD was very much led by the findings of this qualitative review and the learnings taken from intervention development work in the areas of eating speed, portion size and inhibitory control training.

1.10 Tailored approach

As we can see from the increased importance given to patients and context in intervention design (Medical Research Council, 2006; Skivington et al., 2021), there is an emphasis on ensuring patient needs are heard and met during the process of intervention development.

The numerous factors that contribute to the onset and maintenance of the disease, highlight how no two individuals with obesity have the same experience, circumstances, and contributors. Consequently, NICE guideline recommends all patients within tier 3 services are offered;

> "A tailored plan to meet individual needs, appropriate to the child or young person's age, gender, ethnicity, cultural background, economic and family circumstances, any special needs and how obese or overweight they are" (NICE, 2020).

Families themselves recommend tailored programming, with the intervention being specific to their needs and financial situation being particularly important (Perez et al., 2018). It is imperative that patient needs are met, as there is a risk that those who do not initially benefit from the service, drop out (Sabin et al., 2007). With a 26% drop out rate at the COCO clinic (unpublished clinical records, 2021), this is unfortunate both for the individuals themselves, and for the economic effect on the NHS if the patients' co-morbidities become more complex. Ideally, the clinic would have a diverse range of interventions on offer, so that a tailored package of care could be offered to each individual.

1.11 Aims and objectives of this thesis

This thesis aims to develop interventions that are suitable, effective, and acceptable to patients and their families at a tier-three paediatric weight management setting. Chapters 2-5 were conducted in parallel, and all provide key findings and learnings which are implemented where possible in Chapter 6 and expanded on in the discussion.

Chapter 2: When do children learn how to select a portion size?

2.1 Overview

Eating portions that are too large for an individual's energy expenditure is considered to be a major contributor to overweight and obesity (Hetherington & Blundell-Birtill, 2018; Ledikwe et al., 2005), thus reducing portion size is considered an effective weight loss strategy (Barlow, 2007; WHO, 2015).

During the early stages of my PhD, I spent considerable time observing clinical appointments at the Care of Childhood Obesity clinic at the Bristol Children's hospital, and volunteering at the Tier 2 weight management service 'Alive and Kicking'. Whilst these services discuss portion size, establishing what portion sizes people are currently eating can be very difficult as portion size is often discussed subjectively as 'large' or 'not that much' rather than in quantitative measures. In fact, adults frequently misinterpret the portion size, weight and calorie content of their food (de Vlieger et al., 2019; Frobisher & Maxwell, 2003), suggesting that for children, this would be exceptionally difficult task to engage in verbally.

Adults pre-meal plan and serve the amount they want to eat with a great deal of accuracy (J. M. Brunstrom, 2014; Fay et al., 2011), but we do not know at what age we establish this skill. Before this time, it is likely that children would select an amount of food at random and not have a concept of the appropriate or satiating portion, therefore an intervention to guide portion size at this time would be of no benefit. Establishing when children begin to pre-meal plan their portion sizes was essential research to conduct.

A computerised portion size tool has been designed by psychologists at the Nutrition and Behaviour unit at the University of Bristol (Ferriday & Brunstrom, 2010; Hinton et al., 2013). The portion size tool offers opportunities to objective measure portion size, in a way that is usually only possible through observation of eating scenarios and the serving of real food. The tool therefore offers a pragmatic means to understand portion size in clinical settings. The tool has been validated in adults as an accurate representation of the portion size choices made with real food (Wilkinson et al., 2012). Before the tool could be used in a paediatric clinical setting, it was imperative to first understand:

1) At what age children develop a conceptual understanding of portion size
2) Whether children's understanding of a computerised portion size develops at the same time.

The study reported in this Chapter has been published (details below), therefore sections 2.3-2.7 comprise the manuscript as published. Section 2.8 covers the contribution of this work to the thesis. Supplementary materials can be found in Appendix A.

2.2 Statement of contribution

This Chapter has been published in the journal Appetite (Cox, Hinton, et al., 2021). This study was pre-registered on the Open Science Framework for transparency (https://osf.io/h7zmt/?view_only=d911f40d03d64b42a437fef5a59e3ee5) and all deviations to the protocol are detailed in the body of the work. The study was devised in collaboration with EH and JB and the Nutrition and Behaviour Unit at the University of Bristol. JC led the data collection supported by EH and SS. JC was responsible for the analysis, supported by JB, EH and the NIHR BRC statistician, Dr Linda Hunt. JC developed the discussion and wrote the manuscript with all authors approving the final manuscript for publication. Elanor Hinton is the corresponding Author rather than JC as JC began maternity leave shortly after the submission of this work.

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When do children learn how to select a portion size?

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2.3 Abstract

The reduction of portion sizes supports weight-loss. This study looks at whether children have a conceptual understanding of portion size, by studying their ability to manually serve a portion size that corresponds to what they eat. In a clinical setting, discussion around portion size is subjective thus a computerised portion size tool is also trialled, with the portion sizes chosen on the screen being compared to amounts served manually. Children (n = 76) age 5-6, 7-8 and 10-11 were asked to rate their hunger (VAS scale), liking (VAS scale) and 'ideal portion size for lunch' of eight interactive meal images using a computerised portion size tool. Children then manually self-served and consumed a portion of pasta. Plates were weighed to allow for the calculation of calories served and eaten. A positive correlation was found between manually served food portions and the amount eaten ($r = 0.53$, 95%CI [0.34, 0.82, $P < .001$), indicating that many children were able to anticipate their likely food intake prior to meal onset. A regression model demonstrates that age contributes to 9.4% of the variance in portion size accuracy ($t(68) = -2.3$, $p = .02$). There was no relationship between portion size and either hunger or liking. The portion sizes chosen on the computer at lunchtime correlated to the amount manually served overall ($r = .34$, 95%CI [0.07, 0.55], $p < .01$), but not in 5-6-year-old children. Manual portion-size selection can be observed in five-year olds and from age seven, children's 'virtual' responses correlate with their manual portion selections. The application of the computerised portion-size tool requires further development but offers considerable potential.

Keywords: Children; Eating behaviour; Plate clearing; Portion size; Pre-meal planning.

2.4 Introduction

Consuming large portions of food is thought to play a causal role in promoting obesity (Hetherington & Blundell-Birtill, 2018; Ledikwe et al., 2005). At a population level, portion sizes have increased alongside obesity rates (Piernas & Popkin, 2011; van der Bend et al., 2017). Evidence suggests that children may be eating large portions and that in some cases they are offered adult-sized meals (Curtis et al., 2017). In addition, longitudinal studies indicate that meal size is an important driver of weight gain in early childhood (Syrad et al., 2016).

Decreasing portion size is a recommended intervention for weight-management (Barlow, 2007; WHO, 2015). However, exactly how much children should be eating, and how best to achieve this, is unclear (Eck et al., 2018). Currently, the United Kingdom National Health Service guidelines state "There is very little official guidance on precisely how much food children require, so you will need to use your own judgement" (NHS, 2020), leaving children's portion sizes open to errors (Curtis et al., 2017; Eck et al., 2018). We also see evidence that parents who eat larger portions are more likely to feed their children large portions, which is likely to contribute to the intergenerational transmission of obesity within families (Potter et al., 2018).

In adults, large serving sizes promote the consumption of larger meals (Zlatohlavek et al., 2015) and in part, this may reflect a general tendency to engage in plate cleaning (Hetherington & Blundell-Birtill, 2018; Hinton et al., 2013). Remarkably, the same 'portion size effect' is also observed in children (Fisher & Kral, 2008) and some have argued that this sensitivity to portion size is promoted when parents encourage their children to clear their plate (Birch et al., 1987; Ramsay et al., 2010). In response, one suggestion is that children should be encouraged to self-serve in a 'family style' (i.e., from a central dish) (American Academy of Paediatrics, 2005). Self-serving and guidance via self-regulatory cues are thought to support the child's innate self-regulation in response to internal signals associated with hunger and satiety (Birch et al., 1987; Ramsay et al., 2010b).

In addition to encouraging personal portion-size decisions, children might also be trained to select healthier sized portions. One approach might be to monitor selections over a long period and to promote a gradual reduction in size and improved food choices (American Academy of Paediatrics, 2005). However, to realise this benefit it would be helpful to know whether and at what age children acquire a conceptual understanding of portion size. In adults, most meals are preselected and then consumed in their entirety (Fay et al., 2011), suggesting that pre-meal planning indeed plays an important role in energy intake. In children, a similar correspondence between meal planning and

meal consumption would suggest they show the same conceptual understanding. In addition, other indicators might be explored to show evidence for pre-meal planning. For example, we might expect children to select smaller portions of foods that are less preferred or unfamiliar, and to select larger portions when they are hungry. Accordingly, in this study we assessed measures of portion selection, food intake, hunger, and food liking, with the first objective being to explore evidence for the same relationships that are normally observed in adults. Further, to explore a potential developmental trajectory, we actively recruited a range of children in order to achieve representation in three different age groups.

There are important potential therapeutic benefits of assessing meal planning. Specifically, it would be helpful to know how obesity interventions impact meal planning in children and whether new interventions might be developed to foster healthier dietary behaviours in this population. In many settings, the preparation and manual serving of actual food is impractical. Hence, portion selections have been assessed (in adults) using a validated computerised portion-size tool (Wilkinson et al., 2012), with respondents reporting their 'ideal' or 'typical' portion sizes by manipulating the amount of food shown on a computer monitor.

In paediatric weight management sessions, clinicians rely on verbal descriptions to assess food portions; a task that both children and adults find difficult (de Vlieger et al., 2019; Frobisher & Maxwell, 2003). A computerised portion size tool would deliver precise descriptions, but it remains unclear whether children can select portion sizes in this way. Therefore, our second objective was to evaluate this capacity. Using a computerised tool requires an ability to perceive portion size, together with an ability to predict an amount that will be needed to achieve satiation by the end of a meal (de Vlieger et al., 2019; M. Nelson et al., 1994; Subar et al., 2010). Though these skills are clearly evident in adults (Brunstrom, 2011; Brunstrom & Rogers, 2009; Fay et al., 2011; Hinton et al., 2013; Wilkinson et al., 2012), rather less is known about children, partly because studies have tended to focus on their ability to recall past meals (de Vlieger et al., 2019; Foster et al., 2008). One study indicates that children are comparable to adults (Sobo et al., 2000). However, others suggest that children have a limited capacity to form a conceptual representation of portion size and to plan meals on this basis (Baranowski & Domel, 1994; Livingstone & Robson, 2000).

In the present study we addressed two objectives. First, we sought to determine whether children have a conceptual understanding of portion size. Evidence was obtained by quantifying the following outcomes: a) the correspondence between physical self-selected portions and subsequent food intake, b) the correspondence between age and meal size and meal accuracy across three age ranges (5-6 years, 7-8 years, and 10-11 years), c) the relationship between portion size selection and

hunger, d) the association between portion size and the extent to which a food is liked, and e) the associated tendency to plate clean after self-selection of real food. In all cases, we anticipated that these associations would be stronger in older children.

Second, to determine whether children have a capacity to use a computerised portion selection tool, we correlated the amounts of food selected using the computer programme with the amounts that children manually selected and then consumed.

2.5 Methods

A protocol containing all methods and materials was uploaded to the Open Science Framework for transparency, prior to the start of data collection (https://osf.io/h7zmt/?view_only=d911f40d03d64b42a437fef5a59e3ee5).

2.6.1 Participants

Participants were drawn from three different school years, incorporating three distinct age groups (5-6 years, 7-8 years and 10-11 years) and were recruited at a single school in South-West England, UK, during a week-long science-engagement event. Exclusion criteria were an allergy or intolerance to foods within the task (i.e. vegetarian/vegan/gluten/dairy). The majority of participants were of normal weight, as determine by BMI SDS (Pan & Cole, 2002). Participant summary statistics are displayed in Table 2.1. Children were invited to participate via a letter and participant information sheets were sent to the home of all families. Parents of willing participants returned the written consent to the school, together with the child's choice of meal. Assent was requested from each child prior to testing.

Table 2.1. Participant characteristics (%)

	Total	Age 5/6	Age 7/8	Age 10/11
Number of participants	76	23	22	31
Male (%)	43 (57)	17 (74)	12 (55)	14 (45)
BMI-SDS (Pan & Cole, 2002) (%) Underweight	1 (1)	0 (0)	0 (0)	1 (3)
Normal	66 (87)	21 (91)	21 (96)	24 (77)
Overweight	6 (8)	2 (9)	1 (4)	3 (10)
Obese	3 (4)	0 (0)	0 (0)	3 (10)

2.6.2 Ethical approval

Ethics approval was given for this study by the University of Bristol, School of Psychological Science ethics committee REF 63241.

2.6.3 Materials

2.6.3.1 Meals and computerised portion-selection task

The research used a computerised portion task that incorporated images of eight lunches that differed in energy density (ED); penne pasta with tomato sauce (ED= 1.42kcals/g), lasagne (ED= 1.45 kcals/g), chicken curry (ED= 1.68 kcals/g), pizza and chips (ED= 2.77 kcals/g), macaroni cheese (ED= 1.51 kcals/g), breaded chicken with chips and beans (ED= 2.26 kcals/g), sausages with mash potato and peas (ED=1.63 kcals/g), and spaghetti Bolognese (ED= 1.41 kcals/g). A paediatric dietician confirmed that these meals are likely to be familiar to children in the UK.

Meals were displayed on a computer screen and were presented on the same 255-mm diameter white plate. For each meal, a set of 51 images was taken using a high-resolution digital camera. The portion sizes of the meals increased in 25 kcal increments from 25kcal to 1250kcals. Children's portions are discussed throughout in kcals. The lighting and lens angle remained fixed in all images.

For each meal, participants were asked ''What is your perfect amount for lunch?'' Participants were instructed to move between portion sizes, to select a portion size using the arrow keys on the keyboard, and to press the 'Enter' key when they had selected an appropriate portion. Depressing the arrow keys caused the portion size to change with enough speed to give the impression that the plated portion was growing or shrinking. Each trial started with a different and randomly generated portion size. The protocol is based on methods reported previously by the authors (Wilkinson et al., 2012).

2.6.3.2 Hunger, Familiarity and Liking

A paper-based visual-analogue scale (VAS) with a 100-mm line with endpoints "Not hungry" to "Very Hungry" was accompanied by images of a bear with a different quantity of food in its stomach to represent varying hunger levels (Bennett & Blissett, 2014). Children were asked to "Please put a cross on the line according to how hungry you feel right now". The anchor points were read out to ensure the child's comprehension of the scale

Children were shown a picture of each meal and asked for a "Yes" or "no" response to the question "Have you ever eaten food like this before?" Meals that were unfamiliar to the child were not included in the analysis.

Children were asked to rate their expected liking of each meal using a paper-based VAS scale comprising a 100mm line with end points “Very much” to “Not at all”. Five cartoon images of faces in traffic light colours representing different levels of liking from a green smiley face to a red sad face were included above the scale. Children were asked to indicate their liking of the food along the scale according to the question “How much do you like this food?”

A measure of post-meal liking was taken after children had eaten lunch, by asking the question “How much did you like your meal?” using a separate version of the above-mentioned VAS with traffic light cartoon faces.

2.6.3.3 BMI

Measures of height were obtained using a stadiometer (+/- 1 mm) and weight was recorded using a digital scale (+/- 0.1 kg). Measurements were taken in light clothing and were used to compute body mass index standard deviation scores (BMI SDS) using the LMS method that accounts for growth and sex (Pan & Cole, 2002).

2.6.3.4 Measures of actual eating behaviour

Children were asked to manually serve themselves lunch onto the same plates that were used in the computerised portion-selection task. Children chose either penne pasta with tomato sauce (ED= 1.42 kcals/g) or macaroni cheese (ED= 1.51kcals/g) and then self-served a portion from a large bowl. These foods were chosen because they were also included in the computerised portion-size task and because they are homogenous, which enabled us to estimate calorie content of the amount served by weighing the plate after self-serving and the amount eaten by weighing the meal leftovers.

2.6.4 Procedure

2.6.4.1 Initial Testing

The initial testing took place in a classroom at the beginning of the school day and took around ten minutes per child. Children were tested alone. Testing included: confirming assent, followed by assessments of food liking and familiarity. Measure of height and weight were obtained. All testing was carried out by the research team.

2.6.4.2 Mealtime testing

At lunchtime, in a room adjoining the kitchen, separate from the classroom, the children reported their hunger and completed the computerised portion selection task. Participants were then given

access to the pasta meal that they selected upon recruitment, and they were asked to self-serve an amount to consume. In each case, portions were created by selecting food from a large bowl. Participants ate their self-selected meals at a table with 7 of their peers, to replicate the school's typical communal lunchtime style that for some children involved hot meals whilst other children brought packed lunch. One difference was that the table had screens which prevented participants from seeing each other's portions. At the end of the meal, a measure of actual liking was taken, and the children's plates were weighed to measure any remaining food and to calculate the calories consumed. Researchers and a member of staff from the school were present during testing but did not comment or influence the children's serving and consumption directly.

2.6.4.3 Data analysis

One participant from the age 7/8 group was removed from analysis as they did not participate in the ad libitum meal, and two participants were removed from the age 10/11 group because their computer-based data failed to save. Our first objective was to determine whether children in three age ranges have a conceptual understanding of portion size. To explore whether children manually select food portions that correspond with the amounts they subsequently consumed, correlations were conducted using Pearson's R between the food portions manually served and consumed. To understand whether the portion size the child served differed by age, sex, child's hunger, the child's expected or the actual liking of the food, these factors were entered as variables in a bootstrapped multiple regression. To understand how these same factors contributed to the amount consumed, they were entered along with the served portion size into a separate bootstrapped multiple regression. Finally, to understand the impact on portion size accuracy (the amount the child served, minus what they ate), a third bootstrapped linear regression was carried out to look at the impact of meal size predictors.

Next, the proportion of children plate clearing was identified, and Cramer's v was used to understand whether there was evidence of a difference in this behaviour in children of different ages. Our second objective was to determine whether children have the capacity to use a computerised portion size tool. Pearson's correlations investigated whether the portions chosen on the screen correlated with those manually served. The influence of the meal size predictors was also examined using a multiple linear regression. All regressions are bootstrapped with 95% confidence intervals in order to produce more robust effect estimates and confidence intervals.
A power calculation using G*power 3.0 software demonstrated that a sample size of 20 should give 90% power of determining a (non-zero) correlation between the computer and

actual chosen portion size, using the 5% level of significance (one-sided test), assuming the correlation will be of similar magnitude to that found in adults (0.6) (Wilkinson et al. 2012).

2.6.4.4 Deviations from protocol

The protocol stated that portion size data would be collected using the computer-based tool during an initial morning testing period, as well as at lunchtime. In line with the protocol, these initial data were collected but as no hypothesis was included, this work are not discussed here, but is included in Appendix A.

Contrary to the protocol, we did not remove extreme responses. This decision was taken because a large number of outliers were observed and we reasoned that they should remain in order to obtain a more faithful estimate of the validity of the measures.

The protocol stated that the effect of age on portion size would be investigated. In the pre-registration we omitted to also include the effect of age on portion size accuracy, which has now been included in the analysis of this paper and labelled as post hoc. Further, relationships between the expected liking and served meal size were stated *a priori* in our registration. However, the relationship between expected liking and computer portion sizes was omitted, and so this has also been incorporated as a post-hoc analysis.

2.6 Results

Participant characteristics

Participant characteristics are detailed in Table 2.2 Across age groups, participants' hunger and liking differed, with the two younger groups rating themselves as hungrier and liking the food more than the older group (see table 2.2).

Table 2.2. Participant summary statistics (mean and standard deviation)

	Total (n=76)	Age 5/6 (n=23)	Age 7/8 (n=22)	Age 10/11 (n=31)
Lunchtime testing hunger (SD) 0-100 mm VAS scale	82 (20)	90 (14)	88 (19)	74 (21)
Expected liking of meal eaten (SD) 0-100mm VAS scale	82 (21)	83 (25)	84 (18)	80 (21)
Actual Liking (SD) 0-100mm VAS scale	85 (15)	85 (21)	89 (11)	82 (11)

Amount manually self-served (kcal) (SD)	388 (131)	396 (189)	413 (116)	365 (81)
Amount eaten (kcal) (SD)	328 (105)	294 (102)	346 (124)	365 (89)
Kcals left uneaten (SD)	60 (116)	102 (178)	67 (88)	23 (44)
Number of children who plate cleared (%)	45 (59)	10 (44)	10 (46)	25 (81)
Amount chosen on the computer screen at lunchtime, of meal eaten (kcal) (SD)	705 (358)	820 (383)	718 (406)	610 (280)
Discrepancy between meal manually served and that chosen on the computer screen at lunchtime (kcal) (SD)	317 (335)	424 (375)	305 (380)	246 (249)

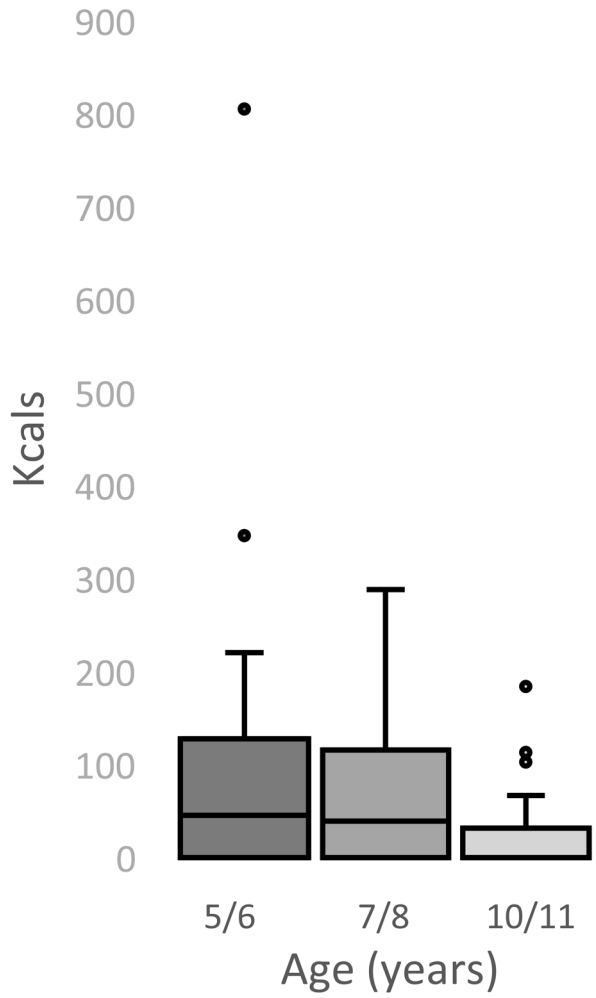
Do children manually serve portions that correspond with the amounts they subsequently consume?

A few children (outliers) chose very large portions (see Figure 2.1). Nevertheless the size of the meals served (M= 388kcals, SD=131kcals) and eaten (M= 328kcals, SD= 105kcals) were broadly consistent with guideline intakes for a child's lunch (NHS, 2015). A positive correlation was found between manually served food portions and the amount eaten (r =.53, 95%CI [.34, .82, P<.001) indicating that many children were able to anticipate their likely food intake, prior to meal onset. There is evidence that this exists in children aged 5/6 (r =.41, 95%CI [.12, .67], P= .01), aged 7/8 (r =.74, 95%CI [.44, .89], P<.001), and age 10/11 (r =.87, 95%CI [.73, .97], P< .01).

As outlined above, a further indication that children show adult-like portion selections would be if they demonstrated sensitivity to liking and hunger. In our sample, manual self-served portions did not correlate with expected liking (r= .02, 95%CI [-.23, .24], p=.88), actual liking (r= -.07, 95%CI [-.10, .22], p=.57) or hunger (r= .16, 95%CI [.01, .31], p=.16).

Linear regression confirmed that the child's serving size was not influenced by age (t(68)= -.50, p=.59), sex (t(68)= -.77, p=.40), expected liking (t(68)= .08, p=.94), actual liking of the meal (t(68)= .41, p=.52), their hunger rating (t(68)= .1.05, p=.16), meal choice (t(68)= .35, p=.71) nor BMI-SDS (t(68)=.1.76, p=.32).

Figure 2.1. Single whiskered boxplot demonstrating the discrepancy between kcals manually self-served and eaten by age group



Interestingly, when these variables were considered along with the amount of food that a child self-served, the combination of age and amount self-served explained 33.2% of the variance in amount consumed. As the child age group increases by one group (e.g., age 5/6 to age 7/8), the amount eaten increases by 35 kcals (t(68)=2.6, p=.02). As the portion size served increases by one unit (1 kcal), the amount eaten increases by .44 kcal (t(68)= 5.5, p=.04). Sex, (t(68)= .06, p=.95), expected liking (t(68)= -.27, p=.78), actual liking (t(68)= .37, p=.72), hunger (t(68)= 1.20, p=.23), meal choice (t(68) = -.87, p= .47) and BMI-SDS (t(68)=-.85, p = .40) do not contribute.

It was acknowledged that an important marker of a child's understanding of portion size, was the precision with which they served a portion that they went on to eat. Therefore, post-hoc, we explored the importance of factors influencing children's portion size accuracy (the amount of food served minus the amount of food eaten). Our regression model revealed that age contributes 9.4% of the variance in portion size accuracy (t(68)= -2.3, p=.02), while sex (t(68)= -.55, p=.52), expected

liking (t(68)= .26, p=.75), actual liking (t(68)= -.01, p=.99), hunger (t(68)= -.24, p=.71) meal choice (t(68)= .9, p=.39) and BMI-SDS (t(68)= 1.79, p=.41) contribute very little.

Finally, 59% of the children cleared their plate (see Table 2.1), this tendency was especially evident in older children (81% of 10/11-year-olds plate cleaned; effect of age, X^2 (2) = 9.98, p=.007, Cramer's V=.36).

Using the computerised portion size tool

Are children able to use a computerised portion size tool to demonstrate the portion size they will manually serve?

The portion sizes chosen on the computer at lunchtime correlated with the amount manually served (r=.34, 95%CI [.07, .55], p<.01). Figure 2.2 details the discrepancy between the lunchtime computer and manual food portions in the three age-groups.

There is weak evidence of a correlation between a child's age and their accuracy at choosing a portion size on the screen that represents the portion they serve, (r =-.221, 95%CI [-.41, -.01], p= .055), where a smaller discrepancy is seen in the older children. We do not see a correlation between children at age 5/6's portion sizes on the computer and those manually served (r =.21, 95%CI [-.18, .56], p= .18), but we do see this correlation at age 7/8 (r =.45, 95%CI [.24, .64, P< .01) and 10/11 (r =.50, 95%CI [.27, .70, P< .01).

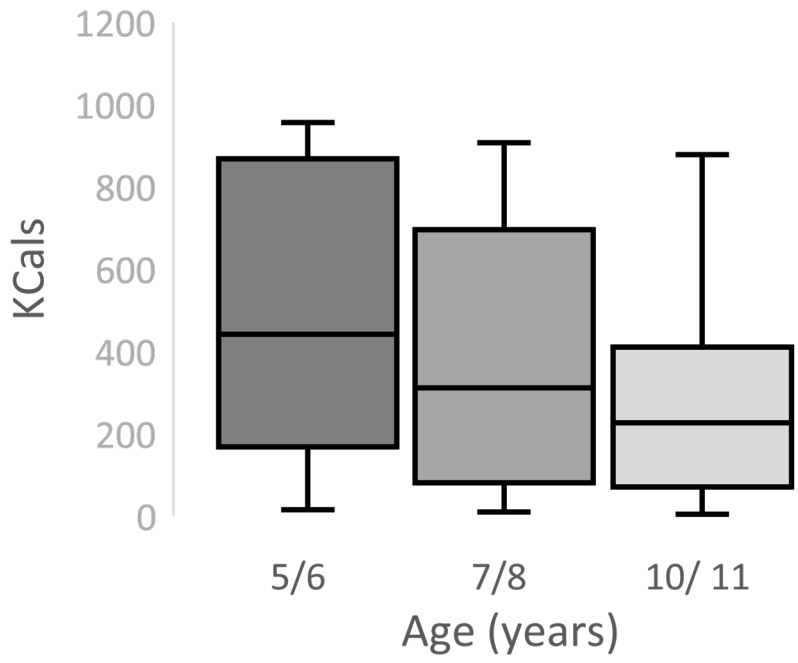


Figure 2.2. Boxplot demonstrating discrepancy between kcals chosen on the computer and calories served manually during a meal

3.4.2 Computerised portion sizes and the relationship with hunger and liking

Post-hoc, a regression model was run to look at portion size accuracy. This explored the similarity between the portion size selected on the computer and the actual served portions of pasta. The model explained 13.9% of the variance in children's accuracy, with higher correspondence in children who were hungrier (t(68)=2.19, p=0.04). This may be due to hungrier children being more likely to plate clear. Age (t(68)= -.82, p=.42), sex (t(68)= -1.8, p=.07), and liking of the meal (t(68)= 1.9, p=.15) did not influence child's accuracy.

2.7 Discussion

This study sought to determine whether children have a conceptual understanding of 'portion size.' Specifically, whether they can form a mental representation of the amount that they will eat in advance of a meal and whether they can express this by manually selecting food portions from a serving bowl and by using a computerised portion size tool. Our findings indicate that manual portion-size selection can be observed in all age groups, including in the five-and-six-year-olds and that children from age seven can use a computerised portion size tool, in as much as their 'virtual' responses correlate with their manual portion selections. Moreover, we see the correspondence between manual portion selection and actual intake (the portion selection accuracy) improves with age. There is of course, the possibility that this improvement is also influenced by older children's greater awareness of being 'tested' and a greater social desire to be correct, which may drive an improvement in their memory and recall of the portion sizes and therefore an improvement in their performance.

Broadly, our data also confirm that children from the ages of 5/6 can self-serve a portion size that is in line with both national recommendations (NHS, 2015) and their own eating behaviour (self-served portions correlate with what is eaten). Overall, these findings indicate that children should be encouraged to self-serve their own portions (consistent with current UK guidelines). However, we also observed large individual differences, with some children at all ages apparently lacking the conceptual ability or training that is needed to select a portion size. The reason for these differences remains unclear but they suggest that simple health messaging around the importance of self-selection may not be appropriate for all children. There is also a possibility that some children might benefit from more tailored support, which is an area in need of future research.

In addition to age-related improvements in manual serving accuracy, we also observed an increase in the tendency to plate clean. In adults, plate clearing levels of around 90% have been observed (Wilkinson et al., 2012), and it would appear that our data match a developmental trajectory that has been observed elsewhere (McCrickerd et al., 2017). Further, the parallel age-related correspondence between serving accuracy and plate cleaning is consistent with the proposition that

plate-cleaning reflects a capacity to accurately anticipate and self-serve an appropriate portion size, before a meal begins (Brunstrom, 2014). However, we cannot say with any certainty that social influences, such as feeding practices, are not driving this increase in plate cleaning. Future research should explore how plate clearing is influenced by socioenvironmental factors, and whether children show different plate clearing behaviours towards pre-plated meals.

In this study, neither hunger nor liking were associated with manual serving size. This is in contrast to previous research suggesting that children's innate reliance on hunger and satiety signalling for portion size selection drives accuracy (Fox et al., 2006; Rolls et al., 2000; Westenhoefer, 2001). This could be because of a high homogeneity of responses in our data that prevents the exposure of a relationship with intake. We see that children rated themselves as very hungry, with a small standard deviation and children also chose to eat a food that was liked, meaning there is little variability in liking to allow an additional effect on portion size to be visible. When the analyses were run on the portion sizes selected on the computer tool that included a broader range of foods, a relationship with both hunger and liking was demonstrated. Whilst this could demonstrate a relationship that was formally not exposed due to the homogeneity of the data, due to the different methodology (screen compared to real-life) we cannot say this with certainty. The lack of an effect of these two variables may also be due to measurement error. Both hunger and liking were measured using a VAS scale, which in other research has been found to elicit polarised answers from children, indicating that the scale lacks sufficient sensitivity (Porter et al., 2017).

We also acknowledge that, unlike the studies using the tool in adults (Wilkinson et al., 2012), the children were not allowed to self-serve a second portion of the food in the dining hall. This decision was made to maintain external validity of the study as it more accurately reflected the usual dining experience at the school where data collection took place. Testing within an ad libitum setting, where children can re-visit the bowl to serve themselves more food, might generate a different outcome. We also acknowledge that no correction for multiple comparison was made during our analysis. In addition to refining our methods, an obvious next step would be to look at how portion selections associate with BMI-SDS. Previous work would seem to indicate that children with a higher BMI respond differently to portion size (Fogel et al. 2020; Mooreville et al., 2015) however, the majority of our participants were of normal weight.

While the results suggest that the computerised tool detects *relative* differences in portion size at all ages (children who manually served a large manual portion size also chose a large portion using the computerised portion size tool) there appears to be a large absolute difference. However, in some children, including some of the youngest children, this difference was small and others, including

some of the oldest children, it was very large (see Table 2.2 and Figure 2.2). For comparison it would be helpful to know how this discrepancy compares to an adult population. One explanation might be that the computer-based portion was perceived to be smaller, partly because the screen displayed 'smaller than life' portions. To help to mitigate this problem, following previous 'paper-based approaches' (Nelson, 1997), we recommend incorporating cutlery or other items of known size into the food images. More generally, efforts of this kind are important because we and others (Foster et al., 2008; Livingstone, Robson, & Wallace, 2004; Vereecken, Dohogne, Covents, & Maes, 2010) recognise the potential benefits of using a portion-selection tool in clinical assessments, and such tools have continued to be valued for their use as pragmatic alternative to group-level observation-based eating studies in children (Foster et al., 2008).

We see an age effect on children's accuracy at serving portion sizes that they go on to eat. A possible explanation is that children's cognitive and spatial abilities develop throughout childhood, which promotes greater accuracy when selecting portion sizes, both manually and on a screen. Jean Piaget's theory of cognitive development (Piaget, 1962) suggests that between the age of 7-11, children reach the 'concrete operational stage' where children acquire cognitive skills such as the conservation of mass and volume – the understanding that an item is of equal quantity despite changing its form develops. For example, that water poured from a tall narrow glass into a short wide glass is the same quantity of water, despite the appearance of the water level decreasing. We hypothesise that children who have reached this critical stage may have an enhanced ability to demonstrate portions on a computer screen and suggest that further research to understand the relationship between portion size and children's cognitive development may help to develop age-appropriate portion guidelines.

In summary, whilst it seems that the majority of children are able to self-serve reasonable size portions for themselves, parents and clinicians should consider the individual child when recommending this approach, as individual differences are apparent. The authors acknowledge the limited sample size and restricted age-groups tested, and recommend that further research is needed to determine how cognitive development and social environment affect children's responses to portion size. In terms of potential clinical applications of the computerised portion size tool, we conclude that individual-level discrepancies with manual measures are a concern, but with further development we see considerable potential for its use in a clinical setting to assess children's portion sizes and to aid conversations about healthy portion size, both with parents and their children. A potential future step would be to understand whether estimation errors occur consistently over time. Whilst between-participant comparisons remain imprecise, if errors occur consistently, the

tool may offer opportunity to measure changes within an individual over time, which is of clinical relevance.

2.8 Contribution to the thesis

This work indicates that from the age of five children develop a conceptual understanding of portion size and self-served appropriate meal sizes. From age seven they understand portion size using the computerised tool meaning that interventions that support appropriate portion size may be of value to children above these ages.

For several reasons, this intervention has not been taken forward to be developed as a clinical tool within this thesis. Firstly, on average children can use the tool, we see that some children are extremely good at identifying portions, whilst other children have an error of over 800kcal. When the tool is being used across a population, such as in research, we can determine overall patterns in behaviour. But for an individual level intervention it is difficult to rely on the tool working effectively in the target child.

Secondly, we see little evidence of long-term effect for interventions that target portion size through education (Almiron-Roig et al., 2020). One intervention that guided participants to reduce portions using picture cards, a portions placemat, cups and spoons or scales found no greater effect than when participants were given standard weight management advice that did not consider portion sizes (Rolls et al., 2017).

Thirdly, the evidence for long-term effects of reducing portions is limited. There is a risk that with portions size reduction comes a lack of satisfaction, enjoyment and reward consequently resulting in compensatory eating (Almiron-Roig et al., 2020). If this compensation occurs through an increase in high calorie, highly processed snacks in lieu of fibre, protein and vegetable heavy meals, this compensation could be detrimental to the child's overall diet quality and raise calorie intake.

It is also important to consider the impact of this for the high proportion of patients at the COCO clinic who experience co-morbid socioeconomic deprivation, food-insecurity and obesity. When food insecurity is high, a known coping strategy is to adopt grazing eating habits instead of eating main meals (McPherson, 2020; Shinwell & Defeyter, 2021). During work with a charity delivering a healthy eating programme within a local school, I conducted interviews with key stakeholders at the primary school. The observations of teachers working within a school with high levels of child hunger identified that at-risk children grazed on sausage rolls, crisps, and biscuits as meal-substitutes, that were inexpensive and accessible to the families. When given school meals at school these children often left lots of food on their plate, understood to be a combination of being unaccustomed to eating full meals so getting full easily, and little exposure to meal-time foods, making them wary of

new tastes (unpublished qualitative interviews, 2018). In instances such as these, it would feel unwise to reduce portion sizes at mealtimes, potentially the most nutritious meal of the day for the child. With the known link between obesity and food insecurity (Tester et al., 2020), if portion size guidance is offered at the COCO clinic, it needs to consider the individuals context and current eating patterns.

The evidence that children understand portion size at a young age offers an optimistic start to other interventions being developed for this clinical setting. The next steps to translation to the clinic for this work would be to understand how clinicians, specifically dieticians, and the patients and families at the clinic feel the tool could be of greatest value, through qualitative interviews and PPI groups with key stakeholders (Skivington et al., 2021). The tool does offer opportunities for dietitians to identify problems within patients' diets that could be the target of interventions. The dietitians at the COCO clinic currently use the 'Carbs & cals' book (Cheyette & Yello, 2013) to support discussions of portion size with families. The book offers six portion images, whilst the portion size tool offers 25 graded portions, which may offer more precision to discussions, helping the dietician identify meals or snacks that are being served in portions that are too large.

It is also optimistic that many children in this study self-served portion sizes that were appropriate and in line with guidelines for a child's lunch (NHS, 2015). Thus, one intervention that could be of benefit is to encourage families to serve their meals family-style, at the centre of the table for the children to self-serve. Guidelines for feeding within childcare settings recommend children's portions are self-selected in this way (American Academy of Paediatrics, 2005). We see this self-regulatory ability exists innately in babies that are able to manage their required intake, if fed responsively (Pérez-Escamilla et al., 2019). Whilst we typically move away from self-regulation in childhood with increasing reliance on external cues to eating, evidence has suggested that attempts to maintain children's connection with self-regulatory mechanisms could be protective of obesity (McCrickerd, 2018). Conversely, parent-selected portion sizes may result in children's overconsumption (McCrickerd & Forde, 2016), and as parents are seen to serve their children portion sizes that are related to their own, they may influence a child's perception of normative portions (Johnson et al., 2014). Self-serving helps children to stay connected to this innate ability to self-regulate their energy needs (Rolls et al., 2000). Again, all interventions discussing portion size in the COCO clinic must be considered on a case-by-case basis as there is likely to be children who need extensive support to manage their consumption in this free-eating environment.

Supporting self-served mealtimes with a narrative that fosters self-regulation (L. A. Daniels et al., 2009), the introduction of mindful eating approaches (Wojtkowska & Barlińska, 2020; Robinson et

al., 2013), a focus on eating for pleasure, rather than for fullness (Hege et al., 2018), and a focus on slowing down eating speed (Andrade et al., 2008) can lead to a decrease in selected portion sizes. Such methods of portion size management can be extrapolated to any circumstance and set the child up to manage eating experiences throughout their life. If an intervention to support reduced portion size is developed successfully, it may offer several advantages over standard weight-loss advice, in that patients can eat the same foods as the rest of the family, without having to restrict foods or food groups, they can appease any cravings and still experience 'treats' (in small amounts) and they may be able to implement portion-size limitation relatively discretely in any eating environment.

Recommendations for future interventions include:

1) Interventions should consider the age and developmental stage of the child, and be tailored accordingly.
2) Interventions designed for use in adults may not always translate to interventions for children without adaptation.

In conclusion, whilst continuing with the translation of the portion size tool to clinical practice did not satisfy the aims of this thesis, the portion size tool may offer potential for supporting discussions around portion size with children and their families in the clinical setting. Supporting children's self-regulation may also help to foster appropriate portion size consumption. To understand how best the tool can be of use, stakeholder involvement would be advised as the next step in translation.

Chapter 3: The feasibility, acceptability, and benefit of interventions that target eating speed in the clinical treatment of children and adolescents with overweight or obesity: A Systematic Review

3.1 Overview

An alternative way to approach the problem of over consumption of calories large portion sizes is to slow eating rate. There is evidence that slower eating rate supports introspective awareness of satiety signals, increasing fullness, memory for recent eating (Higgs et al., 2012) and reduces subsequent food consumption (Hawton et al., 2019; Robinson, Kersbergen, et al., 2014).

We know that eating rate and high body weight are correlated (Fogel et al., 2017), and that interventions to reduce eating speed may reduce weight (Andrade et al., 2008; Bolhuis et al., 2014; Langlet et al., 2019; Scisco et al., 2011; Smit et al., 2011). In parallel with interventions that reduce portion size, interventions that reduce eating speed may offer benefits over typical diet programmes that require high levels of dietary change and restriction. Targeting eating speed may enable patients to continue to eat the full range of foods they wish and still participate in social and family eating environments. Depending on the eating speed intervention used, they may be able to be delivered discretely.

Our research group have experience with delivering eating speed interventions for paediatric clinical settings (Ford et al., 2010; Hamilton-Shield et al., 2014; Hinton et al., 2018). Before any further development, or trialling of eating speed interventions was to take place, it was considered important to systematically review the work to date to understand the feasibility, acceptability, and effectiveness of these interventions, and identify scope for future work. Guidelines support systematic review at this stage in development to ensure that evidence is collated and evaluated to reduce research waste from repeated concepts and repeated errors (Chalmers et al., 2014).

A similar systematic review has been conducted for studies involving adults, that suggests eating speed interventions can aid acute reduction of energy intake (Robinson, Almiron-Roig, et al., 2014), however, we understand that there are considerable differences between adult and child populations, including factors such as choice, willpower and ingrained eating speed habits (Hamilton-Shield et al., 2014). Furthermore, we know that there is a significant difference between interventions that work within a controlled, short-term laboratory setting, and those that can successfully create a sustained influence on real life behaviour. With the aim of developing a

clinically useful tool, we seek to identify here the specific value of eating speed interventions in a paediatric, clinical population.

This work is published in the peer reviewed journal Appetite (details below).

3.2 Statement of contribution

JC contributed at all stages of the design and writing of this review, including writing the first draft of the manuscript. EH and RE contributed during the design of the systematic review and searches, the review and selection process, and the analysis. JHS contributed clinical knowledge to the design of the review and searches. RP contributed expertise in systematic review methodology in the design of the review and searches and conducted the meta-analyses. FK contributed to the data extractions and analysis. All authors read, contributed to, and approved the final manuscript.

The meta-analysis has been removed from the paper contributed here, as the meta-analysis was added to the published paper as a late addition by RP at the request of a reviewer of the manuscript, that occurred when JC was on maternity leave. The Risk of Bias analysis was also updated by RP and RE, but this is included as JC was involved and understood the mechanisms.

Publication: -

The feasibility, acceptability, and benefit of interventions that target eating speed in the clinical treatment of children and adolescents with overweight or obesity: A Systematic Review and Meta-analysis

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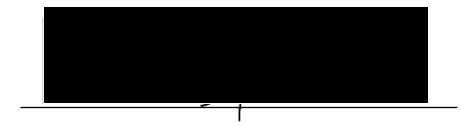
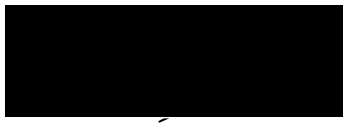




Lead author & PhD Candidate – Jennifer Cox

3.2 Abstract

Eating at a faster speed is positively correlated with having a higher BMI. Modifying eating speed may offer a treatment opportunity for those with overweight and obesity. This review sought to understand the feasibility, acceptability, and benefit to using eating speed interventions in paediatric clinical weight-management settings. The PICO Framework was used. Clinical studies of eating speed interventions as a treatment for paediatric patients with overweight or obesity were included. No limits to search date were implemented. A systematic search of MEDLINE, PsychINFO and EMBASE via OVID, Web of Science and JBI, Database of systematic reviews and Implementation reports, along with trial registers NICE, ClinicalTrials.gov and Cochrane Central Register of Controlled Trials was conducted. Two authors were responsible for screening, extraction, and evaluation of the risk of bias. Fifteen papers reporting twelve interventions addressing eating-speed were identified, involving a total of 486 active participants (range 7-297). Study design was weak with only one full RCT and there were some concerns over quality and risk of bias (Cochrane RoB 2.0). Limited sample sizes and different measured outcomes did not allow powered evaluations of effect for all outcomes. There is some indication, overall, that addressing eating speed has the potential to be a beneficial adjunct to clinical obesity treatment, although the pooled effect estimate did not demonstrate a difference in BMI SDS status following eating speed interventions compared to control [pooled mean difference (0.04, 95% CI -0.39 to 0.46, N=3)]. Developments to improve the engagement to, and acceptability of, interventions are required, alongside rigorous high-quality trials to evaluate effectiveness.

This review is registered on the Prospective Register of Systematic Reviews (PROSPERO) database (ID no. 192719). This review is funded by a GW4 MRC Doctoral training programme grant and supported by the NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol.

Key words
Eating rate, speed of eating, paediatric, obesity, overweight, treatment

3.4 Introduction

Overweight and obesity is highly prevalent in children and young people (National Child Measurement Programme, 2017). Obesity has a multifaceted aetiology, with contributions from genetics, behaviour, psychology, and the environment. Research has demonstrated a link between eating at a faster speed and overweight and obesity (Gross et al., 2016; Mesas et al., 2012; Ohkuma et al., 2015; Robinson, Almiron-Roig, et al., 2014; Slyper et al., 2014). Studies in both school children (Lin et al., 2014; Yamagishi et al., 2018) and clinical patients (Gross et al., 2016; Slyper et al., 2014) found that those with a greater body weight were more likely to report faster eating behaviour, a finding supported by a systematic review (Mesas et al., 2012). Young females with severe obesity scored lower on the slowness in eating subscale on the Child Eating Behaviour Questionnaire (CEBQ) than their peers with less severe obesity (Gross et al., 2016), suggesting that the impact of eating speed is significant even amongst those with the greatest clinical need.

Gastro-intestinal distension and absorption of nutrients trigger initial satiety signals, followed subsequently by the production of gut hormones (Benelam, 2009; Berthoud et al., 2017; Koliaki et al., 2020; Wynne et al., 2005). Faster eating is thought to be problematic due to the way in which greater energy can be eaten before satiety signals prompt fullness (Morton et al., 2006; Ohkuma et al., 2015). Higher concentrations of post-prandial anorexigenic gut peptides PYY and GLP-1 (Kokkinos et al., 2010) and supressed ghrelin (Hawton et al., 2019), were produced when a meal was consumed over a greater time period, and correlated with higher self-reported fullness (Kokkinos et al., 2010) and higher blood-oxygen level dependent (BOLD) activation of the satiety and reward brain regions (Hawton et al., 2019). Consequently, fast consumption may limit one's ability to eat according to satiety and we see that children with obesity who score low on slowness in eating scores, also show weaker satiety responsiveness (Gross et al., 2016).

Other, cognitive mechanisms of effect may be that eating more slowly supports memory for recent eating and/or mindful eating. Greater self-reported satiety has been reported following slower eating episodes (Ferriday et al., 2015), with translation to a reduction in consumption of food at later timepoints (Hawton et al., 2019; Robinson, Kersbergen, et al., 2014). For example, when a meal was eaten slowly, a 25% decrease in later snack intake occurred (Hawton et al., 2019). However, similar studies have reported no impact upon later food intake (Danielle Ferriday et al., 2015). Eating slowly is often recognised as a feature of mindful eating (Román & Urbán, 2019; Zerbo, 2017), allowing time to become aware of senses while eating, and in particular, an awareness of fullness; both key facets of mindful eating (Peitz et al., 2021). Indeed, attentive eating (another aspect of mindful eating) led to reduced subsequent snack intake in one study (Seguias & Tapper, 2018), but not in a further (as yet unpublished) study where eating rate was controlled (Ferriday et al. personal

communication), suggesting that slowing eating may be an integral component to mindful eating interventions.

Eating speed is considered a heritable behavioural trait (additive genetic effect of 0.62; 95% CI: 0.45, 0.74) (Llewellyn et al., 2008) and is thought to be preserved with relative consistency across time and eating episodes (McCrickerd & Forde, 2017). We see that those who eat quickly as newborn babies (2-4 weeks old) have a higher prevalence of overweight at six years old (Agras et al., 1990). Whilst changing such an innate behavioural trait is considered difficult, intervention to slow eating may provide therapeutic benefit (Gross et al., 2016; Robinson, Almiron-Roig, et al., 2014) and have additional, longitudinal gains if formed during childhood (Llewellyn et al., 2008).

Interventions to help both adults and children reduce eating speed have been designed with the objective of weight-loss (Andrade et al., 2008; Bolhuis et al., 2014; Langlet et al., 2019; Scisco et al., 2011; Smit et al., 2011). A systematic review suggests that such interventions can reduce energy intake in adults (Robinson, Almiron-Roig, et al., 2014). However, we understand that findings in an adult population do not always translate to the same conclusions in paediatric populations (Hamilton-Shield et al., 2014). Eating rate interventions fit into three categories: (i) interventions that change the food that is eaten, (ii) those that use technology to support a slower eating speed, and (iii) those that work to change eating speed by cognitive means alone.

i. Interventions that manipulate the texture of foods, focus on slowing down eating by exchanging foods with alternatives that require more chewing, or reformulating foods to make them more difficult to eat quickly (i.e. thickening porridge) (Forde et al., 2013).

ii. Technological devices have been designed to encourage, and in some instances 'train', the user to slow their pace of eating. Tableware such as forks with integrated sensors that detect movement rate (Hermsen et al., 2016; Kadomura et al., 2011, 2013) and weighing scales (i.e. the Mandolean® https://mando.se/en/mandometer-method/; see Appendix B.5 for access details) that can identify at what pace food is taken from the plate, both identify eating rate and then prompt the user to pay greater attention (Ford et al., 2010; Hinton et al., 2018).

iii. Interventions that cognitively manipulate eating speed include focused, attentive or mindful eating interventions that require the user to pay attention to the enjoyment and the sensory qualities of the meal, and in doing so may slow eating speed (Daly et al., 2016).

In controlled laboratory studies, these interventions are capable of eliciting slower eating speed in users. However, less is known about their translation to clinical treatments and in particular their use with children and adolescents. Previous work has provoked concerns about the acceptability and feasibility of attracting and maintaining children's engagement with these interventions (Hamilton-Shield et al., 2014). High drop-out rates, concerns around the increasing of stigma and questions about the translation of interventions designed for adults in the treatment of children have arisen. Therefore, the primary aim of this systematic review is to address the following question:

1) Are eating speed interventions acceptable and feasible in paediatric populations who have experienced such interventions as part of a clinical weight-management programme?

The secondary aim of this systematic review is to address the following questions:

1) Are eating speed interventions clinically beneficial? For example, are changes in eating speed, portion size and body weight found as a result?

2) Do participants experience adverse effects of these interventions? For example, does the intake of vegetables decrease or the participant feel more stigmatised?

3.5 Methods

This review was registered on the Prospective Register of Systematic Reviews (PROSPERO) database (ID no. 192719). This review was conducted in line with the guidelines set out by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-2020) (Page et al., 2021) (see Appendix B.1).

Eligibility criteria

The eligibility criteria for this review was informed by the Population Intervention Comparator Outcome (PICO) framework (Methley et al., 2014). The review criteria included both published and unpublished research including grey literature, research reports, conference proceedings, PhD theses, governmental reports, preprints and white papers to identify further trials for inclusion in the review. No date restrictions were placed on the search criteria. Studies in any language were accepted, and translation was made available via University of Bristol services

a. Participants

This review included research in clinical populations of children and young people aged between 5 and 18 years. Recruitment occurred in either primary or secondary care settings. Non-human studies and those working with adult participants, or those 4 years or younger, were excluded.

b. Intervention

Interventions that target eating speed by any modality, namely interventions that manipulate the texture of the food, those using technology or interventions involving cognitive training were sought. Research involving mindfulness or other cognitive or therapeutic training that did not specifically address eating behaviour was excluded.

c. Comparator

All types of study design were accepted including randomised and non-randomised trials, trials with no control group, case control studies, case-studies, observational studies, pre-post studies, experimental and quasi-experimental studies. For studies with a control group, the following comparators were included: no intervention, waitlist controls or an alternate intervention. There was no expectation of blinding, due to the complications of blinding this form of intervention.

d. Outcome

The primary outcomes for the review were the feasibility and acceptability of eating-rate interventions. These terms were operationalised as follows: recruitment (% of target sample recruited), adherence (% of intervention followed by participant), fidelity (% of intervention followed by staff) and completion rates (% drop-out rate of starting sample). A completion rate of >80% was considered a feasible intervention. Whenever reported, justification for values under each term was included.

Secondary outcomes were indicators of the impact of the interventions, including measures of eating speed (changes to meal duration or pace of eating in minutes/bites-per-minute or as recorded on the Child Eating Behaviour Questionnaire), the amount of food consumed (kcals or grams) and measures of body size. Measures of body size include Body Mass Index (BMI), Body Mass Index Standard deviation score (BMI SDS/z-score), % body fat or waist-circumference. Meta-regression demonstrated that a BMI SDS reduction of 0.6 results in clinical meaningful outcomes (Birch et al., 2019). Un-wanted side effects or difficulties that arose due to the usage of the intervention were extracted. Examples included a reduction of fruit and vegetable consumption or an increase in stigma due to using the device.

Search strategy

An initial scope of the literature was conducted to help inform the search, with the final search being carried out across the following databases: Web of Science, PyschINFO, MEDLINE, EMBASE and JBI Database of systematic reviews and Implementation reports, along with trial registers NICE, ClinicalTrials.gov and Cochrane Central Register of Controlled Trials. A grey literature search was

conducted via OpenGrey and by writing to experts in the field, and all reference lists were checked for additional references. The searches were conducted in June 2020. An example search strategy can be found in Appendix B.4.

Data management

All data were managed, and duplicates found using the open source systematic review software Rayyan (https://rayyan.qcri.org/welcome).

Selection and extraction

All abstracts were screened by a minimum of two independent reviewers (JC, RE, EH). Of these, relevant articles were retrieved, and at least two reviewers conducted the full-paper reviews (JC, RE, EH). Reasons for exclusion were documented. Inconsistencies were resolved through discussion with a fourth reviewer (JHS).

Data were extracted by two independent reviewers (JC, FK). Data regarding the characteristics of the sample was extracted (country, sample size, age, demographics, and setting), the intervention (type of intervention, duration), comparator details, primary outcomes (recruitment, fidelity, drop-out rate, and reasons provided both qualitatively by the patient or as explained by the author) and secondary outcomes (changes in eating speed, energy intake, body size and any unwanted side-effects/problems). A copy of the data extraction template is available on request.

Data synthesis

We collated multiple reports that related to the same study, so that each study, rather than each report, was the unit of interest in the review. For any studies reported in multiple publications, we used the reference that provided the most comprehensive information.

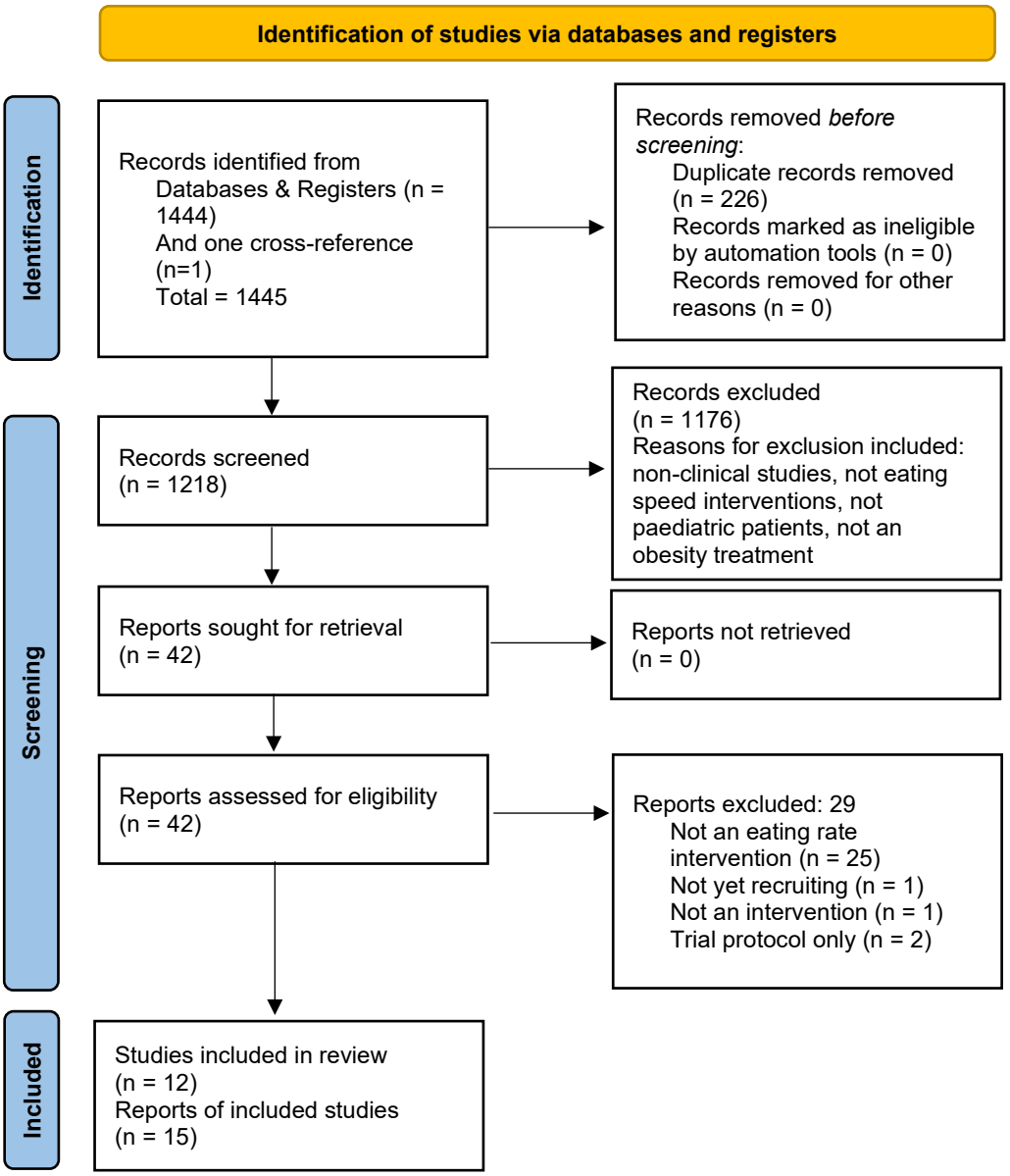
Due to the heterogeneity of the study designs and outcomes reported, it was concluded that the data were unsuitable for meta-analysis for most of the outcomes, therefore, the data were synthesised, and a narrative description provided. The data are also provided in table form. As many of the papers are non-powered pilot or feasibility trials, there are few meaningful statistical analyses of the data possible. Instead, feasibility, acceptability and benefit data has been extracted from the papers' own analysis in more qualitative terms. To distinguish the papers' own conclusions, from those of this review, quotations have been used within tables.

Quality checking

The Cochrane Risk of Bias Version 2.0 tool (Sterne et al., 2019) was used for randomised controlled trials (RCTs). The Newcastle-Ottawa quality assessment scale was used to assess the quality of non-randomised controlled trials (Wells et al., 2019). Two reviewers (JC & RE) independently assessed the quality of each included study, with a third reviewer (RP) resolving any disagreements. If the

information required was not included in the paper, the corresponding author was emailed for more details. Authors that did not respond to these further questions within the three-week timeframe are denoted with an Asterix (*), as this impacted the outcomes.

Figure 3.1 PRISMA 2020 flow diagram for new systematic reviews (Page et al., 2021)



1 Table 3.1. Summary data of included papers

First Author, year, country, trial name	Intervention type	Study design and control duration	Outcomes measured	N in intervention /comparator	Age (years, mean (SD)) Ethnicity	Mental health
Mandolean® Studies						
1.Bergh (2008), UK	Mandolean®	Single-armed trial Mean 617 days (482–651)	BMI, ES, Satiety, EDI & CPRS-SA	7/no comparator	11 - 17, M = 15.5 (SD NR) no data on ethnicity	NR
2.Browne (2020), Ireland	Mandolean®	Feasibility RCT, standard care 4 wks	BMI, behavioural and QOL outcomes, anthropometry, ES and PA	8/12	9 - 16, M = 13.3 (2.7) no data on ethnicity	NR
3a.Ford (2010), UK and Hollinghurst (2012), UK	Mandolean®	RCT vs standard care. 12 month intervention with an 18-month follow-up	BMI SDS, Body fat SDS, metabolic status, QOL, PS and ES.	54/52	9 - 17, M = 12.7 (2.2) Non-white = 5 (9%)	NR
3b.Galhardo (2012), UK	A sub-analysis of Ford (2010)		Ghrelin and peptide tyrosine-tyrosine measured via oral glucose tolerance test	14/13	9 -17, M = 11.45 (SD NR) Non-white = 3 (21%)	NR
4.Hamilton-Shield (2014), UK ComMando	Mandolean®	Pilot RCT, standard care 12 mths	Feasibility, recruitment of surgeries, staff and patients, adherence, ES.	26/35	5 -11, M = 9.1 (1.6) Non-white = 0 (0%)	NR
5.Hinton (2018), UK	Mandolean®	Pilot RCT, standard care 6 mths	Food cue reactivity fMRI, oral glucose tolerance, appetite, feasibility	14/10	11 - 18, M = 13 (IQR 5) no data on ethnicity	Exclusion criteria included psychiatric conditions affecting participation
6.Sabin & Bergh (2006), UK	Mandolean®	Single-armed trial Mean of 213 days (86 - 280)	BMI SDS, ES, satiety, PA	9/no comparator	11 - 18, M = 15 (SD NR) no data on ethnicity	NR
Education studies / Education + mechanical timer + 'chat jar'						

7.Faith (2019), USA RePace	Mechanical timer, a 'chat jar' to promote family dinnertime conversation and behavioural training	Proof-of-concept RCT, DUC 8 wks	Eating behaviour via CEBQ, BMI, observation eating assessment, anthropometrics, 24-hour dietary recall, acceptability, attendance.	14/14	4 - 8, M = 6.1 (1.4) African American 7 (50%), White 4 (28.57%), Mixed 3 (21.43%)	Exclusion criteria included psychiatric conditions affecting participation
8.Torbahn (2017), Germany	Eating behaviour training	Single-arm Observational 1- and 2-year follow-up	Portion size, ES, food frequency, weight, height, BMI-SDS,	297/no comparator	8 - 16, M = 11.74 (SD 1.86) of follow-up complete no data on ethnicity	NR
Mindful eating studies						
9.Cotter (2020), USA	Mindful eating within a mindfulness intervention	Pilot single-arm open-label feasibility trial 6 x 60 minute	Feasibility, recruitment, retention, satisfaction, mindfulness, emotion regulation, disordered eating, QOL, executive functioning, BMI & BP	11/no comparator	12–17, M = 14.36 (SD 1.9) 64% Black/ African American, 18% Hispanic/ Latino, 18% White	Exclusion participants in counselling
10.Kumar (2018), USA	Mindful eating	Pilot RCT, standard dietary counselling 4 x 90 min over, 10-weeks, 12 & 24 mth follow up	Weight, BMI, BMI z-score, feasibility, acceptability, attendance, fasting glucose, insulin, lipids, hs-CRP, triglyceride levels, HDL & LDL cholesterol, BP, MEQ & WEL	11/11	14 - 17, M = 17.1 (Q1 15.5, Q3 17.4) Non-white = 2 (18%)	Exclusion criteria included diagnosis of psychiatric illness within six months
11.Mazzeo (2016), USA	Mindful eating included within CBT and DBT for LOC of eating	Feasibility RCT, 2BFit, will be a behavioural weight management intervention 12 x 90-min & 15month follow-up	Satisfaction, therapist rated feasibility, BMI, LOC-ED, M.I.N.I., EDE-Q, EES-C, EAH-C and an eating disorder examination	28/17	13 - 18, M = 15.5 (SD 1.64_ 12 white and 12 black. No information on the ethnicity of 4.	Inclusion criteria required experiencing binge eating. Excluded severe mental health
12.Sperry (2013), USA CHEER	Mindful eating within a family-centred and mindfulness-based CBT intervention	Pilot RCT turned case study. N. 12 wks with 12 mth follow-up	Weight, BP, health-promoting behaviours, ANQAQ & PAQ	9/8	14 - 18, Case = 15 'Ethnically diverse group' Case studies ethnicity- Hispanic.	NR

ANQAQ = Adolescent Nutrition Quality and Adherence Questionnaire, BE = binge eating, BMI = Body Mass Index, BP = Blood pressure, CBT= cognitive behavioural therapy, CEBQ= Child eating behaviour questionnaire, CPRS-SA= Comprehensive Psychopathological Rating Scale Self-Rating Scale for Affective Syndromes (Svanborg & Åsberg, 1994), DUC= delayed usual care, EAH-C = Eating in the Absence of Hunger Questionnaire for Children and Adolescents, EDEQ= Eating Disorder Examination-Questionnaire, EDI= Eating disorder inventory (Garner, 1991), EES-C = Emotional Eating Scale for children, ES= Eating speed, HDL= High density lipoprotein, hs-CRP= high sensitivity C-reactive protein, LDL= Low density lipoprotein, LOC-ED= Loss of Control Eating Disorder Screening Questionnaire, MEQ= mindful eating questionnaire, M.I.N.I. = International Neuropsychiatric Interview version 6.0, NR= not reported, PA=Physical Activity, PAQ = Physical Activity Questionnaire, PS= Portion Size, QOL=Quality of life, RCT= Randomised control trial, SDS= standard deviation score, WEL= weight-efficacy lifestyle questionnaire.

2

3.6 Results

The literature search identified 1444 papers (Fig.1), of which 226 duplicates were removed and 1218 proceeded to title and abstract screening. Of these, 42 full text articles were retrieved and underwent full text screening. In total, 15 papers were included, including one following hand-screening of reference lists. A table of the full text articles that were excluded can be found in Appendix B.6. These 15 papers included 12 studies. One intervention (Ford et al., 2010) had separate economic evaluations (Hollinghurst et al., 2014) and a sub-section of the sample underwent further testing to explore the effect on satiety hormones (Galhardo et al., 2012). Going forward, Ford et al., 2010, was referred to as the main paper in this document. The Liber8 programme is described across a protocol (Mazzeo et al., 2013) and a results paper (Mazzeo et al., 2016).

Three conference papers and one trial were identified through clinicaltrials.gov as potentially meeting inclusion criteria but could not be included due to results having not yet been available or the authors not responding.

Study Design

Of the studies included, there was one full RCT (Ford et al., 2010) and seven pilot or feasibility RCTs (Browne et al., 2019; Faith et al., 2019; Hamilton-Shield et al., 2014; Hinton et al., 2018; Kumar et al., 2018; Mazzeo et al., 2016; Sperry et al., 2014), one of which is presented as a case-study due to the high drop-out rate (Sperry et al., 2014). Four were single-arm trials (Bergh et al., 2008; Cotter et al., 2020; Sabin et al., 2006; Torbahn et al., 2017).

Demographics

Sample sizes receiving the intervention ranged from 7 to 297 (median=11.5) with a total number of participants being 486. Two studies looked exclusively at children <11 years old (Faith et al., 2019; Hamilton-Shield et al., 2014). Faith et al. (2019) had a mean age of 6.4 (1.4 SD); Hamilton-Shield (2014) had a mean age of 9.1 (1.6 SD). The other studies focused on older children up to the age of 18, with six recruiting above age 11 and four recruiting from the age of eight or nine.

All the studies were conducted in high-income countries: six in the UK, five in the USA, one in Germany and one in Ireland. Five of the studies provided no information of the ethnic diversity of their sample (Bergh et al., 2008; Browne et al., 2019; Hinton et al., 2018; Sabin et al., 2006; Torbahn et al., 2017). Of those that reported on diversity, three interventions included predominantly Black/ African America participants (Cotter et al., 2020; Faith et al., 2019; Mazzeo et al., 2016), three interventions contained predominantly white participants (Ford et al., 2010; Hamilton-Shield et al., 2014; Kumar et al., 2018) and one intervention included 12 white and 12 black participants (Mazzeo

et al., 2016). The final study described their sample as an 'ethnically diverse group' (Sperry et al., 2014). No papers formally quantified socio-economic status (SES).

Two papers excluded all participants with a mental health condition (Cotter et al., 2020; Kumar et al., 2018), and two papers excluded if the mental health condition affected participation (Faith et al., 2019; Hinton et al. 2018). One intervention actively targeted young people with binge-eating disorder (Mazzeo et al., 2016).

In line with the inclusion criteria for this review, all interventions were working with children with a diagnosis of overweight or obesity. One intervention also required a parent to be overweight (Faith et al., 2019). This same intervention required the young people to have recognisable fast eating (Faith et al., 2019). No other interventions required this for participation.

Intervention type

Mandolean®

Six interventions involved the Mandolean® (Bergh et al., 2008; Browne et al., 2019; Ford et al., 2010; Galhardo et al., 2012; Hamilton-Shield et al., 2014; Hinton et al., 2018; Sabin et al., 2006). The Mandolean® is a computerised set of weighing scales, that provides feedback to the user about their eating rate via audio cues and information displayed either on an attached computer screen or on a smartphone. The studies included used the Mandolean® over varying durations, ranging between 4 weeks and 12 months.

Education/ Education + Mechanical timer and 'Chat Jar'

Two studies provided education on eating speed (Faith et al., 2019; Torbahn et al., 2017). One study used a combination of a mechanical timer with psychoeducation and behavioural training and a 'chat jar' to facilitate dinner table conversation to slow eating (Faith et al., 2019). The second intervention provided education within an 80-hour long programme of 'units', of which eating speed was a part, alongside nutrition, physical activity, medical information and psychoeducation (Torbahn et al., 2017).

Mindful eating

Four studies used mindful eating (Cotter et al., 2020; Kumar et al., 2018; Mazzeo et al., 2016; Sperry et al., 2014). For these studies, the session format varied. One delivered a family-based mindful eating intervention as a stand-alone treatment of 4 x 90 minute sessions (Kumar et al., 2018). Two studies incorporated mindful eating in broader programmes: one mindfulness-based cognitive-behavioural therapy (MB-CBT) programme delivered over 12 x 90 minute sessions (Sperry et al., 2014) and another delivered as part of a broader mindfulness intervention delivered in 6 x 60 minute sessions in addition to standard medical care for obesity (Cotter et al., 2020). The fourth study, discussed in two papers (Mazzeo et al., 2013, 2016) incorporated mindful eating within 12 x

90 minute sessions of Cognitive behaviour therapy (CBT) and dialectical behaviour therapy (DBT), specifically targeting loss-of control over eating.

Outcomes

Feasibility

The primary outcomes of feasibility and acceptability of eating speed interventions assessed in this review are provided in Table 3.2. Ten of the 12 studies were designed specifically to explore the feasibility of the intervention (Bergh et al., 2008; Browne et al., 2019; Cotter et al., 2020; Faith et al., 2019; Hamilton-Shield et al., 2014; Hinton et al., 2018; Kumar et al., 2018; Mazzeo et al., 2016; Sabin et al., 2006; Sperry et al., 2014). The Mandolean® studies had mixed outcomes, two perceived it to be a feasible intervention (Bergh et al., 2008; Sabin et al., 2006), two did not (Browne et al., 2019; Hamilton-Shield et al., 2014), and one highlighted the benefits of slowing eating speed but the low acceptability of the Mandolean® (Hinton et al., 2018). The RePace intervention was considered to be a feasible intervention (Faith et al., 2019). The mindfulness interventions showed promising results with two reporting positive feasibility (Kumar et al., 2018; Mazzeo et al., 2016) and one progressing onto a further trial with some modification (Cotter et al., 2020). One highlights the need to adapt the intervention and recruitment strategies to support retention (Sperry et al., 2014).

Recruitment

Seven papers discussed difficulties with recruitment: two Mandolean® (Browne et al., 2019; Hamilton-Shield et al., 2014), one educational (Faith et al., 2019) and four mindful-eating (Cotter et al., 2020; Kumar et al., 2018; Mazzeo et al., 2016; Sperry et al., 2014). The authors explain these difficulties to be due to a reluctance of both healthcare practitioners and parents to recognise and address obesity (Hamilton-Shield et al., 2014), and due to the inclusion criteria of the study requiring patients to experience loss of control overeating (Mazzeo et al., 2016).

Fidelity and Adherence

One paper (Mazzeo et al., 2016) discussed fidelity to the protocol, highlighting difficulties in session delivery reported by the therapists, both in terms of covering the material, and with the adolescents understanding of the content. Eight papers discussed the adherence to the intervention (Browne et al., 2019; Cotter et al., 2020; Faith et al., 2019; Ford et al., 2010; Hamilton-Shield et al., 2014; Hinton et al., 2018; Kumar et al., 2018; Mazzeo et al., 2016). Adherence considered the number of sessions attended and the number of meals conducted using the intervention. Of the three Mandolean® papers that reported on the adherence to device use, few patients were able to adhere to the recommended usage. One reported achieving only 9% of planned exposure (Browne et al., 2019), another reported only 19% achieving the planned 5-meals a week (Hamilton-Shield et al., 2014) and in another only 15% of meals eaten on the device (Hinton et al., 2018). Adherence to the RePace

'Turtle timer' was high in the first week and dropped considerably during the second week. Attendance at sessions was reported by five studies, with three achieving greater than 80% attendance (Cotter et al., 2020; Ford et al., 2010; Kumar et al., 2018), and two not reaching this threshold (Faith et al., 2019; Mazzeo et al., 2016).

Retention

Based on the intention for studies to achieve a retention of >80%, three of the six studies that used the Mandolean® achieved acceptable retention (Ford, et al., 2010; Hinton et al., 2018; Sabin et al., 2006). The remaining three studies (Bergh et al., 2008; Browne et al., 2019; Hamilton-Shield et al., 2014) expressed difficulties with retaining participants, with attrition being notably higher in the intervention than control (Browne et al., 2019) and one intervention resulting in zero participants at follow-up in both conditions (Hamilton-Shield et al., 2014). Reasons for drop out included the practicalities of using the Mandolean® at mealtimes, frustrations with technology (Browne et al., 2019; Hamilton-Shield et al., 2014; Hinton et al., 2018), feeling embarrassed, singled-out or being teased using the device and the lack of impact on food choice and snacking behaviour (Hamilton-Shield et al., 2014).

One educational intervention met retention (Faith et al., 2019) and one did not (Torbahn et al., 2017); no reasons were provided in either. One mindful-eating intervention met acceptable retention (Kumar et al., 2018), two of the interventions reached 60-80% and one study achieved just 22% with one participant remaining at follow up (Sperry et al., 2014). Reasons for poor retention, that affected both intervention and control, were described by the authors to be due to commitments with work and school, transportation and an ambivalence to the idea of change (Sperry et al., 2014). Another study included open-text answers, in which participants described their difficulties in engaging to be most commonly due to difficulty finding the time (Cotter et al., 2020). Overall, many studies appeared to lack strategies to engage and retain young participants.

Table 3.2: Feasibility, Acceptability and benefit outcomes.

First Author, year, country, study title, design	Recruitment	Fidelity	Adherence (%)	Retention (%)	Reasons	Other	Eating speed	Portion size	BMI	Adverse effects
Mandolean® Studies										
1.Bergh (2008), UK Single-armed trial	NR	Mean (range) 62 days (42–185) of treatment before BMI change	2 ppts 'failed to comply'.	71% retention	NR		Median (range) Pre = 40g/min (20-50) Post =20g/min (13-29);*p*=0.028 (N analysed: intervention=5; no comparator)	Median (range) Pre = 413g (219g-775g) Post = 290g (168g–344g) *p* = 0.043(N analysed: intervention=5; no comparator)	3 ppts (43%) reduced BMI (2.3, 3.4, and 8.8 kg/m^2) largely maintained at year follow-up (N analysed: intervention=5; no comparator)	NR
2.Browne (2020), Ireland Feasibility RCT	'Slow recruitment'	Median no. training meals =1 (19.2% of planned exposure)		38% (75% in control)	Connectivity issues, difficult set-up, interfered with family meals, incompatible with routine & forgetting	43/100 (68 min for acceptability) *'Poor acceptability of Mandolean as a home-based tool for treatment'*	NR However, ppts reported being more aware of ES	NR	NR	NR
3a.Ford (2010), and Hollinghurst (2012), UK RCT	70% (106/152)	81% Fidelity	83% adherence to intervention max 15 appts in 12 mths; 89% completed control	86% study retention at 12 mths (in both groups).	NR	*'A useful adjunct to standard lifestyle modification in treating obesity among adolescents'*	No diff to ES (N analysed: intervention=44; comparator=23)	Meal size decreased by 45g (7-84g) no change to fullness. (N analysed: intervention=44 ; comparator=23)	Mean BMI SDS change of 0.36, (95% CI -0.27 to -0.46). Baseline adjusted mean difference in standard treatment arm. Weight loss maintained at 18 months 0.24 (95% CI	NR

									0.11 to 0.36) (N analysed: intervention=43; comparator=46)	
3b.Galhardo (2012), UK sub-analysis of Ford	NR	NR	NR	as part of Ford (2010)	n/a		Meal duration in minutes (CI) -1.81 (-4.79 to 1.17) *p*=0.21(N analysed: intervention=14; comparator=13)	Mean change (CI) -18g (-107 to 70) *p* =0.65. No change to post-meal satiety *p*=.33(N analysed: intervention=14 ; comparator=13)	Mean change (CI) -BMI SDS 0.14 (-0.36 to 0.07) *p* = 0.17(N analysed: intervention=14; comparator=13)	NR
4.Hamilton-Shield (2014), UK ComMando Pilot RCT	58% of target (21/36)	19% of ppts achieved 5 meals / wk (target 90%)	44% attended GP appts every 3 mths. Attendance at the study 3 months = 41, 9 months= 1, 12 months = 0 (intervention and control) 84% completed intervention(but only 20% using Mandolean sufficiently to meet	4 withdrawals from treatment. 7 from study (6 from intervention, 1 control).	Technical difficulties, cumbersome to use, not child-friendly	Fullness hard to envisage for younger patients.	No systematic reductions in ES. Qualitative reports of slower ES	"Data were not formally analysed".No visible systematic changes. Quali reported of smaller PS	NR	Sometimes larger PS required by the Mandolean to work . Prompted faster ES. Evoked teasing / embarrassment

			criteria); 89 % completed control							
5.Hinton (2018), UK Pilot RCT	NR	NR	Median of 28 (1-80) meals over 6-mths used Mandolean® (71% completed intervention ; 90% completed control)	79% (1 due to Mandolean® , 5 due to the protocol).	Illness, relocation, time, difficulty of use, equipment issues, restrictions to food, having to eat at a table & near a source of power	*Preliminary evidence of effect but further work required to design more engaging interventions*	Mean % diff (CI) I = −11.47 (− 143, 120) C= −15.20 (−39, 9) (N analysed: intervention=2; comparator=7) Data not saved for 15% of meals.	Mean % diff (CI) I = -14.40 (−155, 127) C= −13.61 (− 34, 6) (N analysed: intervention=2; comparator=7)	BMI SDS % difference (CI) I = −1.16 (−4.17, 1.85) C = −2.37 (−5.50, 0.76) (N analysed: intervention=10; comparator=9)	NR
6.Sabin & Bergh (2006), UK Single-armed trial	NR	NR	NR	100%	NR	*'May provide a novel approach to the treatment of obesity in childhood'*	NR	NR	7 participants (77%) reduced BMI SDS (mean −0.24 ; range -0.1 to -0.57)(N analysed = 9)	NR
Education studies										
7.Faith (2019), USA RePace Proof-of-concept RCT	Criteria amended to include those with more moderate obesity to support slow recruitment	Turtle Timer 67% (14/21 days). Liking wk1=89%, Liking wk2=50%. Chat Jar used	Mean attendance 3.6 sessions (1.4) (21.4% of families attended <2, 50% attended 3-4 & 28.6% attended 5) 93%	93% retention, 1 drop out intervention, 3 control.	NR	*'This study provides preliminary support'*	Increases in Slowness in Eating CEBQ (p < 0.001) Cohen's d = 1.56. Observed ES Mouthfuls/min (p = 0.12) Kcal/min (p = 0.23 (N analysed:	NR. No change to satiety or food responsiveness (CEBQ)	BMI zscore -0.23 SD less for children in RePace at 8-weeks (p = 0.03) (N analysed: 19 not split by arm)	NR

		6/7 days, liking =100%.	completed intervention ; 79% completed control				19 not split by arm)			
8.Torbahn (2017), Germany Single-arm Observational study	NR	NR	89% completed intervention	66% no reasons given	NR		ES change on a 1-100 scale (of FKE-KJ questionnaire) noted at 1-year. Mean (SD) (–15.74 ± 18.23, <0.01) and 2-years (–15.44 ± 20.44, <0.01). Reduction to ES associated with BMI SDS at 1 year (N analysed=131)	Mean (SD) 1-year (–0.67 ± 1.11 <0.01) and 2-year (–0.54 ± 1.16 <0.01). Reduction in PS associated to BMI SDS at 1 year (N analysed=131)	BMI SDS reduction at 1 & 2 year (N analysed=131)	NR
Mindful eating studies										
9.Cotter (2020), USA Pilot single-arm open-label feasibility trial	'Recruitment was slow', 73% of target	NR	Attendance 85% (91% completed intervention ; 89% completed control)	73% (2=scheduling, 1 =family reasons)	NR	Satisfaction scored 100% *'Attendance and satisfaction rates were promising, recruitment and retention proved more challenging."*	NR	Qualitative '*Helped control eating and portions'*	Pre-mean (SD) 35.70 (5.28), post-mean 32.79 (9.79) 95%CI [−3.38, 9.20] p=.327. Cohen's d, -0.31. Trends towards a decrease in BMI are suggested (mean = 2.9-point decrease) (N analysed=8)	NR

10.Kumar (2018), USA Pilot RCT	Recruitment discontinued at 22 ppts. Target unclear. 7 withdrew consent before beginning	NR	100% completed intervention; 91% completed control	100%	NR	*'Found to be feasible and acceptable in adolescents with obesity"*	NR	NR	Median (IQR) Weight w12 = +2.3kg [-0.7, 3.2] w24 = +4kg [-0.2, 5.2], BMI w12 = +.6 [-0.2, 1.2], w24 = +.9 [0.2, 2.3] BMI z-score w12= .1 [0, 0.2] w24= 0.2 [0, 0.4] (N analysed intervention = 11; Control = 10)	NR
11.Mazzeo (2013), Mazzeo (2016), USA Liber8 Feasibility RCT	164 Reported recruitment challenges	61% =Therapists able to cover all content. 65% believed topics were appropriate 69% believed group understood	64.3% completed intervention; 77% completed control	64.3% completed intervention & 12 (42.9%) completed follow-up.	Low frequency and recognition of BE & LOC	Participants report the intervention Helpful = 76%, Very satisfied =81%. *'Both groups show promise'*	NR	NR	NR	No ppts developed any significant suicidal intention, self-harming behaviours, BN or AN
12.Sperry (2013), USA CHEER Pilot RCT turned case study	Reported recruitment challenges	NR	22% completed intervention; control NR	Case study attended 11/12 sessions	School / work commitments, transportation limitations. Ambivalence to change.	*Recruitment would benefit from 'Readiness scales, and individualisation*	NR	NR	Weight loss of 5.6kg across 12wks (n=1; case study)	NR

AN = anorexia nervosa, ANQAQ = Adolescent Nutrition Quality and Adherence Questionnaire, BE = binge eating, BMI = Body Mass Index, BN =Bulimia nervosa, BP = Blood pressure, c=control, CBT= cognitive behavioural therapy, CEBQ= Child eating behaviour questionnaire, CPRS-SA= Comprehensive Psychopathological Rating Scale Self-Rating Scale for Affective Syndromes (Svanborg & Åsberg, 1994), DCU= delayed usual care, EAH-C = Eating in the Absence of Hunger Questionnaire for Children and Adolescents, EDEQ= Eating Disorder Examination-Questionnaire, EDI= Eating disorder inventory (Garner, 1991), EES-C = Emotional Eating Scale for children, ES= Eating speed, HDL= High density lipoprotein, hs-CRP= high sensitivity C-reactive protein, I = intervention, IQR = interquartile range, LDL= Low density lipoprotein, LOC-ED= Loss of Control Eating Disorder Screening Questionnaire, MEQ= mindful eating questionnaire, M.I.N.I. = International Neuropsychiatric Interview version 6.0, NR= not reported, PA=Physical Activity, PAQ = Physical Activity Questionnaire, PS= Portion size, QOL=Quality of life, RCT= Randomised control trial, SDS= standard deviation score, WEL= weight-efficacy lifestyle questionnaire.

Benefits

The secondary outcome of benefits of the interventions are summarised in Table 3.2. As there was only one powered RCT (Ford et al., 2010) most of these results are preliminary, thus any attempt to pool data needs to be taken with caution. We were only able to pool data for BMI SDS status as both portion size and eating speed did not have sufficient suitable data to combine (i.e. three or more studies).

Eating speed

Mandolean®

Two papers found no evidence of systematic reductions in eating speed (Ford et al., 2010; Hamilton-Shield et al., 2014). One paper, reported a decrease in eating rate from median 40 grams/min (20–50) reduced to median of 20 grams/min (13–29) (Bergh et al., 2008). Another paper described that anecdotally that participants reported being more aware of their eating speed, but this was not measured (Browne et al., 2019).

Education/ Education + Mechanical timer and 'Chat Jar'

RePace found an increase in the 'slowness of eating' subscale of the CEBQ and a large effect size, but no observed eating speed changes to mouthfuls/min or kcals/min (Faith et al., 2019). Torbahn (2017) reported a change in eating speed as denoted by a cumulative average of eating speed score on the FKE-KJ questionnaire (Warschburger & Petermann, 2007) completed by parents.

Mindful eating

No intervention reported on changes in eating speed.

We were unable to pool the eating speed data as (Faith et al., 2019) reported portion size in mouthfuls/minute whereas both (Ford et al., 2010; Hinton et al., 2018) reported in kcal/minute. However, we were able to complete Risk of bias assessments on these three studies.

Risk of bias assessments for Eating speed

We wrote to all authors to provide further information on their study in order to complete risk of bias assessments, only one (Hinton et al., 2018) replied. Just one study (Hinton et al., 2018) was assessed as low risk overall. One was rated as high risk (Ford et al., 2010)and one was rated as having some concerns (Faith et al., 2019) (Fig. 3).

Figure 3.2. Cochrane risk of bias (V2) Eating Speed

STUDY	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Overall risk of bias
Hinton 2018	Low*	Low	Low	Low	Low	Low
Ford Galhardo	Low	High	High	Low	Low	High
Faith 2019	Some concerns	Low	Low	Low	Low	Some concerns

*Author correspondence
Domain 1: Risk of bias arising from the randomization process
Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)
Domain 3: Missing outcome data
Domain 4: Risk of bias in measurement of the outcome
Domain 5: Risk of bias in selection of the reported result

Portion size

Mandolean®

Three papers reported a decrease in meal size; with portions decreasing by a mean of 45g (Range 7 to 84 g);(Ford et al., 2010), mean reduction of 123g (Pre = 413g (219g-775g) Post = 290g (168g–344g)) (Bergh et al., 2008) and a mean reduction of 14.40g (− 155.87, 127.07) (Hinton et al., 2018). Reductions were accompanied by no change to satiety ratings (Ford et al., 2010; Hinton et al., 2018), which was interpreted as a positive aspect.

Education/ Education + Mechanical timer and 'Chat Jar'

RePace (Faith et al., 2019) found no effect on total energy intake via 24-hour dietary recall, but a dose-response was seen with high-attenders reducing total energy and fat but not carbohydrate or protein. In the observational study (Torbahn et al., 2017), following the intervention a decrease in portion size on a 1-7 scale was seen at 1-year.

Mindful eating

No intervention measured portion size, except for a quote from one participant that suggested some impact on portion size anecdotally (Cotter et al., 2020).

We did not attempt to pool the portion size data as we only had suitable data from two studies (Ford et al., 2010; Hinton et al., 2018).

Risk of bias assessment for portion size

Risk of bias assessments (Sterne et al., 2019) were conducted on three studies that reported on portion size (Faith et al., 2019; Ford et al., 2010; Hinton et al., 2018) (Fig.4). Just one (Hinton et al., 2018) was rated as low risk overall. Two were rated as high risk (Faith et al., 2019; Ford et al., 2010).

Figure 3.3: Cochrane risk of bias (V2) Portion Size

STUDY	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Overall risk of bias
Hinton 2018	Low*	Low	Low	Low	Low	Low
Ford Galhardo	Low	High	High	Low	Low	High
Faith 2019	Some concerns	Low	Low	High	Low	High

*Author correspondence
Domain 1: Risk of bias arising from the randomization process
Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)
Domain 3: Missing outcome data
Domain 4: Risk of bias in measurement of the outcome
Domain 5: Risk of bias in selection of the reported result

Body size

Mandolean®

Of the four papers that report BMI status, three report a reduction. One (Ford et al., 2010) reported a mean reduction of 0.36 BMI SDS maintained at 18 months. Sabin et al., (2006) report that seven participants (77%) reduced BMI SDS and Bergh et al., (2008) found that three participants (60% of completers) improved BMI, and maintaining the majority of the loss at 12 month check-up. One paper reports no BMI SDS change following six-month use of the Mandolean® (Hinton et al., 2018), however there was indication of a dose response.

Education/ Education + Mechanical timer and 'Chat Jar'

RePace reported an average decrease in BMI z-score of 0.24 more than control (Faith et al., 2019). Torbahn et al. (2017) also reported a decrease in BMI-SDS score following the intervention at one- and two-year follow-up.

Mindful eating

Of the four mindful eating interventions, three looked at body size. The first study reports a non-significant mean decrease in BMI of 2.9 (Cotter et al., 2020). In the second study, a weight reduction of 14.4lbs was achieved after 12-week intervention (Sperry et al., 2014), however, this is a single-participant finding. The third study demonstrated no differences between intervention and control arms with an increased average BMI at 24 weeks following intervention (Kumar et al., 2018).

Risk of bias assessments for body size

Risk of bias assessments (Sterne et al., 2019) were conducted on four studies that reported on BMI SDS status post intervention (Faith et al., 2019; Ford et al., 2010; Hinton et al., 2018; Kumar et al., 2018) (Fig. 6). Just one (Hinton et al., 2018) was rated as low risk overall. One was rated as high risk (Ford et al., 2010) and two were rated as having some concerns (Faith et al., 2019; Kumar et al., 2018).

Figure 3.4. Cochrane risk of bias (V2) BMI SDS status

STUDY	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Overall risk of bias
Hinton 2018	Low*	low	Low	Low	low	Low
Ford Galhardo	Low	High	High	Low	Low	High
Kumar	Some concerns	Low	Low	Low	Low	Some concerns
Faith	Some concerns	low	Low	low	low	Some concerns

*Author correspondence
Domain 1: Risk of bias arising from the randomization process
Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)
Domain 3: Missing outcome data
Domain 4: Risk of bias in measurement of the outcome
Domain 5: Risk of bias in selection of the reported result

Quality Assessment of single-arm studies

The adapted version of the Newcastle-Ottawa quality assessment scale was used to assess the quality of non-randomised controlled trials (Wells et al., 2019) adapted to be of relevance to single-arm studies (Figure 7). No paper was able to blind participants due to the nature of behavioural research.

	Selection	Comparability	Outcomes
Bergh (2008)	★★★	N/A	★☆
Sabin (2006)	★★★	N/A	★☆
Torbahn (2017)	★★☆	N/A	★☆
Cotter (2020)	★★☆	N/A	☆☆

Legend: The star coding system enables three elements of each study to be assessed. How study groupings were allocated, the comparability of each study group and the ascertainment of either the exposure or outcome of interest for case-control or cohort studies respectively. Each study is awarded one star for each of three items that is met from criteria provided for Selection and Comparability (Wells et al., 2019). A maximum of two stars can be given for Comparability.

Figure 3.5: Newcastle-Ottawa Scale adapted for use with single-arm trials and observational studies

The Newcastle-Ottawa scale was used to assess risk of bias in four studies (Bergh et al., 2008; Cotter et al., 2020; Sabin et al., 2007; Torbahn et al., 2017). Bergh et al. (2008) and Sabin et al. (2007) were awarded the maximum three stars for selection. Due to all the studies being either single arm or

observational studies, there were no stars awarded for comparability. Bergh et al.,= (2008), Sabin et al. (2007) andTorbahn et al. (2017) were awarded one star for outcomes, with (Cotter et al., 2020) not qualifying for any stars.

3.7 Discussion

Summary of main findings

Whilst laboratory studies have shown improvements to eating behaviour and portion size following training to reduce eating speed (Andrade et al., 2008; Scisco et al., 2011; Smit et al., 2011), this review highlights the difficulties in translating these interventions into acceptable paediatric clinical treatments that could improve weight status. On an individual level, some patients derive a positive effect from these interventions (Bergh et al., 2008; Ford et al., 2010; Sabin et al., 2006; Sperry et al., 2014). Ten interventions evaluated feasibility, with six deeming their interventions to be feasible. These six studies used different methodologies in different age children, therefore it is difficult to use these findings so far to characterise a 'successful intervention'. Many noted their studies took a novel and promising approach which they deemed to provide preliminary evidence for feasibility and effectiveness. Only one paper reported quantifiable reductions to eating speed (Bergh et al., 2008), four reported reductions in meal size (Bergh et al., 2008; Hinton et al., 2018; Sabin et al., 2007; Torbahn et al., 2017),and six reducing body size (Bergh et al., 2008; Faith et al., 2019; Sabin et al., 2007, 2006; Sperry et al., 2014; Torbahn et al., 2017). Six studies included longer-term measures, with follow-up time-points at 12 months or longer (Ford et al., 2010; Hamilton-Shield et al., 2014; Kumar et al., 2018; Mazzeo et al., 2016; Sperry et al., 2014; Torbahn et al., 2017). However, this review predominantly highlights the lack of rigorously designed RCT's in this area, with many of the studies being unpowered pilot or feasibility work, or having low participant numbers, meaning any findings must be interpreted with caution.

The suggestion that 'normalisation' of eating pace can be achieved alongside improved perceptions of satiety (Bergh et al., 2008) and without concurrent changes to diet (Sabin et al., 2006) along with the indication of a dose-response (Faith et al., 2019; Hinton et al., 2018) infers that if the interventions were adhered to, they may offer adjunctive, or even alternative treatment to the traditional 'eat less, move more' advice (NHS, 2016). Yet, these results are from under-powered small-scale trials, predominantly pilot and feasibility studies, which have not demonstrated sufficient acceptability and many of which were at risk of some bias in outcome measurement.

Whilst many of the reviewed eating speed interventions demonstrated difficulties with recruitment and retention, this is not uncharacteristic of paediatric weight management interventions being delivered both as health care services and as clinical trials (Fleming et al., 2015; Gerards et al., 2012; Hampl et al., 2011; Markert et al., 2013; Walker et al., 2012). Accordingly, some of the studies included in this review found challenges in retaining both control-group and active participants (Hamilton-Shield et al., 2014; Sperry et al., 2014), with reasons such as time, and competing work and school pressures affecting groups equally. However, the Mandolean® offered additional

challenges (Browne et al., 2019; Hamilton-Shield et al., 2014; Hinton et al., 2018), including technological and practical reasons that may have explained the higher drop out in the intervention arm (Browne et al., 2019). Of note, parents in the ComMando trial reported the intricate set-up of the Mandolean®, sometimes requiring a much larger portion size than typical to be plated. Parents were given training on determining portion sizes (by weight) and the percentage of different food types on the plate, which in some cases, led to larger portions than the children were used to (e.g. light vegetables needed to be served in greater portions)(Hamilton-Shield et al., 2014). The prompts to 'speed-up' confused and rushed children that had, for example, stopped eating to add ketchup to their plate (Hamilton-Shield et al., 2014). Families using the Mandolean® also reported that their child felt a sense of being 'singled-out' which led to teasing and a reluctance to use the device. However, when used in an older population the intervention was deemed both feasible and beneficial (Ford et al., 2010), thus child age may be an important determinant.

In contrast, the RePace timer and 'chat jar' offered an intervention that could be used by the whole family (Faith et al., 2019). Working with the youngest group of patients, with a mean age of 6.4 (1.4 SD), RePace achieved high acceptability and promising outcomes. This was an intervention specifically tailored for use in children of this age group, with puppet characters supporting the intervention story. Adaptions to make the Mandolean® more child-centred, with gamification, child-friendly voices and cartoons were documented during the embedded qualitative study (Hamilton-Shield et al., 2014) and may offer a route to improve adherence in younger age groups.

The mindful eating interventions had variable results. The duration of the programme varied greatly, with shorter programmes (Cotter et al., 2020; Kumar et al., 2018) unsurprisingly achieving higher retention than the longer programmes (Mazzeo et al., 2016; Sperry et al., 2014). These interventions seemed to be largely well tolerated, with reported high satisfaction ratings (Cotter et al., 2020; Mazzeo et al., 2016). However this finding was not universal, with the CHEER programme demonstrating poor feasibility (Sperry et al., 2014). Mindful eating offers a more subtle intervention which may facilitate it to be used more often than the home-based Mandolean®, however no mindful eating studies measured the frequency that the trained techniques were implemented in practice.

Eating speed as the mechanism of effect

No measure of eating speed, nor portion size, was recorded for any of the mindful eating interventions. Therefore, it is not possible to conclude that the associated effects were mediated by slower eating. Whilst we excluded mindfulness-based interventions that did not include eating speed, many of the mindful eating interventions also trained in mindfulness skills more broadly. Such mindfulness-based therapies have been shown to improve mental health outcomes (Fjorback

et al., 2011) and reduce emotional reactivity, rumination and worry (Gu et al., 2015), perhaps consequently, supporting weight management. As with many interventions for weight-management, it is difficult to unpick the mechanisms of effect from within multicomponent interventions, such as the education and mindful-eating programmes included in this review. Evaluations using the Behavioural Change Techniques (BCT) taxonomy (Lou Atkins & Michie, 2014) could be conducted to identify the effective components of such interventions.

There is indication, in line with laboratory-based testing, that Mandolean® training results in a decrease in portion size (Ford et al., 2010). This may potentially be due to increased attention to hunger and satiety signals that result in earlier termination of eating, or through slower eating facilitating the processing of these signals (Robinson, Almiron-Roig, et al., 2014). Interestingly, the reduction in portion size may occur even when eating speed does not show a measured decrease, suggesting there maybe additional mechanisms at play, or that the effect could have been driven by taking part in an eating intervention with the increased focus on consumption. Important to feasibility outcomes, the reduction of portion size is accompanied by equal satiation (Ford et al., 2010; Hinton et al., 2018), and in one case, greater enjoyment of eating (Faith et al., 2019). This suggests that if implemented correctly, these interventions could offer a means to decreased intake and calories whilst providing the same satiety. This is aligned with research that suggests that attentive eating can support memory for recent eating and appetite control (Higgs et al., 2012) and with work looking at how the oral processing of food influences satiation and meal size (Ferriday et al., 2016). The evidence collated in this systematic review is preliminary, with a focus on clinical application in paediatric samples, and sufficiently powered studies would need to be conducted to understand the underlying mechanisms specifically.

Implications for future research

In the introduction, we discussed a broad range of interventions for eating speed including food texture (Bolhuis et al., 2014; Forde et al., 2013; McCrickerd & Forde, 2017) and pacing devices (Kadomura et al., 2011, 2013). Yet this review found no studies where these interventions had been trialled in paediatric, clinical settings. This review highlights the need for the effectiveness of these successful laboratory interventions to be tested in clinical settings, in the search for effective treatments to treat childhood obesity. This review also highlights difficulties that arise in translating successful laboratory interventions, delivered in controlled environments with focused participants to real-life settings where the participants need to engage with the intervention in the context of their everyday life. Future clinical research must consider this, and work with participants to develop both interventions, and research protocols that are feasible and attainable for them. Laboratory research has also focused on aspects of meal eating behaviour such as bite size, and the rate of

deceleration during a meal (Almiron-Roig et al., 2015). No studies were found during our searching that had explored these mechanisms in a clinical, paediatric population, which may also offer opportunity for future research. Several studies used parent-reported measures of eating speed (using subscales of the CEBQ or FKE-KJ questionnaires), either in conjunction with objective measures of eating speed (Faith et al., 2019), or alone (Torbahn et al., 2017). Future research into the effectiveness of novel interventions designed to slow eating speed may benefit from objective, standardised measures of eating speed (grams/min) in participants, where possible.

Strengths and limitations of the review process

This is the first review to explore the use of eating speed in clinical care for obesity exclusively in children and adolescents. Whilst there is always a risk of that not all relevant research has been identified, with the extensive search strategy and the expertise and clinical connections of the review team, we are confident that all relevant research has been included. Limitations to this review include the heterogeneity of the results, which prevented meta-analysis or meta-analyses of additional outcomes being conducted. The studies included in this review are of weak-moderate quality with small sample sizes and often no comparator group, thus results must be considered conservatively. Further limitations of these papers include the generalisability of findings based on the included sample. Many studies excluded participants due to mental health and learning difficulties, known contributors to obesity risk (Public Health England, 2014). Black and minority ethnic (BAME) children are also disproportionately affected by obesity (Caprio et al., 2008; Public Health England, 2019) and whilst some samples were ethnically representative, many included studies did not report these data. In particular, the participants within UK studies were predominantly white. Poor representation in clinical research potentially results in treatments that are maladapted to meet diverse needs and affects interpretation of effectiveness (Byrd et al., 2018; Caprio et al., 2008; Taylor et al., 2016). Furthermore, although the search strategy was thorough, some clinical trials may not have been identified. However, our systematic and detailed search strategy should have assisted in identifying all trials and in reducing publication bias. In addition, while two of the included studies were conducted by two of the authors of this review, to ensure impartiality, these papers were emailed in an identical manner to the co-authors carrying out the RoB analysis and the authors from these two papers were not involved in the conducting of the RoB analysis.

Deviations from protocol

There were no deviations from the protocol.

3.8 Clinical implications and conclusions

This review highlights the shortage of quality evidence in this field. Whilst these studies are small-scale and predominantly not powered to show an effect, there is suggestion that eating speed and mindful eating may be a beneficial adjunctive approach to weight management treatment. As many of these studies have not proceeded on to full-stage trials in response to their poor feasibility scores, further work to develop interventions and research protocols that are simple, engaging, age-appropriate, and adhered to may help children and young people employ eating speed to support their weight-goals. In addition, we recommend that outcomes should include an objective measure of eating speed and long-term (at least 12 months) follow up of BMI change to allow thorough assessment of future trials. Application of the behaviour change taxonomy to evaluate each component of novel interventions may also improve the intervention development process. Moreover, learning from this review, intervention designers should seek to develop interventions and research protocols in a child-centric manner, holding children and families central to the design process. We see that interventions designed for adults, do not necessarily translate to successful interventions in children (Hamilton-Shield et al., 2014). Instead, patient involvement, co-design and a person-based approach (Yardley, Ainsworth, et al., 2015) may enhance the success of the interventions and the research processes.

3.9 Contribution to the thesis

The delivery of this systematic review impacted upon the next steps of this PhD. The Mandolean® has been trialled multiple times within the COCO clinic, and this review highlighted the difficultly with feasibility and acceptability borne out by similar findings from other units. Consequently, the decision was made not to construct further targeted eating speed intervention for the clinic at this time. However, mindfulness and eating awareness remain areas of interest.

Whilst eating speed offers a theoretically sound means to reduce consumption, we see difficulties with translating this into an intervention that is practical and sustainable in every-day life. As discussed in the introduction of this thesis, work into obesity treatments (along with work in many other fields) has a problem with the translational process, with many potentially successful interventions failing to be adopted by clinical practice. The recommendations made by this review go some way to supporting intervention design to bridge this gap. These recommendations will be considered in future work within this thesis, and include: -

1. Working to achieve, and measure, long-term (> 12 months) BMI change,
2. Ensuring interventions and research protocols that are engaging, age-appropriate, and adhered to,

3. Evaluation of the active components of a behaviour change intervention using tools such as the behaviour change taxonomy,
4. Developing interventions and research protocols specifically for children,
5. Engaging children and families with intervention development at every stage.

Experiencing the same satiation (Ford et al., 2010; Hinton et al., 2018) and greater enjoyment (Faith et al., 2019) from eating a reduced portion size slowly is a promising finding, and suggests interventions that support slower, attentive and/or mindful eating may facilitate equal, or greater reward from eating experiences. This finding echoes the contributions of Chapter 2, that portion size (and here eating speed) may be impacted by interventions that heighten the awareness of the eating experience and internal hunger and satiety signals. These self-regulatory eating behaviours may offer protection against problematic eating patterns driven by the obesogenic environment. The portion size effect drives people to consume more (Fisher & Kral, 2008), and at a faster pace (Almiron-Roig et al., 2015), whilst those with high self-regulation take less cues from these external eating triggers and pay more attention to their own internal experience (McCrickerd, 2018).

Interventions that teach mindfulness and 'present moment attention' may offer secondary effects, described as 'spill over effects' in the intervention design framework of the COM-B (Michie et al., 2014). Such interventions may enable the young person to engage more mindfully with other aspects of their life: for example, mindfulness has a known stress reduction impact (Kappes et al., 2021) and can help alleviate mental health problems that may contribute to obesity (Sala et al., 2020). Interventions that focus on encouraging family mealtimes and discussion may enhance family cohesion and reduce family-stress for the young person (Boles & Gunnarsdottir, 2015). These more holistic approaches may be of benefit to the complex patient group at the COCO clinic, with spill over effects making these interventions more cost-effective. However, spill over effects can have both positive or negative affect; family meal times may have a negative spill over effect through the social facilitation of eating, whereby eating with familiar others increases consumption rates (Ruddock et al., 2019). Therefore, intervention development must consider and measure how induced changes impact the whole experience of eating for the young person.

Chapter 4: Inhibitory control training - Lessons from an app-based intervention for paediatric weight-management

4.1 Overview

The overconsumption of high calorie, highly processed meal and snack foods and sugar-sweetened beverages are a key contributor to overweight and obesity (Dereń et al., 2019; Khandpur et al., 2020). The consumption of these foods is in part, in response to cues in our obesogenic environment (Norman et al., 2018) that trigger automatic responses that cue eating (Hofmann et al., 2008, 2009; Strack & Deutsch, 2004). Those with obesity have been found to be more responsive to such cues which is in part thought to be due to lower self-regulation (Lawrence et al., 2012).

Professor Natalia Lawrence at Exeter University has developed an app-based delivery of response inhibition training; the *FoodT* app (University of Exeter, 2022). *FoodT* offers a promising opportunity to support children and young people to regulate their responses to highly desired or craved foods (Porter et al., 2017). Response inhibition training is a form of cognitive brain training that aims to target elements of executive functioning, and reframe associations with food (Veling et al., 2017). Changes to eating behaviour including reductions in intake and food choice in both adults and children, have been seen after just a few training sessions (Porter et al., 2017; Allom et al., 2016; Jones et al., 2016).

The app-based delivery model was thought to enable patients to maintain engagement with the clinic programme between appointments. The time-lapsed between clinic appointments had been raised by patients during a service review at the COCO clinic (Owen et al., 2009), where patients requested more continuous support. As increasing the frequency of appointments was beyond the budget limitations of the clinic, the app could potentially offer a cost-effective, beneficial bridge to maintain patients' engagement between appointments.

The intention of this work was for it to be an initial feasibility study, to test the acceptability, recruitment, and retention of clinic patients in using the *FoodT* app. I sought to explore the initial perceptions of using an app, and their experience of using *FoodT* specifically. A large battery of tests was included to collect patient benefit data such as the impact on food craving and consumption. As this research was to assess feasibility, they were included to test the patient acceptability of these measures and it was hoped that these measures would then be included within a future powered trial of *FoodT*.

For this initial stage feasibility trial, it was hoped that I would recruit 20 COCO clinic patients and their parents. The COCO clinic has a high percentage of patients (23%) with neurodivergent development and used to run an outreach clinic at local special educational needs schools (when this PhD began in 2017). There is a deficit of interventions developed for this clinical population, and this need has been identified by the COCO clinic MDT. As the mechanisms of the app showed additional promise for children with autism spectrum disorder (ASD), I sought to recruit an additional 20 COCO clinic patients with ASD, and their parents through engagement with the COCO clinics outpatient clinics that ran from special educational needs schools. The intention was for the post-test measures to gather both qualitative and quantitative feedback that would inform and shape the intervention in advance of running a larger powered trial. However, due to difficulties with recruitment and retention, exacerbated by COVID-19, the discussion of this chapter concentrates on the learnings we can take from this research into future work in this area.

A manuscript detailing this research piece has been submitted to the Journal of Medical Internet Research, Formative Research. Due to the lack of results available, the decision was made to submit this work as a short report, mainly focusing on the learnings established from this process. At time of writing, the paper is with the journal for consideration, and has been released as a pre-print- https://preprints.jmir.org/preprint/36837. A version with more introductory detail of the potential mechanisms of effect for *FoodT* has been included here in sections 4.3 – 4.7. Due to the clinical nature of this work, this trial required NHS Ethics. The approval is attached as Appendix C.1. The battery of tests used is included as Appendix C.10-11.

4.2 Statement of contribution

FoodT was designed and developed by NL at the University of Exeter. JC designed and delivered this trial to introduce the intervention into this novel clinical setting, along with contributions from EH and NL, and clinical guidance from JHS. JC applied for NHS ethics supported by EH and NL and attended the committee meeting independently. JC was responsible for patient recruitment, intervention delivery and delivering the battery of tests. The running and reporting of the trial to the NHS ethics regulatory board was the responsibility of JC. JC wrote the manuscript for publication and the longer included here, and all authors accepted the manuscript for publication.

Pre-print of Publication

Lessons from an app-based intervention for paediatric weight-management

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4.3 Abstract

Background

Obesity in childhood and adolescence can contribute to poor physical and psychological health. For those with severe and complex obesity, a multi-disciplinary approach to weight management is offered within tier three services. Encouraging dietary change is a major aim, alongside psychological, endocrinological and medical intervention. *FoodT*, is an inhibitory control smartphone app, that has shown positive impacts upon food choice in both adults and children. *FoodT*'s use to support weight management in children has not yet been explored, but its use in adults has been seen to result in weight loss.

Objectives

This research sought to trial the feasibility of using *FoodT*, with a paediatric population at a tier 3 weight management clinic. Recruitment, retention, and app use were primary outcomes.

Methods

FoodT was offered to patients during a routine clinic appointment. Patients were asked to use the app at home, every day for the first week, and once a week for the rest of the month. A battery of tests, including measures of food choice, liking and craving, and eating behaviours such as loss of control over eating, was given before and after use to assess changes to food choice and experience, that people could carry out at home or in the clinic.

Results

Twelve families consented (38.7% of those approached), only one participant achieved the recommended training schedule, and no participants completed post-trial measures. Reasons for non-participation included not considering their weight to be connected to eating choices, and not feeling the app suited their needs.

Conclusions

It is unclear whether the intervention or the research processes prevented completion. Regardless, future interventions should seek to take a patient-centred approach to design, work to reduce connotations of blame that may deter engagement and utilise familiar clinician staff to support recruitment.

4.5 Introduction

It is now well accepted that unhealthy diets in childhood can have detrimental effects on individuals, leading to obesity, coronary heart disease, diabetes and forms of cancer (Jastreboff et al., 2019). It can also cause social stigma and damaged future prospects (Puhl & Brownell, 2001; Puhl & Latner, 2007). For children with severe obesity resulting in health complications or safeguarding concerns attendance at a tier 3 weight management service may be offered. Here, patients are treated with a multi-disciplinary approach, including dietetic and psychological support, the guidance of a specialty nurse, social worker, and endocrinological investigations.

Currently, non-medical interventions demonstrate small to moderate effects on weight loss and when weight loss is achieved, many struggle to maintain it. A systematic review of tier 3 weight management services in the UK declared that whilst there was some evidence to suggest a reduction in BMI-z score during patients attendance there was very limited evidence of any maintenance at the 1-year mark (T. Brown et al., 2018). Recent data from the year 21/22 at the COCO clinic shows that 54% of patients lose weight during their time at the clinic (unpublished communication, 2022). This leaves 46% of patients not losing weight. These patients were found to be those experiencing the highest levels of socioeconomic deprivation and/or the most complicated obesity aetiologies with co-morbid behavioural conditions including ASD and ADHD. Due to medications and secondary elements of ASD, children with this diagnosis are more likely to have problematic weight (Corvey et al., 2016). Currently, there is little to no weight-loss provisions that are specifically proven to be effective in this paediatric population.

The difficulty associated with interventions seeking to create sustained behaviour change may be due in part to the ubiquitous influence of cues for palatable foods in our environment, including advertisement and accessible food outlets (Boswell & Kober, 2016; Boyland & Halford, 2013). Yet as not everyone who is exposed to this environment becomes obese, it is likely that individual differences are at play (Jiang et al., 2016). The reflective-impulsive dual-process model suggests that our eating behaviour is a product of a combination of reflective and impulsive internal drives. Highly palatable foods trigger automatic approach biases, and unless sufficient self-regulation is implemented, can lead to increases in consumption (Hofmann et al., 2008, 2009; Strack & Deutsch, 2004). It is suggested that for some people with a raised reward system and/or difficulties with self-regulation, food cues trigger this hard to control automatic process resulting in a stronger approach response to food (Lawrence, Verbruggen, et al., 2015).

A wide range of research shows that these automatic reward responses are predictive of calorie intake, weight gain and BMI (Bartholdy et al., 2016; Lawrence et al., 2012; Meule & Platte, 2016;

Nederkoorn et al., 2010; Saunders & Robinson, 2013; Stice et al., 2016). Difficulties with self-regulation in adolescents have been connected to loss of control of eating (Van Malderen et al., 2018), and binge eating disorder (Tanofsky-Kraff et al., 2011), known precursors for greater BMI and psychological distress (McCuen-Wurst et al., 2018; Morgan et al., 2002). A meta-analysis of neuroimaging studies in adults suggests that obese participants, compared to healthy weight participants had greater activation in areas of the brain known to mediate reward, such as the orbitofrontal cortex and the insula when presented with food images, especially energy dense foods. They also had a greater response in brain regions, such as the putamen, thalamus and caudate, that could coordinate movements involved in consumption; suggesting an enhanced approach tendency (Pursey et al., 2014).

However, response-inhibition training, in a go/no-go format has been demonstrated to support self-regulation (Houben & Jansen, 2015; Lawrence, O'Sullivan, et al., 2015; Veling et al., 2011). *FoodT*, an app-based form of go/no-go response inhibition training, requires participants to respond to healthy food images (e.g., fruit and vegetables), that appear highlighted in a green circle by pressing the image, and withhold their responses to images of foods high in fat, salt and/or sugar (HFSS) that are highlighted in a red circle. By not responding to HFSS food images on screen, it is theorised that users strengthen their ability to resist these foods in real life. Meta-analyses confirm that both adults and children have shown positive effects on eating behaviour immediately after completing different versions of response-inhibition training (Allom et al., 2016; Cox et al., 2018; Jones et al., 2016),with children choosing significantly more healthy foods in a food choice task compared to controls and compared to their baseline pre-training choices (Porter et al., 2017)

Research in applied settings, looking at longer-term outcomes is also providing promising results (Stice, Yokum, et al., 2017; Veling et al., 2014). A similar go/no-go training has demonstrated feasibility in an adult weight management population (van Beurden et al., 2019). An computer version of *FoodT* resulted in a reduction in energy intake compared to a control and significant weight loss, which importantly was maintained at six-month follow-up (Lawrence, O'Sullivan, et al., 2015). The app was well accepted by adult participants, with excellent adherence to training schedules (Aulbach et al., 2021; Lawrence, O'Sullivan, et al., 2015).

The precise mechanisms of how this training influences food intake are unclear. Researchers have proposed that the training is likely to work through a combination of these mechanisms (Stice et al., 2016):

1) Inhibition of approach behaviours. The training is thought to account for reduction in motor speed towards the trained foods (Veling et al., 2011), reducing the automatic approach-bias

to highly palatable foods. This may be mediated by an automatic activation of a stop-centre within the brain, triggered through bottom-up processing (Lenartowicz et al., 2011; Veling et al., 2017).

2) Stimulus Devaluation. A reduction in the hedonic and rewarding value of the food stimuli, after repeated pairings with no-go signals (Veling et al., 2013). Weight-loss was greater in line with reduction of liking of the foods post-intervention (Lawrence, O'Sullivan, et al., 2015), and changes in reward regions of the brain (Stice, Yokum, et al., 2017)

Compared to traditional weight-loss programmes, response inhibition training holds several advantages. The time taken to complete a round of the training with the *FoodT* app is four minutes, making it much less time consuming and more cost-effective for both the individual participating, and the clinical delivery team (Stice et al., 2016). Secondly, traditional weight-loss via self-restriction can often fail under times of pressure or stress as cognitive resources are low, and willpower wanes (Baumeister & Tierney, 2012). The mechanisms of effect for *FoodT* however, are not reliant on resource-dependent top-down control, instead working via implicit mechanisms that operate without conscious control (Stice, Yokum, et al., 2017). Whilst conscious strategies may only work in those with clear dieting goals, response inhibition approaches were seen to be effective independent to individuals' motivation (van Koningsbruggen et al., 2014).

When delivered alongside more traditional weight loss programmes, the intervention may work as a neat adjunct to dietary restriction, to combat the increase in reward value that can develop for restricted foods (Jones et al., 2017; Lawrence, Verbruggen, et al., 2015). This work seeks to test the feasibility and acceptability of integrating FoodT, an app-based delivery of inhibitory control training, as an adjunctive treatment for paediatric patients within a tier 3 weight management service.

4.6 Methods

Intervention

FoodT is freely available for download on Android and IOS platforms. Study mobile phones were made available to ensure equal access. *FoodT* (University of Exeter, 2022) is based on a Go/No-Go paradigm, where participants are requested to press healthy foods, circled in green, as rapidly as possible and to withhold their response to images of high fat, salt and/or sugar foods, highlighted in a red circle.

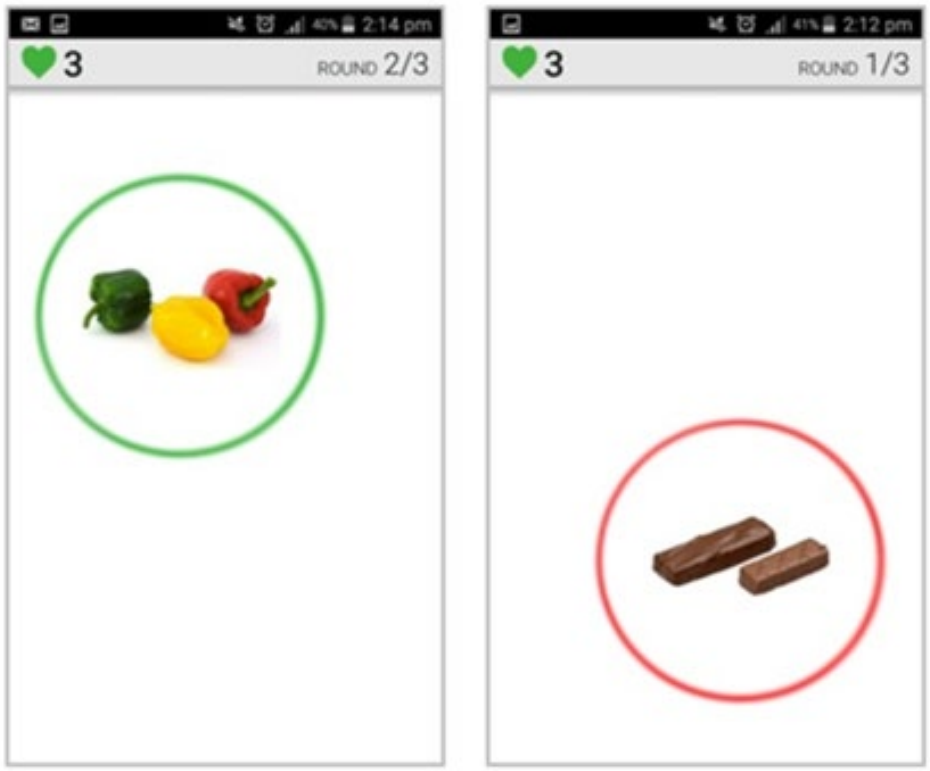

Figure 4.1. Images of the app including 'go' foods circled in green, and 'no-go' foods in red

Procedure

Families at a tier three paediatric weight management service were informed of the intervention via letter. Willing participants were consented at clinic. Families were offered the option of completing the pre-trial questionnaire at the clinic using a laptop or at home. Despite not being a powered trial, the full battery of tests (available in Appendix C10-11) were included in the questionnaire to test the acceptability of the research process. It was requested that participants play *FoodT* every day for the first week, and once a week for the following four weeks, before automatically being sent an online link to complete a post-trial questionnaire. A £5 voucher was given for each questionnaire completed. It was intended to trial this app in a manner that was true to how it would be delivered at the service, if it were to be adopted, therefore the procedure did not involve additional support from researchers or the clinical team.

Measures

Feasibility

The key outcome measures were recruitment (percentage of families that consented to participate), frequency of app-use (target 10 plays) and retention (percentage who completed the intervention).

Families who did not consent were asked if they would share their reason. As part of the pre-trial process, patients were asked to download the app and play a round of the training, before commenting on both the ease of set-up and their initial perceptions of the app.

Questionnaires

Participant characteristics

Demographic data included postcode to determine indices of multiple deprivation, sex, age, height, and weight. Accessibility and acceptability were explored via questions on current app usage, and perceptions on apps for weight management. Children and their families were asked which of eight strategies used by the clinic they were currently using to manage their weight. These included, exercising more, reducing portion size, reducing snacking, eating more fruit and vegetables, eating less foods high in fat, eating less foods high in sugar, changing the timings of their eating and eating more slowly. The Child Readiness to Change scale was included, and is a six-question measure, using a five-point Likert scale (Cobb, 2011) to assesses children's readiness to change their weight. To understand for whom the intervention may be most beneficial, it was important to understand what proportion of the patients' eating behaviour reached thresholds to be classified as disordered. The Loss of Control over eating Scale (LOCES-B) is a seven-question inventory (Vannucci & Ohannessian, 2018). This tool is validated for use in children from age 11 with the intention being for younger children to complete these questions with support of the researcher and/or parent/guardian. The Children's Binge Eating Disorder Scale (C-BEDS) (Shapiro et al., 2007) was included. This is a series of six Yes/no questions about eating behaviour and an estimation of duration of the problematic behaviour, should it be present. It is validated for use in children from age five. Children are classified as meeting binge eating disorder criteria if they report having symptoms for longer than three months, engage in loss of control behaviours and not engaging in purging (Marcus & Kalarchian, 2003).

Measures of how training impacts eating behaviour

Food liking was measured using a 100 mm Visual Analogue Scale (VAS) with endpoints of 'hate' (0 mm) to 'love' (100 mm). Participants were asked to select foods they "frequently experience food cravings for" from fifteen training categories and complete a food frequency questionnaire to establish habitual eating patterns. Two different forced-choice selection tasks were included; a forced-choice selection task asked participants to select 6 snack foods from a grid of 16 'healthy' and 'unhealthy' foods that has been used in children (Porter et al., 2017) and a forced-choice food selection task that requested participants to choose between two snack-foods, when offered 60 different pairings (Potter et al., 2018). In total, the battery of tests took around twenty minutes to complete.

4.7 Results

Recruitment and retention data are detailed in Figure 4.2. Of those approached who declined participation (19/31; 61%), their reasons included not being interested in using an app, parents feeling that that the app was not applicable to the child, not deeming food and/or eating to be the root of the problem, parents feeling that the young person needed to work on more complex issues and their mindset first, feeling overwhelmed by their appointments with the MDT, and not wanting to take on another intervention. The recruitment period started in July 2019 and was cut short due to the COVID-19 pandemic, ending in March 2020.

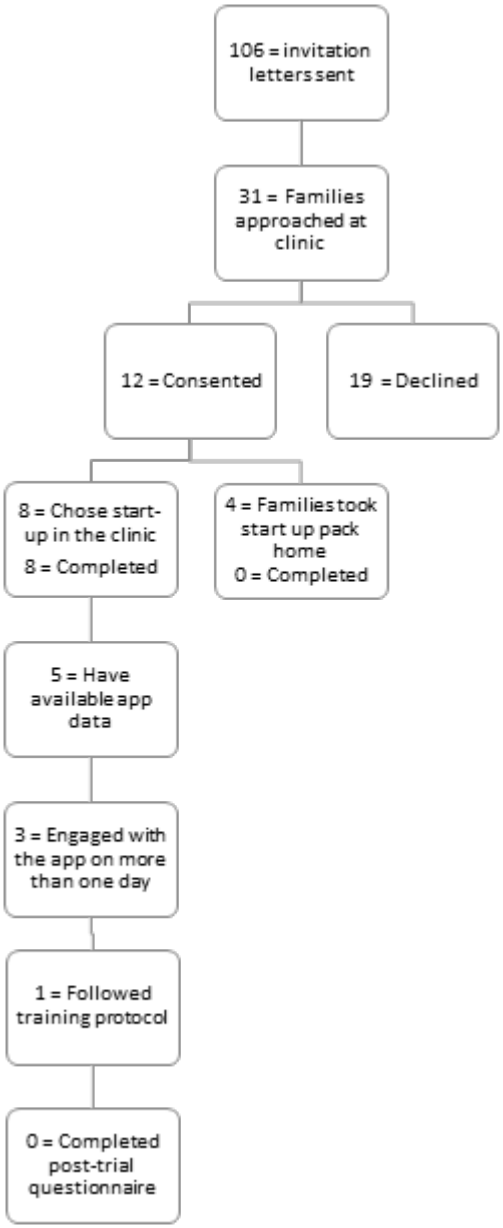

Figure 4.2. Flow-diagram of recruitment, adherence, and retention

Table 4.1. Participant Characteristics, Eating Behaviour and Acceptability

Participants Characteristics N=8	
Age	Mean= 15.3 (SD=.95)
Female	5/8 participants
Weight	Mean=109kg (SD=19kg)
Index of multiple deprivation (1 = Lowest 10 = Highest)	Mean= 3.9 (SD=3.3)
Occasionally or often experience loss of control over eating	7/8 participants
Presence of clinical binge-eating disorder	0/8 participants
Readiness to change	Mean = 3.1/6 SD=1.2
Eating behaviour	
Number of weight management strategies being implemented (Figure 4.4)	Mean=5 (SD=2.4) strategies
Acceptability	
App usage (Target engagement = 10 plays)	Mean=3.6 (SD=3.8) plays
No. of participants with own smart phone	8/8 participants
Time engaged with other apps	Mean= 3 (SD=1.3) hours

Participant characteristics can be seen in Table 4.1. Whilst most young people were engaged with a high number of weight-management strategies (an average of 4.9 out of 8), one young person was not actively engaging with any weight-management approaches (Figure 4.3).

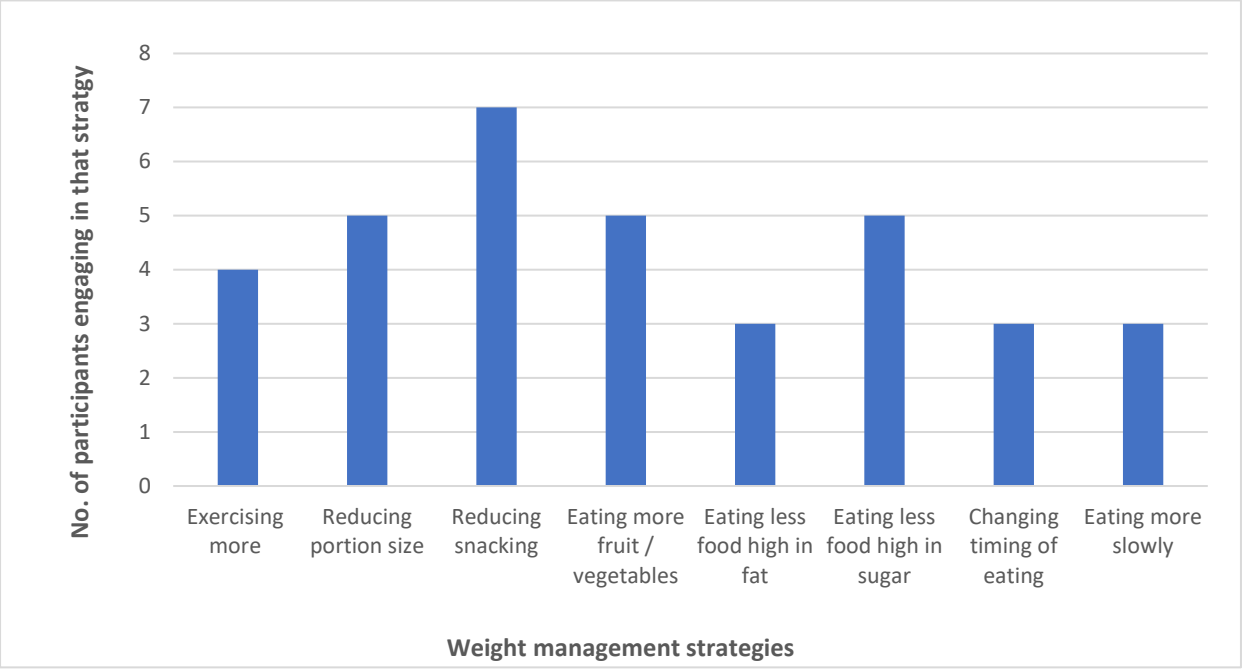

Figure 4.3. Number of participants engaging with current weight management strategies

Whilst none of the young people met clinical thresholds for binge eating disorder, all young people demonstrated tendencies, and several did not classify as binge-eating due to their engagement with

compensatory behaviours such as purging. Participants all experienced relatively high readiness to change, except one young person who scored zero (Figure 4.4).

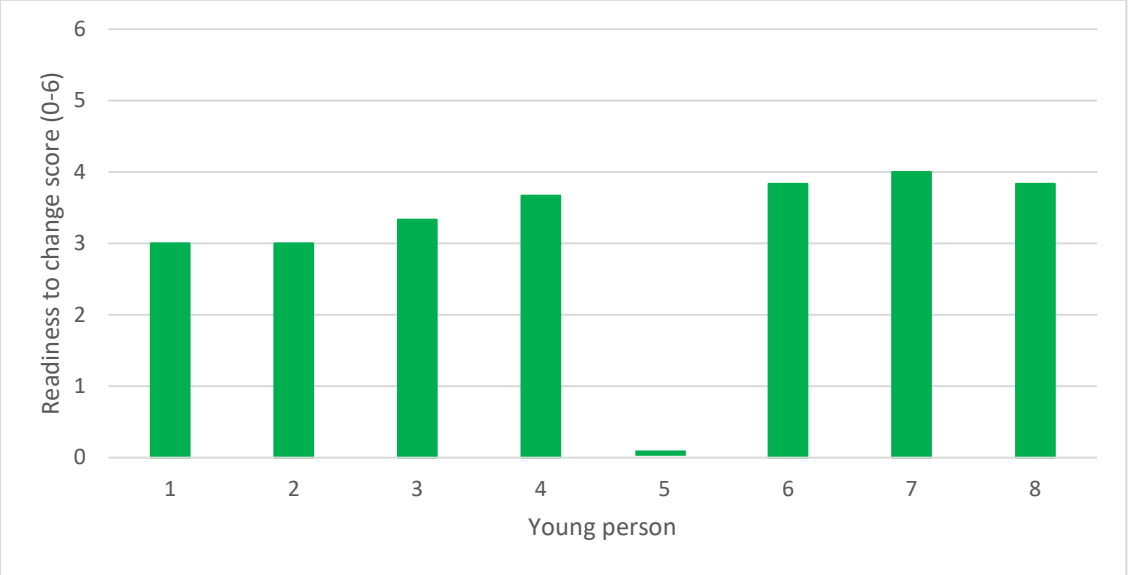

Figure 4.4. Participant readiness to change (Score 0-6) (Cobb, 2011)

The foods included in the app were highly liked and participants often reported cravings for fast food, fizzy drinks, cheese, fruit, and vegetables (Table 4.2).

Table 4.2. Participant experience of craving, and liking of the foods included in the *FoodT* app

	How many YP's craved each food (N=8)	Average liking	SD
Sweets	4	54.0	25.1
Cake	3	65.1	33.1
Chocolate	4	63.1	28.5
Biscuits	Not asked	57.4	23.8
Chips	5	70.9	24.2
Crisps	5	52.8	27.2
Bread	2	63.9	29.3
Cheese	3	74.6	31.7
Fast food	6	83.6	14.7
Fizzy drinks	6	81.3	31.0
Meat	3	61.8	37.6
Pizza	5	64.6	29.6
Fruit	5	85.1	25.8
Veg	3	76.0	33.3
Crispbread	Not asked	22.6	33.8

The delivery of the intervention via app was a suitable approach when considering participants' access to and current engagement with apps (Table 4.2).

Of the eight young people who began the trial, app data is available for five. Remaining participants may not have inputted the code that paired their data or may not have downloaded the app at all. Of the five, one followed the training protocol to meet acceptability thresholds (Figure 4.5). Two participants only engaged with the app during the set-up session None of the young people completed post-trial questionnaires (Figure
4.2).

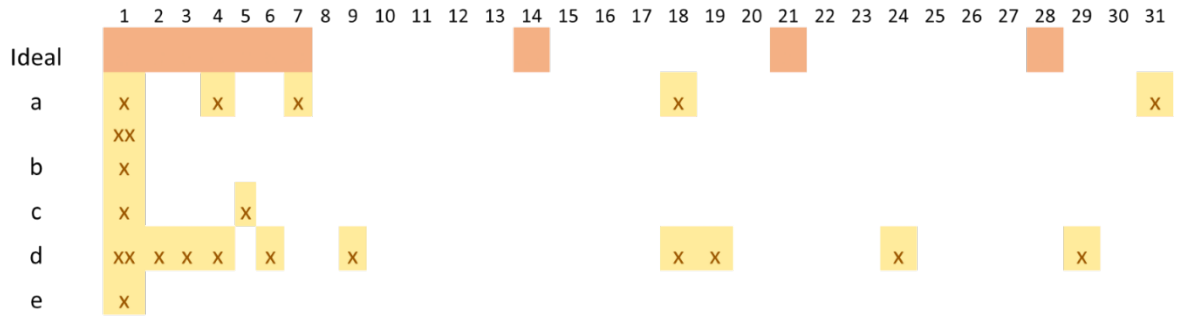

Figure 4.5. Participant app use (orange coding for the recommended training schedule, yellow for participants app use)

4.8 Discussion

This trial was not well accepted, particularly when delivered unsupported, online. As a feasibility trial, we take important learnings from this work, that are informative for planning and delivering future work in a tier three paediatric weight management service.

Firstly, from the reasons for non-engagement, several families questioned the suitability of the intervention for their child. This disparity between patient needs and intervention design may be better addressed in future intervention development work by using a person-based response to intervention design (O'Cathain et al., 2019; Yardley, Morrison, et al., 2015). Secondly, several families declined participation because they did not feel that their child's weight was due to issues with food. This reluctance to accept interventions that target weight via lifestyle changes echo findings from a qualitative study also conducted at this clinic reported in Chapter 5 (Cox et al 2021). In part this may be due to the perception that accepting lifestyle change confers blame (Schmalz & Colistra, 2016). Therefore, work is needed to reduce connotations of stigma and fault attached to the acceptance of lifestyle change, to enable more ready engagement from families (Deci & Ryan, 2009; Teixeira, Silva, Mata, et al., 2012).

Further to intervention content, the low recruitment levels could also be due to how the intervention was perceived by patients. The situating of the researcher in the 'public' waiting room,

or the sense that the intervention was not part of the clinic itself may have been barriers to participation. We recommend that future interventions are introduced by clinicians known to participants, at a relevant time (e.g., when discussing changes to diet), to patients that acknowledge that they would like support changing their eating behaviours. The protocol included many time-intensive measures and was designed to be delivered with minimal researcher involvement to replicate the capacity of the clinical team; however, a more supportive environment may be a necessity. Fundamentally, there is also an uncertainty about whether children and families were deterred from participation due to the concept of *FoodT*, or by engaging in research. Research processes may not have been considered acceptable by participants, or participants may not have felt they had sufficiently engaged with the app to warrant completing the post-trial measures. Again, a patient led approach to research would help to clarify this (O'Cathain et al., 2019; Yardley, Morrison, et al., 2015).

Previous work using *FoodT* with children demonstrates immediate effects on eating behaviour post-training (Allom et al., 2016; Cox et al., 2018; Jones et al., 2016; Porter et al., 2017). It is therefore disappointing that this trial yielded no post-trial measures. Future research in this setting should emphasise patient-centred intervention design as behaviour change apps designed for adult use may not be sufficiently exciting to engage children (Lubans et al., 2014). This issue has been raised by other interventions trialled within this population (Hamilton-Shield et al., 2014). Whilst evidence suggests that go/no-go trainings can have an impact on health, weight and eating behaviour, their impact may only exist in the short-term while engagement with the app is still recent (Allom et al., 2016). This may mean that continued engagement with the app for 'booster' sessions is necessary (Aulbach et al., 2021), therefore strong patient retention will be required for the app to have long-term impact.

Further work to improve engagement in lifestyle-based interventions, including measures to reduce connotations of stigma and blame may be required to facilitate engagement. Furthermore, the utilisation of trusted clinicians to recruit and support with the intervention may improve engagement.

4.9 Contribution to the thesis

The way in which this trial was conducted leaves us with questions as to whether the app itself was an unfeasible intervention, or if burdensome research processes were unacceptable to patients. Optimum intervention development would recommend the involvement of service users at every stage of the intervention design and development phases (Russell et al., 2019). This work was

presented to a young person's advisory group (YPAG) at the NIHR Biomedical Research Centre to discuss the accessibility of the research materials, the language used and the complexity of the research methods. However, discussions were not held about the volume of research processes, nor the app itself, which would be advised in future research. Furthermore, while the YPAG were representative of the age of the young people at the COCO clinic, they were not representative of the clinic population in weight status, lived experience of obesity, or socioeconomic status, meaning their views cannot be generalised to those of the clinic's population. I believe there is potential for the *FoodT* app to create impact within the COCO clinic, if it is packaged and delivered correctly, which to do so needs PPI involvement, co-design, and buy-in from the clinical MDT within the service to support the intervention delivery.

Whilst the outcomes of this trial did not offer us an immediate option for a useable clinical intervention in this setting, conducting this work has raised several valuable lessons for future intervention development.

1. Research processes should seek to minimise patient burden,
2. Where possible, clear distinction should be made between the intervention being trialled, and the research processes in order to make conclusions about the feasibility of the intervention itself,
3. Interventions designed for adults may need adaptions to be acceptable for use in children (Also seen in Chapter 3),
4. Integrating more qualitative research and/or PPI work with key stakeholders during the intervention development stage may help to improve engagement and retention.
5. Patient resistance to lifestyle intervention may be interwoven with connotation of blame and stigma. If behaviour change is to occur, interventions may need to consider how to support patients to take ownership of change whilst not placing blame on families for their child's weight.

Inhibitory control training offers an opportunity to improve self-regulation, a facet of the psychology of eating that also holds influence over portion size and eating speed (McCrickerd, 2018), as well as our response to food cues as discussed here. Self-regulation supports individuals to attend to their own experience of food, eating and eating-related goals, as opposed to responding automatically based on the environment. There is potential, for improvements in self-regulation to impact upon portion size and eating speed. Initially, had the work been deemed feasible, my PhD intended to take *FoodT* forward into a larger trial to explore the effects on these different components of eating

behaviour as well as broader effects on weight. Unfortunately, this was not possible during my PhD for several reasons. Firstly, recruitment for this feasibility trial was paused due to the pandemic in March 2020, and when clinics restarted, I was pregnant and deemed too high risk to be attending face-to-face clinics for recruitment purposes. This meant that no further understanding of the app's feasibility could be established. Using inhibitory control training within the COCO clinic may still offer a potential avenue to support behaviour change, and future work should begin by exploring patient perspectives on the app within the clinical setting.

Chapter 5: Service review - Perceptions of non-successful families attending a weight-management clinic

5.1 Overview

In parallel to developing the interventions detailed within Chapters 2-4, I conducted this qualitative service review to establish an understanding of the young people and their family's perspective of their experience of being a patient at the COCO clinic. A service review had been conducted over ten years prior (Owen et al., 2009), and I felt it was important to update this understanding. The findings from the service review formed the basis of a psychological intervention I developed on the background of self-determination theory using Acceptance and Commitment therapy (ACT) described in Chapter 6.

The population of this review was not purposefully sampled but included only patients who had not lost weight during their time at the COCO clinic. Non-responders are often a hard-to-reach group, and their perspectives are under-heard within the literature. In 2021/22, 46% of patients did not improve their BMI SDS whilst at the clinic (unpublished clinical data, 2022), meaning the views of this report reflect those of a significant proportion of the clinic population. A high proportion of the patients who do not respond to the clinic's approach have high levels of socioeconomic deprivation paired with complex backgrounds, alongside behavioural conditions including autism spectrum disorder (ASD) and attention deficit hyperactivity disorder (ADHD) (unpublished clinical data, 2022), which is reflected in the population interviewed for this review.

This work is published in a peer reviewed journal Archives of Disease in Childhood, and the paper is included as published in sections 5.2 – 5.7, followed by a 'contribution to the thesis' section. The study was taken to an NHS ethical committee, who declared that ethical approval was not required for service review work, therefore approvals were gained from the Patient Experience and Involvement Team at University Hospitals Bristol NHS Foundation Trust. Further theoretic information, not included in the paper, is included in Box 1 at the end of this chapter.

5.2 Statement of contribution

JC contributed at all stages of the design and writing of this service review, including writing the first draft of the manuscript. The study was devised by JC and EH. Access to the clinical population was facilitated by JHS, DG and the clinical MDT at the COCO clinic. All interviews were conducted by JC. JC and AS the independently coded and analysed the data and met to confer. It was JC who drew the parallels with the self-determination theory and incorporated this theory in the coding structure. All authors read, contributed to, and approved the final manuscript.

Publication

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Signed

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First Author and PhD candidate – Jennifer Cox

5.3 Abstract

Objective This study sought to understand families' perceptions of their care at a paediatric weight management service, with a view to informing service improvement.

Design A qualitative service review conducted via semi-structured interviews with parents (n=11) and children (n=3) who attended the clinic. The recruitment was open to all, but those who were not succeeding in their weight-loss goals self-selected to participate. Self-Determination Theory, was used as a framework to explore families' experiences of the clinic.

Setting Recruitment occurred during clinical appointments and interviews were conducted over the phone in the days following the appointments.

Patients The service sees paediatric patients with a body mass index (BMI) >99th percentile, with co-morbidities or safeguarding concerns.

Interventions The clinic's service includes appointments typically every two months, with a multi-disciplinary team including consultant endocrinologists, a dietician, a clinical psychologist, a social worker and a clinical nurse specialist.

Main outcome measures Families' feedback on the MDT clinic, and their perceptions of how improvements could be made.

Results Families perceive a lack of autonomy, competency and feel a lack of connectivity both in their lives broadly and within their experience at the clinic.

Conclusions Interventions in families struggling with weight improvements should see the clinical team placing more emphasis on working alongside parents to develop young people's sense of self-determination. Expectations must be set that success originates from changes outside of clinical appointments, and that the clinical team is in place to support the family's development of sustainable, self-determined lifestyle habits.

5.4 Introduction

Whilst obesity is fundamentally due to a prolonged period of higher energy intake than expenditure (Romieu et al., 2017), the causes are complex and numerous. These include socioeconomic environmental factors (Prentice & Jebb, 2003), biological influences including genetic pre-dispositions (Kaur et al., 2017), medication side-effects (Verhaegen & Van Gaal, 2017) or the psychological implications of stress or trauma (Mason et al., 2016; Tomiyama, 2019). Regardless of aetiology, gaining a balance between energy intake and expenditure remains central to weight control, though these complexities provide competing challenges and barriers to success.

A qualitative review was undertaken to explore family's perceptions of a weight management service for paediatric patients, to improve the service provided. The service sees young people with a body mass index (BMI) >99th percentile, with co-morbidities or safeguarding concerns. A significant proportion (23%) of the clinic have autism spectum disorder (ASD) or diagnoses of learning difficulties (LD), which can introduce complexities for families when compared to their typically developing (TD) counterparts (Curtin et al., 2014; Strahan & Elder, 2013). Fifty-eight percent of attending patients achieve clinically significant weight loss; defined as a reduction of ≥0.35 BMI standard deviation score (SDS) (Birch et al., 2019).

The clinic was previously based on a more traditional medical model of obesity management; staffed by a consultant endocrinologist, dietician and exercise therapist. Patients were seen four-monthly. A service review in 2009 (Owen et al., 2009) suggested that patients from motivated and resourceful families succeeded to lose weight under this approach. However, unsuccessful families reported requiring greater support to overcome barriers to change.

Accordingly, the clinic now offers more frequent appointments, typically every two months, with a wider multi-disciplinary team including consultant endocrinologists, dieticians, clinical psychologist, social worker, and nurse specialist. This clinic seeks to offer a sustainable weight-management strategy, which is delivered over an 18-month period and that is maintainable long-term.

However, as many interventions report, successes are not universal (Zolotarjova et al., 2018), often leading clinicians to question the motivation of families (Skelton et al., 2012). Some professionals recommend that obesity can only be treated by continuous medical care (Artinian et al., 2010), with patients requiring the external motivation of accountability to staff to achieve their goals (Hall & Kahan, 2018). But this resigns patients to a lifetime of clinical appointments, and with the financial limitations of services considered, is often unfeasible (M. Brown et al., 2013; Department of Health and Social Care, 2019).

The ability to initiate and sustain behaviour change is considered greater in patients who are intrinsically motivated (Deci & Ryan, 1985; Katz et al., 2015; Williams et al., 1996). Self-determination theory (SDT) proposes that whilst external motivators such as prizes, rewards and the praise of others can motivate some people in behaviour change, this motivation is contingent and often short-lived and requires continual reinforcement. Intrinsically motivated people do not require repeated external reinforcement, as the action is perceived valuable in and of itself. Being intrinsically motivated is possible when one's environment supports three fundamental psychological needs: feeling autonomous, competent and connected (Deci & Ryan, 1985; Katz et al., 2015; Williams et al., 1996). In a weight management context, autonomy is feeling you can choose, self-endorse, and take responsibility for initiating changes. Competency is defined as operating effectively in one's environment and having mastery over the skills needed to improve weight. Finally, relatedness is achieved when a person feels connected, accepted, and supported (Katz et al., 2015; Williams et al., 1996). When a person does not experience self-determination, poorer wellbeing outcomes and engagement during behaviour change interventions are observed (Silva et al., 2014).

Exploring the families' perspectives, it became clear that these three psychological needs were pertinent to their experience of the clinic and the support they requested and received. SDT was therefore employed to guide the analysis and provide a framework for understanding families' experiences.

5.5 Method

Approval

The service review had approval from Patient Experience and Involvement Team at University Hospitals Bristol.

Participants

Participants were recruited from a tier 3 paediatric weight management clinic. Sampling was opportunistic and did not target non-successful families. Thirty-seven families consented to being contacted. On follow-up, 23 did not respond to calls. Eleven parents and 3 young people participated in semi-structured interviews exploring the experience of 12 families' perceptions. All but one family, had not succeeded in losing a clinically significant amount of weight. The interview from the successful family was removed from the analysis as data saturation for this patient group was not met.

Interviews

Topic guides developed by JC and AS included items about family experiences and what they perceived as the clinic's strengths and limitations. Recruitment occurred during clinic and parents gave informed consent prior to interview. All but one of the interviews were conducted over the phone in the following days. One interview was conducted immediately after the patient's appointment. Interviews were conducted by JC, between January to August 2019, being audio-recorded and transcribed by JC. In keeping with the iterative nature of qualitative research, data were collected and analysed simultaneously with topic guides being revised accordingly.

Analysis

Each transcript was read and re-read for familiarisation by JC and AS prior to conducting thematic analysis (V. Braun & Clarke, 2006). JC and AS independently coded transcripts and coding was refined through discussion until a definitive coding frame was achieved through consensus. Whilst coding initially began inductively, reading of the literature informed the benefits of approaching this work within the framework of SDT to develop a pragmatic intervention to improve success in paediatric weight loss. Thus, this approach led to coding deductively.

The three psychological needs addressed in SDT stood as the themes following the coding procedure, with patient's experiences contributing to understanding the importance of self-determination in treatment outcomes.

5.6 Results

Participants

Participant details in Table 5.1.

Table 5.1. Participant details

Characteristics	Children who attended clinic (N=13)	Interviewed Children (N=3)	Interviewed Parents (N=11)
Gender			
Male / Female	10 / 3	1 / 2	0 / 11
Learning disability			
Autism	2	0	-

Other learning disabilities	1	1	-
Age			
<5			-
5-11	2	1	-
11-17	10	2	-

Autonomy

The ability to choose, self-endorse and take responsibility over the changes being made

Some families felt the onus of responsibility for their child's weight needed to be held by the clinical team [Table 5.2, a], and that solutions were out of their cont*rol. Some felt that the doctor would provide answers through diagnosing a medical condition [Table 5.2, b].*

Other parents felt they held the responsibility for their child's weight [Table 5.2, c]. Some parents explained feelings of guilt and self-blame that the children required the clinic's services [Table 5.2, d]. However, parents reported holding this responsibility alone – with motivation not being echoed in the child [Table 5.2, e] leading parents to report needing to continuously supervise and 'nag' their child [Table 5.2, f]. Often, parents described feeling frustrated, believing they had exhausted all their own strategies [Table 5.2, g]. They wished to defer the responsibility to others [Table 5.2, h] recommending that a 'third-party' would be better placed to mediate changes with their child [Table 5.2, i].

For the child, pressure built around the clinical appointments with many reports of children feeling anxious and not wanting to attend [Table 5.2, j]. There was little evidence of children holding a sense of responsibility [Table 5.2, k], with some expressing surprise at being addressed directly by clinicians during the appointments [Table 5.2, l]. Few children wanted to take part in the interviews.

Table 5.2. Quotations for theme 'Autonomy'

a	*"That they could do a plan, that someone could actually be able to pay for him to go which would help him in the long run, rather than the NHS having to pay loads of money when I can't get the weight off him" Parent of Boy, age 15, Typically developing (TD)*
b	*"I'm still waiting on the results to come back to see if there is something hereditary" Parent of girl, age 13, TD*

	"That's why I wanted to see, the x-ray test and the blood test, to see if there is something else there or if it is just what he eats. Cos it is normal that a kid is hungry all the time, and eats quite a lot, it's all normal. Parent of boy, 13, TD
c	*"I was concerned that he was putting on weight and I didn't want him to end up like me" Parent of boy, 13, TD*
d	*"I think he feels ashamed that he needs to come [to clinic]. I definitely feel ashamed that he is coming" Parent of boy, age 12, TD*
e	*"I put the things we talked about in place, at the beginning he was really keen but has since fallen off the wagon. And I find it very difficult to keep him motivated. I think the biggest thing is that the motivation has to come from him, I can't force it. They gave him a lot of coping strategies that he hasn't really used" Parent of boy, age 16, TD*
f	*"Her dad's the same, he'll, he always watches how much she eats, what she eats, where she goes, what she does" Parent of girl, age 13, TD*
g	*"How can I put it…the fact we keep nagging him, all the time, and he says "I'm not doing that I'm going to my mates" I can't explain it, where I need the help" Parent of Boy, age 15, TD*
h	*"The other thing would be if I could have a plan for something that somebody else could do" Parent of boy 14, TD*
i	*"I think for [child's name] he needs a coach or someone, a medical person, that he is close with, to change his habits" Parent of boy, age 15, TD*
j	*"I get a bit nervous in the waiting room but then when we go in I cool down a bit" Boy, age 12, TD* *"She's like "well, I'm trying" and it's as though they're not taking in what she's saying she is doing and um she can get, she can get very "oh I don't want to go, I don't want to go" and really anxious" Parent of girl, age 13, TD*

k	*"I think that there is a bit of a disconnect between wanting to be less heavy and really understanding how much in terms of practical stuff he needs to do differently, as well as sort of changing your mindset, which is actually a bit of a bigger deal to do" Parent of boy, age 15, TD*
l	*"She says, "I'm still a child, I'm 13 I'm not 24 so I don't know why he is talking to me" Parent of girl, age 13, TD*

Competency

Operating effectively in one's environment and having mastery over the skills needed to produce weight loss

Families described many barriers to implementing lifestyle change [Table 5.3, a]; particularly motivating their child to change their behaviour [Table 5.3, b]. Parents directly requested help to manage behaviour they found challenging [Table 5.3, c] and reported feeling limited by their ability to engage their child, when others appeared to be able to [Table 5.3, d].

Other families felt they needed a structured meal-planned programme [Table 5.3, e], struggling to expand on the example food-switches given [Table 5.3, f]. Frustration was felt that advice repeated what they already knew, when instead they expected a different, more radical approach [Table 5.3, g], perceiving the doctor to be the person they really needed to work with for a solution [Table 5.3, h]. A lack of finances, and access to healthy food products were cited as barriers [Table 5.3,i].

For those children experiencing mental health problems, including emotionally driven eating, binge eating [Table 5.3, j] and difficulties resulting from trauma and bereavement [Table 5.3, k], parents felt unqualified to support them [Table 5.3, l]. Parents with their own weight concerns were worried about the impact it had had on their child [Table 5.3, m].

Table 5.3 Quotations for the theme 'competency'

a	*"I don't think we have ever made a plan at the clinic that we haven't already hoped for in life outside the clinic, but it doesn't seem possible. It doesn't seem very possible to make things happen" Parent of boy, age 15, TD*

	"So, on the activity level he is limited, on the changing the diet front he is limited. Yes he could swim but we don't have money for that, you have to pay for that, so it, we ought, we just sought of feel that we are trapped on a hamster wheel at the moment and there isn't really any- can't really see a way off it. We can't see a way out of the situation" Parent of boy 15, TD
b	*"When it's the holiday he wouldn't go out and play. For seven weeks he spends all the time without movement. Any movement. And that is quite - dangerous. I cannot get him psychologically to go out and play and do any activity. Ever" Parent of boy, age 14, TD*
c	*"I think it's boundaries and things like that I need help on, that we have one [a boundary]. Cos obviously she can't get it at school, like school says, she can't eat at school, she can't snack at school" Parent of girl, 9, LD*
d	*"He is behaving much better there [at his dad's house], I must admit. About food. He would eat broccoli there, where at my place he wouldn't" Parent of boy, age 14. TD*
e	*"I just don't know if I am giving the right things or not. And maybe it's simple but I would like maybe it to be just from Monday to Monday, just to know what to follow" Parent of boy, age 14, TD*
f	*"[The dietician] said about using popcorn, and [*child's name] *was very interested in that… for about a week. And then he was bored of it, cos there is not new ideas coming through" Parent of boy, 13, ASD*
g	*"Last time I thought [dietetic support] was useless, even my husband said "well we have been doing that anyway", But they seemed, they seemed a lot better this time" [having moved their child onto a meal-replacement plan]. Parent of boy, age 15, TD*
h	*"We didn't have the doctor, we just saw the dietician the first time. […] then this is the first time we have had the 'proper' clinic with the doctor" Parent of boy, age 12, TD*

i	*"We can only eat what is in the cupboard, a lot of that is from the food bank, its processed food and it's not the kind of food that. I am not blaming it on the food, I am just saying that getting the right food involves spending money that we don't really have" Parent of boy, age 15, TD*
j	*"We haven't been focusing too much on what his weights been doing recently. Um, partly because his mental health hasn't been brilliant and we don't want to make him too bad, but we will still have days when he will constantly hunt the cupboards, everywhere for food, for comfort. Um, and CAMHS have said again that they recognise that he has some mental health needs but that they don't have the services to deal with him" Parent of boy, age 12, ASD*
k	*"I think that [his father's death] has been a very, very big, probably the trigger that has brought us to the situation he is in now, and it's hard because he is being seen in a clinic about obesity, but the reason why he is obese, he really hasn't had NHS care for" Parent of boy, 15, TD*
l	*"As a parent, I have some knowledge, I can look up things, I can look up certain psychology things, but I am not really qualified to do so. And if I go wrong, I could end up doing him more harm than good" Parent of boy, age 12, ASD*
m	*"Even though I have tried to hide my unhealthy relationship with food, in terms of not, not overeating in front of the children, or…you know I don't really have large portions, it's more the secret binging that happens. I have always tried to hide that. […] But, I am setting an example by my size that food is a way to medicate yourself from other problems. And food is a way to cope. And I know that even without doing it in front of them, you know, having portion size that are too big, I have sent them subliminal messages over the years" Parent of boy, age 15, TD*

Relatedness

Feeling connected to others, met with acceptance, and supported

Families reported feeling unsupported by the wider community, including having poor social connections [Table 5.4, a] and feeling let down by wider social services [Table 5.4, b]. The clinic, then became a primary source of support for some families [Table 5.4, c]. They praised the staff's dedication [Table 5.4, d] but requested increased assistance from them [Table 5.4, e].

Families had complex home lives: parents and children often reporting fractious relationships that were exacerbated by attempts to manage diet and motivation [Table 5.4, f]. In some, the more that parents encouraged their child to follow guidelines, the more the child resisted [Table 5.4, g]. Often, the child was following a different diet to the rest of the family [Table 5.4, h].

Whilst most families noted the increase in their child's motivation and mood following clinic and saw it as an important source of support [Table 5.4, i]; some adolescents were surprised by the frank nature of communication [Table 5.4, j]. They did not always feel met with understanding [Table 5.4, k]. Developing supporting relationships via mentoring or peer support groups was suggested [Table 5.4, l]. Many children did not share their feelings easily with family or friends [Table 5.4, m].

Table 5.4 Quotations from theme 'Relatedness

a	*"He's got one friend that at school that he talks too. To be honest I don't really talk to my mum [child's grandparent], my mum's just a waste of space" Parent of boy, age 7, TD*
b	*"It was very difficult because services weren't coming together in [the local area] and actually it takes a trip to [the clinic] to get some answers" Parent of boy, age 14, ASD*
c	*[Having dis-engaged with local CAMHS team] "I think the thing he didn't really understand, or wasn't able to understand, was that CAHMS would kind of be a key ally to have by our side through the hard times, and without them it is probably me that feels more vulnerable than anything" Parent of boy, age 15, TD*
d	*"I have got more than what I thought we were going to get when we first started. I thought we were just going to get put on a weight chart and go from there you know. So, no. [Child] got, all the support you guys have given him has been amazing, I could not have asked for anymore" Parent of boy, age 7, TD*
e	*"How can I put it… a little bit more* help *than what we're getting, cos we were getting cos we're getting no* help *really" Parent of boy age 15, TD*

f	***Parent:*** *"It's just that is looks like I am the one that's keeping on at him all of the time.* ***Interviewer****: Does this make relationships at home difficult.* ***Parent****: For me Yes. Very much so"* *Parent of boy age 15, TD*
g	*"Maybe because I am nagging him to do it all the time? Maybe because he thinks I really want him to have that broccoli [he refuses], maybe with food I am not that good. Not that good at encouraging him" Parent of boy, 13, TD*
h	*"Especially when you are preparing his meal. With all this meat. Cooking, preparing everything and he is refusing it, it's really annoying me. But what can you do. And I know I shouldn't give him anything after it but I give him pizza because what else am I going to do now…" Parent of boy, age 13, TD*
i	*"It's better going to the hospital than going to the doctors, cos they just make him feel so small, and you're like - why? Why make him feel like he is a little pea in a big bowl, it's not good for him and then you guys laugh with him, make it all bubbly" Parent of boy, age 7, TD*
j	*"One of the people in there, they were like not like child friendly. And I know I'm not a child, but most of the people that were going were younger than me, like, and then they wasn't like, they were all like intrusive and all that" Girl, age 16, TD*
k	*"I know that nobody at the clinic is wanting to make people feel they have been battered with a big stick. It's just funny the things that are going on in your head about it, without anybody ever being overt in saying anything that would give you the impression they wanted to make you feel small or feel silly or feel bad. It's just there is so much shame attached to overeating" Parent of boy, age 15, TD*
l	*"If he were to feel that there were someone he could talk to and get alongside him, that understood and, that wouldn't judge him, that was always going to be consistent, or for a period of time going to be there in his life, I think that would help him". Parent of boy age 14, TD*

m	*"I tend to undermine my problems like "yeah it's not that bad" so none of my friends really know the extent of how bad it is." Girl, age 16, TD* *"I would just rather not. It is none of their business to be honest" Boy, age 13 TD*

5.7 Discussion

A service review was undertaken to understand how families experience their time at a weight-management clinic to inform improvements. Whilst the initial intention was to explore the feedback of a wide range of families, those families who had not lost a clinically significant amount of weight self-selected to participate. On reflection, this may be because of the way the work was framed as a means of informing service development. Whilst this was not the original intention, and it is acknowledged that the data is not generalisable to all patient's experiences, it has enabled a focused assessment of how to improve the service for those who are currently unable to achieve their goals.

The data were analysed and presented within a SDT context, which shows that families, and young people in particular were not experiencing fulfilment of the psychological needs required to utilise intrinsic motivation. Without feeling their outcomes were self-determined, young people were reluctant to participate; being difficult 'to motivate'. Family relationships were strained by the additional burden of weight-management and levels of anxiety were high both within and outside of clinical appointments.

In the previous clinic review (Owen et al., 2009), it was suggested that those who were unsuccessful reported requiring more support. Despite increases to the clinical time and diversity of the support available for patients since this first review; the feedback remains largely unchanged. The gratitude expressed by parents for the support available is testimony to the dedication of the team. However, providing enhanced clinical contact may be unsustainable long-term, feeding into the model of continuous care (Hall & Kahan, 2018).

Some families express wanting to enact change whilst others take a passive stance with the clinician holding overarching responsibility, as may be expected from other medical treatments. However, without the child being invested, neither clinician or parental desire for change results in easy success, instead creating pressure and need for constant interventions that may exacerbate problems within family relationships (Gillison et al., 2016). A further complication in some households, is the parent's difficult relationship with their own weight and feelings of guilt that their child requires clinical support.

Rather than focusing on continual motivation of the child, interventions informed by SDT work to support the child to actively engage in the programme and find their own, intrinsic motivation. Parents and clinicians work together in roles of 'supporter' (Lahey, 2015), setting parameters and ground rules which are followed by the whole family, whilst empowering the child to hold responsibility for enacting the specifics to reach goals that they themselves have set. Providing this improves wellbeing, weight-loss outcomes and supports longevity of the intervention (Santos et al.,

2016) with additional benefits of improving relationships (Katz et al., 2015). Whole family approaches are supported by NICE guidelines (NICE, 2015). Steps that can enhance autonomy have been defined by a new taxonomy of behaviour change techniques (Teixera et al., 2020) and include providing opportunities for patients to make choice, exploring their life values and encouraging self-initiation.

The participating families experience lifestyle changes as unmanageable. Whilst the clinic currently follows the latest guidelines encouraging a flexible approach to healthy eating, this is different to these families' expectations of following the prescriptive programmes that are commonplace in mainstream dieting culture (Haynos et al., 2015). Devaluing dietician's advice is reported, with families overlooking the small changes that can be the stepping-stones to success. Whilst more 'clinical' measures are instigated at the clinic in only more severe cases (such a meal replacement drinks or medication), they are perceived by families as more acceptable and feasible than lifestyle change. To change this attitude, developing a family's sense of competency is necessary. Ensuring that interventions are clear, goal-led and importantly target a single, controllable change at a time, can offer structure and build feelings of competency. Other interventions have used journals or workbooks to document goals and progress, and capture self-monitoring (Teixera et al., 2020). Setting expectations early with families is crucial (Teixera et al., 2020). Whilst the endocrinologist plays an important role, for those families with no known underlying medical aetiology the key to change is collaboration with dietician and MDT to instigate lifestyle changes outside of the clinic.

As an example, where Patient A may currently leave their bi-monthly meetings feeling positive and motivated following the support of the clinical team where they receive reinforcement and praise, this motivation may wane after a few days. Other priorities such a school and friendships take precedent, and the patient is only cognisant of their goals at the clinic when reminded by mum who is deemed to be 'nagging'.

However, a SDT approach would see the patient leaving the clinic with an active, goal that they have chosen themselves, that is meaningful to them, and that feels achievable: they may be aware that their consumption of sugary drinks early in the day makes them feel tired, so reducing intake offers weight management gains and reward by improved concentration in school. Together with their clinical team they would have chosen a means to record their progress (i.e. personal journal/tracking chart/phone app). The patient knows they have the support of clinicians and their family but that they themselves hold the responsibility for creating change.

Notably, in some cases, enhanced professional support may be necessary. Families experienced difficulty accessing community services, thus the clinic's recent inclusion of a social worker is

imperative to ensure families are supported (Farnesi et al., 2019). Furthermore, a notable proportion of those interviewed experienced emotionally triggered eating patterns. In line with population level findings, this was expressed particularly by those who had experienced trauma (Braun et al., 2019), and those with ASD (Christensen et al., 2019). These patients are currently supported by the clinic's psychologist and social worker, but external CAMHS services do not offer support for binge-eating. Targeted psychological support programmes for binge-eating have been shown to support weight-management, and could prove a beneficial addition to the clinic or adjoining CAMHS services (Fairburn, 2015; Safer et al., 2018).

Strengths of this review were that the interviewer was external to the clinical team, and interviews were conducted outside of the clinic in the interests of impartiality and fostering participant candour. Regarding rigour, data analysis was assisted by a qualitative researcher experienced in engagement with health services (AS) with no prior relationship with the clinic. Both data analysts were of the consensus that saturation had been achieved in data from families finding weight-loss difficult; however, this review struggled to recruit successful families. Thus, the sample limits our ability to recommend the SDT approach for all patients despite its potential to have a broad benefit in supporting patients attending weight-management services. Future work should look to understand self-determination in patients who lose weight successfully.

This work describes the perspectives of families failing to lose weight at a paediatric weight-management service. These families, and particularly these young people, do not demonstrate feelings of self-determination. Interventions in families struggling with weight improvements should see the clinical team placing more emphasis on working with parents to utilise young people's intrinsic motivations by understanding their priorities from treatment, develop young people's competency through the process of making one, achievable change at a time and documenting these progresses, supporting autonomy by setting clear, early expectations that success originates from changes outside of clinical appointments and supporting young people to take responsibility for their care outcomes. Together, these components intrinsically build self-determination within the young person, helping them with the weight-management outcomes but also giving them transferable skills for self-management that are of benefit more broadly.

5.8 Contribution to the thesis

Whilst some consider continued clinical management as essential to long term care for weight-management (Hall & Kahan, 2018), this work raises the importance of also developing patients ability to self-manage via enhancing self-determination. The process of establishing self-determination involves taking ownership over lifestyle changes (Deci & Ryan, 2009; Teixeira, Silva, Mata, et al., 2012). This can be complex, in part because in taking ownership over future behaviours to change may result in taking ownership over past behaviours that have contributed to the weight. This process is exacerbated by stigma and public misconceptions around the origins of obesity (R. Puhl et al., 2020). This thesis is written on the understanding of obesity as a disease (Burki, 2021; Jastreboff et al., 2019; World Health Organization., 1997) and acknowledges the myriad of biopsychosocial factors that contribute to obesity and the socioeconomic inequalities that contribute to its development (Butland et al., 2007). This thesis is also written under the belief that individuals, given the right environment and support, can make incremental changes that can improve their health and quality of life (Teixeira et al., 2012; Michie et al., 2014). The findings from this chapter suggest that increasing self-determination is part of this process.

From this work, it is recommended that all future intervention developments consider that;

1) Patient perspective needs to be integrated from the beginning, and throughout intervention development,
2) Psychological wellbeing is pivotal to many patients' experience of obesity,
3) Research processes should seek to minimise patient burden,
4) Interventions that raise patients' sense of competency, relatability and autonomy may support behaviour change via raised self-determination,
5) Interventions should avoid reinforcing patterns of dependence and instead should seek to empower patients to be agents for their own change (and support parents to empower their children and adolescents).

Emphasis on this patient-led process of intervention development may help to reduce to the known translational gap in obesity interventions (Akers et al., 2010). Furthermore, strong, collaborative relationships between clinical and research professionals may improve knowledge transfer, and researchers being supported to shadow and observe clinics, may ensure interventions meet the complex clinical needs of this patient group (Adams, 2008)

Further to the potential importance of self-regulation of eating behaviours highlighted in Chapters 2-4, self-determination has been shown to enhance self-regulation of eating. During an intervention to raise self-determination for weight loss in women, a 'spill over' effect was seen on their self-

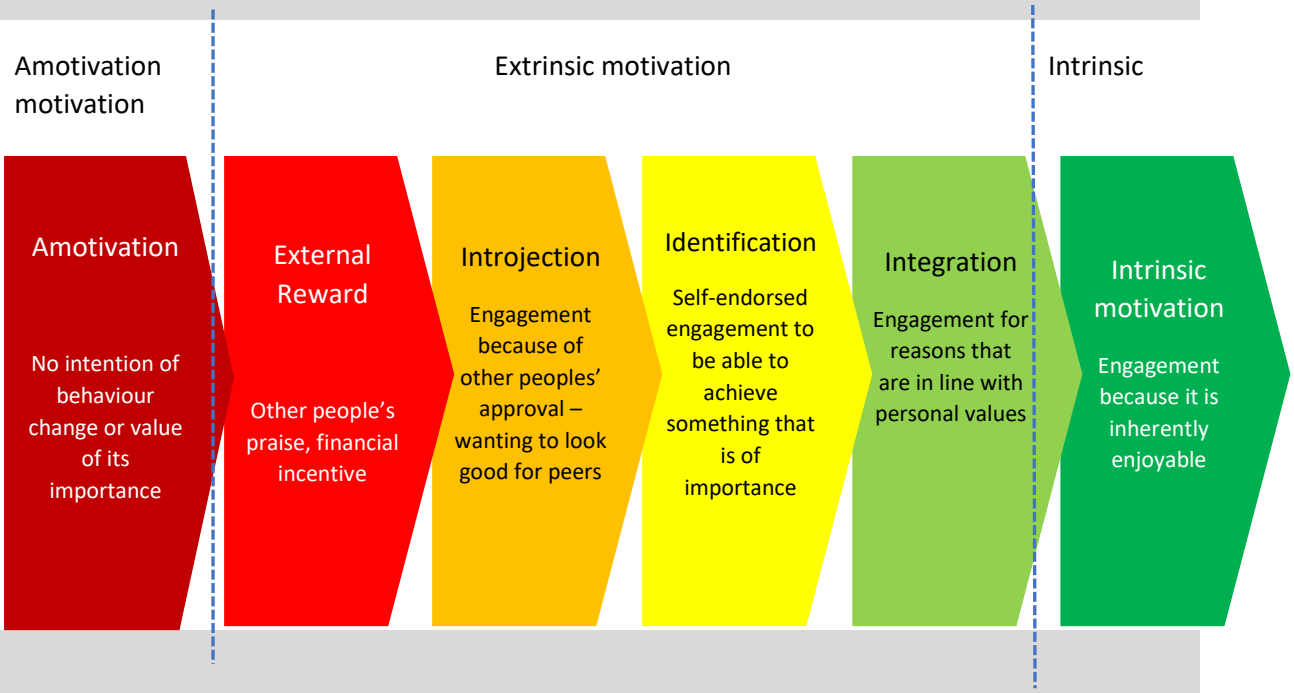
regulation of eating behaviour (Mata et al., 2009). It has been suggested that a raise in intrinsic motivation in one domain mediates improved self-regulation in others (Teixeira, Silva, Mata, et al., 2012), therefore it is possible that an intervention to target self-determination in weight management generally, may create spill over effects for self-regulation of portion size, eating speed or response to high-calorie food cues. This means that a self-determination focused intervention may offer wide-reaching benefits for the patient without the need for multiple tools, reducing demands on patients and offering cost-effectiveness for the service provider.

Following this work, EH and I were approached by DG to conduct a second qualitative service review for a specialist weight-management clinic for patients with Prader-Willi Syndrome. Qualitative interviews were conducted with parents attending a pilot multi-disciplinary team-led specialist clinic. Usual treatment for patients with Prader-Willi Syndrome involves endocrinologist-led care, with additional appointments being held as required at different times and locations. This move to centralise care was considered favourably by families who often travelled long distances frequently for various appointments. Parents perceived this centralised appointment to offer them access to the latest research and developments for care of young people with Prader-Willi syndrome, and a joined-up approach to their child's wellbeing. They considered that it could help them pre-empt difficulties, including with behaviour, as the child gets older. As first author on this paper, this work is included in Appendix D.1. This work was published in The Journal of Clinical Research in Paediatric Endocrinology and formed part of a clinical bid to allocate funding to this much needed service.

Box 1. Motivation & Self-determination

Successful patients at weight management are reported to have high levels of motivation (Farnesi et al., 2019; Owen et al., 2009), suggesting that those who do not lose weight have a lack of motivation, contributing to the stigmatising perception of those with obesity. Motivation is key to weight loss outcomes, but what these reports do not explain, is that not all forms of motivation are equal. The originators of the self-determination theory describe motivation as a continuum (Ryan & Deci, 2000)(Figure 7.1). They suggest that when it comes to weight management, it is the presence of intrinsic forms of motivation that will predict weight loss success.

Figure 7.1 The motivational spectrum (Ryan & Deci, 2000) adapted from (Consortium for Service Innovation, 2022)



By viewing motivation as a continuum, we see how someone may experience weight loss differently if their goals are driven by parents or clinicians compared to someone who is self-motivated. Motivation that stems from a desire for an external reward, or the avoidance of negative reinforcement may create patterns of behaviour based on pressure and feelings of how one "should" be behaving. Whilst this may change behaviour in the short-term, often the change ceases when the 'reward' stops, or the patient is no longer reporting to a clinical team (Ryan et al., 2009; Williams et al., 1996).

If, however, the patient's behaviour changes are intrinsically driven, for example that they find running an inherently rewarding activity, or that their new dietary choices make them feel much more energised than their former diet, lifestyle change may be internalised. As the new behaviours become part of the self (Ryan & Deci, 2000), the participant is less reliant on the long-term support by clinicians. When motivation is intrinsically generated, the person perceives the 'locus of causality' to be chosen of their own volition. Therefore, research has suggested that those with high levels of intrinsic motivation are more likely to maintain engagement with weight management services and more likely to sustain weight loss at follow-up (Masse et al., 2015; Williams et al., 1996). The period of adolescence is characterised by the development of a sense of self, identifying themselves as something separate to the family unit. I suggest that this offers young people a good opening to

integrate new perceptions of themselves, that may support lifestyle change. Being offered the space and support to develop intrinsically motivated choices around their diet, activity and lifestyle may empower them to make sustainable choices that are in line with their newly constructed sense of who they are.

A pre-requisite for intrinsic motivation is the fundamental human needs of relatedness, competency, and autonomy, that generate self-determination. Studies of securely attached (due to the need for relatedness) young children demonstrate that intrinsic motivation is innately present, children are inherently curious, excited and explorative of the world around them (Ryan & Deci, 2000). Autonomy-supportive parenting, offering young people limits not ridged controls, is supportive of intrinsic motivation and healthy self-regulation (Bernier et al. 2010; Lengua et al. 2007).

As we get older, the need to engage with and perform behaviours that are not purely intrinsically motivated becomes important. Tasks associated with education, responsibility and service to others are not always intrinsically motivated, but those with higher levels of self-determination are able to integrate the value of these tasks to the extent that they begin to personally endorse them and become able to generate the self-regulation to perform them (Ryan & Deci, 2000). Those with low self-determination approach these tasks with amotivation or compliance, with low self-regulation, the performance of the behaviour is contingent on external rewards or punishments (Lahey, 2015; Williams et al., 1996). The level to which an individual can integrate tasks with their sense-of-self, is predictive of adherence, effectiveness and wellbeing (Ryan & Deci, 2000).

In the context of the patients attending the tier three service, this is important. Both the literature and our PPI groups (Chapter 6), confirm that ideally, young people would come to weight loss in their own time, for a reason that was intrinsically motivating to them. However, the young people at the COCO clinic are referred for medical reasons and have potentially not made the decision themselves that it is time to make lifestyle change. The challenge here, is therefore, to support the young people with the process of internalizing what for many is an extrinsically generated, clinical aim. Creating an environment that is autonomy, competency, and relatedness supportive provides the foundation for individuals to find the elements that resonate with them, and that they can personally endorse (Teixeira, Silva, António, et al., 2012; Weinstein et al., 2012). From here young people must combine the clinics goals with their own life values in a manner that they control, that is free of external pressure to enable them to become intrinsically supported (Weinstein et al., 2012; Ryan & Deci, 2000).

Chapter 6: An Integrated approach to intervention design, integrating theory and person-based approaches.

6.1 Overview

This chapter integrates the key learnings from work conducted in Chapters 2-5 to create an intervention suitable for adolescents in the COCO clinic. Whilst all other Chapters (2-5) were planned and delivered simultaneously, this work was conducted subsequently and acts as a summary of my understandings to date. This work draws from health psychology theory, including utilising the Behaviour Change Wheel COM-B approach to intervention design, to provide structure to the development process (Michie et al., 2014).

A key element of my learnings has been the importance of integrated and continual PPI and service user involvement in research development. This new research integrates three components of patient-led work: the qualitative service reviews (Chapter 5), PPI groups (Chapter 6) and the involvement of a PPI collaborator, Gail Thornton, who has shared her lived experience of obesity and contributed considerably to the direction of this work.

This work formed the basis of a NIHR Research for Patient Benefit (RFPB) grant, that has been funded (NIHR203605 – AIM2Change: Helping Adolescents to increase their Intrinsic Motivation to change weight), providing us with 18 months from July 2022 to carry out the co-development work described at the end of this chapter. This developmental manuscript has been submitted for publication in BMC Health Services Research. The paper is included as submitted in sections 6.3 –6.7. Appendix E.1 includes intervention development worksheets that for part of the COM-B approach to intervention development. Appendix E.2 includes the Table of Changes, that details changes that have been made as a consequence of PPI feedback.

6.2 Statement of contribution

JC contributed at all stages of the design and writing of the service review that informed this work, including writing the first draft of the manuscript. Additional analysis of this service review is also included here. JC developed the concept of this study following the service review work (Chapter 5). The team would like to acknowledge all of the PPI groups, including the service users of the SHINE programme in Sheffield and the CoCO clinic in Bristol for their invaluable contributions to the development of this intervention. We would like to thank Mike Bell PPI Facilitator for the Bristol Biomedical Research Centre and Ken Clare and the team from Obesity UK with their support for the project and the recruitment to PPI groups. Access to the PPI population was facilitated by collaborators at Obesity UK. This work includes four PPI groups, JC led on three of these groups, however the fourth group fell during maternity leave, and was led by EH and GT. The details of the PPI group and the feedback from the participants are included in this document as they offer valuable contribution to the intervention development. All authors read, contributed to, and approved the final manuscript.

Publication

Integrating COM-B and the Person-Based Approach to develop an ACT based therapy programme to raise self-determination in adolescents with obesity

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6.3 Abstract

This paper details the development of the Adolescent Intrinsic Motivation AIM2Change intervention to support weight-management in young people previously unable to make changes whilst attending a tier 3 weight management service for children and young people. AIM2Change is an acceptance and commitment therapy (ACT) based intervention that will be delivered one-to-one online over a seven-week period. To develop this intervention, we have triangulated results from a qualitative research study, patient and public involvement groups (PPI), and a COM-B (capability, opportunity, motivation, behaviour) analysis, in a method informed by the person-based approach.

The integrated development approach yielded a broad range of perspectives and facilitated the creation of a tailored intervention to meet the needs of the patient group whist remaining pragmatic and deliverable. The next steps for this intervention will be in-depth co-development of the therapy sessions with service users, before implementing a feasibility randomised control trial.

Key words: ACT , obesity, adolescents, clinical, self-determination, behaviour change

6.4 Introduction

Children with high levels of obesity and associated co-morbidities or safeguarding issues may be referred to a tier-three, hospital based multi-disciplinary team clinic (NICE, 2020). The Care of Childhood Obesity (COCO) clinic at Bristol Children's hospital is currently the only fully funded service in England, although the new Complications related to Excess Weight (CEW) clinics starting in 2022 will go some way to addressing inequalities of access (NHS England, 2021). The clinic treats patients using lifestyle guidance, dietetic programmes, and psychological support, from a multi-disciplinary team (MDT). When required, the clinic can access diagnostic testing, pharmaco-therapy, and bariatric surgery. 94% of patients improve their BMISDS, however, just under half of all patients do not improve BMI to a clinically meaningful BMI SDS change (>0.35) using non-medical interventions (unpublished clinic data, 2022). Two reviews of the clinic acknowledged that the approaches used did not suit everyone. Younger patients without a family history of obesity (Sabin et al., 2007) and with the advantage of motivated and more practically and personally resourced families, are most likely to benefit from the clinic's approach (Owen et al., 2009). This suggests that those whose circumstances mean that weight management is more challenging continue to find it challenging within the structure of the clinic and a significant proportion of the clinic's population remain unable to make clinically significant change. For the year 2021/22, this figure was 46% of patients who do not improve their BMISDS during their time at the clinic, and this patient group was found to have complex obesity, with related behavioural issues including autism spectrum disorder (ASD) and attention deficit hyperactivity disorder (ADHD) or socioeconomic deprivation. These patients may drop out of the clinic or may continue to attend but without achieving the desired outcomes (Sabin et al., 2007). Perceived dietary failure can have negative effects on mental wellbeing and self-esteem (Bacon, 2008) and results in young people making the often difficult transition into adult weight management services (Shrewsbury et al., 2014).

Obesity in childhood is associated with a wide range of adverse health outcomes both during childhood and across the life-course, including an increased risk of diabetes (Weiss et al., 2005),

heart disease (Li et al., 2004) and 16 different types of cancers (Secretan et al., 2016). For those who experience obesity in childhood, their weight status often tracks into adulthood (Freedman et al., 2005; Patton et al., 2011). The NHS cost of treating obesity and its associated illnesses reached £6.1 billion in 2014/15 and is increasing year-on-year (Public Health England, 2017). It is therefore in the interests of both the NHS and the individual to develop innovative ways that support every patient within the service.

Overweight and obesity is frequently approached with the incomplete concept of 'eat less and move more' (Correia et al., 2020), which could be perceived to create a calorie deficit resulting in weight loss (Fitch, 2020). However, this vastly underestimates the complex biological, environmental, social and psychological drivers to eating (Barlow, 2007; Obesity Health Alliance, 2021). Maintaining health behaviours in an environment that does not support health (Fraser & Edwards, 2010; Obesity Health Alliance, 2021), and with biological drivers that oppose weight loss for evolutionary survival reasons (Higginson et al., 2016) requires cognitive control, motivation and self-regulation (Forman & Butryn, 2015). Consequently, losing weight is difficult, and maintaining weight-loss is a potentially bigger challenge (Wing & Phelan, 2005). Only a small percentage of people who do lose weight, sustain the weight loss with many regaining weight (Dulloo & Montani, 2015; Wing & Phelan, 2005).

To support long-term success, the implementation of evidence-based behaviour change strategies are recommended (O'Cathain et al., 2019). An understanding of the complex and numerous factors that cause and maintain overweight can be used to implement targeted behaviour change (Teixeira & Marques, 2017). To be effective, the development of the intervention should be theory-led and grounded in behavioural science, but also incorporate the patient perspective (NICE, 2020; O'Cathain et al., 2019). Such integrated approaches to intervention design have been demonstrated to offer enhanced clarity of intervention focus and ability to meet patient needs (Band et al., 2017).

The objective of this research is to develop a feasible, effective intervention tailored for those young people who do not experience progress after six-months in a tier-three weight management service.

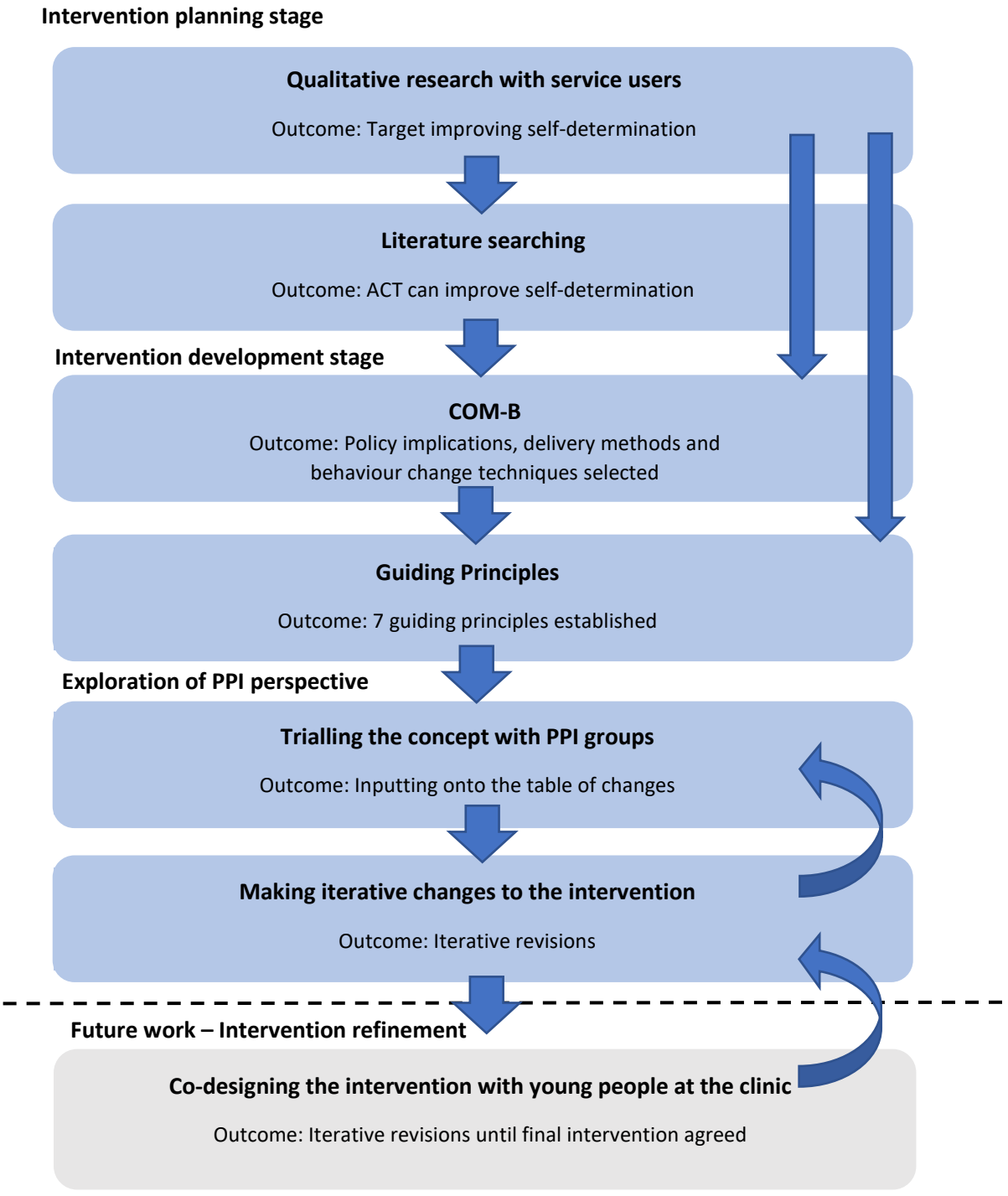
This intervention is planned and designed at the Bristol COCO clinic, with fourteen additional Complication from Excess Weight (CEW) NHS clinics under development (NHS England, 2021). Thus, the scalability and deliverability of the intervention across sites providing broad geographic and demographic reach has been considered in this context.

6.5 Methods

To select frameworks of behaviour change, a recent systematic review of behavioural intervention development tools was consulted (O'Cathain et al., 2019). Based on the target intervention, and the expertise within the research team, methods from (i) the person-based approach (Yardley, Morrison, et al., 2015) and (ii) a theory and evidence-based approach (the COM-B (Michie et al., 2014), were brought together for intervention development. The person-based approach facilitates a focus on patient acceptability and feasibility and the COM-B enables a systematic, theoretically sound process for targeting interventions. The stages were conducted in an iterative manner, with each step informing the next. The intervention planning stage included the gathering of existing data and knowledge through qualitative interviewing and literature reviewing, which drew acceptance and commitment therapy out as the leading potential therapy for this area. The intervention development stage included the design of the intervention using the (Ruiz & Francisco, 2012). COM-B framework and the development of guiding principles (Yardley, Morrison, et al., 2015). Importantly, patient and public involvement (PPI) groups were then consulted to ensure the intervention met the needs of the population.

To ensure lived experience remains the primary focus of our intervention design, a member of the PPI group, with lived experience of obesity (GT), was invited to join the research team as a PPI representative. Her contributions iteratively feed into each stage of the development.

Figure 6.1. Stages of intervention development



Stage 1: Intervention planning

Qualitative interviewing

Rationale

Understanding the population for whom the intervention is being designed is a fundamental first step (Yardley, Ainsworth, et al., 2015). A service review was conducted over ten-years ago (Owen et al., 2009), but to date no formal qualitative review of the patient perspective on the clinic's programme has been conducted. Several changes had been made to the service since the 2009 review, including an increase in the frequency of clinic appointments and the introduction of a clinical psychologist, clinical nurse specialist and a specialist social worker to the MDT. Updating our understanding of the current patient experience was an important first step in intervention planning.

Method

Qualitative interviews were conducted with twelve families who attended the COCO clinic (Cox et al., 2021). The interviews were open to all patients, however all but one of those who took part were not currently seeing changes to their weight or co-morbidities following the current service approach. The views of the patient achieving weight-loss were removed from this analysis as data saturation in this area was not met. Interviews were conducted and audio recorded over the telephone between January and August 2019, except one, which was conducted in person. The interviews were thematically analysed following the six-step procedure of Braun & Clarke (2006) by two independent and experienced qualitative researchers (JC and AS). Coding began inductively. However, as parallels with self-determination theory (SDT) were drawn, coding took a deductive approach guided by the framework of SDT.

Further to the published findings, the transcripts were re-visited to extrapolate useful insights on the pragmatic and logistical aspects of the clinic experience, which were not focused on in the above exploration (Cox, Searle, et al., 2021).

Results

Perceptions of self-determination were evidently low in this population. There was a high reliance on the support of the clinical team and a desire for more intensive medical involvement in the weight-loss process with low levels of patient belief that they had the capability to sustain change themselves. Self-determination theory proposes that three fundamental needs must be met for someone to experience self-determination. The person must feel autonomy - be empowered to make choices and hold the power to make decisions. They must feel relatedness – feeling supported and connected to those around them, and feel competency – feeling able to perform the behaviour, and have the necessary skills and resources to do this consistently (Deci & Ryan, 1985; Katz et al., 2015; Williams et al., 1996). The patients in these interviews did not demonstrate fulfilment of the needs that comprise self-determination, nor did they utilise intrinsic motivations, meaning there is a potential for improving weight-loss outcomes if relatedness, autonomy, and sense of competency are increased.

Those expressing high self-determination are better able to regulate their emotions and behaviour in response to external pressures (in this case, the food environment, the media, parents, peers, clinicians ,etc.) but also in response to their own emotional responses, urges and drivers (Roth et al., 2019). Our ability to regulate based on our own internal state is known as our emotional regulation. Without self-determination which includes being attuned with our intrinsic motivations, weight-loss relies on external factors. Whilst weight may be controlled in the short term via these means, changes based on extrinsically motivating factors will almost always struggle to be maintained (Forman & Butryn, 2015). Without the pressure and approval connected to reporting to clinicians, and the rewards of weight-loss, weight-maintenance may offer fewer incentives. Lifestyle changes that are intrinsically rewarding to the individual in and of themselves, are more likely to be sustained (Ryan et al., 2009; Sebire et al., 2018).

The intervention focus should therefore be on working alongside families to understand what drives the young person and to develop sustainable, intrinsically motivating changes. If self-determination can be increased in this population, it not only offers opportunity for improved weight-management outcomes, but also facilitates improved self-management skills that can be transferable throughout the young person's life.

Pragmatically, the patient group were clear in reporting the difficulties of in-person attendance at this clinic, with travel, missing school and the cost being significant barriers (Table 6.1). The interviews were conducted prior to the Covid-19 pandemic and the concept of online services was considered tentatively. Their perspective on group work was more nuanced, with some in favour of the peer-support offered by group work and others preferring the confidentiality of one-to-one sessions (Table 6.1).

Table 6.1: Additional quotes from qualitative interviews with service users

When asked about access to the current clinic, and the prospect of additional support that could be offered at the clinic…	
Young person, aged 16	Nah, just every single appointment ever, they [school] just start having a go. I haven't had that many days off, like if I am ill. Most of mine are like appointments. I can't really control how many appointments I have.
Parent of girl, aged 16	She just doesn't like having to take the whole day off if we've got to get the bus from school and that cos it affects her attendance but um, they're aware of what it is cos it's a letter, and they know I don't drive at the minute as well.
Parent of boy, aged 15	I am not trying to be difficult, I am in the process of – I have just applied for PIP.[personal independence payment] I should have done it years ago. Things may start to get a little bit easier in terms of parking, transport, so it could become

	easier. But Yes, it could be [unfeasible to come to additional sessions]. But that's because it's expensive, not because I am not happy to travel to the city, I am very happy to travel to the city, it's just practically…it's very difficult at the moment.
Parent of boy, aged 14	No, it's not far, we are only by [district] but in the morning, it is far. It's stationary traffic, crawling in traffic all the way to the hospital. So it can take any time in the car. I came in Yesterday by taxi cos my husband was at work, and I was worried we wouldn't find anywhere to park… and the taxi took 30 minutes, if I had come by myself, and then tried to drive around trying to find somewhere to park, potentially not being able to park, park in the centre and walk up, um, it takes even longer.
Parent of boy, aged 14	It depends on when they are… I don't really want to take him out of school any more if I don't have to. He has done this, with Alive and Kicking [tier two weight management service in the area] we did do their six-week programme, but I don't know if we would do that now. You know. It just depends on the timings really. If it is at the children's hospital, it is all the hassle of getting in there again.
Parent of boy, aged 15	The distance is too long really, he ends up, the school won't be happy. He ends up with a whole day off school each time
Parent of boy, aged 15	It's difficult because I have quite significant mobility issues myself so coming to [the city] is really difficult, really tiring and risky because for me the more I walk, the more likely it is I end up in hospital with a chronic bacterial infection due to complex swelling. I have a complex chronic health condition myself. To be honest, by the time I am going home I am exhausted, in pain and just wanting to go home. But it takes a few hours, to wait for the hospital bus that has been cut back and cut back and you can wait for an hour for the bus to come, and

	then, it's just, it's difficult. It costs a lot of money, even though I can claim the cost of the train back I have to pay for parking at the station, I have to pay for the fuel to get to the station, there is no public transport to the station and I can't walk. You know, it's quite a mission to come, so by the time we are going home, I am just desperate to go home.
Parent of boy, aged 13	I wonder if there is a way, I guess it may be, it might be a difficult area to go into, but whether there was a way of doing something positive via an online platform, could get support, encouragement and be linked up… but it would have to be safe but, but um, whether there is a hope of doing something like that? I think [child] would feel more safe *(sic)* and be more open about how he is feeling and that, than face-to-face. At this stage in teens, in the middle of puberty, at an awkward stage in terms of making new friends and feeling confident about yourself… *[interviews conducted prior to Covid-19 and the increase in online platform use for appointments and schooling]*
When asked their thoughts on group-based interventions	
Parent of girl, aged 13	Um…. No, I am not sure, cos she doesn't like to… she is familiar with the dietician and social worker, but she doesn't like to talk about things…
Parent of boy, aged 14	At this stage in teens, in the middle of puberty, at an awkward stage in terms of making new friends and feeling confident about yourself… But in terms of… he doesn't have much confidence left after the mental health problems he has had over the last… two years now, he doesn't have much confidence left for the new friends at the moment.

Parent of boy, aged 14	I think the group thing would be quite good, and might be better, seeing other families and how they do. Oh, that is the other thing, [child] wouldn't be, it would be important to be with the ages. In the one we went to before, he was 11 and we were pushed into the older group, rather than being with the littler ones, would this be run by age group?
Young person, aged 16	Well, that is worse isn't it [than speaking one-to-one with clinicians] … I get that other people would be in the same boat as you but… I think when it comes to group sessions…I think stuff like that is a bit personal, and not everyone is in the same boat. Like they may think "Yeah, they've got exactly the same thing". No. Cos each person needs the people to kick for them. …. The younger ones no, but like 15plus then that could be like… more helpful. Helpful to comprehend what they are saying and what is helpful to take away from it. Cos with the doctors it is just facts, facts, facts, facts. They try to help but they are not in the situation. Whereas if it was an older group, you could be like "Yeah, I have tried this before, it doesn't exactly work but if you change a few things…" like that. We could all help each other.
Parent of girl, aged13	One-to-one Is better. She doesn't like – like I said, she is quite personal. She'll get upset otherwise and I don't want her to feel like she doesn't want to – not want to come back cos of that reason. I've just got her on a level where she is comfortable talking to certain people. Whereas if it was a group of people that she doesn't- she might lose her temper a little bit, and I don't want her to do that or get upset, or go home crying, or have a negative – that might have a negative feel on her. Me, it wouldn't be too bad cos other parents might have other ideas but, for her it

	probably would help her…. Yeah, if we change it - I don't want to rock it, I've just got her in – it's taken me a year to get her where she is so…

Literature searching

Rationale

Following the finding that the target population expressed low levels of self-determination and intrinsic motivation (Cox et al., 2021), the literature was reviewed to evaluate interventions that are focussed on the aim of raising self-determination in young people.

Method

Three authors (EH, AS and JC) conducted literature reviewing to understand what interventions were currently being used to target self-determination and intrinsic motivation. Based on the findings, a scoping review of the chosen intervention in young people is in preparation (Iturbe, Cox, et al., 2021).

Results

It is acknowledged that emotional regulation is an essential prerequisite to experiencing self-determination (Roth et al., 2019). An increased awareness and mindfulness of our emotional experience (Chang et al., 2015), and an ability to accept the emotional experience non-judgementally enable us to not become dysregulated by our emotions and instead utilise the information being conveyed by these emotional experiences to understand what is of value to us, and to ensure needs are met (Roth et al., 2019).

Whilst CBT is often the default in weight-management (Jensen et al., 2014), there is a developing evidence base in favour of ACT (Ruiz & Francisco, 2012). ACT may offer superiority to CBT in the domain of raising self-determination, due to its ability to enhance emotional self-regulation through its focus on self-awareness and mindfulness, a hallmark of the third-wave therapies. Whilst other third-wave therapies including Mindfulness Based Cognitive Therapy (MBCT) and Dialectical

Behavioural Therapy (DBT) may also offer opportunities to raise self-determination, ACT currently demonstrates the greatest efficacy within weight management (Lawlor et al., 2020).

Acceptance and commitment therapy (ACT) is a third-wave cognitive behavioural intervention, that utilises core processes that support emotional regulation, including acceptance, mindfulness, and values-based work to deepen intrinsic motivation (S. Hayes, 2009). ACT is therefore recognised as an appropriate psychological therapy for increasing self-determination (Roth et al., 2019; Ryan, 2021).

Recent reviews have considered ACT as an important approach to treating obesity in adults (Bailey et al., 2014; Forman & Butryn, 2015; Iturbe, Echeburúa, et al., 2021; Lillis & Kendra, 2014; Vallis et al., 2020). ACT supports patients to tolerate short-term discomfort (e.g. exercise) when it is in line with these overarching values (e.g. to live an active life) (Bailey et al., 2014; Forman & Butryn, 2015), and brings awareness to metacognitive thought, in a way that helps patients learn from their emotions but not get swept away with them (Bailey et al., 2014; S. HaYes, 2009). Indeed, ACT has been adopted in a range of adult weight management services (Iturbe, Echeburúa, et al., 2021; Lillis & Kendra, 2014), including the recent Supporting Weight Management (SWiM) trial (Richards et al., 2022). From this literature searching stage of the intervention development, connections were established with the research team conducting a systematic review of ACT being used within adult services (Iturbe, Echeburúa, et al., 2021) and as a result a collaborative scoping review is now being carried out on the evidence for use in paediatric care (Iturbe, Cox, et al., 2021). Thus far, this scoping review has demonstrated that the approach appears to be relatively novel within the paediatric weight management setting, with just three trials found (Cardel et al., 2021; Iturbe, Cox, et al., 2021; Janson et al., 2021; Tronieri et al., 2019). Furthermore, several iterations of ACT have been successfully developed specifically to work with young people, children and adolescents (Ciarrochi et al., 2012; L. HaYes & Ciarrochi, 2015). These approaches tailor ACT for the developmental stage and autonomy of younger people. The combination of the intervention being tailored successfully for

weight management and for adolescents, but not yet for adolescent weight management, offers an opportunity to refine existing ACT programmes to be of specific value to these young people.

Stage 2: Intervention development

COM-B

Rationale

Whilst knowledge about the behaviours we should be increasing (e.g. exercise), and those we should be decreasing (e.g. fast food consumption), is important, on its own this knowledge is rarely sufficient to create sustained change in behaviour (Nagy-pénzes et al., 2020). Research into the psychology of behaviour change suggests that to be able to sustain changes, the individual needs to have the capability, opportunity and motivation to perform the new behaviour (Michie et al., 2014). This model is referred to as COM-B. First, having the capability to perform a behaviour involves facets such as having the psychological and physical strength, or skills and knowledge to perform the behaviour. Secondly, having the opportunity to perform the new behaviour includes having sufficient environmental resources, such as the time, finances, and space to engage in the behaviour, and the social opportunities to do so, which may be influenced by cultural norms and the social environment. Finally, to engage in a behaviour one must be motivated, which the model suggests involves a combination of being automatically motivated through impulses and desires and being reflectively motivated via processes such as making plans and evaluating outcomes. The COM-B offers a framework on which to design interventions with these key facets of behaviour change in mind (Michie et al., 2014; West & Michie, 2020).

Method

Using the rigorous COM-B framework for intervention design (Michie et al., 2014), an in-depth behavioural analysis was conducted to understand what needs to change before the target group (in this instance a clinical paediatric population with obesity) are able to change the target behaviour (in this instance, self-determination). The analysis is structured through the completion of a series of COM-B worksheets, each focussing on a different aspect to help determine how the behaviour change could be brought about. It also identifies policy areas that the intervention could impact. The

final stages of the COM-B model guide the content and intervention implementation options and involve understanding which of 93 behaviour change techniques (BCTs) would be effective in bringing about change and via what delivery mode. Throughout, the model utilises the APEASE (Acceptability, Practicability, Effectiveness, Affordability, Side-effects, Equity) framework to ensure feasibility of the selected intervention. Three authors (JC, EH & AS) independently completed the COM-B process worksheets then met with clinical expert (JHS) to finalise decisions and create an overarching document (Appendix E.1).

Results

It was apparent that an intervention to raise paediatric patients' sense of self-determination could be successfully achieved by targeting psychological capability; social opportunity; reflective motivation or automatic motivation (Appendix E.1, Worksheet 4). The intervention could be effectively delivered via education, modelling, training, or enablement pathways (Appendix E.1, Worksheet 5). If the intervention was to look at changing policy, the policy categories that could be applicable were to look to influence *guidelines* and *service provision* (Appendix E.1, Worksheet 6).

Based on these results, and the perspective of a clinical expert (JHS) and PPI, it was agreed that a *training* approach was more in-keeping with ACT's standpoint of working alongside patients to develop collaborative solutions, rather than taking a teaching approach. It was also agreed that the clinical team *modelling desired behaviours,* to demonstrate how a patient could embody the behaviour change would be an appropriate technique.

To establish which BCTs were helpful to include, the BCTs were considered through the lens of increasing self-determination and were chosen based on their ability to support self-determination and intrinsic motivation. Worksheet 7a (Appendix E.1) documents all the beneficial BCTs, which include *behavioural practice/rehearsal (*for example practising mindfulness when feeling calm, in order for the skill to be more readily available in times of stress)*,* and *valued self-identity (*affirming the person's self-identity in line with the behaviour change). Furthermore, a tailored list of specific motivational BCTs (MBCTs) has been developed by expert consensus, including the authors of the

COM-B model and the self-determination theory (Teixera et al., 2020). It therefore seemed pertinent to also include these MBCTs in the intervention, with items such as using *empathic listening, clarifying expectations* and *dealing with pressure* being highly relevant (Appendix E.1, Worksheet 7b).

To clarify modes of delivery, COM-B identified *face-to-face* or *phone* to be potential delivery options particularly by video-call (Appendix E.1, Worksheet 8). The qualitative interviews raised the difficulty patients have in accessing the clinic due to its city-centre location and the costs this incurs (Table 6.1), therefore we opted to run the programme via video-call.

Guiding principles

Rationale

The development of guiding principles, in accordance with the person-based approach (Yardley, Morrison, et al., 2015), helps to clarify the intervention's objectives and ensure the design meets the needs of the end user. Throughout intervention iterations, the guiding principles should be consulted to ensure the intervention retains its focus. Guiding principles may also iteratively develop as new information is understood about the target audience and their needs.

Methods

To develop guiding principles, the methods of the person-based approach were utilised (Yardley, Morrison, et al., 2015). Together, the knowledge gained from the COM-B behavioural analysis, qualitative research study, literature reviewing, and the PPI groups was considered, and overarching objectives of the intervention were agreed on by the research team. Key features of the intervention that will ensure each principle is achieved are detailed in Table 6.2. The development of guiding principles and key features is iterative (Figure 6.1) as the intervention continues to evolve in response to PPI feedback and feasibility work with the clinical population, so it is likely that these principles will evolve too.

Results

The guiding principles (at point of publication), and the key features of the intervention that will help the principles be achieved, are detailed in Table 6.2.

Table 6.2: Guiding principles

Guiding principles	Key Features of the intervention that will ensure the principle is achieved
The interventions must be designed specifically for this population.	• PPI work and voices of those with lived experience will be central to the design • Interventions designed for adults are not directly applicable to children (Cox, Elsworth, et al., 2022; Cox, Hinton, et al., 2022), therefore this intervention will be specifically designed.
The Interventions should not create dependency on care, and instead help develop patients' autonomy	• The intervention will work to develop patients' sense of self-determination through the facets of enhanced competency, autonomy and relatedness. • The clinical team and the families will adopt a supportive role, encouraging the young person to take responsibility for change. • The balance of responsibility will be communicated clearly from the offset.
Development of open & trusting relationships is important	• Time will be taken to build rapport and create a trusting, warm environment.

	• Open communication will be encouraged throughout the process
Interventions should not increase pressure on parent/child relationships, and should instead support this sometimes difficult relationship	• The service review highlighted how tensions within some families were exacerbated by disagreements around weight (Cox et al., 2021). This intervention seeks to support parents to enable their children to lead the changes, which has been shown to decrease conflict. • Young people can choose when they would like their parent/guardian present during a session, whether they would like a different support person to attend, or whether they would like to attend alone. This choice may change from session-to-session
The intervention must consider the whole person and not just issues regarding weight	• The intervention will treat eating behaviours in the context of the young person's life and experiences • All changes will be selected for their ability to fit within the context of the young person's life, in order for them to be sustainable

	• The intervention will offer transferable skills that the young person can utilise in other aspects of their life
The intervention must be accessible	• The programme will be delivered online to facilitate access. This avoids travel time and parking costs. • Sessions can be scheduled at times to avoid missing school/parents missing work. • Funding will be allocated for data allowance to ensure access to video-calling, and tablets can be lent to anyone without access to a smartphone or computer. • For those without a private place to speak at home, alternative arrangements will be supported
Interventions should aim to target long-term, sustainable lifestyle change, not offer a quick fix	• Focus will be on changes that can be maintained • Intervention will be tailored to work with the context of each participant's life • The intervention will include meta-cognitive awareness of long vs short term outcomes of our decisions

	• Young people will make the decisions as to the changes they are making, meaning they will be more appropriate than a one-size-fits-all approach.

Stage 3: Testing the concept and iterative development

Rationale

To ensure the programme works for the end-user, PPI is vital throughout the intervention process.

Method

Based on the development work conducted, a protocol ACT therapy manual was developed by a health psychologist trained in ACT (JC). The concepts were discussed with four PPI groups: one with young people of healthy weight and two with adults with obesity who had experienced obesity during their childhood and adolescence (some of these participants' children were also currently experiencing obesity). The fourth group were young people with obesity who were currently engaged with a tier-3 weight management programme (Table 6.3).

Table 6.3: PPI participant details

Group	N	Demographic
Group 1	5	Young people aged 14-17 years
Group 2	5	Adults aged 18+ with lived experience of obesity, including obesity in childhood/adolescence, some with their own children who are currently experiencing overweight and obesity
Group 3	4	Adults aged 18+ with lived experience of obesity, including obesity in childhood/adolescence, some with their own children who are currently experiencing overweight and obesity
Group 4	6	Young people aged 12 – 17 years, currently experiencing obesity.

The feedback of the PPI group members has actively influenced both the content and the delivery of the intervention. This rich and significant feedback, and how it has been incorporated into the development process, is documented in a *Table of Changes* (Appendix E.2).

Results

The PPI group were in favour of the focus on intrinsic motivation and taking an approach of working collaboratively, with many reflecting on their own experiences of failed diet attempts when driven by external reasons, and the negative impact this pressure has had on them. Participants perceived this potential intervention as giving them a *new perspective on weight management ("a new way to consider this"),* whilst resonating with their personal experiences (*"I feel like you described my teenage years").* Changes were made to the structure of sessions (see *Table of Changes* (Appendix E.2), with young people now being given the option as to whether their parent, or another support figure, attends sessions with them or not. The use of the term 'mindfulness' was also challenged due to the term *"constantly being thrown at us at school".* Overall, the group considered the approach to offer them a holistic approach where the therapist would seek to "*build a relationship with them beyond their weight".* The transferability of the skills involved offered them *"help for life",* rather than a programme that was purely about weight loss.

6.6 Discussion

Through integrating person-based insight, theory and evidence, an ACT based approach to raise self-determination in paediatric weight management has been devised. The approach will be further co-developed with young people in the COCO clinic, before a feasibility trial is conducted within the COCO clinic. The intention is to include the intervention in future CEW clinics that are currently in development (NHS England, 2022).

The integration of techniques from COM-B (Michie et al., 2014) and the person-based approach to intervention design (Yardley, Morrison, et al., 2015), and the contribution of a PPI representative (GT) within the research team ensures lived-experience is front and centre of this intervention design. This enables the intervention to meet current NICE guidelines, which request that all

paediatric weight management interventions *"have taken into account the views of children, young people and their families"* (NICE, 2020). Contributions from the patients and their families led the decision to take the novel approach to target self-determination and intrinsic motivation, which is perceived to be the cornerstone to life-long change. The patient perspective has also heavily influenced the logistical aspects of the intervention. The three trials that have assessed ACT use in similar young populations have also shown promising feasibility results; however, none of the interventions have been developed in a patient-led way and all have included ACT as part of an integrated weight-management intervention with multiple elements, making it difficult to unpick the effectiveness and feasibility of the ACT components in this setting (Cardel et al., 2021; Janson et al., 2021; Tronieri et al., 2019). Practical factors such as access, location and timing contribute to the high attrition typically seen with weight-management interventions (Jensen et al., 2012; Sperry et al., 2014). Consequently, as our intervention follows the patient lead on how and when they would like to receive the intervention, we hope to see further enhanced completion rates.

The evidence suggests that ACT processes, including supporting meta-cognitive thought, clarification of values and acceptance of difficult thoughts and feelings, enhance emotional and self-regulation (Forman & Butryn, 2015; Roth et al., 2019). Our PPI feedback celebrated the holistic approach to care, which offers patients a new skill set that is transferable to other elements of their lives. Whilst CBT is the default model for clinical care, theory suggests that ACT as a third-wave CBT therapy may offer enhanced ability to generate autonomous motivation, self-regulation and sustained change (Forman & Butryn, 2015; Iturbe, Echeburúa, et al., 2021). Potentially this is via mechanisms including emotional regulation, non-judgemental awareness and metacognitive thought (Roth et al., 2019). As we are creating a novel, tailored intervention in this paediatric setting, this work is an important step to translating theory into clinical practice.

A further intervention development process will include delivering and interactively developing the seven-week programme, session-by-session, with eight young people and their parents. The

programme will iteratively evolve based on participants' qualitative feedback to result in a programme that is tailored to meet the needs of this population. When necessary, the guiding principles will also evolve based on participant feedback, together with the evidence base including the on-going scoping review (Iturbe, Cox, et al., 2021). To widen the diversity of the patient voice, ensuring ethnicity is considered, further diverse and inclusive PPI advisory groups will be held with the support of Obesity UK. Once developed, the intervention would enter a feasibility study and lead to a randomised study of effect.

Limitations within the methodology of this development work include having a limited number of PPI advisors who were within the target age and weight-status of the intervention. The COCO clinic is currently the only fully funded tier three service in England, and we were mindful not to overload the young people who attend this service. They had already been involved with the service review (Cox et al., 2020), another research trial not connected to this intervention (Cox, Hinton, et al., 2022) and will be involved with the in-depth session-by-session development phase of this intervention. Therefore, we sought alternative groups of people with relevant lived experience to contribute to this early PPI work.

This development paper details the integrative approach taken to establishing *AIM2Change*. With further evidence, theory and patient-led research methods iteratively contributing to the final intervention, we hope to have produced an intervention that is acceptable, effective, and adhered to when rigorously trialled.

6.7 Contribution to the thesis

In practice, many clinics and intervention programmes struggle with the recruitment and retention of young people on their programmes. For those who do sustain attendance, weight-loss is not always achieved, and when it is, it is often moderate and may not be sustained over time (Cox et al., 2022; Brown et al., 2018). By co-developing this new programme, we hope to engage with the outcomes that young people would like to see, in a way that resonates with them, improving engagement and outcomes particularly for those who are currently not losing weight within the current clinic process. Poor motivation is frequently cited as a determining factor in the lack of effect seen by interventions, however, reports frequently fail to distinguish between problems with the quantity of motivation and the quality of the motivation (Ryan & Deci, 2000). Reliance on external motivators for change may facilitate short-term change, but intrinsic motivation is considered to be higher quality and more likely to be sustained.

Self-regulation has been considered throughout this thesis. As self-regulation is considered by some approaches to be akin to energy, in that it is depleted in times of stress and overwhelm (Baumeister & Tierney, 2012). Here we look at ways to bolster self-regulation and self-determination through helping patients to develop healthy coping strategies and connect with their intrinsic motivation to find their own motivations for success. This programme intends to work to develop a patient's self-regulation and intrinsic motivation using the six core processes of ACT. These processes are defusion, self-as-context, acceptance, values, committed action and present moment attention, and are expanded on further in Box 1 below. This development work resulting in an overarching session plan being compiled, which will be iteratively developed and adapted to suit the needs of the young people at the service.

This work formed part of an NIHR RFPB grant, that has successfully been funded for 18 months, enabling the ACT programme to be co-developed with young people at the clinic. The intention would then be to run a HTA (Health Technology Assessment) trial with nested feasibility pilot with

two arms, usual MDT led care, or usual MDT led care with the addition of the ACT programme. With the opening of the 14 new CEW clinics, if effective, there is potential for this work to be adopted by these new centres.

Box 2: Acceptance and Commitment Therapy

It has been postulated that acceptance and commitment therapy may be a suitable intervention to develop self-determination, self-regulation and intrinsic motivation (Forman & Butryn, 2015; Vallis et al., 2020). Many of the core processes of ACT, overlap with the psychological requirements for achieving self-determination, intrinsic motivation, and self-regulation. In an adult weight management context, ACT focuses on developing skills to manage lifestyle changes. In a recent systematic review studying adults, ACT has been demonstrated to be effective at improving psychological wellbeing in 71.4% of the studies, improved health behaviours connected to weight management in 50% of studies, and showed physical health outcomes in 31.8% of studies (Iturbe, Echeburúa, et al., 2021). As a transdiagnostic approach, ACT will likely create a spill over effect in that the approaches can also be used to support mood disturbances and broader wellbeing (Ciarrochi et al., 2012; Harris, 2007; S. Hayes, 2009; Mata et al., 2009).

ACT as a third wave CBT seeks to reduce the impact that internal states (our mood and emotions) have on our behaviours, to help people live a 'rich, full and meaningful life' regardless of diagnosis or mood state (Harris, 2007). In this way, ACT differs from the traditional CBT approach that would seeks to challenge and change internal experiences such as thoughts and feelings. ACT supports the client to accept the presence of the internal experience and try to continue life alongside them (HaYes and Greco, 2008). The desired outcome of ACT is psychological flexibility, defined as

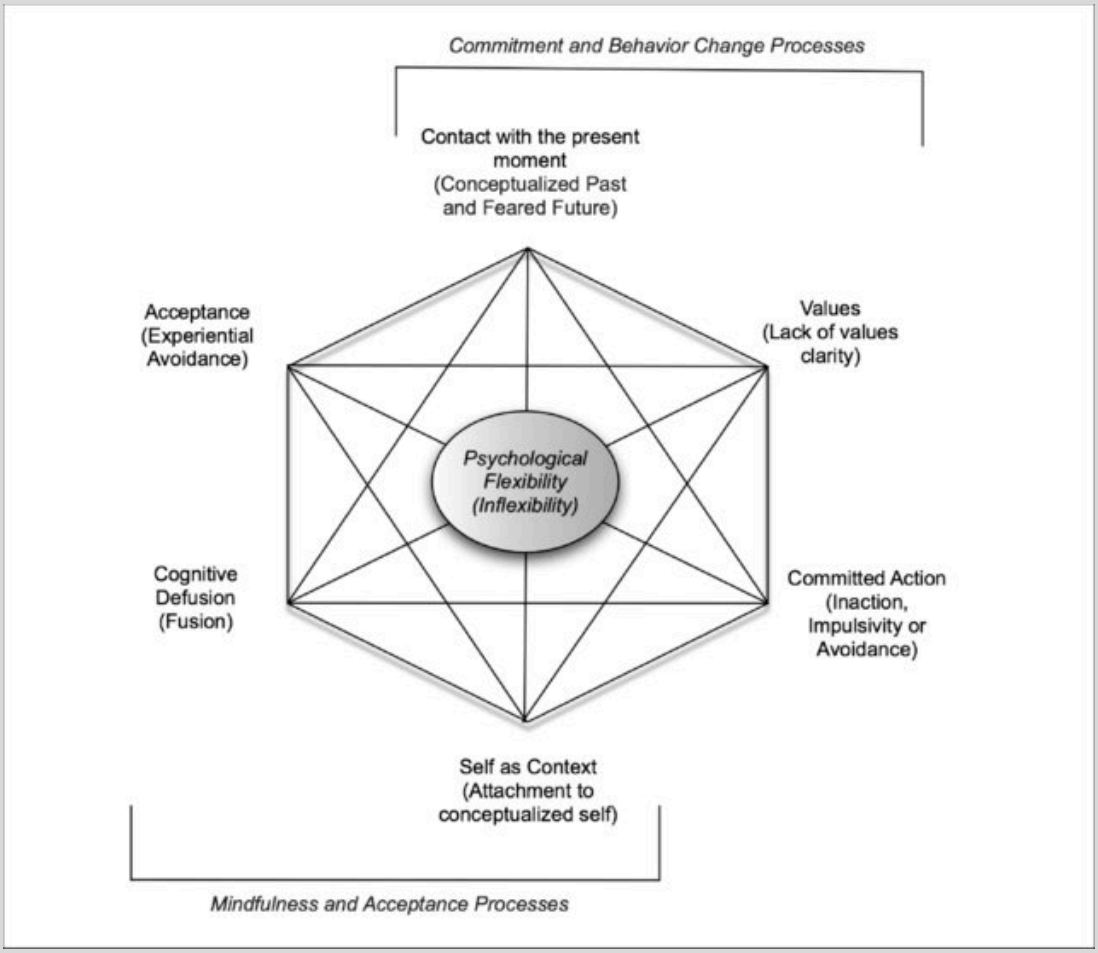
> "*how a person: (1) adapts to fluctuating situational demands, (2) reconfigures mental resources, (3) shifts perspective, and (4) balances competing desires, needs, and life domains"* (Kashdan & Rottenberg, 2010).

Psychological flexibility is therefore the fluidity in which a person adapts to the changing world around them, whilst staying true to their sense of self and their valued direction. In a weight management context, cognitive flexibility has been shown to be important to long term weight maintenance (Hall & Kahan, 2018).

The core ACT model, '*the Hexaflex*' (Figure 7.2) depicts the six-core processes by which ACT seeks to create psychological flexibility. Figure 7.2 is a version by Prevedini et al., (2011) that includes the 'inflexahex' the processes that contribute to mental ill health as the inverse. The six core processes

have been adapted for adult weight management and examples are offered below (Bailey et al., 2014; Forman & Butryn, 2016; Iturbe, Echeburúa, et al., 2021).

Figure 7.2. The Flexahex and Inflexahex (Prevedini et al., 2011)



Contact with the present moment

Beneficial in creating mindful lifestyle practices, ACT uses contact with the present moment as an anchor to prevent attention being drawn to past or future experiences that may move us away from living fully in the present moment (S. HaYes, 2009). In a weight management context, present moment contact can be beneficial for a range of processes including interoceptive awareness of appetite cues and the ability to withstand cravings or urges (Forman & Butryn, 2015).

Values

Clarification of values is a core facet of intrinsic motivation and self-regulation (Forman & Butryn, 2015), and helps to root the individuals' actions within the direction that is important for them personally, and the life outcomes they would desire. Values can be things such as living in a way that is adventurous, kind or family oriented. Values are distinct from goals, in that goals can be achieved, and new goals set, whilst values are ever present as directional guides for life-decisions (Harris,

2007). In a weight management context, values may support the decision to be active, through the life value of spending time in nature, or being a healthy person (Bailey et al., 2014).

Self-as-context

Self-as-context is the process of moving away from the self-stories that can keep us stuck, and instead seeing the self as an evolving, fluid being. In weight management, self-as-context may help us move from the rigid mindset that "I have no willpower" to seeing that in certain contexts, given the right support, willpower is a possibility (Iturbe, Pereda-Pereda, et al., 2021).

Acceptance

Acceptance practices, guide the letting go of struggles that we do not have control over, allowing us to focus attention on things that can be changed (S. C. HaYes & Masuda, 2003). In a weight management context, acceptance may be used to support an individual to acknowledge when they have slipped away from their intended behaviours, without creating a narrative of 'failure' or the 'what the hell effect' (Cochran & Tesser, 1996) that would exacerbate the problem.

Cognitive Defusion (also called deliteralization)

The process of seeing thoughts as just thoughts, and not commands to action. Defusion can support people to maintain their focus on acting in line with their values, despite self-doubting thoughts trying to derail their actions. In a weight management context, defusion could be used to support someone who's mind often provides excuses to stop them achieving their exercise goals (Bailey et al., 2014).

Committed Action

This process of self-management can involve setting goals to help guide living in line with values and holding oneself accountable for meeting the self-chosen behaviours. This is highly applicable to weight management, and often involves SMART targets (specific, meaningful, adaptive (life-enhancing, realistic and time-bound) (Harris, 2011) such as a commitment to meet a friend for a walk at the river every Tuesday afternoon for an hour.

ACT's approach also supports wider research on the psychology of eating. For example, ACT works to develop psychological flexibility which is a congruent approach to dietary approaches that support flexible, not rigid food rules, have been shown to be both more beneficial to weight loss and more sustainable (Roe & Rolls, 2020; L. Thomas, 2019). Allowing for mistakes and slip-up's decreases

pressure, stress and enables participants to realign themselves, and prevent the 'all or nothing' or 'what the hell' approaches.

Models that have developed ACT for young people, in corroboration with a key learning of this thesis, consider that adult interventions cannot be directly translated for use with young people. Specific tailored interventions are required to meet the developmental needs of children and young people (L. HaYes & Ciarrochi, 2015). There are currently versions of ACT that have been specifically developed for use with young people, including models that utilise the six-core processes (Ciarrochi et al., 2012) and new versions that have been developed specifically for use in young people such as the DNA-V model (L. HaYes & Ciarrochi, 2015). The ACT approach has been demonstrated to be useful for treating chronic pain, managing chronic illnesses including cystic fibrosis and acquired brain injury (Gauntlett-Gilbert et al., 2013; Wicksell et al., 2015) and in treating depression (Coyne et al., 2011; L. HaYes et al., 2011). However, an ACT manual for young people in a weight management context has yet to be developed.

Chapter 7: Discussion

7.1 Summary of the findings presented

This thesis has presented a background of the numerous, complex, and interwoven causes of obesity, followed by an exploration of how three interventions that have been demonstrated to be effective in laboratory settings, could translate into clinical settings. The thesis then explores the patient and their family's perspective on the current treatments they are offered at the COCO clinic, before implementing a theory-led intervention design process using the COM-B framework to propose a new intervention that may broaden and improve patient experience.

Chapter 2 details the adaptation of an existing intervention that has shown promise in adult populations. In this early-stage work, I looked to understand whether, and at what age, children had a conceptual understanding of portion size. Secondly, I explored whether that understanding extended to being able to understand portion size when represented on a computer screen. I concluded that on average, children had a concept of portion size from age 5 and could use the portion size computer tool meaningfully from age 7. The next steps for this work would be to explore how the tool could be of greatest use within a clinical weight loss setting, before further developmental work and trialling continues.

Chapter 3 contains a systematic review of eating speed interventions delivered within paediatric weight management clinics. The review concluded that whilst eating speed has theoretical support as a weight management intervention, delivery via the methods used in the papers reviewed were commonly considered to be unfeasible, with poor adherence. The review calls for enhanced child-centric design and youth involvement in research to improve adherence before further clinical trials are conducted, and also calls for research into the long-term impacts of eating speed interventions.

Chapter 4 covers a feasibility trial of an app-based inhibitory control training that was delivered within the COCO clinic. Poor adherence and retention again affected the results here, impacted by complex research processes that mean identifying whether it was the app that was unfeasible, or if the research burden was a deterrent is difficult to untangle. Inhibitory control training has the theoretical basis to support COCO clinic patients with self-regulation and food response, however further translational work is required.

Chapter 5 details a service review that was conducted in parallel with Chapters 2-4. Families whose young people were not losing weight at the clinic took part in interviews, that identified a low level of self-determination in this population. Families sought additional support from the clinical team and were struggling to make and maintain changes at home.

Chapter 6 develops from the work of Chapter 5 and sets out to develop an intervention that could raise self-determination and intrinsic motivation in the young people at the COCO clinic. This Chapter explains the developmental process of the intervention to date, including PPI work, a COM-B analysis and literature searching. The intervention developed utilises ACT as the therapeutic means to raise self-determination. Thanks to NIHR RFPB funding, this intervention will now be co-developed with patients from the COCO clinic, with the intention of running a large-scale trial once co-development is complete.

Throughout this thesis, we see the importance of self-regulation. Whilst attempts to change the global obesogenic food environment are undoubtably needed, focusing solely on this issue implies that humans are helpless to control their response to food – which is not the case for the majority of people. Strong self-regulation is shown to be protective of weight, and can enable individuals to regulate food choice, portion size and eating speed (McCrickerd, 2018). This thesis considers specific eating behaviour tools that guide self-regulation of portion size, eating speed and food choice, before considering an ACT approach that, in part, targets self-regulation via 1-2-1 therapeutic sessions. ACT offers a broad range of skills that encompass self-determination, intrinsic motivation, and emotional regulation. It may offer patients attending a tier three clinic the additional benefit of translational self-regulatory skills that may benefit eating behaviour, emotional regulation, and wellbeing more broadly.

7.2 Developing on the learnings from this thesis

All interventions tested as part of this thesis have identified findings pertinent in the future development of the planned ACT co-design.

To summarise, the learnings drawn from this thesis's chapters are as follows;

1) Interventions must work to achieve and measure both short and long-term (> 12 months) BMI change.
2) Adult interventions do not always translate neatly into interventions for children. Consequently, interventions and research protocols should be designed specifically for children, ensuring they are accessible, engaging, age-appropriate, and adhered to.
3) To address point two, patient perspective needs to be integrated from the beginning, engaging children and families with intervention development at every stage.
4) Interventions must be tailored to the developmental age of the child.
5) Psychological wellbeing is pivotal to many patients' experience of obesity, and obesity treatments need to consider the whole-person, not just the weight element within care.
6) Interventions should avoid reinforcing patterns of dependence on clinical care and instead should seek to empower patients to be agents for their own change (and support parents to empower their children and adolescents). Interventions that raise patients' sense of competency, relatability and autonomy may support behaviour change via raised self-determination.
7) Interventions should not increase pressure on parent/child relationships, and should instead support this sometimes-difficult relationship.
8) Development of open and trusting clinic relationships is important to intervention success.
9) Research processes should seek to minimise patient burden and where possible, clear distinction should be made between the intervention being trialled, and the research processes in order to make conclusions about the feasibility of the intervention itself.
10) The active components of a behaviour change intervention should be understood by using tools such as the behaviour change taxonomy.

These learnings will now be elaborated on through the next sections of this discussion.

7.3 Creating both immediate and sustained change

For patients at the COCO clinic, there are serious health implications of their excess weight meaning that effective ways to lose weight in a timely manner may be deemed medically necessary, to aid complications such as sleep apnoea or pre-diabetes (unpublished communications with clinician,

2022). In this case, the COCO clinic may offer a meal-replacement programme (reduced calorie diet) or pharmacotherapy. When beginning this PhD in 2017, a significant proportion of patients struggled to lose weight. However, the licensing of Liraglutide (a Glucagon-Like-Peptide 1 agonist) has changed outcomes. Between January 2021 and February 2022 Liraglutide injections have supported 94% of those offered this treatment at the COCO clinic to improve their BMI SDS (unpublished clinical data, 2022). This success is important for immediate patient health, whilst the intervention proposed in Chapter 6 seeks to offer a more gradual, stepwise approach to psychological mindset and behaviour change. GLP-1 therapy is time delimited and evidence currently suggests that once off therapy, patients regain weight (Davies et al., 2015; Wadden et al., 2013). Integrating ACT during pharmacotherapy could be treatment enhancing as it would lay the groundwork for effective weight maintenance after treatment. We therefore propose that the intervention could offer a suitable adjunctive treatment to interventions that create more immediate changes to BMI SDS. This would mean that tier three services offered a complete package that could enable young people to garner the health benefits of the immediate weight loss, whilst offering young people the skills to self-regulate their behaviour and eating in a way that supports the maintenance of the weight loss.

It is argued that tailored, holistic approaches that support the individuality of each patient and their circumstances, create more sustained outcomes than a one-size-fits-all approach (Vallis et al., 2020). By considering the individual's circumstance, interventions can work with, not against biology and psychology, to support long-term success. This may help patients avoid the detrimental effects of weight cycling, with associated detrimental effects on cardiac health (Montani et al., 2015) and long-term BMI (Mann et al., 2007; Neumark-Sztainer et al., 2007).

The psychology of habit change suggests that it takes on average 66 repetitions of a behaviour for it to translate from a conscious, effortful task into a habitual behaviour (Lally et al., 2010). It is therefore helpful to explain to patients that whilst implementing the change currently feels difficult, it will soon be normalised and will no longer require so much cognitive control. Initially, self-regulation is required and drawing on the importance of long-term values and motivations may be required, but through reinforcement to the level that the behaviour is habitualised, permanent lifestyle patterns can be established (Gardner et al., 2021; Lally et al., 2010; Michie et al., 2014). Achieving small behaviour changes helps to develop an individuals' feeling of competency (Santos et al., 2016), and experiencing competency further supports self-regulation (Golan & Bachner-melman, 2011), creating a positive feedback loop.

Typically, interventions have focused on prescribing changes to diet and exercise. Interestingly, recent guidelines suggest that instead, changes to diet and exercise should be considered as

outcomes and dependent variables of an intervention (Vallis et al., 2020). Interventions such as ours, that support young people to identify what and how they would like to change, become the independent variable. In this way, behaviour change becomes a marker of the immediate success of an intervention, with improved health and BMI, and sustained behaviour change as longer-term outcomes.

7.4 Developing with children, for children

When designing for the paediatric setting, it is important that interventions are tailored for the age of the child. The COCO clinic sees patients from two to eighteen. Age and developmental stage will affect the appropriateness of interventions and young people's ability to engage. Ideally, interventions should be designed specifically for young populations, or if adult interventions are being adapted, they must monitor suitability and age-appropriateness. This thesis demonstrates that problems in translation occur when adult interventions are not thoroughly adapted for a paediatric audience (Cox et al., 2022; Hamilton-Shield et al., 2014; Hinton et al., 2018). As shown in Chapter 2, preliminary work to understand how children of different ages interpret core eating behaviour concepts such as portion size are required as a fundamental stage of intervention development. As highlighted above, changes in adolescent brain development, including fundamental maturations to the pre-frontal cortex will have a large impact on young people's self-regulatory, and motivational abilities. Consequently, it is vital that interventions tailor to, and work alongside, individuals of the target age to develop interventions.

The importance of patient-led research is gathering momentum, with recent guidelines highlighting the importance of service user input on new developments and many grant applications requiring it as a condition of funding (National Institute for Health Research, 2020; UK Public Involvement Standards Deveopment Partnership, 2019). Co-development ensures interventions are appropriately targeted, meaningful to patients and delivered in a way that is both engaging and sustainable (Craig et al., 2008; O'Cathain et al., 2019). Considering the socioeconomic divide in childhood obesity rates, interventions must be careful not to inadvertently widen the gap by offering solutions that are only adhered to by certain demographics. Involving participants from a broad demographic in early development work helps to tailor interventions to meet the needs of marginalised communities (Rose, 2014). We see in some interventions, adjustments such as supporting financial costs of accessing a programme including travel and parking costs, and offering flexibility on appointment times to avoid the child missing school/parent missing work facilitated better attendance (Farnesi et al., 2019). We can see from interviews with the patients at the COCO clinic (Cox et al. 2021; secondary analysis, Chapter 6) that the travel to the clinic is time consuming, financially challenging and requires patients to take time off school. An identical therapy delivered online would remove

barriers potentially vastly increasing accessibility for all patients, particularly those living with the highest deprivation or disability. It is important to consider the broader barriers and facilitators to engagement a change can make, as to not inadvertently create different barriers (Michie et al., 2014). The outcome of our developmental piece (Chapter 6) has led to us including budget to support young people with access to tablets and internet data allowance to ensure equality of access without financial restrictions for young people without access to Wi-Fi at home, as found in similar studies (Lubans et al., 2014). PPI groups also raised the issue of privacy, if engaging in therapy within a home environment as not all young people have the privilege of private space, to which we have arranged to have private space available at the hospital, should the young person prefer this.

Utilising theory-driven models can ensure all avenues have been considered; a recent review has created a taxonomy of the 21 main approaches that can be used to guide intervention development (O'Cathain et al., 2019). The taxonomy includes six 'partnership' approaches where service users holding equal decision making to researchers, and five 'target population centred' approaches where development is based on service user views (O'Cathain et al., 2019). Many more approaches successfully integrate development processes tailoring to their specific needs (Band et al., 2017; Richards et al., 2022). With complex behavioural interventions holding so many potential mechanisms to action and factors that will affect feasibility and acceptability, these theory-based approaches offer thorough, considered approaches, and help to systemize the recommendations and changes being made.

A final consideration when designing for children is the importance of parental involvement. Before the age when children attend secondary school in the UK, much of the food environment and consumption is controlled by the family, whereas in adolescence young people take more ownership over their eating behaviours, with peer influence becoming an important factor (Andrews et al., 2021). The family functioning, including factors such as having family meals, strong communication and closeness are protective for health and support dietary and exercise choices (Berge et al., 2013; Faith et al., 2019; Smith et al., 2014). As we saw in Chapter 3, this also may support reductions in eating speed (Faith et al., 2019). However, particularly in adolescence family involvement may be counterproductive, as family dynamics may contribute to the young person's stress, and their attendance may be a perceived barrier to open communication (Lee et al., 2021). The COCO clinic typically sees patients with their caregivers, except for psychological therapy, where the young people and parents are seen separately at times. Feedback from the PPI groups (Chapter 6) demonstrated the importance of adolescent choice in whether their caregiver should be in attendance, or if they would like to bring an alternative support person or attend alone. Our currently implementation intention for the new programme is that young people with be given an

overview of the next therapy session, and they can then choose if and who they would like to support them during that session, optimising support, and young person autonomy.

7.5 Psychological wellbeing and treating the whole person

The experience of obesity can be particularly difficult during childhood and adolescence. Being an adolescent with over-weight or obesity often coincides with high rates of emotional distress, social isolation, and problems with self-esteem (Bailey et al., 2019). The type and style of intervention has been shown to influence the young person's wellbeing (Tylka et al., 2014). During the service review (Cox et al., 2021), and the PPI work conducted for Chapter 6, the importance of being seen and treated as a whole person was reiterated by patients. They understood that their, or their child's eating problems were underpinned by complex emotion experiences including grief and trauma, and that their circumstances and home environments contributed to their experience of obesity. Patients requested that these factors were considered in their treatment.

Adolescence is a critical time for the development of body image, and also a time of great changes in body image with the onset of puberty, and increasing importance of peer acceptance (Voelker et al., 2015). Body image is not considered to be a static trait but an evolving and shifting process (Markey, 2010). Body dissatisfaction, over-consumption, increasing weight and negative mood have been linked within a process of feedback loops, described as the 'circle of discontent' (Marks, 2015). Here, negative mood and body dissatisfaction are identified as causal to obesity and overeating. Whilst some consider body dissatisfaction to be a driver for change (Heinberg et al., 2004), it is a strong driver of stress and negative affect, which contribute to overeating and obesity (Wardle et al., 2001). Binge-eating was reduced in patients with obesity, as body dissatisfaction was improved. New guidelines for weight management recommend supporting a positive self-image, and positive affect that will support ability to make healthy food choices (Vallis et al., 2020). Cleverly, interventions seek to establish acceptance of the body as currently is, whilst simultaneously holding the value of health and a strong body as a driver for change. This ability to hold two seemingly contradictory thoughts as true, at the same time is a form of dialectical thinking, and has been used successful as part of dialectical behavioural therapy (DBT) another form of third-wave CBT, in treatments of obesity (Glisenti & Strodl, 2012), eating disorders (Wisniewski & Kelly, 2003) and binge eating disorder (Safer et al., 2018). Other interventions integrate this driver for change by clarifying the values that are important to how someone lives their life, and taking committed action to achieve them, as in ACT (Bailey et al., 2014; L. HaYes & Ciarrochi, 2015), or by creating vivid visual imagery of the benefits felt once the change has been achieved, as in Functional Imagery Training, an offshoot of Motivational Interviewing (MI) (McCarthy, 2019; Solbrig et al., 2018). It is therefore argued here that you do not need to drive negative body image to induce readiness to change in weight loss participants, and

that interventions that support psychological wellbeing and positive self-esteem can improve outcomes via multiple pathways.

Eating behaviour improvements have been demonstrated by therapy-based interventions, including CBT (Wilfley et al., 2011), DBT (Kamody et al., 2019) and ACT (Tronieri et al., 2019), but they also offer more generalised effects. For many of these interventions, the principals being taught can be applied more broadly to situations in the young person's life, and offer benefits including greater self-awareness, improved emotional regulation and better stress management. This offers the patients spill-over effects as 'life skills' that they can use to navigate difficult situations within their lives, helping to break the negative feedback loops that contribute to obesity. In particular, ACT takes the approach that an improvement in quality of life generally, will likely support weight management as a secondary outcome (Bailey et al., 2014).

Holistic interventions seek to improve diverse outcomes. A focus on outcomes that optimise health, rather than measuring success solely on weight is an approach that was favoured by the PPI groups approached in this work. A experience-based co-design programme that took place in a Canadian weight management clinic created a change in culture, widening the measures of success to include mental and physical health not exclusively on weight as an outcome (Green et al., 2019). This involved a cultural shift to ensure person-first language was always used, and the inclusion of measures that incorporated health and family life (Johnson et al., 2002; Epstein et al., 1983). Recent guidelines, and work from organisations such as Health at Every Size (HAES) (Bacon, 2008), and the Association for Size Diversity and Health (ASDAH, 2022) state that the focus should be on QOL, psychological wellbeing and sustained health enhancing behaviour changes, not purely on weight (Vallis et al., 2020). For the patients at the COCO, and future CEW clinics, they are attending to improve their physical health, therefore determining success based on markers of health improvement including blood pressure and diabetes management should be considered (Tylka et al., 2014).

7.6 Supportive relationships in weight management

For some patients, being prescribed weight management is a turning point for lifestyle change. The experience of attending and the advice given is enough to spur changes. In the 2009 review some patients described the stern approach of the lead clinician (JHS) as driving them on to lose weight (Owen et al., 2009). Whilst this approach works for some, including the one patient interviewed for Chapter 5 who had lost weight (unpublished), for patients who had not lost weight the stern approach was not always favoured (Cox, Searle, et al., 2021). Consequently, children's expectations

prior to attending clinic were negative and anxiety around the process was high (Bailey et al., 2019; Cox et al., 2021).

Instead, these patients warmed to the supportive approach of the clinical nurse specialist. There is evidence that demonstrating unconditional support can improve self-determination and support the generation of intrinsic motivation (Teixera et al., 2020). Unconditional regard feeds the human need for relatedness, which underpins self-determination (Ryan & Deci, 2000). This approach takes the pressure off the young person 'having' to do it 'for the doctor', which are mindsets that underpin extrinsically motivated behaviours. Fear of negative repercussions and 'telling off' may mean patients are unable to find connection to the goals and clinical aims on a level that they personally endorse. In a review of factors that influence continued attendance at paediatric weight management; families appreciated the MDT approach, feeling like all elements of the problem were being considered. It was important for families that the clinic was a positive empowering environment, where families did not feel they were being talked down to (Farnesi et al., 2019).

In paediatric care, the parent-child relationship is also critical in the success of weight-management. In the service review we see that attending the clinic and instigating changes was a point of stress and conflict amongst some families, with increase in parents 'nagging' causing further disengagement from the young people (Cox, Searle, et al., 2021). One of the only interventions demonstrating sustained reductions in childhood obesity is the HENRY programme (Rudolf et al., 2019). What makes this programme unique from other diet and lifestyle interventions, is that it is based on the Family Partnership Model, a specific approach that encourages true partnership working with families. The approach itself has demonstrated improvements to parent-child interactions and the psychological functioning the family (Willis et al., 2013).

In ACT, the therapeutic relationship with clinicians is that they travel alongside, as the client navigates the therapeutic journey. This therapeutic stance is described using the two mountains metaphor (S. C. HaYes & Masuda, 2003). For the upcoming intervention development work, I have adapted this exercise for use with both clinicians and parents simultaneously, explored as the Three mountains metaphor (Figure 7.3). It is not that parents and clinicians are telling the young person what to do, but instead using their position of relative distance from the experience to gently guide. The young person takes the responsibility for moving forward, the directions they want to take and how they want to proceed. From work I have completed with the PPI groups, this approach was considered be appropriate and compassionate to the developing autonomy of the young person.

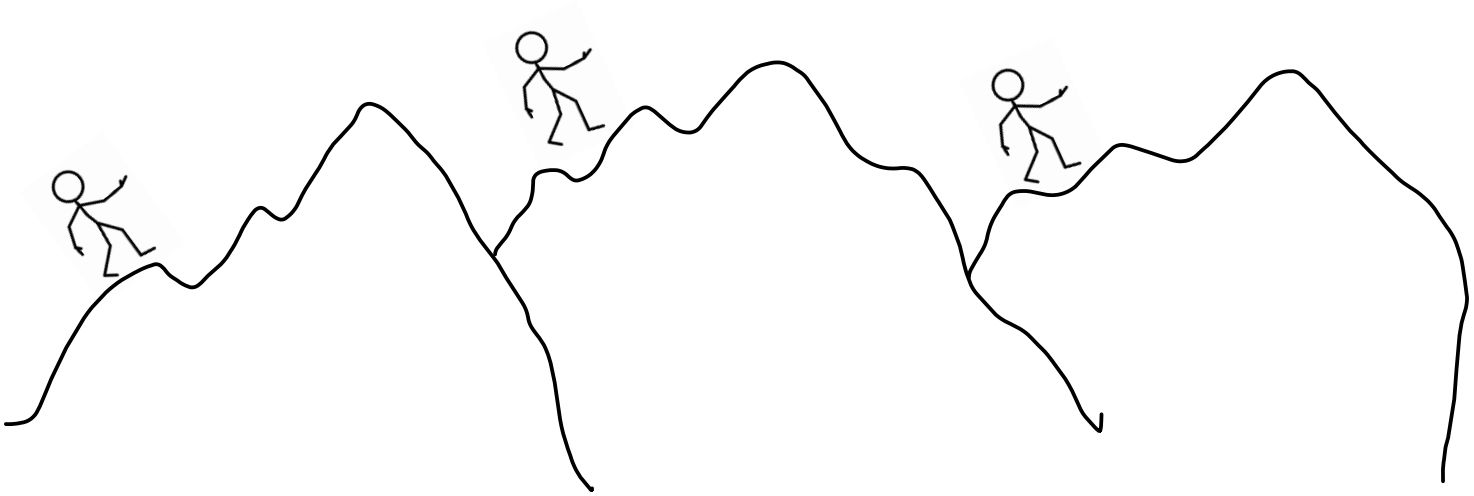


Figure 7.3. The three mountain metaphor, adapted from (Hayes & Masuda, 2003).

7.7 Self-Regulation

Conscious self-regulation is required to perform behaviours which are not automatic, habitual, or intrinsically motivated. Even for those with high levels of motivation, maintaining behaviours consistently enough to affect weight is hard. Our environment is constructed in a way that sedentary behaviour and the consumption of highly energy dense foods is the default position (Forman & Butryn, 2015). Food marketing, food access and cues to eating are prolific (Cetateanu & Jones, 2014; Fraser & Edwards, 2010; Hamano et al., 2017) and we no longer need to exert physical effort to source food (Brunstrom & Cheon, 2018). When paired with the evolutionary developed, biological drive to source and obtain food for survival, weight gain is a likely outcome unless conscious self-regulation is enacted to support motivation (Forman & Butryn, 2015). Self-regulation is considered to be the ability to adjust behaviour to attain long-term goals, not just respond to immediate needs or desires (Golan & Bachner-melman, 2011). Children with stronger self-regulation have increased ability to delay gratification, are less impulsive and less likely to emotionally eat (Mischel et al., 1989).

Self-regulation involves a process of evaluating reward hierarchy. The enacted behaviour will be in the direction that is most highly valued in that moment; whether the young person values the immediate gratification of eating the chocolate, or the long-term benefits of weight management will depend on how integrated the long-term benefits of weight management are with their sense of self. We therefore see that self-regulation is stronger in adolescents when the long-term goal is self-selected, and intrinsically meaningful (Golan & Bachner-melman, 2011). The extent of the self-regulation required in any given situation will be determined by a combination of how triggering the environment is, individual differences in the sensitivity to environmental cues and dopamine-mediated rewards, and present moment differences including hunger, tiredness and mood (McClelland et al., 2017; Vallis et al., 2020). Individual differences are thought to contribute to how some people find it easier than others to maintain a healthy weight living within an obesogenic environment (Lawrence et al., 2012).

Importantly, self-regulation is a variable trait so whilst resistance may be inherently easier for some than others, there are opportunities to strengthen the ability to withstand environmental cues (Forman & Butryn, 2015). Self-regulation develops throughout childhood (Nelson et al., 2019) and is described to function as a muscle – the more that it is enacted, the stronger the self-regulatory abilities become. It is therefore critical that children and young people are supported to practice self-regulation (Golan & Bachner-melman, 2011). There are two critical time periods for self-regulation, which develops first around 36 months taking the form of flexible self-control (McClelland et al., 2017), and advances in adolescence, paired with the development of the prefrontal cortex. As the development of the prefrontal cortex extends into young adulthood, some describe adolescence as the ages between 10 and 24 years, because of the significant role the prefrontal cortex has on the ability to self-regulate and to prioritise long-term over short-term rewards (Sawyer et al., 2018).

> *"The development of subcortical reward-regions precedes the development of the cognitive control network. As such, the regulatory abilities that would typically enable individuals to override the temptations of calorie-dense foods are still developing during adolescence, which may contribute to the poor dietary decisions typically observed within this population; adolescents consume more fast foods and refined sugars than any other age group"* (Lowe et al., 2019).

Metacognition enhances around this same period, and adolescents begin to construct clearer visions of their own self-identity and their future self. Along with this, they develop the ability to behave in line with long-term goals that are congruent with achieving their valued sense of self (McClelland et al., 2017). This delay in the maturation of the prefrontal cortex leaves adolescents susceptible to the high-reward factor of palatable foods, and the multiple cues to eating in our obesogenic food environment (Lowe et al., 2019).

There is suggestion (Forman & Butryn, 2015) that self-regulation can be improved by processes integral to ACT including;

1) Developing clarity on the values that are important, and having a clear commitment to achieving them
2) Developing skills to downgrade and tolerate craving, urges and negative emotional states (Metcalfe & Mischel, 1999)
3) Developing metacognitive awareness including, but not exclusive to, appetitive training. Metacognitive awareness can help to draw attention to potential mindless slips towards the 'default' unhealthy behaviours, and support eating in tune with our body and in line with our longer-term values (McCrickerd, 2018).

As obesogenic behaviours are often the 'default' setting, mindless engagement in processes that contribute to weight are commonplace. Raising awareness of our interoceptive hunger and fullness signals, which function to support the self-regulation of intake can be beneficial (McCarthy, 2019; Blundell et al., 2010) although not always effective (Hinton et al., 2021). Babies and young children are considered to have an innate self-regulatory mechanism that facilitates them to sufficiently meet their energy needs over the long-term, balancing across weeks or months, rather than meal-to-meal (Fomon et al., 1975). Over time, this mechanism is overridden by extrinsic drives to eat, including the portion size effect (Fisher & Kral, 2007), marketing, and environmental cues to eating (Butland et al., 2007) and the experience of eating with others (Hetherington et al., 2006). Interventions that support the maintenance of this self-regulatory process, including the growing field of intuitive eating may be critical in preventing weight gain (Thomas, 2019; Tribole & Resch, 2003). In those who are no longer attuned to their self-regulatory eating patterns, they can be supported to pay attention to interoceptive signals, and to the eating and activity decision-making process, to encourage choices in the direction of long-term reward (McCrickerd, 2018). In young people from disadvantaged backgrounds, an adaptive self-regulatory system was seen to be protective, helping them manage stress, and cope with difficult situations (Quinn & Fromme, 2010).

7.8 Next steps

None of the interventions covered in this thesis are ready for clinical practice in its current form, but each offer avenues for further research and development. In the introduction, I discussed the problem of the translational gap, whereby potentially valuable interventions that come out of successful laboratories worldwide fail to become successful clinically relevant tools because of difficulties in the translation, adaptation and adoption by patients and clinicians (Akers et al., 2010; Johnston & Moreno, 2016). The MRC framework for intervention development guides a return to the central 'core' following each intervention development stage (Skivington et al., 2021). This core encourages an emphasis on context, reconsidering theory and whether amendments need to be made to theoretical understanding, exploring areas of continued uncertainty, intervention refinement, stakeholder engagement and thought to the cost implications (Figure 1.2). It is important that for each chapter, these factors are considered before further developments are made. For each intervention, these factors will be explored (Table 7.1).

The portion size work lends itself to further exploration of its usefulness within a clinical setting. Next steps would include working closely with the MDT, in particular the dietician, to understand how patients and clinicians could see value in the portion size tool to aid eating behaviours. It is suggested that the tool could be used to hold more tangible discussions around food quantities, as an technological version of the 'carbs & cals' (Cheyette & Yello, 2013) book that would offer greater

precision however dieticians may have additional ideas for where the intervention could be beneficial. Working closely with clinical teams is considered an important facet of successful intervention translation (Akers et al., 2010; Johnston & Moreno, 2016).

The next steps for the eating speed work are to work on improved adaptations that are tailored for children and offer sustained effects. The current offerings are not well adopted by families, with considerable logistical and time factors (Hamilton-Shield et al., 2014; Hinton et al., 2018). To begin taking this forward, I would work with families to develop interventions that can be implemented easily at every meal, and that fit around the families lives, in line with behaviour change science and co-development (O'Cathain et al., 2015; Yardley, Ainsworth, et al., 2015). Potentially considering an intervention that focused on improvements in self-regulation that may help slow eating speed amongst other spill-over effects, but families will have a greater understanding of what their needs are (NICE, 2020), and the research could be led by this. There is also a gap in the literature for the translation of the laboratory-based understanding that textures slow eating, into a clinical tool (Bolhuis et al., 2014).

For the inhibitory control training app *FoodT,* future research could include trialling the app within the COCO clinic without the extensive research package, to determine whether the app is taken up, and played by patients sufficiently to warrant further development within this setting. Alternatively, co-development work could also be the next step here, utilising patient experience to guide intervention and research protocol development to optimise acceptability.

Finally, the service review work (Chapter 5) has already actioned next steps (Chapter 6), and we hope to see that ACT has the potential to raise self-determination and intrinsic motivation and self-regulation in the COCO clinic population (Forman & Butryn, 2015; Vallis et al., 2020). This work will now be taken further as along with my research team, including my supervisors, Dr Elanor Hinton, and Professor Julian Hamilton-Shield, we have been awarded an NIHR Research for Patient benefit grant. The grant will enable us to co-develop an ACT-based programme for weight loss in young people attending a Tier-Three weight management service. We will recruit eight families, who will collaborate to tailor activities, feedback on delivery, and ensure that the content is suitable to their needs. Understanding what outcomes are of most interest to the patient group, alongside the commissioned outcome of weight, will also be an important question for this early-stage work. Through co-production, outcome measures can be adopted that reflect the outcomes desired by the clinical population (Dickerson et al., 2019). Appropriate and meaningful outcome measures support engagement, satisfaction, and health outcomes.

Following this 18-month development period, we hope to apply for further funding to run a feasibility study, or a HTA trial with a nested feasibility study that could incorporate more of the CEW clinics and their patients. For this study, it will be important to understand what is being changed. In this thesis we explore several overlapping concepts. We see that acceptance and commitment therapy's aim is to develop psychological flexibility. It involves a lot of work on clarification of values, distress tolerance and metacognitive thoughts which are known to improve self-regulation, and support self-determination and the development of intrinsic motivation. It is yet to be decided which elements will be assessed during the intervention, but it hoped that ACT generates a mechanism of effect via these pathways. Another big question for future research is whether it is possible for an ACT based intervention to support the internalisation of extrinsic clinical goals and generate intrinsic motivation in currently demotivated patients by developing their self-determination. Furthermore, to explore whether this improves self-regulatory behaviour, and creates changes to diet and exercise.

Additionally, following the insightful systematic review conducted by researchers at the University of the Basque Country, Spain, I have been part of a collaborative scoping review to understand the effectiveness of ACT specifically in an adolescent context (pre-registration: (Iturbe, Cox, et al., 2021). The review is currently being written up and concludes that with just three small trials and two protocol papers, there is a lot of scope for further work to develop ACT in this area. The research so far shows promise for the feasibility and acceptability of the intervention, but few other conclusions can be made with such small numbers. None of the interventions developed a structured ACT manual, and all incorporated other therapeutic approaches alongside the ACT.

Table 7.1. Next steps guided by the MRC framework (Skivington et al., 2021).

	Portion size	**Eating speed**	**Inhibitory control**
Consider context	The context of the COCO clinic is quite specific, the intervention needs to be tailored for the specific needs of these clinicians, so it is likely that different developmental work would be required to develop the tool as a preventative intervention, or one used in Tier 2 services or schools.	The context in which the intervention is being used is within families' homes. Co-development and PPI work with families will be important to understand the contextual factors that will impact adherence.	For this intervention to work, it needs to occur with little to no MDT input because of their already busy clinic time. Recruitment would need to occur via poster/leaflet, with information to consent and download the app available in the waiting room.
Develop, refine and (re)test programme theory	The research for Chapter 2 was conducted on healthy weight young people at a primary school, it would be important to retest the portion size understanding of children with high levels of obesity, and those with neurodivergent development as this affects 23% of the COCO clinic population.	Once the intervention is developed, it will need to be tested to retest feasibility and adherence of this specific intervention. Qualitative insights from families will be important alongside quantative measures of feasibility.	In this case, programme theory would be retested at a later date. For this initial trial I would be looking to see who signed up to the app, and how much they used it, to establish whether there was sufficient patient engagement to warrant further intervention development in this context.

Engage stakeholders	Working alongside the MDT, in particular the dietician, will be vital in creating a clinical tool that has value.	Co-development with young people and their families will be key to developing a useful intervention. MDT members will have important insight into families that could benefit.	Being mindful of not overwhelming the clinic patients, PPI work would be sought from a separate group of young people with obesity.
Identify key uncertainties	Whilst I concluded that children on average have a concept of portion size from age 5, there was a lot a variance in children's responses. Further exploration into how individual differences, parenting styles and exposures affects portion size understanding would be of value.	Poor feasibility outcomes on current trials mean that whether eating speed intervention can have a positive impact on the eating behaviours of tier 3 weight management patients is unclear.	The key uncertainty is whether it is the app, or the research package that acts as a deterrent to engagement. Next steps need to separate the two.
Refine Intervention	A key refinement will be in how the tool is used, for example whether it is used within the clinical setting, or as a 'take-home' tool for patients, and this will shape the refinement required. The types of foods included may also be an important	Several iterations of the eating speed intervention will likely be necessary, evolving with patient feedback.	Intervention refinement would occur iteratively in response to patient contribution.

	refinement, to ensure the foods included are valuable and representative		
Economic Considerations	There would be considerable costs implicated in developing the tool as a 'take-home' app for patients, whilst in its current form the tool could be used within the clinic. Training and development costs must also be factored.	Depending on the intervention that is developed, there will be cost implicated for staff to deliver the intervention, the technology should it be required, and the research processes.	There would be considerable costs implicated in developing the tool as a 'take-home' app for patients, whilst in its current form the tool could be used within the clinic. Training and development costs must also be factored.

7.9 Limitations of thesis

The limitations of this thesis include the targeted approach to interventions for one paediatric weight management clinic. The service review, and interventions have all be focused around translating interventions for this specific clinic, therefore the generalisability of findings cannot be guaranteed. The COCO clinic manages patients with severe, health affecting obesity and thus different interventions and experiences may hold true for cases involving less severe obesity. However, populations outside of the COCO clinic were involved in the PPI work for the clinic, and the new grant includes work on developing a continued PPI group and steering committee from outside of the COCO population, to support the diversity of patient perspective and ensure that the intervention would be suited to the UK wide CEW clinics should feasibility be achieved.

Secondly, this thesis covers a small subsection of the global work on obesity management. This thesis deliberately focuses on psychological interventions within a paediatric tier three setting, but I acknowledge the vast array of preventative interventions, medical, biological, and pharmacological advancements in understanding and treatment, and work to change global food systems, policy and environment that this thesis does not have the capacity to explore. From the UK's foresight report presented in the introduction (Figure 1.1) (Butland et al., 2007), we see that the factors that intertwine to influence obesity are too numerous to be adequately portrayed here.

From what I now know about optimum intervention development and health psychology (Michie et al., 2014; O'Cathain et al., 2019; Yardley, Ainsworth, et al., 2015), I understand that the patient-perspective work carried out in the later stages of my PhD would potentially have been more advantageous if it had been conducted before the other interventions were enacted. All consequential intervention decisions would then have been informed by the patients lived experience, likely meaning more tailored interventions, less research waste and better patient outcomes (Michie et al., 2014; O'Cathain et al., 2019; Yardley, Ainsworth, et al., 2015). At the time, I understood the rationale behind developing Chapters 2-4 to be sufficient to take the interventions forward, and I still feel that the was sufficient support for the interventions to be pursued but in future interventions, I would enact co-development processes at an early stage to prevent some of the translational hurdles that were faced.

7.10 Conclusion

Developing tailored psychological interventions that support patients in paediatric weight management is complex. There is a biological predisposition for humans to store energy as a survival mechanism that is now juxtaposed with the obesogenic environment. Many of the factors driving up global obesity rates are out of individual control, however there is an opportunity to help individuals by strengthening their self-regulatory abilities.

I have explored interventions that support regulation of specific eating behaviours, namely portion size, eating speed and inhibitory control; all of which still offer potential in this area if the correct adaptations are made, and delivery is guided by service users. However, I see the greatest value in targeting self-regulation in a broader way, through supporting young people to integrate the healthy lifestyle advice given at the clinic with their own core values, enabling them to generate intrinsic motivation for their new lifestyle changes. Offered alongside continuously developing pharmacotherapy approaches that are seeing promising impact on young people's short-term weight management difficulties, I believe that an ACT based intervention offers the potential to be a useful adjunctive therapy that supports long term weight maintenance.

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Appendix A

Appendix A.1: Additional Data

Addition portion size data was collected using the PS tool at the early testing session as well as at the later testing session. Here, further analysis is presented using this data.

Table A.1.1 Children's portion sizes at time one and time two on the computer screen

	Age 5/6	Age 8/9	Age 10/11
Average portion size at time one (KCals)			
Meal Eaten	725 (237.5)	637.5 (368.8)	475 (275)
Mac & Cheese	725 (681.3)	787.5 (425)	475 (225)
Tomato Pasta	725 (662.5)	587.5 (312.5)	312.5 (343.8)
Average portion size at time two (KCals)			
Meal eaten	775 (268.8)	650 (787.5)	575 (425)
Mac & Cheese	912.5 (587.5)	950 (625)	725 (337.5)
Tomato Pasta	725 (887.5)	487.5 (675)	312.5 (187.5)

When asked at two different time points children of all ages show consistency in their answers. The portion sizes at the two timepoints are correlated; Age 5/6, (τ=.530, 95%CI [.298, .73], p<.001). Age 7/8, (τ=.356, 95%CI [.033, .641], p=.023). Age 10/11, (τ=.713, 95%CI [.545, .856], p=<.001); suggesting that the children are not randomly selecting their choices.

As children's self-reported hunger was a median of 4.5 points greater at the second time point, it suggests children have an understanding of a typical portion, external to current satiety levels.

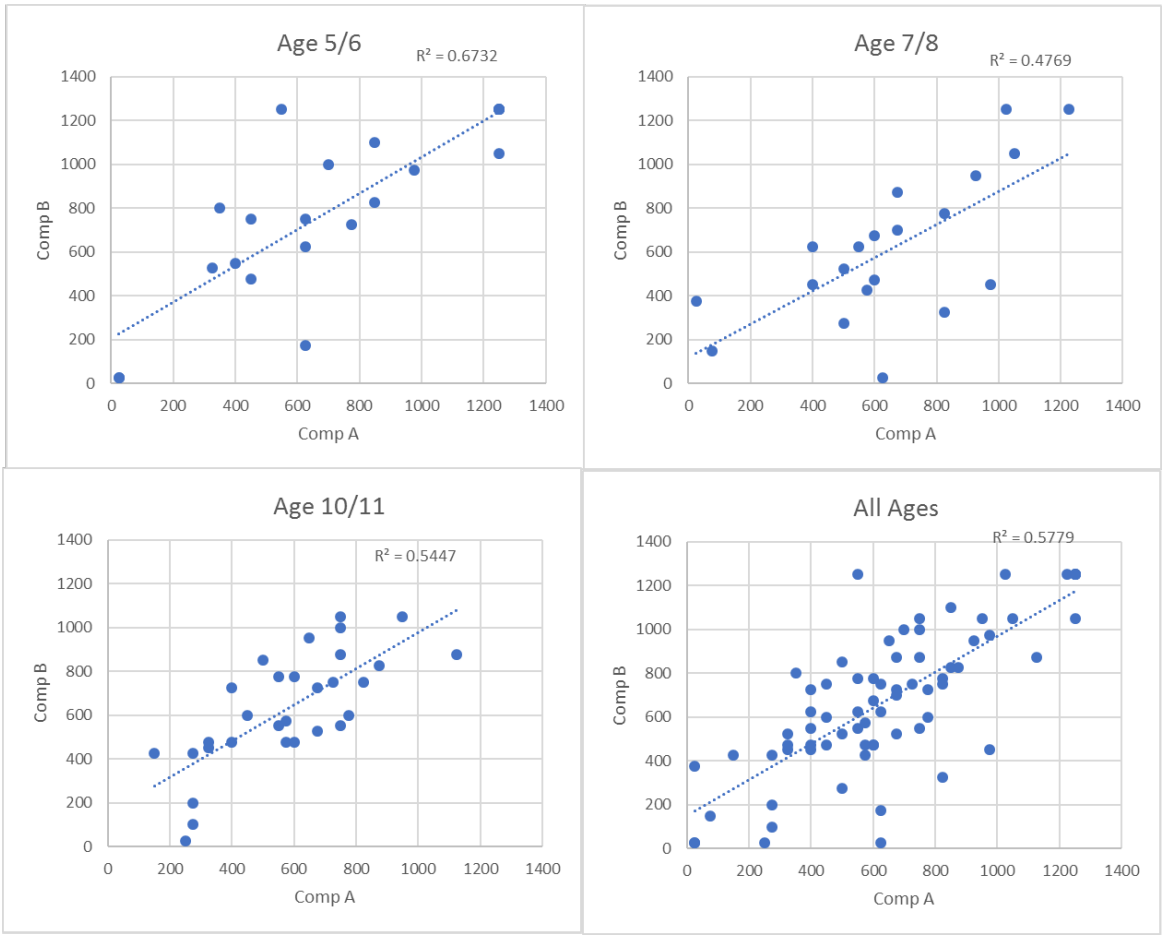


Figure A.1.1: Children's portion size choices at time one and time two.

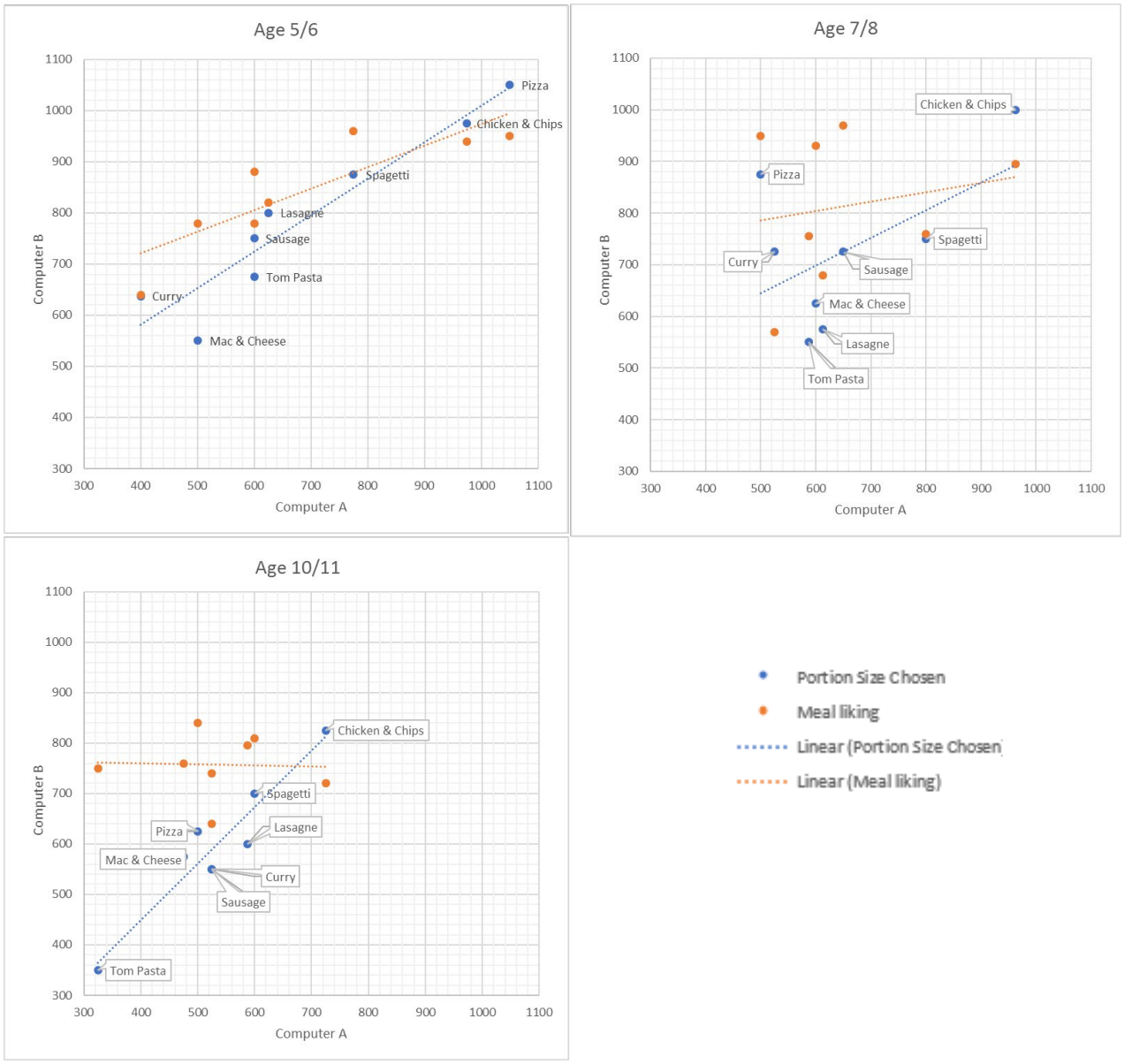


Figure A.1.2.: Median portion size and liking for each Meal at Computer A and Computer B

Appendix A.2: Ethical Approval Portion Size Study

SCHOOL OF EXPERIMENTAL PSYCHOLOGY
12a Priory Road Bristol
BS8 1TU
Telephone: (0117) 928 9000

22nd March, 2018
Miss Jennifer Cox
School of Experimental Psychology
The Priory Road Complex
Priory Road
Clifton
Bristol
BS8 1TU

Dear Miss Cox

63241 – Validation of a computerised measure of portion size for use in children

Thank you for responding to the issues raised by the ethics committee as stated in our letter dated 09.03.18. The following required changes have been made:

- Confirmation was received about the schools and charities that were being contacted for participation and the researcher agreed to inform the committee updated when more schools were included for permission of access purposes.
- Confirmation was received that the term 'healthy' would be removed, and the exclusion of children will occur only on the grounds of any allergies they may have.
- The importance of protecting those whom identified with having an eating disorder was received. Confirmation has been received that there is a statement added into the information sheets to ensure that parents are aware of the option to withhold their child's participation if they anticipate it causing them distress due to eating disorders, and an equivalent line for each of the older children's information sheets, in the case that they would like to opt out themselves.
- Confirmation was received that the word 'science' would be removed from the information sheet.
- Confirmation was received that the debrief to be addressed to all the participants, not just the parents and guardians.
- Confirmation was received that the reference to the supervisor's children was removed from the schools that they didn't attend and a additional invitation letter was created for Christ Church School and the other schools.
- Confirmation was received that the information sheet to parents would state that the researchers are DBS checked.
- Confirmation was received that the letter to parents needs to come from the researchers or the school administration and feature school letter headed paper.

SCHOOL OF EXPERIMENTAL PSYCHOLOGY
12a Priory Road Bristol
BS8 1TU
Telephone: (0117) 928 9000

Your response to the issues raised have been reviewed and approved. Your ethics approval code is **22021863241**.

Good luck with your research.

Nathan Street

Research Governance and Ethics Administrator

pp

Dr. Jonathan Evans,

Chair - Faculty of Science Human Research Ethics Committee

Appendix A.3: Participant Invite letter

SCHOOL HEADED PAPER

Dear Parents/Guardians,

Your child has been invited by researchers at the University of Bristol to take part in some research. This is an exciting opportunity to participate in a real scientific study!

We are looking at understanding eating behaviours in children, to better inform research into obesity and to do this the researchers are working on developing a simple computer game. As part of understanding if it works, the researchers would like to see if children of different ages can understand how to use it, and whether it works accurately. This game/programme could then be used in a variety of settings, such as weight-loss clinics held for children in the Bristol Royal Infirmary for Children.

Attached is a full information sheet and a consent form. We would be grateful if you could read this information and decide if you are happy for your child to take part in this research. If Yes, please sign the consent form and return to the school office by Tuesday 17th July 2018.

If you have any questions, please contact Jennifer Cox on Jennifer.cox@bristol.ac.uk who will be happy to provide further information.

Many thanks,

Appendix A.4: Information sheets

University of BRISTOL

Parent/Guardian Information Sheet **Ethical Approval Code: 22021863241**

Thinking about eating

Background

We are looking at understanding eating behaviours in children to better inform research into obesity. We are developing a new computerised tool for use in children. This research study is designed to investigate the use of this tool in children.

What will happen?

1) We will ask you child how hungry they are, on a scale.
2) Your child will be shown a picture of a meal and asked if they have ever eaten the food.
3) Then we will ask them to rate how much they like the meal on a scale
4) Your child will be asked to use the computerised tool, to choose the amount of food they would like to eat for lunch. Six different meals will be presented on screen.
5) We will take your child's height and weight, this will be done away from other children.
6) Following this, your child will be asked to serve themselves pasta and sauce / macaroni cheese and sit down to eat the meal.

On the day of the trial please give your child breakfast, snacks and drinks as usual. The children will eat their lunch with us as part of the taking part in the study (tomato pasta or macaroni cheese), and an apple.

The whole process should take about 10 minutes in the morning and then 20 minutes at lunch time.

If your child has an eating disorder and/or participation will cause them distress, please do not consent their participation. If at any point, yourself or your child no longer wants to participate in the research, or becomes uncomfortable, you can withdraw at any time without having to give a reason.

Data handling

All data will be held confidentially and kept secure by storage in line with the Data Protection Act, by the University of Bristol. Yours or your child's personal details (e.g. name, identity) will never be made public.

After the week of testing, all data collected in this study will be anonymised. There will be no record that links the data collected from you and your child with personal data from which you or your child could be identified (i.e. the signed consent form). You are free to withdraw your family's data from the study at any point on the week of testing. After that, we cannot withdraw your data because any links between your child and their responses will be removed.

Other information

(i) This study has been approved by the University of Bristol, Faculty of Science Human Research Ethics Committee
(ii) All researchers involved in this study have been DBS checked
(iii) If you have any questions about the study or would like more information, please contact Jennifer Cox on jennifer.cox@bristol.ac.uk
(iv) If you have any concerns related to your participation in this study, please direct them to the Faculty of Science Human Research Ethics Committee, via Liam McKervey (Liam.McKervey@bristol.ac.uk, 0117 928 7841)

Appendix A.5: Consent & Assent forms

School of Experimental Psychology
Jennifer Cox
Jennifer.cox@bristol.ac.uk

University of BRISTOL

CONSENT FORM – for Parents/Guardians to fill in
Thinking about Eating

Please answer the following questions to the best of your knowledge

	YES	NO
DO YOU CONFIRM THAT YOUR CHILD:		
• Is between 5 -17 years of age?	☐	☐
• Is not allergic to pasta, gluten or tomato pasta sauce?	☐	☐
• Is not a vegetarian or a vegan?	☐	☐

Please ask your child to choose ***one*** of the following options for lunch
Pasta and simple tomato pasta sauce ☐ Macaroni cheese ☐

HAVE YOU:		
• Read the information sheet explaining about the study?	☐	☐
DO YOU UNDERSTAND:		
• That you are free to withdraw your consent at any time during the data collection, and for a period of one week after your child is tested?	☐	☐
• Without having to give a reason for withdrawing?	☐	☐
• That the session will stop if your child asks or appears uncomfortable?	☐	☐

I hereby fully and freely consent to my child's participation in this study

I understand the nature and purpose of the procedures involved in this study as communicated to me on the information sheet.
I understand that the investigation is designed to promote scientific knowledge and I agree that the University of Bristol can keep and use the data my family provide for research purposes only.
I understand that the data my family provide will be kept **confidential**, and that my consent is conditional upon the University complying with its obligations under the Data Protection Act.
I understand that on completion of the study my child's data will be anonymised by removing all links between his/her name and his/her study data. This will be done **one week** following the date of collection, and before any presentation or publication of data.

Parent/Guardian signature: _____ Date: _____

Name in BLOCK Letters: _____

Child's name _____ Child's Date of Birth: _____

Future Interest

Following the completion of this research, there may be future opportunities to take part in research with us. If you would be interested in being contacted about these projects, please provide contact details here: -

Name in BLOCK Letters: _____

Email address: _____ Contact number: _____

School of Experimental Psychology
Jennifer Cox
Jennifer.cox@bristol.ac.uk

University of BRISTOL

ASSENT FORM – For your child to fill in
Thinking about Eating

	YES	NO
HAVE YOU:		
• Read the sheet about the study?	☐	☐
DO YOU UNDERSTAND:		
• The study?	☐	☐
• That you can stop at any time, if you want to?	☐	☐
• That you don't have to tell us why?	☐	☐
ARE YOU:		
• Happy to take part?	☐	☐

If you are happy to take part please fill this in with your parents/guardians at home: -

Child's Name _____

Signature: _____ Date: _____

The researcher will check that you are still happy on the day and sign here: -

Child's Name: _____

Signature: _____ Date: _____

Child's Name: _____

Participant number : _____

Age : _____

Date of Birth: _____

Gender : _____

Height : _____

Weight : _____

Hunger Scale – First session

Please put a cross on the line according to how hungry you feel right now.

Not hungry Very Hungry

When you are at home, do your parents/guardians ask you to finish everything on your plate?

Yes / No / Sometimes / Some people

More info. Given?

Pasta and tomato sauce

Have you ever eaten this food before? YES / NO

How much do you like this food?

Very much Not at all

Chicken, chips and peas

Have you ever eaten this food before? YES / NO

How much do you like this food?

Very much Not at all

Macaroni cheese

Have you ever eaten this food before? YES / NO

How much do you like this food?

Very much Not at all

Chicken Curry and Rice

Have you ever eaten this food before? YES / NO

How much do you like this food?

Very much Not at all

Pizza and chips

Have you ever eaten this food before? YES / NO

How much do you like this food?

Very much Not at all

Sausage, mash and peas

Have you ever eaten this food before? YES / NO

How much do you like this food?

Very much Not at all

Spaghetti Bolognese

Have you ever eaten this food before? YES / NO

How much do you like this food?

Very much Not at all

Lasagne

Have you ever eaten this food before? YES / NO

How much do you like this food?

Very much Not at all

Hunger Scale – Second Session

Not hungry Very Hungry

How much did you like your lunch?

Very much Not at all

Parent/Guardian Debriefing Sheet **Ethical Approval Code:22021863241**

Thinking about eating

What is the best way to measure children's portion size?

So what is this research for?

Over the last 20 years, the average portion sizes in the UK have doubled. During weight-loss clinics in the health-care setting, patients often visit a dietitian. Along with discussions of what types of food patients are eating, the dietitian will ask about how much people are eating and portion sizes. Often, we don't know the specific weight and calorie content of all the foods we eat. So in scientific research, we would often learn about a person's portion size through watching them serve and eat a meal. However, this is impractical in the real world, especially in medical settings.

The computerised tool that your child used during the study has been developed at the University of Bristol to enable us to understand more about a person's portions size. The tool has been shown to be accurate in adults and as currently 1 in 3 children leave primary school obese or overweight, and child obesity continues to rise, we think it is important to see if the tool can be of value for children. We hope that this tool will allow dietitians and doctors to give more tailored advice to people in clinic.

If your parents/guardians have any further questions, please contact:

Jennifer.cox@bristol.ac.uk and Elanor.hinton@bristol.ac.uk

Age 10-13 Debrief form **Ethical Approval Code: 22021863241**

Thinking about eating

What is the best way to measure portion size?

For you and your parents/guardians-

Over the last 20 years, the average portion size of food in the UK has doubled. When people come to hospital needing to lose weight, they will talk to the doctors and nurses about how much they are eating and their portion sizes, how much food they put on their plate at dinner time.

In laboratory studies, we would learn about a person's portion size through asking them to serve and eat a meal. This is often hard to do in the real world, especially in hospitals.

The computer tool you used today has been made, to helps us learn about the portion sizes a person chooses. The tool has been shown to be accurate in adults, and you have helped us test if it works for children and teenagers.

As currently 1 in 3 children leave primary school obese or overweight, we think it is important to make sure we can use this to help.

If you parents/guardians have any further questions, please contact:

Jennifer.cox@bristol.ac.uk and Elanor.hinton@bristol.ac.uk

Age 7-9 Debrief Form **Ethical Approval Code:22021863241**

Thinking about eating

What is the best way to measure portion size?

For You -

In science, we learn about a how much a person eats by asking them to serve and eat a meal. This is often hard to do, like in hospitals.

The computer tool you used today has been made to helps us learn about it. It works for adults, so we want to see if it works for children.

If it does, then we can look at using it to help people in hospitals to lose weight.

Thank you for helping us do these tests!

For your parents/guardians - So what is this research for?

Over the last 20 years, the average portion sizes in the UK have doubled. During weight-loss clinics in the health-care setting, patients often visit a dietitian. Along with discussions of what types of food patients are eating, the dietitian will ask about how much people are eating and portion sizes. Often, we don't know the specific weight and calorie content of all the foods we eat. So in science research, we would often learn about a person's portion size through watching them serve and eat a meal. However, this is impractical in the real world, especially in medical settings.

The computerised tool that your child used during the study has been developed at the University of Bristol to enable us to understand more about a person's portions size, allowing dietitians and doctors to give more tailored advice to people in clinic. The tool has been shown to be accurate in adults and as currently 1 in 3 children leave primary school obese or overweight, and child obesity continues to rise, we think it is important to see if the tool can be of value for children.

If you have any further questions, please contact: Jennifer.cox@bristol.ac.uk and Elanor.hinton@bristol.ac.uk

Age 5-6 Debrief Sheet **Ethical Approval Code: 22021863241**

Thinking about eating

What is the best way to measure portion size?

For you-

Why are we doing this?

In science, how much food we eat is important.

The computer game you used today helps us know about how much a person eats.

Thank you for helping us see if it works!

For your parents/guardians- So what is this research for?

Over the last 20 years, the average portion sizes in the UK have doubled. During weight-loss clinics in the health-care setting, patients often visit a dietitian. Along with discussions of what types of food patients are eating, the dietitian will ask about how much people are eating and portion sizes. Often, we don't know the specific weight and calorie content of all the foods we eat. So in science research, we would often learn about a person's portion size through watching them serve and eat a meal. However, this is impractical in the real world, especially in medical settings.

The computerised tool that your child used during the study has been developed at the University of Bristol to enable us to understand more about a person's portions size, allowing dietitians and doctors to give more tailored advice to people in clinic. The tool has been shown to be accurate in adults and as currently 1 in 3 children leave primary school obese or overweight, and child obesity continues to rise, we think it is important to see if the tool can be of value for children.

If you have any further questions, please contact:

Jennifer.cox@bristol.ac.uk and Elanor.hinton@bristol.ac.uk

Appendix B.

Appendix B.1 – PRISMA Checklist 2020

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	See below
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	4, 5 & 6
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	6
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	6 & 7
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	8
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix B
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	8 & 9
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	8 & 9
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	7 & Appendix B
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	7 & Appendix B
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	9
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	9
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	8,9
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	8

Section and Topic	Item #	Checklist item	Location where item is reported
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	8,9
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	9
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	9
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Fig 1
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Appendix D
Study characteristics	17	Cite each included study and present its characteristics.	14, 15, 16
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	25 - 29
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	25 - 29
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	25- 29
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Fig 2 & Fig 5
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	17
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	25 - 28
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	30
	23b	Discuss any limitations of the evidence included in the review.	33
	23c	Discuss any limitations of the review processes used.	33
	23d	Discuss implications of the results for practice, policy, and future research.	35
OTHER INFORMATION			
Registration and	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	2 & 6

Section and Topic	Item #	Checklist item	Location where item is reported
protocol	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	6
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	34
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	35
Competing interests	26	Declare any competing interests of review authors.	35
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	35

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Appendix B.2: PRISMA-S Checklist

Section/topic	#	Checklist item	Location(s) Reported
INFORMATION SOURCES AND METHODS			
Database name	1	Name each individual database searched, stating the platform for each.	8
Multi-database searching	2	If databases were searched simultaneously on a single platform, state the name of the platform, listing all of the databases searched.	8
Study registries	3	List any study registries searched.	8
Online resources and browsing	4	Describe any online or print source purposefully searched or browsed (e.g., tables of contents, print conference proceedings, web sites), and how this was done.	8
Citation searching	5	Indicate whether cited references or citing references were examined, and describe any methods used for locating cited/citing references (e.g., browsing reference lists, using a citation index, setting up email alerts for references citing included studies).	8
Contacts	6	Indicate whether additional studies or data were sought by contacting authors, experts, manufacturers, or others.	8
Other methods	7	Describe any additional information sources or search methods used.	8
SEARCH STRATEGIES			
Full search strategies	8	Include the search strategies for each database and information source, copied and pasted exactly as run.	Appendix B for the OVID search strategy
Limits and restrictions	9	Specify that no limits were used, or describe any limits or restrictions applied to a search (e.g., date or time period, language, study design) and provide justification for their use.	6
Search filters	10	Indicate whether published search filters were used (as originally designed or modified), and if so, cite the filter(s) used.	N/A

Prior work	11	Indicate when search strategies from other literature reviews were adapted or reused for a substantive part or all of the search, citing the previous review(s).	N/A
Updates	12	Report the methods used to update the search(es) (e.g., rerunning searches, email alerts).	N/A
Dates of searches	13	For each search strategy, provide the date when the last search occurred.	8
PEER REVIEW			
Peer review	14	Describe any search peer review process.	N/A
MANAGING RECORDS			
Total Records	15	Document the total number of records identified from each database and other information sources.	Figure 1
Deduplication	16	Describe the processes and any software used to deduplicate records from multiple database searches and other information sources.	8

PRISMA-S: An Extension to the PRISMA Statement for Reporting Literature Searches in Systematic Reviews
Rethlefsen ML, Kirtley S, Waffenschmidt S, Ayala AP, Moher D, Page MJ, Koffel JB, PRISMA-S Group.
Last updated February 27, 2020.

Appendix B.3: PRISMA 2020 for Abstracts Checklist (Page et al., 2021)

Section and Topic	Item #	Checklist item	Reported (Yes/No)
TITLE			
Title	1	Identify the report as a systematic review.	Yes
BACKGROUND			
Objectives	2	Provide an explicit statement of the main objective(s) or question(s) the review addresses.	Yes
METHODS			
Eligibility criteria	3	Specify the inclusion and exclusion criteria for the review.	Yes
Information sources	4	Specify the information sources (e.g. databases, registers) used to identify studies and the date when each was last searched.	Yes
Risk of bias	5	Specify the methods used to assess risk of bias in the included studies.	Yes
Synthesis of results	6	Specify the methods used to present and synthesise results.	Yes
RESULTS			
Included studies	7	Give the total number of included studies and participants and summarise relevant characteristics of studies.	Yes
Synthesis of results	8	Present results for main outcomes, preferably indicating the number of included studies and participants for each. If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (i.e. which group is favoured).	Yes
DISCUSSION			
Limitations of evidence	9	Provide a brief summary of the limitations of the evidence included in the review (e.g. study risk of bias, inconsistency and imprecision).	Yes
Interpretation	10	Provide a general interpretation of the results and important implications.	Yes
OTHER			
Funding	11	Specify the primary source of funding for the review.	Yes
Registration	12	Provide the register name and registration number.	Yes

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Appendix B.4 – Search Strategy from OVID

1. ((Chew* or bite* or Eat* or meal or food or oral-process* or intake) adj2 (speed or pace or slow* or behav* or rate or duration or size or frequency or min* or attentive* or focus* or curve)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
2. 2. (child* or paediatric* or pediatric* or adolesce* or teen* or youth or infant or boy* or girl*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3. 3. ((child* or paediatric* or pediatric* or adolesce* or teen* or youth or infant or boy* or girl*) not (woman or women or man or men or adult or pregnan* or maternal or gestation* or fetal or rat or mouse or animal)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
4. 4. 1 and 2
5. 5. 1 and 3
6. 6. (Interven* or adjust* or adapt* or modif* or manipulate* or monitor or reduc* or retrain* or treat* or slow or normali* mandolean* or manometer or hapifork or "smart fork" or "bite counter" or "mindful eat*" or "mindful-eat*" or texture or consistency).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7. 7. 1 and 3 and 6
8. 8. (hospit* or clinic* or patient* or "health care" or "primary care" or "secondary care" or doctor or nurse or consultant or dietician).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
9. 9. 1 and 3 and 6 and 8
10. 10. (overweight or obes* or BMI* or "body weight" or "metabolic syndrome" or "metabolic disorder" or "body fat" or "fat mass" or "adipose" or "waist-hip" or "waist circumference" or "abdominal fat").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept

word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

11. 11. ((overweight or obes* or BMI* or "body weight" or "metabolic syndrome" or "metabolic disorder" or "body fat" or "fat mass" or "adipose" or "waist-hip" or "waist circumference" or "abdominal fat") not (anorex* or bulima* or underweight)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
12. 12. 1 and 3 and 6 and 8 and 11
13. 13. remove duplicates from 12

Appendix B.5: Mandometer/lean access details

Mandometer devices can be accessed for research studies through Mandometer AB, S-141 04 Huddinge +46 8 556 406 00 info@mandometer.com.

Appendix B.6: Details of excluded full-text articles

No.	First author	Year	Title	Reason for exclusion
1	Skjåkødegård, HF	2016	Study Protocol: A randomized controlled trial evaluating the effect of family-based behavioral treatment of childhood and adolescent obesity–The FABO-study	Intervention does not involve eating rate
2	Rigondet, R	2019	An innovative family and home-based intervention for the prevention and management of pediatric obesity: The ProxOB program	Intervention does not involve eating rate
3	Ramalho, S	2018	APOLO-Teens, a web-based intervention for treatment-seeking adolescents with overweight or obesity: study protocol and baseline characterization of a Portuguese sample	Intervention does not involve eating rate
4	Saelens, BE	2002	Behavioral Weight Control for OverweightAdolescents Initiated in Primary Care	Intervention does not involve eating rate
5	Warschburger, P	2001	Conceptualisation and evaluation of a cognitive-behavioural training programme for children and adolescents with obesity	Intervention does not involve eating rate
6	Njardvik, U	2018	Incorporating Appetite Awareness Training Within Family-Based Behavioral Treatment of Pediatric Obesity: A Randomized Controlled Pilot Study	Intervention does not involve eating rate
7	Henes, ST	2010	Medical nutrition therapy for overweight youth in their medical home: The KIDPOWER experience	Intervention does not involve eating rate
8	Wald, ER	2011	Treating Childhood Obesity in Primary Care	Intervention does not involve eating rate
9	Hilbert, A	2020	Cognitive-Behavioral Therapy for Adolescents with an Age-Adapted Diagnosis of Binge-Eating Disorder: A Randomized Clinical Trial	Intervention does not involve eating rate
10	Chirita-Emandi, A	2014	Outcomes of Neurofeedback Training in Childhood Obesity Management: A Pilot Study	Intervention does not involve eating rate
11	Fiechtner, L	2018	Rationale and design of the Clinic and Community Approaches to Healthy Weight Randomized Trial	Intervention does not involve eating rate
12	Martinez-Gomez, D	2009	Design and evaluation of a treatment programme for Spanish adolescents with overweight and obesity. The EVASYON Study	Intervention does not involve eating rate
13	López-Alarcón, M	2020	Mindfulness affects stress, ghrelin, and BMI of obese children: a clinical trial	Intervention does not involve eating rate

14	Robertson, W	2011	Two-year follow-up of the Families for Health' programme for the treatment of childhood obesity	Intervention does not involve eating rate
15	Dreimane, D	2007	Feasibility of a hospital-based, family-centered intervention to reduce weight gain in overweight children and adolescents	Intervention does not involve eating rate
16	Smith, KL	2015	Do Overweight Adolescents Adhere to Dietary Intervention Messages? Twelve-Month Detailed Dietary Outcomes from Curtin University's Activity, Food and Attitudes Program	Intervention does not involve eating rate
17	Myers, ML	2018	Case study: behavior changes in the family-focused obesity prevention HOME Plus program	Intervention does not involve eating rate
18	Serra-Paya, N	2015	Effectiveness of a Multi-Component Intervention for Overweight and Obese Children (Nereu Program): a Randomized Controlled Trial	Intervention does not involve eating rate
19	Looney, SM	2014	Examining the effect of three low-intensity pediatric obesity interventions: a pilot randomized controlled trial	Intervention does not involve eating rate
20	Robinson, TN	2013	Family, community and clinic collaboration to treat overweight and obese children: stanford GOALS-A randomized controlled trial of a three-year, multi-component, multi-level, multi-setting intervention	Intervention does not involve eating rate
21	O'Connor, TM	2011	Feasibility of an obesity intervention for paediatric primary care targeting parenting and children: helping HAND	Intervention does not involve eating rate
22	Weyhreter, H	2003	Evaluation of an outpatient treatment program for obese children and adolescents	Intervention does not involve eating rate
23	Lallemand-Jander, D	2014	Beneficial Effects of Family-Based Multiprofessional Therapy on Obesity and Eating Behavior in Children Are Independent on Group or Individual Settings	Intervention does not involve eating rate
24	Berge, JM	2016	Family Matters Intervention: a Three-Arm Superiority RCT	Not yet recruiting when review conducted
25	Slyper, AH	2014	Increased hunger and speed of eating in obese children and adolescents	Not an intervention
26	Wake, M	2016	Let's Nudge: pilot randomised trial for a nudge-based obesity intervention in the home for children presenting to paediatricians	Trial registration only, no published works
27	Buchter, D	2017	Does a health information technology developed by children and their parents improve obesity therapie?	Intervention does not involve eating rate
28	Dominique Durrer	2015	Ambulatory health information system for obesity prevention and treatment (pathmate) tailored for teenagers: A preliminary longitudinal study	Intervention does not involve eating rate

29	Vanessa A	2009	A randomised controlled trial of a community-based healthy lifestyle program for overweight and obese adolescents: The Loozit study protocol	Study protocol, no trial information found

Appendix C

Appendix C.1: Ethical approval letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Miss Jennifer Cox
PhD student
University of Bristol
NIHR Bristol Biomedical Research Centre Nutrition Theme
3rd Floor, Education & Research Centre
Upper Maudlin Street
BS2 8AE

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

08 November 2018

Dear Miss Cox

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**A feasibility study exploring patient perceptions of a paediatric weight-management programme, and the suitability of introducing a response inhibition training app to the treatment programme**
IRAS project ID:	**242624**
Protocol number:	**2964**
REC reference:	**18/SC/0471**
Sponsor	**University of Bristol**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales? You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in

the “*summary of assessment*” section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a ‘green light’ email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?

You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Dr Birgit Whitman
Tel: 0117 331 7130
Email: birgit.whitman@bristol.ac.uk

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **242624**. Please quote this on all correspondence.

Yours sincerely

Kevin Ahmed
Assessor

Telephone: 0207 104 8171

Copy to: *Dr Birgit Whitman, Sponsor Contact, University of Bristol*
Ms Diana Benton, R&D Contact, University Hospitals Bristol

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Covering letter on headed paper [Response to REC comments]	Version 1	11 October 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Non-NHS Sponsor Evidence of Insurance/Indemnity]	Version 2	03 August 2018
GP/consultant information sheets or letters [GP letter]	Version 1	03 October 2018
GP/consultant information sheets or letters [Clinical sign-up sheets]	Version 1	18 June 2018
Interview schedules or topic guides for participants [Interview Schedules]	Version 1	18 June 2018
Interview schedules or topic guides for participants [Adolescent - Clinical Service Review topic guide]	Version 1	18 June 2018
Interview schedules or topic guides for participants [Children - Clinical Service Review]	Version 1	18 June 2018
Interview schedules or topic guides for participants [Clinical staff Interviews]	Version 1	18 June 2018
Interview schedules or topic guides for participants [Clinical Service Review Children]	Version 1	18 June 2018
Interview schedules or topic guides for participants [Clinical Service Review, Parent/guardian]	Version 1	18 June 2018
IRAS Application Form [IRAS_Form_22082018]		22 August 2018
Letter from funder [Letter from funder]	Version 1	17 July 2018
Letters of invitation to participant [Letter of Invitation]	Version 2	02 October 2018
Letters of invitation to participant [Schools invitation letter]	Version 1	01 October 2018
Letters of invitation to participant [Invite letter 16+]	Version 2	02 October 2018
Non-validated questionnaire [Pre-Trial Questionnaire Children]	1	18 June 2018
Non-validated questionnaire [Pre-trial Questionnaire Adolescents]	Version 1	18 June 2018
Non-validated questionnaire [Post-Intervention Questionnaire Adolescents]	Version 1	18 June 2018
Non-validated questionnaire [Post-Intervention Questionnaire child]	Version 1	18 June 2018
Non-validated questionnaire [Pre-trial Questionnaire Parents / guardians]	Version 1	18 June 2018
Non-validated questionnaire [Post-Intervention Questionnaire - Parents / Guardians]	Version 1	18 June 2018
Non-validated questionnaire [Clinical Staff Post-trial Questionnaire]	Version 1	18 June 2018
Participant consent form [Assent Form- -16]	Version 2	04 October 2018
Participant consent form [Consent Clinical Staff]	Version 2	04 October 2018
Participant consent form [Consent form Parent / Guardian]	Version 2	04 October 2018
Participant consent form [Consent Form 16+]	Version 2	01 October 2018
Participant information sheet (PIS) [PIS School involvement]	Version 1	18 June 2018
Participant information sheet (PIS) [Information on Downloading the app]	Version 1	18 June 2018
Participant information sheet (PIS) [Adolescent (11-15) Participant Information Sheet]	Version 2	01 October 2018
Participant information sheet (PIS) [PIS 16 +]	Version 2	01 October 2018
Participant information sheet (PIS) [Clinical Staff Participant Information Sheet]	Version 2	01 October 2018
Participant information sheet (PIS) [Parent/ Guardian Participant	Version 2	01 October 2018

Information Sheet]		
Participant information sheet (PIS) [Child Participant Information Sheet]	Version 2	01 October 2018
Research protocol or project proposal [Protocol and Flowchart]	Version 1	18 June 2018
Summary CV for Chief Investigator (CI) [PI CV]	Version 1	01 August 2018
Summary CV for student [CV student]	Version 1	01 August 2018
Summary CV for supervisor (student research) [Supervisor CV]	Version 1	01 August 2018
Validated questionnaire [Child Pre-trial Measures]	Version 1	18 June 2018
Validated questionnaire [Pre-trial Parent Measures]	Version 1	18 June 2018

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	This is a non-commercial single site study taking place in the NHS. Although no Joint Research Office arrangements exist between the NHS organisation and associated academic Sponsor, it has been agreed that no study agreement or Statement of Activities is required.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	External study funding has been secured from a GW4 MRC doctoral training programme.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments

Section	Assessment Criteria	Compliant with Standards	Comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
If this study is subsequently extended to other NHS organisation(s) in England or Wales, an amendment should be submitted, with a Statement of Activities and Schedule of Events for the newly participating NHS organisation(s) in England or Wales. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS, the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Principal Investigator should be appointed at study sites. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in A18 or A19 of the IRAS form would be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

Feasibility Trial in Paediatric Weight-Management

Researcher: Jennifer Cox Jennifer.cox@bristol.ac.uk

IRAS ID: 242624

Sponsorship Study Number: 2964

Participant Number:

Parent / Guardian Information Sheet

You and your child are invited to take part in a research trial being run by the University of Bristol, the University of Exeter and the COCO clinic in the Bristol Royal Hospital for Children. Next time you are in clinic you can meet with the researcher who can give you some more details.

What is the research about?

The research is looking at introducing a new app for your child to use between appointments. The app is a healthy eating app, for use on smartphones, iPads and tablets, called "**FoodT**".

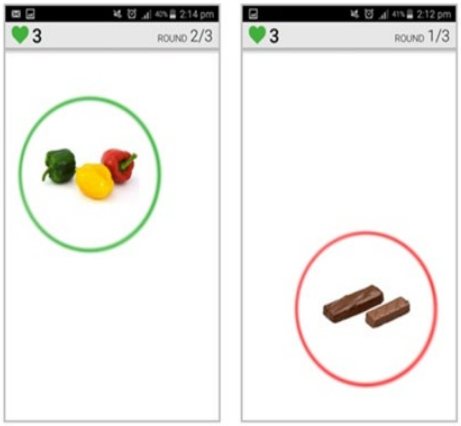
We have done some research that shows that the FoodT app may help people to eat less of foods that are high in fat, salt and sugar. So far, we've tried it with adults and found that it helped them **lose weight**.

We would like to understand if:

- Food T is a **useful** addition to the support you and your child get from the weight-management clinic
- If FoodT is something your child has the **time** to do in their daily life
- If FoodT is something they **don't mind** doing

We are asking your child to play the game at home, then inviting you both to tell us what you think by taking part in questionnaires or interviews with us.

All research will take part at the same time as your appointments, you will not need to come to the clinic any additional times.



How do you play the app?

The app contains a simple brain training game. It will show pictures, one by one. When there is a **green** circle around the picture, the aim is to **tap it as quickly as possible.** When there is a **red** circle around the picture, **try not to tap it.**
Information of how to download and play the FoodT app will be provided at your next clinic appointment, should you want to take part. You can download the app onto your smartphone/iPad/tablet and use the app at home or when you are out-and-about.

What are the benefits?

Based on evidence from previous work with this app, there is a chance that the app will support your child with making healthy food choices, that may lead to weight loss.

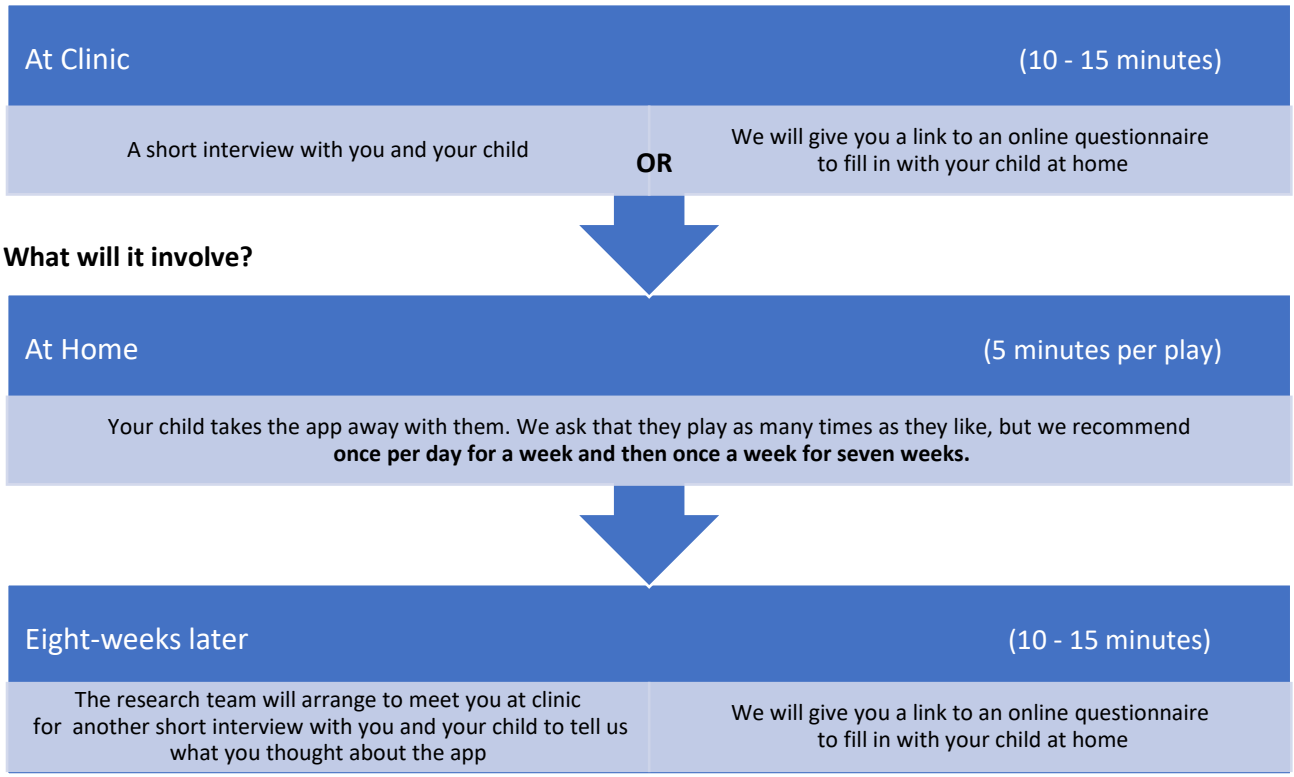
What are the potential disadvantages?

Based on research so far, there is no evidence that playing this app is a risk of any kind. However, the training will take up more time that the standard clinic appointments alone and may not be effective for your child.
In less than 1 in 1000 people, the training increased food cravings. If you or your child notice an increase in cravings, we will advise you to stop the training immediately.

Expenses / Payment

To compensate for you and your families time, we will offer a £5 Amazon voucher for each questionnaire filled in or a £10 Amazon voucher for each interview that is participated in.

These vouchers can be allocated to parent and child if both take part.



What will it involve?

Do we have to take part? What if I start but decide I do not want to carry on?

No, you do not need to take part, it is your choice to take part and you can stop taking part at any time without explaining why. The decision to not be involved in the trial does not affect your child's usual treatment. Choosing to stop taking part will prevent further data being submitted. The data that has been collected by the app, up to this point may have already been analysed, but your data from questionnaires and interviews may be removed from the trial.

If your child no longer wants to take part, you may continue to answer our questionnaires/interviews. You may also decline to take part, whilst your child chooses to carry on with the study.

Who can give consent to participating?

If your child is 16 or over, they can give their own consent to take part in the research. The forms to fill out will be given to them in the clinic at the next appointment.

If your child is aged 15 or younger, you as parents/guardians will need to give consent to them taking part in this research. The forms to fill out will be given out in the clinic at your child's next appointment. These will need to be completed by a legal parent or guardian.

We will also ask your child to sign an assent form to let us know that they are also happy to take part. Without both of these forms, we will not begin the research with your child, but you may take part in the interviews/questionnaires.

What happens to my data?

- Everything you say in interviews, on questionnaires, and the data received from the app will be stored and analysed anonymously.
- The information will be stored using a user number given to you to protect your identity.
- All the information will be kept securely within University of Bristol and the University of Exeter.
- Whenever your child completes a round of the FoodT app, your scores, and answers to the questions will automatically be sent to the University of Exeter.
- Any interviews you take part in with us will be recorded and stored until the information is transcribed by a member of the research team. The recordings will then be destroyed, and a written copy of the interview stored.
- The findings of the study will be published in an academic journal and used as part of a PhD thesis.
- The anonymous data will be made available to other research teams, which may be used for purposes not related to this study, however, it will not be possible to identify you from this data.

NB/ If during the research, information is shared that would be considered a safeguarding or medical concern, this information will be shared with the clinical team to ensure your families safety.

How does this fit in with GDPR?

The University of Bristol is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Bristol will keep non-identifiable research data you provide for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the Information Governance Manager at data-protection@bristol.ac.uk.

The research team will collect information from you for this research study in accordance with our instructions.

The NHS clinical team only, not the researchers, will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Individuals from The University of Bristol and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in The University of Bristol who will have access to information that identifies you will be people who need to contact you or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. The University of Bristol will keep identifiable information about you from this study for 1 year after the study has finished.

When you agree to take part in a research study, information collected related to the research be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research**.**

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Funding

This study is being funded by the GW4 biomedical doctoral training programme and has been reviewed by senior academics within the University of Bristol and the University of Exeter and the NIHR's young person's advisory group for research.

Ethics

Ethical Approval has been granted by South Central – Berkshire B Research Ethic Committee.

If you have any questions or concerns about the study, please contact the principal investigator Jennifer Cox at Jennifer.cox@bristol.ac.uk

or speak to a member of the team at your next clinic appointment.

Feasibility Trial in Paediatric Weight-Management

Researcher: Jennifer Cox Jennifer.cox@bristol.ac.uk

IRAS ID: 242624

Sponsorship Study Number: 2964

Participant Number:

Young Person (16+) Information Sheet

You are invited to take part in a research trial being run by the University of Bristol, the University of Exeter and the COCO clinic in the Bristol Royal Infirmary for Children. Next time you are in clinic you can meet with the researcher who can give you some more details.

What is the research about?

The research is looking at a new healthy eating app, for use on smartphones, iPads and tablets, called "**FoodT**".

We have done some research that shows that the FoodT app may help people to eat less of foods that are high in fat, salt and sugar. So far, we've tried it with adults and found that it helped them **lose weight**.

We would like to understand if:

- Food T is a **useful** addition to the support you get from the weight-management clinic
- If FoodT is something you have the **time** to do in your daily life
- If FoodT is something you **don't mind** doing

We are asking you to play the game at home, then tell us what you think by taking part in questionnaires or interviews with us. Taking part will not affect the rest of your treatment in the clinic. All research will take part at the same time as your appointments, you will not need to come in for any additional time.

How do you play the app?

The app contains a simple brain training game. It will show you pictures, one by one. When there is a **green** circle around the picture, you should **tap it as quickly as possible.** When there is a **red** circle around the picture, **try not to tap it.**

Information of how to download and play the FoodT app will be provided at your next clinic appointment, should you want to take part. You can download the app onto

your smartphone/iPad/tablet and use the app at home or when you are out-and-about.

What are the benefits?

Based on evidence from previous work with this app, there is a chance that the app will support you with making healthy food choices, that may lead to weight loss.

What are the potential disadvantages?

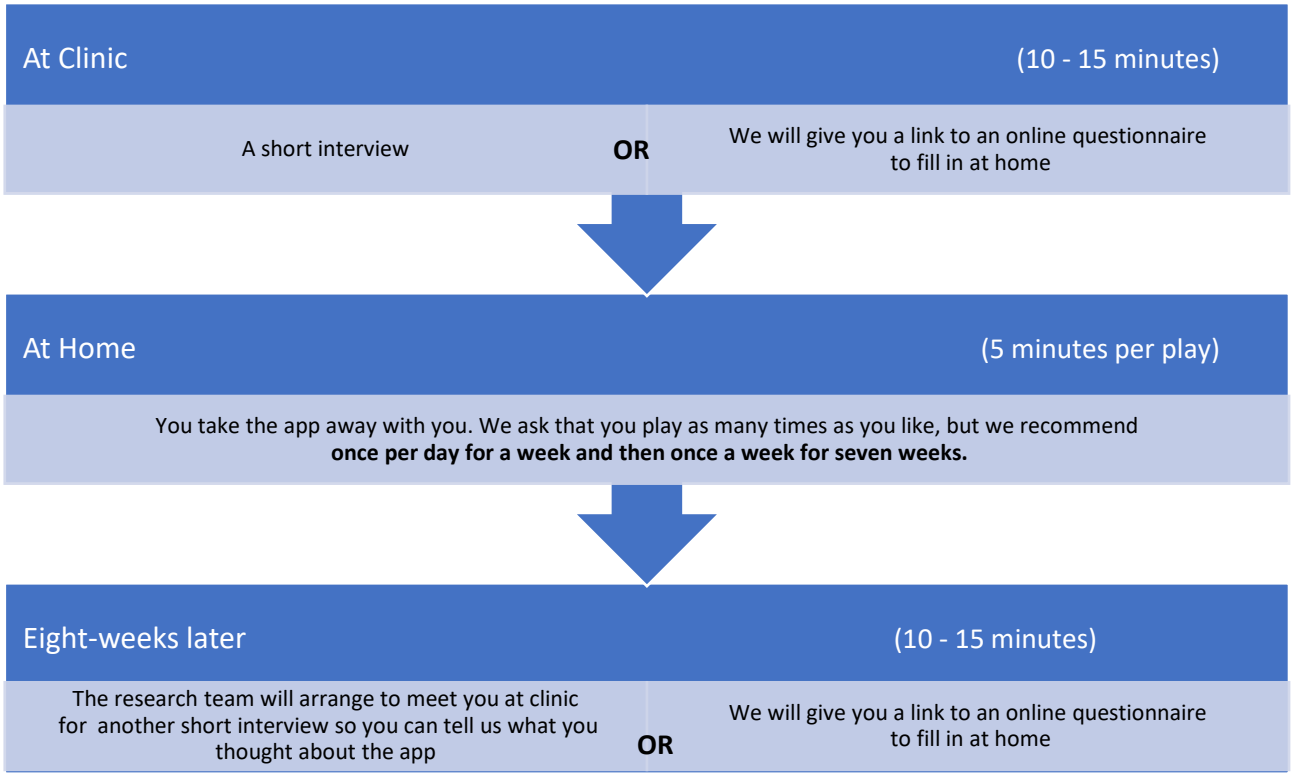
Based on research so far, there is no evidence that playing this app is a risk of any kind. However, the training will take more time that standard clinic appointments alone and may not be effective for you. In less than 1 in 1000 people, the training increased food cravings. If you notice an increase in cravings, we will advise you to stop the training immediately.

Expenses / Payment

To compensate for yours and your families time, we will offer a £5 Amazon voucher for each questionnaire filled in or a £10 Amazon voucher for each interview that is participated in.

These vouchers can be allocated to you and your parent if both of you take part.

What will the whole research process look like?



Do I have to take part? What if I start but decide I do not want to carry on?

No, you do not need to take part, it is your choice to take part and you can stop taking part at any time without explaining why. The decision to not be involved in the trial does not affect your usual treatment. Choosing to stop taking part will prevent further data being submitted. The data that has been collected by the app, up to this point may have already been analysed, but your data from questionnaires and interviews may be removed from the trial.

Who can give consent to participating?

As you are 16 or over, you can give your own consent to take part in the research. The forms to fill out will be given to you in the clinic at your next appointment. It is still a good idea to let your parents know that you are taking part in the research, so do show them the attached letters.

What happens to my data?

- Everything you say in interviews, on questionnaires, and the data received from the app will be stored and analysed anonymously.
- The information will be stored using a user number given to you to protect your identity.
- All the information will be kept securely within University of Bristol and the University of Exeter.
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- The anonymous data will be made available to other research teams, which may be used for purposes not related to this study, however, it will not be possible to identify you from this data.

NB/ If during the research, information is shared that would be considered a safeguarding or medical concern, this information will be shared with the clinical team to ensure you and your families safety.

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Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you

withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

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Funding

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Ethics

Ethical Approval has been granted by South Central – Berkshire B Research Ethic Committee.

If you have any questions or concerns about the study, please contact the principal investigator Jennifer Cox at Jennifer.cox@bristol.ac.uk

or speak to a member of the team at your next clinic appointment.

Feasibility Trial in Paediatric Weight-Management

Researcher: Jennifer Cox Jennifer.cox@bristol.ac.uk

IRAS ID: 242624

Sponsorship Study Number: 2964

Participant Number:

Young Person (<16) Information Sheet

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What is the research about?

The research is looking at a new healthy eating app, for use on smartphones, iPads and tablets, called "**FoodT**".

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We are asking you to play the game at home, then tell us what you think by taking part in questionnaires or interviews with us. Taking part will not affect the rest of your treatment in the clinic. All research will take part at the same time as your appointments, you will not need to come in for any additional visits.

How do you play the app?

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What are the benefits?

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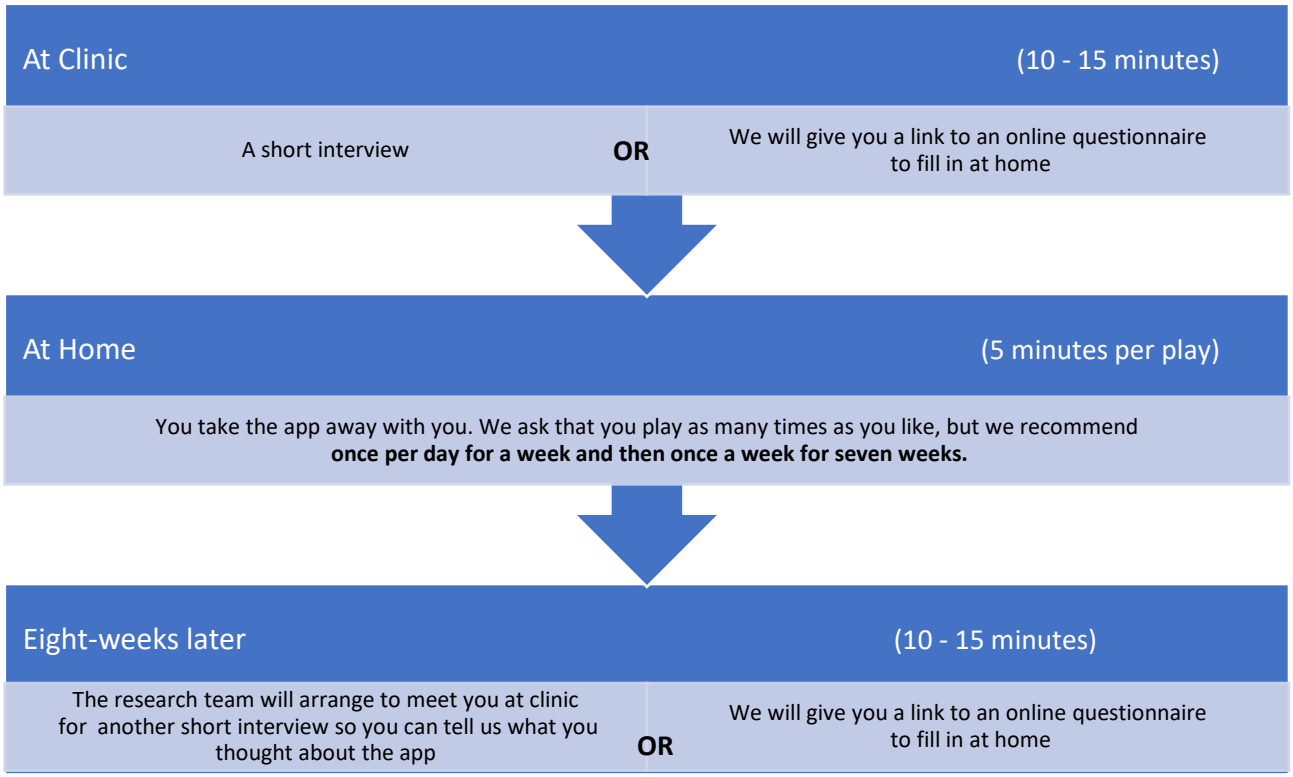

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Who can give consent to participating?

As you are aged 15 or younger, your parent/guardian will need to give consent to you taking part in this research. We will also ask you to sign an assent form to let us know that you are also happy to take part. The forms will be given to you in clinic at your next appointment. Without both forms, we will not begin the research.

What happens to my data?

- Everything you say in interviews, on questionnaires, and the data received from the app will be stored and analysed anonymously.
- The information will be stored using a user number given to you to protect your identity.

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If you have any questions or concerns about the study, please contact the principal investigator Jennifer Cox at Jennifer.cox@bristol.ac.uk

or speak to a member of the team at your next clinic appointment.

Feasibility Trial in Paediatric Weight-Management

Researcher: Jennifer Cox Jennifer.cox@bristol.ac.uk

IRAS ID: 242624

Sponsorship Study Number: 2964

Participant Number:

Research Project

You have been invited to take part in some research.

Some of it will happen in the clinic and some will happen at home.

You won't need to come to the clinic any more than usual.

What is it about?

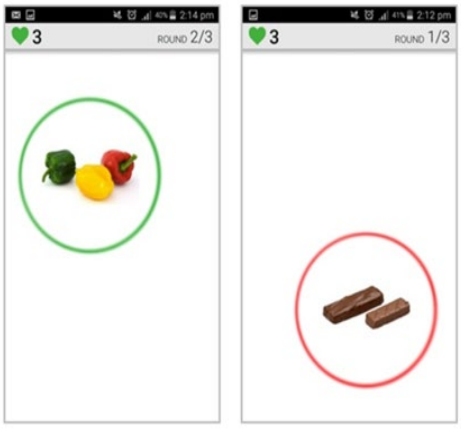
Trying a new app
There is a new healthy eating app, called "**FoodT**".

FoodT may help people to eat less of foods like crisps and chocolate.

We would like to know if:

- Food T is **helpful?**
- You have **time** to play it?
- If you **like** playing it?

How do you play the app?



The app is a simple game.

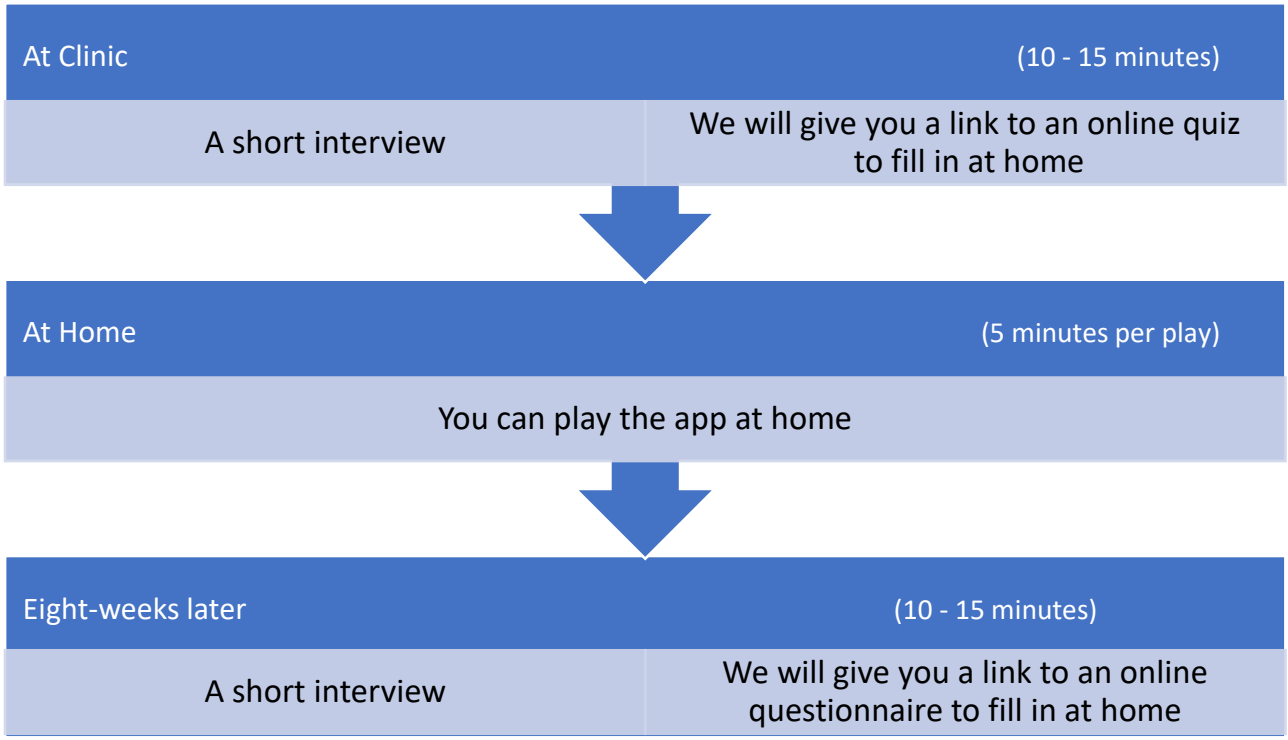
It will show you pictures, one by one.

When there is a **green** circle around the picture, you should **tap it as quickly as possible.**

When there is a **red** circle around the picture, **try not to tap it.**

If you want to take part, we will help you to set it up when you come to clinic. Then you can play at home.

What will happen?



Your information

- Your information will be kept safe. It will not have your name on, so no one outside the research team will know what you have told us
- What you tell us will help us make the app better

Do I have to take part?

No, you do not need to take part. **It is your choice.** You can **stop taking part at any time and you do not have to tell us why.**

If you have questions or worries about the study, please tell your parents / guardians and you can speak to the researchers when you are next at clinic.

Contact: Jennifer.cox@bristol.ac.uk

Appendix C.6: Parents/ Guardians Consent form

Feasibility Trial in Paediatric Weight-Management

Researcher: Jennifer Cox Jennifer.cox@bristol.ac.uk

IRAS ID: 242624

Sponsorship Study Number: 2964

Participant Number:

CONSENT FORM – For Parents/Guardians to Complete

Please initial box

1. I confirm that I have read the information sheet dated 01/10/2018 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation and the participation of my child is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to mine and my child's data. ☐

4. I understand that the information collected about me and my child will be used to support other research in the future and may be shared anonymously with other researchers. ☐

_____

Name of Child

_____	_____	_____
Name of Parent/Guardian	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Appendix C.7: Age 16+ Adolescent Consent Form

Feasibility Trial in Paediatric Weight-Management

Researcher: Jennifer Cox Jennifer.cox@bristol.ac.uk

IRAS ID: 242624

Sponsorship Study Number: 2964

Participant Number:

CONSENT FORM – for Ages 16+

Please write initials in the box

1. I confirm that I have read the information sheet dated 1/10/2018 (version 2). I have had the opportunity to think about the information, ask questions and have them answered. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or rights being affected. ☐

3. I understand that relevant sections of data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, when relevant. I give permission for these individuals to have access to my data. ☐

4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously, ensuring it cannot be traced back to me, with other researchers. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Feasibility Trial in Paediatric Weight-Management

Researcher: Jennifer Cox Jennifer.cox@bristol.ac.uk

IRAS ID: 242624

Sponsorship Study Number: 2964

Participant Number:

ASSENT FORM –
For children aged 5-11 to fill in with support from the research team/parents/guardians

Please write initials in the box

1. I have read/been read the information sheet and have had the chance to ask questions and understand the answers. ☐

2. I understand that I can stop taking part at any time without having to tell the team why ☐

3. I understand that the information I give will be used in research and shared with other people involved, but this information will not be connected to my name. ☐

Name of Participant	Date	Signature

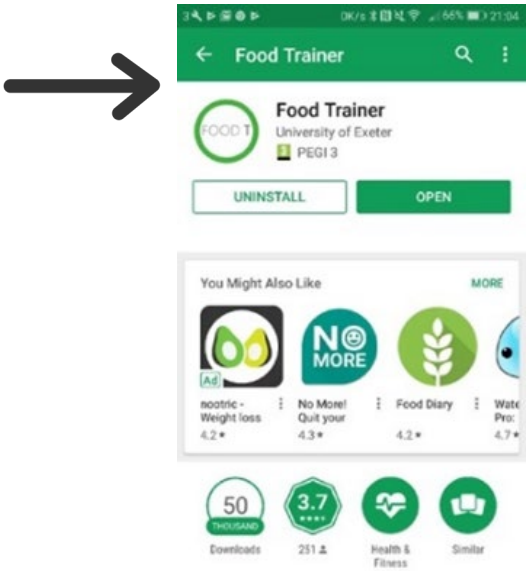
Name of Person taking consent	Date	Signature

FoodT Information Sheet

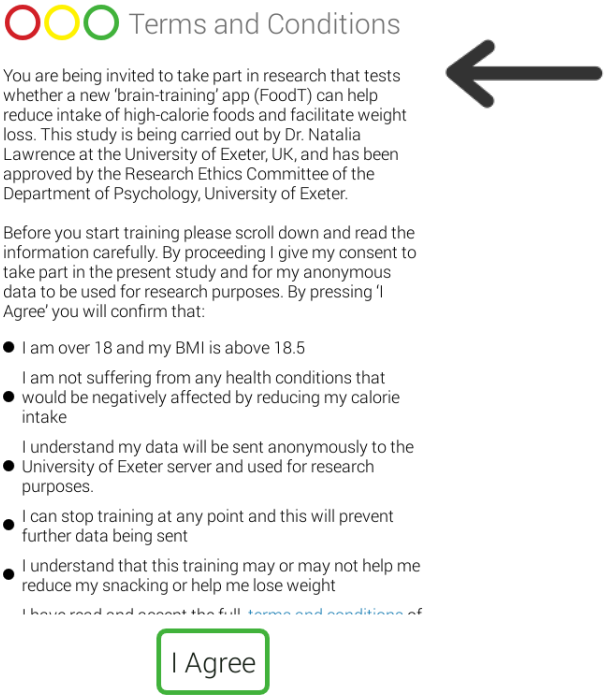
Thank you for agreeing to take part in this study. This sheet gives you some more information about **downloading and playing** the FoodT app. For a step-by- step video of the information on this sheet, please see our YouTube video at:

How do I download the FoodT app?

The FoodT app is FREE to download. Simply type in "Food Trainer" into your app provider (Googleplay / AppStore).



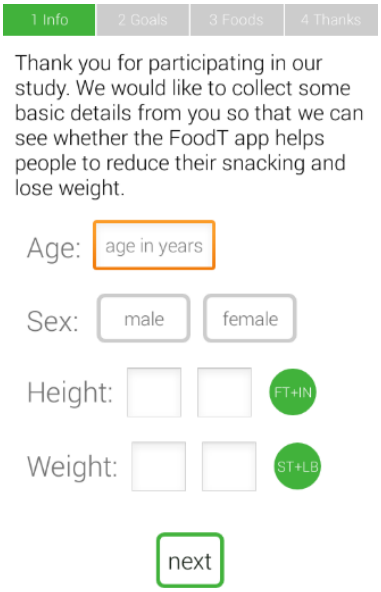
How do I set up the FoodT app?

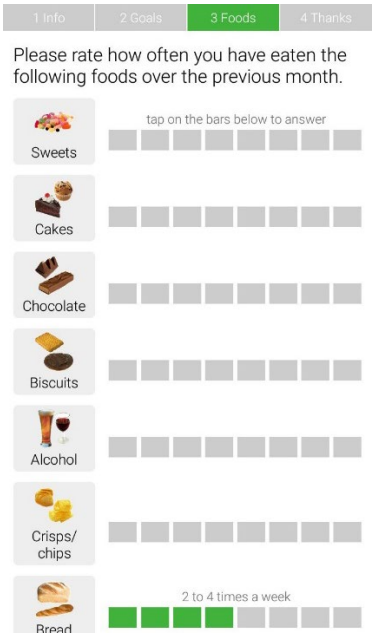


Step 1: When you first go on to the app, you
will see some statements followed by an "I agree" button. One of the statements is "I am 18 years old".

If your child is playing this app as part of this research, it is suitable for them to continue because your child and yourself will have signed separate paper assent and consent forms. Therefore, you may press "I agree" regardless of the child's age.

Step 2: Next you will be asked questions on your child's details. Please answer these as accurately as possible





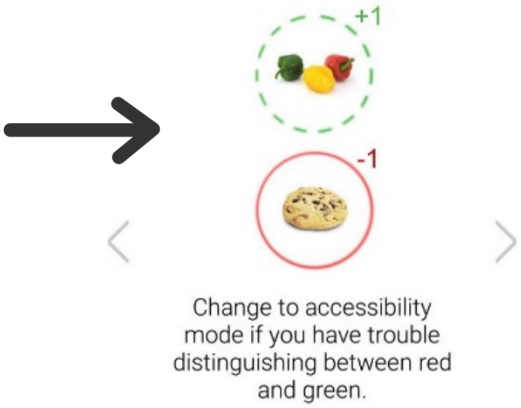
Step 3: Next you will be asked questions on how frequently your child consumes certain foods. Please answer these as accurately as possible.

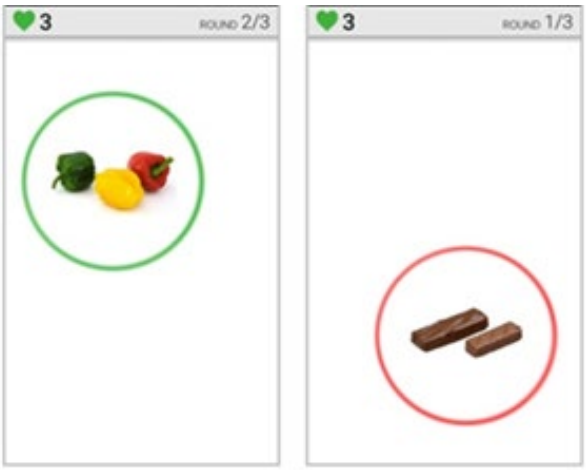
Options are
4 or more times a day
2 or 3 times a day
Once a day
5 or 6 times a week
2 to 4 times a week
Once a week
1 to 3 times a month
Less often or never

Step 4: You are now ready to start the FoodT game. You will see a homepage screen like this.
For further instructions or a quick 'tour' of the app please tap on "**Instructions"** on the home screen.

Step 5: You have the option to **choose** up to three unhealthy food categories to **train your brain to "stop"** to (e.g., foods you or your child might have trouble resisting) – click on "**Options"** on the home screen and then go to "Personalise". Otherwise, the game will run with a standard set of foods.

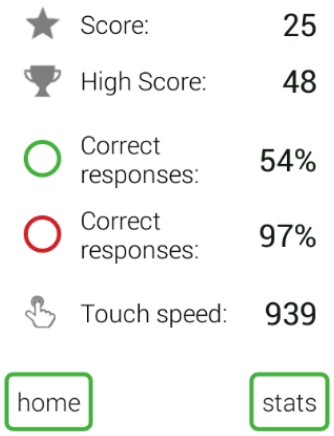
Step 6: If your child has difficulties distinguishing red and green, click on the Accessibility Mode, and you will be able to change the green to a dashed line to help with differentiation





Step 7: Press "start" when you are ready to start.
You will see images of foods appear on the white screen some will be of items such as clothing or stationery, and others will be of foods. When you see an image that is surrounded by a green ring, tap the image on the screen with your finger.
When you see an image on the screen surrounded by a red ring, do not tap it and try and stay as still as possible

Step 8: When you have completed a round, you will get your accuracy scores reported back to you. Try and beat these by being as fast and accurate as you can.



We encourage you to play as much as you like but we recommend playing everyday for one week and then once a week for one month.

If you have any questions at all do not hesitate to contact us:

Jennifer.cox@bristol.ac.uk

Appendix C.10: Computerised Measures

Thank you for taking part in this research, if you have any problems, questions or would prefer to complete this via interview, please contact the researcher Jennifer Cox on jennifer.cox@bristol.ac.uk or 07811990600

Please enter your date of birth:

10 May 2022

Gender

Please Select...

Please give your height and specify units (e.g. cm/feet & inches)

Please give your weight and specify units (e.g. stones/pounds/Kg)

What is your postcode?

Are you currently dieting to loose weight?

Please Select...

If yes, what methods are you currently using? (select all that apply)

- [ ] Exercising more
- [ ] Reducing portion size
- [ ] Reducing snacking
- [ ] Eating more slowly
- [ ] Eating more fruit / vegetables
- [ ] Eating less food high in fat
- [ ] Eating less food high in sugar
- [ ] Changing timing of eating
- [ ] Other (please specify)

What things do you find easy to do, that help you loose weight?

What things do you find hard to do, that help you loose weight?

Are you trying to restrict your intake of unhealthy food/drink?

Please Select...

Are you trying to increase your intake of healthy food/drink?

Please Select...

Do you have a metabolic disorder? (i.e. diabetes, thyroid disorders etc.)

Please Select...

If yes, which disorder(s)

How long have you been coming to the clinic?

Please Select...

Who do you talk to about your weight? (Select all that apply)

- [ ] Clinic staff
- [ ] Friends
- [ ] Mum
- [ ] Dad
- [ ] Guardians
- [ ] Brother/sister/siblings
- [ ] Grandparents
- [ ] I don't talk to anyone
- [ ] Other (please specify)

Thinking about your weight-managment goals. Do any of the following people make it easier for you to maintain a healthy weight? (Select all that apply)

- [ ] Clinic staff
- [ ] Friends
- [ ] Mum
- [ ] Dad
- [ ] Guardians
- [ ] Brother/sister/siblings
- [ ] Grandparents
- [ ] No one makes it easier
- [ ] Other (please specify)

Typically, when do you use apps? (Select all that apply)

- [ ] In the morning before school
- [ ] During school
- [ ] At lunch time in school
- [ ] Straight after school
- [ ] After dinner time
- [ ] At night
- [ ] On the weekends
- [ ] Never

How long do you spend on apps each day?

- [ ] No time
- [ ] Less than 10 minutes
- [ ] 10-30 mins
- [ ] 30 min - 1 hour
- [ ] 1-2 hours
- [ ] 2-3 hours
- [ ] 3+ hours

Have you used any apps to help with your food choice or weight?

Please Select...

If yes, which apps?

How do you feel about using an app to help with your food choices?

Great! I think this will help me	Okay. Maybe this could help	Unsure. I don't know if this will help me	Not positive. I don't think this will help but I am willing to try	Negative. I don't think this will help

Why do you feel this way?

Do you frequently experience food cravings?

Please Select...

For what foods? (Select all that apply)

- [ ] Sweets
- [ ] Cakes
- [ ] Chocolate
- [ ] Biscuits
- [ ] Crisps
- [ ] Chips
- [ ] Bread
- [ ] Cheese
- [ ] Fast Food (Burgers/ takeaways)
- [ ] Fizzy (soft) drinks
- [ ] Meat
- [ ] Pizza
- [ ] Fruit
- [ ] Vegetables
- [ ] Crispbread/ Ricecakes
- [ ] Other (please specify)

Do you find it hard to say no if food is available?

Please Select...

Fizzy (soft) drinks

Hate **Love**

Meat

Hate **Love**

Pizza

Hate **Love**

Fruit

Hate **Love**

Vegetables

Hate **Love**

Crispbread / ricecake

Hate **Love**

Sweets

4 or more times a day	2 or 3 times a day	Once a day	5 or 6 times a week	2 to 4 times a week	Once a week	1 to 3 times a month	Less often or never

Cakes

4 or more times a day	2 or 3 times a day	Once a day	5 or 6 times a week	2 to 4 times a week	Once a week	1 to 3 times a month	Less often or never

Chocolate

4 or more times a day	2 or 3 times a day	Once a day	5 or 6 times a week	2 to 4 times a week	Once a week	1 to 3 times a month	Less often or never

Biscuits

4 or more times a day	2 or 3 times a day	Once a day	5 or 6 times a week	2 to 4 times a week	Once a week	1 to 3 times a month	Less often or never

Fruit

4 or more times a day	2 or 3 times a day	Once a day	5 or 6 times a week	2 to 4 times a week	Once a week	1 to 3 times a month	Less often or never

Vegetables

4 or more times a day	2 or 3 times a day	Once a day	5 or 6 times a week	2 to 4 times a week	Once a week	1 to 3 times a month	Less often or never

Crispbread/Ricecakes

4 or more times a day	2 or 3 times a day	Once a day	5 or 6 times a week	2 to 4 times a week	Once a week	1 to 3 times a month	Less often or never

Please select the answer that best represents how you feel:-

I think I am overweight

Not at all	0	1	2	3	4	Very Much

I am ready to change my weight

Not at all	0	1	2	3	4	Very Much

I am ready to change how and what I eat?

Not at all	0	1	2	3	4	Very Much

I am ready to change what I do and be active

Not at all	0	1	2	3	4	Very Much

I feel I will be successful in making these changes

Not at all	0	1	2	3	4	Very Much

I am losing hope of losing weight

Not at all	0	1	2	3	4	Very Much

Do you ever want to eat when you are not even hungry?

Please Select...

Do you ever feel that when you start eating you just cannot stop?

Please Select...

Do you ever eat because you feel bad, sad, bored, or any other mood?

Please Select...

If yes, how long have you been doing this?

Do you ever want food as a reward for doing something?

Please Select...

If yes, how long have you been doing this?

Do you ever sneak or hide food?

Please Select...

If yes, how long have you been doing this?

Do you ever do anything to get rid of what you ate?

Please Select...

If yes, how long have you been doing this?

In the last 4 weeks (28 days), how often have you had the following experiences during a time when you were eating? Please respond to each item using the following scale:

Never, Rarely, Occasionally, Often, Always

I continued to eat past the point when I wanted to stop

Never	Rarely	Occasionally	Often	Always

I felt like I had "blown it" and might as well keep eating.

Never	Rarely	Occasionally	Often	Always

I felt helpless about controlling my eating.

Never	Rarely	Occasionally	Often	Always

My eating felt like a ball rolling down a hill that just kept going and going.

Never	Rarely	Occasionally	Often	Always

I found myself eating despite negative consequences.

Never	Rarely	Occasionally	Often	Always

I felt like the craving to eat overpowered me

Never	Rarely	Occasionally	Often	Always

I felt like I could not do anything other than eat.

Never	Rarely	Occasionally	Often	Always

Take some time now to download and set up the app, using the information sheet in the pack. Play a round of the game. Then come back to this questionnaire.

Do you think the app will help with your weight?

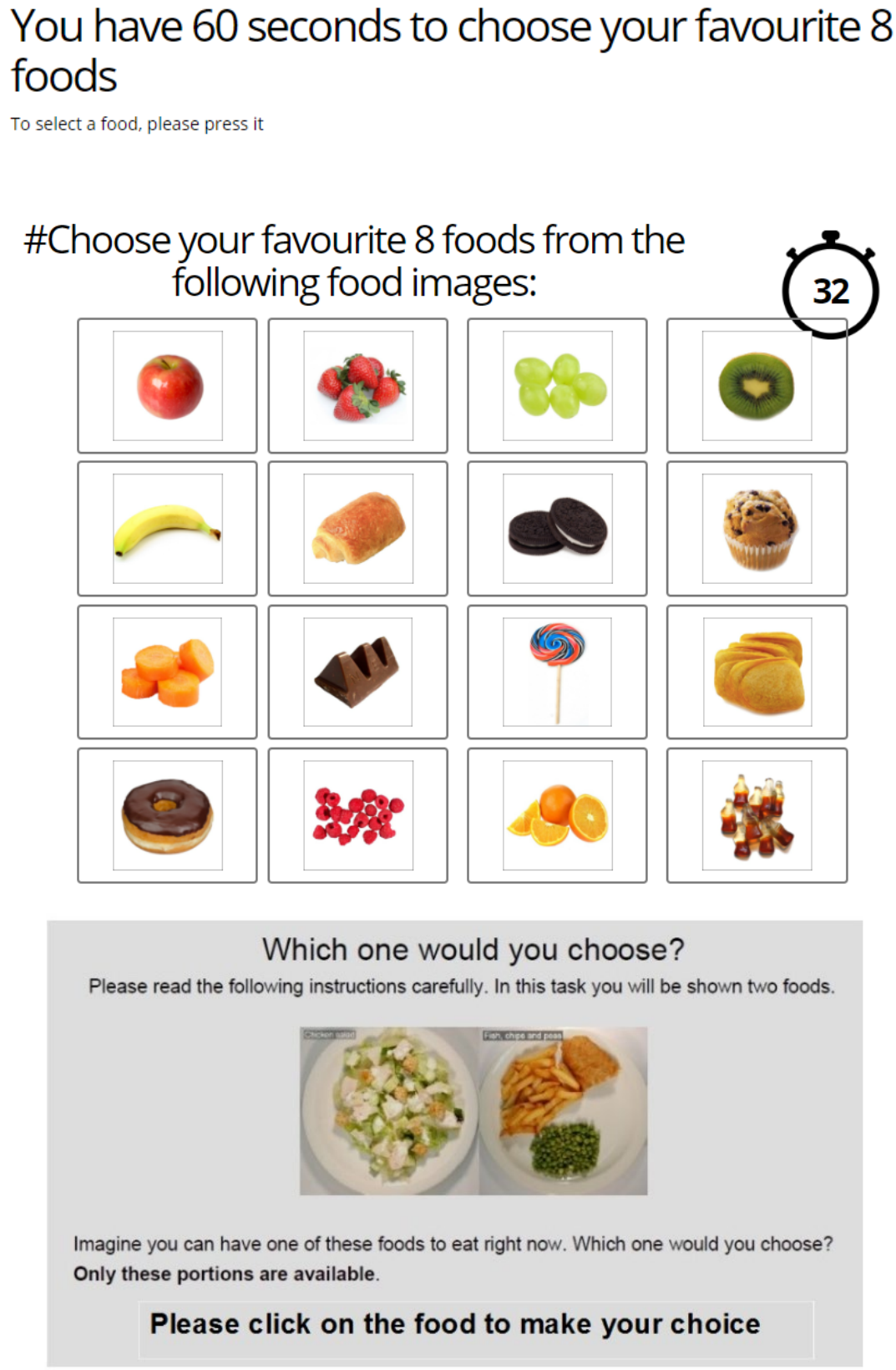
Yes I think this app will definitely help	This app may help	I am unsure	I don't think this app will have much effect	No this app won't help

Why do you feel like that?

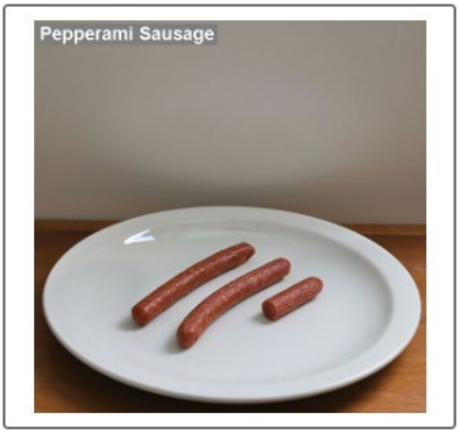
Thank you for participating in this research, all the information you have given us is helpful for us making this app better!

If you have any questions, please contact Jennifer Cox on jennifer.cox@bristol.ac.uk or 07811990600

Appendix C:11 Examples of forced choice food tasks



Which one of these two foods would you like to eat right now?



Which one of these two foods would you like to eat right now?

Which one of these two foods would you like to eat right now?

Appendix C.12: Debriefing form

Feasibility Trial in Paediatric Weight-Management

Researcher: Jennifer Cox Jennifer.cox@bristol.ac.uk

IRAS ID: 242624

Sponsorship Study Number: 2964

Participant Number:

Research Study – FoodT App

Thank you for taking part in this research!

You are receiving this letter because you/your child recently took part in a project to see whether a new app (FoodT) can help individuals attending weight-management services to make healthy changes to their lifestyles.

Lots of research has shown that a simple game could help people to eat a bit less of foods that are high in fat, salt and sugar. FoodT is an app that allows people to try this game at home and play it anywhere they like.

The aims of our research were…

- To see whether FoodT is a useful addition to your work at the lifestyle and weight-management service
- To see if FoodT fits in well with daily life, both at home and in the clinic
- To see if FoodT is enjoyable and easy to use

As part of your participation in this study, you/your child may have filled in questionnaires and interviews. If you used FoodT on your phone or device, we will also have collected data about how often you used FoodT and how you got on with the app. Considering this, we just wanted to remind and reassure you of the following points:

- We will only have collected your data if you agreed to this at the start of the project
- All of the data will be kept in a way that makes it completely anonymous (so nobody will be able to look at it and work out that it is yours)
- All of the data will be stored very securely (in locked filing cabinets in locked offices at the university OR in password-protected folders on password-protected, university-owned computers)
- Your data will only be shared anonymously, and it may be made available to other researchers working in this field if we publish our results but nobody will be able to trace the data back to you

The reason we conducted this research was to see whether FoodT is a useful and enjoyable app for individuals attending weight-management services to use alongside their programmes. By taking part, you have helped to develop an app that could help people to

make healthy changes to their lifestyle more easily. With your input, we can continue to work on FoodT and turn it into a healthy-eating app for all.

We will share the results of our study with you once we have finished analysing them, by distributing information at the clinic.

In the meantime, you can get in touch with us at Jennifer.cox@bristol.ac.uk if you have any questions.

Thank you.

The Research Team

Appendix D

Appendix D.1: Qualitative parental perceptions of a paediatric MDT clinic for Prader-Willi Syndrome

Short title: Perceptions of MDT Prader-Willi Syndrome Care

Jennifer S. Cox[1], Claire Semple[2], Rhian Augustus[2], Melanie Wenn[2], Shelley Easter[2], Rebecca Broadbent[2], *Dinesh Giri[2,3], *Elanor C. Hinton[1]

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Key Words

Paediatric, Prader-Willi syndrome, multi-disciplinary team, qualitative

Word Count - 2683

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Acknowledgements

The authors wish to thank the families who contributed to the writing of this paper, and the clinical staff members who ran the trial clinic, enabling this review to be conducted.

Conflicts of interest

The staff members responsible for delivering the clinic are authors on the paper due to their contributions in the design and delivery of the intervention. In order to preserve integrity, clinical staff were not involved with the analysis or interpretation of the data set. They have not influenced, nor amended the result section, but have contributed clinical expertise to the validity of the recommendations.

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Abstract

Objective: This preliminary review was conducted to inform the design of a new service to support families with children with Prader-Willi Syndrome. Families were invited to attend a pilot clinic at a hospital outpatient department, comprising of appointments with a multi-disciplinary team.

Method: Following the clinic, families (n=6) were invited to partake in semi-structured qualitative interviews that were audio-recorded, transcribed and analysed using thematic analysis.

Results: Families reported that the clinic offered enhanced support within the following categories; integrated care; professional input; signposting to social support (respite and financial); connection with the wider PWS community; and behavioural support.

Conclusion: This is the first paper that documents the parental perspective of a multi-disciplinary team (MDT) clinic for children with Prader-Willi syndrome. The families felt an MDT led clinic was superior to current care, offering more convenient access to an enhanced service, which would provide integrated and consistent care for their children's diverse, changing needs.

Statements

What is already known on this topic:

- Prader-Willi syndrome (PWS) is a complex multisystemic neurodevelopmental genetic disorder.
- Clinical symptoms vary with age and include infantile hypotonia, hyperphagia, excessive weight gain, endocrine dysfunction, behavioural problems and psychiatric issues.
- The MDT approach has been recommended in guidelines to provide a multi-faceted approach to manage diverse symptoms.

What this study adds:

- Medical and social care access varies greatly, and no family had previously accessed an MDT.
- Parents value the connection with the specialist clinical team and with other families
- Parents perceive an MDT clinic to be an efficient way to manage appointments and receive integrated timely support.

Introduction

Prader-Willi syndrome (PWS) is a neurodevelopmental genetic disorder caused by a lack of expression of paternal chromosome 15 (q11-q13 region) through three genetic subtypes (Butler et al., 2019). PWS is found in approximately 1 in 15,000 people (Butler et al., 2019). Clinical symptoms vary with age: beginning with infantile hypotonia, failure to thrive, short stature, hypogonadism and other endocrine dysfunctions, switching to hyperphagia and excessive weight gain if left uncontrolled. PWS is also associated with behavioural problems such as tantrums, self-harm and psychiatric issues (Angulo et al., 2015; Butler et al., 2019; Cassidy & Driscoll, 2009; Goldstone et al., 2008; Miller et al., 2011).

The multifaceted nature of this disorder provides challenges to clinicians, and medical care alone may leave needs unmet (Duis et al., 2019). A multidisciplinary team (MDT) clinic is shown to be best-practice, providing a patient-centred biopsychosocial approach to treatment (Duis et al., 2019; Goldstone et al., 2008). Here, patients are seen by a wider range of health professionals equipped to support with behaviour, diet and community connections, and have resulted in improved mortality and morbidity (Duis et al., 2019).

MDT clinics for PWS are not widespread across the UK. There is no specialist MDT clinic that can be accessed by the patients in the South West of England. As part of a funding bid to initiate a clinic in this area, a single pilot MDT PWS clinic was conducted. Due to the low prevalence of PWS (Cassidy & Driscoll, 2009), the clinic would support families across a wide geographical area. To ensure the future clinic was designed around patients' needs, the parents who attended this pilot clinic were asked to take part in a qualitative review that discussed the needs of their family and their perceptions of the clinic. Whilst several recent works declare the MDT as the best model of care from a health professional point of view (Duis et al., 2019; Goldstone et al., 2008; McCandless et al., 2011), this preliminary work, for the first time, presents the parents' perspective of the MDT PWS clinics.

Methods

Experimental subjects

Families (N=6) were selected from the regional database of children with PWS and confirmed their willingness to attend a pilot clinic. Participant characteristics are detailed in Table D.1.1. On invitation, parents were informed about the opportunity to provide feedback. On arrival, a member of the clinical team introduced the clinic and the research

team. All six sets of parents agreed to participate in the review and were consented by the research team.

Table D.1.1. Participant characteristics

	Patients (n=6)	**Parents (n=9)**
Characteristics	**N**	**N**
Female	5	6
Ethnicity		
Caucasian	6	9
Age		
<5	3	
5-11	1	
12+	2	

Materials and methods

Interviews were conducted by EH (researcher) and JC (researcher) who were external to the clinical team and accompanied by RA (social worker). Interviews took place on a single day, in an outpatient ward of a large community hospital, where the clinic would likely be held if funded. Interviews were carried out in a private appointment room, adjacent to the clinical team. Interviews were semi-structured (See appendix A for interview schedule). Three interviews took place prior to the clinic appointments; five took place after, with clinic scheduling allowing two families to be interviewed both before and after the clinic appointments, resulting in eight interviews in total. All interviews were audio recorded using a Dictaphone. The duration of each interview was between 10 and 25 minutes.

Data analysis

Interviews were transcribed verbatim by external, approved services and were anonymised. Thematic analysis was used to code the transcripts independently by both EH and JC due to its applicability in applied work (V. Braun & Clarke, 2014). EH and JC met to refine coding as part of the iterative analysis process. Transcripts were re-read and recoded with

amendments. Sub-themes and overarching themes were decided upon collaboratively between EH and JC.

The service review had approval from Patient Experience and Involvement Team at University Hospitals Bristol and all interviewees provided informed consent.

Interventions

The clinic itself comprised of three appointments, first families were seen by the Consultant Paediatric Endocrinologist, a weight management nurse specialist, and a Paediatric Endocrine nurse specialist. The clinic also included a Consultant adult Psychiatrist with an interest in PWS as a voluntary observer. Following this, patients were seen by a clinical psychologist and a dietician together, finally, patients were seen by the social worker, who also participated in the clinic interviews.

Main outcome measures

The interviews sought to explore parents' experience of the MDT clinic compared with their previous care and understand the areas of greatest need for families. They sought to engage parents in the design of both the structure and the content of the clinic, and thus feedback was requested to facilitate co-design.

Results

Each of the identified themes, as displayed in Figure D.1.1, will be presented in turn along with illustrative quotes in Table D.2. (Figure D.1.1 and Table D.2 to be included within the results section).

Figure D.1.1. Families experienced integrated support from an MDT led clinic.

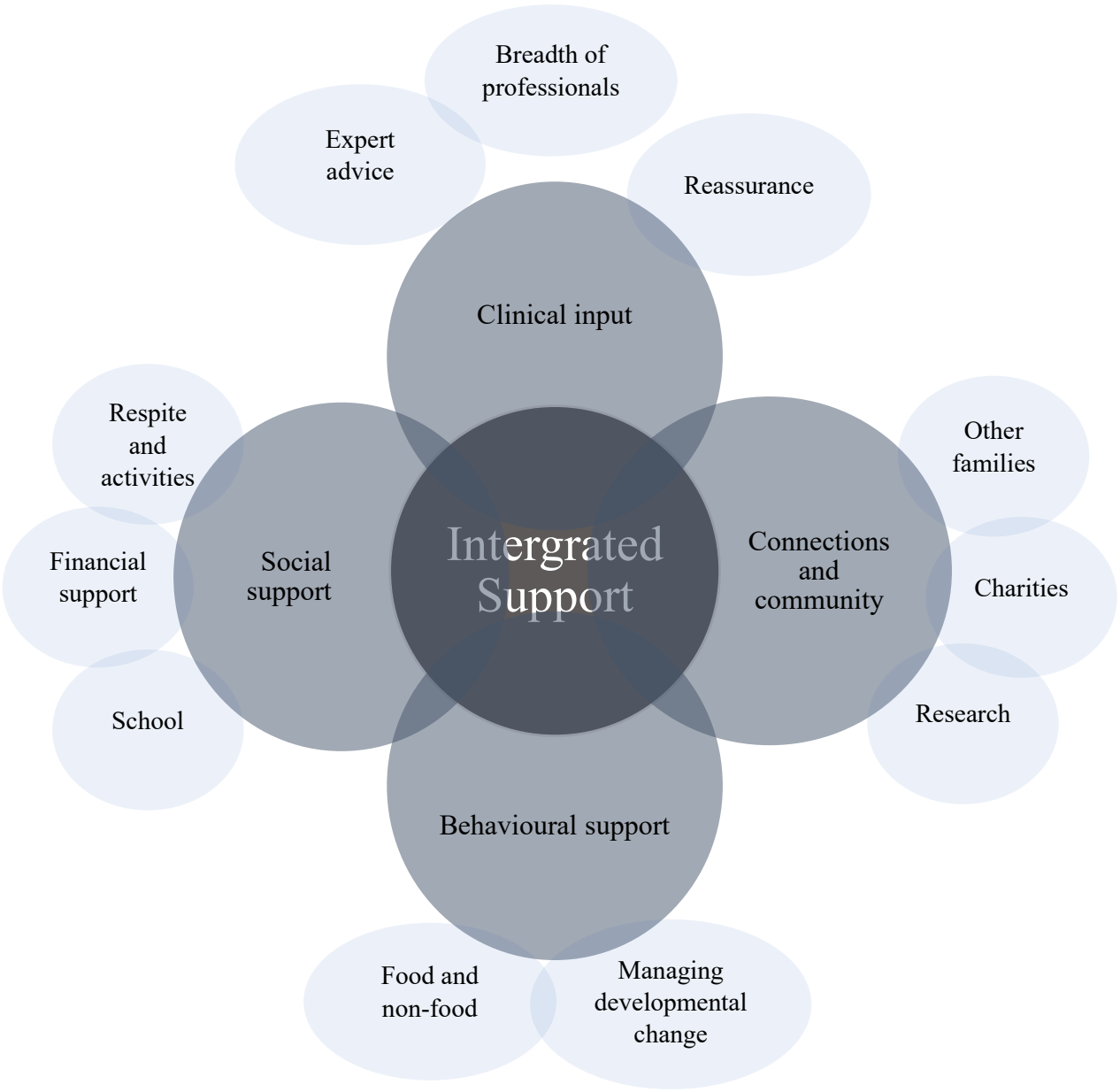

Table D.1.2: Illustrative Quotations

Integrated support	*(1a) To have those professionals together, that is a success in itself, because they communicate then. The fact that the dietician is in the same place, if there's an issue with the weight, we can go straight in and see the dietician." (Mother to Belinda, after).* *(1b) "We had so many appointments all the time. That, when you are trying to run your life, as well, it is a lot just to fit all that in. So, to be able to come to one place and to see all these different people, that's been really good" (Mum to Freya, after)* *(1d) "I was saying, "I hope it's worth the trip this time," because we didn't really know what to expect. Yes, if it was something like this, it would be definitely worth the trip" (Mother of Freya, after)*
Professional Input	
Breadth of professionals	*(2a) "Yes, so we go to endocrinology. We don't see a dietician anymore; we don't see physio. She has speech through school" (Mother of Belinda, after)* *(2b) "Language and communication would be good. We did see speech and language at school, but we haven't seen her for about a year" (Mother of Abigail, before)* *(2c) "To have play leaders here or play workers, because obviously there is stuff that you want to talk about, you can't talk with your child present, but to have a play team available in these clinics […] a lot of things are really big triggers for her at the moment, and I imagine for others with Prader-Willi of a similar age, they'd struggle. Sometimes anyway even*

	when she was younger, you don't necessarily want to say the really bad stuff in front of your own child" (Mother of Alice, after)
Expert Advice	*(2d) ""Why don't we have that? I'd love access to something like that." So, I think this is ideal" (Mother of Belinda, before)* *(2e) "The best people to speak to really are the Prader-Willi Association, because over the years we've had loads of training and conferences from them" (Mother of Alice, after)*
Reassurance	*(2f) "Feeling that you can go back, having some questions answered that, maybe, have been making us feel like we're not doing the best job sometimes, to then being able to get some support with that and then go home and start to feel better again and like we're ready to tackle that" (Mother of Freya, after)*
Behavioural support	
Food and non-food management	*(3a) "When she steals food, I was talking about it feels wrong to discipline her, because she can't help it, but at the same time, I want her to know that she shouldn't be stealing food. So, just being able to talk, and the fact that they [psychologist and dietitian] were in the room together really helped" (Mother of Belinda, after)* *(3b) "She [mother] can't even… well, she's powerless… she's glued at home with him, […] And it has been like that where it's kicked off, he's had to be restrained, everything […] It's quite sad, isn't it?" (Father of Jason, before)*
Managing developmental milestones	*(3c) "I'm very much aware that things are going to get harder as she gets older and I want to be proactive rather than reactive. I want to be on the*

	ball and the more I can do to learn and to meet people, and just the more I can do to be prepared, the better." (Mother of Belinda, after) *(3d) "It's going to be quite a big shift when she goes to school in September, especially with the behavioural stuff. You know, if they come to us and say, "She's been doing this today," it's like, "Okay, we don't know how to do this, we don't know what to tell them", because we know how to deal with it when it's us but not when she's left" (Father of Freya, after)*
Social support	
Respite and activities	*(4a) "But we do need… The thing is what I struggle with is getting him doing activities, because there's nothing around my way for disability… children with disabilities, and, basically, if there is […] but they want £30 a day, and there's no… You know, that's the reason why he can't" (Mother of Jason, before)* *(4b) "…my mum died, so we don't even have my mum. Another lady who used to help a lot has got Alzheimer's and obviously I can't rely on that family because they've got enough of their own woes" (Mum of Alice, after)*
Financial support	*(4c) "There's nothing for him. Well, there is, but you've got to pay for it" (Mother of Jason, before)* *(4d) "The biggest thing, really, is we've got DLA [disability learning allowance] due through now and I just don't know how to word stuff, so that's really frustrating for us. We do feel that she is entitled to it." (Mother of Sarah, before)*
School	*(4e) "School are brilliant. Yes, school are fantastic. They do lots of clinics and the dentist comes to the school as well so […] No, I don't think she'd*

	cope anywhere else. It's the best facility for her, it really is" (Parent of Abigail, before) *(4f) "The school have just fobbed us off […] they haven't even put the lunch boxes out of sight […] I mean they won't go to the toilet with her because they say they haven't got enough staff and they won't want a one-to-one, they don't encourage it, they say it's not healthy for the child because they get too attached" (Mother of Sarah, before)*
Connections and Community	
Connections to other families	*(5a) "It's not like you can talk to the school mums, like I would with my other children. I can't say, "Oh, is he doing this and that? […]To me, that is the most useful, because other parents that've done it- which is why I think it would nice today, if I get see other parents in the waiting room, it's just, again, another reassurance that we're all in the same boat and we're doing what we can" (Mother of Belinda, before)* *(5b) "But it's always scary seeing the adults and stuff who have it, because it's looking into the future, before we are ready. But the future is always changing, the research is always changing…" (Mother of Freya, after)*
Connections to PWS charities	*(5c) "I'm always ringing them up, PWS to ask for- when it comes to things like- do you know? […] Obviously they know what they're talking about these people." (Father of Jason, after)* *(5d) "The PWSA, the charity, or the FPWR the charity, they could be useful, kind of thing, liaising. So, they maybe a representative for them here" (Parent of Freya, after)*

Connection to research	*(5e) "Obviously, the conferences are either alternate years or really random and far away, but to be able to offer here some of the expertise locally to us, that would be really good" (Mother of Alice, after)* *(5f) "Any new research, happy to have that. That would be really good. Any clinic trials, I'm happy for her to be involved in trials if there are any that she would be suitable for" (Parent of Abigail, before)*

Integrated support

Overall, parents perceived the clinic to both enhance their access to support and be an improved delivery mode when compared to current care. Whilst families valued appointments with the endocrinologist – the typical care received by most families - they felt the MDT approach to be superior. Importantly, parents felt that an MDT clinic would enable a more joined-up approach to their care, facilitating collaborative, coordinated strategies without lengthy referral times (Table 2, 1a).

The clinic offered families a *"one-stop-shop"* reducing the disruption and time-off school caused by multiple appointments. This was beneficial when considering their children's need for routine and gave parents the freedom to better manage other life commitments (Table 2, 1b). Whilst families acknowledged the sometimes-lengthy travel time to reach the clinic, parents felt it was acceptable to facilitate access to this breadth of support (Table 2, 1e).

Clinical input

Breadth of professionals

Families typically had, or had previously had, frequent contact with a wide range of medical professionals; however, there was a large disparity in access to services. Some schools were reported to host clinics; however, this access was not universally received. Most noted they had no current regular contact with other health professionals other than their endocrinologist, therefore this element of clinic was praised (Table 2, 2a).

Families felt that it was beneficial to see every staff member present at the clinic. In addition, families recommended the inclusion of the speech and language teams (Table 2, 2b), physiotherapists, orthotics, and creative therapies would enhance the service further. Parents discussed how the inclusion of a play-worker would improve the clinics impact, reducing distractions for parents of younger children, and enabling parents of older children to converse more candidly with clinicians about difficulties without these discussions taking place in front of the child (Table 2, 2c).

Expert Advice

Some parents were highly informed about best-practice in other clinics in the UK and internationally and were keen to ensure their child had the same access to current, top quality care (Table 2, 2d). They had participated in these interviews in part, to ensure staff connected with, and replicated the programmes running elsewhere and recommended that staff work collaboratively with charities to access specialist training (Table 2, 2e).

Reassurance

Other families explained that the greatest benefit to attending a specialised PWS clinic was to be able to *"check in"* with professionals, to ensure they were doing everything they could for their child. This reassurance renewed their sense of strength as parents, restoring their energy to maintain the levels of care required (Table 2, 2f).

Behavioural support

Parents felt strongly about pro-actively managing children's behavioural problems and felt that the pilot clinic had already given them helpful strategies to implement.

Food and non-food management

Parents explained that as behavioural problems were often triggered by food, seeing the dietitian and psychologist together enabled them to fully explore the relevant issues (Table 2, 3a). Strategies for wider behaviour management were also valued, particularly the parents of the older children who sought help for difficulties with violent outbursts, which had previously escalated to require police involvement in one case. They had previously refused offers of assistance, but they now felt they needed support to manage and were willing to accept this from the pilot clinic (Table 2, 3b).

Managing developmental milestones

The families reported that the consistency of the clinic would enable them to feel more supported throughout times of change (Table 2, 3c). Parents valued having clinical input on adjustments such

as moving schools or their child progressing to independent living and also felt this expert input made them feel more equipped to share this knowledge with other key caregivers (Table 2, 3d).

Social support

The inclusion of a social worker was integral to the family's experience of the clinic. Many families were juggling their child's care needs with the support of their wider families, without having access to the full range of support available to them. Respite and Activities

Families were often not receiving formalised support packages, therefore for those who were not able to pay children had little access to extra-curricular activities or social time with peers (Table 2, 4a). Parents of the older children specifically raised this *"The two main things are respite and activities for him" (Mother to Child E, after).* When children did attend activities, the parents reported being required to stay with their child, giving them little time for themselves or other family needs. Some families were occasionally supported by informal respite time with grandparents or friends. However, this was felt to be non-sustainable (Table 2, 4b).

Financial support

Finances were a perceived barrier to improving the child's wellbeing, independence and making dietary change (Table 2, 4c). Families were not always aware of the extent of the support available to them, and how to access it. The social worker was able to support with this, and families saw this as an asset to the clinic (Table 2, 4d).

School

School was a polarising experience for the families. Some parents reported schools being extremely supportive, typically those at special educational needs schools. These families had access to wider range of support and additional health care facilities (Table 2, 4e).

Other families reported the school to be unsupportive, offering little in the way of additional assistance. These families perceived the prospect of the clinic's nurse and social worker aiding mediations with schools as an advantage.

Connections and community

There was a variance in family's knowledge about the condition, and the extent they were connected to other services and families.

Connections to other families of children with PWS

Some families reported feeling isolated from others with PWS. Those who had engaged in either in-person or online support groups reported them to be a beneficial source of comradery and advice, as well as allowing parents to give back and support others. The

clinic was felt to be beneficial in offering further opportunities to meet other families, regardless of their current level of connection (Table 2, 5a).

It is important to note that one family expressed that they had had concerns prior to the clinic about meeting older children with PWS due to an apprehension of experiencing what their life may be like in the future (Table 2, 5b).

Connection to PWS specific charities

The advice from, and connection to, Prader-Willi syndrome charities including Prader-Willi syndrome association (PWSA) and Foundation for Prader-Willi research (FPWR) were highly valued. Even the family who refused most help, regularly contacted charities for advice (Table 2, 5c). Parents felt that having a representative from these organisations at the clinic would be beneficial (Table 2, 5d).

Research

Families sought to stay informed with the latest developments but feared that they would miss out due to the complex wording of academic works, and the geographical and cost barriers to attending conferences. Parents felt that having a professional who could summarise what recent research findings mean for their family would be advantageous (Table 2, 5e). Families were willing for their children to take part in research and were keen to support developments in PWS treatment and understanding (Table 2, 5f).

Discussion

Parents in this preliminary study felt that the MDT clinic facilitated the holistic care required to manage their child's diverse needs. The clinic was perceived to be a potential hub of their child's care (McCandless et al., 2011), a sounding-board where families could share concerns and keep up-to-date with developments. Families felt a sense of apprehension about what the future held, knowing that their child's condition and thus the challenges they faced would vary with age (McCandless et al., 2011). By having consistent appointments, potentially every six months (Duis et al., 2019), throughout their child's life, families were optimistic that the clinic could offer sustainable management that would enable concerns to be pre-empted (McCandless et al., 2011). As access to specialist care is currently not universally accessible (Prader-Willi Syndrome Association UK, 2019) this clinic would facilitate equal access to all in the region, regardless of geography or finances.

Families understood the MDT clinic to enable integrated care, with enhanced communication and reported coming-away with tangible, implementable actions, without

lengthy referral times. Families in this review were more concerned about treatment outcomes involving health and social integration, and less directly concerned about weight. “Centres of excellence” for PWS care, are suggested to support socialisation by including family-based therapeutic options, liaising with schools and developing education health and care plans (Duis et al., 2019). This clinic goes a further with an integrated social worker to implement links between healthcare, education, respite and activities to help their children thrive (Grosse et al., 2009). Notably, the collaboration between the psychologist and dietician was valued, addressing the need to manage behavioural difficulties alongside the relationship with food (Allen, 2011). Further inclusion of staff to support with language, communication and movement were requested by parents, and have concurrently been recommended in guidelines (Duis et al., 2019; Goldstone et al., 2008; McCandless et al., 2011).

Every family commented on how they valued meeting other families. Whilst clinics may not perceive peer support to be the primary function of this kind of appointment, other UK clinics do list this as an aim for their clinic (Imperial Centre for Endocrinology, 2020). As families highly appreciated these relationships signposting to the relevant charities and networks to obtain further connection would be valuable.

The clinic was considered to be practical and worked logistically. Long journey times were considered worthwhile to receive this standard of care. The MDT condenses some children’s extensive calendar of appointments, reducing disruption; particularly important when the importance of routine (Allen, 2011) and the high prevalence of autism or autism-like characteristics in children with PWS is considered (Dykens et al., 2017). Whilst this long appointment was preferable, in the interest of quality, privacy and attention, families voiced the importance of a play-worker to support their child during appointments.

The views expressed may be transferable to other similar regions where families do not have access to an MDT. Should the clinic trial the MDT approach as their core offering, this would open opportunities to both quantitatively and qualitatively evaluate patient outcomes in a larger trial. An economic evaluation of the cost-effectiveness of the service may also provide insightful, and important data outcomes at this point.

Study Limitations

It is important to note that all-but-one of these families were previously engaged with treatment thus further work with patients who are currently disengaged with care would help to create a service that has broad appeal. In order to maintain research impartiality, researchers were external, and the clinical team and with the exception of the social worker, were not involved in interviews. However, as the interviews took place in the same setting and researchers had an in-depth understanding of PWS (Hinton, Holland, Gellatly, Soni, & Owen, 2006; Hinton, Holland, Gellatly, Soni, Patterson, et al., 2006; Holland et al., 2003), this division may not have been absolute and may have influenced responses.

Conclusion

In conclusion, families felt the experience of an MDT clinic was superior to visiting the endocrinologist alone, enabling them to address issues around social support and behaviour in addition to health. They felt the sustained presence of a specialist clinic offered the support needed to feel competent in pro-actively meeting their child's needs.

Authorship Contribution

Elanor Hinton and Dinesh Giri contributed equally to this paper and thus would like to be considered joint last author.

All named authors met ICMJE recommendations for authorship, contributing to the conception and design of the work, facilitated the delivery of the intervention and the acquisition of data. All authors contributed to the drafting of intellectual content. All authors approved the final draft and agreed to be accountable for all aspects of the work.

Declarations

This work is a service review and thus no ethical approval was required. The service review had approval from Patient Experience and Involvement Team at University Hospitals Bristol and all interviewees provided informed consent to their participation and the publication of the results. All names used in this work are pseudonyms to protect the patient's anonymity.

Data availability

Anonymised data sets can be made available on request.

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Appendix E

Appendix E.1 Using the COM-B to understand intervention need in the development of a paediatric clinical weight management intervention targeted at those young people who are not experiencing weight change from attending the clinic.

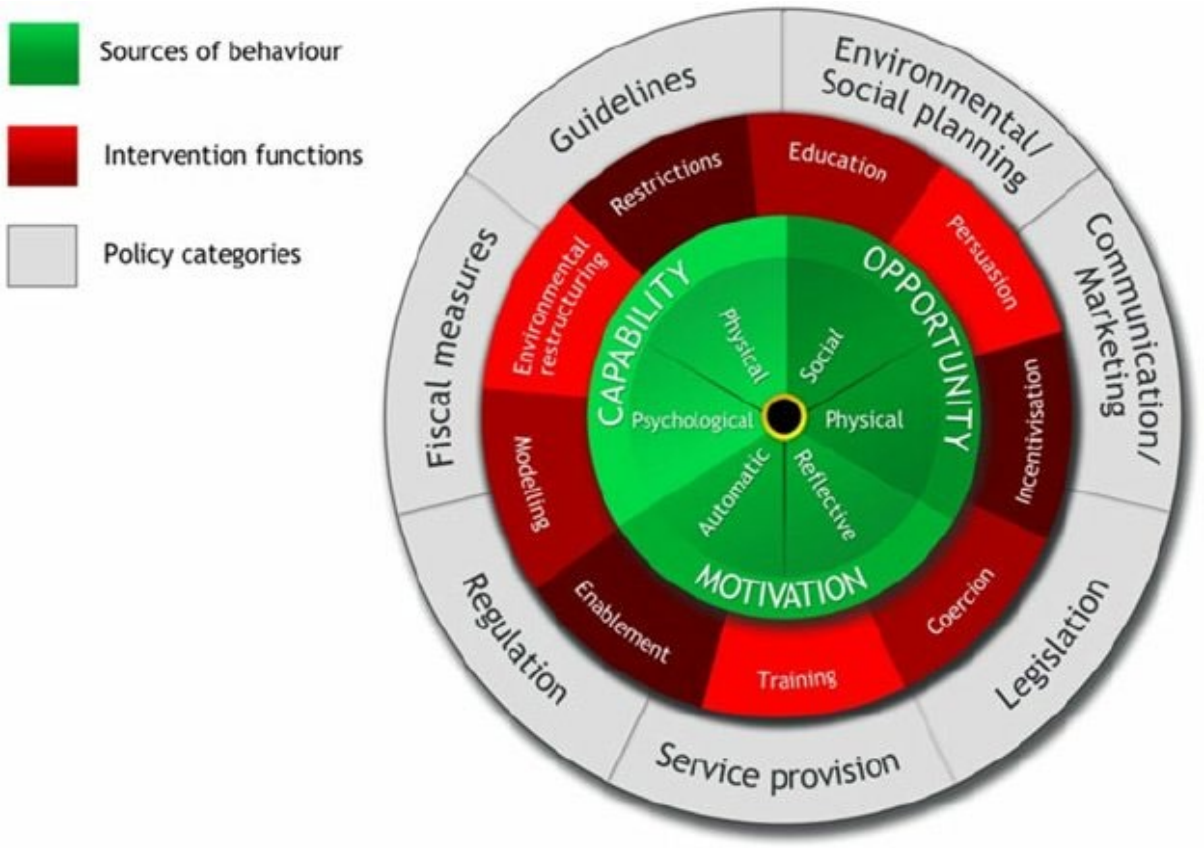


Figure E.1.1. The behaviour change wheel with sources, intervention functions and policy categories

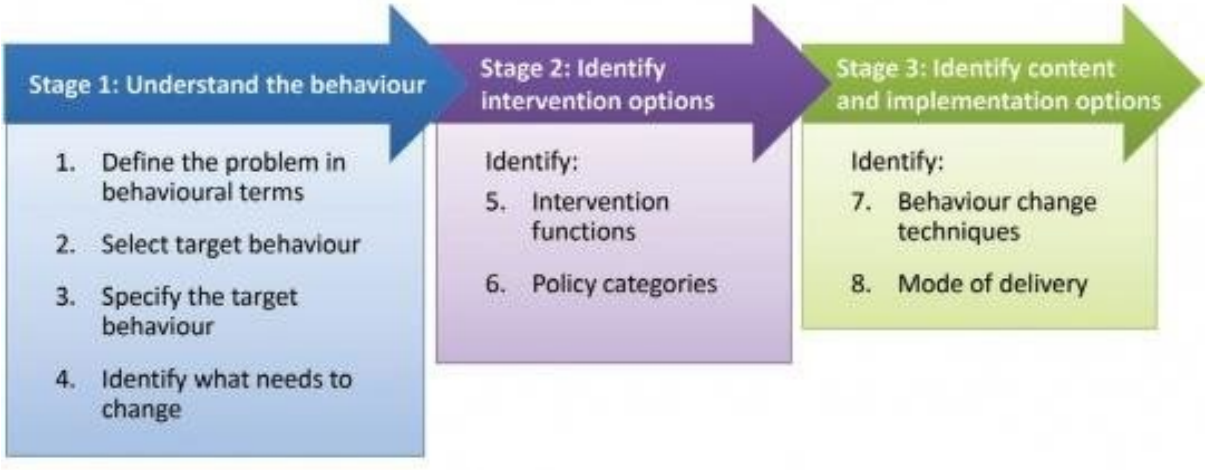


Figure E.2.2. The process of completing the behaviour change wheel guide to designing an intervention.

NB As the intervention aim has been established via qualitative interviews and literature searching, the COM-B process for this intervention begins at Stage 1. Step 4.

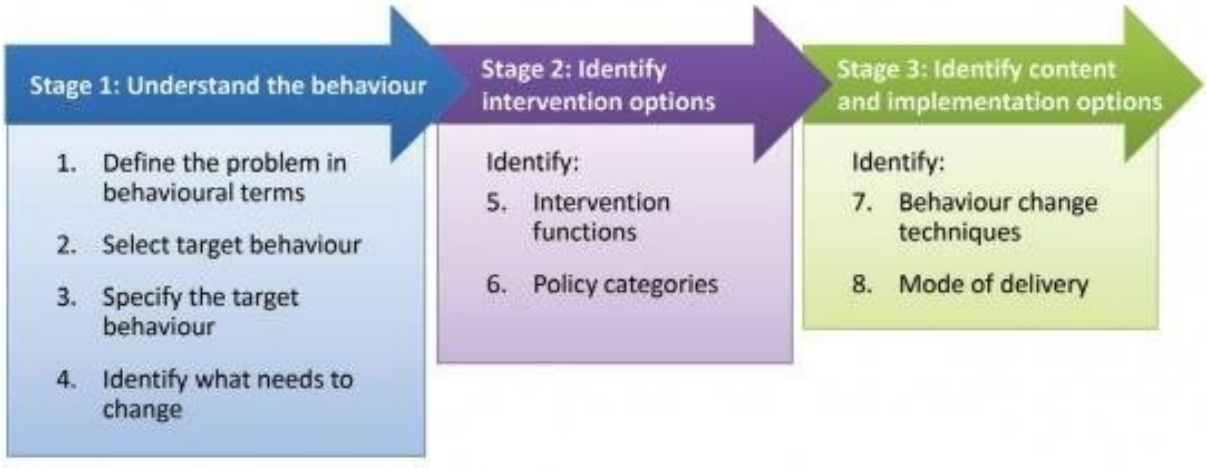
Stage 1. Step 4. Understanding the behaviour: Identify what needs to change.

Table E.1.1 Worksheet 4

Using the COM-B model to identify what needs to change to enable young people to increase their intrinsic motivation.		
COM-B Component	**What needs to happen for the target behaviour to occur?**	**Is there a need for change?**
Physical capability: our physical strength, skill or stamina	N/A	No
Psychological capability: our knowledge/ psychological strength, skills or stamina	Perseverance and stamina will be required for these patients as it's possible they will need to manage and monitor changes for a long period. Psychological strength to make decisions based on long-term not short-term reward. Increase in self-efficacy. Psychological skills in identifying what their values and goals are. Skills to appraise their environment and to understand how to operationalise this to their benefit (environmental restricting, cueing etc). Skills to negotiate conflict. Skills to negotiate sabotage by friends/family/etc.	Yes Yes Yes Yes Yes Yes Yes
Physical Opportunity: opportunities provided by the environment, such as time, location and resource	N/A	No
Social Opportunity: opportunities as a result of social factors, such as cultural norms and social cues	Young people need to be supported by an 'autonomy-supportive' environment and support style from parents and clinicians. Patients will need this form of support from their close family and friends to allow them the autonomy to take responsibility for their own behaviour. This will be a change in the power-balance	Yes

	for many families, where parents usually have the greater control over their child's eating. Engaging peer support. Parental modelling of intrinsic motivation and behaviour change driven from intrinsic means. Challenging stigma and external drivers for change.	 Yes Yes Yes
Reflective Motivation: reflective processes, such as making plans and evaluating things that have already happened	Patients will need to be prepared to evaluate their values and goals for this approach to work. They will need to develop skills in reflecting on their behaviour (both past and current) as the course goes on and making plans to take forward ideas from the clinic into their everyday behaviour. Improved self-knowledge of what motivates oneself. Reflection on past experiences and what helps/hinders in own life.	Yes Yes Yes
Automatic Motivation: automatic processes, such as our desires, impulses and inhibitions	Learning skills to inhibit automatic behaviours that allow short-term rewards and to favour a longer-term view, for example targeting the automatic processes that result in emotional/comfort eating. Developing new behaviours as habits. This will support self-regulation as actions are less focused around conscious decisions. Healthy behaviours become embedded.	Yes Yes

Behavioural diagnosis of the relevant COM-B components	Psychological capability; Social Opportunity; Reflective Motivation; Automatic Motivation



Stage 2: Identifying intervention content and implementation options.

Step 5. Identify intervention functions.

This stage involves using the results of the behavioural diagnosis carried out in Stage 1 to guide decisions regarding the content and delivery of the intervention. This involves first selecting suitable intervention functions (e.g. education, incentivisation) and policy categories (e.g. guidelines, legislation). (Fig. 1) Based upon these decisions, suitable BCTs are identified for inclusion in the intervention before finally deciding upon a suitable mode of delivery.

First, the intervention functions most suited to target the domains identified in the COM-B behavioural analysis carried out in stage 1 were selected using established links between COM-B and intervention functions (Table E.1.2). The identified intervention functions suitable in the context of the target behaviours are then considered using APEASE criteria (affordability, practicability, effectiveness/cost-effectiveness, acceptability, side-effects/safety, equity) which allowed for evaluation of the appropriateness of the identified functions for incorporation into the intervention.

Table E.1.2. Links between COM-b & intervention functions

INTERVENTION FUNCTIONS -->	EDUCATION	TRAINING	PERSUASION	INCENTIVISATION	COERCION	RESTRICTION	EBABLEMENT	ENVIRONMENTAL RESTRUCTURING	MODELLING
COM-B COMPONENTS									
Physical Capability									
Psychological Capability									
Reflective Motivation									
Automatic Motivation									
Social Opportunity									
Physical Opportunity									

Table 2. examples of intervention functions

Intervention function	Definition	Example of intervention function
Education	Increasing knowledge or understanding	Providing information to promote healthy eating
Persuasion	Using communication to induce positive or negative feelings or stimulate action	Using imagery to motivate increases in physical activity
Incentivisation	Creating an expectation of reward	Using prize draws to induce attempts to stop smoking
Coercion	Creating an expectation of punishment or cost	Raising the financial cost to reduce excessive alcohol consumption
Training	Imparting skills	Advanced driver training to increase safe driving
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)	Prohibiting sales of solvents to people under 18 to reduce use for intoxication
Environmental restructuring	Changing the physical or social context	Providing on-screen prompts for general practitioner to ask about smoking behaviour
Modelling	Providing an example for people to aspire to or imitate	Using television drama scenes involving safe-sex practices to increase condom use
Enablement	Increasing means/reducing barriers to increase capability (beyond education and training) or opportunity (beyond environmental restructuring)	Behavioural support for smoking cessation, medication for cognitive deficits, surgery to reduce obesity, prostheses to promote physical activity

Table E.1.3 Worksheet 5

Candidate intervention function	**How would the intervention work in the context of improving a paediatric patient's intrinsic motivation?**	**Does the intervention function meet the APEASE criteria (affordability, practicability, effectiveness/cost-effectiveness, acceptability, side-effects/safety, equity) in the context of improving a paediatric patient's intrinsic motivation? Consider this on the basis of this being an individual level intervention (not a population level intervention)** **Explain whether or not each function is appropriate, including your rationale.**
Education	This function is appropriate as linked to 'Psychological Capability' – patients will need educating in psychological techniques and behaviours to increase their strength and stamina. Psycho-education could be used to help support understanding of motivation and psychological pathways to success, self-understanding and evaluation, and planning for the future.	Affordability could be questioned given we're planning a 1:1 therapy, one hour a week for 7 weeks. However, the intention is that this would reduce overall duration of time the patient is in the clinic. Targeted at current non-responders to the current treatment, so would likely go on to having complex health conditions/ NHS expense. Using online platform (e.g. zoom) reduces cost. No clinic space required.

		The feasibility trial is designed to determine if it is acceptable.
Persuasion	No – this approach is too 'top-down' to be fitting with generating intrinsic motivation	N/A
Incentivisation	No - this approach is in contrast with generating intrinsic motivation (instead generating extrinsic motivation)	N/A
Coercion	No – this approach is too 'top-down' to be fitting with generating intrinsic motivation	N/A
Training	Yes – would be a fitting approach to impart skills for self-motivation and management, and for parents in creating an autonomy-supportive environment.	Affordability could be questioned given we're planning a 1:1 therapy, one hour a week for 7 weeks. However, the intention is that this would reduce overall duration of time the patient is in the clinic. Targeted at current non-responders to the current treatment, so would likely go on to having complex health conditions/ NHS expense. Using online platform (e.g. zoom) reduces cost. No clinic space required. The feasibility trial is designed to determine if it is acceptable.
Restriction	No – this approach is too 'top-down' to be fitting with generating intrinsic motivation however the restriction of patients' exposure to interventions that engage extrinsic motivation would be beneficial.	
Environmental Restructuring	N/A	No
Modelling	Parents and therapists will be encouraged to model behaviours driven by intrinsic motivation, which will support the young person to learn vicariously.	Yes
Enablement	Using ACT to increase self-determination will hopefully help reduce barriers patients have so far found in their weight management.	Yes
	Selected intervention functions: Modelling, enablement, training & education	

Step 6: Identify policy categories

Of the seven policy categories, as listed below in Table 2, use APEASE criteria to identify the categories best suited to deliver the identified intervention functions within the resource constraints of the work.

Table E.1.4. Matrix of links between intervention functions and policy categories

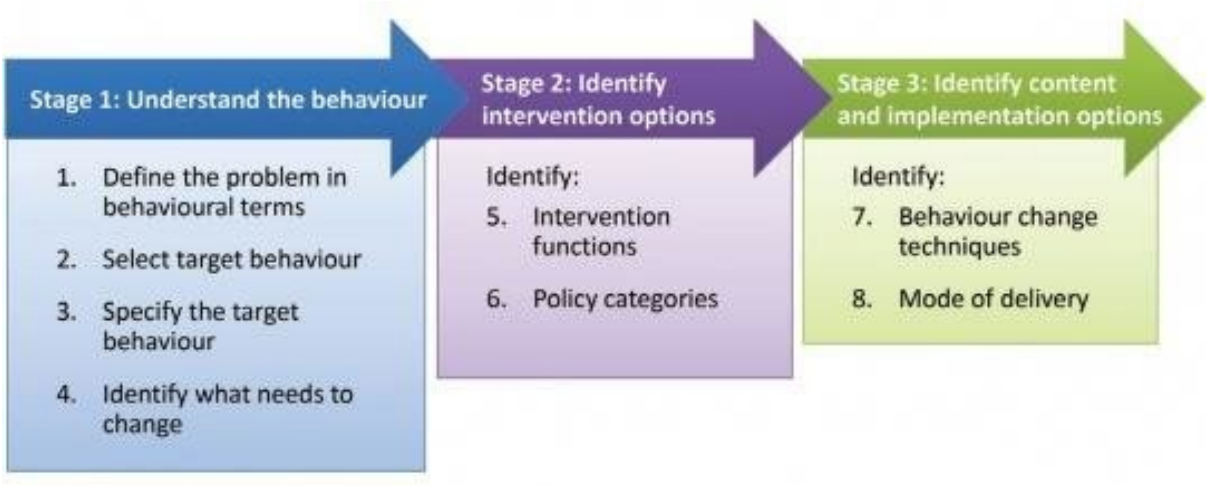
Policy Categories	Intervention Functions								
	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
Communication/ Marketing									
Guidelines									
Fiscal									
Regulation									
Legislation									
Environmental/ social planning									
Service provision									

Table E.1.5. examples of the policy categories

Policy category	Definition	Example
Communication/ marketing	Using print, electronic, telephonic or broadcast media	Conducting mass media campaigns
Guidelines	Creating documents that recommend or mandate practice. This includes all changes to service provision	Producing and disseminating treatment protocols
Fiscal measures	Using the tax system to reduce or increase the financial cost	Increasing duty or increasing anti-smuggling activities
Regulation	Establishing rules or principles of behaviour or practice	Establishing voluntary agreements on advertising
Legislation	Making or changing laws	Prohibiting sale or use
Environmental/social planning	Designing and/or controlling the physical or social environment	Using town planning
Service provision	Delivering a service	Establishing support services in workplaces, communities, etc.

Table E.1.6 Worksheet 6.

Intervention function	**COM-B component**	**Potentially useful policy categories**	**Does the policy category meet the APEASE criteria in the context of improving paediatric patients' intrinsic motivation?**
Education	Psychological Capability	Communication/marketing	No
		Guidelines	Yes
		Regulation	No
		Legislation	No
		Service provision	Yes
Training	Psychological Capability	Guidelines	Yes
		Fiscal measures	No
		Regulation	No
		Legislation	No
		Service provision	Yes
Modelling	Social Opportunity	Communication/marketing	No
		Service provision	Yes
Enablement	Reflective motivation	Guidelines	Yes
		Fiscal measures	No
		Regulation	No
		Legislation	No
		Environmental / Social planning	No
		Service provision	Yes
Policy Category selected: Guidelines & Service Provision			



Stage 3: Identify content and implementation options.

Step 7: Identify behaviour change techniques.

Whilst the COM-B model traditionally leads us to utilise the behaviour change taxonomy of 93 individual behaviour change techniques (BCTs) covering all areas of COM-B (capability, opportunity and motivation), in this case the behaviour we are seeking to change is that of intrinsic motivation. For this, a specific set of 21 behaviour change techniques has been devised based on expert consensus (Teixera et al., 2020). As this tailored resource exists, we will continue the COM-B process but with reference to these behaviour change techniques instead, referred to as MBCTs (Motivational behaviour change techniques).

The suitability and potential efficacy of each identified BCT will be considered, guided by APEASE, to produce a final set of BCTs for inclusion in the intervention.

We have also considered the BCTs needed to run the wider intervention, based on the area raised in the earlier stages of this behavioural analysis.

Table E.1.7 Worksheet 7a

Intervention Function	**COM-B Component**	**Most Recently used BCTs**	**Does the BCT meet the APEASE criteria (affordability, practicability, effectiveness/cost-effectiveness, acceptability, side-effects/safety, equity) in the context of raising patients' intrinsic motivation?**
Education	**Psychological capability Reflective motivation**	Information about social and environmental consequences	**Yes-** about the benefits of intrinsic motivation not weight loss
		Information about health consequences	**Yes-** about the benefits of intrinsic motivation not weight loss
		Feedback on behaviour	**Yes**
		Feedback on outcome of the behaviour	**Yes**
		Prompts/cues	**Yes**
		Self-monitoring of behaviour	**Yes**
		Biofeedback	Not practical to deliver
		Self-Monitoring of the outcomes of behaviour	Not relevant in this context

		Cue signally reward	Not relevant in this context
		Satiation	**Yes**
		Information about antecedents	**Yes**
		Reattribution	**Yes**
		Behavioural experiments	**Yes**
		Information about emotional consequences	**Yes-** about the benefits of intrinsic motivation not weight loss.
		Information about others' approval	**Unlikely to be effective in this context**
Training	**~~Physical capability~~ Psychological Capability Automatic motivation ~~Physical opportunity~~**	Demonstration of the behaviour	**Yes**
		Instruction on how to perform a behaviour	**Yes**
		Feedback on the behaviour	**Yes**
		Feedback on outcomes of behaviour	**Yes**
		Self-monitoring of behaviour	**Yes**
		Behavioural practice/rehearsal	**Yes**
		Biofeedback	Not practical to deliver.
		Self-monitoring of outcomes of behaviour	**Yes**
		Habit formation	**Yes**
		Habit reversal	**Yes**
		Graded tasks	**Yesif set collaboratively.**
		Behavioural experiments	Not relevant in this context,

		Mental rehearsals of successful performance	**Yes**
		Self-talk	**Yes**
		Self-reward	**Yes**
Modelling	**Automatic motivation** **Social opportunity**	Demonstration of the behaviour	Yes
Enablement	**Psychological capability** **Automatic motivation** **Social opportunity**	Social support (unspecified)	**Yes– if in line with autonomy support**
		Social support (practical)	**Not likely to effective in this context**
		Goal setting (behaviour)	**Yes**
		Goal setting (outcome)	**Yes**
		Adding objects to the environment	**Not relevant**
		Problem solving	**Yes– promoting the person to problem solve, not problem solving for them**
		Action planning	**Yes**
		Self-monitoring of behaviour	**Yes**
		Restructuring the physical environment	**Not relevant**
		Review behavioural goals	**Yes**
		Review outcome goals	**Yes–**
		Social support (emotional)	**Yes – if in line with autonomy support**
		Reduce negative emotions	**Not likely to be effective**
		Conserve mental resources	**Not likely to be effective**
		Pharmacological support	**Not relevant**
		Self-monitoring of outcomes of behaviour	**Yes**
		Behavioural substitution	**Not likely to be effective**
		Overcorrection	**Not likely to be effective**
		Generalisation of a target behaviour	**Not likely to be effective**
		Graded tasks	**Yes – if self-set**
		Avoidance/reducing exposure to cues for the behaviour	**Not likely to be effective**
		Restructuring the environment	**Not relevant**
		Distraction	**Not likely to be effective**

		Body changes	**Not relevant**
		Behavioural experiments	**Yes**
		Mental rehearsal of the successful performance	**Yes**
		Focus on past success	**Yes**
		Self-talk	**Yes**
		Verbal persuasion about capability	**Not likely to be effective**
		Self-reward	**Yes**
		Behavioural contract	**Not likely to be effective**
		Commitments	**Not likely to be effective**
		Discrepancy between current behaviour and goal	**Collaboratively**
		Pros and cons	**Yes**
		Comparative imagining of future outcomes	**Yes**
		Valued self-identity	**Yes**
		Framing / reframing	**Yes - collaboratively**
		Incompatible beliefs	**Yes – but manner of delivery is important**
		Identity associated with changed behaviour	**Yes**
		Identification of self as a role model	**Yes**
		Salience of consequences	**Not likely to be effective**
		Monitoring of emotional consequences	**Yes**
		Anticipated regret	**Not likely to be effective**
		Imaginary punishment	**Not likely to be effective**
		Imaginary reward	**Not likely to be effective**
		Vicarious consequences	**Not likely to be effective.**

Table E.1.8 : Worksheet 7b: Additional MBCTs applicable to this intervention

Label	Definition	Function	Description	Does the MBCT meet the APEASE criteria?
Autonomy-Support Techniques				Code: Yes, Not relevant in this context, Unlikely to be effective in this context or Not practical to deliver
MBCT1.	Elicit perspectives on condition or behaviour	Encourage exploration and sharing of perspectives on current behaviour (e.g. causes, perpetuating factors etc.).	Allows exploration of behaviour in more depth (self-knowledge), which can inform the programme and personal choices.	Yes
MBCT2.	Prompt identification of sources of pressure for behaviour change	Prompt identification of possible sources of external (or partially internalized) pressures and expectations and explore how they may relate to client's desired goals and outcomes.	Explores locus of causality and potential sources of external/introjected regulation and its consequences	Yes
MBCT 3.	Use noncontrolling, informational language	Use informational, non-judgmental language that conveys freedom of choice, collaboration, and possibility when communicating (avoiding constraining, pressuring, or guilt-inducing language). For example, use "might" or "could" instead of "should" and "must".	Avoids being a source of pressure or creating internal pressure, countering external locus of causality for actions.	Yes

MBCT 4.	Explore life aspirations and values	Prompt identification and listing of important life aspirations, values, and/or long-term interests and explore how changes in behaviour (or maintaining the status quo) could be linked to them.	Explores integrity and internal coherence between aspirations, values, and goals/behaviours, which can sustain autonomous regulation.	Yes
MBCT 5.	Provide a meaningful rationale	Prompt client to identify rationale for behaviour change and its maintenance that is tailored, explanatory, and personally meaningful or valuable.	Highlights and reinforces motives/reasons that could form the basis of autonomous motivation.	Yes
MBCT 6.	Provide choice	Provide opportunities to make choices from a collaboratively devised menu of behavioural options and autonomous goals. It includes the decision not to change, delay change, select focus/intensity of change, personally endorsed intrinsic goals and standards for success, including the timing or pace for certain outcomes.	Promotes personal input and ownership over behaviour change and responsibility through choice	Yes
MBCT 7.	Encourage the person to experiment and self-initiate the behaviour	Prompt the person to experiment and self-initiate (new) target behaviour that could be fun and enjoyable, is experienced as positive challenge, opportunity for learning or personal expression, and/or is associated with skill development, all of which provide experiential / immediate positive reinforcement".	Supports autonomous action via intrinsic motivation.	Yes
Relatedness-support techniques				

MBCT 8.	Acknowledge and respect perspectives and feelings	Provide statements of empathy and acknowledgment of the person's perspective, conflicts/ambivalence, distress, and negative affect (fear, confusion, etc.) and also expression of positive feelings when communicating with client (concerning the target behaviour, treatment, or other related matters).	Indicates attention and respect for the person's attitudes, thoughts, perceptions, and feelings, which creates an accepting and warm social environment.	Yes
MBCT 9.	Encourage asking of questions	Prompt the client to pose questions regarding their goals/behavioural progress.	Creates an open and collaborative relationship that promotes trust.	Yes
MBCT 10.	Show unconditional regard	Express positive support regardless of success or failure.	Demonstrates unconditional respect, care and support and promotes warm social environment.	Yes
MBCT 11.	Demonstrate/show interest in the person	Provide statements of interest and curiosity about the person's thoughts and perceptions, personal history and background, social context, life events, etc. when communicating.	Displays involvement, indicates to the person that their experiences and input are valued.	Yes
MBCT 12.	Use empathic listening	Demonstrate attentiveness to the client's responses (e.g. stay silent to allow the person to complete sentences), and provide reflective and summary statements when appropriate (directed at affect or content) when communicating. Prompt permission to	Creates open, collaborative relationship that promotes trust; Displays respect for the person.	Yes

		provide new information, guidance or advice		
MBCT 13.	Providing opportunities for ongoing support	Offer the person an appropriate venue and means to contact you in the event of difficulties or questions during the behaviour change process.	Shows care and personal involvement.	Not practical to deliver
MBCT 14.	Prompt identification and seek available social support	Prompt identification of sources of support for behaviour change (if relevant), acknowledge challenges in recruiting adequate support (autonomous vs controlled), and promote effective ways of seeking positive support.	Includes strategies that will help in feeling confident to overcome potential challenges and meet behavioural goal (e.g. information about available programmes, active involvement of others such as family members).	Yes
Competence-support techniques				
MBCT 15.	Address obstacles for change	Prompt identification of likely barriers to behaviour change, based on previous attempts, and explore how to overcome them (e.g. what may have worked in the past).	Increases confidence and reinforces existing skills.	Yes
MBCT 16.	Clarify expectations	Prompt statements of client's own expectations in terms of behaviour change (e.g. identify a clear goal or learning objective), both its experiential elements (process) as well as outcomes.	Provides structure and minimizes future failure (and perceived incompetence).	Yes

MBCT 17.	Assist in setting optimal challenge	Assist in identification of goals that are realistic, meaningful challenging, and achievable.	Provides structure and minimizes future failure (and perceived incompetence)	Yes
MBCT 18.	Offer constructive, clear, and relevant feedback	Provide relevant, tailored, non-evaluative feedback on goal/behavioural progress. This can include specific, process-focused feedback.	Provides encouragement and information to guide future behaviour.	Yes
MBCT 19.	Help develop a clear and concrete plan of action	Develop and provide summary of action plan to work toward a behavioural goal.	Provides structure, increases confidence, and minimizes future failure (and perceived incompetence).	Yes
MBCT 20.	Promote self-monitoring	Prompt monitoring of progress, skill level, or performance such as suggesting options for monitoring tools/means and metrics for success, including steps in the direction of behaviour change.	Provides structuring information that reinforces success and self-awareness.	Yes
MBCT 21.	Explore ways of dealing with pressure	Provide information to manage and limit effects of pressuring contingencies that would undermine competence such as extrinsic rewards, criticism, negative feedback.	Increase confidence to deal with sources of controlling pressure from others and themselves.	Yes

Step 7: Identify mode of delivery.

The final step involves considering the following in relation to intervention delivery: content, provider, recipients, intensity, duration and fidelity. The various potential modes of intervention delivery were considered using the APEASE criteria to assess the options that would be suitable within the constraints and resources of the feasibility trial.

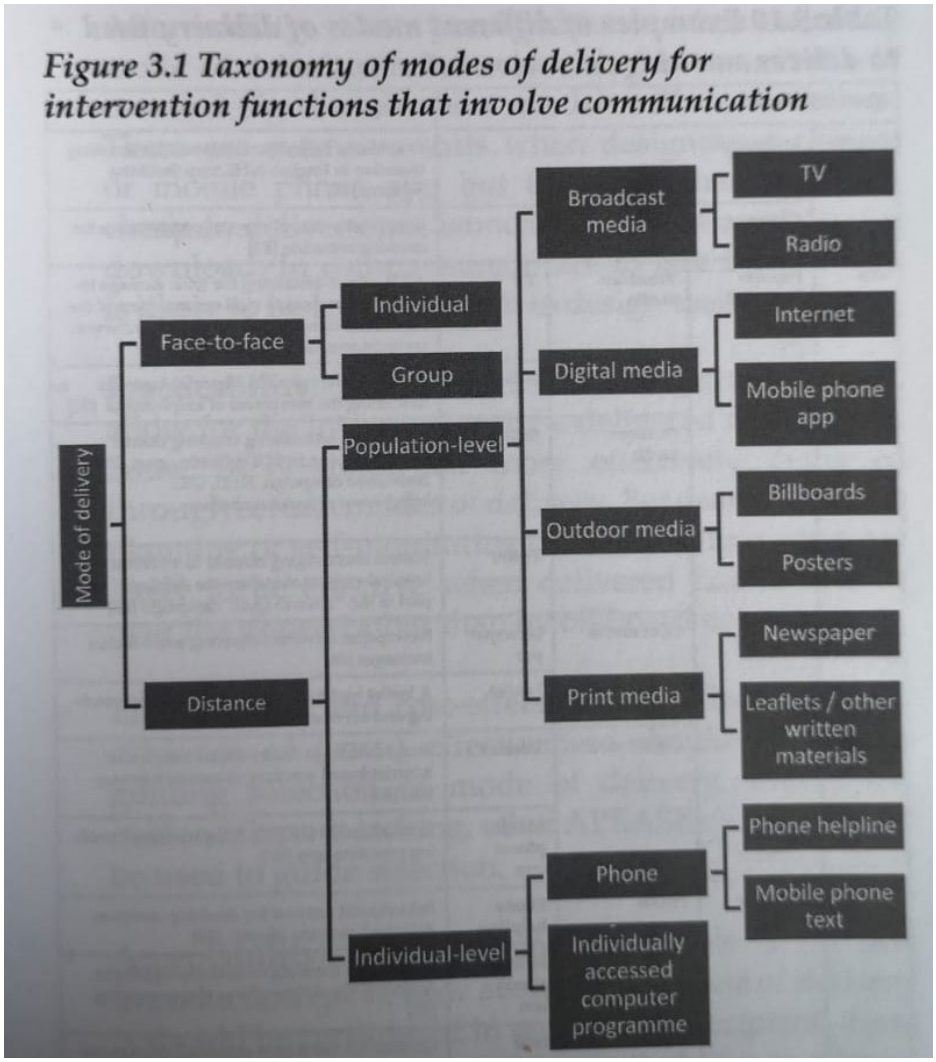


Table E.1.9: Worksheet 8.

Mode of delivery				Does the mode of delivery meet the APEASE criteria in the context of increasing paediatric patients' intrinsic motivation?
Face-to-face	Individual			Yes – will need to consider the costing / cost-effectiveness as face-to-face is expensive
	Group			Yes
Distance	Population level	Broadcast media	TV	Not applicable
			Radio	Not applicable
		Outdoor media	Billboard	Not applicable
			Poster	Not applicable
		Print media	Newspaper	Not applicable
			Leaflet	Not applicable
		Digital media	Internet	Not applicable
			Mobile phone app	Not applicable
	Individual level	Phone	Phone helpline	Yes – partially if video calling. Calls could be used if preferred by patient, although much easier to share materials and build rapport using a platform such as zoom (or equivalent).
			Mobile phone text	The intervention is too complex to be delivered over text. Needs discussion between therapist and patient
		Individually accessed computer program		Yes – could be delivered as a remote program, but patients would potentially lose out through not working with a clinician. Cost-benefit analysis required.

Appendix E.2: Table of changes

The table of changes is an iterative document that has been contributed to following PPI meetings, and will be updated throughout the iterative development phase of the intervention.

Coding key:
IMP = Important behaviour change
EAU = Easy and uncontroversial
REP = Repeatedly
EXP = Experience (specify PPI, experts, literature)
NCON = Does not contradict experience or the guiding principles
NC = not changed (give a reason)
MoScoW = Must do, Should do, Could do, Would like to do

Aspect of the intervention	Negative Comments	Positive comments	Possible changes	Reason for change code	Agreed change	MoScoW (Must do, Should do, Could do, Would like to do)
Concept feedback						
Novel		The approach was novel and enabled them to think about their feelings in a way they had not before.				
Internal/self-motivation	PPI members explained repeated failed attempts at weight loss until they themselves felt they were ready. Our challenge is that the YP's have been referred, we need to tap into a way of getting them ready to start, from a place where they may not have chosen to be referred.	Thought to be v important for successful weight change. Not going to continue with an intervention that "makes them feel rubbish". GB "Got to have that moment where you think I need to do this for me" and GT agreed need to "decide for myself" to	Consider methods to drive internal motivation including visualisation, clarification of values. Reduction of external pressures may give	IMP, EXP	Incorporate methods to drive internal motivation including visualisation, clarification of values. Reduction of external pressures may give space for internal motivations.	Must do

		make the change and to stop thinking of healthy eating as a negative thing to be doing, instead framing it as a positive change.	space for internal motivations.			
Wholistic		This concept came up in both adult PPI sessions – the importance of seeing the whole person rather than purely focussing on what they eat. BC towards end felt the approach was "empowering, hopeful and for the whole person" The lack of focus on specific food, and more about whole person and behaviour as a strong benefit.				
Flexible approach as opposed to strict rules.	For those with poor nutritional knowledge, more guidance may be required to establish a healthy diet.	PPI members reflected on their experience of wanting something more because it had been restricted- a flexible approach is preferred.		Exp. NCON	As the clinic already offers nutritional education we hope that patients have learnt during their initial 6-months at the COCO clinic. Dietary guidelines and calorie counting is also offered so this intervention seeks to take a different approach to support those for whom that approach has not worked.	
Individualised approach	The importance of making the intervention relevant to the individual's interests and motivations (gave example of his therapist using his interest in cars)		Develop individual rapport with patients enabling metaphors and examples to be tailored to their needs	EXP,	Therapists' confidence with the programme material will need to be considered when thinking about their ability to adapt interventions on the spot. If possible, this would be the	Would like to do

					ideal, but feasibility will need to be reviewed.	
Logistical factors						
1-2-1 sessions		Felt that YP need to be a certain age before being able to share their feelings within a group				
Where to hold the sessions		As much choice given to the young people as possible.				
Parents joining in the sessions.	Young people may struggle to discuss how they feel in front of parents, especially before they have built rapport with the clinical team enough to feel safe to discuss their feelings. Holding these discussions in front of family may be particularly sensitive if the young person feels their upbringing and/or home food environment has contributed to their weight problem. Equally parents may have questions and experiences they want to share with the clincians but not in front of the young person.		Splitting sessions so part is done with the YP alone to develop trust and confidence to share with their PG Or Offering the young person the chance to invite their parent to join or not	REP, EXP, NCON	The young person will get the chance to invite their parent when they want to - session topics will be give a week ahead so young people can make a session by session choice. Currently, no session time has been allocated for parents-only, however this will be reviewed.	Should do
Default of inviting the parent to support	The parent may not be the most appropriate support, in some cases a grandparent, or other figure may be the child's key support.	As much choice given to the young person about the session is a good thing.	Young people being given the option to bring an alternative support person, not defaulting to always being the parents.	EXP, NCON	This option will be offered to patients, and continually reviewed.	Could do

Online video as the platform for therapy	But might create problems if nowhere to go at home without parents. Don't know who else is there to 'make sure they are saying the right things'.	Some cases zoom better, eg video off, may help to be relaxed in a comfortable place, more honest.				
Terminology						
Terminology – unhooking		The wording resonated – in particular 'unhooking' and 'hooked' was described to explain how they feel about being absorbed by darker thoughts, with strategies such as going for a walk being 'unhooking' they reflected.	offer several activities to try for each session as individual differences in how each activity will be viewed and received.	/		
The use of the term 'Choice'	Does choice have connotations of fault and blame? That 'choice' is a difficult word. As YP often told they have choices but often they are already made (by adults, socioeconomic position, genetics - CG). HH "YP may not yet understand that they are in control of their behaviour." That they might not realise they are making choices. JW – remembered feeling that she didn't understand her emotions "never mind that I had a choice". Linked to DF (Thurs11th) who felt when muddled, she didn't feel she had a		think about how to use the word choice so it avoids negative feelings surrounding not having made good ones previously. Raising awareness of the choices we make all the time – some YP may not be aware or even able to make 'good' choices when feeling emotional and pressured.		Work to be done on explaining the concepts, before then introducing choice as something we would work on giving the YP. Rather than inferring that they have always had choice and have been taking the wrong choice up until this point.	

	choice in the way she behaved around food.					
Using the term 'mindfulness'	The term 'mindfulness' is overused especially during school and when stress is discussed. It makes people stop listening as it feels like more of the same.	Some adolescent PPI members had positive experiences and a regular mindfulness practice, therefore connecting that the activities were mindfulness allowed them to build on their skills Important to not underestimate young people's interest and engagement:	Using the term 'awareness' i.e. bringing your awareness to certain experiences, rather than mindfulness may help tap into the beneficial effects of mindfulness without the cliché preconceptions.	EAU, REP, EXP NCON	Both terms will be used and the preferred language will be discussed with each young person. This is an area for continued monitoring and can be changed if there is a clear pattern.	Could do
Specific activities						
Three mountain metaphor	The metaphor simplifies the challenges of the journey and the external pressures including peer pressure and technology that impact the journey one person felt it could be viewed competitively, so suggested making sure it wasn't viewed as a race or competition	The collaborative aspects of the therapy relationship ae clear, the approach of tackling these problems together, with lots of emphasis on how the young person is involved in shaping this process. it was felt this approach felt "inviting". "Invitation to come on a joint journey" "makes them know it's what they want rather than being told to do something."	Ensure that the diagram of the mountain includes notable up's and down's and discuss them in the explanation of the metaphor	EAU, EXP, NCON	Yes	Should do
Lottery	YP's weren't as keen on the lottery example as made them feel selfish.					

	Found it hard to decide how to see yourself.					
Inflatable ball activity		The activity facilitated conversation; it was easier to discuss having done the activity together. People then built on the metaphor, continuing to use it in new ways to explain how they felt. "Feel like you described my teenage years" "a new way to consider this". Strength in that the conversation evolved, with people still using the metaphor to explain how they felt in other situations				
The choice point video	The video simplifies the decision to make the life-enhancing decision, rather than the habitual non-healthful behaviour. Video features a very slim woman with protruding collarbones with PPI members found drew their attention. Video only features a woman.	The video captured attention and offered a concise snapshot of what was perceived as an interesting and novel approach. Left people wanting to know more about the approach. The video offered hope that there was a solution not just to their weight but to how they were feeling more broadly. Gave them a sense that they didn't need to feel stuck and left them feeling more positive.	Caveat the video with the understanding that this is a simplified version of what is actually going on. There are two versions of the video, so ensuring the version with the slim woman is not used.	Exp. NCON		Should do

	Some of the language/issues were not necessarily the right focus for YP (e.g. financial worries).	Discussions were held about how the video was targeted at adults, but that this wasn't necessarily a negative thing as for many YP's it would be empowering to know that they were being treated as adults. "Got the point across without being super cringy".				
Visualising your mind as a character	Not all people enjoyed trying to draw and visualise their minds. One person who was less keen on the activity felt their mind often encouraged them to engage in the health beneficial behaviours.	Some people found the idea that our mind tells us the same repeated stories useful and enjoyed reflecting on this. Members explained battling with the two sides of their mind	Assessing where the YP is at individually may help to understand whether this is a useful activity for them	EXP,	developing the baseline that these are all things to experiment with/try. Some will feel helpful, others may not, and that is okay – we can just keep working with/building on the things that feel they work for that individual. Not everything will work for everyone.	Could do