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A pedometer-based walking intervention supplemented with a counseling component: implementation into clinical practice

Summary of doctoral dissertation

by

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Abstract

Background: Insufficient physical activity is one of the leading modifiable risk factors responsible for numerous chronic diseases and for premature death. Walking can be considered as the most natural form of physical activity and can be easily incorporated into many activities of daily living. Interventions aimed at promoting walking could substantially contribute towards increasing physical activity levels of the most sedentary individuals; within these interventions, pedometers are commonly used as effective motivational instruments to increase walking in healthy adults and across a range clinical conditions. Additional counseling provided in regular intervals throughout the intervention period can positively influence patients' adherence and help patients overcome certain psychological or lifestyle barriers, ultimately increasing physical activity.

Objectives: The main objectives are: (1) To evaluate the feasibility of a pedometer-based walking intervention supplemented with a counseling component in a pilot randomized controlled trial. (2) To assess the preliminary efficacy of the intervention on PA levels and health-related outcomes, including measures of mental health and health-related quality of life. (3) To qualitatively explore the views of patients participating in the intervention. (4) To translate the new insight from the pilot study and qualitative research into clinical practice and develop a protocol for a large-scale randomized controlled trial.

Methods: In a pilot randomized controlled trial, physically inactive patients were recruited from four general practices and randomized to a 12-week pedometer-based intervention with or without email counseling. The speed and efficiency of recruitment, adherence to wearing the pedometer, and engagement with email counseling were assessed to explore the feasibility of the intervention. To evaluate the potential efficacy, daily step-count was the primary outcome and blood pressure, waist and hip circumference, and body mass were the secondary outcomes. In addition, a quasi-experimental single group study was conducted alongside the trial that compared pre- and post-intervention scores of participating patients on the Hospital Anxiety and Depression Scale (HADS) and MOS 36-Item Short-Form Health Survey (SF-

36) questionnaires. Furthermore, the content of email messages from participants was extracted, coded, and qualitatively analyzed using thematic analysis in order to explore patients' experiences during counseling. Finally, the results of the studies were used to develop a protocol of a definitive large-scale randomized controlled trial in chronic heart failure patients.

Results: Thirty-seven patients were recruited and 23 of them were randomized. Their baseline characteristics were similar between groups. Mean age was 41 years (± 10), body mass index was 32.8 kg.m^{-2} (± 7.3), and baseline daily step count was 5043 steps (± 1377). Patients manifested high adherence, wearing the pedometer on 83% (± 20) of days. All patients from the counseling group actively participated in email communication and responded to 46% (± 22) of the emails they received. Both groups significantly increased their daily step-count (pedometer-plus-email, + 2119, p = 0.002; pedometer-alone, + 1336, p = 0.03), but the difference between groups was not significant (p = 0.18). When analyzing both groups combined, there was a significant decrease in body mass (− 0.68 kg, p = 0.04), waist circumference (− 1.73 cm, p = 0.03), and systolic blood pressure (− 3.48 mmHg, p = 0.045). In addition, both the anxiety (−1.4, p = 0.011) and depression (−2.4, p = 0.001) subscales of HADS decreased, while the physical functioning (+6, p = 0.023), social functioning (+9, p = 0.035), mental health (+12, p = 0.001), vitality (+12, p = 0.003), and general health (+7, p = 0.013) subscales of SF-36 increased. Furthermore, the qualitative analysis of email messages showed that behavior change techniques like action planning, self-monitoring, goal setting, and barrier identification can be widely adopted by intervention participants.

Conclusion: The studies demonstrated that adding email counseling to a pedometer-based intervention is feasible and might have the potential to increase the efficacy of such an intervention in increasing physical activity levels. Building on the knowledge from the studies, a study protocol for a definitive full-scale randomized controlled trial was developed and published with the aim to translate the pedometer-based walking intervention into routine clinical practice.

Keywords: Pedometer, Email counseling, Walking, Physical activity

Summary

This summary gives a brief overview of my doctoral dissertation. The dissertation contains seven chapters. Chapter 1 (Introduction) establishes the key themes of the dissertation: health benefits of physical activity and walking as a cornerstone of interventions meant to increase physical activity levels in sedentary adults. Chapter 2 (Background) extensively summarizes the knowledge on health benefits of walking both from observational studies and randomized controlled trials with special focus on pedometer-based interventions and email counseling.

Chapters 3 to 5 of the dissertation comprise of three studies that were published individually in three different papers (at the time of writing the dissertation, one of them is still under review and has not yet been accepted). Thus, the Methods, Results, and Discussion sections for each study are presented separately in the form of the published paper. In addition, each of the three papers is briefly introduced to link the chapters together and indicate how the findings from each study build on each other.

Chapter 3 includes the paper "A pedometer-based walking intervention with and without email counseling in general practice: a pilot randomized controlled trial" (Vetrovsky et al. 2018), published in BMC Public Health (IF = 2.265). This paper demonstrated that adding email counseling to a pedometer-based intervention might yield additional benefits in terms of increasing PA levels. It also showed that patients recruited opportunistically during preventive visits to their general practitioners demonstrate excellent adherence to wearing the pedometer and high levels of engagement with email counseling.

In Chapter 4, the paper "Mental health and quality of life benefits of a pedometer-based walking intervention delivered in a primary care setting" (Vetrovsky et al. 2017a), published in Acta Gymnica, reports on the results of a pre-post study of the walking intervention. Despite the limitations of the quasi-experimental design, the study indicated that after a pedometer-based walking intervention delivered in a primary care setting, both mental health and health-related quality of life can be improved in a general, non-clinical population.

Chapter 5 includes the paper "A qualitative exploration of experiences of primary care patients engaged in email counseling to increase physical activity" that has been submitted to Patient Education and Counseling journal (IF = 2.429). By thematically analyzing the content of email messages written by patients participating in the counseling intervention, this paper has identified several behavior change techniques used by participants and determined the most common barriers encountered by patients in their efforts to increase the PA levels.

The results of the empirical research described in Chapters 3 to 5 were used to develop a protocol of a definitive large-scale randomized controlled trial in chronic heart failure patients. The protocol is presented in Chapter 6 in the form of the paper "Effect of a 6-month pedometer-based walking intervention on functional capacity in patients with chronic heart failure with reduced (HFrEF) and with preserved (HFpEF) ejection fraction: study protocol for two multicenter randomized controlled trials" (Vetrovsky et al. 2017b) published in the Journal of Translational Medicine (IF = 3.786).

Chapter 7 (Conclusion) summarizes the results of the individual papers. The "References" section list only the references that were cited in the Introduction and Background chapters. The references cited in the published papers have their own reference lists at the end of each paper and are not duplicated in this section.

Background

Physical activity (PA) and exercise have benefits for both healthy adults and patients with chronic diseases (Pedersen and Saltin 2006; Warburton et al. 2006; Kujala 2009; Woodcock et al. 2011; Reiner et al. 2013). Specifically, being physically active reduces the risk of all-cause mortality (Woodcock et al. 2011) and high levels of moderate intensity PA even seem to eliminate the increased risk of death associated with high sitting time (Ekelund et al. 2016).

With the increasing prevalence of sedentary lifestyles and the resulting deficit of PA, the incidence of diseases related to inactivity is growing, and interventions to increase PA are needed. Although many different modes of exercise ultimately increase PA levels, walking interventions could contribute substantially towards increasing the activity levels of even the most sedentary individuals, helping walking to become an important cornerstone in many PA promotion campaigns (Ogilvie et al. 2007).

Walking has been described as near perfect exercise: it is the most natural exercise and the only PA that is convenient to everyone except for the seriously disabled or very frail (Morris and Hardman 1997). Even walking at a moderate pace of 5 kph expends sufficient energy to meet the definition of moderate intensity PA. Compared with many sports and other recreational pursuits, walking is a popular, familiar, and convenient form of exercise that can be incorporated into everyday life and sustained into old age (Ogilvie et al. 2007). Walking is also deemed to be one of the most effective forms of PA, with little risk of injury among low-activity populations; it has been used successfully as an intervention to reduce the burden of a number of chronic diseases including hypertension, cardiovascular risk, obesity, and osteoarthritis (Lee et al. 2010; Tessier et al. 2010; Mansi et al. 2014).

Activity monitors (pedometers and more recently accelerometers) have been commonly employed to provide immediate patient feedback, remote control online and as a motivational instrument within intervention programs designed to increase activity and improve the quality of life, across a range of clinical conditions (Bravata et al. 2007; Richardson et al. 2008; Mansi et al. 2014). Interventions that have incorporated pedometers have yielded

both a significant increase in participants' levels of PA, and a significant decrease in their BMI, blood pressure and hepatic fat (Bravata et al. 2007; Richardson et al. 2008; Goodpaster et al. 2010). Focus groups revealed that pedometers are well accepted and are considered to be highly useful tools for goal-setting, feedback, and self-monitoring, capable of immediately increasing personal awareness of PA levels, and providing sources of readily available visual feedback (Tudor-Locke and Lutes 2009).

The pedometer-based interventions might be further improved by adding a counseling component. Additional counseling provided in regular intervals throughout the intervention period can positively influence patients' adherence and help patients overcome certain psychological or lifestyle barriers, ultimately increasing PA. Considering the various types of counseling that can be used to communicate with patients, email counseling may be more effective than traditional face-to-face and telephone counseling, as it gives both patients and counselors greater flexibility regarding when and where the interactions occur. Indeed, email counseling has been demonstrated to be effective in various health behavior interventions such as reducing fatigue in multiple sclerosis patients (van Kessel et al. 2016), achieving weight loss in overweight adults (Tate et al. 2006; Hageman et al. 2017), or improving diet in college students (Schweitzer et al. 2016).

However, there is only weak evidence on the use of email-based PA interventions. Limited number of small randomized controlled trials with only short follow-up time and mostly self-reported outcome measures is insufficient to reliably inform clinical practice. Furthermore, it is not clear, whether email counseling further increases the effect of a pedometer-based intervention when compared with pedometer alone. Thus, future research needs to use high-quality study designs to formulate clear recommendations regarding the most effective form and the content of pedometer-based PA interventions supplemented with a counseling component.

Objectives

The dissertation focuses on the development and assessment of a pedometer-based walking intervention supplemented with a counseling component and its implementation into clinical practice. The main objectives are:

(1) To evaluate the feasibility of a pedometer-based walking intervention supplemented with a counseling component in a pilot randomized controlled trial.

(2) To assess the preliminary efficacy of the intervention on PA levels and health-related outcomes, including measures of mental health and health-related quality of life.

(3) To qualitatively explore the views of patients participating in the intervention.

(4) To translate the new insight from the pilot study and qualitative research into clinical practice and develop a protocol for a large-scale randomized controlled trial.

Methods

As the dissertation contains three different studies, the methods of each study are described separately.

A pedometer-based walking intervention with and without email counseling in general practice: a pilot randomized controlled trial (Chapter 3)

Design and settings

A two-arm parallel pilot randomized controlled trial comparing a pedometer-based intervention with and without email counseling was conducted in four general practices across the Czech Republic. Outcomes were assessed at baseline and 12 weeks post-randomization.

Participants and enrollment

Patients were opportunistically recruited from four general practices that were selected to represent a large city, a middle-sized town, and a small town in the Czech Republic. The general practitioners approached patients during routine preventive health checkups. Patients were eligible if they met all of the following inclusion criteria: (1) registered at a selected general practice, (2) provided written informed consent before any assessment related to the study, (3) were over 18 years of age, (4) identified themselves as regular email users, and were willing to use email as part of the study, (5) had a home computer with access to the internet, (6) were physically inactive, as determined by a negative response to the following question: "As a rule, do you do at least half an hour of moderate or vigorous exercise (such as walking or a sport) on five or more days of the week?". This screening question has a high positive predictive value (86.7%) for identifying individuals who do not achieve the recommended 150 minutes of moderate level PA per week (Rose et al. 2008).

Patients were excluded if they: (1) had co-morbid conditions that would affect adherence to trial procedures (e.g. inflammatory arthritis, active malignancy, renal disease requiring dialysis, uncontrolled diabetes, major depression or other significant psychiatric disorders, dementia or cognitive impairment, significant hearing or visual impairment, or a terminal illness), (2) had a

medical, personal, or family condition which the GP considered to affect mean daily step count at baseline (e.g., acute illness, holiday or business trip), (3) were unable to walk for any reason, (4) were pregnant women, (5) were currently engaging in regular sports or exercise (at least twice a week), (6) were already tracking their steps with their own device, or (7) were achieving 8000 steps or more at the baseline assessment.

After signing the informed consent, participants received a pedometer blinded with adhesive tape, were instructed to wear it on their neck for 7 full days during waking hours except when swimming or bathing, and were told to not change their usual PA levels. After 7 days, participants were requested to remove the adhesive tape and upload the data to a website for viewing online.

Following the upload of pedometer data, mean daily step count from the 7 days was calculated for each participant, and those with a mean daily step count lower than 8000 were randomized to either a pedometer-alone (PED) or pedometer-plus-email (PEMAIL) group at a 1:1 ratio. Participants who failed to upload pedometer data and those whose mean daily step count was 8000 or more were excluded from the study.

Interventions

Once randomized, all participants were informed of their allocated group by an email. In this email, all participants were instructed to wear the pedometer around the neck daily for the next four months, check the step count every evening, and gradually increase the daily number of steps up to 10,000. They were also required to upload data to a website at least once a week and were encouraged to contact technical support if they experienced problems with uploading the data.

The eVito 3D Step Counter SL three-dimensional pedometer (HMM Diagnostics GmbH, Dossenheim, Germany) was chosen for the intervention as it features three-dimensional accelerometers to record the number of steps made per minute, memory to store data for more than 30 days, and ANT+ wireless technology to upload data to a website where data could be viewed online by the participants or a member of the research team.

PED group

Participants in the PED group were only contacted if they failed to upload the pedometer data for more than 2 weeks. In that case, they were sent a brief email reminder to do so. Apart from checking the pedometer every evening and trying to increase the daily step count up to 10,000 steps, they received no further instructions or specific goals.

PEMAIL group

Participants in the PEMAIL group received the same pedometer and instructions as those in the PED group. In addition, the participants were sent eight counseling emails during the intervention period. In the first counseling email, participants were set an individual progressive goal expressed as a weekly increase in the daily number of steps, determined as 15% of the subject's baseline value rounded to nearest hundred. The participants were asked to suggest their own strategies to achieve this goal by identifying opportunities in their daily routine when they could include at least a 10-minute walk (e.g., park farther away, walk to/from lunch, walk before/after work).

The subsequent emails were drafted individually, tailored to the specific needs of the participant and the circumstances of their case, and meant to elicit their response. Whenever a participant responded to an email, the subsequent email from the researcher was drafted as a response to the participant's email, thus giving the feeling of a natural email conversation. Although individual, the emails always incorporated some common features: (a) encouragement of the participants based on their objectively measured achievement in the previous week, (b) reminder of the benefits of PA for the physical and mental health relevant to the individual participant, (c) discussion of individual behavioral strategies, what works for them, and what does not, and (d) setting of the goal for the upcoming week.

Outcome measures

Feasibility of the recruitment procedure

To evaluate the feasibility of the recruitment procedure, the speed of recruitment (expressed as the number of patients per week of the active

recruitment period per general practice), and efficiency of the recruitment (expressed as the ratio of randomized to recruited patients) were assessed.

Patients' adherence and engagement

The percentage of valid days was calculated as a measure of patients' adherence to wearing the pedometer. For the purposes of this study, a valid day was defined as one with at least 8 hours with a step count above zero. The percentage of patients who completed the study was also evaluated and reasons of discontinuation were identified. Additionally, in the PEMAIL group, the percentage of patient email responses to the counselor's emails was calculated to express patient engagement.

Potential efficacy of the interventions

Though this was a pilot study that was not adequately powered to assess differences between groups, the potential efficacy of the interventions was evaluated for the purpose of the power analysis of a future trial. The primary efficacy outcome was a change in mean daily step count from baseline (T0) to 12 weeks post-randomization (T12). The secondary outcomes were the changes from T0 to T12 in systolic and diastolic blood pressure, waist and hip circumference, and body mass.

Data analysis

Primary and secondary efficacy outcomes were compared between the two groups using a two-sided two-sample t test or its non-parametric alternative, if necessary. Changes from baseline to post-intervention were evaluated by a one-sided paired t-test or its non-parametric alternative, if necessary. A p value of ≤0.05 was considered as statistically significant. Effect sizes (Cohen's d) were calculated for differences between the two groups and for changes from baseline to post-intervention. All statistical analyses were performed using the statistical package R (version 3.3.3).

Qualitative analysis

A qualitative analysis of structured interviews performed with the 4 participating general practitioners was conducted after the end of the trial but before they became aware of the study's results. The interviews were based on a topic guide focused on the feasibility of the trial and how to

improve it; specifically, it comprised topics such as screening and addressing the patients, the recruitment procedure, dealing with patients' refusal, the burden of the baseline assessment, thoughts regarding the follow up assessment, interference with their workflow, and the role of pedometers in promoting PA.

Mental health and quality of life benefits of a pedometer-based walking intervention delivered in a primary care setting: a quazi-experimental pre-post study (Chapter 4)

Before and after the previously described intervention, patients from both groups were asked to fill in two self-administered questionnaires to assess their mental health and health-related quality of life: the Hospital Anxiety and Depression Scale and the MOS 36-Item Short-Form Health Survey.

The Hospital Anxiety and Depression Scale (HADS) is a 14-item questionnaire consisting of depression and anxiety subscales. The items are graded on a four-point Likert scale from 0-3 with the total score for each subscale ranging from 0-21 (Zigmond & Snaith, 1983).

The MOS 36-Item Short-Form Health Survey (SF-36) is a validated measure of health-related quality of life that consists of 36 questions divided into eight individually analyzed dimensions: (1) limitations in physical activities because of health problems (physical functioning); (2) limitations in usual role activities because of physical health problems (role-physical); (3) limitations in social activities because of physical or emotional problems (social functioning); (4) bodily pain; (5) general mental health; (6) limitations in usual role activities because of emotional problems (role-emotional); (7) vitality (energy and fatigue); and (8) general health perceptions. Each dimension is scored on a 0-100 scale with higher scores representing better self-reported health (Ware & Sherbourne, 1992).

Data were tested for normality using Shapiro-Wilk test. As their distribution was not normal, the differences between pre- and post-intervention scores were analyzed using the nonparametric Wilcoxon signed rank test. A p value of ≤ .05 was considered as statistically significant and all tests were two-tailed. Furthermore, two-sided 95% confidence intervals were constructed to

describe the differences. All statistical analyses were performed using the statistical package R (version 3.3.3).

A qualitative exploration of the experiences of primary care patients engaged in email counseling meant to increase physical activity (Chapter 5)

The qualitative study was conducted alongside the previously described pilot randomized controlled trial. Altogether, the participants allocated to email counseling wrote 31 email messages, all of which were collected and analyzed. The content of the email messages was extracted and analyzed using thematic analysis. The content was coded using an inductive approach to identify themes naturally emerging from the data. The resulting themes were clustered in categories and subcategories.

Results

As in the previous Methods section, the results are described separately for each of the three studies.

A pedometer-based walking intervention with and without email counseling in general practice: a pilot randomized controlled trial (Chapter 3)

Feasibility of the recruitment procedure

The recruitment procedure, though feasible, appeared to be relatively slow and inefficient. A total of 79 eligible patients from four general practices were addressed to participate in the study. Of those 79, about every second patient refused to participate, resulting in 37 recruited patients. On average, 0.63 (± 0.36) patients were recruited per week of the active recruitment. Of the 37 recruited, 23 (62%) patients were randomized.

Patients' adherence and engagement

Once randomized, the patients manifested high adherence to the study protocol and the PEMAIL group also exhibited a high level of engagement with the email counseling. All randomized patients completed the study. and were included in the analysis.

Patients wore the pedometer on 83% (± 20) of the days during the 12-week intervention period. There was no significant difference between the groups in the number of valid days (i.e. days in which pedometer was worn for at least 8 hours). Technical issues were frequent during the study: 10 (43%) patients had their pedometer defunct for at least one day.

Patients in the PEMAIL group were sent, on average, 6.7 (± 1.3) counseling emails during the intervention period. All PEMAIL patients actively participated in email communication and, on average, they responded to 46% (± 22) of the emails they received.

Potential efficacy of the interventions

Though the pilot randomized controlled trial was not powered to demonstrate significant differences between the groups, it has suggested that adding email counseling to a pedometer-based intervention might potentially

increase the efficacy of such an intervention. Baseline characteristics of 23 randomized patients (11 females, 12 males) are summarized in Table 1.

Table 1: Baseline characteristics of study participants, mean (SD)

	PEMAIL (n = 10)	PED (n = 13)
Age (yr)	44 (10)	39 (9)
BMI (kg/m^2)	33 (7)	33 (8)
Females (%)	30	62
Systolic blood pressure (mmHg)	133 (9)	130 (18)
Diastolic blood pressure (mmHg)	89 (10)	83 (15)
Waist circumference (cm)	114 (17)	102 (17)
Hip circumference (cm)	116 (10)	115 (17)
Steps per day	5034 (1431)	5050 (1393)

There were no significant differences between the two groups, and the baseline characteristics of the non-randomized patients were not significantly different from those who were randomized. Interestingly, the mean body mass index of the randomized patients was 33, indicating that GPs preferentially recruited overweight and obese patients (only 3 out of 23 randomized patients had a body mass index below 25). This is also reflected in the high waist and hip circumferences of the randomized patients. Of note is the equal proportion of men and women, which is atypical for lifestyle interventions.

Both groups showed a significant increase in the average number of daily steps. The increase was greater in the PEMAIL group (2119 ± 1761 vs 1336 ± 2283, effect size 0.38), but the difference (783) was not significant. To detect this difference in a future trial, with a power of 80% using a 2-sided 0.05 significance level (alfa), 108 subjects in each arm would be needed. There were no differences between groups in any of the secondary outcomes.

When the two groups were analyzed as a whole, there was a significant improvement from T0 to T12 in daily step count, body mass, waist circumference, and systolic blood pressure. With the exception of change in

daily step count, the effect sizes of these improvements were small or very small (Table 2).

Table 2: Baseline (T0) and post-intervention (T12) values of both groups combined, mean (SD)

	T0	T12	Change	p value	Cohen's d
Steps per day	5043 (1377)	6719 (2359)	1676 (2066)	.0004	.87
Body mass (kg)	102.8 (21.7)	101.7 (21.6)	-0.7 (1.8)	.044	.05
Systolic blood pressure (mm Hg)	131.5 (14.3)	128.0 (12.4)	-3.5 (9.4)	.045	.26
Diastolic blood pressure (mm Hg)	85.5 (12.9)	83.7 (8.3)	-1.8 (9.7)	.193	.16
Waist circumference (cm)	107.2 (17.7)	105.4 (17.2)	-1.7 (4.0)	.029	.11
Hip circumference (cm)	115.4 (14.5)	114.8 (14.0)	-0.6 (5.0)	.292	.04

Lessons learned from the qualitative research

Several specific topics emerged from the interviews with general practitioners that can influence the design of future trials regarding the recruitment process, intervention, and outcomes.

Recruitment. All general practitioners agreed that the preventive visits (i.e. general checkups) are a good opportunity to recruit patients because they can spend more time explaining the study, and it is natural to discuss life style changes during these preventive visits. Even though they considered the recruitment procedure to be a simple one, they often deliberately avoided approaching suitable patients due to time pressure. Despite the broad eligibility criteria of the study, the general practitioners did a considerable amount of patient pre-selection. They typically addressed patients with obesity, diabetes, hypertension, and depression and anxiety, because they felt that these patients would be more prone to participate in the study.

Intervention. Technical issues related to pedometers, troubles with uploading step count data, and insufficient technical support were criticized by all general practitioners. They warned that these issues negatively influenced patients' adherence to the study protocol, but also threatened

their own reputations as patients tended to attribute these troubles to the general practitioner who recruited them to the study.

Outcomes. While general practitioners appreciated that the study protocol was relatively simple to follow, they suggested adding other secondary outcomes when designing a future trial; specifically, they mentioned serum lipid profile and blood sugar levels. On the other hand, the general practitioners questioned the relevance of assessing hip and waist circumferences, pointing out that such measurements are rather subjective, and that their changes are more relevant to diet than to PA.

Mental health and quality of life benefits of a pedometer-based walking intervention delivered in a primary care setting: a quazi-experimental pre-post study (Chapter 4)

All 23 patients filled out and returned the questionnaires both before and after the 3-month intervention, resulting in 100% of the patients being included in the analysis.

At baseline, both the anxiety and the depression scores were lower than 7, which is considered as a cut-off point for the presence of anxiety and depression. This is in line with the study eligibility criteria that excluded patients with a previous diagnosis of anxiety disorders or depression. Post-intervention, these scores further decreased as detailed in Table 3.

Table 3: Baseline and post-intervention values of the subscales of the Hospital Anxiety and Depression Scale (HADS), mean (SD)

	Baseline	Post-intervention	Change (95% CI)	p value
Anxiety subscale	6.6 (3.3)	5.2 (2.3)	-1.4 (-2.4 to -0.4)	.011
Depression subscale	5.3 (3.7)	2.8 (2.3)	-2.4 (-3.7 to -1.2)	.001

Accordingly, the mental health subscale of SF-36 improved, as did four other subscales of SF-36: vitality, social functioning, physical functioning, and general health, as listed in Table 4.

Table 4: Baseline and post-intervention values of the subscales of the MOS 36-Item Short-Form Health Survey (SF-36), mean (SD)

	Baseline	Post-intervention	Change (95% CI)	p value
Physical functioning	83 (15)	89 (10)	+6 (+1 to +11)	.023
Role-physical	78 (34)	77 (34)	-1 (-20 to +18)	.937
Bodily pain	86 (21)	81 (23)	-5 (-18 to +8)	.609
General health	59 (16)	66 (15)	+7 (+2 to +12)	.013
Vitality	51 (17)	63 (18)	+12 (+5 to +18)	.003
Social functioning	80 (19)	89 (17)	+9 (+1 to +17)	.035
Role-emotional	71 (37)	89 (27)	+17 (-2 to +36)	.120
Mental health	66 (17)	79 (12)	+12 (+6 to +19)	.001

A qualitative exploration of the experiences of primary care patients engaged in email counseling meant to increase physical activity (Chapter 5)

Twenty-two themes were identified and grouped into 3 categories that were further divided in to a total of 9 sub-categories (Table 5). In general, the intervention was well accepted by most participants: they enjoyed walking and appreciated the pedometer. Action planning, goal setting, self-monitoring, and barrier identification were the most popular BCTs implemented by the participants. Time constraints, weather conditions, and lack of motivation were the most common barriers that got in the way of increasing PA.

Table 5: Key categories and subcategories identified

Categories	Sub-categories
Reflections on pedometer-based intervention	Perceived benefits of physical activity Pedometer use
Use of behavior change techniques	Action planning Goal setting Self-monitoring Other behavior change techniques
Barriers to engagement in physical activity	Time constraints Weather Lack of motivation

Conclusion

In spite of the well-documented ability of pedometer-based walking interventions to increase PA levels, their effectiveness in primary care settings is far from optimal and there remains a need for their further improvement, possibly by adding a counseling component. Considering the various types of counseling that can be used to communicate with patients, email counseling may be an effective approach, as it gives both patients and counselors flexibility regarding when and where the interactions occur.

Indeed, the pilot randomized controlled trial (Chapter 3) demonstrated that adding email counseling to a pedometer-based intervention in a primary care setting is feasible and might have the potential to increase the efficacy of such an intervention. Specifically, it showed that patients achieve a high level of adherence to wearing the pedometer and manifest high engagement in email communication with the counselor. The study also provided important information for conducting future randomized controlled trials assessing the additional benefit of email counseling added to a pedometer-based intervention delivered in general practice.

In addition, the quasi-experimental pre-post study (Chapter 4) showed that a pedometer-based walking intervention in a primary care setting with a positive effect on PA levels has the potential to improve mental health and health-related quality of life in a general population. However, due to limitations of the quasi-experimental design of the study and the fact that recent large randomized controlled trials have failed to display similar findings, this conclusion should be viewed with caution and should be verified in future large randomized controlled trials with mental health and quality of life measures as the primary outcomes.

Furthermore, the qualitative analysis of the content of patients' emails written throughout the course of an email counseling intervention (Chapter 5) identified key behavior change techniques used by patients to increase their daily step count (e.g. action planning, self-monitoring, goal setting, and barrier identification) and revealed several novel aspects of these behavior change techniques that should be taken into consideration when designing an intervention (e.g. negative attitudes to goal setting, learning from own

data, self-monitoring as enjoyable activity). The study also identified common barriers encountered by intervention participants in their effort to increase their level of PA (i.e. time constraints, weather conditions, lack of motivation).

Building on this knowledge, a protocol was developed to create a large-scale randomized controlled trial (Chapter 6) with the purpose of translating the intervention into clinical practice as an integral part of the management of heart failure patients. The trial protocol has been registered in ClinicalTrials.gov (identifiers: NCT03041610, NCT03041376) and published in the Journal of Translational Medicine. The trial has received funding from Czech Health Research Council and is currently recruiting patients. If shown to be effective, dissemination of such an intervention in both primary and secondary care will help physicians better fulfill their role as promoters of healthy behavior: a role that is perceived as fundamental by both physicians and their patients.

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