Process Evaluation of a Cluster Randomised Controlled Trial of a Monitoring and Feedback Tool Embedded in a Counselling Protocol to Stimulate Physical Activity

Study protocol procesevaluation RCT *It's LiFe!*

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***Abstract*— This paper describes the study protocol of the process evaluation of a cluster randomized controlled trial of a monitoring and feedback tool embedded in a counselling protocol to increase physical activity of people with COPD or type 2 diabetes in primary care. Both qualitative and quantitative data were collected from participating patients and nurses of the two intervention groups. Functioning and use of the tool were evaluated by system, - and helpdesk logging. The researchers developed questionnaires and interview topics by translating key elements of process evaluations (recruitment, reach, context, fidelity, dose delivered, dose received, - exposure and satisfaction) into structured questions regarding the different components of the intervention; the Self-management Support Program and the use of the tool.**

Keywords- physical activity, behavior change, self-management support, primary care nursing, remote sensing technology, proces evaluation.

I. INTRODUCTION

Physical inactivity is one of the key risk factors for noncommunicable diseases such as type 2 diabetes (DM2) and Chronic Obstructive Pulmonary Disease (COPD). In the global action plan for the prevention and control of noncommunicable diseases, the World Health Organization proposes a 10% relative reduction in prevalence of insufficient physical. All sort of actions are needed to reduce physical inactivity, for example through people-centered primary health care. Primary health care interventions are necessary to empower people with noncommunicable diseases to seek early detection and manage their own condition better, by providing them with tools for self-care and self-management through information and communication technologies such as eHealth or mHealth [1].

In the project Interactive Tool for Self-management through Lifestyle Feedback! (*It's LiFe!*), a monitoring and personalized feedback tool was developed [2] and tested [3][4] according to User Centered Design principles. The tool aims to support patients with DM2 or COPD in achieving a more active lifestyle. The tool consists of three elements:

- a 3D accelerometer worn on the hip;
- an application (app) on a Smartphone;
- a web application[1].

Patients receive different types of feedback concerning the amount of activity in relation to an activity goal (constantly), automatic feedback messages from the system (intermittent), and feedback from their practice nurse (during and in between consultations). Use of the tool is part of a behavior change counselling protocol for practice nurses named the Self-management Support Program (SSP).

The effects of this intervention were evaluated during a cluster randomized controlled trial (RCT *It's LiFe!*) among 24 practices, which were randomized in three groups. The nurses in the two intervention groups provided the SSP, one intervention group with and the other group without the use of the *It's LiFe!* tool. The third group received care as usual. The program was carried out by the nurses during four consultations spread over a period of six months. A detailed study protocol of this effect study has been published in advance [5].

Incorporating a process evaluation is necessary to examine the receipt of the intervention in depth [6-9]. From

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the results of a related feasibility study [10], it was known that for most participating nurses and patients the use of mobile technology would be a new experience. Also a wide range of differences in the performance of the intervention by the nurses and in the adherence of participants in using the tool was expected. Therefore, the aim of the process evaluation of the RCT *It's LiFe!* was to examine:

- who participated in the intervention, who dropped out and for what reasons (recruitment, reach and context);
- to what extent was the intervention executed and received as intended (fidelity, dose delivered, dose received-exposure);
- how participants experienced different aspects of the intervention (both the monitoring and feedback tool and the SSP) (dose received-satisfaction); and what suggestions participants had for improvements.

Section (II) of this paper presents the methods of the process evaluation, which was conducted in parallel with the effect study.

II. METHODS

A. Study design

From December 2012 until July 2014, the process evaluation was conducted amongst the participating general practices in the intervention groups of the RCT *It's LiFe!* The research questions were derived from the following elements of the framework of Saunders: recruitment, reach, context, fidelity, dose delivered, dose received - exposure, and dose received – satisfaction [6][11]. The researchers developed the questionnaires and interview topics by translating these theoretical key elements of process evaluations into structured questions regarding the different components of the intervention (Table 1).

B. Data collection

Table 2 provides an overview of the data collection methods and the timing of the process evaluation.

After informed consent was given by the participant, participant characteristics (i.e., demographics) were gathered by means of self-administered questionnaires. The researchers collected reasons for refusal and dropout through-out the intervention period. To establish exposure, the nurses in both intervention groups were asked to keep record of all consultations. Compliance with the use of the tool was also measured objectively by extracting information from the *It's LiFe!* server. Technical problems were logged by members of the help-desk.

TABLE I. COMPONENTS OF THE INTERVENTIONS

Intervention components	
SSP	**TOOL**
Materials and Instruction	
Instruction booklet about the SSP	Manual and instruction by the PN
Leaflet disease specific information	Instruction movies on the website
Leaflet with local sports,-activities	Helpdesk
Consultations 1-4: different aspects	*The accelerometer*, the app and/or the website
Assessment physical activity level (SQUASH and diary)	Views of physical activity results
Risk communication	Use of the "remarks by measurement of today" option
Goal setting and SMART activity planning	Send and respond to sessions: "registration" "diary" "preparation for goal setting" "set up an action plan" "feedback"
Discussing barriers and facilitators	
Feedback	

Approximately two weeks after the second consultation, all nurses of both intervention groups were interviewed per telephone to ask them about their experiences. In the interviews, which lasted approximately half an hour, special attention was given to the factors that influenced compliance with the intervention at two levels: complying with the advised strategies during the first two consultations and using the monitoring and feedback tool. Directly after the intervention period, a questionnaire about their experiences and the feasibility of the intervention was sent to all nurses and participants.

TABLE II. DATA COLLECTION

Data Collection
Patients
Dropout call researchers (when it occurred)
Questionnaire (after the intervention)
Practice Nurses
Inclusion list (at baseline)
Consultation evaluation forms (per consultation)
Interview (by phone after 2th consultation)
Questionnaire (after the intervention)
Tool
System log file server (continuously)
Helpdesk log file (continuously)

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In choosing the outcomes and measurements of the process evaluation, the potential for increased Hawthorne effects was taken into account by minimizing the contacts between researchers and patients, for example by arranging a website for participating patients and an helpdesk which they could contact in case there were questions or problems. For the same reason, patients were not interviewed during the intervention [12].

C. Data analysis

Quantitative data were analyzed by means of descriptive statistics, and Fishers exact and Pearson Chi-square tests, using the IBM Statistical Product and Service Solutions statistics version 22. Qualitative data (results of open questions and interviews) were analyzed by two researchers (RV, SvdW) independently using NViVo version 9 in order to identify relevant themes. A concurrent triangulation strategy was applied to confirm, cross validate and corroborate the findings. The analysis of the process data took place before the outcome data were analyzed, to avoid bias in interpretation [13].

Hypotheses and possible outcomes of the process evaluation were based on the outcomes of a previous conducted feasibility study in two family practices with 20 participants [10]. We expected:

- Difficulties in finding enough practices who were willing to cooperate in the study;
- A drop-out rate of 10% of the patients and 0% of the practice nurses;
- A complete and acceptable execution of the intervention in more than 50%;
- Less technical problems compared to the feasibility study;
- That more than 75% of the participants in group 1 would use the tool until the end of the intervention;
- An overall satisfaction with the intervention in more than 75% of the participants (both patients and practice nurse).

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