Sedentary Behavior Counseling Intervention in Aging People With Type 2 Diabetes: A Feasibility Study

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ABSTRACT: This study examined the feasibility and effect of sedentary behavior (SB) counseling on total sitting time (TST) and glycemic control in people with type 2 diabetes (T2D). Community-dwelling sedentary adults with T2D (n = 10; 8 women; age 65.6 ± 7.31) completed SB counseling (motivational interviewing-informed education about SB) aided by an activity monitor with a vibrotactile feature (activPAL3TM). The monitor was worn for 7 days, on weeks 1 and 13 (without the vibrotactile feature) and during weeks 5 and 9 (with the vibrotactile feature). Intervention feasibility was determined by study retention rates and activity monitor tolerability, and differences between pre- and post-intervention average daily TST. Paired *t*-test were performed. The effect size (ES) was calculated using Cohen *d*. All participants attended all study sessions with only 20% reporting moderate issues tolerating the activity monitor. TST time decreased from 11.8 hours ± 1.76 at baseline to 10.29 hours ± 1.84 at 3 months' assessment ($P < .05$) with a large ES (Cohen $d = .88$). HbA1c was decreased by 0.51% ($P < .05$) at the end of the intervention. This study found that the intervention was feasible for sedentary adults with type 2 diabetes.

KEYWORDS: Diabetes, activity monitor, feasibility, sitting time, physical activity, glycemic control

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Introduction

Sedentary behavior (SB) is a serious health risk for people with type 2 diabetes (T2D),[1,2] further, the majority of people with T2D are considered sedentary.[3,4] T2D results in devastating health complications with significant morbidity and mortality rates.[5] Additionally, T2D accelerates normal aging processes causing individuals with T2D to experience age-related health conditions such as sarcopenia and frailty at a younger age compared to their counterparts with no T2D.[6] Therefore, there is a crucial need for SB interventions to decrease the burden of T2D and its complications.

SB is physiologically and behaviorally distinct from physical activity (PA).[7] SB is defined as "any waking behavior characterized by energy expenditure <1.5 METs while in a sitting or reclining posture,"[8] whereas PA is defined by the World Health Organization as "any bodily movements produced by skeletal muscles that require energy expenditure." It is important to distinguish SB from PA because people can meet recommendations for moderate to vigorous activity (150 minutes of moderate or 75 minutes of vigorous activity per week)[9] and still have extended periods of SB.[10,11] Epidemiological studies have concluded that this SB is associated with an increased risk of all-cause mortality and increased risk of T2D, independent of PA levels.[12,13] Moreover, negative changes in lipid metabolism, insulin sensitivity, and glycemic control have been shown to be specifically associated with increased SB in both adults[14,15] and older adults.[16,17]

Studies targeting SB as a primary intervention goal are relatively new. Generally, SB interventions utilizing activity permissive workstations, step counters, and/or face-to-face SB counseling using behavioral goal setting, self-efficacy, and motivational interviewing techniques have shown promising results for decreasing SB in sedentary adults.[18-21] These studies indicate the potential effectiveness and feasibility of several SB interventions for the general healthy population. In older adult population, 2 preliminary studies utilizing behavior approaches targeting SB showed a significant but small decrease in total sitting time.[22,23] In people with T2D, one large randomized clinical trial (n = 300, age 61.6 ± 8.5) comparing standard care with a combined intervention of SB counseling and supervised exercise sessions over a 3-year period found that participants had a sustained levels of PA and decreased their SB time at the end of the study.[24] This study used behavioral interventions to increase PA and reduce SB. Thus, it is possible that an intervention focused only on SB change may be more sustainable than the combined exercise and counseling approach used by this large RCT.

The main objective of this study was to test the feasibility (as determined by study retention rates and activity monitor tolerability) of SB counseling using an activity monitor in older adults with T2D. This counseling consisted of SB education informed by a motivational interviewing approach, and vibrotactile feedback provided by an activPAL3TM activity monitor. The vibration feature was intended to interrupt SB after a specified duration of SB. A secondary objective was to test the effectiveness of our approach on decreasing SB and increasing PA, and to determine if the changes had an impact on improving glycemic control.

Methods

Design and participants

This study utilized a pilot pre-post-intervention design. The study was approved by the University Institutional Review Board and Human Subjects Committee (STUDY00140490). Informed consents were obtained in writing from each participant prior to the study. Potential participants were recruited (March 2017-April 2018) from an ongoing cross-sectional research study (association between SB and health variables, n = 59) at the time.[25] The first 10 participants that met the inclusion/exclusion criteria and were interested in the intervention study were included. Participants were included in the study if they were sedentary (>7 hours of objectively measured total sitting time per day via an activity monitor),[26] 50 to 75 years of age, have T2D which was confirmed by reviewing medications, and able to ambulate independently without an assistive device for at least 50 m. Individuals were excluded if they had any impairments that would interfere with testing.[25] Participants received no monetary incentives.

Intervention

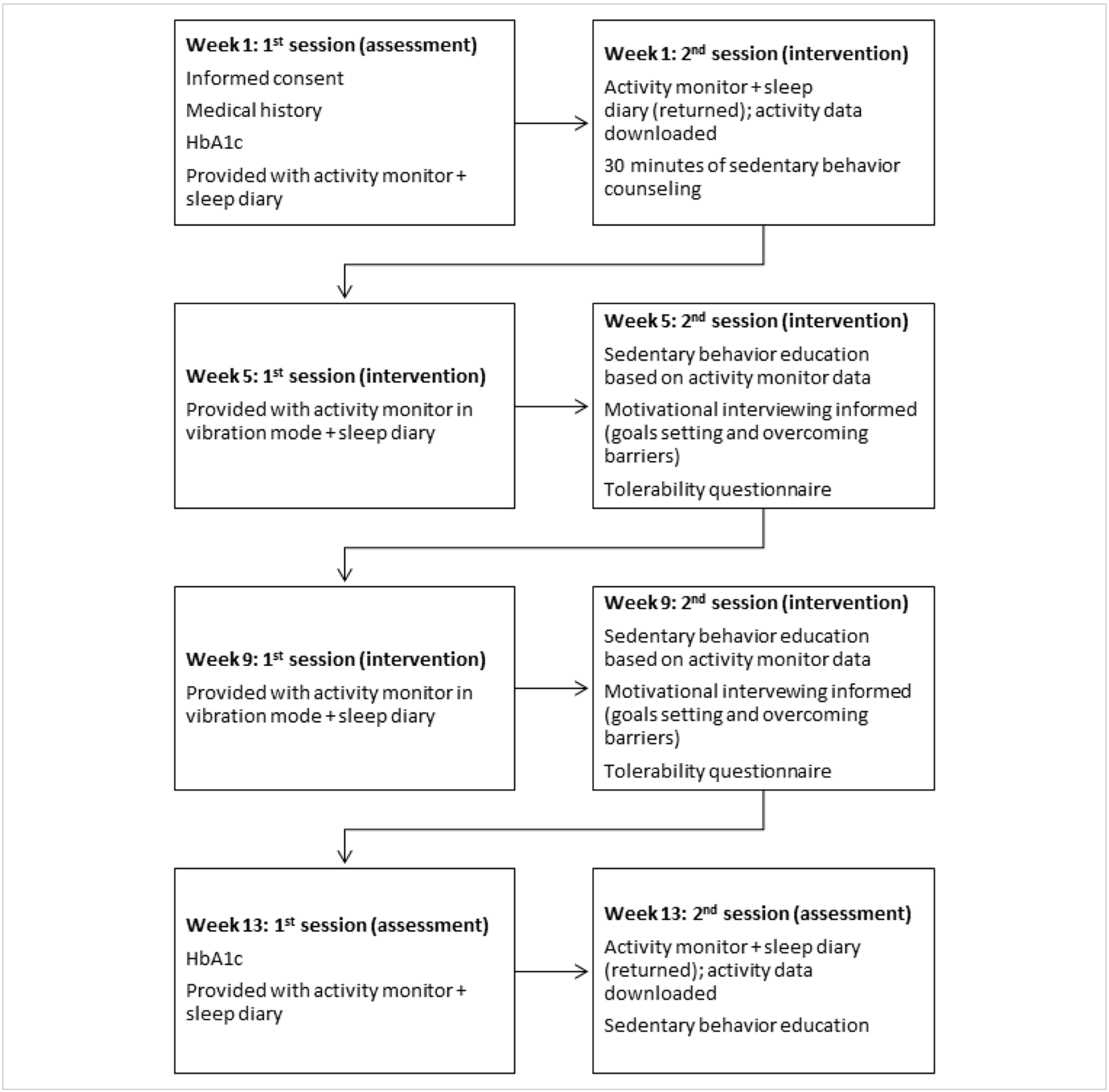
This study intervention was based on the transtheoretical model of health behavior change[27] incorporating self-efficacy[28] and motivational interviewing techniques.[29] The intervention consisted of SB counseling delivered at the end of weeks 1, 5, and 9, and aided by the activity monitor vibrotactile feature at weeks 5 and 9 (Table 1). The intervention was delivered by a physical therapist in person at a university research laboratory. Each participant wore an activity monitor with the vibrotactile feature enabled for a 7-day period at weeks 5 and 9. During waking hours, participants received vibrotactile feedback after 20 minutes of sitting, as a prompt to stand and/or walk for at least 2 minutes. Participants can turn off the vibrotactile feature during sleep time.

Counseling sessions started by reviewing the activity monitor printout, which included a summary of activity events (sitting/lying, standing, stepping, and transitioning) per day. This printout and the sleep diary were reviewed with each participant as a visual illustration of their SB and sleep pattern. The printout also helped in facilitating SB education. The education was based on American Diabetes Association lifestyle management (PA and SB) recommendations published as part of the 2017 Standards of Medical Care in Diabetes.[30] That included the recommendation of 150 to 75 minutes of MVPA per week, strengthening and balance exercises 2 to 3 times per week, 10 000 steps per day, and break sitting time frequently. Participants were given SB informational flyers with brief descriptions and instructions to read at home and bring any related questions to the next visit. Interested participants were provided with a more detailed explanation at the same time. Then, information about the benefits of breaking SB with frequent activity on glucose metabolism were explained. The depth of the information was depended on participant interest and questions, however, the following main points were discussed: the physiological benefits of decreasing total siting time and breaking sitting time[31] and the benefit of breaking sitting time every 20 to 30 minutes with any level of PA in terms of glucose and insulin metabolism.[10,14,32,33]

After providing the participants with the above information and reviewing individual sedentary behavior patterns, potential strategies to decrease sitting time and increase physical activity plan as a whole were developed. Participants completed 1-page questionnaire to guide them during plan development. Questions included: my top reasons for becoming more active? Specific activities that I will be able to do to decrease my sitting time, things might make it hard, things that will help me succeed, and who is supportive. Based on this questionnaire, the motivational interviewing informed approach were utilized to include setting goals for activity (ie, decrease my sitting time by break sitting every 30 minutes), recognizing barriers (ie, my job require me to sit a lot) and resources (ie, I can set my phone to remind me to stand up every hour) to decrease sedentary time, and identifying support systems (ie, me and my friend can remind each other to sit less and move more) needed to be successful in the intervention. Examples used above are just for explanation purposes, each participant developed their own unique plan. During the plan development, participants were encouraged to come up with their own goals while reminded to have one overall goal with multiple small but achievable goals. Therefore, they can assess their goals weekly and adjust them as they see fit based on their circumstances of that week. The role of the researcher was to manage participant expectation that is, a participant with a step average of 2000 steps per day goal should not be reaching 8000 steps per day by the next week. Moreover, they were encouraged to revise their plan weekly and write any questions that they have and bring it with them to the next session. Participants were given the ActivPAL printout and their plan page to take with them home.

In subsequent sessions' the plan developed at week 1 was reviewed and if needed it was modified. Participants were given positive feedback on the improved areas, and they were asked how they could change their plans if needed to achieve further improvement. Participants were reassured that it is ok if they did not improve; at least they know now what does not work

Table 1. Study timeline. The first and second sessions for each week were separated by at least 7 but not more than 14 days.



for them to increase the activity. Furthermore, they were asked to review their activity plan critically and come up with a new strategy that they think will work for them. Participants were reminded briefly of the benefits of reducing SB.

Assessment

Demographic information and medical history were collected at the baseline (week 1) session. At this baseline session, the activPAL3TM activity monitor (PAL Technologies Ltd. Glasgow, UK, http://www.palt.com/) and a sleep/non-wear time diary were given to the participant with instructions of their use. The activity monitor was wrapped in a waterproof covering and attached directly to the skin on the front of the right thigh with transparent 3M Tegaderm tape. Participants were asked to wear the activity monitor for 7 consecutive days, removing the monitor only if it was to be fully submerged in water. Participants were asked if they planned to engage in any nonroutine PA in the next week, such as traveling, prior to being given the activity monitor. If they answered yes, a different measurement week was selected. This was done to ensure that the habitual SB was captured.

The next session was scheduled 7 to 14 days later at which time the participant returned the activity monitor and sleep/non-wear time diary. The post-intervention assessment session was scheduled at week 13, during which time the activity monitor and sleep/non-wear time diary were given to the participants. Again, participants were asked to wear the device for 7 consecutive days. The final session was scheduled 7 to 14 days later, repeating the procedure described for session 2.

Intervention feasibility outcomes

Feasibility was assessed through calculating retention rates, activity monitor tolerability. Retention rate was reported as the number of participants completing all intervention sessions divided by the number of enrolled participants. Activity monitor tolerability was determined using a 6-question multiple-choice questionnaire (Supplement Appendix 1). The questions assessed the relative ease of using the monitor, problems wearing the monitor, participants' feelings about wearing the device, the device's impact on daily life, and any complications experienced while wearing the monitor. The results from the questionnaire were classified as: no issues with tolerability, mild issues with tolerability, moderate issues with tolerability, and severe issues with tolerability.

Sedentary behavior and physical activity outcomes

An activPAL3TM was used to measure SB and PA. The activPAL3TM directly measures SB via postural allocation. Activity monitor data was downloaded at baseline and weeks 5, 9, and 13, and assessed to ensure that sufficient data was obtained. This was defined as at least 4 days with 10 hours per day of activity data.[34] If activity data was not sufficient, participants were asked to wear the activity monitor for another week.

Glycemic control

At weeks 1 and 13 of the study, glycemic control was determined using the HbA1c test via a disposable blood finger stick test kit (A1cNow+). This test measures the level of glycosylated hemoglobin, indicating average glucose blood levels over the past 6 to 12 weeks.[35]

Data acquisition

For data analysis, the time-stamped "event" data file generated by the activPAL3TM software (version 7.2.32) was exported as a.csv file for further analysis in RStudio. R is an open-source computing language and statistics package available free of charge at www.r-project.org.[36] The R package we used was developed by Lyden[37] and used to extract the outcomes of interest from the activity monitor. In addition, the R package needed an additional.csv file that included sleep time and device on and off time for all participants to run the analysis.

Table 2. Participant's demographics.

CHARACTERISTIC	N = 10
Age, y	65.6 ± 7.31
Gender, Women	8 (80%)
BMI, Kg/m^2	32.67 ± 4.89
Race	
Caucasian	8 (80%)
African American	2 (20%)
Neuropathy, Yes	3 (30%)
Retired, Yes	6 (60%)

Data reported as mean ± SD or frequency.

This package produced 3.csv files that summarize (1) sleep/wake time and wear/non-wear time, (2) stand time, step count, and sit time per day, and (3) per visit.

Statistical analysis

Descriptive statistics for continuous variables included means and standard deviations, with frequencies used for feasibility and categorical variables. SB and PA outcomes were tested for normality. Normally distributed data was analyzed using 1-tailed paired *t*-tests, and Wilcoxon tests were used for non-normally distributed data. The effect sizes for sit time and step count were calculated using Cohen *d*. Statistical evaluation was done using GraphPad Prism (version 7.04 for Windows, GraphPad Software, La Jolla, California, USA, www.graphpad.com). Level of significance was set at alpha = .05.

Results

Ten participants completed the study (Table 2). All participants attended and completed each study session, resulting in a 100% retention rate. All participants completed the tolerability questionnaire. Five participants indicated no issues with tolerability, 3 reported mild issues with tolerability, and 2 reported moderate issues with tolerability, including skin irritability or redness due to the 3M Tegaderm tape. No participants reported severe issues with tolerability that necessitated removing the device.

On average, participants spent 11.88 ± 1.76 hours/day sitting at baseline and decreased their sitting time to 10.29 ± 1.84 hours/day post-intervention with a significant mean difference of 1.59 hours/day (P = .017; Table 3). The effect size for sitting time was 0.88. Mean participants' step counts were 4024 ± 1179 steps/day at baseline and increased to 4770 ± 1967 steps/day post-intervention with a significant mean difference of 746 steps (P = .032). The effect size for step count was 0.46. Participants on average increased their standing time from 2.94 ± 1.25 hours/day at baseline to 3.69 ± 1.86 hours/day post-intervention, resulting in a mean

Table 3. Study outcomes: sedentary behavior, physical activity, and glycemic control averages pre and post intervention. (n) = 10 except for HbA1c (n) = 9. Data are presented as mean ± SD.

OUTCOME	BASELINE	POST-INTERVENTION	*P*-VALUE
Sitting time (hours/day)[a]	11.88 ± 1.76	10.29 ± 1.84	.017*
Steps Count (step/day)[b]	4024 ± 1179	4770 ± 1967	.032*
Standing time (hours/day)[a]	2.94 ± 1.25	3.69 ± 1.86	.069
HbA1c (%)[b]	7.08 ± 0.86	6.57 ± 0.65	.012*

[a]Data was analyzed via paired *t*-test.
[b]Data was analyzed using Wilcoxon non-parametric test.
*Significant *P* value.

difference of 44.87 minutes ($P = .069$). HbA1c was 7.08 ± 0.86% at baseline and decreased to 6.57 ± 0.65% post-intervention, resulting in a significant mean difference of 0.51% ($P = .012$).

Discussion

This study aimed to test the feasibility and effectiveness of an intervention to treat SB in people with T2D. Our intervention utilized individualized, motivational interviewing-informed SB counseling, and vibrotactile sensory feedback. Overall, we found the intervention was feasible and effective in treating SB in people with T2D.

Feasibility was assessed via participant retention and activity monitor tolerability. All study participants completed all study intervention visits and returned for all post-intervention assessments. Similar feasibility studies have reported excellent acceptability and adherence to interventions that aimed to reduce SB.[22,23,38] One study utilized a single session of goal-setting to reduce SB based on assessed sitting time in older adults, with weekly reminder phone calls reporting 90% acceptability and adherence to the intervention protocol.[23] Another intervention study utilizing 2 weeks of individualized consultation based on activity monitor data to reduce SB in older adults, demonstrated excellent adherence to the study protocol and no issues with activity monitor tolerability.[22] These studies, alongside our results, indicate that SB modification interventions are feasible and demonstrate promising potential for impacting SB.

Most participants in our study indicated either no to mild issues in terms of activity monitor tolerability. Although 2 participants reported moderate issues related to skin irritation due to the use of the Tegaderm tape, neither participant actually removed the monitor. A study by Dall et al[39] used the same activity monitor affixed with a hypoallergenic adhesive pad and medical grade waterproof dressing reported that only 8 of the 733 adults that wore the monitor for 9 days removed it due to skin irritation. However, this study did not report whether some participants reported mild skin irritation but did not take the activity monitor off. Regardless, it seems likely that providing multiple options for activity monitor mounting would decrease the possibility of skin irritation.

We also found that the SB intervention decreased SB by 95 minutes/day on average. A similar feasibility study with a 2-week intervention showed that individualized SB consultation based on activity monitor data in older adults decreased SB by 24 minutes/day.[22] The greater decrease in SB we observed in our study might be due to our longer intervention time and our utilization of sensory feedback in addition to SB counseling. Furthermore, our combined approach showed superior results when compared to a meta-analysis of 15 randomized control trials (total n = 3262) that tested the effectiveness of step counter usage for decreasing SB. This analysis revealed a small but significant association between step counter usage and reduction in SB (23 minutes/day) compared to control.[19] Additionally, our combined approach indicated superior results when compared to a meta-analysis of 19 randomized control trials (total n = 2800) that tested the effectiveness of self-monitoring as a behavior change technique. The analysis indicated a small but significant reduction in SB (34 minutes/day) compared to control.[40] Overall, a combined approach to reduce SB in people with T2D might be promising arena for future research.

At the end of the intervention, participants had decreased their HbA1c by an average of 0.51%. Several studies have shown that an acute reduction in sitting time is associated with positive changes in glucose and insulin metabolism.[14,31,41] However, only one study have previously described the long-term effects of combine PA and SB interventions on glycemic control in people with T2D.[24] Exercise interventions have been reported to decrease HbA1c by 0.66%, while pharmacological agents such as metformin may decrease HbA1c by 0.6%. These changes were associated with positive changes in diabetes and general health outcomes.[42,43] Although it has long been established that exercise interventions have many health benefits, including improved glycemic control in people with T2D, patient engagement and adherence to these programs are low.[44] Thus, based on our results, further research may examine whether interventions aimed at decreasing SB might result in similar changes in glycemic control while fostering greater treatment adherence.

This study was not designed or powered to test the efficacy of the SB intervention used here. Future studies should utilize randomized clinical trial designs with adequate power to evaluate the unbiased true effect of the intervention. This study included only people aged 50 to 75 years; which is not the typical older adult population (>65 years). However, we believe that our age restriction is appropriate because people with diabetes demonstrate physiologic/function changes associated with aging much earlier than those without diabetes. Additionally, due to the small sample size, we exclude individuals older than 75 years to avoid variability in the data because of age. Although, recruitment effort were directed for both sexes the final sample was predominantly female. Therefore, findings of this study should not be generalized with no further research. This study assessed the feasibility and effectiveness of the intervention on decreasing SB immediately after the completion of the intervention. Thus, the long-term effect of the intervention cannot be assessed. Further, cost-benefit analysis in terms of time was not feasible with current data set. These limitations need to be addressed in future research. Lastly, HbA1c results demonstrated in this study should be interrupted with caution when compared to other study due to a higher measurement error associated with A1cNow+ compared to high-performance liquid chromatography.[45] However, this study took into consideration the effect size and the difference after intervention was clinically significant.

Conclusion

This study investigated the feasibility, protocol adherence, tolerability, and provided a pilot estimates of the intervention: SB counseling (SB education informed by a motivational interviewing approach) and vibrotactile feedback provided by an activPAL3TM activity monitor (intended to interrupt SB after a specified duration) used for people with T2D. The results demonstrated that the intervention was feasible and effective. Further, the results indicate promising opportunities for future research to decrease SB in people with T2D. The specific assessment of the activity monitor tolerability will help researchers in evaluating their proposed interventions using the same activity monitor for larger samples. This type of intervention could be easily implemented into any clinical practice utilizing a commonly available commercial activity tracking devices equipped with a vibrotactile features in conjunction with SB educational guided counseling.

Author Note

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Author Contributions

SA designed the study, preformed data collection, data entry, interpretation, and wrote the first draft of the manuscript. AA and MA helped in data collection and results interpretation. JL, JT, and JR supported interpretation and appraisal. PK was advisor throughout the project and supported manuscript interpretation and appraisal. All authors read and approved the final manuscript.

Ethical Approval/Patient Consent

"All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards." The study was approved by the University Institutional Review Board and Human Subjects Committee (STUDY00140490). Informed consents were obtained in writing from each participant prior to the study.

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Supplemental Material

Supplemental material for this article is available online.

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