

# Research: Educational and Psychological Aspects

## Randomized controlled feasibility trial of supported self-management in adults with Type 2 diabetes mellitus and an intellectual disability: OK Diabetes

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### Abstract

**Aims** To undertake a feasibility randomized controlled trial of supported self-management vs treatment as usual in a population of adults with obesity, Type 2 diabetes and an intellectual disability.

**Methods** We conducted an individually randomized feasibility trial. Participants were adults aged >18 years with a mild or moderate intellectual disability, living in the community with Type 2 diabetes, on any therapy other than insulin. Participants had mental capacity to consent to research and the intervention. Inclusion criteria included HbA<sub>1c</sub> > 48 mmol/mol (6.5%), BMI >25 kg/m<sup>2</sup>, or self-reported physical activity below national guideline levels. The experimental intervention was standardized supported self-management delivered by diabetes specialist nurses plus treatment as usual, compared with treatment as usual alone. Feasibility outcomes included: recruitment and retention; intervention acceptability and feasibility; data collection and completeness for physiological state and values for candidate primary outcomes (HbA<sub>1c</sub> and BMI).

**Results** A total of 82 participants (89% of those contacted and eligible) were randomized. All supported self-management sessions were completed by 35/41 participants (85%); only four completed no sessions. Data on the follow-up candidate primary outcomes HbA<sub>1c</sub> and BMI were obtained for 75/82 (91%) and 77/82 participants (94%), respectively. The mean baseline HbA<sub>1c</sub> was 56±16.5 mmol/mol (7.3±1.5%) and the mean BMI was 34±7.6 kg/m<sup>2</sup>.

**Conclusions** Adherence to supported self-management and willingness to have blood taken for outcome measurement was good. A definitive randomized controlled trial is feasible in this population. (Trial registration: Current Controlled Trials ISRCTN41897033)

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### Introduction

It is estimated that ~1.5% of the population has a mild or moderate intellectual disability. People with intellectual disabilities have higher rates of Type 2 diabetes than the general population [1–4], which is related to a high prevalence of obesity [5,6] and prescription medications that increase diabetes risk. Higher rates of hospital admissions from diabetes-related ambulatory-care-sensitive conditions have been recorded in this population [4]. People with an

intellectual disability have difficulty understanding complex information and learning new skills, combined with a reduced ability to cope independently. This further affects their ability to self-care [7].

Supported self-help or self-management for health problems is now reasonably well established [8–10]. Existing approaches in people with intellectual disability are largely educational and didactic, with little or nothing that facilitates self-management, or have had problems with uptake [11]. Many adults with an intellectual disability do not live entirely independently, even when living in the community [12,13], but there is little content on the interaction between the person with diabetes and others supporting their care [14–18].

A definitive pragmatic phase III trial of a suitably designed supported self-management is therefore indicated, but there

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**What's new?**

- This is the largest published randomized study of Type 2 diabetes mellitus self-management in community-living adults with an intellectual disability.
- Recruitment was 89% of contacted eligible respondents.
- Over 90% of randomized participants were retained in the study, with primary outcome data collected at follow-up.
- Adherence to self-management was good; 85% completed all sessions.
- HbA<sub>1c</sub> levels were in line with general population rates for Type 2 diabetes.
- Obesity and physical inactivity were a major problem.
- We have demonstrated the feasibility of conducting a definitive phase III trial in adults with an intellectual disability.

remain feasibility questions to be addressed first. The present trial, OK-DIABETES, was commissioned for this purpose.

**Methods****Design, setting and objectives**

We conducted an individually randomized, controlled, parallel-group feasibility trial of standardized supported self-management delivered by diabetes specialist nurses plus treatment as usual vs treatment as usual alone. An easy-read booklet was provided in both study arms. The trial was based in three sites around cities in West Yorkshire, UK.

The main study aims were: to estimate recruitment, retention and follow-up rates for a definitive (phase III) trial; to assess the acceptability and feasibility of implementation of the self-management intervention by measuring adherence, drop-outs and negative outcomes (such as distress and agitation); to assess data collection and the feasibility of collecting a range of physiological, psychological, behavioural and cost-effectiveness outcome measures and maintaining the blind for subjective outcomes; and to measure variability in the candidate primary outcomes: HbA<sub>1c</sub> and BMI.

Further details of the overall project are reported elsewhere [19,20].

**Participants and eligibility**

Participants were eligible if they met all inclusion criteria: age  $\geq 18$  years; current diagnosis of Type 2 diabetes not requiring insulin therapy; mild or moderate intellectual

disability; mental capacity to consent to research participation; provision of written or verbal informed consent; willingness to undergo a blood test and measurements for HbA<sub>1c</sub> and BMI or, up-to-date (within 6 weeks) routine values of HbA<sub>1c</sub> and BMI; suboptimal diabetes control, defined as HbA<sub>1c</sub>  $>48$  mmol/mol ( $> 6.5\%$ ); and BMI  $> 25$  kg/m<sup>2</sup> or physical activity below national guideline levels [21].

Participants were excluded if they: were referred for insulin or put on insulin between identification and randomization; were likely to require insulin in the next 3 months; were not living in the community; or declined further assistance with diabetes self-management.

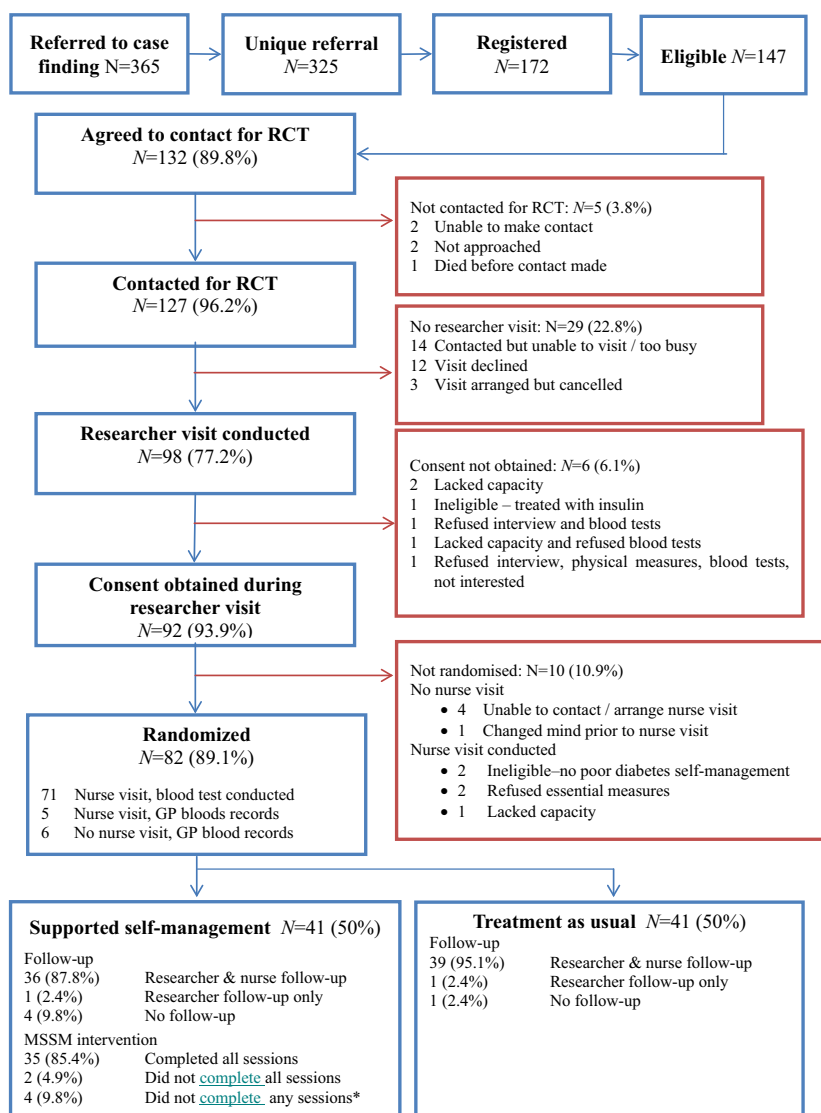
'Supporters' were eligible if they met the operational definition of 'a key person in providing regular practical support in diabetes self-management, who is in contact with the person with diabetes at least weekly' and gave informed consent. We identified one main supporter for participants, although other people could be included as 'other helpers'.

Most referrals to a preliminary case-finding study came from primary care physicians [22]. Baseline assessment at face-to-face interview was assisted by participant information and consent materials produced in an easy-read format. An overview of randomization was provided in easy-read format with a visual aid. Consent was obtained in writing, or verbally if the participant did not want to, or could not, write or make a mark (see Appendices S1, S2 for the explanation of randomization and consent forms used for participants). If present and willing, consent was obtained from a key supporter.

Participants were randomized on a 1:1 basis to receive supported self-management or treatment as usual using a secure, automated 24-h telephone randomization service based at the University of Leeds to ensure allocation concealment. A computer-generated minimization algorithm incorporating a random element accounting for: site (Leeds, Bradford, Wakefield); supporter (none, not living with supporter, living with supporter); HbA<sub>1c</sub> ( $\leq 48$  mmol/mol,  $>48$  to  $69$  mmol/mol,  $>69$  mmol/mol); BMI ( $\leq 25$  kg/m<sup>2</sup>,  $>25$  kg/m<sup>2</sup>); and physical activity level below, at, or above national guidelines (Fig. 1).

**Intervention****Supported self-management**

The intervention was based on modifying existing approaches to supported self-management, with adjustments made to respond to barriers to self-care in people with an intellectual disability. It emphasized realistic goal setting, identifying resources and barriers likely to influence success in reaching goals, and regular self-monitoring of goal attainment. For the 'supported' element we chose to use face-to-face contact and employed two diabetes specialist nurses from the local diabetes service, with no prior experience in learning disability or involvement in research concerning trials of complex interventions.



**FIGURE 1** CONSORT flow chart for feasibility randomized controlled trial. GP, general practitioner.

We started with three principles in deciding the format and content of supported self-management. First the intervention should respond to known barriers to self-management reported by people with a disability, including practical problems such as transport, likely attrition through drop-out when multiple attendances are expected, and inability to accommodate the presence of a supporter. Second, the format of the intervention should be likely to encourage self-maintained change beyond an early supported element; in our target population this meant especially that the intervention should involve supporters involved with any aspect of lifestyle (shopping, food choice, physical activity, medication monitoring and so on) relevant to diabetes. Third, the intervention should be designed to be readily integrated into usual healthcare provision in the National Health Service, to ensure sustainability.

Based on all the advice we received from those working with our target group, we wanted to give particular salience to: practical aspects of self-care; use of simple (accessible) written materials and charts; supportive contact both with a professional and with a supporter if one could be identified; use of practical goal setting and self-monitoring.

By contrast we decided that less helpful aspects would be education of a more theoretical sort about the nature of diabetes, food values and so on; however, all participants received factual information about managing their diabetes in a booklet as part of the treatment as usual arm of the randomized controlled trial ([https://www.diabetes.org.uk/about\\_us/news/learning-disabilities-leaflet](https://www.diabetes.org.uk/about_us/news/learning-disabilities-leaflet)). We did not include information technology-based interventions (e.g. web-, DVD-, mobile phone-based interventions), because these are usually not readily accessible by our participants. Finally, we

decided against group-based interventions as attendance is typically poor and meeting the specific individual needs arising in a heterogeneous population is harder in such settings.

The final intervention had four standardized components with associated materials. How they were delivered depended on participant and supporter characteristics and preferences.

(1) *Establishing the participant's daily routines and lifestyle.*

Establishing the participant's daily routines and lifestyle included current diet and activity routines, participation in daytime social activities or work, shopping and food preparation, current self-reported health and self-management. The main aim of this component was to identify the social and personal influences in the life of the person with diabetes that would limit their ability to self-manage, or that might be mobilized as a resource in supporting self-management.

(2) *Identifying all supporters and helpers and their roles.*

Identifying all supporters and helpers and their roles led to key supporters and other helpers being given written information about the project and if they agreed to support a goal set by the participant they were given a written reminder of their role. The main aim was to identify people who might be a useful resource in supporting self-management, and to ensure any changes were embedded in the social network for longer-term maintenance of change.

(3) *Setting realistic goals for change.* In setting realistic goals for change the main aim was to avoid prescribing change in the way of good dietary practice or other lifestyle change, but to support goals suggested by the person with diabetes that were specific, simple and achievable given the person's current routines and social support, and consonant with their willingness to make change. The intention was to encourage engagement in a population usually thought of as having little agency, and to introduce the idea of selectable elements in a repertoire of self-management options.

(4) *Monitoring progress against agreed upon goals.* To allow monitoring of progress against agreed upon goals we devised a simple system that did not depend on high levels of functional literacy, using tear-off calendar sheets on which participants noted goal attainment in a Yes/No format. The main aim was to encourage active participation in an activity that is a core feature of self-management.

We prepared materials to accompany these activities. For the nurses we provided templates for a weekly timetable, a chart to record friends and family and other helpers, charts to be completed in collaboration with the person with diabetes ('my life', 'my likes and don't likes', 'looking after my diabetes'). For the person with diabetes there was an OK

Diabetes board to place in a prominent position at home with a visible record of goals, including pictorial prompts, e.g. 'snack swaps', a written action plan in multiple formats, and tear off slips to record daily actions. For supporters and helpers we provided an information sheet explaining the study and a card summarizing what their role was in helping to support the person with diabetes in meeting their chosen goals.

More detail on development of the intervention is reported elsewhere [19].

#### *Treatment as usual*

Uncomplicated Type 2 diabetes is managed in primary care. With our third-sector (voluntary sector, non-governmental) partners we developed an accessible 'easy-read' information booklet about Type 2 diabetes [[http://www.easyhealth.org.uk/listing/diabetes-\(leaflets\)](http://www.easyhealth.org.uk/listing/diabetes-(leaflets))] and provided it to all participants.

#### **Measures**

Data were collected from medical notes by researcher interview and nurse assessment. Researchers were blinded for medical note review but, at follow-up, participants often revealed the group they were in or were known to the research nurse.

Outcomes related to feasibility of recruitment, retention and comprehensiveness of outcome data were collected by project researchers.

Outcomes related to intervention delivery and physiological state (including candidate primary outcomes HbA<sub>1c</sub> and BMI) were collected by nurses (where possible this was a different nurse from the one delivering the intervention). Outcomes related to other aspects of contact with clinical services and clinical measures where a nurse visit was not possible were obtained from primary care records.

Self-reported health economics questionnaire data, participant mood, health-related quality of life, negative outcomes, hospital attendances, physical activity and diet data were collected through researcher interview. We found self-reported physical activity too unreliable in this population to use as an outcome measure, because, although people were able to describe their daily routine in enough detail to allow us to estimate that they were not meeting recommended levels of activity, there was insufficient detail to allow monitoring of change.

A 6-month follow-up was originally planned, but was reduced for some to 4 months because of project deadlines. A full list of outcome measures and how they were collected is provided in Table 1.

#### **Analysis**

##### *Progression criteria*

We prespecified that if any of the following were met, a definitive trial would be unfeasible: enrolment of  $\leq 20$

**Table 1** Assessments at baseline and follow-up in the randomized controlled trial

	Medical notes review /check	Pre-baseline phone call	Baseline research interview	Baseline research nurse visit	6-month medical/research nurse follow-up	6-month follow-up research interview	GP medical notes follow-up
<b>Eligibility and consent</b>							
Presence and role of a supporter and/or research advocate			X			X	
Mental capacity to consent to RCT			X				
Eligibility for RCT	X	X	X				
Consent for RCT			X				
<b>Follow-up data</b>							
Negative outcomes						X	X
Related and unexpected serious adverse events						X	
Hospital attendances						X	X
Current physical health state (e.g. HbA <sub>1c</sub> , blood pressure, BMI, weight, cholesterol, HDL/LDL cholesterol, triglycerides, urea and electrolytes, waist-hip ratio)	X			X	X		
Thyroid function, height				X			
Q Risk, retinal screening, diabetes medication, serum creatinine, microalbuminuria							X
Details of treatment received						X	
Adherence to the intervention						X	
Prescribed diabetes regime (diet, exercise)						X	
Resource use: service and hospital usage							X
<b>Questionnaires (completed at researcher visit)</b>							
Health economics questionnaire to cover health and social care costs, participant and supporter expenses and productivity costs			X			X	
Participant mood (PHQ-2)			X			X	
Health-related quality of life (EQ5D-3L)			X			X	

EQ5D-3L, three-level health-related quality-of-life instrument; GP, general practitioner; Patient Health Questionnaire-2; RCT, randomized controlled trial.

participants after 6 months of recruitment; active or passive withdrawal from follow-up of  $\geq 40\%$  of recruited participants; and  $\geq 50\%$  participants in the supported self-management sessions attending no sessions.

#### Sample size

We planned to recruit 80 participants, randomized equally between intervention and control arms, in order to obtain follow-up data on at least 30 participants per arm [23], assuming loss to follow-up would be no greater than 25% at 6 months. A formal power calculation was not appropriate because effectiveness was not being evaluated. Estimates of non-adherence [24] and loss to follow-up rates, and variability of candidate primary outcomes were intended to inform power calculations for a definitive trial.

Analyses were conducted on the intention-to-treat population using SAS version 9.4.

Data were summarized using descriptive summary statistics and estimation with 95% CIs.

Feasibility and success of recruitment was evaluated by summarizing the screening, eligibility, consent and

randomization processes, and evaluation included the numbers of participants involved at each stage and reasons for non-participation.

We reported summary statistics for each treatment arm for candidate primary outcomes and other physiological outcomes at baseline and follow-up. To assess sensitivity to change, we reported the distribution of outcomes and change in BMI and HbA<sub>1c</sub> between baseline and follow-up, and estimated the effect size in participants. Measures of diabetes control, and metabolic complications are presented categorically according to abnormal ranges on standard criteria.

## Results

Of 147 initially eligible participants identified during case-finding [22], 132 (90%) agreed to further research contact, and 127/132 (96%) were contacted. More than three-quarters of participants (98/127) agreed to be visited by the researcher, and the majority (92/98) consented to take part in the trial. A total of 82/92 people (89%) went on to be randomized (Fig. 1).

## Characteristics of the study population

Participant demographics, including age, sex and ethnicity were largely comparable to the case-finding population, and were well balanced across trial arms (Table 2).

Table 3 gives details of the participants' supporter and living arrangements for the 82 people randomized.

## Intervention delivery

### Supported self-management

Forty-one participants (50%) were allocated to receive supported self-management, of whom 35 (85%) completed all required sessions, which ranged from two to four sessions, with more than three-quarters of all participants (78%) completing at least three sessions. Four participants (10%) did not complete any sessions. Thirty participants (73%) had another person present with them during at least one session.

Sessions mostly took place in the participant's home (92%). Sessions lasted a mean (range) of 45 (13–95) min,

and the focus included getting started, setting goals, mapping supporter, and checking progress. Participants had a typical total intervention time of 2 h.

A summary of engagement was reported by the nurse who delivered the intervention: 23/40 participants (58%) were deemed to be very engaged with the sessions and 12/40 (30%) with the materials; 15/41 (37%) were reported to have a very engaged supporter; and 18/41 (44%) had a further or different person engaged in intervention implementation.

### Adherence and fidelity

Independent review of adherence and fidelity of the intervention took place for all supported self-management sessions completed ( $n=37$ ).

All components of the supported self-management intervention concerned with assessing day-to-day living arrangements and diabetes management were covered in all the first sessions, and at least some of these components were revisited during the second session for 10/35 participants (29%) completing at least two sessions.

**Table 2** Characteristics and randomization stratification factors of participants

	Case-finding study		Feasibility trial randomized participants		
	Referred population N=325	Eligible population N=147	Supported self-management N=41	Treatment as usual N=41	Total N=82
<b>Age at referral/registration</b>	N=22 missing				
Mean (sd)	53.5 (13.81)	54.4 (12.82)	54.8 (10.83)	56.2 (12.46)	55.5 (11.62)
Median (range)	54.0 (18, 93)	56.0 (19, 83)	56.0 (29, 76)	57.0 (19, 79)	56.5 (19, 79)
<b>Age at randomization</b>					
Mean (sd)			55.6 (10.75)	57.3 (12.26)	56.4 (11.49)
Median (range)			57.0 (30, 77)	58.0 (20, 79)	58.0 (20, 79)
<b>Gender, n (%)</b>	n=14 missing				
Male	174 (55.9)	74 (50.3)	20 (48.8)	20 (48.8)	40 (48.8)
Female	137 (44.1)	73 (49.7)	21 (51.2)	21 (51.2)	42 (51.2)
<b>Ethnicity, n (%)</b>	N=22 missing				
White	249 (82.2)	125 (85.0)	36 (87.8)	39 (95.1)	75 (91.5)
Mixed	6 (2.0)	3 (2.0)	2 (4.9)	0 (0.0)	2 (2.4)
Asian	45 (14.9)	17 (11.6)	3 (7.3)	2 (4.9)	5 (6.1)
Black	2 (0.7)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
Other ethnic group	1 (0.3)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Randomization stratification factors, n (%)</b>					
<b>Area</b>					
Leeds			18 (43.9)	18 (43.9%)	36 (43.9%)
Bradford			12 (29.3)	12 (29.3%)	24 (29.3%)
Wakefield			11 (26.8)	11 (26.8%)	22 (26.8%)
<b>HbA<sub>1c</sub></b>					
≤48 mmol/mol (≤6.5%)			15 (36.6)	16 (39.0%)	31 (37.8%)
>48 to 69 mmol/mol (>6.5 to 8.5%)			20 (48.8)	20 (48.8%)	40 (48.8%)
>69 mmol/mol (>8.5%)			6 (14.6)	5 (12.2%)	11 (13.4%)
<b>BMI</b>					
≤25 kg/m <sup>2</sup>			1 (2.4)	2 (4.9)	3 (3.7)
>25 kg/m <sup>2</sup>			40 (97.6)	39 (95.1)	79 (96.3)
<b>Physical activity</b>					
At or above national guidelines			1 (2.4)	0 (0.0)	1 (1.2)
Below national guidelines			40 (97.6)	41 (100.0)	81 (98.8)
<b>Supporter available</b>					
No supporter			9 (22.0)	11 (26.8)	20 (24.4)
Participant does not live with supporter			23 (56.1)	22 (53.7)	45 (54.9)
Participant lives with supporter			9 (22.0)	8 (19.5)	17 (20.7)

**Table 3** Participant details and living arrangements at baseline

	Supported self-management N=41	Treatment as usual N=41	Total N=82
<b>Someone who helps/supports you with your diabetes in day to day life?*</b>			
Yes, <i>n</i> (%)	26 (63.4)	32 (78.0)	58 (70.7)
<b>If yes, main person, <i>n</i> (%)</b>			
Paid supporter	16 (61.5)	24 (77.4)	40 (70.2)
Immediate family	7 (26.9)	5 (16.1)	12 (21.1)
Partner/husband/wife	1 (3.8)	1 (3.2)	2 (3.5)
Grown-up child of person	1 (3.8)	1 (3.2)	2 (3.5)
Other family member	1 (3.8)	0 (0.0)	1 (1.8)
Friend	0 (0.0)	0 (0.0)	0 (0.0)
Missing	0	1	1
<b>Is there anyone who helps you with shopping and cooking?</b>			
Yes, <i>n</i> (%)	33 (80.5)	36 (87.8)	69 (84.1)
<b>If yes, main person, <i>n</i> (%)</b>			
Paid supporter	20 (60.6)	22 (64.7)	42 (62.7)
Immediate family	7 (21.2)	8 (23.5)	15 (22.4)
Partner/husband/wife	2 (6.1)	1 (2.9)	3 (4.5)
Other family member	3 (9.1)	0 (0.0)	3 (4.5)
Grown-up child of person	1 (3.0)	2 (5.9)	3 (4.5)
Friend	0 (0.0)	1 (2.9)	1 (1.5)
Other relationship	0 (0.0)	0 (0.0)	0 (0.0)
Missing	0	2	2

The most frequent goals identified were to increase physical activity and to make dietary changes.

### Outcome data collection

#### Retention/ loss to follow-up

After randomization, withdrawals (researcher or nurse follow-up) were made for six participants (7%): four allocated to supported self-management and two to treatment as usual.

The follow-up researcher visit was conducted for 77 participants (94%). A baseline nurse visit was conducted for 76 participants (93%) and was not required for five participants as in-date physical measures were obtained from their general practitioner (GP). It was also possible to obtain GP records for a further participant who declined the baseline nurse visit. Nurse follow-up was conducted for 75 participants (92%), with no visit for the six participants who had withdrawn, and GP records were obtained for the remaining participant.

Researcher follow-up took place a mean (range) of 4.4 (3–6.2) months after randomization, followed by nurse visits at a mean (range) of 4.8 (4–8) months after randomization.

#### Unblinding

The follow-up nurse was unblinded for 34 trial participants (41%); 20 (49%) in the supported self-management arm and 14 (34%) in treatment as usual arm. Researchers were unblinded for 16 participants (20%; with all but one in the supported self-management arm), all of which occurred before the follow-up assessment.

#### Physical measures

For 14 participants at baseline and 13 at follow-up, results could not be obtained during the nurse visit or because there was no nurse visit. GP records were therefore obtained for 11/14 participants (79%) and 5/13 participants (38%), respectively.

#### Statistical outcomes

The participants' clinical characteristics at baseline and follow-up are shown in Table 4 for HbA<sub>1c</sub>, BMI and all other outcomes.

At baseline, participants had a mean  $\pm$  SD HbA<sub>1c</sub> of 56.1  $\pm$  16.5 mmol/mol (7.3%), with 29 participants (35%) above the threshold for desirable control [ $\geq$ 58 mmol/mol (7.5%)], which were similar figures to those for the general population with Type 2 diabetes in West Yorkshire [19].

Obesity posed a greater problem, with mean  $\pm$  SD BMI among the study cohort of 34.0  $\pm$  7.6 kg/m<sup>2</sup> and two-thirds of participants classed as obese and 19% morbidly obese (BMI  $\geq$  40 kg/m<sup>2</sup>).

Candidate primary outcomes were similar across trial arms at baseline and follow-up (Table 4); however, when comparing within-participant reduction in HbA<sub>1c</sub> and BMI in individuals with measures at baseline and follow-up, an effect size in the supported self-management arm of 0.33 (0.5/1.5) was observed for BMI, and for HbA<sub>1c</sub> it was 0.30 (0.17/0.57), whilst minimal effects were observed in the group receiving treatment as usual (Figs 2 and 3).

Scores for participant mood, obtained from the Patient Health Questionnaire-2 (PHQ-2) [25] are shown in

**Table 4** Distribution of HbA<sub>1c</sub>, BMI, blood pressure, other measures and lipids at baseline and follow-up

	Baseline Supported self-management N=41	Treatment as usual N=41	Total N=82	Follow-up Supported self-management N=41	Treatment as usual N=41	Total N=82
<b>HbA<sub>1c</sub></b>						
<b>mmol/mol</b>						
Missing	0	0	0	4	3	7
Mean (sd)	57 (15.1)	55 (18.0)	56 (16.5)	54 (13.5)	55 (19.5)	54 (16.7)
95% CI	(52.2, 61.8)	(49.60, 61.0)	(52.5, 59.8)	(49.5, 58.5)	(48.2, 61.0)	(50.5, 58.2)
<b>%</b>						
Mean (sd)	7.4 (1.38)	7.2 (1.65)	7.3 (1.51)	7.1 (1.24)	7.1 (1.79)	7.1 (1.53)
95% CI	(6.93, 7.80)	(6.69, 7.73)	(6.95, 7.62)	(6.68, 7.51)	(6.56, 7.73)	(6.77, 7.47)
<b>HbA<sub>1c</sub> category, n (%)</b>						
<48 mmol/mol (6.5%)	15 (36.6)	15 (36.6)	30 (36.6)	12 (32.4)	18 (47.4)	30 (40.0)
48 to <58 mmol/mol (6.5 to <7.5%)	10 (24.4)	13 (31.7)	23 (28.0)	15 (40.5)	9 (23.7)	24 (32.0)
≥58 mmol/mol (7.5%)	16 (39.0)	13 (31.7)	29 (35.4)	10 (27.0)	11 (28.9)	21 (28.0)
Missing				4	3	7
<b>BMI, kg/m<sup>2</sup></b>						
Missing	1	0	1	4	1	5
Mean (sd)	33.8 (6.94)	34.3 (8.23)	34.0 (7.58)	34.2 (8.67)	34.1 (8.46)	34.1 (8.51)
95% CI	(31.54, 35.98)	(31.73, 36.93)	(32.37, 35.72)	(31.28, 37.06)	(31.41, 36.82)	(32.21, 36.07)
<b>BMI category, n (%)</b>						
Normal: 18.5–24.9 kg/m <sup>2</sup>	1 (2.5)	1 (2.4)	2 (2.5)	3 (8.1)	1 (2.5)	4 (5.2)
Overweight: 25–29.9 kg/m <sup>2</sup>	11 (27.5)	14 (34.1)	25 (30.9)	10 (27.0)	14 (35.0)	24 (31.2)
Obese Class I: 30–34.9 kg/m <sup>2</sup>	14 (35.0)	9 (22.0)	23 (28.4)	9 (24.3)	10 (25.0)	19 (24.7)
Obese Class II: 35–39.9 kg/m <sup>2</sup>	7 (17.5)	9 (22.0)	16 (19.8)	7 (18.9)	6 (15.0)	13 (16.9)
Obese Class III: ≥40 kg/m <sup>2</sup>	7 (17.5)	8 (19.5)	15 (18.5)	8 (21.6)	9 (22.5)	17 (22.1)
Missing	1	0	1	4	1	5
<b>Weight, kg</b>						
Missing*	2	5	7	5	2	7
Mean (sd)	89.6 (20.54)	90.5 (25.14)	90.0 (22.71)	91.4 (25.91)	87.2 (23.74)	89.2 (24.72)
95% CI	(82.99, 96.30)	(81.94, 98.96)	(84.81, 95.26)	(82.61, 100.1)	(79.49, 94.88)	(83.51, 94.89)
<b>Systolic blood pressure, mmHg</b>						
Missing	2	1	3	4	3	7
Mean (sd)	127.8 (16.07)	125.7 (16.47)	126.7 (16.20)	119.4 (18.06)	122.6 (16.65)	121.1 (17.32)
95% CI	(122.6, 133.0)	(120.5, 131.0)	(123.1, 130.4)	(113.4, 125.5)	(117.2, 128.1)	(117.1, 125.0)
<b>Systolic blood pressure category, n (%)</b>						
<140 mmHg	29 (74.4)	33 (82.5)	62 (78.5)	33 (89.2)	30 (78.9)	63 (84.0)
≥140 mmHg	10 (25.6)	7 (17.5)	17 (21.5)	4 (10.8)	8 (21.1)	12 (16.0)
Missing	2	1	3	4	3	7
<b>Diastolic blood pressure, mmHg</b>						
Missing	2	1	3	4	3	7
Mean (sd)	78.7 (10.93)	77.7 (11.56)	78.2 (11.19)	76.3 (9.89)	74.6 (10.50)	75.4 (10.17)
95% CI	(75.15, 82.23)	(73.98, 81.37)	(75.67, 80.68)	(72.97, 79.57)	(71.18, 78.08)	(73.10, 77.78)
<b>Diastolic blood pressure category</b>						
<80 mmHg	20 (51.3)	27 (67.5)	47 (59.5)	24 (64.9)	24 (63.2)	48 (64.0)
≥80 mmHg	19 (48.7)	13 (32.5)	32 (40.5)	13 (35.1)	14 (36.8)	27 (36.0)
Missing	2	1	3	4	3	7
<b>Waist measurement, cm</b>						
Missing	1	6	7	5	2	7
Mean (sd)	112.5 (17.74)	109.2 (16.58)	110.9 (17.17)	113.0 (18.97)	109.2 (15.91)	111.0 (17.43)
95% CI	(106.8, 118.1)	(103.5, 114.9)	(107.0, 114.9)	(106.6, 119.4)	(104.0, 114.3)	(107.0, 115.0)
<b>Waist circumference and risk of metabolic complications<sup>†</sup>, n (%)</b>						
Not at increased risk	4 (10.0)	3 (8.6)	7 (9.3)	3 (8.3)	3 (7.7)	6 (8.0)
Increased risk	3 (7.5)	3 (8.6)	6 (8.0)	3 (8.3)	4 (10.3)	7 (9.3)
Substantially increased risk	33 (82.5)	29 (82.9)	62 (82.7)	30 (83.3)	32 (82.1)	62 (82.7)
Missing	1	6	7	5	2	7
<b>Waist–hip ratio</b>						
Missing	1	6	7	5	2	7
Mean (sd)	0.93 (0.11)	0.92 (0.21)	0.93 (0.16)	0.96 (0.07)	0.93 (0.07)	0.94 (0.07)
95% CI	(0.90, 0.97)	(0.85, 0.99)	(0.89, 0.96)	(0.94, 0.98)	(0.91, 0.95)	(0.93, 0.96)
<b>Waist: hip ratio and risk of metabolic complications<sup>‡</sup>, n (%)</b>						
Not at increased risk	7 (17.5)	8 (22.9)	15 (20.0)	3 (8.3)	5 (12.8)	8 (10.7)
Substantially increased risk	33 (82.5)	27 (77.1)	60 (80.0)	33 (91.7)	34 (87.2)	67 (89.3)
Missing	1	6	7	5	2	7



Table 4 (Continued)

	Baseline Supported self-management N=41	Treatment as usual N=41	Total N=82	Follow-up Supported self-management N=41	Treatment as usual N=41	Total N=82
<b>Total cholesterol, mmol/l</b>						
Missing	5	2	7	5	4	9
Mean (SD)	4.0 (0.85)	4.2 (1.06)	4.1 (0.96)	3.8 (0.90)	4.1 (1.07)	4.0 (0.99)
95% CI	(3.76, 4.33)	(3.84, 4.53)	(3.90, 4.34)	(3.52, 4.13)	(3.77, 4.48)	(3.75, 4.21)
<b>Total cholesterol, n (%)</b>						
<4 mmol/l	17 (47.2)	19 (48.7)	36 (48.0)	21 (58.3)	18 (48.6)	39 (53.4)
≥4 mmol/l	19 (52.8)	20 (51.3)	39 (52.0)	15 (41.7)	19 (51.4)	34 (46.6)
Missing	5	2	7	5	4	9
<b>Triglycerides, mmol/l</b>						
Missing	6	6	12	6	6	12
Mean (SD)	2.0 (1.15)	2.2 (1.36)	2.1 (1.25)	1.9 (1.04)	2.0 (1.12)	2.0 (1.07)
95% CI	(1.65, 2.44)	(1.68, 2.62)	(1.80, 2.40)	(1.58, 2.29)	(1.60, 2.37)	(1.71, 2.22)
<b>Triglycerides category<sup>†</sup>, n (%)</b>						
<4.5 mmol/l	33 (94.3)	33 (94.3)	66 (94.3)	34 (97.1)	34 (97.1)	68 (97.1)
4.5–9.9 mmol/l	2 (5.7)	2 (5.7)	4 (5.7)	1 (2.9)	1 (2.9)	2 (2.9)
Missing	6	6	12	6	6	12
<b>eGFR, ml/min/1.73 m<sup>2</sup></b>						
Missing	9	5	14	6	5	11
Number known only to be >90	17 <sup>§</sup>	23	40 <sup>§</sup>	22	23	45
Mean (SD)	67.3 (18.84)	66.5 (16.47)	66.9 (17.46)	68.4 (17.56)	69.1 (17.78)	68.7 (17.32)
95% CI	(56.83, 77.70)	(56.59, 76.49)	(60.16, 73.70)	(57.77, 79.00)	(58.33, 79.82)	(61.74, 75.73)
<b>eGFR category, n (%)</b>						
Normal kidney function: ≥90 ml/min/1.73 m <sup>2</sup>	20 (62.5)	23 (63.9)	43 (63.2)	22 (62.9)	23 (63.9)	45 (63.4)
Mildly reduced kidney function: 60–89 ml/min/1.73 m <sup>2</sup>	6 (18.8)	10 (27.8)	16 (23.5)	8 (22.9)	10 (27.8)	18 (25.4)
Moderately reduced kidney function: 30–59 ml/min/1.73 m <sup>2</sup>	6 (18.8)	3 (8.3)	9 (13.2)	5 (14.3)	2 (5.6)	7 (9.9)
Severely reduced kidney function: <30 ml/min/1.73 m <sup>2</sup>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	1 (1.4)
Missing	9	5	14	6	5	11
<b>Urea, mmol/l</b>						
Missing	9	3	12	8	6	14
Mean (SD)	6.0 (1.85)	6.2 (1.81)	6.1 (1.81)	6.1 (1.66)	6.0 (1.73)	6.1 (1.68)
95% CI	(5.33, 6.66)	(5.59, 6.78)	(5.66, 6.53)	(5.53, 6.71)	(5.40, 6.58)	(5.65, 6.46)
<b>Creatinine, µmol/l</b>						
Missing	8	3	11	4	0	4
Mean (SD)	73.7 (24.49)	66.8 (24.02)	70.0 (24.32)	70.1 (24.89)	67.7 (26.64)	68.8 (25.68)
95% CI	(65.01, 82.38)	(58.89, 74.68)	(64.24, 75.76)	(61.78, 78.38)	(59.30, 76.11)	(63.04, 74.62)

eGFR, estimated GFR.

\*There were more missing data for weight compared to BMI as where possible BMI (but not weight) was collected from the general practitioner where weight was not obtained at research visits.

<sup>†</sup>Waist circumference and risk of metabolic complications: not at increased risk: ≤94 cm (men), ≤80 cm (women); increased risk: >94 cm (men), >80 cm (women); substantially increased risk: >102 cm (men), >88 cm (women).

<sup>‡</sup>Waist–hip ratio and risk of metabolic complications: not at increased risk: <90 cm (men), <85 cm (women); substantially increased risk: ≥90 cm (men), ≥85 cm (women).

<sup>§</sup>Reported eGFR was ≥90 ml/min/1.73 m<sup>2</sup> for a further three participants in the supported self-management arm.

<sup>¶</sup>UK National Institute for Health and Care Excellence: Clinical Guideline CG181.

Table 5. Major depression (score ≥3) was indicated for 17/70 participants (24%) at baseline, and 21/59 participants (36%) at follow-up. Participants expressed difficulty answering the PHQ-2 questions, with just under 50% reporting some or extreme difficulty, those who found the questions most difficult were no more likely to rate above the threshold for likely major depressive disorder (≥3).

We were able to obtain results from the three-level health-related quality-of-life instrument, the EQ5D-3L, on 80 participants at baseline and 76 at follow-up (Table 6).

### Safety

Unplanned hospital attendances were identified by the research team for 10 participants (12%): four participants

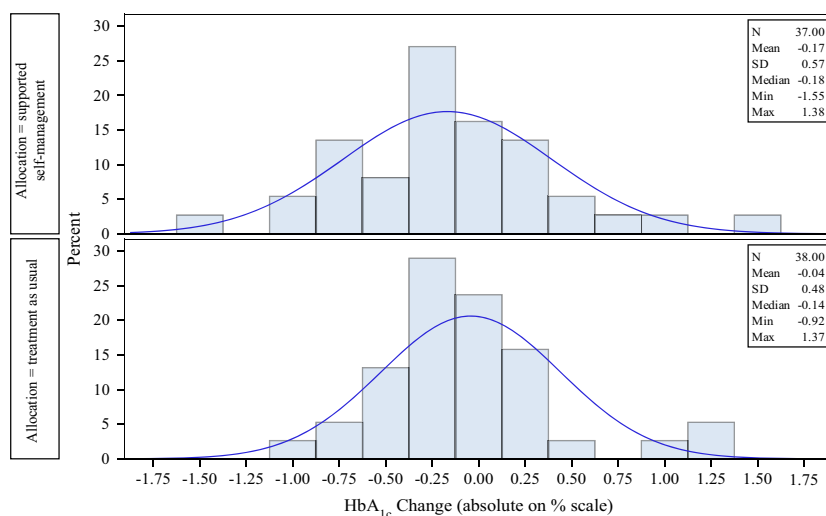


FIGURE 2 Distribution of change in HbA<sub>1c</sub> by allocation.

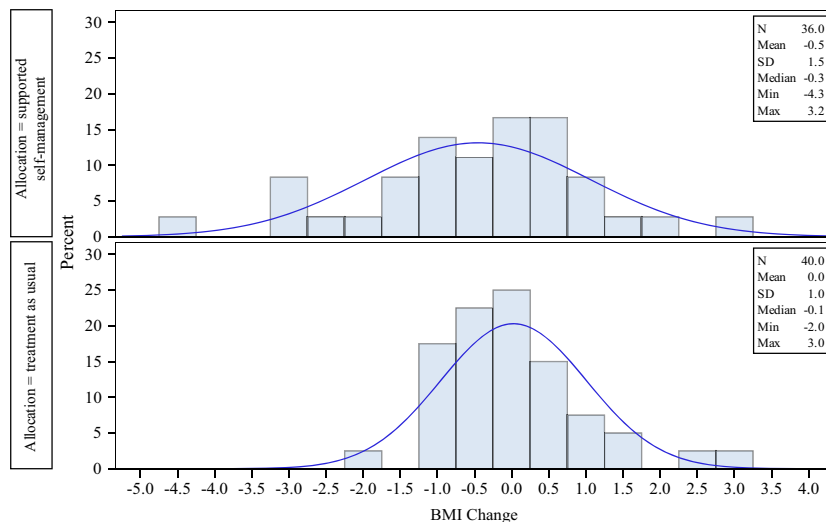


FIGURE 3 Distribution of change in BMI by allocation.

receiving supported self-management and six participants receiving treatment as usual. Hospital attendance (Accident and Emergency department attendance or admission) was reported by the participant's GP for 12/66 participants (18%); seven allocated to supported self-management and five to treatment as usual. Of 66 participants, six (9%) had attendances for non-diabetes physical illness, and one participant with a previous psychiatric history had an attendance for mental illness. On two occasions, nurses were sufficiently concerned about the mental state of participants to discuss the problem in supervision and subsequently to contact the GP, both of whom were already in contact with mental health services.

There was no report from either researchers or GPs indicating that hospital contacts were attributable to

changes brought about either by research participation or by exposure to the supported self-management intervention. Participant qualitative interviews confirmed the opinion that there were no untoward outcomes associated with the intervention; participants were clear that they did not regard contact with researchers or nurses as a stressor.

The participant advocacy service did not give us details of individuals but told us they had received fewer than six contacts and all were requests about changing appointment times for research or nurse visits.

## Discussion

We found that it was possible to identify eligible participants in the target population and recruit them into the trial.

**Table 5** Participant mood, assessed using the Patient Health Questionnaire-2

	Baseline			Follow-up		
	Supported self-management N=41	Treatment as usual N=41	Total N=82	Supported self-management N=41	Treatment as usual N=41	Total N=82
<b>Little interest or pleasure doing things, n (%)</b>						
Not at all	27 (65.9)	28 (68.3)	55 (67.1)	22 (59.5)	33 (86.8)	55 (73.3)
Several days	9 (22.0)	9 (22.0)	18 (22.0)	10 (27.0)	2 (5.3)	12 (16.0)
More than half the days	3 (7.3)	3 (7.3)	6 (7.3)	1 (2.7)	0 (0.0)	1 (1.3)
Nearly every day	2 (4.9)	1 (2.4)	3 (3.7)	4 (10.8)	3 (7.9)	7 (9.3)
Missing	0	0	0	4	3	7
<b>Feel down, depressed, n (%)</b>						
Not at all	11 (32.4)	15 (41.7)	26 (37.1)	8 (26.7)	18 (60.0)	26 (43.3)
Several days	15 (44.1)	15 (41.7)	30 (42.9)	7 (23.3)	6 (20.0)	13 (21.7)
More than half the days	3 (8.8)	3 (8.3)	6 (8.6)	5 (16.7)	2 (6.7)	7 (11.7)
Nearly every day	5 (14.7)	3 (8.3)	8 (11.4)	10 (33.3)	4 (13.3)	14 (23.3)
Missing	7	5	12	11	11	22
<b>PHQ-2 Score, n (%)</b>						
Missing	7	5	12	11	12	23
Mean (sd)	1.7 (1.66)	1.3 (1.51)	1.5 (1.59)	2.4 (1.87)	1.1 (1.80)	1.7 (1.93)
Median (range)	1.0 (0, 6)	1.0 (0, 6)	1.0 (0, 6)	2.5 (0, 6)	0.0 (0, 6)	1.0 (0, 6)
<b>PHQ-2 score: major depression, n (%)</b>						
Not indicated (<3)	24 (70.6)	29 (80.6)	53 (75.7)	15 (50.0)	23 (79.3)	38 (64.4)
Indicated (≥3)	10 (29.4)	7 (19.4)	17 (24.3)	15 (50.0)	6 (20.7)	21 (35.6%)
Missing	7	5	12	11	12	23
<b>Difficult answering PHQ-2, n (%)</b>						
No difficulty	24 (60.0)	23 (56.1)	47 (58.0)	20 (54.1)	19 (50.0)	39 (52.0)
Some difficulty	15 (37.5)	17 (41.5)	32 (39.5)	16 (43.2)	13 (34.2)	29 (38.7)
Extreme difficulty	1 (2.5)	1 (2.4)	2 (2.5)	1 (2.7)	6 (15.8)	7 (9.3)
Missing	1	0	1	4	3	7

PHQ-2, Patient Health Questionnaire-2.

Retention was excellent, with 85% of participants completing all intervention sessions and candidate primary outcomes obtained in >90%. Furthermore, our concerns that many participants would not allow blood samples to be taken were unfounded. Conducting blood tests proved a time-efficient method in comparison to seeking medical record information from a participant's GP, which is a reflection of the number of contact attempts, low response rates and high levels of missing data from GPs, despite a large amount of researcher time spent contacting practices.

Our researchers and nurses were able to work effectively with adults with a mild to moderate intellectual disability despite not having previous experience in this area. By working with a professional, accessible information organization and

our Patient and Public Involvement collaborators, we were able to create accessible materials for information that facilitated informed consent to a trial, and supported the research process.

Obesity was a major problem, and was coupled with low levels of self-reported physical activity. Given these findings, glycaemic control was not as poor as we had expected. Many of our participants reported dissatisfaction with their diet and their weight, and it may be that this was an important part of their expressed desire for help with their diabetes management.

This is the largest published trial of supported self-management for Type 2 diabetes in adults with an intellectual disability. Participants were typical of those identified in our initial case-finding study [22], and also (as far as we can ascertain from published figures) of the wider population with Type 2 diabetes and intellectual disability. Our choice of diabetes nurses as therapists increases the prospects for generalizability of our findings; in routine practice, adults with milder intellectual disabilities are rarely seen in specialist learning disability services. Unblinding of research outcome assessment was high but, given the nature of the candidate primary outcomes (BMI, HbA<sub>1c</sub>), was unlikely to be a source of significant bias.

There were a number of limitations to the study. The exclusion of people on insulin treatment was part of the

**Table 6** Three-level health-related quality-of-life instrument, EQ-5D-3L, at baseline and follow up

	Baseline N=82	Follow-up N=82
<b>EQ-5D-3L score</b>		
Missing	2	6
Mean (sd)	0.67 (0.288)	0.66 (0.346)
Median (range)	0.73 (0.24, 1)	0.79 (0.24, 1)
Interquartile range	(0.60–0.85)	(0.43–1)

funder's commissioning brief, but in retrospect led to the omission of a substantial proportion of the target population with the worst glycaemic control and therefore potentially the most to gain from an intervention.

It also proved more difficult than anticipated to obtain the sustained participation of key supporters. Although most participants could name a supporter, in only a minority did that person have regular, engaged involvement with the intervention. A familiar scenario was the participant living in a shared house with other adults with an intellectual disability and paid staff providing support; supporters then changed day-by-day according to shifts or the use of agency staff.

Characterizing usual care was problematic. Informal supportive contacts in primary care, where most support for Type 2 diabetes occurs, are unlikely to be recorded and recollection of our participants was unlikely to be robust enough for research purposes.

Two further limitations were specific to the intervention. One is the number of face-to-face sessions involved. Recent reviews suggest that the number of sessions/hours of personal contact is an important determinant of success in changing risks for diabetes onset or cardiovascular disease [26–30]. Effective interventions for adults with an intellectual disability probably involve more therapeutic contact than is usual in standard approaches to self-management, and more than we offered in the present trial, even though, with a planned four sessions, our intervention involved more contact than is available in many self-management programmes. The second characteristic of our intervention was its emphasis on diabetes self-management in a broadly defined sense rather than specifically on weight reduction through a calorie-deficit diet. Given the centrality of obesity to Type 2 diabetes and its very high prevalence in our population this may have been a limitation

A clinically important reduction in HbA<sub>1c</sub> is usually taken to be 5 mmol/mol (0.5%) which is equivalent to an effect size of 0.3 (based on our SD of 16.5). For a definitive trial to have 90% power (two-sided  $\alpha = 0.05$ ), a sample size of 194 per arm would be required after accounting for loss to follow-up and potential clustering. An alternative approach may be to focus research on establishing the effectiveness of treatments that reduce obesity and target the high levels of sedentary behaviour in this group.

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#### Competing interests

None declared.

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## Supporting Information

Additional Supporting Information may be found in the online version of this article:

**Appendix S1.** Form used with participants to explain randomization in the RCT.

**Appendix S2.** Form used with participants to obtain consent for research participation