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ORIGINAL ARTICLE

Diabetes and Technology for Increased Activity (DaTA) Study: Results of a Remote Monitoring Intervention for Prevention of Metabolic Syndrome

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Abstract

Objective:

An increasingly aged, overweight, and sedentary population has resulted in elevated risk of cardiovascular disease (CVD). The escalating incidence of diabetes and other chronic illnesses, deficits in health care budgets, and physician shortages, especially in rural communities, have prompted investigations of feasible solutions. The Diabetes and Technology for Increased Activity (DaTA) study was designed to test the effectiveness of a lifestyle intervention driven by self-monitoring of blood glucose (BG), blood pressure (BP), physical activity (PA), and weight to positively impact CVD risk factors in a medically underserviced rural population with a high incidence of metabolic syndrome (MS).

Research Design and Methods:

Conducted in a community-based research setting, this single-center open feasibility study used smart phones to transmit BP, BG, pedometer, weight, heart rate, and activity measurements to a database. Technology allowed participants to interface with the clinical team and self-monitor their personal health indicators.

Results:

Twenty-four participants aged 30 to 71 years completed the 8-week intervention. Participants had significant improvement in clinic ($p = .046$) and self-monitored diastolic BP ($p = .001$), body mass index ($p = .002$), and total cholesterol ($p = .009$), and steps per day. Daily PA increased as well as participants' interest in and willingness to make lifestyle changes that impact health outcomes.

Conclusions:

The DaTA study demonstrated that self-monitoring of the risk factors for MS and increased PA improved the participant's CVD risk profile. Considering the 8-week time period of this intervention, results are encouraging. This lifestyle intervention, which uses education and technology as tools, confirms the utility of remote health monitoring.

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Abbreviations: (BG) blood glucose, (BMI) body mass index, (BP) blood pressure, (CT) clinical team, (CV) cardiovascular, (CVC) cardiovascular complication, (CVD) cardiovascular disease, (DaTA) Diabetes and Technology for Increased Activity, (DBP) diastolic blood pressure, (HbA1c) hemoglobin A1c, (HDL) high-density lipoprotein, (HR) heart rate, (HT) hypertension, (LDL) low-density lipoprotein, (PA) physical activity, (PI) principal investigator, (SBP) systolic blood pressure, (STEP) Step Test and Exercise Prescription, (TSS) technology implementation and systems administration specialist

Keywords: diabetes, lifestyle management, remote monitoring, rural primary care, technology

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Introduction

An increasingly aged, overweight, and sedentary population has resulted in elevated risk of cardiovascular disease (CVD). Cardiovascular (CV) risk factors include hypertension (HT), dysglycemia (elevated fasting glucose and insulin resistance), dyslipidemia [elevated trigylcerides and low-density lipoprotein (LDL) cholesterol and decreased high-density lipoprotein (HDL) cholesterol], and obesity (central adiposity).[1] These risk factors are the hallmark of metabolic syndrome (MS), more often occur together than in isolation,[1] and have been shown to directly increase atherosclerotic CVD.[2] In 2001, Adult Treatment Panel III guidelines called specific attention to the importance of targeting CV risk factors of MS as a method of CVD risk reduction therapy.[3] Current Canadian Diabetes Association clinical guidelines state that there is evidence to support an aggressive approach to identify those individuals with MS.[4] A study demonstrated the important connection between precursors for development of diabetes, MS, and increased risk for cardiovascular complications (CVCs).[5] A retrospective analysis of the prevalence and treatment of HT and dyslipidemia, in Southwestern Ontario, Canada, identified that treatment patterns were not in alignment with current guidelines and that treatment levels are low and recommended control levels even lower.[5] Furthermore, the increasing incidence of diabetes and other chronic illnesses in rural communities, deficits in health care budgets, and physician shortages have prompted researchers and policy makers to investigate feasible solutions.

Health complications of diabetes, including hyperglycemia, are associated with an increased risk of developing macrovascular and microvascular complications (i.e., myocardial infarction and stroke, neuropathy, nephropathy, and retinopathy).[6,7] The U.K. Prospective Diabetes Study[8,9] and the Diabetes Control and Complications Trial[10] demonstrated that progression of these complications can be prevented through improved blood glycemic control. Importantly, these studies found that increased physician contact had a positive effect and improved patient glycemic control. Research has demonstrated the efficacy of exercise and nutrition counseling to decrease the incidence of type 2 diabetes in a MS population.[11–13] However, despite this positive evidence that diabetes and MS are preventable with relatively simple interventions such as lifestyle management adoption, implementation of change has been disappointing. The Step Test and Exercise Prescription (STEP) program positively enhanced lifestyle changes by including comprehensive exercise counseling with goal setting and a written exercise prescription.[14] The STEP test as an intervention in a primary care setting elicited significant improvements in waist circumference, diastolic blood pressure (DBP) and systolic blood pressure (SBP), fasting blood glucose (BG), weight, body mass index (BMI), resting heart rate (HR), and total and LDL cholesterol levels in MS patients.[2] However, it is not clear if dietary changes or changes in physical activity (PA) were the driving force behind these positive results.

Health monitoring technologies, including BG, blood pressure (BP), and HR monitors as well as pedometers (devices to promote PA), in tandem with clinically prescribed exercise, may encourage lifestyle modifications through patient self-management. In fact, remote monitoring technologies have been shown to reduce BG[15–17] and BP[18] and increase PA.[19] Remote monitoring studies to date have failed to effectively monitor both intended behavior change, such as diet and PA, and risk factor modification, such as BP and BG. Moreover, it is not known if it is feasible to employ health monitoring technologies, particularly in a rural setting. Therefore, the objective of the Diabetes and Technology for Increased Activity (DaTA) study was to test the effectiveness of a lifestyle intervention driven by self-monitoring of BG, BP, PA, and weight to positively impact CV risk factors in a medically underserviced rural population with a high incidence of MS.

Research Design and Methods

Study Design and Participant Recruitment

Hosted in a community-based research setting, the DaTA study was an open single-center feasibility study conducted between November 2009 and May 2010. Research was conducted according to the Declaration of Helsinki with ethics approval from Institutional Review Board Services (Aurora, Ontario, Canada) and the University of Western Ontario Research Ethics Board. An academic-industry research team consisted of: (1) a principal investigator (PI); (2) a technology implementation and systems adminis-tration specialist (TSS; Sykes Technical Assistance Corp.); (3) technical and database applications experts (Healthanywhere, IgeaCare Inc.); and (4) a clinical team (CT; study coordinator, certified kinesiologist, graduate students, consultants, physicians, and nurses dedicated to this study).

Participants were recruited with social marketing techniques, including newspaper advertisements and posters placed in family medical clinics, pharmacies, and community bulletin boards, as well as by word-of-mouth recommendations. Interested potential candidates contacted the study coordinator to confirm eligibility. Only candidates who met all inclusion and exclusion criteria and provided written informed consent were enrolled. Inclusion criteria were a minimum of two risk factors for MS, including high waist circumference or obesity, elevated SBP and DBP (SBP ≥130 mm HG or DBP ≥85 mm HG), fasting plasma BG >6.1 mmol/liter, or impaired glucose tolerance and fasting lipid levels (triglycerides >1.7 mmol/liter, HDL cholesterol; males <1.04 mmol/liter, females <1.29 mmol/liter).

Study Protocol

At week 0 (visit 1), study participants were provided with: (1) a Smartphone (BlackBerry™ Curve 8300); (2) a Bluetooth™-enabled BP monitor (A & D Medical #UA-767PBT); (3) a glucometer (Lifescan One Touch Ultra2™ with Polymap wireless adaptor PWR-08-03); and (4) a pedometer (Omron # HJ-150; **Figure 1**). All Bluetooth-compatible devices were paired with a unique Smartphone. Dedicated to the study, Smartphones transmitted self-monitoring measurements to the database and allowed participants to interface with the CT and TSS, as needed, as well as view graphical outputs of their personal health indicators. At the first visit, participants were trained by the CT how to take proper clinical measurements and by the CT or TSS on the technologies provided. The Smartphone was available for 24 h support for technology and health issues.

The CT provided counseling regarding PA and lifestyle modifications based on American College of Sports Medicine guidelines and tailored to each individual stage of change and fitness level. Exercise was prescribed based on baseline STEP test results, and changes to the exercise regimen were made as required by feedback to the CT through the remote monitoring device, as well as repeat STEP tests at week 4 and 8 study visits.

At the community research center (Gateway), at week 0 (visit 1), week 4 (visit 2), and week 8 (visit 3), participants had a complete physical examination (height, weight, waist circumference, SBP, DBP, and HR), phlebotomy, STEP test, and completed Stages of Change for Physical Activity[20] and other questionnaires. Body mass index was calculated and waist circumference was measured as an index of abdominal adiposity. Blood pressure measurement was performed by a health care professional with a sphygmomanometer (BpTRU™). Venipuncture was performed for analyses of BG; hemoglobin A1c (HbA1c); total, LDL, and HDL cholesterol; triglyceride; and C-reactive protein. Level of fitness was measured using the STEP test to assess maximal oxygen uptake, VO_{2max}.[14] Each individual exercise program was set at an exercise HR of 70–85% of age-predicted maximal HR. Using SMART (specific, measurable, attainable, realistic, and timely) principles of goal-setting, participants set personal PA goals, including pedometer steps, for the next 4-week period. The recommended goal of 10,000 steps/day, with increments of improvement of 1000 steps/day, was suggested to some less active participants.[21] Participants received a stage-matched activity booklet addressing self-efficacy, decisional balance, and stage-appropriate processes of change.

Self-monitoring measurements, wirelessly transmitted to a database via the Bluetooth-enabled Smartphone, included twice daily finger prick BG [fasting morning and nonfasting before sleep (automatically from the glucometer)]; daily number of steps walked (readings from the pedometer entered manually into the Smartphone); three times weekly SBP, DBP, and HR upon waking in the morning (automatically from the BP monitor); and weight once per week at home or at Gateway (manually entered into the Smartphone). Stage of Change for Physical Activity questionnaires were sent to the participants' Smartphone weekly. The Smartphone wirelessly transmitted clinical measurements to Healthanywhere servers. Health monitoring measurements were available to be viewed by the study staff within seconds of receipt at the data center. Study participants could monitor personal readings and progress by signing into a secure portal using their Smartphone to view readings and graphical outputs. Participants were provided with a 2-month data plan that allowed them to contact the CT or TSS by email, as required.

Predetermined thresholds for MS and CVD risk factor variables were programmed into the database, with alarms for readings outside threshold limits immediately triggering an email directly to the PI's dedicated Smartphone. Real-time alerts for technical issues such as late or missed readings were triggered by the database and notices sent to the TSS, which prompted follow-up with the participant. Complete details about technical aspects of the study, including data access and security, are reported elsewhere.[22]

All study data were analyzed with SPSS version 17, and *t*-tests were used to assess significant changes in the variables measured. A paired *t*-test was used to compare

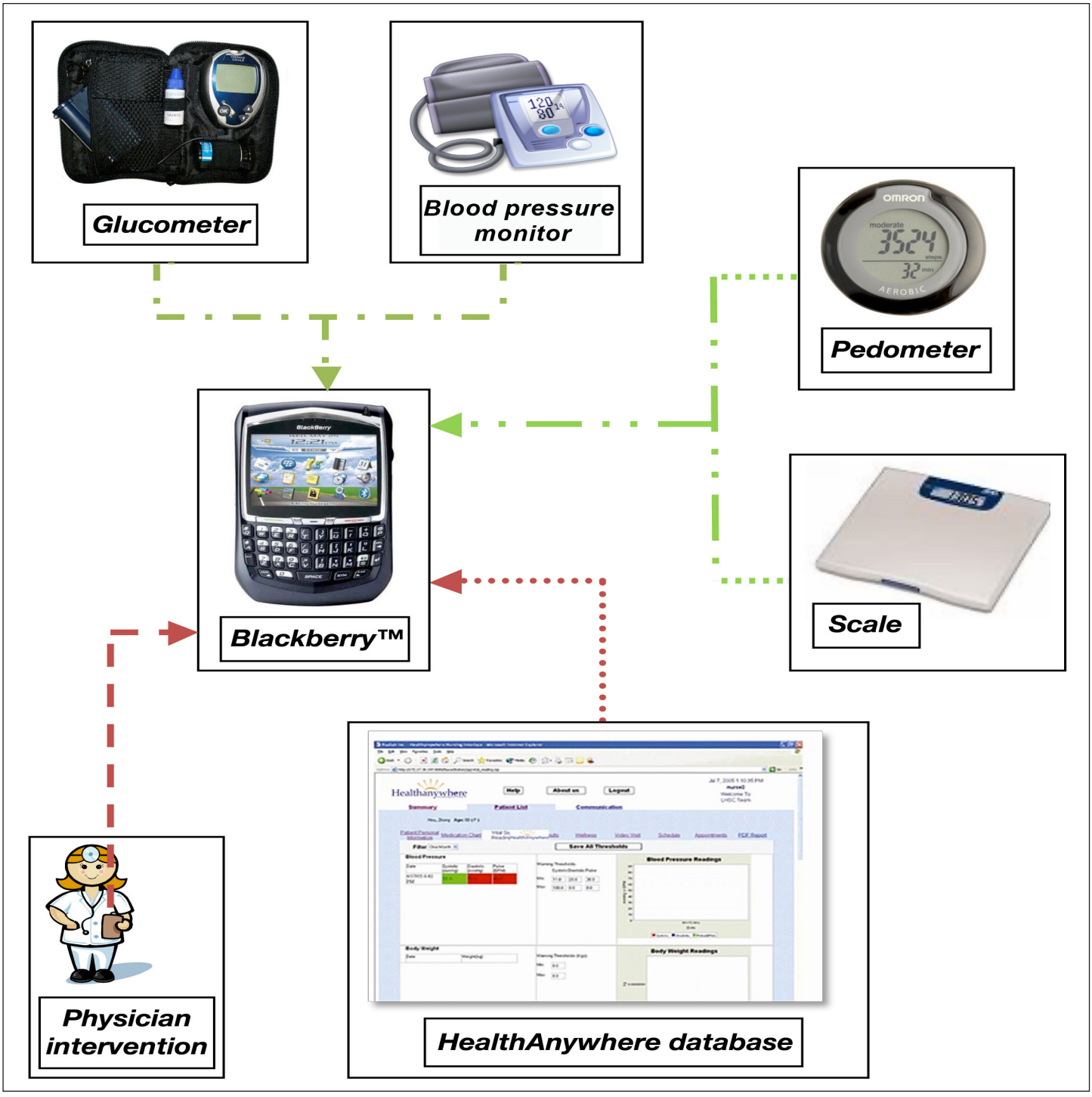

Figure 1. Transmission of data via manual and Bluetooth-enabled devices. Wireless data transmission from Blackberry to database. Solid line, Bluetooth data entry; dash–dot line, manual data entry; dashed line, automated database responses; dotted line, physician interventions.

results at week 0 and week 8. All results are expressed as a mean plus or minus one standard deviation with a p value of $< .05$ determining statistical significance. Any self-monitoring measurements transmitted between the hours of midnight and 5:00 AM were considered as data from the previous calendar day. Missing data were handled using the mean substitution approach.

Results

Twenty-six potential candidates were screened. Six participants had a diagnosis of type 2 diabetes and one of prediabetes. Of the 25 participants who met all inclusion criteria and provided informed consent, 1 withdrew shortly after enrollment because of hospitalization for respiratory

infection not related to the study. Twenty-four sedentary participants (18 female and 6 male) between the ages of 30 and 71 years (mean age of 56.6 ± 8.9 years), completed the 8-week intervention. Thirteen participants had never smoked, and 11 participants were former smokers.

No serious adverse events were reported. At day 10 of the study, a participant transmitted an elevated BG (20.9 mmol/liter) that triggered an alarm to the PI. The participant was immediately contacted by the PI and referred to a local family physician for corrective action and monitoring. A new diagnosis of type 2 diabetes was confirmed as a result of this protocol. An unexplained, markedly elevated BP was noted by the CT when monitoring the database, and the study participant was referred to a primary health care provider. A new diagnosis of HT was made. Adherence to self-monitoring protocols was high. Participant compliance and satisfaction are reported elsewhere.[21]

This intervention improved some clinical markers of MS and CVD risk factors (**Table 1**), increased daily exercise, and most notably increased interest in and willingness to make lifestyle changes that impact health outcomes. For clinic assessments, at baseline, BMI was 33.1 ± 2.4 kg/m^2 compared with 32.7 ± 4.3 kg/m^2 at week 8 (p = .03) and waist circumference significantly changed from week 0 to week 8 (p = .002). These changes occurred without a statistical change in weight. There was no significant change in fasting clinic or self-monitored BG (p = .221 and p = .264, respectively). Hemoglobin A1c did not change from week 0 to week 8 (p = .22).

Table 1.
Clinical Measurements Conducted at Gateway for Assessment of Impact of the 8-Week Intervention

Clinic measurements	*n*	Mean week 0	±Standard deviation	Mean week 8	±Standard deviation	*t*-test	Mean difference ± standard deviation	95% confidence interval, lower	95% confidence interval, upper
Waist circumference (cm)	24	111.54	81.04	107.68	135.47	0.002[a]	-3.86 ± 5.43	-6.16	-1.57
BMI kg/m^2	24	33.14	19.01	32.67	18.76	0.03[a]	-0.465 ± 0.987	-0.88	-0.05
Glucose (mmol/liter)	24	6.03	5.74	5.52	1.22	0.221	-0.508 ± 1.981	-1.345	0.328
HbA1c (%)	16	0.060	0.000	0.059	0.000	0.182	-0.001 ± 0.003	-0.002	0.000
SBP (mm Hg)	24	141	95	139	351	0.475	-2.125 ± 14.342	-8.181	3.931
DBP (mm Hg)	24	85	71	80	80	0.046[a]	-4.458 ± 10.37	-8.836	-0.081
Total cholesterol (mmol/liter)	24	5.48	1.61	5.19	1.23	0.009[a]	-0.295 ± 0.508	-0.510	-0.080
LDL cholesterol (mmol/liter)	24	3.14	2.37	3.13	1.15	0.983	-0.04 ± 0.189	-0.396	0.388
HDL cholesterol (mmol/liter)	24	1.34	0.11	1.35	0.16	0.655	0.013 ± 0.029	-0.048	0.074
Triglycerides (mmol/liter)	24	1.80	1.76	1.53	0.55	0.153	-0.273 ± 0.905	-0.655	0.109
C-reactive protein (mmol/liter)	24	3.98		3.49		0.284	-0.493 ± 2.198	-1.420	0.435
Training HR (bpm)	24	118	63	124	85	<0.000[a]	5.958 ± 6.182	3.348	8.569
VO_{2max} (ml/kg/min)	24	29.54	31.39	34.68	49.24	<0.000[a]	5.139 ± 4.911	7.213	3.066
Self-monitoring measurements									
SBP (mm Hg)	24	136	15	133	18	0.165	3.875 ± 13.224	-1.709	9.459
DBP (mm Hg)	24	88	10	84	9	0.001[a]	4.375 ± 5.640	1.993	6.757
HR (bpm)	24	70	12	67	13	0.008[a]	2.91 ± 6.8	0.0046	5.82
Glucose AM (mmol/liter)	24	6.71	2.40	6.30	1.20	0.264	1.731 ± 0.353	-0.327	1.135
Glucose PM (mmol/liter)	24	7.48	2.80	6.93	1.54	0.213	0.550 ± 2.105	-0.339	1.439
Pedometer (steps/day)	24	5671	1989	6757	2454	0.003[a]	-1085 ± 1613	-1767	-404
Weight (kg)	21	92.74	13.97	92.12	13.77	0.312	0.620 ± 2.942	-0.622	1.863

[a] Significant statistical difference for values from week 0 to week 8.

For BP measurements (clinic), mean SBP did not change significantly from week 0 to week 8 (p = .475); however, mean DBP decreased significantly from 85 ± 71 mm Hg at baseline to 80 ± 80 mm Hg at week 8 (p = .046). For self-monitored measurements, only DBP decreased significantly from week 0 to week 8 (p = .001).

Total cholesterol decreased significantly from 5.48 ± 1.61 mmol/liter (week 0) to 5.19 ± 1.23 mmol/liter (week 8; p = .009). There were no significant changes in LDL or HDL cholesterol and triglycerides or C-reactive protein. Pedometer steps improved significantly (p = .003) from 5671 steps/day (week 0) to 6757 steps/day (week 8). Physical activity changed significantly from week 0 to week 8 (p < .001) as shown by the improved training HR. Some participants achieved the 10,000 step/day goal, with most improving from sedentary to low active step count ranges. VO_{2max} increased from 29.54 ± 31.39 to 34.68 ± 49.24 ml/kg/min (p < .001).

Conclusions

This novel program was based on a wireless platform where participants, their lifestyle team, and health care professionals (physician, nurse) had remote, real-time access to their markers of CVCs of diabetes and the ability to modify their personal lifestyle prescription. This study demonstrated the utility of self-monitoring of the risk factors for MS and resulted in improved PA and CVD risk profile. Results are very encouraging considering the short, 8-week time period for this intervention. Participant compliance and willingness to complete the activity requirements were positive outcomes. Our findings support findings from a review of clinical benefits of pedometers to increase PA.[19] We also demonstrated a significant change in DBP, BMI, total cholesterol, and steps per day. Notably, there was little change in SBP (-3 mm Hg) compared with a significant decrease of 3.8 mm Hg in the review.[19] However, the impact of a decrease by 3 mm Hg is important, as a 2 mm Hg reduction in SBP translates into a 10% reduction in stroke mortality and a 7% reduction in mortality from vascular causes in a middle-aged population.[23] Diastolic blood pressure was significantly decreased when measured at home and in the clinic, and changes were greater than published data from pedometer trials (-5 and -4 mm Hg, respectively, versus -0.3 mm Hg).[19] Our findings may be attributed to participant use of an exercise prescription in tandem with their pedometer. The technology-supported intervention may have contributed to an increased interest in overall health, thus informing other lifestyle changes such as dietary improvement, which were not monitored. Our findings are supported by a short-term (4-month) remote BP monitoring study that found -10 and -4 mm Hg changes in SBP and DBP, respectively.[18] Improved vascular function may be the mechanism responsible for the reduction in BP. Aizawa and colleagues[24] found a significant increase in distensibility in patients with MS following 8 weeks of physician-prescribed exercise and Mediterranean diet.

Studies have reported either significant decreases[15–17] or no change[25] in HbA1c following remote BG monitoring interventions with cellular phones, but changes in home-monitored BG were not reported in these studies. Exercise is known to help control BG in insulin resistance and diabetes, and intracellular mechanisms have been investigated. A study examined the effects of a 4-week therapeutic lifestyle modification in rural women with MS[26] and showed that the intervention group had significant reductions in body weight, waist circumference, triglyceride, BG, SBP, and LDL and increased HDL. These results differ from ours and may be due to racial differences (Korean versus Caucasian) or differences in intervention delivery. Information booklets were provided to all participants at the onset of the trial, and the intervention group attended education and exercise sessions three times per week for 2 hours each time. The intervention focused on both nutrition and exercise. In the DaTA study, we provided basic exercise prescription, but the participants were left to exercise on their own, and dietary advice was not given. Tjønna and associates[27] noted greater improvements in MS in a group of patients completing high-intensity interval training compared with a continuous moderate exercise group, thus reinforcing that higher intensities are better for reducing CV risk. Our participants were prescribed a target HR of 70–85% (moderate intensity) of predicted maximum from the STEP test. Greater improvements may have been elicited from higher intensity activities, but as our participants were in an unsupervised setting, moderate intensity was chosen for safety.

Although only some DaTA study participants met the goal of 10,000 steps/day, this increase in PA (mean of 2239 steps/day) was sufficient to improve markers of MS. However, the population sample remained in a low-active exercise class. Furthermore, DaTA study participants may not reflect a typical response of MS patients because volunteers are generally more motivated than nonvolunteers. Nonetheless, the intervention helped participants increase PA successfully in a short time frame. Individual exercise prescriptions were tailored to include other activities

as well as walking, with several participants involving physical activities that are not conducive to pedometer monitoring including cycling, swimming, and resistance training exercise. In retrospect, an accelerometer and/or exercise journal may have more effectively captured nonwalking exercise. The results suggest that the intervention may be helpful in preventing stage regression (relapse). It has been proven that short-term exercise interventions have higher adherence rates than long-term interventions, thus the results of this pilot study may not be applicable to a longer-term intervention.

Improvements in VO_{2max} suggest that participant PA increased during the study. VO_{2max} has been shown to improve with weight loss alone; however, weight loss was not accomplished in our study participants. Therefore, the improvements in aerobic fitness are likely attributed to increased PA. Participants were prescribed a target HR of 70–85% of their maximum; however, this value was not captured, and therefore we cannot be sure that they achieved this target.

The DaTA study was conducted as a feasibility study; therefore, a control group was excluded. This limitation does not allow us to conclude that the interventions alone were responsible for the improvement in MS risk factors and clinical outcomes.

Our objective was to assess utility of the intervention to change health outcome measures of the precursors of MS. This pilot study demonstrated that, in a short time frame, a lifestyle intervention using the STEP protocol, education, and, importantly, interactive monitoring driven by technology is effective in a rural setting. Our findings support evidence that remote self-managed monitoring technologies can effectively impact risk factors of MS and can be used where access to health care is limited. Further validation with a rigorous clinical trial process is required. This study confirms the willingness by participants to change and to invest their time in remote health monitoring measurements and increase their levels of exercise that, in turn, will prevent development of CVCs of type 2 diabetes. Furthermore, database-generated health reports proved to be a valuable two-way tool for communication between the patients and their primary care physician or other health care providers (dieticians, pharmacists). For those without a care provider, the interventions employed provided an awareness of the impact of lifestyle modification recommendations as well as their overall physical health, which may not otherwise be available to them.

In conclusion, this feasibility study supports the foundation for a large-scale randomized clinical trial. We have shown that it is possible for those at risk for MS to monitor BP, BG, PA, HR, and weight remotely and to respond to extraordinary changes with confidence at arm's length from their primary health care provider. Moreover, in an underserved rural setting, health care can be supplemented with a remote monitoring system. Through the technologies, the participants are integrated into the process of personal health care and become responsible for healthy living choices, therefore favorably impacting their CVCs of diabetes.

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