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Pilot feasibility study examining a structured self-management diabetes education programme, DESMOND-ID, targeting HbA_{1c} in adults with intellectual disabilities

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Abstract

Aim To report on the outcomes of a pilot feasibility study of a structured self-management diabetes education programme targeting HbA_{1c}.

Methods We conducted a two-arm, individually randomized, pilot superiority trial for adults with intellectual disability and Type 2 diabetes mellitus. A total of 66 adults with disabilities across the UK met the eligibility criteria. Of these, 39 agreed to participate and were randomly assigned to either the DESMOND-ID programme (n = 19) or a control group (n = 20). The programme consisted of seven weekly educational sessions. The primary outcome was HbA_{1c} level, and secondary outcomes included BMI, diabetes illness perceptions, severity of diabetes, quality of life, and attendance rates.

Results This study found that the DESMOND-ID programme was feasible to deliver. With reasonable adjustments, the participants could be recruited successfully, and could provide consent, complete the outcome measures, be randomized to the groups and attend most of the sessions, with minimal loss to follow-up. The fixed-effects model, the interaction between occasion (time) and condition, showed statistically significant results (0.05 level) for HbA_{1c}; however, the CI was large.

Conclusion This is the first published study to adapt and pilot a national structured self-management diabetes education programme for adults with intellectual disability. This study shows it is possible to identify, recruit, consent and randomize adults with intellectual disabilities to an intervention or control group. Internationally, the results of this pilot are promising, demonstrating that a multi-session education programme is acceptable and feasible to deliver. Its effectiveness should be further tested in an adequately powered trial.

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Introduction

Diabetes mellitus affects approximately one in 20 people across Europe [1]. According to the WHO (2016), rates of diabetes worldwide will increase from 177 million in 2000 to 366 million by 2030, a global prevalence rate of 6.3%. Blindness, renal failure, amputation and cardiovascular problems (stroke and myocardial infarction) are key complications of poorly controlled Type 2 diabetes, leading to premature death.

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In two recent systematic reviews, the prevalence rates of Type 2 diabetes in people with intellectual disabilities were higher than in people without disabilities, and were reported to be between 8.3% and 8.7% [2,3]. The reasons for such higher estimates are based on the increasing life expectancy of this population, and people with intellectual disabilities leading a more sedentary lifestyle, undertaking low levels of exercise, consuming high-fat diets and being prescribed high levels of anti-psychotic medications, all of which can contribute to obesity [4–6].

A number of studies have reported that diabetes management for people with intellectual disability and Type 2

What's new?

- No study has previously used a theoretically driven, evidence-based structured education programme specifically adapted to address diabetes self-management for adults with intellectual disability and Type 2 diabetes, and their carers.
- The present pilot study examined the feasibility of a structured education programme, DESMOND-ID, to improve diabetes self-management in this population.
- Although people with intellectual disability have previously been identified as a 'hard-to-reach' population, this study shows that it is possible to identify, recruit and obtain consent from adults with a mild to moderate intellectual disability to take part in an intervention study.

diabetes is poor [7,8]. A study in Northern Ireland by Taggart *et al*. [8] showed that many people with intellectual disability did not have an annual review of HbA_{1c} levels, cholesterol levels, blood pressure, BMI or microalbuminuria, and found low levels of diabetic retinopathy screening, all conditions that are routinely assessed for change and management review [8]. On average, people with intellectual disabilities have fewer opportunities to actively engage in diabetes self-management education programmes that are routinely offered to people without disabilities [4].

Self-management of diabetes is recommended by health services across the world for people without disabilities [1]. People with diabetes are encouraged, where possible, to attend structured self-management education programmes, such as Dose Adjustment for Normal Eating (DAFNE) for adults with Type 1 diabetes (www.dafne.uk.com) or DESMOND for adults with Type 2 diabetes (www.desmond-project.org.uk); however, neither are routinely offered to people with intellectual disability at a level that is appropriate to their needs [9].

To date, no study has examined the effectiveness and acceptability of structured diabetes education programmes for adults with intellectual disabilities and Type 2 diabetes and their family/paid carers. The aims of the present study, therefore, were: 1) to explore the feasibility of a 7-week adapted structured diabetes self-management education programme for people with diabetes and intellectual disability; 2) to assess eligibility, rate of consent, randomization, recruitment process, attendance levels and loss to follow-up of adults with intellectual disabilities and their carers; 3) to determine the appropriateness and the acceptability of the proposed outcome measures; and 4) to measure the fidelity of delivery of the education programme.

Participants and methods

The present study was a two-arm, individually randomized, pilot superiority trial for adults with intellectual disability and Type 2 diabetes, and their carers. The study protocol has been published previously [11]. The participants were recruited from their local communities in three UK countries (Northern Ireland, Scotland and Wales).

Intellectual disability is a disorder with genetic, biological and psycho-social aetiologies, which manifest in cognitive impairment (attention and memory deficits; difficulties in processing information, perception, reasoning, problem-solving, self-monitoring and self-awareness; limited comprehension), communication difficulties and problems with adaptive functioning (self-care, domestic skills, social skills, self-direction, community, academic skills, work, leisure, health and safety). There are different levels of intellectual disability (mild, moderate, severe and profound), some people will therefore need a lot of help in their adaptive functioning and daily lives, while others need less support and are more independent.

The eligibility criteria were: age $\geq$ 18 years; living in the community; mild/moderate intellectual disability and Type 2 diabetes, as identified in their clinical notes by the community team and/or general practioner; sufficient communication skills to participate; and the capacity to consent. The definition of a family or paid carer was either a family relative or residential member of staff who engages in the support of the person with intellectual disabilities.

Recruitment occurred between November 2014 and February 2015, and a range of approaches was used to identify potential participants. The primary sources of recruitment were intellectual disability statutory services (community nursing/social work teams, day centres and residential providers), general practices and diabetes clinics. We had already established relationships with the three health organizations and key personnel in each of the countries from an earlier diabetes study. This aided the research team in identifying 89 adults with intellectual disability and Type 2 diabetes; however, some of the participants were unable to travel to the intervention site if randomized, and they were therefore excluded (25.8%). Funding for participants' travel by taxi to participate in the intervention had not been allowed for in the research budget. This was an important learning point arising from this study.

Procedure

Potential participants with intellectual disabilities were screened for eligibility by the primary healthcare team or community team, who provided them with a user-friendly information sheet and consent form. Both forms were developed in consultation with a user group of adults with intellectual disabilities. After consent to participate had been

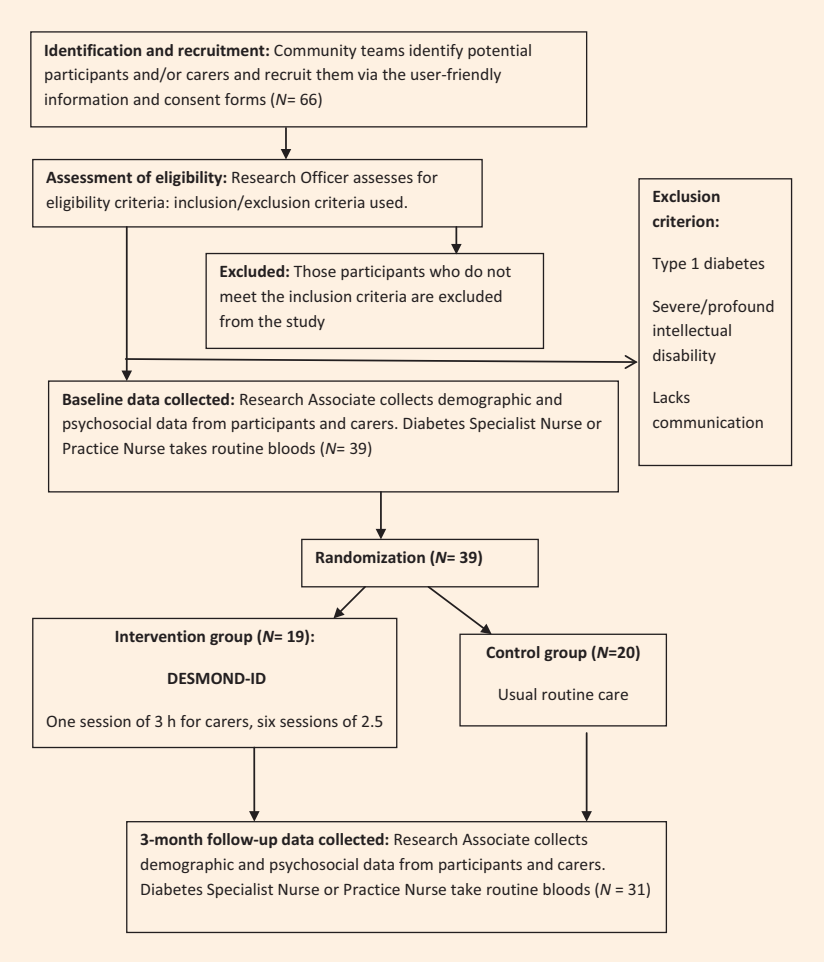

FIGURE 1 Flow chart of the study protocol.

obtained from those screened, the research team contacted the participant and their carer to arrange baseline metabolic and cardiovascular data collection. In addition, participants were asked to complete three standardized questionnaires made up of instruments, validated from the mainstream diabetes population, that explored their severity and perceptions of diabetes illness and quality of life [12–14]. These same assessments were administered 12 weeks after the intervention.

Out of 66 eligible participants with intellectual disabilities, 39 were recruited and assigned to one of two study arms using a computerized random allocation system [RALLOC module within STATA 13 (StataCorp LP, London, UK)] with concealment allocation (Fig. 1). Of the 27 participants who did not participate in the pilot study, the majority refused to consent because the intervention was on the same day as another activity, they were unwell or they lived in the same residential facility. For the 39 who were included in the pilot study, details of each participant and their carer were forwarded to a research secretary at Ulster University, who was not connected to the study.

Measures

Demographic details were collated, including age, gender, level of intellectual disability, marital status, living arrangements, carer details, diabetes duration and diabetes management treatment. Metabolic and cardiovascular measures were collected at assessment and 12-week follow-up (HbA_{1c} and BMI). The primary outcome measure was HbA_{1c} level.

Three standardized measures were used. The Illness Perception Questionnaire-Revised (IPQ) [12] was used to examine the participants' understanding of diabetes (illness coherence score), perception of the duration of their illness (timeline score) and the perception of their ability to affect the course of their diabetes (personal responsibility score). The Diabetes Illness Representation Questionnaire (DIRQ) [13] was used to examine the participants' perceptions about the seriousness and impact of diabetes. The WHO quality of life questionnaire (WHOQOL-BREF) [14] is a short version of a measure of general quality of life, developed by the WHO simultaneously in 17 different countries to ensure cultural comparability and generalizability. This

questionnaire generates a general health score and four domain scores: physical, psychological, social and environmental quality of life.

The reliability and validity of the IPQ and DIRQ have been reported to be strong with people without disabilities; however, no study has examined the psychometric properties of these two scales with regard to adults with intellectual disabilities. The reliability and validity of the WHOQOL-BREF scale has been reported to be strong with people with and without intellectual disabilities [15].

The IPQ and DIRQ required adaptation to make them accessible to this population of adults with a mild to moderate intellectual disability. First a consultation group was formed with academic and clinical staff to discuss and refine the wording of each item of the two scales into a conceptual and linguistic form accessible to adults with cognitive impairments. Each item was then adjusted in such a manner as to keep the same meaning, but to simplify the grammatical structure and to present the response scales in a less abstract manner supported by pictorial cues. A reference group of adults with intellectual disabilities with Type 2 diabetes was also shown the scales and some of the items/statements were further amended, making them easier to understand, and pictures/symbols were used alongside the Likert ratings. The research team supported the person with the intellectual disability by reading the instructions and items aloud if needed.

Intervention

The DESMOND-ID programme was adapted from the original DESMOND programme (Diabetes and Self-Management for Ongoing and Newly Diagnosed for patients with Type 2 diabetes: http://www.desmond-project.org.uk/about.html), which provided theoretically based structured education to support adults with Type 2 diabetes to self-manage their condition. The original DESMOND education programme has been shown to be robust and effective for those with Type 2 diabetes [18–22].

The DESMOND-ID programme was delivered in a community setting over 6 weeks, with one session per week, each lasting ~2.5 h, to the participants with intellectual disabilities and their carers. The DESMOND-ID programme has an additional, separate introductory education session that was aimed at, and held separately for, family/paid carers to support their understanding of diabetes and how it is managed. Carers gained an understanding of how the DESMOND-ID programme works and their specific role in supporting the person with disability throughout the programme.

Each participant with intellectual disabilities and their carer (if appropriate) were encouraged to attend the 6-week sessions together. The education sessions were delivered by two educators in each country, who received 2 days' standardized training, described as the DESMOND core training, which covers a range of topics including patient philosophy, theories of learning and supporting behaviour change, as well as 1 day of training in the delivery of DESMOND-ID programme. The educator team comprised three community intellectual disability nurses, two diabetes specialist nurses and one intellectual disability health facilitator.

The education intervention is founded on concepts of self-management and empowerment, and covered a range of topics (Table 1). Each of the education sessions comprised two 30–45-min sections, with a break in the middle for refreshments. Previous work has shown that flexibility is

Table 1 Curriculum of DESMOND-ID programme

DESMOND-ID sessions	Outline of session
Part one: Carer session	
	What are DESMOND and the DESMOND-ID programmes?
	What is Type 2 diabetes?
	Break
	Having a go (practical activities)
	Carers role: what can I do?
	Questions
Part two: The participant course	
Session 1	Welcome and introductions
	My story with diabetes (part 1)
	My body and diabetes
	Break
	What is diabetes?
	What did I learn today and preparing for next week?
Session 2	Welcome back
	My story with diabetes (part 2)
	What diabetes does to your body?
	Break
	Food and blood sugar
	What did I learn today?
Session 3	Welcome back
	Knowing what your blood sugar levels mean
	Break
	Being active
	What did l learn today?
Session 4	Welcome back
	Heart and circulation problems: what can I do to keep healthy (part 1)
	Break
	Other diabetes health problems: what can I do to keep healthy (part 2)
	What did I learn today?
Session 5	Welcome back
	Food and fats
	Break
	Making healthier food choices
	What did I learn today?
Session 6	Welcome back
	Diabetes health action plan: what will I work on?
	Break
	Keeping my plan going
	Important questions and celebration of achievement

required in delivery and timing of the education sessions to meet individuals' concentration levels and learning needs [8].

Control group

Participants with intellectual disabilities and their carers who were randomly allocated to the control group received usual routine care; they were not offered any form of structured education. Routine care normally included health centre visits every 3 months in which the person with diabetes and disabilities met with their primary healthcare team. All those in the control group completed the data-gathering instruments at baseline and at 12-week follow-up.

Intervention vs control

Nineteen of the participants were randomly allocated to the intervention group and the other 20 participants were allocated to the control group. A total of 12 carers supported participants in the intervention group and 15 carers supported participants in the control group.

Statistical analyses

An examination was made of the descriptive data obtained and exploratory multi-level analysis was conducted on the data. The demographic characteristics of the sample were described as mean (SD) values if continuous, and counts and percentages if categorical. The attendance rate was summarized for the 7 weeks of the intervention and the 12-week follow-up period as mean (SD) number of sessions attended.

A series of repeated measures was undertaken to examine if there were significant differences between the intervention and the control groups at baseline and at follow-up on the metabolic measures (HbA_{1c}, BMI), and psychological measures (IPQ, DIRQ and WHOQOL-BREF) at baseline and 12-week follow-up, within the context of data collected from three sites (Northern Ireland, Scotland and Wales). There were eight individuals without an HbA_{1c} reading on the second occasion. These individuals were included within the analysis under the assumption that they were missing at random, the default in the mixed models option in SPSS. A linear mixed model with measures at two points in time was used. An interaction between time and conditions was created, with an auto-regressive error structure (AR1). Time, condition and site were all fixed effects within the model.

Process evaluation analysis

Using the updated Medical Research Council guidelines for process evaluation [16,17], focus groups with the adults with intellectual disabilities and their carers, and a series of one-to-one interviews with the six educators were conducted in each of the three countries focusing on implementation, mechanisms and context. We explored the identification and recruitment of the participants, outcome measures, the randomization process, training of educators, the DESMOND-ID curriculum and resources, retention and drop-out. These were documented by the researchers and reviewed by the Steering Committee members to inform adaptations to the protocol to enable a realistic definitive randomized controlled trial to be conducted in the future.

Fidelity

As only three complete intervention programmes were delivered as part of the feasibility pilot, intervention fidelity aimed to explore the effect of training on the facilitators' ability to deliver sessions, while keeping aligned to the programme's philosophical foundation and in accordance with its theoretical basis. Educators were encouraged to undertake personal and peer reflections after each session, using tools developed as part of the original DESMOND programme. One session at each site was observed by a member of the research team. Additionally, a focus group with the educators was conducted as part of a feedback day after the research.

As the approach to delivery used in this intervention was novel and unfamiliar to the novice educators, unsurprisingly, they demonstrated the need for further training and mentorship to support skills development; however, they also communicated a high degree of acceptability and satisfaction with their role, which is promising for further testing of the intervention. As the intervention was being delivered for the first time under formal conditions and the sample size was consequently small, it was neither possible, nor intended, to define the number of sessions which would indicate criteria for intervention completers.

Ethics

Ethical approval was received by the Office for Research Ethics Northern Ireland, and research governance was obtained from all health participating health boards. Verbal and/or written consent was obtained from the adults with intellectual disability and from their carers prior to study commencement.

Results

Demographics

Participants had a mean (range) age of 54.7 (35–75) years and 56.4% were women. Most participants were reported by the community teams to have a mild intellectual disability; the others had a moderate disability. More than three-quarters (76.9%) lived in their own accommodation, 17.9% lived within supported accommodation, 5.1% lived within their family home. A total of 23% of participants were

Table 2 Outcomes at baseline and follow-up for intervention and control

	Intervention group		Control group	
	Time 1	Time 2	Time 1	Time 2
HbA_{1c}				
mmol/mol	66 (23)	57 (18)	61 (15)	65 (17)
%	8	7.5	7.7	8
	N = 16	*N* = 16	*N* = 15	*N* = 15
BMI, kg/m^2	30.63 (4.97)	30.4 (4.51)	37.30 (5.81)	37.57 (6.33)
	N = 13	N = 13	*N* = 14	*N* = 14
IPQ score				
Coherence	12.5 (2.5)	15.56 (3.72)	13.95 (3.57)	13.95 (3.5)
	N = 16	*N* = 16	*N* = 19	*N* = 19
Timeline	16.25 (2.57)	17.94 (2.38)	17.32 (2.38)	17.11 (1.91)
	N = 16	*N* = 16	*N* = 19	*N* = 19
Responsibility	14.94 (3.3)	14.56 (1.63)	14.79 (2.02)	14.47 (1.58)
	N = 16	*N* = 16	*N* = 19	*N* = 19
DIRQ score				
Seriousness	16.25 (2.65)	16.88 (1.82)	16.11 (2.23)	15.79 (2.25)
	N = 16	*N* = 16	*N* = 19	*N* = 19
Impact	24.69 (3.95)	24.87 (3.16)	24.06 (5.72)	23.11 (5.06)
	N = 16	*N* = 16	*N* = 18	*N* = 18
WHOQOL-BREF score				
General	7.63 (1.93)	7.88 (1.54)	7 (2.36)	7.74 (2.38)
	N = 16	*N* = 16	*N* = 19	*N* = 19
Physical	25.94 (3.87)	29 (2.53)	26.05 (5.93)	25.63 (6.23)
	N = 16	*N* = 16	*N* = 19	*N* = 19
Psychological	21.94 (3.04)	23.63 (2.99)	22.58 (3.52)	22.42 (3.76)
	N = 16	*N* = 16	*N* = 19	*N* = 19
Environmental	31.44 (4.43)	20.13 (3.1)	31.11 (5.47)	18.89 (3.48)
	N = 16	*N* = 16	*N* = 19	*N* = 19
Social	12.13 (1.86)	12.13 (2.34)	12.22 (2.07)	12.33 (1.68)
	N = 16	*N* = 16	*N* = 18	*N* = 18

IPQ, Illness Perception Questionnaire-Revised; DIRQ, Diabetes Illness Representation Questionnaire; WHOQOL-BREF, WHO quality of life questionnaire.
Values are mean (SD).

supported by a family carer, 46% were supported by a paid carer and 31% participants lived independently.

Recruitment and retention

A total of 66 adults with disabilities across the three countries met the inclusion criteria, of whom 39 agreed to participate in the study (consent rate of 59%). Of the 19 participants with disabilities allocated to the intervention group, 90% attended between four and six sessions, and 94% of the carers attended between six and seven sessions.

Biomedical outcomes at baseline and 12-week follow-up

An exploratory multi-level analysis within the mixed-models option in SPSS was undertaken to examine time, intervention condition and study site. Based on the results from a fixed-effects model the interaction between occasion (time) and condition, the result for HbA_{1c} was statistically significant at the 5% level [F (1, 31.66.07) = 4.79, $P = 0.04$, effect size = 15.19, 95% CI 1.04, 29.34]. The mean HbA_{1c} scores by site showed no difference, and the intra-class correlation was zero.

In terms of BMI, the interaction between condition and time was not statistically significant [F (1, 34.24) = 0.02, $P = 0.89$, estimate = 42.86, 95% CI −39.59, 45.31]. Respondents in Scotland had a higher mean BMI than those in Northern Ireland. No other mean comparisons between the sites were statistically significant.

Psychosocial outcomes at baseline and 12-week follow-up

With regard to the participants' IPQ scores, those in the intervention group obtained a higher score on the second occasion on the coherence measure (Table 2). In the formal test this indicated the shift was statistically significant [F (1, 33.26) = 0.50, $P = 0.00$, effect size = −3.37, 95% CI −5.59, −1.16]. Site was not statistically significant (0.05 level); however, the timeline measure was statistically significant [F (1, 30.23) = 5.04, $P = 0.03$, effect size = −3.13, 95% CI −4.07, −0.19]. Respondents in Scotland had a higher mean score than those in Wales; no other differences were significant at the 5% level. In terms of the measure of responsibility, both means decreased in value in a parallel manner on the second occasion, resulting in no difference (0.05 level) in terms of the interaction [F (1, 28.21) = 0.35,

Table 3 Themes from the focus groups with the participants with intellectual disabilities and carers

Themes	Adults with intellectual disabilities	Carers
User-friendly content and delivery of the programme	'It was very good because you can understand it better.' 'I felt it was a lot helpful for me with my diabetes.'	'I think it accessible to our clients and there was the right level of information.' 'What I did like was the repetition going over what was done in the previous week so it was solidifying and giving them (participants) a foundation and as more information came in it was building upon that rather than having all this information thrown at you.'
Knowledge and skills of the educators		'I think the educators blew me away with their knowledge and how they delivered the programme and the comradery amongst the group. The group coming together for a common purpose and common illness and being open and honest about it.' 'When the educator was talking, she was cutting it down to different levels so I could understand it better.'
Support of the carers	'Having my carer along with me helped me to buy the right foods'.	'It was good to meet other carers and share our similar experiences about managing their diabetes at home'.
Social aspect	'Making new friends'.	'We all got on as a group and enjoyed the craic.'
Difficulties in understanding significance of fat and carbohydrates	'The big words like carbohydrates I couldn't get the sense of it. They explained it but then I'd forget. If I keep on looking at my book I would remember.' 'The only thing I couldn't understand was the session on the fats.'	

$P = 0.56$, effect size = −0.63, 95% CI −2.81, 1.55). There was a site difference with the scores for those in Northern Ireland being higher (statistically at the 0.05 level) than those in Scotland.

Examining the participants' DIRQ scores, the baseline scores were similar in the two groups in terms of the measures for both seriousness and impact. The interaction between seriousness and condition was not statistically significant [F (1, 31.74) = 2.77, $P = 0.11$, effect size = −1.11, 95% CI −2.44 0.25). Respondents from Scotland had a statistically (0.05 level) higher score than individuals in Wales. The results from the impact measure also indicated that the interaction between time and condition was not statistically significant [F (1, 29.41) = 1.75, $P = 0.20$, effect size = −1.56, 95% CI −3.97 0.85]. Respondents in Scotland had a higher average score (0.05 level) than those in Wales or Northern Ireland.

With regard to the WHOQOL-BREF, the change in the measure of general health was not large enough to be statistically significant [F (1, 35.16) = 0.58, $P = 0.45$, effect size = 0.49, 95% CI −0.82, 1.81). The mean results from the different sites were very similar. The change in physical scores was statistically significant [F (1, 35.02.25) = 7.96, $P = 0.01$, effect size = −3.53, 95% CI −6.05, −0.99). No significant mean differences were shown for site. On the psychological measure, while the results are not statistically significant, there is shift in a desirable direction on the scores within the intervention group [F (1, 35.53) = 3.05, $P = 0.09$, effect size = −1.92, 95% CI −4.16, 0.31). The differences between the three sites were not statistically significant. On the environment measure the treatment effect was not statistically significant [F (1, 32.42) = 0.99, $P = 0.33$, effect size = 1.23, 95% CI −3.75, 1.28); however, on average, individuals from Scotland had a higher score on the environment measures than those from Wales or Northern Ireland. Difference on the social measure was small in both conditions and the interaction term between condition and the outcome measure was not statistically significant [F (1, 33.60) = 0.15, $P = 0.70$, effect size = 0.21, 95% CI −0.90, 1.33]. On average, the participants from Scotland had a higher average mean score on the social measure.

Process evaluation

Table 3 describes the themes that emerged from the process evaluation focus groups with the participants with disabilities and their carers, and the educators. The five major themes were: 1) the user-friendly content and delivery of the programme; 2) the knowledge and skills of the educators; 3) the support of the carers; 4) social aspects; and 5) difficulties in understanding the nature of fats and carbohydrates.

All the educators reported that they delivered the training in accordance with the DESMOND-ID curriculum. The educators reported they valued delivering the programme as it clearly addressed the lack of and sometimes incorrect understanding of Type 2 diabetes and its implications among both the participants with disabilities and their carers, and, more importantly, explained how to better self-manage the condition, such as through diet, exercise and medication compliance. The educators reported that the adapted

programme content, structure, curriculum, length of sessions, resources, health action plans and interactive sessions were developed at the appropriate level for those with a range of cognitive impairments and communication difficulties; although having an opportunity to provide booster sessions would further reinforce the messages of this programme.

The educators also found session 1, for the carers only, a useful means of creating a relationship with the carers, and was supportive of them working through the programme together with the adults with intellectual disabilities. The only reservation expressed by some of the educators was the increased preparation time needed prior to delivery of the programme; however, this is a common preoccupation of novice educators in general, and can be addressed by organization support, and increased competency of the educators over time.

Discussion

This is the first study to adapt and pilot a national structured self-management education programme for adults with intellectual disabilities and Type 2 diabetes targeting HbA_{1c}.

This study found some methodological and practical challenges in recruiting participants because of difficulties in locating potential participants, engaging with various gatekeeper agencies, obtaining informed consent, and ethical limitations that prevented the investigators from directly approaching potential participants. In undertaking a study with adults with a cognitive disability, such as those with an intellectual disability, it is important to develop good relationships with relevant service providers such as community nursing/social work teams, day centres and residential providers, general practices and diabetes clinics. Despite such challenges, this study shows that it is possible to identify, recruit and obtain consent from adults with a mild to moderate intellectual disability for an intervention study, who have previously been identified as a 'hard-to-reach' population [8]. In consenting the 39 participants with intellectual disabilities to either the intervention or control group, no difficulties were raised regarding the randomization process. This study clearly demonstrates the DESMOND-ID structured education programme is acceptable to the adults with intellectual disabilities, their carers, and prospective educators.

Attendance for both the adults with intellectual disabilities and their carers throughout the duration of the 7-week intervention was very good. The reasonable adjustments the research team made to the questionnaires (wording, using pictorial cues alongside the Likert responses) have been reported as helpful and acceptable by all participants [14,15]. There were no difficulties in collating the metabolic measures and psychosocial social measures at Time 1; however, we were not able to collate some of these data for three participants in the intervention group (15%) and five participants in the control group (20%) at the 12-week follow-up period. The present sample of 39 participants, identified and recruited from a sample of 66 participants (response rate 59%), is a substantial sample, particularly from this difficult-to-reach population, and contrasted with other similar pilot disability feasibility studies. This study shows that adults with intellectual disabilities and chronic health conditions can be identified and recruited from across three different countries.

This was a pilot feasibility study and no power calculation was undertaken prior to recruitment. Nevertheless, the reduction in HbA_{1c} from baseline to the 12-week follow-up that produced significance for the DESMOND-ID intervention group is very promising. Nevertheless, these metabolic results must be interpreted with caution given the small sample size and the exploratory nature of the study. In any future power analysis, the results from this pilot study would be considered in the context of results from other trials, but based on the results of this pilot study, 50 individuals in each condition may be sufficient. Based on results from other trials, a previous statistical power calculation suggested that a sample somewhat below 300 individuals would be required in total. The results from the present study suggest the possibility that a full trial could be based on 100 from each of the three countries, and that separate analyses could be conducted within each of the three countries, thus producing replication of results; and in the event that the results from the present study were overly optimistic, then the study would still be sufficiently powered if the results were combined. Based on the prior information that the present study (and indeed other studies) has produced, a Bayesian approach to the final analysis would be optimal, given the much smaller sample size requirements in such a situation.

Although we did observe what appears to be an important reduction in HbA_{1c} over the course of the intervention, improvements in BMI were not detected at the follow-up period. These improvements could be associated with any number of demographic-related factors; however, any explanation would be speculative in nature. For this reason, further investigation using a randomized controlled trial is needed to determine the specific mechanisms underlying improved health outcomes.

Disentangling the support that carers offer the person with disabilities from the lack of this for those who have no carers has both methodological and practical implications for future trials. One approach could be that future trials are designed so that they only include those adults with disabilities who have a carer; the consequences of this would mean increasing the sample size. Another approach could be to exclude those adults without support from a carer, but it would be morally and ethically wrong to prevent such participants from accessing potential new and innovative strategies to help them self-manage their diabetes and thereby have better health outcomes. It would be a trade-off by which steps to improve internal validity are at the

expense of external validity. In real life, education must be provided to both those with an intellectual disability who attend on their own and those who are accompanied: the evidence base for both is urgently required.

Acknowledging the inter-relatedness of the relationship between the dyad, an interaction between the intervention and the presence of the carer is plausible, this will mean that future studies need to control statistically for this and include an interaction term in the analysis to evaluate how the presence of a carer can modify the effect of the intervention.

The present study has a number of limitations. The DESMOND-ID programme was only delivered once in each site. Our sample included adults with disability with varying degrees of communication difficulties, some of whom were supported by carers; this poses challenges for the educators thereby requiring greater creativity in how the DESMOND-ID programme is delivered. This flexibility and creativeness can subsequently affect the fidelity of the core principles of the DESMOND-ID programme. We accept the issue of fidelity needs to be more fully addressed in future studies in terms of the quality assurance measures used to assess the design of the study, training educators, delivery of the education programme as intended, receipt of the programme and enactment of the self-management behavioural skills in real-life settings. Furthermore, it is well recognized that in educational interventions it may be the additional attention provided by those involved in the research as opposed to the intervention itself that makes a difference to outcomes [23]; further study is required.

Another limitation of this study was that we did not collate information on the participants' physical activity levels and sedentary levels, as well as dietary intake. We acknowledge that BMI is difficult to modify in a short period of time, although this was not the primary outcome of the DESMOND-ID programme. Any intervention programmes must be multi-component, including awareness of the health condition, education, physical activity, dietary advice and medication compliance [5].

As this was a pilot feasibility study, the intervention and control groups would not be representative of the larger population; therefore, there may be demographic differences among the two groups. We attempted to minimize this by the randomization, but with small numbers in each group there is no guarantee that we were successful in evading any systematic differences. Despite being able to recruit 39 participants (59%) from a potential 66 people who met the inclusion criteria, ~40% remained who did not provide consent to participate in the trial. To increase the conversion from possible participants to those who consent to participate, future studies could develop closer working relationships with key health personnel, sharing clearer information about the nature and purpose of the study.

In conclusion, there is limited access to evidence-based diabetes self-management education programmes for adults with intellectual disabilities and Type 2 diabetes compared with people without disabilities [2–4,8,10]. This study has shown that it is feasible to identify, recruit and obtain consent from adults with intellectual disabilities and Type 2 diabetes, and to maintain excellent attendance throughout the programme and during the post-intervention period. Both the metabolic measures and psycho-social questionnaires were acceptable to the adults with disabilities and their carers. All the adults with intellectual disabilities, their carers and educators have reported the DESMOND-ID education programme to be user-friendly and engaging. This study design and the positive results based on the reduction in HbA_{1c} levels can serve as a framework or model on which to base development of a full-scale definitive clinical trial. Based on the favourable results of the pilot study and the *post hoc* power calculations, funding for a larger randomized controlled trial will be sought.

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Completing interests

None declared.

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