

**Title page**

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

L Taggart (1), M Truesdale (2), ME Carey (3), L Martin-Stacey (3), J Scott (4), B  
Bunting (5), V Coates (1), M Brown (2), T Karatzias (2), R Northway (6),  
J M Clarke (7)

1: Institute of Nursing & Health Research, Ulster University, Northern Ireland

2: Edinburgh Napier University, Scotland

3: Leicester Diabetes Centre, University Hospitals of Leicester NHS Trust, England

4: Northern Health & Social Care Trust, Northern Ireland

5: Institute of Psychology, Ulster University, Northern Ireland

6: University of South Wales, Wales

7: MRC Hub for Trials Methodology Research, Queen's University Belfast, Northern  
Ireland

Dr Laurence Taggart: [l.taggart@ulster.ac.uk](mailto:l.taggart@ulster.ac.uk)

Dr Maria Truesdale: [m.truesdale@napier.ac.uk](mailto:m.truesdale@napier.ac.uk)

Dr Marian Carey: [marian.carey@uhl-tr.nhs.uk](mailto:marian.carey@uhl-tr.nhs.uk)

Lorraine Martin-Stacey: [lorraine.martinstacey@uhl-tr.nhs.uk](mailto:lorraine.martinstacey@uhl-tr.nhs.uk)

Jillian Scott: [jillian.scott@northerntrust.hscni.net](mailto:jillian.scott@northerntrust.hscni.net)

Prof Brendan Bunting: [bp.bunting@ulster.ac.uk](mailto:bp.bunting@ulster.ac.uk)

Prof Vivien Coates: [ve.coates@ulster.ac.uk](mailto:ve.coates@ulster.ac.uk)

Prof Michael Brown: [m.brown@napier.ac.uk](mailto:m.brown@napier.ac.uk)

Prof Thanos Karatzias: [t.karatzias@napier.ac.uk](mailto:t.karatzias@napier.ac.uk)

Prof Ruth Northway: [ruth.northway@southwales.co.uk](mailto:ruth.northway@southwales.co.uk)

Prof Mike Clarke: [m.clarke@gub.ac.uk](mailto:m.clarke@gub.ac.uk)

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**Correspondence:** Dr Laurence Taggart, Institute of Nursing & Health Research,  
Ulster University, Newtownabbey, Co Antrim, N. Ireland.

E-mail: [l.taggart@ulster.ac.uk](mailto:l.taggart@ulster.ac.uk)

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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.



99 **Introduction**

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

106  
107 In two recent systematic reviews, the prevalence rates of Type 2 DM in people with  
108 intellectual disabilities was higher compared to people without disabilities, reported to  
109 be between 8.3%-8.7% (2, 3). The reasons for such higher estimates are based  
110 upon the increasing life expectancy of this population, people with intellectual  
111 disabilities leading a more sedentary lifestyle, undertaking low levels of exercise,  
112 consuming high-fat diets and being prescribed high levels of anti-psychotic  
113 medications: all of which can contribute towards obesity (4, 5, 6).

114  
115 A number of studies have reported that diabetes management for people with  
116 intellectual disability and Type 2 DM is poor (7, 8). Taggart et al. (2013) in N Ireland  
117 found that many people with intellectual disability did not have an annual review of  
118 their HbA1c, cholesterol levels, BP, BMI or micro-albuminuria, as well as low levels  
119 of diabetic retinopathy screening, all conditions that are routinely assessed for  
120 change and management review (8). On average, people with intellectual disabilities  
121 have fewer opportunities to actively engage in diabetes self-management education  
122 programmes that are routinely offered to people without disabilities (4).

123  
124 Self-management of DM is recommended by health services across the world for  
125 people without disabilities (1). People with DM are encouraged where possible to  
126 attend structured self-management education programmes such as DAFNE for adults  
127 with Type 1 DM ([www.dafne.uk.com](http://www.dafne.uk.com)) or DESMOND for adults with Type 2 DM  
128 ([www.desmond-project.org.uk](http://www.desmond-project.org.uk)). However, neither are routinely offered to people with  
129 intellectual disability at a level that is appropriate to their needs (9).

130

## Adapted structured education programme for adults with intellectual disabilities

131 To date, no studies have examined the effectiveness and acceptability of structured  
132 diabetes education programmes for adults with intellectual disabilities and Type 2  
133 DM and their family/paid carers. Therefore the objectives of the present study were:  
134 1) to explore the feasibility of a 7-week adapted structured diabetes self-  
135 management education programme for people with diabetes and intellectual  
136 disability; 2) to assess eligibility, consenting rate, randomization, recruitment  
137 process, attendance levels and loss to follow-up of adults with intellectual disabilities  
138 and their carers; 3) to determine the appropriateness and the acceptability of the  
139 proposed outcome measures; and 4) to measure the intervention fidelity of delivery  
140 of the education programme.

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144

145 **Patients and Methods**

146 This study was a two arm, individually randomized, pilot superiority trial for adults  
147 with intellectual disability and Type 2 DM, and their carers (see Taggart et al., 2015  
148 for the protocol of this study (11)). The participants were recruited from their local  
149 communities in three UK countries (Northern Ireland, Scotland and Wales).

150

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

160

161 The eligibility criteria were: 1) participants were 18yrs of age or older, 2) living in the  
162 community, 3) had a mild/moderate intellectual disability and Type 2 DM as identified  
163 in their clinical notes by the community team and/or GP and 4) had sufficient  
164 communication skills to participate and the capacity to consent. The definition of a  
165 family or paid carer was either a family relative or residential member of staff who  
166 engages in the support of the person with intellectual disabilities.

167

168 Recruitment occurred between November 2014 - February 2015 and a range of  
169 approaches were used to identify potential participants. The primary sources of  
170 recruitment were from intellectual disability statutory services (that is, community  
171 nursing / social work teams, day centres and residential providers), from GP  
172 practices and diabetes clinics. We had already established relationships with the  
173 three health organisations and key personnel in each of the countries from an earlier  
174 diabetes study. This aided the research team in identifying 89 adults with intellectual  
175 disability and Type 2 DM. However, due to some of these participants not being able  
176 to travel to the intervention site if randomized, they were thereby excluded (25.8%).  
177 Funding for participants travel by taxi to participate in the intervention had not been  
178 allowed for in the research budget. This was an important learning point arising from

179 this study.

180

### 181 **Procedure**

182 Potential participants with intellectual disabilities were screened for eligibility by the  
183 primary healthcare team or community team, who provided them with a user-friendly  
184 information sheet and consent form. Both forms were developed in consultation with  
185 a user group of adults with intellectual disabilities. Following consent to participate,  
186 the research team contacted the participant and their carer to arrange baseline  
187 metabolic and cardiovascular data collection. In addition, participants were asked to  
188 complete three standardized questionnaires made up of instruments validated from  
189 the mainstream diabetes population that explored their severity and perceptions of  
190 diabetes illness and quality of life (12-14). These same assessments were  
191 administered at 12-weeks post intervention.

192

193

### **INSERT FIGURE 1 HERE**

194

195 Out of 66 eligible participants with intellectual disabilities, 39 were recruited and  
196 assigned to one of two study arms using a computerized random allocation system  
197 (the RALLOC module within Stata 13 (StataCorp LP, London, England)) with  
198 concealment allocation (see Figure 1). As for the 27 participants who did not  
199 participate in the pilot study, the majority refused to consent as a result the  
200 intervention being on the same day as another activity, they were unwell or lived in  
201 the same residential facility. For the 39 included in the pilot study, details of each  
202 participant and their carer were forwarded to a research secretary at Ulster  
203 University, who was not connected to the study.

204

### 205 **Measures**

206 Demographic details were collated, including age, gender, level of intellectual  
207 disability, marital status, living arrangements, carer details, diabetes duration and  
208 diabetes management treatment. Metabolic and cardiovascular measures were  
209 collected at assessment and 12-week follow-up (HbA1c and BMI). The primary  
210 outcome measure was HbA1c.

211

212 Three standardized measures were used. The Illness Perception Questionnaire-

213 Revised (IPQ) (12) examined the participants' understanding of diabetes (illness  
214 coherence score), perception of the duration of their illness (timeline score) and the  
215 perception of their ability to affect the course of their diabetes (personal responsibility  
216 score). The Diabetes Illness Representation Questionnaire (13) (DIRQ) examined  
217 the participants' perceptions about the seriousness and impact of diabetes. The  
218 WHO Quality of Life (WHOQOL-BREF) (14) is a short version of a measure of  
219 general quality of life: developed by the WHO simultaneously in 17 different  
220 countries to ensure cultural comparability and generalisability. This questionnaire  
221 generates a general health score and four domain scores: physical, psychological,  
222 social and environmental quality of life.

223

224 The reliability and validity of the IPQ and DIRQ have been reported to be strong with  
225 people without disabilities. However, no studies have examined the psychometric  
226 properties of these two scales with adults with intellectual disabilities. The reliability  
227 and validity of the WHOQOL-BREF scale has been reported to be strong with people  
228 with and without intellectual disabilities (15).

229

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

242

### 243 **Intervention**

244 The DESMOND-ID programme was adapted from the original DESMOND  
245 programme (Diabetes and Self-Management for Ongoing and Newly Diagnosed for  
246 patients with Type 2 DM: <http://www.desmond-project.org.uk/about.html>) that



## Adapted structured education programme for adults with intellectual disabilities

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

250

251 The DESMOND-ID programme was delivered in a community setting, over 6-weeks,  
252 with one session per week, each lasting approximately two and a half hours to the  
253 participants with intellectual disabilities and their carers. The DESMOND-ID  
254 programme has an additional, separate introductory education session that was  
255 aimed at, and held separately for, family/paid carers to support their understanding  
256 about diabetes and how it is managed. Carers gained an understanding of how the  
257 DESMOND-ID programme works and their specific role in supporting the person with  
258 disability throughout the programme.

259

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

268

269

### **INSERT TABLE 1 HERE**

270

271 The education intervention is founded on concepts of self-management and  
272 empowerment and covered a range of topics (see Table 1). Each of the education  
273 sessions was comprised of two 30-45 minute sections, with a break in the middle for  
274 refreshments. Previous work has shown that flexibility is required in delivery and  
275 timing of the education sessions to meet individuals' concentration levels and  
276 learning needs (8).

277

### **Control group**

278  
279 Participants with intellectual disabilities and their carers who were randomly  
280 allocated to the control group received usual routine care: they were not offered any

281 form of structured education. Routine care normally included health centre visits  
282 every 3-months in which the person with diabetes and disabilities met with their  
283 primary healthcare team. All those in the control group completed the data gathering  
284 instruments at baseline and at 12-week follow-up.

285

### 286 **Intervention versus control**

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

291

### 292 **Statistical analyses**

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

299

300 A series of repeated measures were undertaken to examine if there were significant  
301 differences between the intervention and the control groups at baseline and at  
302 follow-up on the metabolic measures (HbA1c, BMI), and psychological measures  
303 (IPQ, DIRQ and WHOQOL-BREF) at baseline and 12-week follow-up, within the  
304 context of data collected from 3 sites (Northern Ireland, Scotland and Wales). There  
305 were eight individuals without a HbA1c reading on the second occasion. These  
306 individuals were included within the analysis under the assumption that they were  
307 missing at random: the default in the mixed models option in SPSS. A linear mixed  
308 model with measures at two points in time was used. An interaction between time  
309 and conditions was created, with an auto-regressive error structure (AR1). Time,  
310 condition and site were all fixed effects within the model.

311

### 312 **Process evaluation analysis**

313 Using the updated MRC guidelines for process evaluation (16; 17), focus groups with  
314 the adults with intellectual disabilities and their carers, and a series of 1-1 interviews

Adapted structured education programme for adults with intellectual disabilities

315 with the 6 educators were conducted in each of the three countries focusing on  
316 implementation, mechanisms and context. We explored the identification and  
317 recruitment of the participants, outcome measures, the randomization process,  
318 training of educators, the DESMOND-ID curriculum and resources, retention and  
319 drop-out. These were documented by the researchers and reviewed by the Steering  
320 Committee members to inform adaptations to the protocol to enable a realistic  
321 definitive RCT to be conducted in the future.

322

### 323 **Fidelity**

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

332

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

341

### 342 **Ethics**

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

347

348



350 **Results**

351 **Demographics**

352 Participants were aged between 35-75yrs (mean 54.69yrs). A total of 56.4% were  
353 female and 43.6% were male. Most participants were reported by the community  
354 teams to have a mild intellectual disability; the others had a moderate disability. Over  
355 three-quarters (76.9%) lived in their own accommodation, and 17.9% lived within  
356 supported accommodation, 5.1% lived within their family home. A total of 23% of  
357 participants were supported by a family carer, 46% were supported by a paid carer  
358 and 31% participants lived independently.

359

360 **Recruitment and retention**

361 In terms of eligibility, 66 adults with disabilities across the three countries met the  
362 inclusion criterion, of these, 39 agreed to participate in the study (consenting rate of  
363 59%). Of the 19 participants allocated to the intervention group, 90% of the  
364 participants with disabilities attended between 4-6 sessions. Likewise, 94% of the  
365 carers attended between 6-7 sessions.

366

367 **INSERT TABLE 2 HERE**

368

369 **Biomedical outcomes at baseline and 12-week follow-up**

370 An exploratory multi-level analysis within the mixed models option in SPSS was  
371 undertaken to examine time, intervention condition, and site of the study. Based on  
372 the results from a fixed-effects model the interaction between occasion (time) and  
373 condition, the result for HbA1c was statistically significant at the 5% level ( $F(1, 31.66.07) = 4.79, p = 0.04, \text{effect size} = 15.19, \text{CI: } 1.04 \text{ } 29.34$ ). (The 95% confidence  
374 interval is shown). The mean HbA1c scores by site showed no difference, and the  
375 intra-class correlation was zero.

377

378 In terms of BMI the interaction between condition and time was not statistically  
379 significant ( $F(1, 34.24) = 0.02, p = 0.89, \text{estimate} = 42.86, \text{CI: } -39.59 \text{ } 45.31$ ).

380 Respondents in Scotland had a higher average BMI score than those in Northern  
381 Ireland. No other mean comparisons between the sites were statistically significant.

382

383 **Psychosocial outcomes at baseline and 12-week follow-up**

384 With regards to the participants' IPQ scores, those in the intervention group obtained  
385 a higher score on the second occasion on the coherence measure (see Table 2). In  
386 the formal test this indicated the shift was statistically significant ( $F(1, 33.26) = 0.50$ ,  
387  $p = 0.00$ , effect size =  $-3.37$ , CI:  $-5.59 -1.16$ ). Site was not statistically significant (0.05  
388 level). However, the timeline measure was statistically significant ( $F(1, 30.23) = 5.04$ ,  
389  $p = 0.03$ , effect size =  $-3.13$ , CI:  $-4.07 -0.19$ ). Respondents in Scotland had a higher  
390 mean score than those in Wales; no other differences were significant at the 5%  
391 level. In terms of the measure of responsibility, both means decreased in value in a  
392 parallel manner on the second occasion, resulting in no difference (0.05 level) in  
393 terms of the interaction ( $F(1, 28.21) = 0.35$ ,  $p = 0.56$ , effect size =  $-0.63$ , CI:  $-2.81$   
394  $1.55$ ). There was a site difference with the scores for those in Northern Ireland being  
395 higher (statistically at the 0.05 level) than those in Scotland.

396

397 Examining the participants' DIRQ scores, the baseline scores were reasonably  
398 similar for both groups in terms of the measures for both seriousness and impact.  
399 The interaction between seriousness and condition was not statistically significant ( $F$   
400  $(1, 31.74) = 2.77$ ,  $p = 0.11$ , effect size =  $-1.11$ , CI:  $-2.44 0.25$ ). Respondents from  
401 Scotland had a statistically (0.05 level) higher score than individuals in Wales. The  
402 results from the impact measure also indicated that the interaction between time and  
403 condition was not statistically significant ( $F(1, 29.41) = 1.75$ ,  $p = 0.20$ , effect size =  $-$   
404  $1.56$ , CI:  $-3.97 0.85$ ). Respondents in Scotland had a higher average score (0.05  
405 level) than those in Wales or Northern Ireland.

406

407 With regards to the WHOQOL-BREF, the change in the measure of general health  
408 was not large enough to be statistically significant ( $F(1, 35.16) = 0.58$ ,  $p = 0.45$ , effect  
409 size =  $0.49$ , CI:  $-0.82 1.81$ ). The mean results from the different sites were very  
410 similar. The change in physical scores was statistically significant ( $F(1, 35.02.25) =$   
411  $7.96$ ,  $p = 0.01$ , effect size =  $-3.53$ , CI:  $-6.05 -0.99$ ). No significant mean differences  
412 were shown for site. On the psychological measure, while the results are not  
413 statistically significant, there is shift in a desirable direction on the scores within the  
414 intervention group ( $F(1, 35.53) = 3.05$ ,  $p = 0.09$ , effect size =  $-1.92$ , CI:  $-4.16 0.31$ ).

415 The differences between the three sites were not statistically significant. On the  
416 environment measure the treatment effect was not statistically significant ( $F(1, 32.42) = 0.99, p = 0.33, \text{effect size} = 1.23, \text{CI: } -3.75 \text{ } 1.28$ ). However, on average  
417 individuals from Scotland had a higher score on the environment measures than  
418 those from Wales or Northern Ireland. Difference on the social measure was small in  
419 both conditions and the interaction term between condition and the outcome  
420 measure was not statistically significant ( $F(1, 33.60) = 0.15, p = 0.70, \text{effect size} =$   
421  $0.21, \text{CI: } -0.90 \text{ } 1.33$ ). On average the participants from Scotland had a higher  
422 average mean score on the social measure.  
423

424

425

### 426 **Process evaluation**

427 Table 3 describes the themes that emerged from the process evaluation focus  
428 groups with the participants with disabilities and their carers, and the educators. The  
429 5 major themes were: 1) the user-friendly content and delivery of the programme; 2)  
430 the knowledge and skills of the educators; 3) the support of the carers; 4) social  
431 aspect and 5) difficulties in understanding the nature of fats and carbohydrates.  
432

432

433

### **INSERT TABLE 3 HERE**

434 All the educators reported that they delivered the training in accordance with the  
435 DESMOND-ID curriculum. The educators reported they valued delivering the  
436 programme as it clearly challenged both the participants with disabilities and their  
437 carers lack of and sometimes incorrect understanding of what Type 2 DM was, its  
438 implications and more importantly how to better self-manage the condition, such as  
439 diet, exercise and medication compliance. They reported that the adapted  
440 programme content, structure, curriculum, length of sessions, resources, health  
441 action plans and interactive sessions were developed at the appropriate level for  
442 those with a range of cognitive impairments and communication difficulties; although  
443 having an opportunity to provide booster sessions would further reinforce the  
444 messages of this programme.

445

## Adapted structured education programme for adults with intellectual disabilities

446 The educators also found Session 1, for the 'carers only', a useful means of creating  
447 a relationship with the carers, and supportive of them working through the  
448 programme together with the adults with intellectual disabilities. The only reservation  
449 made by some of the educators was the increased preparation time needed prior to  
450 delivery of the programme. However, this is a common preoccupation of novice  
451 educators in general, and can be addressed by organization support, and increased  
452 competency of the educators over time.

453

454



455 **Discussion**

456 This is the first study to adapt and pilot a national structured self-management  
457 education programme for adults with intellectual disabilities and Type 2 DM targeting  
458 HbA1c.

459  
460 This study found some methodological and practical challenges in identifying,  
461 recruiting and consenting participants due to some difficulties in locating potential  
462 participants, engaging with various gatekeeper agencies, obtaining informed  
463 consent, and ethical limitations which prevented directly approaching potential  
464 participants. In undertaking a study with adults with a cognitive disability such as  
465 those with an intellectual disability, it is important to develop good relationships with  
466 relevant service providers such as community nursing / social work teams, day  
467 centres and residential providers, GP practices and diabetes clinics. Despite such  
468 challenges, this study shows that it is possible to identify, recruit and consent adults  
469 with a mild to moderate intellectual disability to an intervention study, where they  
470 have previously been identified as a 'hard-to-reach' population (8). In consenting the  
471 39 participants with intellectual disabilities to either the intervention or control groups,  
472 no difficulties were raised regarding the randomization process. This study clearly  
473 demonstrates the DESMOND-ID structured education programme is acceptable to  
474 the adults with intellectual disabilities, their carers, and to prospective educators.

475

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

488 conditions can be identified and recruited, and recruited from across three different  
489 countries.

490

491 This was a pilot feasibility study and no power calculation was undertaken prior to  
492 recruitment. Nevertheless, the reduction in HbA1c from baseline to the 12-week  
493 follow-up period that produced significance for the DESMOND-ID intervention group  
494 is very promising. However, these metabolic results must be interpreted with caution  
495 given the small sample size and the exploratory nature of the study. In any future  
496 power analysis, the results from this pilot study would be considered in context of  
497 results from other trials, but based on the results of this pilot study some 50  
498 individuals in each condition may be sufficient. Based on results from other trials a  
499 previous statistical power calculation suggested that a sample somewhat below 300  
500 individuals would be required in total. The results from the current study suggest the  
501 possibility that a full trial could be based on 100 from each of the three countries, and  
502 that separate analysis could be conducted within each of the three countries, thus  
503 producing replication of results; and in the event that the results from the current  
504 study were overly optimistic, then the study would still be sufficiently powered, if the  
505 results were combined. Given the prior information that the current study (and indeed  
506 other studies) has produced, a Bayesian approach to the final analysis would be  
507 optimal, given the much smaller sample size requirements in such a situation.

508

509 Although we did observe what appears to be an important reduction in HbA1c over  
510 the course of the intervention, improvements in BMI were not detected at the follow-  
511 up period. These improvements could be associated with any number of  
512 demographic-related factors; however, any explanation would be speculative in  
513 nature. For this reason, further investigation using a randomized controlled trial is  
514 needed to determine the specific mechanisms underlying improved health outcomes.

515

516 Disentangling the support that carers offers the person with disabilities compared to  
517 those who have no carers, has both methodological and practical implications in  
518 such future trials. One approach would be that future studies need to design trials  
519 that only include those adults with disabilities who have a carer, the consequences of  
520 this would mean increasing the sample size. Another approach would be to exclude

521 those adults without support from a carer, yet this would be morally and ethically  
522 wrong to prevent such participants from accessing potential new and innovative  
523 strategies to help them self-manage their diabetes and thereby have better health  
524 outcomes. It would be a trade off in which steps to improve internal validity are at the  
525 expense of external validity. In real life, education must be provided to those with an  
526 intellectual disability who attend on their own and those who are accompanied: the  
527 evidence base for both is urgently required.

528

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

534

### 535 **Limitations**

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

550

551 Another limitation of this study was that we did not collate information on the  
552 participants' physical activity levels and sedentary levels, as well as dietary intake.  
553 We acknowledge that BMI is problematic to modify in a short period of time although  
554 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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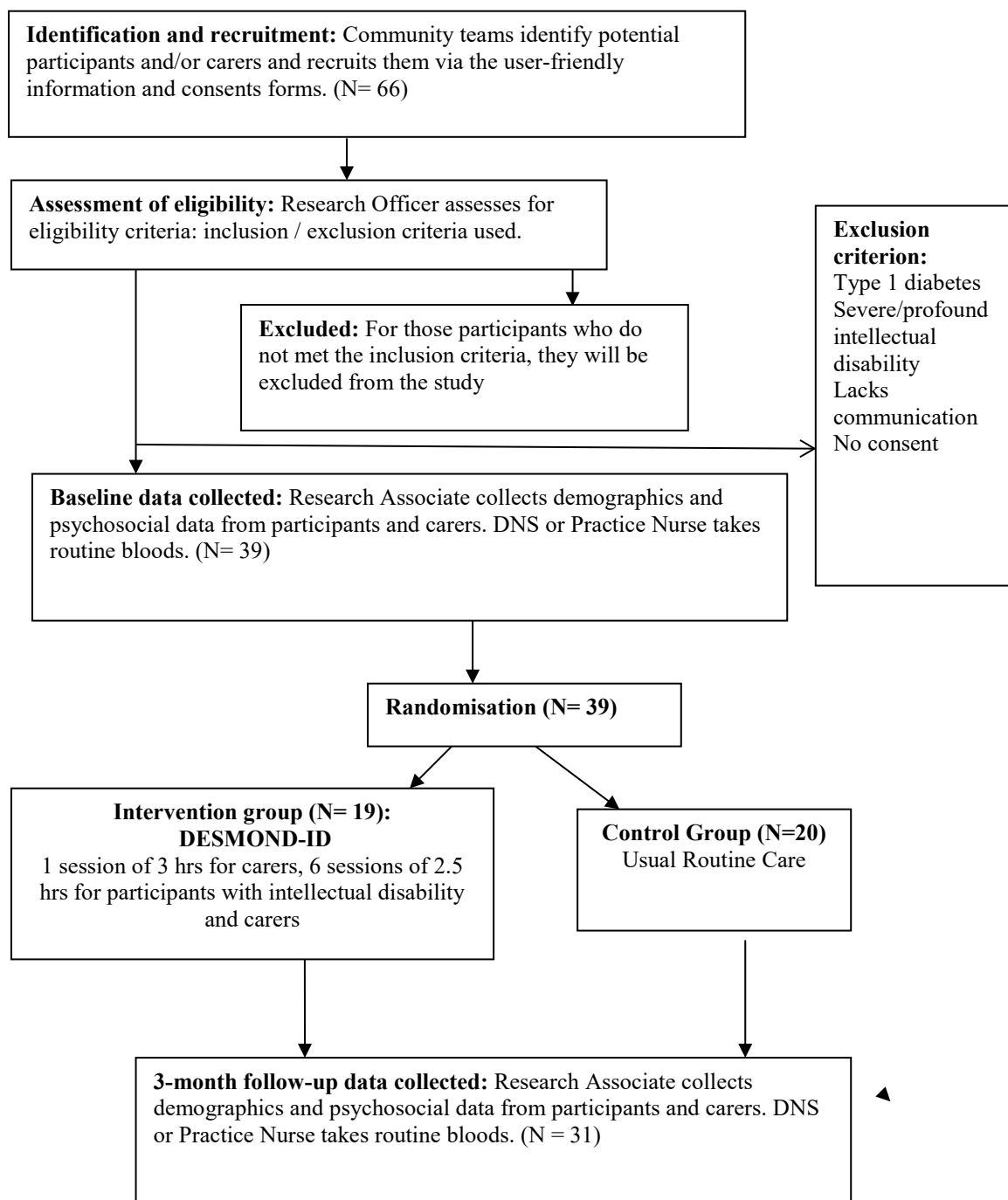
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686 **Figure 1: Flowchart of the study protocol**



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

<b>DESMOND-ID sessions</b>	<b>Outline of session</b>
<b>Part one: Carer session</b>	
	<p>What is DESMOND and the DESMOND-ID programs?</p> <p>What is type 2 diabetes?</p> <p>Break</p> <p>Having a go (practical activities)</p> <p>Carers role – what can I do?</p> <p>Questions</p>
<b>Part two: The participant course</b>	
Session 1	<p>Welcome and introductions</p> <p>My story with diabetes (part 1)</p> <p>My body and diabetes</p> <p>Break</p> <p>What is diabetes?</p> <p>What did I learn today and preparing for next week?</p>
Session 2	<p>Welcome back</p> <p>My story with diabetes (part 2)</p> <p>What diabetes does to your body?</p> <p>Break</p> <p>Food and blood sugar</p> <p>What did I learn today?</p>
Session 3	<p>Welcome back</p> <p>Knowing what your blood sugar levels mean</p> <p>Break</p>

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	<p>Being active</p> <p>What did I learn today?</p>
Session 4	<p>Welcome back</p> <p>Heart and circulation problems: what can I do to keep healthy (part 1)</p> <p>Break</p> <p>Other diabetes health problems: what can I do to keep healthy (part 2)</p> <p>What did I learn today?</p>
Session 5	<p>Welcome back</p> <p>Food and fats</p> <p>Break</p> <p>Making healthier food choices</p> <p>What did I learn today?</p>
Session 6	<p>Welcome back</p> <p>Diabetes health action plan: what will I work on?</p> <p>Break</p> <p>Keeping my plan going</p> <p>Important questions and celebration of achievement</p>

691

692

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

	<b>Intervention</b>	<b>Group</b>		<b>Control</b>	<b>Group</b>
	<b>Time 1</b>	<b>Time 2</b>		<b>Time 1</b>	<b>Time 2</b>
<b>HbA1c</b>	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
<b>BMI</b>	30.63 (4.97)	30.4 (4.51)		37.30 (5.81)	37.57 (6.33)
	N= 13	n= 13		N= 14	N= 14
<b>IPQ (Coherence)</b>	12.5 (2.5)	15.56 (3.72)		13.95 (3.57)	13.95 (3.5)
	N= 16	N= 16		N= 19	N= 19
<b>IPQ (Timeline)</b>	16.25 (2.57)	17.94 (2.38)		17.32 (2.38)	17.11 (1.91)
	N= 16	N=16		N= 19	N= 19
<b>IPQ (Responsibility)</b>	14.94 (3.3)	14.56 (1.63)		14.79 (2.02)	14.47 (1.58)
	N= 16	N= 16		N= 19	N= 19
<b>DIRQ (Seriousness)</b>	16.25 (2.65)	16.88 (1.82)		16.11 (2.23)	15.79 (2.25)
	N= 16	N= 16		N= 19	N= 19
<b>DIRQ (Impact)</b>	24.69 (3.95)	24.87 (3.16)		24.06 (5.72)	23.11 (5.06)
	N= 16	N- 16		N= 18	N= 18
<b>QoL (General)</b>	7.63 (1.93)	7.88 (1.54)		7 (2.36)	7.74 (2.38)
	N= 16	N= 16		N= 19	N= 19
<b>QoL (Physical)</b>	25.94 (3.87)	29 (2.53)		26.05 (5.93)	25.63 (6.23)
	N= 16	N= 16		N= 19	N= 19
<b>QoL (Psychological)</b>	21.94 (3.04)	23.63 (2.99)		22.58 (3.52)	22.42 (3.76)
	N= 16	N= 16		N= 19	N= 19
<b>QoL (Environmental)</b>	31.44 (4.43)	20.13 (3.1)		31.11 (5.47)	18.89 (3.48)
	N= 16	N= 16		N= 19	N= 19

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<b>QoL (Social)</b>	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)**

695

696

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

697

Themes	Adults with intellectual disabilities	Carers
<b>The user-friendly content and delivery of the programme</b>	<p>“It was very good because you can understand it better.”</p> <p>“I felt it was a lot helpful for me with my diabetes.”</p>	<p>“I think it accessible to our clients and there was the right level of information.”</p> <p>“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.”</p>
<b>Knowledge and skills of the educators</b>		<p>“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.”</p> <p>“When the educator was talking, she was cutting it down to different levels so I could understand it better.”</p>
<b>The support of the carers</b>	‘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’.
<b>Social aspect</b>	“Making new friends”.	“We all got on as a group and enjoyed the craic.”

<b>Difficulties in understanding significance of fat and carbohydrates</b>	<p>“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.”</p> <p>“The only thing I couldn’t understand was the session on the fats.”</p>	
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