Feasibility of integrating an exercise specialist supported by *m*Health techn*o*logy to increase exercise and physical ac*tiv*ity *a*dherence in a Complica*t*ions from *E*xcess Weight Service: MOTIVATE-CEW

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Abstract

Introduction: To address the increasing prevalence of childhood obesity NHS England has established 21 Complications of Excess Weight (CEW) services. Despite physical activity (PA) and exercise forming cornerstones of successful weight management programmes CEW services do not include specialists in the delivery of PA or exercise. **Aim:** To assess the feasibility of embedding an mHealth supported PA and exercise intervention, led by an exercise specialist, to a CEW service. **Methods:** A 12-week feasibility, parallel group, randomised control trial was conducted in 23 obese adolescents receiving care from the Alder Hey Children's Hospital (AHCH) CEW service. Participants randomised to usual care continued with the CEW service and the MOTIVATE-CEW group received usual care alongside an mHealth supported exercise and PA intervention. A process evaluation assessed reach, dose and fidelity and preliminary effectiveness was measured (health related quality of life (HRQOL), body composition and cardiovascular disease risk factors). **Results:** 45% of eligible participants were recruited and 87% completed post-intervention assessments. Recruited participants shared similar demographics to the AHCH CEW service cohort in terms of age, sex and deprivation. Large effect sizes favouring MOTIVATE-CEW were shown for device derived number of exercise session (d=1.02) and mean time spent exercising (d= 0.97). Data availability for in-clinic outcomes was good (≥85%), but adherence to wear time criteria for PA (GENEActiv 43%, ActivPAL 41%) and flash glucose (35%) monitors was poor. **Conclusion:** The MOTIVATE-CEW intervention showed promising effects on exercise behaviour. Good reach and data availability suggests the study design could be feasible within future trials.

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Declaration

I declare that the work contained in this thesis is entirely my own and no portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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Abbreviations

AHCH	Alder Hey Children's Hospital
ALT	Alanine transaminase
AST	Aspartate aminotransferase
BCT	Behaviour change technique
BMI	Body mass index
BMI-SDS	Body mass index standard deviation score
CEP	Clinical Exercise Physiologist
CEW	Complications of Excess Weight
CHIS	California Health Interview Survey
CI	Confidence intervals
CRAE	Combined resistance and aerobic training
CRF	Cardiorespiratory fitness
DBP	Diastolic blood pressure
fGM	Flash glucose monitor
GLTEQ	Godin Leisure Time Exercise Questionnaire
HCP	Health care professional
HDL	High density lipoprotein cholesterol
HIIT	High intensity interval training

HOMA-IR	Homeostatic model assessment for insulin resistance
HRQOL	Health related quality of life
IMD	Index of Multiple Deprivation
LDL	Low density lipoprotein cholesterol
MAP	Mean arterial blood pressure
MDT	Multidisciplinary team
mHealth	Mobile health
MVPA	Moderate- to- vigorous physical activity
NCMP	National Child Measurement Programme
PA	Physical activity
PedsQL	Paediatric quality of life inventory
RCT	Randomised control trial
RT	Resistance training
SBP	Systolic blood pressure
SD	Standard deviation
T1D	Type 1 diabetes
T2D	Type 2 diabetes
VLDL	Very low-density lipoprotein
WHO	The World Health Organisation

1. Literature Review

1.1 Childhood Obesity Prevalence

Childhood and adolescent obesity has become a major public health problem globally. The World Health Organisation (WHO) estimated that in 2016 over 340 million children and adolescents aged 5-19 were classed as overweight or obese (W.H.O, 2021). This figure accounts for 18% of the population for that age bracket. In comparison, only 4% of 5- to 19-year-olds were obese in 1975. Overweight and obesity are defined using standard deviations of body mass index (BMI) for age. The WHO define overweight and obese children as a BMI standard deviation score (BMI-SDS) above 1 and 2, respectively. The WHO do not define severe obesity but studies have previously used a BMI-SDS above 3 (Hoedjes et al., 2018).

This pandemic of childhood obesity is one that is especially prevalent in England and the proportion of children or adolescents with obesity in England has risen dramatically in the last decade. Data from the National Child Measurement Programme (NCMP) highlights the increase in obesity prevalence within the UK over the last 10 years. The NCMP (NHS-Digital, 2022) England, is part of the UK Governments attempt to tackle obesity and provides up to date and accurate data, annually, for the proportion of children aged 4-5 and 10-11 who are classed as obese and severely obese. In 2012, 19.2% of children aged 10-11 were obese and this has risen to 23.4% in 2022. Of concern, this trend is mirrored in the number of children with severe obesity. When the NCMP started in 2006 3.2% of the population were living with severe obesity by the age of 11 and now in 2022 5.8% of 10–11-year-olds are

severely obese. Data from the English NCMP is only available for children aged 10-11 but data from the US suggests severe obesity is more prevalent in the later stages of childhood. A study of 6,863 US children showed that 8.4% of 12-19 year-olds were severely obese compared to 4.8% of 6-11 year-olds in 2016 (Ogden et al., 2018).

There is a disparity in who childhood obesity most commonly affects. As well as an increase in the prevalence of children and adolescents with obesity across England, there is increased prevalence in more deprived areas. To assess deprivation the Index of Multiple Deprivation (IMD) is commonly used (McLennan et al., 2019). IMD uses seven different domains that are associated to deprivation, these are income, employment, education, skills and training, health, disability, crime, barriers to housing and services and living environment deprivation. These are weighted and then combined to provide a rank for each area within England. Areas are ranked from least deprived to most deprived and this rank can then be grouped into deciles or quintiles to express deprivation. The NCMP shows that in 2022, 31.3% of children aged 10-11, who live in areas that rank in the lowest IMD decile, are obese. In comparison, only 13.1% of children in the highest ranked IMD decile are obese. The gap in obesity prevalence between the most and least deprived deciles also has increased in the last ten years with a difference of just 10.6% in 2012 and a difference of 17.8% in 2022. The prevalence of severe obesity is also far greater in more deprived areas, with 9.2% of children in the most deprived areas classed as severely obese. This is more than 4 times the prevalence in the least deprived areas (2.1%). This pattern of prevalence associated to deprivation is highlighted in the childhood obesity rates in

Liverpool. Liverpool is classified as one of the most deprived cities in the UK and obesity prevalence was shown to have increased by 2.61% in boys and by 3.34% in girls between 2006 and 2012. Disparities in the prevalence of children living in the most deprived communities and children living in the least deprived communities increased within Liverpool between 2006 and 2012 (Noonan, 2018).

1.2 Health consequences of childhood obesity

Childhood obesity can result in a number of short and long-term health problems. The variety of health conditions that stem from obesity have varying levels of severity and prevalence, however, the risk of mortality in early adulthood is higher as a result of childhood obesity (Lindberg et al., 2020). The review by Reilly et al. (2003) synthesised a large amount of evidence that showed an association between paediatric obesity and most cardiovascular risk factors including hypertension, dyslipidaemia, abnormal endothelial function, and insulin resistance.

High blood pressure (hypertension) is commonly associated with childhood obesity (Wühl, 2019). The mechanisms of obesity related hypertension are still being studied, but two obesity related causes include increased insulin stimulation of the sympathetic nervous system, and increased activation of the renin-angiotensin-aldosterone system as a result of obesity (Landsberg et al., 2013). There is a greater risk of hypertension for severely obese children (Bass and Eneli, 2015). Children and adolescents with obesity are at greater risk of dyslipidaemia as a result of their excess weight. The review by Skinner et al. (2015) found that there was a greater risk of low, high density lipoprotein

(HDL) cholesterol and high triglyceride levels with a greater severity of obesity. This increase in triglycerides predicts atherosclerosis in early adulthood which greatly increases the risk of cardiovascular disease (Koskinen et al., 2018). Early signs of the manifestation of atherosclerosis can be detected by monitoring endothelial dysfunction and there is a clear impairment of endothelial function in children who are obese compared to healthy weight children and adolescents (Järvisalo et al., 2002; Pena et al., 2006; Skilton and Celermajer, 2006). In particular, the study by Järvisalo et al. (2002) showed that flow mediated dilation, which is an indicator for nitric oxide bioavailability, was reduced in children with a higher BMI. Nitric oxide is responsible for a number of atheroprotective processes (Eisenmann et al., 2004) and its impairment can result in elevated risk of cardiovascular disease or stroke. Sleep apnoea (effecting up to 60% of obese children), is also associated with changes in vascular function/structure, hypertension, arterial stiffness and metabolic syndromes suggesting that it may magnify any underlying cardiovascular or metabolic burden (Narang and Mathew, 2012). Finally, insulin resistance (Steinberger and Daniels, 2003), increased risk of cancer (Lauby-Secretan et al., 2016; Weihrauch-Blüher, Schwarz and Klusmann, 2019) and earlier onset of puberty (Ahmed, Ong and Dunger, 2009) are also all associated with childhood and adolescent obesity.

As well physiological changes for children and adolescents with obesity there are also substantial effects on quality of life as a result of excess weight. There is a greater risk of obese youth having reduced quality of life and children's perception of their appearance, athletic ability and social competence are all compromised. (Braet, Mervielde and Vandereycken, 1997; Gibson et al.,

2008). These perceptions result in lower self-regard as a result of their weight and are all factors that can lead to mental health problems (Griffiths, Parsons and Hill, 2010). A study evaluated the health related quality of life (HRQOL) of 106 children and adolescents using the Paediatric Quality of Life Inventory and compared this to healthy controls and children diagnosed with cancer (Schwimmer, Burwinkle and Varni, 2003). The severely obese children reported significantly lower HRQOL than the healthy children across all domains of the questionnaire. The HRQOL scores from the severely obese children and adolescents was also similar to the scores from the children diagnosed with cancer, suggesting that severely obese children have a HRQOL as children with cancer.

It is clear from the evidence presented that childhood and adolescent obesity has a significant impact on both immediate physical health and on quality of life. However, the long-term health conditions that result from this are a far greater concern. It has regularly been shown that childhood and adolescent obesity tracks into adulthood (Serdula et al., 1993; Li et al., 2004) with obese children at least twice as likely to be obese as adults than nonobese children. Children with severe obesity are also more at risk of developing these conditions which include type 2 diabetes, metabolic syndrome and fatty liver disease (Bass and Eneli, 2015).

Type 2 diabetes (T2D) is a long-term condition that can be caused by obesity (Biro and Wien, 2010; Franks et al., 2010). Not only does childhood and adolescent obesity result in a greater risk of developing T2D as an adult but there is also risk of having an earlier onset of T2D. The prolonged duration of T2D that comes with an earlier onset is a concern for patients, and an earlier

onset is associated with a quicker progression to β-cell failure (Gungor et al., 2005). This progression increases the risk of health complications in later life with visual impairment, kidney failure (Pavkov et al., 2006) and limb amputations (Dean and Sellers, 2007) all more likely, due to the earlier onset of T2D. The risk of developing cardiovascular diseases in adulthood is also increased as a result of childhood obesity (Faienza et al., 2020). Two large cohort studies have assessed the association between increased BMI in childhood and increased risk of adulthood cardiovascular disease and mortality and both of these studies show an increased risk as a result of childhood obesity (Baker, Olsen and Sørensen, 2007; Twig et al., 2016). Baker et al. (2007) showed that a 1 unit increase in the BMI-Z score of a 13-year-old child almost doubled the risk of cardiovascular disease in adulthood.

1.3 Reasons for increased prevalence

The growing prevalence of childhood obesity requires intervention in order to reduce complications and prevent the development of long-term health conditions. To be able to do this, it is first important to understand what causes childhood obesity. For the majority, obesity is the result of an imbalance between energy intake and expenditure (Goran, 2000). However, there are some circumstances where genetic factors can account for obesity, but, this is thought to only account for a very small proportion of cases (Anderson and Butcher, 2006). Results from cross-sectional studies suggest there is no one reason for the cause of childhood obesity but it is suggested that obesity can be a result of a combination of lifestyle and environmental factors (Grundy, 1998; Rennie, Johnson and Jebb, 2005; Sahoo et al., 2015). Changes to the

diets consumed by children are one potential cause for obesity. The consumption of fast food and portion sizes have increased over time (Nielsen, Siega-Riz and Popkin, 2002; Nielsen and Popkin, 2003) which can both result in increased energy consumption. However, there is limited evidence to support the idea of an overall increase in energy intake, possibly due to the variability of dietary measurement techniques used in overweight and obese young people which often lead to under-reporting of dietary intake (Bandini et al., 1990; Perks et al., 2000; Rennie, Johnson and Jebb, 2005). A lack of physical activity (PA) or exercise and increased periods of sedentary behaviour are other potential causes of reduced energy expenditure, contributing to increased childhood obesity prevalence. An increase in the time spent watching television (Hernández et al., 1999; Crespo et al., 2001) or playing video games (Rey-López et al., 2008) results in increased sedentary time which can present a higher risk of obesity when this replaces activity. PA results in the utilisation of energy, and so fundamentally a lack of PA and an increase in sedentary time (that requires less energy to be expended) will likely result in weight gain. Overweight/obese children have been shown to spend more time sedentary and less time in moderate or light intensity activity than their normal weight peers (Lazzer et al., 2003) which could contribute to weight gain. Although data on PA and sedentary behaviour suggest a role in the development of obesity, McManus et al. (2012) suggest that excessive energy intake is commonly to blame for childhood obesity, and it is the ensuing obesity that results in reduced PA in children. This differs from the suggestion that initial physical inactivity induces obesity. Even though the role of physical inactivity as a cause for childhood obesity is unclear, the role of exercise and

PA in the treatment of childhood obesity and the prevention of health-related consequences is clear.

1.4 The Role of exercise and PA in the management of obesity and its health-related consequences

Controlled laboratory trials have shown that exercise is an efficacious intervention to improve health related outcomes in obese young people. The changes associated with these interventions are beneficial both acutely and in the long term. Increased exercise and PA have regularly been shown to produce improved outcomes for body composition, cardiovascular risk factors, glycaemic control, mental health, and cardiorespiratory fitness.

1.4.1 Body composition

A systematic review of meta-analyses conducted by Garcia-Hermoso et al. (2019) assessed the impact of exercise alone on body composition in overweight and obese children and adolescents (aged 6-18). When exercise type (aerobic, resistance or combined) was not considered the analysis showed a significant medium reduction in BMI (g = −0.50;95% CI, −0.70 to −0.30) and small improvements in fat mass and central obesity using pooled data from five, four and two meta-analyses, respectively. When investigating the influence of training type on body composition in adolescents (aged 8-18), a recent meta-analysis suggested that combined training and high intensity interval training (HIIT) were more effective at reducing BMI than aerobic or resistance training (RT) (Li and Chen, 2021). However, BMI may not be the best measure to conduct this analysis on as it may be confounded by increases in lean mass following RT. A consistent finding of both analyses was

the heterogeneity in responses which may be explained by the diversity in participant characteristics (e.g., age, overweight and obese) and exercise protocols (e.g., exercise intensity and duration and intervention length). To the authors knowledge no trials have been conducted in children with severe obesity alone, but a study by Monterio et al. (2015) explored the effect of a 20-week aerobic exercise intervention on obese adolescents aged 11-17. The aerobic training was performed 3 times a week with each session consisting of 50 minutes of supervised walking and running intended to be completed between 65 % and 85 % of VO2peak. The intervention resulted in significant decreases in body weight, BMI, body fat %, and waist circumference ($P<0.05$). The effect of RT on body composition was assessed by Benson et al. (2008) in a cohort of 78 obese adolescents aged 10–15-year-olds over a period of 8-weeks. The progressive RT programme was completed twice a week with the supervision of the research team and 11 different exercises were each completed (2 sets of 8 repetitions). RT resulted in no change in BMI, but significant reductions in waist circumference (-0.8cm, $p=0.008$) and body fat % (-0.3%, $p=0.004$). Son et al. (2017) evaluated the impact of combined resistance and aerobic training (CRAE) on obese adolescent girls aged 14-16. The study recruited 40 obese adolescents who completed three 60-minute sessions per week of CRAE over a 12-week intervention period while supervised by the research team. The CRAE intervention resulted in significantly reduced waist circumference (-2.2cm, $P < 0.05$) and body fat % (-1.35%, $P<0.05$). HIIT has recently received increased attention as an alternative modality due to its potential as a time efficient training mode. The study by Racil et al. (2013) assessed the impact of 12-weeks of HIIT (2x(6-

8x30s at 100-110% maximum aerobic running speed) on body composition measures of adolescents (mean age 15.9) with obesity, compared to a moderate intensity interval training (2x(6-8x30s at 70-80% maximum aerobic running speed) and a control group. The HIIT intervention resulted in significant decreases in body weight ($P < 0.05$), Z-score BMI ($P < 0.01$), waist circumference ($P < 0.05$), and body fat % ($P < 0.01$). In the between groups' comparison, BMI-Z-score, and body fat % in the HIIT group were significantly different ($P < 0.05$) from the two other groups.

1.4.2 Cardiovascular disease risk factors

The systematic review of meta-analyses by García-Hermoso et al. (2019) also considered changes in lipid profile, blood pressure and flow mediated dilation. The analysis showed exercise resulted in a significant medium improvement in triglycerides and flow mediated dilation and a small improvement in systolic and diastolic blood pressure, using pooled data from two (triglycerides) and one (flow mediated dilation and blood pressure) meta-analyses. The meta-analysis of Li et al. (2021) also aimed to assess the influence of training type on cardiometabolic risk factors in obese adolescents (aged 8-18). The analysis suggested that aerobic training resulted in greater improvements in lipid profile than combined training, HIIT or RT. The analysis also suggested that an intervention duration greater than 12-weeks had an advantage in improving lipid profile in obese adolescents than a shorter intervention (<12 weeks). To the authors knowledge no trials assessing exercise impacts on cardiovascular disease risk factors have been conducted in children with severe obesity alone. However, the study by Monterio et al. (2015),investigating the impact of

a 20-week aerobic exercise intervention on obese adolescents aged 11-17, demonstrated aerobic training significantly decreased triglycerides, and very low density lipoprotein (VLDL) and significantly increased HDL between baseline and week 20. In contrast, the control group experienced significant increases in triglycerides and VLDL and a significant decrease in HDL over the same duration. The study by Benson et al. (2008) investigating the impact of an 8-week progressive RT intervention on obese adolescents also showed an increase in HDL. Lee et al. (2010) conducted a 10-week supervised exercise intervention in obese adolescents (12-14 years) that involved an aerobic group exercise and a CRAE group. Both groups were directed to exercise three times a week with the duration for each exercise session lasting 60 minutes. The CRAE programme included two circuit weight training routines at 70-80% of maximum strength and one aerobic exercise routine at 60-80% of VO_{2max}. The aerobic exercise group completed three aerobic exercise routines a week, once again at 60-80% of VO_{2max}. All sessions for the CRAE were performed with an instructor while 2 of the 3 sessions for the aerobic group were supervised by an instructor. Both the CRAE and aerobic exercise groups had significantly reduced low-density lipoprotein (LDL), however, the CRAE group also significantly increased HDL between baseline and week 10. Farah et al. (2014) compared the effects of HIIT (3 sessions a week at the ventilatory threshold I) to low intensity aerobic exercise (3 sessions a week at 20% below the ventilatory threshold I) over a 6-month period in obese adolescents (aged 13-18). Both groups received three personalised, supervised treadmill-based exercise sessions a week. Both HIIT and aerobic training resulted in reductions in systolic and diastolic blood pressure.

1.4.3 Glycaemic control

The systematic review of meta-analyses of Garcia-Hermoso et al. (2019) showed exercise resulted in a medium reduction in fasting glucose and a small reduction in fasting insulin , using pooled data from 4 meta-analyses. The meta-analysis by Li et al. (2021) suggested CRAE training was more effect than aerobic training, RT or HIIT for improving homeostatic model assessment for insulin resistance (HOMA-IR). Again, there is no data from studies in severely obese adolescents. However, Lee et al. (2013) presented the results of a 12-week study in obese adolescents comparing the impact of aerobic training and RT on measures of glycaemic control. The study randomised 44 adolescent girls aged 12-18 to either aerobic training, RT, or control. Both exercise groups participated in 3 sessions a week lasting 60minutes, supervised by exercise physiology graduate students. The aerobic exercise programme consisted of a progressive treadmill programme completed at 60–75% of VO_{2peak}. The RT group performed two sets of 8-12 repetitions of 10 whole body exercises at 60% of baseline one-repetition maximum (1RM). After 4 weeks the programme progressed with each exercise being performed to fatigue. Compared with control significant reductions in peripheral insulin sensitivity (measured using a hyperinsulinemic euglycemic clamp) were observed in the aerobic group but not the RT group. Son et al. (2017) showed that a 12-week CRAE intervention in obese adolescent girls aged 14-16 significantly decreased fasting glucose, fasting insulin, and HOMA-IR compared to control. To the authors knowledge studies that assess the use of HIIT in obese adolescents have not included measures of glycaemic control.

1.4.4 Mental health

Quality of life is not a commonly assessed outcome measure for exercise interventions in obese adolescents. Lopera et al. (2016) completed the paediatric quality of life inventory (PedsQL) which assesses HRQOL by evaluating children's functioning across four dimensions (physical, emotional, social, school) in obese adolescents pre and post a 16-week exercise intervention, made up of combined strength and RT. While the control group was unchanged the total quality of life score was significantly improved from baseline to post-intervention for the exercise group ($P<0.001$). Improvements were also seen in the physical, social, and psychosocial dimensions of the quality of life questionnaire. The HEARTY Trial also assessed health related quality of life (HRQOL) using the Paediatric Quality of Life Inventory. The study recruited 151 obese 14–18-year-olds undertaking aerobic exercise, RT, or combined training for 22 weeks. All the exercise groups showed significant improvements in overall HRQOL, physical functioning, psychosocial HRQOL, and emotional functioning following the 6-month exercise intervention, with no differences between the different exercise types for any HRQOL indicators (Goldfield et al., 2017).

1.4.5 Cardiorespiratory fitness

Cardiorespiratory fitness (CRF) is an important health outcome as improved CRF is associated with reduced metabolic risk factors (Ruiz et al., 2006). In addition, CRF has a stronger association to cardiovascular risk factors than components of objectively measured PA (Hurtig-Wennlöf et al., 2007). The meta-analysis of Li et al. (2021) showed that exercise was effective at

improving CRF with a significant improvement in CRF across the 12 studies. The analysis also evaluated the effect of different exercise types on cardiorespiratory fitness, suggesting that CRAE and HIIT were more effective in improving the CRF than aerobic training and RT.

1.5 Multicomponent interventions for the management of Childhood and Adolescent Obesity

Although the above outlines the key role of exercise in the management of paediatric obesity the majority of interventions used within weight management services are multicomponent. These multicomponent programmes involve a variety of different methods including dietary education, dietary restriction, cognitive behavioural education, and psychological support as well as education on the benefits of exercise and exercise interventions. The methods of delivering these multicomponent interventions vary, influencing their effectiveness. In addition, how the exercise component is delivered differs, with various levels of supervision being employed. Again, this influences the feasibility and effectiveness of the intervention, with the positives and negatives of each approach being discussed below.

1.5.1 Inpatient and residential interventions

Long term inpatient interventions have been utilised, where patients are admitted to hospitals or treatment centres for extended periods of time to receive intensive lifestyle interventions. Patients will normally attend the centres alone and will be able to visit home for the weekend on a biweekly basis, but this varies between programmes. The study by Aguer et al. (2010) evaluated the effect of a 5-month inpatient multidisciplinary programme on

body composition, habitual PA, and aerobic fitness. There were eighteen obese adolescent girls, aged 14-18, that completed the intervention which included a personalised and controlled diet, weekly dietary lessons, and an exercise intervention. The exercise intervention consisted of 4 sessions a week supervised by exercise scientists and nurses. Three of the exercise sessions completed were aerobic and one was a strength session. The intervention proved to be very effective with significant reductions in body weight, BMI, fat mass and fat free mass immediately after the 5-month programme. In addition, participants CRF was improved by 4.4 ml/min/kg at the end of the intervention. Accelerometer recorded moderate intensity PA was increased by 25minutes per week ($P<0.05$) and the time spent in vigorous intensity PA also increased by 25minutes per week ($P<0.01$). Braet et al. (2003) also studied the effect of an inpatient multicomponent intervention on obese adolescents, aged 10-17, lasting 10 months. The exercise portion of this intervention consisted of 4 hours a week of individualised physical training and additional PA was encouraged through education sessions involving PA advice and the availability of leisure time and sports facilities for the adolescents to use. Unlike Aguer et al, (2010) the intervention included the addition of a cognitive behaviour treatment programme. Another additional component was the use of parental education to encourage healthy lifestyle changes such as improved diet and increased exercise for after the children left the inpatient intervention. The intervention resulted in reduced BMI at both 5- and 10-month time points during the intervention. The study also included a 4- and 6-month follow-up period, with BMI showing a small but significant increase compared to immediately-post intervention. However, at both follow

up time points BMI was noticeably reduced from the pre-intervention levels. The intervention also resulted in significant improvements in perceptions of physical appearance, athletic competence and social competence when recorded through the Self-Perception Profile for Children (Harter, 1988). The influence of the trial of CRF or habitual PA was not assessed. Prado et al. (2009) admitted 728 extremely obese adolescents (mean age 15.25) to the Rehabilitation Centre Insula, Germany, for a mean duration of 5.88 months. The intervention consisted of calorie restriction (1,500-1,800 kcal per day), dietetic education, exercise, and psychotherapy. Exercise was completed four times a week for a minimum of 90 minutes and was primarily aerobic exercise based but had the option for strength training. Body weight, BMI, fat mass, and fat free mass all significantly improved as a result of the inpatient intervention, but again no measures of PA or CRF were taken to assess the effectiveness of the exercise component. As such, the effectiveness of these long duration (3-12months) inpatient interventions on body composition is clear.

Trials have also assessed the impact of shorter-term (1-2 month) inpatient interventions. Karner-Rezek et al. (2013) and Knöpfli et al. (2008) both assed the impact of 8-week interventions consisting of calorie restriction, personalised exercise programmes, anthropometric measurement and cardiorespiratory fitness testing. The exercise interventions completed within these multicomponent interventions consisted of twice daily endurance exercise to improve aerobic performance. Following the interventions both studies reported significant decreases in body weight and % body fat and improvements in mean peak power (watt/kg). Knöpfli et al. (2008) also reported significantly improved CRF and improved quality of life for all domains

measured within the ILQAKJ questionnaire which is a standardized questionnaire in German (Radtke and Stoll, 2003). An alternative approach to inpatient care is adopted in the study by Makkes et al. (2016). This study assessed the effect of two different inpatient interventions and monitored changes 6 months later with a follow up visit. The study assessed the effect of a two month in patient period followed by four months of biweekly return visits lasting two days at a time. This intervention was compared to a continuous six-month inpatient group. The intervention included completion of an aerobic games-based exercise program supervised by an exercise specialist four times a week and nutrition education/behaviour modification sessions once per week. The same intervention was delivered for both groups during their inpatient stay and no additional support was provided during the outpatient periods. Both groups experienced significant reductions in BMI at the end of the 6-month intervention period and these reductions were maintained at follow-up (12-months post baseline). Significant improvements to waist circumference, diastolic blood pressure and HDL-cholesterol were also observed in both groups at follow-up. The data from these studies clearly highlights the effectiveness of inpatient multicomponent interventions on obesity related health. Supervised controlled exercise programmes are common components in all these interventions. However, it is difficult to assess the effectiveness of the exercise components as only Aguer et al. (2010) and Knöpfli et al. (2008) assessed habitual PA or CRF immediately following the intervention, and no trials assessed these outcomes at follow-up.

1.5.2 Outpatient and clinic-based interventions

While long-term inpatient interventions are effective their feasibility within routine care is questionable. Outpatient interventions offer an alternative approach that could be more commonly utilised within routine care due to potential improvements in feasibility. Carnier et al. (2013) recruited 26 obese adolescents to a 12-month multicomponent intervention that included clinical support, nutrition lessons, a weekly psychological orientation group session and physical exercise. The intervention also compared the effect of aerobic training to a CRAE programme, delivered within the multicomponent intervention. Exercise was completed three times a week for 60 minutes with the CRAE intervention completing 30minutes of each exercise modality supervised in hospital by a health care professional (HCP). Although 6-month data suggested only the CRAE group improved BMI and body weight, at 12-months both interventions were effective at reducing body weight, BMI, and body fat. Eliakim et al. (2002) studied the effect of a multicomponent outpatient approach in obese adolescents for a duration of 3 months compared to 6 months. Monthly dietetics meetings and a series of four evening lecturers delivered to parents and patients were accompanied by a twice weekly supervised exercise programme (1hour per session). The exercise was predominately made up of endurance activities and patients were also encouraged to complete PA outside of these sessions at least once a week. BMI reduced significantly at 6-months in both the 3-month and 6-month interventions, but the reduction in the 6-month group was significantly greater. Improvements in endurance time were also shown in both groups at 6-months. The Freiburg Intervention Trial for Obese Children is another example of an

interdisciplinary outpatient programme for obese children (Korsten-Reck et al., 2005). The 8-month trial consisted of regular physical exercise (1 hour three times a week) plus comprehensive dietary and behavioural education. Exercise sessions consisted of a combined approach with endurance, strength, flexibility, and coordination elements all built into the sessions. Each session was completed at a local sports centre and supervised by a sport teacher. BMI, BMI-SDS, cholesterol, LDL and watt/kg all showed statistically significant improvements following the intensive intervention. Hintze et al. (2021) studied the effect of an intensive interdisciplinary treatment compared to a semi-intensive interdisciplinary treatment. Both interventions offered psychological support, nutrition education and exercise programmes, but the delivery of these varied. In the intensive group nutrition and psychology support was provided in person once a week and a CRAE programme was delivered three times a week for 1hour. These sessions were delivered in-person at the Federal University of Sao Paulo and were supervised by a member of the research team. The semi-intensive group received six in person exercise orientation sessions, six in person psychological support sessions alongside weekly online recorded nutrition lessons. Following the exercise orientation, the participants followed online classes in the other sessions for which participants used a self-guided program to select the physical activities that they wanted to undertake. Body weight, BMI and fat mass reduced after the 5-month intervention in both groups. However, improvements for all anthropometric and body composition measurements were greater in the intensive group. Waist circumference, glucose, and triglycerides also

decreased significantly in both groups (P<0.001), but both SBP and DBP only decreased in the intensive group (P<0.001).

As such, it appears clinic-based and outpatient approaches are effective at improving body composition and cardiovascular risk factors. However, there is a lack of studies involving follow-up periods to assess long term effectiveness. Again, supervised exercise plays a key role in all the interventions, but it is difficult to directly assess the role of this component as PA and CRF have not been measured.

1.5.3 Home-based or unsupervised interventions

Home-based multicomponent interventions are uncommon in the treatment of childhood obesity and there is a lack research evaluating home-based multicomponent approaches. However, evidence from Hintze et al. (2021) suggests that the use of a blended approach of outpatient and home-based intervention could prove effective. Lison et al. (2012) studied the effect of a home-based diet and exercise programme to a hospital-based one. Both groups attend two 1-hour educational sessions at the hospital based around nutrition and the importance of weight loss. The structure of the exercise intervention was the same for both groups and consisted of five 60-minute exercise sessions a week, with patients instructed to attend or complete at least 3 of the 5 each week. Within each session 35 minutes was dedicated to aerobic activity while the other 20 was for RT. Despite the structure of these sessions being the same the way in which session were performed was different. The hospital-based intervention received supervised sessions onsite from HCPs, while the home-based group were provided with demonstrations of how to perform the exercises and detailed written instructions. Patients were

then instructed to complete this exercise unsupervised at home. Following the 6-month intervention BMI-SDS, body fat and waist circumference were significantly reduced in both groups. When the effects of the different interventions were compared, there was no statistical differences for any outcome. Ahmadi et al. (2020) also studied the effect of an 8-week home based intervention consisting of nutritional recommendations and exercise. The nutrition element of the intervention was the same for all groups, consisting of three 60-minute, in-person educational sessions. Participants then received educational pamphlets of sports exercises and healthy eating recommendations to continue learning at home. Three different exercise interventions were evaluated: HIIT, RT and combined HIIT and RT. Participants were given instructions on how to complete their given exercise modality at the study clinical centre before completing the 24 sessions over 8-weeks from home. Participants received weekly phone calls to update the research team of what exercise they had completed. Between baseline and post intervention there was a significant increase in the waist and hip circumference of the RT group and no other measures of body composition or lipid profiles were improved. As such, Home-based or unsupervised multicomponent interventions have mixed results, and the evidence is less clear as to the benefits of these interventions. There is a lack of research in this area and future research should again consider the long-term benefits as well as the immediate intervention effect. In addition, greater assessment of adherence and dose of exercise are required to better understand the effectiveness of home-based exercise.

Inpatient and supervised multicomponent interventions have been shown to have positive outcomes on obesity related health outcomes in children. However, there is a lack of data evaluating the exercise components of these interventions. Cardiorespiratory fitness and minutes of moderate-to-vigorous physical activity (MVPA) are not commonly reported which means conclusion cannot be drawn on the effectiveness of the exercise and PA elements of the interventions. The majority of studies also lack a longer-term follow-up (6-months post intervention completion) which prevents any conclusions being drawn on the effectiveness of these interventions to incite long term changes to health outcomes. Despite positive outcomes from in-patient and clinic-based childhood obesity interventions, attrition to clinic-based programmes is high. The study by Zeller et al. (2004) had a withdrawal rate of 50% which aligns with common attrition rates for clinic-based obesity programmes. These results suggest that the multicomponent models adopted as in-patient services and within clinics have value but should look to be adapted to better improve adherence and prevent withdrawals.

1.6 The UK approach to weight management in children and adolescents with severe obesity

Due to the alarming increase in prevalence of children and adolescents with severe obesity the NHS Long Term plan (2019) committed to treat a further 1,000 children a year for severe complications related to their obesity in order to prevent children going on to require more invasive treatment. As a result of this pledge, and due to the perceived success of multidisciplinary approaches to obesity treatment, NHS England has established 21 Complications from Excess Weight (CEW) services across England. These CEW services adopt

a holistic approach to treating children and young people for conditions related to obesity, and the care is delivered by a multidisciplinary team (MDT). Each MDT consists of a physician, dietician, psychologist, physiotherapist and social worker. The MDT adopt a blended approach to care with inpatient clinic appointments, remote telehealth appointments and in some cases home and school visits. All the patients also receive different levels of interaction with members of the MDT based on their needs which are assessed when first being referred on to the service. However, despite the essential role of exercise and PA within any weight management programme CEW services currently do not include trained exercise specialists embedded within the MDT or support supervised exercise sessions. As a result, the only PA or exercise element of CEW services is promoting exercise through community links or providing generic PA advice for patients to act on in their own time. This means that current provisions within CEW services are not able to develop personalised graded PA and exercise advice or programmes for patients.

1.7 Mobile health technology to support exercise in obese children and adolescents

The introduction of personalised and graded PA and exercise prescriptions within CEW services could be supported by mobile health (mHealth) technology. mHealth technology refers to the use of smartphones, apps, text messages and smart watches to engage populations in improving their health. The utilisation of these methods could help overcome the challenges faced within normal in-person exercise interventions, such as the need for dedicated space which can reduce the scalability of inpatient and clinic-based interventions. High attrition rates to in-person interventions from children and

adolescents that are economically disadvantaged (Zeller et al., 2004) is another barrier that could be influenced with the use of mHealth technology. Devices incorporating biometrics such as habitual PA and heart rate (HR) could be a potential solution to bridge the gap between supervised exercise and PA advice.

1.7.1 Remote coaching

The use of virtual appointments or telemedicine has increased as a result of the COVID-19 pandemic (Schinasi et al., 2021). Remote coaching offers solutions to the problems of travel, parking, and missed school/work that often leads to high attrition of obese children attending clinics (Vajravelu and Arslanian, 2021). Patients have reported high satisfaction with telemedicine appointments for treating childhood obesity, and the clinical efficacy of these programmes have been shown to not be inferior to in-person programmes (DeSilva and Vaidya, 2021). Staiano et al. (2018) evaluated the use of remote coaching paired with a home-based video game that required PA as part of game play. Overweight and obese youth between 10-12years were recruited to participate in 3, 1-h gameplay sessions per week for 24 weeks, with the remote coaching group receiving additional video calls while the control group were left only with the game. MVPA was significantly greater in the remote coaching group, and blood pressure, cholesterol and LDL all reduced while the control group experienced increases in these metrics. As such, trials suggest that interventions should look at ways they can adapt programmes or integrate virtual appointments into their service.

1.7.2 Improved feedback through text messages

The use of text messages to promote adherence to PA interventions has been well reported. The inclusion of a text element in conjunction with other intervention components, such as websites to promote activities or pedometers to measure habitual PA, has been shown to optimise PA behaviour change in older adults (Kim and Glanz, 2013). Increased PA as a result of a programme including text messages has also been shown in adolescents at risk of type 2 diabetes (Patrick et al., 2013). The study by Patrick et al. (2013) evaluated the use of text messages as part of website based mHealth technology intervention. The website and its tutorials provided educational topics and challenges based on weekly nutrition or physical activity goals, and text messages were sent at least three times a week. The content of the texts related to the weekly challenges and intervention goals and reminded participants to use the website if it had been observed that they had not logged on to it. The study resulted in significant increases in MVPA at both 6-months and 12-months. Despite the positive results from these studies the review by Ludwig et al. (2018) suggested that the influence of text messages on PA could not be established due to high levels of variation between text messaging interventions. This highlights the importance of delivering text messages using the appropriate frameworks. To this end the use of behaviour change theory within messaging interventions has been shown to be successful in changing a target behaviour (Van't Riet et al., 2010). This suggests that the inclusion of text messages with behaviour change theory embedded could prove to be effective as part of an mHealth technology intervention within obese children and adolescents.

Furthermore, advances in technology may be able to facilitate greater personalisation of feedback through text messages or other remote communication platforms. For example, the development of online cloud-based portals now allows sharing of biometric data with health professionals. Such advances could be used to recreate the relationship between patients and health professionals experienced during supervised interventions, but with the added advantage of communication in the patient's own environment at convenient times. Such an approach has not been tested in children or adolescents but work from our group in adults with type 1 diabetes (T1D) suggests such remote monitoring of biometrics and subsequent feedback may encouraged adherence to prescribed exercise (Scott et al., 2019a)

1.7.3 Self-monitoring through devices

Providing real-time exercise and PA feedback through technology could be another effective method for supporting obese children during PA and exercise interventions. Real-time feedback is made possible through the use of wearable technologies such as pedometers or accelerometers. The use of such wearables in obese children and adolescents has been previously reviewed by Wang et al. who conducted a meta-analysis consisting of 12 randomised control trials and 3227 participants. The results of this analysis showed that when compared to a control group the use of wearables had significant beneficial effects on BMI (mean difference [MD] -0.23, p=0.03), body weight (MD -1.08, p=0.05), and body fat (MD -0.72, P=0.003). However no significant change was found in waist circumference. The changes in body composition are likely due to an increase in PA as a result of wearable technology, but the review did not assess this. To the authors knowledge the

only study in obese adolescents that reports changes in PA following the use of wearables as part of an intervention to promote PA is the study by Chen et al. (2017). A cohort of 40 adolescents aged 13 -18 years with overweight or obesity took part in a 6-month mobile phone-based intervention that had three components. These components were the use of a fitness watch (Fitbit Flex), an online educational program consisting of nutrition and PA advice, and text messages. The control group for the intervention were given a pedometer and a food diary for the study duration. PA was assessed using a question from the California Health Interview Survey (CHIS) that asked about the number of days that the participant was physically active on, for at least 60 minutes. The study reported that the number of physically active days as a result of the intervention increased from 2.4 at baseline to 3.1 at 6-months, resulting in a significant time and group effect. However, there are currently no studies using wearables to assess PA using device derived measures of PA in obese adolescents. The influence of wearable technology on device-derived PA has been previously studied in healthy weight young men (n = 276, mean age 17.9, SD 0.7 years) (Jauho et al., 2015). The intervention group were provided with a wrist-worn PA monitor for 3 months, which provided feedback on the time spent in MVPA, PA levels, steps, and calorie expenditure from that day. Meanwhile the control group received a blinded PA monitor. Compared to the control group the intervention group increased MVPA and decreased sedentary time.

The use of accelerometers to promote greater habitual PA has been shown to be effective. However, recent advances in smart watch technology allows heart rate (HR) monitoring to now become a more accessible tool which may

be effective in promoting activities of greater intensity through live exercise coaching. The use of HR monitoring to promote adherence to structured exercise programs has a number of advantages over pedometer and accelerometer technologies. HR is the most accurate way to track the body's response to PA and exercise, providing objective personalised data that accounts for age, body mass and fitness level (Garber et al., 2011). HR reflects exercise intensity regardless of the type of exercise performed (Nes et al., 2017). Such an approach has not been used in children or adolescents but work from our group in adults with T1D (Scott et al., 2019a) and obese adults with elevated cardiovascular disease risk (Scott et al., 2019b) suggests it may be effective. In these trials participants were prescribed individualised home-based exercise programs, and then educated on how to perform the prescribed exercise using HR zones. Participants were given a HR monitor to provide live feedback during exercise, helping participants complete the sessions as prescribed without supervision. Importantly, in both studies >90% of prescribed sessions were completed, with >85% of the sessions completed at the prescribed intensity, improving CRF. Qualitative data from an online survey in the people with T1D suggested that the availability of instant feedback during exercise contributed to the high adherence (Scott et al., 2019a). We hypothesize that the availability of live HR data facilitates training programmes by educating participants on how to exercise at an intensity most likely to elicit health changes (Miller et al., 2014), and by developing autonomous motivation through feelings of competence (Kinnafick et al., 2018).

New developments in smart watch technology also allow pre-set exercise sessions to be stored within monitors, so participants receive live coaching on how to complete the prescribed exercise sessions (duration of the session/ phases within the session, and prescribed exercise intensity through HR). Given that lack of knowledge on how to exercise is a major barrier to exercise, the provision of live instructions may improve adherence by further developing autonomous motivation through feelings of competence.

The perceived success of the integration of mHealth technologies into interventions that look to increase PA, suggests that use of mHealth technology should be explored within childhood and adolescent obesity. An approach that combines all of the technologies outlined above might offer the best solution and would allow for goal setting, self-monitoring and feedback on behaviour to all be embedded within an exercise and PA intervention. The culmination of these different factors may increase adherence to unsupervised exercise/habitual PA programmes, which in turn would improve clinical outcomes and improve health in children and adolescents with obesity.

1.8 Summary

Childhood and adolescent obesity prevalence has continually increased in recent years. The proportion of children in England with severe obesity has also increased and children and adolescents in the most deprived areas are most commonly affected. Cardiovascular risk factors, poor HRQOL and T2D are all associated with adolescent obesity and the health consequences of adolescent obesity often tracks into adulthood. Exercise has been shown to be an effective treatment for adolescent obesity with positive impacts on body

composition, cardiovascular disease risk, glycaemic control, HRQOL and cardiorespiratory fitness. Due to these positive effects exercise is often included within multicomponent interventions for weight management, which have been shown to be effective. However, the influence of exercise on these positive outcomes is difficult to assess as specific analysis of the exercise component is rarely completed. NHS England's approach to tackle the increased prevalence of adolescent obesity has been the development of CEW services which use a MDT to treat adolescents with severe obesity. Currently CEW services do contain a designated exercise specialist with the knowledge and experience to prescribe exercise for patients with complex health issues, despite exercise being the cornerstone of any weight management service. Embedding CEPs supported by mHealth technology has the potential to address this gap within the current service provision. mHealth technology may be useful to support increased PA and adherence to unsupervised exercise, with remote coaching, self-monitoring and text messages all having been shown to be effective approaches. Therefore, the aim of this thesis is to assess the feasibility of embedding an mHealth supported PA and exercise intervention, led by an exercise specialist, within a CEW service.

2. Introduction

Childhood and adolescent obesity is one of the most serious global public health challenges of the 21st century (W.H.O, 2021). In the UK, the prevalence of childhood obesity has notably increased in the last ten years, with obesity now affecting 1 in 4 children (NHS-Digital, 2022). Obese children have a higher risk of developing diseases including asthma and type 2 diabetes (Gungor et al., 2005). Obesity usually tracks into adulthood which is associated with increased risk of cardiovascular disease (Li et al., 2004) and 16 different cancers including liver, thyroid and pancreatic (Lauby-Secretan et al., 2016). Alarmingly, a sharp increase in the number of children and adolescents who are severely obese (defined as a BMI-SDS above 3 based on sex and age Hoedjes et al. (2018)) has also been reported (NHS-Digital, 2022). The risk of immediate health issues and long-term conditions is increased in severe obesity (Bass and Eneli, 2015), and quality of life of children with severe obesity is similar to children with cancer (Schwimmer, Burwinkle and Varni, 2003).

The increasing prevalence of severe obesity in children has led to NHS England establishing twenty-one specialist paediatric Complications from Excess Weight (CEW) clinics. These services aim to treat the complications associated with severe obesity through an individualised holistic approach. To achieve this, CEW services are delivered by multidisciplinary teams (MDT) including endocrinology consultants, dieticians, physiotherapists, psychologists, and social workers to ensure treatment is provided for physical, mental, and social needs. However, current CEW services do not include specialists in physical activity (PA) and exercise. This is despite PA and

exercise forming cornerstones of any weight management service for children with obesity (Roberts, 2000). Integrating appropriately trained exercise specialists within CEW services would provide patients with the necessary support to develop personalised graded PA and exercise programmes to promote long-term wellness through behaviour change across the lifespan.

Recent research has suggested that mobile health (mHealth) technologies may be an effective method of reaching young people and encouraging them to engage with PA and exercise (Vajravelu and Arslanian, 2021). Interventions incorporating remote coaching (Vajravelu and Arslanian, 2021) and those aiming to improve self-monitoring, feedback, and goal setting through wearable activity trackers (Darling and Sato, 2017) and text messages (Ludwig et al., 2018) have been shown to be promising approaches for increasing PA. Consequently, research is needed to evaluate the feasibility of introducing an mHealth supported PA and exercise intervention to CEW services, supported by appropriately trained exercise specialists, and thus is the aim of this study.

The specific objectives are to:

1. Determine the number of patients eligible to participate, the proportion of these who would be willing to take part in a trial and their characteristics, and the number of participants retained at 12 weeks (Reach).
2. Define the rates of adherence to the MOTIVATE-CEW intervention (Dose).
3. Assess the fidelity of delivery of the MOTIVATE-CEW intervention

4. Qualitatively explore facilitators and barriers to exercise and PA in participants randomised to the MOTIVATE-CEW intervention.
5. Pilot methods for collecting outcome measures, estimating their precision for sample size estimations for the definitive RCT.

3. Methods

3.1 Study design

A feasibility, parallel group, randomised controlled trial, whereby participants completed pre-intervention assessments before a 12-week exercise and PA intervention. The intervention consisted of either active control, within which participants continued with their usual clinical care within the CEW service (usual care control), or usual care plus working with an exercise specialist supported by mHealth technology (MOTIVATE-CEW). Immediately post-intervention participants repeated assessments. The reporting of this study conforms with the CONSORT 2010 statement: extension for pilot and feasibility trials (Eldridge et al., 2016). Eligible participants aged 16 to 18 provided written informed consent. Participants aged 12-15 provided written assent with their parent/guardian providing consent. The study was approved by the East Midlands - Derby NHS Research Ethics Committee (21/EM/0030) and conformed to the Declaration of Helsinki. The protocol was prospectively registered on clinicaltrials.gov (identifier: NCT04854915).

3.2 Participants

Between August 2021 and July 2022, 23 participants (10 male, 13 female) were recruited with a mean age of 15(±1) and a mean BMI of 41.9(±7.6). All participants were receiving care from the CEW service at Alder Hey Children's Hospital (AHCH). A member of the MDT approached participants regarding participation in the study. Participants were recruited from all stages of care within the service with both new and long-term patients eligible to participate. Participants had a BMI >30, those prescribed Metformin were receiving a

stable dose for 3-months or more. Patients with severe learning/ behaviour difficulties, severe autism, secondary causes of obesity, syndromic causes of obesity, type 1, or type 2 diabetes mellitus and those receiving GLP-1 analogues for obesity were excluded from participation.

3.3 Randomisation

Participants were randomly assigned in a 1:1 ratio to usual care control or MOTIVATE-CEW using a computer-generated sequence that was maintained by an independent researcher acting as a gate keeper. Randomisation was stratified by age (12-15 or 16-18). Participants were informed of their group following pre-intervention assessments. It was not possible to blind the study team, members of the MDT or participants to the condition due to the presence of the additional support received in MOTIVATE-CEW.

3.4 Interventions

3.4.1 Usual Care Control

Usual care within the AHCH CEW service was provided by an MDT. Clinics adopted a blended approach of face-to-face and virtual appointments. The initial needs were discussed with the patient and their family before the patient's care was reviewed with the MDT as a whole. An individualised care plan was then developed to allow the specific relevant care to be provided to the patient. Patients were then seen approximately every four weeks for follow up appointments. The specific tools, treatments and care methods adopted by each member of the MDT can be found in Table 1.

Table 1. Multidisciplinary clinical team treatment and care methods

Role	Treatment/Care
Consultant Endocrinologist Physician Associate Clinical Fellow	• Patient History • Monitor clinical outcome and their changes over time • Referrals to other specialities that provide care for specific issues causing obesity • Prescribe medications • General lifestyle advice
Psychologist	• One to one meetings • Group sessions • School and medical team liaison
Dietician	• Food diaries • Eatwell plate • National Diet Resource leaflet • In house resources for alternative recipes and healthy swaps
Physiotherapist	• Sleep questionnaires • Sleep hygiene resources • TOSCA studies to review partial pressure of carbon dioxide (PCO_2) and oxygen saturation (SpO2). • Community links with partners offering activities • Safe exercising advice
Nurse Specialist	• Blood glucose monitoring teaching for parents and patients • Teaching parents and patients how to administer daily injections of medications
Key Worker	• School visits • Home visits • Provide contacts and facilitate links with community-based support

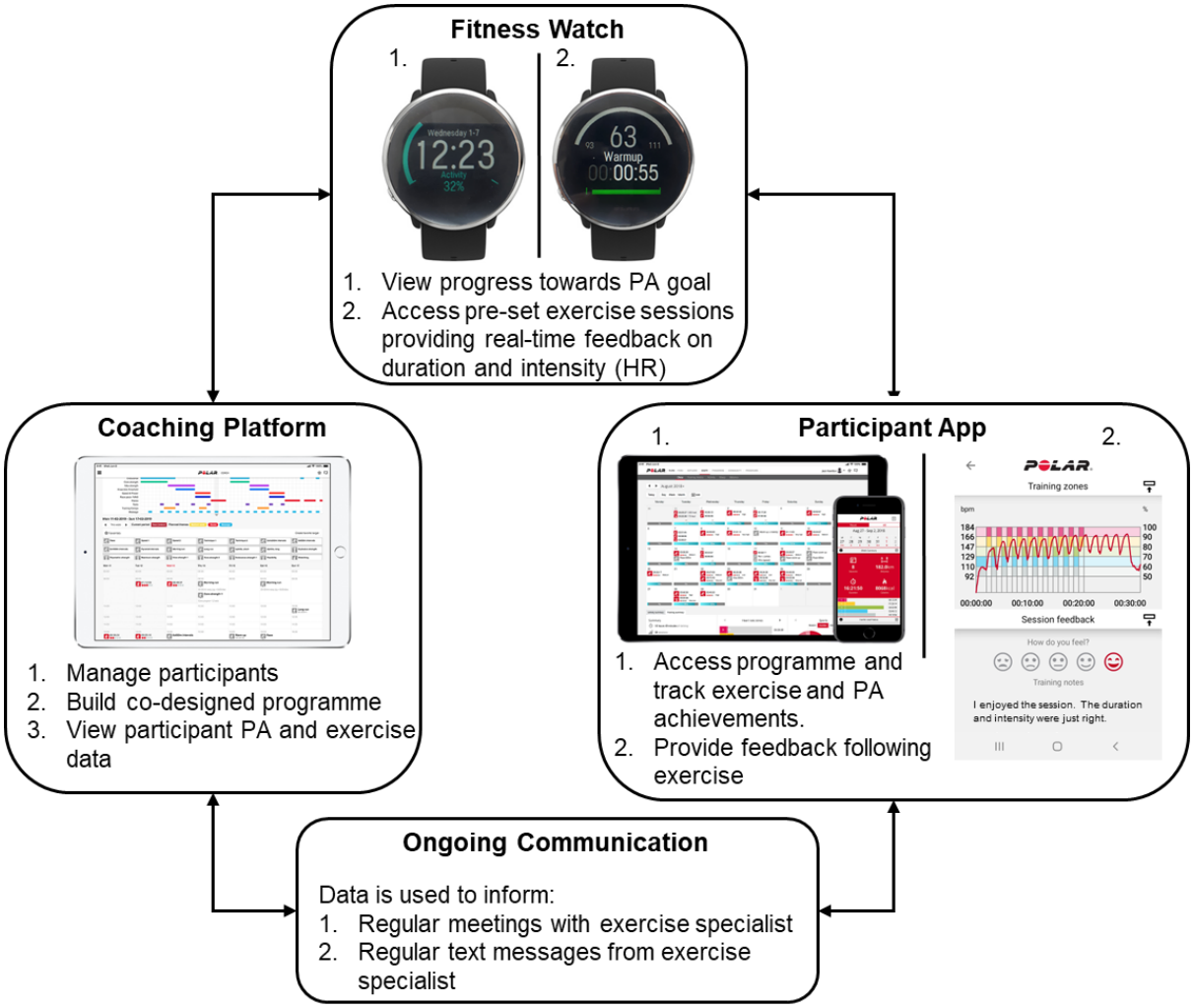

Figure 1. *Outline of how mHealth technology supports the MOTIVATE-CEW intervention*

HR Heart Rate; PA, Physical Activity.

3.4.2 Intervention: mHealth supported exercise counselling

Participants co-designed a 3-month personalised and progressive exercise and PA programme alongside an exercise specialist (Figure 1). The development of the programme was supported by the participant with obesity specific consultation framework and resources developed by the 'Moving Medicine' initiative (https://movingmedicine.ac.uk/consultation-guides/condition/young-person/obesity-yp/more_minute/) and the Brief Action Planning guide and flow chart developed by The Centre for Collaboration Motivation and Innovation (https://centrecmi.ca/brief-action-planning/). Participants and their parents/ guardians (where participants were

under 16 or wished for their inclusion) attended five virtual consultations (Teams, Microsoft Corporation) with their exercise specialist (Table 2). During the initial consultation together, they explored the participant's motivation and developed a SMART (specific, measurable, achievable, relevant, and time-bound) graded exercise and PA plan. Each participant's programme was individualized based on preferences

Table 2. Details of the counselling intervention

	Date	Details
Consultation 1	Prior to intervention	Initial meeting to assess current beliefs/concerns, explore the benefits of exercise and agree on a SMART (specific, measurable, achievable, relevant, and time-bound) plan
Consultation 2	Prior to intervention	Development of the personal exercise program and education on how to use the mHealth technology
Consultation 3	Month 1	Participant feedback and refinement of the exercise program with the aim of progressing the program. Data recorded in the smart phone app and online coaching platform was used to guide discussions
Consultation 4	Month 2	Participant feedback and refinement of the exercise program with the aim of progressing the program or maintaining if personalised goals are being met. Data recorded in the smart phone app and online coaching platform was used to guide discussions
Consultation 5	Month 3	Participant feedback and review of progress. Discussion on strategies for maintaining exercise and PA. Data recorded in the smart phone app and online coaching platform was used to guide discussions

(e.g., endurance, high-intensity interval, resistance, exercise classes, dance, or sports) and availability of equipment (e.g., outside, indoor calisthenics, commuting or gym-based) but focused on increasing exercise intensity and duration up to 150min of moderate-intensity or 75min vigorous-intensity exercise per week during the intervention. Participants were also encouraged to increase their daily PA through tips within their routine.

Participants attended a second consultation with their exercise specialist to review their self-directed plan and be introduced to the mHealth technology. The intervention was supported by 3 mHealth elements; 1) a fitness watch, featuring a 3D accelerometer and optical HR monitor (Polar Ignite, Polar Electro, Finland), 2) a smartphone app for participants and parents/guardians (Polar Flow – Sync & Analyze), and 3) a coaching platform (Polar Flow for Coach, www.polar.com/coach). The 3 elements were synced, allowing data to be transferred between platforms.

Coaching platform: allowed the exercise specialist to manage participants. Within the platform the exercise specialist built the co-designed exercise programme, prescribing the duration and intensity (measured through HR) of phases within each exercise session i.e., warm up, workout and cool-down. These exercise sessions were available as pre-set sessions on the participant's fitness watch.

Smartphone app for participants: Participants accessed their programme and tracked exercise and PA achievements. Following all exercise sessions participants used the app to rate their enjoyment and provide written feedback about the sessions. Participants were instructed to provide comments that informed the exercise specialist about the appropriateness of the session's duration and intensity, as well as their enjoyment of the exercise session and exercise type.

Fitness watch: Participants were able to view progress towards their daily PA goal and inactivity alerts were provided if participants had been sedentary for more than 55 minutes. Participants received real-time feedback (visual and haptic) on duration and intensity (through HR zones) of exercise during both pre-set and other exercise sessions, coaching participants to execute the session as prescribed.

Exercise videos were also available to participants on the MOTIVATE-CEW trial website (https://www.motivateljmu.com/loop-1) with prescribed exercise sessions on the watch matching the videos format.

Following the initial meetings participants met with their exercise specialist on a monthly basis during the intervention (1-, 2-, and 3-months). In addition, participants and their parents/guardians received messages from their exercise specialist within the Teams App (Teams, Microsoft Corporation), initially after each exercise session (0-1month), then weekly (2-3 months). The data collected in the participant app and coaching website were used to create a dialogue between the participant, their parents/guardians and exercise specialist in meetings and messages. This information was then used to reassess exercise and PA goals and adapt future schedules where necessary.

MOTIVATE-CEW was informed by existing evidence (Hesketh et al., 2021), key service user perspectives (patients and HCPs) and social cognitive theory (Bandura, 2001). The MOTIVATE-CEW intervention aimed to emphasize the behaviour change technique (BCT) categories; “Goals and Planning,” “Feedback and Monitoring” and “Shaping Knowledge” (Michie et al., 2013) and motivational interviewing technique processes; “Engaging” and “Evoking” (Hardcastle et al., 2017). It was anticipated that these mechanisms would improve, 1) competence to engage in exercise and PA, through the development of individualised graded action plans and specific behavioural goals and providing instructions on how to perform behaviours and biofeedback to assist this, 2) autonomous motivation for exercise and PA, through understanding the value and health benefits of exercise and self-monitoring of exercise and PA behaviours, and relatedness with healthcare professionals, through regular feedback on exercise and PA behaviour from the participants exercise

specialist, leading to greater uptake and maintenance of exercise and PA as depicted in the intervention logic model (Figure. 2).

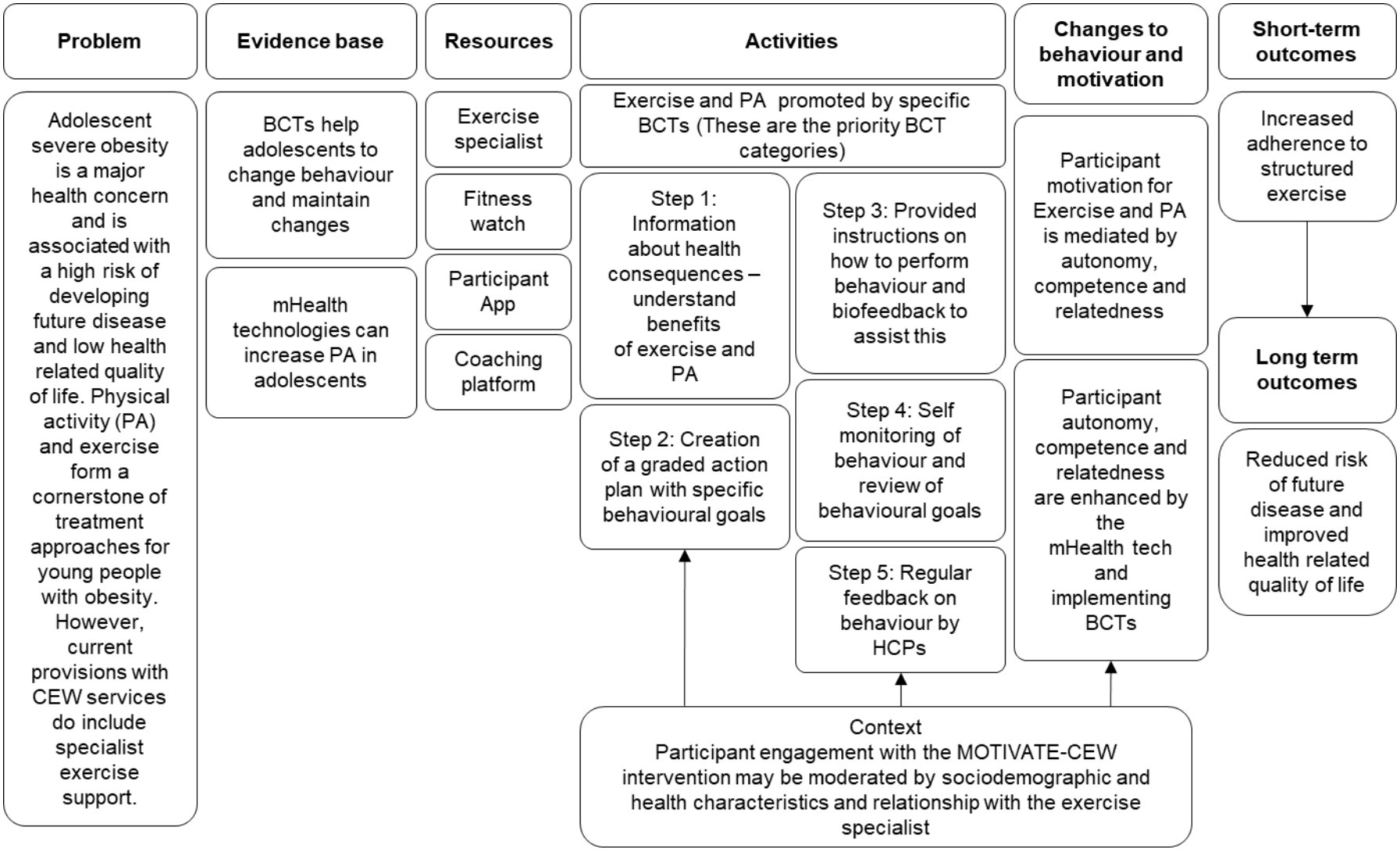

Figure 2. MOTIVATE-CEW Logic Model

CEW, Complications from excessive weight

3.5 Process evaluation

A mixed-methods process evaluation was completed, designed in accordance with the Medical Research Council guidance framework (Skivington et al., 2021). The approach included assessment of all key functions: context; implementation (reach, fidelity, dose) and mechanisms of impact.

3.5.1 Reach

Recruitment frequency and participant retention were assessed. In addition, to provide context the consented participants were compared with the AHCH CEW service as a whole. To do this sex, age, ethnicity and Index of Multiple Deprivation (IMD) of the whole AHCH CEW cohort were collected from clinical records.

3.5.2 Dose

The intervention aimed to increase completion of structured exercise sessions and habitual PA, as such three methods aimed at assessing these factors were evaluated.

Device derived measurement of structured exercise sessions: Optical HR monitoring was used to record HR during exercise sessions. The usual care control group were provided with a Polar Verity Sense for the duration of the trial and asked to wear it during structured exercise sessions. The monitor was not paired with a smart watch or phone, meaning HR data was stored but no real-time/historic feedback was available to participants. This ensured the usual care control group were blinded to their HR during exercise for the duration of the intervention. For consistency of measurement with the usual

care control group, data for the MOTIVATE-CEW group was collected using a Polar Verity sense paired to the Ignite fitness watch (Polar Electro, Finland) provided as part of the intervention. Using the data uploaded to www.flow.polar.com the following metrics were assessed:

- Frequency of structure exercise: The mean number of exercise sessions per week recorded by the optical HR monitor per week was determined.
- Time spent completing structured exercise: the mean minutes spent exercising recorded by the optical HR monitor per week. Data are presented as a mean over the whole 12-week intervention and during weeks 11-12 of the intervention.
- Intensity of structured exercise: the mean minutes spent in moderate-to-vigorous intensity exercise recorded by the optical HR monitor per week. Moderate intensity exercise was defined as a HR ≥50% and <70% of the participants predicted maximum (220-age). Vigorous intensity exercise was defined as a HR ≥70% of the participants predicted maximum. Vigorous intensity exercise was multiplied by two in the calculation of moderate-to-vigorous intensity exercise. Again, data are presented as mean and during weeks 11-12 of the intervention.
- Training drop-off: defined as the week which participants no longer completed any training sessions.

Survey reported exercise behaviour: Information about participants' quantity, frequency, and intensity of exercise participation was assessed using the Godin Leisure Time Exercise Questionnaire (GLTEQ; (12)). The GLTEQ was

administered at pre- and post-intervention. To assess dose of exercise the number of sessions of moderate and strenuous intensity exercise of at least 30 minutes in duration was calculated. This outcome closely reflected the expected exercise prescription during the final week of the intervention.

Device derived measurement of habitual physical activity and sedentary time: Participants were given a wrist-worn tri-axial accelerometer (GENEActiv, Activinsights, Kimbolton, Cambridge, UK) and a leg worn micro-accelerometer (ActivPAL, (PAL Technologies Limited; Glasgow, Scotland, UK) for 14 days before the intervention began and for the last 14 days of the intervention.

The GENEActiv was pre-set to record at 50Hz to account for transit in the post, while optimising the battery life of the device. Accelerometer data was downloaded using GENEActiv PC Software Version 3.3 (Activinsights, Kimbolton, Cambridge, UK) and analysed using the open-source R software package, GGIR (R package for accelerometery) beta v1.6-1 (https://cran.r-project.org/web/packages/GGIR/index.html). GGIR performs autocalibration with the reference of local gravity (Van Hees et al., 2014). Raw acceleration data were used to compute Euclidean norm minus one (ENMO in mg) (Van Hees et al., 2013). Data were analysed from the first to the final midnight using 5-second epochs. Participants were included in the main analysis if they achieved a minimum of 16 hours of wear time for a minimum of 4 days (irrespective of weekday/weekend day). Non-wear was detected if the standard deviation (SD) of two axes was < 13 mg with a range of < 50 mg in windows of 60 minutes. Time spent in activity intensities was established using published thresholds (Phillips, Parfitt and Rowlands, 2013). Moderate PA was defined as ≥20 gs and ≤60 gs, and vigorous PA was defined as ≥61 gs. The

following metrics of PA were assessed, moderate-to-vigorous PA (MVPA) recorded in ≥10-minute bouts (MVPA10+) and number of weekly minutes of total, light, moderate, vigorous and MVPA.

To explore if different ways of processing GENEActiv data influenced the findings, four additional wear-time criteria were calculated:

1. ≥ 16 hours over any 4 days (including at least 1 weekend day)

2. ≥ 10 hours for 4 days (including at least 1 weekend day)

3. ≥ 10 hours over any 4 days (irrespective of weekday/weekend day)

4. a minimum wear criterion of 1 day for ≥ 10 hours

Participants wore the ActivPAL on the anterior aspect of the right thigh, placed within a flexible nitrile sleeve and attached using Tegaderm Transparent Film (3M Health Care; St. Paul, MN, USA). Participants were included in the main analysis if they achieved a minimum of 20 hours of wear time for a minimum of 4 days (including at least 1 weekend day). A sampling frequency of 20 Hz was used, and data were interpolated in 2 second bins. Waking time was defined as the duration of time between the first steps or standing in the morning and the cessation of steps or standing in the evening. Daily step count and sedentary time averages were calculated.

To explore if different ways of processing ActivPAL data influenced the findings, four additional wear-time criteria were calculated:

1. ≥ 20 hours over any 4 days (irrespective of weekday/weekend day)

2. ≥ 20 hours for 1 day

3.5.3 Fidelity

The exercise specialist logged all contact with participants and their parents/guardians. This included 1) the number of counselling sessions attended and the duration of these sessions, 2) the number of Teams messages sent to participants and the reply rate (replies relative to messages sent). Participant feedback following exercise sessions in the 1st month was also logged. To provide context attendance at AHCH CEW service appointments and dietician meetings were also collected during the same period of time as the study.

3.5.4 Qualitative Survey

Post-intervention all participants in the MOTIVATE-CEW group were invited to complete an anonymous online survey exploring barriers and facilitators to exercise and PA (Table 3). Questions were developed, piloted within, and revised by the research team using appropriate literature (Scott et al., 2019a).

3.6 Outcome Measures

Participants attended AHCH for pre-intervention assessments. Following clinical assessments participants underwent a 2-week monitoring period (flash glucose monitoring and objective PA) before starting the 12-week intervention. At week 11 of the intervention participants began a 2-week post-intervention monitoring period. Within 2 weeks of the intervention ending participants attended AHCH for post-intervention testing, identical in all respects to pre-intervention.

3.6.1 Health related Quality of life

To assess generic health related quality of life (HRQOL) participants completed the EQ-5D-Y (Wille et al., 2010) and PedsQL 4.0 (Varni, Seid and Kurtin, 2001) as suggested by Hoedjes et al. (2018) three instruments were used as each of these measures generic HRQOL in a different manner and detects different relevant generic HRQOL domains. The parent proxy-report version of the PedsQL (5-18 years) (Varni, Seid and Kurtin, 2001) was completed by the participants parent/guardian to gain additional insights into HRQOL outcomes from the perspective of the parents.

Table 3. Survey questions post-intervention for MOTIVATE-CEW participants

	Questions
1.	Did you find any factors particularly helpful in increasing your exercise levels?
2.	What barriers did you face to increasing your exercise levels?
3.	What did you like about the extra support (e.g., Polar Flow app, fitness watch, counselling sessions and feedback from researcher and HR feedback during exercise)? What could be improved?
4.	What did you like about the counselling sessions? What could be improved?
5.	What did you like about the Teams messages? What could be improved?
6.	Were there any challenges to accessing or using the participant app? How could these challenges be overcome?
7.	Were there any challenges to using the fitness watch? How could these challenges be overcome?
8.	Were there any challenges to using the exercise videos? How could these challenges be overcome?

3.6.2 Body Composition

Waist circumference was measured in triplicate at the level of the minimal waist as previous work has suggested that this is a better indicator for visceral adipose tissue, cardiometabolic alterations and cardiovascular disease risk (Willis et al., 2007; Pinho et al., 2018). Body composition was assessed using Bio-Impedance Scales (Tanita innerscan dual, Tanita Corporation of America, Inc, Arlington Heights, IL, USA). The device was used to assess body mass and body fat percentage. SDS BMI was calculated using clinical access to the growth chart software GrowthXP Endo.

3.6.3 Cardiovascular disease risk factors

Blood pressure was measured in triplicate using an automated blood pressure monitor (Propaq LT monitor; Welch-Allyn, Beaverton, OR, USA). Lipid profile (total cholesterol, high-density lipoprotein, low-density lipoprotein, and triglycerides) and HbA1c were assessed from a venous blood sample. Blood samples were analysed by the AHCH clinical chemistry laboratory using three different methods. Lipid profile was measured using spectrophotometric assays on an Abbott Alinty ci analyser. HbA1c was measured by immunoassay using a Siemens DCA Vantage analyser.

3.6.4 Liver function

Aspartate aminotransferase (AST), alanine aminotransferase (ALT) and Albumin were assessed from a venous blood sample. The result of these blood samples was quantified using spectrophotometric assays on an Abbott Alinty ci analyser by the AHCH clinical chemistry laboratory.

3.6.5 Flash glucose monitoring

To provide data on intra- and inter-day glucose variation free-living glycemia was assessed over a 14-day period using a blinded Abbott Freestyle Libre Pro (Abbott Diabetes Care, CA, USA) flash glucose monitor (fGM), inserted subcutaneously into the interstitial fluid of the upper arm. As recommended for young people with obesity time in target range was split into two zones 3.9 - 7.8mmol/l and >7.8 – 10.0mmol/l (Rijks et al., 2016). As such, 9 metrics of glycaemic control were reported: 1) mean glucose, 2) % of time in target range (3.9–10.0mmol/L), 3) % of time in target range zone 1 (3.9–7.8mmol/L), 4) % of time in target range zone 2 (>7.8 – 10.0mmol/L), 5) % of time in level 2 hypoglycaemia (<3.0mmol/L), 6) % of time in level 1 hypoglycaemia (3.0-3.9mmol/L), 7) % of time in level 1 hyperglycaemia (10.0-13.9mmol/L), 8) % of time in level 2 hyperglycaemia (>13.9mmol/L), 9) glycaemic variability, reported as coefficient of variance and SD (Battelino et al., 2022). In line with recommendations, participants were included in the main analysis if they achieved a minimum of 70% of data over 14 days (Battelino et al., 2022). To explore if different ways of processing the data influenced the findings 70% of data over 12 and 7 days, respectively, was also considered.

3.7 Analysis techniques

Data analyses for the feasibility objectives of this study were descriptive. Data for outcome measures are expressed as mean, with uncertainty in all estimates expressed as 95% confidence intervals (CI). In keeping with guidance for the analysis of pilot trials (Lancaster et al., 2004), Cohens d effect sizes (Cohen, 1988) were derived for between group change from pre-

intervention values and findings were interpreted as follows; trivial <0.2, small 0.2–0.3, moderate 0.4–0.8, and large >0.8. We did not undertake null hypothesis testing or report P-values (neither absolute nor Bonferroni-corrected), in keeping with reporting guidance for exploratory pilot studies (Lancaster et al., 2004; Lee et al., 2014).

The qualitative survey responses were analysed deductively using the five-priority BCT categories outlined in the logic model (Figure 1). All transcripts were independently analysed by the researcher (AD) and three other members of the research team (MC, KH, FK) acted as “critical friends” during the analytical process (Smith and McGannon, 2018). The analysis consisted of coding transcripts according to the logical model priority BCT categories. Each of the codes was critically discussed, refined, and challenged and themes were developed through discussion between the researcher and “critical friends”. The researcher then analysed the content of each priority group to develop the key themes in each. This information was used to reach a consensus on the relevance of each priority BCT category to adherence behaviour for participants. A priority group was agreed to be ‘relevant’ if it was frequently coded and the content linked directly to the behaviour of interest. The researcher also conducted disconfirming analysis where transcripts were additionally reviewed to specifically look for cases that did not fit within the BCT categories.

4. Results

4.1 Reach

A consort diagram showing participant flow through the study is shown in Figure 3. Between August 2021 and July 2022 162 patients were screened for eligibility. Of the 51 patients eligible, 23 consented to participate, a recruitment rate of 45%. Final data

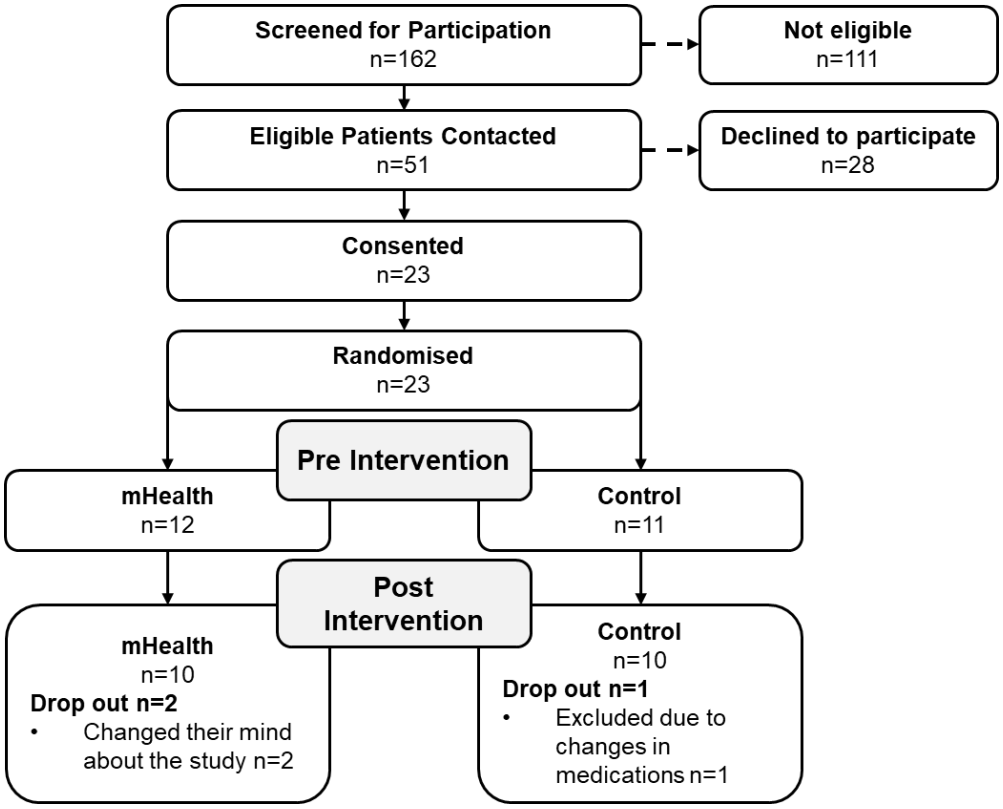

Figure 3. *Participant consort diagram*

collection was completed in October 2022. The intervention had a retention rate of 87%. Reasons for withdrawal were a change of opinion about the study (n=2) and changes to medications (n=1).

To provide context on the population recruited participant demographics in this study have been presented alongside the whole AHCH CEW cohort (Table 4). Participants in the study shared similar demographics to that of the AHCH CEW service cohort in terms of age, proportion of males and the number of

patients occupying different indices of multiple deprivation (IMD) quintiles. However, participants from non-white backgrounds made up 12% of the AHCH CEW service but only 4% of study participants, suggesting participants from non-white ethnicities appeared less likely to participate.

Table 4. Pre-intervention demographics of study participants and the whole AHCH CEW cohort.

		Study Participants (n = 23) n (%)	CEW Service (n = 92) n (%)
Age ±*SD*	*mean*	15±1	15±2
	12-15	16 (70)	56 (61)
	16-18	7 (30)	36 (39)
Sex			
	Male	10 (43)	41 (45)
	Female	13 (57)	51 (55)
Ethnicity			
	White	19 (83)	70 (76)
	Other	1 (4)	11 (12)
	Not Stated	3 (13)	11 (12)
IMD Quintile			
	1	17 (77)	62 (72)
	2	1 (5)	7 (8)
	3	1 (5)	8 (9)
	4	2 (9)	6 (7)
	5	1 (5)	3 (3)

AHCH, Alder Hey Children's Hospital; CEW, complications of excessive weight; IMD, indices of multiple deprivation

4.2 Dose

4.2.1 Device derived measurement of structured exercise sessions

Participants completing the MOTIVATE-CEW intervention exercised, measured via optical HR monitor, more regularly than those receiving usual care, representing moderate to large effect sizes in favour of MOTIVATE-CEW

for all measures of exercise adherence (Table 5). In usual care, 82% of participants did not complete any exercise sessions compared to 17% in MOTIVATE-CEW. At week 12 of the intervention, 9% of participants in usual care were still exercising compared to 33% in MOTIVATE-CEW. Figure 4 displays the percentage of participants completing exercise sessions at each week of the intervention. When the usual care participants were asked how often they wore the optical HR monitor for training, 10% stated they wore the monitor for all sessions, 10% for most sessions, 60% for some sessions and 20% did not wear the monitor for any sessions.

Table 5. Device derived measures of structured exercise sessions during the 12-week intervention period: means and 95% CI.

Outcome	Timepoint	MOTIVATE-CEW	Usual Care	Effect Size
Frequency of exercise (number of sessions per week)	Intervention Period	2 (0 to 3)	0 (0 to 0)	1.02
Mean time spent exercising (mins)	Intervention Period	80 (15 to 145)	9 (-6 to 24)	0.97
	Week 11&12	39 (2 to 75)	9 (-11 to 28)	0.67
Time spent completing moderate intensity exercise (mins)	Intervention Period	48 (7 to 89)	4 (-2 to 10)	0.96
	Week 11&12	23(-2 to 48)	5 (-6 to 15)	0.62
Time spent completing vigorous intensity exercise (mins)	Intervention Period	15 (4 to 27)	1 (-1 to 2)	1.19
	Week 11&12	9 (-1 to 18)	0 (0)	-
Time spent completing moderate to vigorous intensity exercise (mins)	Intervention Period	97 (16 to 177)	5 (-6 to 15)	1.01
	Week 11&12	51 (8 to 93)	5 (-1 to 4)	0.96

When calculating time spent completing moderate to vigorous intensity exercise, vigorous intensity exercise was multiplied by two.

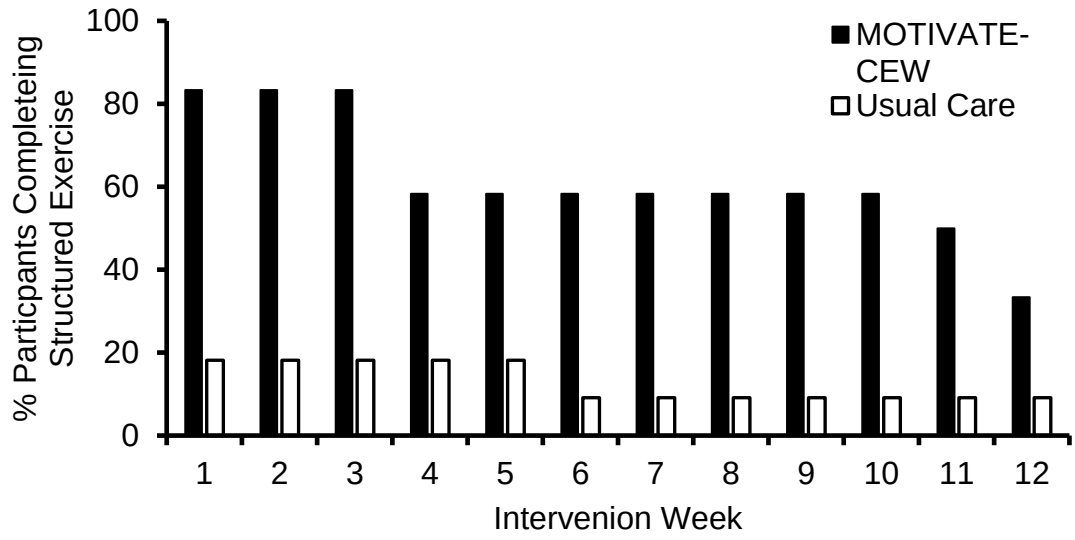

Figure 4. Training drop-off by week in MOTIVATE-CEW participants and usual care participants

4.2.2 Survey reported exercise behaviour

Table 6 shows the mean values for survey reported exercise behaviour at pre- and post-intervention. Participants receiving usual care showed a reduction in survey reported exercise behaviour (number of sessions of moderate and strenuous intensity exercise obtained from the GLTEQ) from pre- to post-intervention (*mean*= -1, *CI*= -3 to 1, *n*= 10) while those receiving MOTIVATE-CEW increased exercise behaviour (*mean*= 1, *CI*= -1 to 4, *n*= 10) which represented a large effect size difference (*d*= 0.87) in favour of MOTIVATE-CEW. A medium effect size difference in favour of MOTIVATE-CEW was also reported for change in total GLTEQ score from pre-intervention (usual care *mean*= -10, *CI*= -27 to 7, *n*= 10; MOTIVATE-CEW *mean*= 7, *CI*= -12 to 26, *n*= 10; *d*= 0.66).

4.2.3 Device derived habitual physical activity and sedentary time

Using the predetermined wear time criteria both pre- and post-intervention data was available from 39% and 13% of participants for the GENEActiv and ActivPAL, respectively. Using alternative wear time criteria made little

difference to the data availability (Table 6). Reasons for missing data are shown in Table 6. Due to the poor data availability change from pre-intervention and effect sizes have not been calculated but means and CI at pre- and post-intervention have been presented in Table 7.

Table 6. Data Availability- Survey reported exercise behaviour and device derived habitual physical activity and sedentary behaviour

Measure	Overall (%)	MOTIVATE-CEW		Usual Care		Reasons for missing data (n)
		Pre-intervention (%)	Week 12 (%)	Pre-intervention (%)	Week 12 (%)	
GLTEQ Questionnaire		100		91		Drop Out (3), Participant refused (1)
GENEActiv						
GENEActiv Returned	80	92	83	91	55	Drop out (3), Participant refused (5), Lost in Post (1)
4 days (≥1WE, ≥3WK) (>16hrs)	43	67	42	45	18	Drop out (3), Insufficient number of days (11), Insufficient Weekend days (5), Participant refused (5), Lost in Post (1), Insufficient Weekdays (1)
4 days (≥1WE, ≥3WK) (>10hrs)	43	67	42	45	18	Drop out (3), Insufficient days (11), Insufficient Weekend days (5), Participant refused (5), Lost in Post (1), Insufficient weekdays (1)
4 days (>16hrs)	57	83	58	64	18	Drop out (3), Insufficient number of days (11), Participant refused (5), Lost in Post (1)
4 days (>10hrs)	57	83	58	64	18	Drop out (3), Insufficient number of days (11), Participant refused (5), Lost in Post (1)
1 day (>10hrs)	67	83	67	91	27	Drop out (3), Insufficient number of days (11), Participant refused (5), Lost in Post (1)
ActivPAL						
ActivPAL Returned	78	100	83	91	45	Drop out (3), Participant refused (7), Drop Out (3)
4 days (≥1WE, ≥3WK)	41	50	50	45	18	Drop out (3), Participant removed device (7), Participant refused (7), Device Failed (6), Insufficient days recorded by device (4)
4 days	43	58	50	45	18	Drop out (3), Participant removed device (7), Participant refused (7), Device Failed (6), Insufficient days recorded by device (3)
1 day	59	67	75	64	27	Drop out (3), Participant refused (7), Device Failed (6), Participant removed device (3)

GLTEQ, Godin Leisure Time Exercise Questionnaire; 4 days (≥1WE, ≥3WK), 4 day inclusive of 1 weekend day and 3 weekdays; >16hrs, 16-hour wear time validation; >10hrs, 10-hour wear time validation.

Table 7. Survey reported exercise behaviour and device derived habitual physical activity and sedentary behaviour: time point means and 95% CI

Outcome	MOTIVATE-CEW		Usual Care	
	Pre-intervention	Week 12	Pre-intervention	Week 12
GLTEQ				
Number of Moderate/ Strenuous Exercise sessions	4 (3 to 5)	5 (3 to 7)	5 (3 to 7)	4 (2 to 6)
n	*12*	*10*	*10*	*10*
Total Score	39 (27 to 50)	42 (25 to 60)	48 (29 to 67)	38 (23 to 53)
n	*12*	*10*	*10*	*10*
GENEActiv				
Total Weekly PA	1315 (978 to 1652)	1582 (1042 to 2122)	1243 (776 to 1711)	1265 (-3138 to 5667)
n	*10*	*7*	*7*	*2*
Sedentary Time per week	8765 (8428 to 9102)	8498 (7958 to 9038)	8837 (8369 to 9304)	8816 (4413 to 13218)
n	*10*	*7*	*7*	*2*
Light PA per week	1075 (812 to 1338)	1321 (870 to 1772)	1058 (690 to 1426)	1108 (-1865 to 4081)
n	*10*	*7*	*7*	*2*
Moderate PA per week	230 (134 to 326)	253 (149 to 358)	179 (69 to 289)	156 (-1261 to 1572)
n	*10*	*7*	*7*	*2*
Vigorous PA per week	11 (2 to 19)	8 (4 to 12)	6 (-3 to 16)	2 (-11 to 15)
n	*10*	*7*	*7*	*2*
MVPA per week	241 (139 to 342)	261 (154 to 368)	185 (72 to 298)	157 (-1279 to 1593)
n	*10*	*7*	*7*	*2*
MVPA+10	29 (10 to 49)	25 (9 to 41)	40 (-12 to 92)	52 (-603 to 706)
n	*10*	*7*	*7*	*2*
ActivPAL				
Mean Steps Per Day	7115 (3399 to 10831)	8523 (5567 to 11478)	7223 (2431 to 12016)	7377 (-9288 to 24041)
n	*6*	*6*	*5*	*2*
Mean Daily Sedentary Time	630 (566 to 693)	599 (519 to 680)	595 (529 to 660)	679 (188 to 1171)
n	*6*	*6*	*5*	*2*

GLTEQ, Godin Leisure Time Exercise Questionnaire, MVPA, moderate to vigorous intensity physical activity; MVPA10+, MVPA recorded in ≥10-minute bouts. GENEActiv wear time criteria was 16 hours for a minimum of 4 days irrespective of weekday/weekend day. ActivPAL wear time criteria was 20h of data for a minimum 4 days including one weekend day and three weekdays.

4.3 Fidelity

For those receiving MOTIVATE-CEW 70% (42 out of 70) of consultations were attended. To provide context during the same period 66% and 68% of AHCH CEW service appointments and dietician meetings were attended, respectively. The mean duration of MOTIVATE-CEW consultations was 33±11 minutes.

The mean number of messages sent to participants during the intervention was 29±17 and the mean number of replies received was 21±17, a response rate of 72%. During the first month participants left feedback on 66% of their exercise sessions.

4.4 Qualitative Survey

The responses to the qualitative survey for those receiving MOTIVATE-CEW are summarised in Table 8. From the logic model the priority BCT category most commonly referred to by participants was regular feedback on behaviour by HCPs. Participants spoke of the benefit of having a regular personalised advice from an experienced exercise specialist. Having this regular contact motivated them to believe in their abilities. The creation of a graded action plan with specific behavioural goals priority was another popular BCT category referred to by participants. There were limited participant responses that could be related to the information about health consequences BCT category. There were a number of barriers mentioned in the survey that were not related to a BCT, so a separate barriers section is found in Table 8. Poor health was the most common barrier to increasing exercise and PA.

Table 8. Priority behaviour change technique (BCT) groups taken from the logic model, sub themes, summary of context and participant quotes.

Priority BCT Category	Sub-Theme	Summary of context	Example Quote
Step 1: Information about Health Consequences	• Importance of weight loss	A small number of participants felt that understanding the need for weight loss and being able to discuss how best to achieve this was valuable. However, the majority of participants did not comment on how information about health consequences helped motivate them.	*"Good to be able to talk about what I can do to lose weight the quickest and easiest"*
Step 2: Creation of a graded action plan with specific behavioural goals	• Personalized exercise	The personalised nature of the exercise programme was well supported by participants with the majority mentioning this as a facilitator for exercise. A small number of participants cited a lack of variety and a lack of time as issues, highlighting that further personalisation would be beneficial.	*"Letting me choose what I do and not forcing me to do things I don't want to do"*
	• Graded exercise	Graded exercise was another positive of the programme that was highlighted.	*"The length of the exercises made me more likely to do it and to do it more often"*
Step 3: Instructions on how to perform behaviour and biofeedback	• Live feedback from the watch	A small number of participants commented on how the programme enabled them to exercise correctly with live feedback from the watch. However, there were limited responses that referred to improved ability to perform tasks.	*"Instant feedback (from the watch)"*
Step 4: Self-monitoring of behaviour and review of behavioural goals	• Monitoring exercise via the watch	Most of the participants mentioned having access to feedback through the watch as being a beneficial aspect of the intervention. However, further detail on how the watch was beneficial was absent and so more probing questions would help to obtain this information in the future.	*"I liked the watch as it helped me and reminded me to exercise and gave me motivation and helped me a lot with maintaining my exercise sessions."*

Table 8 cont. Priority behaviour change technique (BCT) groups taken from the logic model, sub themes, summary of context and participant quotes.

BCT	Sub-Theme	Summary of context	Example Quote
Step 5: Regular feedback on behaviour by HCPs	• Personalised advice • Experienced specialist • Instilling belief • Someone to talk to	All participants cited having someone to talk to as a key benefit of the intervention. Instilling belief in the participants through communication with the exercise specialist was a reoccurring theme, and the personalised advice participants received about their programmes was also mentioned by all participants. Having an experienced exercise specialist was also a common response from participants.	*"The fact that it was easy to communicate, and it was nice to get the congratulations after completing an exercise session"* *"That I knew that someone was checking up on what I was doing- it made more motivated to do the actual exercise."*
Barriers	• Poor Health • Weather • Lack of Motivation	A number of barriers to increased exercise and PA were mentioned. However, these did not apply to any of the BCT groups. The most common barriers were based around sickness, injury, and mental health. In addition to this a lack of motivation and weather were also said to have been barriers for a small number of participants.	*"Sometimes I have (an) injury like back ache"* *"Sometimes not wanting to go out (is a barrier to exercise)."*

4.5 Outcome measures

4.5.1 Data Availability

A full summary of data availability and reasons for missing data can be found in Tables 9 and 10. When dropouts were considered 91% of data was available for health-related quality of life questionnaires, body composition, cardiovascular disease risk factors and liver function, with each measure having ≥85% availability. Using the predetermined wear time criteria of 70% of data over 14 days both pre- and post-intervention data was available from 17% of participants for flash glucose monitoring. When the alternative wear time of 70% of 7 days was used 39% of data was available at both time points. Due to the poor data availability for flash glucose monitoring change from pre-intervention and effect sizes have not been calculated but means and CI at pre- and post-intervention have been presented in Table 11.

4.5.2 Preliminary effectiveness: health related quality of life

Table 12 shows the mean values of the HRQOL outcomes measures at each time point. When change from pre-intervention was considered there was a large effect size difference in favour of MOTIVATE-CEW for the EQ-5D-Y visual analogue scale score (Table 13), representing participants direct valuation of their current generic HRQOL. All other effect sizes suggested trivial to small differences between groups.

4.5.3 Preliminary effectiveness: health outcomes

Table 14 shows the mean values for body composition, cardiovascular disease risk factors and liver function measures at each time point. When change from pre-intervention was considered there were medium effect size differences in

favour of MOTIVATE-CEW for HDL, triglycerides, and ALT (Table 15). However, the was a large effect size difference in favour of usual care for HbA1c. All other effect sizes suggested trivial to small differences between groups.

Table 9. Data Availability- health related quality of life questionnaires, body composition, cardiovascular disease risk factors and liver function

Measure	Overall (%)	MOTIVATE-CEW		Usual Care		Reasons for missing data (n)
		Pre-intervention (%)	Week 12 (%)	Pre-intervention (%)	Week 12 (%)	
Health related quality of life						
EQ-5D-Y	91	100	83	91	91	Drop Out (3), Participant refused (1)
PedsQL - Self-report	87	100	83	82	82	
PedsQL - Proxy	91	100	83	91	91	Drop Out (3), Participant refused (1)
Body composition						
Height	93	100	83	100	91	Drop Out (3)
Weight	93	100	83	100	91	Drop Out (3)
BMI	93	100	83	100	91	Drop Out (3)
Waist Circumference	93	100	83	100	91	Drop Out (3)
Body Fat %	89	100	83	91	82	Drop Out (3), Tanita Error (1), Participant refused (1)
Cardiovascular disease risk						
Blood Pressure	93	100	83	100	91	Drop Out (3)
Lipid Profile	93	100	83	100	91	Drop Out (3)
HbA1c	85	75	83	100	91	Drop Out (3), Lab Error (3), Insufficient Sample (1)
Liver function	93	100	83	100	91	Drop Out (3)

Table 10. Data Availability- Flash glucose monitoring

Measure	Overall (%)	MOTIVATE-CEW		Usual Care		Reasons for missing data (n)
		Pre-intervention (%)	Week 12 (%)	Pre-intervention (%)	Week 12 (%)	
Monitor returned	74	83	75	73	64	Drop Out (3), Participant refused (4), Sensor was not returned (4)
14 day	35	25	25	45	45	Drop Out (3), Sensor fell out (18), Refused (4), Sensor was not returned (4), Participant removed sensor (1), Insufficient data (1)
12 day	46	33	25	64	64	Drop Out (3), Sensor fell out (12), Refused (4), Sensor was not returned (4), Participant removed sensor (1), Insufficient data (1)
7 day	54	50	42	64	64	Drop Out (3), Sensor fell out (9), Refused (4), Sensor was not returned (4), Insufficient data (1)

Flash glucose monitoring data availability was set to 70% in all conditions.

Table 11. Flash glucose monitoring: time point means and 95%CI

Outcome	MOTIVATE-CEW		Usual Care	
	Pre-intervention	Week 12	Pre-intervention	Week 12
Mean Glucose (mmol)	5 (4 to 6)	5 (4 to 6)	5 (4 to 6)	5 (4 to 6)
n	*3*	*3*	*5*	*5*
SD	1 (1 to 1)	1 (0 to 1)	1 (1 to 1)	1 (1 to 1)
n	*3*	*3*	*5*	*5*
CV	18 (12 to 24)	13 (10 to 16)	18 (11 to 24)	19 (15 to 22)
n	*3*	*3*	*5*	*5*
TIR (%)	89 (66 to 112)	98 (97 to 100)	80 (52 to 108)	85 (62 to 108)
n	*3*	*3*	*5*	*5*
TIR zone 1 (3.9-7.8) (%)	89 (67 to 110)	98 (95 to 101)	78 (52 to 104)	83 (62 to 104)
n	*3*	*3*	*5*	*5*
TIR zone 2 (7.8-10) (%)	1 (-1 to 2)	1 (-1 to 2)	1 (-2 to 5)	2 (-3 to 8)
n	*3*	*3*	*5*	*5*
Time spent in hypoglycaemia (%)	11 (-12 to 34)	2 (0 to 3)	20 (-8 to 48)	15 (-8 to 38)
n	*3*	*3*	*5*	*5*
Time spent in level 1 hypoglycaemia (%)	9 (-10 to 28)	2 (0 to 3)	17 (-5 to 39)	13 (-7 to 32)
n	*3*	*3*	*5*	*5*
Time spent in level 2 hypoglycaemia (%)	2 (-2 to 6)	0 (0 to 0)	3 (-5 to 11)	2 (-2 to 6)
n	*3*	*3*	*5*	*5*
Time spent in hyperglycaemia (%)	0 (0)	0 (0)	0 (0 to 0)	0 (0 to 1)
n	*3*	*3*	*5*	*5*
Time spent in level 1 hyperglycaemia (%)	0 (0)	0 (0)	0 (0 to 0)	0 (0 to 1)
n	*3*	*3*	*5*	*5*
Time spent in level 2 hyperglycaemia (%)	0 (0)	0 (0)	0 (0)	0 (0)
n	*3*	*3*	*5*	*5*

TIR, Time in range; SD, Standard deviation; CV, Coefficient of variation. Flash glucose monitoring data availability was set to 70% of 14 days.

Table 12. Health related quality of life questionnaires: time point means and 95%CI

Outcome	MOTIVATE-CEW		Usual Care	
	Pre-intervention	Week 12	Pre-intervention	Week 12
EQ-5D-Y				
EQ-5D-Y VAS	59.67 (45.43 to 73.91)	76.6 (67.52 to 85.68)	60 (48.32 to 71.68)	66 (48.82 to 83.18)
n	*12*	*10*	*10*	*10*
Mean Score	0.60 (0.31 to 0.88)	0.48 (0.3 to 0.67)	0.57 (0.24 to 0.9)	0.42 (0 to 0.83)
n	*12*	*10*	*10*	*10*
PedsQL				
Mean Score	62 (49 to 74)	69 (60 to 79)	63 (44 to 82)	70 (55 to 86)
n	*12*	*10*	*9*	*9*
Psychosocial Health Summary	56 (40 to 71)	63 (51 to 76)	58 (36 to 80)	66 (50 to 83)
n	*12*	*10*	*9*	*9*
Physical Health Functioning	73 (62 to 83)	80 (72 to 87)	72 (57 to 88)	78 (61 to 94)
n	*12*	*10*	*9*	*9*
Emotional Functioning	55 (39 to 70)	63 (50 to 75)	59 (34 to 85)	64 (48 to 81)
n	*12*	*10*	*9*	*9*
Social Functioning	63 (42 to 83)	71 (55 to 88)	65 (43 to 87)	69 (46 to 93)
n	*12*	*10*	*9*	*9*
School Functioning	50 (31 to 70)	56 (37 to 75)	47 (20 to 74)	63 (47 to 80)
n	*12*	*10*	*9*	*9*
Parent PedsQL				
Mean Score *(95% CI)*	47 (34 to 61)	60 (48 to 71)	56 (38 to 73)	65 (50 to 80)
n	*12*	*10*	*10*	*10*
Psychosocial health Summary	44 (30 to 59)	57 (43 to 71)	54 (36 to 72)	64 (48 to 80)
n	*12*	*10*	*10*	*10*
Physical Functioning	54 (38 to 69)	64 (52 to 77)	59 (43 to 76)	67 (53 to 80)
n	*12*	*10*	*10*	*10*
Emotional Functioning	40 (26 to 53)	48 (31 to 64)	48 (30 to 66)	57 (37 to 76)
n	*12*	*10*	*10*	*10*
Social Functioning	50 (30 to 70)	62 (45 to 79)	55 (33 to 76)	66 (48 to 84)
n	*12*	*10*	*10*	*10*
School Functioning	43 (23 to 63)	61 (45 to 77)	61 (39 to 83)	71 (53 to 90)
n	*12*	*10*	*10*	*10*

Table 13. Health related quality of life questionnaires: changes from baseline means and 95%CI

Outcome		Mean change		Effect size
		MOTIVATE-CEW	Usual Care	
EQ-5D-Y				
	EQ-5D-Y VAS	20 (8 to 31)	6 (-7 to 19)	0.80
	n	*10*	*10*	
	Mean Score	-0.13 (-0.41 to 0.14)	-0.15 (-0.36 to 0.06)	0.05
	n	*10*	*10*	
PedsQL				
	Mean Score	8 (-3 to 18)	8 (-1 to 16)	0.03
	n	*10*	*9*	
	Psychosocial Health Summary	9 (-4 to 22)	9 (-3 to 20)	0.02
	n	*10*	*9*	
	Physical Health Functioning	6 (-3 to 15)	5 (-3 to 13)	0.09
	n	*10*	*9*	
	Emotional Functioning	9 (-7 to 24)	5 (-8 to 18)	0.18
	n	*10*	*9*	
	Social Functioning	8 (-8 to 24)	4 (-7 to 16)	0.21
	n	*10*	*9*	
	School Functioning	9 (-5 to 23)	17 (0 to 33)	-0.38
	n	*10*	*9*	
Parent PedsQL				
	Mean Score *(95% CI)*	14 (2 to 25)	9 (2 to 16)	0.32
	n	*10*	*10*	
	Psychosocial health Summary	14 (4 to 23)	10 (5. to 15)	0.35
	n	*10*	*10*	
	Physical Functioning	13 (-4 to30)	8 (-5 to 20)	0.25
	n	*10*	*10*	
	Emotional Functioning	10 (-3 to 23)	8.5 (-1 to 18)	0.10
	n	*10*	*10*	
	Social Functioning	14 (-3 to 30)	12 (1 to 22)	0.11
	n	*10*	*10*	
	School Functioning	18 (4 to 31)	10 (-5 to 25)	0.38
	n	*10*	*10*	

Table 14. Body composition, cardiovascular disease risk factors and liver function: time point means and 95%CI

Outcome	MOTIVATE-CEW		Usual Care	
	Pre-intervention	Week 12	Pre-intervention	Week 12
Body composition				
Height (cm)	167.5 (162.2 to 172.8)	165.8 (161.7 to 169.9)	165.5 (161.2 to 169.7)	167 (161.8 to 172.2)
n	*12*	*10*	*11*	*10*
Weight (kg)	114.8 (102.1 to 127.4)	111.6 (98.8 to 124.3)	118.2 (99.9 to 136.4)	117.7 (96.3 to 139.2)
n	*12*	*10*	*11*	*10*
BMI (kg/m^2)	41.0 (36.3 to 45.6)	40.7 (35.5 to 45.9)	42.9 (37.4 to 48.4)	41.9 (35.6 to 48.1)
n	*12*	*10*	*11*	*10*
SDS BMI	3.45 (3.08 to 3.82)	3.42 (2.98 to 3.86)	3.63 (3.3 to 3.96)	3.56 (3.13 to 3.98)
n	*12*	*10*	*11*	*10*
Body Fat (%)	48.3 (44.5 to 52.2)	46.7 (42.1 to 51.2)	51.5 (44.9 to 58.1)	50.1 (45.3 to 54.9)
n	*12*	*10*	*10*	*9*
Waist Circumference (cm)	114 (103 to 125)	111 (100 to 122)	120 (110 to 129)	117 (108 to 127)
n	*12*	*10*	*11*	*10*
Cardiovascular disease risk factors				
SBP (mmHg)	131 (121 to 141)	134 (125 to 143)	130 (122 to 138)	129 (123 to 136)
n	*12*	*10*	*11*	*10*
DBP (mmHg)	82 (75 to 89)	82 (74 to 89)	85 (79 to 90)	87 (78 to 95)
n	*12*	*10*	*11*	*10*
MAP (mmHg)	107 (100 to 113)	108 (101 to 115)	108 (102 to 114)	108 (102 to 115)
n	*12*	*10*	*11*	*10*
HbA1c (mmol/mol)	32 (30 to 35)	34 (31 to 37)	34 (32 to 36)	33 (32 to 35)
n	*9*	*10*	*10*	*10*
Cholesterol (mmol/l)	4.1 (3.6 to 4.5)	3.9 (3.5 to 4.2)	4.5 (4.1 to 5.0)	4.5 (4.0 to 5.0)
n	*12*	*10*	*11*	*10*
HDL (mmol/l)	1.07 (0.95 to 1.20)	1.10 (0.99 to 1.20)	1.07 (0.94 to 1.19)	0.97 (0.80 to 1.13)
n	*12*	*10*	*11*	*10*
LDL (mmol/l)	2.35 (1.98 to 2.72)	2.18 (1.86 to 2.50)	2.86 (2.46 to 3.26)	2.75 (2.22 to 3.28)
n	*12*	*10*	*11*	*10*
Triglycerides (mmol/l)	1.4 (1.0 to 1.8)	1.3 (0.8 to 1.7)	1.4 (1.0 to 1.8)	1.8 (1.2 to 2.3)
n	*12*	*10*	*11*	*10*

Table 14 cont. Body composition, cardiovascular disease risk factors and liver function: time point means and 95%CI

Outcome	MOTIVATE-CEW		Usual Care	
	Pre-intervention	Week 12	Pre-intervention	Week 12
Liver function				
AST (U/L)	22 (17 to 28)	22 (18 to 26)	30 (19 to 41)	25 (17 to 34)
n	*12*	*10*	*11*	*10*
ALT (U/L)	33 (23 to 44)	28 (20 to 36)	39 (21 to 57)	39 (18 to 60)
n	*12*	*10*	*11*	*10*
Albumin (g/L)	43 (41 to 45)	43 (42 to 45)	42 (40 to 43)	42 (40 to 43)
n	*12*	*10*	*11*	*10*

BMI, Body Mass Index; SDS-BMI, standard deviation scores body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; MAP, mean arterial blood pressure; HDL, high density lipoprotein cholesterol; LDL, low density lipoprotein cholesterol; AST, aspartate aminotransferase; ALT, alanine transaminase.

Table 15. Body composition, cardiovascular disease risk factors and liver function: changes from baseline means and 95%CI

Outcome	Mean change		Effect Size
	MOTIVATE-CEW	Usual Care	
Body composition			
Height (cm)	0.7 (0.3 to 1)	1.3 (0.1 to 2.5)	-0.50
n	*10*	*10*	
Weight (kg)	1.2 (-1.3 to 3.6)	1.3 (-1.3 to 3.8)	0.03
n	*10*	*10*	
BMI (kg/m^2)	0.2 (-0.7 to 1)	-0.2 (-1.3 to 0.9)	-0.27
n	*10*	*10*	
SDS BMI	0.01 (-0.08 to 0.1)	-0.03 (-0.14 to 0.08)	-0.30
n	*10*	*10*	
Body Fat (%)	-1.5 (-4.2 to 1.1)	-0.6 (-3.3 to 2.1)	0.25
n	*10*	*9*	
Waist Circumference (cm)	0 (-6 to 6)	0 (-3 to 4)	0.04
n	*10*	*10*	
Cardiovascular disease risk factors			
SBP (mmHg)	1 (-9 to 12)	-2 (-9 to 5)	-0.25
n	*10*	*10*	
DBP (mmHg)	0 (-8 to 8)	2 (-5 to 9)	0.17
n	*10*	*10*	
MAP (mmHg)	1 (-5 to 7)	0 (-5 to 5)	-0.12
n	*10*	*10*	
HbA1c (mmol/mol)	1 (-1 to 4)	-1 (-3 to 1)	-0.90
n	*8*	*9*	
Cholesterol (mmol/l)	-0.1 (-0.4 to 0.2)	0 (-0.3 to 0.3)	0.35
n	*10*	*10*	
HDL (mmol/l)	-0.02 (-0.11 to 0.06)	-0.10 (-0.18 to -0.02)	0.67
n	*10*	*10*	
LDL (mmol/l)	-0.14 (-0.34 to 0.07)	-0.08 (-0.31 to 0.16)	0.19
n	*10*	*10*	
Triglycerides (mmol/l)	0.0 (-0.2 to 0.3)	0.4 (-0.1 to 0.9)	0.62
n	*10*	*10*	

Table 15 cont. Body composition, cardiovascular disease risk factors and liver function: changes from baseline means and 95%CI

Outcome		Mean change		Effect Size
		MOTIVATE-CEW	Usual Care	
Liver function				
	AST (U/L)	-1 (-5 to 3)	-3 (-9 to 3)	-0.26
	n	*10*	*10*	
	ALT (U/L)	-5 (-14 to 4)	4 (-3 to 10)	0.79
	n	*10*	*10*	
	Albumin (g/L)	1 (-1 to 2)	0 (-1 to 1)	-0.31
	n	*10*	*10*	

BMI, Body Mass Index; SDS-BMI, standard deviation scores body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; MAP, mean arterial blood pressure; HDL, high density lipoprotein cholesterol; LDL, low density lipoprotein cholesterol; AST, aspartate aminotransferase; ALT, alanine transaminase.

5. Discussion

The MOTIVATE-CEW study is the first trial to work within a UK CEW service to assess the feasibility of introducing additional exercise and PA support to the existing MDT. The study suggested that the trial design had good reach, with high recruitment and retention rates and the ability to recruit a representative sample. The dose data suggests participants receiving MOTIVATE-CEW had good uptake and adherence to structured exercise compared to those receiving normal care. Qualitative data supported the assessment of dose, suggesting the targeted behaviour change categories, particularly regular feedback on behaviour by the exercise specialist, were important for the increases in exercise behaviours observed. Finally, although the study was not powered to detect statistically significant differences in health outcomes, preliminary evidence suggests MOTIVATE-CEW may be effective for improving HRQOL and lipid profile compared with usual care.

5.1 Feasibility Outcomes

5.1.1 Reach

As this was the first trial to work with adolescents from a CEW services, predetermined criteria for proceeding to a larger trial were not developed for recruitment or retention. However, the recruitment rate of 45% compares well with other feasibility trials which use criteria of 20-40% of eligible participants recruited as criteria for future feasibility (Ennis et al., 2017; Hesketh et al., 2021). The retention rate of 87% also compares well with other feasibility trials where 80% of participants retained is often used as a measure of feasibility (Ennis et al., 2017). The recruitment and retention rate also compares well

with previous work in multidisciplinary weight management services for obese adolescents (Eliakim et al., 2002; Lisón et al., 2012; Barlow et al., 2017).

A strength of the trial is the generalisability of the participants recruited with the target population for age, sex and deprivation. The mean age (MOTIVATE-CEW =15yrs, CEW service 15yrs) and proportion of males and females (MOTIVATE-CEW Males= 43%, CEW Service Males=45%) were very similar to the CEW cohort as a whole. In contrast to previous research, which suggests recruitment of participants from deprived background could be a barrier to mHealth interventions (Van Dijk, 2005; Yu, 2006; Bommakanti et al., 2020), a real positive was the trials' ability to recruit a representative sample of participants from deprived backgrounds. The IMD data showed 77% of MOTVATE-CEW participants were from the most deprived quintile, in comparison to 72% of the CEW service as a whole. Another positive was that availability of smartphones and/or having access to data plans or Wi-Fi were not stated as reasons for not participating in the trial. This is in keeping with national data suggesting 95% of adolescents have access to smartphones (Anderson and Jiang). The feasibility of recruiting a representative ethnic sample was less positive, with only 4% of participants recruited being from non-white ethnicities compared to 12% of the CEW cohort. Recruitment of participants from different ethnicities has also been a problem in previous research conducted within weight management services for children (Barlow et al., 2017). As such, future work should consider methods to encourage participation of adolescents from more diverse ethnicities.

5.1.2 Dose

Another strength of the study was the adherence to structured exercise in participants receiving the MOTIVATE-CEW intervention compared with usual care. The device-derived measurements of structured exercise demonstrated participants receiving MOTIVATE-CEW were more likely to exercise (MOTIVATE-CEW = 2 sessions/wk, Usual Care = 0 sessions/wk) and that mean weekly exercise duration, total (MOTIVATE-CEW= 80 mins, Usual Care = 9 mins) and at moderate and vigorous intensities (MOTIVATE-CEW=96 mins, Usual Care = 5 mins), were greater than usual care participants, with moderate to large effect size differences observed in favour of MOTIVATE-CEW. While the data recorded across the 12-week intervention period was encouraging only 33% of participants were still exercising in the final week of the programme, although, this was again greater than Usual Care (9%). This suggests that the long-term impact of the intervention may need to be investigated further and additional strategies put in place to ensure participants continue to engage. It also highlights the importance of including a long-term follow up in any future trials of the intervention. It is difficult to compare the current data with previous trials as to the authors knowledge there are no studies that assess adherence to structured exercise within obese adolescents receiving multidisciplinary weight management treatment. It is acknowledged the data should be interpreted with caution as only 10% of the Usual Care group stated they wore the optical HR monitor for all exercise sessions, suggesting this data may underrepresent exercise behaviour in the Usual Care group. However, the optical HR measures were supported by the self-reported exercise behaviour data (GLTEQ) which showed the number of

moderate/ strenuous exercise sessions completed in the MOTIVATE-CEW group increased from pre- to post-intervention, while the number of sessions completed was reduced in the Usual Care group during the same period.

As well as increasing structured exercise the MOTIVATE-CEW intervention aimed to increase habitual PA and reduce sedentary behaviours. As such, the trial captured data on habitual PA and sedentary time using GENEActiv and ActivPAL monitors. However, the data availability for these devices was poor, regardless of the wear time criteria used, meaning conclusions could not be drawn from the sample available. In contrast, Aguer et al. (2010) showed good availability of device derived PA data (78% met wear time criteria) in a study of obese adolescents completing a multicomponent weight management intervention. Given the importance of assessing habitual PA and sedentary behaviours for evaluating CEW service interventions, future qualitative work should be conducted with CEW patients to understand why data availability was low and how this can be overcome.

5.1.3 Fidelity

Based on the fidelity measures, the intervention appeared to have been delivered as intended. Participant attendance at MOTIVATE-CEW counselling sessions (70%) was similar to attendance at CEW service clinic appointments as part of participants usual care (66%). The mean duration of the consultations (33 minutes) also aligns closely with the length of clinic appointments within the CEW service, which are scheduled to last for 30 minutes. Participant engagement with the mHealth messaging feedback was also positive with a response rate of 72%. This is better than the response rate (61%) shown within previous literature assessing children's responses to SMS

messages to promote healthy behaviours (Fassnacht et al., 2015). Despite the positive results in this trial, in the future a greater proportion of the intervention should be analysed to give a true representation of fidelity, including the content of the meetings, text messages and feedback comments. Therefore, future trials should look to develop additional measures to assess fidelity.

5.1.4 Qualitative Outcomes

The MOTIVATE-CEW intervention aimed to use 5 priority BCT categories to support uptake and maintenance of exercise and PA. The qualitative survey provided insight into participant perceptions of how these BCT categories supported them throughout the intervention. Participants considered the regular feedback on behaviour by the exercise specialist as instrumental in facilitating behaviour change. Within the BCT category participants particularly focused on the provision of personalised advice from an experienced specialist who instilled belief as being key subthemes. Based on the current data, it is hypothesised that this relationship enhanced participant confidence to perform and manage free-living exercise, which has been deemed essential when initiating new behaviours (Bandura, 1997). To the authors knowledge, this is the first intervention to use mHealth technology and biometrics to support a two-way connection between HCPs and obese young people. We believe participant perceptions emphasise the potential role of such technologies in facilitating future exercise and PA interventions. The creation of a graded action plan with specific behavioural goals appeared to be another important BCT category discussed by participants. There is little information on effective BCTs for exercise or PA in children with obesity, but research in adults suggests provision of personalised flexible programmes as instrumental

in facilitating adherence to exercise (Morgan et al., 2016). Although participants mentioned the mHealth technology as a facilitator the information was brief and required more depth for conclusions to be drawn. Future work should incorporate interviews or focus groups to develop richer data. Interestingly there was very little mention of the BCT category information about health consequences. An analysis of effective BCTs in the management of childhood obesity (interventions targeting PA and/or eating behaviour) suggested that providing information on consequences of behaviour to the individual was a key BCT for effective interventions (Martin, Chater and Lorencatto, 2013). As such, future versions of the intervention should look to further develop support in this area.

The qualitative survey also highlighted the barriers that prevented participants from competing exercise and PA. The most common barrier was poor health with participants citing sickness, injury and poor mental health as reasons for not exercising. The identification of these barriers may highlight the need for greater communication within the MDT in future versions of MOTIVATE-CEW. Drawing on other HCPs (e.g., physiotherapist and psychologist) specialisms to tackle the underlying causes of these barriers. This could be made possible by embedding an exercise specialist within the MDT.

5.2 Outcome Measures

5.2.1 Data Availability

The data availability for in-clinic measured health outcomes was good throughout the intervention and the majority of missing data was the result of participant drop out. Over 85% of data was available for all in-clinic

measurements adding to the suggestion that the trial design was feasible. However, similar to PA and sedentary behaviour, the availability of fGM data was poor. Over the intervention 74% of the fGM sensors were returned but only 35% of participants met the wear time criteria (70% of 14 days). The poor data availability does not appear to be due to participants fitting the monitors themselves during post-intervention measures, as data availability was improved compared to pre-intervention. Our data is different from a recent trial investigating the feasibility of continuous glucose monitor use in adolescents with obesity, where adherence to continuous glucose monitor wear time criteria was good (96% of data available) (Naguib et al., 2022). It is unclear why data availability was low in the current trial, but it appears adherence to measurements requiring participants enrolled in a CEW service to collect data from wearable devices during activities of daily living was poor (Ramirez-Rico et al., 2014; Downs et al., 2016). As discussed above, future work should look to further understand the reasons for this lack of adherence by speaking with CEW patients.

5.2.2 Preliminary effectiveness

The study observed preliminary evidence of a large effect on HRQOL, measured through the EQ-5D-VAS score, in MOTIVATE-CEW participants compared to usual care. The increase in EQ-5D-VAS score observed following MOTIVATE-CEW was greater than following a 1-year multidisciplinary intervention in severely obese adolescents that involved an inpatient period (Hoedjes 2018). Changes in other measures of HRQOL were negligible, although they did favour MOTIVATE-CEW. Compared with the usual care group, the study also observed medium improvements in the blood lipids HDL

and triglycerides and liver enzyme ALT in the intervention group. The systematic review and meta-analyses by García-Hermoso et al. (2019) also reported exercise resulted in a medium improvement in triglycerides, but not HDL or ALT. The data also showed a large improvement in HbA1c in usual care participants compared to the intervention group, which requires further investigation. Other health related outcomes demonstrated trivial to small changes. A recent meta-analysis has suggested that exercise interventions lasting greater than 12 weeks may be more effective at improving body composition and cardiovascular risk factors in obese adolescents (Li and Chen, 2021). Thus, future trials should consider increasing the intervention length to optimise possible health benefits.

5.3 Future Directions

The aim of this trial was to assess the initial feasibility of implementing additional exercise and PA support within a CEW service. As such, the trial design did not include a follow-up period. However, future trials examining the MOTIVATE-CEW intervention should include a follow-up assessment 12 months post randomisation to assess the long-term impact of the intervention.

Although MOTIVATE-CEW was able to increase exercise uptake and weekly exercise duration compared with normal care, drop off data suggested that long term adherence could have been better. Despite the involvement of stakeholders within the development of the MOTIVATE-CEW intervention, future work looking to improve the intervention should consider actively engaging children, parents, and healthcare professional in the process. Guidance from the medical research council has highlighted the value of

engaging with appropriate stakeholders to maximise the potential of developing an intervention that is likely to have positive impacts on health (Skivington et al., 2021).

A collaborative design process could also help with the development of recruitment strategies, a primary outcome for a future RCT and a study design which minimises missing data. As previously mentioned, the current study did not recruit a representative proportion of ethnicities when compared to the wider CEW service. Previous interventions that adopted collaborative approaches have been able to identify solutions for overcoming barriers to the recruitment of racially and ethnically diverse participants (Clark et al., 2019). The development of an appropriate primary outcome is essential before any future RCT can be considered. Currently, there is no consensus from the 21 established CEW services on what the primary clinical outcome should be for CEW services. Instead, a mapping exercise identifying 9 key metrics has been completed. These metrics include measures of HRQOL, physical fitness, PA levels, school attendance and mental health. Previous literature has highlighted the importance of including participants within the process of establishing research priorities (Sacristán et al., 2016). Considering stakeholder priorities could contribute to more efficient clinical research and is essential in achieving translation of research (Van der Scheer et al., 2017). Data availability from wearable devices during free living periods was poor. Therefore, improved adherence to wear time criteria will be required to assess device derived outcomes in future interventions within CEW services. Research has suggested that including participants in the research design can

help prevent missing data with benefits observed for the research process and research outcomes (Slattery, Saeri and Bragge, 2020).

An additional health outcome that should be integrated in future trials is CRF. CRF is another modifiable outcome that is associated with a number of serious short- and long-term complications within obese adolescents (Mota et al., 2012). However, measuring CRF within a hospital-based service is challenging and a lack of resources and space make obtaining a worthwhile measure of CRF a challenge. Therefore, a future trial should consider a variety of methods of integrating CRF assessment within a service and look to utilise the knowledge of the MDT to understand the feasibility of such a metric before attempting to integrate it within a trial.

Finally, before any future RCT, research work should consider who would be best to deliver the intervention within a clinic on a day-to-day basis and how they would be integrated. Clinical exercise physiologists (CEP-UK) are a professionally recognised health care professionals specialising in the prescription and delivery of exercise to patients with complex health issues (CEP-UK, 2021). The integration of CEPs within CEW services would enable exercise and PA to be a core component within any care plan for an adolescent with obesity.

5.4 Conclusion

The current study shows promising evidence that the MOTIVATE-CEW intervention had positive effects on exercise behaviour in severely obese children compared to usual care offered within CEW services. This suggests that the addition of exercise specialists supported by mHealth technologies to

multidisciplinary CEW services may be an effective strategy to improve care. However, high exercise drop-off towards the end of the intervention suggests additional work is needed to refine the MOTIVATE-CEW intervention and improve long-term adherence to exercise and PA. Finally, high recruitment and retention rates, good generalisability of the participants recruited with the target population and high data availability for in-clinic measures suggests the study design could be feasible for use within future trials.

6. References

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