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A manualised weight management programme for adults with mild–moderate intellectual disabilities affected by excess weight: A randomised controlled feasibility trial (Shape Up-LD)*

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Abstract

Background: The aim was to pilot an adapted manualised weight management programme for persons with mild–moderate intellectual disabilities affected by overweight or obesity ('*Shape Up-LD*').

Method: Adults with intellectual disabilities were enrolled in a 6-month trial (3-month active intervention and 3-month follow-up) and were individually randomised to *Shape Up-LD* or a usual care control. Feasibility outcomes included recruitment, retention, initial effectiveness and cost.

Results: Fifty people were enrolled. Follow-up rates were 78% at 3 months and 74% at 6 months. At 3 and 6 months, controlling for baseline weight, no difference was observed between groups (3 months: β: −0.34, 95% confidence interval [CI]: −2.38, 1.69, 6 months: β: −0.55, 95%CI −4.34, 3.24).

Conclusion: It may be possible to carry out a trial of *Shape Up-LD*, although barriers to recruitment, carer engagement and questionnaire completion need to be addressed, alongside refinements to the intervention.

KEYWORDS
feasibility, group, intellectual disability, pilot, RCT, weight management

1 | INTRODUCTION

There have been substantial increases in obesity rates over the past three decades, and in the UK, there are now more than a quarter of adults with obesity (Connolly, 2017). Individuals with obesity are at greater risk of poor health (Pi-Sunyer, 1993; Upadhyay et al., 2018), and there are large costs related to excess weight (Goettler et al., 2017; Tremmel et al., 2017). Individuals with obesity report decreased quality of life and face weight-based stigma and discrimination (Kolotkin & Andersen, 2017; Spahlholz et al., 2016).

There is an increased prevalence of obesity among people with intellectual disabilities both in the UK and the USA (Emerson et al., 2016; Hsieh et al., 2014). Lower levels of physical activity and

* We recognise that the term 'intellectual disability' is now preferred; at the time of the study conception, learning disability was used hence the intervention was named 'Shape Up-LD'.

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poorer diets are thought to contribute to increased risk of excess weight in this group (Hsieh et al., 2014; McGuire et al., 2007). However, there are no existing weight management services specifically for people with intellectual disabilities, and the National Institute for Health and Care Excellence (NICE) has recognised there are difficulties in accessing the information and support available to the general population (NICE, 2014a).

There is a need to tailor weight management interventions for adults with intellectual disabilities to take into account difficulties with communication and lower levels of health literacy (Cooper et al., 2004). Many people with intellectual disabilities need support to help them with their daily lives and often make decisions collaboratively with support staff or family carers. It is crucial to involve these carers in any intervention intended to help adults with intellectual disabilities to make healthier choices (Hamilton et al., 2007; Spanos, Hankey, et al., 2013). In light of this, Public Health England have developed a Health Charter to encourage organisations providing social care to sign up to working to improve the health and wellbeing of those with intellectual disabilities (PHE, 2017).

There have been a small number of studies of weight management programmes for adults with intellectual disabilities (King et al., 2014; Spanos, Melville, & Hankey, 2013). A systematic review of weight management interventions in adults with intellectual disabilities, covering studies published between 1982 and 2011 (Spanos, Melville, & Hankey, 2013), identified 22 studies, 12 of which were non-randomised or uncontrolled. Several reported that carers were involved but the detail was poorly described. Most interventions were group rather than individual although there was insufficient evidence that one approach had superior outcomes. Surprisingly, only some studies discussed the importance of tailoring the intervention to the abilities of participants.

A more recent review explored the content of lifestyle interventions for individuals with intellectual disabilities more systematically, coding behaviour change techniques according to the Coventry, Aberdeen and London – Refined taxonomy (Michie et al., 2011; Willems et al., 2017). They found that most interventions included behaviour change techniques, but the choice of technique was rarely theory-driven and there was typically no underpinning theoretical framework. This is contrary to guidelines for intervention design and evaluation, which recommend a systematic approach to designing interventions that considers theory and evidence (MRC, 2006; O'Cathain et al., 2019). They also suggested that techniques may need simplifying to meet the specific needs of this group.

A cluster randomised pilot trial indicated a trend for greater weight loss from a multicomponent programme comprising behaviour change techniques and an energy deficit based on estimated requirements, operationalised by providing guidelines on number of portions of each food group, compared to a standard health education programme (Harris et al., 2017). Of note, sessions were carried out in the home setting and carers were invited to attend. Another randomised controlled trial (RCT) compared two dietary approaches (conventional diet versus enhanced stoplight diet, which comprised traffic light classification of foods based on energy content plus portion recommendations) within a multicomponent programme based on Social Cognitive Theory (Ptomey et al., 2018). Both produced clinically meaningful weight losses (defined as between 3% and 5% of initial body weight (NICE, 2014b)), although this was significantly greater with the stoplight diet. These studies suggest it is possible to provide weight management programmes, tailored to the needs of adults with intellectual disabilities, which can produce significant weight losses and are at least as effective as those currently available to the general population.

Recent work in the UK has focused on adapting a mainstream weight management programme (Slimming World) to make it accessible to those with intellectual disabilities alongside participants from the general population (Croot et al., 2018). The adaptations involved simplifying the study content and producing easy read materials for participants. A non-randomised pilot study found that of the nine participants enrolled to attend Slimming World for 8 weeks, six remained in the study, and all lost weight (between 1.4 and 6.6 kg). This work shows promise; however, the researchers found that a number of potential participants were not comfortable participating in groups with members from the general population, and it is therefore important to examine the impact of groups for only participants with intellectual disabilities.

We adapted 'Shape-Up: A lifestyle programme to manage your weight' for people with intellectual disabilities (*Shape Up-LD*). The original Shape Up (Chadwick & Miller, 2006; Wardle et al., 2001, 2006) is a theory-based manualised group-based weight management service for the general population, that is in line with NICE guidance on lifestyle weight management services (NICE, 2014b) and individual approaches in behaviour change (NICE, 2007). The Shape-Up programme is based upon Social Cognitive Theory and Control Theory and uses principles from cognitive behavioural therapy. It has been delivered under the Tier 2 NHS weight management services (Department of Health, 2013), including two London boroughs as part of the local joint strategic needs assessment. The aim of the current study was to determine the feasibility of designing a large-scale RCT that would answer the following question: Is *Shape Up-LD* more effective than usual care in helping service users with mild–moderate intellectual disabilities, affected by overweight or obesity, reduce body weight?

2 | METHODS

2.1 | Design

The trial was a multi-centre (three sites), parallel, two-arm, individually randomised (1:1 allocation ratio), controlled feasibility trial in adults with mild–moderate intellectual disabilities with overweight or obesity in London (Beeken et al., 2013). We took an intention to treat approach so that once participants were randomised to a treatment arm, they are analysed in this arm whether they chose to participate in the intervention or not.

2.1.1 | Trial Registration

The trial was registered with the International Standard Randomised Controlled Trial Registry (ISRCTN39605930).

2.2 | Participants

Adults with mild–moderate intellectual disabilities with overweight or obesity (body mass index [BMI] ≥25 kg/m^2) were recruited from three intellectual disability services in inner London between October 2012 and January 2014. Participants could self-refer or be referred by staff members, family or carers.

We restricted the study to adults (age ≥18 years) living in the community. Level of intellectual disability was assessed by a scoring system from the 'Ability & Development' scale (Melville et al., 2008), and participants were eligible if their score reflected an intellectual disability in the mild to moderate range. If potential participants were receiving regular care, then the presence of a carer (paid or informal), who was willing to participate in the intervention was required. We excluded anyone who had (i) acute mental illness, requiring hospitalisation, (ii) a history of substance misuse or (iii) a confirmed diagnosis of Prader–Willi syndrome.

Potentially eligible service users were provided with an information sheet and asked by their health and social care professionals if they were interested in being contacted by the researchers. Where required, carers were also provided with an information sheet. Interested service users and their carers (if required) then attended an appointment at which eligibility was confirmed. We obtained informed consent from all eligible service users and carers to participate in the study.

2.3 | Randomisation

Telephone-based randomisation was used to randomise at the level of the patient, ensuring allocation concealment. Randomisation took place after the participant had provided informed consent and baseline data, at which point the researcher carrying out the assessment telephoned the trial manager to confirm group allocation. RO (statistician) generated the randomisation list using random permuted blocks of size 2–4 to ensure equal numbers in the intervention and control arms. When enough participants were randomised to the intervention, a group started the *Shape Up-LD* sessions. Those randomised to usual care initially had the pro forma discussion with the researcher immediately after randomisation (within the same appointment). However, due to participants finding this difficult, this was amended, and participants were asked to return for a second appointment to have this discussion.

2.4 | Interventions

2.4.1 | Shape Up-LD

Shape Up-LD is a manualised healthy lifestyle programme that helps adults with intellectual disabilities to learn new behaviours to manage their weight. Participants were assigned to groups of 4–6. These groups met once a week for 3 months. Sessions lasted for 120 min and were delivered by two members of staff (either from the intellectual disability services or University College London), at least one of whom had previous experience working with people with intellectual disabilities. Sessions, included four introductory sessions to establish a rapport, provide a foundation for the course and focused on basic healthy eating messages. The following eight sessions taught strategies for improving healthy eating and physical activity. Behaviour change techniques used included self-monitoring with the use of food and physical activity diaries, relapse prevention and goal setting. The key messages from each session were emphasised through illustrations and games. The use of simple spoken and written communication based on the recommendations of the Royal College of Nursing[1] (Royal College of Nursing, 2020) was encouraged throughout. Participants discussed their food diaries during the sessions and facilitators provided encouragement and suggestions where appropriate, but they were not formally reviewed and it was up to the participants what information they shared. The sessions were run in rooms within the intellectual disability services. Participants arranged their own transport to attend the sessions.

Training for staff delivering the intervention

Weight concern, who developed *Shape Up-LD*, trained the staff delivering the programme. The training consisted of 1-day *Shape Up-LD* specific training and a half-day observing the programme being delivered.

Carer involvement

Carers were encouraged to attend *Shape Up-LD* sessions with participants and were invited to attend an information/training session to introduce *Shape Up-LD* and explore how behaviour change could be supported. This was initially planned to be half-day but on discussion with carers and staff at the intellectual disability services it became clear that it was unlikely carers would be able to find the time for this. We, therefore, reduced the session to an hour.

2.4.2 | Usual care

Participants randomised to 'usual care' had a short (approximately 30 min) discussion with the researcher that followed a simple pro forma covering healthy eating choices and increasing physical activity. Participants were provided with a leaflet and a DVD developed by the intellectual disability services involved in the study. Although usual care varies between different services, this was intended to reflect what most participants would receive as the best practice of standard care.

2.5 | Outcome measures

2.5.1 | Demographics

Demographic data (gender, date of birth, ethnicity and marital status) were collected at baseline. We had initially planned to collect

[1]The documents referenced during the design of the intervention are no longer available. The document listed in the references of this paper is an updated version.

educational qualifications and postcode but instead collected living circumstances (family/independent/support living) and employment as these were considered to be more useful for characterising our population.

2.5.2 | Feasibility outcomes

We recorded recruitment numbers and loss to follow-up. We had planned to record the numbers of eligible participants to calculate recruitment rate, but neither BMI nor level of intellectual disability was routinely recorded. We recorded participant compliance rates (number of sessions attended) and assessed facilitator fidelity to the manual (recordings of the sessions were scored against a list of planned topics). We completed the measures listed below and researchers kept notes on their perceptions of how acceptable these measures were to participants.

The cost of delivering *Shape-Up-LD* to the service users was estimated based on the cost of running six Shape-Up groups (25 participants with 4–5 participants per group). The associated costs considered were as follows: training staff within an learning disability service to deliver the intervention (2 days training and support), the staff time required to deliver the intervention (based on a Band 5 staff member; £30 an hour in 2013 when the study was run (Personal Social Services Resource UnitCosts (Curtis, 2013)), room hire and resources (food models, photo cards, manuals and handouts).

2.5.3 | Anthropometric outcomes

Weight (kg), body fat % (assessed using a Tanita body composition analyser, which uses bioelectrical impedance) and waist circumference (cm) were measured at baseline, 3- and 6-month follow-ups.

2.5.4 | Psychological and behavioural outcomes

Participants completed the following measures:

1. Mental health was assessed using the Clinical Outcomes in Routine Evaluation for Learning Disabilities (CORE LD), which has been used extensively in clinical settings (Brooks & Davies, 2008).
2. Quality of life was measured by QoL for the person with learning disability, which has good internal consistency (Schalock & Keith, 1993). It contains 40 items and has four sub-scales: 'satisfaction', competence/productivity', 'empowerment/independence' and 'social belonging/community integration'. We also measured quality of life using the EQ-5D, a scale that had not at the time been validated in an intellectual disability population but which would be optimal for health economics analysis in a main trial for calculation of Quality Adjusted Life Years (EuroQoLGroup, 1990). At the 6-month assessment, we used the Youth version of this questionnaire (EQ-5D-Y) (EuroQol Research Foundation, 2020) following feedback from participants that this was easier to complete.
3. Self-esteem was measured using the Rosenberg Self-Esteem Scale for people with an intellectual disability (Dagnan & Sandhu, 1999).
4. Diet and activity behaviours were assessed using simple frequency items.
5. Attitudes to healthy behaviours were assessed using an adapted measure from the Change4Life Survey (Croker et al., 2012). This measure assesses the importance, ease and intentions participants have towards healthy eating behaviours, doing physical activity and limiting screen time.
6. The adapted Client Service Receipt Inventory (CSRI; Beecham & Knapp, 2001) for this study measured service use for the preceding 3 months.
7. Participants were also asked to bring shopping receipts to their appointments, which could potentially be used to assess changes in food purchasing.

2.5.5 | Acceptability of measures

The questionnaire measures were completed by researchers who asked the participants the questions. This meant there was a high level of compliance and low levels of missing data. During the study, researchers felt that a number of questionnaires were not working well for participants and that the answers being recorded might not be a true reflection of the constructs the questionnaires are designed to measure. We, therefore, asked researchers to start recording on the questionnaire situations where there was any involvement of the researcher or the carer in helping the participant to choose an answer to the questions. There was a coding system for doing this (e.g., CA meant the carer answered for the participant). As this was introduced part-way through the study, we report this data for the 6-month assessment point when this was in place for all the assessments.

2.6 | Blinding

All measurements at 3 and 6 months were administered by a researcher blind to group allocation.

2.7 | Statistical analysis

Baseline data are described by randomised group with frequencies (%) for categorical variables and mean (SD) for continuous variables. As this is a feasibility study, the statistical analyses are only exploratory and we only report the anthropometric data. Other measures have been assessed for acceptability only.

As weight would be the primary outcome in a future RCT, multiple linear regressions were calculated to predict weight at 3 and 6 months with experimental group (usual care or intervention) and baseline weight as predictors. For body fat percentage and waist circumference, we simply report the mean difference at 3 and 6 months for the two groups.

Two variables were generated from the researchers' codes regarding the help participants required to provide answers to the questionnaire items. *Researcher help* includes situations where participants needed the researcher to explain any of the questions using different words, or to interpret their response onto the scale, or the researcher noted that they did not think that the participant understood the question. *Carer support* includes situations where the participant needed the carer to help them to choose an answer or where the carer provided the answer for them. These codes were used for each individual question for the shorter scales (CORE LD, EQ-5D-Y and Rosenberg Self-Esteem Scale) but at sub-scale level for the QoL for the person with learning disability. They were used to summarise across the diet and physical activity questions. We summarise the researcher's views of the Chage4life questions, because this was not used at 6 months due to researchers concerns, and for the CSRI, because this is a long and involved questionnaire with different types of questions so it is much harder to summarise the coding system. We report the number of participants who had each type of code noted for any questions within a scale, and among those the average percentage of questions/sub-scales that this applied to. We also report these numbers for missing items in a scale. For the CSRI, we examined questions where we would expect the answers to remain stable over time; hours of carer support received (we consider a change of more than 6 h a week to be unlikely) and epilepsy, vision and hearing impairments (long-term conditions).

3 | RESULTS

3.1 | Recruitment

Figure 1 describes the flow of participants through the study. We aimed to recruit 60 participants over 12 months. We were able to

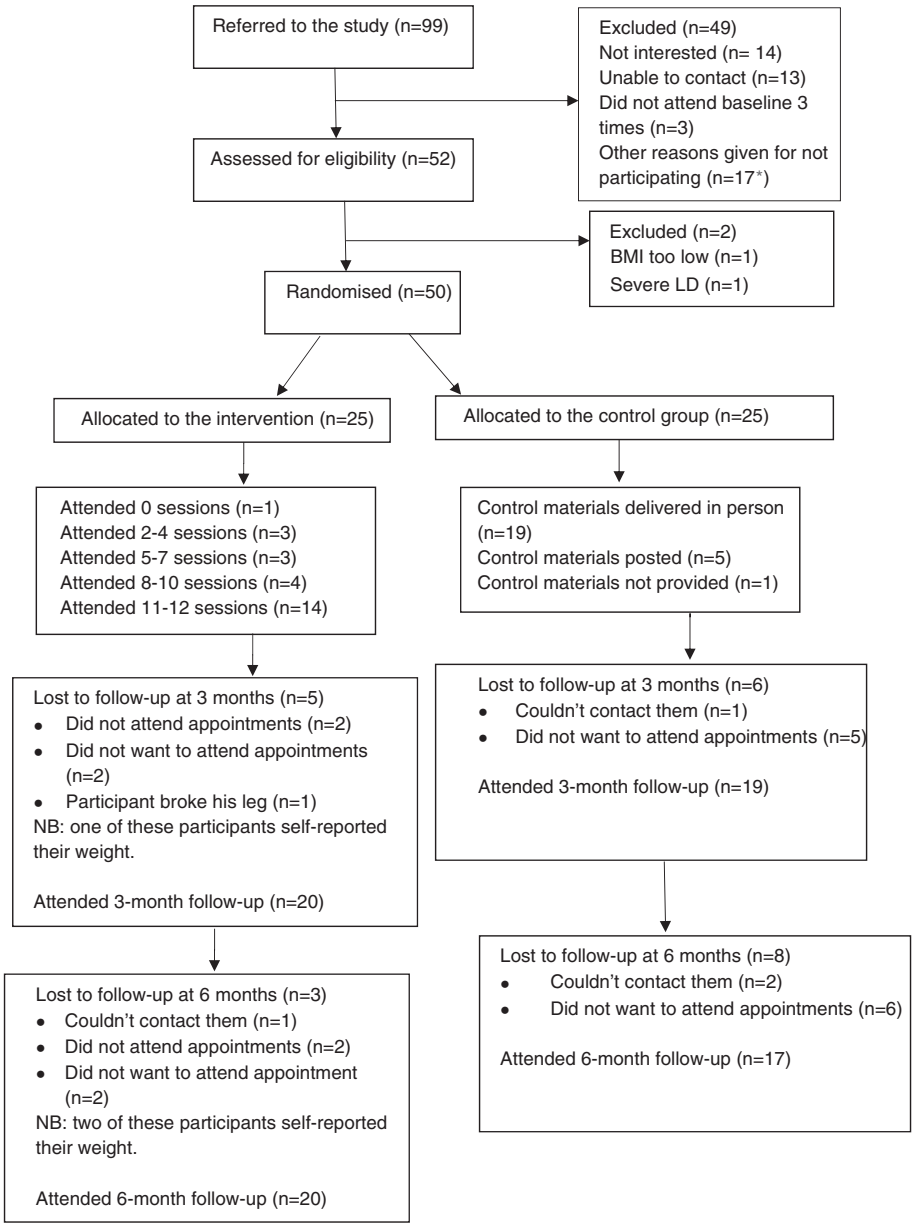

FIGURE 1 Consort diagram
*Reasons potential participants gave for not participating were: personal problems (3), housebound due to weight (1), does not like group things (1), "too skinny to take part" (1), does not want to be a research guinea pig (2), too many other things going on (4), problem with wording of study material (1), can't find assessment building on own and carer has ID and would not be able to help (1), employer would not give them time off work (1), participant found eligibility assessment challenging and left (2)

recruit 50 participants over 15 months. The recruitment strategy was adapted over time to increase the recruitment rate. The study was advertised in the reception of intellectual disability services visible to potential participants, carers and health professionals. This resulted in a small number of referrals. We presented the study at staff meetings and asked professionals to refer those on their caseload affected by overweight or obesity. The majority of staff were willing to refer potential participants once they had spoken to them about the study. We made contact with local organisations that work with adults with intellectual disabilities and asked them to speak to their service users about the study and refer those interested, and presented directly to potential participants at these services. Lastly, we added a participant identification centre (PIC) (another intellectual disability service) and asked them to also refer eligible service users.

In total, 99 potential participants were referred to the study. Of those who did not participate, two did not meet the eligibility criteria, 13 did not respond to our attempts to contact them and 34 did not want to take part. Health professionals acted as gate keepers and chose whom to approach about the study, and did not inform the study team of these details. Furthermore, it was not possible to calculate the number of potentially eligible participants who saw the study advertised or attended meetings promoting the study. We cannot therefore calculate a figure for uptake to the study, but 51% of those with a confirmed referral were randomised.

Table 1 describes the baseline demographics and anthropometrics of the study sample. The two arms appear similar, with the exception of living conditions; the intervention arm included a higher number of individuals living in supported living (14 versus 9); in contrast the control arm included more individuals living independently (9 versus 3).

3.2 | Loss to follow-up

Follow-up rates were 78% at 3 months and 74% at 6 months. Of those randomised to the intervention, 20 (80%) attended both the 3-month and the 6-month follow-up assessments. Follow-up rates for those randomised to the control group were slightly lower; 19 (76%) at 3 months and 17 (68%) at 6 months.

TABLE 1 Baseline characteristics[a]

	Control ($N = 25$)		Intervention ($N = 25$)	
Variable	***n* or mean**	**% or (SD)**	***n* or mean**	**% or (SD)**
Socio demographics				
Male	12	48	14	56
Age (years)	41	(13)	40	(15)
White	20	80	13	52
Married/live in partner	3	12	4	16
Separated/divorced	0	0	1	4
Single	22	88	20	80
Living with family carers	7	28	8	32
Living independently	9	36	3	12
Living in supported living	9	36	14	56
No employment/college/day centre	6	24	3	12
Part-time employment[a,b]	5	26	1	5
Full-time employment[b]	0	0	0	0
Voluntary work[b]	7	37	11	50
College[b]	10	53	10	45
Day centre[b]	7	37	7	32
Anthropometrics				
Weight (kg)	95	(19)	100	(20)
Height (m)	1.61	(0.10)	1.65	(0.09)
Body mass index (kg/m^2)	37	(8)	37	(8)
Body fat (%)	40	(10)	39	(8)
Waist circumference (cm)	116	(13)	117	(15)
Systolic blood pressure (mm/Hg)	121	(18)	120	(14)
Diastolic blood pressure (mm/Hg)	75	(12)	77	(11)

[a]Among the Controls: three part-time workers also volunteered.
[b]For these variables $N = 19$ in the control and $N = 22$ in the intervention.

3.3 | Intervention compliance

Seven *Shape Up-LD* groups were run within the trial. The mean time between randomisation and starting a group was 42 days (interquartile range (IQR): 29, 56). Sessions were audio-taped and a selection (one example of each session) were rated using a provider check list based on the components of the intervention. Facilitator fidelity to the manual was good (across the sessions assessed the mean percentage of planned content covered was 81% (SD 10)). Seventeen (68%) of the participants randomised to the intervention attended at least 10 of the 12 sessions (median 11, IQR 6.5–11). One participant did not attend any sessions.

Carer engagement with the programme was mixed. Almost 1/3 (30%) of participants attended without a carer at any of the sessions, and for 35% a carer attended only some of the sessions. Of those who had a carer attend every session 7/9 (78%) had the same carer every time. Of those who had a carer at some of the sessions 3/7 (40%) had the same carer on the occasions a carer attended. Ten carers attended the carers' sessions, but of these three did not attend any subsequent sessions.

3.4 | Acceptability of questionnaire measures

Overall participants seemed to find the CORE-LD and EQ-5D-Y easiest to understand, and QoL for the person with learning disability was very difficult for them. The Rosenberg Scale required additional explanation from the researcher (Table 2). Researchers did not make notes on individual questions relating to diet and activity but noted if participants required help for any of these questions. At 6 months, 20 of the 36 participants who answered this questionnaire required some help from their carer and 11 required help or further explanation from the researcher.

The Change4life questions often required the researchers to interpret participants' answers and were removed from the 6-month follow-up because of lack of researcher confidence in the measure. The CSRI was time-consuming to complete. While most of the measures took less than 5 min, the CSRI took around 15 min. Participants found the CSRI challenging to complete, particularly information about the duration of appointments. Although the questions did not need explanation and participants often tried to respond independently, the researchers believed that the responses were unlikely to be accurate. When comparing answers from baseline to 3 months, 33% of participants reported a difference in the number of hours of care they receive a week of more than 6 h. When looking at epilepsy, and vision and hearing impairments across the three time-points, one participant said that they had epilepsy and later said they did not, three said they had vision problems and later did not and one said they had a hearing impairment and later did not. The information on medication use was also inconsistent over time. Carers were often unable to assist participants as the carers who attended often did not know the participant well enough to have this information.

Participants were asked to bring shopping receipts to their appointments. Of the 126 assessments carried out, on only 20 occasions did a participant bring a shopping receipt with them, suggesting this was not an acceptable/easy outcome for participants to provide.

3.5 | Anthropometric outcomes

The intended primary outcome for a subsequent trial was weight change. At 3 months, participants in the usual care group had gained weight (0.3 kg, SD 3.5), while the intervention group remained stable (a gain of 0.00 kg, SD 2.8). At 6 months, the usual care arm had gained more weight (0.5 kg from baseline, SD 5.1), and the intervention arm had continued to maintain their weight (a loss of 0.02 kg, SD 6.1). These differences were not significant in exploratory linear regressions adjusting for baseline weight (3 months: β: −0.34, 95% confidence interval [CI] = −2.38, 1.69, 6 months: β: −0.55, 95%CI −4.34,

TABLE 2 Acceptability of questionnaires at 6-month assessments

Questionnaire		Core-LD (14 items)	EQ-5D-Y (six items)	Rosenberg self-esteem scale	QoL for the person with LD
N		36	37	36	35
Missings	*N*/% of participants who missed any questions	2/6%	0	2/6%	17/49%
	Of those who missed any, the mean/median % of questions they missed	10.7/10.7	N/A	16.7/16.7	4.9/5.0
Researcher help	*N*/% of participants who had this noted for any question	13/36%	18/49%	26/72%	32/91%
	Of those had this noted, the mean/median % of questions this applied to	17.6/14.3	41.7/16.7	67.9/83.3	69.5/75.0
Carer support	*N*/% of participants who had this noted for any question	9/25%	10/27%	7/19%	17/49%
	Of those had this noted, the mean/median % of questions this applied to	24.6/7.1	35.0/33.3	35.7/16.7	50.0/50.0

3.24).[2] Body fat measurements were obtained from 15/16 (intervention/control) participants at 3 months and 16/16 (intervention/control) participants at 6 months. At 3 months, the intervention group had reduced their body fat percentage by 0.2% (SD 2.5) and the control group had increased theirs by 0.7% (SD 3.4). At 6 months, the intervention group had reduced their body fat percentage for baseline by 0.4% (SD 3.2) and the control group maintained their increase (0.6% SD 2.7).

Researchers found it difficult to obtain accurate waist measurements as many participants found this uncomfortable. Although this data was collected on the majority of participants (19/17 intervention/control at 3 months and 18/16 intervention/control at 6 months), the data do not fit well with the weight and body fat results as it showed a reduction in waist circumference in the control group by 1.7 cm (SD 6.3) and 0.3 cm (SD 6.4), at 3 and 6 months, respectively, and an increase in the intervention group by 0.7 cm (SD 1.7) and 0.8 cm (SD 6.2), at 3 and 6 months, respectively.

3.6 | Intervention costs

The costs of delivering the intervention to 25 service users were estimated to be £14,960 (£2230 for staff training, £4680 for staff time, £7800 for room hire and £250 for resources) or £598.40 per service user.

4 | DISCUSSION

This is one of the first studies of an adapted theory-based weight management programme for adults with intellectual disabilities in the UK. As such, it has important implications for future research in this area given the epidemic of obesity and the inequity of access to interventions by people with chronic conditions and hard to reach groups. The main aim of the study was to determine the feasibility of designing a large-scale RCT that would answer the following question: Is *Shape Up-LD* more effective than usual care in helping service users with mild–moderate intellectual disabilities, affected by overweight or obesity, reduce body weight? Our findings suggest such a study is possible, but refinements are required to the outcome measures, trial design and intervention before proceeding.

With respect to the trial design, one of the main challenges encountered was the low number of participants identified and referred to the study by local professionals. A study in Glasgow recruited 50 participants to a weight management trial over 8 months (Harris et al., 2017), whereas in our study, this took 15 months (three extra months than the planned 12-month recruitment period) and an additional PIC. A potential reason for this difference may be that the Scottish study adopted a previously developed multi-point recruitment strategy (Foster et al., 2011), whereas in our study, the strategy developed as the study progressed and multiple organisations were not involved from the beginning. An additional challenge was the lack of available data on eligible numbers of participants. Because data were not available, we were reliant on judgements made by staff. Perceptions of level of intellectual disability were variable and visual judgements of BMI are notoriously unreliable (Robinson et al., 2014). Based on previous estimates, at least 180 service users were potentially eligible within the two community services initially recruiting to the study (Beeken et al., 2013). Our figures suggest less than half of these were referred, consistent with difficulties in recruitment seen in other RCTs (Mulhall et al., 2018). It is our view that the participants could be recruited from primary care as well as secondary intellectual disability services as changes in health care mean that the incentivised health checks are more likely to identify those in need of such a programme. In this way, records could be checked and all eligible patients identified and invited to participate, removing reliance on the already busy staff in intellectual disability services to identify and invite potential participants.

Of those referred to our study, 50% chose to take part. Previous weight loss studies in this population have not reported uptake rates, but this is considerably higher than weight loss trials in the general population (Ahern et al., 2016; Beeken et al., 2016). Our sample consisted of roughly 50% men, which is also higher than is usually observed in weight loss trials within the general population (Ahern et al., 2016; Beeken et al., 2016; Pagoto et al., 2012) and in studies in adults with intellectual disabilities (Harris et al., 2017). Loss to follow-up rates in this trial were comparable or better than rates observed in weight loss trials in the general population, and within the intervention group, attendance at the sessions was high. These findings suggest that once participants are recruited, studies of this nature can proceed with low levels of attrition. Compliance from participants was good; unfortunately, this was not the case with carers.

It was a challenge to engage carers in this study, and for those participants without a consistent carer, it was difficult to ensure information was shared between carers. Those with consistent and engaged carers, appeared to benefit more from the intervention. This was particularly the case for those attending with family.

In their work adapting Slimming World, Croot et al. also identified the importance of carers to support participants and tried to encourage their engagement by sending a letter encouraging carers to attend groups and highlighting the important role they play in supporting weight loss. Despite this they found that carers did not always engage with the programme and the participants who continued with the programme were those who had carers to support them at the sessions. Some carers did not read the letter, others did not implement dietary changes because of providing meals to others not on the programme and some because they felt it was against the participant's autonomy. Carers often determine what food choices are available to adults with intellectual disabilities, and Croot et al. (2018) found that this was determined by their knowledge and skills and other pressures on their time and money. This has a significant impact on whether any intervention delivered to an adult with intellectual disabilities can make an impact on their diet. We attempted to engage carers with an introductory session

[2]These analyses include self-reported follow-up data for one participant at 3 months and two at 6 months.

which they were invited to attend without the participants. The intention here was to explain the importance of their role in supporting the participants during the sessions but also in their home environment to help them meet the goals they set in the sessions and to self-monitor their behaviour using a diary. Only 10 participants had a carer who attended this session and three of those did not then attend the actual *Shape Up-LD* sessions with participants. To enable carers to better support those with intellectual disabilities to make healthy changes to their diet and physical activity at home, it may be necessary to have more regular meetings with carers to help address any challenges they are facing and provide positive reinforcement for any changes they are promoting. With paid carers, it may be necessary to pay them for attendance at this type of event or to work with employers to enable it to be considered part of their working hours. With family carers, it is likely to be important to identify a way to deliver this information that fits in with their busy lives.

A key observation from this study concerns the use of questionnaire measures in this population. Participants found it difficult to answer the majority of the measures themselves even with explanation, with the exception of the CORE-LD and EQ-5DY. The completion of the CSRI was a particular challenge, and the information provided did not appear consistent over time when this would be expected. Data quality for duration of appointments was particularly poor. Thus, careful consideration should be given to which questionnaires should be used in studies such as these, and keeping this to a minimum, using as few items as possible. The CSRI should focus on community services, asking simpler yes/no questions and avoiding asking about duration of appointments. The EQ-5D was also challenging for participants in our study, and a recent study evaluated the feasibility of using the EQ-5D with this population and also found that individuals found it difficult to answer the questions without assistance from researchers (Russell et al., 2018). Following feedback from participants, we moved to the youth version of the EQ-5D, the language of which they found easier to understand. A study in a more severe population found that the EQ-5D-Y was sensitive to changes in challenging behaviour, although this was predominately completed by proxies (Hunter et al., 2020). We, therefore, suggest the EQ-5DY be considered for use in future studies with this population. Self-reported questionnaires have been used successfully with adults with mild to moderate intellectual disabilities (Jahoda et al., 2017) to assess intervention effects, but these need to be carefully chosen and well tested among the target population before definitive trials are conducted. It is notable that one of our most acceptable measures, the CORE-LD, was specifically designed for this population. Digital technologies may provide novel ways for supporting completion of outcome measures by service users themselves. Other studies have found that objective measures of PA, such as accelerometers, are acceptable to users (Harris et al., 2017) and would provide more reliable data on behavioural changes, though these are associated with additional expense.

The planned primary outcome for a full-scale trial of *Shape Up-LD* would be change in weight (kg) over 3 months. The amount of weight loss observed in this study is not clinically significant, and a clinically significant difference (5% of initial weight) did not fall within the 95% CIs for the change observed. The intervention could potentially be more effective for prevention of weight gain. It is promising that benefits appeared to be sustained even after the groups had finished. The waist circumference measurements were not aligned to the observed changes in weight and body fat percentage, which may reflect that these measurements were inaccurate, particularly given researchers found it difficult to obtain these measures due to participant discomfort. Future weight management studies should consider the utility of including waist circumference as an outcome and consider approaches to mitigate participant discomfort, such as training individuals known to the participants to take these measurements.

More effective weight management programmes in this population have been of longer duration, delivered on a one-to-one basis and involved individualised dietary recommendations (Harris et al., 2017; Ptomey et al., 2018). Although Croot et al. (2018) showed potential with an adapted Slimming World approach, this was a very small pilot and weight change was reported only for 2/3 of the sample who completed 8 weeks of the programme. Group-based approaches are of value in the general population, and peer learning is a key component of Shape Up. However, it is not clear if this was useful with this population, and an alternative would be to adapt Shape Up to be delivered individually. Similarly, more focus could be put on the dietary changes recommended in Shape Up and less on those aspects that focus on the psychology of eating. Sessions around triggers for over-eating and emotional eating may have been too complex. Simpler approaches to weight loss that focus on routines, such as those based on habit theory (Lally & Gardner, 2013), may be more helpful. Research needs to establish if behaviour change techniques such as goal setting, self-monitoring and rewards are as effective for individuals with intellectual disabilities as they are for the general population.

Overall, this study demonstrates that it may be possible to carry out a RCT of *Shape Up-LD* for people with mild–moderate intellectual disabilities. However, we encountered barriers to recruitment and challenges around engaging carers and the completion of self-report questionnaires that would need addressing. Furthermore, some consideration should be given as to whether *Shape Up-LD* should be offered for promotion of weight loss or for weight gain prevention.

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CONFLICT OF INTEREST

Dr Beeken and Dr Croker are trustees of the charity Weight Concern, which holds the copyright for the Shape Up Programmes. The authors have no other conflicts of interest.

ETHICS STATEMENT

This study was approved by the Cornwall & Plymouth Research Ethics Committee via IRAS (Ref No. 12/SW/0089, approval granted 05/04/12). All participants gave informed consent before taking part in the trial. Camden & Islington NHS Foundation Trust was the sponsor of this trial.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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