Cluster Randomised Controlled Trial of a Mobile Monitoring and Feedback Tool Embedded in a Counselling Protocol to Stimulate Physical Activity in Chronically Ill Patients

Study protocol of the *It's LiFe!* RCT

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***Abstract*—Physical inactivity is an increasing public health concern. The *It's LiFe!* monitoring and feedback tool embedded in the Self-management Support Program (SSP) is an attempt to stimulate physical activity in people with Chronic Obstructive Pulmonary Disease or type 2 diabetes treated in primary care. This paper describes the study protocol of the *It's LiFe!* three armed cluster randomized controlled trial in which the effects of the SSP and the added value of the tool were evaluated. The main hypothesis was that the complete intervention increases participants moderate to vigorous physical activity with at least 10 minutes per day, after a 4-6 months intervention period.**

Keywords- physical activity, self-management support, remote sensing technology, primary care, chronic obstructive pulmonary disease, type 2 diabetes.

I. INTRODUCTION

According to the World Health Organization (WHO) physical inactivity is the fourth leading risk factor for global mortality and the cause of 6% of all deaths [1]. Physical activity (PA) reduces the risk of developing several diseases, and in people with an existing chronic condition it improves quality of life and delays complications [2] [3]. Despite the benefits of PA, 31% of the people worldwide were insufficiently active in 2008 [1]. Therefore, the WHO Member States try to reduce physical inactivity by 10% in 2025 by, e.g., making active transportation accessible and safe, developing labor and workplace policies to encourage physical activity, encouraging and supporting schools to have safe accessible spaces for free time activities of the students, and by improving physical education for children [1]. Another strategy is by incorporating the improvement of PA levels of patients into the healthcare process. Especially for practice nurses (PN's) in primary care, coaching people with a chronic disease to become more active has become part of regular care according to guidelines [4] [5]. However, using the right strategies to stimulate people and keep them encouraged to be active, remains challenging. A clear coaching strategy and the implementation of rapid developing technical tools could reinforce and help the PN in this coaching role [6]. In the *It's LiFe!* project a coaching strategy for the PN, which is called the Self-management Support Program (SSP), and a monitoring and feedback tool which should be embedded in this SSP, were developed [7] [8]. A three-month pilot study in two general practices with 20 patients with Chronic Obstructive Pulmonary Disease (COPD) or type 2 diabetes (DM2) showed promising results [9]. However, in this feasibility study no control group was present.

Therefore, the objective of this three armed cluster randomized controlled trial (RCT) was to evaluate the effects of the SSP and the added value of the *It's LiFe!* tool on 40-70 years old patients with COPD and DM2 in primary care. The primary outcome measure was physical activity in daily life. Secondary outcome measures were quality of life, self-efficacy and health status. Section 2 of this paper describes the study protocol of the *It's LiFe!* RCT of which an extended version has been published in advance[10].

[1] Both authors contributed equally to this study.

 ISBN: 978-1-61208-384-1

II. METHODS

A. Study design

A cluster randomized controlled trial was performed in 24 general practices in the South of the Netherlands. Practices were randomized in three groups. Practice nurses, in practices in group one executed the SSP and provided the tool, practices in group 2 executed the SSP alone and practices in group 3 performed care as usual. Every practice was asked to include 5 patients with COPD and 5 patients with DM2, which made a total of 240 patients.

B. Eligibility

Participants were eligible when they complied with the following criteria:

- Diagnosed with COPD or DM2
- Between 40 and 70 years old
- Treated in primary care
- Did not comply with the Dutch Norm for Healthy Exercise, according to the practice nurse
- Additional inclusion criteria for the DM2 patients were a Body Maxx Index>25 and for the COPD patients: a clinical diagnosis of COPD according to the GOLD-criteria stage 1-3, being at least six weeks respiratory stable and on a stable drug regimen
- Access to a computer with an internet connection
- Not participating in another PA intervention
- Sufficient mastery of the Dutch language
- No coexisting medical conditions with a low survival rate, severe psychiatric illness or chronic disorders or diseases that seriously influence the ability to be physically active

C. Recruitment

1) Recruitment of practices

General practices in the South of the Netherlands were invited by an invitation letter, by telephone and personal contact with general practitioners, practice managers, and PNs.

2) Recruitment of participants

The PN's sent 20-32 patients, which met the inclusion criteria, a general invitation letter. After randomization, the PN called the patients to give specific information about the group in which the practice was allocated and to ask if they wanted to participate. Patients, who decided to participate, received an information letter and an informed consent form.

D. Intervention

Both components of the intervention, the tool and the SSP, were developed in a previous user-centred design process and tested in an usability and feasibility study [7-9] [11]. See Figure 1 for a picture of the *It's LiFe!* tool and Figure 2 for the course of the interventions.

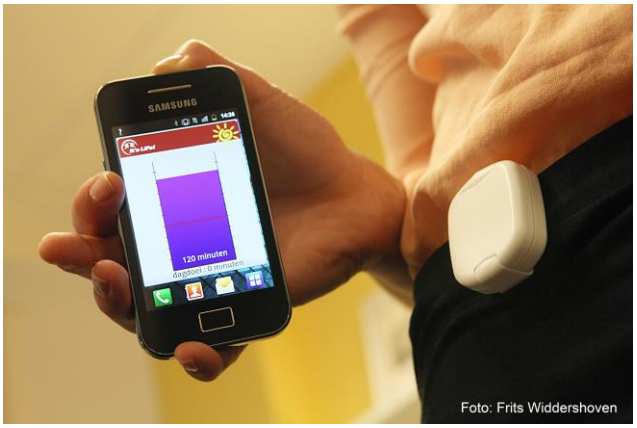

Figure 1. The It's LiFe! activity monitor and Smartphone app

1) Self-management Support Program (group 1 and 2)

The SSP consisted of four consultations with the PN and is based on the Five A's model (Assess, Advise, Agree, Assist, Arrange), a counselling protocol to support self-management in a primary care setting [12]. Before the consultations, the participants received an information booklet with information about the course of the intervention, local PA activities and a questionnaire to assess their activity level (SQUASH) [13]. In the first consultation the PN talked with the participants about the current activity level based on the completed SQUASH questionnaire, and the PN tried to increase the awareness of the health risks of a sedentary lifestyle. The participant received a leaflet with information about PA in relation to COPD/DM2 [14] [15]. During the two weeks in between the first and the second consultation, the PA level of the participant was assessed (the pre-measurement); in group 1, objectively by the tool and in group 2, by filling out a PA diary. Additionally, questions about barriers and facilitators for physical activity were answered during this period. In the second consultation, the PN and participant set a PA goal in minutes per day, based on the pre-measurement and the PN encouraged the participant to set up an activity plan to reach their goals. The third consultation, 8-12 weeks after the start, by mail, phone or in real-life, functioned as an evaluation, PA results, goals, barriers and facilitators were discussed and if necessary adapted. In the last consultation, 16-24 weeks after the start, PA performance was discussed in relation to behaviour changes, habit formation and challenges and goals for the future.

 ISBN: 978-1-61208-384-1

2) The tool (group 1)

The *It's LiFe!* tool consists of a 3 dimensional accelerometer, a Smartphone app and a web application for the participant and the PN. The participants could wear the accelerometer at the hip or in their pocket and see on the Smartphone app their activity in minutes per day. In addition, dialogue sessions were sent which could be answered on the Smartphone app or the web application. After a goal was set in the second consultation, the real time activity results were presented in comparison to the personal goal and automated feedback messages were send based on the achieved results.

E. Data collection

For the data collection the participants received questionnaires and a physical activity monitor three times per post; at baseline, direct after the intervention (4-6 months after the start) and 3 months after completion of the intervention (7-9 months after the start).

F. Outcome measures

The primary outcome measure, minutes of physical activity per day in the moderate to vigorous category was measured with the Pam AM300 (PAM) [16]. Participants were asked to wear the PAM on 8 consecutive days. A measurement was considered valid if the Pam was worn on ≥ 5 days for ≥ 8 hours.

Secondary outcome measures were measured with questionnaires. Quality of life was assessed with the RAND-36 [17] [18], exercise self-efficacy with the Exercise Self-efficacy Scale [19-21] and general self-efficacy with the General Self-efficacy Scale [22]. Health status was measured with the Chronic Respiratory Questionnaire [23] [24] in participants with COPD and with the Diabetes Symptom Checklist Revised [25-27] in participants with DM2.

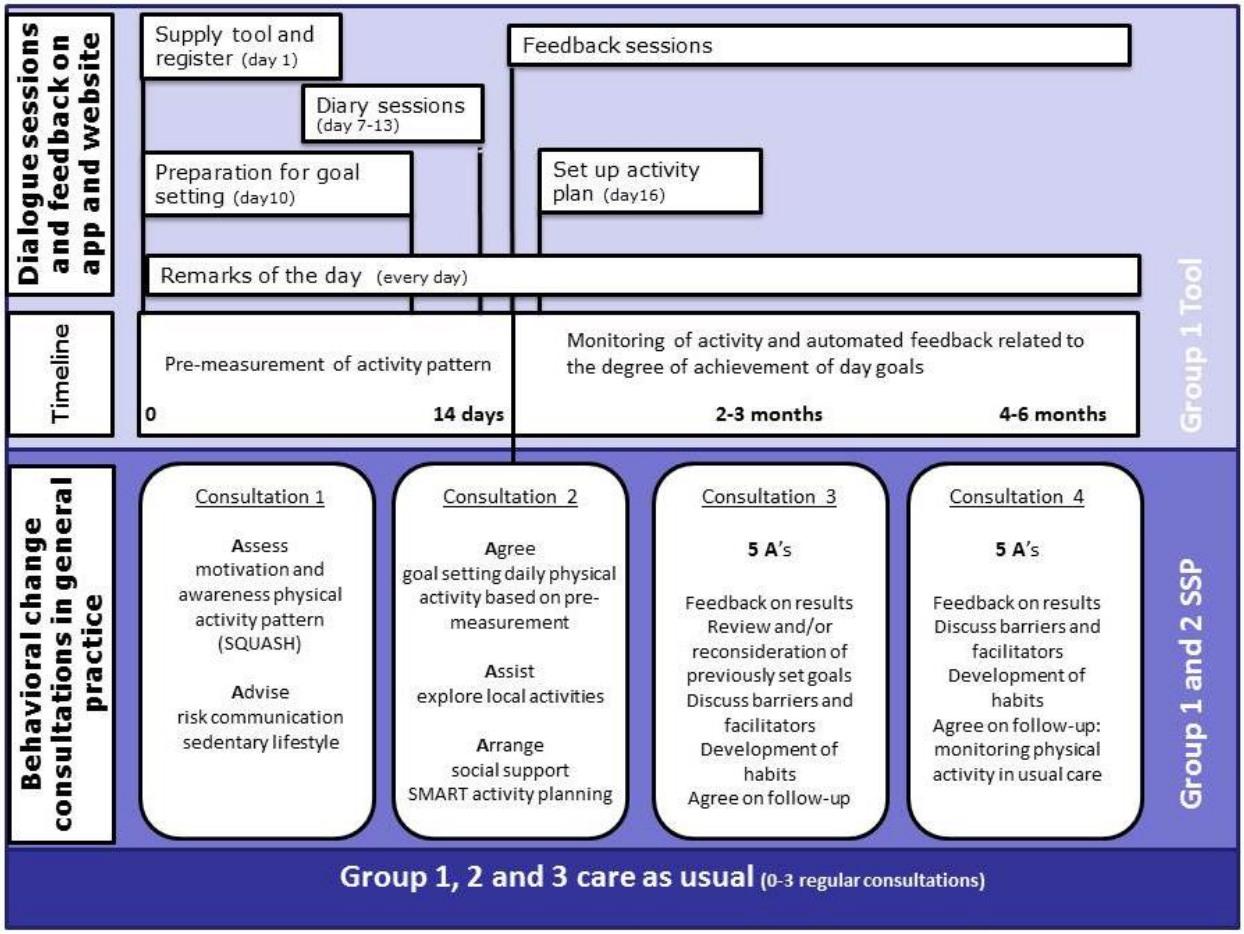

Figure 2. The different components of the (intervention) groups

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G. Statistical analysis

Differences at baseline between the three groups were identified with chi-square, ANOVA and Kruskal Wallis tests, p-value ≤0.10 and those variables were considered as potential confounder in further analysis. To account for dependency among participants in the same general practice multilevel analyses were performed.

The main hypothesis was that the complete intervention, where the tool was embedded in the SSP increases participants' moderate to vigorous physical activity by at least 10 minutes per day, after a 4-6 month intervention period, compared to care as usual and that participants maintained this increase over three months.

ACKNOWLEDGMENT

We would like to thank all participants and practice nurses for their time and efforts. The project is funded by ZonMw. The companies involved in the development of the tool are:

- IDEE Maastricht UMC+ Universiteitssingel 50, 6229 ER Maastricht, the Netherlands, www.idee-mumc.nl
- Maastricht Instruments Ltd. Oxfordlaan 70, 6229 EV Maastricht, the Netherlands, www.maastrichtinstruments.nl
- Sananet Care Ltd. Rijksweg Zuid 22A, 6131 AP Sittard, the Netherlands, www.sananet.nl

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 ISBN: 978-1-61208-384-1