Replicating group-based education interventions for the management of type 2 diabetes: a review of intervention reporting

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Running Head: Replicating group-based education interventions for Type 2 diabetes

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Novelty Statement:

What is already known?

- Group-based education for the management of Type 2 diabetes is effective at improving glycated haemoglobin, fasting blood glucose, body weight, waist circumference, triglycerides, and diabetes knowledge.
- Poorly reported interventions impede intervention replication and research translation.

What this study found?

- Group-based education interventions for the management of Type 2 diabetes are poorly reported and often incomplete.

What are the clinical implications of the study?

- Authors should use the TIDieR checklist to plan and report interventions completely in the literature to assist the replication and implementation of interventions and improving group-based education and outcomes for people with Type 2 diabetes in practice.

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Keywords: type 2 diabetes, diabetes mellitus, patient education, intervention studies
Abstract

Aims: Reporting all components of complex interventions is essential for replication and translation of evidence into practice. This study aimed to assess the completeness of reporting of group-based education interventions for the management of Type 2 diabetes.

Methods: A previous systematic review of group-based education programs for adults with Type 2 diabetes identified eligible intervention studies. Data were extracted and assessed using the Template for Intervention Description and Replication (TIDieR) checklist. Missing data were sourced from other published material, or by contacting authors.

Results: Fifty-three publications describing 47 studies were included. No publications sufficiently described all items. Authors of 43 of the 47 included studies (91%) were contacted via email to obtain missing data to complete the TIDieR checklist. Seven (16%) did not respond. Additional data was obtained for 33/47 (70%) studies. Most studies (45/47; 96%) described intervention duration and frequency, detailed the procedures and rationale (40/47; 85%), provided a brief intervention name and explained any individual tailoring (38/47; 81%), and defined whether providers received training and adequately described how the program was delivered (37/47; 79%). However, few described any modifications (28/47; 60%), whether the intervention was delivered as planned (27/47; 57%), where it was delivered (21/47; 45%), whether materials were provided (19/47; 40%), and who delivered the intervention (13/47; 28%).

Conclusions: Group-based education interventions for the management of Type 2 diabetes are poorly reported. To translate effective research into practice, practitioners need sufficient detail to implement evidence-based interventions. Researcher adoption of the TIDieR checklist will assist translation and replication of published interventions.
Introduction

Compared with individually-focused interventions, group-based education interventions offer several advantages including increased time for the provision of more detailed information, ease of incorporation of families and carers, decreased time demands on health workers, and enabling discussions and support from others facing similar challenges [1]. Furthermore, group-based education may be more cost effective and efficient than individual education, due to the reduced time and funding required to educate a growing number of people in one session [1]. A recent systematic review showed that group-based education for the management of Type 2 diabetes is effective at improving glycated haemoglobin (HbA1c), fasting blood glucose (FBG), body weight, waist circumference, triglycerides, and diabetes knowledge [2]. A recent consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) recommended that all people diagnosed with Type 2 diabetes should be offered access to ongoing diabetes self-management education and support, such as group-based education programs [3].

Effective self-management interventions improve clinical outcomes. However, comprehensive and transparent reporting are required to translate findings for intervention studies into clinical practice [4]. One of the challenges faced by health professionals wanting to facilitate evidence-based group-based education programs with persons diagnosed with Type 2 diabetes, is that published reports often do not contain adequate descriptions of the interventions. This makes it difficult to compare intervention studies, assess the interventions, or replicate the interventions in practice [5-7]. Although substantial research has compared group versus individual education for the management
of Type 2 diabetes, very few studies provide detailed descriptions of the interventions, making them difficult to evaluate and replicate in clinical practice [7, 8].

Incomplete intervention reporting reduces the replicability of potentially effective interventions, reduces researchers’ ability to comprehensively explore the differences between interventions and the effects of intervention variables on outcomes. It may limit research in the area as researchers are spending time developing and piloting new interventions, rather than repeating or refining previous interventions, which have demonstrated effectiveness and may therefore result in clinicians being unable to reliably implement beneficial interventions [9]. Additionally, interventions may be used incorrectly or not at all if they are inadequately reported [10, 11] resulting in other researchers being unable to build on the findings [9] and increasing research waste. Published reports of intervention trials tend to focus on the results rather than describing the interventions adequately [10]. The reporting of non-pharmacological interventions, which are often complex and multifaceted, has been regarded as particularly poor [9, 12]. For example, one study assessed 137 non-pharmacological interventions using an eight item checklist and found that only 39% of interventions were adequately described [9].

The growing evidence of the inadequate reporting in scientific studies has resulted in the development of reporting guidelines [13] with many scholarly journals mandating clinical trials be reported according to the Consolidated Standards of Reporting Trials (CONSORT) for randomized controlled trials [14]. Despite the endorsement of the CONSORT statement by many journals, intervention reporting remains substandard [15]. The Template for Intervention Description and Replication (TIDieR) [15], an extension
of the CONSORT 2010 statement (item 5) and the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) 2013 statement (item 11) introduced in 2014, aims to improve transparency in intervention reporting and replicability. The CONSORT statement suggests that authors report on interventions with sufficient details to allow replication, and the SPIRIT statement provides guidance for the content of trial protocols, whilst the TIDieR checklist extends on the CONSORT and SPIRIT statements providing more generic and comprehensive guidance including clear ways to implement this guidance [15].

The TIDieR checklist has the potential to reduce research waste by improving the ability to replicate interventions, enabling clinicians to implement effective interventions because of the availability of adequate information, and could streamline future research [15]. The TIDieR checklist has been widely used to report on non-pharmacological interventions at several stages of the research process since it was published in 2014 [16], including by studies examining exercise-based cardiac rehabilitation [12], physiotherapy interventions [17], upper limb therapies in unilateral cerebral palsy [18], as well as by two systematic reviews assessing telehealth-delivered dietary intervention trials in chronic disease [19], and printed education material interventions [20]. The findings from two of the studies [17, 18] found that none of the included studies completely reported all aspects of the interventions according to the TIDieR checklist. Furthermore, the systematic review which assessed telehealth-delivered dietary interventions [19], and the study assessing printed education materials [20] both only had one included study that completely reported every checklist item.
This study aims to assess the completeness of reporting of group-based education interventions for the management of Type 2 diabetes in published trials using the TIDieR checklist.

**Research Design and Methods**

This study is a secondary analysis of the studies identified in a systematic review of group-based education interventions for the management of Type 2 diabetes completed by the same research team and which has been previously published [2]. Included studies were those that measured glycated haemoglobin (HbA1c) as an outcome measure and followed participants for at least six months [2]. Fifty-three publications describing 47 studies were included (n=8533 participants) (references provided in Supplemental Files) [2]. Results suggested group-based education interventions were more effective than usual care, wait-list control and individual education at improving clinical, lifestyle and psychosocial outcomes in people with Type 2 diabetes [2].

The current study utilised the search results from this review to assess the completeness of reporting of group-based education interventions for the management of Type 2 diabetes for randomized controlled trials, cluster randomized trials, and controlled clinical trials which met the inclusion criteria described in the initial study [2]. From the included studies, data were extracted using the TIDieR checklist to assess the completeness and replicability of reporting of each group-based intervention (Figure 1) [15]. For the purposes of this study, items 11 and 12 of the TIDieR checklist were combined and item 5 was expanded to explore provider training (Table 1). Data were extracted from the 47 studies and appraised for completeness of reporting using the
TIDieR checklist. Control groups were not included in the TIDieR assessment, as none of the control groups in the included studies received a group-based intervention.

Figure 1: Stages of Study Identification (A) and Author Contact Process (B)
(black or dashed boxes represent the steps taken in the existing systematic review; blue or line boxes represent the steps taken for this study)
**Table 1: Template for Intervention Description and Replication (TIDieR) (adapted from reference)**

<table>
<thead>
<tr>
<th>Item number</th>
<th>Item name</th>
<th>Item description</th>
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<tbody>
<tr>
<td>1</td>
<td>Brief name</td>
<td>A name or phrase that describes the intervention</td>
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<tr>
<td>2</td>
<td>Why</td>
<td>Describe any rationale, theory or goal of the elements essential to the intervention</td>
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<tr>
<td>3</td>
<td>What: Materials</td>
<td>Describe any physical or informational materials used in the intervention (including those provided to participants or used in delivery or training of intervention providers) and where to access these</td>
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<tr>
<td>4</td>
<td>What: Procedures</td>
<td>Describe each of the procedures, activities and/or processes used in the intervention including any support activities and the inclusion/exclusion of family and friends</td>
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<tr>
<td>5a</td>
<td>Provider/s</td>
<td>Intervention providers and their expertise, and background</td>
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<td>5b</td>
<td>Training</td>
<td>Any specific training given to intervention providers</td>
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<tr>
<td>6</td>
<td>How</td>
<td>Describe modes of delivery of the intervention and whether it was provided individually or in a group (including the number of participants per group)</td>
</tr>
<tr>
<td>7</td>
<td>Where</td>
<td>Describe the type of location/s where the intervention occurred and any necessary infrastructure or relevant features</td>
</tr>
<tr>
<td>8</td>
<td>When and How Much</td>
<td>Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, their duration and intensity</td>
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<tr>
<td>9</td>
<td>Tailoring</td>
<td>If the intervention was planned to be personalised or adapted, then describe what, why, when and how</td>
</tr>
<tr>
<td>10</td>
<td>Modifications</td>
<td>If the intervention was modified during the course of the study, describe the changes (what, why, when and how)</td>
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<tr>
<td>11</td>
<td>How well: Planned</td>
<td>If intervention adherence or fidelity was assessed, describe how planned and by whom and strategies utilized to maintain fidelity</td>
</tr>
<tr>
<td>12</td>
<td>How well: Actual</td>
<td>If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.</td>
</tr>
</tbody>
</table>
All studies were assessed by the first author (KOJ). Another author (LEB) independently assessed a random selection of 25% of the included studies using the checklist. There was a 72% agreement (agreement on 104 of 144 items) between the two reviewers before the initial discussion. Conflicts were resolved by discussion between the authors. After the discussion and reappraisal, there was 100% consensus. If consensus could not be achieved, a third researcher (JTK) was available to resolve any conflicts. Intervention items which were reported in sufficient detail in the original publication were recorded as a ‘yes’, whilst intervention items in which sufficient detail was obtained from other publications, clinical trial registration or study websites were recorded as ‘other’, or from email responses from the study authors were recorded as ‘email’, or from a combination of both were recorded as ‘both’. If the required information was unable to be obtained from the original publication or any of the additional sources, the intervention item was recorded as ‘no’.

Authors from included studies were contacted up to three times to obtain missing data (sample questions provided in Supplemental Files). If the corresponding author did not respond, or the email address was no longer in use, a web search of the author’s most recent publications or workplace staff directory was completed to find an updated email address, or the study coauthors were contacted. Data were analyzed using descriptive statistics (number and percentages) in Microsoft Excel 2010 both before and after additional information about the intervention items were obtained from supplementary sources such as email responses from authors, study websites, clinical trial registrations, or other publications by the author/s.
Results

The intervention descriptions included in the 53 publications were assessed for completeness and replicability using the TIDieR checklist [15]. The studies by Gagliardino et al and Huisman et al (references provided in Supplemental Files) reported more than one intervention (e.g. two interventions versus a control). Both interventions were assessed using the TIDieR checklist and no differences in results were noted. A summary of these results are provided in Figure 2, and the details for each study are provided in Table 2.
Figure 2: Number and percentage of studies adequately describing each TIDieR checklist item (N=47)
Table 2: TIDieR checklist results for included publications (n=53)

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Key: ‘Other’ indicates the information was obtained from additional sources such as other publications, clinical trial registration or study websites; ‘Email’ indicates the information was obtained from email responses from the authors; ‘Both’ indicated the information was obtained from a combination of email responses from authors as well as other publications.
Authors of 43 (91%) of the included studies were contacted via email up to three times for missing data. Contact information of authors was not available or invalid for four (9%) publications. Of the 43 contacted authors, 2 (4%) of the emails were returned and no alternative email addresses were found. Of the authors emailed, only seven (16%) did not respond, and one (2%) responded but did not provide any additional data. If the authors responded with the missing data, the data were included in the review and the completeness of the relevant TIDieR checklist item was reassessed. Email enquiries resulted in additional data for 33 (70%) studies.

None of the intervention publications sufficiently described all required items. Once the data obtained from additional sources were included in the review, 10 (21%) of the studies met the requirements for all TIDieR checklist items. The majority of studies described intervention duration and frequency (item 8) (45/47; 96%), the intervention procedures (item 4) and rationale (item 2) (40/47; 85%), provided a brief intervention name (item 1) and explained any individual tailoring (item 9) of the intervention (38/47; 81%), and defined whether providers received training (item 5b) or how the program was delivered (item 6) (37/47; 79%). Fewer studies detailed any intervention modifications (item 10) (28/47; 60%) or whether the intervention was delivered as planned (items 11 and 12) (27/47; 57%). Fewer than half of the studies defined the intervention delivery location (item 7) (21/47; 45%), whether intervention materials were provided and could be accessed by others (item 3) (19/47; 40%), or adequately described who delivered the intervention (item 5a) (13/47; 28%). There were no differences in the adequacy of reporting between study designs.
When additional sources, primarily study authors, were contacted or accessed for further information regarding intervention characteristics, the greatest increase in reporting description occurred for information about program delivery (item 6) (26/47; 55% increase), intervention procedures (item 4) (25/47; 53% increase), modifications (item 10) (23/47; 49% increase), and location (item 7) (21/47; 45% increase). Characteristics such as the provision of materials and where to find them (item 3), and who delivered the intervention (item 5a) (11/47; 23% increase), whether the intervention was delivered as planned (item 10) (10/47; 21% increase), and information regarding any individual tailoring (item 9) (7/47; 15% increase) were less commonly provided by study authors (Figure 2).

Discussion

The current study demonstrates that group-based interventions for Type 2 diabetes are poorly reported and consistently incomplete in details that are essential for replication and implementation. None of the 47 interventions described in 53 publications were reported with sufficient detail to satisfy all 12 items of the TIDieR checklist. Only three of the 47 studies replicated previous interventions, which may be due to the poor reporting of preceding interventions. Two of these studies were replicated by the same group of researchers, which was expected given that only those with a detailed knowledge of an intervention could replicate it in subsequent research.

When assessing only the original publications, without the addition of information from other published sources or details provided over email by study authors, none of the
publications completely described the venue from which the intervention was delivered, including any necessary infrastructure and relevant features (item 7). Once additional data were included and the studies were reanalysed, the most poorly described components of the interventions assessed were: who delivered the study (item 5a), the materials provided to intervention participants and where to find them (item 3), where the intervention was delivered (item 7), whether it was delivered as planned (items 11 and 12), and any intervention modifications (item 10).

The majority of these findings are consistent with previous evaluations of non-pharmacological interventions using the TIDieR checklist, with all five previous studies reporting that intervention modifications (item 10) and fidelity (items 11&12) were most poorly reported [12, 17-20]. Reporting modifications to the planned intervention can enable readers to judge potential threats to internal and external validity, and may assist clinicians to avoid the same mistakes in practice [21]. Intervention fidelity includes various aspects, including the intervention design, delivery, receipt and how well intervention participants are able to use the learned skills in real-life settings [22]. Adequate reporting of these items allows readers to assess the feasibility of the intervention, identify potential barriers to intervention implementation, interpret trial results, and potentially improve the efficacy of replicated interventions in research and clinical practice [12, 19].

More than half (28/47; 60%) of the included studies in this review did not describe whether they provided materials to intervention participants, what the materials were if they were provided, or provided information on where to access them (item 3). This was in line with previous studies which reported a lack of information about, and availability
of, materials provided (item 3) to intervention participants [12, 17-19]. Previous research has indicated that group-based education studies for Type 2 diabetes which provide materials to their intervention participants may be more effective at improving HbA1c than studies that do not provide materials to their participants [2]. If authors are unable to provide the materials or describe them completely in the main publication, they should specify where further information or copies of the material can be located. To be effective practitioners and to implement evidence-based practice, clinicians and researchers need to know what these materials are. Understanding these intervention components is critical to assist the interpretation, analysis and replication intervention studies for research purposes or in clinical practice.

On the contrary, only two of the previous studies indicated a lack of clarity regarding intervention providers (item 5a) or the training (item 5b) provided to them, [18, 20] and none of the previous studies reported the location of the intervention as a poorly reported item (item 7). In assessing item 7, where the intervention was delivered, for the included studies, we decided that the item was not adequately described or replicable in practice if the type of location and any necessary infrastructure or relevant features were not described. This may account for the inconsistency in findings for this item when compared with previous studies.

One of the most poorly described items from the TIDieR checklist in this review was item 5a, providers, with the majority (72%) of the intervention studies included in this review not adequately describing the providers, their expertise or background. Previous research in the area has highlighted similar problems including: that interventions are not described in adequate detail, education themes are not standardised, and the professional
background of educators and their training are often unclear [23]. A qualitative study, which explored group participants’ experiences of a patient-directed group-based education program for the management of Type 2 diabetes, indicated that the provider played a significant role and can have a positive influence on participants’ knowledge, motivation, and their feeling supported or reassured [24]. Further studies have identified the important role of the provider in setting the tone and guiding the direction of groups, which may influence the participant outcomes [25].

Reasons for inadequate intervention reporting in the studies included in this review are unclear. It has been suggested that potential limitations to transparent reporting of interventions may include imposed word limits in journals [26], and copyright or intellectual property concerns [27]. However, approximately 75% of journals have now progressed to online or hybrid publishing in which authors can publish supplementary information in linked appendices and websites thereby reducing at least one potential barrier [15]. While it is possible to obtain additional information about interventions by contacting study authors, it is unrealistic to expect clinicians to perform this additional, often time consuming activity, which greatly impacts on the likelihood of results being translated into clinical practice [28]. Furthermore, authors’ contact details often change, they may only retain study files for the period of time required by ethical review boards [9] then destroy the files, and some authors are unable to provide sufficient detail for intervention replication despite prompting.

Strategies to improve intervention reporting in the literature may include publishing discrete manuscripts which describe the development and piloting of interventions in detail, publishing intervention details through databases of interventions of trial registries
The benefits of utilizing the TIDieR checklist have been recognized by various journals such as the British Medical Journal (BMJ), BioMed Central journals and Implementation Science. These journals now require that authors accompany intervention-based manuscript submissions with appropriate reporting guidelines, and suggest TIDieR as an example [16].

This study is the first to assess the completeness of reporting of group-based education interventions for the management of Type 2 diabetes and uses the TIDieR checklist. The use of the TIDieR checklist provided rigour to the review and allowed the assessment of group-based intervention completeness and replicability, highlighting areas of focus in ensuring future interventions are more replicable. Additional strengths of the study include the thorough systematic evaluation by two independent reviewers, evaluating additional sources of published information and email correspondence with authors. However, the scope of this study was limited to group-based interventions for the management of Type 2 diabetes in adults delivered in person. As such, the conclusions drawn cannot be generalised to other chronic disease management interventions, or interventions delivered through other methods.

Despite the comprehensiveness of the TIDieR checklist, it does not directly describe other intervention attributes such as the personal attributes of the intervention facilitator, the group dynamics or other difficult to measure attributes. The TIDieR checklist was only introduced in 2014, after which the majority of the studies included in this review were published, however poor intervention reporting in diabetes self-management interventions had been identified in the literature since the early 2000’s [7, 8]. This study
highlights that group-based education interventions for the management of Type 2 diabetes need to clearly and adequately describe each component of the intervention for accurate evaluation, replication and translation into clinical practice.

Conclusions

Group-based education interventions for the management of Type 2 diabetes are poorly reported and incomplete. Future group-based intervention studies should design and publish their results using the TIDieR checklist to ensure the completeness of reporting and replicability of interventions. Published studies which do not adequately report the intervention details are at risk of redundancy because they cannot be used to either progress research, nor improve clinical outcomes.

Author Contributions

KOJ undertook this project as part of her Doctor of Philosophy and had a principal role in study conception and design, data extraction, data analysis and interpretation, and wrote the manuscript. LEB assisted with the study conception and design, and data analysis and interpretation. JTK assisted with the study conception and design, data extraction, and data interpretation. RT, EAI and DPR assisted with the study conception and design. All six authors commented critically on the manuscript and approved it for submission. KOJ takes responsibility for the contents of the article.
References:


Supplemental Item 1: References for Included Studies


for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomized controlled trial. BMJ. 2008;336:491.


Supplemental Item 2: Sample questions emailed to study authors for further intervention information (relating to each TIDieR checklist item)

1. Brief name: Please provide the name or phrase which describes the intervention.

2. Why: Please describe any rationale, theory or goal of the intervention (for example: the intervention aimed to assess the influence of group interactions on individuals with type 2 diabetes).

3. Materials: Please describe any materials provided to intervention participants or providers (e.g. handouts, brochures, videos) used in the intervention and where to access these.

4. Procedures: Were there any activities for participants to support the intervention. Were family and friends allowed to attend the intervention sessions?

5a. Provider/s: Who provided the intervention and what were their qualifications and background?

5b. Training: Did the intervention providers received any specific training?

6. How: What was the mode of delivery of the intervention (e.g. face-to-face group-based) and how many participants were in each intervention group?

7. Where: Where was the intervention delivered? Please describe any necessary infrastructure or relevant features (e.g. ramps for wheelchair access; whiteboard to write on).

8. When and how much: How many sessions were provided to participants? How often were the sessions provided, and how long did they run for.
9. Tailoring: Was the intervention planned to be personalized or individualized (e.g. individual medication reviews)? If yes, please describe how this occurred.

10. Modifications: Was the intervention modified during the study (i.e. did the intervention change from the original plan or protocol)? If yes, please describe the changes.

11 & 12: How well: Was intervention adherence or fidelity assessed (e.g. intervention providers were videoed or observed by the lead researcher to ensure fidelity)? Also, please describe the extent to which the intervention was delivered as planned.