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Does the short-term use of continuous glucose monitoring enhance diabetes self-management behaviour in type 2 diabetes? The DISCO GM Study: A randomised, controlled cross-over study

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ABSTRACT

Introduction: There is little evidence on the impact of Continuous Glucose Monitoring (CGM) on self-management behaviour in people with type 2 diabetes using participant reported outcome measures. We aimed to assess whether self-management behaviour, measured by the Diabetes Self-Management Questionnaire (DSMQ), is altered by the short-term use of CGM in people with complex type 2 diabetes.

Methods: Open, single-centre, randomised crossover study lasting 36 weeks. Participants were aged >18 years, diagnosed with type 2 diabetes >1 year and HbA1c ≥ 9%/75 mmol/mol. All were receiving care from a specialist diabetes team. Following basic diabetes self-management education and a 10 day period of blinded CGM, participants were randomised to one of two sequences. Sequence 1: 12 weeks routine diabetes care followed by 12 weeks CGM use; Sequence 2: 12 weeks CGM followed by 12 weeks routine diabetes care. Both sequences undertook a 12 week follow up period with no CGM use.

Results: Fifty-one participants were randomised, 25 to sequence 1, 26 to sequence 2. At baseline, 62.7% were male, mean age 59.7 years, mean (SD) HbA1c 10.7% (1.07)/93 mmol/mol (11.74) and 88.2% were prescribed insulin therapy. DSMQ mean total score pre-CGM was 7.0 (1.37). Following CGM use, DSMQ total and subset scores improved, with total score increasing significantly (mean difference 0.62, 95% CI 0.27, 0.98; p = 0.001). Present quality of life, HbA1c and %Time in Range also significantly improved following CGM use.

Conclusion: In people with complex type 2 diabetes, the introduction of CGM can significantly improve diabetes self-management behaviour and other important outcomes.

1. Introduction

Self-management of a chronic condition such as diabetes comprises of daily practical, cognitive and socio-emotional commitment such as lifestyle adjustments, medication management, accessing resources, meal planning and self-monitoring of blood glucose levels. It also involves managing the input and expectations of others such as friends and family members. It is therefore, physically, emotionally, intellectually and socially demanding and requires continuous effort [1]. People with type 2 diabetes requiring support from specialist diabetes teams have complex health care needs. They typically experience multiple co-morbidities related and unrelated to their diabetes and are frequent healthcare users. Engagement in self-management behaviours, such as adopting a healthy diet, exercising regularly, and taking medication as prescribed, is difficult due to the complexity of managing multiple health conditions and when time for self-care is limited, people often prioritise managing one dominant health condition over others [2].

To effectively participate in self-management, an individual needs to have adequate knowledge, skills, motivation, and confidence to be capable of undertaking health promoting behaviour. Patient activation aims to increase an individuals' knowledge and confidence and facilitates skills building to enable a more active role in self-management of health conditions [3]. Measuring patient activation levels allows interventions to be tailored to the needs of the individual, improving the

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likelihood of positive engagement and change. Higher levels of patient activation have been shown to be associated with improved clinical outcomes such as HbA1c and blood pressure [4].

The use of structured self-monitoring of blood glucose (SMBG), i.e. paired pre- and post-prandial blood glucose measurements, can improve HbA1c [5], and glycaemic variability [6] in people with type 2 diabetes, even after a short period of time, through the ability to visualise blood glucose levels. The paired blood glucose readings enable people with diabetes to see the impact their self-management behaviours have on their blood glucose levels, thereby improving their understanding of diabetes self-management and reinforcing positive lifestyle choices. Some people however, express difficulty in undertaking structured SMBG due to the inconvenience and additional time and resources required. It can be particularly difficult for people with mobility and dexterity impairments, for example those with co-morbidities such as arthritis, fibromyalgia and Parkinson's Disease. Therefore, continuous glucose monitoring may be an acceptable alternative to SMBG as it provides real time feedback on glucose control without the inconvenience of undertaking finger prick sampling.

Real time continuous glucose monitoring (rtCGM) systems provide a 24 h clinical overview of glucose control and typically provide glucose values at 5 min intervals. The CGM profiles produced enable glucose patterns to be visualised and trends over time to be identified. CGM can characterise dysglycaemia in terms of magnitude, frequency, distribution and duration [7]. Programmable alarms can warn of hypo- and hyperglycaemia and can provide additional safety and reassurance for the user.

Studies have shown that in people with type 1 and type 2 diabetes, CGM can be beneficial in reducing HbA1c and glucose variability whilst also reducing the number of hypoglycaemic episodes and increasing confidence to manage them [8,9]. Additionally, CGM can warn of acute events and can help optimise glucose control. People living with diabetes who make use of the information provided by CGM report an increase in safety, diabetes control and quality of life [10,11]. Being able to visualise the glycaemic impact of actions taken (healthy eating, exercise, taking medication) can increase the interest and willingness of people to follow their management regimens and engage in positive lifestyle changes, i.e. self-management behaviours. However, as with the use of conventional blood glucose monitoring methods, the evidence in people living with type 2 diabetes is conflicting. In addition to the benefits already mentioned, CGM has been reported to increase diabetes distress through the use of alarms, lower self-confidence through the need to wear a device, and present a constant reminder of having diabetes. It also has the potential to increase a sense of helplessness as some people may feel whatever they do is never enough to control their diabetes [12,13]. There is also a feeling amongst some people living with type 2 diabetes that sharing data with healthcare professionals or family members is an invasion of their privacy and can result in negative feedback and judgement on the way they manage their diabetes [14]. Much of the evidence on the use and impact of CGM on quality of life in people living with type 2 diabetes has come from qualitative studies and it has been noted in recent reviews that further research is needed, particularly using Patient Reported Outcome Measures as a primary outcome [13,15].

We hypothesised that CGM, used for a short period, could help to support and enhance diabetes self-management behaviour. The primary objective of the DISCO GM study (Type 2 DIabetes Self-management using COntinuous Glucose Monitoring) was to assess whether the short-term use of CGM alters diabetes self-management behaviour, as measured by the Diabetes Self-Management Questionnaire (DSMQ), in people with complex type 2 diabetes under specialist care. Secondary objectives included assessing whether the short-term use of CGM alters diabetes related quality of life, emotional well-being and patient activation levels in this population. The impact on blood glucose control and other clinical outcomes such as total cholesterol and body mass index (BMI) were also assessed.

2. Participants, materials and methods

2.1. Participants and study setting

Adults with established type 2 diabetes under the care of one of the specialist diabetes teams within Swansea Bay University Health Board were eligible to take part in the study if they had an HbA1c $\geq$ 9.0% ($\geq$75 mmol/mol), were willing and able to use CGM and willing and able to give informed consent. Participants were receiving care from a specialist diabetes team due their complex health needs, related and unrelated to diabetes. Full eligibility criteria can be found via the ISRCTN registry [16].

The Dexcom G6, a rtCGM device that has received a CE Mark for treating people with diabetes aged two years and above in the UK, was used within its indication in this study. At the time of study recruitment, high doses of paracetamol (>1 g every 6 h) and hydroxyurea were listed as interfering substances for the Dexcom G6 CGM device, therefore, people taking high-dose paracetamol or any dose of hydroxyurea were excluded from the study.

Contraindications, warnings, precautions and other important user information detailed in the Dexcom G6 product instructions were discussed with the participant at the initial study visit as part of the informed consent process. All participants received a written and verbal explanation of the study and gave written informed consent to take part prior to any study activity taking place. Participants were also informed of their right to withdraw from the study at any time, without giving a reason.

All study activities took place at the Clinical Research Facility within Morriston Hospital, Swansea.

2.2. Study design

The study was a randomised, crossover study of 36 weeks duration comparing two sequences of 12 weeks, followed by a 12 week follow-up period (Fig. 1). Sequence 1 comprised of 12 weeks routine diabetes care followed by 12 weeks CGM use. Sequence 2 was the reverse comprising of 12 weeks CGM use followed by 12 weeks routine diabetes care. A 12-week follow-up period of routine care with no CGM use followed both sequences. There was a total of 6 study visits, plus 2 telecare visits during the CGM period.

The treatment sequence was determined at random using a computer-generated list of random study sequence. Participants were stratified according to whether they were receiving insulin therapy and approximately equal numbers were allocated to each sequence. The list, with password protected access, was held by the trial management team who revealed allocation to the study team at visit 2 (randomisation visit) following an email request.

Each participant acted as their own control allowing both within group and between group comparisons.

2.3. Study procedures and intervention

On enrollment to the study (visit 1), participants were assessed against the study eligibility criteria and gave a blood sample to confirm whether they met the HbA1c criteria. They also undertook an initial 10 day 'blinded' CGM session (between visit 1 and visit 2). The blinded CGM session involved the participant wearing the CGM device without being able to see the glucose data being collected. The purpose of this was to enable participants to experience wearing the CGM device and see whether they could engage with the technology before actively taking part in the study. This initial blinded CGM session also gathered pre-intervention data on glucose variability and frequency of hypoglycaemia.

Following confirmation of HbA1c eligibility by the Good Clinical and Laboratory Practice accredited central laboratory, all those eligible to continue in the study who reconfirmed their willingness to take part,

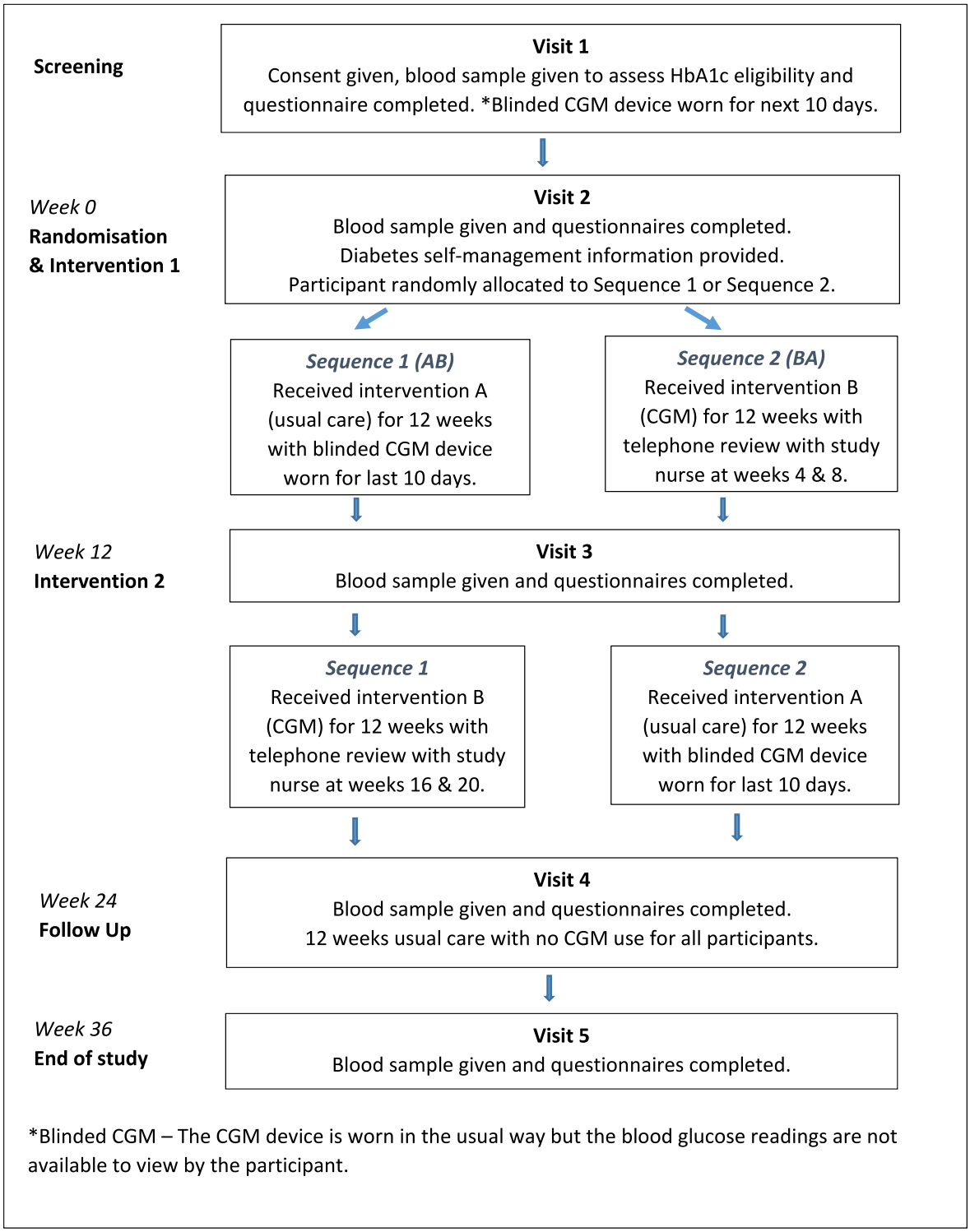

Fig. 1. Study overview.

gave a blood sample for the measurement of HbA1c and total cholesterol when they attended visit 2. They also undertook clinical measurements such as weight and waist circumference and completed a series of questionnaires that included the Diabetes Self-Management Questionnaire (DSMQ) [17], Audit of Diabetes Dependent Quality of Life (ADDQoL) [18], Problem Areas in Diabetes-5 (PAID-5) [19] and Patient Activation Measure (PAM) [20]. They were then given general diabetes self-management education using a combination of standardised materials which they retained for reference throughout the study.

The purpose of the education was to build knowledge, skills and confidence in relation to diabetes self-management and included a description of diabetes, the importance of self-management, the role of diet and exercise and tailored information on medications. The materials used included a general 'Living with Type 2 Diabetes' booklet produced by Diabetes UK [21], a self-management support tool that provided a simple visual guide to examples of lifestyle changes that could help manage blood glucose levels (Fig. 2), and a copy of the Eatwell Guide plate [22]. All participants also received a self-management plan 'diary'

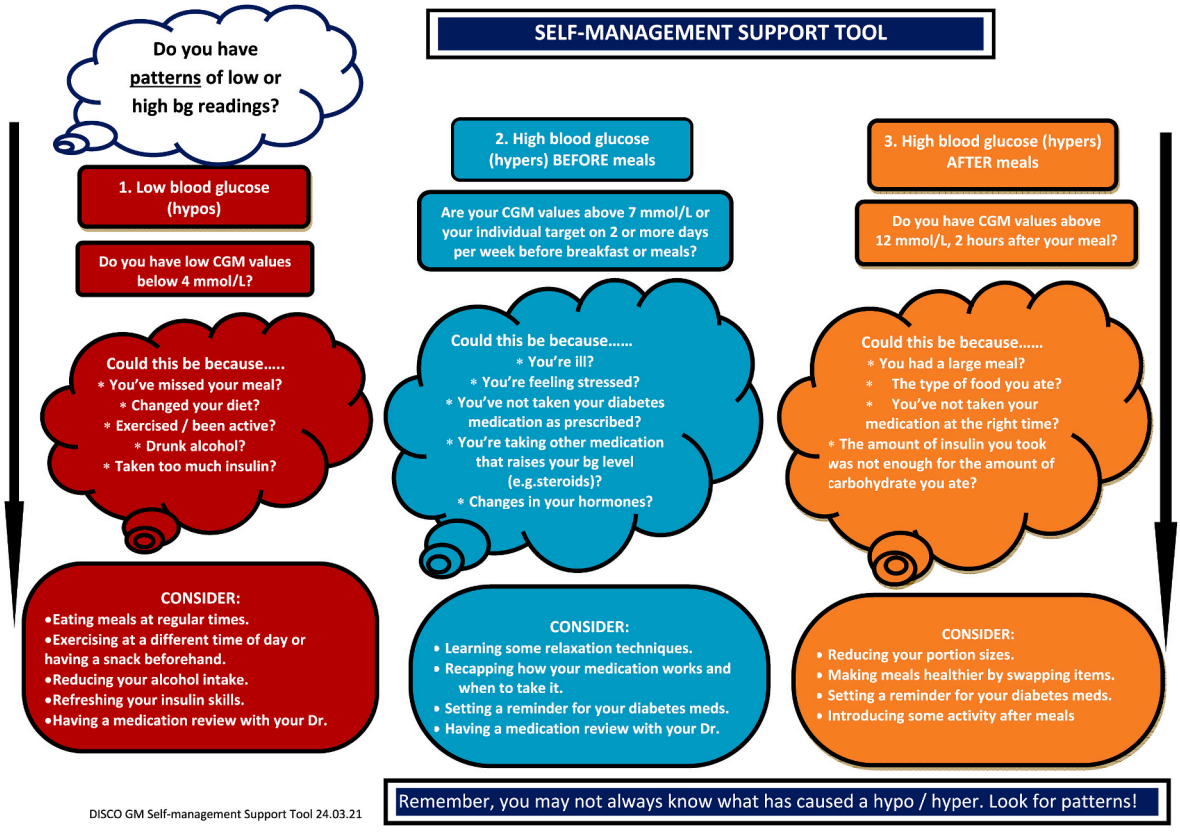

Fig. 2. Self-management support tool.

that they could use to document their action plans at study visits and record any significant events or questions in-between visits. The diary also contained helpful tips for using the CGM based on the "Nine tips to improve glucose control using CGM" developed by Barnard-Kelly and Polonsky [23] and encouraged shared decision making and goal setting when producing the action plans at study visits.

A blood sample to measure HbA1c and total cholesterol was given at each study visit and clinical measurements recorded.

2.4. Continuous glucose monitoring

Blinded CGM was undertaken by all participants for a period of 10 days on entry to the study. To undertake the 12 week CGM sequence, participants were taught how to use the device, including how to apply and remove the sensor, how to view and interpret the data either on their smartphone using the G6 App or with a Dexcom receiver device and actions that could be taken in response to high and low readings. A telecare visit took place at 4 weekly intervals during the active CGM period so that readings could be shared with the research nurse and any issues discussed. An additional period of blinded CGM was undertaken during the last 10 days of the usual care sequence. This was to collect comparison data with the last 10 days of the 'active' CGM sequence. During the blinded CGM periods, the alarm indicating high readings was not activated, however the low alarm indicating hypoglycaemia was active for safety reasons.

2.5. Outcome measures

Clinical and participant reported outcome measures were collected at each of the study visits. The clinical outcomes measured at each visit were HbA1c, total cholesterol, weight, BMI and waist circumference. An Ambulatory Glucose Profile (AGP) report that was generated by the CGM data was produced for each participant covering both 10 day blinded CGM periods and during the 12 week active CGM sequence at 4 weekly intervals and for the last 10 days. Metrics such as 'time in range' (TIR), 'time above range' (TAR) and 'time below range' (TBR) were collected using these reports.

2.5.1. Participant reported outcome measures (PROMS)

The Diabetes Self-Management Questionnaire (DSMQ) is a self-completed, validated tool used to assess diabetes self-care activities associated with glycaemic management. The questionnaire consists of 16 items covering five self-care behaviours including dietary management, medication engagement, blood glucose monitoring, physical activity and contact with healthcare professionals. The items refer to the previous 8 weeks and are formulated as behavioural descriptions from the respondents' point of view. The respondent is asked to rate the extent to which each statement applies to them on a 4-point Likert scale (0 = does not apply to me, 3 = applies to me very much) [17,24].

The Audit of Diabetes Dependent Quality of Life (ADDQoL) questionnaire is designed to measure an individual's perception of the impact of diabetes on their quality of life. It is a self-completed, validated questionnaire containing 19 domain specific items covering topics such as work, leisure, relationships and the future [18,25]. Each domain is scored according to the impact diabetes has on it and how important that domain is to the respondents' quality of life. There are also two general quality of life questions at the beginning of the questionnaire. The first question measuring present quality of life has been used in this study as an overall measure of quality of life for each time point.

The Problem Areas In Diabetes (PAID) scale comprises of 20 statements identified as common areas of diabetes emotional distress reported in individuals with type 1 and type 2 diabetes. The PAID-5 is a shortened version of the scale containing five statements that the individual rates on a 5-point Likert scale ranging from 0 (no problem) to 4 (serious problem), to indicate the level of diabetes emotional distress [19].

The Patient Activation Measure (PAM) is a validated tool that measures people's knowledge, skill and confidence in managing their own well-being [20]. It is a 13 item, self-completed questionnaire with scores ranging from 0 (not applicable) to 4 (strongly agree). A mean score is produced and then transformed into a score between 0 and 100. The score equates to one of the four levels of patient activation ranging from level 1, where the individual feels disengaged and overwhelmed by managing their own well-being, to level 4 where individuals have adopted many behaviours to support their own health and can maintain these behaviours even under stress. Those with higher levels of patient activation are more likely to adopt healthy behaviours and achieve better health outcomes.

All PROMS were administered at visits 2, 3, 4 and 5. In addition, PAM data was also collected at visit 1, on entry to the study.

2.6. Sample size and statistical analysis

The sample size for this pilot study was 50 participants randomised which was selected primarily for pragmatic reasons, with consideration taken of the study timeline, budget and Covid-19 pandemic.

With a sample of 50 participants randomised to one of the two treatment sequences, there was a probability of 80 % that the study would detect a treatment difference at a two-sided 0.05 significance level, if the true difference in primary outcome between GCM and usual care was no smaller than 0.57 standardised units. This was based on the assumption that the within-person standard deviation of the DSMQ total

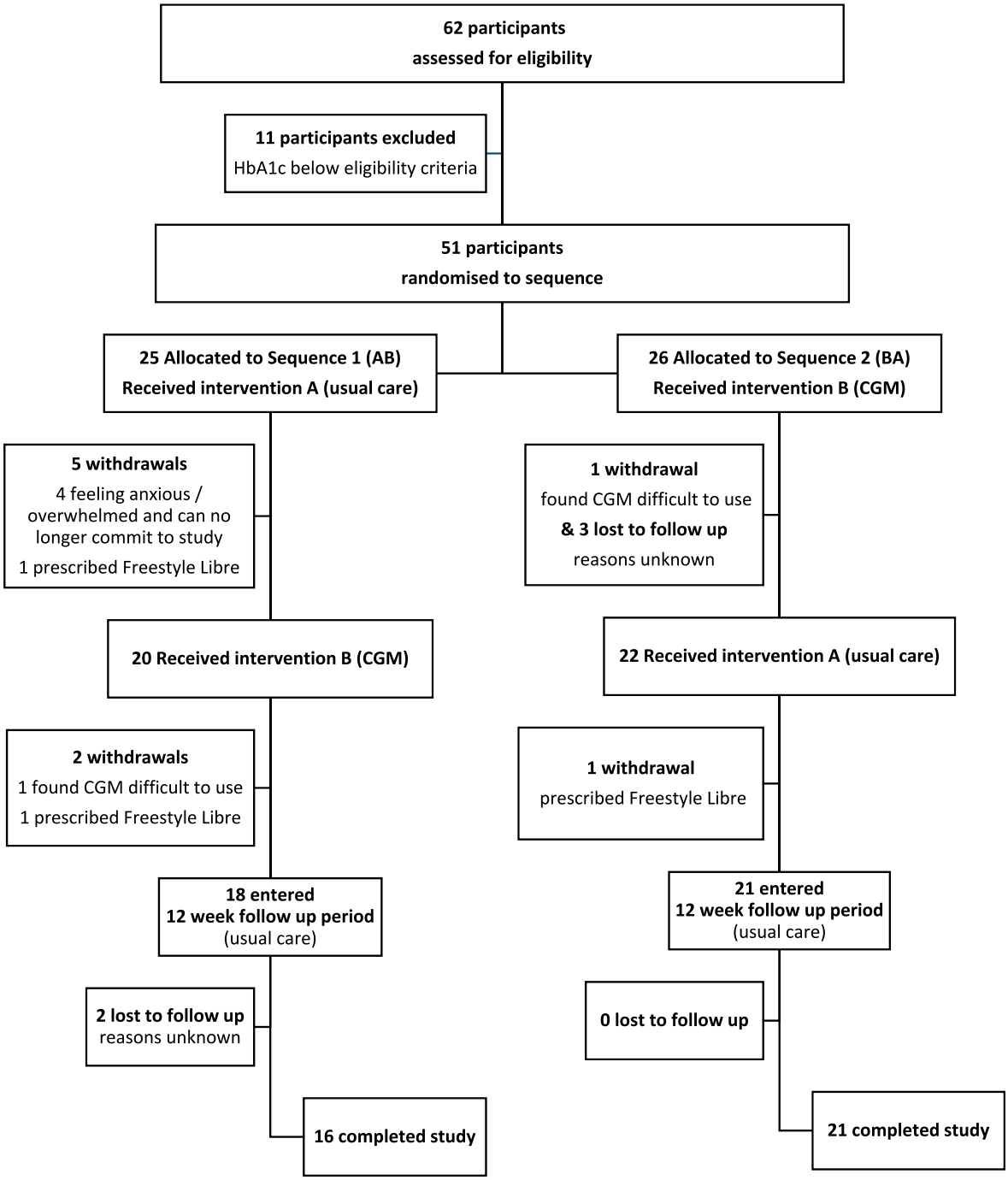

Fig. 3. Participant flow through the study.

score was 1.

Analyses was undertaken according to the intention to treat principle. The primary endpoint was change in diabetes self-management behaviour, measured by the DSMQ. Paired samples t-tests were performed to explore within participant differences. Any significant differences between treatment phases were further analysed using a linear mixed model with participants as a random factor and block (4 levels: weeks 0,12, 24 and 36) and treatment (2 levels: CGM and usual care) as fixed factors to explore potential visit, carryover and treatment effects. Only 3 levels were used for the linear mixed model to analyse the CGM data as there were no CGM data collected at visit 5 (week 36). Differences between the two treatments with the secondary endpoints were modelled in a similar way.

Each PROM was analysed in accordance with their individual guideline.

2.7. Ethical considerations

The study received ethical approval from Wales Rec 6 (ref:20/WA/0349) on January 12, 2021. The study opened to recruitment on June 15, 2021 and completed recruitment on July 1, 2022. All participant involvement was completed by March 31, 2023.

3. Results

Of the 62 participants who were screened to take part in the study, 51 met all eligibility criteria and were randomised to sequence 1 (25 people) or sequence 2 (26 people). In total, 37 participants attended the final visit (16 allocated to sequence 1, 21 allocated to sequence 2) with 9 participants withdrawing from the study and 5 lost to follow up. Participant flow through the study and reasons for withdrawal are shown in Fig. 3.

3.1. Baseline characteristics

The baseline characteristics of all those who enrolled in the study and those who went on to be randomised are shown in Table 1. Of the 51 participants who were randomised, 32 (62.7%) were male with a mean (SD) age of 59.7 (11.98) years. The majority, 96.1% (49/51) described their ethnicity as white, which is reflective of the local population. Just over a third of participants (39.2%, 20/51) had retired from work and 62.3% (32/51) lived in an area categorised by Welsh Government as amongst some of the most deprived in Wales. Mean (SD) HbA1c on entry to the study was 10.7% (1.07)/93 mmol/mol (11.74) and mean (SD) time spent within the glycaemic target range of 3.9–10 mmol/L during the initial 10 day blinded CGM period was 28.2% (22.73). Just over a third of those randomised (39%, 20/51) had experienced a low glucose reading of below 3.9 mmol/L during the initial blinded CGM period which accounted for ~0.5% of the time using CGM. On average, participants had lived with diabetes for 14.8 (7.55) years, 43.1% (22/51) had experienced diabetes complications such as neuropathy and were taking an average of 8.8 (3.76) medications for diabetes and other conditions. The majority of participants (88.2%, 45/51) were prescribed insulin therapy in addition to oral diabetes agents. On the whole, participants' BMI were above the healthy range with 42 (82.4%) falling within the obese or morbidly obese ranges with the mean (SD) BMI at 34.3 (7.68) kg/m^2. A large proportion of those who took part in the study had a moderate (51%, 26/51) or high (17.6%, 9/51) patient activation level on entry to the study.

There were no significant differences in the characteristics of those randomised to sequence 1 and sequence 2 at baseline.

3.2. Primary outcome – diabetes self-management

The primary outcome for this study was diabetes self-management behaviour, measured by the DSMQ. At randomisation, there was no

Table 1
Baseline demographic data for all participants enrolled in the study.

All figures are number (%) unless stated otherwise. All % are within group	All Participants n = 62	Eligible n = 51	[a]Not Eligible n = 11
Gender:			
Female	20 (32.3 %)	19 (37.3 %)	1 (9.1 %)
Male	42 (67.7 %)	32 (62.7 %)	10 (90.9 %)
Age (years):			
Mean (SD)	60.5 (11.51)	59.7 (11.98)	64.0 (8.60)
Median	61.5	59.0	67.0
Range	35 to 84	35 to 84	49 to 72
Ethnicity: White	60 (96.8 %)	49 (96.1 %)	11 (100 %)
Employment:			
Employed	19 (30.6 %)	17 (33.4 %)	2 (18.2 %)
Unemployed	14 (22.6 %)	14 (27.4 %)	0
Retired	29 (46.8 %)	20 (39.2 %)	9 (81.9 %)
[b]Education:			
Further	7 (11.3 %)	3 (5.9 %)	4 (36.4 %)
Higher	8 (12.9 %)	5 (9.8 %)	3 (27.3 %)
O Level	26 (41.9 %)	23 (45 %)	3 (27.3 %)
Other	4 (6.6 %)	4 (7.8 %)	0
None	15 (24.2 %)	14 (27.5 %)	1 (9.1 %)
Missing	2 (3.2 %)	2 (3.9 %)	0
[c]Welsh Index of Multiple Deprivation (WIMD) Quintile:			
1 (most deprived)	16 (25.8 %)	13 (25.5 %)	3 (27.3 %)
2	20 (32.3 %)	19 (37.3 %)	1 (9.1 %)
3	15 (24.2 %)	11 (21.6 %)	4 (36.4 %)
4	4 (6.5 %)	2 (3.9 %)	2 (18.2 %)
5 (least deprived)	7 (11.3 %)	6 (11.8 %)	1 (9.1 %)
Patient Activation Measure (PAM) Level:			
1 (low)	3 (4.8 %)	3 (5.9 %)	0
2 (low)	14 (22.6 %)	12 (23.5 %)	2 (18.2 %)
3 (moderate)	33 (53.2 %)	26 (51 %)	7 (63.6 %)
4 (high)	11 (17.7 %)	9 (17.6 %)	2 (18.2 %)
Missing	1 (1.6 %)	1 (2 %)	0
PAM Score:			
Mean (SD)	62.4 (11.96)	62.3 (12.63)	62.9 (8.68)
Range	43.7 to 100	43.7 to 100	51 to 77.7
Smoker:			
No	20 (32.3 %)	16 (31.4 %)	4 (36.4 %)
Previously	29 (46.8 %)	22 (43.1 %)	7 (63.6 %)
Yes	13 (21 %)	13 (25.5 %)	0
Duration of Diabetes: Mean (SD)	14.5 (7.21)	14.8 (7.55)	13.0 (5.44)
Diabetes Complication Present: Yes	26 (41.9 %)	22 (43.1 %)	4 (36.4 %)
BMI (kg/m^2):			
Mean (SD)	34 (7.20)	34.3 (7.68)	32.7 (3.87)
Range	22.3 to 58.2	22.3 to 58.2	28.5 to 40.5
Weight (kg):			
Mean (SD)	99.4 (19.97)	98.9 (20.72)	101.7 (16.33)
Range	54.9 to 151.2	54.9 to 151.2	84.4 to 140.3
Waist circumference (cm):			
Mean (SD)	116.1 (17.86)	116.5 (19.02)	114.3 (11.74)
Range	86 to 204	86 to 204	102 to 144
[d]HbA1c (mmol/mol):			

(*continued on next page*)

Table 1 (*continued*)

All figures are number (%) unless stated otherwise. All % are within group	All Participants n = 62	Eligible n = 51	[a]Not Eligible n = 11
Mean (SD)	87.8 (15.83)	93 (11.74)	63.4 (6.65)
Range	54 to 121	75 to 121	54 to 72
% Time spent in target Range: Mean (SD)	31.2 (25.82)	27.8 (24.25)	46.5 (28.37)

[a] Participants not eligible for the study as HbA1c below eligibility criteria at screening (V1).

[b] Pearson's chi-squared p = 0.018 indicating a statistically significant association between education and eligibility for the study. Those ineligible for the study tended to have higher educational attainment than those who were eligible for the study.

[c] The Welsh Index of Multiple Deprivation (WIMD) is the Welsh Government's official measure of relative deprivation for small areas in Wales. It identifies areas with the highest concentrations of several different types of deprivation. WIMD ranks all small areas in Wales from 1 (most deprived) to 1909 (least deprived). These rankings are then often grouped into 5 roughly equal sized groups known as 'quintiles' with quintile 1 representing the most deprived areas and quintile 5 the least deprived areas.

[d] There was a statistically significant difference (p < 0.001) between the mean HbA1c levels in those eligible and ineligible for the study, as would be expected, due to the eligibility criteria. Those ineligible for the study all had an HbA1c below 75 mmol/mol.

difference between the groups in mean DSMQ total score or any sub-score. In total, 57% of participants (29/51) had an improved DSMQ total score following use of CGM, i.e. 73% of those who completed the study (27/37). Mean (SD) DSMQ total score pre-CGM for all participants was 7.0 (1.37). This increased significantly to 7.6 (1.31) following 12 weeks CGM use (mean difference = 0.62; 95% CI 0.27, 0.98; p = 0.001). Total score also improved significantly for both sequences individually (Fig. 4). After adjusting for visit and carryover effect, DSMQ total score remained significantly improved following use of CGM (mean difference = 0.86; 95% CI 0.13, 1.60; p = 0.02). Visit and carryover effect did not have a significant effect on DSMQ mean total score.

Within the DSMQ sub-scores, all improved following use of CGM with glucose monitoring (mean difference = 0.96, 95% CI 0.21, 1.71; p = 0.014) and physical activity sub-scores (mean difference = 0.97, 95% CI 0.23, 1.70; p = 0.011) improving significantly (Supplementary data 1). There was a trend for sub-scores to decrease after the 12 week follow-up period.

The primary outcome of DSMQ total score was also analysed in relation to the key covariates of age, gender, highest educational qualification, PAM score and HbA1c at baseline. Only age had a significant impact on DSMQ total score with increased age increasing the likelihood of an improved DSMQ total score (0.05 unit of DSMQ total score increased per year of age; 95% CI 0.01, 0.08; p = 0.009).

3.3. Secondary outcomes

3.3.1. Quality of life and emotional well-being

The use of CGM had an overall positive impact on diabetes related quality of life and emotional well-being, as measured by the ADDQoL and PAID-5 questionnaires. 'Present quality of life', recorded by the ADDQoL questionnaire, significantly improved from 0.59 to 1.35 (mean difference = 0.76, 95% CI, 0.29, 1.22; p = 0.002) post CGM use and remained significantly improved after adjusting for visit and carryover effect. There was no significant visit or carryover effect. 'Present quality of life' significantly improved following the use of CGM despite diabetes having an increased impact on 16 of the 19 life domains recorded in the ADDQoL questionnaire (Supplementary data 2). Diabetes was reported to have a significantly greater impact on leisure activities and independence following CGM use but a reduced impact on working life, self-confidence and freedom to eat, although statistically non-significant. The mean total score and all sub-scores measured by the PAID-5 reduced following CGM use, indicating diabetes was felt to be less of a problem after using CGM, although this reduction was not statistically significant.

3.3.2. Patient activation

The mean PAM score and PAM level both improved significantly

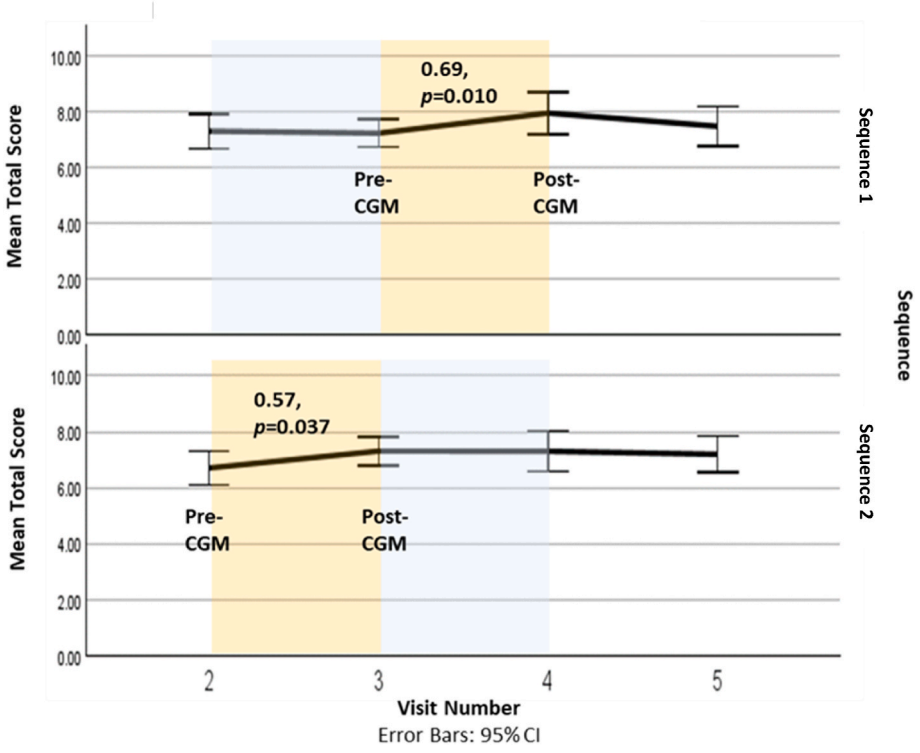

Fig. 4. DSMQ mean total score by visit number and sequence.

following 12 weeks CGM use. Mean score increased from 63.7 to 69.8 (mean difference = 6.07, 95% CI 0.85, 11.29; p = 0.02) and the mean level increased from 2.7 to 3.1 (mean difference = 0.40, 95% CI 0.11, 0.68; p = 0.01). However, after adjusting for visit and carryover effect, there was no longer a significant difference in either PAM score or PAM level. PAM score at visit 2 (randomisation) appears to have had a significant effect on subsequent PAM scores. There was no carryover effect. Twenty five participants had an improved PAM score after undertaking CGM (49% of those randomised into the study and 66% of those who completed the CGM period).

3.3.3. Glucose control

As required by the eligibility criteria, the HbA1c on entry to the study was high. However, following 12 weeks CGM use, mean HbA1c reduced significantly from 10% to 8.8%/86 to 73 mmol/mol (mean difference = −1.2%, 95% CI -1.67, −0.76/−13.3 mmol/mol, 95% CI -18.27, −8.31; p=<0.001). After adjusting for visit and carryover effect, the reduction lessened to −0.8%/−8.7 mmol/mol (95% CI -1.61, 0.04/−17.59, 0.40; p = 0.06). Mean HbA1c values at visit 2 (10.1%/86.72 mmol/mol) were significantly higher than those at visit 3 (9%/75.16 mmol/mol, p=<0.0001), visit 4 (9.2%/76.86 mmol/mol, p = 0.002) and visit 5 (9.3%/78.44 mmol/mol, p = 0.001), after adjusting for visit and carryover effect. (Supplementary data 3).

The percentage of time participants spent within the glucose target range (3.9–10 mmol/L) was measured using blinded CGM for 10 days immediately prior to the 12 week active CGM period. This was compared to CGM data from the last 10 days of the 12 week active CGM period. There was a significant increase in the 'Time in Range' from 29.6% to 38.1 % at the end of the 12 week CGM period (mean difference 8.51, 95% CI 0.46, 16.57, p = 0.04). There was also a significant reduction in the 'Time Above Range', (over 10 mmol/L) from 69.8% to 61.3% (mean difference −8.53, 95% CI -16.73, −0.29; p = 0.04) which included a reduction from 40% to 29.4% of time spent in the very high range of over 13.9 mmol/L (mean difference −10.57, 95% CI -21.09, −0.05; p = 0.05). However, when controlling for visit using the mixed model analyses, neither %TIR nor %TAR remained significantly different. There was no significant difference in the '% time spent below range' i.e. in the hypoglycaemic range, at the end of 12 weeks use of CGM (<3.9 mmol/L). In total 4 participants experienced episodes of severe hypoglycaemia (<3 mmol/L) whilst using CGM. Two participants recorded a severe hypoglycaemic event during the blinded CGM period with no additional episodes whilst using the unblinded CGM. Two further participants recoded episodes of hypoglycaemia during their last 10 days of unblinded CGM.

3.3.4. Clinical measures

Of the clinical measurements assessed, total cholesterol was the only one to show a significant difference post CGM use with a mean reduction of −0.62 mmol/L (95% CI -0.97, −0.26; p = 0.001) from 5.46 to 4.85 mmol/L. This significant reduction was maintained through to the end of the 12 week follow up period with mean total cholesterol at visit 5, 4.84 mmol/L compared to 5.37 mmol/L at visit 2 (mean reduction = −0.53 mmol/L, 95% CI -0.99, −0.07; p = 0.026). When the analysis was adjusted for visit and carryover effect, the significant improvement remained, with a significant carryover effect detected. Mean weight, waist circumference and BMI all increased slightly post CGM use.

3.3.5. Engagement with self-management and the CGM device

The diary given to participants to record their self-management plans throughout the course of the study was returned by 23 people (45% of all participants; 62% of those who completed the study). Within the plans that were returned, there was quite a lot of missing or incomplete data, particularly in the later visits and amongst participants enrolled later in the study. Of those who did engage with the plans as intended, reasons for wanting to use CGM included, wanting to understand their diabetes better, wanting to understand the effect of diet and exercise on their glucose control, wanting to manage their weight, manage or avoid hypoglycaemia and being less painful than using finger pricks. Twelve participants reported positive behaviour changes in their plans and 6 specifically noted improvements in their glucose control due to the use of the CGM. Barriers to self-management, such as injuries restricting exercise and low mood impacting food choices were also reported, along with a few issues using the CGM and applying the sensors. Three participants had difficulty using the CGM, in addition to 2 people who withdrew from the study for issues related to the device which included skin irritation at the sensor site, alarm fatigue, phone incompatibility and difficulty being able to see the glucose readings due to poor eyesight. Usability rates were good with the median length of time CGM was active over the 12 weeks being 94.6%.

4. Discussion

In this study we found that despite their complex health needs, the majority of those who consented to take part exhibited high levels of patient activation at the start of the study and a willingness to engage with CGM and diabetes self-management. This willingness to engage with CGM and other more general self-management behaviours led to a significant improvement in diabetes self-management, evidenced by the improved DSMQ score, along with significantly improved glucose control, evidenced by a reduction in HbA1c and improved time in glycaemic range.

Although many participants had high levels of patient activation on enrolment, there was still some improvement in PAM scores and levels, suggesting CGM facilitated improvement in diabetes knowledge, skills and self-management behaviours, as has been found in previous qualitative studies in this area [11,26]. Also in line with previous studies, the impact diabetes had on individuals' daily lives increased following the use of CGM [13], likely through a heightened awareness of the condition. Importantly, this did not have a detrimental effect on overall quality of life which improved immediately following the CGM use with diabetes reportedly feeling less of a problem.

The benefits reported in this study were seen whilst 'active' CGM was being used and it is noticeable that the greatest benefits were achieved when education and CGM were used in combination. Once CGM was discontinued, improvements in self-management behaviour and HbA1c started to diminish, suggesting diabetes education on its own was not sufficient to sustain continuous self-management behaviour and glucose management. This is in line with other recent studies and it has been suggested that regular intermittent use of CGM be offered to those with type 2 diabetes not prescribed insulin therapy to help maintain engagement with self-management behaviour on a longer term basis [9].

Strengths of this study include the crossover design that minimised the risk of confounding factors and allowed all participants the opportunity to experience the intervention. This design was also adopted to make the most efficient use of the limited resources available during the post COVID-19 pandemic period when recruitment was taking place. A washout period was not felt to be necessary due to the nature of the intervention. However, testing for a carryover effect was included in the analysis plan. The primary outcome assessed diabetes self-management behaviour using a participant reported outcome measure, the DSMQ. The lack of evidence on the impact of CGM on quality of life and self-management behaviour in people with type 2 diabetes reported through PROMS has been previously noted [15] and this study will contribute to that knowledge gap. Also, the participants invited to take part in the study were specifically selected because they had complex health needs, and were representative of the local population. This should increase the generalisability of these study findings to a wider population of people with type 2 diabetes than is often the case with RCTs.

4.1. Study limitations

There are also some limitations to this study. As with most studies, some participants decided not to continue taking part. While not all participants gave a reason, some of those who did, felt overwhelmed or anxious about taking part in a diabetes self-management study, suggesting they did not have the capacity at that time to dedicate the time and resource to managing their diabetes. They had however, been willing to try. Engagement with the self-management plans was quite low, even amongst those who engaged with the CGM and completed the study. The reasons for lack of engagement are unclear, although the time and effort required to undertake self-management is a limiting factor and may have been a factor in completing the plans. Interestingly, people engaged with some aspects of diabetes self-management, i.e. the CGM and modifying aspects of their lifestyle, which led to health benefits, even if they were unable to fully engage with all aspects of the diabetes self-management plan.

4.2. Conclusion

In conclusion, this study has demonstrated the value of offering short-term CGM to people with type 2 diabetes, even those with complex health needs, to enhance their self-management behaviours. CGM enhanced diabetes self-management behaviour by facilitating a better understanding of diabetes without having a detrimental impact on quality of life or increasing diabetes distress. It has the ability to reinforce positive behaviours and motivate individuals to engage with diabetes self-management short-term. Further research is needed to determine the optimal frequency of CGM use in this population to improve diabetes self-management behaviour longer term without having a detrimental impact on overall quality of life.

Author contributions

SNP: Conceptualization, Methodology, Formal analysis, Resources, Data curation, Writing original draft, Visualization, Project administration, Funding acquisition; SDL: Conceptualization, Methodology, Resources, Writing – review & editing, Supervision, Project administration, Funding acquisition; SCD: Resources, Data curation, Writing – review & editing, Project administration; GJD: Validation, Investigation, Resources, Writing – review & editing, Project administration; WYC: Methodology, Validation, Formal analysis, Writing – review & editing, Visualization; SLG: Project administration, Writing – review & editing; DRO: Conceptualization, Methodology, Supervision, Writing – review & editing; JWS: Methodology, Investigation, Writing – review & editing, Supervision, Project administration; Funding acquisition.

Novelty statement

- In people with type 1 and type 2 diabetes, CGM has been shown to be beneficial in reducing HbA1c, hypoglycaemic episodes and glucose variability. However, the evidence on the impact of CGM on quality of life indicators is variable with the majority of research being conducted in people with type 1 diabetes and those with type 2 diabetes on insulin therapy.
- Recent published reviews in this area have recommended expanding the knowledge base on patient reported outcomes in people with type 2 diabetes using CGM and have called for greater data harmonization around PROMs.
- The primary objective of this study was to assess whether the short-term use of CGM alters diabetes self-management behaviour in people with complex type 2 diabetes using the Diabetes Self-Management Questionnaire, a validated patient reported outcome measure.
- The results of our study showed that short term use of CGM significantly enhanced diabetes self-management behaviour. It also significantly improved quality of life and reduced diabetes distress whilst also increasing the impact diabetes had on aspects of daily living.
- Our study highlights the importance of offering CGM to people with type 2 diabetes and complex health needs, regardless of their treatment regimen, to encourage engagement with and enhance diabetes self-management behaviours.

Generative AI

AI-assisted technologies and third party writers were NOT used in this research or the production of this manuscript.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Sharon Parsons reports financial support and equipment, drugs, or supplies were provided by Dexcom Inc. David Owens reports financial support was provided by Dexcom Inc. Stephen Luzio reports financial support was provided by Dexcom Inc. If there are other authors, they 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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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.dsx.2025.103283.

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