

**Process evaluation of a patient-centred, patient-directed, group-based education program for the management of type 2 diabetes mellitus**

Odgers-Jewell, Kate; Isenring, Elisabeth; Thomas, Rae; Reidlinger, Dianne P.

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1 **Abstract**

2 **Aim:** This study developed and evaluated a patient-centred, patient-directed, group-  
3 based education program for the management of type 2 diabetes mellitus.

4 **Methods:** Two frameworks, the MRC Framework for Developing and Evaluating  
5 Complex Interventions and the RE-AIM framework were followed. Data to develop the  
6 intervention were sourced from scoping of the literature and formative evaluation.  
7 Program evaluation comprised analysis of primary recruitment of participants through  
8 general practitioners, baseline and endpoint measures of anthropometry, four validated  
9 questionnaires, contemporaneous facilitator notes and telephone interviews with  
10 participants.

11 **Results:** A total of 16 participants enrolled in the intervention. Post intervention results  
12 were obtained from 13 participants with an estimated mean change from baseline in  
13 weight of -0.72kg (95%CI -1.44 to -0.01), BMI of -0.25kg/m<sup>2</sup> (95%CI -0.49 to -0.01),  
14 and waist circumference of -1.04cm (95%CI -4.52 to 2.44). The group education  
15 program was acceptable to participants. The results suggest that recruitment through  
16 general practitioners is ineffective and alternative recruitment strategies are required.

17 **Conclusions:** This patient-centred, patient-directed, group-based intervention for the  
18 management of type 2 diabetes mellitus was both feasible and acceptable to patients.  
19 Health professionals should consider the combined use of the MRC and RE-AIM  
20 frameworks in the development of interventions to ensure a rigorous design process,  
21 and to enable the evaluation of all phases of the intervention, which will facilitate  
22 translation to other settings. Further research with a larger sample trialling additional  
23 recruitment strategies, evaluating further measures of effectiveness, and utilizing  
24 lengthier follow up periods is required.

25

## 1 **Introduction**

2 Diabetes is the fastest growing disease nationally and internationally, with one  
3 Australian being diagnosed every eight minutes.<sup>1</sup> Each year approximately 1 million  
4 Australians are diagnosed with diabetes; 85% with type 2 diabetes mellitus (T2DM).<sup>2</sup>  
5 Patient education, the cornerstone of chronic disease self-management, is essential in  
6 achieving improved outcomes and has been acknowledged as an integral and vital  
7 component of successful T2DM care.<sup>3, 4, 5, 6</sup> The main goal of diabetes patient education  
8 is to promote and support positive self-management behaviours in order to optimize  
9 metabolic control, improve quality of life (QOL), prevent acute and chronic  
10 complications, and reduce morbidity and mortality.<sup>6, 7</sup>

11

12 Group-based education for patients with T2DM has the potential to be a more cost  
13 effective and efficient intervention than individual education, due to the reduced time  
14 and funding required to educate numerous patients in one session.<sup>5, 8</sup> Group-based  
15 education allows time for the provision of more detailed information, decreases time  
16 demands on health workers, allows the easy incorporation of families and carers, and  
17 facilitates patient discussions and support from others in a similar situation.<sup>9, 10</sup> Research  
18 assessing the effectiveness of group-based education compared with usual care for the  
19 management of T2DM has found that the benefits in patient outcomes include  
20 significant improvements in glycaemic control, fasting blood glucose (FBG), diabetes  
21 knowledge, self-management skills, self-efficacy, and treatment satisfaction, as well as  
22 significant reductions in body weight, systolic blood pressure, and the need for diabetes  
23 medication.<sup>10, 11</sup>

24

1 Despite the evidence supporting group-based education for the management of T2DM,  
2 it is surprisingly difficult to define the ideal content and process by which effective  
3 group-based education should be delivered.<sup>12</sup> Group-based education programs can be  
4 structured or unstructured, depending on the level of prescription in the content covered  
5 and the delivery. Structured programs contain lesson plans with clearly defined content,  
6 which can allow programs to be replicated by multiple group facilitators, however are  
7 more likely than unstructured programs to utilize a didactic facilitation style, reducing  
8 the time for patient interactions and discussion.<sup>13</sup> Unstructured or patient-directed  
9 programs utilize a non-didactic facilitation style and can allow participants to explore  
10 their own agenda, interests and needs, rather than content that may not interest or assist  
11 them in improving their self-management skills or knowledge.<sup>14</sup>

12  
13 Within Australia, dietitians in particular overwhelmingly favour the provision of  
14 individual patient education services over group-based education. The utilization of  
15 group services for T2DM management provided by dietitians has continued to decrease  
16 in recent years whilst individual dietetic services have consistently increased.<sup>15</sup> Previous  
17 research has proposed that service system issues, workforce capacity, awareness among  
18 practitioners and practitioner attitudes and preferences are the main factors impeding the  
19 utilization of group-based education by Australian dietitians.<sup>16</sup> A recent study exploring  
20 group facilitators' perceptions and experiences of group-based chronic disease  
21 management programs found that interventions were being delivered with limited  
22 quality control and that facilitators had inadequate knowledge of the evidence base  
23 underpinning the programs they were facilitating.<sup>13</sup> An additional surprising finding  
24 from this study was that the outcome measures being utilized by facilitators in practice

1 were minimal, with many only collecting an overview of patient satisfaction through  
2 surveys, which as a solitary measure, is inadequate in assessing patient outcomes or  
3 improving the quality of future programs.<sup>13</sup>

4  
5 The development of a group-based intervention informed by the literature and formative  
6 research, followed by feasibility testing and a rigorous process evaluation may result in  
7 an intervention that can be easily translated into practice by health professionals  
8 interested in delivering group-based education programs and unsure where to start.  
9 Additionally, the dissemination of findings from feasibility studies could contribute to  
10 health practitioners' knowledge by furthering an understanding of the methodological  
11 and practical challenges of developing and implementing intervention studies in a 'real-  
12 world' setting, and may highlight outcome measures which are suitable for the  
13 evaluation of intervention effectiveness.<sup>17</sup>

14

15 The aim of this study was to develop and evaluate a patient-centred, patient-directed,  
16 group-based education program for the management of T2DM, using two process  
17 evaluation frameworks, the MRC Framework for Developing and Evaluating Complex  
18 Interventions, and the RE-AIM framework.

19

## 20 **Methods**

21 The development and process evaluation of the intervention using the two frameworks  
22 occurred over a number of phases (Figure 1). In brief this involved a formative  
23 evaluation including a scoping of the literature, interviews with facilitators and  
24 participants of existing chronic disease management group programs; recruitment and

1 initial assessment of participants; baseline outcome measurements, the facilitation of the  
2 intervention, follow up outcome measurements, and the completion of telephone  
3 interviews with participants to assess the acceptability of the intervention.

4 *[Insert figure 1 here]*

5

6 The Medical Research Council (MRC) Framework for Developing and Evaluating  
7 Complex Interventions (2008) was used to guide the intervention development and  
8 evaluation.<sup>18</sup> The framework incorporates four phases: development, feasibility and  
9 piloting, evaluation and implementation, which aim to help researchers to recognise and  
10 adopt appropriate measures for the design and evaluation of complex health behaviour  
11 change interventions.<sup>18</sup> The RE-AIM framework is an evaluation framework that  
12 includes multiple process indicators to evaluate various aspects of an intervention:  
13 reach, effectiveness, adoption, implementation and maintenance.<sup>19, 20</sup> The RE-AIM  
14 framework not only evaluates the effectiveness or strengths of an intervention, but also  
15 the program's translatability, feasibility and limitations, which can potentially be  
16 improved upon in future research.<sup>21</sup> Combining both the MRC and RE-AIM frameworks  
17 in the process evaluation of the intervention ensures a thorough and rigorous evaluation  
18 of all aspects of the program including development, and enables the identification of  
19 strengths and limitations.

20

21 To develop the intervention data were collected from three sources: a preliminary  
22 literature review and scoping of group-based interventions for T2DM management, a  
23 formative evaluation based on interviews with facilitators of a range of existing chronic  
24 disease management (CDM) group education programs and their participants, and a

1 review of the Medicare group services information pack, which is evidence-based,  
2 available to Australian health-professionals, and is likely to influence the development  
3 of group-based education programs in practice.<sup>22</sup> Triangulation was achieved by  
4 comparing the attributes of effective group-based education interventions with the  
5 results obtained from the group facilitator and group participant interviews, and the  
6 information provided in the Medicare group services information pack.<sup>22</sup> Triangulation  
7 is commonly utilized in health service research as an evaluation method as it enables the  
8 integration of methods and approaches to conduct better evaluation studies.<sup>23</sup>

9

10 The intervention design, resulting from the systematic development process, was a  
11 patient-centred, patient-directed, group-based education program. The program content  
12 employed a non-didactic approach, group discussions were encouraged, and the content  
13 covered in the group education sessions was decided by group participants in the first  
14 session. The intervention is described using the Template for Intervention Description  
15 and Replication (TIDieR) checklist and guide (Supporting Information: Appendix I).<sup>24</sup>

16

17 A recruitment target of 90 participants for the single-arm feasibility study was set. The  
18 sample size, although not necessary for a feasibility study, was determined from a  
19 practice perspective. The sample size of 90 participants was originally calculated for a  
20 two-armed study, in which each intervention group would be composed of 45  
21 participants, allowing for at least 20% attrition, resulting in three groups of 12  
22 participants (per intervention group). General Practitioner (GP) referrals were chosen as  
23 the primary recruitment strategy for the feasibility study, based on literature suggesting  
24 they are the 'gatekeepers' of primary care, and the initial point of contact for patients

1 who require primary or non-emergency health care.<sup>25</sup> Invitation letters were mailed to  
2 all medical centres (n=132) within a 50km radius of the intervention site and each  
3 medical centre was telephoned to follow up within two weeks of postage.

4

5 Participants were included if they self-reported a diagnosis of T2DM or were referred  
6 by their GP as a diagnosed T2DM patient, were 18 years of age or over, had adequate  
7 cognitive ability, and had a sufficient understanding of English. Ethical approval was  
8 obtained from the Bond University Human Research Ethics Committee (protocol  
9 number RO1815), and written informed consent was obtained from each participant  
10 prior to the commencement of the intervention, which was provided free of charge.

11

12 An Accredited Practising Dietitian (KOJ) conducted all of the initial consultations and  
13 intervention sessions. Participants attended an initial individual consultation to assess  
14 whether they met the inclusion criteria, and to obtain demographic and baseline data.  
15 Group-based education sessions were conducted at a local community centre to ensure  
16 easy access for group participants. The participants were allocated to one of two groups;  
17 both groups were facilitated using the same approach. Group allocation depended on  
18 participant availability and to ensure participant numbers were fewer than 12 per group  
19 to align with the Medicare CDM group service item guidelines. Groups were facilitated  
20 on a weekday morning for two hours for a six-week period.

21

22 The group intervention was evaluated using process and participant measures including  
23 questionnaires and anthropometric data to assess the feasibility of the intervention, and  
24 semi-structured interviews with group participants to assess the acceptability of the



1 intervention. Additionally, the group facilitator (KOJ), kept a researcher journal  
2 throughout the intervention to record reflections and logistics such as participant  
3 attendance, suitability of the venue, and peer interactions.

4

5 Baseline (2-3 weeks prior to commencing the intervention) and endpoint data (taken  
6 during the final group session of the program) included weight, waist circumference and  
7 height measurements, and four validated questionnaires assessing nutrition  
8 knowledge<sup>26</sup>, diabetes self-efficacy<sup>27</sup>, diabetes knowledge<sup>28</sup> and diabetes-related QOL.<sup>29</sup>  
9 Only the first two sections (related to dietary recommendations and nutrient sources)  
10 from the nutrition knowledge questionnaire<sup>26</sup> were administered, due to the relevance  
11 and length of the questionnaire.

12

13 Data were assessed for normality and analysed, where appropriate, using the statistical  
14 package SPSS (Statistical package for the social sciences, version 23.0). Prior to  
15 analysis, each of the data sets was assessed for normality. Normally distributed data was  
16 analysed using paired sample t-tests to assess differences in the baseline and endpoint  
17 measures of the group participants for the five normally distributed measures.  
18 Wilcoxon-signed rank tests were performed on two measures that were not normally  
19 distributed.

20

21 The adoption, implementation and acceptability of the intervention were measured by  
22 the number of face-to-face sessions attended and by individual telephone interviews  
23 conducted by an independent research assistant following the completion of the group-  
24 based intervention. The interview questions were developed from earlier research

1 (Odgers-Jewell, et al. 2016, unpublished data).<sup>13</sup> The interviews were audio-recorded,  
2 transcribed, checked, anonymised and corrected against the audio files by the first  
3 author (KOJ). Content was extracted from the interview transcripts by the first author  
4 and confirmed with the senior author (DPR) in order to answer the pre-defined set of  
5 questions, which explored the acceptability of the intervention. Responses to the  
6 demographic questions were categorized and enumerated.

7

## 8 **Results**

9 Three sources were used to develop the intervention. The literature review indicated that  
10 patient-centred group education with the following attributes were favoured: patient  
11 involvement in the design, planning, goal setting and decision making process, regular  
12 reinforcement after education, individualised content, and non-didactic facilitation by an  
13 individual or multidisciplinary team or peer leaders.<sup>10, 11</sup> These were combined with  
14 information provided to allied health professionals in the Medicare group services  
15 information pack including the need for programs to be: patient-centred, facilitated by a  
16 multidisciplinary team, developed according to a plan with achievable and measurable  
17 goals and objectives, to incorporate group rules, and to allocate time for patients to  
18 discuss their experiences.<sup>22</sup> Finally, formative interviews with group facilitators and  
19 participants from existing CDM group education programs indicated: a preference for a  
20 strong focus on group interactions by providing patients with a non-didactic, interactive,  
21 discussion-based program; the importance of group rules set at the commencement of  
22 the group-based education sessions; and goal-oriented and patient-centred content.

23

1 After triangulating these data, the elements used in the development of the final  
2 intervention included a non-didactic, patient-centred approach, the incorporation of  
3 group rules, and adequate time for group discussions. There was a lack of consensus on  
4 the materials or educational content ideally provided to patients in a group-based  
5 education setting, suggesting that more emphasis should be placed on encouraging  
6 group interactions, rather than a sole focus on the content of sessions. There was  
7 divergence in the appropriate length and number of sessions, however two-hour  
8 sessions were chosen as the literature review and formative interviews indicated that  
9 this was an appropriate amount of time to allow group participants to have in depth  
10 discussions. Additionally, it was decided that the sessions would run for six weeks -  
11 again to align with the findings of the literature review and formative interviews, and to  
12 ensure that the time commitment from patients was not unreasonable.

13

14 Recruitment targets through GPs were not met: only two out of 132 (1.5%) medical  
15 centres responded to multiple requests to display recruitment flyers in waiting rooms or  
16 consultation rooms. Due to this low response rate, alternative strategies were used  
17 including advertisements and stories in two local newspapers, recruitment flyers in six  
18 local pharmacies, and an advertisement on the University website. Group participants  
19 were all recruited through feature stories in a free local newspaper.

20

21 An accurate estimation of the reach of the recruitment strategy was not possible,  
22 however it is estimated that the number of persons diagnosed with T2DM within the  
23 50km recruitment radius would be approximately 950 persons.<sup>30</sup> Thirty-three  
24 (approximately 3.5% of the estimated area population with T2DM) potential

1 participants made initial contact with the researcher of which a total of 16 participants  
2 enrolled in the study. Three did not complete the intervention (Figure 2).

3 *[Insert figure 2 here]*

4

5 Demographics of the 13 group participants who attended the program and completed  
6 the telephone interviews are presented in Table 1. The intervention participants were  
7 predominantly Australian, however some participants were born in Europe (United  
8 Kingdom, Croatia, France, Poland and Germany).

9 *[Insert Table 1 here]*

10

11 The results of the four questionnaires and anthropometric measures are shown in Table  
12 2. The results suggest reductions in body weight, BMI, waist circumference, and  
13 increased diabetes knowledge, nutrition knowledge, diabetes self-efficacy, and diabetes-  
14 related QOL. However, despite two of these outcomes reaching statistical significance,  
15 the small sample size of the study was not sufficiently powered to reliably detect  
16 significant statistical differences.

17 *[Insert Table 2 here]*

18

19 The key results of the process evaluation of the intervention study are summarized in  
20 Table 3.

21 *[Insert Table 3 here]*

22

23 Telephone interviews were used to explore the acceptability of the program,  
24 participants' preferences for group program structure and facilitation, and their

1 perceptions of the effect of group interactions. The group-based intervention was  
2 acceptable, with all group participants stating that they would recommend the program  
3 to friends or family as they found it informative, indicated they enjoyed speaking with  
4 other people who had been diagnosed with T2DM, and found the information provided  
5 interesting. Participants noted aspects they liked most were: group interactions, the  
6 facilitators' relaxed attitude, and the length of the group program. A few participants  
7 stated a preference for sessions where they perceived that discussions remained on the  
8 agreed topic. Participants frequently reported that other group members helped their  
9 learning through peer identification and from others' experiences. Participants from  
10 both groups exchanged contact details at the completion of the intervention with the  
11 intention to maintain contact beyond the program.

12

### 13 **Discussion**

14 This study reports on the process evaluation of a single-arm patient-centred, patient-  
15 directed, group-based education program, and this paper has described its development,  
16 feasibility testing and evaluation. Two frameworks were used to capture each phase of  
17 the development and evaluation. The triangulation of data from three sources resulted in  
18 the development of a non-didactic, patient-centred intervention, which was delivered to  
19 participants weekly for a six-week period. The results of the evaluation suggest that the  
20 intervention was feasible, and acceptable to the target group. However, the recruitment  
21 strategy was inadequate and resulted in an insufficient reach of the target population.

22 As such, the maintenance phase of the RE-AIM framework, or the equivalent  
23 implementation phase of the MRC Framework for Developing and Evaluating Complex

1 Interventions, could not be explored.

2

3 Group education research has established the ineffectiveness of didactic education  
4 techniques when compared to non-didactic patient education.<sup>11, 31</sup> Evidence supports the  
5 use of a patient-centred approach, care that is respectful of, and responsive to,  
6 individual patient preferences, needs and values, and has shown that engaging patients  
7 in their health care decisions can enhance their adherence to therapy.<sup>32</sup> Within T2DM,  
8 patient-centred interventions have been effective in improving patient knowledge, blood  
9 glucose levels, weight, and medication usage, and have been shown to improve self-  
10 management behaviours.<sup>17</sup> A patient-directed approach, in which the content of the  
11 group-education program is decided by the patients, reflects patients' own needs and  
12 questions, and includes discussions initiated by patients, has been successfully utilized  
13 by various group-based education studies for the management of T2DM.<sup>33, 34</sup> Allowing  
14 patients to direct their own learning through negotiated topics proposed by group  
15 members may support self-management.

16

17 A key finding and limitation of this feasibility study was the ineffectiveness of  
18 recruiting people with T2DM through GPs. The overall poor recruitment rate may have  
19 been due to the use of GPs as a primary strategy and the generally low uptake of group  
20 education programs by T2DM patients. Despite their principal role in the management  
21 of T2DM patients in the primary health care setting, engaging GPs and recruiting  
22 participants through GPs was difficult. Barriers to recruitment via GPs have previously  
23 been suggested as time and workload pressures<sup>35, 36</sup>, negative attitudes towards research,  
24 concerns about researchers' motives, a lack of interest in the topic of research, and a

1 lack of recognition.<sup>37</sup> Monetary and nonmonetary incentives, endorsement by relevant  
2 authorities, and multiple reminder contacts with clinicians may have boosted research  
3 response rates.<sup>38</sup> In addition, clinicians may have felt overwhelmed with requests for  
4 research participation, desired a greater involvement in the study, or been concerned  
5 about the potential lack of effectiveness of a new trial that would not be an ongoing  
6 addition to the health care system.<sup>39</sup>

7  
8 The generally poor uptake of group-based programs for the management of T2DM may  
9 have also contributed to the reduced recruitment.<sup>30, 40-42</sup> A recent study found that the  
10 three main reasons for non-attendance of group-programs as reported by T2DM patients  
11 were the lack of information or perceived benefit of the programs, unmet personal  
12 preferences such as poor timing or accessibility of group locations, and the shame and  
13 stigma of diabetes.<sup>43</sup> Practitioners should consider how health professionals in primary  
14 care communicate with their T2DM patients in regards to group-education programs,  
15 the optimal timing and location of group programs, and focus on recruitment methods  
16 that minimise any health-related stigma around T2DM.<sup>43</sup>

17  
18 The evaluation found modest improvements in body weight, BMI and waist  
19 circumference as well as the quality of life domains, nutrition knowledge, diabetes  
20 knowledge and self-efficacy measures. Despite the improvements in these measures, the  
21 results should not be overstated due to the small sample size, short follow-up period and  
22 natural fluctuations in weight, BMI and waist circumference which may have occurred  
23 over the same time period. Feasibility study results should in general be interpreted  
24 cautiously, as effects may be smaller or more variable when a full-scale study is

1 conducted.<sup>18</sup> The effectiveness of feasibility studies should primarily be measured using  
2 descriptive statistics, qualitative analysis and basic process evaluation data such as  
3 administrative data.<sup>44</sup>

4

5 The participant evaluation component of this feasibility study, through interviews with  
6 each participant, provided insightful and valuable data from which various conclusions  
7 can be drawn. These included satisfaction with the intervention, willingness of patients  
8 to recommend the intervention, and the positive evaluations of group interactions.  
9 Patient satisfaction has been shown to be clinically relevant, with satisfied patients  
10 being more likely to comply with treatment and to self-manage their condition.<sup>45</sup> The  
11 majority of group participants found other group members added to their learning,  
12 generally through peer identification and learning from others' experiences. Providing  
13 social support to patients with T2DM has been shown to extensively affect patient  
14 behaviour.<sup>46</sup> In particular, group interactions and peer identification may promote self-  
15 efficacy, self-esteem, self-perception, awareness, and positive attitudes towards T2DM  
16 and reduce disease-related anxiety.<sup>46, 48</sup> The group interactions and discussions  
17 encouraged in this study are likely to have had a positive impact on the acceptability  
18 and effectiveness of the intervention.

19

20 Conducting a feasibility study, which trials components of a randomized controlled trial  
21 (RCT), as opposed to a pilot study which trials the operation of all aspects of the  
22 developed RCT, allows researchers to assess the design, methodology and feasibility of  
23 a larger pilot study, and to identify and prepare for the challenges of evaluating an  
24 intervention.<sup>17, 44</sup> Intervention studies are commonly plagued with problems of



1 acceptability, compliance, delivery of the intervention, recruitment and retention, and  
2 smaller than expected effect sizes, which could have been predicted, and potentially  
3 avoided, through feasibility testing and piloting.<sup>17</sup> Feasibility testing an intervention  
4 prior to completing a pilot study additionally allows researchers to assess the  
5 acceptability of an intervention and enhances the scientific rigour of the larger study.<sup>17</sup>

6

7 There were a number of strengths of the study. The utilization of two complementary  
8 development and process evaluation frameworks enabled a comprehensive evaluation of  
9 all aspects of the program, and may provide a useful guide for the development of  
10 interventions in future. The developed intervention reflects facilitator-patient contact  
11 time that is suitable for Australian health professionals planning to facilitate group-  
12 based education programs through the Medicare CDM group service rebates. The  
13 implementation of the intervention in a real-world setting enabled the researchers to  
14 explore the feasibility of the program in the context in which diabetes is usually  
15 managed. The inclusion of interviews to assess the acceptability of the intervention  
16 from the perspective of group participants, and the inclusion of participants from a  
17 range of backgrounds and with a range of years since diagnosis, ensured participant  
18 evaluation was robust.

19

20 There were also several limitations. Recruitment utilizing GPs as a primary recruitment  
21 strategy was unsuccessful, however this resulted in key learnings, which may be applied  
22 when translating the program to practice. Recruitment to future interventions may be  
23 improved through the additional use of specialist clinics, such as diabetes outpatient  
24 clinics, which utilize electronic health records enabling the identification and

1 monitoring of participants<sup>30</sup>, involving participants in trial design<sup>49</sup>, using shorter and  
2 more informative recruitment flyers<sup>50</sup>, and providing monetary incentives to  
3 participants.<sup>51</sup> The potential for sampling bias cannot be ruled out - the sample  
4 characteristics of the group participants were dissimilar to the characteristics of  
5 participants in the AusDiab study.<sup>52</sup>

6

7 This process evaluation indicated that a patient-centred, patient-directed, group-based  
8 intervention for the management of T2DM was both feasible and acceptable to patients.  
9 Additionally, a number of factors were identified as requiring refinement prior to the  
10 facilitation of a pilot study, particularly in regards to recruitment issues. Health  
11 professionals should consider the use of the RE-AIM and MRC frameworks in the  
12 development of group-based interventions to ensure a thorough and complete design,  
13 and evaluation of all phases of the intervention. Furthermore, describing an intervention  
14 using the TIDieR checklist and guide can improve the completeness of intervention  
15 reporting and enable replicability.<sup>24</sup> Further research trialling additional recruitment  
16 strategies, evaluating further measures of effectiveness, and utilizing lengthier follow up  
17 periods is required.

18

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- 8

*Table 1: Group participant sample attributes summary (n=13)*

<b>Attribute</b>	<b>N</b>
<b>Gender:</b>	
Male	7
Female	6
<b>Age:</b>	
55-64 yrs	3
65-74 yrs	5
≥75 yrs	5
<b>Marital Status:</b>	
Married	8
Divorced	2
Separated	1
Widowed	2
<b>Education:</b>	
Primary	1
Secondary	6
Tertiary	6
<b>Employment:</b>	
Casual	1
Self-employed	1
Retired	11
<b>Years since diagnosis:</b>	
<1 yr	2
1-3 yrs	2
4- 6 yrs	4
7-9 yrs	2
≥10 yrs	3
<b>Previous group attendance:</b>	11

**Table 2: Change in anthropometry and questionnaire outcomes (n=13)**

<b>Paired t-tests</b>	<b>Pre-intervention Mean (SD)</b>	<b>Post-intervention Mean (SD)</b>
<b>Body weight (kg)</b>	87.1 (14.88)	86.4 (14.52)*
<b>BMI (kg/m<sup>2</sup>)</b>	30.5 (5.3)	30.3 (5.22)*
<b>Waist circumference (cm)</b>	108.7 (16.29)	107.7 (17.44)
<b>Diabetes Knowledge<sup>(a)</sup></b>	13.38 (4.13)	13.92 (4.19)
<b>Diabetes-related QOL<sup>(a)</sup></b>	121.5 (47.42)	112.08 (46.63)
<b>Wilcoxon-signed rank tests</b>	<b>Pre-intervention Mean (SD)</b>	<b>Post-intervention Mean rank (SD)</b>
<b>Nutrition Knowledge<sup>(a)</sup></b>	44.77 (11.56)	47.54 (7.83)
<b>Diabetes Self-Efficacy<sup>(a)</sup></b>	60.6 (17.96)	67.15 (12.88)

<sup>(a)</sup> Improved scores post-intervention, ns

\* Indicates post intervention measures were assessed as significant ( $P \leq 0.05$ )

**Table 3: Summary table of evaluation results**

MRC framework for complex interventions <sup>16</sup>	Key Findings	RE-AIM process evaluation framework <sup>17, 18</sup>
<b>Development phase</b>	<p><b>Literature scoping</b></p> <p>Two systematic reviews<sup>9, 10</sup>: recommendations were 5 to 16 participants per group; 8 to 52 hours of facilitator-patient contact time over 6 to 12 sessions</p> <p>Medicare group services information pack<sup>20</sup>: recommendations were 2 to 12 participants per group, minimum of 8 x one hour sessions (8 hours of facilitator-patient contact time), individual assessment prior to commencement</p> <p><b>Formative evaluation</b></p> <p>Facilitator and participant interviews: recommendations were 5 to 25 participants per group; 10 to 24 hours of contact time over 4 sessions</p>	-
<b>Feasibility and piloting</b>	<p><b>Recruitment of participants</b></p> <p>33 potential participants made initial contact with the researcher; a total of 16 participants enrolled (3 dropouts) in the study; 13 completed the study (14.4% of the initial target)</p> <p><b>Initial assessment</b></p> <p>100% met the inclusion criteria, were suitable to participate and provided demographic data</p>	<b>Reach</b>
<b>Evaluation</b>	<p><b>Baseline measures- anthropometry</b></p> <p>Mean body weight (<math>\pm</math>SD) (kg): 87.1 (14.88); Mean BMI (<math>\pm</math>SD) (<math>\text{kg}/\text{m}^2</math>): 30.5 (5.3); Mean waist circumference (<math>\pm</math>SD) (cm): 108.7 (16.29)</p>	<b>Effectiveness</b>
-	<p><b>Delivery of intervention</b></p> <p>Participants from both groups attended 4 to 6 (67-100% attendance) sessions; those who missed sessions were unable to attend due to other medical appointments, illness or travel plans.</p>	<b>Implementation</b>
<b>Evaluation</b>	<p><b>Follow up measures- anthropometry</b></p> <p>Mean body weight (<math>\pm</math>SD) (kg): 86.4 (14.52); Mean BMI (<math>\pm</math>SD) (<math>\text{kg}/\text{m}^2</math>): 30.3 (5.23); Mean waist circumference (<math>\pm</math>SD) (cm): 107.7 (17.44)</p>	<b>Effectiveness</b>
<b>Implementation<sup>(a)</sup></b>	<p><b>Interviews</b></p> <p>Program structure: Aspects liked most: Group interactions and facilitator's relaxed attitude</p>	<b>Adoption</b>

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Aspects liked least: Discussions can go off topic  
Recommended changes: Program could have gone for longer  
Ideal program length: 6 weeks, for 2 hours per week (as delivered)  
Group interactions:  
Helped/ hindered learning: Helped; Peer identification and learning from others' experiences  
Role of group facilitator: Facilitating the group; Explaining points  
Patient satisfaction:  
Recommend program: Yes

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<sup>(a)</sup> The implementation phase of the MRC framework refers to aspects of maintenance more aligned with the adoption and maintenance phases of the RE-AIM framework

## *Appendix I: Intervention study design using the TIDieR Checklist and Guide*

<b>1</b>	<b>Brief name</b>	The Bond Diabetes Intervention (ANZCTR registration:12614000572662)
<b>2</b>	<b>Why</b>	<p>Rationale or theory: Patient-centred care, non-didactic approach, patient-directed intervention</p> <p>Goal: To evaluate the feasibility and acceptability of the Bond Diabetes Intervention using two process evaluation frameworks (MRC Framework for Developing and Evaluating Complex Interventions and RE-AIM)</p>
<b>3</b>	<b>What: Materials</b>	Participants were provided with freely available handouts from the Diabetes Queensland website <sup>1</sup> and the Australian Government Department of Health Eat for Health website <sup>2</sup> ; and simple recipes were given to the participants of group 2 only at the request of group members
<b>4</b>	<b>Procedures</b>	<p>Participants were phoned by the group facilitator a week before the commencement of the program to remind them of the commencement date and location.</p> <p>The first session commenced with an introduction by the facilitator, followed by introductions by each of the participants who also explained when they were diagnosed with T2DM. A brainstorming process was used whereby suggested topics were transcribed onto a whiteboard, and then assigned to the sessions to guide content. The topics chosen varied slightly between groups:</p> <p>Group 1 (n= 7) selected understanding diabetes, medications, diet and glycaemic index, hunger pains, margarines and spreads, controlling and checking blood glucose levels (BGLs), BGL diaries, and feeling overwhelmed or stressed;</p> <p>Group 2 (n= 6) selected glycaemic index, gluten free food, sugar cravings, reading food labels, BGL testing, exercise, HbA1c levels, medications, simple recipes, and what to eat.</p> <p>Group rules, informed by previously published 'responsibilities of the group', were established at the first session and discussed to ensure that all participants were aware of expectations.<sup>2</sup> These rules included: 1. Come to every session, 2. Ask anything you want, 3. Maintain confidentiality, and 4. Give new activities at least a 2-week trial.<sup>3</sup></p> <p>A short break was taken in the middle of each session for morning tea, which was provided, in order to allow the participants to become better acquainted in a relaxed environment.</p> <p>The final session included a summary of the topics and farewell.</p>
<b>5</b>	<b>Who provided</b>	Provider: Accredited Practising Dietitian (KOJ); Training: Informal group education training (online) and formal training during University degree (Master of Nutrition and Dietetics, Griffith University) and professional placements across Individual Case Management.
<b>6</b>	<b>How</b>	Face-to-face, group-based, non-didactic delivery using a discussion based, patient-centred and patient directed approach.

- |           |                          |  |
|-----------|--------------------------|--|
| <b>7</b>  | <b>Where</b>             | Local community centre (Robina Town Centre).   |
| <b>8</b>  | <b>When and How Much</b> | 12 hours: 6 weeks of sessions (2 hours each); Group 1: Thursday mornings 9-11am; Group 2: Friday mornings 9:30-11:30am.  |
| <b>9</b>  | <b>Tailoring</b>         | Personalization: The intervention was personalized in that participants received the first session as an individual session in which the topics for the sessions were brainstormed, and group sessions were patient-directed.  |
| <b>10</b> | <b>Modifications</b>     | Nil modifications to the intervention were made, apart from the tailoring of content to each group's needs.  |
| <b>11</b> | <b>How well: Planned</b> | Intervention adherence and fidelity was assessed by the group facilitator (KOJ) who kept a researcher journal throughout the intervention to record reflections and logistics. A three armed, randomized study comparing the effectiveness of the patient-directed intervention, to a structured intervention and a wait-list control group was planned. |
| <b>12</b> | <b>Actual</b>            | The recruitment target was not met resulting in an amendment of the planned study to a single armed feasibility study with no randomization.   |
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