

Novel Smartphone Game Improves Physical Activity Behavior in Type 2 Diabetes



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Introduction: Many type 2 diabetes patients show insufficient levels of physical activity and are often unmotivated to change physical activity behaviors. This study investigated whether a newly developed smartphone game delivering individualized exercise and physical activity promotion through an elaborate storyline can generate sustained improvements in daily physical activity (steps/day).

Study design: Thirty-six participants were enrolled in this 24-week RCT between August 2016 and April 2018. After baseline assessment, participants were randomized in equal numbers to the intervention or control condition. Data analysis was performed in May–June 2018.

Setting/participants: Inactive, overweight type 2 diabetes patients, aged 45–70 years, were recruited through advertising and from hospitals and diabetes care centers in the Basel, Switzerland, metropolitan area.

Intervention: Participants were instructed to play the innovative smartphone game (intervention group) or to implement the recommendations from the baseline lifestyle counseling (control group) autonomously during the 24-week intervention period.

Main outcome measures: Primary outcomes were changes in daily physical activity (steps/day); changes in aerobic capacity, measured as oxygen uptake at the first ventilatory threshold; and changes in glycemic control, measured as HbA1c.

Results: Daily physical activity increased by an average of 3,998 (SD=1,293) steps/day in the intervention group and by an average of 939 (SD=1,156) steps/day in the control group. The adjusted difference between the two groups was 3,128 steps/day (95% CI=2,313, 3,943, $p<0.001$). The increase in daily physical activity was accompanied by an improved aerobic capacity (adjusted difference of oxygen uptake at the first ventilatory threshold of 1.9 mL/(kg·min), 95% CI=0.9, 2.9, $p<0.001$). Glycemic control (HbA1c) did not change over the course of the intervention.

Conclusions: A novel, self-developed smartphone game, delivering multidimensional home-based exercise and physical activity promotion, significantly increases daily physical activity (steps/day) and aerobic capacity in inactive type 2 diabetes patients after 24 weeks. The ability of the game to elicit a sustained physical activity motivation may be relevant for other inactive target groups with chronic diseases.

Trial registration: This study is registered at www.clinicaltrials.gov NCT02657018.

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INTRODUCTION

In recent years, type 2 diabetes has developed into a global health burden that presents one of the great healthcare challenges of this time.¹ In 2014, more than 400 million adults worldwide had diabetes mellitus, predominantly of type 2,² representing a key determinant of morbidity and mortality in both developed and developing countries.¹

Regular physical activity (PA) with its well-documented health benefits is a cornerstone of successful diabetes management.³ Despite the apparent benefits of regular PA, only 25% of adults with type 2 diabetes meet PA recommendations and 40% are physically inactive, engaging in less than 10 minutes of moderate or vigorous activity per week during work, leisure time, or transportation.⁴ By contrast, physical inactivity not only increases the risk of type 2 diabetes by more than 100% but also significantly contributes to the development of several comorbidities⁴ and a 1.5-fold increased risk of all-cause mortality.⁵ Lack of motivation and lack of PA enjoyment, as well as aversion to exercise facilities, missing social support, and health concerns, such as hypoglycemia or fear of injury, are the main reasons that keep patients with type 2 diabetes from becoming more physically active or cause them to discontinue participation in a PA-promoting program.⁶ Motivating and enjoyable low-threshold forms of PA are therefore desperately needed to encourage this target group to sustainably become more physically active.

In recent years, PA-promoting games (exergames) have increasingly been used and examined to encourage regular PA in those who cannot be motivated through conventional PA-promoting interventions.⁷ By making PA an enjoyable and meaningful experience, this “gamified” approach aims to attenuate the negative perception of PA, as often is the case in inactive target groups, and thereby lowers the subjectively perceived cost of being physically active.⁷ Console-based exergaming has been shown to improve glycemic control, quality of life, and subjectively (questionnaire) assessed PA in type 2 diabetes⁸; however, evidence is very limited, and longer-term results of any gamified approach regarding objectively (accelerometer) measured increases in PA are missing.⁹ In addition, current exergames seldom offer exercise modes that concur in intensity and duration with established exercise guidelines and fail to provide a sufficient extent of individualization that is required for an effective and safe training in patients with chronic diseases who often have a significantly lower fitness level than healthy target groups.⁹ Further, for exergames, and more generally, for serious games with a behavioral intervention objective to be enjoyably effective, they need to

engage their intended audience in terms of narrative premise, gameplay, and storytelling.⁷ To address these design challenges, as well as the shortcomings of existing exergames, a mobile smartphone-based game application was developed that is specifically designed for type 2 diabetes patients with the goal to encourage a healthier, more active lifestyle through gamified daily PA.¹⁰

The aim of this RCT is to assess the effect of the game on daily PA (steps/day) in physically inactive individuals with type 2 diabetes. It is hypothesized that the use of the game application will lead to higher increases in steps/day after 24 weeks than a control intervention consisting of a one-time lifestyle counseling. Secondary aims are to assess the effect of the game on glycemic control, circulating cardiovascular risk factors, and aerobic capacity.

METHODS

This 24-week RCT (two-arm) was conducted in accordance with the Declaration of Helsinki¹¹ between August 2016 and April 2018 at the Department of Sport, Exercise and Health of the University of Basel, Switzerland. The study was registered at ClinicalTrials.gov (NCT02657018) and approved by the local ethics committee (Ethikkommission Nordwest-und Zentralschweiz, Reg.-No. EKNZ 2015-424). Permuted block randomization with randomly varying block sizes was used to allocate participants at random and in equal numbers to one of the two groups. All outcome assessors were blinded with respect to group allocation. The detailed study protocol can be found in a previous publication.¹⁰

Study Population

Participants were recruited in cooperation with several hospitals, doctor's offices, and diabetes care centers in the Basel, Switzerland, metropolitan area and through online and newspaper advertising. Participants were eligible to participate if they met the following inclusion criteria: (1) physician-diagnosed and medically treated non-insulin-dependent diabetes mellitus; (2) BMI ≥ 25 ; (3) aged 45–70 years; (4) <150 minutes of moderate-intensity PA per week; and (5) regular smartphone use during the year before the study to ensure that participants were familiar with the use of smartphones and would be able to play the PA-promoting smartphone game without additional assistance beyond the in-game tutorial. Exclusion criteria were health risks that contraindicate exercise testing,¹² impaired physical mobility, and acute infections or injuries. There was no racial or gender bias in the selection of participants. Eligible participants received detailed information about purpose and procedures of this study and gave written informed consent before participation.

Participants in the intervention group received a novel, self-developed smartphone game. The game includes individualized multidimensional (strength, endurance, balance, flexibility) exercise and daily PA (walking) promotion following established PA guidelines.¹³ A key component of the game's PA-related content is the integration of exercise tests such as the 1-min Sit-to-Stand Test¹⁴ and the Six-Minute Walk Test.¹⁵ These tests assess the fitness level of each individual user at baseline and

periodically during play and allow building tailored exercise regimens with appropriate entry levels and individualized rates of intensity progression. For the Sit-to-Stand Test, the phone is placed in the pants pocket and repetitions are counted via the phone's accelerometer and predefined threshold values for the seated and standing position. For the Six-Minute Walk Test (to be conducted outdoors), the distance is measured via GPS. Both measuring techniques have been validated before (unpublished data). Execution of in-game exercises (130 exercise variations) and daily PA are tracked via the phone's sensors (accelerometer/pedometer, camera, and audio sensor). Camera tracking can be used for certain strength exercises in which the phone is placed in front of the player and the repetitions of the exercise are auto-counted via movement recognition by the front-facing camera. Audio tracking requires the player to count the repetitions out loud. Key elements of the game's storyline are the restoration of a garden (used as a metaphor for one's own body) and the taming of the Schweinehund (in German, a self-deprecating idiom denoting one's weaker self, often referring to the lazy procrastination regarding PA), both of which can be achieved through regular in-game PA and the related in-game rewards. The game mechanics are anchored in the Coventry, Aberdeen, and London—Refined taxonomy of behavior change techniques,¹⁶ whereby the progression in the storyline is independent of the player's initial fitness level but depends rather on the regularity of game use and the meeting of personalized PA goals. The behavior change techniques incorporated into the game design among others are action planning/goal setting, instruction on how to perform the behavior, prompts/cues, graded tasks, and feedback/rewards, which have been found to be particularly effective in changing PA behavior in recent meta-analyses.^{17,18} By combining manageable challenges with appealing rewards, the game aims to increase the players' game- and PA-related self-efficacy and enjoyment—key factors for a long-term adherence.^{7,19} Because the game was designed to encourage regular use through the motivating character of the game design, and because the game is self-explanatory, an extensive in-game tutorial explaining all features and mechanics of the game is already provided. The participants in the intervention group only received very basic verbal instructions from the study personnel on how to use and control the game but not on how often or when to use it.

Participants in the control group received a one-time individual lifestyle counseling (60 minutes) by health professionals that included the promotion of baseline activities of daily life,²⁰ as well as a structured exercise plan including strength and endurance exercises with moderately increasing intensity and duration, essentially comparable with the content of the game, that was to be implemented autonomously.

Measures

At baseline and after the 24-week intervention, all participants underwent a clinical examination including medical history and a physical examination consisting of measurements of height, BMI, body fat content via bioelectrical impedance analysis, resting blood pressure, and resting electrocardiography. To verify that participants met the PA-related inclusion criteria, habitual PA was assessed at the first measurement appointment using the Freiburg Questionnaire of PA.²¹

During the clinical examination and after an overnight fast of ≥ 8 hours, blood samples were drawn by trained medical staff and transported to the laboratory of the University Hospital Basel, Switzerland, for further analysis. Analyzed parameters included HbA1c, total cholesterol, low- and high-density lipoprotein, and triglycerides.

Following the clinical examination, participants underwent a cardiorespiratory fitness test on a bicycle ergometer to assess the maximum oxygen uptake ($\dot{V}O_{2\text{peak}}$) and the first ventilatory threshold (VT1).²² After a 3-minute warm-up phase at 25 watts (W), workload increased linearly (ramp protocol) by 15 W/minute until participants' exhaustion. Respiratory gas parameters were analyzed breath by breath. Maximal exhaustion was accepted if at least two of the following four criteria were met: (1) respiratory exchange ratio ≥ 1.1 , (2) blood lactate concentration > 8 mmol/L, (3) rating of perceived exertion ≥ 18 , and (4) maximum heart rate (HRmax) $> 95\%$ of predicted HRmax [$208 - 0.7 \times \text{age (years)}$].²³

After the cardiorespiratory fitness test, participants received a Vivofit 2 accelerometer wristband with the instruction to wear it continuously during the following week for the assessment of the daily PA. The Garmin Vivofit has previously been shown to be valid for step detection under various walking conditions with constant as well as varying walking speeds.^{24,25} To eliminate any impact of a step count feedback on the participants' PA behavior, the devices' displays were irreversibly blackened out. In addition to the accelerometer wristbands, participants received a diary to record any non-wear time during the monitoring period. Only days with uninterrupted wear were considered for data analyses, and a minimum of 4 complete days was required. Day 0 (the day participants received the device) of the monitoring period was not considered for data analyses, as is common in the assessment of PA, because participants are known to change their activity pattern on the initial day of data recording.²⁶

Statistical Analysis

Analyses were performed in May–June 2018. Summary statistics were calculated to characterize the study sample and for pre- and post-intervention data as appropriate. Continuous data were summarized using the mean (SD) or the median (IQR). The primary outcome of daily PA (steps/day) after the intervention and further outcomes were analyzed by analysis of covariance.²⁷ Results are presented as differences in outcome (with 95% CI) between participants in the intervention group and those in the control group, adjusted for the corresponding values at baseline. Correlations between total in-game training (minutes) and outcome measures were analyzed using Spearman's rank correlation coefficient. R, version 3.4.0, was used for statistical analyses and graphics with the significance level set to 0.05 (two-sided).

It was hypothesized that the expected difference in daily PA (primary outcome) after 24 weeks between the two groups would be 2,500 steps/day with an SD in either group of 3,000 steps/day.²⁸ By including daily PA (steps/day) at baseline as a covariate in the analysis, it was further aimed to reduce error variability and therefore hypothesized that the correlation between baseline and outcome daily PA would be 0.7. With a significance level of 0.05 (two-sided), the sample size needed to attain a targeted power of 90% for showing superiority of the experimental intervention over control was determined as a total of 34 participants (17 in each group).

RESULTS

Sixty-eight participants were assessed for eligibility (Figure 1). Thirty-two subjects were excluded because they did not meet inclusion criteria ($n=19$) or declined to participate ($n=13$). All remaining participants ($n=36$) were randomly assigned to either the intervention group ($n=18$) or the control group ($n=18$). Baseline characteristics of study participants were balanced between both groups (Table 1). All participants received anti-diabetic drug treatment prior to enrollment in the study and did not change medication during the intervention period. One participant was lost to follow-up because of medical reasons not related to the study. Thirty-five participants completed the study and were included in the analysis of the primary outcome.

All participants wore the accelerometer wristband continuously for a minimum of 5 full days. Daily PA increased by an average of 3,998 (SD=1,293) steps/day in the intervention group and by an average of 939

(SD=1,156) steps/day in the control group during the 24-week intervention (Table 2). The adjusted difference of the increase in daily PA between both groups was 3,128 steps/day (95% CI=2,313, 3,943, $p<0.001$) in favor of the intervention group.

HbA1c remained unchanged at 6.2% (SD=0.7) in the intervention group and increased by 0.1 percentage points (SD=1.3) in the control group during the intervention period with an adjusted difference of -0.9 percentage points (95% CI= -1.5 , -0.2 , $p=0.016$) in favor of the intervention group. There were no apparent changes in total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol or triglycerides over the course of the intervention in either group.

Relative $\dot{V}O_{2peak}$ increased by 1.4 mL/(kg·min) (SD=2.0) in the intervention group and decreased by 0.3 mL/(kg·min) (SD=1.1) in the control group during the intervention period with an adjusted difference of 1.9

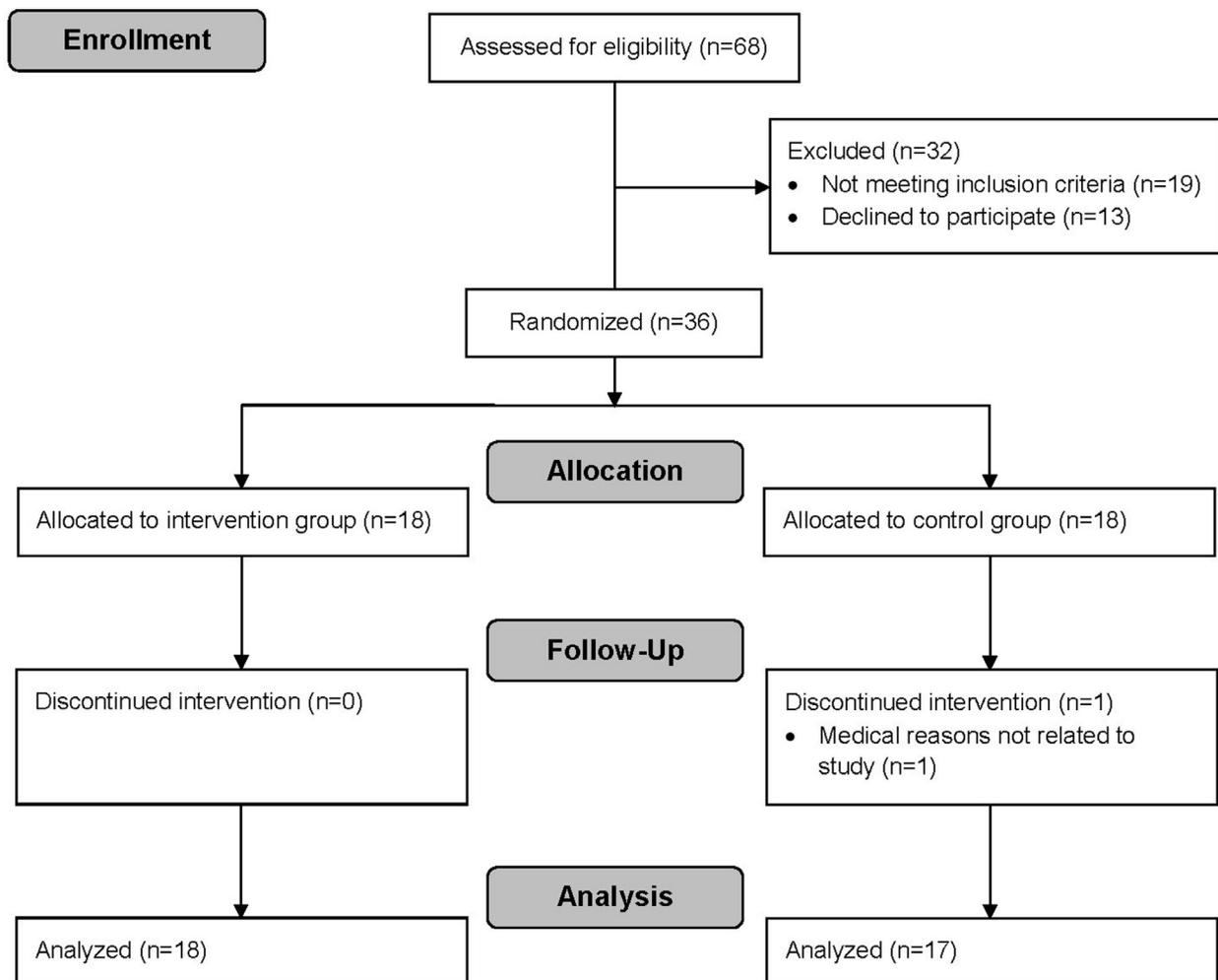


Figure 1. Flow diagram of study participants.

Table 1. Baseline Characteristics of Study Participants

Characteristics	Intervention (n=18)		Control (n=18)	
	n	Median (IQR)	n	Median (IQR)
Basic				
Sex				
Female	8		9	
Male	10		9	
Age, years	18	57 (53, 60)	18	60 (54, 63)
Height, m	18	172 (166, 177)	18	172 (165, 177)
Weight, kg	18	93 (89, 96)	18	98 (88, 111)
BMI	18	31 (29, 34)	18	33 (30, 36)
Fat mass, %	18	39 (35, 43)	18	35 (33, 43)
MVPA, minutes/week	18	45 (0, 60)	18	38 (0, 68)
Medical record				
Diabetes duration, years	18	3.3 (1.4, 4.3)	18	4.1 (1.5, 7.0)
Antidiabetic drug intake				
Metformin	18		18	
DPP-4-inhibitor	7		6	
Thiazolidinedione	—		1	
SGLT2 inhibitor	—		1	
GLP-1 receptor agonist	1		2	
Sulfonylurea	2		1	
Antihypertensive drug intake	12		11	
Lipid-lowering drug intake	4		7	

DPP-4, dipeptidyl peptidase 4; GLP-1, glucagon-like peptide 1; MVPA, moderate-to-vigorous physical activity; SGLT2, sodium-glucose cotransporter 2.

mL/(kg·min) (95% CI=0.7, 3.0, $p=0.002$) in favor of the intervention group. Absolute values did not change significantly in either group with an adjusted difference of 0.10 L/min (95% CI= -0.02, 0.23, $p=0.110$) between both groups. Relative and absolute $\dot{V}O_2$ at VT1 increased by 1.8 mL/(kg·min) (SD=1.2) and 0.13 L/min (SD=0.09) in the intervention group and decreased by 0.1 mL/(kg·min) (SD=1.4) and 0.03 L/min (SD=0.15) in the control group. The adjusted difference between the two groups was 1.9 mL/(kg·min) (95% CI=0.9, 2.9, $p<0.001$) and 0.14 L/min (95% CI=0.05, 0.23, $p=0.003$) in favor of the intervention group. Increases in workload at VT1 were observed for both groups post-intervention, with an adjusted difference between both groups of 10.8 W (95% CI=7.1, 14.5, $p<0.001$) in favor of the intervention group.

Total body fat mass decreased by 2.7 kg (SD=2.5) in the intervention group and by 0.9 kg (SD=3.4) in the control group. The adjusted difference between the two groups was -2.1 kg (95% CI= -4.2, 0.0, $p=0.045$) in favor of the intervention group. Skeletal muscle mass did not change significantly in either group during the intervention with an adjusted difference of 0.2 kg (95% CI= -1.0, 1.5, $p=0.710$). No apparent changes were observed for resting HR as well as for systolic or diastolic blood pressure at rest.

Strong positive correlations were found between total time of in-game training and change in daily PA (steps/day; $r=0.91$) as well as change in workload at VT1 ($r=0.66$), indicating that those who used the game as a training tool more, increased their daily PA and aerobic capacity more than those who used the game less (Figure 2).

DISCUSSION

In this RCT, the use of a novel, self-developed smartphone game that included individualized exercise and daily PA promotion led to a significantly higher increase in daily PA (3,000 steps) after 24 weeks than a control intervention consisting of a one-time lifestyle counseling. The magnitude of the shown increase in steps/day is comparable to that of a 24-week pedometer-based behavioral modification program including a face-to-face session and regular telephone follow-ups (2,800 steps),²⁸ providing strong evidence that a smartphone game that incorporates personalized PA recommendations and step count goals in the storyline can generate meaningful and sustained improvements in daily PA in a previously inactive target group. Increases of 2,000 steps/day in daily life over a 12-month period have been shown to be of clinical relevance in patients

Table 2. Effects of Game Use Compared to a One-Time Lifestyle Counseling on Daily Physical Activity, Aerobic Capacity, and Anthropometric, Metabolic, and Physiological Parameters

Outcome	Intervention (n=18)		Control (n=17)		Adjusted difference ^a (95% CI)	p-value
	Pre-intervention, M (SD)	Post-intervention, M (SD)	Pre-intervention, M (SD)	Post-intervention, M (SD)		
Steps per day	5,785 (793)	9,783 (1,334)	5,612 (1,192)	6,552 (1,280)	3,128 (2,313, 3,943)	< 0.001
Total body fat mass, kg	35.1 (8.7)	32.4 (9.1)	38.7 (10.6)	37.9 (9.8)	−2.1 (−4.2, 0.0)	0.045
Skeletal muscle mass, kg	32.1 (5.7)	32.7 (5.8)	34.1 (6.6)	34.5 (7.0)	0.2 (−1.0, 1.5)	0.710
HbA1c, %	6.2 (0.6)	6.2 (0.7)	6.9 (0.7)	7.0 (1.0)	−0.9 (−1.5, −0.2)	0.016
Total cholesterol, mmol/L	4.9 (0.9)	5.1 (0.8)	4.6 (1.0)	4.8 (0.9)	0.2 (−0.4, 0.7)	0.546
HDL cholesterol, mmol/L	1.2 (0.2)	1.2 (0.3)	1.3 (0.3)	1.3 (0.2)	0.0 (−0.1, 0.2)	0.463
LDL cholesterol, mmol/L	2.8 (0.9)	3.0 (0.9)	2.5 (0.9)	2.7 (0.8)	0.1 (−0.4, 0.6)	0.740
Triglycerides, mmol/L	2.0 (0.9)	1.9 (0.8)	1.9 (1.0)	1.8 (0.9)	0.0 (−0.4, 0.4)	0.951
HR at rest, bpm	66 (10)	64 (10)	68 (11)	69 (9)	−3 (−7, 1)	0.099
SBP at rest, mmHg	136 (14)	133 (15)	134 (12)	134 (14)	−3 (−9, 4)	0.384
DBP at rest, mmHg	88 (8)	85 (8)	86 (8)	87 (9)	−3 (−7, 1)	0.180
$\dot{V}O_{2peak}^b$, mL/(kg·min)	24.0 (4.3)	25.5 (3.5)	23.2 (4.1)	22.9 (4.0)	1.9 (0.7, 3.0)	0.002
$\dot{V}O_2$ at VT1 ^c , mL/(kg·min)	15.4 (2.5)	17.2 (2.6)	15.0 (1.7)	14.9 (2.2)	1.9 (0.9, 2.9)	< 0.001
Workload at VT1 ^c , W	82.2 (17.3)	95.6 (15.7)	84.8 (15.8)	87.1 (15.9)	10.8 (7.1, 14.5)	< 0.001

Note: Boldface indicates statistical significance ($p < 0.05$).

^aAnalysis of covariance comparing post-intervention values between the intervention group and the control group adjusted for the corresponding pre-intervention values.

^bPre- and post-intervention data available in 17/18 participants in the intervention group and in 13/17 participants in the control group.

^cPre- and post-intervention data available in 13/17 participants in the control group.

bpm, beats per minute; DBP, diastolic blood pressure; HDL, high-density lipoprotein; HR, heart rate; LDL, low-density lipoprotein; SBP, systolic blood pressure; $\dot{V}O_{2peak}$, peak oxygen uptake; $\dot{V}O_2$, oxygen uptake; VT1, first ventilatory threshold.

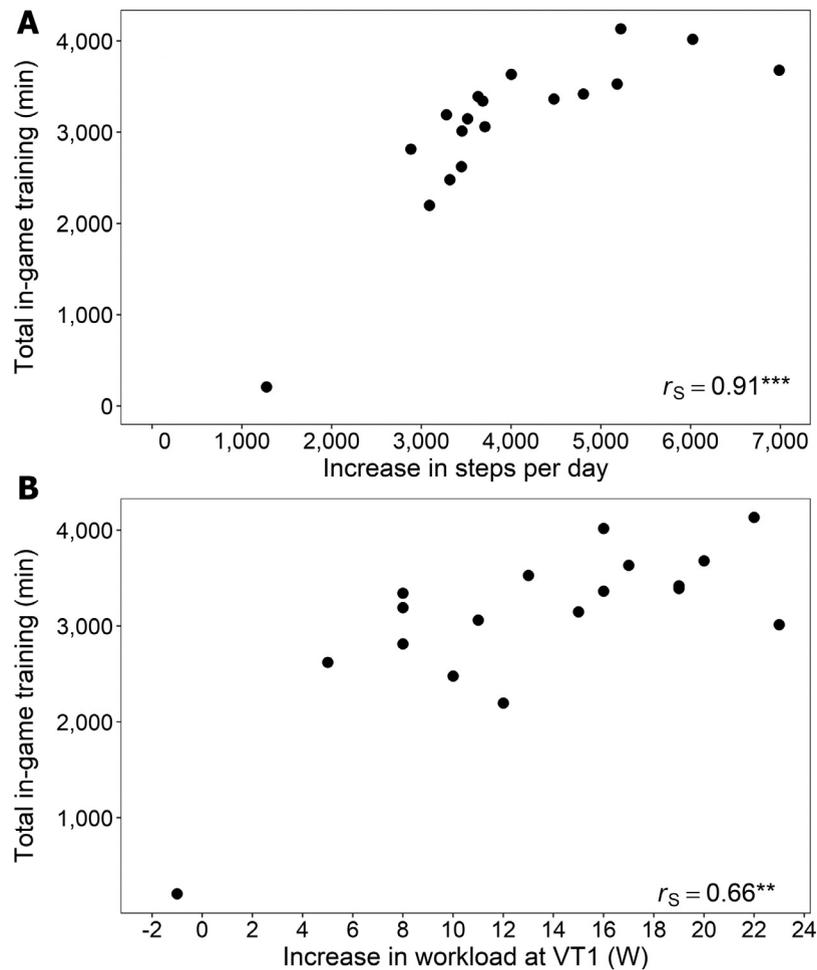


Figure 2. Correlation between total in-game training (minutes) and (A) increase in steps per day and (B) increase in workload at VT1 (W). $^{**}p < 0.01$ and $^{***}p < 0.001$ (Spearman's rank correlation coefficient).

with an impaired glucose tolerance as they are associated with an 8% lower cardiovascular event rate.²⁹ The strong positive correlation ($r = 0.91$) between the total time of in-game training and the increase in steps/day in the intervention group suggests that indeed the game played a decisive role in motivating participants to become and remain more physically active.

The increased amount of daily PA in this study was accompanied by an improvement in aerobic capacity. Relative $\dot{V}O_2$ (mL/[kg·min]) at VT1 increased by 11.7% and absolute $\dot{V}O_2$ (L/min) by 9.2%, indicating a de facto improvement in aerobic capacity. The increased $\dot{V}O_2$ enabled participants to generate an 18% higher workload (14.7 W) at VT1. A higher $\dot{V}O_2$ at VT1 has been shown to be inversely and independently associated with fatal cardiovascular and all-cause mortality events,³⁰ underlining the clinical relevance of the found improvements in aerobic capacity. Relative $\dot{V}O_{2peak}$ (mL/[kg·min]) increased as well (6.3%) but was not accompanied by significant increases in absolute $\dot{V}O_{2peak}$ (L/min). This is not

surprising, as the game was not designed to improve $\dot{V}O_{2peak}$, but rather to improve basic endurance through increases in daily PA. The slight change in relative $\dot{V}O_{2peak}$ was presumably influenced by the decrease in body weight caused by the reduction in total body fat mass of 2.7 kg (7.7%) during the intervention. The reduction in body fat in this study was modest when compared with the 15% reported for an intensive 12-week lifestyle intervention,³¹ consisting of dietary changes, exercise, and cognitive-behavioral modifications. It should further be acknowledged that the adjusted difference between both groups was only weakly significant and that multiple comparisons potentially inflated the Type I error probability. However, the reduction in body fat mass in the aforementioned study, and congruent with other large lifestyle interventions targeting weight loss,³² was accompanied by a loss in lean body mass of 2.3 kg (3.5%), whereas in this study skeletal muscle mass was preserved. Because type 2 diabetes is associated with a 3-fold increased risk of sarcopenia,³³ preservation of muscle

mass is crucial and should be the focus of any lifestyle intervention to prevent an accelerated functional decline and maintain independent functioning, a central component of health-related quality of life.³⁴ It is therefore advisable to design lifestyle interventions to target weight loss more moderately and incorporate sufficient amounts of regular PA to prevent possible diet and inactivity-related losses of skeletal muscle mass.

Despite the strong increase in daily PA and the associated improvement in aerobic capacity, no improvements in glycemic control were found. Although significant decreases in HbA1c of 0.5 percentage points following walking interventions of durations between 8 and 36 weeks have been found in a recent meta-analysis,³⁵ an inconclusive glycemic control benefit of step goal/pedometer use in type 2 diabetes, similar to the findings of this study, has also been reported before.³⁶ This recent meta-analysis found no association between step goal/pedometer-mediated increases in daily PA and improvements in glycemic control despite average increases in daily PA of 3,200 steps/day.³⁶ A recent RCT that promoted daily PA through pedometers and physician-prescribed step count goals did find reductions in HbA1c of 0.38 percentage points following a 1,200-steps/day increase in daily PA (60% lower increase than this study) after 1 year.³⁷ It is possible that the longer intervention duration of 1 year in that study played a role in eliciting the improvements in HbA1c and that the present study would have yielded similar improvements in a comparable time frame. This assumption is supported by the findings of a recent study³⁸ investigating the effects of a novel online game delivering diabetes self-management education content to patients with diabetes that showed the greatest impact on HbA1c in the 6 months after completing the intervention (12 months after baseline). It is thus conceivable that a similar time lag applies to the present study through which it may take more time than 24 weeks before the gradual adoption of health-improving PA behaviors induced by the game lead to glycemic improvements that are reflected in a lower HbA1c. It can further be conjectured that a higher exercise intensity, as may be the case in certain console-based exergames,³⁹ would have elicited (more detectable) improvements in glycemic control, comparable with the 0.3–percentage point reduction in HbA1c found after only 12 weeks of autonomous exergame use.⁸ However, because this may have then potentially affected the adherence to the game over 24 weeks and subsequently compromised the shown increases in PA, the game was deliberately designed to be mainly of low-intensity character to lower the threshold for regular use in an inactive, low-motivation target group and to support sustained changes in PA behavior. In addition, it is noteworthy that the participants of the studies included

in the aforementioned meta-analysis³⁵ and those of the exergame intervention⁸ had a markedly higher average HbA1c at baseline than did the participants in the intervention group of this study. Average HbA1c values of 6.9%–8.1%³⁵ and 7.1%⁸ leave more room to improve glycemic control through increases in daily PA than does a baseline value of 6.2% that indicates a medically already well-controlled HbA1c. The fact that HbA1c actually slightly increased in the control group despite unchanged medication, along with the significant adjusted difference of –0.9 percentage points in favor of the intervention group, further suggests that the PA promotion through the game is more effective than a one-time lifestyle counseling and at the very least contributes to a successful stabilization of a well-adjusted glycemic control.

This study has a number of strengths, including the novelty of the smartphone game–based intervention, the longer-term intervention of 24 weeks, and the objective 1-week assessment of daily PA. The individualized fitness level–adjusted training regimen and PA promotion were administered remotely via the game and without the need for physical contact between study personnel and participants. This may set a potential precedent for future PA-promoting interventions with the potential for a wide and easy dissemination even in geographically dispersed healthcare settings. As initial increases in daily steps have been shown to diminish during the subsequent weeks with a return to baseline values after 6 weeks in other PA-promoting game apps, such as Pokémon GO,⁴⁰ the fact that this study found significant increases in accelerometer-measured daily PA after 24 weeks is a major strength that suggests a longer-term sustainability of the game-induced increases in daily PA.

Limitations

A limitation of this study is that it remains uncertain which conceptual ideas and behavior change mechanics incorporated into the game have caused the increase in daily PA, and more general, whether it was the behavior change theme, the cell phone modality, or both that drove the increase in daily PA. This would be important knowledge for the design of future game applications and interventions targeting changes in PA behavior in unmotivated, inactive target groups. It remains to be determined if the general theme of taming the Schweinehund would work in other cultures/countries, particularly those that are sensitive to self-deprecating language. Further, future studies should incorporate a 1-year follow-up to assess how many study participants continue to play the game after the intervention period and to what extent they play the game. It will be insightful to see if the game is able to serve as a stepping stone

towards increased PA levels beyond the game particularly in those who cease to play after the intervention or if participants who quit playing the game after the intervention relapse into physical inactivity.

CONCLUSIONS

This RCT demonstrates that a novel, behavior change technique–based smartphone game delivering multidimensional home-based exercise and PA promotion significantly increases daily PA (steps/day) and aerobic capacity after 24 weeks and seems to contribute to the stabilization of a medication-supported diabetes treatment. The playful approach of the game seems to elicit a sustained PA motivation that would be beneficial to other inactive target populations with and without chronic diseases. Future studies with preferable larger sample sizes are needed to examine and confirm the effectiveness of the game in different target populations and help identify those populations that are most responsive to a PA-promoting smartphone game.

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