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Title: Process evaluation of a cluster randomised controlled trial of multi-component weight management programme in adults with intellectual disabilities and obesity.

Abstract

Background

Providing effective weight management to adults with intellectual disabilities is necessary to challenge the high rates of obesity. The aim of this process evaluation was to explore the feasibility of conducting a full-scale clinical trial of the TAKE 5 multi-component weight management programme.

Methods

The study was a 12-month pilot cluster-randomised controlled trial. Adults with intellectual disabilities and obesity were randomised to either TAKE 5, which included an energy deficit diet (EDD) or Waist Winners Too (WWT00), based on health education principles. A mixed-methods process evaluation was conducted focussing on the reach, recruitment, fidelity, implementation, dose (delivered/ received), and context.

Results

The study successfully recruited adults with intellectual disabilities. Both weight management programmes were delivered with high fidelity and implemented as intended. Only one weight management programme, TAKE 5, demonstrated potential efficacy in reducing body weight and body composition. The effectiveness was largely attributed to the EDD and social support from carers.

Conclusions

The extensive process evaluation illustrated that a full-scale trial of a multi-component programme including an EDD is feasible and an acceptable approach to weight management for adults with intellectual disabilities and obesity.

Key words: Obesity: Weight management: Process evaluation: Intellectual disabilities: TAKE 5

Introduction

The high prevalence of obesity in adults with intellectual disabilities is a serious challenge affecting the health of this population group (Hoey *et al.*, 2017; Hsieh *et al.*, 2014; Melville *et al.*, 2007). There is a growing body of research focussed on evaluating “complex interventions” for the management of obesity in adults with intellectual disabilities (Harris *et al.*, 2018). Weight management programmes developed thus far have predominantly shown to have small effect sizes and have not supported a clinically meaningful weight loss of 5-10% of initial body weight (Harris *et al.*, 2018). Process evaluations are recognised as a key methodology to understand why an intervention had the observed effect (Grant *et al.*, 2013; Linnan & Steckler, 2002; Moore *et al.*, 2015). However, there have been no published studies conducting a comprehensive process evaluation of weight management programmes in adults with intellectual disabilities.

Process evaluations can include an extensive evaluation of a range of measures including the delivery and implementation of a programme, the influence contextual factors could have on intervention outcomes, and the contribution of components to the intervention effectiveness. Recent guidelines published by the Medical Research Council (MRC) for the development and evaluation of complex health-related interventions has guided the conduct and reporting of process evaluations (Moore *et al.*, 2015). The framework by Linnan & Steckler, (2002) is recommended as a comprehensive and uniform approach to undertake process evaluations. This involves key components including understanding the recruitment, delivery, and implementation of an intervention and, therefore, provides a detailed foundation for understanding the process of involving adults with intellectual disabilities in weight management research.

This paper describes the findings of a mixed-methods process evaluation of weight management in adults with intellectual disabilities. The study is part of a programme of research (Melville *et al.*, 2011; Spanos *et al.*, 2013; Spanos *et al.*, 2014; Spanos *et al.*, 2016) and involved a pilot cluster-randomised controlled trial examining the feasibility and potential efficacy of a multi-component weight management programme, TAKE 5 (Harris *et al.*, 2015; Harris *et al.*, 2017). TAKE 5 was adapted specifically for adults with intellectual disabilities

and developed to reflect UK weight management guidelines including an energy deficit diet (EDD; 600 kcal deficit/ day), support to increase physical activity, and behaviour change techniques (e.g. self-monitoring, and goal setting). This study aimed to investigate the context, recruitment and reach, dose delivered/ received, fidelity, implementation, and the components contributing to the effectiveness of the weight management programme.

Methods

Study design

This pilot randomised trial was conducted in Scotland, UK. Participants were randomised to TAKE 5 or a comparator weight management programme, Waist Winners Too (WWT00) for a 12-month period; a six-month weight loss period (9-12 sessions) followed by a six-month weight maintenance period (six sessions). Participants and carers were offered additional sessions if necessary to maximise their engagement and understanding of complex weight management information. Both programmes were delivered on a one-to-one basis (with support from carers where applicable) by a dietitian and a health professional. Full details of the study design, procedures, and weight management programmes have been reported in detail (Harris *et al.*, 2015; Harris *et al.*, 2017). The primary and secondary outcomes are summarised in Table 1. The study protocol received ethical approval from the Scotland A Research Ethics committee (reference number: 13/SS/0229 and the trial was registered prior to data collection (<http://www.isrctn.com/ISRCTN52903778>)).

INSERT Table 1. Approximately Here

Informed consent

To facilitate understanding for adults with intellectual disabilities easy read information sheets and consent forms were developed (National Equalities Partnership, 2005; Department of Health, 2010). A trained researcher (initials) obtained written informed consent from participants who had capacity. In circumstances where a participant did not have capacity, written informed consent was provided by the nearest relative or welfare guardian.

Randomisation

Participants were randomised using cluster-randomisation to minimise potential risk of contamination between programmes, clustering of outcomes, and to minimise imbalance between study groups. Participants who were supported by the same group of carers and/or lived in shared tenancies were randomised in a cluster. Participants were stratified by presence

of Down's syndrome, level of intellectual disabilities, and number of participants within a cluster.

Study population

Adults diagnosed with intellectual disabilities and obesity (Body Mass Index; BMI ≥ 30 kg/m²) who were ambulatory (defined as the ability to walk, with or without a walking aid, for 10 minutes at a time), not currently on a prescribed or restricted diet (e.g. for phenylketonuria or diabetes), and had not intentionally lost weight (>3 kg) in the previous three months were included. Participants taking prescribed medication for weight loss, and individuals who were pregnant or became pregnant during the study were excluded. Individual genetic syndromes (Prader–Willi syndrome, Cohen syndrome or Bardet–Biedl syndrome) were excluded, as they require more intensive support for weight management including prescription of a very low-calorie diet, restricted access to food, and in some cases pharmacological intervention (Goldstone *et al.*, 2008).

Multi-component weight management programmes

Both weight management programmes are described in detail in the protocol paper and quasi-experimental feasibility trials (Harris *et al.*, 2015; Jones *et al.*, 2015a; Melville *et al.*, 2011; Spanos *et al.*, 2016). Both programmes were specifically designed for adults with intellectual disabilities and obesity. To tailor the programmes to the individual participants' needs, at the start of each programme, participants were asked to provide their motivation for losing weight (Jones *et al.*, 2015b).

TAKE 5

TAKE 5 adheres to international clinical recommendations on the management of obesity (NICE, 2014; SIGN, 2010; Yumuk *et al.*, 2015) and was founded on the Glasgow and Clyde Weight Management Service (GCWMS) in the UK (Logue *et al.*, 2014). A logic model describing the theory of the programme is illustrated in Figure 1. The key elements of TAKE 5 include an individualised daily EDD, support to increase physical activity, the incorporation of behaviour change techniques, and social support from carers. Each intervention session followed a set structure (Figure 2).

INSERT Figure 1. Approximately Here

Waist Winners Too (comparator programme)

WWT00 was modelled based on the mainstream Waist Winners programme developed in Glasgow, UK. It is based on a health education approach, relaying information in healthy and unhealthy food groups, advocating the benefits of regular physical activity and incorporating behaviour change techniques (goal setting and self-monitoring; Jones *et al.*, 2015a). For the purpose of this study, the format was adapted from the original community group programme with eight weekly sessions to an individualised programme, delivered on a one-to-one basis. Participants in WWT00 were also supported by carers and received the same number of sessions as participants in the TAKE 5. The primary distinction between the two programmes is that TAKE 5 offers quantitative dietary intake in the form of an EDD in comparison to the non-quantitative advice provided in the WWT00 programme.

INSERT Figure 2. Approximately Here

Process evaluation

The framework by Linnan & Steckler, (2002) guided the process evaluation. The key components and the data collection methods are illustrated in Table 2. Both qualitative and quantitative methods were used in combination to provide a detailed insight into the above processes (Moore *et al.*, 2015).

INSERT Table 2. Approximately Here

Semi-structured interviews (Appendix I) were conducted by an independent researcher (initials). The interviews were conducted after the 12-month data collection and explored the dietitian's and health professional's views relating to the fidelity, implementation, dose received, and context of conducting the weight management programmes. The interviews were audio-recorded using Olympus DSS player 2300. The interviews were transcribed verbatim (initials) and analysed for information related to the above processes.

Results

Reach

Of the 82 participants who returned their participant invitation, 65 were willing to participate (response rate 76%). Of those not willing/able to participate, nine declined without providing a reason and eight reported other reasons such as commitment to the project and illness. Seven adults with intellectual disabilities were not assessed for their eligibility to participate due to individuals expressing their interest in participating after the recruitment period had ended (n

= 4), and participants identified as a cluster (living in the same residential housing unit) after a participant had been randomised ($n = 3$). Including these participants would have negatively affected the randomisation procedures and meant that their participation would have been exempt from inclusion in any statistical analysis. Fifty participants in total of the 69 individuals screened were eligible to participate and were enrolled in the study.

Participant demographic characteristics are presented in Table 3. All participants had obesity, with higher rates of morbid obesity in comparison to previous studies (Hoey *et al.*, 2017; Hsieh *et al.*, 2014). Participants had a broad demographic spread in relation to age, although more females participated than males. This is the first study to provide weight management to adults with all levels of intellectual disabilities (mild to profound). The participant health characteristics and deprivation levels in this study are similar to a large population-based sample of adults with intellectual disabilities from the same geographical location (Cooper *et al.*, 2007; Cooper *et al.*, 2011).

INSERT Table 3. Approximately Here

Recruitment

Participants were recruited from the following organisations: specialist intellectual disabilities services, provider organisations (including referrals from the GCWMS), and local day centres. Successful recruitment (rate approximately six participants per month) was achieved by following a pre-defined recruitment strategy developed by Foster *et al.* (2011) and shown to be successful in recruiting adults with intellectual disabilities to a walking programme (Mitchell *et al.*, 2013; Melville *et al.*, 2015; Matthews *et al.*, 2016). The framework was adapted to overcome the challenges of recruiting adults with intellectual disabilities such as ethical processes including procedures with informed consent and the inability to directly approach potential participants (Cleaver *et al.*, 2010; Lennox *et al.*, 2005). This consisted of four stages (Figure 3).

INSERT Figure 3. Approximately Here

Key facilitators to recruitment were identified at each stage. Establishing links with multiple-recruitment sites, specialist intellectual disabilities services, provider organisations, and local day centres, allowed a widespread dissemination of the study (stage one). Through email and telephone contact, the researcher established a rapport and relationship with key workers (Casey & Griffiths, 2017) known to adults with intellectual disabilities and arranged to deliver presentations to communicate study information (e.g. at health team meetings and day centres).

This personal approach towards recruitment also extended into stage two. Meeting potential participants (and where applicable carers/ welfare guardians) in person allowed the researcher to build up a rapport and eliminate the potential barriers with taking part in a research study (Foster *et al.*, 2011; Nicholson *et al.*, 2013). The researcher met with the participants in their home or a convenient location to them (e.g. day centre). It was important that adults with intellectual disabilities were given the opportunity to make an informed decision on whether or not to participate. The complex information was conveyed through easy read information sheets and meeting with the researcher to answer any questions. Extra time was also provided and if necessary additional appointments were scheduled (stage three). Once informed consent was obtained, the researcher met with participants prior to being enrolled in the study to assess their eligibility. This provided an opportunity for additional reassurance about the study procedures and established continuity with regular meetings from the study team (stage four).

Main efficacy outcomes

Full details of the main study outcomes have been published (Harris *et al.*, 2017) and are summarised in Table 3. In brief, participants in TAKE 5 achieved significant reductions in weight loss and body composition outcomes (BMI, waist circumference, and percentage body fat) at six and 12 months. Moreover, 50% of adults with intellectual disabilities achieved a clinically important weight loss of 5-10% of initial body weight. These findings were not replicated for participants in the WWToo programme. Both programmes were ineffective at improving health-related quality of life, increasing physical activity, or reducing sedentary behaviour.

INSERT Table 4. Approximately Here

Effective programme components

The effectiveness of the TAKE 5 intervention is largely attributed to the EDD component and social support from carers. Providing quantitative dietary advice through an individually specified number of portions allowed participants, carers, and the dietitian and health professional to monitor and adjust dietary intake to create an energy deficit and achieve weight loss goals. Although the dietitian and health professional observed small changes in physical activity, including an increase in walking and dancing, they were not of significant magnitude to effect study outcomes. Carer involvement was a key facilitator in the success of the interventions. In particular, adults with severe and profound intellectual disabilities were found to have less autonomy over food preparation and were more dependent on carers support to

make healthy choices. In such cases, carers took full responsibility for implementing the intervention for example planning, shopping for and preparing healthy meals.

Fidelity

Challenges with delivering the weight management programmes per-protocol were identified early in the study by the dietitian, who was at the time the only facilitator employed to deliver the weight loss programmes. Due to the high recruitment rate and the time required to deliver both programmes, the dietitian had to increase their working hours above the contracted time (0.5 Full-Time Equivalent; FTE) and shorten the duration of scheduled appointments to facilitate additional appointments. This issue was resolved by spreading out the enrolment of participants, and recruiting another health professional (0.5 FTE), to deliver the programmes. Although the duration of the programme sessions was reduced, the fidelity of the programme content was not compromised as each session protocol did not need the allocated time of 60 minutes and in practice only required between 30-45 minutes to successfully deliver each session.

To assess protocol fidelity the dietitian and health professional kept a record of each individual session content completed by the participants. Fidelity was reported to be high with only deviations from the manual due to extraneous content (e.g. alcohol intake when a participant was abstinent from alcohol) or the interchange of session content to facilitate the participant's needs (e.g., moving a topic such as 'binge eating' to an earlier session as the issue was raised and became relevant).

Context

Increasing physical activity was included as a component in both weight management programmes. However, barriers were identified to achieving the physical activity goals centred around walking. It was reported that in some circumstances the area in which adults with intellectual disabilities lived was perceived as unsafe to go out for a walk.

Dose delivered

The dose of both weight management programmes delivered to participants was in accordance with the allocated dose in the protocol (nine weight loss sessions, six weight maintenance sessions). The variability in the number of weight loss sessions was to allow appointments to be organised flexibly to maximise the consistent involvement, however, carers or participants did not request any additional appointments. Retention to the weight management programmes was high (90%). Across the 12-month trial (15 sessions), attendance was 88% in both weight

management programmes. Attendance at each individual session was high $\geq 75\%$ in both programmes (range: 75% - 100%).

Dose received

Both weight management programmes were reported from the dietitian's and health professional's perspective to be well received by participants and carers. In particular, the TAKE 5 programme was highly credited by carers due to the structured format of the sessions and the reputability of TAKE 5 which is based on a clinical weight management service.

Adapting complex behaviour change programmes for adults with intellectual disabilities is challenging. Visual resources, for example fat and sugar models, were used to facilitate and convey complex health information to adults with intellectual disabilities in both programmes. Food diaries were also found to be an effective resource for monitoring of dietary intake.

Implementation

Social support from carers and the dietitian and health professional were highlighted as key facilitators in implementation of the weight management programmes. Consistent engagement from carers throughout the weight management programmes was reported to be associated with greater weight loss. Professional support from the dietitian and health professional was also seen as motivation for participants to achieve their goals and lose weight at each session.

A lack of engagement from carers and continuity in carer support was also reported as a barrier to behaviour change. Carers did not always recognise the importance of healthy lifestyle habits, and in some cases more able adults with mild/ moderate intellectual disabilities, although they had autonomy to make decisions, were not supported by carers to make an informed health choice. Moreover, due to rotations in shift patterns and a high turnover of carers, it was sometimes challenging to convey the participants' goals and session information to multiple carers.

A key component of the mainstream weight management programmes is the incorporation of behaviour change techniques including goal setting and self-monitoring of diet and physical activity, for example, self-monitoring of step counts using pedometers. It was uncertain whether adults with intellectual disabilities had the cognitive abilities and skills to understand, reflect on, and implement these techniques. Furthermore, adults with more severe to profound intellectual disabilities required the involvement of carers to facilitate changes in behaviour.

Discussion

This is the first process evaluation of a clinical trial of multi-component weight management programmes in adults with intellectual disabilities. This study was able to successfully recruit adults with intellectual disabilities and both weight management programmes were implemented as intended. Only one weight management programme, TAKE 5, demonstrated potential efficacy in reducing body weight and body composition. The effectiveness was largely attributed to the EDD and social support from carers.

Barriers to recruiting adults with intellectual disabilities to lifestyle behaviour change research were overcome by employing a personal approach to recruitment. This is in agreement with previous research and it is recommended that researchers take time to build a relationship and rapport with participants through developing appropriate resources, identifying key support networks, and meeting potential participants in person (Cleaver et al., 2010; Corby & Sweeny, 2007; Lennox et al., 2005). The study successfully recruited 50 participants, although, this fell short of the projected sample size of 66 participants (Harris *et al.*, 2015). The decision to stop recruitment was influenced by limited time resources to meet the demands of recruitment, schedule participant appointments, and complete the study in the time restrictions imposed by the researchers' PhD. However, the decision was felt justified as the main aim of the study, to provide insight into the feasibility of recruitment and retention rates, which would inform a full-scale trial, had been achieved. Consequently, to successfully implement a future full-scale clinical trial and keep up with high recruitment rates sufficient resources are required.

The role of social support from engaged carers was considered a key facilitator in supporting behaviour change, particularly for adults with increasing severity of intellectual disabilities. This is consistent with previous research (Spanos *et al.*, 2013; Matthews et al., 2016). Inconsistent and limited support from carers was also identified as a barrier. The role of social support in implementing behaviour change in adults with intellectual disabilities is diverse and dependent on individual cognitive, communication, and support needs. However, financial cuts to the provision of social care (Reeves et al., 2014) have limited the availability of carer support, therefore even when social support is available, it is often not at a sufficient level to allow adequate support for adults with intellectual disabilities to engage in healthy lifestyle activities (Temple & Walkley, 2007; van Schijndel-speet *et al.*, 2014). Melville *et al.*, (2009) illustrated that carers may have limited knowledge of dietary and physical activity recommendations; consequently, lifestyle behaviour change might not be seen as a priority. Developing information and education specifically targeted at carers may be an effective approach to

support adults with intellectual disabilities to lose weight and improve the health of this population group.

Professional support from the dietitian and health professional was also considered a key facilitator and motivator for weight loss, which was achieved by developing a rapport with participants over the study. The weight management programmes were delivered by an experienced and appropriately qualified dietitian and health professional which ensured the programmes were delivered with high fidelity. The method used to measure fidelity in this study was selected as it was considered to be feasible (Linnan & Steckler, 2002) and the criterion method of direct observation by external researchers (Hill *et al.*, 2007) unknown to the participants was thought to negatively affect the relationship between the participant and dietitian/ health professional. However, to ensure fidelity of the weight management programmes on a larger scale, utilising audio-recording of a random sample of sessions would provide a more valid measure of fidelity.

The one-to-one delivery and domiciliary setting of the weight management programmes contributed to the high level of adherence, and high retention rates. The effectiveness of the method of delivery of weight management programmes has not been explored in adults with intellectual disabilities. Previous studies have predominantly delivered weight management programmes in a group format and in community settings (Harris *et al.*, 2018), and demonstrated a limited effect. Moreover, studies have only included adults with mild/ moderate intellectual disabilities and, therefore, this mode of delivery may not be suitable for adults with more complex support needs. This present study is the first to include adults with severe/ profound intellectual disabilities. An economic evaluation was not conducted as part of this study, although, delivering the weight management programmes on this basis may be an expensive resource. Further research is required to evaluate the clinical and cost-effectiveness of delivering weight management programmes (one-to-one versus group format, and home-based versus community/ out-patients setting) and tailoring the delivery of the programme specific to the individual needs of adults with intellectual disabilities.

This study is the first to investigate the effectiveness of two distinct dietary prescription approaches (EDD versus health education). Although this study was not sufficiently powered to determine the effectiveness of the weight management programmes, it demonstrated potential efficacy that quantitative dietary advice (EDD) supported clinically meaningful weight loss in comparison to a health education approach. This is consistent with previous

multi-component weight management programmes utilising an EDD, which achieved clinically important weight loss (Ptomey *et al.*, 2017); whereas weight management programmes based on a health education approach have shown to be ineffective (Harris *et al.*, 2018).

This study failed to demonstrate an effect on increasing physical activity which is consistent with previous lifestyle intervention research (Melville *et al.*, 2015; Ptomey *et al.*, 2017). The ineffectiveness of interventions could in part be explained by the additional, personal and social, barriers to engaging in physical activity experienced by this population group including impairment-specific factors (e.g. mobility problems) and increased social support from carers (Bodde & Seo, 2009; Cartwright *et al.*, 2017; Taliaferro & Hammond, 2016). There is also recent evidence in which environmental factors further perpetuate physical inactivity in adults with intellectual disabilities, including accessing transport and opportunities for physical activity (Bossink *et al.*, 2017; Taliaferro & Hammond, 2016). Although walking is considered a feasible form of physical activity, environmental barriers hindered walking in this current study, were reported to be due to concerns that the environment was unsafe. Perception of safety has shown to be a barrier to physical activity in the general population (Poortinga, 2006), however, perceptions of the neighbourhood environment in adults with intellectual disabilities have not been extensively explored. To develop effective lifestyle programmes in this population group further research is necessary to move beyond an individualised perspective and understand the relationship between wider environmental factors and physical activity (Sallis *et al.*, 2012).

Both weight management programmes were founded on a theoretical framework of behaviour change based on evidence in the general population (Michie *et al.*, 2009). However, questions on the applicability of behaviour change techniques to adults with intellectual disabilities were raised due to the limited cognitive ability and the level of abstraction required to understand some of these techniques. Previous researchers focussing on increasing physical activity (Melville *et al.*, 2015; Kuikjen *et al.*, 2016; Williems *et al.*, 2017) have also questioned this. Only one study has investigated the feasibility of behaviour change techniques (Ptomey *et al.*, 2017). Ptomey *et al.*, (2017) examined the feasibility of self-monitoring step counts and identified that adults with mild/ moderate intellectual disabilities could successfully wear pedometers over an 18-month intervention period, yet, their ability to accurately record data was limited. Further research needs to investigate the feasibility of other behaviour change

techniques in order to develop evidence- and theory-informed interventions specific to adults with intellectual disabilities.

Strengths and limitations

The key strengths of this study include the evaluation of a large number of processes measured using both qualitative and quantitative research methods. This enriched the understanding of the key mechanisms and the triangulation of data from different sources (case reporting forms, clinical notes, and semi-structured interviews) increased the results validity. Moreover, the evaluation was conducted by independent researchers, minimising the risk of response and reporting bias.

As the process evaluation was conducted retrospectively and after the randomised controlled trial had commenced, there were limitations in measuring some of the process outcomes. For example, there was a lack of a formal measure of compliance with the EDD and physical activity. Self-report/ carer report of these behaviours was used as part of the weight management programmes, although, not recorded as an outcome. Furthermore, although the qualitative interviews with the dietitian and health professional enriched the perceptions of the acceptability and implementation of the weight management programme, further insight could have been achieved by interviewing participants and carers.

Conclusion

This study contributes to the evidence-base on understanding the processes involved in including adults with intellectual disabilities in a weight management trial. Important information into how weight management programmes were delivered, received and the process involved in understanding the effectiveness of the weight management programmes were explored. A multi-component weight management programme that included an EDD and tailored to meet the needs of adults with intellectual disabilities is feasible and further research is required to investigate the efficacy of the TAKE 5 programme in a full-scale clinical trial.

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Tables**Table 1.** Outcome measures

Outcome	Measure
<i>Anthropometric measures</i>	
Weight	Calibrated digital scale
BMI (weight/height)	Calibrated digital scale, stadiometer
Waist circumference	Tape measured as the midpoint between the iliac crest and the lowest rib
Percentage body fat	Calculated using the triceps skinfold thickness (measured using callipers), waist circumference and age of the participant. Separate regression equations used for male and female participants.
<i>Physical activity and sedentary behaviour</i>	IPAQ-S, Actigraph GT3X+ accelerometer worn for seven days
Health-related quality of life	EQ-5D

BMI: Body mass index; EQ-5D: European Quality of Life-5dimension youth version; IPAQ-S: International Physical Activity Questionnaire-Short.

Table 2. Process evaluation elements

Process evaluation component	Definition	Assessment
Reach	The proportion of the intended target audience that participated in the weight management programmes.	This was assessed by the number of participants who expressed interest in the study. Data were obtained from the record of postal participant invitations returned expressing interest (or disinterest) in participating and finding further details about the study.
Recruitment	The procedures and strategies used to approach and identify participants to enrol in the study.	Recruitment rates were calculated as the number of participants enrolled in the study per month. The success of the recruitment strategy is also provided from a narrative perspective by the researcher (insert initials) from information provided through liaising with the organisations.
Fidelity	The extent to which the weight management programmes were implemented as intended. Individual sessions in both	The dietitian and health professional were instructed at the end of each session to complete a checklist of the session components delivered. Deviations from

	programmes followed a set protocol.	the protocol and rationale for these were also noted in the dietitian's and health professional's clinical notes. Semi-structured interviews
Dose delivered	The number of intended sessions and the number of each weight management programme component (e.g. diet and physical activity) delivered to the participants.	Data were obtained from the attendance records recorded by the dietitian and health professional and their session checklists.
Dose received	The extent to which participants engage with the content of the weight management programmes they received.	This includes materials or resources and the extent to which they implement these as they are intended.
Implementation	A composite measure of the extent to which the weight management programmes were delivered as intended (fidelity) and received by participants (dose received).	Semi-structured interviews
Context	The environment that may influence study outcomes and implementation of the weight management programmes such as the setting in which the programmes were delivered.	To measure this element, information on participants' geographical location and level of social deprivation was obtained from the case reporting forms. Semi-structured interviews

Semi-structured interviews explored the dietitian's and health professional's views relating to the fidelity, implementation, dose received, and context of conducting the weight management programmes.

Table 3: Baseline characteristics of participants in TAKE 5 and WWToo weight management programmes

Characteristic	TAKE 5 n = 26	WWTOO n = 24
	n (%)	
<i>Gender</i>		
Male	8 (30.8)	10 (41.7)
Female	18 (69.2)	14 (58.3)
<i>Ethnicity</i>		
Caucasian	26 (100.0)	22 (91.7)
Other Asian Background	0 (0.0)	2 (8.3)
<i>Marital Status</i>		
Married-Live with a partner	1 (3.8)	0 (0.0)
Separated-Divorced	1 (3.8)	0 (0.0)
Single	24 (92.3)	24 (100.0)
<i>SIMD (% living in quintiles)</i>		
1 (most deprived)	12 (46.2)	9 (37.5)

2	6 (23.1)	5 (20.8)
3	2 (7.7)	4 (16.7)
4	5 (19.2)	5 (20.8)
5 (least deprived)	1 (3.8)	1 (4.2)
<i>Social Support</i>		
Lives Independently	10 (28.4)	8 (33.3)
Family Carer	8 (30.8)	8 (33.3)
Paid Carer	8 (30.8)	8 (33.3)
<i>Level of intellectual disabilities</i>		
Mild	8 (30.8)	6 (25.0)
Moderate	11 (42.3)	10 (41.7)
Severe	4 (15.4)	7 (29.2)
Profound	3 (11.5)	1 (4.2)
<i>Obesity</i>		
Obesity class I (30 -34.9 kg/m ²)	8 (30.8)	6 (25.0)
Obesity class II (35-39.9 kg/m ²)	5 (19.2)	7 (29.2)

Obesity class III (≥ 40 kg/m ²)	13 (50.0)	11 (45.8)
Health		
Epilepsy, Seizures or Fits	6 (23.1)	5 (20.8)
Vision impairment	16 (61.5)	9 (37.5)
Hearing Impairment	6 (23.1%)	3 (12.5%)
Mental Health Problems	6 (23.1)	3 (12.5)
Problem Behaviour	10 (38.5)	9 (37.5)
High Blood Pressure	12 (46.2)	11 (45.8)
Type II Diabetes	1 (3.8)	3 (12.5)
	Mean (SD)	
Age (years)	40.6 (15.0)	43.6 (14.0)
Weight (kg)	102.3 (25.4)	104.1 (28.9)
BMI (kg/m ²)	40.2 (6.8)	41.2 (8.1)
Physical activity (minutes/day)*	176.8 (53.3)	191.2 (85.1)
Sedentary Behaviour (minutes/day)*	501.1 (125.9)	522.3 (165.3)

Values represent number (%) for categorical variables and, means (SD) for continuous variables. *Data is for TAKE 5 n = 25 and WWT00 n = 22. SIMD: Scottish Index of Multiple Deprivation; SD: Standard Deviation.

Table 4: Change in anthropometric, physical activity and sedentary behaviour, and health-related quality of life at six months and 12 months from baseline.

	TAKE 5			WWTOO			Difference between groups		
Outcomes	N	Mean (95% CI) *	p-value	N	Mean (95% CI) *	p-value	Mean (95% CI) *	p-value	ICC
Anthropometric outcomes									
Weight (kg)									
6 months	24	-2.93 (-4.42 to -1.44)	< 0.001	22	-1.26 (-2.82 to 0.30)	0.110	-1.67 (-3.84 to 0.50)	0.126	0.059
12 months	24	-3.55 (-5.59 to -1.52)	0.001	24	-1.66 (-3.69 to 0.38)	0.108	-1.90 (-4.80 to 1.01)	0.195	0.00 0
BMI (kg/m²)									
6 months	24	-1.19 (-1.77 to -0.62)	<0.001	22	-0.46 (-1.06 to 0.15)	0.133	-0.74 (-1.58 to 0.11)	0.085	0.000
12 months	24	-1.48 (-2.29 to -0.66)	0.001	24	-0.59 (-1.41 to 0.23)	0.154	-0.89 (-2.05 to 0.28)	0.134	0.000
Waist circumference (cm)									
6 months	22	-3.15 (-4.91 to -1.40)	0.001	20	-1.45 (-3.29 to 0.40)	0.120	-1.71 (-4.28 to 0.86)	0.186	0.176
12 months	22	-3.60 (-5.99 to -1.21)	0.004	21	-1.83 (-4.24 to 0.58)	0.132	-1.77 (-5.20 to 1.67)	0.304	0.267
Percentage body fat (%)									
6 months	22	-1.79 (-3.08 to -0.50)	0.008	18	-1.02 (-2.45 to 0.41)	0.155	-0.77 (-2.72 to 1.19)	0.430	0.187
12 months	22	-2.23 (-3.95 to -0.51)	0.013	18	-0.65 (-2.56 to 1.26)	0.493	-1.58 (-4.21 to 1.05)	0.231	0.000
Physical activity and sedentary behaviour outcomes**									

Sedentary behaviour (% time spent/day)									
6 months	20	-2.08 (-0.27 to 4.43)	0.080	15	-2.00 (-0.67 to 4.67)	0.136	-0.09 (-3.50 to 3.67)	0.962	0.450
12 months	16	-0.91 (-4.05 to 2.24)	0.556	13	1.05 (-2.33 to 4.42)	0.526	-1.95 (-6.61 to 2.70)	0.394	0.994
Light PA (% time spent/day)									
6 months	20	-1.79 (-3.69 to 0.11)	0.064	15	-1.22 (-3.40 to 0.96)	0.262	-0.57 (-3.50 to 2.35)	0.692	0.164
12 months	16	0.79 (-2.22 to 3.81)	0.591	13	-0.92 (-4.15 to 2.31)	0.561	1.71 (-2.75 to 6.17)	0.434	0.994
MVPA (% time spent/day)									
6 months	20	-0.32 (-1.17 to 0.54)	0.455	15	-0.81 (-1.77 to 0.15)	0.093	0.50 (-0.79 to 1.78)	0.434	0.895
12 months	16	0.10 (-0.94 to 1.13)	0.849	13	-0.17 (-1.28 to 0.95)	0.758	0.26 (-1.28 to 1.80)	0.726	0.818
Total PA (% time spent/day)									
6 months	20	-2.08 (-0.27 to 4.43)	0.079	15	-2.00 (-0.67 to 4.67)	0.137	-0.09 (-3.50 to 3.67)	0.962	0.449
12 months	16	0.91 (-2.24 to 4.05)	0.556	13	-1.05 (-4.42 to 2.33)	0.526	1.95 (-2.70 to 6.61)	0.394	0.994
Health related-quality of life									
EQ-5D index									
6 months	24	0.07 (-0.03 to 0.17)	0.177	22	0.04 (-0.07 to 0.14)	0.500	0.03 (-0.12 to 0.18)	0.652	0.118
12 months	24	0.00 (-0.14 to 0.14)	0.977	24	-0.04(-0.18 to 0.10)	0.569	0.04 (-0.16 to 0.24)	0.675	0.000

* Adjusted for cluster, baseline value and stratification variables (number of participants within a cluster, level of intellectual disability and presence of Down syndrome). CI: Confidence Interval; ICC: Interclass correlation coefficient; kg: kilogram; m²: meters squared; cm: centimetres; %: percentage; MVPA: moderate to vigorous physical activity; ED-5D: European Quality of Life-5 dimensions.

** Data are present for objective measures on physical activity and sedentary behaviour only due to concerns over the validity and reliability of self-report measures using the International Physical Activity Questionnaire- Short version.

Figures

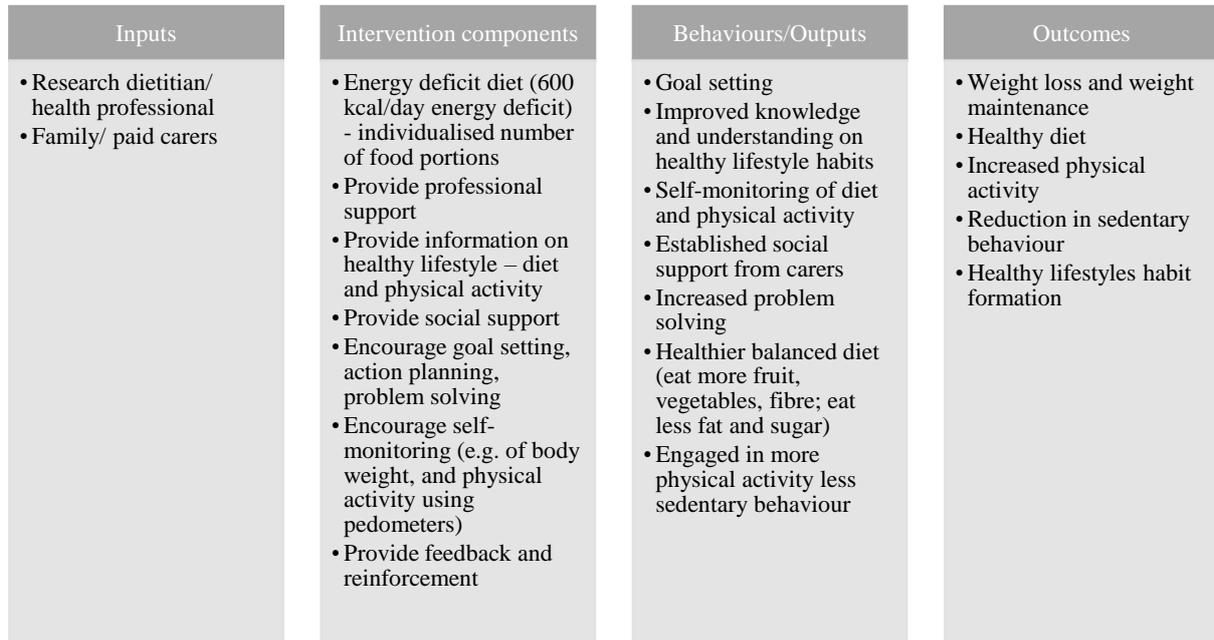


Figure 1. TAKE 5 logic model

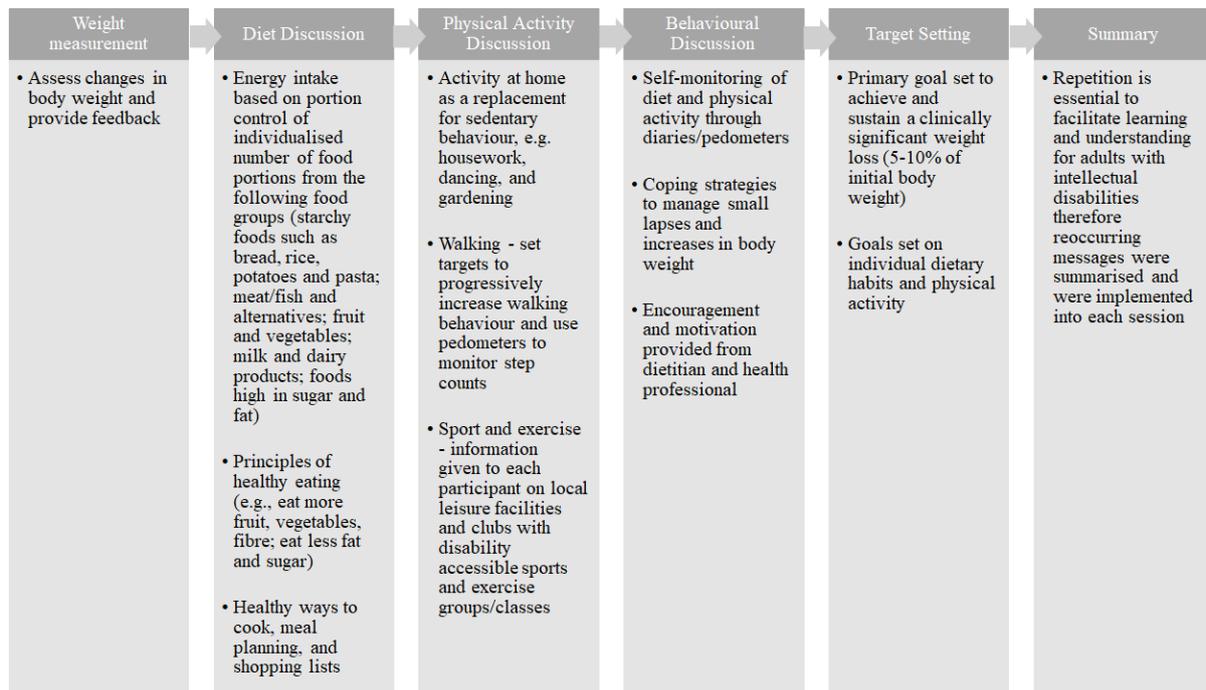


Figure 2. TAKE 5 session plan

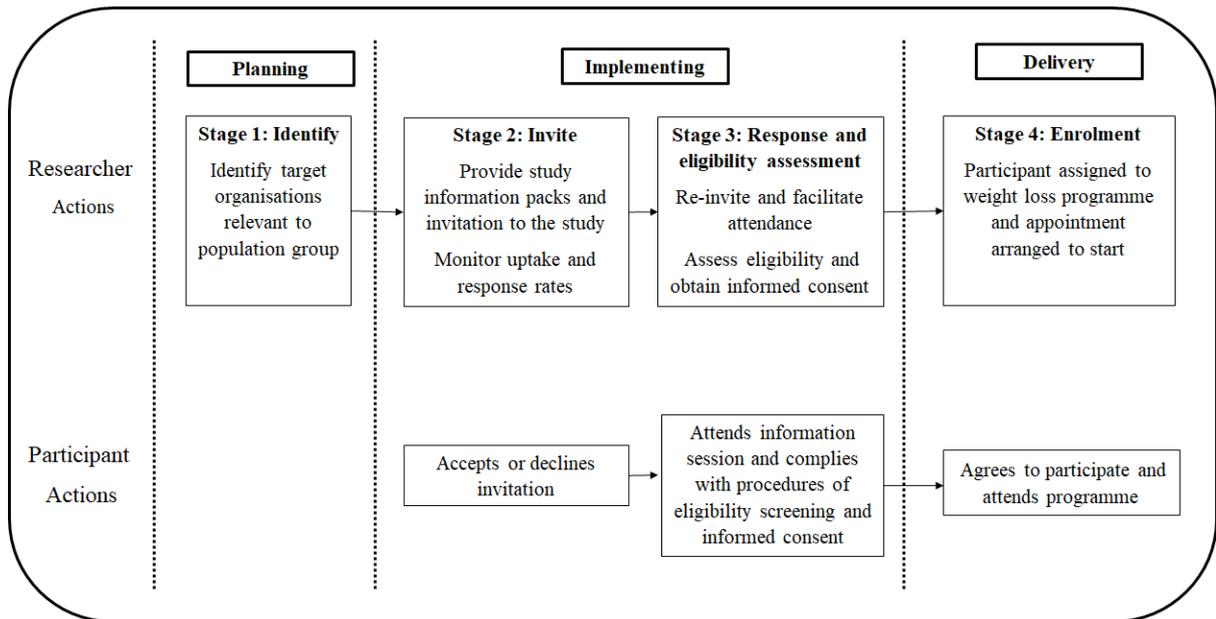


Figure 3. Framework for stages of recruitment (Adapted from Foster *et al.*, 2011)