Title page

A pilot feasibility study examining a structured self-management diabetes education program (DESMOND-ID) for adults with intellectual disabilities targeting HbA1c

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Completing interests
None declared.

What's new? (87 words)

- No studies have 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
- This study examined the pilot 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 consent adults with a mild to moderate intellectual disability to an intervention study.

A pilot feasibility study examining a structured self-management diabetes education program (DESMOND-ID) for adults with intellectual disabilities targeting HbA1c

Abstract

Aim: To report on the outcomes of a pilot feasibility study of a structured self-management diabetes education programme targeting HbA1c.

Methods: A two arm, individually randomized, pilot superiority trial for adults with intellectual disability and Type 2 diabetes mellitus (DM). 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 7-weekly educational sessions. Primary outcome was HbA1c, 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 successfully recruited, consented, completed the outcome measures, be randomized to the groups, attend most of the sessions and have minimal loss to follow-up. Based on the results from a fixed-effects model the interaction between occasion (time) and condition, the result for HbA1c was statistically significant (0.05 level); however, the confidence interval was large.

Conclusion: This is the first published study to adapt and pilot a national structured self-management diabetes education programme for this population. 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, feasible to deliver, and that its effectiveness should be tested in an adequately powered trial.

Introduction

Diabetes mellitus (DM) affects approximately 1 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 DM, leading to premature death.

In two recent systematic reviews, the prevalence rates of Type 2 DM in people with intellectual disabilities was higher compared to people without disabilities, reported to be between 8.3%-8.7% (2, 3). The reasons for such higher estimates are based upon the increasing life expectancy of this population, 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 towards obesity (4, 5, 6).

A number of studies have reported that diabetes management for people with intellectual disability and Type 2 DM is poor (7, 8). Taggart et al. (2013) in N Ireland found that many people with intellectual disability did not have an annual review of their HbA1c, cholesterol levels, BP, BMI or micro-albuminuria, as well as 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 DM is recommended by health services across the world for people without disabilities (1). People with DM are encouraged where possible to attend structured self-management education programmes such as DAFNE for adults with Type 1 DM (www.dafne.uk.com) or DESMOND for adults with Type 2 DM (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 studies have examined the effectiveness and acceptability of structured diabetes education programmes for adults with intellectual disabilities and Type 2 DM and their family/paid carers. Therefore the objectives of the present study 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, consenting rate, 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 intervention fidelity of delivery of the education programme.

Patients and Methods

This study was a two arm, individually randomized, pilot superiority trial for adults with intellectual disability and Type 2 DM, and their carers (see Taggart et al., 2015 for the protocol of this study (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 needing more support, while others need less support and are more independent.

The eligibility criteria were: 1) participants were 18yrs of age or older, 2) living in the community, 3) had a mild/moderate intellectual disability and Type 2 DM as identified in their clinical notes by the community team and/or GP and 4) had 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 - February 2015 and a range of approaches were used to identify potential participants. The primary sources of recruitment were from intellectual disability statutory services (that is, community nursing / social work teams, day centres and residential providers), from GP practices and diabetes clinics. We had already established relationships with the three health organisations 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 DM. However, due to some of these participants not being able to travel to the intervention site if randomized, they were thereby 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. Following consent to participate, 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 at 12-weeks post intervention.

INSERT FIGURE 1 HERE

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 (the RALLOC module within Stata 13 (StataCorp LP, London, England)) with concealment allocation (see Figure 1). As for the 27 participants who did not participate in the pilot study, the majority refused to consent as a result the intervention being on the same day as another activity, they were unwell or lived in the same residential facility. For the 39 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 (HbA1c and BMI). The primary outcome measure was HbA1c.

Three standardized measures were used. The Illness Perception Questionnaire-

Revised (IPQ) (12) examined 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 (13) (DIRQ) examined the participants' perceptions about the seriousness and impact of diabetes. The WHO Quality of Life (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 generalisability. 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 studies have examined the psychometric properties of these two scales with 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 were 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 DM: http://www.desmond-project.org.uk/about.html) that

provided a theoretically based structured education to support adults with Type 2 DM to self-manage their condition. The original DESMOND education programme has been shown to be robust and effective for those with Type 2 DM (18-22).

The DESMOND-ID programme was delivered in a community setting, over 6-weeks, with one session per week, each lasting approximately two and a half hours 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 about 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 two-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 one-day in the delivery of DESMOND-ID programme training. The educator team comprised three community intellectual disability nurses, two diabetes specialist nurses (DSNs) and one intellectual disability health facilitator.

INSERT TABLE 1 HERE

The education intervention is founded on concepts of self-management and empowerment and covered a range of topics (see Table 1). Each of the education sessions was comprised of two 30-45 minute sections, with a break in the middle for refreshments. Previous work has shown that flexibility is 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 versus 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 were 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 (HbA1c, BMI), and psychological measures (IPQ, DIRQ and WHOQOL-BREF) at baseline and 12-week follow-up, within the context of data collected from 3 sites (Northern Ireland, Scotland and Wales). There were eight individuals without a HbA1c 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 MRC guidelines for process evaluation (16; 17), focus groups with the adults with intellectual disabilities and their carers, and a series of 1-1 interviews

with the 6 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 RCT 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 in 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, they unsurprisingly 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 intervention completer criteria.

Ethics

Ethical approval was received by the Office for Research Ethics Northern Ireland (ORECNI) 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 were aged between 35-75yrs (mean 54.69yrs). A total of 56.4% were female and 43.6% were male. Most participants were reported by the community teams to have a mild intellectual disability; the others had a moderate disability. Over three-quarters (76.9%) lived in their own accommodation, and 17.9% lived within supported accommodation, 5.1% lived within their family home. A total of 23% of participants were supported by a family carer, 46% were supported by a paid carer and 31% participants lived independently.

Recruitment and retention

In terms of eligibility, 66 adults with disabilities across the three countries met the inclusion criterion, of these, 39 agreed to participate in the study (consenting rate of 59%). Of the 19 participants allocated to the intervention group, 90% of the participants with disabilities attended between 4-6 sessions. Likewise, 94% of the carers attended between 6-7 sessions.

INSERT TABLE 2 HERE

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 site of the study. Based on the results from a fixed-effects model the interaction between occasion (time) and condition, the result for HbA1c was statistically significant at the 5% level (F (1, 31.66.07)= 4.79, p= 0.04, effect size= 15.19, CI: 1.04 29.34). (The 95% confidence interval is shown). The mean HbA1c 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, CI: -39.59 45.31). Respondents in Scotland had a higher average BMI score 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 regards to the participants' IPQ scores, those in the intervention group obtained a higher score on the second occasion on the coherence measure (see 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, 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, 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, p= 0.56, effect size= -0.63, 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 reasonably similar for both 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, 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, CI: -3.97 0.85). Respondents in Scotland had a higher average score (0.05 level) than those in Wales or Northern Ireland.

With regards 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, 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, 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, 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, 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, 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 5 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 aspect and 5) difficulties in understanding the nature of fats and carbohydrates.

INSERT TABLE 3 HERE

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 challenged both the participants with disabilities and their carers lack of and sometimes incorrect understanding of what Type 2 DM was, its implications and more importantly how to better self-manage the condition, such as diet, exercise and medication compliance. They 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 supportive of them working through the programme together with the adults with intellectual disabilities. The only reservation made 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 DM targeting HbA1c.

This study found some methodological and practical challenges in identifying, recruiting and consenting participants due to some difficulties in locating potential participants, engaging with various gatekeeper agencies, obtaining informed consent, and ethical limitations which prevented 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, GP practices and diabetes clinics. Despite such challenges, this study shows that it is possible to identify, recruit and consent adults with a mild to moderate intellectual disability to an intervention study, where they 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 groups, 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 to 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 this 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 current sample of 39 participants, identified and recruited from a sample of 66 participants (response rate 59%), is a substantial sample particularly more so 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, 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 HbA1c from baseline to the 12-week follow-up period that produced significance for the DESMOND-ID intervention group is very promising. However, 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 context of results from other trials, but based on the results of this pilot study some 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 current study suggest the possibility that a full trial could be based on 100 from each of the three countries, and that separate analysis could be conducted within each of the three countries, thus producing replication of results; and in the event that the results from the current study were overly optimistic, then the study would still be sufficiently powered, if the results were combined. Given the prior information that the current 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 HbA1c 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 offers the person with disabilities compared to those who have no carers, has both methodological and practical implications in such future trials. One approach would be that future studies need to design trials that only include those adults with disabilities who have a carer, the consequences of this would mean increasing the sample size. Another approach would be to exclude

those adults without support from a carer, yet this 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 in which steps to improve internal validity are at the expense of external validity. In real life, education must be provided to 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.

Limitations

Our 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 impact upon 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 recognised 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 problematic to modify in a short period of time although this was not the primary outcome of the DESMOND-ID programme. Any intervention

555 programmes must be multi-component including awareness of the health condition,
556 education, physical activity, dietary advice, medication compliance (5).
557
558 As this was a pilot feasibility study, the intervention and control groups would not be
559 representative of the larger population, therefore there may be demographic
560 differences among the two groups. However, we attempted to minimise this by the
561 randomisation but with small numbers in each group there is no guarantee that we
562 were successful in evading any systematic differences. Despite being able to recruit
563 39 participants (59%) from a potential 66 participants who met the inclusion criterion,
564 there were still approximately 40% of participants who were not consented to this
565 trial. Therefore, to increase the conversion from possible to consented, future studies
566 could develop closer working relationships with key health personnel sharing clearer
567 information about the nature and purpose of the study.
568
569 **Conclusion**
570 Globally, there is limited access to evidence-based diabetes self-management
571 education programmes for adults with intellectual disabilities and Type 2 DM
572 compared to people without disabilities (2, 3 4, 8, 10). This study has shown that it is
573 feasible to identify, recruit, consent, and maintain excellent attendance throughout
574 the programme and at the post intervention period. Both the metabolic measures
575 and psycho-social questionnaires have been acceptable to the adults with disabilities
576 and their carers. All the adults with intellectual disabilities, their carers and educators
577 have reported the DESMOND-ID education programme to be user friendly and
578 engaging. This study design and the positive results based upon the reduction on
579 HbA1c can serve as a framework or model on which development of a full-scale
580 definitive clinical trial can be based. Based upon the favourable results of the pilot
581 study and the post hoc power calculations, funding for a larger RCT trail will be
582 sought.
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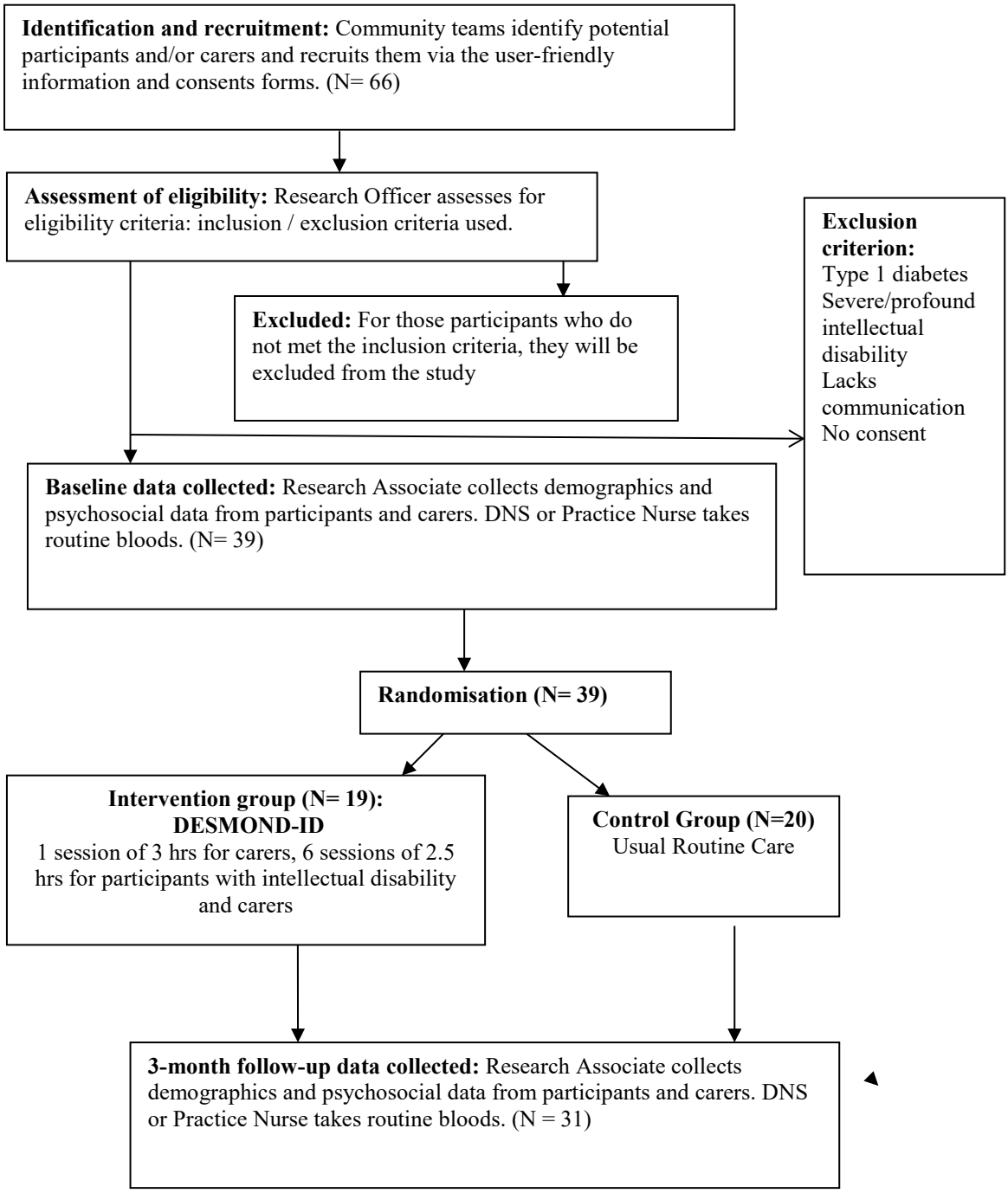
686 **Figure 1: Flowchart of the study protocol**



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690 **Table 1: Curriculum of DESMOND-ID programme**

DESMOND-ID sessions	Outline of session
Part one: Carer session	
	What is DESMOND and the DESMOND-ID programs? 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 I 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

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

	Intervention	Group		Control	Group
	Time 1	**Time 2**		**Time 1**	**Time 2**
HbA1c	66 mmol/mol (23) 8%	57 mmol/mol (18) 7.5%		61 mmol/mol (15) 7.7%	65 mmol/mol (17) 8%
	N= 16	N= 16		N= 15	N= 15
BMI	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 (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
IPQ (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
IPQ (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 (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
DIRQ (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
QoL (General)	7.63 (1.93)	7.88 (1.54)		7 (2.36)	7.74 (2.38)
	N= 16	N= 16		N= 19	N= 19
QoL (Physical)	25.94 (3.87)	29 (2.53)		26.05 (5.93)	25.63 (6.23)
	N= 16	N= 16		N= 19	N= 19
QoL (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
QoL (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

QoL (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

694 **Mean (sd)**

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696 **Table 3: Themes from the focus groups with the participants with intellectual**
697 **disabilities and carers**

Themes	Adults with intellectual disabilities	Carers
The 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."
The 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."	