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A combined diabetes and continuous glucose monitoring education program for adults with type 2 diabetes

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ABSTRACT

Objective: The lack of descriptions for education programs in studies evaluating the efficacy of continuous glucose monitoring (CGM) compared to blood glucose monitoring (BGM) for individuals with T2DM makes it difficult to compare results across trials. This study aimed to develop and evaluate a new education program for adults with insulin-treated T2DM and HbA1c ≥58 mmol/mol (7.5 %) initiating CGM.
Methods: A 3-h education program was created to provide information on diabetes self-management and CGM or BGM based on international guidelines and a pre-evaluation based on user needs assessment. Questionnaires were used to post-evaluate participant-rated benefits from the program.
Results: Seven individuals attended a user needs assessment of the program and 96 participated in the final education program (61.5 % men, mean age 61 (59.5;63) years, mean diabetes duration 18.2 (16.9;19.5) years, and median HbA1c 69 (63–78)mmol/mol (8.5 (7.9–9.3)%). Benefit from this program was rated good/very good by 95.5 % with no statistically significant difference between glucose monitoring groups.
Conclusions: This study presents a new well-received education program for T2DM for both the CGM and BGM group.
Innovation: The description of the development process and the education provided for both glucose monitoring groups may be useful for CGM initiation in clinics and trials.

1. Introduction

Continuous glucose monitoring (CGM) is becoming widely accepted as an important part of diabetes management. Studies have concluded that CGM may serve as a valuable educational and management tool, particularly for individuals on insulin therapy [1-4]. Compared to traditional monitoring of glucose levels with HbA1c and blood glucose monitoring by finger pricks (BGM), CGM offers a more comprehensive understanding of glucose levels through the measurement of Time In Range (TIR), Time Below Range (TBR), Time Above Range (TAR), and glycaemic variability (GV), enabling more informed decision-making between users and healthcare providers [5,6].

Recent studies have shown that TIR and GV are associated with diabetes complications [7,8]. The benefits of CGM use in individuals with type 1 diabetes, including reduced HbA1c levels and rates of hypoglycaemia, and increased TIR, are well-established [9-11] why CGM has become the standard of care [12]. While the evidence for CGM use in type 2 diabetes (T2DM) is less extensive, similar benefits have been demonstrated [9,13-17]. However, to our knowledge, these studies have not adequately addressed the educational components provided to both healthcare providers and participants in CGM and control/BGM groups. This lack of information may complicate the interpretation and replication of study results. If the educational content provided to CGM users and a control group differ, it may lead to an inaccurate interpretation of the CGM's effectiveness. Education and training are required for the participants to interpret their glycaemic data and to modify their lifestyle behaviour accordingly. Therefore, if participants in the CGM group only receive training on device insertion and not on how to actively use data, the true potential of CGM may be underestimated. Furthermore, enhanced education and support for diabetes management, as well as the optimal use of the CGM, may increase CGM adoption and implementation. Yet, if only the CGM group received structured diabetes education and not the control/BGM group, this could lead to false positive effects of the CGM itself. Accordingly, a clear and detailed education program is necessary to compare outcomes and can serve as a guide for future studies.

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1.1. Objective

The objective was to develop and evaluate a new education program on diabetes self-management and glucose monitoring (CGM or BGM) for individuals with insulin-treated T2DM. The paper describes the development with the pre-evaluation process, the education program content, and post-evaluation of the program.

2. Methods

2.1. Research design

The content of the education program was developed based on international and national guidelines on DSME including core elements from the ADCES7 (healthy coping, healthy eating, being active, taking medication, monitoring, reducing risk, problem-solving), from the Danish health authorities, and the Danish Endocrine Society, as well as a user needs assessment from a pre-evaluation [18-21].

The new education program was developed to be used in the Steno2tech study, a 12-month randomized controlled trial (RCT) evaluating the use of CGM vs. BGM in 96 adults with insulin-treated T2DM and with an HbA1c ≥58 mmol/mol (7.5 %), recruited from the Steno Diabetes Center Copenhagen (SDCC), Denmark [22]. Participants were randomized 3:2 to CGM or BGM. The impact of CGM compared to BGM over 12 months, incorporating the influence of the educational courses, is detailed in a separate paper outlining the differences in change in several glycaemic, metabolic, and participant-reported outcomes [23]. In contrast, the current paper focuses on elucidating and assessing the education courses implemented to enhance generalization and reduce the risk of bias when comparing studies on the efficacy of CGM.

All participants received this two-part education program; a main diabetes self-management education (DSME) part for all participants, and a glucose monitoring part, either CGM or BGM, depending on allocation group. The total duration of the education program was three hours including the glucose monitoring part of 1 h.

2.2. Pre-evaluation procedures

To perform a user needs assessment by a pre-evaluation when designing the program, a group of seven individuals with T2DM, not participating in the RCT, was invited to give their perspectives on the content and planned presentation of the program. This process involved a thorough exploration of the user group's wishes and needs for both the glucose monitoring education and diabetes self-management (re-)education. This included aspects such as the design, content, and how the education program should be evaluated. The user group was provided with the education plan, complete with visual element examples, through email. They were instructed to document any questions or suggestions for improvement. Subsequently, we conducted focus-group interviews to explore their ideas for improvements. The program was modified accordingly.

2.3. Course procedures

Afterwards, the included participants in the RCT all attended the developed face-to-face two-part education course in groups of 4–10 people. The language was set to be neutral, non-judgmental, and respectful, and based on facts, evidence, and guidelines following the recommendations from the American Association of Diabetes Educators (AADE – now ADCES) and the American Diabetes Association (ADA) [24]. This program aimed to ensure that the participants had the knowledge, support, and confidence to work collaboratively with their health care professionals (HCPs) and with shared decision-making to increase TIR and decrease HbA1c, and to ensure that all participants, regardless of which group they were allocated to, received comparable education including the same basic DSME. The programs were of similar length to avoid the influence of more time with the HCPs on the outcome for the CGM group. The education was provided by the study investigator, a trained diabetes care and education specialist.

The content of the developed DSME part of the program appears in Table 1 and contains general information on T2DM management including the influence of different antidiabetics, food items, and physical activity on glucose fluctuations.

For the CGM group, the glucose monitoring part of the education program, included hands-on training on the insertion and handling of the CGM device and data interpretation information. In this study, the Dexcom G6 CGM were used, however, the CGM education was very general except for the device-specific elements on how to insert, wear and change the CGM.

Clinical case examples were included to identify patterns and discuss plans to reduce the risk of hypo and hyperglycaemia.

Similar to the CGM group, the glucose monitoring part for the BGM group encompassed practical instruction on BGM usage and interpretation of glucose values. Likewise, it included case studies to recognize patterns and deliberate on strategies for mitigating the risk of hypoglycaemia and hyperglycaemia.

See Table 2 for further details regarding the unique glucose monitoring part of the program.

After each session component, a discussion opportunity was provided using a question-and-answer format to reduce any uncertainties and concerns, and to enhance a correct understanding of the educational content, while also encouraging participants to discuss with others in the education group. For instance, one participant inquired about the frequency of glucose level measurements among others, the type of glucose-lowering treatments they received, and methods for assessing the carbohydrate content in food and fluids.

Furthermore, a compendium containing written information about the educational content was distributed before the commencement of the education program. This compendium also included contact

Table 1
The diabetes self-management education content in the education program.

What is diabetes?	Differences between T1DM and T2DM Pathophysiology of diabetes
Healthy eating	Following the recommendations on: Portion awareness Types of food choices Identifying carbohydrates also including fluids Amount consumed and timing of meals The effect of carbohydrates on glucose levels
Being active	Following the recommendations of 30 min of activity per day and 2 weekly sessions with high-intensity exercise Examples of different types of physical activity, durations, and intensity The effect of being active on glucose levels
Taking medication	Treatment options in T2DM: Types of anti-diabetic medication Mechanisms Side effects Glycaemic trends Weight changes
Monitoring	HbA1c Target values When and how to measure their blood glucose correctly
Reducing risk	Therapeutic goals, including the latest standard of care Symptoms of and management of hypo- and hyperglycaemia Weight management Complications
Healthy coping, problem-solving, and behaviour-change strategies	Personalized goal setting and the use of shared decision-making to empower participants

Abbreviations: T1DM; type 1 diabetes, T2DM; type 2 diabetes.

Table 2
The glucose monitoring part of the education program, with either CGM or BGM content.

	CGM	BGM
Basic principles	How to insert, wear and change the CGM device How the CGM works and wear time The participants insert their sensor	How to measure, change strips and finger-prick needles How the BGM works The participants measure their blood glucose
Understanding glucose levels	The effects of alarms with a discussion and reflection on the optimal, but realistic individual settings Differences between blood glucose and interstitial glucose levels (Time delay and accuracy)	How to track trends and identify highs and lows
Optimal glycaemic range	TIR, TBR, TAR, GV	Glycemic range, pre- and postprandial targets
How to interpret glucose information to better understand the relationship between participants' glucose levels and their diabetes self-management	Immediate, real-time feedback to guide lifestyle adjustments	Retrospective analysis to guide lifestyle adjustments
Examples	Identifying patterns Discussing plans to reduce the risk of hypo and hyperglycaemia by acting early and by using personal alarms	Identifying patterns Guidance based on specific test results Discussing plans to reduce the risk of hypo and hyperglycaemia by acting early
Discussion on possible barriers and problems glucose minoring device	When to measure blood glucose by finger pricks (symptoms, MRI, CT, etc.) How to prevent adhesion problems, skin reactions, alarm fatigue, and information overload	

Abbreviations: CGM; Continuous glucose monitoring, TIR; Time in range, TBR; Time below range, TAR; Time above range, GV; Glycemic variability, MRI; magnetic resonance imaging, CT; computerized tomography.

information for addressing any follow-up questions.

2.4. Post-evaluation assessment instruments

At the end of the education course, participants evaluated the program using an electronic questionnaire before leaving the clinic to assess the program's effectiveness and determine any between-group differences. The post-evaluation included the following: 1. Participants were asked to rate their pre-existing diabetes knowledge and the benefit they received from each of the session components on a 5-point Likert scale; 2. Participants were asked to rate their overall pre-existing diabetes knowledge and benefits from the education program on the same scale. Additionally, participants were asked about their previous experience with structured diabetes education programs, including whether they had participated in individual or group sessions, and how long ago their last structured education session occurred.

2.5. Data analysis

REDCap, an electronic data capture program [25] was used for data management in the study. This allowed the provision of electronic questionnaires, that questions only could be answered once, and that all items were completed.

Participant characteristics at baseline were summarized for each group. For each questionnaire, the scores were averaged. Continuous outcomes were compared with *t*-test for parametric (the mean and CI 95 % are shown) and Wilcoxon rank sum for non-parametric continuous variables (the median and quartile (IQR) are shown). For categorical variables, Fisher's exact test was calculated (shown in percentages). Statistical significance was inferred at a 2-tailed *p*-value of 0.05 with a CI of 95 %. All statistical analysis were done using R software, version 4.1.2. We did not use any specific r-packages for the statistics, however, the "tidyverse" package was used to see the distribution of continuous data (plots; histograms, boxplots, etc.).

2.6. Research ethics and participant consent

The study was carried out in accordance with the Helsinki Declaration and was approved by the Regional Scientific Ethics Committee (H-20000843). Data collection and handling were performed in accordance with the General Data Protection Regulation and approved by the Danish Data Protection Agency (J-2020-100). The study is registered at www.clinicaltrial.gov (NCT04331444). All participants received written and oral information on the study and signed an informed consent form before entering the study.

3. Results

3.1. Pre-evaluation

In general, the user group involved in the pre-evaluation reported a high usability and acceptability of the education program and the educational content. However, they reported ideas of improvements. This entailed morning-class scheduling, allocated time for case studies, group discussions, and opportunities for questions during the courses. The user group emphasized the importance of maintaining simplicity in language. Moreover, the user group expressed a desire for the written material to be easy to read but sufficiently comprehensive, enabling its use as a compendium.

3.2. Course participants

A total of 96 persons with insulin-treated T2DM participated in the education program in the RCT (CGM group: 60, BGM group: 36).

Baseline characteristics are provided in Table 3, with no between-group differences. For the entire population, the mean age was 61.3 years (CI 95 %: 59.5;63.0), with 61.5 % men. The mean diabetes duration was 18.2 years (CI 95 %: 16.9;19.5). The median HbA1c was 69 mmol/mol (IQR: 63–78) (8.5 (7.9–9.3)%) and the mean body mass index (BMI) was 31.6 kg/m^2 (CI 95 %: 30.4;32.9).

The results regarding self-rated previous experience with diabetes education, pre-existing diabetes knowledge, and benefits with this education program are shown in Table 4.

3.3. Previous structured diabetes education experience

Out of the 96 participants, 60.2 % reported having previously participated in a structured diabetes education program. In total, 27.7 % of the participants reported having received structured diabetes education within the last 5 years, and only 4.8 % within the last year.

Baseline HbA1c was found to be comparable between participants who reported having previously received structured diabetes education and those who reported not having received it (70 and 72 mmol/mol (8.6 and 8.7 %), respectively, $p = 0.32$).

3.4. Pre-existing diabetes knowledge

In general, participants rated their pre-existing knowledge of diabetes as very bad (1.5 %), bad (4.5 %), fair (32.8 %), good (46.3 %), or very good (14.9 %).

HbA1c was similar regardless of participants reported having a high

Table 3
Baseline characteristics of participants in the education program.

	Total (n = 96)	CGM education group (n = 60)	BGM education group (n = 36)	Between-group difference (p-value)
Sex, Male	61.5 %	61.7 %	61.1 %	1.00
Age (years)	61.3 (59.5;63.0)	61.3 (59.0;63.5)	61.3 (58.4;64.2)	0.96
BMI (kg/m^2)	31.6 (30.4;32.9)	31.8 (30.1;33.5)	31.3 (29.4;33.3)	0.72
Diabetes duration (years)	18.2 (16.9;19.5)	18.7 (17.0;20.4)	17.4 (15.2;19.5)	0.33
Ethnicity, Caucasians	92.7 %	93.3 %	91.7 %	1.00
Living alone	37.5 %	31.7 %	47.2 %	0.19
Baseline HbA1c*				0.72
mmol/mol	69 (63–78)	72 (63–79)	68 (62–76)	
%	8.5 (7.9–9.3)	8.7 (7.9–9.4)	8.4 (7.8–9.1)	
Educational level				0.51
Primary school	9.4 %	11.7 %	5.6 %	
High school	4.2 %	5.0 %	2.8 %	
industrial education	27.1 %	25.0 %	30.6 %	
Short education <3 years	19.8 %	23.3 %	13.9 %	
Medium education 3–4 years	19.8 %	20.0 %	19.4 %	
Long education >4 years	19.8 %	15.0 %	27.8 %	

Baseline characteristics are shown as mean with 95 %CI or in numbers (percentage) unless other is stated.
Abbreviations: Body mass index (BMI).
* Median and quartiles.

Table 4
Self-rated previous experience with diabetes education, pre-existing diabetes knowledge, and benefits with this education program.

	Total (n = 96)	CGM education group (n = 60)	BGM education group (n = 36)	Between-group difference (p-value)
Previously received structured diabetes education	60.2 %	59.3 %	62.1 %	0.99
Last received				0.70
0-1 Year ago	8.0 %	6.3 %	11.1 %	
2–5 years ago	38.0 %	34.4 %	44.4 %	
6–10 years ago	36.0 %	37.5 %	33.3 %	
>10 years ago	18.0 %	21.9 %	11.1 %	
Received structured diabetes education within the last 5 years in total	27.7 %	24.1 %	34.5 %	0.47
The overall self-reported pre-existing diabetes knowledge				0.74
Very bad	1.5 %	2.0 %	–	
Bad	4.5 %	3.9 %	6.3 %	
Fair	32.8 %	33.3 %	31.3 %	
Good	46.3 %	43.1 %	56.3 %	
Very good	14.9 %	17.6 %	6.3 %	
Self-rated good or very good diabetes knowledge	61.2 %	60.8 %	62.5 %	1.00
The overall self-reported benefits of the program				0.60
Very bad	–	–	–	
Bad	–	–	–	
Fair	4.5 %	5.9 %	–	
Good	37.3 %	37.3 %	37.5 %	
Very good	58.2 %	56.9 %	62.5 %	

(good/very good) pre-existing diabetes knowledge or not (69 and 72 mmol/mol (8.5 and 8.7 %), respectively, $p = 0.24$).

Although not reaching statistically significance, participants who reported having previously received structured diabetes education also indicated a higher self-rated level of pre-existing diabetes knowledge when compared to those with no education experience (68.2 % and 45.5 %, respectively, $p = 0.13$).

3.5. Rated benefits of the education program

The post-evaluation showed a high self-reported benefit with the education program, regardless of allocated glucose monitoring part (No statistically significant difference, $p = 0.60$). Most participants (95.5 %) rated their benefits from the program as good (37.3 %) or very good (58.2 %). The remaining participants rated it as fair (4.5 %).

Neither self-rated pre-existing diabetes knowledge nor self-rated previous experience with structured diabetes education was associated with the participants' self-rated benefits from the new diabetes education program ($p = 0.68$ and $p = 0.53$, respectively).

4. Discussion and conclusions

4.1. Discussion

The paper describes the development process, the content, and the evaluation of a two-part diabetes education program provided in a study on CGM efficacy. The pre-evaluation led to the modification of the education program after a focus on the usability and acceptability with the incorporation of user needs assessment, and the post-evaluation showed a high self-rated benefits with the program, regardless of allocated glucose monitoring group. The modified education program was feasible, acceptable, and well received by individuals with T2DM commencing CGM as well as individuals continuing using BGM. Lastly, this paper documented that less than 2/3 had previously received structured diabetes education and only a minority within the last five years.

Evidence suggests that DSME itself is associated with favourable changes in diabetes knowledge, and psychosocial and clinical outcomes [18,26-29]. Unfortunately, our findings are supported by other studies, which have shown that up to 50 % of people with diabetes have never received DSME [26,30] and as few as 6 % of those newly diagnosed [31]. Consequently, a considerable number of individuals lack essential knowledge related to diabetes, diabetes management, lifestyle behaviour, and the risk of complications [32]. The large proportion of participants who had not previously received any structured diabetes education in the current study highlights the continued need for more DSME, despite the increased focus on it in recent years. Although no statistically significant difference in self-rated diabetes knowledge was observed between individuals who had previously received structured diabetes education and those who had not, there was a tendency for previously received education to be associated with lower HbA1c levels and higher diabetes knowledge.

While most guidelines recommend DSME at the time of diagnosis, there appears to be a gap in addressing the need for re-education at key points such as, for the participants in this study, when not meeting glycaemic target, or following changes in treatment modality. The

diabetes duration in this study ranged from 5 to 43 years. The significant changes in diabetes management over the past decade have emphasized the importance of continued follow-up on DSME. Moreover, the correlation between HbA1c and diabetes education shows that the effect of DSME decreases over time [33]. This necessitates re-education, especially during changes in treatment modality or when changes occur. Thus, there is significant potential for a simple effective method to enhance diabetes outcomes. Further, this supports the inclusion of a similar structured education program for both groups in studies comparing the effect of CGM and BGM to improve generalization and reduce the risk of bias when comparing studies on CGM efficacy.

Our study demonstrated that participants found the DSME with both the CGM and the BGM educational part to be equally beneficial, regardless of their previous DSME history or diabetes knowledge. This is noteworthy given that CGM is a relatively new technology that some might anticipate being more challenging to learn. However, it is important to acknowledge the potential for ceiling effect bias in our results. Participants may have a general tendency to rate educational interventions favorably.

Our findings support the integration of CGM and DSME programs. They suggest that, with adequate educational support, participants can find CGM just as accessible and useful as BGM, thereby enhancing their ability to manage their diabetes effectively. This is supported by the results from the main RCT comparing the effect of CGM with BGM, which demonstrated that over 12 months, CGM led to a 15.2 % increase in TIR, a 9.4 mmol/mol reduction in HbA1c, lower total daily dose of insulin and weight, as well as improvements in self-reported general health, diabetes-related health, and health behaviour, compared to BGM [23].

One notable advantage of this program is its short duration of only three hours, which makes it a feasible option for both participants and clinicians with limited time for education. Additionally, the well-received education program was developed in alignment with international guidelines and tailored to the preferences and needs of potential participants by incorporating user input. However, the program's short duration precluded the inclusion of practical components such as cooking or exercise instructions and did not feature any follow-up sessions, despite being a desired feature among the users.

The study population was primarily of Caucasian descent and native Danish speakers, which raises questions about the generalizability of the program in other contexts. Moreover, the inclusion criteria of HbA1c $\geq$58 mmol/mol may limit the program's applicability to individuals with an optimal HbA1c at the onset of CGM use. Despite this, the participant population included a wide range of HbA1c levels, educational backgrounds, and ages.

4.2. Innovation

To the best of our knowledge, this is the first study to address the development process and the education provided in a study comparing the effect of CGM with BGM. This is needed to assess, compare, and replicate outcomes of CGM efficacy. User needs assessment was central in the program development and evaluation. The evaluation of the integrated DSME and glucose monitoring (CGM or BGM) education program demonstrated significant high user benefit irrespective of the specific glucose monitoring part. This program has the potential to serve as a model for future studies on CGM efficacy, and as an educational program in clinical settings when initiating CGM, or as re-education for individuals already using CGM.

4.3. Conclusion

This paper encompasses the development, content, as well as the evaluation of a diabetes education program designed for individuals with insulin-treated T2DM. The program comprises general DSME as well as specific content related to glucose monitoring. Most participants rated the program as highly beneficial, regardless of previous experience with structured diabetes education experience, pre-existing diabetes knowledge, or randomisation group.

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CRediT authorship contribution statement

Nanna Lind: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Merete Bechmann Christensen:** Writing – review & editing, Validation, Supervision, Conceptualization. **Kirsten Nørgaard:** Writing – review & editing, Validation, Supervision, Resources, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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