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Self-tracking of Physical Activity in People With Type 2 Diabetes

A Randomized Controlled Trial

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The purpose of this study was to determine the efficacy of an online self-tracking program on physical activity, glycated hemoglobin, and other health measures in patients with type 2 diabetes. Seventy-two patients with type 2 diabetes were randomly assigned to an intervention or control group. All participants received usual care. The intervention group received an activity tracker (Fitbit Zip) connected to an online lifestyle program. Physical activity was analyzed in average steps per day from week 0 until 12. Health outcome measurements occurred in both groups at baseline and after 13 weeks. Results indicated that the intervention group significantly increased physical activity with 1.5 ± 3 days per week of engagement in 30 minutes of moderate-vigorous physical activity versus no increase in the control group ($P = .047$). Intervention participants increased activity with 1255 ± 1500 steps per day compared to their baseline ($P < .010$). No significant differences were found in glycated hemoglobin A1c, with the intervention group decreasing −0.28% ± 1.03% and the control group showing −0.0% ± 0.69% ($P = .206$). Responders (56%, increasing minimally 1000 steps/d) had significantly decreased glycated hemoglobin compared with nonresponders (−0.69% ± 1.18% vs 0.22% ± 0.47%, respectively; $P = .007$). To improve effectiveness of eHealth programs, additional strategies are needed.

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More than 400 million people worldwide have diabetes, with an increased risk of cardiovascular disease, cancer, and dementia.[1] Physical inactivity and being overweight due to an unhealthy lifestyle are key factors in both the onset and progression of type 2 diabetes.[2,3] Increasing physical activity and adopting a healthy lifestyle are essential for preventing long-term complications and comorbidity, as these improve glycemic control (measured by glycated hemoglobin A1c levels [HbA1c]) and reduce weight.[3–6] Therefore, stimulating physical activity is of great importance within daily clinical practice for people with type 2 diabetes, especially for nursing care. Physical activity guidelines for this population recommend engagement in progressive, moderate to vigorous resistance training, in addition to a minimum of 150 minutes of moderate to vigorous physical activity (MVPA) per week and avoidance of prolonged sedentary activities.[6,7] Since walking is generally an appropriate activity for those with diabetes, these recommendations can be translated into taking at least 7500 steps per day (steps/d), of which 3000 steps should be at a moderate to vigorous intensity.[8] A recent report suggests that beginning with 10 minutes of MVPA per day (1000 steps/d) would be a feasible start toward achieving these guidelines for sedentary individuals in midlife.[9]

Many people worldwide, including people with type 2 diabetes, do not comply with physical activity guidelines.[3] Moreover, people who are overweight tend to overestimate their level of physical activity compared with people who have a healthy weight.[10] Adherence to physical activity recommendations from healthcare professionals is low in people with diabetes,[11] or may not have sustainable effects on physical activity behavior and glycemic control. A large trial of an intensive lifestyle program found significant improvements in health outcomes after 1 year of follow-up. However, these effects diminished after 10 years of follow-up.[12] Factors that

influence the absence of long-term adherence to exercise advice can vary; for example, low levels of health literacy, lack of motivation, negative beliefs about physical activity, inconvenience of being active, lack of time, lack of an adequate exercise plan, and overly vigorous intensification leading to injuries.[11,13]

Several behavioral intervention components have been identified as crucial for facilitating incremental physical activity, including those for individuals with type 2 diabetes. According to Social Cognitive Theory, certain beliefs about the desired behavior and oneself are needed to accomplish behavioral change. These beliefs include a positive attitude about the desired behavior, positive outcome expectations, and adequate self-efficacy beliefs for performance of the behavior. The latter plays a significant role because self-efficacy beliefs directly affect behavior and the goals that people set for themselves.[14,15] Positive beliefs about physical activity and self-efficacy for exercise can be influenced by education, tailoring of health information, use of a trusted source, and a gradual intensification of activity aimed at small goals.[14,15] In addition, setting goals is an important component of many interventions, because goals motivate individuals to decrease discrepancy between the current and desired states.[16] Goals should be both behavioral (eg, increase steps per day) and outcome related (eg, weight loss).[16–18] After an individual has made adjustments in behavior, positive feedback on this new behavior is very important for maintaining motivation. Self-monitoring of behavior is recognized as an essential strategy to gain personalized feedback and to stimulate positive learning experiences.[15,17,19] These strategies are part of a well-known taxonomy of behavioral change techniques (BCTs).[17,18] These BCTs enable intervention designers to use an evidence-based, reproducible, and uniform intervention description.

Electronic health systems, such as mobile health technology, are increasingly used in the treatment for people with type 2 diabetes, in order to optimize diabetes self-management behaviors.[20] These systems make it possible to design interventions that include evidence-based strategies to improve physical activity and glycemic control in people with diabetes.[20–22] In the past several years, different activity monitoring devices have been developed.[23] Modern consumer-level activity trackers can increase awareness about an individual's actual physical activity and facilitate goal setting and personalized feedback.[17,18,23] Previous studies have shown that early versions of activity monitors, such as simple pedometers, can encourage an increase in physical activity in people with diabetes.[24,25] However, there is a gap between the introduction of these newly developed consumer level technologies and the evidence for the effectiveness of their use in clinical care.[26] In addition, stimulation of physical activity within nursing care is not yet considered to be "usual care" and requires further exploration.[27,28] Therefore, we designed an online behavioral intervention program that was connected to a modern consumer-level activity tracker. The purpose of this program was to assist individuals with type 2 diabetes to establish a healthy lifestyle.

Study Purpose

The purpose of this randomized controlled trial (RCT) was to evaluate this online self-tracking program for physical activity, glycemic control (measuring HbA1c) and other health outcome measures (advanced glycation end product [AGE], weight, body mass index [BMI], waist-hip ratio, and self-reported health) in patients with type 2 diabetes. We hypothesized that the online self-tracking program would positively affect physical activity, HbA1c, and other health outcome measures in the intervention group compared to the control group. In addition, we hypothesized that, within the intervention group, participants who increased physical activity with a minimum of 1000 steps/d would demonstrate a greater reduction in HbA1c compared with participants who increased physical activity with fewer than 1000 steps/d.

METHODS

Study Design

This study was designed as an RCT. In addition to usual care, the intervention group received an activity tracker connected to an online program that was meant to encourage them to initiate a healthy lifestyle. The control group received only usual care, that is, visits every 3 months with a diabetes nurse and/or an internist for monitoring HbA1c and advice regarding medication, lifestyle, and weight reduction in order to normalize blood glucose levels.[29] No restrictions were specified regarding the prescription of additional medication before or within the study period. The study had a total duration of 13 weeks (baseline week 0 and intervention weeks 1–12). Primary and secondary outcome measures were assessed at baseline (T0) and at the end of the trial (T1). The research and intervention were conducted by diabetes nurses (ie, nurses with additional training to care for patients with diabetes) employed in two hospitals in the Netherlands. The diabetes nurses received a study protocol and training by the research team before the beginning of the study. The study protocol described the enrollment, measurement, and intervention procedures in detail. The research team provided support to the diabetes nurses during the entire study period.

Participants

Eligible participants were patients with type 2 diabetes, 18 years of age or older, with HbA1c of 7.5% (58 mmol/mol) or greater, access to the Internet, and the ability to use a computer. Exclusion criteria were pregnancy, already

engaging in more than 3 hours of intensive exercise per week, or comorbidity or cognitive dysfunction interfering with physical activity. Participants received outpatient care and were not hospitalized. All participants provided informed consent. The complete study protocol was approved by the medical ethics committee of the University Medical Center Groningen (file number 2014-334) and was published in the Dutch Trial Register (NTR5215).

Recruitment, Randomization, and Allocation

Participants were recruited at the Bethesda General Hospital (Bethesda Diabetes Research Center, Hoogeveen, the Netherlands) and the Martini Hospital (Groningen, the Netherlands). Recruitment methods included flyers, letters, and an advertisement in a local newspaper, and eligible patients were invited by the diabetes nurse. After stratification for HbA1c and BMI (based on the mean values of participants included thus far), participants were randomly assigned to the intervention or control group using block randomization.[30] A predetermined formula per block (eg, ICCI) determined to which group a patient was assigned. Figure 1 illustrates the flowchart of recruitment of the participants in the study.

Intervention

The intervention group received usual care plus an activity tracker (Fitbit Zip; Fitbit Inc, San Francisco, CA) and access to the online self-tracking (eHealth) program. The activity tracker was linked to the personal accounts of the participants in the eHealth program. The program was designed by a project group composed of members from healthcare organizations, health training institutes, and technology companies. The complete content of the program aimed to optimize knowledge about a healthy lifestyle, increase awareness of individual physical activity, increase self-efficacy for exercise, and ultimately optimize and maintain a healthy lifestyle. Important BCTs of the intervention were providing information about health consequences; setting behavioral goals; setting outcome goals; barrier identification/problem solving and action planning (through the eHealth program); behavioral self-monitoring and review of behavioral goals (through the Fitbit device); and providing feedback on behavior, habit formation, habit reversal, and graded tasks (through both the Fitbit device and the eHealth program).[14–18] In more detail, the participants were instructed to maintain their usual activity pattern in week 0 to determine their baseline activity level. Beginning in week 1, they were encouraged by the diabetes nurse and the eHealth program to set incremental activity goals, based on their individual baseline activity level (ie, behavioral goals) and outcome goals (eg, losing weight). Participants were encouraged to begin with small goals such as increasing 500 or 1000 steps/d and, depending on their individual capabilities, continuing to increase to the norm of a minimum of 7500 steps/d or 150 minutes of MVPA

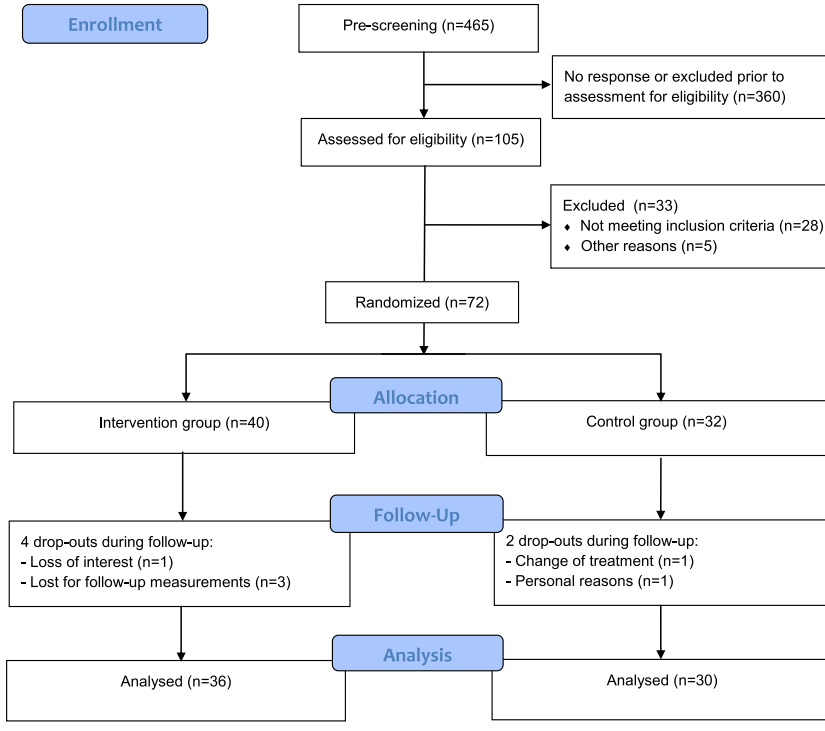

FIGURE 1. Flowchart of recruitment process for participants in the study.

per week.[6,8] The participants could easily contact the diabetes nurse throughout the program for questions and support. The program provided weekly information about physical activity, a healthy diet with sample recipes appropriate for those with diabetes, and videos of strength exercises with an explanation of how to build muscle strength. The information explained the benefits of healthy behavior and addressed frequent barriers that people experience when engaging in physical activity.[11,13] For example, to counteract a frequent barrier "lack of time," information and instructions on physical activity included several strategies to increase steps per day that could be integrated even during the workday. In addition, tailored feedback messages were provided through the program once per week based on the number of steps taken in the past week. These messages were based on whether the participants had increased their steps per day with an average minimum of 500 steps/d, stayed the same, or decreased their steps per day compared to the previous week. All messages, including in the event of a decrement in activity, had a positive tone, provided fun facts, and were meant to encourage the participant to increase activity levels.

Outcome Measures

Data collection was undertaken by the research nurse at T0 and T1. The self-reported behavioral measures were completed by the participants at T0 and T1 via digital questionnaires provided by the eHealth program.

Physical Activity

Physical activity was the intermediate outcome measure and was measured with a 1-item physical activity questionnaire that indicated how many days per week a participant engaged in 30 minutes of MVPA. This questionnaire has strong reliability and good validity compared to expert classification of subjects in the 30 minutes of MVPA recommendation.[31] In addition, within the intervention group, physical activity was measured with the Fitbit Zip in steps/d. This activity tracker could be clipped to the clothing or placed in a trouser pocket. The Fitbit Zip has been shown to be reliable and valid.[32] Participants were asked to place the activity tracker consistently in the preferred wearing position to optimize validity and reliability of the data.[32]

Primary Outcome

The primary outcome was HbA1c (percentage and millimoles per mole), as measured during usual care in specialized laboratories.

Secondary Health Outcome Measures

Advanced glycation end products were measured in skin fluorescence (SF; fluorescent properties of AGEs in the skin) with the AGE Reader mu (Diagnoptics, Groningen, the Netherlands), according to the device protocol. This device has been shown to be reliable and valid.[33,34]

For weight (kilograms) or BMI (kilograms per square meter), body weight was measured on a regular scale without shoes or extra clothing and was translated to BMI using the height of the participant. Height was measured in a standing position without shoes using a measuring bar.

Waist-hip ratio in centimeters was calculated by dividing the waist circumference by the hip circumference. Waist circumference was measured according to a protocol, with the participant in a standing position, at the midpoint between the lowest rib and the iliac crest.[35]

Subjective health score was measured on a visual analog scale ranging from 0 to 10, with 10 indicating the best health an individual could imagine and 0 indicating the worst. This score has been shown to be reliable and valid.[36]

For changes in the use and dosage of medication, per participant, all diabetes-related medications, including oral medication (metformin, Sulfonylureas [SU], acarbose, and Dipeptidyl peptidase-4 [DPP-4] inhibitor), Glucagon-like peptide-1 (GLP-1) therapy, and units of insulin use per day, were assessed at baseline and T1. An adjustment for changes in HbA1c-influencing medication was needed to reliably study the effects of the intervention on the primary endpoint (HbA1c). Clinically relevant extra medication at T0 was defined as a dose increase of 25% of oral medication, an increase of a minimum of 4 units of insulin, or additional diabetes medication. A clinically relevant change in medication at T1 was defined as a change of at least 4 units of insulin or a change of more than 25% of other glucose-lowering medications.

Self-reported Behavioral Measures

Four domains of behavioral factors were used, including intention, attitude, self-efficacy, and social norm toward engagement in exercise (minimally 5 d/wk for 30 minutes of MVPA), which is consistent with behavioral literature.[15,37] These domains were measured with a 17-item questionnaire that was based on the items of Boudreau and Godin.[38] Participants could indicate their extent of agreement on a 5-point Likert scale. For example, with social norm, participants could respond to the statement, "The most important persons in my immediate area advise me to increase my physical activity." Answers could range from strongly disagree (a score of 1) to strongly agree (a score of 5). Per domain (eg, for attitude, self-efficacy, and social norm), all scores were added and subsequently divided by the number of items. To determine the internal consistency of the different items, Cronbach's α was calculated for attitude (seven items), self-efficacy (six items), and social norm (three items).

After completion of the program intervention, participants were contacted by a member of the research team to inquire about the perceived usefulness of the activity tracker

and the eHealth program, as well as the impact of the program on their physical activity and perceived health.

Statistical Analyses

A sample size computation with an expected mean HbA1c of 7.5% ± 0.34% (59 ± 4 mmol/mol) at baseline indicated the need for the inclusion of a minimum of 28 participants per group in order to demonstrate a minimal relevant reduction of 0.27% (3 mmol/mol) with a statistical power of 80% and a significance level of 5%.

Analysis occurred for all of the participants (intention-to-treat analysis) using a repeated-measures analysis of variance, with self-reported physical activity, HbA1c, AGEs, weight, BMI, and waist-hip ratio as the dependent variables. Two time intervals were included, T0 (week 0) and T1 (week 12), to investigate for statistical differences between the intervention and control groups over time. Age, sex, extra medication at T0, perceived health at T0, intention to increase physical activity at T0, attitude, self-efficacy, and social norm were included as covariates.

Within the intervention group, a mixed models analysis was used to analyze the change of physical activity over time, measured as average steps per day from week 0 (baseline) until week 12. The advantage of mixed models is that this method can handle missing data; for example, a participant with a missing week of average steps per day data would still be included in the analysis. The intervention group was categorized into responders (eg, increasing a minimum of 1000 steps/d compared to baseline) and nonresponders (increasing with <1000 steps/d) to further examine the effect on HbA1c and other outcome measures.[7–9] The average steps per day were calculated by dividing the total steps of the specific week by the number of days the participant had measured steps with the activity tracker. It was determined that it was necessary for any given participant to have at least 4 days of valid measurement per week in order to make a reliable calculation. It was decided that at least 500 steps had to be measured during a day for it to be included in the analysis, since 500 steps represents 10% of 5000 steps, which is the established cutoff point for sedentary behavior.[39] It was reasoned that, when an individual had even 90% fewer steps than the cutoff point of sedentary behavior, the activity tracker was probably either not worn or not worn for the complete day.

RESULTS

Inclusion

Study participants were recruited between April 2015 and July 2016. A total of 465 patients were screened, of whom 105 were eligible for inclusion. From these, 72 adults (47.2% female) were randomly assigned to the intervention or control group (Figure 1). During the study period, two participants from the control group and one participant from the intervention group dropped out. Three intervention participants were unavailable for the follow-up primary outcome measurement at T1. Therefore, 66 participants were included in the analysis for the primary outcome (Figure 1). The baseline characteristics of the participants are depicted in Table 1. At baseline, the mean age was 56 ± 11 years, mean diabetes duration was 15.3 ± 6.7 years, mean HbA1c was 8.6% ± 1.0% (70.0 ± 11.3 mmol/mol), and mean BMI was 32.9 ± 5 kg/m^2. The participants were primarily white (98.6%). No significant differences existed between the intervention group and the control group at T0. Ten participants (six in the intervention group and four in the control group) received extra antihyperglycemic medication at baseline (Table 2).

Adherence

Adherence to the intervention program was defined as having worn the Fitbit on more than 75% of intervention days and having read more than 50% of program content. The latter was verified digitally and with the telephonic evaluation. In this way, 82.5% of the intervention participants were defined as being adherent.

Physical Activity

The intervention group demonstrated an increase of 1.5 ± 3 d/wk of self-reported engagement in a minimum of 30 minutes of MVPA, while the control group showed no increase (0.0 ± 1.8; $F = 4.164$, $P = .047$; Figure 2A). Within the intervention group, physical activity data from the activity tracker were available for 36 of 40 participants (due to one dropout, one nonadherence to the intervention procedure, and two participants experiencing technical problems while pairing their activity trackers with the eHealth program). The activity tracker disclosed a mean of 5975 ± 2982 steps/d at the baseline week that significantly increased during all of the intervention weeks ($P < .010$, mixed models analysis; Table 3). Figure 2B illustrates the average steps per day of the participants during all of the intervention weeks. On average, participants increased activity, with 1255 ± 1500 steps/d during the intervention period. The control group participants, who received activity trackers after finishing the control period at T1, averaged 6113 ± 2478 steps/d during their baseline week. This was approximately the same as the baseline average steps per day of the intervention group (mean difference, 138 steps/d; $P = .859$).

Glycemic Control

There was no significant difference in HbA1c change between the intervention group and the control group ($F = 1.634$, $P = .206$). The intervention group showed a nonsignificant mean decrease of −0.28% ± 1.03% (−3.1 ± 11.3 mmol/mol),

Table 1. Baseline Characteristics and Differences in Changes of Health Outcome Measures Between the Intervention and Control Groups

ITT	Intervention Group (N = 40)		Control Group (N = 32)		F[b]	P[b]
	Baseline[a]	Δ	Baseline[a]	Δ		
Age, y	56.8 ± 11.4	NA	55.8 ± 11.4	NA	NA	NA
Diabetes duration, y	15.5 ± 7.7	NA	14.9 ± 5.3	NA	NA	NA
Medication use, %						
Oral medication	77.5	NA	65.6	NA	NA	NA
GLP-1 therapy	25		21.9			
Insulin	55		53.1			
Insulin (based on users), units	62.9 ± 41.8	4.7 ± 15.2	76.4 ± 54.8	5.0 ± 10.3	NA	NA
HbA1c, %	8.5 ± 0.87	−0.28 ± 1.03	8.6 ± 1.22	−0.0 ± 0.69	1.634	.206
HbA1c, mmol/mol	69.9 ± 9.5	−3.1 ± 11.3	70.2 ± 13.3	−0.03 ± 7.5	1.634	.206
AGEs, SF	2.46 ± 0.57	0.14 ± 0.34	2.60 ± 0.4	0.05 ± 0.35	0.661	.421
Weight, kg	102.2 ± 19.3	−0.1 ± 3.2	99.8 ± 16.3	0.5 ± 2.5	0.602	.441
BMI, kg/m^2	33.2 ± 5.3	−0.02 ± 1.1	32.6 ± 4.5	0.17 ± 0.8	0.550	.462
Waist circumference, cm	112.1 ± 11.6	0.05 ± 3.4	116.4 ± 13.2	0.17 ± 5.2	0.011	.918
Hip circumference, cm	115.3 ± 8.9	0.0 ± 3.2	114.6 ± 11.5	−0.4 ± 4.1	0.140	.709
Waist-hip ratio, cm/cm	0.96 ± 0.17	0.03 ± 0.03	1.00 ± 0.17	0.04 ± 0.04	0.008	.928
Self-perceived health, points	5.7 ± 2	1.1 ± 2.3	5.6 ± 1.8	−0.3 ± 1.4	5.874	.020[c]

Abbreviations: NA, not applicable; SF, skin fluorescence; Δ, change between T0 and T1.

[a]All variables were checked for normality, and influence of nonnormality was checked with Cook's distance.

[b]Repeated-measures analysis of variance for differences in change over time between the intervention and control groups.

[c]$P < .05$.

and the control group showed no decrease (0.0% ± 0.69%, −0.03 ± 7.5 mmol/mol) (Table 1).

Secondary Health Outcome Measures

No significant differences on the health-related outcomes (AGEs, weight/BMI, and hip-waist ratio) were found between the intervention and control groups ($P > .05$) except for the subjective health score ($P = .02$). No differences existed in the change in medication prescription at T1, with eight intervention group participants and six control group participants receiving extra medication at T1. One intervention group participant decreased medication at T1 (Table 2). All of the results on the health outcome measures are presented in Table 1.

Subgroup Analyses and Covariates

More than half of the participants (56%) were defined as "responders" (activity increased by at least 1000 steps/d compared to baseline). When "being a responder" was included in a subanalysis of intervention participants, a significant interaction effect was found for being a responder and HbA1c over time: −0.69% ± 1.18% (−7.6 ± 12.9 mmol/mol) for responders and 0.22% ± 0.47% (2.4 ± 5.3 mmol/mol) for nonresponders ($F = 8.430$, $P = .007$). No significant results were associated with being a responder for other health outcome measures (Table 4).

Cronbach's α for the different domains of the behavioral questionnaire was .845, .860, and .683 for attitude, self-efficacy, and social norm, respectively.

Table 2. Medication Use at Baseline and T1

Extra Medication at T0 (N = 10)[a]	Intervention Group, n	Control Group, n
Started with metformin	1	0
Started with SUs	0	0
Started with acarbose	0	0
Started with DPP-4	0	0
Started with GLP-1	0	0
Started with insulin	1	4
Increased insulin > 4 units	3	0
Started with more than one type of medication	1	0
Change in Medication at T1	**Intervention Group (N = 40), n**	**Control Group (N = 32), n**
No change in medication	32	26
Increased insulin > 4 units	4	6
Decreased insulin > 4 units	1	0
Increased dosage of other medication	3	0
Decreased dosage of other medication	0	0

[a]Six participants in the intervention group and four participants in the control group received extra medication at baseline.

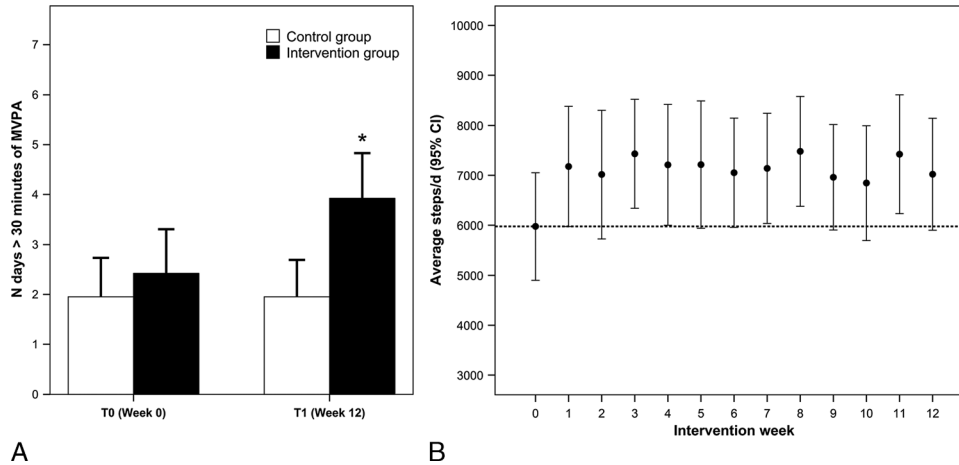

FIGURE 2. Change in physical activity from T0 to T1 in both groups (A) and change in steps per day from baseline till week 12 within the intervention group (B).

Social norm was a significant covariate when added to the main analysis ($F = 7.475$, $P = .009$). Age, sex, BMI, intention to increase physical activity, attitude, and self-efficacy showed no significant effects on HbA1c change. Also, extra medication at T0 had no significant main effect on HbA1c ($F = 3.102$, $P = .088$). Within the intervention group, responders had a significantly higher social norm score at baseline ($P = .020$) compared to nonresponders.

Patient Evaluations

Ninety percent of the intervention participants perceived the activity tracker as being useful or very useful. A lower percentage (46%) qualified the eHealth program as being useful or very useful, 28% as neutral, and 24% as not useful. Almost three-quarters of participants (74%) indicated that they had increased physical activity behavior due to the intervention program; 41% of the participants indicated that they increased their activity levels a lot (daily changes), and 33% indicated a moderate change (weekly changes). Slightly more than half of the participants (51%) indicated that they felt more fit or healthier since their participation in the program, 26% were uncertain, and 20% indicated that they did not feel more fit or healthy.

Suggestions included improving the ease of use of the eHealth program, providing an activity tracker with a Dutch mobile application instead of English, and including content (ie, video instruction on building physical strength) that is more tailored to individual needs.

DISCUSSION

The goal of this study was to examine the effects of an online self-tracking program on physical activity, glycemic control, and other health outcome measures in people with type 2 diabetes. Physical activity significantly increased in the intervention group and, from a certain level of increase (≥1000 steps/d), a clinically relevant decrease of HbA1c was determined. Overall, for responders and nonresponders, no effects were found on HbA1c or the other health outcome measures except on the subjective health score. Changes in medication at baseline did not affect the results.

To explain the lack of an overall effect on HbA1c, a more thorough analysis was conducted on the activity tracker data measured within the intervention group. The average steps per day increased compared to the individual baselines of the intervention group participants, with 1255 ± 1500 steps/d. Therefore, 39% of the participants complied with the guideline of taking 7500 steps/d or more during the

Table 3. Change in Physical Activity (Average Steps per Day) Over Time

Week	Estimate (SE)[a]	Confidence Interval		P
		Lower	Upper	
1	1284 (372)	552	2016	.001[b]
2	1172 (371)	442	1902	.002[b]
3	1536 (378)	793	2280	.000[b]
4	1351 (378)	607	2095	.000[b]
5	1399 (375)	660	2137	.005[b]
6	1116 (372)	385	1847	.003[b]
7	1063 (375)	326	1800	.005[b]
8	1384 (378)	641	2127	.000[b]
9	1031 (372)	301	1771	.006[b]
10	959 (372)	227	1690	.010[b]
11	1435 (375)	697	2173	.000[b]
12	1135 (369)	409	1860	.002[b]

All intervention weeks are compared with the baseline week (N = 36).

[a]Linear mixed models. The estimates from weeks 1 to 12 indicate the estimated changes compared with baseline.

[b]$P < .010$.

Table 4. Results on Health Outcome Measures for Responders Versus Nonresponders Within the Intervention Group (N = 36)

	Responders (N = 20)	Nonresponders (N = 16)	F[a]	P[a]
HbA1c, %	−0.69 ± 1.18	0.22 ± 0.47	8.430	.007[b]
HbA1c, mmol/mol	−7.6 ± 12.9	2.4 ± 5.3	8.430	.007[b]
AGEs, SF	0.06 ± 0.33	0.26 ± 0.32	1.816	.192
Weight, kg	−0.3 ± 3.6	0.3 ± 2.7	0.388	.538
BMI, kg/m^2	−0.08 ± 1.3	0.06 ± 0.9	0.416	.524
Waist circumference, cm	−0.8 ± 3.7	1.4 ± 3.9	0.563	.459
Hip circumference, cm	−0.3 ± 2.8	−0.4 ± 3.8	0.062	.805
Waist-hip ratio, cm/cm	−0.08 ± 3.7	1.4 ± 3.9	0.796	.380

[a]Repeated-measures analysis of variance for differences in change over time between responders and nonresponders within the intervention group.
[b]$P < .01$.

intervention, and 61% did not. Substantial variability was present in the increase of steps per day among the participants, from −1355 to 5049 steps/d. This variability was supported by the evaluation results; that is, 74% of the intervention participants indicated having increased their physical activity (41% daily and 33% weekly activity), while 26% had not. This interindividual variability may well explain the absence of an overall significant decline in HbA1c in the intervention group. Indeed, subgroup analysis showed that responders had a significant and clinically relevant decline in HbA1c (−0.69% vs 0.22%, $P = .007$). Thus, for the complete intervention group, the increase in physical activity was probably not enough to improve HbA1c. However, the combined improvement of physical activity and HbA1c in responders with advanced type 2 diabetes is clinically relevant and promising for the future. The prediction of responsiveness might be a target of further research. Compared to the literature, the increase in steps per day was lower than the standardized mean difference of 1822 steps/d found in the meta-analysis by Qiu et al.[40] This may be explained by the additional support, such as counseling or telephonic support, that was provided in the studies reviewed by Qiu et al. In a recent comparable, but larger, study by Dasgupta et al,[41] physical activity was increased by 1190 steps/d (95% confidence interval, 550-1840) and HbA1c was decreased by 0.38% compared to the control group. This is consistent with the results found in our study.

The secondary health outcomes showed no significant changes, even in the comparison of responders to nonresponders. Advanced glycation end products are complex linkage products measured in the tissue, and because the accumulation of AGEs also depends on other factors such as smoking behavior and intake of certain foods,[34] it is likely that more long-term lifestyle changes are necessary to achieve significant results on AGEs. Also, for body weight and waist-hip ratio, no effects were found. As an increase of at least 2000 steps/d is needed to achieve relevant effects on weight and body composition,[8,42] the lack of findings on these measures is probably explained by the smaller increase in the number of steps per day found in this study.

Interestingly, social norm scores were a significant confounder for the HbA1c results, and responders had a higher social norm score at baseline compared with nonresponders. This result emphasizes the importance of taking into account the social support of a patient with type 2 diabetes. In accordance with this, the use of theory-based BCTs within self-monitoring devices or lifestyle interventions is receiving increasing attention within physical activity research. Several studies pointed out the importance of providing information, goal setting, action planning, self-monitoring, barrier identification, personalized feedback, and rewards.[17,25,43] These BCTs were present in our study; however, other important BCTs, such as facilitating social support, changing environmental factors, and using follow-up prompts, were lacking in our intervention at a structural basis.[43–46] In addition, the BCT "action planning" was incorporated within the informational documents but not structurally tailored for individual participants. Since these BCTs are associated with improved intervention outcomes in people with diabetes, the lack of an overall effect may well be explained by insufficient structural implementation of these BCTs in our study.[45,46] This should be improved in future studies; for instance, social support may be enhanced by the creation of a system in which patients with diabetes are connected to each other, perhaps for activities such as walking groups. Next to the inclusion of additional evidence-based BCTs, effects of future programs may also be enhanced by improving the ease of use of digital techniques, incorporating additional advances to use personal generated health data in a meaningful way,[20] and providing technical support from a person other than the nurse. This will enhance the role of the nurse for providing personal lifestyle support.[20,29] Future programs should incorporate a systematic approach to

include all of these factors, including an analysis for appropriate intervention strategies.[18]

Our study has a number of strengths and limitations. The first limitation is the relatively short-term follow-up period of 3 months, which was selected to afford the control group the opportunity to engage in the program after finishing the control period. This was intended to prevent an increased withdrawal rate in the control group. However, a longer duration may have been beneficial for incorporating lifestyle habits and for a longer-term comparison with the control group. Second, this study had a relatively small sample size. Although we met the minimum number of participants necessary from our sample size calculation, a larger group would have strengthened the results. Third, this study missed an objective physical activity instrument for both groups. Because the Fitbit was an important component of the intervention, the control group did not receive a Fitbit. However, from the baseline step measurements that the control group made after finishing their control period, it appeared that they walked the same average steps per day compared with the baseline steps per day of the intervention group. This reinforces our finding that the intervention group increased their average steps per day. A strength was that the study was conducted in a general hospital setting, embedded in the usual nursing care for patients with type 2 diabetes. This real-life setting simplifies an extrapolation of the data to the general population with type 2 diabetes. Also, as determined from the evaluations, most participants were satisfied with the self-tracking program; 90% indicated that the activity tracker was useful or very useful for them. This indicates that patients with type 2 diabetes are willing to engage in lifestyle programs based on self-tracking.

CONCLUSIONS

In our study, self-tracking of physical activity did improve physical activity in patients with advanced type 2 diabetes. The intervention did not improve glycemic control overall, due to a large interindividual variability in responsiveness to the intervention. However, it did relevantly improve glycemic control in 56% of the participants who increased their physical activity with a minimum of 1000 steps/d. To improve the effectiveness of online self-tracking programs on health outcomes, more development in the ease of use of eHealth technology, integration of BCTs, and tailoring of intervention programs is required, for example, based on presence of social support.

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References

1. International Diabetes Federation. *IDF Diabetes Atlas, 8th ed*. Brussels, Belgium: International Diabetes Federation; 2017. http://www.diabetesatlas.org. Accessed August 24,2017.
2. Madden KM. Evidence for the benefit of exercise therapy in patients with type 2 diabetes. *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy*. 2013;6: 233–239.
3. Lee IM, Shiroma EJ, Lobelo F, et al. Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy. *Lancet*. 2012;380(9838):219–229.
4. Knowler WC, Barrett-Connor E, Fowler SE, et al; Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *The New England Journal of Medicine*. 2006; 346(6): 393–403.
5. Diabetes Prevention Program Research Group. Long-term effects of lifestyle intervention or metformin on diabetes development and microvascular complications over 15-year follow-up: the Diabetes Prevention Program Outcomes Study. *The Lancet. Diabetes & Endocrinology*. 2015;3(11): 866–875.
6. Kirwan JP, Sacks J, Nieuwoudt S. The essential role of exercise in the management of type 2 diabetes. *Cleveland Clinic Journal of Medicine*. 2017;84(7 suppl 1): S15.
7. Haskell WL, Lee IM, Pate RR, et al. Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. *Medicine & Science in Sports & Exercise*. 2007;39(8): 1423–1434.
8. Tudor-Locke C, Craig CL, Brown WJ, et al. How many steps/day are enough? for adults. *International Journal of Behavioral Nutrition and Physical Activity*. 2011;8(1): 79.
9. Brannan M, Varney J, Timpson C, Foster C, Murphy M. 10 Minutes brisk walking each day in mid-life for health benefits and towards achieving physical activity recommendations (evidence summary). 2017. https://www.gov.uk/government/publications/everybody-active-every-day-a-framework-to-embed-physical-activity-into-daily-life. Accessed August 24,2017.
10. Tully MA, Panter J, Ogilvie D. Individual characteristics associated with mismatches between self-reported and accelerometer-measured physical activity. *PLoS One*. 2014;9(6): e99636.
11. García-Pérez LE, Alvarez M, Dilla T, Gil-Guillén V, Orozco-Beltrán D. Adherence to therapies in patients with type 2 diabetes. *Diabetes Therapy*. 2013;4(2): 175–194.
12. Look AHEAD Research Group; Wing RR, Bolin P, Brancati FL, et al. Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes. *The New England Journal of Medicine*. 2013;369: 145–154.
13. Justine M, Azian A, Hassan V, Manaf H. Barriers to participation in physical activity and exercise among middle-aged and elderly individuals. *Singapore Medical Journal*. 2013;54(10): 581–586.
14. Bandura A. Health promotion by social cognitive means. *Health Education & Behavior*. 2004;31(2): 143–164.
15. Bandura A. Health promotion from the perspective of social cognitive theory. *Psychology & Health*. 1998;13(4): 623–649.
16. Mann T, de Ridder D, Fujita K. Self-regulation of health behavior. *Health Psychology*. 2013;32(5): 487–498.
17. Michie S, Ashford S, Sniehotta FF, Dombrowski SU, Bishop A, French DP. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. *Psychology & Health*. 2011;26(11): 1479–1498.
18. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Annals of Behavioral Medicine*. 2013;46(1): 81–95.
19. Kluger AN, DeNisi A. The effects of feedback interventions on performance: a historical review, a meta-analysis, and a preliminary feedback intervention theory. *Psychological Bulletin*. 1996;119(2): 254–284.

20. Greenwood DA, Gee PM, Fatkin KJ, Peeples M. A systematic review of reviews evaluating technology-enabled diabetes self-management education and support. *Journal of Diabetes Science and Technology*. 2017;11(5): 1027–1015. 1932296817713506.
21. Arnrich B, Mayora O, Bardram J, Trster G. Pervasive healthcare. *Methods of Information in Medicine*. 2010;49(1): 67–73.
22. Van Gemert-Pijnen JEWC, Peters O, Ossebaard HC. *Improving eHealth*. The Hague, The Netherlands: Eleven International Publishing; 2013. http://lib.myilibrary.com?ID=673579.
23. Sanders JP, Loveday A, Pearson N, et al. Devices for self-monitoring sedentary time or physical activity: a scoping review. *Journal of Medical Internet Research*. 2016;18(5): e90.
24. El-Gayar O, Timsina P, Nawar N, Eid W. A systematic review of IT for diabetes self-management: are we there yet? *International Journal of Medical Informatics*. 2013;82(8): 637–652.
25. Cotter AP, Durant N, Agne AA, Cherrington AL. Internet interventions to support lifestyle modification for diabetes management: a systematic review of the evidence. *Journal of Diabetes and its Complications*. 2014;28(2): 243–251.
26. McMillan KA, Kirk A, Hewitt A, MacRury S. A systematic and integrated review of mobile-based technology to promote active lifestyles in people with type 2 diabetes. *Journal of Diabetes Science and Technology*. 2017;11(2): 299–307.
27. Old N. Paving the way for health promotion nurses: an international perspective. *Creative Nursing*. 2014;20(4): 222–226.
28. Frank JR, Danoff D. The CanMEDS initiative: implementing an outcomes-based framework of physician competencies. *Medical Teacher*. 2007;29(7): 642–647.
29. American Diabetes Association. Standards of medical care in diabetes—2011. *Diabetes Care*. 2011;34(suppl 1): 11.
30. Kernan WN, Viscoli CM, Makuch RW, Brass LM, Horwitz RI. Stratified randomization for clinical trials. *Journal of Clinical Epidemiology*. 1999;52(1): 19–26.
31. Milton K, Bull FC, Bauman A. Reliability and validity testing of a single-item physical activity measure. *British Journal of Sports Medicine*. 2011;45(3): 203–208.
32. Kooiman TJ, Dontje ML, Sprenger SR, Krijnen WP, van der Schans CP, de Groot M. Reliability and validity of ten consumer activity trackers. *BMC Sports Science, Medicine & Rehabilitation*. 2015;7(1): 1–11.
33. Meerwaldt R, Graaff R, Oomen PHN, et al. Simple non-invasive assessment of advanced glycation endproduct accumulation. *Diabetologia*. 2004;47(7): 1324–1330.
34. Bos D, de Ranitz-Greven W, de Valk H. Advanced glycation end products, measured as skin autofluorescence and diabetes complications, a systematic review. *Diabetes Technology & Therapeutics*. 2011;13(7): 773–779.
35. World Health Organization. *Measuring Obesity—Classification and Description of Anthropometric Data. Report on a WHO Consultation of the Epidemiology of Obesity. Warsaw, 21–23 October 1987 (Nutrition Unit Document EUR/ICP/NUT. 1987;123)*. Copenhagen, Denmark: WHO; 1989.
36. Janssen MF, Pickard AS, Golicki D, et al. Measurement properties of the EQ-5D-5 L compared to the EQ-5D-3 L across eight patient groups: a multi-country study. *Quality of Life Research*. 2013;22(7): 1717–1727.
37. Ajzen I. The theory of planned behavior. *Organizational Behavior and Human Decision Processes*. 1991;50(2): 179–211.
38. Boudreau F, Godin G. Participation in regular leisure-time physical activity among individuals with type 2 diabetes not meeting Canadian guidelines: the influence of intention, perceived behavioral control, and moral norm. *International Journal of Behavioral Medicine*. 2014;21(6): 918–926.
39. Tudor-Locke C, Craig CL, Thyfault JP, Spence JC. A step-defined sedentary lifestyle index: <5000 steps/day. *Applied Physiology, Nutrition and Metabolism*. 2013;38(4): 100–114.
40. Qiu S, Cai X, Chen X, Yang B, Sun Z. Step counter use in type 2 diabetes: a meta-analysis of randomized controlled trials. *BMC Medicine*. 2014; 12(1): 36.
41. Dasgupta K, Rosenberg E, Joseph L, et al Physician step prescription and monitoring to improve ARTERial health (SMARTER): a randomized controlled trial in type 2 diabetes and hypertension. *Diabetes, Obesity & Metabolism*. 2017;19(5): 695–704.
42. Musto AA. The effects of an incremental pedometer program on metabolic syndrome components in sedentary overweight women. *Dissertation Abstracts International*. 2008;69(3-B): 1598.
43. Sullivan AN, Lachman ME. Behavior change with fitness technology in sedentary adults: a review of the evidence for increasing physical activity. *Frontiers in Public Health*. 2017;4(289): 1.
44. Gardner B, Smith L, Lorencatto F, Hamer M, Biddle SJ. How to reduce sitting time? A review of behaviour change strategies used in sedentary behaviour reduction interventions among adults. *Health Psychology Review*. 2016; 10(1): 89–112.
45. Avery L, Flynn D, vanWersch A, Sniehotta FF, Trenell MI. Changing physical activity behavior in type 2 diabetes: a systematic review and meta-analysis of behavioral interventions. *Diabetes Care*. 2012;35(12): 2681–2689.
46. Cheng L, Sit JWH, Choi K, Chair S, Li X, He X. Effectiveness of interactive self-management interventions in individuals with poorly controlled type 2 diabetes: a meta-analysis of randomized controlled trials. *Worldviews on Evidence-Based Nursing*. 2017;14(1): 65–73.