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

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by

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I hereby declare that this dissertation is the result of my own work. I have indicated all used information and literature sources. This thesis has not been used for obtaining either another or the same academic title.

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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 ($- 0.68 \text{ kg}$, $p = 0.04$), waist circumference ($- 1.73 \text{ cm}$, $p = 0.03$), and systolic blood pressure ($- 3.48 \text{ mmHg}$, $p = 0.045$). 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

Foreword

Despite compelling evidence showcasing the health benefits of regular physical activity (PA), the majority of adults do not achieve the recommended levels of PA. To counteract the apparent lack of PA, researchers and doctors have begun to experiment with different types of interventions that aim to increase PA levels in a variety of populations. Of these different types of interventions, pedometer-based walking interventions have the potential to increase PA levels both in primary and secondary care settings.

This dissertation will focus on the development and assessment of a pedometer-based walking intervention and its implementation into clinical practice. The main objectives are:

- To evaluate the feasibility of a pedometer-based walking intervention supplemented with a counseling component in a pilot randomized controlled trial.
- 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.
- To qualitatively explore the views of patients participating in the intervention.
- 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.

Following the introduction (Chapter 1), theoretical background will be discussed in Chapter 2, reviewing the current knowledge about the health benefits of walking and interventions to increase walking with a special focus on pedometer-based walking interventions and email counseling.

As this dissertation comprises of three studies that were published individually in three different papers, the methods, results, and discussion for each study are presented together in the form of the published papers that make the basis of Chapters 3 to 5. In addition, each of the three papers in this dissertation 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", 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", 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" published in the Journal of Translational Medicine (IF = 3.786).

1. Introduction

Nearly 70 years ago, the health benefits of PA were explained by Morris and his group who found that physically active conductors of London's double-decker buses have lower incidence of coronary heart disease than their sedentary colleagues - the drivers. These findings were reproduced in physically active postmen compared with sedentary telephonists and other government workers (Morris et al. 1953). Almost 30 years later, in 1986, Paffenbarger and his team at Harvard University followed nearly 17 thousand Harvard alumni and found that their mortality rates were significantly lower among the physically active (Paffenbarger et al. 1986). Flash-forward another 30 years, and at present, there is conclusive evidence that shows the benefits of PA and exercise for preventing disease and treating 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 km/ hour expends sufficient energy to meet the definition of moderate intensity PA. Compared with many sports and other recreational pursuits, walking is a popular, familiar, convenient, and free 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).

In the next chapter, I will summarize the health benefits of walking both in primary prevention and in chronic diseases as demonstrated by numerous observational and experimental studies.

2. Background

Health benefits of walking

Walking has been shown to have a positive effect on most cardiovascular risk factors (e.g. hypertension, body mass, aerobic fitness) and it plays an important role in managing bodyweight and obesity. Furthermore, walking is beneficial for patients with numerous chronic diseases, e.g. diabetes, chronic heart failure, or chronic obstructive pulmonary disease. In addition, walking has benefits for mental health and health-related quality of life in both healthy and clinical populations.

Evidence from observational studies

In 2008, Hamer and Chida published a seminal paper reporting on meta-analysis quantifying an association between walking and risk of cardiovascular disease and all-cause mortality in healthy men and women. They included 18 prospective studies in the overall analysis, which incorporated 459,833 participants free from cardiovascular disease at baseline with 19,249 cases at follow-up. The volume of walking in the highest walking category averaged more than 5.2 hours per week (more than 17.2 km per week) and ranged from more than 1 hour per week to more than 2 hours per day (more than 9.7 km per week to more than 20 km per week). The pooled hazard ratio in the highest walking category compared with the lowest was 0.69 (95% CI 0.61 to 0.77, $p < 0.001$) for cardiovascular disease, and 0.68 (95% CI 0.59 to 0.78, $p < 0.001$) for all-cause mortality. Walking pace was a stronger independent predictor of overall risk compared with walking volume (48% versus 26% risk reductions, respectively) (Hamer and Chida 2008).

A year later, Boone-Heinonen et al. reviewed 21 observational studies examining walking in relation to cardiovascular disease. The majority of studies were prospective, but case-control designs were common as well. Generally, there were dose-dependent reductions in cardiovascular disease risk with higher walking duration, distance, energy expenditure, and pace. Associations appeared to be stronger for ischemic stroke than other

outcomes such as coronary heart disease or hemorrhagic stroke (Boone-Heinonen et al. 2009). For example, in Women's Health Study participants with no vigorous PA, the risk of coronary heart disease was reduced by 14%, 51%, and 52% in those reporting 1–59 minutes, 1–1.5 hours, and >2 hours/week of walking, respectively, compared to no regular walking (Lee et al. 2001). Similarly, among women in the Nurses Health Study, fully adjusted risk ratios for fatal and non-fatal coronary events were 0.78, 0.88, 0.70, and 0.65 for increasing walking MET-hour quintiles (Manson et al. 1999). Dose-dependent associations between walking pace and cardiovascular disease were particularly strong. In Women's Health Initiative Observational Study participants reporting walking paces of 2–3, 3–4, and >4 mph experienced a significant negative trend (14%, 24%, and 42% fully adjusted reductions, respectively) in cardiovascular disease incidence compared to those who rarely or never walk (Manson et al. 2002).

A smaller meta-analysis (Zheng et al. 2009) focused specifically on the dose-response relationship between walking and coronary heart disease risk reduction in the general population. It included a total of 11 prospective cohort studies and one randomized control trial with 295,177 participants free of coronary heart disease at baseline and 7,094 cases at follow-up. The meta-analysis indicated that an increment of approximately 30 min of normal walking a day for 5 days a week, which is consistent with PA recommendations, was associated with 19% coronary heart disease risk reduction (95% CI 14 to 23). It further showed that the risk for developing coronary heart disease decreases as walking dose increases (Zheng et al. 2009).

More recently, Kelly et al. published a meta-analysis of 18 cohorts from 14 prospective cohort studies with individuals healthy at baseline and reporting walking exposure and mortality as an outcome. The included studies contained 280,000 individuals and 2.6 million person years. The majority of results showed a reduced risk of all-cause mortality from walking, though only 5 from 18 (28%) were statistically significant. The results of the meta-analysis suggest that groups reporting an additional 11.25 MET.hours per week of walking (compared to groups reporting none or very little) reduce the risk of all-cause mortality by 11% after adjustment for other PA. The

analysis also showed that walking had the greatest effect on risk for all-cause mortality in the first (lowest) exposure interval and suggested a slowing of the rate of benefit after 8 MET.hours per week, equivalent to 120 minutes per week at an intensity of 4.0 METs (Kelly et al. 2014).

To summarize, there is conclusive evidence that higher amount and intensity of walking reduces the risk of all-cause mortality in dose-dependent manner with the greatest benefits in those who are the least physically active.

Interventions in cardiovascular prevention

In 2007 Murphy et al. performed a meta-analysis of 24 randomized controlled trials of walking interventions in order to quantify the walking-induced changes of six traditional cardiovascular risk factors: body weight, body mass index (BMI), percentage body fat, aerobic fitness (VO₂max) and resting systolic and diastolic blood pressure. The mean total volume of walking was 188.8 min per week (range 50–270 min per week). The mean length of the walking program was 34.9 weeks (SD 4.9, range 8–104 weeks) and the mean frequency of days on which walks were performed was 4.4 days per week (range 2–7 days per week). They concluded that walking interventions increased VO₂max and decreased bodyweight, BMI, percent body fat and resting diastolic blood pressure in previously sedentary adults ($p < 0.05$ for all) (Murphy et al. 2007).

Walking interventions often use pedometers as a motivational tool to increase walking. In 2007, Bravata et al. published a systematic review of studies that employed pedometers to increase number of steps per day. They included 26 studies (8 randomized controlled trials and 18 observational studies) with a total of 2767 participants. The participants' mean age was 49 years and 85% were women. The mean intervention duration was 18 weeks. Pedometer use was associated with significant increases in PA of about 2000 steps. When data from all studies were combined, pedometer users significantly decreased their systolic blood pressure by 3.8 mm Hg (95% CI 1.7 to 5.9 mm Hg, $p < 0.001$) (Bravata et al. 2007).

Lee et al. focused specifically on the evidence for the effectiveness of walking intervention on blood pressure. A total of 27 randomized controlled trials were included. The participants' blood pressure measurements at baseline

tended to be lower than the level of hypertension (140/90 mm Hg), although 14 studies aimed to recruit hypertensive participants. Nine of the 27 trials found an effect of walking intervention on blood pressure control. Of these studies the overall mean differences in blood pressure between the intervention and control groups, from the baseline to the end point of the follow-up, ranged from -5.2 to -11.0 mm Hg in systolic pressure and -3.8 to -7.7 mm Hg in diastolic blood pressure. Trial interventions which showed a beneficial effect on blood pressure tended to have larger sample size, higher baseline blood pressure level and employed moderate to high-intensity walking compared to those trials not showing a beneficial effect (Lee et al. 2010).

A recent meta-analysis of 32 randomized control trials that examined the effect of walking on risk factors for cardiovascular disease showed that walking increased aerobic capacity ($3.04 \text{ ml.kg}^{-1}.\text{min}^{-1}$, 95% CI 2.48 to 3.60) and reduced systolic (-3.58 mm Hg , 95% CI -5.19 to -1.97) and diastolic (-1.54 mm Hg , 95% CI -2.83 to -0.26) blood pressure, but failed to alter blood lipids (Murtagh et al. 2015).

Taken together, walking has positive benefits on most cardiovascular risk factors, especially on blood pressure and aerobic fitness and thus should play an important role in cardiovascular prevention programs. However, it is important to note that to achieve these benefits, walking needs to be of at least moderate intensity in order to improve aerobic fitness. Additionally, evidence has demonstrated that even greater fitness improvements can be attained from walking at vigorous intensity (Murtagh et al. 2015).

Walking and weight loss

Prevalence of adult obesity and overweight is increasing. In 2009, the prevalence of adult obesity and overweight in the Czech Republic was 23% and 34%, respectively, of adult population (Matoulek et al. 2010). Overweight and obesity are significantly associated with diabetes, high blood pressure, high cholesterol, asthma, arthritis, and poor health status (Mokdad et al. 2003).

Cross-sectional observational studies have shown that people who walk more tend to be thinner than those who walk less (Richardson et al. 2008). This

observation is supported by experimental studies. In the systematic review by Bravata et al., intervention participants significantly decreased their BMI by 0.38 from baseline ($p=0.03$). Interestingly, this decrease was associated with older age, and interventions of longer duration, but not with baseline steps per day, diet counseling, or BMI at the start of the intervention (Bravata et al. 2007).

Richardson et al. included 9 studies (4 randomized controlled trials and 5 prospective cohort studies) in their meta-analysis of pedometer-based walking studies without a dietary intervention that reported weight change as an outcome. Cohort sample size ranged from 15 to 106, for a total of 307 participants, 73% of whom were women. The pre-intervention mean weight of participants ranged from 79.4 to 98.8 kg. The duration of the intervention ranged from 4 weeks to 1 year, with a median duration of 16 weeks. The pooled estimate of mean weight change from baseline was -1.27 kg (95% CI -1.85 to -0.70 kg). Longer intervention duration was associated with greater weight change. On average, participants lost 0.05 kg per week during the interventions (Richardson et al. 2008).

In a meta-analysis by Murphy et al., eighteen studies with a mean baseline weight of 70.4 kg were included. The mean length of the walking program was 34.9 weeks (range 8–104 weeks) and the mean total volume of walking was 188.8 min per week (range 50–270 min per week). A weighted mean weight loss of -0.95 kg was observed after the walking programs. BMI at both pre- and post-intervention was reported in 16 studies with a weighted mean treatment effect of -0.28 kg/m². These decreases represent a relative reduction of 1.4% in body weight and 1.1% in BMI from baseline (Murphy et al. 2007).

A more recent meta-analysis assessed effect of walking on several anthropometric factors. It showed a statistically significant reduction in BMI of 0.53 kg/m² (95% CI -0.72 to -0.35), a significant reduction in waist circumference of 1.51 cm (95% CI -2.34 to -0.68), a small non-significant reduction in waist-to-hip ratio of 0.01 (95% CI -0.02 to 0.00), an overall reduction in body weight of 1.37 kg (95% CI -1.75 to -1.00), and an overall reduction in body fat of 1.22% (95% CI -1.70 to -0.73) in those participating in a walking intervention (Murtagh et al. 2015).

Qiu et al. explored effect of walking on weight reduction in type 2 diabetes in a meta-analysis including sixteen trials with 649 patients. It showed that walking was associated with a significant reduction in BMI by 0.91 kg/m² (95% CI 21.22 to 20.59 kg/ m²) (Qiu et al. 2014). Similarly, in a recent meta-analysis of 11 randomized controlled trials assessing effects of pedometer intervention on weight loss among adults with type 2 diabetes, pedometer intervention led to significantly decreased BMI (weighted mean difference 0.15 kg/m², 95% CI 0.29 to 0.02 kg/m²) and reduced weight (weighted mean difference 0.65 kg, 95% CI 1.12 to 0.17 kg). Dietary counseling seemed to be a key predictor of the observed changes. However, after completion of the pedometer intervention, only non-significant declines in BMI and weight were observed during the follow-up periods (Cai et al. 2016).

To conclude, walking is one of the few feasible exercise regimens in the treatment of overweight individuals because cardiovascular functional capacities are likely to be poor, and other exercise such as jogging and aerobics may be hazardous (Morris and Hardman 1997). For example, a 6-month continuous walking program with energy expenditure of 3970 kJ per week was useful for the improvement of body composition in senior women (Bunc et al. 2014). Thus, together with dietary energy restriction, walking should be considered a cornerstone in weight management (Reiner et al. 2013).

Effect on mental health

Anxiety disorders and depression are the most frequently diagnosed psychological diseases, severely impacting the lives of the persons affected (Demyttenaere et al. 2004; Moussavi et al. 2007). Regular PA protects against the development of anxiety disorders and depression, reduces their symptoms, and increases the quality of life among patients with diagnosed anxiety disorders or depression (Cooney et al. 2013). Meta-analysis by Robertson et al. including 8 randomized controlled trials showed that walking has a statistically significant, large effect on the symptoms of depression in some populations (effect size 0.86) (Robertson et al. 2012).

However, symptoms of anxiety and depression are common even among

people without clinically diagnosed anxiety disorders or depression. Fortunately, PA seems to positively impact mental health and quality of life in these general, non-clinical populations, as well. Meta-analyses quantifying the effect of PA interventions on depression and anxiety in non-clinical populations found that PA reduces anxiety by a small effect and depression by a medium effect (Conn 2010a; 2010b; Rebar et al. 2015). Similarly, a meta-analysis of 56 studies totaling 7937 participants varied in size from 9 to 264 participants and including patients from seven broad disease categories (e.g. cancer, cardiovascular diseases, neurological diseases) and well people found a small but significant effect of PA interventions on the psychological and physical domains of quality of life even in non-clinical populations (Gillison et al. 2009).

Recently, several large randomized controlled trials of pedometer-based walking interventions in primary care settings assessed anxiety and depression symptoms as secondary outcomes, but none of them showed significant effects on anxiety, depression, and health-related quality of life (Harris et al. 2017; Yates et al. 2017). Despite that, one group of authors indicated that during qualitative research conducted alongside the trial, most of their intervention participants verbally expressed that they were feeling better, sleeping better, had an improved mood, and had more energy and less pain (Normansell et al. 2014).

Walking and chronic conditions

Walking programs have been successfully implemented in the management of various chronic conditions, including chronic heart failure, chronic obstructive pulmonary disease, non-alcoholic fatty liver disease, diabetes, musculoskeletal disorders, peripheral artery disease, and depression, to improve health outcomes.

Chronic heart failure

Chronic heart failure (CHF) is a debilitating and progressive condition with increasing prevalence and burden on the health care systems of the developed countries. The prevalence of CHF is 2.2% in the American population (Mozaffarian et al. 2015) and 1-2% in the Czech Republic (Špínar

et al. 2012).

Exercise intolerance is the most frequent and bothersome symptom in patients with CHF, and is both a cause and result of the cycle of physical inactivity and subsequent deconditioning. The resulting reduction in functional capacity of the patients with CHF has detrimental effects on their activities of daily living, health-related quality of life, and ultimately their hospital admission rate and mortality (Hoodless et al. 1994; Walsh et al. 1997; Witham et al. 2006; Shoemaker et al. 2012).

Until only three decades ago, bed rest and the restriction of exercise were recommended for people with CHF. This concept, however, was challenged in 1980s (Conn et al. 1982; Musch et al. 1986; Kellermann 1987), and the first study on the effects of exercise in CHF reporting improvement of CHF symptoms and physical capacity with exercise training, without adverse events, was published in 1990 (Coats et al. 1990). Further research has demonstrated that PA is of benefit to all patients with CHF unless they are in NYHA class IV or have other limiting symptoms such as angina. Large meta-analyses show no evidence of adverse events from exercise training for CHF (Piepoli et al. 2004; Taylor et al. 2014).

The HF-ACTION trial, the largest randomized trial to date, compared 3-month exercise training program with usual care in 2331 heart failure patients. When analyzed per protocol, exercise training led only to a non-significant 7% reduction in all-cause mortality or hospitalization. Only after adjustment for pre-specified major prognostic factors, the composite primary endpoint was significantly reduced by 11% ($p=0.03$). Exercise training also conferred modest but statistically significant improvements in self-reported health status compared with usual care without training. As far as the adverse events related to exercise in CHF patients are concerned, HF-ACTION showed no difference to usual care during the entire study period (Flynn et al. 2009; O'Connor et al. 2009).

Anyway, intense, highly supervised, and structured interventions, such as the program used in the HF-ACTION trial, are not applicable to the wider population of patients with CHF in real-life and need to be supplemented with approaches to change sedentary lifestyle to a more active one. These involve

the promotion of common daily activities, such as climbing stairs (rather than taking the lift), doing more house work and gardening, engaging in active recreational pursuits, and brisk walking (Piepoli et al. 2010).

Heart failure with preserved ejection fraction (HFpEF) represents approx. 50% of heart failure cases and its morbidity and mortality is comparable to heart failure with reduced ejection fraction (Owan et al. 2006). Unlike heart failure with reduced ejection fraction, no pharmacological therapy has been shown to be effective in patients with HFpEF in large clinical trials (Holland et al. 2011). In a recent meta-analysis, only 6 randomized controlled trials of exercise training in HFPEF have been identified (Pandey et al. 2015). Kitzman et al. demonstrated that four months of endurance exercise training increases peak VO₂, 6-minute walk distance and quality of life (Kitzman et al. 2010; 2013). Similar results were achieved in a multicenter study of 64 patients with HFpEF randomized to three months of combined endurance and strength training (Edelmann et al. 2011).

Taken together, exercise training is an effective non-pharmacologic therapy that improves exercise tolerance and quality of life in patients with CHF (Pandey et al. 2015).

Chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of death in the world (World Health Organization 2000). In the Czech Republic, its prevalence in adult population is 8%; every year 16,000 patients are hospitalized because of COPD, and 2,500 of them die (Koblizek et al. 2013). The prevalence and burden of COPD is projected to further increase in the coming decades due to continued exposure to risk factors and the changing age structure of the population (Lopez et al. 2006).

It is well documented that individuals with COPD spend less time walking and standing compared to their healthy-aged matched counterparts (Pitta et al. 2005). Even compared with patients with other chronic diseases, such as rheumatoid arthritis or diabetes, significantly fewer patients with COPD attain recommended PA levels (Arne et al. 2009). This inactivity may contribute to a downward spiral of deconditioning, increased dyspnea, exacerbations, declining lung function, and mortality. Indeed, PA level is recognized as the

strongest predictor of mortality and hospitalization in patients with COPD, independent of lung function, and contributes to disease progression and poor outcomes (Waschki et al. 2011).

Conversely, regular PA is known to reduce rates of hospitalization and all-cause and respiratory mortality (Garcia-Aymerich et al. 2006). Thus, increasing PA is a desirable outcome, and the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guideline states that PA is recommended for all patients with COPD to improve their exercise capacity and decrease their dyspnea and fatigue (GOLD 2015).

Pulmonary rehabilitation is an essential component of COPD management with strong evidence supporting its efficacy (Lacasse et al. 2006), and multiple guidelines for COPD recommend pulmonary rehabilitation for all symptomatic patients, regardless of disease severity (Qaseem et al. 2011; GOLD 2015). Exercise training is considered to be the cornerstone of pulmonary rehabilitation and an official statement of American Thoracic Society/European Respiratory Society recommend that the exercise session include both endurance exercise training and resistance training (Spruit et al. 2013). Accordingly, the Czech guidelines recommend regular aerobic exercise for all symptomatic patients, regardless of pulmonary function (Koblizek et al. 2013).

In pulmonary rehabilitation, walking has the advantage of being a functional exercise that can readily translate to improvement in walking capacity, and - together with cycling - is the most commonly applied exercise modality of endurance exercise training (Spruit et al. 2013). Compared to cycling, ground-based walking was equally beneficial in improving both peak walking and cycling capacity but achieved a greater endurance shuttle walk time in COPD patients (Leung et al. 2010). A more recent study showed that ground-based walking training is an effective training modality that improves quality of life and endurance exercise capacity in people with COPD (Wootton et al. 2014). A meta-analysis of supervised endurance training in COPD patients suggested that walking training is adequate to improve functional exercise capacity evaluated by the six-minute walking test (Alison and McKeough 2014).

Based on the available evidence, there has been an increased awareness of the efficacy of leisure walking as a mode of exercise training in COPD in the official joint statement of American Thoracic Society/European Respiratory Society (Spruit et al. 2013).

Non-alcoholic fatty liver disease

Non-alcoholic fatty liver disease (NAFLD) is a leading cause of chronic liver disease and has been associated with an increased risk of diabetes and ischemic heart disease (Anstee et al. 2013). It is an important public health issue: based on a variety of assessment methods, its worldwide prevalence ranges from 6.3% to 33% with a median of 20% in the general population (Vernon et al. 2011). At present, pharmacotherapy options are limited and lifestyle interventions are the cornerstone of NAFLD management. Numerous studies have demonstrated the beneficial effects of weight loss in the management of NAFLD (Musso et al. 2012; Vilar-Gomez et al. 2015) and current practice guidelines from the American Association for the Study of Liver Diseases (AASLD) recommend loss of 3–5% of body weight to improve hepatic steatosis (Chalasani et al. 2012).

Physical activity and exercise training are integral components of lifestyle interventions aimed at weight loss, but it has been suggested that PA can improve hepatic steatosis due to independent benefits even without weight loss (Rodriguez et al. 2012; Hannah and Harrison 2016). A systematic review and meta-analysis assessing the effects of exercise in patients with NAFLD has shown that exercise is effective in improving liver fat (effect size=0.37; $p<0.020$) despite a minimal or absent weight loss in studies employing exercise alone versus control, i.e. without concurrent diet intervention in both groups. Unfortunately, the mechanism for the direct hepatic benefit of exercise training remains unclear (Keating et al. 2012).

Despite compelling evidence of benefits of PA interventions in NAFLD, its clinical utility is limited for several reasons. The first issue is compliance. Patients with NAFLD demonstrate low confidence to perform PA (Frith et al. 2010) and not all of them are able or willing to perform structured high intensity exercise. Indeed, the dropout rate is high in the published trials regarding PA in NAFLD. For example, 25% of the patients enrolled in one

study were unable to complete the prescribed exercise program (Sreenivasa Baba et al. 2006). Secondly, incorporating an exercise prescription into already rushed office visits can be difficult and most supervised PA interventions require significant financial and professional resources that limit their applicability to the wider population of NAFLD patients (Rodriguez et al. 2012).

In conclusion, while there is clear evidence that exercise improves hepatic steatosis and underlying metabolic abnormalities in NAFLD, the role of walking in NAFLD management is less clear and more studies are needed to define the most beneficial form and duration of exercise treatment.

Musculoskeletal disorders

Walking can be recommended as an effective form of exercise or PA to reduce pain and improve function in individuals with chronic musculoskeletal pain and osteoarthritis. Roddy et al. reviewed 13 randomized controlled trials of subjects with knee osteoarthritis comparing aerobic walking or home based quadriceps strengthening exercise with a non-exercise control group. The mean age of study participants ranged from 61.9 to 73.7 years. The meta-analysis showed that both aerobic walking and home based quadriceps strengthening exercises are effective at reducing pain and disability in subjects with knee osteoarthritis. No advantage of one form of exercise over the other was found on indirect comparison of pooled data (Roddy 2005).

A review by Hendrick et al. explored the effectiveness of walking in managing acute and chronic low back pain. Four studies met inclusion criteria: two randomized controlled trials, one case-control and one cohort study. Of those, three laboratory-based studies used a treadmill and one study evaluated walking in free living. Three lower ranked studies reported a reduction in low back pain from a walking intervention, while the highest ranked study observed no effect. Authors concluded that there is only low-moderate evidence for walking as an effective intervention strategy for low back pain (Hendrick et al. 2010). Unfortunately, authors did not attempt to analyze whether the effect of walking on low back pain was moderated by weight loss.

Mansi et al. examined the effects of a pedometer-based walking intervention

to increase PA levels and improve physical function and pain in patients with musculoskeletal disorders. Seven randomized controlled trials with 484 patients were included and showed significant increases in step count (mean increase of 1950 steps per day) following the intervention. Four studies reported improved scores for pain and/or physical function at the intervention completion point relative to controls (Mansi et al. 2014).

A recent systematic review of 26 randomized and quasi-randomized controlled trials in adults with chronic low back pain, osteoarthritis or fibromyalgia compared walking interventions to a non-exercise or non-walking exercise control group. Interventions were associated with small to moderate improvements in pain at short and medium-term follow-up and in function at short to long-term follow-up (O'Connor et al. 2015).

Based on available evidence, it can be concluded that increased walking results in significant improvements in disability, functional limitation, and pain scores. However, further research is required to support the role of walking interventions as a long-term intervention for management of musculoskeletal disease (Mansi et al. 2014).

Interventions to increase walking

Interventions to promote walking could contribute substantially towards increasing the activity levels of the most sedentary and has become an important cornerstone in many PA promotion campaigns (Ogilvie et al. 2007). Walking programs have been successfully implemented in the primary prevention and in the management of various chronic conditions, including diabetes, chronic obstructive pulmonary disease, musculoskeletal disorders, peripheral artery disease, and depression, to improve health outcomes (Lee et al. 2010; Tessier et al. 2010; Mansi et al. 2014).

Interventions in primary care

As 70-80% of adults in developed countries visit their general practitioner at least once a year (van Doorslaer et al. 2006), general practitioners are well situated to deliver PA interventions to physically inactive adults (Gusi et al. 2008; Orrow et al. 2012). Moreover, most general practitioners believe that PA counseling is important and that they play a role in promoting PA among

their patients (Hébert et al. 2012). In addition, general practitioners are generally viewed as being credible sources of health information, particularly among older adults and those with multiple chronic diseases (Schofield et al. 2005).

A body of literature suggests that a well-designed PA intervention delivered in primary care can increase PA levels, as has been shown in the large PACE-UP trial where a pedometer plus three individually-tailored practice nurse consultations were more effective at increasing PA levels in 1023 physically inactive 45- to 75-year-olds at 3 months than pedometer alone distributed by post mail. Interestingly, 12 months after the start of the trial, the difference between both intervention groups disappeared, though they were both still significantly better in daily step-count and time spent doing moderate-to-vigorous PA than a control group that received usual care (Harris et al. 2017). In addition, many smaller trials have suggested that PA interventions in a primary care setting have potential to increase habitual PA of patients (Glynn et al. 2014; van der Weegen et al. 2015; Gao et al. 2016; Pears et al. 2016; Richards and Cai 2016; James et al. 2017) and a meta-analysis found that promoting PA to sedentary adults in primary care can significantly increase PA levels (Orrow et al. 2012).

On the other hand, several large recent trials, while confirming the positive effect of PA interventions, clearly showed that the effectiveness of these interventions in a primary care setting is far from optimal (Harris et al. 2015), especially in the long term (Harris et al. 2017; Yates et al. 2017), due to both patient- and provider-related factors. Though patients perceive PA interventions delivered in primary care as motivating, their efforts to increase PA levels are often hindered by substantial barriers such as inflexible work routines, long working hours, domestic duties, suboptimal weather conditions, a lack of motivation, and other commitments (Patel et al. 2013; Morrison et al. 2014; Normansell et al. 2014). General practitioners consider walking interventions to be helpful for increasing PA levels of their patients, but they often lack the time and appropriate training necessary to deliver them (Hébert et al. 2012; Patel et al. 2014).

Regardless of these barriers, primary care remains a favorable setting for PA interventions (Hébert et al. 2012; Orrow et al. 2012; National Institute for

Health and Care Excellence 2013) with potential to reach those who can benefit most from the increased PA levels.

Use of activity monitors

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).

An important factor to take into consideration is the activity monitor outcome. Typically, total energy expenditure, different levels of PA intensity, and step count are the three most frequently available outcomes. While energy expenditure seems to be the most appropriate outcome, it is not necessarily the most suitable outcome for the PA intervention studies, because total energy expenditure is to a large extent driven by patients' characteristics (like body weight, age, height) and only 19% of the total energy expenditure is accounted for by PA (Plasqui et al. 2005; van Remoortel et al. 2012). On the other hand, step counting is one of the most commonly used measures of PA and is often used in interventions because steps are a more intuitive and clear measure for the layperson, making it easier for participants to interpret (Tudor-Locke and Lutes 2009).

Currently, there is a wide range of commercially available PA monitors that use accelerometer type mechanisms, produced by various manufacturers. A number of smartphones also have tri-axial accelerometers with specifications similar to accelerometer-based PA monitors and smartphones have been examined as a potentially cost-efficient and low-burden tool for monitoring

PA (Nolan et al. 2014; Hekler et al. 2015). However, the validity of newly introduced monitors, including smartphones, needs to be carefully examined (Welk et al. 2012) as they may be potentially inaccurate. Despite it, their ease of use and widespread availability make them suitable for use in PA interventions.

Interventions in cardiovascular diseases

A body of evidence has shown the potential for utilizing activity monitors to help cardiac patients increase their daily PA levels (Butler et al. 2009; Furber et al. 2010; Houle et al. 2012). However, with one exception (Houle et al. 2012), all studies were short-term studies with the intervention length ranging from 3 to 8 weeks. Most of the studies included small number of patients (between 18 and 65) with only two studies (Butler et al. 2009; Furber et al. 2010) recruiting higher numbers (110, and 215, respectively) of patients.

Ayabe et al. found that patients who had attended a maintenance cardiac rehabilitation program for >6 months could increase PA through the use of self-monitoring with a pedometer over a 3-week time period (Ayabe et al. 2010). Similarly, Butler et al. found cardiac patients obtained greater increases in PA after completion of a cardiac rehabilitation program through the use of pedometer feedback over a 6-week time period in conjunction with goal-setting and telephone follow-up (Butler et al. 2009).

In an 8-week pilot randomized controlled study of 18 subjects entering a maintenance cardiac rehabilitation program, Kaminsky et al. found that providing pedometers with individualized step count goals is superior to the usual time-based recommendations for increasing PA (Kaminsky et al. 2013). A randomized controlled trial of 65 patients has shown that use of a pedometer concomitantly with a socio-cognitive intervention improves adherence to PA and quality of life during the year after an acute coronary syndrome event (Houle et al. 2012).

In a prospective randomized 8-week study of 29 stable noncompliant cardiac patients, including heart failure patients, Guiraud et al. found that telephone support based on accelerometer recordings appeared to be an effective strategy to improve adherence to PA in noncompliant patients (Guiraud et al.

2012). Furber et al. conducted a 6-week randomized controlled trial among 215 cardiac patients not attending cardiac rehabilitation and found that pedometer-based telephone intervention was successful in increasing PA levels (Furber et al. 2010).

To conclude, walking interventions based on pedometers or accelerometers have potential to increase PA levels in patients with cardiovascular diseases. However, larger studies with longer follow-up are needed to confirm their positive effect on disease progression. In addition, the minimum effective intensity and volume of walking needs be established in future trials.

Email counseling

Non-face-to-face PA intervention delivery modalities have the potential to offer a cost-effective means of providing the repeated contacts necessary to promote behavior change (Goode et al. 2012). Indeed, telephone delivery as one of the most accessible of these approaches has been recognized as an effective tool for PA and dietary behavior change (Eakin et al. 2007; Goode et al. 2012).

Compared with telephone support, email support may provide greater flexibility for the patients, as it does not rely on fixed availability and appointments, and offers potential for effective personalized feedback. Both human email counseling and fully automated algorithm-driven email-based systems were found to be effective for weight loss (Levine et al. 2015), improved glycemic control in pre-diabetic participants (Block et al. 2015), or reducing cardiovascular risk factors among hypertensive adults (Cicolini et al. 2014). However, when directly compared with telephone counseling, email counseling led to significantly lower weight loss in a 6-month randomized trial in obese patients (Digenio et al. 2009).

One of the earliest studies evaluating the effectiveness of email intervention on exercise behavior in 2002 assigned 525 employees of a large private university to either one of two intervention groups or a control group. In both intervention groups, participants received an initial email followed by 5 weekly emails with either stage-based content or action-message content. The stage-based emails were tailored to a stage of readiness to change as described by Transtheoretical Model of behavior change (Prochaska and

DiClemente 1983). The action-message emails were not tailored and simulated strategy of "one-size-fits-all". The control group received 5 weekly emails encouraging proper nutrition. After 6-week intervention, the action-message group demonstrated significant increases in leisure time activity, occupational activity, and daily energy expenditure estimated from a 7-day recall. The stage-based message group demonstrated significant increases in leisure time activity only. All three groups demonstrated small but significant improvements in stage of readiness to change. The data showed no significant differences among groups and authors concluded that the results might suggest that traditional hard-copy written information is more influential about positive health behavior changes than similar materials presented in an online format (Hager et al. 2002).

A year later, Marshall et al. compared the effects of an 8-week stage-targeted PA program delivered via an email to those of a previously successful print intervention in 655 members of the staff of an Australian university. The participants from the email group were sent four personalized and stage-based emails, at 2-week intervals, that contained PA related information similar in content to the print letters but included hyperlinks to a website. There was no significant increase in total self-reported PA within or between groups when analyzed by intention to treat. The authors explained the lack of intervention effects by the lack of engagement with program materials. In fact, less than half of the participants who were prompted by the emails to enter the website actually did so. Furthermore, only 26% of the email group participants logged onto the website more than once (Marshall et al. 2003).

Simultaneously, Napolitano et al. published results of a study designed to test the efficacy of a theory-based email intervention that consisted of 12 weekly non-tailored emails with tips approximately six sentences in length and a link to a website where, after completing a quiz, participants were guided to an appropriate stage-of-change section. Sixty-five sedentary adult employees of several large hospitals, who at baseline spent weekly 74 minutes walking, were randomly assigned to the intervention or a waiting list control group. At the 1-month assessment, the intervention group exhibited significant increases, relative to the control group in the number of minutes of moderate activity; however, at the 3-month assessment this difference was no longer

significant. In secondary analyses, the intervention group exhibited significant increases, relative to the control group, in walking minutes, both at the 1-month and 3-month assessments. So, for the very first time, these findings showed that a theoretically based email intervention can have at least a short-term impact on PA behavior (Napolitano et al. 2003).

The contrast between the engagement of Marshall's participants demonstrating limited interest in accessing and using the website and Napolitano's participants showing much higher levels of initial engagement and website use might be explained by different recruitment procedures. While Marshall recruited participants in a way that minimized a self-selection bias (655 study participants were not different to the original contact sample of 1409 university staff in terms of demographics or baseline PA levels), the Napolitano's participants had joined the program by responding on their own initiative to recruitment advertising (Marshall et al. 2003; Napolitano et al. 2003).

Another study compared two 12-week email-based walking programs to examine the extent to which theoretical fidelity in replicating theory-based recommendations, influenced the effectiveness of a program based on Social Cognitive Theory (Bandura 1986). All participants met individually with the project coordinator for approximately 30 minutes and were instructed to walk three times per week for approximately 30 minutes each time. Each week, participants in both groups were sent an email tip of the week (which included half to one page of information on topics such as enlisting social support, creating environmental cues for walking, planning walking, and preventing muscle sprains and relapse) and were instructed to email the project coordinator a walking log. Within 6 hours after walking logs were due, participants received a tailored emailed feedback note. Fifty out of 61 participating women completed the study. Both groups improved significantly on 1-mile walk test time with the high-fidelity group improvement more than twice as high as the low fidelity group (86 vs. 32 seconds, $p < 0.05$) (Rovniak et al. 2005). While the primary purpose of the study was to examine the influence of theoretical fidelity on the quality of PA intervention and not the impact of an email intervention per se, it contributed to the field of email interventions in several ways: (1) it used a test of physical fitness as an

outcome instead of the unreliable self-reported PA, and (2) it was the first study that involved prompted self-monitoring and true human email counseling and not just educational emails.

Kosma et al. conducted a short 4-week study of a leisure-time PA motivational program based on the Transtheoretical Model and tailored to 75 inactive adults with physical disabilities (amputation, cerebral palsy, multiple sclerosis, muscular dystrophy, spinal cord injury). The intervention group was sent 4 emails with a link to a web-based PA motivational program with a different lesson plan for each week. The control group received a 'thought of the week' and encouraging messages through email to maintain their attention and interest in the study. The results showed no statistically significant differences in leisure-time PA scores between the treatment and control groups at post-test (Kosma et al. 2005).

A study published in 2007 by Dinger et al. used email-delivered, pedometer-based interventions designed to increase walking to assess the effectiveness of strategies based on Transtheoretical Model. 74 women were randomly assigned to one of two 6-week intervention groups. Both groups wore pedometers, submitted step logs, and received weekly email reminders to wear the pedometer and return that week's log in a self-addressed stamped envelope provided. In one group, these weekly emails reminders also contained suggested strategies based on Transtheoretical Model for increasing PA. The changes in walking measured by the International PA Questionnaire did not differ between groups but participants in both groups combined increased weekly time spent walking ($p=0.002$) from baseline to post-intervention (Dinger et al. 2007). Similarly to Rovniak et al., this study did not examine the effectiveness of email intervention per se. However, it was the first study to combine email intervention with pedometers and its results indicated that that this low-cost method of intervening may be an effective approach to combat physical inactivity (Dinger et al. 2007).

In a 3-arm randomized controlled trial in 170 sedentary college students, Parrott et al. compared positively ("engage in activity") and negatively ("discontinue sedentary behavior") framed email messages based on Theory of Planned Behavior (Ajzen 1985) received every other day for 2 weeks with a control group receiving no emails. While both types of messages affected

exercise attitude and intention, only positively framed persuasive email messages improved exercise behavior as measured by the Godin Leisure Time Exercise Questionnaire (Parrott et al. 2008).

Dunton et al. evaluated the feasibility and efficacy of an individually tailored, internet-plus-email PA intervention utilizing theoretical framework provided by the Health Belief Model (Rosenstock et al. 1988) and the Transtheoretical Model. The intervention included an interactive computer program that produced individualized PA feedback on the basis of information provided in an online assessment. Intervention participants also received 10 weekly email newsletters that addressed topics such as how to measure activity intensity, how to keep an activity journal, goal setting, strength training, a review of the number of minutes recommended for activity and a link to downloadable log. 156 healthy and ethnically-diverse adult females (with more than 2/3 being at least college graduated and 3/4 being from households with yearly income 50,000 USD and higher) were randomly assigned to the intervention or waitlist control group. As compared to the control condition, the intervention group increased walking (+69 versus + 32 min per week) and total moderate-to-vigorous PA (+ 23 versus – 25 min per week) after three months (Dunton and Robertson 2008).

A study of a 12-week social cognitive theory-based email intervention designed to influence the PA of survivors of breast cancer recruited 74 volunteers. The intervention group received email messages designed specifically for breast cancer survivors and targeting PA: for the first 6 weeks of the intervention, they received messages weekly, from weeks 7 to 12, they received messages every other week and had access to an e-counselor. The control group did not receive email messages, nor did they have access to an e-counselor. At 6 and 12 weeks, significant differences in levels of self-reported vigorous PA were found between groups. Significant differences were also found for self-reported moderate PA at 12 weeks (Hatchett et al. 2012).

Adams et al. conducted a quasi-experimental study examining effects of a combined face-to-face and online intervention to reduce sedentary behavior in 64 overweight and obese women. The intervention, based on the Social Cognitive Theory, combined group sessions with email messages over 6

weeks. Weeks 1 and 2 were led in-person by the researcher, weeks 3–6 were conducted by email. Seven emails contained the computer-delivered content. The messages consisted of either goal reminders, individualized goal feedbacks, or examples of less sedentary behaviors. Participants self-monitored PA with a pedometer. Baseline and post measures of PA and sedentary behavior were assessed by accelerometer and self-report. Self-reported sedentary behavior and light PA in the intervention group changed significantly over time. However, no significant changes over time or differences between the intervention and waitlist groups were found for the accelerometer-determined sedentary behavior or PA (Adams et al. 2013).

Devi et al. recruited patients diagnosed with angina from general practitioners in primary care and randomized them to an intervention or control group. Intervention group participants were offered a 6-week web-based rehabilitation program introduced during a face-to-face appointment and then delivered via the internet (participants communicated with rehabilitation specialists through an email link or by joining a scheduled chat room held on a weekly basis). The intervention used several behavior change techniques (setting/reviewing goals, self-monitoring, feedback on behavior). Participants in the control group continued with treatment as usual. The primary outcome measure was change in daily steps at 6 weeks, measured using an accelerometer. A total of 94 participants were randomized; 84 and 73 participants completed the 6-week and 6-month follow-ups, respectively. The mean number of log-ins to the program was 18.68 (SD 13.13, range 1-51), an average of 3 log-ins per week per participant. Change in daily steps walked at the 6-week follow-up was +497 (SD 2171) in the intervention group and -861 (SD 2534) in the control group (95% CI 263-2451, $P=.02$). Significant intervention effects were observed at the 6-week follow-up in weight, self-efficacy, angina frequency and other measures (Devi et al. 2014).

A recent study by Richards et al. evaluated the ability of an email intervention based on social cognitive theory to increase walking in two distinct groups: dog owners and non-dog owners. 40 adult dog owners and 65 non-dog owners were randomized into the study. Intervention groups received bi-weekly emails for first 4 weeks and then weekly email for the next 8 weeks

targeting self-efficacy, social support, goal setting, and benefits/barriers to walking. Dog owner messages focused on dog walking while non-dog owners received general walking messages. Control groups received a 1-time email reviewing current PA guidelines. At 6 months, both intervention groups reported greater increases in walking and maintained these increases at 12 months. The greatest increases were seen in the dog owner intervention group (Richards et al. 2017).

Generally, 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. Using pedometers for self-monitoring may increase the likelihood of success. However, it is not clear, whether email counseling further increases the effect of a pedometer-based intervention when compared with pedometer alone. Future research needs to use high-quality study designs considering the complexity of email counseling to formulate clear recommendations regarding the most effective form and content of email-based PA interventions.

To summarize, PA has multiple health benefits and is a cornerstone of health prevention and disease management. With the increasing prevalence of sedentary lifestyle, pedometer-based walking interventions have great potential to increase PA both in community and in primary care settings. However, when used in general practices, they need to be simplified and carefully adapted to fit into the workflow of a general practitioner. Supplementing the interventions with email counseling provided outside the general practice might be a useful approach to increase patients' engagement and long-term adherence to the intervention.

3. Walking intervention in primary care

Walking is the most natural form of PA that can be easily incorporated into activities of daily living and is suitable for everyone except the seriously disabled: the human body is highly adapted to walking and due to the lack of a flight phase, there is a low risk of excessive overload and injury. Self-monitoring interventions using pedometers have been shown to increase total walking distance, and general practitioners consider pedometers to be helpful for increasing PA levels of their patients. However, the effectiveness of pedometer-based interventions in primary care settings is still far from optimal and there remains a need for their further improvement, possibly by adding a counseling component. Indeed, several studies that investigated the effects of a pedometer plus counseling have shown promising results.

With the increasing popularity of online communication channels (e.g. social networks, chats, email) by the general population, email counseling might be a useful alternative to more traditional forms of face-to-face and telephone counseling. Email counseling has several advantages, for example, it gives both patients and counselors greater flexibility regarding when and where the interactions occur. However, although email communication has long been used in internet-based PA interventions, it is usually employed only as a channel for one-way researcher-initiated delivery of reminders. Only a handful of studies have used email for delivering two-way interactive PA counseling, and studies combining email counseling with personalized feedback based on objectively measured PA using pedometers are practically non-existent.

Therefore, I have designed a pilot randomized controlled trial to assess the feasibility and potential efficacy of the email counseling added to a pedometer-based intervention. The methods and results of this study were reported in a paper that has been published in BMC Public Health journal and is reprinted here (Vetrovsky et al. 2018).

The study has demonstrated that adding email counseling to a pedometer-based intervention might yield additional benefits in terms of 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. Several issues were identified that need to be addressed when translating the intervention into clinical practice, namely the relatively slow and inefficient recruitment process, selective recruitment, various technical issues, and the optimization of outcome measures. Thus, the study provides important information for conducting the future definitive randomized controlled trial of a pedometer-based walking intervention in clinical practice (see Chapter 6).

RESEARCH ARTICLE

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

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Abstract

Background: General practitioners play a fundamental role in combatting the current epidemic of physical inactivity, and pedometer-based walking interventions are able to increase physical activity levels of their patients. Supplementing these interventions with email counseling driven by feedback from the pedometer has the potential to further improve their effectiveness but it has to be yet confirmed in clinical trials. Therefore, the aim of our pilot randomized controlled trial is to evaluate the feasibility and potential efficacy of future trials designed to assess the additional benefit of email counseling added to a pedometer-based intervention in a primary care setting.

Methods: Physically inactive patients were opportunistically recruited from four general practices and randomized to a 12-week pedometer-based intervention with or without email counseling. To explore the feasibility of future trials, we assessed the speed and efficiency of recruitment, adherence to wearing the pedometer, and engagement with email counseling. 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. Additionally, we conducted a qualitative analysis of structured interviews with the participating general practitioners.

Results: The opportunistic recruitment has been shown to be feasible and acceptable, but relatively slow and inefficient; moreover, general practitioners selectively recruited overweight and obese patients. 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, $p = 0.045$).

Conclusions: This study demonstrates 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 in increasing physical activity levels.

Trial registration: The trial was retrospectively registered at ClinicalTrials.gov (ID: [NCT03135561](https://clinicaltrials.gov/ct2/show/study/NCT03135561), date: April 26, 2017).

Keywords: Primary care, Pedometer, Email counseling, Walking, Physical activity, General practitioner, Recruitment, Adherence, Qualitative research

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Background

Insufficient physical activity (PA) is one of the leading modifiable risk factors responsible for numerous chronic diseases and for premature death [1–4]. As 70–80% of adults in developed countries visit their general practitioner (GP) at least once a year [5], GPs are well situated to deliver PA interventions to physically inactive adults [6, 7]. Moreover, most GPs believe that PA counseling is important and that they play a role in promoting PA among their patients [8]. In addition, GPs are generally viewed as being credible sources of health information, particularly among older adults and those with multiple chronic diseases [9]. Thus, it is not surprising that the National Institute for Health and Care Excellence in the UK recommends that GPs should identify inactive adults and advise them to increase their PA levels [10].

Walking can be considered as the most natural form of PA as it is easily performed by everyone except for the seriously disabled or very frail. As such, walking can be easily incorporated into many activities of daily living and has been the main option for increasing PA in sedentary populations [11]. Interventions aimed at promoting walking could substantially contribute towards increasing PA levels of the most sedentary individuals and serve as an important cornerstone in many PA promotional campaigns [12]. Within these interventions, pedometers are commonly used as effective motivational instruments to increase walking in healthy adults and across a range of clinical conditions [13–18].

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 [19–23] due to both patient- and provider-related factors. Though patients perceive self-monitoring with pedometers as motivating, their efforts to increase PA levels are often hindered by substantial barriers such as inflexible work routines, long working hours, domestic duties, suboptimal weather conditions, a lack of motivation, and other commitments [24–26]. Despite these barriers, GPs consider pedometers to be helpful for increasing PA levels of their patients, but they often lack the time and appropriate training necessary to deliver pedometer-based PA interventions [8, 27].

Hence, there remains a need for further improvement of pedometer-based interventions in primary care settings, possibly by adding a counseling component that could be delivered face-to-face, over the telephone, or via the internet [28–30]. Counseling provided in regular intervals throughout the intervention period could positively influence patients' adherence, and employing effective behavioral techniques during counseling could help a patient overcome certain psychological or

lifestyle barriers, ultimately increasing PA. Moreover, such counseling can be performed by a trained counselor outside normal office hours, thus reducing the burden on the GP [30].

Several studies investigated the effects of a pedometer-plus-counseling intervention, however they compared it to either a usual care group [19, 20] or a counseling-alone group [22, 31], not allowing the effects of pedometer-plus-counseling to be compared to only a pedometer. Additionally, those few studies that have directly compared pedometer-based interventions with and without counseling in primary care settings [21, 32–34] gave inconclusive results. Currently, a handful of ongoing studies have combined a pedometer with some form of face-to-face or phone counseling in primary [35, 36] and secondary [37, 38] care settings, but their results are not yet publicly available.

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 [39], achieving weight loss in overweight adults [40–42], or improving diet in college students [43].

Also, email communication has long been used in internet-based PA interventions [44–47], but it is usually employed only as a channel for one-way message delivery from the researcher to the participant [48, 49] or as a reminder to encourage participants to visit a web-based intervention program [50]. Few studies have used email as a tool for delivering two-way interactive PA counseling [51, 52], and studies combining email counseling with personalized feedback based on objectively measured PA using pedometers are practically non-existent.

Therefore, the aim of this pilot randomized controlled trial was to assess feasibility and to support the development of future trials in a primary care setting, designed to assess the additional benefit of email counseling added to a pedometer-based intervention. The specific objectives were to: (a) explore the feasibility of the recruitment procedure, (b) evaluate patients' adherence to the interventions, (c) examine patients' engagement with the email counseling, (d) assess the potential efficacy of the interventions on daily step counts and other health-related outcomes. In addition, we conducted a qualitative analysis of structured interviews with the participating GPs to gain more insight into the feasibility of the trial and how to improve it.

Methods

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. Recruitment started in November 2015 and was completed in June 2016. Outcomes were assessed at baseline and 12 weeks post-randomization. A CONSORT flow diagram of the progress through the phases of the study is illustrated in Fig. 1 [53].

The study was reviewed and approved by the ethics committee of the Faculty of Physical Education and Sports, Charles University (081/2015), and it was conducted according to the principles of the Declaration of Helsinki. Eligible patients were informed about all relevant aspects of the study before enrolling, notified about the right to refuse to participate or to withdraw consent at any time without reprisal, and then provided written informed consent. The trial was retrospectively registered at ClinicalTrials.gov (ID: NCT03135561, date: April 26, 2017).

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 GPs, who are co-investigators in this trial, approached patients during routine preventive health checkups, screened them for eligibility, introduced the study to the eligible subjects, and obtained written informed consent from those who were interested. The GPs also maintained a log where all excluded patients were recorded, noting the reasons why there were excluded.

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 min of moderate level PA per week [54].

Patients were excluded if they: (1) had co-morbid conditions that would affect adherence to trial procedures

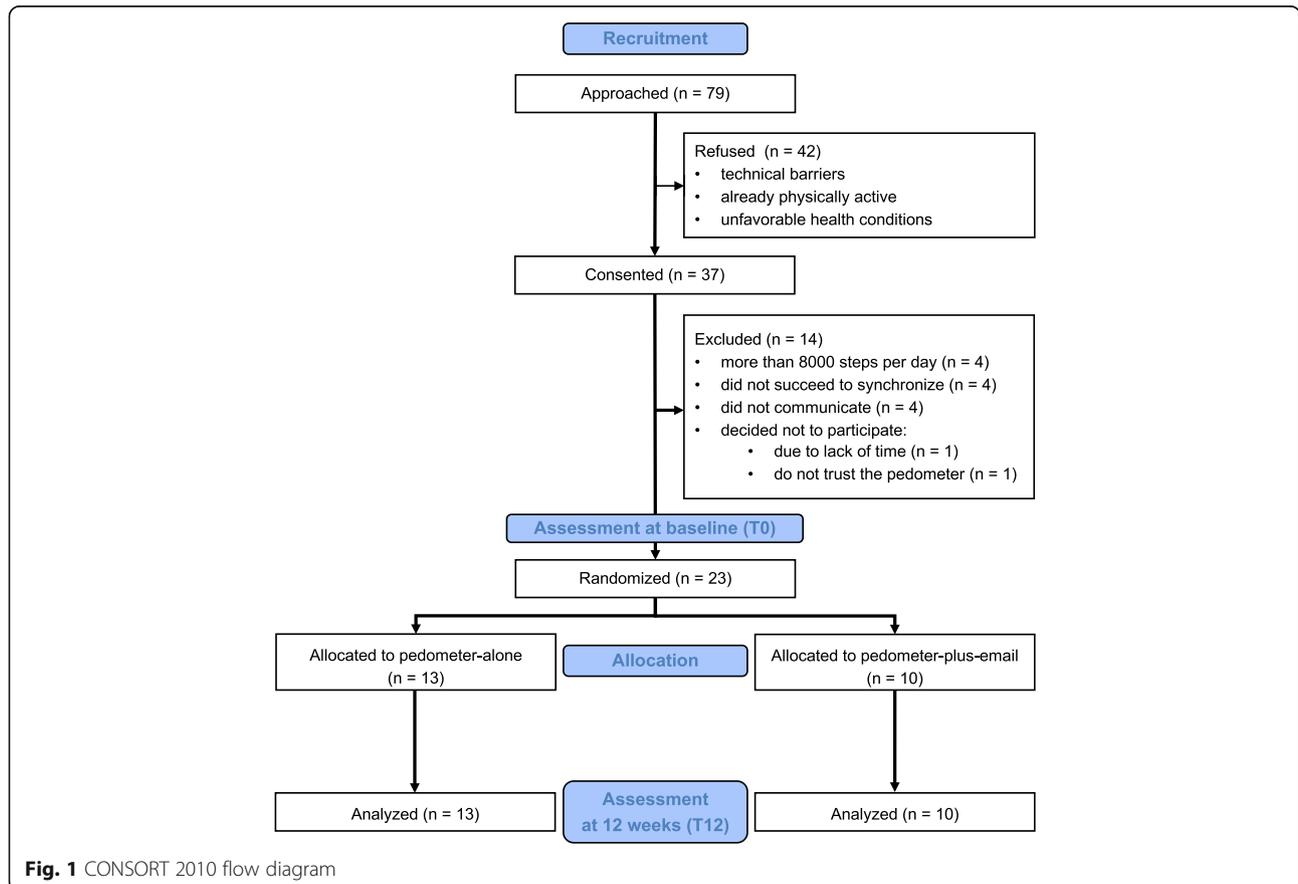


Fig. 1 CONSORT 2010 flow diagram

(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 during the same initial GP visit, anthropometric measures and resting blood pressure were assessed. Finally, 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. Patient allocation was performed using a free online tool at <http://www.sealedenvelope.com>, using a permuted block randomization scheme stratified by practice. Participants who failed to upload pedometer data and those whose mean daily step count was 8000 or more were excluded from the study.

It was not possible to blind the participants or researchers since both were naturally aware of the group allocation due to their active roles in the intervention. However, post-intervention assessments were undertaken by a nurse who was blinded to the group allocation.

Interventions

Once randomized, all participants were informed of their allocated group by an email from the main researcher. In this email, all participants were instructed to wear the pedometer around the neck daily for the next 4 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.

PED group

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.

This pedometer can be worn in the pockets, on the belt, or around the neck. For the purpose of this study we instructed participants to wear it around the neck, as this location has been shown to be highly accurate and preferred by participants [55]. We assessed the validity and reliability of the eVito 3D Step Counter SL pedometer across several velocities (3.0, 3.6, 4.2 kph) on a treadmill and during six-minute walk test in a laboratory corridor by using visually counted steps as a criterion (mean absolute percentage error between 1.3% and 5.6; Pearson correlation coefficient between 0.62 and 0.99).

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 main researcher, trained in behavioral techniques, communicated with them regularly during the 12-week intervention period via email using effective behavioral principles [13, 56, 57] that were focused on helping the participants achieve their daily step goals. Self-monitoring, action planning, goal setting, and personalized feedback were the key techniques used in the intervention.

During the first 4 weeks of the intervention, the participants were sent emails on a weekly basis. For the remaining 8 weeks, emails were sent on a bi-weekly basis. The last email was sent at least 10 days before the assessment period to avoid immediate reactivity. Altogether, eight counseling emails were sent 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. For example, a participant with a baseline value of 4000 steps per day was recommended to increase the daily step number by 600 each week, aiming for at least 10,000 steps a day. 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-min 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, we assessed 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).

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 h with a step count above zero. Periods with known technical issues related to the pedometer were excluded from this analysis. 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, we still aimed to evaluate the potential efficacy of the interventions 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. In addition, patient-reported outcomes (health-related quality of life, and depression and anxiety) were collected before and after the intervention for the purpose of a quasi-experimental pre/post study whose results were published separately [58].

The same eVito 3D Step Counter SL pedometer that was used for the intervention in both groups was employed to objectively measure average daily step count. Mean daily step count from the first 7 days of wearing the blinded pedometer was used as a baseline value. The T12 mean daily step count was calculated from the 7-day period starting 84 days after randomization. As participants in both groups were instructed to continually wear pedometers and to regularly upload step data to a website without knowing at which time point their step performance is to be evaluated, we could use their uploaded data as the outcome measure without the risk of a Hawthorne effect, even though the pedometer was not blinded by the adhesive tape at that point.

Body mass, waist and hip circumference, and blood pressure were measured by a practice nurse blinded to the participants' group allocation. Body mass was measured to the nearest kilogram using a standard calibrated scale available in the GP's office. Waist and hip circumferences were recorded with a measurement tape to the nearest centimeter, according to established protocols [59]. Blood pressure was assessed using an automated monitor available in the GP's office.

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. A group-by-time interaction was examined for number of valid days and mean daily step count during the intervention period using cumulative link mixed models and linear mixed-effects models, respectively.

For the purpose of the mean daily step count, at least four valid days (at least 8 h with step count above zero) were required. If there were fewer than 4 valid days within the 7-day measurement period, additional valid days immediately after this period were added until 4 valid days were reached. All statistical analyses were performed using the statistical package R (version 3.3.3).

Qualitative analysis

To improve the recruitment activity of the GPs, it is recommended to use qualitative research to identify and overcome barriers to recruitment and reduce the clinical workload associated with participation in clinical trials [60]. Therefore, we conducted a qualitative analysis of structured interviews performed with the 4 participating

GPs 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. The interviews were recorded and transcribed verbatim. The coding and the thematic analysis were performed by the main researcher.

Results

Feasibility of the recruitment procedure

The patients were recruited opportunistically, i.e., they were approached by their GP during their routine preventive visits. This 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 (their reasons are depicted in Fig. 1), 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. The reasons for not randomizing the recruited patients are summarized in the CONSORT flow diagram (Fig. 1).

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 h). The cumulative link mixed model revealed a significant effect of time for both groups for the entire intervention period with the highest number of valid days in the first week post-randomization (Fig. 2). However, from the third week on, there was no significant effect of time on the number of valid days in either of the group anymore. Technical issues were frequent during the study: 10 (43%) patients had their pedometer defunct for at least 1 day (11 days on average) due to technical issues (flat battery, syncing troubles).

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. There was no time-dependent change in the probability of responding to a counseling email during the intervention period.

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. There were no significant differences between the two groups, and the baseline characteristics of the non-randomized patients were

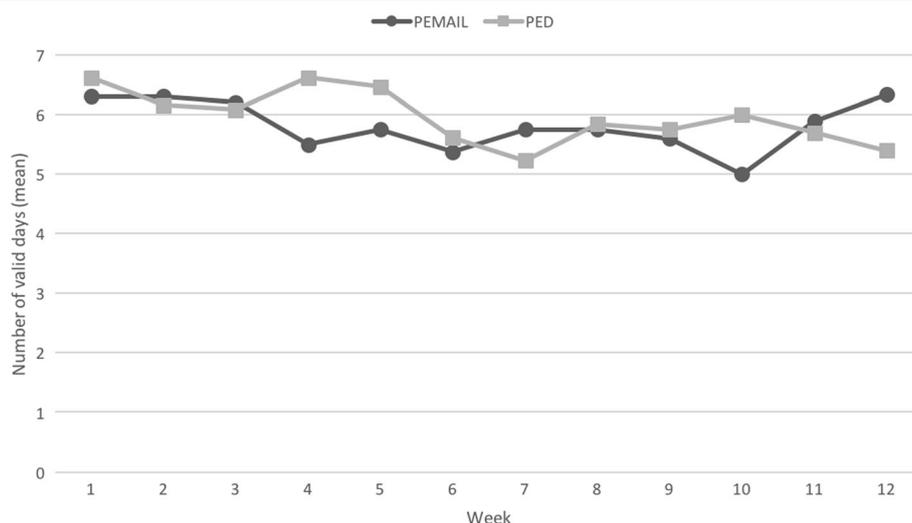


Fig. 2 Adherence to pedometer wear during the intervention period. The effect of time was significant ($P = 0.008$), whereas the effect of group was not

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

	Pedometer-plus-email (n = 10)	Pedometer-alone (n = 13)
Age (yr)	44 (10)	39 (9)
BMI (kg/m ²)	33 (7)	33 (8)
Females (%)	30	62
Systolic blood pressure (mm Hg)	133 (9)	130 (18)
Diastolic blood pressure (mm Hg)	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)

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 (Fig. 3). 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 (alpha), 108 subjects in each arm would be needed. There was no group- or time-dependent change in the mean daily step count found during the intervention period (Fig. 4), which suggests that both groups increased their daily step count at the start of the intervention and then maintained it at the same level, despite the recommendation to increase their daily steps gradually. 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).

Lessons learned from the qualitative research

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

Recruitment

Most GPs believed that the opportunistic recruitment by a physician is more appropriate for the study than the systematic recruitment using email or post mail. Even the nurse was not regarded as an appropriate person to approach the patients. They also mentioned that remuneration for the GPs could increase their motivation to recruit patients. All GPs 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. When patients expressed a lack of interest in participating in the study, the GPs did not try to convince them, as they supposed these patients would be non-adherent further in the study. 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 GPs 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. The GPs were well aware of the health benefits of PA in sedentary but otherwise healthy people that were eligible for the study; in spite of that, they were reluctant to recruit them because they were afraid of refusal.

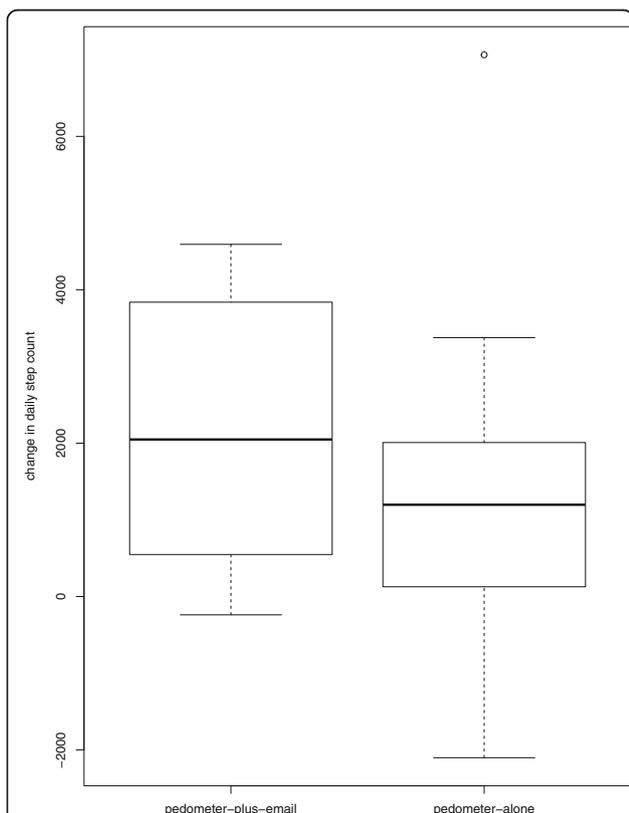


Fig. 3 Changes in the number of steps per day from baseline to post-intervention. The difference between groups was not significant (p = 0.36)

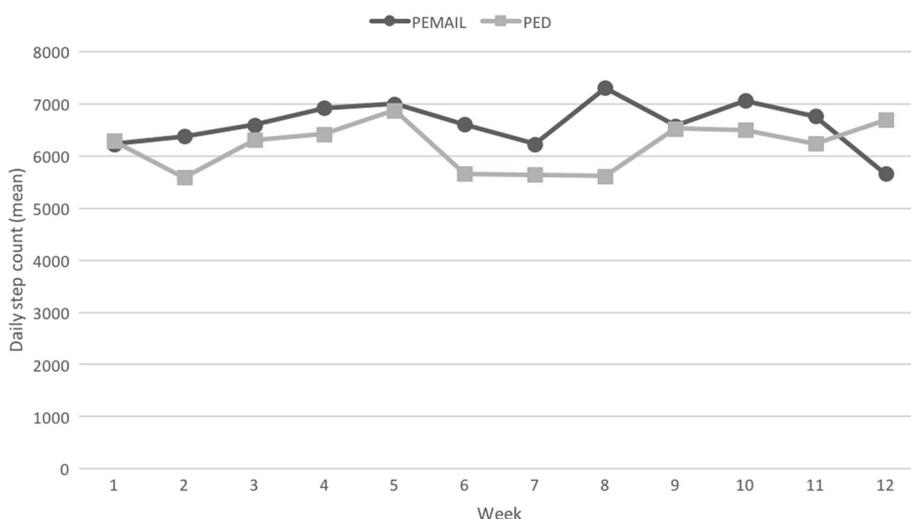


Fig. 4 Mean daily step count during the intervention period. No effect of group or time was observed

Intervention

Technical issues related to pedometers, troubles with uploading step count data, and insufficient technical support were criticized by all GPs. 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 GP who recruited them to the study. One GP described a negative experience with several of her patients who refused to participate in the study as they did not like the idea of being monitored and supervised. At one point, she admitted that she personally would not be happy if someone else were “watching and judging” her.

Outcomes

While GPs 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 GPs 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.

Discussion

Email counseling may be an effective approach for increasing the effectiveness of pedometer-based walking interventions delivered in primary care settings. Unfortunately, this approach has never been tested in a randomized controlled trial and little work has been done to provide a basis for designing such a trial. This pilot study indicates that adding email counseling to a pedometer-based intervention might yield additional benefits in terms of PA levels. The study also showed that patients recruited opportunistically during preventive visits to their GP demonstrate excellent adherence to wearing the pedometer and high levels of engagement with email counseling. This pilot study has also identified several issues that need to be addressed when designing future trials, namely the relatively slow and inefficient recruitment process, selective recruitment, technical issues, and the optimization of outcome measures.

Results in the context of other literature

A limited body of literature suggests that a well-designed robust counseling protocol can potentiate the pedometer’s effect on PA levels, as has been shown in the PACE-UP trial where a pedometer plus three

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

individually-tailored practice nurse consultations were more effective at increasing PA levels in 1023 physically inactive 45- to 75-year-olds at 3 months than pedometer alone distributed by post mail. However, 12 months after the start of the trial, the difference between both intervention groups disappeared, though they were both still significantly better in daily step-count and time spent doing moderate-to-vigorous PA than a control group that received usual care [21].

Compared to the PACE-UP trial, the increase in the daily step count in our study was substantially higher, which can be explained by lower baseline levels of PA in our study (5043 vs 7478 steps per day) with more room for improvement. Unlike the PACE-UP trial, our study detected small but significant improvements in body mass and waist circumference from T0 to T12, which might be related to a higher proportion of overweight and obese patients, but is also consistent with other pedometer-based interventions [14].

In general, the improvements in the daily number of steps observed in our study were higher than those reported in recent pedometer-based trials in primary care [19, 23]. For example, in a large trial with 571 primary care patients at risk of type 2 diabetes, a pedometer-based intervention supported with an initial 3-h group-based structured education program only increased the mean daily step count by 411 after 12 months compared to control group [19]. Difficulties in maintaining PA in the long term and the relatively high baseline PA levels (6585 steps per day) might have both contributed to the small effect of that intervention. Indeed, greater improvements (1029 steps per day) were demonstrated in another primary care trial with lower baseline PA levels (4771 steps per day) and a shorter follow-up period (8 weeks), despite no additional counseling component; of note is that this study used a step-counting mobile application instead of a pedometer device [23].

One of the strengths of our study is that we objectively assessed subject adherence to wearing the pedometer on a daily basis. This is a very important factor because low adherence (i.e. failure to use the pedometer daily) can hinder what would be an otherwise well-designed intervention. In spite of that, published data on adherence to pedometer wear are almost nonexistent. One study noted that 25 overweight or obese postmenopausal women wore the pedometer on 80% of intervention days during a 16-week intervention [61]. Despite minor differences in the intervention period from our protocol (12 vs 16 weeks) and methodology (valid day defined as 8 vs 10 h), this number is very close to the 83% that we observed in our study.

A unique feature of our study is that it reports on patients' engagement with email counseling. One of the few studies that also reported on patients' engagement

with email counseling compared a complex web-based intervention for weight loss (including self-monitoring with a pedometer) alone or in combination with email counseling. In that study, no differences were observed between groups in objectively assessed PA, in spite of the high level of engagement: during the first 6 months, 89% of participants sent email responses, even though they were not required to do so [42]. As that study did not report on the total percentage of emails that were answered, our study builds on this by reporting that nearly half (46%) of all emails were responded.

One of the objectives of our pilot study was to explore the feasibility of the recruitment procedure because the success of research in primary care often depends on the recruitment of the target number of participants; indeed, many RCTs fail to recruit the actual target number [62]. Based on previous research, we have chosen opportunistic recruitment in which patients are approached while attending the practice, as this approach was associated with less time to target recruitment compared with systematic recruitment when patients are selected from practice lists and approached by post mail [63]. In our study, opportunistic recruitment was less successful, which might be attributed to the fact that, unlike in the study by Warren et al. where patients were approached by a researcher, it was the GP who personally approached the patients during routine preventive visits. Participant eligibility based on self-reported physical inactivity could also contribute to a lower than expected number of patients, as people tend to overestimate their level of physical activity [64, 65], thus effectively excluding themselves from the study.

On the other hand, once randomized, all patients in our study completed the 12-week follow-up which is in contradiction with the high dropout rate after 12 weeks (28.8%) that was observed by Warren et al. This may be explained by our pre-randomization procedure that demanded patients to upload their pedometer data to a website, which 27% failed to do. Therefore, it may be that only highly motivated patients were randomized and ultimately participated.

An additional reason for choosing opportunistic recruitment was our assumption that it would reduce the self-selection bias typical for systematic recruitment, where only those patients ready for a behavioral change respond, thus decreasing the external validity of a study. While our assumption was more or less confirmed, as only about half of the approached patients refused to participate in the study (for comparison, in the PACE-UP trial, 85% of systematically invited patients either did not respond or refused to participate [21]), the opportunistic recruitment strategy introduced a different type of a selection bias caused by GPs who only approached a small proportion of their patients who were eligible for

the study. This selection bias is supported by the unexpectedly high body mass index of our randomized patients and is also confirmed in our qualitative analysis of the GP interviews. Our finding is in line with a Cochrane review that concluded that clinicians are concerned that their relationship with the patients would be adversely affected by participating in a trial [66].

In spite of this ambiguous experience with opportunistic recruitment, the qualitative analysis revealed that GPs still consider opportunistic recruitment during the routine preventive visits as an appropriate way to recruit participants, a view that is also supported in the literature [67]. However, to speed up the recruitment process, a mix of opportunistic and systematic recruitment should be considered when designing the main trial.

Study strengths and limitations

The strengths of this pilot study are (a) the involvement of 4 general practices representing various urban areas, (b) a balanced representation of men and women, (c) the detailed reporting of patients' adherence and engagement, (d) the complementation of quantitative outcomes with a qualitative analysis.

The limitations of the study include the selection bias towards overweight and obese patients and the high number of recruited participants that were not randomized. The reasons for non-randomization mainly include three factors, each representing approximately one-third of such patients: (1) technical issues that hindered the upload of data, (2) patients were excluded due to achieving > 8000 steps a day at T0, (3) patients stopped communicating after they were recruited. The technical issues should be resolved in a future trial by using another type of pedometer. The exclusion of patients achieving > 8000 steps a day at baseline is pre-specified in the eligibility criteria, and their number corresponds to the expected positive predictive value of the screening question [54], so it is a limitation that cannot be addressed. The non-communication of the patients might be related to the opportunistic recruitment strategy, where patients who would not normally participate when approached by post mail are too shy to refuse participation when confronted face-to-face with their GP, despite not feeling committed to cooperate once they leave the practice. A more neutral way of extending the invitation to participate and avoiding any inadvertent push or forceful recruitment strategies might resolve this issue.

The selection bias towards overweight and obese patients is a more serious weakness that limits the external validity of this study. Although GPs understood that inactive but otherwise healthy patients could benefit from increasing PA levels, they preferentially recruited obese patients as they believed that these patients would be

less likely to reject the invitation. The fear of rejection has also been described elsewhere [66], and thus it is not likely that better training would change the GPs recruitment behavior. Therefore, another effective strategy, e.g., stratified sampling, should be adopted to eliminate this bias in a future trial.

Another limitation of the study is the small sample size, which has implications not only for the insufficient power of the trial, but also for the eventual scaling up of the intervention. Specifically, the counseling emails in this pilot study were all individually tailored by the main researcher and thus the intervention cannot be simply translated into real world practice. This issue needs to be addressed in future trials, for example by training physiotherapists or nutritional therapists to provide the email counseling, or by employing automated computer-tailored counseling.

Implications for practice

This is the first study to evaluate the additional benefit of email counseling on top of a pedometer-based intervention aimed at increasing PA. Our data generally agree with previous studies of face-to-face or phone counseling added to a pedometer and extends their findings to email counseling. The study was intended as a pilot study and yielded important findings supporting the feasibility of future trials, specifically:

- (1) Patients manifest high adherence to wearing the pedometer daily for the period of at least 12 weeks.
- (2) The study protocol is easy to follow both for GPs and patients, as indicated by 0% attrition during a 12-week period.
- (3) Email counseling is well accepted by patients who manifested high engagement, as demonstrated by their responses to the counselor's emails.
- (4) Though not sufficiently powered to demonstrate superiority of the PEMAIL group over the PED group, the study indicated that email counseling might have the potential to increase the efficacy of a pedometer-based intervention; the efficacy data have been used to calculate sample size of a future trial.

On the other hand, the study has also revealed possible areas for improvement:

- (1) The inefficiency of the opportunistic recruitment procedure and the selection bias introduced by GPs, who preferentially approached overweight and obese patients, need to be addressed to ensure that future trials have implications for public health, possibly by finding the right mix of opportunistic

and systematic recruitment and implementing a stratified sampling method. Financial incentives for participating GPs to recruit more patients should be considered as well, carefully weighing their pros and cons [68].

- (2) The pedometer used in this study should be replaced by a more user-friendly, bullet-proof technology to avoid technological failures and subsequent annoyance for patients and GPs.
- (3) Additional outcomes could be possibly introduced (serum lipid profile, blood sugar levels) while keeping the study protocol simple and easy to follow.
- (4) A longer follow-up of at least 12 months is generally required in PA interventions to assess the maintenance of the intervention effect [6].

Conclusions

To the best of our knowledge, this is the first study demonstrating 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. Thus, the study provides 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. If shown to be effective, dissemination of such an intervention in primary care will help GPs better fulfill their role as promoters of healthy behavior: a role that is perceived as fundamental by both GPs and their patients.

Abbreviations

GP: General practitioner; PA: Physical activity; PED: Pedometer-alone group; PEMAIL: Pedometer-plus-email group

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

TV is the main researcher and drafted the manuscript. VB advised on the study design and reviewed the manuscript. VC contributed to data analysis. JC, MD, BK, KV advised on the development of the intervention and recruited the participants. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was reviewed and approved by the ethics committee of the Faculty of Physical Education and Sports, Charles University (081/2015), and it was conducted according to the principles of the Declaration of Helsinki. Eligible patients were informed about all relevant aspects of the study before enrolling, notified about the right to refuse to participate or to withdraw consent at any time without reprisal, and then provided written informed consent.

Competing interests

The authors declare that they have no competing interests.

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4. Mental health benefits of walking

As has been stated earlier, PA has various health benefits, including but not limited to decreased risk of cardiovascular diseases, improved glycemic control in diabetes patients, and improved symptoms in chronic obstructive pulmonary disease. PA is also beneficial for patients with various psychological diseases, including depression and anxiety disorders. Interestingly, PA seems to positively impact the mental health of people without any clinically diagnosed depression or anxiety disorders.

Thus, PA interventions delivered in primary care, like the one I have described in the previous chapter, might have a profound impact on the mental health of the general population. Surprisingly, little focus has been directed toward the benefits of pedometer-based walking interventions in primary care settings for mental health and quality of life in general, non-clinical populations. In fact, walking facilitates social contact and mutual communication and can be performed in natural environments - factors that might have positive effects on one's wellbeing and mental health.

Therefore, I analyzed pre- and post-intervention data on depression and anxiety symptoms and health-related quality of life from the study described in the previous chapter with the aim to assess whether a pedometer-based walking intervention delivered in a primary care setting affects anxiety and depression symptoms and health-related quality of life in a general population of physically inactive adults without clinically-diagnosed anxiety disorders or depression. The methods and results of this study were reported in a paper that has been published in *Acta Gymnica* journal and is reprinted here (Vetrovsky et al. 2017a).

The study showed 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. However, due to limitations of the quasi-experimental pre-post 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 the future large-scale randomized controlled trial (see Chapter 6).

Mental health and quality of life benefits of a pedometer-based walking intervention delivered in a primary care setting

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Background: Physical activity level is positively associated with mental health and health-related quality of life. Primary care providers are ideally situated to offer physical activity interventions, and pedometers are commonly used as motivational tools to increase walking. However, several recent trials of pedometer-based interventions in primary care settings neither improved patients' quality of life nor reduced anxiety or depression, but these interventions only had relatively modest effects on physical activity levels. **Objective:** Our aim was to assess whether a pedometer-based walking intervention delivered in a primary care setting affects anxiety, depression, and health-related quality of life. **Methods:** A quasi-experimental, pre-post, single group study was conducted in 23 physically inactive patients from four general practices who participated in a pedometer-based intervention. The patients were administered the Hospital Anxiety and Depression Scale (HADS) and MOS 36-Item Short-Form Health Survey (SF-36) questionnaires before and after the 3-month intervention. **Results:** Following the intervention, the patients increased their walking volume by 1,676 steps per day ($p < .001$). Both the anxiety ($-1.4, p = .011$) and depression ($-2.4, p = .001$) subscales of HADS decreased, while the physical functioning ($+6, p = .023$), social functioning ($+9, p = .035$), mental health ($+12, p = .001$), vitality ($+12, p = .003$), and general health ($+7, p = .013$) subscales of SF-36 increased. **Conclusions:** Providing physically inactive patients with a pedometer and encouraging them to walk more in a primary care setting was associated with lower anxiety and depression scores, and improved health-related quality of life.

Keywords: Hospital Anxiety and Depression Scale, MOS 36-Item Short-Form Health Survey, pedometer, physical activity, primary care, quality of life, walking

Introduction

Anxiety disorders and depression are the most frequently diagnosed psychological diseases, severely impacting the lives of the persons affected (Demyttenaere et al., 2004; Moussavi et al., 2007). Regular physical activity protects against the development of anxiety disorders and depression, reduces their symptoms, and increases the quality of life among patients with diagnosed anxiety disorders or depression (Cooney et al., 2013).

However, symptoms of anxiety and depression are common even among people without clinically

diagnosed anxiety disorders or depression. Fortunately, physical activity seems to positively impact mental health and quality of life in these general, non-clinical populations, as well. Meta-analyses quantifying the effect of physical activity interventions on depression and anxiety in non-clinical populations found that physical activity reduces anxiety by a small effect and depression by a medium effect (Conn, 2010a, 2010b; Rebar et al., 2015). A small but significant effect of physical activity interventions on the psychological and physical domains of quality of life has also been reported in non-clinical populations (Gillison, Skevington, Sato, Standage, & Evangelidou, 2009).

Primary care providers are ideally situated to offer physical activity interventions to these general populations. A meta-analysis found that promoting physical activity to sedentary adults in a primary care setting can

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significantly increase physical activity levels (Orrow, Kinmonth, Sanderson, & Sutton, 2012). In addition, primary care providers themselves believe that they have a role in promoting physical activity among their patients (Hébert, Caughy, & Shuval, 2012).

Although there are various types of physical activity, walking is one of the most effective; with little risk of injury among low-activity populations, it has been described as near perfect exercise (Morris & Hardman, 1997). Compared with many sports, walking is a convenient and flexible form of exercise that can be incorporated into everyday life and sustained throughout a person's lifetime (Ogilvie et al., 2007). To increase the amount of walking, pedometers have been successfully employed as they serve as motivational instruments that provide feedback to patients (Bravata et al., 2007).

Surprisingly, little focus has been directed toward the benefits of pedometer-based walking interventions in primary care settings for mental health and quality of life in general, non-clinical populations. Most studies indicating that walking improves health-related quality of life utilize populations with chronic conditions (Conn, Hafdahl, & Brown, 2009), and evidence from randomized controlled trials in general populations is limited (McMurdo et al., 2010; Mutrie et al., 2012). A meta-analysis of 8 walking-based clinical trials (Robertson, Robertson, Jepson, & Maxwell, 2012), which found a large effect of walking on symptoms of depression, included adult participants who were already experiencing depression, and thus, it is uncertain whether its results can be generalized to non-clinical populations in primary care settings.

Recently, several large randomized controlled trials of pedometer-based walking interventions in primary care settings assessed anxiety and depression symptoms as secondary outcomes, but none of them showed significant effects on anxiety, depression, and health-related quality of life (Harris et al., 2017; Yates et al., 2017). Despite that, one group of authors indicated that during qualitative research conducted alongside the trial, most of their intervention participants verbally expressed that they were feeling better, sleeping better, had an improved mood, and had more energy and less pain (Normansell et al., 2014).

As a whole, the body of evidence on mental health and quality of life benefits of pedometer-based walking interventions in general, non-clinical populations in a primary care setting is contradictory and inconclusive. Therefore, our aim was to assess whether a pedometer-based walking intervention delivered in a primary care setting affects anxiety and depression symptoms and health-related quality of life in a general population of physically inactive adults without clinical anxiety disorders and depression.

Methods

A quasi-experimental, pre-post study was conducted in 4 general practices in the Czech Republic. The general practices were selected to represent various urban settings: 2 in a large city, 1 in a middle-sized town, and 1 in a small town. The protocol of the study was reviewed and approved by the Ethics committee of the Faculty of Physical Education and Sports, Charles University (081/2015).

Physically inactive adult patients were recruited during routine preventive visits with their general practitioner. Eligibility criteria for inclusion were: (1) less than 8,000 steps a day, determined objectively using accelerometers during a 7-day period; (2) age 18-64 years; and (3) written informed consent obtained before any assessment related to the study. Patients were excluded from participation on the following grounds (1) diagnosis of anxiety disorders or depression; (2) inability to walk for any reason; (3) co-morbid conditions that would affect adherence to the study procedures (e.g., inflammatory arthritis, active malignancy, renal disease requiring dialysis, cognitive impairment, or significant hearing or visual impairment); (4) pregnancy.

Before the intervention, all patients received a tri-axial pedometer (eVito 3D Step Counter SL; HMM Diagnostics GmbH, Dossenheim, Germany) sealed with tape and were instructed to wear the pedometer every day and to not purposely increase their physical activity levels during the next week. After that, the average daily step count over the 7-day period was calculated and those patients who achieved more than 8,000 steps were excluded from the study. Patients without at least 4 valid days of measurement were also excluded. For the purpose of this study, a valid day was defined as having 8 or more hours of wear time.

Patients included in the study then participated in a 3-month physical activity intervention that consisted of a pedometer-based walking program with weekly step goals. The patients received an e-mail from a researcher, asking them to unseal the pedometer, wear it daily during their waking hours except when swimming or bathing, check the step count every evening, and gradually increase the daily number of steps to 10,000. They were also required to upload data to a website at least once a week and encouraged to contact technical support if they experienced problems with data upload.

A subgroup of the patients also received additional e-mail-based counseling to help them achieve their step goal. A member of the research team, trained in behavioral techniques, sent them 8 e-mails based on behavioral principles, such as goal setting, self-monitoring, and personalized feedback. Specifically, the patients were assigned 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. Further, they 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 their cars farther away from a building's entrance, walk to/from lunch, walk before/after work). All e-mails were drafted individually and tailored to the specific needs of the participant and the circumstances of their case. However, the e-mails always incorporated some common features: (a) encouragement of the participants based on their achievement in the previous week, (b) reminder of the benefits of physical activity for the physical and mental health relevant to the individual participant, (c) discussion of individual behavioral strategies, (d) setting the goal for the upcoming week.

Before and after the intervention, patients were asked by a member of the research team 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 the 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 $\leq .05$ 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; R Foundation for Statistical Computing, Vienna, Austria).

Results

Twenty-three patients (12 males and 11 females) were included in the study with a mean age of 41 years (± 10). With 13 obese and 5 overweight patients, the mean body mass index was 33 kg/m^2 (± 7). Their baseline physical activity during the 7-day period before the intervention was 5,043 steps per day ($\pm 1,377$). There were no significant differences in baseline characteristics between male and female patients.

Post-intervention, the average daily step count over the 7-day period increased by 1,676 steps per day (95% confidence interval: 783 to 2,569, $p < .001$), which represents an increase of 33% from baseline. There were no significant differences between the subgroup that received the additional e-mail counseling and the subgroup that did not receive any additional support.

All 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 1. 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 1.

Discussion

Our study shows 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. The strengths of our study are the pragmatic design with recruitment from general practices, the proportional representation of both sexes, no dropouts or other losses for the entirety of the study duration, and a substantial increase in physical activity during the intervention in comparison with other walking interventions in primary care settings (Harris et al., 2017; Yates et al., 2017).

Our results are in line with those of previous meta-analyses of physical activity interventions in general populations that showed small but significant effects of physical activity on anxiety symptoms (Conn, 2010a; Rebar et al., 2015) and health-related quality of life (Gillison et al., 2009) in addition to small-to-medium effects on depression symptoms (Conn, 2010b; Rebar

Table 1
Baseline and post-intervention values of the Hospital Anxiety and Depression Scale (HADS) and the MOS 36-Item Short-Form Health Survey (SF-36)

	Baseline, Mean (SD)	Post-intervention, Mean (SD)	Change [95% CI]	<i>p</i> value
HADS				
Anxiety	6.6 (3.3)	5.2 (2.3)	-1.4 [-2.4, -0.4]	.011
Depression	5.3 (3.7)	2.8 (2.3)	-2.4 [-3.7, -1.2]	.001
SF-36				
Physical functioning	83 (15)	89 (10)	+6 [+1, +11]	.023
Role-physical	78 (34)	77 (34)	-1 [-20, +18]	.937
Bodily pain	86 (21)	81 (23)	-5 [-18, +8]	.609
General health	59 (16)	66 (15)	+7 [+2, +12]	.013
Vitality	51 (17)	63 (18)	+12 [+5, +18]	.003
Social functioning	80 (19)	89 (17)	+9 [+1, +17]	.035
Role-emotional	71 (37)	89 (27)	+17 [-2, +36]	.120
Mental health	66 (17)	79 (12)	+12 [+6, +19]	.001

et al., 2015). Although these data agreed with ours, these meta-analyses included studies with a large variety of interventions, populations, and settings. As a result, it may be more appropriate to interpret our results in light of the more recent large trials of pedometer-based walking interventions in primary care settings (Harris et al., 2017; Yates et al., 2017). Surprisingly, none of these trials showed a significant effect of the intervention on anxiety, depression, or health-related quality of life compared to control groups.

This might be explained by a relatively modest effect of these trials' interventions on physical activity levels. While our intervention improved the daily step count by about 33%, these trials only reported improvements ranging from 6% to 15%. Interestingly, one older pedometer-based walking intervention in older adults succeeded to increase daily steps by 28% and improved the physical health (but not mental health) dimension score of the SF-36 questionnaire (Mutrie et al., 2012). Unfortunately, that study did not assess the anxiety and depression symptoms.

Another, though less probable, explanation of the confounding data between previous studies and the present could be the lower baseline anxiety and depression scores in the trial by Harris et al. (2017). While the baseline values in our study (anxiety 6.6, depression 5.3) are categorized as normal, the baseline values by Harris et al. (2017), who used the same HADS instrument, were markedly lower (anxiety 4.7, depression 3.9) and thus more difficult to improve by the end of the intervention. Unfortunately, Yates et al. (2017) also used the HADS instrument, but did not publish

baseline values, meaning our data can only be directly compared to the data from Harris et al. (2017).

Although there were no dropouts within the present study and the intervention had a positive effect on physical activity as well as anxiety and depression symptoms, the low number of participants and especially the quasi-experimental design are limitations of the study and should be considered when interpreting our findings.

First, the quasi-experimental study cannot attribute the improvement in mental health and quality of life to the increase in physical activity. In fact, other factors like increased attention of the general practitioners and research staff, or increased self-awareness of patients due to repeated testing and regular self-monitoring might contribute to improved mental health and quality of life. However, as our aim was to test the effect of the intervention, not the causal role of the increased physical activity, our results are still valid with implications in primary care settings.

Second, the positive outcomes could be explained by natural improvement in anxiety and depression symptoms due to change of the season. Indeed, as our patients were recruited predominantly in winter months (from November to June), this might partially explain the increase in physical activity and improvement in depression scores, as the seasonal variations of physical activity (McCormack, Friedenreich, Shiell, Giles-Corti, & Doyle-Baker, 2010; Shephard & Aoyagi, 2009; Tucker & Gilliland, 2007) and depression symptoms (Harmatz et al., 2000) are well documented. To examine this explanation, we tested whether the season of patients' recruitment was associated with their

outcomes. Using the Kruskal-Wallis rank sum test, we did not find any association between the season of recruitment and the improvement in daily step count, anxiety and depression scores, and SF-36 subscales. Thus, we can effectively exclude that the improvements were due to the seasonal variations.

Conclusion

Our study showed that a pedometer-based walking intervention in a primary care setting with a positive effect on physical activity 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 our 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.

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Conflict of interest

There were no conflicts of interest.

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5. Walking intervention: the patients' view

In the previous chapters, I have shown that a pedometer-based walking intervention supplemented with email counseling increases PA levels in primary care patients and also provides mental health and quality of life benefits. I have also reported that these patients demonstrate excellent adherence to wearing the pedometer and high levels of engagement with email counseling. However, it remains unknown how these patients perceive the intervention, what can change their attitudes towards PA, what techniques they use to change their sedentary behavior, and what the most common barriers are that negatively affect their engagement in PA.

Recently, several groups have studied the beliefs, attitudes, behaviors, and experiences of patients participating in primary care delivered PA interventions as well as barriers and facilitators to their increased PA. Most of these studies used qualitative analysis of interviews with the participants that were performed after the interventions were completed. While this is a valid and useful approach, it also has its disadvantages and supplementing it with the analysis of counseling content can yield additional insight.

Therefore, I employed thematic analysis of the content of email messages written by patients participating in the intervention described in the previous chapters with the aim to explore factors influencing their effort to increase and maintain their PA levels. The methods and results of this study have been described in a paper that has been recently submitted to the Patient Education and Counseling journal, and the submitted manuscript is reprinted here.

The study found that the intervention was well-accepted by most participants, many of whom enjoyed walking and appreciated the pedometer they were given. The study has also identified several behavior change techniques used by participants, with action planning, goal setting and self-monitoring being the most popular. The study has also determined the most common barriers patients encountered, which include time constraints, bad weather conditions, and lack of motivation. This knowledge will be reflected in the future definitive randomized controlled trial of a pedometer-based walking intervention, described in the next chapter.

Article "A qualitative exploration of the experiences of primary care patients engaged in email counseling meant to increase physical activity" is published in the printed version of the dissertation (pages 56 to 71). Until it is accepted by a journal, it will not be published online.

6. Translation into clinical practice

This chapter does not bring any new empirical data, rather, it builds on the knowledge from the three studies described in the previous chapters to develop a study protocol for a definitive full-scale randomized controlled trial. Unlike the pilot trial described in Chapter 3, conducted in a general population of primary care patients, this definitive trial is being conducted in heart failure patients that will be recruited from five cardiovascular centers in academic hospitals throughout the Czech Republic. Unlike the pilot trial where counseling was delivered via email, this trial uses telephone counseling as it is more appropriate for the population of patients with chronic heart failure.

Regardless of these differences, the results of the pilot trial (see Chapter 3) were paramount for the development of the protocol of the definitive trial. Specifically, the slow and inefficient recruitment process was adapted, the intervention was further fine-tuned, and the unsatisfactory eVito pedometer was replaced with a more user-friendly and bullet-proof Garmin vívoFit device. The knowledge from the second study on the mental health benefits of walking (see Chapter 4) have also contributed to the development of this protocol, specifically, the measures of mental health and health-related quality of life have been included in the secondary outcomes of the study. Finally, the patients' view of the intervention, reported in the third study (see Chapter 5), have been taken into consideration when designing the intervention.

Thus, the aim of the definitive trial is to translate the pedometer-based walking intervention into clinical practice and to determine whether a 6-month intervention improves functional capacity in patients with chronic heart failure compared to usual care. Not incidentally, the study protocol of the trial has been published in the *Journal of Translational Medicine*; the paper with the study protocol is reprinted here (Vetrovsky et al. 2017b).

The trial has been registered in ClinicalTrials.gov (identifiers: NCT03041610, NCT03041376) and received funding from the Czech Health Research Council (www.azvcr.cz) amounting to 10,454,000 CZK (NV18-09-00146) after ranking 3rd out of 47 grant applications. The trial is currently recruiting patients and its expected completion date is December 2020.

PROTOCOL

Open Access



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

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Abstract

Background: Regular physical activity is recommended for patients with chronic heart failure to improve their functional capacity, and walking is a popular, effective, and safe form of physical activity. Pedometers have shown potential to increase the amount of walking across a range of chronic diseases, but it is unknown whether a pedometer-based intervention improves functional capacity and neurohumoral modulation in heart failure patients.

Methods: Two multicenter randomized controlled trials will be conducted in parallel: one in patients with chronic heart failure with reduced ejection fraction (HFrEF), the other in patients with chronic heart failure with preserved ejection fraction (HFpEF). Each trial will consist of a 6-month intervention with an assessment at baseline, at 3 months, at the end of the intervention, and 6 months after completing the intervention. Each trial will aim to include a total of 200 physically inactive participants with chronic heart failure who will be randomly assigned to intervention or control arms. The 6-month intervention will consist of an individualized pedometer-based walking program with weekly step goals, behavioral face-to-face sessions with a physician, and regular telephone calls with a research nurse. The intervention will be based on effective behavioral principles (goal setting, self-monitoring, personalized feedback). The primary outcome is the change in 6-min walk distance at the end of the 6-month intervention. Secondary outcomes include changes in serum biomarkers levels, pulmonary congestion assessed by ultrasound, average daily step count measured by accelerometry, anthropometric measures, symptoms of depression, health-related quality of life, self-efficacy, and MAGGIC risk score.

Discussion: To our knowledge, these are the first studies to evaluate a pedometer-based walking intervention in patients with chronic heart failure with either reduced or preserved ejection fraction. The studies will contribute to a better understanding of physical activity promotion in heart failure patients to inform future physical activity recommendations and heart failure guidelines.

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Trial registration The trials are registered in ClinicalTrials.gov, identifiers: NCT03041610, registered 29 January 2017 (HF_rEF), NCT03041376, registered 1 February 2017 (HF_pEF)

Keywords: Chronic heart failure, Physical activity, Walking, Functional capacity, Pedometer, 6-min walk test, NT-proBNP

Background

Chronic heart failure (CHF) is an increasingly costly burden on the health care systems of the developed countries, with a 2.2% prevalence in the American population in 2012 [1]. Impaired functional capacity in CHF patients has detrimental effects on their activities of daily living, health-related quality of life, and ultimately their hospital admission rate and mortality [2–4]. Regular aerobic exercise or physical activity is encouraged in patients with CHF, serving as a safe and effective method of improving their functional capacity and reducing their symptoms [5, 6].

Unfortunately, exercise recommendations are poorly implemented [7] and even those patients who are enrolled in a supervised exercise training program show low adherence [8]. In fact, intense, highly supervised, and structured interventions, such as the program used in the HF-ACTION trial, are not applicable to the wider population of patients with CHF in real-life [9].

As patients are not likely to adhere to such intense exercise programs on a daily basis without supervision, a lifestyle approach can be adopted to promote physical activity. This approach involves the promotion of common daily activities, such as climbing stairs (rather than taking the lift), doing more house work and gardening, engaging in active recreational pursuits, and brisk walking [10].

Walking is a crucial component of the lifestyle approach and it has been described as near perfect exercise [11]. Even walking at a moderate pace of 5 km/h expends sufficient energy to meet the definition of moderate intensity physical activity [12]. Compared with many sports and other recreational pursuits, walking is a popular, familiar, convenient, and flexible form of exercise that can be incorporated into everyday life and sustained throughout the lifespan [13]. Walking is also deemed to be one of the most effective forms of physical activity, 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 [14–17].

Pedometers have been commonly employed to provide feedback to patients and have served as a motivational instrument within intervention programs designed to increase activity and improve the quality of life across a range of clinical conditions [17–19]. Results

of meta-analyses showed that interventions that have incorporated pedometers have yielded both a significant increase in participants' physical activity, and a significant decrease in their body mass index and blood pressure [18, 19].

Evidence has shown that utilizing pedometers helps cardiac patients increase their daily physical activity levels [20–25]. However, the large majority of pedometer-based studies in cardiac patients were short-term studies ranging from 3 to 8 weeks, with the exception being one study that lasted 12 months [23]. In addition, most of the studies included fewer than 65 patients with only one study recruiting 110 patients [21] and another recruiting 215 patients [25]. Lastly, and most importantly, none of the studies focused specifically on patients with CHF.

Rationale and aims

As a whole, the body of literature does not indicate whether using a pedometer-driven walking program increases physical activity in patients with CHF, and if this increase in physical activity translates into improved functional capacity and CHF prognosis. Thus, the main purpose of our randomized controlled multicenter trials is to determine whether a 6-month pedometer-based intervention combining behavioral face-to-face sessions and regular telephone contact improves functional capacity in patients with CHF compared to usual care. We hypothesize that such an intervention would increase an average distance in 6-min walk test (6MWT) by at least 45 m, which is considered as the minimal clinically important difference in patients with CHF [26].

Methods/design

Design and settings

Two multicenter randomized controlled trials will be conducted in parallel: one in patients with chronic heart failure with reduced ejection fraction (HF_rEF), the other in patients with chronic heart failure with preserved ejection fraction (HF_pEF). Patient allocation will be performed as permuted block randomization with a 1:1 ratio. The trials will be conducted across five cardiovascular centers in academic hospitals throughout the Czech Republic:

- General University Hospital, Prague.
- University Hospital, Brno.
- University Hospital, Olomouc.

- University Hospital, Hradec Kralove.
- Tomas Bata Hospital, Zlin.

The study protocol has been approved by the Ethics Committee of the General University Hospital, Prague (20/16 Grant VES 2017 AZV VFN), and the studies will be conducted according to the principles of the Declaration of Helsinki. Eligible patients will be informed of all relevant aspects of the study before enrollment. Participation in the study will be voluntary and will be confirmed via written informed consent. Participants may refuse to participate and will be able to withdraw their consent at any time without reprisal.

Recruitment has started in April 2017 and the expected completion date for the trials is December 2019. Data will be assessed at baseline (T0), at 3 months (T3), after the 6-month intervention (T6), and at a follow-up visit that will occur 6 months after the cessation of the intervention, which would be 12 months after randomization (T12). A CONSORT flow diagram of the progress through the phases of each study is illustrated in Fig. 1 [27].

This paper is written following the SPIRIT 2013 guidelines [28]. The trials are registered in ClinicalTrials.gov, identifiers: NCT03041610 (HFref), NCT03041376 (HFpEF).

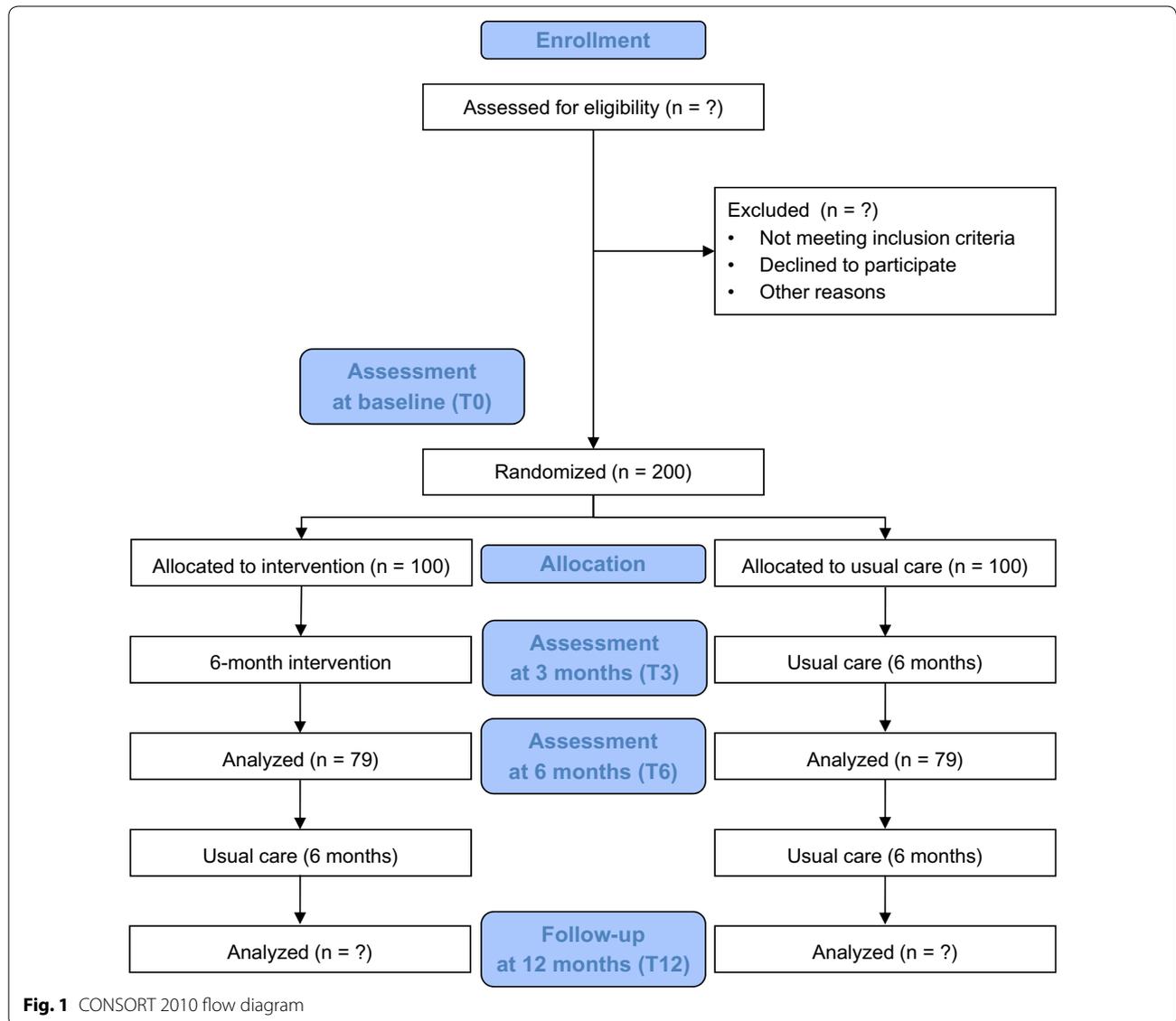


Fig. 1 CONSORT 2010 flow diagram

Participants and enrollment

Eligibility

To participate in one of the trials, patients must comply with all of the following at randomization:

1. Diagnosis of CHF according to the 2016 ESC Guidelines [5] with NYHA class II or III symptoms. Patients will be assigned to one of the two trials:
 - A trial that will include patients with heart failure with reduced ejection fraction (HFrEF); i.e. left ventricular ejection fraction (LVEF) <40%;
 - A trial that will include patients with heart failure with preserved (HFpEF) or mid-range (HFmrEF) ejection fraction; i.e. fulfilling all of the following criteria: (a) LVEF \geq 50 or 40–49%, respectively, (b) the presence of at least one typical symptom and one specific sign of heart failure as defined by the 2016 ESC Guidelines [5], (c) elevated levels of natriuretic peptides (BNP >35 pg/ml and/or NT-proBNP >125 pg/ml), (d) objective evidence of other cardiac functional and structural alterations underlying heart failure.
2. Physically inactive, as determined by 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 min of moderate level physical activity per week [29].
3. Age \geq 18 years.
4. Written informed consent obtained before any assessment related to the study.

Patients with both ischemic and non-ischemic etiology of CHF will be included. In patients with ischemic etiology, complete revascularization prior to enrollment into the study will be recommended.

Patients with HFrEF will be required to be on evidence-based standard medication with maximally tolerated dosages. Investigators will be advised to reassess medication dosages before enrolment into the study.

Individuals will be excluded from participation on the following grounds:

1. Signs and symptoms of decompensated heart failure, uncontrolled arrhythmia or effort angina, severe or symptomatic aortic stenosis, or persistent hypotension.
2. Recent (<3 months) myocardial infarction, percutaneous coronary intervention, implantation of an

implantable cardioverter defibrillator or bi-ventricular pacemaker, or shocks delivered by the automated implantable cardioverter defibrillator.

3. 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, cognitive impairment, or significant hearing or visual impairment).
4. Major surgery planned within the next 12 months.
5. Life expectancy shorter than 12 months.
6. Inability to walk from any reason.
7. Baseline 6-min walking distance >450 m. Patients covering more than 450 m in the baseline 6MWT are excluded due to a possible ceiling effect, which has been documented in patients with pulmonary artery hypertension and may also occur in patients with CHF [30, 31].
8. Pregnancy.
9. Failure to perform the 6MWT.

Sample size

For the purpose of the power analysis, we have chosen a change in six-minute walk distance (6MWD) of 45 m as suggested by a recent review [32]. It has shown that at least moderate effect size of an exercise-based intervention on health-related quality of life appears to be associated with a change in 6MWD greater than 45 m thereby making a change of 45 m the minimum clinically important difference in patients with CHF. It has also suggested that in order to have a reasonable degree of confidence that a change in 6MWD is not due to test-retest variability or measurement error, the amount of change must exceed 43 m [32]. The standard deviation of the response variable in similar populations varies between 38 and 96 m [32]. Therefore, to detect a clinically meaningful change of 45 m on the 6MWT with a power of 80% using a 2-sided 0.05 significance level (α) and assuming that the standard deviation is 100 m, 79 subjects in each arm will be needed. To account for an expected attrition rate of 20%, we plan to recruit 100 patients for each arm, resulting in 200 patients for each trial.

Recruitment and consent

Participants will be identified and recruited during routine clinical visits at each of the participating centers. Potential participants will undergo a screening phase, which will include a review of their medical records for assessment of eligibility. A research team member will evaluate the inclusion and exclusion criteria and will maintain a log where all excluded patients will be recorded, noting the reason why they were excluded.

A research nurse will explain the study in detail to all potentially eligible and interested individuals. Those who will agree to participate following the briefing will be provided with an informed consent form, indicating their full understanding of the study and their protected rights for confidentiality and withdrawal from the study without giving a reason.

Baseline assessment

After providing consent, patients' sociodemographic characteristics (ethnicity, marital status, date of birth, education level, and employment status), medical history (heart failure history and etiology, hypertension, hyperlipidemia, etc.), current smoking status and alcohol intake, and current medications will be collected. Then the baseline assessment will be conducted by the research nurse.

During the same visit, participants will be fitted with an ActiGraph accelerometer to measure baseline physical activity. They will be required to wear it for 7 consecutive days and will be instructed to continue their normal physical activities. They will be asked to complete a log of wear time, showing time that the accelerometer is put on and taken off each day and the time and reason that the accelerometer is taken off during the day. The research nurse will then schedule an appointment (at least 8 days after the ActiGraph fitting) to return the device.

Randomization and blinding

After returning the ActiGraph, individuals will be randomly assigned in a 1:1 ratio to either the control or the intervention group. The randomization will be performed using a central computer-automated randomization system to guarantee adequate allocation concealment. The trials will use a permuted block randomization scheme stratified by center, NYHA class, sex, and age (18–65, ≥ 66) to ensure equal representation in the groups.

Due to the nature of the study protocols, the process of group allocation cannot be blinded, as the participants and researchers will both be aware of the group allocation due to their active role in the intervention. However, assessments at T3, T6, and T12 will be undertaken by an assessor who is blinded to treatment allocation.

Intervention and control groups

Intervention group

The intervention will be delivered over a 6-month period and will consist of: (1) an individualized pedometer-based walking program with weekly step goals, (2) behavioral face-to-face sessions with the physician, and (3) regular telephone calls with the research nurse in between the face-to-face contacts.

The intervention will be based on effective behavioral principles. Goal setting, self-monitoring using the pedometer and an exercise diary, and receiving personalized feedback during the face-to-face sessions and telephone calls are the key behavioral techniques used in the intervention [33].

Pedometer-based walking program

Following their randomization, participants allocated to the intervention group will receive a triaxial wrist-worn pedometer. The Garmin vivofit (Garmin, Schaffhausen, Switzerland) has been selected as the pedometer of choice to encourage walking behavior of participants in the intervention group as it is currently the most cost effective device that features all of the following characteristics: (1) wrist-worn device as we suppose it might improve patients' adherence, (2) data can be uploaded online, making data accessible to the research team, (3) a battery life of at least 8 months.

Participants will be asked to wear the pedometer every day, from waking to sleeping, and to upload data online on a weekly basis (eventually with the help of their spouse or younger relatives) at <http://www.garminconnect.com>. Those unable to upload data will be assisted by the research nurse during face-to-face appointments or during telephone calls. Participants will also be instructed to record the daily number of steps in the exercise diary provided, review the diary at least once a week, and bring both the pedometer and the diary to each appointment.

Goal setting

Goal setting will be used as an important behavioral component of the intervention. Participants will be instructed not to purposely increase their activity levels during the first week to obtain their habitual daily step count. After the first week, they will be instructed to gradually increase their daily step count during the next 6 weeks to achieve an increase of at least 3000 steps per day above their habitual daily step count at the end of this 6-week period. For the remainder of the intervention period, participants will be encouraged to at least maintain or continue to increase their daily step count.

With an average cadence of 100 steps/min, 3000 steps are equivalent to around 30 min of walking. Participants will be advised to incorporate the walking into their daily routine as either a single 30-min walk or multiple bouts of at least 10 min per bout.

Face-to-face behavioral sessions

The face-to-face behavioral sessions with a physician will take place during the clinic visits at baseline, at 3 months, and at 6 months. At all sessions, the patients will be reminded of the health benefits of walking, encouraged

to integrate walking into their daily routine and implement self-monitoring to achieve their goals. Lastly, they will be reminded to wear the pedometer on a daily basis, regularly upload their data, and maintain their steps-per-day diary. During the session at 3 months, they will be given feedback on their progress based on the diary. During the last face-to-face session at 6 months, participants will return the Garmin vívofit and will be encouraged to maintain or to continue to increase their new level of physical activity without the assistance of the device.

Telephone calls

The phone calls will be delivered monthly by the research nurse who will have access to the participants' activity data at <http://www.garminconnect.com>. The calls will be designed to assess participants' progress, provide individualized feedback, monitor their adherence, discuss their personal goals and diary, assist them to identify barriers and solutions to physical activity participation, and provide encouragement. The phone calls will be individually tailored based on the current physical activity level and needs of every patient, thus being highly individualized.

Control group

The participants allocated to the control group will receive their usual care. At the baseline visit, they will neither receive a pedometer nor participate in behavioral session; they will only be educated about the beneficial effects of regular physical activity for patients with CHF and encouraged to increase their physical activity levels. Then, they will be asked to come back for the assessments at 3, 6, and 12 months. During these assessments, no behavioral sessions will take place. The control group participants will not receive any phone contact with the members of the research team.

Outcome measures

Assessment schedule

The primary and secondary outcomes detailed below will be assessed at baseline (T0), at 3 months (T3), after the 6-month intervention (T6), and at a follow-up visit 12 months after randomization (T12), as described in Table 1. Regular clinical examinations (NYHA class, vital signs, ejection fraction) will also be performed at T0, T3, T6, and T12. Adverse events will be monitored and recorded throughout the study period.

Primary outcome

The primary outcome will be the change in distance covered during the 6MWT from T0 to T6. The 6MWT is a practical, simple test that measures the distance that a patient can quickly walk on a flat, hard surface in a period

Table 1 Assessment schedule

	T0	T3	T6	T12
Sociodemographic characteristics, medical history	X			
Clinical examination (NYHA class, vital signs)	X	X	X	X
Echocardiography (ejection fraction)	X		X	X
6MWT	X	X	X	X
NT-proBNP	X	X	X	X
hsCRP	X		X	X
Lung ultrasound	X		X	X
Physical activity measured by ActiGraph	X		X	X
Beck depression inventory-II (BDI-II)	X		X	X
36-item short-form health survey (SF-36)	X		X	X
General self-efficacy scale (GSE)	X		X	X
Body weight, height	X	X	X	X
Waist and hip circumference	X		X	X
MAGGIC risk score	X		X	X
Adverse events	X	X	X	X

of 6 min. Strong evidence suggests that the 6MWT is responsive to clinical change following cardiac rehabilitation [34]. Lower levels of functional capacity (a distance <300 m during 6MWT) have proven to be predictive of mortality (total or cardiovascular) and morbidity (hospitalization from worsening heart failure) both in patients with asymptomatic left ventricular systolic dysfunction and in those with mild-moderate and advanced heart failure [35].

The test will be performed on a 30-m indoor hallway course with a controlled environment. Patients will be instructed, encouraged, and monitored as recommended in the American Thoracic Society (ATS) guidelines [36]. Briefly, patients will be instructed to walk back and forth in the corridor with the goal to walk as far as possible for 6 min, but they won't be allowed to run. Only the standardized phrases for encouragement will be used during the test [36].

Although the ATS guidelines suggest that a practice test is not needed in most clinical settings, the guidelines also acknowledge that a learning effect may occur and test performance can be improved during a second trial [36]. In addition, since the ATS guidelines were published, several studies suggest that the test should be duplicated at baseline and at the end of the study [37–39]. Therefore, participants will perform a “practice trial” at all assessment time points; this should refamiliarize the patients with the exercise test and produce valid and reliable results [40]. According to the ATS guidelines, approximately 1 h will separate the practical trial and the measured trial, and the furthest distance will be recorded [36].

Secondary outcomes

Secondary outcomes include serum biomarker levels, pulmonary congestion assessed by ultrasound, objectively measured physical activity, patient reported outcomes, anthropometric measures, and MAGGIC risk score.

Biomarker levels

N-terminal pro-B-type natriuretic peptide (NT-proBNP) and high-sensitivity C-reactive protein (hsCRP) have been selected as secondary outcomes as standard, reproducible, and cost-effective assays are available for both biomarkers.

NT-proBNP is the gold standard biomarker for determining the diagnosis and prognosis of CHF. It is used routinely in the clinical management of patients with heart failure as an indicator of heart failure progression, and has a strong prognostic value of death in acute and chronic heart failure [41].

The concentrations of hsCRP are significantly increased with the severity of CHF. An elevated level of hsCRP is an independent predictor of prognosis in CHF, and can provide additional prognostic information for the risk stratification and treatment in patients with CHF [42].

Both markers were used in the HF-ACTION study, and while the exercise training program did not lead to improvements in plasma concentrations of NT-proBNP or hsCRP compared to usual care, serial improvements in NT-proBNP have been associated with increases in peak VO_2 levels and decreased risk of adverse clinical outcomes [43].

A recent secondary analysis of data from the HF-ACTION trial concluded that exercise therapy was protective for reducing the frequency of membership in the elevated/worsening biomarker pattern of NT-proBNP and hsCRP, indicating that exercise may be helpful in delaying the progression of heart failure [44].

Lung ultrasound

Lung ultrasound is a novel technique that may allow for the detection and quantification of subclinical pulmonary congestion. B-lines are vertical lines on lung ultrasound which, when quantified, provide a graded measure of pulmonary congestion. A greater number of B-lines have been associated with increased morbidity and mortality [45].

Physical activity

The ActiGraph GT3X-BT activity monitor (ActiGraph, Pensacola, FL, USA) will be used to objectively measure average daily step count measured over 7-day periods at T0, T6, and T12. The ActiGraph has been found to be reliable and valid in laboratory testing and for the measurement of everyday activities [46].

The activity monitor will be affixed to an elastic belt and worn on the waist for 7 full days during waking hours, except when swimming or bathing. Participants will also be asked to complete an activity monitor log to indicate when the monitor was removed. For the purpose of these studies, valid wear time will be determined as at least 8 h of activity on at least 5 of the 7 days.

Patient reported outcomes

Patient reported outcomes include symptoms of depression (BDI-II), health-related quality of life (SF-36), and self-efficacy (GSE).

The Beck Depression Inventory-II (BDI-II) is a 21-item, self-reported measure of depressive symptoms using a 0–3 scale [47]. The BDI-II has excellent psychometric properties and has been widely studied in cardiac patients, including the HF-ACTION trial [48].

The SF-36 is a validated measure of health-related quality of life that assesses mental and physical health [49]. It consists of 36 questions divided into eight individually analyzed dimensions: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health.

Self-efficacy is the degree of confidence an individual has in their ability to perform behavior under specific circumstances [50] and it plays an important role in the adoption and maintenance of physical activity in older adults [51]. Self-efficacy will be assessed by the Czech version [52] of the General Self-Efficacy Scale (GSE) [53].

Anthropometric measures

Height, body weight, and waist and hip circumference will be measured by an assessor blinded to the participants' group allocation. Participants will be asked to remove any footwear and to wear only light clothing for anthropometric measurements. Height will be measured using a stadiometer to the nearest 0.1 cm. Body weight will be measured on a calibrated electronic scale to the nearest 0.1 kg. Body mass index will be calculated by dividing the body weight (kg) by the square of the height (m^2). Waist and hip circumference will be recorded with a measurement tape to the nearest 0.1 cm, according to established protocols [54].

MAGGIC risk score

The MAGGIC risk score is a simple method to predict survival in heart failure patients. It includes 13 highly significant independent predictors of mortality: age, ejection fraction, NYHA class, serum creatinine, diabetes, beta-blocker usage, systolic blood pressure, body mass, time since diagnosis, current smoking status, presence of chronic obstructive pulmonary disease, gender, and

usage of ACE-inhibitors or angiotensin-receptor blockers [55]. The MAGGIC risk score calculator is available at <http://www.heartfailurerisk.org>.

Adverse events

Adverse events will be monitored and recorded throughout the study period. Data regarding falls, injuries, musculoskeletal problems, major cardiovascular disease events, and any other events potentially related to implementation of the study protocol will be collected at T3, T6, and T12.

Data analysis

The primary analysis will compare the change in 6MWD from T0 to T6 between the intervention and control groups. The analysis of the primary and secondary outcomes will be undertaken on an intention-to-treat basis. Primary and secondary measures will be compared between the two groups using two-sample *t* tests or their non-parametric alternative, if necessary. A *p* value of ≤ 0.05 will be considered as statistically significant and all tests will be two tailed.

Furthermore, two-sided 95% confidence intervals will be constructed to describe the differences. Differences at T12 will be tested only if the 6-month intervention is shown to be successful at the T6 measurements. Baseline characteristics will be compared between the intervention and control groups. If significant differences will be demonstrated, the measure will be added into statistical models as a covariate. If significant differences will be demonstrated in more measures which are correlated, only one measure will be added as a covariate in order to avoid multicollinearity.

The impact of missing data will be assessed using a sensitivity analysis and missing data will be imputed using a multiple imputation procedure, where necessary. All statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) and the statistical package *R*.

Discussion

Despite the proven benefits of regular physical activity in heart failure patients, their participation rates in cardiac rehabilitation programs remain low. The purpose of these studies is to evaluate the effect of pedometer-based walking intervention combining regular face-to-face appointments and telephone contacts on functional capacity in patients with CHF using a multicenter randomized controlled approach. Such studies have not been performed before.

Other strengths of our studies include: (1) The pragmatic design of the study, when only regular physicians and nurses of the cardiology department without any extensive behavioral training deliver the intervention,

makes it (if beneficial) applicable to routine clinical practice. (2) Unlike most pedometer-based interventions so far, the device used in our study synchronizes easily with the server, making the step data in minute epochs for the 6-month period of the intervention available for an auxiliary analysis of physical activity patterns of heart failure patients. (3) While most walking interventions to date employed waist-worn pedometers and accelerometers, we have chosen a new wrist-worn device as this might improve adherence to wearing it. (4) The step goal for each patient is set individually, based on their baseline physical activity levels which again increases patient's commitment and their willingness to achieve it.

The HF-ACTION trial, the largest randomized trial in CHF patients to date, compared 3-month exercise training program with usual care in 2331 heart failure patients. When analyzed per protocol, exercise training led only to a non-significant 7% reduction in all-cause mortality or hospitalization. Only after adjustment for pre-specified major prognostic factors, the composite primary endpoint was significantly reduced by 11% ($p = 0.03$) [9]. This lower than expected effect can be partially attributed to a low level of adherence to the prescribed training regimen [8]. Thus, a potential challenge of our studies will be to maximize adherence to the proposed intervention. We aim to address the challenge by ensuring frequent contact with the clinical staff and employing effective behavioral strategies that enhance patient self-efficacy, such as realistic goal setting, self-monitoring, feedback, and positive encouragement [56].

Our studies will contribute to a better understanding of physical activity promotion in heart failure patients. If shown to be beneficial, it will indicate that using pedometers provides enough feedback for patients to adhere to a program without the overbearing supervision of a rigid, intense exercise program, encourage clinicians to prescribe exercise and physical activity as an integral part of heart failure management, and improve health outcomes for heart failure patients.

Abbreviations

CHF: chronic heart failure; HFREF: heart failure with reduced ejection fraction; HFpEF: heart failure with preserved ejection fraction; HFmrEF: heart failure with mid-range ejection fraction; LVEF: left ventricular ejection fraction; 6MWD: six-minute walk distance; 6MWT: six-minute walk test; ATS: American Thoracic Society; ESC: European Society of Cardiology; NT-proBNP: N-terminal pro-B-type natriuretic peptide; BNP: B-type natriuretic peptide; hsCRP: high-sensitivity C-reactive protein; GSE: General Self-Efficacy Scale; BDI-II: Beck Depression Inventory-II; SF-36: Medical Outcome Study Short Form-36; NYHA: New York Heart Association; MAGGIC: Meta-Analysis Global Group in Chronic Heart Failure.

Authors' contributions

JB is the principal investigator and project lead. TV drafted the manuscript and contributed to the study design. MS helped draft the manuscript and contributed to the study design. JP, MG, JS, JP, RP, VB, AL advised on the development of the intervention and reviewed the manuscript. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests.

Ethics approval and consent to participate

The study protocol has been approved by the Ethics Committee of the General University Hospital, Prague (20/16 Grant VES 2017 AZV VFN). Participation in the study will be voluntary and will be confirmed via written informed consent. Participants may refuse to participate and will be able to withdraw their consent at any time without reprisal.

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7. Conclusions

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).

Based on these findings, 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 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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