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Item Type	article
Authors	Allen, Nancy A.;Jacelon, Cynthia S.;Chipkin, Stuart R.
DOI	/10.1111/j.1365-2702.2008.02533.x
Download date	2025-05-13 14:43:48
Link to Item	https://hdl.handle.net/20.500.14394/38249



Published in final edited form as:

J Clin Nurs. 2009 February ; 18(3): 373–383. doi:10.1111/j.1365-2702.2008.02533.x.

Feasibility and Acceptability of Continuous Glucose Monitoring and Accelerometer Technology in Exercising Individuals with Type 2 Diabetes

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Abstract

Aims and Objectives—The aim of this study was to develop role model data for an intervention to motivate non-exercising individuals with type 2 diabetes mellitus to engage in regular physical activity. Toward that end, the study 1) described Continuous Glucose Monitoring System data and obtained role model CGMS graphs, 2) described a monitor to measure exercise amount and intensity and 3) explored participants' experiences of the monitors and perceptions of the glucose monitoring data.

Background—Physical activity is a cornerstone of diabetes treatment yet the majority of individuals with diabetes are inactive. Thus, increasing physical activity in these individuals demands innovative interventions.

Design—A two-phase, multi-method design was used.

Methods—In phase 1, a descriptive design was used to describe physical activity patterns and glucose levels for 72 hours in nine exercising adults with type 2 diabetes. In phase 2, a focus group interview was used to collect data from seven phase-1 participants. Verbatim transcripts of the audio taped focus group were analyzed for themes and trends.

Results—The glucose monitor data captured lower glucose levels after exercise. Compared to formal diabetes education, visual data from the glucose monitoring technology were perceived as more relevant to participants' particular, everyday experiences with exercise, diet and stress. Participants reported a reinforced commitment to their exercise and diet regimens after using Continuous Glucose Monitoring System. Technology issues were identified, e.g. discomfort wearing activity monitors and forgetting to enter calibration and event data in glucose monitors.

Relevance to Clinical Practice—Participants found that visual glucose monitoring data reinforced self-management behaviors, such as exercise.

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Contributions

Study design NA, SC, BB; Data collection and analysis NA; Manuscript preparation NA, SC, BB

Relevance to Clinical Practice—Our results suggest that data depicting the response of glucose levels to diet and exercise could be a useful tool to change behavior in individuals with type 2 diabetes.

Keywords

nurses; nursing; Diabetes; Technology; Exercise Intervention; Self-Efficacy

INTRODUCTION

The incidence of type 2 diabetes has risen as the world population has become increasingly overweight and obese. Diabetes now affects 171 million people worldwide and is responsible for 2.9 million deaths per year (Roglic *et al.* 2005, Wild *et al.* 2004). By 2030, the global incidence of diabetes is projected to rise to 366 million. Although exercise is a cornerstone of diabetes treatment, only 39% of individuals with diabetes regularly engage in leisure time physical activity versus 59% of adults without diabetes (Morrato *et al.* 2007). Two major problems in diabetes therapy are how to increase participation in physical activity and how to accurately measure physical activity levels.

The majority of sedentary people with type 2 diabetes can safely benefit from a moderate-intensity physical activity program defined as 40–60% of an individual's maximum oxygen uptake (Albright *et al.* 2000). Moderate-intensity activities, e.g. brisk walking, have been associated with reduced risk of coronary heart disease (Hu *et al.* 2007), stroke (Bauman 2004, Hu *et al.* 2000) and type 2 diabetes (Diabetes Prevention Program Research Group 2002), due primarily to beneficial effects on body weight, blood pressure, serum cholesterol and glucose tolerance. Modest increases in physical fitness, which can reduce the risk of overall mortality two-fold (Myers *et al.* 2002), can be more easily incorporated into the daily routine of all individuals, regardless of income or race (Schneider & Shindler 2001, United States Surgeon General 1996).

Two aspects of lifestyle that are most difficult for most people with type 2 diabetes to change are diet and physical activity (Nelson *et al.* 2002, Peyrot *et al.* 2005). Moreover, changing these behaviors by education alone has been shown to be ineffective (Kulzer *et al.* 2007). However, behavioral strategies derived from social learning theories (Bandura 1986, Fishbein & Ajzen 1975, Prochaska 1979) have improved diabetes knowledge and self-reported behaviors such as adhering to diet, physical activity, glucose testing and medication (Norris *et al.* 2001, Whittemore 2000). These results led to the current standard for diabetes education, which combines educational and behavioral strategies (Mensing *et al.* 2000).

According to Social Cognitive Theory (SCT), an individual's behavior constantly interacts with internal personal characteristics such as cognition, affect, biological factors and the environment (Bandura 1986). A major construct in this theory is self-efficacy, which states that changing and maintaining behaviors are related to expectations about one's ability to perform a certain behavior and one's expectations of the outcomes. An individual's sense of self-efficacy is strengthened by two information sources: vicarious experiences (e.g. role modeling) and performance accomplishment (Bandura 1997). Vicarious experience is gained from seeing peer models master a particular behavior, such as engaging in a regular exercise program. Conversely, seeing others fail despite significant effort can weaken one's self-efficacy. To maximise the influence of vicarious experience, role models should be similar to patients in experiences and characteristics (Gonzalez *et al.* 1990, Rogers *et al.* 2005). Performance accomplishments are derived from personally mastering certain tasks. For example, experiencing success in a physical activity enhances self-efficacy expectations, while failure decreases self-efficacy. Although physical activity is a cornerstone of diabetes

treatment, few theory-based counseling interventions specifically target this behavior in individuals with type 2 diabetes.

New technologies are currently available that may promote self-efficacy related to exercise and type 2 diabetes. One such technology used in diabetes clinical practices is the Continuous Glucose Monitoring System (CGMS; (Gross & Mastrototaro 2000). This system continuously records patients' glucose levels over 72 hours and allows patients to input events such as meals, physical activity and self-monitored blood glucose values. These data are displayed graphically to show how physical activity and blood glucose are related. CGMS use in individuals with type 2 diabetes has included adjusting insulin doses (Zick *et al.* 2007), describe glucose control in pregnancy (Monnier *et al.* 2007), measure glycemic variability (Kohnert *et al.* 2007), evaluate the effectiveness of an intervention (King *et al.* 2007), evaluate different insulin types and regimens (Berthe *et al.* 2007, McNally *et al.* 2007) and to measure the effects of exercise on hyperglycemia (Praet *et al.* 2006). Although it has been suggested (Monnier *et al.* 2007, Weber *et al.* 2007), no studies to date have examined the effectiveness of using CGMS to counsel individuals with type 2 diabetes about physical activity behavior. Another type of technology, the activity monitor, objectively measures walking and other ambulatory activities and provides graphical output over one-minute intervals (Schmidt *et al.* 2003). A study using the activity monitor to provide physical activity feedback is in progress (Slootmaker *et al.* 2005). These technologies can be used by nurses counseling people with diabetes to graphically convey interactions between their physical activity and glucose levels (CGMS) and to electronically record activity over defined periods of time (activity monitors).

As a first step toward using these technologies in a SCT-based intervention to motivate inactive individuals with diabetes to engage in regular physical activity, this pilot study tested the effect of these technologies and obtained role model data. The specific objectives were to: 1) describe CGMS data and obtain role model CGMS graphs, 2) describe an activity monitor for measuring exercise amount and intensity and 3) explore participants' experiences wearing the CGMS and activity monitors and their perceptions of CGMS graphs.

METHODS

Design

This multi-method study was conducted in two phases. In phase 1 a descriptive design was used to explore objective data about glucose and exercise levels from CGMS and activity monitors, respectively. In phase 2, a qualitative descriptive design was used to describe perceptions from phase-1 participants' using a focus group interview.

Sample and Setting

A convenience sample of nine individuals was recruited from a cardiac rehabilitation program and an endocrinology clinic in a large healthcare system. Seven of these individuals also participated in the focus group. Because pilot/feasibility studies are used to develop and refine a research protocol (Burns & Grove 2001), the sample size was intentionally small. Pilot studies often include homogenous samples due to the nature of this early exploratory stage in the development of an intervention (Whittemore *et al.* 2002). However, subsequent studies that have larger and more diverse samples are necessary in the later stages of intervention development to allow for an examination of subgroup differences. Individuals included in this trial had to meet the following criteria: 1) known history of type 2 diabetes, 2) >18 years old, 3) engaged in moderate-level physical activity for a minimum of 30 minutes per day at least two times per week and 4) not using insulin. Participants were

excluded if they were taking glucocorticoids that could interfere with interpretation of glucose levels on CGMS reports.

Written informed consent was obtained from each participant in accordance with study protocols and approvals obtained from two institutional review boards. Two eligible patients declined participation due to family illness and discontinuation of cardiac rehabilitation.

Study Variables

Glucose levels—Participants' glucose levels were continuously monitored over 72 hours by the Minimed CGMS (Medtronic, Minneapolis, MN; Figure 1). The CGMS has four components: a pager-sized glucose monitor, a sterile, disposable subcutaneous glucose sensor with an external electrical connector; a connecting cable; and a communication device for downloading monitor data to a personal computer (Gross & Mastrototaro 2000). Glucose is measured in the extracellular fluid of subcutaneous tissue by a glucose oxidase-based reaction in the CGMS sensor; this glucose level is calibrated against self-monitored blood glucose values entered by the wearer. Accuracy of glucose values obtained with the CGMS has been correlated with laboratory measurements of plasma glucose concentrations (Rebrin *et al.* 1999) and home glucose values (Gross & Mastrototaro 2000). The subcutaneous glucose sensor sends signals every 10 seconds to the monitor, which averages and stores the signals every five minutes. These data are not available to the wearer, but must be downloaded after 72 hours by a clinician to a computer. The data are processed by CGMS software and printed as daily glucose trend plots, a table summarising average glucose levels, glucose ranges and standard deviations. CGMS-measured glucose values have been correlated with laboratory measurements of plasma glucose concentrations ($r=0.90$) (Rebrin *et al.* 1999) and home-measured blood glucose values ($r=0.91$) (Gross & Mastrototaro 2000).

Physical Activity—Over the same 72 hours that glucose levels were measured, exercise was objectively measured using the activity monitor, the Actigraph uniaxial accelerometer (Manufacturing Technologies Incorporated, Fort Walton Beach, FL). The Actigraph accelerometer, a small ($5.1 \times 3.8 \times 1.5$ cm) monitor worn at the right side of the waist, measures the frequency and intensity of accelerations at 1-minute intervals. The signal from the activity monitor was automatically converted to counts and stored in the memory. Count values corresponding to specific physical activity intensity ranges (light, moderate etc.) have been determined in laboratory testing (Freedson *et al.* 1998). The intensity of physical activity was categorised by the following cut points: sedentary (<499), light activity (500–1951), moderate activity (1952–5724) and vigorous activity (≥ 5725 counts) (Freedson *et al.* 1998). Data from activity monitors is reported as activity counts and/or minutes spent at different activity intensity levels (1,440 = 24 hours).

Demographic and Clinical Information—Demographic and clinical data were collected using a standardised self-report form. Demographic data included gender, race, ethnicity, marital status, education and age. Clinical data included diabetes duration, body mass index (BMI; weight [kg]/height [m²]) and hemoglobin A1c (A1c) level. Participants' BMI was measured at baseline by the first author. Each participant's most recent A1c level was obtained following Health Insurance Portability and Accountability Act procedures from laboratory reports. All A1c levels were assayed by high pressure liquid chromatography (Bio-Rad variant). Baseline information was also collected on three self-reported variables: 1) co-morbidity history (cardiovascular-related conditions, smoking history and family history of cardiovascular disease), 2) current type, frequency, duration and intensity of physical activity and 3) current diabetes medications.

Procedure

Phase 1—The interventionist instructed participants about wearing the CGMS monitor and inserted the CGMS sensor, which was worn for 72 hours. Participants were also instructed and fitted with activity monitors, which were worn during the period. After 72 hours, participants returned to the clinic for removal of the CGMS and activity monitors. At the same appointment, CGMS data were downloaded and reviewed with each participant. The activity monitor data were not reviewed with participants; these data were used only for analysis.

Phase 2—After completing phase 1, all participants were asked to attend a one-hour, tape-recorded focus group interview moderated by the interventionist. An expert in focus group methodology assisted with the focus group and summarised participant responses and handled logistical issues. During and immediately following the focus group, field notes were taken on key discussion points and observations (e.g. body language, group mood).

Focus group discussions were structured as outlined by (Krueger 1998b). The discussion was guided by open-ended questions such as, ‘What was it like to wear the CGMS? What was it like to wear the activity monitor? What were your thoughts when you saw the CGMS graphs? What advice would you give others who might be considering an exercise program to improve their diabetes?’

Statistical Analysis

Demographic variables were described by frequency distributions and appropriate summary statistics for central tendency and variability. Phase-1 data (CGMS glucose levels and activity counts) were examined by frequency distributions and appropriate summary statistics for central tendency and variability. Summary analyses were performed using Statistical Package for Social Science (SPSS) version 15. Daily and summary graphic displays were downloaded from factory CGMS software for each participant that illustrated daily glucose patterns in relation to exercise, meals, medications and stress. Information from the activity monitor was imported into ActiGraph software (DOS RIU256K.EXE, software 2.27) and then transferred to a SAS program (version 9.1; Cary, NC) to categorise data as sedentary/light, moderate and vigorous using Freedson’s cut points (Freedson *et al.* 1998). An assessment of glucose level changes following exercise was determined by analyzing the start time of physical activity from activity monitor data and evaluating the duration and amount of change from CGMS data. Pre- and post-prandial glucose levels were measured using CGMS data for the meal before and after exercise.

Phase-2 data from the audio taped focus group interview were transcribed verbatim. The resulting transcript was coded for categories and examined for themes both within and across coding categories. The analysis strategy consisted of content analysis of transcripts and field notes (describing and counting responses). The following questions about the group dynamics and data guided the analysis (Krueger 1998a): (1) What are people saying? (2) What are people feeling? (3) What is really important? (4) What are the themes? (5) Were any bits of wisdom said only once but merit noting? (6) Which quotes really give the essence of the conversation? and (7) What ideas will be especially useful to understanding participants’ perceptions?

RESULTS

Participants

Most participants were male (7/9) and white (9/9). On average, they were obese (BMI=32.5 SD 4.2 kg/m²), about 56 SD 8.5 years old) and had a four-year history of diabetes. The

majority had either a college or a postgraduate degree (5/9) (Table 1). Few participants reported diabetes-related co-morbidities (n=3), but all had a history of hypertension (9/9) and the majority had undergone cardiac surgery (5/9) (Table 2). All participants were non-smokers, with a minority reporting a history of smoking (4/9) (Table 2).

All participants were engaged in a regular physical activity regimen (Table 3). The most frequently reported types of physical activity were walking (9/9), lifting weights (6/9) and bicycling (6/9) at moderate intensity (9/9). Participants engaged in physical activity 4–7 days per week, from 30–90 minutes each time.

Participants' current diabetes medications that could affect glucose levels and interpretation of CGMS data were metformin (5/9), a glitazone (4/9) and a sulfonylurea (4/9). All participants were taking long-acting diabetes medications.

Physical Activity

Participants averaged 313,726 (SD 138,017) activity counts per day. Over an average day, their measured activity indicated that they were sedentary/light (1403 SD 22 min/day), moderate (34 SD 13 min/day) and vigorous (4 SD 10 min/day) activity. A sample of activity monitor data is shown in Figure 2. Participants' problems related to using activity monitors were pinched skin when bending (n=1), sweaty and irritated skin under monitor (n=4), unclear instructions (n=1) and data lost from incorrect download (n=1) and monitor failure (n=1).

Physical activity data (amount and duration) from activity monitors were compared to the same data self-reported by participants. Of the seven participants with complete activity monitor reports, three males underreported and one male overrepresented the duration of exercise. Two female participants self-reported moderate exercise intensity, but their activity monitor data showed light activity for one participant and mixed light (1 day) and moderate activity (2 days) for the other participant.

Glucose Levels

All participants' glucose levels were recorded without incident by CGMS technology; no sensors or monitors failed. Some data were missing from one 24-hour CGMS graph due to the participant failing to enter three self-monitored blood glucose meter results in one 24-hr period, but these data were retrieved after entering the participant's logged data.

Participants' average blood-glucose levels over 72 hours were similar when measured by CGMS (133 SD 23 mg/dl; 7,831 sensor readings) and participants self-monitored blood glucose readings (134 SD 22 mg/dl; 122 self-monitored blood glucose readings). These values ranged from 40–338 mg/dl and 69–274 mg/dl for CGMS and self-monitored readings, respectively. Data from the CGMS software include the number of high and low excursions, their duration and the glucose area above the upper target (140 mg/dl glucose) and below the lower target (70 mg/dl glucose) (Table 4). The glucose area above 140 represents the sum of the area created when the sensor tracing exceeds the upper target for glucose levels. Similarly, the glucose area under 70 represents the area created when the sensor tracing drops below the lower target for glucose levels. Overall, participants averaged 8 episodes of hyperglycemia lasting an average of 17 min, with an insignificant amount of hypoglycemia (Table 4). There were an insufficient number self-monitored blood glucose values (≤ 3 –4) entered on the first and last days of wearing the monitor (n=9).

An assessment of CGMS glucose and activity data showed that moderate physical activity lowered glucose levels on average 63 (SD 38) mg/dl (range = 0–160 mg/dl) within 5 (SD 3) hours (range = 0–12 hours) after exercise. Glucose levels were also analyzed before

(preprandial) and after (postprandial) meals. After a bout of exercise, preprandial to postprandial glucose levels increased on average only 2 (SD 20) mg/dl (range=-27-45 mg/dl) compared to an increase of 71 (SD 48) mg/dl (range = -20-170) at other meals.

Participants' Experiences and Perceptions

Analysis of focus group transcripts revealed a central metaphor of 'a picture is worth a thousand words.' The visual depiction of glucose levels in relation to meals and activity on the CGMS graphs (Figure 3) was more meaningful than a discussion of these topics. Further analysis identified four themes about the CGMS feedback: 1) Made the need for behavior change real, 2) Reinforced diet and exercise program, 3) Showed the effect and interrelatedness of exercise, diet and stress on glucose levels and 4) Individualised feedback was valuable for behavioral change. First, the visual CGMS feedback emphasised the need for behavior change. One male participant with a history of several myocardial infarctions and a BMI of 38 stated:

Most people with diabetes don't feel bad and that's the problem with diabetes when [doctors and nurses] tell you [that] you have to change your diet and you have to do all this stuff. And we don't do it. If I had been given this graph a year ago, I would have changed my diet and my exercise.

Another theme was that CGMS feedback reinforced diet and exercise programs. One male participant stated, 'After seeing the output [CGMS data], I noticed that it [glucose level] went up and it went right back down because that happened to be the day I exercised. So that to me shows that exercise is really effective in maintaining sugars'. Similarly, another male said, 'For me it proved that I should continue doing what I'm doing and I can't lay off whether it's the golf or the treadmill or whatever, but continue doing the exercise'.

The third theme in the focus group data was that CGMS feedback showed the effect and interrelatedness of exercise, diet and stress on glucose levels. A female participant commented, 'When you get the numbers back you really see, OK, I gotta cut down on breakfast because too many carbs, but the exercise brought it down! It was really amazing! You got feedback'.

The last theme was that individualised feedback was valuable for behavioral change. A male participant, stated, 'It changed my thoughts because I could actually see it on the graphs how 'I' was reacting [to diet and exercise] and what was changing inside of me and the benefits [of diet and exercise on blood sugar levels]. I could actually see it on the graphs!'

Several participants (n=4; 3 male, 1 female) reported forgetting to use the event buttons on their CGMS monitor to enter the times of their meals, physical activity and medications. One participant attributed this difficulty to cognitive issues following a 'heart attack' and elaborated: 'I found it [the CGMS monitor] occupying a lot of my time and even then I think I forgot once or twice to enter [events]'. Another participant stated, 'I just figure I'm getting old'. A third participant felt he needed time to develop a routine. In contrast, participants did not report any difficulty using the manual log to record events.

Other issues identified during the focus group were related to the CGMS were wearing proper clothing to attach the monitor at night (n=4), forgetting to enter meals and events (n=3), losing instructions (n=1) and monitor cord length 'too long' (n=2) or 'too short' (n=5). Focus group participants suggested motivating physically inactive individuals with diabetes by: 1) using the CGMS with all newly diagnosed patients, 2) having individuals wear the CGMS a second time, after changing diet and exercise behaviors, to see how glucose levels are affected, 3) using phone calls to monitor progress, 4) stress the

seriousness of diabetes and the need for exercise, 5) telling patients to ‘get moving’ and 6) ‘think seven days of exercise, not five’.

DISCUSSION

These findings provide preliminary support for the benefit of using CGMS data as part of a behavioral counseling program. The CGMS graphs enhanced participants’ performance accomplishment for exercise behavior by visually capturing the decrease in glucose levels following bouts of exercise and the duration of this effect and by showing the greater decrease in glucose levels pre to post prandial following exercise. Since performance accomplishment or actually doing an intended behavior enhances self-efficacy (Bandura, 1997), the CGMS graphs appears to have enhanced participants’ self-efficacy for managing their glucose levels with their diet and exercise behaviors although self-efficacy was not measured in this study.

In the focus group, participants told how seeing the CGMS data reinforced their sense of performance accomplishment for exercise behaviors (Theme 2) and helped them understand how diet and exercise behaviors were interrelated with glucose levels (Theme 3). This visual feedback allowed participants to recognise how daily events were related to higher glucose levels and made the need to change exercise and dietary behaviors ‘real’ to them (Theme 1). Moreover, participants described the individualised, visual CGMS feedback as more persuasive in changing their dietary and exercise behaviors than generalised discussions common in standard diabetes education (Theme 4). Discussions about diabetes education can enhance knowledge but are more effective if they include information about individual mastery of the target behavior (mastery performance), thus influencing one’s cognition about that behavior (Bandura 1997).

After visualising and reviewing the CGMS data, participants identified dietary and behavioral changes they should make to stabilise their glucose levels, indicating a high level of self-efficacy in this sample. Several participants (n=3; 2 males and 1 female) requested an opportunity to wear the CGMS monitor a second time to see how these behavioral changes would affect their glucose levels. Unfortunately, such an opportunity was not allowed by the study design. Although performance mastery is theoretically the strongest information source for increasing self-efficacy (Bandura 1997), further study is warranted to determine whether individual CGMS graphs can enhance self-efficacy in a non-exercising population of individuals with type 2 diabetes.

The second strongest information source theorised to increase self-efficacy is role modeling (Bandura 1997). Such role modeling can be provided by the CGMS graphs of this study’s participants (Figure 3). These data, which show the effects of certain dietary and physical activity behaviors on glucose levels, can be used as role model data by nurses counseling patients with diabetes to change their behaviors. Seeing role model CGMS graphs may motivate patients to change their behaviors for reasons similar to those of this study’s participants.

Overall, the CGMS technology was easy to use, reliable and provided meaningful data. However, individuals, researchers and clinicians need to anticipate some technology-related problems. The CGMS requires that participants enter at least three self-monitored blood glucose values within 24 hours. This requirement was not met by one participant so his CGMS graph had missing data. Although the participant had checked his glucose level, he unsuccessfully entered the data into the CGMS monitor. These data were retrieved by a Medtronic sensor expert who imputed the logged glucose data. Lost data may be minimised by ensuring that patients grasp the data entry process. However, this issue may be

unavoidable with CGMS technology, particularly for older patients who are not familiar with entering data. It is possible that other individuals with diabetes (e.g. peripheral neuropathy, visual impairments and cognitive impairments) may experience difficulty entering glucose and event data into the CGMS monitor. Further studies with larger samples are needed to identify these limitations and to recommend strategies for optimising CGMS data input. Participants also reported difficulty remembering to enter events into the CGMS monitor. This finding suggests that older individuals be encouraged to keep a log of blood glucose values and events, as writing notes may be easier for them.

Another issue related to using the CGMS technology was a warning on a few CGMS reports to 'use clinical judgment' due to entering too few self-monitored blood glucose values on the first and last days. On these days, participants wore the monitor for a shorter time, possibly accounting for their omission. A similar problem was found in a CGMS study (Chico *et al.* 2003) where 'some' of its 70 participants with type 1 and type 2 diabetes failed to initially enter the necessary number of glucose readings. In that study, the problem was resolved with extra education of participants and researchers. In the current study, insufficient glucose entries did not compromise interpretation of the CGMS graphs, except in the one case described above.

Participants identified two comfort-related issues with wearing the CGMS monitor. The first issue was the length of the monitor cord (either 'too long' or 'too short'). In overweight/obese individuals, placement of the sensor alters the length of the monitor cord. To enhance wearing comfort, researchers and providers can position the sensor more laterally to optimise cord length or more medially to shorten its length, thus enhancing wearing comfort. The second issue was finding proper clothing to attach the monitor at night. Before agreeing to wear the monitor, individuals should be informed of the nighttime clothing requirement. Newer CGMS monitors are cordless because the sensor and monitor communicate by radio frequency. Since many older CGMS monitors are used in clinical practices, clinicians and researchers need to be aware of comfort-related issues in obese/overweight persons.

The activity monitors used in this pilot study were generally reliable. They proved feasible for objectively measuring physical activity at different activity levels (sedentary/light, moderate, vigorous). The seven-year-old monitors used in this study presented some problems for users that may be negated by using newer models (ActiGraph) that are smaller and can be clipped to a belt or placed in a pouch. Nonetheless, clinicians and researchers need to anticipate a period of familiarisation with any technology and the potential for technology-related failures and data loss. Since relatively little information is available on activity monitor problems and possible solutions, more research is needed to evaluate this technology.

Two issues with wearing activity monitors were identified. Participants reported sweaty, irritated skin under the monitor and pinched skin when bending over. These problems may be related to participants' central obesity, which makes it difficult to place the monitor at the waist and directly on the skin. To relieve skin irritation and pinching, a transparent dressing could be placed beneath the monitor, the monitor could be attached to a belt worn on outer clothing, or the monitor could be placed in a pouch attached to a waist strap. Whether or not these strategies minimise discomfort needs to be verified by research.

Data from activity monitors were not provided to participants due to the study's pilot design. However, activity monitors are being used with individually tailored, web-based advice to motivate adolescents and young adults to change their physical activity behaviors (Slootmaker *et al.* 2005). In the current study, individuals with type 2 diabetes found the CGMS graphs more meaningful than diabetes education alone. To determine if activity

monitor data may also be more motivating than physical activity education alone, further research is needed.

Limitations

Our study results have some limitations. Some variables were not controlled for which may have affected interpretation of glucose levels following physical activity. First, this study was conducted in a free-living environment and no controls were placed on meal amount and quantity. Second, four participants were taking a long acting sulfonylurea which stimulates the release of insulin from pancreatic beta cells and may decrease glucose levels following physical activity (Bell & Ymuk 1997). Lastly, the time and duration of physical activity was determined by each individual. Therefore, some bouts of physical activity were not followed by a meal thus limiting interpretation of the post-prandial exercise effect on glucose levels.

Pilot studies with small sample sizes prohibit generalising findings to a larger group of people with diabetes nor was this the intent of this exploratory study. Moreover, the majority of participants were male and motivated exercisers. However, these initial results suggest further study with a larger, more diverse sample is warranted.

Conclusions

Personal CGMS data on glucose levels, meals and physical activity provided opportunities to counsel individuals with type 2 diabetes on the interrelationships among these variables. Participants indicated that CGMS data reinforced their current physical activity behavior and was more meaningful than traditional education about diet and physical activity. Using the CGMS and activity monitors raised several issues that may serve to inform researchers and clinicians working with these technologies.

Data from this study will be used to develop counseling interventions for non-exercising individuals with poorly controlled type 2 diabetes. The CGMS graph in Figure 3, which clearly depicts how physical activity affects glucose levels, will serve as role model data in a larger study to enhance individual self-efficacy. These newer technologies (CGMS and activity monitors) can enhance behavioral interventions in individuals with type 2 diabetes.

Relevance to Clinical Practice

The CGMS has frequently been used since 1999 to adjust insulin doses in individuals with type 1 diabetes and more recently in individuals with type 2 diabetes. Our preliminary data suggest that CGMS may have a role in counseling and motivating behavior change in individuals with type 2 diabetes. In particular, our study provides preliminary evidence for using the CGMS to motivate changes in dietary and exercise behaviors.

Acknowledgments

This study was supported by a small equipment grant from Minimed Medtronic and by a grant from the National Institute of Nursing Research (Grant T32). We are grateful to our editor, Claire Baldwin, and to Dave Peckinpugh and Dawn Roberts for their statistical analysis of accelerometer data.

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Figure 1.
Continuous Glucose Monitoring System

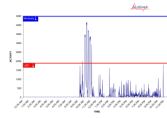


Figure 2.
Activity Monitor Data

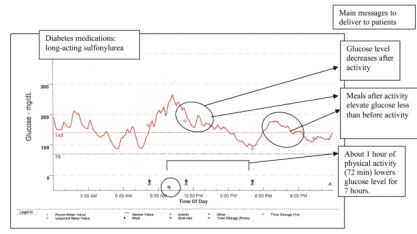


Figure 3.
CGMS Graph from Subject 001

Table 1Sample Characteristics ($N=9$)

Characteristic	Number	Mean \pm SD
Gender		
Male	7	
Female	2	
Race		
White	9	
Ethnicity		
Not Hispanic or Latino	9	
Marital status		
Married	7	
Single	2	
Education		
High school diploma	4	
Partial college education	4	
College degree	1	
Postgraduate degree	4	
Age (years)		56.0 \pm 8.5
Diabetes duration (years)		3.7 \pm 3.7
BMI (kg/m ²)		32.5 \pm 4.2
A1 _c (%)		6.4 \pm 7.0

Table 2Self-reported Co-morbidity History (*N*=9)

Co-morbidity	Number
Diabetes	
Neuropathy	1
Autonomic Neuropathy	1
Nephropathy	1
Retinopathy	0
Cardiovascular	
Hypertension	9
Chest Pain	5
Cardiac Surgery	5
Cardiac Procedure (e.g. Stent)	3
Myocardial Infarction	2
Family History of Cardiovascular Disease	
Family History of Premature Heart Disease (father ≤ 55 yrs, mother ≤ 65 yrs)	2
Smoking History	4
Currently Smoking	0
Total Time Smoked (years)	
Mean ± SD	14 ± 19
Range	4-44

Table 3Participants' Current Physical Activity ($N = 9$)

Current Physical Activity	Number
Type of Activity	
Treadmill/Walking	9
Bicycling	6
Weights/Universal	6
Swimming	1
Aerobics	1
Rowing	1
<hr/>	
Activity Frequency (days/week)	
2	1
3	4
4	1
5	2
7	1
<hr/>	
Activity Duration per Session (min)	
30	2
45	1
60	4
90	2
<hr/>	
Activity Intensity	
Moderate	9

Table 4

Mean CGMS Glucose Data (N=9)

	Excursions (n)	Duration of excursion (min)		Glucose area(mg/dl per day)			Glucose area(mg/dl per day)
		High	Low	>140mg/dl glucose	70-140mg/dl glucose	<70mg/dl glucose	
Mean	8	2	17	53	2	7	<70
SD	7	3	17	18	2	8	0.22
Range	2-18	0-8	0-49.7	20.3-84.3	0-4.4	0-21	0-1