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

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

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

**Keywords:** Pedometer, Email counseling, Walking, Physical activity