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Tolerability and acceptability of real-time continuous glucose monitoring and its impact on diabetes management behaviours in individuals with Type 2 Diabetes – A pilot study

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ABSTRACT

Introduction: Emerging evidence suggests us of real-time continuous glucose monitoring systems (RT-CGM), can assist to improve glucose control in Type 2 Diabetes (T2D) treatment, however the impact of these devices on patients' stress levels and behaviour is poorly understood. This study aimed to examine the effects of RT-CGM on tolerance and acceptability of device wear, stress and diabetes management and motivation to change.

Methods: Twenty adults (10 men, 10 women) with T2D (aged 60.6 ± 8.4 years, BMI 34.2 ± 4.7 kg/m^2), were randomised to a low-carbohydrate lifestyle plan whilst wearing a RT-CGM or an 'offline-blinded' (Blinded-CGM) monitoring system continuously for 12 weeks. Outcomes were glycaemic control (HbA1c), weight (kg) perceived stress scale (PSS), CGM device intolerance, acceptability, motivation to change and diabetes management behaviour questionnaires.

Results: Both groups experienced significant reductions in body weight (RT-CGM −7.4 ± 4.5 kg vs. Blinded-CGM −5.5 ± 4.0 kg) and HbA1c (−0.67 ± 0.82% vs. −0.68 ± 0.74%). There were no differences between groups for perceived stress ($P = 0.47$) or device intolerance at week 6 or 12 (both $P > 0.30$). However, there was evidence of greater acceptance of CGM in the RT-CGM group at week 12 ($P = 0.03$), improved blood glucose monitoring behaviour in the RT-CGM group at week 6 and week 12 ($P \leq 0.01$), and a significant time x group interaction ($P = 0.03$) demonstrating improved diabetes self-management behaviours in RT-CGM.

Conclusion: This study provides preliminary evidence of improved behaviours that accompany RT-CGM in the context of diabetes management and glucose self-monitoring. RT-CGM may provide an alternative approach to glucose management in individuals with T2D without resulting in increased disease distress.

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1. Introduction

As the prevalence of Type 2 Diabetes (T2D) grows, therapeutic treatment options are extending into self-monitoring and mobile-health device delivered therapies to support patients to achieve better disease control [1]. This includes real-time continuous glucose monitoring systems (RT-CGM) that provide users with immediate feedback by enabling them to observe their current glucose levels every 1–5 min [2,3].

Emerging data suggests RT-CGM can promote and enhance diabetes self-management [4–7] and that the use of RT-CGM is an effective interventional tool in assisting patients and health professionals to tailor their diet and exercise behaviours to achieve better glycaemic control, in a time efficient manner. However, despite the promising efficacy of RT-CGM to promote behaviour change and improve glycaemic control, there appears to be no studies that have examined the effect of these devices on outcomes including patient acceptance, tolerance and overall stress or perceived diabetes self-management behaviours. Many people with chronic disease must adjust emotionally, often grieving about the changes they face related to management of their disease [8]. One quarter of those with T2D may have an affective disorder as a result of their disease [8] and others may adhere less closely to treatment advice due to the stress induced by the diagnosis and the consequent requirements for treatment monitoring [9]. Any negative effects of RT-CGM technology on acceptance, tolerance, stress levels and behaviour may limit its usefulness as a strategy for T2D. Accordingly, greater examination of these effects will assist understanding of the use for RT-CGM in clinical practice [10,11]. Therefore, the purpose of this study was to examine the effects of RT-CGM compared to blinded CGM, on tolerance and acceptability of device wear, stress and diabetes management and motivation to change.

2. Methods

2.1. Study participants

Recruitment criteria, study design and the primary study outcomes have been previously described [12]. In brief, 20 overweight/obese adults (BMI 26–45 kg/m^2, age range 20–75 yrs) with T2D (HbA1c: 5.9–6.9% [41.0–51.9 mmol/mol], Diabetes Duration mean 10.8 ± 5.4 yrs) were recruited through public advertisement at the Commonwealth Scientific and Industrial Research Organisation (CSIRO), Health and Nutrition Research Unit (Adelaide Australia), Fig. 1(Participant Flow). Exclusion criteria included type 1 and gestational diabetes and any poorly controlled endocrinopathies. The study was registered with the Australian New Zealand Clinical Trials Registry (ANZTR: 372898) and approved by the Human Research Ethics committees of the CSIRO and the University of Adelaide. Participants provided written informed consent before trial commencement.

In a parallel study design, participants were matched for age and gender and randomised (www.randomisation.com) to one of two, 12-week lifestyle intervention groups: (i) Real Time Continuous Glucose Monitoring group (RT-CGM; n = 10) with use of a real-time continuous glucose monitor and access to real-time visual data, or (ii) Blinded-CGM Group (Blinded; n = 10), with use of a non-display, continuous glucose monitor without access to real-time visual data. All participants wore the Medtronic™ Guardian Connect ® device with the Harmony® glucose sensor (Medtronic, Los Angeles, CA). The minimally invasive glucose sensor was inserted into subcutaneous tissue on the body (usually on the abdomen) to continuously and automatically measure interstitial glucose levels at 5-minute interviews, 24 h a day 288 glucose readings every 24 h) throughout the study. At the first insertion all participants were instructed to conduct a calibration finger-stick (capillary blood) at 2 h and again at 6 h post insertion, then 12-hourly for the duration of the sensor wear. Sensors were removed and replaced with a new sensor every 10 days.

2.2. Intervention

One week prior to baseline in preparation for the intervention, all participants were instructed by the research nurse and dietitian on daily self-monitoring of blood glucose levels (SMBG), including daily fasting and 2hr postprandial readings, as per standard practice, and how to perform CGM glucose sensor insertion, calibration and hygiene requirements, which were performed every 10 days. Additional education to the RT-CGM group was provided by the clinical trial manager that included how to activate the CGM glucose sensor and initiate connectivity to the proprietary Guardian Connect® Application (Medtronic, Los Angeles, CA) for translating the glucose feedback into readable glucose curves and identification of acceptable glucose ranges. To facilitate compliance with CGM device wear, all participants were provided adequate supplies free of charge to enable self-care and hygiene regimes. Every 3 weeks participants returned to the clinic for a body weight check and for the research nurse to review glucose sensor insertion and initiation techniques and to restock supplies.

In addition to wearing the glucose monitors all participants were provided a prescriptive low carbohydrate, high protein and unsaturated fat diet (LC diet) and exercise plan incorporating moderate intensity aerobic and resistance exercises in the form of a commercial publication [13]. This dietary profile and program components have been previously demonstrated to optimise glycaemic control, including diurnal blood glucose stability and reduce CVD risk markers and to facilitated dietary compliance [14–16]. At week 3, participants were provided a 30-minute group-based education session on food exchanges, which informed the participant of food groups and proportions of foods that are matched for the benchmark food (i.e. 1 slice of bread can be exchanged for 3 regular sized crispbreads). A food exchange booklet, to assist participants in making informed food exchanges, to maintain the prescribed energy level and macronutrient profile was provided at visit 2. Participants received no further formal lifestyle counselling or support regarding the diet and exercise plan, or clinical counselling to provide individual strategies that would assist them to achieve their blood glucose goals.

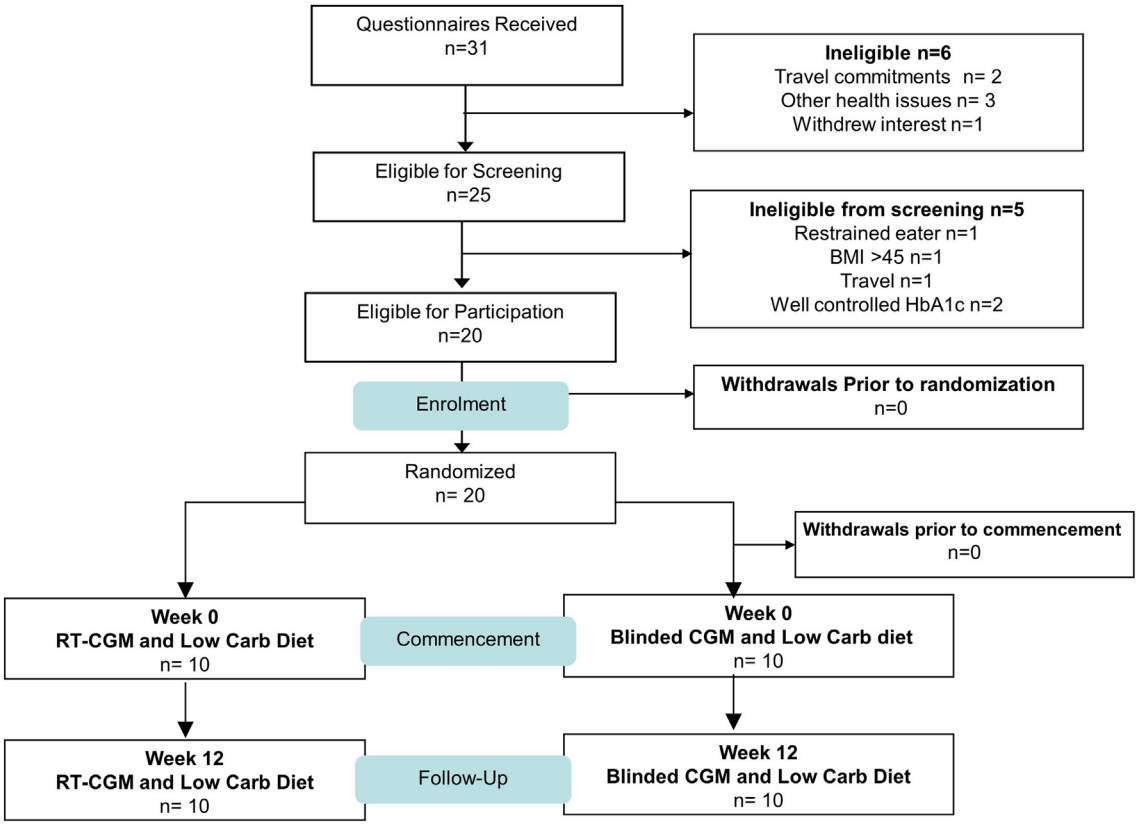

Fig. 1 – Participant flow.

3. Outcomes

3.1. *Glycated haemoglobin (HbA1c) and weight*

Outcomes were assessed at baseline (wk 0) and end of study (wk 12). HbA1c was measured by a certified pathology laboratory (Clinpath Adelaide, Australia). Weight (kg) was assessed using bioelectrical impedance scales (InBody 230, InBody Co. Ltd. South Korea) [12].

3.2. *Perceived stress scale*

At baseline and Week 12, the Perceived Stress Scale (PSS-14), a 14-item (7 positive and 7 negative, see supplementary table) self-report measure, was used to assess the degree to which participants perceive the impact of CGMS wear on levels of chronic stress. Responses range from "never" (0) to "very often" (4) on a 5-point Likert scale. A higher score indicates higher perceived stress, with a total score ranging between 0 and 56. The PSS-14 is a well validated measure that has been shown to correlate well with stressful life events measures and social anxiety [17].

3.3. *CGM device tolerance and acceptability questionnaire*

To assess participant's acceptance or intolerance of the CGM device, a purpose-designed questionnaire was developed because of the apparent absence of any other validated measures pertaining to this technology. The questionnaire consisted of 16 items (see supplementary table), each scored using a 5-point Likert scale ranging from 1 = strongly disagree to 5 = strongly agree. A total of 9-items measured intolerance of the device (e.g., "The sensor and recorder caused me problems with regards to showering", "Installation of the sensor caused me pain", "It was difficult to be intimate with others whilst wearing the sensor and recorder" etc), and 7-items measured acceptability (e.g., "Installing the sensor was easy for me", "I was easily able to calibrate the sensor using my finger-prick lancet", "I was satisfied with the look and feel of the sensor and recorder" etc). Participants completed the questionnaire at Week 6 and Week 12. Scores were summed across items measuring the same domain, and internal consistency of the questionnaire—assessed using Chronbach's alpha—was high at each time point (Week 6: intolerance $\alpha_r = 0.96$, acceptability $\alpha_r = 0.85$. Week 12: intolerance $\alpha_r = 0.89$, acceptability $\alpha_r = 0.81$). Higher scores were associated with higher acceptance, or greater intolerance as per their respective domains.

3.4. *CGM motivation to change questionnaire*

The extent to which the CGM device directly motivated behavioural change was assessed using a purpose-designed CGM motivation questionnaire. This measure included 20-items (see supplementary table) assessing four broad behavioural areas (diet, exercise, blood glucose, and social). Each item

was answered in response to the phrase: "*Wearing the Continuous Glucose Monitor motivated me to …*". A total of 5-items were used for diet behaviours (e.g., " … reduce my meal portions", " … modify my diet to better suit my diabetes" etc), 6-items assessed exercise behaviour (e.g., " … increase my exercise frequency", " … increase the duration of my exercise sessions" etc), 6-items assessed blood glucose related behaviours (e.g., " … understand the impact of difference foods on my blood glucose levels", " … monitor and take note of my blood glucose levels" etc), and 3-items assessed social behaviour (e.g., " … educate my friends about my health needs", " … interact with my Doctor about my diabetes management" etc). The questionnaire was administered at Week 6 and Week 12. Scores were summed across items measuring the same domain, and internal consistency of the questionnaire—assessed using Chronbach's alpha—was high at each time point (Week 6: diet $\alpha_r = 0.86$, exercise $\alpha_r = 0.84$, blood glucose $\alpha_r = 0.90$, social $\alpha_r = 0.82$. Week 12: diet $\alpha_r = 0.63$, exercise $\alpha_r = 0.83$, blood glucose $\alpha_r = 0.88$, social $\alpha_r = 0.72$). Higher scores on each domain were associated with improved behaviours in relation to managing diabetes.

3.5. *Diabetes management questionnaire*

Change in diabetes management behaviours was assessed using a purpose-designed questionnaire. This questionnaire consisted of 18-items (see supplementary table) assessing a range of behavioural domains (e.g., "I set goals for managing my diabetes", "I feel in control of my diabetes", "I often binge on food" etc). Each item is answered using a 5-point Likert scale (ranging from 1 = strongly disagree to 5 = strongly agree). The questionnaire was administered at Week 6 and Week 12 and obtained estimates of diabetes self-management behaviours at each time point. In addition, following the retrospective pre-test methodology [18], participants provided retrospective ratings of their diabetes-related behaviours before commencing the study (both at Week 6 and again at Week 12). This approach overcomes the phenomenon of response-shift which occurs as a result of interventions, and controls for the effect of participants *overestimating* their behaviours at baseline, which often occurs in traditional pre-then-post designs [19]. Distributions of reverse-coded items were reflected, and scores were summed across items to produce a total diabetes self-management score. Internal reliability of the scale was strong at Week 6 (baseline $\alpha_r = 0.082$, current $\alpha_r = 0.85$) and Week 12 (baseline $\alpha_r = 0.71$, current $\alpha_r = 0.88$). Higher scores on this measure signify better behavioural management of diabetes.

3.6. *Statistical analysis*

Statistical analysis was conducted using SPSS Statistics 25 (IBM Corp, 2017) and data were examined for normality (no violations were noted). Analysis of covariance (ANCOVA) was used to test between group differences at Week 12, using baseline measures as covariates for Weight (kg) and HbA1c [20]. The model residuals were assessed for normality and constant variance, assumptions were met.

For the Diabetes Management Questionnaire, retrospective pre-study estimates of behaviour provided at Week 6 and Week 12 were not significantly different ($p > 0.05$) and were strongly correlated ($r = 0.65$, $p = 0.002$), demonstrating participants' ability to retrospectively rate their baseline self-management behaviours. The baseline score for this measure was therefore generated by averaging the retrospective responses provided at each time point. Linear mixed effects models were used to examine change over time for the Diabetes Management Questionnaire and the Perceived Stress Scale. Time was modelled as a continuous variable to enable a comparison of difference in slopes of change through the study. Parameter estimates (using time as a fixed factor) were used to interpret significant interaction effects if present. For measures that did not obtain baseline data (Device Tolerance and Acceptability Questionnaire and the Motivation to Change Questionnaire), independent samples t-tests were used to compare scores across groups within each of the data collection time points. All models were two-tailed and used a threshold of $p \leq 0.05$ for statistical significance. Cohen's d is reported to reflect the magnitude of the effects observed between groups.

4. Results

A total of 20 participants completed the study. For the duration of the intervention (12 weeks, 84 days) all participants achieved 100% compliance to wear time; the only exception being one participant from the RT-CGM group who did not wear the glucose sensor and recorder for 3 non-consecutive days secondary to participation in aquatic activities.

Over the 12 weeks, reduction in weight (RT-CGM – 7.41 ± 4.5 kg vs. Blinded CGM −5.45 ± 4.03) and HbA1c (RT-CGM; −0.67 ± 0.82 kg vs. Blinded CGM −0.68 ± 0.74) were not statistically different between groups ($p > 0.30$).

Descriptive statistics for all behavioural measures are provided in Table 1. Over the course of the study, there was no differential change in PSS scores between groups. CGM intolerance scores were not different between groups at either Week 6 or Week 12. CGM acceptance scores were similar between groups at Week 6, but there was a significantly higher score in the RT-CGM group at Week 12 (Cohen's $d = 1.04$).

For the motivated behaviour change scales, social and exercise behaviour scores did not differ between groups at either Week 6 or Week 12. For diet behaviour, there was no difference between groups at Week 6, but a trend for a higher score in the RT-CGM group at Week 12 was noted ($d = 0.81$). For blood glucose monitoring behaviour, scores were significantly higher in the RT-CGM group compared to the Blinded group at both Week 6 ($d = 1.24$) and Week 12 ($d = 2.06$).

For the total diabetes self-management behaviour assessment, there was a significant effect between treatments ($p = 0.03$ time × group interaction), such that there was a greater overall increase and maintained improvement in behaviour throughout the trial in the RT-CGM group compared to the Blinded group. Post-hoc, within group analysis revealed that scores for the Blinded group had increased significantly from baseline to Week 6 ($p = 0.03$, $d = 1.24$) but were reduced at Week 12 such that scores were not different from baseline ($p > 0.05$, $d = 0.90$). In contrast, scores in the RT-CGM

Table 1 – Means (±SD) for behavioural measures throughout the study for each treatment group.

Measure	Condition	Baseline	6-weeks	12 weeks
Perceived Stress Survey[¥]	Blind CGM	35.5 ± 3.5	–	35.2 ± 2.53
	RT-CGM	33.2 ± 5.1	–	33.7 ± 4.67
Diabetes Management Behaviours	Blind CGM	53.3 ± 6.4	62.9 *[a] ± 8.87	58.9 ± 6.06
	RT-CGM	51.5 ± 8.90	67. 3 *[a] ± 9.86	66.3 *[a] ± 8.45
Acceptance of CGMS	Blind CGM	–	27.2 ± 5.31	27.5 ± 3.38
	RT-CGM	–	30.2 ± 3.79	31.2 *[b] ± 3.73
Intolerance of CGMS	Blind CGM	–	18.4 ± 11.55	16.3 ± 6.60
	RT-CGM	–	14.9 ± 4.51	13.4 ± 5.44
Social Behaviours	Blind CGM	–	9.8 ± 2.97	10.4 ± 1.58
	RT-CGM	–	10.0 ± 2.82	11.2 ± 2.49
Exercise Behaviour	Blind CGM	–	22.9 ± 4.09	21.4 ± 3.09
	RT-CGM	–	20.3 ± 5.48	23.0 ± 4.62
Diet Behaviour	Blind CGM	–	20.1 ± 4.12	19.7 ± 1.49
	RT-CGM	–	20.7 ± 2.98	21.5 ‡[b] ± 2.76
Blood Glucose Monitoring Behaviour	Blind CGM	–	21.8 ± 4.07	24.2 ± 2.57
	RT-CGM	–	26.4 **[b] ± 3.31	28.7 **[b] ± 1.70

Blind CGM, $n = 10$; RT-CGM, $n = 10$; RT-CGM = Real Time Continuous Glucose Monitoring; [a]Within group comparison to baseline; [b]Between group comparison for respective time point; ‡ $p = 0.08$, * $p < 0.05$, ** $p < 0.01$, [¥]Perceived Stress Scores: 0–13 = low perceived stress; 14–26 = moderate perceived stress; 27–40 = high perceived stress. Possible range of scores were: Acceptance of CGMS (0–35); Intolerance of CGMS (0–45); Social Behaviours (0–15); Exercise Behaviours (0–30); Diet Behaviours (0–25); Blood Glucose Monitoring Behaviours (0–30); Higher scores on these measures signify better behavioural management of diabetes.

group were significantly higher compared to baseline at Week 6 ($p < 0.001$, $d = 1.68$) and remained higher at Week 12 ($p < 0.001$, $d = 1.71$).

5. Discussion

This study demonstrates that individuals with T2D who were prescribed to follow a self-directed lifestyle modification program expressed good tolerance and compliance to wearing a CGM for 12 weeks as demonstrated by the high level of wear time achieved. Furthermore, compared to wearing a blinded device, access to glucose data in real time was linked with greater device acceptance and improvements in diabetes self-management behaviours over a 12-week period. Interestingly, both groups experienced similar reductions in HbA1c suggesting that possibility that the potency of the prescriptive lifestyle plan that was administered to both groups may have overridden additional benefits of the RT-CGM over this short time period. Future longer studies (>12 weeks) are required to better understand the chronic effects of RT-CGM when used in conjunction with prescriptive lifestyle interventions.

Previous reports suggest that monitoring of blood glucose in patients with diabetes is associated with general stress and/or anxiety which can impact quality of life [21,22] and promote poorer diabetes self-management and glycaemic control [9,23]. In contrast, the present study showed no evidence of changes in stress levels over time or between groups, suggesting that exposure to real-time blood glucose data does not adversely affect stress. The specific reason for discrepant findings between this and previous studies is not clear. However, previous studies reporting high stress levels associated with blood glucose monitoring have included newly diagnosed participants who may have had insufficient time to adjust to their diabetes diagnosis. Unlike the current study, previous studies also monitored blood glucose using the 7-point blood glucose self-monitoring method that involved 7 or more finger sticks daily, a method that may result in pain from multiple finger sticks and requires greater patient effort that could explain the reported negative effects on stress [21,22]. It is possible that differences between studies in device wear and support protocols could influence the effects of RT-CGM use on stress levels and that differences in the type and frequency of technical and clinical professional support also could contribute to differences between the current and previous findings. Future studies directly comparing the effects of RT-CGM to traditional SMBG on diabetes management and stress are warranted [24–26]. In the present study, the device was also administered with a prescriptive lifestyle plan that engendered improvements in clinical outcomes such as weight and HbA1c. It is therefore possible that these positive clinical effects, some of which were obvious to participants, may have countered any possible negative effects of stress that were associated with glucose monitoring.

In the present study, there was no significant difference in tolerance of the device between groups but there was evidence of higher acceptance in the RT-CGM group at Week 12 compared to the blinded condition. Changes in acceptance and tolerance of RT-CGM device wear with time are rarely reported in the literature [7]. Overall, on the basis of compliance reports, a consistently high level of device acceptance and tolerance has usually been observed [25–27]. Studies that examined acceptance and tolerance to RT-CGM use by applying a system usability score [25] or a purpose designed acceptability and utility survey [28] also reported no change in either acceptance or tolerance following 12 week interventions [25,28]. Therefore, there is novelty to the present finding that RT-CGM produced a greater level of acceptance by study endpoint. This is highly likely due to the perceived value and positive reinforcement of the visual display of real-time blood glucose data for participants in this condition compared to those who could not access their glucose data in real time.

Current diabetes management guidelines promote patient engagement in self-management behaviours. If patients have increased engagement in their own health, this should increase their motivation towards adapting appropriate diet and lifestyle strategies [29]. The present study showed that access to RT-CGM did not change diet, exercise and social behaviour domains compared to blinded-CGM, although there was some preliminary evidence of improved diet behaviour in RT-CGM at Week 12. However, direct measures of dietary and physical activity compliance were not measured. It is also important to note, that both groups were provided a lifestyle intervention consisting of diet and exercise changes, thus precluding our ability to explore specifically the impact of RT-CGM on diet and exercise behaviour in individuals who are otherwise not asked to modify such behaviours.

Access to RT-CGM did appear to have a positive influence on other behaviours, blood glucose monitoring and overall self-management behaviour. Self-monitoring blood glucose is considered an integral part of diabetes self-management that can optimise glycaemic control to prevent the onset of diabetes related complications [30–33]. Traditional SMBG in people with diabetes presents compliance challenges that are well documented and include high levels of avoidance (a desire not to think about blood glucose levels and diabetes), perceived pointlessness (the belief that self-monitoring is not of personal value), and low engagement with health professionals including limited sharing of glucose data with their health care provider [34,35]. The current data provide preliminary evidence that RT-CGM may offer a solution to overcome difficulties with compliance and improve diabetes self-management leading to improvements in diabetes-related outcomes. Larger, longer-term studies are required to understand the effects of prolonged RT-CGM use upon self-management behaviour and diabetes control.

Although this experiment provides early insights into the effects of RT-CGM on diabetes management and self-monitoring glucose behaviour, there are several study limitations. The study had a small sample size and was conducted in a well-controlled and possibly highly-motivated population of individuals with T2D that limit the generalisability of the findings. Future larger studies conducting in diverse populations including those newly diagnosed with either T2D, T1D, Gestational Diabetes or have poorer glycaemic control should be conducted. The study duration was also relatively short and longer-term studies are needed to better understand the durability and tolerability of this intervention approach before the practical applications can be fully realised. Both groups wore a CGM device making it difficult to understand the effects of general device wear on the study's outcomes, however this was not the purpose of this study. Provision of RT-CGM compared to usual control (SMBG) is likely to have more profound effects and should be incorporated in designs of future studies. It is also important to acknowledge that health professionals, although providing lifestyle information, were not actively involved in reinforcing the lifestyle intervention and patient management protocols, only providing device support (calibration, insertions and hygiene management). Health professionals play an important role in the management of patients with T2D [31] and further research should examine the effects of RT-CGM administered with a structured lifestyle program that includes close professional support and interaction. RT-CGM should help health professionals to understand the educational needs of patients and enable integration of this technology with other management paradigms to enhance patient practice and glucose management advice and support.

Strengths of this study included the prospective, randomised controlled trial design used, inclusion of individuals with T2D from the free-living population and the provision of minimal professional support to deliver the intervention that facilitates translation of the findings into clinical practice.

6. Conclusion

In summary, this pilot study showed a high degree of tolerability and acceptance of an RT-CGM device continuously-worn over a 12-week period. There were accompanying improvements in diabetes self-management behaviour in those with real time visual access to frequent BGL data, suggesting CGM offers an alternative approach to glucose management that may effectively support some individuals with T2D without promoting disease distress. Moreover, the use of RT-CGM systems opens the prospect for more insightful patient interaction relative to current practice. RT-CGM could overcome negative barriers associated with traditional glucose monitoring methods. Focussed device education and technical support for participants may explain differences between these findings and others'. RT-CGM should be evaluated further for its use as a lifestyle management tool because it encourages patient engagement with diabetes self-management behaviours.

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Compliances with ethics guidelines

Ethics approval for the conduct of this clinical trial was provided by The Adelaide University, Human Research Ethics Committee and the study has conformed to the Helsinki Declaration 1964, as reviewed by 2013, concerning human rights. Springers policy concerning informed consent has been followed. All procedures performed in this study, were in accor-

dance with the ethics standards of the Adelaide University Human Ethics and Research Committee and with the 1964 Helsinki Declaration and its later amendments. Informed consent was obtained from all individual participants included in the study.

Declaration of Competing Interest

All authors, Pennie Taylor, Campbell Thompson, Natalie Luscombe-Marsh, Thomas Wycherley, Gary Wittert Grant Brinkworth, and Ian Zajac, state that they have no conflict of interest to declare with respect to the research, authorship or publication of this article.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2019.107814.

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