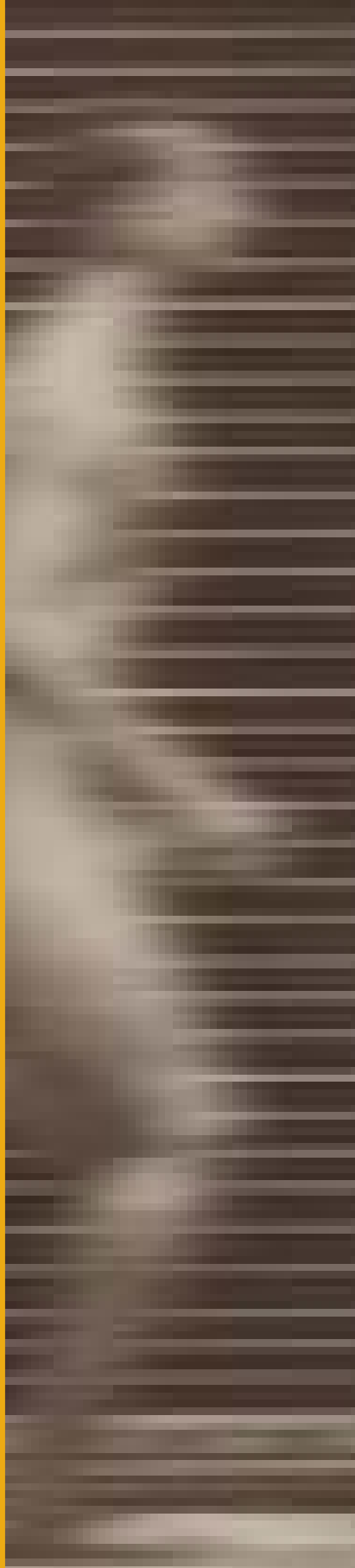
Renée Verwey

Get moving!

Self-management support using mobile technology

A counselling protocol extended with a web-based coaching system to promote physical activity in patients with COPD or type 2 diabetes in primary care:
the *It's LiFe!* study



The studies presented in this thesis were performed at the Department of Health Services Research, School for Public Health and Primary Care (CAPHRI), Maastricht University. CAPHRI is part of the Netherlands School of Primary Care Research (CaRe), which has been acknowledged since 1995 by the Royal Netherlands Academy of Arts and Sciences (KNAW).

The studies described in this thesis are all part of the research project *Interactive Tool for Self-management through Lifestyle Feedback!(It's LiFe!)*. This project was funded by the program 'Disease management chronical illnesses'. Through this program the Netherlands Organisation for Health Research and development (ZonMw) and the Netherlands Organisation for Scientific Research (NWO) want to promote the development of new technology for healthcare. At a later stage, the theme 'New Instruments for Healthcare (NIG)' was added to this program.

The companies involved in the development of the technology were:

- 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

Printing and dissimination of this dissertation was financially supported by the following companies: Maastricht Instruments Ltd, Sananet Care Ltd. and PAM Ltd.

Design cover lay-out by Leana Bekker
Based on the work of Eadweard Muybridge, British photographer known for his pioneering work in photographic studies of motion and in motion-picture projection.

Printing: Datawyse | Universitaire Pers Maastricht

ISBN 978 94 6159 457 0

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PROEFSCHRIFT

ter verkrijging van de graad van doctor
aan de Universiteit Maastricht
op gezag van de Rector Magnificus, Prof. Dr. L.L.G. Soete,
volgens het besluit van het College van Decanen,
in het openbaar te verdedigen
op woensdag 16 september 2015 om 15.15 uur

door

Renée Verwey
Geboren op 10 mei 1961 te Ede

UNIVERSITAIRE PERS MAASTRICHT

Promotor

Prof. dr. L.P. de Witte

Copromotores

Dr. M.D. Spreeuwenberg
Dr. H. J. Tange

Beoordelingscommissie

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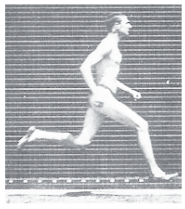

CHAPTER 1

General introduction

Two major challenges facing health-care systems nowadays are an aging population and increasing prevalence of chronic conditions. Before the start of the *It's LiFe!* project in 2010, it was estimated that approximately 28% of the Dutch population suffered from one or more chronic disease.[1] At present, figures from CBS statistics Netherlands show that nearly half of the Dutch population suffers from at least one chronic disease. This growing number of people with chronic conditions and their use of health care causes pressure on available health-care resources.[2] People with a chronic disease are among the main users of the Dutch health-care system,[3] and in particular the number of people visiting a general practitioner or practice nurse for type 2 diabetes mellitus (DM2) has increased substantially in recent years.[4]

To counter this development, there is a growing emphasis on the promotion of healthy behaviours and self-care or self-management by patients with long-term conditions.[5] The Dutch Ministry of Health, Welfare and Sport has identified five priorities for improving public health: the prevention of obesity, diabetes, depression, smoking and alcohol abuse. In 2011, these priorities were extended with a specific focus on the promotion of physical activity.[6] More recently, based on the National eHealth Implementation Agenda (2014), the ministry has formulated the ambition that within five years, 75% of the chronically ill, such as patients with diabetes or chronic obstructive pulmonary disease (COPD), who are motivated and able to do so, will independently perform measurements, often in combination with remote data monitoring by the primary care provider, with the purpose of following the progress of the disease and, by getting regular feedback, understand the impact of their behaviour on their illness.[7] This policy represents a major directive for primary care providers: a focus on physical activity and self-management support using eHealth. To realise this ambition, the development and implementation of mobile technology embedded in primary care is an important prerequisite. Therefore, this thesis will focus on the promotion of physical activity and self-management support in patients with type 2 diabetes or COPD who are treated in primary care, using mobile technology.

Physical (in)activity

Physical activity is defined as any bodily movement produced by skeletal muscles that requires the expenditure of energy. Physical activity includes exercise as well as other activities that involve bodily movement and is done as part of playing, working, active transportation, house chores and recreational activities.[8] In 2011, the proportion of Dutch inactive adults that reported non-compliance with the Dutch Public Health Physical Activity Guidelines[9] was approximately 41%. Groups who did not meet the guidelines were more often non-workers, persons of non-Dutch origin, persons with chronic disease(s) and persons who were overweight.[10]

The physical activity recommendations for adults are at least 30 minutes of moderate-intensity aerobic physical activity (equivalent to brisk walking and noticeably accelerating the heart rate) on five days of the week and at least 20 minutes of vigorous-intensity aerobic physical activity (equivalent to jogging, causing rapid breathing and a substantial increase in heart rate) on two days of the week or an equivalent combination of moderate- and vigorous-intensity activity. Aerobic activity should be performed in bouts of at least 10 minutes duration. In addition, every adult should perform activities that maintain or increase muscular strength and endurance a minimum of two days each week. When older adults cannot commit to the recommended amounts of physical activity due to health conditions, they should be as physically active as their abilities and conditions allow.[11] Participation in physical activity is influenced by a diverse range of factors: personal (biological and psychological attributes), social (family, affiliation group and work factors) and environmental (contexts for different forms of physical activity and availability of relevant settings and opportunities).[12]

Physical inactivity has major health effects.[13] Because physical inactivity is the fourth leading risk factor for global mortality, the World Health Organization agreed on targets which include a 10% decrease in physical inactivity by 2025.[14] The importance of encouraging physical activity is crystal clear. People who are insufficiently active have a 20 to 30% increased risk of premature death compared to people who adhere to the guidelines.[15] All forms of physical activity, be it structured (e.g. exercise performed in a special facility) or unstructured (e.g. activities of daily living), are associated with meaningful health benefits.[16] Analysis shows that, if the effects of age, gender and disorders are taken into account, the risk of inactive people rating their own health as less good is 2.6 times higher than people with a healthy lifestyle.[17] There would be a substantial improvement in public health if large numbers of people were to increase their level of physical activity in line with the recommendations.[18]

The Advocacy Council of the International Society for Physical Activity and Health identified the 'best investments that work for physical activity'. The promotion of physical activity integrated into primary care is one of them, alongside investments in the field of public education, transport and urban design. Health-care systems should include physical activity as an explicit element of regular behavioural risk factor screening, patient education and referral and this should be integrated with communicable disease management systems.[19]

Physical activity promotion in people with type 2 diabetes or COPD

Percentages of diabetic patients meeting recommendations for physical activity range between 30 and 50%.[20-22] It is estimated that no less than 10% of the incidence of diabetes in the Netherlands can be attributed to inactivity.[23] Diabetes patients often suffer from obesity, and physical activity has a beneficial effect on body weight and body

fat percentage, on blood pressure, on glucose tolerance and insulin sensitivity, and it reduces the risk of cardiovascular disease.[24,25]

For people with COPD these figures are comparable: 40% of the people with COPD have a physical activity level considered too low to maintain good health.[4,26] Symptoms such as dyspnoea and muscle fatigue lead to exercise intolerance, which, together with behavioural issues, triggers even more physical inactivity.[27-29] For people with COPD, regular physical activity slows the decline of lung function, reduces the frequency of exacerbation and hospitalization and the risk or progression of co-morbidities, and improves health-related quality of life.[30,31] All this indicates that increased attention to the promotion of physical activity is necessary to minimise the burden of both diseases.[32] For the above mentioned reasons, (inter)national care standards and guidelines include the promotion of physical activity.[33-36]

Although patients usually know that they should improve their lifestyle in terms of physical activity,[37] adhering to guidelines for healthy exercise is challenging.[38] As mentioned before, obesity in patients with type 2 diabetes and dyspnoea and muscle fatigue in COPD patients are additional complicating factors in becoming more physically active. Therefore, primary care providers should support people in meeting this challenge,[39,40] by providing physical activity counselling. This counselling should include practical advice to patients and families on the benefits of increased levels of physical activity, combined with support to help patients initiate and maintain healthy behaviours.[41-44] But physical activity counselling is not yet a standard part of primary care. To combat the inactivity of patients with chronic conditions, it would be a good thing if doctors and nurses considered exercise as 'medicine'; promoting physical activity should be seen and dealt with in the same way as pharmaceuticals and other medical interventions.[45]

Much knowledge is already available about physical activity interventions in primary care; effective interventions for increasing physical activity include at least one consultation, with brief negotiation or discussion to decide on reasonable, attainable goals, a follow-up consultation, and targeted information.[46] These interventions are more likely to be effective if they are firmly rooted in health behaviour change theory.[47] Additionally, reviews have suggested that individually tailored feedback (i.e. feedback based on the user's own characteristics and advice) is more likely to be effective than generic information about physical activity.[48]

Research into correlates (factors associated with activity) or determinants (those with a causal relationship) has shown that age, sex, health status, self-efficacy and motivation are associated with physical activity.[49] It is therefore important that the promotion of physical activity is tailored to these specific factors. In addition, other studies have demonstrated that interventions to promote physical activity should emphasise behavioural strategies over cognitive strategies.[50] Furthermore, interventions should reach beyond the consulting room; they should affect people's daily lives and support self-management. But unfortunately, high drop-out rates have been reported in

intervention trials on physical activity,[51-53] and also, in the long run, results are disappointing as patients seem to have difficulty in adhering to a new lifestyle. Therefore there is an emerging need for well-designed primary care interventions that are aimed at self-management support related to physical activity.

Self-management support

According to the definition of Lorig and Holman, self-management support means a dynamic, interactive and daily process aimed at helping patients maintain a wellness perspective by engaging in a set of tasks: medical management (maintaining, changing, and creating new meaningful behaviours or life roles) and emotional management (dealing with the emotional consequences of having a chronic condition).[54] The success of physical activity counselling depends on the degree to which patients succeed in executing these self-management tasks. Therefore, primary care providers should support self-management by involving patients in decisions on self-management, and seek together with the patient lifestyle interventions that fit with the motivation, needs and capabilities of the patient.[55,56]

Since 2010, a broad innovative approach to disease management based on care standards has been implemented in primary care in the Netherlands. This disease management approach is based on the Chronic Care Model, which is aimed at transforming primary care towards a more proactive care, not only focussed on acute illness but also on maintaining health and preventing or postponing disease through a planned, long-term and proactive approach, focussing on keeping an individual as healthy as possible. The model identifies the essential elements of a health-care system that encourage high-quality chronic disease care. These elements are the community, the health system, self-management support, delivery system design, decision support and clinical information systems. Evidence-based change concepts under each element, in combination, foster productive interactions between informed patients who take an active part in their care and providers with resources and expertise.[57] One of these elements, delivery system design, has led to a greater role for the practice nurse in the care of the chronically ill, particularly regarding lifestyle counselling.[58]

Lifestyle counselling to encourage people to acquire self-management skills is essential in the Chronic Care Model and it often includes the 'Five A's counselling technique' (Assess–Advise–Agree–Assist–Arrange).[59,60] This consultation appraoch served as the basis of the intervention that is presented in this dissertation. But patients visit the family practice occasionally, while behaviour change needs day-to-day attention, therefore mere advice from the practice nurse, or the integration of a physical activity counsellor into the primary care team, does not result in significant behavioral change when it comes to increasing physical activity.[61,62] Therefore, the use of technology by patients in everyday life could complement these actions.

Mobile technology

New technological developments emerge at a rapid pace: last year 64% of the Dutch population used mobile Internet[63] and more than 40,000 health apps for smartphones are available at present.[64] This uptake of mobile technology offers opportunities for self-monitoring of physical activity, new methods of self-management support and remote delivery of interventions, thereby improving patient care and changing the traditional organisation of care processes.[65,66] The range of novel and engaging intervention strategies, such as the use of accelerometers for monitoring and smartphone applications for feedback, and user perceptions on their usefulness and viability, highlights the potential that mobile technology has for the promotion of physical activity.[67-71] A review by Cowan et al. revealed that in 2012, 127 different apps with a high user rate, exclusively for quantifying exercise, were already available on the market.[72] Therefore, theoretically grounded behaviour change interventions that recognise and act on the potential of smartphone technology could provide investigators with an effective tool for increasing physical activity.[73] But, although these developments are promising, health-care users should be more aware of the opportunities available,[66] and research is needed to clarify how technology can be used to maximise its benefits.[67] But with the growth of Web-based and mobile technology opportunities comes the daunting responsibility of designing interoperable, easy-to-use, engaging and accessible applications.[74] A well-known approach in the development of technology to meet all these criteria is the so-called 'user-centred design' process.

User-centred design

User-centred design (UCD) is a design philosophy in which the end-user's needs, wants and limitations are a focus at all stages within the design process and development life cycle. An important condition for designing according to these principles is the involvement of prospective users in the development of new technology.[75] Products developed using the UCD methodology are optimised for end-users and emphasis is placed on how the end-users need or want to use a product instead of forcing the end-user to change his or her behaviour to use the product. The main principle of user-centred design is the active involvement of users from early development stages onwards. This involvement of users in the development and testing of technologies is associated with significant benefits such as: the generation of ideas by users; an improvement in system designs and user interfaces; considerable improvement in the functionality, usability, and quality of the technology; access to and knowledge about user perspectives.

Other principles of user-centred design are searching for design solutions in an iterative way while working within a multidisciplinary group, and developing and

evaluating in a real-life context. Usability tests are essential for improving the usability and workflow integration, and they are widely recognised as critical to the success of interactive health-care applications.[76] The mobile technology that is presented in this thesis is therefore developed in a user-centred way, working closely with two patient representatives from the Dutch Diabetes Association and the Netherlands Asthma Foundation.

Objectives and outline

This dissertation will focus on the development, testing and evaluation of physical activity counselling by practice nurses in primary care with the use of mobile technology. The main objectives are:

1. To develop a counselling protocol, combined with the use of a monitoring and feedback tool for patients, together with an additional coaching system for practice nurses to stimulate the physical activity of COPD and diabetes type 2 patients in primary care.
2. To test the usability and feasibility of the tool and the additional coaching system embedded in this counselling protocol.
3. To evaluate the effectiveness of this counselling protocol with and without the use of the tool on physical activity, (exercise) self-efficacy and quality of life in a cluster randomised controlled trial.
4. To conduct a process evaluation in parallel with the trial to examine the reach, implementation and satisfaction regarding this counselling protocol with and without the use of the tool.

In addition, in a second dissertation based on the *It's LiFe!* project, written by my colleague Sanne van der Weegen, the research questions related to objectives three and four are identical and jointly examined. Her dissertation specifically focusses on the development and usability testing of the monitoring and feedback tool for the patients and on the validation of the accelerometer as part of this tool, whereas in this thesis the focus is on the development and testing of the counselling protocol and the additional coaching system for practice nurses.

In the first three chapters the development of the counselling protocol and the monitoring and feedback tool are presented. Chapter 2 describes the development of the counselling protocol for practice nurses in primary care. This protocol aims to support COPD or DM2 patients in achieving a more active lifestyle (objective 1). Chapter 3 describes the development and usability testing of the nurses' part of the tool: the coaching system, called the *It's LiFe!* monitor, which enables the nurses to view physical activity results from the patients who are using the *It's LiFe!* tool (objective 1). In

Chapter 4, the pilot study is presented in which the technical performance, acceptance and user satisfaction of the tool combined with the counselling protocol in daily practice are investigated (objective 2).

The second chapters focus on the evaluation of the tool embedded in the counselling protocol. Chapter 5 describes the study protocol of the three-armed cluster randomised controlled trial in 24 family practices (objective 3), while in Chapter 6 the effects of this protocol and the added value of the tool on patients' physical activity levels, quality of life and (exercise) self-efficacy are presented (objective 3). As a last part of the evaluation, in Chapter 7 a process evaluation conducted in the two intervention groups of this trial is described. In this study the reach, the implementation and satisfaction with the two aspects of the intervention – the counselling protocol, which was delivered by practice nurses in intervention groups 1 and 2, and the use of the tool, which was delivered in group 1 – were investigated (objective 4).

The two last chapters of this dissertation provide a summary and a discussion of the main findings in the context of existing literature, followed by implications for research, practice and policy (Chapter 8), and finally, in Chapter 9, the possibilities for valorization of knowledge that was gained during the research presented in this dissertation are explored.

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CHAPTER 2

Upgrading physical activity counselling in primary care in the Netherlands

This chapter was published as:

Verwey R, van der Weegen S, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. Upgrading physical activity counselling in primary care in the Netherlands. *Health Promot Int.* 2014;1:11.

Abstract

Aim The systematic development of a counselling protocol in primary care combined with a monitoring and feedback tool to support chronically ill patients to achieve a more active lifestyle.

Methods An iterative user-centred design method was used to develop a counselling protocol: the Self-management Support Programme (SSP). The needs and preferences of future users of this protocol were identified by analysing the literature, through qualitative research, and by consulting an expert panel.

Results The counselling protocol is based on the Five A's model. Practice nurses apply motivational interviewing, risk communication and goal setting to support self-management of patients in planning how to achieve a more active lifestyle. The protocol consists of a limited number of behaviour change consultations intertwined with interaction with and responses from the It's LiFe! monitoring and feedback tool. This tool provides feedback on patients' physical activity levels via an app on their smartphone. A summary of these levels is automatically sent to the general practice so that practice nurses can respond to this information.

Conclusions A SSP to stimulate physical activity was defined based on user requirements of care providers and patients, followed by a review by a panel of experts. By following this user-centred approach, the organization of care was carefully taken into account, which has led to a practical and affordable protocol for physical activity counselling combined with mobile technology.

Introduction

Increased physical activity of people with chronic diseases has positive effects on prognosis and quality of life.[1,2] It is, however, a challenge to adhere to guidelines for healthy exercise.[3,4] By integrating physical activity counselling into routine practice, primary care providers can support patients in meeting this challenge.[5,6] The majority of chronically ill people in the Netherlands are treated by practice nurses, supervised by their General Practitioner (GP). The effects of lifestyle counselling depend mainly on the degree to which patients succeed in executing their self-management role. Therefore, healthcare providers should involve patients in self-management decisions and seek lifestyle interventions that fit the motivation, needs and capabilities of the patient.[7-9]

Physical activity counselling has the potential to produce increases in activity levels in the short term.[10] However, the evidence about which methods of exercise promotion work best in the long term is still limited.[11] Although primary care providers recognize the importance of physical activity counselling[12,13], numerous barriers need to be addressed. The Five A's model (Assess, Advise, Agree, Assist and Arrange) is a counselling protocol that could be helpful in supporting self-management in a primary care setting.[14,15] In the Five A's specified model for physical activity promotion, the care provider first assesses the patient's current physical activity level, as well as any contraindications to physical activity and the patient's readiness to change, followed by providing a tailored counselling message and an agreement with the patient by collaborating on a plan of action. Finally, the care provider provides educational materials to support change and arranges a follow-up visit to motivate the patient and to evaluate progress.[16,17] The Five A's model is based on several behaviour change theories, namely the Theory of Planned Behaviour[18], the Goal-Setting Theory[19], the Self-Determination Theory[20] and Motivational Interviewing.[21]

The most common method of physical activity promotion is verbal advice, followed by print- and computer-based interventions.[12] Computer-based physical activity interventions may be an effective way to provide physical activity counselling without increasing the time demands on primary care providers.[22] Although computer-based counselling may be feasible, the circumstances of use with respect to the target group and its integration into the care process have to be clarified during the development of new technology.[23,24] Therefore, it is recommended to develop technology in a user-centred way and to collect user requirements by composing *use cases*.[25] Use cases are narrative scenario´s with the description of four main elements (PACT): the people involved (P), their activities (A), the context (C) and the technology used (T).[26]

Interventions incorporating technology that is readily accessible on a daily basis for monitoring activity levels, such as computers or mobile phones, may facilitate long-term follow-up[10,27] and may also support care providers to coach patients in establishing behavioural change.[28] We therefore developed a monitoring and feedback tool called *It's LiFe!* with the aim of integrating this tool in physical activity counselling in primary care.

The basic ideas behind the tool were providing an objective measurement of physical activity via an accelerometer for patients and their care providers, and collaborative goal setting and automatic feedback via an application on a smartphone, combined with human feedback from the care provider.

It is not known how to combine the use of this mobile technology with face-to-face counselling based on the Five A's model, and how this combination could be integrated in routine practice, according to primary care providers and patients. Therefore the following research questions were posed:

- How can the use of the monitoring and feedback tool to stimulate physical activity be integrated in a counselling protocol based on the Five A's model?
- How can this counselling protocol be integrated in the care process?

Method

Approach

The project focused on patients with Chronic Obstructive Pulmonary Disease (COPD) or type 2 diabetes (DM2) and their care providers in primary care. A user-centred design process (Figure 1) was followed to elicit the requirements of the counselling protocol and the tool. Two patient representatives, from the Netherlands Asthma Foundation and the Dutch Diabetes Association, participated in the research group to provide feedback on every development stage. This group consisted of researchers with expertise in nursing, movement science, psychology, family medicine and implementation science.

The arrows in Figure 1 indicate that the development was an iterative process. This paper reports the results from phase A (Stages 1-3), in which the objective was to establish a counselling protocol named the Self-management Support Programme (SSP), based on current insights from the literature, preferences of users and comments from experts. Simultaneously in collecting the user requirements for the SSP also the user requirements for the tool were collected.[29]

Recruitment and respondents

Sixteen care providers, representing all the involved disciplines working in primary care and treating patients with COPD and/or DM2, 15 patients and 12 experts were recruited by a snowball sampling approach through the network of researchers and the patient representatives.

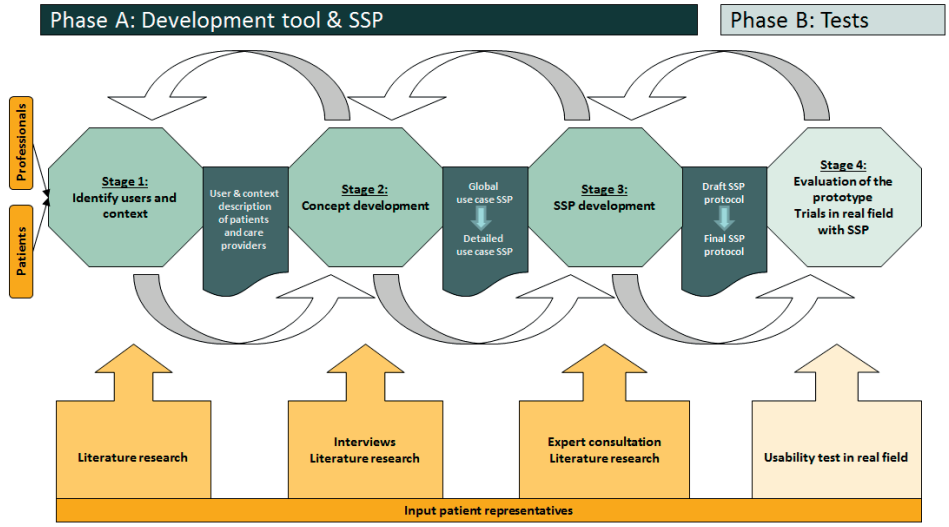

Figure 1 The *It's LiFe!* User Centred Design Process

Data collection and analysis

The user requirements for the SSP were collected over three stages, from November 2010 until December 2011. Various qualitative methods of data collection were used (Figure 1).

Stage 1

Stage 1 started with a literature review to identify the users and their context, resulting in a user and context description. Users were projected into the Five A's model and its contextual restraints were identified. Based on care standards for COPD and DM2 care, a use case was written by the researchers, and this document was verified by the patient representatives and by two physicians and a nurse practitioner. The use case consisted of a description of patients, healthcare providers and assumptions about care as usual, plus the basic ideas of the technology, followed by a narrative story of the course of all consultations in which all elements of the Five A's model were incorporated, including fragments of the conversation between a patient who started to use the tool and his practice nurse and GP.

Stage 2

During Stage 2, the care providers were interviewed about the use case in two rounds.[30] In the first round we interviewed a cross section of professionals involved in the care for COPD and DM2 patients, in the second round only those responsible for self-management support. In the first round, 11 care providers were interviewed with open questions. In the second round, five practice nurses were interviewed with more specific

questions that emerged from the open interviews (Table 1 interview questions) and photos of a prototype of the tool were shown to them. The user requirements for the SSP were completed with results from interviews with 15 patients with COPD or DM2. Interviews were audiotaped and transcribed. Open coding was applied to the first four interviews by two reviewers separately (R.V., S.v.d.W.), using the QSR NVivo 2 software package. Differences were discussed and revised based on mutual agreement, and a coding scheme was determined. The remaining interviews were coded accordingly and analysed following a directed content analysis method.[31] As a next step, the results of the interviews were discussed in the research team together with the patient representatives and with the technical team. Decisions about the issues were made based on progressive insight and in mutual consensus. Based on the results of the interviews and the minutes of these meetings the global use case was specified.

Table 1 Interview questions

Stage 2 Interview topics first round
What does it mean: maintaining a healthy lifestyle (physical activity) while suffering from DM2 or from COPD?
What does "care as usual" for people with DM2 or COPD look like in this region of the Netherlands and what new developments could interact with the project?
How do care providers support self-management of patients with DM2 or COPD concerning physical activity, which disciplines are involved in this process and how do they cooperate with each other?
What is the opinion of care providers towards the main aspects of the Self-management Support Program: motivational interviewing, risk assessment and goal setting?
What is the general attitude of care providers to using technology in health care and what are their ideas about using technology to support self-management in maintaining a healthy lifestyle?
How do care providers define their role when using such technology and what is the opinion of care providers towards the global use case?
Interview topics second round
What is the opinion of practice nurses towards the specified use case?
Which specific patient characteristics should be taken into account when developing the SSP and which patients could benefit most from this way of supporting self-management using the intended technology?
What is the usual content and duration of the consultations and how could the practice nurse give more attention towards supporting the physical activity of patients?
What is the opinion of practice nurses about applying behaviour change techniques such as risk assessment and motivational interviewing?
How would practice nurses like to use the technology and what is their opinion about giving feedback in between consultations?
What enhancing and constraining factors do practice nurses foresee when implementing this program?

Stage 3:
Questions to the experts

What is your opinion about:
- The self-management support programme?
- The developed technology, the *It's LiFe!* tool?
- The combination of both?

Are specific aspects with regard to exercise of patients with DM2 and COPD taken into account?

What do you think of the description of the current demand and supply of care for those patients? Do you have any suggestions for additions or improvements that may affect the application of the intervention?

Is becoming more physically active optimally supported with this intervention in the two groups? Do you have any ideas for additions or improvements?

Is self-management optimally supported by the target groups? Do you have any ideas for additions or improvements?

The consultations follow a certain approach, called the Five A model. What is your opinion about this model? Do you find this model suitable for this situation?

The intervention includes several behaviour modification techniques. What is your opinion? Are those applicable in this context? Is it possible to integrate these techniques in the consultations?

The intervention will be carried out by the practice nurse. What do you think of that choice? Do you consider practice nurses capable to perform this after the described introduction of the intervention?

The intervention includes some (extra) consultations with the practice nurse. What do you think of that? Is this enough or too much? Is this feasible?

In some cases, the consultation approach will also be performed during the regular consultations, which than will take 10 min longer. Is this feasible? Is this desirable?

What do you think of the period (6 months) and the distribution of the consultations over this period?

What is your opinion about the way the intervention will be introduced to the practice nurses? Do you recommend specific attention to certain aspects?

Stage 3

During stage three, the specific elaboration of the Five A's model towards physical activity promotion was used to write detailed instructions for practice nurses per consultation,[16,17] and the counselling techniques were specified according to the behaviour-change techniques as defined in the taxonomy of Abraham and Michie.[32] Subsequently, 12 experts with a wide range of expertise were asked for their opinion about this draft SSP (Table 2.). This detailed counselling protocol, with a description of the activities of the patient and the practice nurse, instructions for the course of the consultations and a theoretical underpinning of the main issues was the input for the experts' consultation. It was commented upon by a group of 12 experts during face-to-face and telephone consultations and mail correspondence. Using open questions their opinion was asked about the aim of the protocol, the number and content of consultations needed, the counselling techniques and about the introduction of the protocol to practice nurses (Table 1 Interview questions). Expert consultations were

audiotaped and summarized and a member check was carried out, by asking the experts if they agreed upon this summary. Subsequently the results of the expert consultations were discussed in the research team together with the patient representatives. Based on the consultations of the experts and the minutes of this meeting, the counselling protocol was then adjusted into a final version, which is presented in this paper.

Results

The results are reported based on the successive steps which were taken during the stages.

Stage 1 The global use case

The practice nurse, in collaboration with the GP, identifies patients who could benefit from increased physical activity. These patients are invited for an extra consultation to assess their physical activity and their motivation to change, to inform them about the risks of a sedentary lifestyle and to provide them with the tool. In the following three months, another four consultations take place to support patients with setting concrete personal activity goals, and giving feedback on the physical activity results, which are accessible to the practice nurse via a secured website.

Stage 2 A detailed use case based on interviews with care providers

The characteristics of the interviewees are summarized in Table 2. The mean age of the professional respondents was 42, most were female, and 10 out of 16 treated both COPD and DM2 patients. The results of the interviews were divided into three themes: care as usual, the SSP, and the combination of the tool with the SSP. The subjects which were discussed more often (main issues) are summarized in Table 3.

'Care as usual'

Barriers for paying attention to physical activity during regular consultations are co-morbidity or other limitations of patients, and the assumption of the respondents that nowadays the patient decides on the topics of the consultation. Many patients do not perceive physical activity as an important issue and tend to overestimate their own physical activity.

Respondents agreed that the standard for healthy exercise (30 minutes moderate intensity per day, five days per week) is an unrealistic goal for most patients, and nobody uses a standardized assessment for physical activity.

According to the respondents, people with COPD (GOLD 1 and 2) experience a low disease burden. They adapt unnoticed to their declining physical condition, and often

perceive that they are doing pretty well. This group could benefit most from an active lifestyle. Exacerbations and related hospitalizations are viewed as trigger points to start a lifestyle intervention.

Table 2 Characteristics of the respondents

Stage 2 Interviews

Care providers	Overall (n=16)	First round (n=11)	Second round (n=5)
Profession			
Practice Nurse (PN)	7	2	5
Diabetes Nurse (DN)	2	2	0
Pulmonary Nurse (PN)	2	2	0
General Practitioner (GP)	3	3	0
Physiotherapist (PT)	2	2	0
Age			
Years	42 (26-58)	42 (26-58)	42 (29-53)
Sex			
Male	4	4	0
Female	12	7	5
Treating patients with			
COPD	6	6	0
DM	4	2	2
Both	6	3	3
Patients	Overall (n=15)	First round (n=8)	Second round (n=7)
Diagnosed with			
COPD	7	4	3
DM	8	4	4
Age			
Years	62 (46-76)	63 (55-76)	62 (46-72)
Sex			
Male	6	4	2
Female	9	4	5

Stage 3. Expert consultation

Experts	Overall (n12)
Expertise	
Movement science, physical activity	3
Primary care	2
Health education and promotion and use of e-health	2
Medical specialists in COPD and diabetic care	2
Self-management	1
Motivational interviewing	1
Goal setting	1

The Self-management Support Program

Respondents all agreed that the SSP should focus on patients at an early stage of the disease, before the emergence of potential co-morbidity. They indicated that giving the practice nurse a central role in the SSP is right, although the physiotherapists had doubts about their ability to adequately assess the physical activity level. The majority saw only a role for the physiotherapist in the case of severe breathing problems of COPD patients. Also, the role of the GP in lifestyle counselling was regarded as limited.

> *It is the task of the practice nurse, she is much better than me at doing that; by the way, she has time for it*
> *[GP, aged 51, interview 9].*

Motivational interviewing is considered a positive way of approaching people with chronic diseases and this technique is often used. But respondents differed in defining this technique.

> *The patient sets the agenda of the consultation.*
> *[PN, aged 57, interview 1].*
> *I search for intrinsic motivation, tickle them: 'Are you really feeling OK?'*
> *[GP, aged 42, interview 11].*

Most of the respondents were sceptical about the effects of risk communication. Comments were that it is counterproductive, that there are often too few clinical data available to clearly outline certain risk factors, and that talking about risks frightens people.

Although all respondents were positive about self-management support, some suggested that there is a category of patients who do not take responsibility for self-management, but simply ask for clear directives. Overall, however, giving straight advice is not seen as the best way of supporting patients. Respondents indicated that collaborative goal setting is an essential part of counselling.

Most respondents were generally positive about the use case, but they indicated that three or four extra consultations were far too many. Furthermore, a few practice nurses were not enthusiastic at all about the focus on physical activity.

> *It is the responsibility of the patient to see to it that he or she gets enough exercise. That is not my responsibility; I have more than enough other tasks to do [DN, aged 34, interview 10].*

Application of the tool within the SSP

Most respondents liked the idea that using the tool would give both patient and practice nurse the ability to monitor physical activity levels.

With this tool I can give these patients something tangible to help them improve their daily activity levels
[PN, aged 47, interview 12].

They saw the added value compared with self-reported activity, but practice nurses had doubts about giving feedback in between consultations. Furthermore, they argued that the tool was probably more suitable for younger patients who are used to mobile technology. The most important arguments against the SSP were a lack of time and money. Respondents indicated that the programme should be reimbursed by insurance companies, and almost every practice nurse complained about a heavy caseload.
As a next step, the use case was specified and adjusted by:

- adding a standardized questionnaire to assess the level of physical activity of patients;
- specifying risk communication through an information chart with both the advantages of an active lifestyle and the disadvantages of a sedentary lifestyle;
- reducing the number of visits;
- providing the patients with interactive sessions via the tool instead of a real consultation, to inform them about the pros and cons of physical activity, confidence, behaviour change strategies, self-efficacy, family and peer influences, enjoyment, activity choices, and environmental influences related to physical activity (based on the PACE).[33]

Table 3 Main issues about the use case

	Stage 1. Global use case	Stage 2. Detailed use case	Stage 3. Draft protocol	Final SSP
Aim of the programme	*Increase physical activity (PA) towards the norm*	*Increase PA, less towards the norm and more focused on personal abilities*	*More focus on PA in daily living, less towards exercise and sports*	*Also prevent longer periods of continuous inactivity*
Approach	*Professional driven*	*Professional driven*	*Professional and patient driven More flexibility*	*More patient driven More flexibility*
Patients' characteristics	*All COPD and DM patients without severe co-morbidities*	*All COPD and DM patients aged < 70 without severe co-morbidities*	*All COPD and DM patients (aged < 70) without severe co-morbidities*	*All COPD and DM patients (aged < 70) without severe co-morbidities, willing to change their lifestyle*
Assessment of physical activity level	*On professional indication without standardized assessment*	*Collaborative using a standardized assessment and objective results of the tool*	*Collaborative using a self-assessment questionnaire and objective results of the tool*	*Collaborative using a self-assessment questionnaire and objective results of the tool*

	Stage 1. Global use case	Stage 2. Detailed use case	Stage 3. Draft protocol	Final SSP
When to apply the programme	*To all patients*	*Preferable at an early stage of the disease*	*Preferable at an early stage of the disease*	*Every patient who is motivated*
Which professional applies the programme	*The GP, practice nurse and/or the physiotherapist*	*Preferably the practice nurse*	*Practice nurse*	*Practice nurse*
Which behaviour change techniques are used	*Motivational interviewing* *Risk communication* *Goal setting*	*Motivational interviewing* *Risk communication* *Goal setting based on subjective baseline measurement and objective measurement by the tool*	*Motivational interviewing* *Risk communication* *Goal setting based on subjective baseline measurement and objective measurement by the tool, extended with a dairy*	*Motivational interviewing* *Risk communication* *Goal setting based on subjective baseline measurement and objective measurement by the tool, extended with a dairy*
Time frame	*3 months*	*3 months*	*3 months*	*6 months*
How many consultations and in what way	*5 (3-4 extra)* *2 by telephone*	*4 (2-3 extra)* *all face-to-face*	*4 (2-3 extra)* *2 by telephone or mail depending on the preference of the patient*	*Min 2 and max 3 (1-2 extra) number on preference of the patient* *2 by telephone or mail depending on the preference of the patient*
Monitoring and feedback in between consultations	*Yes*	*No, but voluntary, depending on preference of the practice nurse*	*Voluntary, depending on preference of the patient and practice nurse and intermittent automatic feedback by the tool*	*Voluntary, depending on preference of the patient and practice nurse and intermittent automatic feedback by the tool*

Stage 3 Towards a 'draft SSP'

Experts were, to a large extent, positive about the draft SSP and the focus on stimulating physical activity in daily life. Two experts emphasized the growing evidence about the negative effects of long unbroken periods of inactivity, which is also mentioned in the literature.[34] Comments were most critical about the feasibility of the extra consultations, and the expertise of practice nurses to apply motivational interviewing. Another comment was that the programme was too directive and therefore not really supporting self-management and not focusing on patients' own needs and choices. Given the feedback, the SSP was adjusted on the following points by:

- giving more attention towards personal abilities of patients and the need to avoid periods of continuous inactivity;
- giving more clarity about the motivational interviewing technique and mainly focusing on patients who are in the contemplation and preparation stages of change of the Transtheoretical Model of Behaviour Change;[35]
- extending the programme over a period of six months (so that more than one regular consultation is included);
- providing the patient with a leaflet with local facilities for physical exercise;
- giving the programme more flexibility (number and timing of consultations) to follow the needs and preferences of the patients;
- supporting the patient with automatic feedback via the tool so that the practice nurse can focus on giving personal feedback during consultations.

The end result: a self-management support programme

The end result of stage 3 of the requirements analysis is summarized in Table 3 column final SSP. The combination of the programme with the tool is depicted in Figure 2.

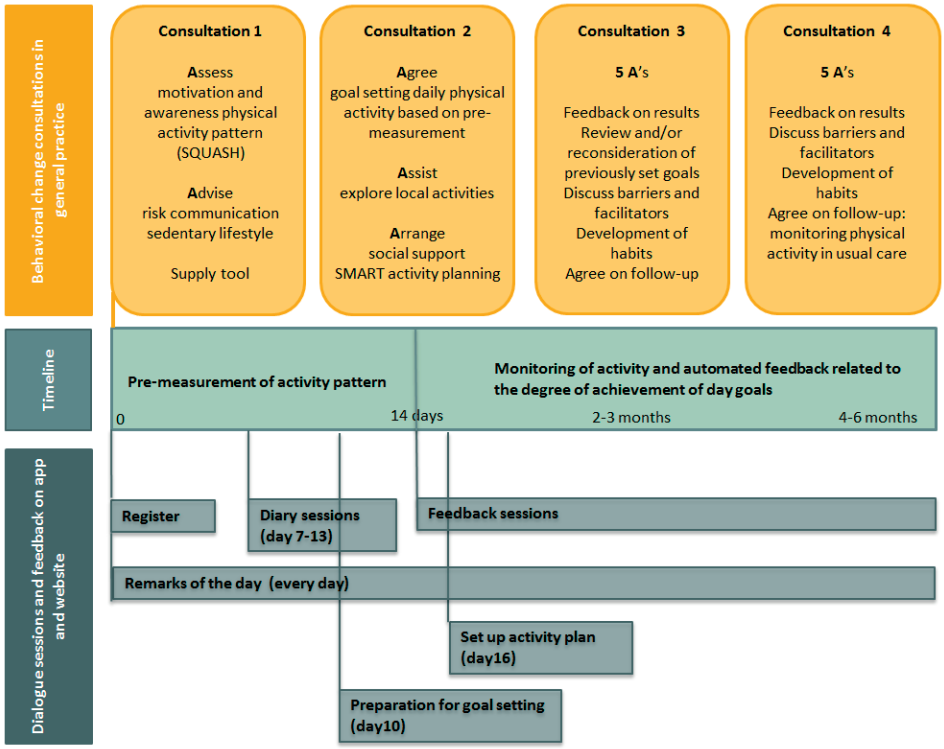

Figure 2 The final SSP combined with the use of the tool

The aim of the SSP is to increase physical activity in daily living and to prevent longer periods of continuous inactivity. The programme is characterized by collaboration between patient and practice nurse. It is a patient oriented, flexible way to support self-management of all COPD and DM2 patients who are willing to change their lifestyle. During a maximum of one to three extra consultations spread over a period of at least six months, the practice nurse performs an assessment of the patient's activity pattern using a self-assessment questionnaire, supported by information from a baseline measurement and a diary supplied by the tool. The nurse provides information about the risks of a sedentary lifestyle and the benefits of physical activity on disease prognosis, using an information card. In collaboration with the patient, an activity goal in minutes per day is set, based on personal abilities. Both the practice nurse and interactive sessions supplied by the tool facilitate the patient in writing a plan on how to become more physically active. The patient receives a list of local sport's activities. Feedback on physical activity performance is given by the practice nurse during consultations, while the tool gives automatic feedback on this performance in between.

Discussion

We hypothesized that stimulating physical activity of chronically ill patients in primary care could be improved by using a physical activity counselling protocol together with a monitoring and feedback tool. Practice nurses are well aware of the need to stimulate physical activity, but the necessary attention is lacking. It is expected that through the integration of the monitoring and feedback tool in primary care, practice nurses will be more focused on exercise promotion. The tool is equipped with automated feedback based on predefined and personalized activity goals. Further investigation should reveal information about the best balance between this form of feedback and the feedback given during consultations.

It remains a challenge to inform patients about the risk of a sedentary lifestyle in such a way that patients take responsibility for this behaviour change. Success will largely depend on the personal circumstances of patients; their lifestyles are influenced by their culture and social status and their understandings of physical exercise and how they associate this with health issues.[36] Furthermore, success will also depend on the competences of practice nurses in performing the counselling techniques. This is why the SSP gives directives about the number and content of the consultations. If the SSP succeeds in bringing about change, it is expected that this will be sustained in the long term, because chronically ill patients usually have a long-term relationship with their practice nurse.

Different opinions were expressed about monitoring physical activity results in between planned consultations, notwithstanding the fact that the technology supports this. Unfortunately, lifestyle counselling for chronically ill patients in the Netherlands is

organized and reimbursed based on regular scheduled consultations, not yet on supporting self-management by continuous monitoring conditions in collaboration with patients.[37]

Some methodological limitations should be considered when interpreting the findings of the study. The purposeful recruitment of respondents ensures internal validity, but the external validity is threatened because respondents who participated had an innovative attitude towards technology. However, the expert consultation was undertaken to enhance the external validity. A strength of the study is that from the start of the development, future users were involved in defining the requirements for the SSP.[38] The circumstances of use with respect to the target group and its integration into the management process were investigated in a profound way by collecting user requirements from both patient and care provider's perspective. This was achieved through an iterative development process characterized by finding a match between evidence-based health care on the one hand and practical and affordable care on the other. The feasibility of the SSP will be tested in a pilot study in two general practices followed by a randomized controlled trial to test the effects of its use.

Acknowledgements

We would like to thank the respondents and experts who were willing to share their time, thoughts and experience with us and especially the patient representatives, Jos Donkers and Ina van Opstal for their critical remarks.

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CHAPTER 3

Get moving: the practice nurse is watching you! A case study of the user-centred design process and testing of a web-based coaching system to stimulate the physical activity of chronically ill patients in primary care

This chapter was published as:

Verwey R, van der Weegen S, Tange H, Spreeuwenberg M, van der Weijden T, de Witte L. Get moving: the practice nurse is watching you! A case study of the user-centred design process and testing of a web-based coaching system to stimulate the physical activity of chronically ill patients in primary care *Inform Prim Care.* 2012;20(4):289-298.t

Abstract

Background The system informs the nurse about levels of physical activity in the daily living of patients who are using the It's LiFe! tool. The tool consists of an accelerometer that transfers data to a smartphone, which is subsequently connected to a server. Nurses can monitor patients' physical activity via a secured website. Physical activity levels are measured in minutes per day compared to pre-set activity goals, which are set in dialogue with the patient.
Objective To examine the user requirements and to evaluate the usability of the secured website, so as to increase the probability of effective use by nurses.
Method The needs and preferences of nurses towards the system were determined through qualitative research. The usability of the system was evaluated in a laboratory situation and during a three-month pilot study.
Results A monitoring and feedback system to support patients in their intention to be more active was developed in a systematic way. Automatically generated feedback messages were defined based on the requirements of nurses. The results from the usability tests gave insights into how to improve the structure and the quality of the information provided. Nurses were positive about the features and ease of use of the system, but they made critical remarks about the time that its use entails.
Conclusion The system supports nurses when performing physical activity counselling in a structured and profound way. The opportunity to support self-management of patients in between regular consultations needs further investigation, and adaptation into the clinical workflow of the nurses.

Introduction

According to guidelines and care standards, stimulating physical activity (PA) should be an important element in the treatment of people with a chronic disease such as chronic obstructive pulmonary disease (COPD) or type II diabetes (DM2).[1, 2] In the Netherlands, the majority of chronically ill patients are treated in primary care. They visit the family practice regularly to monitor their condition and it is the task of the practice nurse to provide lifestyle counselling during these consultations.[3, 4] The use of technology for long-term monitoring and feedback could support patients in achieving a more active lifestyle and could also help nurses to coach patients in establishing this behavioural change.

An example of a technological lifestyle intervention is self-monitoring of PA using a pedometer or an accelerometer. Although this has been identified as an effective approach towards behaviour change, it is not often used in practice.[5, 6] In the project *It's LiFe!* (an acronym for Interactive Tool for Self-management through Lifestyle Feedback!) we therefore developed and tested an innovative monitoring and personalized feedback tool (Figure 1) and a PA counselling protocol for nurses. The tool aims to support patients in achieving an active lifestyle as part of their self-management. The system consists of three elements:

- a 3D accelerometer worn on the hip together with;
- an application (app) on a smartphone (*It's LiFe!* tool);
- the coaching system: a server and a website (*It's LiFe!* monitor).

The patient receives three types of feedback on the mobile phone concerning the amount of activity, the amount of activity in relation to an activity goal, and the response of a nurse based on the measured activity. In this paper, the emphasis is on the third element: the development and testing of the server and the web-based coaching system used by nurses in primary care.

The involvement of users in the development and testing of technologies is associated with significant benefits such as: the generation of ideas by users; an improvement in system designs and user interfaces; considerable improvement in the functionality, usability and quality of the system; access to and knowledge about user perspectives.[8] Usability testing should be incorporated into routine development to avoid the pitfalls of developing applications which can't be readily integrated into clinical workflow.[9] Therefore the aim of this study was to examine the user requirements of nurses working in family practices for the *It's LiFe!* monitor and to test the extent to which nurses were satisfied with the system.

Figure 1 The *It's LiFe!* tool: accelerometer and app on a smartphone[7]

Methods

We followed a user-centred design process for the development and testing of the tool, the coaching system and the Self-management Support Programme (SSP), the behaviour change counselling protocol for nurses. This strategy was based on several existing models for the design of medical devices (Figure 2).[10-12]

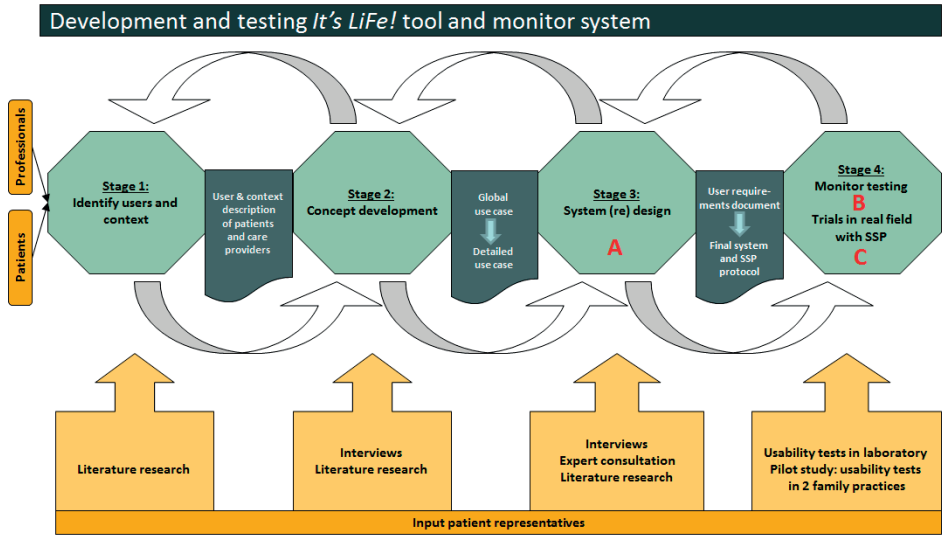

Figure 2 The *It's LiFe*! user-centred design process

From November 2010 until September 2012 we conducted three sub-studies: (A) a user requirements study, (B) a usability test of the system in a laboratory situation, and (C) a pilot study in two practices.

All studies were approved by the ethical committee of azM/UM. The studies were successive in time, but user-centred design requires iteration, which is why some results of the final study revealed new user requirements additional to the results of the first study. The optimization of the system is therefore an on-going process which started with a general project idea. This project idea was developed together with several experts and business partners. It was based on a literature review of studies on coaching patients to achieve a more active lifestyle.[13, 14] The project focussed on patients with COPD or DM2 and their care providers in primary care. Subsequently we wrote a 'use case', a description of the use of the system by a nurse coaching a patient who started using the tool.[15] A use case is a narrative scenario comprising a description of four main elements (PACT): the people involved (P), their activities (A), the context (C) and the technology used (T).[16]

User requirements analysis (A)

We chose a qualitative study design using semi-structured, audiotaped interviews in two iterative cycles to determine the user requirements of the system. We conducted 16 interviews with primary care providers, directly involved in the care of patients with COPD or DM, to ask their opinions of the use case, different aspects of the system and using it in daily practice. We transcribed the interviews verbatim and analysed the data, using the QSR NVivo 2 software package, following a directed content analysis method.[17, 18] General themes emerged and these themes were input for the user requirements document. Based on this document, we built the system in collaboration with two companies: Sananet Ltd developed the web-based system and IDEE/Maastricht Instruments Ltd provided the accelerometer, the app on the smartphone and the upload of the data to the server.

Usability study (B)

Five nurses tested the system in a laboratory setting at Maastricht University to discover its usability.[19] First, we asked them to perform six predefined tasks. The tasks were: registering new patients; viewing individual client charts; setting daily targets; viewing progress reports; changing thresholds; sending new usernames and passwords. We asked the nurses to give comments while performing these tasks (think-aloud method) and afterwards to provide their feedback for each task and to indicate the difficulty of each task on a scale from 1 (very difficult) to 7 (very easy). The sessions lasted approximately 1-1.5 hours, and were directly observed and videotaped by the

researcher. We used two laptops with the Morae™ usability assessment software (TechSmith, Inc., Okemos, MI, USA) to record the sessions (Figure 3).

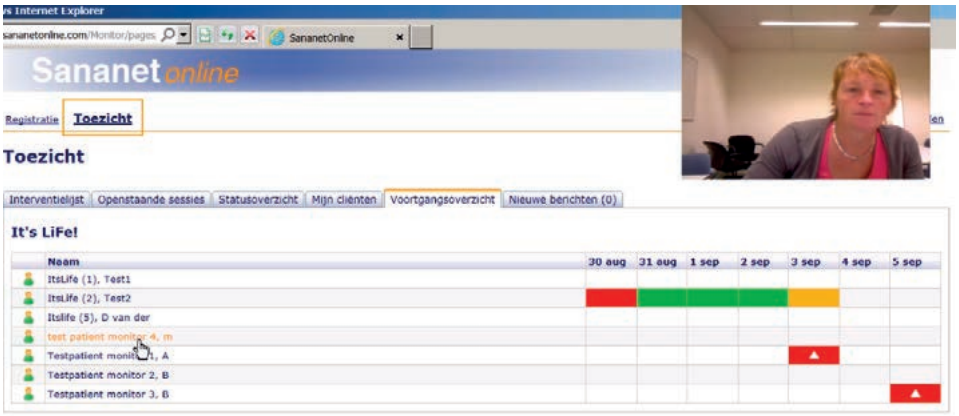

Figure 3 Screenshot of the evaluation of the *It's LiFe!* monitor using Morae™

Secondly, we asked the nurses to complete the 19-item Post-Study System Usability Questionnaire (PSSUQ). [20] Finally, to obtain an impression of the desirability of the system, we asked them to mark 5 words from a list of 118 words (product reaction charts) that in their view best characterized the system.[21] We used descriptive statistics and simple content analysis to organize the data into categories that reflected the emerging usability themes. We tagged frequently occurring errors while analysing the video tapes. Based on the results of the usability tests, we improved the system.

Pilot study (C)

As a next step, a pilot study took place with 20 patients and three nurses at two general practices. In each practice 10 patients with COPD or DM2 used the tool. The patients visited the practice three times: in the first week, after two weeks, and after 8-12 weeks for PA counselling.[22-24] During the first consultation the nurse supplied the tool, registered the patient in the coaching system and instructed the patient on how to use the tool. During the second consultation, a daily activity goal was set in minutes a day, based on the results of a pre-measurement, and in mutual agreement with the patient. During the third consultation the patient received feedback from the nurse, based on the results of PA performance, which were represented on the monitor. For patients, those results were also visible on the app of the smartphone. Before the start of the pilot study, nurses received a personal account for the system, and were instructed how to use the tool and the coaching system by the researchers. We advised them to use the tool and to sign up themselves as a patient in the system beforehand to get familiar with it.

During the pilot study we interviewed the nurses three times. We asked questions concerning their experience with the monitor and whether technical problems occurred. We audiotaped the interviews and made field notes. At the end of the pilot study, a focus group interview took place to discuss and complement the analysed interview results.

Results

User requirements analysis (A)

We interviewed 16 primary care providers (11 nurses, 3 GPs and 2 physiotherapists), of which 4 were male and 12 female. Their mean age was 42, with a range between 26 and 58 years. The following themes emerged:

The opinion towards the use case
Most interviewees liked the idea that using the tool would give both patient and nurse the ability to monitor PA levels. They confirmed the added value compared to self-reported activity because patients often overestimate their level of activity. Interviewees stressed the importance of goal setting being part of supporting self-management. Furthermore, they indicated that the goals should be flexible, tailored to the individual situation of the patient, and that co-morbidities of patients should be taken into account when setting a goal.

The role of the nurse in stimulating physical activity
Although nurses often see a sedentary lifestyle with COPD or DM2 patients, most nurses indicated that normally they do not spend much time on the assessment of the level of PA. Therefore, the use of this tool by patients to assess PA levels objectively was considered valuable. Furthermore, interviewees suggested that if a diary were part of the system, this would give more insights into the normal activity patterns of the patients.

How the information generated by the system should be presented
The activity data should be clearly presented and embedded in the information system or they should be linked with this system. Several nurses complained about using two or more systems and they wanted to avoid 'double registration'. Furthermore, the system should present a summary of all information about all their patients' performance and goal attainment at a single glance, presented in numbers and graphs.

Integration of the system into the workflow

The majority of the nurses were not enthusiastic about giving feedback on the PA levels of patients in between regular consultations. Only a few mentioned that they would probably monitor activity levels to find out whether the patient was actually using the tool. They did not, by any means, want to receive push information, such as notifications from the system.

After the interviews it was clear that providing feedback in between consultations was too much to ask of the nurses and therefore it was decided to provide patients with automatically generated feedback messages, directly from the coaching system. Furthermore, dialogue sessions were developed and automatically provided, to support the nurse and the patient in preparing for a consultation.

The coaching system

Based on the user requirements elicited, the *It's LiFe!* monitor was developed. The system consists of a server with two portals, one for care providers and one for patients. The nurse signs the patient into the system. The login name and password are sent to the patient by email. At home, the patient has to complete an additional questionnaire online (a session) concerning PA preferences. At 6 a.m. the smartphone automatically connects to the *It's LiFe!* server to store the PA data from the previous day on the server. There is a pre-measurement period of 14 days. In the second week, patients receive short sessions every day to keep a diary. These can be accessed both on the smartphone and on the website. Furthermore, patients receive two sessions concerning goals and activity planning based on the PACE.[25] The nurse can see the answers given by patients in the system on the individual chart of the patient (Figure 4).

After two weeks a daily goal in minutes per day is set in the system by the nurse in dialogue with the patient. Based on the PA data related to this goal, patients receive feedback messages. There are several types of message (tips, encouragement, positive trends, rewards, barriers, facilitators and adjusting goals). Patients get such messages when they reach or do not reach their goal after 3, 5 and 14 days. All messages are written in a positive tone, e.g. 'Good that you still try to be more active. We can see that it is hard to reach your daily target. If you want to adjust your goal, contact your nurse or click here.'

Usability study (B)

All five nurses who were invited took part in the test sessions. They were female and their mean age was 45 with a range of 31-54 years.

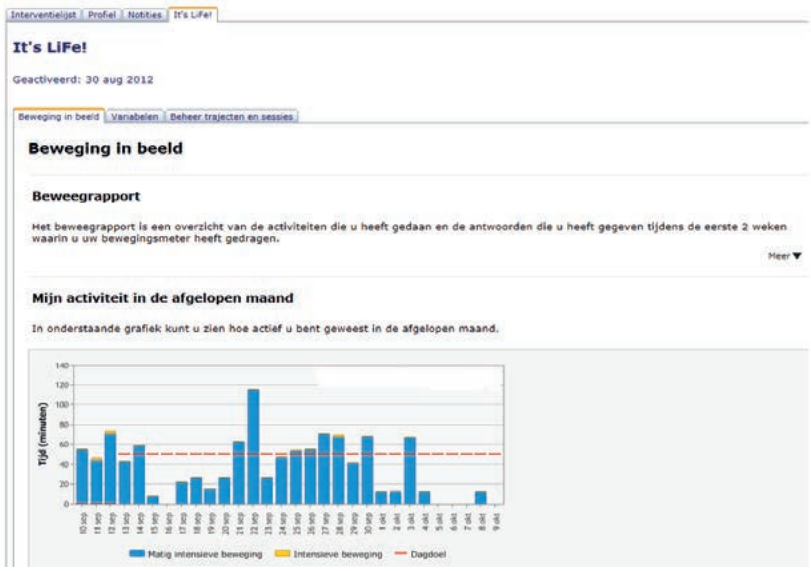

Figure 4 Screenshot of an individual patient chart

Task performances and feedback on the manual

Although it was the first time nurses had used the system, they were mainly positive about the ease of use. Scores on task performance ranged from 5.5 to 6.6 on a scale from 1 to 7 (Table 1).

Table 1 Task performance

Tasks	N	Mean (SD) scores [A]
Register a new patient	5	6.6 (0.5)
View an individual client chart	5	5.8 (0.8)
Set a daily target	5	5.6 (1.5)
View the progress report	4	5.5 (1.0)
Change the threshold	4	5.5 (1.9)
Send new username and password	4	6.3 (1.0)

A Scores range from 1 (very difficult) to 7 (very easy)

Observed problems

When registering a new patient in the system, three nurses used the back button of the web browser instead of the back button of the application itself. This caused an error with the connection to the server. Furthermore, the 'more▼' button in the individual charts with information about the preferences of patients was overlooked by four of the five participants. Finally, sometimes the system was slow due to Internet connectivity problems.

Participants' remarks

Most remarks made by the nurses related to the structure and the quality of the information.

Structure of information:

- The system is organized in four different layers (subpages). Many participants commented on the complexity of navigation.
- Participants asked whether it were possible to remove subpages which were not necessary for the coaching of PA (e.g. medication charts).
- Remarks regarding the individual charts: the most important information should be presented at the top of the page and this page was too long (users had to scroll to view all the information).

Quality of information:

- Participants liked the use of the graph indicating the level of activity over the past months and they were satisfied with the content of the individual charts. They said that it was useful information and that this could support them when talking to the patients during consultations.

Questionnaire

The results of the PSSUQ (Table 2) were positive and in line with the positive remarks of the respondents concerning the information provided by the system. The overall score of the PSSUQ was 2.6 on a scale from 1 to 7. Scores on the subscales were 2.4 for System Usefulness, 2.7 for Information Quality and 2.3 for Interface Quality.

The product reaction word list

From the 118 words that the respondents could choose to characterize the system, the following five words were chosen twice: "professional", "motivating", "valuable", "customizable" and "innovative". Most words selected were positive. Only two negative words were chosen: "slow" and "time-consuming". An overview of all the words is represented in Table 3.

Table 3 Product reaction word list

Respondent	Chosen words[A]				
1	*Enthusiastic*	*Novel*	***Professional***	*Stimulating*	*Interesting*
2	*Confident*	*Convenient*	*Familiar*	***Motivating***	***Valuable***
3	*Approachable*	***Customizable***	***Innovative***	*Relevant*	*Slow*
4	***Innovative***	***Motivating***	*Personal*	***Professional***	***Valuable***
5	*Clean*	*Controllable*	***Customizable***	*Essential*	*Time-consuming*

A Words given in bold were chosen twice.

Table 2 PSSUQ

	PSSUQ Questions	N	Mean(SD) scores [A]
1	*Overall, I am satisfied with how easy it is to use this system.*	5	3.4 (0.9)
2	*It was simple to use this system.*	5	2.6 (1.5)
3	*I could effectively complete the tasks and scenarios using this system.*	5	2.0 (0.7)
4	*I was able to complete the tasks and scenarios quickly using this system.*	5	3.6 (1.8)
5	*I was able to efficiently complete the tasks and scenarios using this system.*	5	2.0 (0.7)
6	*I felt comfortable using this system.*	5	1.4 (0.9)
7	*It was easy to learn to use this system.*	5	1.8 (0.8)
8	*I believe I could become productive quickly using this system.*	5	2.6 (1.8)
9	*The system gave error messages that clearly told me how to fix problems.*	4	3.0 (2.8)
10	*Whenever I made a mistake using the system, I could recover easily and quickly.*	4	3.3 (2.6)
11	*The information (such as online help, on-screen messages and other documentation) provided with this system was clear.*	5	1.8 (0.4)
12	*It was easy to find the information I needed.*	5	2.4 (1.7)
13	*The information provided by the system was easy to understand.*	5	2.6 (1.8)
14	*The information was effective in helping me complete the tasks and scenarios.*	5	3.2 (1.5)
15	*The organization of information on the system screens was clear.*	5	3.6 (2.0)
16	*The interface of this system was pleasant.*	5	2.0 (0.7)
17	*I liked using the interface of this system.*	5	2.0 (0.7)
18	*This system has all the functions and capabilities I expect it to have.*	5	3.0 (1.6)
19	*Overall, I am satisfied with this system.*	5	2.8 (1.3)
	Overall PSSUQ	5	2.6 (0.8)
	System Usefulness	5	2.4 (0.8)
	Information Quality	4	2.7 (1.2)
	Interface Quality	5	2.3 (0.8)

A Scores range from 1 (strongly agree) to 7 (strongly disagree)

Pilot study (C)

The following comments on using the system in daily practice were given in the interviews and the focus group:

- All nurses found it helpful to try out the tool and the coaching system first by themselves.
- They thought the system was valuable and easy to use, and instructing the nurses to use the system was done in a few minutes.
- They all agreed on the usefulness of obtaining objective PA data via the system, because they indicated that it is difficult to assess this level otherwise.

- Due to some connection problems nurses were not always able to see the data, but during the consultations this was partly solved by looking on the app of the smartphone.
- On the one hand, all nurses indicated that when looking at the data together with the patient, it was much easier to talk about barriers and facilitators for becoming more active. But on the other hand, this often resulted in a longer consultation time.
- These nurses differed in their opinion about monitoring results and giving personal feedback in between consultations, compared to the nurses we interviewed during the user requirements study. They would probably do this if they would receive a notification when patients didn't reach their goals and if an option would be part of the system to create feedback messages.

Discussion

Principal findings

The *It's LiFe!* monitor was built for nurses to support self-management of PA of chronically ill patients in primary care. Different components of the system were based on the user requirements, such as the development of automatically generated feedback messages. The iterative approach resulted in a system which was appreciated by the nurses. The results of the usability tests gave insights into how to improve the structure and the quality of the information provided. When used in practice, nurses were positive about the features and ease of use of the system, but they made critical remarks about the time that its use entails.

Implications of the findings

On the basis of the studies presented in this article, the system was improved in several areas. The results are promising with respect to usability, providing a sufficient basis for a large-scale effectiveness study. After such a study the system might be further improved and could be linked with existing medical record systems.

Comparison with the literature

We developed the system in an iterative way, not neglecting usability and following agile principles.[9,26]

The concept of a users' smartphone connected to a sensor device, and providing patients with phone-based feedback together with nurse support is previously applied in the telemedicine system to support young adults with type 1 diabetes.[27] In this system

the monitoring of PA was based on self-reported performance. In addition to this, *It's LiFe!* informs patients and practice nurses about more objective PA results through the use of an accelerometer.

Different opinions were expressed about monitoring PA results in between planned consultations. Unfortunately, lifestyle counselling for chronically ill patients in the Netherlands is organized and reimbursed based on regular scheduled consultations, not yet on supporting self-management by continuous monitoring conditions in collaboration with patients.[28,29]

Limitations of the method

The user-centred design takes into account the requirements of all users, both care providers and patients. Requirements of patients were not reported in this paper, but all development steps were carefully commented upon by two patient representatives, from the Netherlands Asthma Foundation and the Dutch Diabetes Association.

Call for further research

The tool is equipped with an option for patients to get automated feedback based on their PA goals. Further investigation should reveal information about the best balance between this form of feedback and the feedback given during consultations. An RCT will be set up to measure the effects of the tool and the coaching system embedded in the Self-management Support Programme.

Conclusions

A monitoring and feedback system to support patients in their intention to be more active was developed in a systematic and iterative way. The system allows the daily PA levels of patients to be monitored, and supports nurses when performing PA counselling in a structured and profound way. The option of supporting self-management of patients in between regular consultations needs further investigation and adaptation into the clinical workflow of the nurses.

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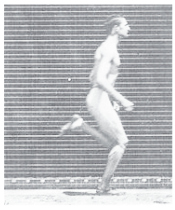
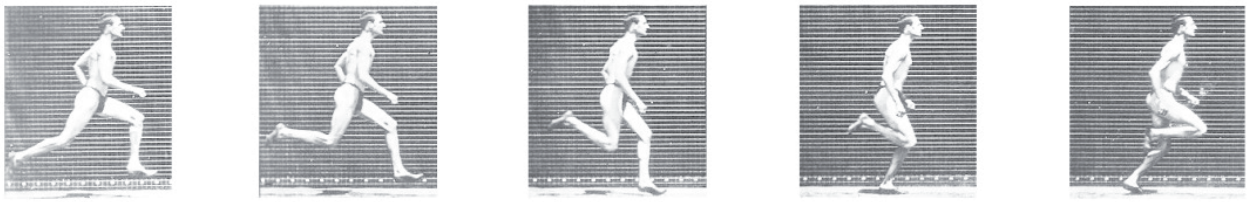


CHAPTER 4

A pilot study of a tool to stimulate physical activity in patients with COPD or type 2 diabetes in primary care

This chapter was published as:

Verwey R, van der Weegen S, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. A pilot study of a tool to stimulate physical activity in patients with COPD or type 2 diabetes in primary care. *J Telemed Telecare* 2014;20(1):29-34.



Abstract

Objective We tested the performance, acceptance and user satisfaction of a tool to stimulate physical activity. The tool consisted of an accelerometer, a smartphone app and a server/web application. Patients received feedback concerning their physical activity relative to a goal, which was set in dialogue with their practice nurse. Nurses could monitor their patients' physical activity via a website.

Method Twenty patients with COPD or type 2 diabetes used the tool for three months, combined with behaviour change counselling. Physical activity data were collected at the server and a log file was used to record technical problems. We interviewed patients and nurses after every consultation. At baseline, and after the intervention, patients completed questionnaires.

Results Participants were positive about the tool, although motivation dropped when technical problems occurred caused by log-in and connectivity errors. On average, physical activity increased from 29 (SD 21) min per day in the first two weeks to 39 (SD 24) min a day in the last two weeks (P=0.02), and quality of life scores increased from 0.76 (SD 0.21) to 0.84 (SD 0.17) (P=0.04).

Conclusion Provided that no connectivity problems occur, the tool is a feasible intervention when embedded in primary care, and has a positive effect on physical activity levels.

Introduction

Patients with COPD or type 2 diabetes usually know that they must improve their lifestyle in terms of physical activity (PA).[1] However, adhering to guidelines for healthy exercise is difficult.[2] By integrating PA counselling into routine practice, primary care providers can support patients in meeting this challenge.[3-5] Therefore, assessment of PA should be part of routine consultations for these patients and activity levels should be considered as a vital sign.[6]

Primary care may be a suitable context for PA promotion, since changing behaviour demands regular contact between patient and healthcare professional. In the Netherlands, people with COPD or type 2 diabetes visit the family practice at least once a year and it is the task of the practice nurse to monitor treatment outcomes, provide education and support for behaviour change, and offer follow-up contact.[7] Practice nurses perform lifestyle counselling according to generally acknowledged criteria. However, there is room for improvement in the tailoring of information and advice about lifestyle behaviour.[8]

Activity interventions have a moderate effect on self-reported PA, especially when the interventions include some professional guidance and on-going professional support.[9] Self-monitoring of behaviour, risk communication and the use of social support are effective elements in interventions to promote exercise, but providing knowledge, materials and professional support is not sufficient for patients to accomplish change.[10] In a recent literature review on promoting PA, 20 out of 29 studies showed significant differences in favour of computer-tailored interventions.[11] However, the circumstances of use with respect to the target group and its integration into the care process have to be clarified during the development process.

In the project *It's LiFe!*, a monitoring and feedback tool aimed at supporting patients in achieving an active lifestyle was developed and tested,[12] along with a counselling protocol. We conducted a pilot study to test the technical performance of the tool in daily life, to test the acceptance and satisfaction with the tool and the counselling protocol and to obtain information to design a subsequent randomised controlled trial.

Methods

The study took place from April until July 2012 in two general practices in the Netherlands. We asked the practice nurses to include 10 patients aged over 40 years, five of whom had type 2 diabetes with a BMI >25 kg/m2 and five of whom had COPD according to the GOLD-criteria stage 2 or 3, who could benefit from more PA. Patients with complex co-existing medical conditions, insufficient mastery of the Dutch language, or without an Internet connection were excluded.

The tool consists of an accelerometer, a smartphone app and a web application (Figure 1). Patients receive personalized feedback on the smartphone concerning their activity in relation to an activity goal, which was set in dialogue with their practice nurse. Nurses could monitor patient activity via the website.[13]

Patients were provided with the accelerometer (MOX Activity Monitor, Maastricht Instruments, The Netherlands) and a smartphone (Galaxy Ace, Samsung) with a data subscription, and equipped with the web application. The use of the tool started when the patient was registered on the server by the practice nurse. The login name and password were sent to the patient by email. At home, the patient had to complete a short questionnaire online concerning activity preferences. There was a pre-measurement period of 14 days. Patients could enter comments about being ill or having forgotten to wear the accelerometer. In the second week, patients were asked to keep an activity diary. They also received two sessions via the server concerning goals and activity planning based on the Physician-based Assessment and Counselling for Exercise intervention,[14] with the aim of modifying factors known to influence PA, such as social support and self-efficacy. After two weeks, the patient and nurse together set a goal for the number of minutes of activity per day. Patients then received feedback based on their performance against this target.

Treatment protocol

The intervention consisted of the use of the tool in daily living, intertwined with consultations with the practice nurse – the Self-Management Support Programme. The programme was based on the Five A's model, a counselling protocol to support self-management in a primary care setting.[15] The main elements of the intervention are shown in Figure 2.

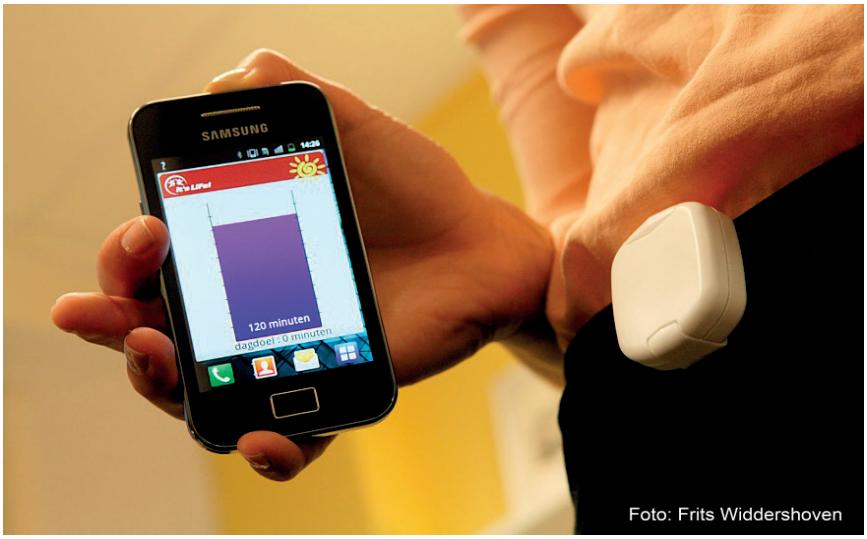


Figure 1 Smartphone and accelerometer

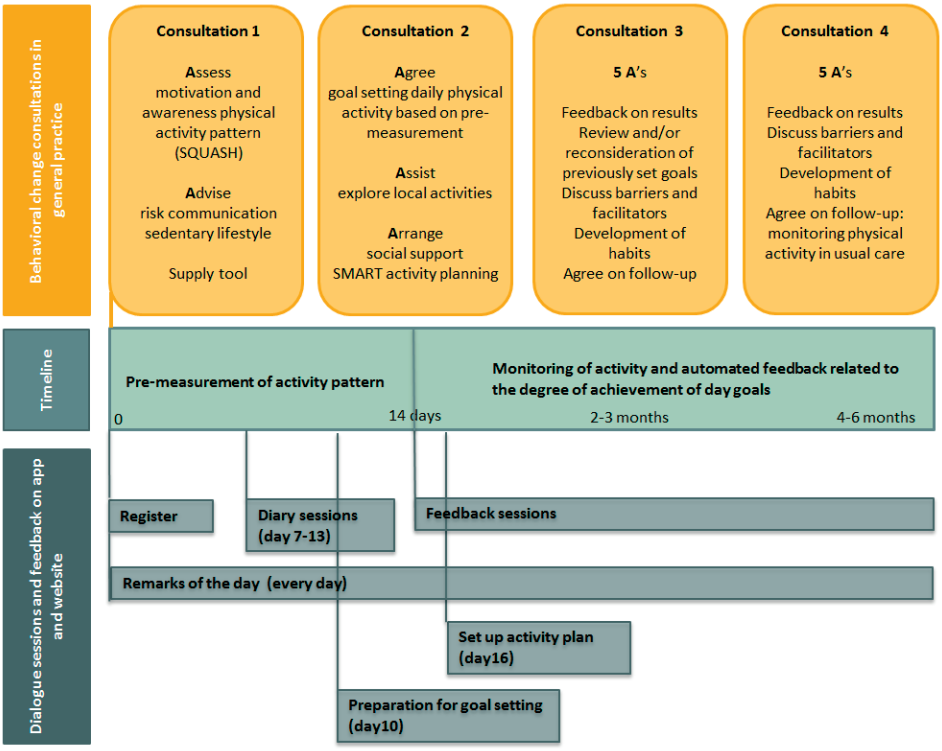


Figure 2 Main elements of the intervention

Before the start of the study, the nurses were provided with instruction charts for the course of the consultations with information about the intended counselling techniques,[16] namely motivational interviewing,[17] risk communication[18] and goal-setting.[19] They received instruction in how to use the system and were advised to try out the tool for themselves.

The patients visited the practice three times: in the first week, after two weeks, and after 8-12 weeks. The consultations (20 min) could be extra or an extension of a routine consultation (10 min).During the first consultation the nurse performed an assessment of the patient's activity pattern using an online self-assessment questionnaire,[20] provided information about the risks of a sedentary lifestyle and the benefits of PA on disease prognosis using an information card, and gave the patient a leaflet containing details of locally organized physical activities. The nurse supplied the tool, registered the patient in the system and instructed the patient how to use the tool. During the second consultation, the daily activity goal was set and the nurse stimulated the patient to think about which types of activities would suit the patient best in reaching this goal. During the third consultation the patient received feedback from the nurse, based on the results of the PA performance.

The study was approved by the appropriate ethics committee.

Measurements

We used qualitative and quantitative measurements. All patients and nurses were interviewed (30-60 min), shortly after every consultation. We asked questions about the technical functioning, acceptability, and user satisfaction with the tool and the consultations. At the end of the study, there was a focus group interview with the participating nurses and GPs to discuss the results.

At baseline (T0) and a few days after the last consultation (T1), patients completed questionnaires. We used the EQ-5D for measuring quality of life and self-rated health. Self-efficacy has been shown to be a mediator of PA behaviour. This was measured with the 10-item General Self-efficacy Scale (GSS), designed to assess optimistic self-beliefs to cope with a variety of difficult demands in life,21 and with the Exercise Self-efficacy Scale (ESS) which describes 18 situations during which it could be difficult to adhere to an exercise routine. Patients rated their degree of confidence to continue with regular exercise in the listed situations.

We collected the PA data (minutes spent per day of moderate-intense walking, i.e. at >3.5 km per hour) which was measured by the accelerometer and the responses given by the patients on the sessions from the server. We recorded technical problems in a log file. Patients could contact the researchers during working hours if there were technical problems.

Analysis

We recorded and summarized all interviews. We followed a directed content analysis method by coding and organizing the data into categories that reflected the emerging feasibility themes for each aspect of the intervention.[22]

We analysed the PA data from the first two weeks and from the last two weeks, and the questionnaires, with paired t-tests using a standard package (SPSS version 18). We used a non-parametric test (Wilcoxon Signed-rank test) to analyse the PA data.

Results

A total of 20 patients (10 with COPD, 10 with type 2 diabetes) participated in the study and completed data collection at baseline. A total of 18 patients completed data collection directly after the intervention period. In all, 19 participants (95%) were interviewed after the first consultation, 18 participants (90%) after the second consultation and 17 participants (85%) after the third consultation. The reasons for drop-out were: the tool had not worked from the start (n=1), the patient accidentally put the accelerometer into the washing machine (n=1), and the patient used the tool for only six weeks because of a planned holiday (n=1). The characteristics of the participants are summarised in Table 1.

Patients' overall experiences of the intervention

Most participants who were enthusiastic in the first interview confirmed this opinion in the third, i.e. their ideas about the usefulness of the intervention did not change over time. There were four participants who indicated that they regretted having to return the tool at the end of the study. A total of 12 patients were positive about the effect of the intervention on their PA performance and five patients were neutral about it; the latter were patients who were already sufficiently active.

During the final interview, all patients were asked to characterize the intervention in one word. The following words were chosen: stimulating (n=4), good (n=4), fun (n=3), positive, meaningful, could be effective, a boost, a helping hand, a big stick.

Table 1 Characteristics of the participants

Patients (n=20)	
Mean age, years	60
Age range, years	41–84
Sex, number (%)	
Male	11 (55)
Female	9 (45)
Employment status, number (%)	
Employed	9 (45)
Unemployed /retired	11 (55)
Computer experience, number (%)	
Yes	18 (90)
No	2 (10)
Smartphone experience, number (%)	
Yes	6 (30)
No	14 (7%)
Patients with diabetes (n=10)	
>5 years since diagnosis	9
<1 year since diagnosis	1
Patients with COPD (n=10)	
>5 years since diagnosis	8
2-5 years since diagnosis	1
<1 year since diagnosis	1
Comorbidities, Number (%)	
Yes	8 (40)
No	12 (60)
Types of complications or diseases	Both COPD and diabetes Asthma Coronary heart disease Hypertension Back pain Polyneuropathy Ménière
Nurses (n=3)	
Mean age, years	34
Age range, years	26-48
Sex, number (%)	
Male	0 (0)
Female	3 (100)
Working experience, years	Mean 7 (range 4-9)
Computer experience, number (%)	
Yes	3 (100)
No	0(0)
Smartphone experience, number (%)	
Yes	2 (66)
No	1 (33)

Effects on activity levels

For 13 patients it was possible to calculate the mean activities for five days or more, whereas for the other seven patients this was not possible due to drop-out and/or because of connectivity problems between the smartphone and the server. Mean activity significantly increased by 10.6 min per day, from 28.7 (SD 21.1) min per day in the first two weeks compared to 39.3 (SD 24.2) in the last two (P=0.02), see Table 2. At baseline the mean activity level of the type 2 diabetes patients was 6 min higher than that of the COPD patients.

Table 2 Physical Activity, Quality of Life, General and Exercise Self-Efficacy

Measures	n	Mean T0 (SD)	Mean T1 (SD)
Physical activity in minutes per day	13	28.7 (21.1)	39.3 (24.2)
EQ-5D	18	0.76 (0.21)	0.84 (0.17)
General Self-efficacy Scale (GSS)	16	3.14 (0.45)	3.24 (0.43)
Exercise Self-efficacy Scale (ESS)	15	60.2 (16.7)	59.4 (12.0)
ESS situational/interpersonal factor	16	50.8 (19.7)	56.5 (17.1)
ESS competing demands factor	17	69.8 (20.4)	66.8 (13.8)
ESS internal feelings factor	14	59.8 (16.4)	56.9 (11.0)

Tool

Information on the server indicated that adherence regarding the use of the tool was high (on average 80%). Adherence towards the sessions is summarized in Table 3.

Table 3 Adherence to the sessions

Session type	Adherence of n=19 patients (%)
Register	95
Remarks of the day	95
Mean of 7 diary sessions	63
Preparation for goal setting	84
Set up activity plan	79
Feedback	63

Although most of the patients were positive about the tool, the motivation of some patients dropped when technical problems occurred. Those problems occurred frequently (18 out of 20 participants) and had to do with log-in difficulties (small keyboard) and connectivity errors (not recognizing if Bluetooth was off or flight mode was on). A total of six patients needed some extra advice about how to log in, which was given to them during the first interview and during consultations with the nurse. The

connectivity problems were twofold: between the accelerometer and the smartphone, as a result of which the app indicated the activity some time later, and between the smartphone and the server. This was not a major problem for the patients, because the results were also stored on the smartphone. However, they did not receive feedback sessions, and the nurses were unable to see the results on the website.

Most comments were given about the fact that some activities (cycling or gardening) did not account for many minutes of activity. Another comment on the recorded number of minutes was given by a patient with severe breathing problems and a patient with an orthopaedic shoe. When active, neither reached a speed of more than 3.5 km/h. Their impression was that they had really tried very hard, but the tool had not given them enough minutes as a reward.

Consultations

More than 50% of the patients mentioned the added value of the consultations and the involvement of the nurse. During the first consultation, attention to the tool dominated the consultation, and less attention was paid to the counselling protocol. The majority of the patients indicated that the nurse did not talk about the benefits of being more active because this was a topic which had already been frequently discussed before. Overall patients were satisfied with the course of the first consultation: they felt there was a good atmosphere and it was informative and clear.

The second consultation was partly executed as planned, with the main focus-setting goals in collaboration with the patient. Patients were satisfied about goal-setting. In some cases the nurse had to temper patients' overly ambitious goals. There was less attention to setting up the plan and to the leaflet containing locally organized physical activities. Most patients simply intended to increase their walking and cycling activities. In the final consultation the use of the tool was evaluated and patients talked about how to maintain their PA performance at a higher level. Positive feedback was given on PA performance and patients appreciated this.

Questionnaires

In the EQ-5D and the GSS patients scored higher after the intervention, but this was only significant for the EQ-5D, see Table 2. Quality of life scores increased from 0.76 (SD 0.21) to 0.84 (SD 0.17) (P=0.04). At baseline the mean Quality of Life scores of the diabetes patients were 0.2 higher than the mean scores of the COPD patients.

Nurses' opinions of the intervention

All nurses agreed on the usefulness of obtaining objective PA data via the tool, indicating that it was difficult to assess otherwise. They saw that patients reacted positively to

reaching their target goals. The most critical remarks were made about receiving a lot of queries from patients because of the technical problems. The nurses spent more time explaining the tool than on activity counselling. All nurses indicated that when looking at the data together with the patient, it was much easier to talk about barriers and facilitators for becoming more active. However, this often resulted in a longer consultation time.

The activity meter started counting if the average speed was approximately 3.5 km/h. During the focus group, the possibility of lowering the threshold was discussed. Participants agreed that the stimulus of "earning minutes" was more important than recording the intensity. Therefore an option to adapt the threshold if the pre-measurement period revealed that the patient did not reach 3.5 km/h was implemented. Furthermore, the dialogue sessions were not flexible in time, whereas the study revealed that this was important. In a lot of cases, the second consultation was not scheduled exactly two weeks after the first consultation.

Discussion

In a pilot study, the intervention stimulated patients to become more physically active and supported nurses in performing activity counselling. Although the average gain in duration was modest, the relative increase in activity was quite high. Because the tool itself and its technical problems dominated the consultations, the counselling protocol was only partly executed as planned. But all participants valued the attention to PA and collaborative goal-setting during the consultations.

There was a positive trend in the level of PA during the study, which increased by more than 10 min per day, and patients reported a higher quality of life. Although the sample size of 20 was sufficient to evaluate the feasibility of the intervention, 23 conclusions about the effects should be made with great caution. There may have been selection bias towards patients known by the nurse to be highly cooperative, there was no control group and the accelerometer had not been validated. However, the results of the PA levels were consistent with the self-reported levels obtained during the interviews with the patients and nurses. Besides the positive effects of the tool and the consultations on the level of PA, the interviews themselves could have functioned as an extra motivator. It is not known if the positive results will be sustained in the longer term, when there is less human support.

On the basis of the pilot study, the tool and the counselling protocol were improved, with attention paid to the connectivity problems and the time required by the nurses. The results are promising with respect to increasing PA and reported quality of life, and encourage a large-scale effectiveness study. In conclusion, once the connectivity problems are solved and the nurses have gained some experience, the *It's LiFe!* tool appears to be a feasible intervention in primary care.

Acknowledgements

We thank the participating patients, practices nurses and GPs of the family practices in Wijlre and in Ulestraten. The companies involved in the development of the tool were: IDEE Maastricht UMC+, Maastricht Instruments Ltd and Sananet Care Ltd.

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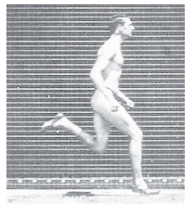


CHAPTER 5

A monitoring and feedback tool embedded in a counselling protocol to increase physical activity of patients with COPD or type 2 diabetes in primary care: study protocol of a three-arm cluster randomised controlled trial

This chapter was published as:

Verwey R, van der Weegen S, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. A monitoring and feedback tool embedded in a counselling protocol to increase physical activity of patients with COPD or type 2 diabetes in primary care: study protocol of a three-arm cluster randomised controlled trial. *BMC Fam Pract*. 2014;15(1):93.

Abstract

Background Physical activity is important for a healthy lifestyle. Although physical activity can delay complications and decrease the burden of the disease, the level of activity of patients with chronic obstructive pulmonary disease (COPD) or type 2 Diabetes Mellitus (DM2) is often far from optimal. To stimulate physical activity, a monitoring and feedback tool, consisting of an accelerometer linked to a smartphone and webserver (*It's LiFe!* tool), and a counselling protocol for practice nurses in primary care was developed (the Self-management Support Program). The main objective of this study is to measure the longitudinal effects of this counselling protocol and the surplus of using the tool.

Methods/Design This three-armed cluster randomised controlled trial with 120 participants with COPD and 120 participants with DM2 (aged 40-70), compares the counselling protocol with and without the use of the tool (group 1 and 2) with usual care (group 3). Recruitment takes place at GP practices in the southern regions of the Netherlands. Randomisation takes place at the practice level. The intended sample (three arms of 8 practices) powers the study to detect a 10-minute difference of moderate and intense physical activity per day between groups 1 and 3. Participants in the intervention groups have to visit the practice nurse 3-4 times for physical activity counselling, in a 6-month period. Specific activity goals tailored to the individual patient's preferences and needs will be set. In addition, participants in group 1 will be instructed to use the tool in daily life. The primary outcome, physical activity, will be measured in all groups with a physical activity monitor (PAM). Secondary outcomes are quality of life, general - and exercise - self-efficacy, and health status. Follow-up will take place after 6 and 9 months. Separately, a process evaluation will be conducted to explore reasons for trial non-participation and the intervention's acceptability for participating patients and nurses.

Discussion Results of this study will give insight into the effects of the *It's LiFe!* monitoring and feedback tool combined with care from a practice nurse for people with COPD or DM2 on physical activity.

Background

Because increased physical activity (PA) has positive effects on prognosis and quality of life, [1,2] stimulating PA is an important element in the treatment of people with chronic diseases such as chronic obstructive pulmonary disease (COPD) or type II diabetes (DM2).[3,4] It is, however, a challenge to adhere to guidelines for healthy exercise (at least 30 minutes of moderate activity five days a week).[5,6] By integrating PA counselling into routine practice, primary care providers can support patients in meeting this challenge.[5,7] In the Netherlands the majority of chronically ill patients visit the family practice regularly to monitor their condition, and it is the task of the practice nurse (PN) to provide lifestyle counselling during those consultations.[8,9]

The most common method of PA promotion is verbal advise, followed by print- and computer-based interventions.[10] Interventions incorporating technology that is readily accessible on a daily basis for monitoring activity levels, such as computers or mobile phones, can support care providers to coach patients in establishing behavioural changes.[11] Those interventions may facilitate long-term follow-up, [12,13] and may be an effective way to provide PA counselling without increasing the time demands on primary care providers.[14]

PA counselling has the potential to increase PA levels in the short term.[13] However, evidence regarding which methods of exercise promotion works best in the long term is still limited.[15] Furthermore, computer-based patient self-management programs, delivered in health-supported settings, show the potential for changing health behaviours and improving clinical outcomes, but more well designed trials are warranted to test their effectiveness.[16] Those trials should especially focus on the effects of theory-based intervention development, combined with the effect of tailored advise and feedback.[17]

We therefore, developed and tested a monitoring and feedback tool called *It's LiFe!*[18,19] and a corresponding counselling program for primary care nurses (the Self-management Support Program). The basic ideas behind this combination are: providing an objective measurement of PA via an accelerometer, collaborative goal setting and automatic feedback via an application on a smartphone combined with PA counselling by the PN. Results from a feasibility study showed that participants were positive about the tool. Regarding the effects of using the tool, a positive trend was seen: the mean level of PA increased by more than 10 minutes per day and patients reported a higher quality of life.[20]

This paper describes the study protocol of a three-armed cluster randomised controlled trial with 120 participants with COPD and 120 participants with DM2 (aged 40-70), comparing the Self-management Support Program with and without the use of the tool (group 1 and 2) with usual care (group 3).

Objectives and hypotheses

The objective of this randomised controlled trial is to evaluate the longitudinal effects of the *It's LiFe!* tool embedded in a Self-management Support Program (SSP) on 40-70 years old patients with COPD and DM2 in primary care. The primary outcome measure is PA in daily life. Secondary outcome measures are self-efficacy, quality of life and health status. The main difference that is evaluated is between the whole intervention and usual care. Additionally, the added value of the tool is evaluated. Apart from the effect evaluation, a process evaluation will be performed, aimed at getting insight into the adherence to the intervention and the acceptance of the intervention by participating patients and PNs.

The main hypothesis is that the whole intervention will increase PA on a moderate level by at least 10 minutes per day, over a six-month period, and to maintain this increase over three months.

Methods/design

This paper was written according to the CONSORT 2010 statement: extension to cluster randomised trials.[21]

Study design

The study is designed as a cluster randomised controlled trial with GP practices as the unit of randomisation. To compare the whole intervention with both usual care and SSP only (to isolate the effect of the tool), the trial has three arms: the use of a monitoring and feedback tool embedded in the SSP (group 1), the SSP without the tool (group 2), and usual care (group 3). The CONSORT flowchart (figure 1) summarises the trial design. The population consists of 120 participants with COPD and 120 participants with DM2 from 24 GP practices. Each practice provides 5 COPD patients and 5 DM2 patients, which makes a total of 40 patients with COPD and 40 patients with DM2 from 8 practices per trial arm.

Eligibility

Participants between 40 and 70 years old are eligible when they are diagnosed with COPD or DM2, are treated in primary care, and in the opinion of the PN, do not comply with the Dutch Norm for Healthy Exercise.[6] Additional inclusion criteria for the DM2 patients are a BMI>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.

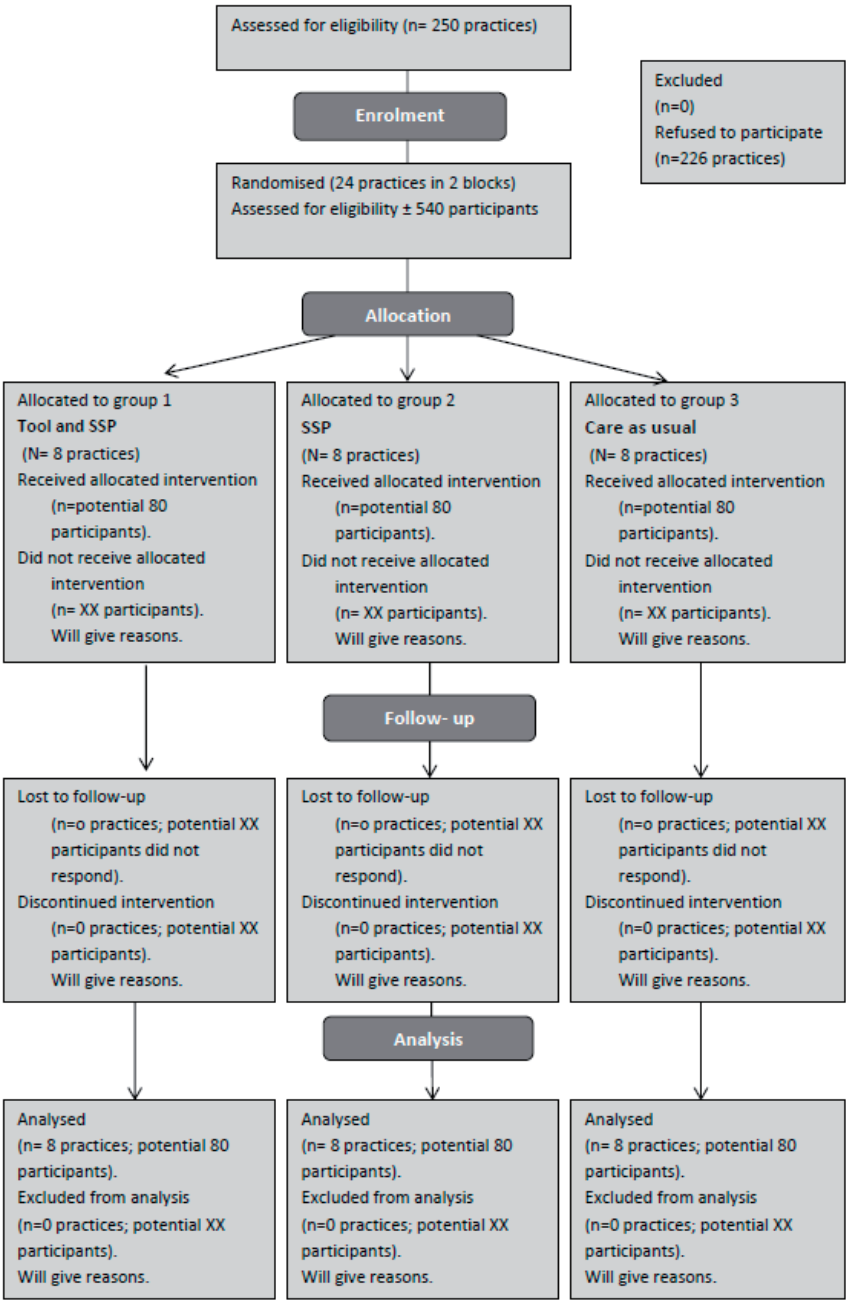

Figure 1 CONSORT flowchart trial design; potential flow of participants

Furthermore, patients should have access to a computer with an internet connection.

Exclusions are patients with 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 and those being primarily treated by a medical specialist or participating in another PA intervention, as well as patients with insufficient mastery of the Dutch language.

Recruitment

Recruitment of practices

GP practices located in southern regions of the Netherlands will be approached by an invitation letter, by telephone and personal contact with GP's, practice managers, and PNs, to invite them to participate in the study, until a maximum of 24 practices is reached. On the basis of the number of patients with DM2 treated per practice, the practices will be categorised into small (<90), medium (90-190), large (190-390) and extra-large (>390).

Recruitment of participants

To recruit participants for the study, PNs will identify 20-32 eligible patients per practice, who fulfil the inclusion criteria. This will be done before the randomisation of the practices. When the PN considers a patient eligible for participation, the nurse will send a recruitment letter to the patient with general information about all groups. After the randomisation, the PN will call those patients to give specific information about the group in which the practice is allocated and to ask patients if they want to participate; non-responders will be asked for their reasons not to participate. Each general practice will be instructed to include 10-14 participants, with an equal distribution of COPD and DM2 patients. When the patient decides to participate, he or she will receive an informational letter and informed consent form.

Randomisation procedure

A total of 24 practices will be randomly allocated into the three groups in two blocks of twelve practices. Before randomisation, the practices will be pre-stratified into four strata based on the size of the practice. The practices will be stratified into groups of 3 per size and randomised by an independent person into either one of the two intervention groups or the control group by numbering sealed envelopes which contain the names of the practices.

As they have to contact participating nurses to inform them about the relevant intervention, the executing researchers (S.v.d.W. & R.V.) will be aware of which practices are in which group. Patient data will be analysed anonymously, without any recognition of names or practices. An independent person will store the coding key. All cleaning and

processing of data will be carried out on the whole database (i.e., all three groups). The group and practice variable will only be revealed at the end of the study.

Intervention

The different components of the interventions are summarised in figure 2.

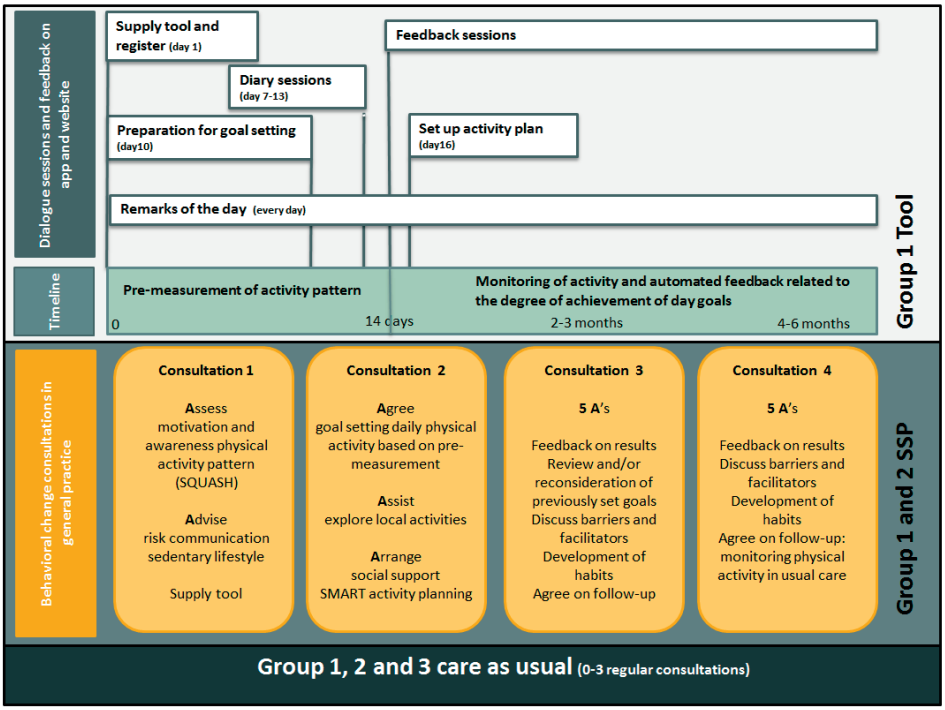

Figure 2 Interventions RCT *It's LiFe!*

The interventions have been designed in a user-centred manner; two patient representatives, from the Netherlands Asthma Foundation and the Dutch Diabetes Association, participated in the research group to provide feedback on every aspect of the project.

The tool (Group 1)

The *It's LiFe!* tool consists of an accelerometer, a smartphone app, and a server/web application. Participants receive personalised feedback on the smartphone concerning their amount of activity in relation to an activity goal, which is set in dialog with their PN [18] after a two week pre-measurement period. Nurses can monitor patients' PA via a secure website.[19]

The use of the tool starts when the participant is registered on the server by the PN. The server has two portals, one for care providers (*It's LiFe!* monitor) and one for patients (*It's LiFe!* online). The PN creates an account for the participant and then the log-in name and password are sent by email. At home, the participant has to complete a short questionnaire online (a dialog session) concerning PA preferences and has to log in on the phone. Daily at 1 a.m. the smartphone automatically connects to the server to upload the PA data from the previous day. There is a pre-measurement period of 14 days. Participants can enter 'remarks of the day' whenever they want, such as comments about being sick or having forgotten to wear the meter. In the second week, they receive dialog sessions about the enjoyment and exertion of performed activities. Furthermore, participants receive two sessions from the server concerning barriers and facilitators and activity planning based on the Physician-based Assessment and Counselling for Exercise intervention (PACE), [22] with the aim of modifying factors known to influence PA, such as social support and self-efficacy. After two weeks, together the patient and nurse set a goal in minutes of activity per day, which is entered into the system by the nurse. Based on the PA data related to this goal, participants receive feedback sessions. There are several types of messages (e.g., tips, encouragement, positive trend, reward, barriers, facilitators and the suggestion to adjust goals). Participants will get such messages when they reach their target goal after 3, 5 and 14 days or when they do not reach their target after 3, 5 and 14 days. In some cases, the goals have to be reached 100% and others are based on 80% achievement. All messages are written in a positive tone, e.g., 'Good that you still try to be more active. We can see that it is hard to reach your daily target. If you want to adjust your goal, contact your care provider or click here'.

Instruction tool

The PNs in group 1 practices will receive a personal account for the monitor, a manual and the researchers (S.v.d.W. & R.V.) will instruct PNs on how to use the system. These researchers will also advise the nurses to try out the tool themselves and to sign up as a patient in the system to get familiar with it. In addition to a manual, there are several short instructional films available on a special website; the films cover a variety of topics, for example, how to log on to the app and how to respond to a session. For technical questions about the use of the tool, participating patients and PNs are able to contact a helpdesk during working hours.

The Self-management Support Program (Groups 1 and 2)

The intervention in group 1 consists of the use of the tool in daily living, intertwined with consultations with the PN – the Self-Management Support Program (SSP). The intervention in group 2 consists of this program without the use of the tool. The program 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.[23,24]

This program consists of four consultations with the PN: in the first week, after 2

weeks, after 8-12 weeks and after 16-24 weeks. Before the consultations, the participants receive an informational booklet about the course of the intervention containing the Short Questionnaire to Assess Health-enhancing PA (SQUASH) [25] and a list of locally organised PA options. The duration of the consultations is 20 minutes, or a 10-minute extension of a regular consultation. In the first consultation, the PN will try to increase awareness of the PA pattern of the patient, and inform the patient about the health risks related to a sedentary lifestyle. The patient and the PN will get an idea about the PA level of the patient by discussing the previously completed SQUASH questionnaire. Furthermore, the patient gets a leaflet with disease specific information related to PA.[26,27]

During the second consultation, a goal will be set regarding physical activity in minutes per day, based on the results of the measurements of the first two weeks (pre-measurement). The pre-measurement in group 1 is an objective measurement based on the tool, in group 2 this is a subjective measure achieved by asking participants to keep a PA diary. The results of the pre-measurement of group 1 are visible for the nurse on the monitor portal of the *It's LiFe!* server. In both intervention groups, the nurse will encourage the patient to focus on goals that fit the patient's preferences and to set up a Specific, Measureable, Attainable, Realistic, and Timely (SMART) plan to reach personal goals, and the nurse will inform the participant about locally organised exercise opportunities.

In the third consultation, possibly by mail or telephone, the nurse will discuss the results, barriers and facilitators related to PA. In the last consultation, the nurse will discuss the results, behaviour change(s) and habits with the participant. The proposed behaviour change counselling techniques have been classified according to Abraham and Michie's taxonomy as listed in Table 1.[28]

Care as usual (group 3)

Care as usual (for all three groups) consists of regular consultations with the PN (COPD patients have 1-2 consultations and DM2 patients have 4 consultations per year). Participants in the usual care group will not be offered any programme besides usual contacts with the GP and PN.

Instruction for SSP

Informational booklets are produced, focusing on PA behaviour change, with an explanation and a timeline of the intervention. Before the start of the intervention, these booklets will be sent to participants.

The nurses in group 1 and 2 practices will receive a personal instruction at their workplace; these instructions will also be available as an online web lecture. The nurses will receive an information file with detailed instruction charts for the course of each consultation, and an explanation of the intended counselling techniques.

Table 1 Details of the tool and the PA counselling consultations and proposed Behavioural Change Techniques[28]

	Proposed Behavioural Change Techniques (BCT)	Number according to BCT Taxonomy Abraham and Michie
Condition 1: Tool		
Tool widget (continuous)	Prompt specific goal setting	10
	Provide feedback on performance	13
	Prompt review of behavioural goals	11
Tool sessions	Provide general encouragement	6
	Provide general information	1
	Provide information on consequences	2
	Prompt intention formation	4
	Plan social support/social change	20
	Prompt barrier identification	5
Condition 1 and 2: Self-management Support Programme		
Consultation 1	Provide general information	1
	Motivational interviewing	24
	Provide general encouragement	6
	Provide information on consequences	2
	Prompt intention formation	4
Consultation 2	Provide general encouragement	6
	Motivational interviewing	24
	Prompt specific goal setting	10
	Plan social support/social change	20
Consultation 3	Provide general encouragement	6
	Provide feedback on performance	13
	Motivational interviewing	24
	Prompt review of behavioural goals	11
	Prompt barrier identification	5
	Relapse prevention	23
Consultation 4	Provide general encouragement	6
	Provide feedback on performance	13
	Motivational interviewing	24
	Prompt review of behavioural goals	11
	Prompt barrier identification	5
	Relapse prevention	23

Data collection

All participants are asked (by a letter from the researchers) to wear the PAM and complete questionnaires at three different time points; namely at baseline (t0), at the end of the intervention after 4-6 months (t1), and at follow-up, 3 months after the end of the intervention (t2). Measurements and time points are summarised in Table 2.

Table 2 Measurements and time points

Concept (questionnaires)	*Intervention groups*			*Control group*		
	t0	*t1*	*t2*	*t0*	*t1*	*t2*
Demographic variables	*x*			*x*		
Physical activity (PAM)	*x*	*x*	*x*	*x*	*x*	*x*
Quality of life (SF 36)	*x*	*x*	*x*	*x*	*x*	*x*
General Self-Efficacy (GSS)	*x*	*x*	*x*	*x*	*x*	*x*
Exercise Self-Efficacy (ESS)	*x*	*x*	*x*	*x*	*x*	*x*
Health status (DSC-R or CRQ-SAS)	*x*	*x*	*x*	*x*	*x*	*x*
Process evaluation		*x*				

PAM: Personal Activity Monitor
DSC-R: Diabetes Symptom Checklist-Revised
CRQ-SAS: Chronic Respiratory Questionnaire-Self-Administered Standardised
t0 – baseline
t1 - after 4-6 months (end of intervention)
t2 - after 9 months (post intervention)

Outcome parameters

Primary outcome measure

Physical activity

PA will be measured with the Personal Activity Monitor (PAM AM300).[29] The PAM is a small tri-axial accelerometer that can be easily attached to a belt and is worn on the hip. The PAM registers all hip movements that are made during a day. Via a docking station, and connection to the internet, the PAM scores and data of minutes a day in a sedentary category (< 1.8 METS), a living category (1.8-3 METS), a moderate category (3-6 METS), and a vigorous category (>6 METS) will be uploaded. [29] The number of minutes of PA in the moderate and vigorous category (>3 METS) will be considered as the primary outcome measure. We will also report about the number of minutes of PA in the living, moderate and vigorous category >1.8 METS. These measures indicate all types of activity during the day. The possibility for the users of noticing their activity scores on the PAM will be deactivated; the displays will only show a digital clock. Participants will be asked to wear the PAM during 8 consecutive days for more than 12 hours a day. They will be asked to register the days and times that they wear the PAM; activities that are difficult

to measure (swimming, cycling and strength training) will be recorded on a paper log. A measurement will be considered valid if the wear time is > 8 hours per day and if there is data of > 5 days.

Secondary outcome measures

Quality of life

To measure the quality of life the SF-36 will be used.[30,31] The SF-36 consists of 36 items, organised into 8 subscales, including vitality, physical functioning, body pain, general health perceptions, emotional role functioning, social role functioning, and mental health. A higher score indicates a better quality of life.

Self-efficacy

An important mediator of PA behaviour is self-efficacy; therefore this will be measured with two different questionnaires. The 10-item General Self-efficacy Scale (GSS) is designed to assess optimistic self-beliefs to cope with a variety of difficult demands in life, scores for each item range from 1 (totally disagree) to 4 (totally agree).[32] The Exercise Self-efficacy Scale (ESS) describes 18 situations during which it could be difficult to adhere to an exercise routine, for example 'without support from family and friends'. Participants are asked to rate their degree of confidence to continue with regular exercise in the listed situations. The ESS uses a 100-point scale for each item, ranging from 0 'I cannot do this at all' to 100 'I am certain that I can do it', with higher scores reflecting higher levels of exercise self-efficacy.[33-35]

Additional measures

Health status

Personal reported health status will be measured by two disease specific questionnaires, the Diabetes Symptom checklist-revised (DSC-R) for participants with DM2 and the Chronic Respiratory Questionnaire (CRQ) for participants with COPD.

DSC-R consists of 34 items and 8 sub-dimensions; hyperglycaemia, hypoglycaemia, psychological – cognitive, psychological – fatigue, cardiovascular, neurological –pain, neurological – sensoric and ophthalmological. On the DSC-R, patients indicate for each of the 34 listed symptoms whether or not they suffered from it in the last month. If they did experience the symptom, patients rate the perceived burden on a scale from 1 (not at all) to 5 (extremely).[36-38]

The Chronic Respiratory Questionnaire (CRQ-SAS) consists of 20 items across four dimensions: dyspnoea, fatigue, emotional function, and mastery (the patient's feeling of control over their disease). The dyspnoea portion is individualised for each patient: the person is asked to select the five activities associated with breathlessness that they perform frequently and are most important to them. Dyspnoea items can be selected

from a list of 26 suggested items or may be written in by the patients. Items are scored from 1 (most severe) to 7 (no impairment).[39,40]

Process evaluation

Because of the expected wide range of differences in the performance of the intervention by the PNs and in the adherence of patients in using the tool, a process evaluation is necessary.[41,42] The purpose of the process evaluation is to examine the context, implementation and receipt of the intervention. The evaluation consists of registration forms, a process evaluation questionnaire for participants in the intervention groups at t1, interviews by telephone with the PNs responsible for the study and a focus groups with PNs at the end of the study. During the interviews, information is gathered about the inclusion of participants, the course of the consultations, the education and motivation of the PNs, experienced motivation and treatment possibilities of the participants and the perceived effect of the intervention. Time spent on the intervention is recorded on registration forms. In the questionnaires, participants in both groups and the PNs are asked about their experiences with the SSP and the tool. All process evaluation components, operationalization, and measurements are summarised according to the framework of Saunders. [43]

Sample size and power calculation

For this study, 240 patients are required, with a minimum of 80 participants per group. Based on a validation study, we assume that the PA level of participants is an average of 24 minutes with a range of 14.6 minutes. A mean difference between group 1 and group 3 of ten minutes (42%) of moderate to vigorous PA spent per day will be seen as clinically relevant. While assuming an intra-class correlation of 10% based on practice, to account for the dependency of the data, with a power of 80% and a significance level of 0.05, a total of 72 patients over 8 general practices are required in each group. Because a drop-out rate of 10% is expected, practices will be asked to include 8-14 patients per practice in each subgroup, depending on the size of the practice.

Planned statistical analyses

Descriptive statistics

Demographic data (e.g., age, gender, disease, co-morbidities) will be described for the total group and for the subgroups separately. Continuous variables will be denoted with means and standard deviations. Categorical variables will be denoted in numbers and percentages. The participants included in the 3 arms will be tested on differences between characteristics, with chi-square and ANOVA with Bonferroni–adjustment. If variables differ between groups, with a p-value ≤0.10, they will be considered to be potential confounders in further analysis.

Data analysis for primary and secondary outcomes
An intention to treat analysis and a per protocol analysis will be conducted. For each outcome measure (all outcomes are continuous) data will be expressed as mean +/- SD. The between group comparisons will be analysed with multilevel analysis to account for the dependency of observations within practices; the level of statistical significance will be set at 0.05 (two-tailed). Separate models (random intercept and random slope models) will be set up for each outcome measure. The independent variables in each model are two dummy variables indicating the group, with the group of patients receiving usual care as the reference category and two dummy variables for time and their interaction effects. In addition, an extra dummy variable will be included to indicate the patient group (COPD versus DM2), to study whether the effects in COPD patients differ from the effects in patients with DM2. We will also add interaction variables into the model. If needed, additional baseline variables will be included to account for possible confounding. If normality assumptions are violated, outcome variables will be log-transformed and if necessary non-parametric tests will be used. SPSS, version 19 and Mlwin, version 2.02 will be used to analyse the data.

Data analysis process evaluation
Quantitative data will be analysed by means of descriptive statistics. In order to identify relevant themes, qualitative data (results of open-ended interviews and focus groups) will be independently analysed by two researchers using NViVo version 9. A concurrent triangulation strategy will be applied to confirm, cross validate and corroborate the findings.

Procedure for accounting for missing, unused and unexpected data
Accounting for missing values on items in questionnaires will be handled according to the scoring algorithms of the questionnaires. Missing variables in follow-up data will not be imputed since it has been shown that multilevel analysis is a very flexible method for handling missing data.[44]

Stopping rules
There are no formal statistical stopping rules. If a patient decides to withdraw (e.g., hospital admission), the nurse may discontinue the intervention, but all participants will be asked to complete follow-up assessments. Patients can withdraw from the study at any time.

Ethical principles

The study protocol was approved by the research ethics committee of azM/UM, Maastricht, the Netherlands in 2013 (METC12-3-071).

Discussion

This study fills a gap in the literature about how to improve self-management of patients with COPD or DM2 in increasing their level of PA by using technology embedded in primary care.

Post-recruitment selection bias, a well-known problem of cluster randomised controlled trials, will be partly avoided by asking the nurses to include patients and send a general invitation letter before the randomisation of the practices. But not informing the patients about the intended intervention (the randomisation outcome of their GP practice), is insuperable because patients have to be informed about the intervention before they agree to participate.

During a pragmatic trial, which aims to measure the effectiveness of an intervention in routine practice, it is important to collect process data to avoid Type III errors (evaluating an intervention that was inadequately implemented). In choosing the outcomes and measurements of the process evaluation, the potential for increased Hawthorne effects will be taken into account by minimising the contacts between researchers and participants, and by avoiding overlapping roles between researchers and PNs, for example by asking the PNs to include patients for the study, and by arranging an independent helpdesk. Patients will not be interviewed during the intervention in order to distinguish between the intervention and its evaluation.

Conclusion

In conclusion, the need to increase the level of PA in people with COPD or DM2 is evident, in which the use of a monitoring and feedback tool embedded in a counselling protocol can play an important role. In the present three-arm cluster randomised controlled trial, we will evaluate the effectiveness of this counselling protocol and the surplus of using the *It's LiFe!* monitoring and feedback tool.

Abbreviations

COPD: Chronic Obstructive Pulmonary Disease; DM2 : Type 2 Diabetes Mellitus;
It's LiFe!: Interactive Tool for Self-management Through Lifestyle Feedback;
GP: General Practitioner; PAM: Physical Activity Monitor AM300; PA: Physical Activity
SSP:Self-management Support Program

Competing interests

The author(s) declare that they have no competing interests.

Author's contributions

LdW, TvdW, MS, HT, SvdW and RV conceived and designed the study. SvdW and RV are collecting the data. SvdW, RV and MS will analyse the data. RV wrote the paper. All authors edited, revised and approved the final manuscript.

Acknowledgements

The project is funded by ZonMw (The Netherlands Organisation for Health Research and development) in the programme 'New Instruments for Healthcare'.
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

We would like to thank the patient representatives, Jos Donkers and Ina van Opstal, for sharing their time, thoughts and experience with us and for their critical remarks.

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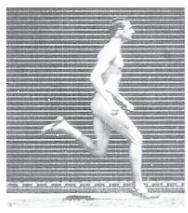


CHAPTER 6

It's LiFe! Mobile and Web-Based Monitoring and Feedback Tool Embedded in Primary Care Increases Physical Activity: A Cluster Randomised Controlled Trial

This chapter was published as:

van der Weegen S & Verwey R, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. It's LiFe! Mobile and Web-Based Monitoring and Feedback Tool Embedded in Primary Care Increases Physical Activity: A Cluster Randomised Controlled Trial. *J Med Internet Res* 2015;17(7):e184

Abstract

Background Physical inactivity is a major public health problem. 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.

Objective Our aim was to evaluate whether the SSP combined with the use of the monitoring and feedback tool leads to more physical activity compared to usual care and to evaluate the additional effect of using this tool on top of the SSP.

Design A three-armed cluster randomised controlled trial. Twenty four family practices were randomly assigned to one of three groups in which participants received the tool + SSP (group 1), the SSP (group 2), or care as usual (group 3).

Methods The secondary outcomes were general and exercise self-efficacy and quality of life. Outcomes were measured at baseline, after the intervention (4-6 months), and 3 months thereafter.

Results The group that received the entire intervention (tool + SSP) showed more physical activity directly after the intervention than group 3 (mean difference 11.73, 95%CI 6.21 to 17.25; P<0.001), and group 2 (mean difference 7.86, 95%CI 2.18 to 13.54; P=0.003). Three months after the intervention this effect was still present and significant (compared to group 3: mean difference 10.59, 95%CI 4.94 to 16.25; P<0.001; compared to group 2: mean difference 9.41, 95%CI 3.70 to 15.11; P<0.001). There was no significant difference in effect between group 2 and group 3 on both time points. There was no interaction effect for disease type.

Conclusion The combination of counselling with the tool proved an effective way to stimulate physical activity. Counselling without the tool was not effective. Future research about the cost-effectiveness, application under more tailored conditions and in other target groups is recommended.

Trial registration ClinicalTrials.gov: NCT01867970

Introduction

Physical inactivity is a major public health problem[1,2] because it increases the risk of several diseases, such as coronary heart disease, type 2 diabetes, and several types of cancer. It also shortens life expectancy.[1] For people with a chronic disease, physical inactivity enhances the chance of complications and comorbidities.[3] Unfortunately, about one-third of adults worldwide do not reach public health guidelines for recommended levels of physical activity (PA).[4] Therefore, the promotion of PA is a public health priority.[5] One of the approaches to increase PA is through primary health care.[6] Because practice nurses have frequent contact with people with chronic conditions to monitor treatment outcomes, it is recommended that they incorporate support to change physical inactivity behaviours.[7,8] However, providing only verbal advice has proven to be insufficient.[9] Despite the heterogeneity in results of physical activity intervention studies, the most effective approach is professional advice and guidance with continued support and combining a mix of behaviour change strategies.[10-12] Effective behaviour change strategies for the promotion of PA are self-monitoring, providing feedback for behaviour, goal setting, providing tools to facilitate behaviour, action planning, social support, barrier identification, and providing information on the consequences specific to the individual.[10,11,13]

An example of a tool to facilitate behaviour is the use of innovative technology such as smartphones with built-in, or in combination with, pedometers or accelerometers. These technologies can facilitate self-monitoring, goal setting, and real-time feedback. Despite, the fact that general smartphone use is growing as well as smartphone use in PA research,[14] there is a lack of well-designed experimental studies with appropriate intervention periods and sample sizes[15] to explore whether these technologies add value on top of behaviour change counselling by the practice nurse (PN). The *It's LiFe!* intervention is a combination of behaviour change strategies delivered by the PN in a Self-management Support Programmeme (SSP) that is partly integrated with usual care as well as the use of a monitoring and feedback tool for patients in daily life.

A cluster randomised controlled trial was conducted to evaluate the longitudinal effects of this multifaceted intervention on 40–70 year old patients with chronic obstructive pulmonary disease (COPD) and diabetes type 2 (DM2) in primary care. Furthermore, the additional effect of using this tool on top of the SSP was evaluated. The main hypothesis was that after a four to six month intervention period, the complete intervention increases participants' moderate to vigorous physical activity by at least 10 minutes per day compared to care as usual, and that this increase maintains over three months.

Methods

The study methods, intervention, and outcomes have been reported in detail previously.[16]

Study design

A three-arm clustered randomised controlled trial among 24 general practices in the south of the Netherlands was conducted. A cluster design was chosen to avoid contamination by unintended influence of the PN in the control group. After stratification based on the number of registered DM2 patients per practice, two blocks of 12 practices were randomly assigned in three groups using sealed envelopes. Practices allocated to Group 1 received the complete intervention (monitoring and feedback tool and SSP), practices in Group 2 received the SSP only, whereas practices in Group 3 received care as usual. Four strata were defined: small (<90 DM2-patients), medium (90-190), large (190-390), and extra-large (>390). There was no blinding for allocation of practices. The research team was blinded for allocation of participants during the analysis phase. Data were analysed anonymously and coding was revealed after analyses.

Participants: Practices and Patients

We invited 250 family practices in the South of Netherlands by invitation letter, telephone, or personal contact, until 24 practices agreed to participate. Eligibility for participants was determined as follows: between 40 and 70 years old with DM2 or COPD, and who did not, according to the PN, comply with the Dutch Norm for Healthy Exercise (having at least 30 minutes of moderate to vigorous physical activity on 5 or more days of the week).[17] Additional inclusion criteria for the DM2 patients was a BMI>25, and for the COPD patients, a clinical diagnosis of COPD according to the GOLD-criteria stage 1-3, known to be stable in their respiratory function for at least six weeks and on a stable drug regimen. Furthermore, participants needed to be able to access a computer with an internet connection and master the Dutch language sufficiently.

Exclusion criteria were the presence of 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, and being treated primarily by a medical specialist or participating in another PA intervention.

The PNs in each practice were asked to send 20-32 general invitation letters to patients who met the inclusion criteria. After randomisation, the PN called the patients to give specific information about the allocated condition and ask if they wanted to participate. If the patient decided to participate, they received a specific information letter and an informed consent form. Each practice was instructed to include five to

seven patients with DM2 and five to seven patients with COPD. This study was approved by the Medical Ethical Committee of the Maastricht University/Academic Hospital Maastricht in the Netherlands (12-3-071).

Intervention

The complete *It's LiFe!* intervention consisted of the Self-management Support Programmeme and a monitoring and feedback tool. Both elements were developed in a user-centred design process and tested on usability and feasibility.[18-22] Furthermore, two patient representatives from the Netherlands Asthma Foundation and the Dutch Diabetes Association participated in the research group to provide feedback on every aspect of the trial.

The Self-management Support Programmeme (SSP)

The programme consisted of four individual consultations with the PN; in the first week, after two weeks, after two to three months, and after four to six months (Figure 1).[18] First, the participants received an information booklet about the course of the intervention containing the Short Questionnaire to Assess Health-Enhancing PA (SQUASH)[23] and a list of locally organised PA activities.

In the first consultation, the PN raised awareness about the risks of physical inactivity, and the PA level of the patient was discussed using the previously completed SQUASH questionnaire. In addition, participants received a general and a disease specific pamphlet about PA.[24-26] Between the first and the second consultation, a pre-measurement of the activity pattern was taken, and participants answered questions about barriers and facilitators for PA. In group 1, PA was objectively measured by the tool, and all questions were answered via a dialogue session on the tool. Group 2 kept a PA diary on paper and answered questions about barriers and facilitators in the information booklet. During the second consultation, a personal goal was set in minutes of activity per day based on the pre-measurement, and the PN encouraged the participants to set up an activity plan to reach personal goals. Furthermore, the nurse informed the participants about locally organised PA options. In the third consultation, possibly by mail or telephone, activity results, barriers, facilitators, and the creation of new PA habits were discussed, and some participants reconsidered their activity goal. In the last consultation, activity results, barriers, facilitators, and PA habits were evaluated. Furthermore, how the PN and patient would continue the lifestyle coaching was discussed. The consultations were based on the "Five 'A's Cycle" counselling technique (assess–advise–agree–assist–arrange).[27,28]

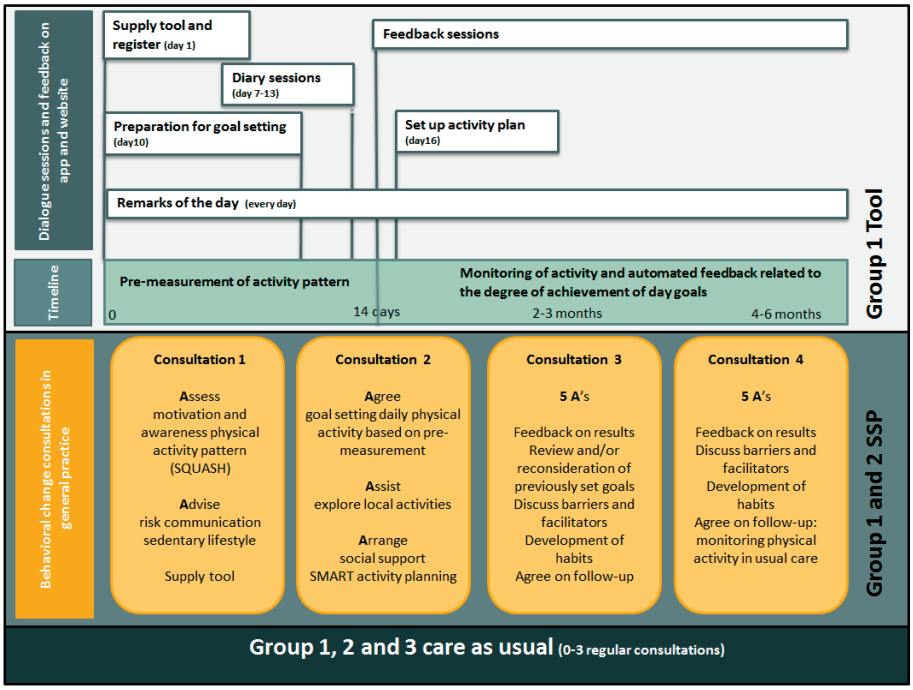

Figure 1 Course of the *It's LiFe!* interventions

Figure 2 The *It's LiFe!* activity monitor and smartphone app

The tool

The tool consists of a three-dimentional (3D) activity monitor, a smartphone app, and a web application (Figure 2).[19] Participants were asked to wear the activity monitor on a daily basis and they could see their real time activity results and history in minutes of moderate to vigorous activity on the smartphone and web application, in relation to a personal goal. During the pre-measurement, participants participated in dialogue sessions (Figure 1). In the "diary sessions," they were asked about enjoyment and exertion of performed activities. In the "preparation for goal setting" they were asked about barriers and facilitators to exercise. Based on the activity results and the answers in the dialogue sessions, a personal activity goal was set in the second consultation of the SSP. Hereafter, automated feedback messages were sent related to the personal goal. Moreover, the participant was asked in a dialogue session to set up an activity plan to achieve the daily goal. During the entire intervention, activity results and answers to dialogue sessions were visible for the PN on a secured web application.[19,22] The applications were not changed or updated during the trial (version 2.7). For technical questions and problems with the tool, the participants and PNs could contact a helpdesk during working hours to avoid contact between researchers and participants.

Training of the practice nurses

For mastering the execution of the intervention, PNs in group 1 and 2 received an online web lecture and consecutively a personal instruction session at their workplace. In addition they received on paper, an explanation of the Five A's model, the associated counselling techniques and detailed instruction charts for each consultation. Nurses in group 1 were able to try out the tool before the start of the consultations.

Data collection

All participants received a Personal Activity Monitor AM300 (Pam)[29-31] and questionnaires by regular mail, at baseline (t0), after the intervention at four to six months after baseline (t1), and three months after the end of the intervention, approximately nine months after baseline (t2). The last measurement was initially set at 6 months after the intervention, but due to time and money constraints, this could not be realised. The Pam was blinded, which means that participants could not read the display with activity information to prevent any feedback and intervention effect of this measurement.

Outcome measures

The primary outcome measure was the average minutes per day of PA per patient, measured with the Pam.[29-31] The participants were asked to wear the Pam for eight

consecutive days clipped to their waistband on the hip, and to record in a diary the time it was worn. A measurement was considered valid if the tool was worn on ≥5 days for ≥8 hours. Minutes per day were divided in three categories according to metabolic equivalent tasks (METS): light (1.8-2.99 METS), moderate (3-6 METS), and vigorous (>6 METS). The number of minutes of PA in the moderate and vigorous category (≥3 METS) was considered the primary outcome measure because moderate to vigorous activity is recommended by the World Health Organization.[32] Secondary outcome measures were general self-efficacy (general self-efficacy scale),[33] exercise self-efficacy (exercise self-efficacy scale),[34-36] and quality of life (RAND 36).[37,38]

Statistical analysis

The sample size calculation was based on the primary outcome measure (minutes of moderate to vigorous PA per day). Based on a power of 80%, an alpha of 0.05 (two-tailed testing), an expected difference between group 1 and 3 of ten minutes of PA per day per participant, and an assumed intra-class correlation between the practices of 0.15, 72 participants over eight general practices were required in each group. A drop-out rate of 10% was taken into account, which resulted in a desired number of 80 participants per group.

Intention to treat and per protocol analyses were performed. Participants of the intervention groups were included in the per protocol analysis if they received a minimum of three consultations (75%) spread over at least three months based on registration forms of the consultations obtained from the PNs. Participants from all groups were excluded from the per protocol analysis if they did not complete the second measurement (t1). Per protocol analysis were conducted to investigate whether results were different if only participants were included who adhered sufficiently to the interventions.

Normal distribution of the data was checked visually using normal q-q plots and histograms. Outliers were not removed. Continuous variables were presented as means, and standard deviation and categorical variables as numbers and percentages. Differences in baseline characteristics between groups at baseline were investigated with chi-square and analysis of variance (ANOVA). Variables that differed with a P-value of 0.10 or smaller were considered as potential confounders in further analysis. For the RAND 36 outcomes only the physical component and the mental component were used in further analysis, since the eight subscales strongly correlated. To adjust for the dependency of patients within time and practices (intra class correlation [ICC]) restricted maximum likelihood (REML) multilevel analyses with random intercepts were used. The differences of the -2 log likelihood and degrees of freedom between models were examined to decide if a one, two, or three-hierarchical (time, participants, and general practices) model had to be applied (model selection was performed with a maximum likelihood [ML]). Separate models were set up for each outcome measure, adjusted with Bonferroni correction. The independent variables in each model were two dummy

variables indicating the group, with the group of participants receiving care as usual as the reference category, and two dummy variables for time and their interaction effects. In addition, outcome estimates of the multilevel analyses were corrected for baseline and for potential confounders (differences between groups at baseline). Potential confounders were stepwise included in the model if the regression coefficients of time, group, and the interaction of group x time, changed by ≥10% on average. To study whether the effects in COPD patients differed from the effects in participants with DM2, a subgroup analysis was done by including interaction effects. Missing values on items in questionnaires were handled according to the questionnaire's analysis manual; missing data in follow up were not imputed as multilevel analysis accounts for that.[39] All analyses were carried out with IBM Statistical Product and Service Solutions (SPSS) Statistics for Windows, version 22.0.

Results

In total, 24 general practices were randomly assigned to Group 1 (tool and SSP), Group 2 (SSP), or Group 3 (care as usual). In every group, we included one small practice, three medium, three large, and one extra-large practice. The individual practices included 3 to 14 participants with a median (interquartile range) of nine participants (7-10 participants). As shown in Figure 3, PNs sent approximately 540 patients a general invitation letter and 199 patients (Group 1: 65 participants, Group 2: 66 participants, Group 3: 68 participants) agreed to participate and completed the baseline measurement. In June 2013, the first practices started with the intervention, and in April 2014 PNs in the last practices performed their last consultations. In Group 1, one participant did not start with the intervention because in his opinion, the intervention was not tailored to his age group, and 12 participants did not receive the minimal intervention as intended. In Group 2, two participants dropped out before the start of the intervention and seven participants did not receive the minimal intervention as intended. In total, 23 participants were lost to follow-up. In the "intention to treat" analyses, data from all participants were taken into account (n=199) (Figure 3). Table 1 shows the baseline characteristics of participants in each group, and Table 2 shows the mean outcome values at baseline. Significant group differences, which were included as confounders in further analyses, were found for Body Mass Index (BMI), computer use, minutes of PA (≥3 METS), and quality of life (physical component scale).

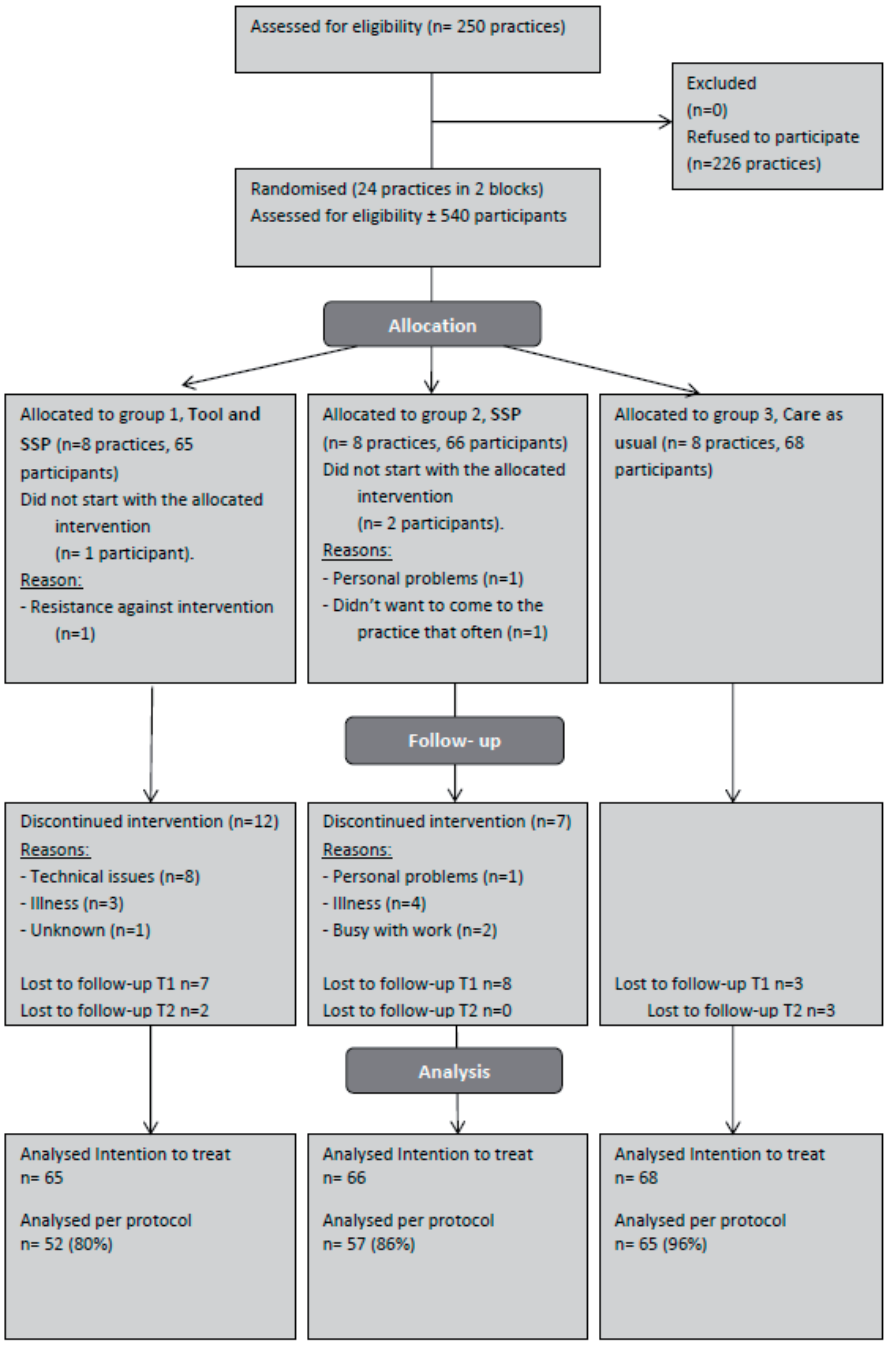

Figure 3 *It's LiFe!* CONSORT flow diagram

Table 1 Baseline characteristics of participants. Values are numbers (percentages) unless stated otherwise.

Characteristics of participants	Group 1 (n=65)	Group 2 (n=66)	Group 3 (n=68)
	Tool & SSP	*SSP*	*CAU*
Female sex	34 (52.3)	31 (47.0)	37 (54.4)
Age in years, mean (SD)	57.5 (7.0)	56.9 (8.3)	59.2 (7.5)
BMI*, mean (SD)	30.4 (5.7)	29.5 (5.9)	28.2 (4.3)
Origin non-Dutch	5 (7.7)	4 (6.1)	3 (4.4)
Married or cohabiting partners	48 (73.9)	46 (69.7)	55 (80.9)
Education			
Low	19 (29.2)	19 (28.8)	15 (22.1)
Medium	35 (53.8)	40 (60.6)	43 (63.2)
High	11 (16.9)	6 (9.1)	10 (14.7)
Employed	31 (47.7)	31 (47.0)	31 (45.6)
COPD	25 (38.5)	26 (39.4)	31 (45.6)
Gold stadium			
GOLD stadium 1	9 (36.0)	13 (50.0)	15 (48.4)
GOLD stadium 2	15 (60.0)	12 (46.2)	16 (51.6)
GOLD stadium 3	1 (4.0)	1 (3.8)	0 (0.0)
Diabetes type 2	40 (61.5)	40 (60.6)	37 (54.4)
Insulin use	3 (7.5)	6 (15.0)	8 (21.6)
Co-morbidities	51 (78.5)	46 (69.7)	43 (63.2)
Asthma	6 (9.2)	8 (12.1)	4 (5.9)
Cardiac/vascular	12 (18.5)	8 (12.1)	7 (10.3)
Hypertension	22 (33.8)	29 (43.9)	20 (29.4)
Arthritis	13 (20.0)	11 (16.7)	16 (23.5)
Depression	3 (4.6)	5 (7.6)	5 (7.4)
Also diabetes	2 (3.1)	1 (1.5)	1 (1.5)
Also COPD	2 (3.1)	6 (9.1)	2 (2.9)
Other	28 (43.1)	22 (33.3)	27 (39.7)
Computer use*			
Regularly	50 (76.9)	43 (65.2)	47 (69.1)
Rarely	15 (23.1)	23 (34.8)	21 (30.9)
Mobile phone use			
Owns a smartphone	24 (36.9)	24 (36.3)	19 (28.0)
Uses mobile phone frequently	20 (30.8)	20 (30.3)	15 (22.1)
Uses mobile phone rarely	19 (29.2)	19 (28.8)	33 (48.5)
Does not own a mobile phone	2 (3.1)	3 (4.5)	1 (1.5)

** P≤0.10, tested with chi square or ANOVA*

Table 2 Values at baseline. Values are means with (standard deviations).

	Group 1 (n=65) *Tool & SSP*	Group 2 (n=66) *SSP*	Group 3 (n=68) *Care as usual*
Physical activity			
Minutes per day in moderate and vigorous ≥3 METS*	39.3 (18.1)	47.5 (26.5)	44.1 (20.3)
Wear time of the Pam in hours a day	14.3 (1.7)	14.5 (1.5)	14.3 (1.3)
Self-efficacy			
General self-efficacy scale	3.2 (0.5)	3.2 (0.5)	3.1 (0.5)
Exercise self-efficacy scale	55.4 (17.0)	53.1 (21.3)	54.0 (19.2)
Factor 1 Situational/interpersonal	51.2 (18.7)	45.9 (20.8)	48.3 (23.2)
Factor 2 Competing demands	62.0 (18.5)	60.0 (21.6)	62.6 (20.2)
Factor 3 Internal feelings	53.8 (18.8)	53.3 (22.2)	52.4 (21.1)
Quality of life			
Physical Component Score*	42.5 (11.1)	46.1 (9.8)	45.8 (9.4)
Mental Component Score	48.2 (10.3)	48.6 (11.7)	50.1 (9.5)
RAND36 physical functioning	68.7 (22.2)	74.6 (20.4)	74.7 (21.9)
RAND36 role functioning physical**	55.8 (45.9)	72.2 (36.7)	70.8 (39.5)
RAND36 role functioning emotional	72.8 (38.1)	77.4 (34.4)	78.4 (35.4)
RAND36 social functioning	77.1 (22.8)	77.7 (23.8)	80.5 (20.8)
RAND36 body pain	66.0 (24.8)	70.7 (25.1)	70.8 (23.1)
RAND36 mental health	73.9 (15.1)	74.9 (19.7)	76.5 (14.9)
RAND36 vitality**	55.2 (19.1)	62.5 (20.8)	64.3 (16.4)
RAND36 general health	51.3 (19.6)	55.6 (20.6)	55.2 (16.2)

** P≤0.10, tested with ANOVA*

*** P≤0.05, tested with ANOVA*

Primary outcome (Intention to treat)

For the primary outcome, a two level hierarchical model dealing with dependency of measurements in time within patients (but not family practices) was applied with a correction for baseline physical activity and wear time. ICC for repeated measures was 0.77, ICC for participants in the same practice was 0.005. Directly after the intervention, participants in group 1, who received the tool and the SSP, showed 8 minutes more moderate and vigorous physical activity (≥ 3 METS) than participants in the SSP, and 12 minutes more PA than the care as usual group. This improvement difference was 9 minutes and 11 minutes, respectively, three months after the end of the intervention. No difference was observed between group 2 (SSP) and group 3 (care as usual). Results are shown in Table 3.

Table 3 Multilevel analyses for differences between the three groups for physical activity.

		Unadjusted mean (SD)			Adjusted mean difference 95% CI, *p*-value[A]			ICC[B]
	Time points	Tool & SSP	SSP	CAU	Tool & SSP – CAU	SSP – CAU	Tool & SSP – SSP	
PA moderate and vigorous (≥3METS)[A]	Baseline (t0)	39.29 (18.1)	47.47 (26.5)	44.13 (20.3)	-0.34 (-5.65 to 4.97); 1.000	0.15 (-5.13 to 5.44); 1.000	-0.50 (-5.83 to 4.84); 1.000	0.77
	4-6 months (t1)	48.16 (23.8)	46.28 (30.8)	39.61 (19.5)	11.73 (6.21 to 17.25); 0.000**	3.87 (-1.60 to 9.24); 0.270	7.86 (2.18 to 13.54); 0.003**	
	9 months (t2)	48.82 (23.8)	45.34 (31.3)	42.40 (18.9)	10.59 (4.94 to 16.25); 0.000**	1.19 (-4.38 to 6.76); 1.000	9.41 (3.70 to 15.11); 0.000**	

A Adjusted for baseline physical activity and wear time
B 2-level random intercept (repeated measurements)
***p <0.01*

Secondary outcomes

For all secondary outcome measures, a two level hierarchical model was applied. Table 4 shows that in general and exercise self-efficacy, no significant differences were observed. After 9 months, participants in Goup 2 (SSP) did score significantly higher for the physical component of the quality of life scale than participants in Groups 1 (tool + SSP) and 3 (care as usual (CAU)). At the end of the intervention (6 months), participants in both intervention groups did score significantly higher on the mental component scale compared to the care as usual group.

Per protocol analyses

The results from 174 participants (Figure 3) were analysed for the per protocol analysis. All per protocol analysis confirmed the intention to treat analysis.

Subgroup analyses

No differences were observed in outcomes for people with COPD or type 2 diabetes (results not presented).

Table 4 Multilevel analyses for differences between the three groups for secondary outcome measures

		Unadjusted mean (SD)			Adjusted mean difference 95% CI, p-value[A]		
	Time points	Tool & SSP	SSP	CAU	Tool & SSP-CAU	SSP-CAU	Tool & SSP-SSP
Self-efficacy							
General self-efficacy scale[B]	Baseline (t0)	3.2 (0.5)	3.2 (0.5)	3.1 (0.5)	0.03 (-0.10 to 0.16); 1.000	0.03 (0.10 to 0.16); 1.000	-0.00 (-0.13 to 0.13); 1.000
	4-6 months (t1)	3.3 (0.4)	3.3 (0.5)	3.2 (0.4)	0.05 (-0.09 to 0.18); 1.000	0.02 (-0.11 to 0.15); 1.000	0.03 (-0.10 to 0.16); 1.000
	9 months (t2)	3.2 (0.5)	3.3 (0.5)	3.2 (0.4)	0.01 (-0.13 to 0.15); 1.000	0.00 (-0.13 to 0.13); 1.000	0.01 (-0.13 to 0.14); 1.000
Exercise self-efficacy scale[C]	Baseline (t0)	55.4 (17.0)	53.1 (21.3)	54.0 (19.2)	1.10 (-5.04 to 10.38); 1.000	-0.68 (-8. 36 to 7.01); 1.000	2.67 (-5.04 to 10.38); 1.000
	4-6 months (t1)	59.7 (17.3)	59.7 (19.6)	54.5 (17.4)	4.86 (-3.12 to 12.83); 0.431	5.41 (-2.52 to 13.35); 0.304	-0.56 (-8.61 to 7.50); 1.000
	9 months (t2)	52.1 (16.1)	60.3 (19.1)	56.5 (19.2)	-0.03 (-8.01 to 7.94); 1.000	3.60 (-4.33 to 11.53); 0.828	-3.63 (-11.69 to 4.43); 0.838
Quality of life							
RAND physical component[D]	Baseline (t0)	42.5 (11.1)	46.1 (9.8)	45.8 (9.4)	-0.31 (-2.48 to 1.86); 1.000	0.20 (-1.96 to 2.35); 1.000	-0.51 (-2.69 to 1.68); 1.000
	4-6 months (t1)	45.2 (9.5)	46.8 (10.0)	47.0 (10.0)	-0.07 (-2.32 to 2.19); 1.000	-0.08 (-2.33 to 2.17); 1.000	0.01 (-2.30 to 2.33); 1.000
	9 months (t2)	44.1 (9.5)	48.2 (8.6)	45.8 (9.5)	0.34 (-1.96 to 2.64); 1.000	2.99 (0.72 to 5.26); 0.005**	-2.65 (-4.99 to -0.32); 0.020*
RAND Mental component[D]	Baseline (t0)	48.2 (10.3)	48.6 (11.7)	50.1 (9.5)	-0.30 (-3.27 to 2.68); 1.000	-0.39 (-3.34 to 2.56); 1.000	0.09 (-2.90 to 3.09); 1.000
	4-6 months (t1)	48.8 (10.6)	51.6 (11.3)	47.7 (9.8)	3.23 (0.14 to 6.32); 0.04*	4.39 (1.32 to 7.47); 0.002**	-1.16 (-4.33 to 2.01); 1.000
	9 months (t2)	48.3 (11.7)	50.1 (10.9)	50.3 (8.3)	0.21 (-2.94 to 3.36); 1.000	0.23 (-2.88 to 3.34); 1.000	-0.02 (-3.22 to 3.17); 1.000

A Linear mixed model 2-level random intercept (repeated measurements)
B Adjusted for baseline General self-efficacy scale, computer use, and baseline physical activity moderate + vigorous
C Adjusted for baseline Exercise self-efficacy scale
D Adjusted for baseline RAND physical component and baseline RAND mental component
** P <0.05*
*** P <0.01*

Discussion

Principal findings

The complete *It's LiFe!* intervention led to significant improvement of moderate to vigorous physical activity among patients with COPD or type 2 diabetes between 40 and 70 years old in primary care, compared to usual care. Right after the intervention period, the entire intervention added 12 minutes per day of moderate to vigorous physical activity compared to care as usual. Three months after the intervention period, this progress was still significant (11 minutes). This study also proved that use of the tool on top of the SSP is more effective than the SSP only. The added value of the tool was an additional 8 minutes of moderate to vigorous physical activity per day. The SSP alone had no significant effect on physical activity compared to care as usual. For the secondary outcome measures, the intervention effect was not evident. It did not result in higher self-efficacy levels. Only the scores on the mental component scale of quality of life showed higher levels directly after both interventions, compared to care as usual, but this difference was not maintained after nine months. At nine months follow up, participants in the SSP group scored significantly higher on the physical component of the quality of life scale compared to the other groups.

Strengths and limitations

To the best of our knowledge, this is the first randomised controlled trial that tests the added value of a monitoring and feedback tool in addition to counselling by the PN. An important strength of this study is the objective measurement of the primary outcome measure—physical activity—by an activity monitor instead of a subjective questionnaire. Other strengths are randomisation at the practice level to minimise contamination, delay of randomisation until after inclusion of the participants, the minimisation of Hawthorne effects by avoiding contacts between the researchers and participants; and simultaneous with the effect study, a process evaluation was conducted. The latter revealed that despite technical difficulties, the intervention was carried out as intended by the PNs. Another strength of this study is the pragmatic approach. Since the interventions were adapted and embedded in care as usual, it is more likely that the effects will be sustained in the daily primary care setting.[40]

Limitations of this study were that the mean baseline physical activity was above the recommended level of 30 minutes of moderate to vigorous activity a day, only 10% of the approached family practices agreed to participate in the study and only 37% of the approached patients agreed to participate in the intervention. These factors may have induced a selection bias, which makes the results less generalizable. However, a common reason for family practices to refuse participation was the required time investment for the practice nurse. Part of the time investment was for research purposes, which will

be eliminated, if embedded in daily practice. The low reach among patients may be explained by the fact that in this study patients with low physical activity levels who were not aware of the problem of their inactivity (according to the transtheoretical model of behaviour change,[41] the precontemplation phase of change) were not included, because the decision to participate had to be made before the consultation with the PN to create awareness could have taken place. In daily practice, the PN starts with raising awareness in regular consultations, which may result in a shift to the contemplation or preparation phase of change, and after this, patients will be asked if they are willing to work on their lifestyle with the help of the *It's LiFe!* intervention. Another limitation of this study was that cycling, swimming, strength training, and all upper body movements were not taken into account in the primary outcome measure because these could not be captured with the Pam. Furthermore, the follow-up was relatively short, three months after the intervention period. Ideally, a 12 month follow-up is recommended.[42] Due to time constraints, this was not possible. Clinical outcomes were not measured to avoid the Hawthorne effect in the care as usual group.

Comparison with prior work

From the result that the tool embedded in the SSP is effective in contrast to the SSP alone, it can be concluded that the automated self-monitoring and feedback component and/or the fact that the PN could see the objective measured PA results, was the most powerful element of the combined intervention. This is in line with the conclusion of a meta-analysis, that PA intervention studies for chronically ill patients incorporating self-monitoring showed a greater effect than studies without self-monitoring.[43] In the SSP, participants only monitored their behaviour during the first two weeks by using an activity diary. The fact that PA was measured objectively in group 1 may also have reinforced the goal setting component. Goal setting is more effective if goals are set with a specific outcome, proximal in terms of attainment, and realistic for the individual.[13] This is easier to achieve if objective PA results are available for the patient and the PN, and goals can be adapted during the intervention period based on the obtained results. The individual effect of the tool without the guidance by the PN cannot be extracted from this research, although we do expect that guidance by the nurse is an essential element of the intervention for first raising awareness, risk communication, social support, perseverance with the intervention, and adoption and persistent use of the tool. From the pilot study, it was learned that participants felt a desire to succeed due to the commitment they made with the PN and the effort she put into them.[21] Other research also showed the importance of professional advice and guidance with continued support for the improvement of physical activity levels.[12]

Other studies demonstrated that a reduction in the number of contacts diminished the behaviour change that had been already achieved, especially when the intervention

ends.[13,44,45] In this study, three months after the intervention period, group 1 was still significantly more active than the care as usual and the SSP group.

Although exercise self-efficacy is positively correlated with physical activity levels,[34] no significant differences were found on this scale between the groups, nor on general self-efficacy. This is in line with the findings from the *It's LiFe!* pilot study.[21] Surprisingly, no effects were found on the physical component of the quality of life scale directly after the intervention, but it did improve in the SSP group three months after the intervention. We have no explanation for this observation. Awareness that physical activity is being monitored might influence habitual behaviour.[46] For the intervention, this was a desirable effect of the *It's LiFe!* tool. However, it was an undesired effect of the use of the Pam. In this view, the proven effectiveness of the total intervention on the primary outcome—moderate to vigorous physical activity—is even more distinct considering the fact that those participating in research often show social desirable behaviour while wearing an accelerometer for a short period of the time.[47] Participants in group 1, however, became used to being observed with an accelerometer for four and six months, which could have led to less social desirable behaviours during the research measurement periods, compared to the other groups.

Implications for practice and future research

Results of this study revealed the powerful addition of continuous support by the use of a monitoring and feedback tool in addition to behaviour change counselling. Because of this added value, it seems worthwhile to implement the intervention on a larger scale. However, cost-effectiveness should be investigated. To encourage general practices to adopt this intervention, health insurance companies should stimulate self-management support regarding physical activity with financial reimbursements for general practices. The fact that the availability and use of smartphones and wearables to measure physical activity is growing[48] is promising for the adoption of the intervention. In daily practice, the intervention can be easily tailored to the individual needs of the patient—for example, more time for raising awareness, or referral to an exercise programme with a physiotherapist if exercise self-efficacy or capacity is considered too low. In addition, the intervention can be more extensive or recurrent in care as usual with more emphasis on habit formation, instead of a determined period of four to six months. The application of this intervention to other target groups should be investigated just as the execution by other care providers as physiotherapists and dieticians.

Conclusions

The monitoring and feedback tool, if embedded into a counselling protocol, was an effective instrument to improve physical activity of patients with COPD or type 2 diabetes between 40 and 70 years old. This improvement was sustained for 3 months.

Counseling without the tool was not effective. The use of technology added to counseling is promising for physical activity behaviour change. Future research about the cost-effectiveness and application under more tailored conditions and in other target groups is recommended.

Acknowledgements

The project is funded by ZonMw (The Netherlands Organization for Health Research and Development) in the program, "New Instruments for Healthcare", and partly by the insurance company CZ. The companies involved in the development of the tool were IDEE Maastricht (the Netherlands); Maastricht Instruments Ltd. (the Netherlands); and Sananet Care Ltd. (the Netherlands). During the trial, Sananet Care Ltd. manned the helpdesk and Maastricht Instruments Ltd. sent new tools to the participants if technical problems arose.
The authors would like to thank the participants in the study: the patients, practice nurses and GPs, and the patient representatives, Jos Donkers and Ina van Opstal. Furthermore, we would like to acknowledge April Boessen for her help with the data entry, Claudia Valentijn for her help at the service desk, and Willem Bekker for the 100% physical activity data check.

Conflicts of Interest

A grant from ZonMw and from Insurance Company CZ was received during the conduct of the study.

Abbreviations

COPD: chronic obstructive pulmonary disease
DM2: type 2 diabetes
GP: general practitioner
It's LiFe!: Interactive Tool for Self-management through Lifestyle Feedback
METS: metabolic equivalents
ML: maximum likelihood
PA: physical activity
Pam: Physical Activity Monitor AM300
PN: practice nurse
REML: restricted maximum likelihood
SSP: self-management support program

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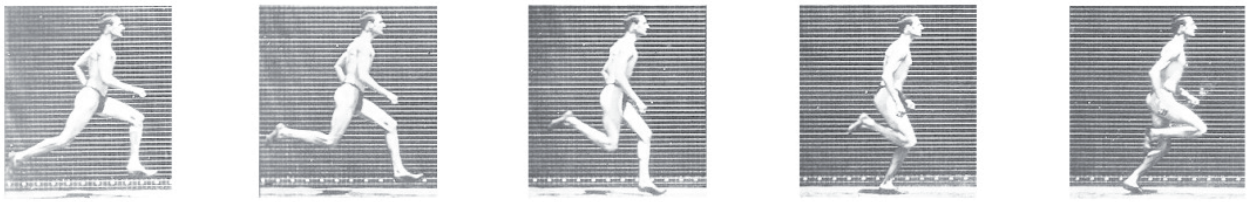
CHAPTER 7

Process evaluation of physical activity counselling with and without the use of mobile technology: a mixed methods study

Submitted

Verwey R & van der Weegen S, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L. Process evaluation of physical activity counselling with and without the use of mobile technology: a mixed methods study



Abstract

Background A monitoring-and-feedback tool was developed to stimulate physical activity by giving feedback on physical activity performance to patients and practice nurses. The tool consists of an activity monitor (accelerometer), wirelessly connected to a Smartphone and a web application. Use of this tool is combined with a behaviour change counselling protocol based on the Five A's model (Assess–Advise–Agree–Assist–Arrange).

Objectives To examine the reach, implementation and satisfaction with the counselling protocol and the tool.

Design A process evaluation was conducted in two intervention groups of a three-armed cluster RCT, in which the counselling protocol was evaluated with (group 1) and without (group 2) the use of the tool using a mixed methods design.

Settings Sixteen family practices in the South of the Netherlands.

Participants Practice nurses (n=20) and their associated physically inactive patients (n=131), diagnosed with COPD or type 2 diabetes, aged between 40-70 years old, and having access to a computer with an internet connection.

Methods Semi structured interviews about the receipt of the intervention were conducted with the nurses and log files were kept regarding the consultations. After the intervention, questionnaires were presented to patients and nurses regarding compliance to and satisfaction with the intervention. Functioning and use of the tool were also evaluated by system and helpdesk logging.

Results Eighty-six percent of patients (group 1: n=57 and group 2: n=56) and 90% of nurses (group 1: n=10 and group 2: n=9) responded to the questionnaires. The execution of the intervention was adequate; in 83% (group 1: n=52, group 2: n=57) of the patients, the number and planning of the consultations were carried out as intended. Eighty-eight percent (n=50) of the patients used the tool until the end of the intervention period. Technical problems occurred in 58% (n=33). Participants with the tool were significantly more positive about the intervention than those without the tool: patients: $\chi^2(2, N=113)=11.17$, p=0.004, and nurses: $\chi^2(2, N=19)=6.37$, p=0.040. Use of the tool led to greater awareness of the importance of physical activity, more discipline in carrying it out and more enjoyment.

Conclusions The interventions were adequately executed and received as planned. Patients from both groups appreciated the focus on physical activity and personal attention given by the nurse. The most appreciated aspect of the combined intervention was the tool, although technical problems frequently occurred. Patients with the tool estimated more improvement of physical activity than patients without the tool.

Background

People who are insufficiently active have a 20% to 30% increased risk of death compared to people who engage in at least 30 minutes of moderately intense physical activity on most days of the week.[1,2] Since physical inactivity is the fourth leading risk factor for global mortality, the World Health Organization agreed on targets that include a 10% reduced prevalence of insufficient physical activity (PA) by 2025.[3] To achieve this goal, it is recommended that routine patients' contacts in primary care should include assessment of PA, advice on the benefits of increased levels of PA, and practical support to help patients initiate and maintain healthy behaviours.[4-7] Practice nurses (PNs) have regular contacts with chronically ill patients who can benefit from an active lifestyle; therefore these contacts are an excellent opportunity for promoting physical activity. Effective interventions to stimulate PA include consultations with brief negotiation or discussion to decide on reasonable and attainable goals, targeted information, and follow-up.[8] New modes to support self-management through computer or mobile phones are promising.[9-11] Interventions including these technological innovations show potential to change health behaviours and to improve clinical outcomes in patients with a chronic illness.

In the project Interactive Tool for Self-management through Lifestyle Feedback! (*It's LiFe!*) a personalized monitoring and feedback tool (Figure 1) was developed[12] and tested[13,14] according to User Centred Design, a design philosophy in which the end-user's needs, wants and limitations are a focus at all stages within the design process.[15] This tool aims to support patients with type 2 diabetes (DM2) or Chronic Obstructive Pulmonary Disease (COPD) in achieving a more active lifestyle. The tool consists of three elements:

1. a three-dimensional activity monitor (accelerometer) worn on the hip;
2. a smartphone application (app);
3. a web application (for both patients and nurses).

The tool is employed within a behaviour change counselling protocol which is executed by PNs, named the Self-management Support Programme (SSP).[16]

After a successful feasibility study of the complete intervention,[17] a three armed cluster randomised controlled trial was conducted to evaluate the effect of the intervention on PA, (exercise) self-efficacy, quality of life, and patient health. A detailed study protocol of the It's LiFe! RCT was published in advance, including the process evaluation of this effect study.[18]

Figure 1 The tool

Incorporating a process evaluation is necessary for complex interventions to examine the context, implementation, and receipt of the intervention in depth.[18-23] Process evaluations are also necessary in multi-centre trials, where 'the same' intervention may be implemented and received in different ways.[24] For this study both arguments are appropriate. The intervention is complex, because it consists of a number of different aspects; both the SSP and the use of the tool, which may influence the effects of the study separately and in combination with one another.[21] Furthermore, the study was set up as a multi-centre trial in which each family practice might encounter different problems with the tool and each PN following the SSP might develop her own style of coaching. The research questions of the process evaluation were:

1. Who participated in the intervention, which patients dropped out, and for what reasons?
2. To what extent was the intervention executed and received as intended?
3. How did patients and nurses experience the different aspects of the intervention (the SSP and the monitoring and feedback tool), and what suggestions did they have for improvements?

This paper presents the results of the *It's LiFe!* process evaluation.

Methods

Design of the process evaluation

From December 2012 until July 2014 a process evaluation amongst participating family practices in the intervention groups of the trial was conducted. Research questions were drawn up according to the how-to guide of Saunders for developing a process-evaluation plan to assess the implementation of a targeted health promotion intervention; they focused on the following components: recruitment, reach, context, fidelity, dose delivered, dose received - exposure, and dose received – satisfaction.[23,25] Table 1 shows an overview of these components, their operationalisation and corresponding measurements and timing.

Setting and participants

From June 2013 until April 2014 a three-armed cluster randomised controlled trial was conducted to measure the effects of the use of the tool embedded in a counselling protocol. The trial compared this counselling protocol with and without the use of the tool (groups 1 and 2) with usual care (group 3). A total of 24 family practices were randomly allocated into one of the three conditions: eight practices (group 1) received the complete intervention (SSP and tool), eight practices (group 2) received only the SSP, and eight practices (group 3) received care as usual. Nurses and patients randomised in the third arm, which performed and received care as usual (group 3), were not involved in the process evaluation. The intended study population for the trial consisted of 120 patients with DM2 and 120 patients with COPD.

Participants and recruitment

General practices located in southern regions of the Netherlands were invited by an invitation letter, telephone and personal contact with GP's, practice managers, and PNs, until a maximum of 24 practices was reached. In the practices that agreed to participate, the PN was asked to invite 20-32 patients (aged between 40-70 years old, and with access to the internet) who, according to the PN, did not comply with the Dutch Norm for Healthy Exercise (at least 30 minutes of moderate-intensity aerobic physical activity (equivalent to brisk walking and noticeably accelerating the heart rate on five days of the week)[26] and were sufficiently motivated to become more active. All eligible patients received an information letter with a general explanation about the trial. After randomisation on practice level, specific invitation letters were sent to these patients, according to the group their practice was assigned to, followed by a telephone call from the PN to ask the patient if he or she wanted to participate. Non-responders were asked for their reasons not to participate. Each practice was asked to include at least five patients with COPD and five patients with DM2.

Table 1 Key components of the process evaluation

Component and definition	Operationalisation	Measurements and timing							
		Dropout (call researchers)	System log file server (continuously)	Helpdesk log file (continuously)	Inclusion list by PN (at baseline)	Questionnaire (after the intervention)	Consultation evaluation forms (per consultation)	Questionnaire (after the intervention)	Interview (by phone after 2nd consultation)
		Patients					*Nurses*		
1. Who participated in the intervention, which patients dropped out, and for what reasons?									
Recruitment *The recruitment procedures that were used.*	Characteristics of practices and patients that were invited and that refused to participate.				x				
Reach *The proportion of the intended target population that participated in the intervention groups.*	Characteristics of patients.	x				x	x		
	Number of patients that completed the programme or dropped out.	x							
	Reasons for withdrawal.	x							
Context	Characteristics of general practices.								x
	Characteristics of practice nurses.								x
2. To what extent was the intervention executed and received as intended?									
Fidelity *Extent to which the tool functioned as planned.*	Extent to which technical problems occurred.			x		x		x	
Dose delivered *The extent to which the intervention components were carried out as often and for as long as planned, regarding the SSP.*	Consultations and other contacts (dates, time, planned and executed, within regular consultations or extra).						x		
	Extent to which the PN: assessed the PA level; informed the patient about the risks of a sedentary lifestyle; collaboratively set goals and set up an action plan with the patient; gave feedback based on the PA goals; discussed with the patient barriers and facilitators for being active;- used motivational interviewing techniques.					x	x		x

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		Dropout (call researchers)	System log file server (continuously)	Helpdesk log file (continuously)	Inclusion list by PN (at baseline)	Questionnaire (after the intervention)	Consultation evaluation forms (per consultation)	Questionnaire (after the intervention)	Interview (by phone after 2nd consultation)
		Patients					*Nurses*		
Dose received (exposure) *Extent of patients' active engagement in and receptiveness to the intervention* *- Regarding the SSP* *- Regarding the tool: extent to which the tool was used as intended*	Overall opinion of the patient and the practice nurse regarding the patient's engagement in the programme.					x	x		x
	Instruction of the SSP and the tool (use of the manual and the instruction movies).					x			x
	Adherence towards the tool (completion sessions, wearing the tool).		x			x			
	Monitoring results in between consultations.							x	x
	Experiences using the tool Activity monitoring Sessions Feedback messages		x			x			x
	Experience using the web application by practice nurses during the consultations. Set up and change goals View patients' results		x		x				x
3. How did patients and nurses experience the different aspects of the intervention (the SSP and the monitoring and feedback tool), and what suggestions did they have for improvements?									
Dose received (satisfaction) *Satisfaction of patients and practice nurses with the different components of the intervention*	How satisfied were the patients and the practice nurses with the programme, with the tool and with the combination of both?					x		x	x
	How did the patients and the practice nurses perceive the outcomes and relevance of the interventions?					x		x	x

Ethical approval

The study protocol of the trial, including the process evaluation, was approved by the Medical Ethics Committee of the Maastricht University/Academic Hospital Maastricht. Written informed consent from all participating family practices and included patients was obtained.

The intervention

Patients in group 1 received the monitoring and feedback tool embedded in the SSP, whereas patients in group 2 received the same programme without the use of the tool.

Different aspects of the intervention

The different aspects of the interventions are depicted in Table 2.

The SSP

The SSP consisted of four consultations with the PN spread over a period of four to six months: in the first week, after two weeks, after two to three months and after four to six months. The consultations were based on the 'Five A's cycle' counselling technique (Assess–Advise–Agree–Assist–Arrange).[27,28] Beforehand, patients received an information booklet about the course of the intervention containing the Short Questionnaire to Assess Health (SQUASH)-enhancing PA[29] and a list of locally organised PA activities. In the first consultation the PN increased the awareness about the risks of physical inactivity (Advise) and the PA level of the patient was discussed using the previously completed SQUASH questionnaire (Assess). In addition, all patients received a general and a disease specific leaflet about PA (Advise).[30,31] Between the first and the second consultation, patients completed an activity diary and answered questions about barriers and facilitators for PA. During the second consultation, a personal goal was set in minutes of activity per day (Agree), the nurse informed the participants about locally organised PA options (Assist), and the PN encouraged the participants to set up an activity plan to reach personal goals (Arrange). In the third consultation, possibly by mail or telephone, activity results, barriers, facilitators, and the creation of new PA habits, were discussed and some participants reconsidered their activity goal. In the last consultation, activity results, barriers, facilitators, and new habits were evaluated.[18]

Table 2 Different aspects of the intervention

SSP (groups 1 and 2)		Tool (only group 1)	
Materials	Instruction booklet about the Self-management Support Programme Leaflet disease specific information Information about local sports/activities	*Instruction*	Instruction booklet about the Self-management Support Programme and tool Instruction by practice nurse during consultation 1 Manual Instruction movies on the website Helpdesk
Consultations 1-4		*Use of the ativity monitor*	
Different aspects of the consultations (based on the Five A's model)	Assessment of physical activity level by discussing the completed SQUASH questionnaire ***A**ssess* Discussing the activity diary ***A**ssess* Discussing the risks of a sedentary lifestyle ***A**dvice* Goal setting ***A**gree* Discussing the preferred activities of patients ***A**gree* SMART action planning ***A**ssist* Discussing tips for local activities ***A**ssist* Discussing barriers and facilitators for physical activity ***A**rrange* Discussing habit formation ***A**rrange*	Use of the app and/or the website	Views of physical activity results Use of the "remarks of todays' measurement" option Send and respond to sessions ("register session", 7 "diary sessions", "preparation targets session", "set up activity plan session", "feedback sessions regarding illness, tips, encouragement, positive trend, increase or decrease target, rewards, opportunities or barriers")

The Tool

During the first consultation the nurse provided the patients allocated in group 1 with the tool and registered the patient into the web application. Patients were asked to wear the activity monitor on a daily basis. They could see their real time activity results and history in minutes of moderate to vigorous activity on the smartphone and the web application. They were given a (data) subscription to be able to make telephone calls and to go online, with the intention that they would use the Smartphone in daily living, and consequently look at their activity results more frequently. Furthermore, they received

dialogue sessions and - after the second consultation- feedback messages on the app on the Smartphone concerning their amount of activity in relation to their activity target. During the whole intervention, activity results and answers to dialogue sessions were visible for the PN on a secured web application and they could be used as input for the coaching in the consultations.[17]

Acceptable delivery of the intervention

The accomplishment of at least three out of four consultations in a period of at least three months was considered an acceptable delivery of the SSP. Consultation number 3 could also be conducted by telephone or by mail contact. PNs provided the patients with all materials during the first consultation.

Conditions for an acceptable delivery of the tool were that the tools should work according to plan, e.g. that every patient was adequately signed up, measurements were uploaded daily to the server, and that the tools were free of technical failure. To maintain these conditions, a helpdesk facility was running during working days/hours to answer technical questions, solve user problems, and replace the tool within five days, if needed.

Education and training

Patients were sent an information booklet about the course of the intervention. Further materials and instruction were given by the practice nurse.

The nurses in groups 1 and 2 were asked to watch an online web lecture and consecutively received a two-hour personal instruction at their workplace. They also received an information file with detailed instruction charts for each consultation and an explanation of the Five A's model and the intended counselling techniques.

The nurses in group 1 received a personal account, a manual, and personal instruction on how to use the web application. Through this application the nurses could monitor their patients. Furthermore, they were able to try out the tool before the start of the consultations. For technical issues they could refer to the same helpdesk as their patients.

Data collection

Both quantitative and qualitative information were collected from patients and nurses (Figure 2). The researchers developed questionnaires and interview topics by translating theoretical key elements of process evaluations[23,25] into structured questions regarding the different components of the intervention. Table 1 provides a detailed overview of the data collection methods and the timing of the process evaluation. After informed consent, patient characteristics (i.e. demographics) were gathered by means of self-administered questionnaires. The researchers collected dropout reasons throughout the intervention period by calling the patients and asking them to give reasons.

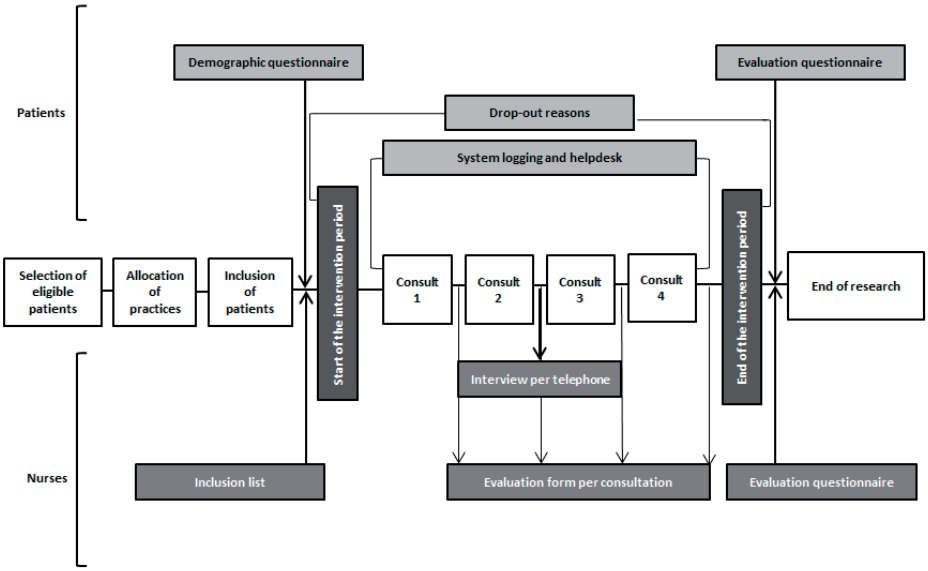

Figure 2 Data collection

To measure exposure to the SSP, the nurses were asked to keep a record of all consultations in log files. To measure exposure to the tool, the use of the tool was measured objectively by extracting information from the server. Technical problems were logged by members of the helpdesk.

Approximately two weeks after the second consultation, all nurses of groups 1 and 2 were interviewed by telephone about their experiences so far. In the interviews, that lasted approximately half an hour, special attention was paid to the factors that might influence compliance with the intervention on two levels: complying with the advice and feedback given during the consultations, and with 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 patients.

To diminish Hawthorne effects, there were no direct contacts between researchers and patients. Patients were not interviewed in order to distinguish between the intervention and its evaluation.[32]

Data analysis

Quantitative data were analysed by means of descriptive statistics, and Fisher's exact tests were used to test if there were differences between the groups, using the IBM Statistical Product and Service Solutions (SPSS) version 22. Qualitative data (results from open questions and interviews) were analysed by two researchers (RV, SvdW) independently using NViVo version 9 in order to identify relevant themes. In cases of

disagreement, mutual agreement was found by discussion. A concurrent triangulation strategy was applied to confirm, cross validate, and corroborate the findings. The timing of the analysis of the process data was planned before the data from the effect study were analysed, to avoid interpretation bias.[24]

Results

Characteristics of the respondents

One hundred and thirty-one patients were assigned to the intervention groups in 16 family practices; 86% (n=113) of them responded to the process evaluation questionnaire (51% male, mean age 58 years SD ±7.7; group 1: n=57 and group 2: n=56). Sixty-three percent (n=71) of these respondents were diagnosed with DM2 and 37% (n=42) with COPD.

Of the 20 nurses (group 1: n=11 and group 2: n=9) who performed the intervention, 95% responded to the questionnaire (group 1: n=10 and group 2: n=9) and 90% participated in the interviews (group 1: n=9 and group 2: n=9).

Participants (recruitment, reach, and context)

From October 2012 until May 2013 approximately 250 general practices, were invited to participate in the study. Although practices were offered an appropriate reimbursement of expenses, most practices refused because they were too busy with regular patient care.

The size of participating practices ranged from small (<90 DM2 patients) to large (>390 DM2 patients). In group 1, two practices were located in a city, in group 2 three were. In three practices in group 1 and in one practice in group 2, the intervention was carried out by two practice nurses. All nurses were female, the nurses who were interviewed had a mean age of 43.4 years (range 26-54), and their average working experience as a PN was 13.5 years (range 2-32); 11 nurses finished secondary vocational education and seven nurses higher professional education.

All nurses were instructed as planned, but the web lectures were rarely watched. All nurses were satisfied with the instruction charts per consultation. Nurses in group 1 experienced the instruction as too brief, especially to become familiar with the web application.

Nurses from the participating practices indicated that it was very difficult to find enough eligible patients, because their patient population consisted mainly of people above the age of 70, or the patients did not master the Dutch language well enough. Before randomisation, approximately 540 patients received a general invitation letter and a call from their nurse, and 131 agreed to participate in the intervention groups.

Reasons for not taking part in the trial were: patients were not motivated, had no time, were too busy with work, had no access to internet/computer, did not feel the need because they were physically active enough, had physical or psychosocial disabilities, or thought they were clumsy with the computer.

In both intervention groups 80% of the intended number of patients (n=64) started the intervention. In total, 17% of the patients (group 1: n=13, group 2: n=9) did not receive the minimal intervention as intended. The average intervention period of the remaining patients was 25 weeks. Of the 131 patients who agreed, 2% (n=3) never started the intervention, 5% (n=6) had only one consultation, 8% (n=11) had two consultations, 11% (n=15) had three consultations, and 73% (n=96) had all four consultations. Dropout reasons were technical problems with the tool (n=8), becoming ill (n=7), personal or family circumstances (n=3), too busy with work (n=2), or lack of perceived usefulness (n=2).

Execution of and receptiveness towards the interventions (fidelity - dose delivered - dose received (exposure))

The first practices started with the intervention in June 2013, and the last practices finished in April 2014.

Self-management Support Programme

According to the log files per consultation, often the consultations took longer than the intended 20 minutes. This was the case with the first consultation (group 1: 77% n=49 and group 2: 50% n=33), the second consultation (group 1: 40% n=26 and group 2: 33% n=21), and the last consultation (group 1: 22% n=14 and group 2: 52% n=34). Thirty-six percent of the consultations were conducted within a regular consultation, whereas 64% were planned as extra. The nurses had the opportunity to contact patients in between consultations to monitor results and experiences of patients; in group 1 this happened more often (60% n=6) than in group 2 (33% n=3). In group 1 the nurses had more contact with patients in between consultations; this was mostly related to technical problems with the tool.

Regarding the execution of the Five A's model, there were no significant differences between the groups and most components were executed as planned.Table 3 shows percentages of patients who remembered the different aspects of the Five A's model. The nurses stated that, by performing the intervention, they became more conscious about the PA of patients. They also mentioned the fact that lots of patients indicated that they were already sufficiently active, and that despite the wish of patients to become more active, there were always lots of excuses for not doing so.

Table 3 Execution of the Five A's model within the SSP according to patients

	Group 1 n=57		*Group 2 n=56*	
	n	% yes[A]	n	% yes[A]
Assessment of PA level by discussing the completed SQUASH questionnaire	45	70%	45	73%
Discussing the activity diary	49	63%	46	64%
Discussing the risks of a sedentary lifestyle	55	91%	49	80%
Goal setting	52	84%	41	63%
Discussing the preferred activities of patients	55	97%	47	84%
SMART action planning	53	67%	40	57%
Discussing tips for local activities	50	60%	41	50%
Discussing barriers and facilitators for physical activity	51	72%	40	55%
Discussing habit formation	53	79%	42	63%

A Answer options were yes, no, and not applicable.
Differences between the groups were tested with Fisher's Exact Test p <0.05

All nurses agreed on the importance of self-management support, because they expect better results when patients formulate their own behaviour change goals but nurses from group 2 encountered difficulties for physical activity counselling because they had only vague ideas of physical activity levels of patients. Seventy-four percent (n=13) of the nurses were positive about the SQUASH questionnaire; it gave a clear picture of patients' activities. Nurses valued talking about the risks of a sedentary lifestyle, although 22% (n=4) said that for most patients this was nothing new. Some nurses found it difficult to discuss these risks in cases of severe disability (n=2) or when they had already known the patient for a longer time.

Although collaborative goal setting and composing a plan of action were important parts of the intervention, some patients indicated that goals had not been discussed during the consultations. Goals were mainly set by patients themselves (61% n=69) or in collaboration with the nurse (32%, n=36). There was a significant difference between groups 1 and 2 in the responses regarding goal achievement; (group 1: 84% n=48, group 2: 61% n=34) thought they had reached their goals $\chi^2(1, N=110)=7.50$, p=0.006. Reasons for not achieving activity goals were: physical/psychological symptoms and illness (n=14), job (n=3), and family problems (n=3). All nurses stressed the importance of setting small achievable goals and helping patients to draw up a specific plan, but 17% (n=3) of the nurses had difficulties with advising patients to plan activities in this way

(too scholarly). More than half of the patients remembered discussing the tips for local activities; most patients simply increased their normal activities like walking and cycling.

The tool

Mobile devices (patients)

In group 1, 88% (n=50) of the patients used the tool until the end of the intervention. Reasons to stop wearing the tool were: malfunction of the tool, the belief that using it was not necessary anymore because of an appropriate activity level, or quitting the study. Only 12% (n=7) of the patients did use the phone on a daily basis for purposes other than the intervention, 56% (n=32) only occasionally, whereas 32% (n=18) never used the phone to make calls or use the internet.

Of the 64 patients who were registered in the system by the nurse, one patient did not complete the register session, due to having bad eyesight. Figure 3 A shows the percentages of patients who completed sessions and read feedback messages. Figure 3 B shows how often different types of feedback messages were received by the patients as percentages of the total number of feedback messages (n=1664).

The median of number of times that patients (n=63) used the 'remarks of today's measurement' session was 30 (IQR=15-52). There were 6 diary sessions on consecutive days. On each day, 70 % of the patients completed this session. The median that patients (n=53) read feedback messages was 23 (IQR=6-35). The most frequently given feedback message was the request to increase the daily target goal. This message was automatically sent when a patient reached his or her current target goal for more than 10 days during the previous two weeks.

Fifty-eight percent (n=33) of the patients experienced problems using the tool. During the intervention period, 190 issues were registered by the helpdesk. Most problems occurred with the connection between the sensor and the phone (n=88) or the connection between the phone and the server (n=30). A big issue in the beginning of the trial was that most phones were of a newer type than the one the app originally was developed for. After implementation by six patients, it appeared that those phones logged out automatically and patients had to login again every day. These phones were taken back and new phones were distributed to the practices.

Complications with the connection between the activity monitor and the phone were in some cases due to a user error or misinterpretation of the results; patients disabled the connection between sensor and phone by disconnecting Bluetooth, they did not charge the sensor correctly, or they expected more results than showed. However, in most cases it was a technical problem, and therefore a new sensor was sent or brought to the patient. Regarding the connection between the phone and the server, there were 21 login issues; patients forgot to login on the phone or experienced problems during login. Another reason for a lack of data in the monitor was disconnection of the internet connection by the patient. There were also some hardware

problems with the activity monitor; the case broke (n=3) or the clip broke (n=3). Other issues ranged from a forgotten password to accidentally deleting the app and/or widget. Most registered issues that occurred were relatively easily solvable registration problems.

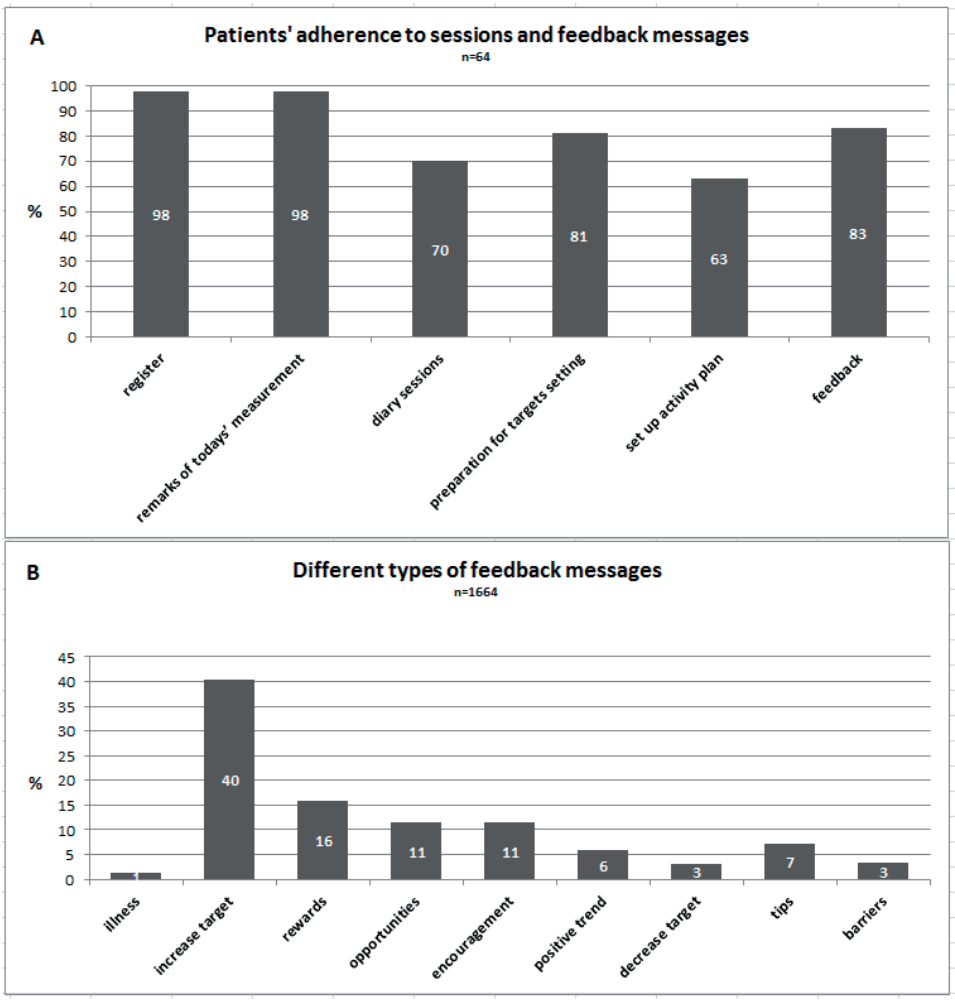

Figure 3 Sessions and feedback messages

Web application (nurses)

Ninety percent (n=9) of the nurses viewed the results using the web application during consultations, and 50% (n=5) viewed results in between consultations. The frequency of use varied from rarely, two times in total, to twice a month per patient. Twenty percent

(n=2) of the nurses experienced problems in using the web application. Some nurses mentioned that PA results from certain patients were not available or not representative for the activity of the patient. In general, the activity levels were lower than the patients expected.

Satisfaction with the intervention (dose received (satisfaction))

Eighty-four percent of the patients in group 1 and 70% in group 2 were satisfied with the intervention. Patients in both groups indicated that they were more physically active, more conscious about being physical active, more motivated to exercise, and that their physical fitness improved. Patients from group 1 were significantly more positive about the intervention than those in group 2 ($\chi^2(2, n=113)=11.17$, $p=0.004$). Those patients were more explicit in their positive opinions about the intervention, specifically about the fact that use of the tool was fun; it led to greater awareness and more discipline.

Patients from group 2 appreciated the extra coaching by the nurse. The opinions on how effective the total programme was, differed significantly between the groups; 75% of the patients in group 1 and 46% of patients in group 2 thought that PA levels were improved ($\chi^2(2, n=110)=8.18$, $p=0.004$). Among the nurses 80% in group 1 and 33% in group 2 thought the intervention was effective and led to higher levels of physical activity. According to group 1 patients, the effectiveness was specifically attributed to the tool (n=11). The nurses in group 2 indicated that participants became more aware of the need for PA, but they doubted the actual change. Suggestions for improvement were very diverse; patients and nurses in group 1 mainly came up with improvements for the tool, patients and nurses in group 2 suggested group sessions, more consultations or supervised training sessions.

Satisfaction with the SSP

Eighty-seven percent (group 1: 88% and group 2: 86%) of the patients and 74% (group 1: 90% and group 2: 56%) of the nurses were satisfied with the number of the consultations. The majority were also satisfied with the content of the consultations, but there was a significant difference between the groups ($\chi^2(2, N=19)=6.37$, $p=0.040$). Group 1 nurses were mainly satisfied or neutral (90%), while the view of group 2 nurses varied more; 67% were satisfied and 33% were dissatisfied with the content of consultations. In group 1, the nurses indicated that the intervention encouraged people to be more physically active because they had more insight into their exercise habits, and nurses liked the possibility to monitor their patients through the use of the web application. The nurses from group 2 mainly emphasised the importance of attention to PA. However, they indicated that the execution of the intervention was rather time-consuming, especially in the beginning.

Satisfaction with the tool

Although most patients in group 1 were positive about the tool, the functioning could be improved. Also the nurses indicated that the technical problems were demotivating. Daily wear of the activity monitor was not a problem. Only 9% (n=3) of the patients were not satisfied with the sessions; however, the feedback messages could be improved according to 32% (n=19) of the patients. Suggestions for improvement of the feedback messages were: more variation (n=9), send less frequently (n=6), and to make them more personalised (n=6).

Discussion

The aim of this process evaluation of the *It's LiFe* RCT was to examine the reach, the implementation, and satisfaction with the interventions: the counselling protocol (SSP), which was delivered in both groups; and the use of the tool, which was used only by patients in group 1.

It proved extremely difficult to find enough practices and patients to participate in the study. Ten times the number of practices had to be approached until a sufficient number of practices agreed, and within the practices, almost three times the number of patients.

Within the participating patients, the execution of the intervention was adequate; in 83% of the patients, the number and planning of the consultations were carried out as intended, and patients remembered the different aspects of the Five A's model as being part of the conversation in 71% of the cases. Of all components of the SSP, discussing the risks of a sedentary lifestyle and the preferences of patients for specific activities were carried out the best, and discussing the tips for local activities the least. In addition, a large proportion of the patients in group 1 used the tool as intended; no less than 88% used it until the end of the intervention period, in spite of the technical problems which occurred in more than 50% of cases.

Patients and nurses in group 1 were more satisfied about the intervention; nurses indicated that the self-monitoring encouraged people to be more physically active and they liked the possibility to monitor their patients through the use of the web application. Surprisingly, the technical problems had little impact on satisfaction; patients from group 1 were significantly more positive about the intervention than those in group 2. There is a possibility that the rapid and adequate service of the helpdesk contributed to this. But it remains highly important to test and retest mobile technology several times before scheduling a large effect study.

The encountered difficulties in finding enough participating practices is in line with the conclusions of a study in which barriers for physical activity promotion in primary care were investigated; identified barriers were a lack of time for health promotion activities, and inadequate practice capacity.[33] Integrating lifestyle counselling into busy

daily practice while simultaneously complying with the many other clinical demands remains a challenge.[34] The difficulty in recruiting sufficient numbers of patients was to some extent related to the fact that one of the inclusion criteria was 'access to the internet', and the fact that the intervention involved the use of a smartphone. However, a recent study revealed that 93% of Dutch care users have internet access, and 51% use a smartphone, with 12% already using self-monitoring devices to access physical activity levels.[35] Based on these figures it is plausible that these barriers for the adoption of the intervention will decrease in the near future.

Compared to other physical activity promotion interventions in primary care,[36] a relatively high percentage of the patients received the minimal intervention, especially when compared to exercise referral programmes, in which 80% of the patients seem to drop out before the end of the programme.[37] The high adherence rate towards the tool is comparable with other studies, in which interventions using a smartphone also resulted in high adherence rates.[38]

Although a minimum amount of time was spent instructing the nurses in how to perform the intervention and, despite the often busy schedules of the nurses, the execution of the consultations and the Five A's model therein was adequate. A study in Scotland revealed that in regular care, practice nurses are likely to recommend patients to take moderate exercise. However, only few correctly describe the current PA recommendations.[39] These conclusions were confirmed by a study observing the Five A's in PA counselling in the United States, which revealed that interventions to increase skills of nurses in exploring ambivalence and readiness to change, as well as improve explicit mention of recommended guidelines for PA are needed.[40] In this trial the instruction charts per consultation contributed to the performing of the intervention. They contained clear directions about the guidelines and how to apply motivational interviewing, and the nurses appreciated this.

Since 2010 a broad innovative approach to disease management based on care standards was implemented in primary care in the Netherlands. The Chronic Care Model is the basis of this disease management approach, which aims to transform primary care towards a more proactive care, not only focussed on acute illness but also on maintaining health and preventing or postponing disease.[41] Self-management support and patient empowerment are essential elements of this approach, in which the practice nurse fulfils an important role.[42] It is already known that patients with COPD or type 2 diabetes are generally positive about the self-management support by practice nurses,[43] this is in line with the satisfaction with the SSP we measured in this study. Regarding the use of the tool, patients mentioned similar experiences as described in the SMART MOVE study,[44] such as more awareness and knowledge, control and focus, and confidence. Patients were satisfied with the automatic tracking of physical activity, the goal setting and visual feedback provided by the tool. Behaviour change theories lay at the basis of the development of the tool, this adds to a better satisfaction of apps to promote exercise.[45]

Although this is an extensive process evaluation executed among all intervention practices of the *It's LiFe!* trial, it has several limitations. At first, the Self-management Support Programme was only evaluated subjectively through the opinion of nurses and patients. No measurements were available to test these elements more objectively, for example through audio-recording of the consultations. Secondly, although the response rate to the patient's evaluation questionnaire was high, it was an assessment of a group of patients who were likely to be rather positive about the intervention, because the majority of dropouts did not return the process evaluation questionnaire. However, a strength of the study was its pragmatic approach; the trial was conducted in very diverse practices with patients with two types of chronic conditions, although ethnic minority groups were represented by only a few patients. Therefore it is unknown how translatable the intervention might be for diverse ethnic and linguistic populations. Further strengths of this study are that it is based on an existing theoretical framework: Saunders' model for process evaluation. In addition, all individual aspects of the Five A's model were evaluated. Also the mixed methods approach is considered as positive; especially the fact that qualitative content analyses were carried out by two researchers independently and before effect outcomes of the RCT were known to them.

As a next step, a more flexible approach towards the intervention should be investigated. The strict inclusion process of the RCT led to exclusion of people who were not yet motivated. In daily practice the practice nurse can execute the intervention in a more gradual way, adapted to the stage of change of the patient, which may lead to a higher reach. In the end, using mobile technology will change the way consultations for monitoring chronic conditions in primary care will take place. In the Netherlands at the moment, reimbursement is based on regular scheduled consultations rather than on supporting self-management by continuous monitoring of conditions in collaboration with patients. The organisational and cost aspects should be further investigated when implementing on a larger scale.

Conclusion

The results of this process evaluation provide a clear distinction between patients' satisfaction of physical activity counselling with and without the use of the tool, although in both cases patients valued the attention to physical activity promotion by the PN. Patients who used the complementary tool were more positive about their physical activity improvement, despite the fact that technical problems frequently occurred. The results of the trial confirm this positive impression.[46] The execution of the consultations, based on the Five A's model, was adequate, although some nurses struggled to fit the extra consultations into their busy daily practice.

Acknowledgements

The authors thank all patients, PNs and GPs who participated in this study, Babette van Doorn and April Boessen for their help recruiting general practices and Claudia Valentijn and Arjan Hageman for their work at the helpdesk. Furthermore, Eveline Habets is acknowledged for her help in conducting and transcribing the interviews, and April Boessen is acknowledged for her help with the data entry.

The project was funded by ZonMw (the Netherlands Organisation for Health Research and Development).

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CHAPTER 8

General Discussion





Introduction

Evidence confirms the benefits that regular physical activity has for the management of chronic conditions; it has a positive effect on prognosis and quality of life. Furthermore, sufficient activity is associated with a lower risk of hospital admission and a decreased risk of mortality, and it also places patients at lower risk of developing co-morbidities.[1] However, despite the well-known benefits of physical activity, many patients do not engage in sufficient physical activity; they do not meet the current guidelines.[2] Therefore, developing both effective and sustainable approaches to promoting physical activity in patients with chronic conditions is important.

The aim of the research presented in this dissertation was first to develop, and then test, the usability and feasibility of a monitoring and feedback tool, together with an additional coaching system for practice nurses embedded in a counselling protocol, to stimulate the physical activity of COPD and type 2 diabetes patients in primary care and, as a next step, to evaluate the effectiveness of this counselling protocol with and without the use of the tool on physical activity, (exercise) self-efficacy and quality of life in a cluster randomised controlled trial, and finally, to evaluate the reach and implementationof, and satisfaction with, this intervention.

This final chapter summarises the main findings from the individual studies and explores methodological considerations regarding the user centred design and testing of a physical activity promotion intervention combined with mobile and Web-based technology. In addition, considerations for the evaluation of the effectiveness of technology-based health behaviour change interventions in primary care, using a cluster randomised controlled trial design, are discussed. Subsequently theoretical considerations regarding behaviour change and lifestyle coaching and their consequences for the changing role of practice nurses are described. The chapter ends with the implications of the findings for research, practice and policy.

Main findings

At the start of the *It's LiFe!* project the original hypothesis was that stimulating the physical activity of chronically ill patients in primary care can be improved by using mobile and Web-based technology embedded in primary care nursing. In close cooperation with two business partners, the tool and the coaching system were developed with the aim of further improving the quality of physical activity counselling by practice nurses. The initial ideas behind the tool were to provide an objective measurement of physical activity via an accelerometer to patients and nurses, collaborative goal-setting and automatic feedback through an application on a smartphone, and a Web-based coaching system, combined with face-to-face feedback from the nurse during consultations.

Development and usability

The counselling protocol, the Self-management Support Programme (SSP), was developed in an iterative user centred design (UCD) manner (Chapter 2).[3] This programme is based on the Five A's model, a counselling technique for supporting self-management.[4,5] The protocol consists of a limited number of behaviour change consultations (one to three extra consultations, designed to complement usual care, spread over a period of at least six months) intertwined with interaction with and responses from the *It's LiFe!* monitoring and feedback tool.[6] This tool provides feedback on patients' physical activity levels via an app on a smartphone. It also sends dialogue sessions and – after the second consultation – feedback messages concerning the amount of activity in relation to an activity goal, which is set in mutual agreement with the practice nurse based on a two-weeks pre-measurement. Activity results and answers to dialogue sessions are visible for the practice nurse on a secured Web application, with the intention of using this information as input for the coaching. During the consultations the practice nurse performs an assessment of the patient's activity pattern using a self-assessment questionnaire, supported by information from a baseline measurement and a diary supplied by the tool. The nurse provides information about the risks of a sedentary lifestyle and the benefits of physical activity for disease prognosis, using an information card. In collaboration with the patient, an activity goal in minutes per day is set, based on personal abilities. Both the practice nurse and interactive sessions supplied by the tool help the patient to write a plan on how to become more physically active. The patient receives a list of local sports activities. Feedback on physical activity performance is given by the practice nurse during consultations, while the tool gives automatic feedback on this performance in between.

Different components of this secure Web application (the *It's LiFe!* monitor) were based on the user requirements of practice nurses, such as the development of automatically generated feedback messages (Chapter 3).[7] The UCD development and testing of this monitor resulted in a system that was appreciated by the nurses. The results of the usability tests gave insights into how to improve the structure and the quality of the information provided by the system. When used in practice, nurses were positive about the features and ease of use, but they made critical remarks about the time that its use entails. Different opinions were expressed about monitoring physical activity results by practice nurses in between planned consultations, notwithstanding the fact that the system supports this. The development of the system in an iterative way made it possible to constantly improve the system and to adapt its use to the care process.

Feasibility and study design

As a next step, the feasibility of the combination of the counselling protocol and the use of the tool together with the coaching system (the *It's LiFe!* intervention) wasevaluated in a pilot study in two family practices with 20 participants (Chapter 4).[8] The results of this study were promising: the intervention stimulated patients to become more physically active and supported nurses in performing physical activity counselling. Physical activity increased by more than 10 minutes per day, and patients reported a higher quality of life. Because the tool itself and its technical problems dominated the consultations, the counselling protocol was only partly executed as planned. But all participants valued the emphasis on physical activity and collaborative goal-setting during the consultations. Without the connectivity problems, and once the nurses had gained some experience in using the system, the tool embedded in the counselling protocol appeared to be a feasible intervention.

On the basis of these outcomes, the tool and the protocol were improved and a three-armed cluster randomised trial in 24 family practices was set up to evaluate the effectiveness of the SSP with (group 1) and without (group 2) the use of the tool compared with usual care (group 3) (Chapter 5).[9] In group 2, the nurses executed the SSP without the tool, with the intention to evaluate the added value of using the tool in combination with the coaching system. The primary outcome was the number of minutes of moderate to vigorous physical activity per day, measured with a physical activity monitor (PAM) and analysed with multilevel mixed-methods. The secondary outcomes were general and exercise self-efficacy, quality of life and health status. Outcomes were measured at baseline, after the intervention (four to six months), and three months thereafter.

Self-management support using mobile technology – outcomes

The complete intervention led to a significant improvement of moderate to vigorous physical activity, compared to usual care (Chapter 6).[10] Right after the intervention period, the entire intervention added 12 minutes per day of moderate to vigorous physical activity compared to usual care. Three months after the intervention period, this progress was still significant (11 minutes). The trial also proved that using the tool on top of the SSP is more effective than the SSP only. The added value of the tool was an additional eight minutes of moderate to vigorous physical activity per day. The SSP alone had no significant effect on physical activity compared to usual care. For the secondary outcome measures, the intervention effect was not evident. From the result that the tool embedded in the SSP is more effective than the SSP alone, it can be concluded that the automated self-monitoring and feedback component, and/or the fact that the practice nurse could see the objectively measured physical activity results, was the most powerful element of the combined intervention.

Self-management support using mobile technology – process

The aim of the process evaluation of the *It's LiFe!* trial was to examine the reach, and implementation of, and satisfaction with, the two main aspects of the intervention: the SSP, which was delivered in both groups and the use of the tool, which was used only by patients in group 1 (Chapter 7).[11] It proved extremely difficult to find enough practices and patients to participate in the study. Ten times the number of practices had to be approached until a sufficient number of practices agreed, and within the practices, almost three times the number of patients. The dropout rate was 17%. The execution of the intervention was adequate: the number and planning of the consultations were as intended (83%), patients remembered the different aspects of the Five A's model (71%), and although technical problems occurred frequently, most patients (88%) used the tool until the end of the intervention. Explicit attention to promoting physical activity in primary care nursing using the Five A's model was valued by patients as well as nurses. The technical problems had little impact on the satisfaction; patients from group 1 were significantly more positive about the intervention than those in group 2. The complete intervention led to more awareness and discipline regarding physical activity. Practice nurses considered the objective measurements a useful addition to their counselling.

Methodological considerations

Besides the limitations of the studies that were described in Chapters 2 to 6 of this dissertation, there were two overall methodological considerations, one being the complexity of developing technology embedded in primary care according to UCD principles, and the other one using a randomised controlled trial (RCT) design to measure the effects of using mobile technology in daily life and practice.

User-Centred Design

The counselling protocol, combined with the use of the tool and monitor presented in this dissertation, was developed according to UCD principles to create an optimal fit between technological, human and contextual factors.[12] Attention to those factors was given from the very early stage of the project, to maximise the likelihood of successful implementation and adoption.[13] This UCD process was characterised by several iterations to determine user requirements, a multidisciplinary development approach, and continuous and systematic evaluation.[14] It is known that when technology is embedded in existing care services, these interventions yield more positive results and are more sustainable, because human support increases adherence to an eHealth intervention.[15] The fact that the goal was to develop such a 'blended' intervention, consisting of consultations intertwined with the use of technology, contributed to the

complexity of the development process. Moreover, different users wereinvolved, both patients with two types of chronic conditions, and practice nurses, all with diverse backgrounds, needs and expectations. This variation was also a complicating factor in the developing process.

It was a challenge to recruit enough practice nurses who were willing and able to express user requirements. This is in line with a literature review by Shaw et al. in which finding enough end-users was also identified as a major barrier to the UCD process.[16] Questions arose over wether a relatively small group of 11 nurses could capture all user requirements. But after the user requirement study, the subsequent usability and feasibility studies and the process evaluation did not reveal completely new or contradictory user requirements. Those studies produced very similar conclusions: most practice nurses valued more attention to promoting physical activity; they were not accustomed to using standardised physical activity assessment tools or questionnaires; they liked the possibility of seeing objectively measured physical activity results; and they had difficulty giving feedback in between consultations. Therefore it can be concluded that doubts about the number of interviewees were unnecessary. For the usability study, recruiting enough practice nurses was also difficult, but this was less of a problem because large numbers are not required to conduct usability tests; prior research revealed that no more than five users are needed to get a maximum user testing's benefit-cost ratio.[17]

Clarifying user requirements was especially difficult at the beginning of the project when little was specified on the mobile and Web-based technology to be developed. Practice nurses were accustomed to disease-specific electronic health systems, but they had no experience whatsoever with mobile technology or systems in which they could continuously monitor conditions. A review by Chaudhry et al. about health information technology revealed that only 8% of the described systems used in primary care had specific consumer health capabilities, and only 1% had capabilities that allowed systems from different facilities to connect with each other and share data.[18] It proved difficult to imagine the usage requirements for something totally new.

Not only was the intended technology a novelty, but the nurses also had little experience in the promotion of physical activity. Although knowledge was available on this topic,[19,20] at the moment, physical activity counselling by practice nurses in the Netherlands is not implemented to its full potential. The study of Noordman et al. about patients' lifestyle behaviour during real-life consultations revealed that in 84% of the consultations an average of 90 seconds was spent on providing generic information and advice about physical activity. To overcome this lack of familiarity, and in line with the recommendations of de Rouck et al., 'a use case' was therefore written to illustrate the daily use of the proposed system in a real-life scenario.[21] This use case consisted of a narrative scenario of four main elements (PACT): the people involved (P), their activities (A), the context (C) and the technology used (T).[22] This story was used in the first round at the end of the interviews, so as not to give too much steering in advance, and in the

second round at the beginning of the interviews in order to be able to tighten the user requirements somewhat further. The use of this use case and, at a later stage, showing a prototype of the tool were helpful in supporting the process of revealing user needs and expectations.[23] In the end, this process led to clear user requirements.

With regard to user requirements, decisions had to be taken on a number of issues where opinions varied, such as the number of required consultations or monitoring the physical activity levels of patients in between consultations. These decisions were made by the multidisciplinary team and aligned with the opinion of the patient representatives. Minutes were taken of all meetings, but, as suggested in the study of Martin et al., the quality of the decision processes in those meetings could have been enhanced by choosing a more formal decision process.[24] This could have resulted in a less fuzzy approach to decision-making based on all the available information. In addition, decisions about the user requirements for the tool and the monitor were also framed by the available time, knowledge and financial resources of the companies involved in developing the technology, whereas decisions about the requirements for the SSP were restricted by the existing capacity and experience of practice nurses and the regulations and financing of care for patients with chronic conditions. These factors prevented the combined intervention from capturing all user requirements; some of them, such as the integration of the monitor into the electronic health record systems that were used in the family practice, could not be realised during the design phase.

The cooperation between the technical developers, the researchers and the end-users was studied alongside the *It's LiFe!* project.[25] This study revealed that the developers, researchers and end-users had different views on their roles, tasks and responsibilities: although all members of the project team had read and agreed on the same project plan and UCD methodology to be used, differences still existed between team member expectations regarding topics such as who should deliver the content of the intervention, which parties should translate user requirements into technical requirements, and how many iterations could be made in the UCD process. Normally, in UCD, the roles of the researcher and the technical developer are distinct, yet interdependent, and the user is not part of the team, but spoken for by the researcher.[26] But gradually, during the process of developing and testing the tool and monitor, it became a more participatory experience and the roles of the technical developers, the researchers and the users became more mixed up. This happened, for example, during the pilot study when developers and patients met and discussed the features of the tool when technical problems occurred. Furthermore, the cooperation was also influenced by the involvement of the patient representatives in the project team.

Evidence supports the notion that involving patients has contributed to changes in the provision of services across a range of different settings.[27] The 'ideal patient representative' is defined in the study by de Wit et al. as 'a patient research partner with a relevant disease who operates as an active research team member on an equal basis with professional researchers, adding the benefit of his or her experiential knowledge to

any phase of the project'.[28] Although the study of de Wit had not yet been published at the start of the *It's LiFe!* project, the thorough way in which the patient representatives were involved was in line with the recommendations about patient participation of this study, such as capturing the role of patient research partner (they attended all project team meetings during the development stage of the project), the phases of involvement (they were involved from the beginning until the evaluation), the minimum recommended number of representatives (two), and their recruitment and selection (via patient associations). The representatives supported the recruitment of study participants, and often stressed the importance of reimbursements for the use of the tool and monitor. Furthermore, they created awareness of the practical implications such as the available time and expertise of practice nurses. Overall, the active participation of the patient representatives kept the team firmly rooted in reality.

The iterations were an important point in the chosen UCD methodology, but the number of iterations needed appeared questionable afterwards. Between each iteration, adjustments were made to the technology and the SSP: for example, after the pilot study, the sending of dialogue sessions to patients at other time points, so that these were better aligned with the consultations, or choosing another physical activity self- assessment questionnaire, because the original list proved impractical. Nevertheless, the most important problem in the whole project was the occurrence of many unforeseen technical issues. It's a simple basic requirement, it doesn't all have to be 'plug and play', but the technology should work according to plan. Because of these problems, in the pilot study[29] the SSP and the feedback messages were not sufficiently evaluated, and in the trial, the technical issues led to a higher dropout of participants.[11] For this reason it is not entirely clear what the outcome of the RCT would have been if the technical problems had not occurred. The extent to which the technology has to be 'robust' and how many iterations have to be made before proceeding with an effect study remain questions to be answered. Looking back, a second usability test in the real field in order to test the improvements that were made based on the pilot study, would probably have avoided a number of technical problems during the trial.

A cluster RCT design to measure effectiveness

A randomised controlled trial is regarded as the most scientifically vigorous study design, and is the best design to minimise bias and to provide the most accurate estimate of intervention benefits.[30] Unfortunately, newly introduced interventions to promote physical activity using mobile or Web-based technology, such as the interesting example of the 'flower phone' of Klasjna et al.,[31] or the computer based counselling system of Becker et al.,[32] often stagnate in the development stage or after a feasibility study. As a result, although it is the most desirable study design, not many RCT's have been conducted in this field yet. A Cochrane review of Foster et al.,[33] conducted in 2013, identified only 11 studies that met the inclusion criteria for an RCT. In this review,

consistent evidence was found to support the effectiveness of remote and Web 2.0 interventions for promoting physical activity. These interventions had positive, moderate-sized effects on increasing self-reported physical activity at 12 months after baseline. But all these trials were based on self-reported physical activity, whereas in the *It's LiFe!* trial the primary outcome was measured objectively with an accelerometer, which is preferable because it provides detailed intensity, frequency, and duration data about physical activity.[34]

Feasibility and pilot studies play an important role in the preliminary planning of a proposed full-size RCT. In essence, feasibility studies are used to help develop trial interventions or outcome measures, whereas pilot studies replicate, in miniature, a planned full-size RCT.[35] The terms used for these preliminary studies are sometimes considered synonymous, and in practice may overlap considerably or be combined. Craig et al. recommend conducting a pilot study before an RCT to examine the key uncertainties identified during the development of an intervention, and to investigate the intervention content in its context so as to maximise the likelihood of delivering a definitive trial that is high in terms of both internal and external validity.[36] The *It's LiFe!* pilot study resulted in fact in a number of insights into the planning of the subsequent RCT, such as how to instruct both patients and nurses, the adherence to the use of the tool, and perhaps most importantly, the obvious need to set up a help desk for answering questions about the use of the tool and monitor. Therefore, both elements as defined in the definition of feasibility and pilot studies were combined.

Health behaviour change interventions, as in the *It's LiFe!* trial, are considered complex interventions. Complex interventions are built up from a number of components, which may act both independently and inter-dependently. These components usually include behaviours, and parameters of behaviours (e.g. frequency, timing and intensity). Normally, it is not easy to define precisely the 'active ingredients' of a complex intervention. Studies evaluating technology as part of such a complex multicomponent intervention should attempt to tease out the relative contribution of each intervention component.[37] By introducing a third arm in the trial, the specific added value of the tool on top of the counselling protocol was evaluated. This specific aspect – the third arm – was a crucial point of the trial design for identifying its active ingredients.

However, in complex interventions, effects are not only produced by the intervention, but are also strongly linked to context, so issues relating to the transferability of results are therefore critical, and require adjustments to the RCT model.[38] Besides context, the distinction between efficacy and effectiveness should also be considered. The efficacy of an intervention is classically defined as its effect under 'ideal conditions', while effectiveness is its effect under normal conditions. For complex interventions the 'idealised condition' can hardly be created and is also irrelevant from a generalisability and transferability perspective as the environment and conditions of implementation are themselves determinants of the intervention outcomes.[39] The fact that it is difficult to adapt RCTs to the inherent complexity of health behaviour change

interventions is also the main conclusion of the review by Tarquinio et al.[39] Complex interventions may require a less linear and more flexible evaluation model as in a classical RCT design.[36] In the *It's LiFe!* trial a high degree of flexibility in the execution of the intervention was chosen with the aim of ensuring that it could be adapted to both local circumstances and patients' needs, although this may have led to large differences in the execution of the intervention. Unfortunately, the performance of a subanalysis per practice to identify the contextual differences was not possible due to small numbers. But the process evaluation alongside the trial was conducted with the aim of gaining further insight into the execution of the intervention within its context.

A cluster design for the trial was chosen to avoid treatment group contamination. However, cluster designs have a number of disadvantages; for example, this design could have been one of the reasons why it turned out to be so difficult to find enough practices and patients willing to participate in the study. Participants did not know beforehand which group they would be assigned to. Furthermore, post-recruitment selection bias, a well-known problem of cluster randomised controlled trials, was partly avoided by asking the nurses to include patients before the randomisation of the practices.[40] But this method of post-randomization consent design, known as the 'Zelen' design,[41] might still have led to a confounding factor imbalance between the interventions and control groups. Other commonly known risks of a cluster design, such as baseline imbalance or within-cluster correlation,[42] turned out not to be a problem. There were some differences at baseline between the groups, but they were adjusted for in the multilevel analysis and the intra-class correlation coefficient (ICC) for physical activity was much lower than expected (0.005).

The potential for increased Hawthorne effects was taken into account by minimising the contact between the researchers and participants, and by avoiding overlapping roles between researchers and practice nurses, for example by asking the nurses to include patients in the study, and by arranging an independent help desk. Furthermore, patients were not interviewed during the intervention in order to distinguish between the intervention and its evaluation. This approach was a strength in terms of measuring unbiased effects of the intervention, but a limitation in terms of the process evaluation. The intervention lasted between four and six months, and because of this relatively long period, recall bias may have occurred in answering the process evaluation questionnaires.

It is remarkable how many similarities there were between the results of the *It's LiFe!* pilot study and the RCT. The pilot study proved a good predictor of the main outcome measure (an increase of more than 10 minutes of moderate to vigorous physical activity) as well as of the secondary outcome measures (no significant differences in (exercise) self-efficacy and some differences in quality of life). The pilot study also proved a good predictor of the main conclusion of the process evaluation: the positive appreciation of the tool by the participants, despite the technical problems.

Theoretical considerations

In this section, theoretical considerations regarding behaviour change and lifestyle coaching will be discussed followed by their consequences for nursing practice in primary care.

Behaviour change and lifestyle coaching

The *It's LiFe!* trial showed positive significant outcomes for physical activity levels when patients used the tool in daily life, but it also showed the limitation of the consulting room. Despite the fact that the SSP was based on the Five A's model, consisting of theory-based communication techniques to achieve behaviour change, and although the programme was executed as planned, it showed no significantly different results compared to usual care. The review of Hillsdon et al. showed results in line with this outcome: boosting physical activity needs more than a limited number of consultations.[43] However, other physical activity counselling studies in primary care reported moderate effects on physical activity in the short term.[44,45] From the *It's LiFe!* RCT it can be concluded that self-monitoring, goal-setting and feedback are the most powerful aspects of the intervention. This conclusion is in line with the results of the review of Bratava et al., which also revealed that self-monitoring through the use of a pedometer leads to a significant increase in physical activity levels,[46] and in addition, according to Leung et al., when combined with a physical activity prescription or brief advice, these primary care interventions are also cost-effective.[47]

Behavioural strategies are known to be superior to cognitive strategies in physical activity behaviour change.[48] Most aspects of the tool were typically behavioural, such as self-monitoring, goal-setting and feedback, whereas most aspects of the SSP were cognitive, such as its health education and risk communication elements. According to the meta-analysis by Conn et al., health education does not increase the effect size of physical activity interventions, probably because most patients are already convinced of the health benefits of physical activity.[48] Participants mentioned several times that they had already talked a lot about the benefits of physical activity with their practice nurse, before the start of the intervention. So the distinction between the SSP and usual care regarding this health education element could have been less pronounced and therefore a reason why no significant differences were found between the SSP and the usual care group.

In the SSP, participants were given the choice of how to change their behaviour. They were offered a broad variety of tips on becoming more active, general tips such as watching the TV broadcast 'Nederland beweegt', and specific information regarding all kinds of sporting activities in their immediate living environment. However, most people mainly increased their normal walking and cycling pattern; only a few participants managed to create new physical activity habits. According to Gardner et al., habit

formation is of great importance in behaviour change. Habit formation advice can be delivered briefly, it is simple for the patient to implement, and it has realistic potential for long-term impact.[49] Perhaps if the instruction for practice nurses regarding the execution of the SSP had put more emphasis on this habit formation aspect –repeat a chosen behaviour in the same context, until it becomes automatic and effortless – the SSP could have led to more new activity habits.

The underlying change model of the SSP was based on a cognitive-rational paradigm, in which change is conceptualised as a linear, deterministic process where individuals weigh pros and cons, and at the point at which the benefits outweigh the cost, change occurs. Resnicow et al. suggest that many decisions to change are random events; motivation arrives as opposed to being planned.[50] But given the 'pandemic of physical inactivity', practice nurses have a responsibility to alert every patient to the far-reaching effects of a sedentary lifestyle, regardless of their readiness or willingness to change. As expressed by Khan et al., physical activity levels should be seen as 'vital signs',[51] and assessing physical activity levels is beneficial for all, so that people at risk are detected earlier, even before chronic conditions occur.

Consequences for nursing practice

It turned out that not all practice nurses were able to estimate the level of inactivity of their patients; most patients had levels at baseline that already met the norm for healthy exercise. As mentioned before, practice nurses should pay more attention to all dimensions of physical activity: the type, frequency, duration and intensity and the domains – occupational, domestic, transportation and leisure time – in which those activities occur. This should be done incrementally, starting with a global short physical activity assessment questionnaire, such as the Physical Activity Vital Sign,[52] to assess and record the physical activity levels, as stated in the Healthcare Providers' Action Guide – Exercise is Medicine.[53] The use of an accelerometer as in the *It's LiFe!* tool could be a valuable addition to this assessment, because patients tend to overestimate their physical activity levels. Then, if a patient is sedentary, patient and nurse should decide in mutual agreement on the necessary degree of supervision for self-management support, the stimulation of goal-setting and the use of the tool for a longer period. In daily practice, the intervention can be easily tailored to the individual needs of the patient – for example, more time for raising awareness, or referral to an exercise programme with a physiotherapist if exercise self-efficacy or capacity is considered too low. In addition, the intervention can be more extensive or recurrent with more emphasis on habit formation, instead of a fixed period as in the RCT. This more flexible approach to the intervention may maximise patients' ability to participate but also the ultimate 'real-world' generalisability of the results. Given current trends in health-care and rising health-care costs, the question is whether stand-alone physical activity consultations

with a practice nurse are desirable, because eHealth interventions can strengthen the self-management of the patient and thus minimise the role of the professional carer.

Implications

In the last section of this chapter the implications for research, practice and policy are discussed.

Research

The results of the RCT revealed the powerful influence of the use of a monitoring and feedback tool on top of behaviour change counselling. Because of this added value, it seems worthwhile implementing the intervention on a larger scale. However, before a large-scale implementation, an evaluation of the embedded use of the tool in primary care without extra consultations should be investigated first because this is likely to be more cost-effective. Furthermore, the application of this intervention to other target groups, for example patients with cardiovascular disease, should be investigated too because for these patients, physical activity is also important. The execution of the intervention could also be done by other care providers, such as physiotherapists who want to aim to improve daily physical activity as well as exercise capacity, and dieticians for the treatment of patients with obesity. And finally, further investigations should reveal information about which types of automated feedback messages provided by the tool are most encouraging and the best balance between this form of feedback and the feedback given during consultations.

Practice

The fact that the availability and use of smartphones and wearables to measure physical activity is growing is promising for the adoption of the intervention. But before implementation on a larger scale, the technology should be fool proof and the app should be available in an app store. Furthermore, in line with the 'blue button' initiative, integration of physical activity data in a personal health record application is desirable for the uptake of the intervention.

Policy

Health-care systems should include physical activity as an explicit element of regular behavioural risk factor screening and promote the use of the *It's LiFe!* tool. Therefore, insurance companies should stimulate the introduction of this eHealth intervention by reimbursing family practices and patients if they decide to use it.

Increased attention to the promotion of physical activity fits well with the new educational profile of the HBO nurse,[54] in which a shift has been made from a focus on disease and care towards promoting health and healthy behaviours. Preventive tasks, such as promoting physical activity, should therefore recieve more explicit attention in nursing education. Nurses should be proficient in the use of motivational interviewing skills and encouraging healthy habit formation. They should learn more about how to mobilise the social environment, and about how they can make the link between the care domain and the public domain, for example by setting up collaboration with local gyms, clubs and the municipality. Prevention on an individual level is not enough; nurses should also pay more attention to preventive tasks in the community.

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CHAPTER 9

Valorisation

Valorisation

Lifestyle coaching 2020: a use case

Despite the fact that Mr. Black is actually a digital immigrant, born in the last century when Internet did not yet existed, he carries his smartphone always with him. He is rather overweight and suffers from high blood pressure, for which he uses daily medication. Without suggesting a direct causal relationship, he has an extremely unhealthy lifestyle combined with a stressful busy job and a heartfelt hate towards sports of any kind. His way to relax is to cook, read or watch TV. Coffee with chocolates and wine with French cheese are his favourite daily intake.

His digital bathroom scale is connected via his smartphone with his personal health record (PHR) and whenever he weighs himself, his weight and BMI is automatically recorded therein. But he does not like to measure his weigh, because he finds that quite annoying. On the other hand, he checks his blood pressure regularly via his smart watch, because he wants to know if the medication is doing its job. His blood pressure values are automatically uploaded to his PHR in a similar way as his weight. When he orders medication online, the system of his GP automatically requests access to his PHR to check his weight and blood pressure values. The GP system interprets these values and sends a warning message: 'You are seriously at risk, may we follow your activity data over a period of 10 days?' Measuring his physical activity takes place automatically via his smart watch. 'Alright then', he thinks, and he gives permission within his PHR to access this data as well'.

The results are obvious; he falls far short of meeting the standard for healthy exercise. So after ten days he gets an offer from a company called 'Lifestyle for you', a partnership between his employer and his health care insurer, to try out a new program called 'lifestyle coaching 2020'. This program starts with a screen session with a lifestyle coach. She is a nurse, who works from her home located in a suburb of New Delhi. She asks permission to access his PHR and sees that he has been treated before by a dietitian, unfortunately with no results. Mr. Black notes that the conversation with her is pleasant; he dares to talk about his insecurities and his estimation that he lacks perseverance and probably will fail again. She is not in any way patronizing and he likes that in particular. Together with the nurse, they estimate what his preferences and habits concerning diet and exercise, they talk about achievable goals, what type of assistance he needs and where 'quick profit' can be achieved.

After subscribing to the program, giving some basic information and answering questions about his actual lifestyle, the system can not only view his physical activity data, but through very brief question and answer sessions with a virtual coach, the system gets a total picture of his lifestyle. He stated his preference to get these questions and answers from the system through voice messages and voice recognition (Siri) because he is accustomed to this when he uses his smartphone. In this way, a user profile is being built and consequently the system sends exactly at key moments personalized messages that help him to change his behaviour. These messages are based on the amount of daily physical activity, his blood pressure levels, his whereabouts, and they are given at times when he is tempted to overeat (at some point he also linked his smart fridge to the system) or when he is sedentary for too long. The messages come from a huge open source database that all app vendors of lifestyle coaching systems are using in collaboration. Through artificial intelligence this database provides the most motivating and suitable coaching messages.

Introduction

The research in this dissertation resulted in an effective blended mobile health intervention executed by practice nurses to stimulate physical activity. The intervention consists of a monitoring and feedback tool, an associated coaching system and a counselling protocol. More research is needed to evaluate the effects of this intervention on a larger scale and its cost-effectiveness. However, there are already relevant insights gained during the user-centred development and evaluation of the intervention which are of importance for the value-creation for the different stakeholders involved. Therefore this chapter focusses on emerging opportunities for valorisation that could be taken on the basis of the research presented in this dissertation. Furthermore, this chapter also describes which actions have already been taken to disseminate the knowledge gained in this research. The following definition of 'valorisation' is assumed: The process of value-creation out of knowledge, by making this knowledge suitable and available for economic or societal utilization and to translate this into high-potential products, services, processes and industrial activity.[1] It concerns the value that can be created through the transfer of scientific knowledge gained during *the It's LiFe!* project; not only commercializing the monitoring and feedback tool and the coaching system, but also the transfer of acquired knowledge in order to carry out the intervention.

Relevance

Worldwide many people are not sufficiently active. This is a major problem since physical inactivity has major health effects. According to the World Health Organization insufficient physical activity is one of the ten leading risk factors for death worldwide and a key risk factor for non-communicable diseases, such as diabetes, cancer and cardiovascular disease. Therefore a lot of initiatives are undertaken to encourage people to become more active, such as national campaigns and initiatives at school, at work and in the neighbourhood. Also primary care providers try to stimulate physical activity of patients. The *It's LiFe!* intervention helps people with COPD or diabetes type 2 to become more active. More generally, the results of the studies of this dissertation indicate that guidance by a care provider can be reinforced by daily monitoring, feedback and goal setting.

Target groups

For the following different target groups the results of the *It'sLiFe!* project are valuable.

Patients

In the studies presented in this dissertation the focus was on people with COPD or type 2 diabetes, aged between 40 and 70, but there is actually no need to set a maximum age to the target group. The most important non-age-related condition is that the patient is triggered to change, in the possession of a smartphone and able to download the app.

The following activities were undertaken to inform the current target group. Patients randomised in the tool group had access to a special website[2] with information about physical activity and about the use of the tool. All participating patients in the trial received an overview of their physical activity data afterwards. They also received the PAM accelerometer, which they could use optionally in order to continue with self-monitoring of their daily activity. Furthermore, participating patients received newsletters about the project to inform them about the overall results and conclusions of the studies. During the project the patient representatives acted as ambassador, but further dissemination of knowledge could be done by bringing the results to the attention of other COPD or diabetes type 2 patients through the regular information channels of the patient associations.

As the conditions of people with COPD and type 2 diabetes are very diverse, it is to be expected that the intervention could be beneficial for all people who visit the practice nurse regularly and experience barriers to become more physically active. One could even think about using it as a preventive tool for chronic conditions to guide people in general that could benefit from more physical activity regardless their current condition. Therefore, additional actions could be taken to inform a wider public in many different ways such as articles in newspapers and information on websites. The latter was already done by the companies involved in the project.[3, 4]

Health-care professionals

In this research the Self-management Support Program (SSP) was applied by practice nurses. Those nurses were chosen as a mode of delivery since they are explicitly responsible for the promotion of a healthy lifestyle. However, the intervention could also be applied by other care professionals who stimulate a healthy lifestyle, such as physiotherapists, dietitians when treating people with obesity, and general practitioners. Experiences gathered from COPD patients during the user centred design process indicated that especially during rehabilitation programs, which focus on improving exercise capacity, more attention is needed on physical activity in daily living. Patients indicated that extra guidance after a rehabilitation program is desirable to maintain the benefits. Furthermore, employees from fitness centres, municipalities and people involved in neighbourhood initiatives that focus on stimulating physical activity could use the knowledge gained during *the It's LiFe!* project.

To inform the professionals involved in the studies, newsletters about the project were sent to them, and those letters were also available on a special website.[5] Furthermore, several articles were posted in professional journals for nurses, general

practitioners and physical therapists. In addition, the end results were announced on (inter)national conferences, which were attended by various health professionals involved in eHealth and chronic care. Finally, it is important that the end results of the project, which are currently described in English-language scientific journals, will also be published in Dutch professional journals.

The importance of an active lifestyle and how to encourage this should be a standard part of the training for healthcare professionals. Some study results have already been described in a newsletter of the professional association of nurses V&VN VZI (nurses and healthcare informatics),[6] but the adapted five A's model for physical activity counselling, expanded with the use of the monitoring and feedback tool could also be of interest for practise nurses who are not acquainted with eHealth interventions. The consultation cards, designed to support the practice nurses in how to perform the consultations, are a ready- to- use instrument in the implementation of the intervention on a larger scale. In addition, the knowledge gained in this project will be made available through EIZT, the Centre of Expertise for Innovative Care and Technology of Zuyd University of Applied Sciences.[7] At this centre, teachers/researchers are working together to give 'technology in care' a more explicit place in the curricula of the various study programs of the faculty of health.

Industry

Despite the growing emphasis on eHealth in recent years to improve care processes and outcomes, the scientific evidence of its use often lags behind. This research indicates that automated self-monitoring of physical activity with direct feedback and goal setting embedded in the care process is effective. Companies could use this knowledge in their marketing strategies for self-monitoring devices. Furthermore they can use the knowledge gathered during the user-centred design process to improve their designs and effectuate products which are better adapted to the end users. An insight which could be valuable for future product development is that if self-monitoring takes place and its data is shared with somebody else, the user should have the opportunity to make annotations, to clarify unusual data. Furthermore, especially for the elderly target group, clear instructions and a helpdesk are a necessary condition for acceptation and implementation.

Health insurance companies

The research presented in this dissertation indicates that self-monitoring embedded in care is an effective intervention to stimulate people to have more physical activity. If the results endure over a longer period of time, this might result in health benefits which will eventually lead to a healthier population, less complications and thus reduces health cost which makes it attractive for insurance companies to offer it to their customers. Especially, if the intervention will be implemented as a preventive method to avoid the onset of chronic disease, this would be profitable. With this in mind, it would also be

worthwhile to consider providing the intervention in a modified form at work or at school to anybody at risk of an inactive lifestyle.

Innovation

The It's LiFe! monitoring and feedback tool is not the only tool which enables an objective measurement of one's physical activity level. Step counters, accelerometers worn at the hip or around the wrist with related applications and Smartphones with integrated accelerometers pursue the same goal. However, the marketing around these devices and apps is mostly targeted at people who are already conscious about a healthy lifestyle and act accordingly (the quantified self).[8] The innovative aspect about this research is that it was targeted at people with a chronic disease who are difficult to motivate and that it brought together the strengths of new technologies and the coaching role of a care provider. With this combination, people who are normally not triggered by persuasive technology are involved and the coaching role from the care provider is reinforced by providing objective measurements. Daily monitoring and feedback broadens the scope of the consultation room.

Planning and realization

The research in this dissertation did reveal some suggestions for improvement of the tool such as more tailored and diverse feedback messages, making the tool suitable for the measurement of swimming and cycling, and adding a possibility to share results with peers for extra social support. The latter was waived by participants in the user requirements research, but opted as a suggestion for improvement in the process evaluation of the RCT. The feasibility study and the process evaluation of the RCT among the nurses revealed that nurses want the physical activity results of their patients to be visible in their own electronic health system, rather than on a website. Furthermore, they indicated that they would like to have the possibility to send feedback messages to the patient, rather than call them in between consultations. This would be a valuable option to explore, since it will personalize the feedback for the patient and in this way it can be sent and read whenever possible.
At this moment, the involved companies, Maastricht Instruments and Sananet are working together with a start-up company named 'A.motion' to bring the *It's LiFe!* tool and its services to the market. Their aim is that at the end of 2015 the product and services should be available. They have already launched a pilot project in physiotherapy practices to further explore the possibilities of the *It's LiFe*! intervention.

In the future more people will monitor their own health variables to get more control over their own health and also be an equal partner in contact with their health professionals. The challenge for system developers and care providers will be to integrate, interpreted and react properly on all these different data. Furthermore, a

number of ethical, privacy and interoperability issues have to be solved before the scenario of Mr. Black can become reality.

Referred websites

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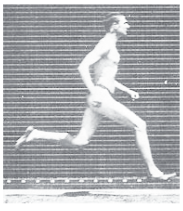
2. http://www.maastrichtuniversity.nl/web/show/id=6637066/langid=43.
3. http://www.maastrichtinstruments.nl/portfolio/its-life/
4. http://www.sananet.nl/its-life.html
5. http://www.zuyd.nl/onderzoek/lectoraten/technologieindezorg/projecten/its-life
6. http://issuu.com/venvn_vzi/docs/vzi_nieuwsbrief_mei_2014
7. http://www.innovatiesindezorg.eu/
8. http://www.quantifiedself.nl/





SUMMARY

SAMENVATTING

DANKWOORD

ABOUT THE AUTHOR

LIST OF PUBLICATIONS





Summary

This dissertation reports on five of the eight studies of the project named **I**nteractive **T**ool for **S**elf-management through **Li**festyle **Fe**edback (*It's LiFe!)*. This tool aims to support chronically ill patients in achieving a more active lifestyle. The dissertation of my colleague Sanne van der Weegen, which is also based on this project, reports on studies of the development and usability testing of the monitoring and feedback tool for COPD and diabetes type 2 patients and on the validation of the accelerometer as part of this tool.

The first study of this dissertation includes the development of a physical activity counselling protocol for practice nurses to support self-management of patients with COPD or type 2 diabetes (DM2) who are treated in primary care (Chapter 2). The second study describes the development and testing of a Web-based coaching system as part of the tool (the *It's LiFe!* monitor) (Chapter 3). In the third study the feasibility of the tool and the monitor embedded in the counselling protocol was evaluated in two family practices (Chapter 4). The fourth study, in 24 family practices, describes the effectiveness of this counselling protocol with and without the use of the tool and monitor on physical activity, (exercise) self-efficacy and quality of life (Chapter 6). Finally, the fifth study describes the process evaluation that was conducted to examine the reach and implementation of, and satisfaction with, this intervention (Chapter 7). During the trial and its process evaluation Sanne van der Weegen and Renée Verwey contributed equally to the work, therefore they share the first authorship of the last two articles. These chapters are part of both dissertations.

Chapter 1 provides information about 'physical (in) activity' and 'self-management support' in patients with COPD or type 2 diabetes. In this chapter the relevance of the promotion of physical activity by practice nurses is discussed along with the need to 'reach beyond the consultation room' by extending this promotion with the use of mobile technology. Such a 'blended' intervention (combining physical activity counselling and a monitoring and feedback system) is necessary because behaviour change is difficult for patients with these chronic conditions. This behaviour change needs day-to-day attention. Furthermore, in this chapter the potential of mobile technology for promoting physical activity is discussed, followed by the reasons why applying a 'user-centred design approach' to develop and test such technology is recommended.

Chapter 2 describes the systematic development of a physical activity counselling protocol for practice nurses. This protocol, the Self-management Support Programme

(SSP), was developed in an iterative manner, following user centred design (UCD) principles. The needs and preferences of practice nurses were identified by analysing the literature, by conducting 16 interviews with care providers, and by consulting 12 experts. The SSP is based on the 'Five A's model' (Assess- Advise- Agree- Assist- and Arrange), a counselling model for supporting self-management. The protocol consists of a limited number of behaviour change consultations with a practice nurse (one to three extra consultations, designed to complement usual care, spread over a period of at least six months) combined with the *It's LiFe!* monitoring and feedback tool. This tool provides feedback on a patient's physical activity level via an app on a smartphone. It also sends dialogue sessions and feedback messages concerning the amount of activity in relation to an activity goal. Activity results and answers to dialogue sessions are visible for the practice nurse on the *It's LiFe!* monitor, with the intention of using this information as input for the coaching. During the consultations the practice nurse performs an assessment of the patient's activity pattern using a self-assessment questionnaire, supported by information from a baseline measurement and diary supplied by the system. The nurse provides information about the risks of a sedentary lifestyle and the benefits of physical activity, using an information card that was developed in the project. In collaboration with the patient, an activity goal in minutes per day is set, based on personal (dis)abilities. Both the practice nurse and interactive sessions supplied by the tool help the patient to write a plan on how to become more physically active. The patient receives a list of local sports activities. Feedback on physical activity performance is given by a practice nurse during consultations, while the tool gives automatic feedback on this performance in between.

Chapter 3 describes the user requirements of practice nurses towards the *It's LiFe!* monitor, which enables the nurses to view physical activity results from the patients who are using the *It's LiFe!* tool. The requirements of practice nurses were determined during 16 interviews. The usability of the system was evaluated by five nurses in a laboratory situation and by three nurses during a three-month pilot study. A number of components of the system were based on these requirements, such as the development of automatically generated feedback messages. The UCD development and testing of the *It's LiFe!* monitor resulted in a system that was appreciated by the nurses. The results of the usability tests gave insights into how to improve the structure and the quality of the information provided by the system. When used in practice, nurses were positive about the features and ease of use, but they made critical remarks about the time that its use entails. Different opinions were expressed about monitoring physical activity results in between planned consultations, although the system supports this. The development of the monitor in an iterative way made it possible to constantly improve the system and to adapt its use to the care process.

The feasibility of the combination of the SSP and the use of the tool and the monitor was evaluated in a pilot study in two family practices. Chapter 4 reports on this study in which 20 patients with COPD or type 2 diabetes used the tool for three months, coached by three practice nurses. The aim of the study was to evaluate the technical performance, acceptance and user satisfaction of this intervention. Physical activity data were collected at the server and technical problems were recorded. Average physical activity increased by more than 10 minutes per day, and patients reported a higher quality of life. Patients and practice nurses were interviewed after every consultation. At baseline, and after the intervention, patients completed questionnaires. The results showed that the intervention stimulated patients to become more physically active. Also, the monitor aided the nurses in performing physical activity counselling. Participants were positive about the tool, although motivation dropped when technical problems occurred, which were caused by registration and connectivity errors. Because the tool itself and its technical problems dominated the consultations, the SSP was only partly executed as planned. But all participants valued the emphasis on physical activity and collaborative goal-setting during the consultations. It was concluded that without the connectivity problems, and with some experience on the part of the nurses in using the system, the intervention is feasible.

On the basis of the outcomes of the pilot study, the tool and the SSP were improved. Subsequently a three-armed cluster randomised trial in 24 family practices was set up with 240 participants in total (120 with COPD and 120 with DM2 aged 40–70). The study protocol of this study is described in Chapter 5. The aim of the trial was to evaluate the effectiveness of the SSP with (group 1) and without (group 2) the use of the tool with usual care (group 3). In group 2, the nurses executed the SSP without the tool, with the intention of evaluating the added value of using the tool in combination with the monitor. Recruitment of family practices took place in the southern regions of the Netherlands and randomisation took place at practice level. The intended sample (three arms of eight practices) powered the study to detect a 10-minute difference in moderate and intense physical activity per day between groups 1 and 3. The primary outcome was the number of minutes of moderate to vigorous physical activity per day, measured in all three groups with a physical activity monitor (PAM). These data were analysed by multilevel mixed methods. The secondary outcomes were general - and exercise self-efficacy, quality of life and health status. Outcomes were measured at three time points: at baseline, directly after the intervention (four to six months) and three months thereafter.

Chapter 6 reports on the effectiveness of the *It's LiFe!* interventions. The combined intervention (tool + SSP) led to a significant improvement of moderate to vigorous physical activity, compared to usual care. Right after the intervention period, the progress was 12 minutes per day. Three months after the intervention period, this

progress was still significant (11 minutes). The trial also proved that use of the tool on top of the SSP is more effective than the SSP only (an additional eight minutes). The SSP alone had no significant effect on physical activity compared to usual care. For the secondary outcome measures the intervention effect was not evident. From these results it can be concluded that the automated self-monitoring and feedback component and/or the fact that the practice nurse was able to see the objectively measured physical activity results were the most powerful elements of the combined intervention.

Chapter 7 reports on the process evaluation of the *It's LiFe!* trial whose aim was to examine the reach, the implementation, and satisfaction regarding the two main aspects of the intervention: the SSP, which was delivered in both groups, and the use of the tool, which was used only by patients in group 1. It proved extremely difficult to find enough practices and patients to participate in the study. Ten times the number of practices had to be approached until a sufficient number of practices agreed, and within the practices, almost three times the number of patients. The drop-out rate during the trial was 17%. The execution of the intervention was adequate; the number and planning of the consultations were carried out as intended (83%), patients remembered the different aspects of the Five A's model (71%), and although technical problems occurred frequently, most patients (88%) indicated that they used the tool until the end of the intervention. Explicit attention to promoting physical activity in primary care nursing using the Five A's model was valued by patients as well as nurses. The technical problems had little impact on the satisfaction; patients from group 1 were significantly more positive about the intervention than those in group 2. The complete intervention led to more awareness and discipline regarding physical activity. Practice nurses considered the objective measurements of the physical activity of their patients a useful addition to their counselling.

Chapter 8 of this dissertation summarises the main findings from the individual studies and explores methodological considerations regarding the user centred design of a physical activity promotion intervention combined with mobile technology. In addition, considerations for the evaluation of the effectiveness of technology-based health behaviour change interventions, using a cluster randomised controlled trial design, are discussed. Subsequently theoretical considerations regarding behaviour change and lifestyle coaching and their consequences for the role of practice nurses are described. This chapter ends with implications for research, practice and policy. Given the positive outcomes of the trial and the process evaluation, it is recommended that practice nurses include physical activity as an explicit element of regular behavioural risk factor screening and if needed promote the use of the *It's LiFe!* tool.

Finally, in Chapter 9 the possibilities for the valorisation of knowledge gained during the research presented in this dissertation are explored.

Samenvatting

Dit proefschrift doet verslag van vijf van de acht onderzoeken die deel uitmaken van het *It's LiFe!* project (**I**nteractive **T**ool for **S**elf-management through **Li**festyle **Fe**edback). In het proefschrift van collega Sanne van der Weegen, dat eveneens gebaseerd is op dit project, staan onderzoeken beschreven over de ontwikkeling en de bruikbaarheidstesten van de monitoring en feedback tool en over de validatie van de accelerometer als onderdeel van deze tool.

Het eerste onderzoek van dit proefschrift gaat over de ontwikkeling van een begeleidingsprotocol voor praktijkondersteuners ter ondersteuning van zelfmanagement van COPD en diabetes type 2 (DM2) patiënten bij meer bewegen (Hoofdstuk 2). Het tweede onderzoek gaat over de ontwikkeling en het testen van het online coaching systeem behorende bij de tool (de *It's LiFe!* monitor) (Hoofdstuk 3). Gevolgd door het derde onderzoek waarin de haalbaarheid van het gebruik van de tool, de monitor en het protocol werd geëvalueerd bij twee huisartspraktijken (Hoofdstuk 4). In het vierde onderzoek is de effectiviteit van dit protocol onderzocht bij 24 huisartspraktijken zowel met als zonder het gebruik van de tool op lichamelijke activiteit, (exercise) self-efficacy en kwaliteit van leven (Hoofdstuk 6). Ten slotte is in het vijfde onderzoek de procesevaluatie beschreven die werd uitgevoerd om het bereik, de uitvoering en de tevredenheid met deze interventie te onderzoeken (Hoofdstuk 7). Tijdens de RCT en de procesevaluatie hebben Sanne van der Weegen en Renée Verwey in gelijke mate bijgedragen aan deze onderzoeken, daarom delen zij het eerste auteurschap van beide artikelen. Deze hoofdstukken maken dan ook deel uit van beide proefschriften.

Hoofdstuk 1 geeft informatie over 'fysieke (in)activiteit' en 'zelfmanagement-ondersteuning' bij patiënten met COPD of met type 2 diabetes. In dit hoofdstuk wordt de relevantie van het promoten van voldoende beweging door praktijkondersteuners toegelicht en de noodzaak om hierbij 'verder dan de spreekkamer te gaan' middels het gebruik van mobiele technologie. Een dergelijke gemixte interventie (de combinatie van consulten met het gebruik van een monitoring en feedback systeem) is noodzakelijk omdat het voor patiënten met een chronische aandoening vaak moeilijk is om van gedrag te veranderen. Een dergelijke gedragsverandering nastreven heeft dagelijkse aandacht nodig. Daarnaast wordt in dit hoofdstuk het potentieel van mobiele technologie voor het stimuleren van meer bewegen besproken en de redenen waarom het goed is om een 'User Centred Design' aanpak te hanteren bij de ontwikkeling en het testen van dergelijke technologie.

In hoofdstuk 2 wordt de systematische ontwikkeling van een begeleidingsprotocol voor praktijkondersteuners ter stimulering van meer bewegen beschreven. Dit protocol, het Zelfmanagement Ondersteunings Programma (ZOP) werd op een iteratieve manier ontwikkeld gebruik makend van 'User Centred Design' (UCD) principes. De behoeften en voorkeuren van de praktijkondersteuners werden geïdentificeerd door het bestuderen van literatuur, door het uitvoeren van 16 interviews met zorgverleners en door het raadplegen van 12 experts. Het ZOP is gebaseerd op het 'Vijf A's model' (Assess- Advise- Agree- Assist- and Arrange) een begeleidingsmodel ter ondersteuning van zelfmanagement. Het protocol bestaat uit een beperkt aantal consulten met de praktijkondersteuner (1-3 extra ter aanvulling op de gebruikelijke zorg, verspreid over een periode van ten minste zes maanden) in combinatie met de *It's LiFe!* monitoring en feedback tool. Deze tool geeft feedback op de lichamelijke activiteit van de patiënt via een app op een smartphone. Het systeem stuurt ook dialoog sessies en feedback berichten gerelateerd aan de mate van de activiteit in relatie tot een bewegingsdoel. Beweegresultaten en antwoorden op dialoog sessies zijn toegankelijk voor de praktijkondersteuner op de *It's LiFe!* monitor, met de bedoeling om deze informatie te gebruiken als input voor de coaching. Tijdens de consulten evalueert de praktijkondersteuner systematisch het bewegingspatroon van de patiënt met behulp van een zelfevaluatievragenlijst, ondersteund door informatie uit de voormeting en het dagboek verkregen via het systeem. De praktijkondersteuner geeft informatie over het risico van een sedentaire levensstijl en het voordeel van voldoende beweging aan de hand van een in het onderzoek ontwikkelde infokaart. In samenwerking met de patiënt, wordt een bewegingsdoel in minuten per dag ingesteld in het systeem, op basis van de (on)mogelijkheden van de patiënt. Zowel de praktijkondersteuner als de interactieve sessies van de tool faciliteren de patiënt in het opstellen van een ik-ga-meer-bewegen-plan. De patiënt ontvangt tevens een lijst met mogelijkheden voor sport, - en bewegingsactiviteiten in de buurt. Feedback op beweegresultaten wordt gegeven door de praktijkondersteuner tijdens de consulten, terwijl de tool tussentijds automatisch feedback geeft.

Hoofdstuk 3 beschrijft de gebruikerseisen van praktijkondersteuners ten opzichte van de *It's LiFe!* monitor, waarin zij de beweegresultaten van de patiënten kunnen bekijken die gebruik maken van de *It's LiFe!* tool. De gebruikerseisen van de praktijkondersteuners werden verkregen via 16 interviews. De bruikbaarheid van het systeem werd geëvalueerd door vijf verpleegkundigen in een laboratoriumsituatie en door drie verpleegkundigen tijdens een pilot onderzoek van drie maanden. Verschillende componenten van het systeem zijn gebaseerd op deze gebruikerseisen zoals de ontwikkeling van automatisch gegenereerde feedbackberichten. De UCD ontwikkeling en het testen van de *It's LiFe!* monitor resulteerde in een door de praktijkondersteuners gewaardeerd systeem. De resultaten van de bruikbaarheidstests gaven inzicht in hoe de structuur en kwaliteit van de informatie uit het systeem verbeterd kon worden. Bij

gebruik in de praktijk uitten praktijkondersteuners zich positief over de functies en het gebruiksgemak van de monitor, maar ze maakten tevens kritische opmerkingen over de tijd die het gebruik ervan met zich meebrengt. De meningen verschilden over de wenselijkheid van het monitoren van beweegresultaten tussen geplande consulten door, al biedt het systeem daartoe de mogelijkheid. Door de iteratieve ontwikkeling van de monitor was het mogelijk om het systeem aan het gebruik in het zorgproces aan te passen.

De haalbaarheid van de combinatie van het ZOP en het gebruik van de tool en de monitor werd geëvalueerd in een pilot onderzoek bij twee huisartspraktijken. Hoofdstuk 4 beschrijft dit onderzoek waarbij 20 patiënten met COPD of diabetes type 2 de tool gedurende drie maanden gebruikten, begeleid door drie praktijkondersteuners. Het doel van dit onderzoek was om de technische prestaties, acceptatie en tevredenheid van de gebruikers over deze interventie te evalueren. Op de server werden de gegevens over de beweegresultaten verzameld en als er technische problemen ontstonden werden deze genoteerd. Patiënten en praktijkondersteuners werden na ieder consult geïnterviewd. Bij aanvang en na de interventie vulden patiënten vragenlijsten in. Uit de resultaten bleek dat patiënten door de interventie gestimuleerd werden om meer te gaan bewegen. De gemiddelde bewegingsactiviteit was gestegen met meer dan 10 minuten en de kwaliteit-van-leven-scores waren toegenomen. Tevens bleek de monitor een handig hulpmiddel voor de praktijkondersteuners bij de consulten. Echter wanneer er technische problemen ontstonden (bv. met het registreren van de bewegingen of met de verbindingen tussen de diverse onderdelen van de tool) dan zakte de motivatie wel. Omdat de technische problemen met de tool de gang van zaken tijdens de consulten domineerden, werd het ZOP slechts gedeeltelijk uitgevoerd zoals gepland. Maar alle deelnemers waardeerden de nadruk op meer bewegen en het in samenspraak doelen stellen tijdens de consulten. Er werd geconcludeerd dat het een haalbare interventie is mits er geen technische problemen ontstaan en de praktijkondersteuners tevoren enige ervaring kunnen opdoen met het systeem.

Op basis van de uitkomsten van het pilot onderzoek werden de tool, de monitor en het ZOP verbeterd. Vervolgens werd een cluster gerandomiseerd onderzoek (RCT) bij 24 huisartspraktijken opgezet bestaande uit drie groepen met in totaal 240 deelnemers (120 met COPD en 120 met DM2 tussen de 40 en 70 jaar). Het studieprotocol van dit onderzoek wordt beschreven in hoofdstuk 5. Het doel van dit onderzoek was om de effectiviteit van het ZOP met (groep 1) en zonder (groep 2) het gebruik van de tool te evalueren in vergelijking met gebruikelijke zorg (groep 3). In groep 2 voerden de praktijkondersteuners enkel het ZOP uit, met de bedoeling om de toegevoegde waarde van het gebruik van de tool in combinatie met de monitor te evalueren. Werving van huisartspraktijken vond plaats in de zuidelijke regio's van Nederland en er werd gerandomiseerd op praktijkniveau. De beoogde steekproef (drie groepen van acht

praktijken) was voldoende groot om een gemiddeld verschil van 10 minuten in matige en intensieve beweging per dag tussen de groepen 1 en 3 aan te kunnen tonen. De primaire uitkomstmaat was het aantal minuten matige en intensieve beweging per dag, gemeten in alle drie de groepen met behulp van een accelerometer (PAM). Deze gegevens werden geanalyseerd middels multilevel mixed methods. De secundaire uitkomstmaten waren algemene self-efficacy, op sport en bewegen gerichte self-efficacy, kwaliteit van leven en gezondheidsstatus. Uitkomsten werden gemeten op drie tijdpunten: bij aanvang, meteen na de interventie (4-6 maanden) en drie maanden na afloop.

In hoofdstuk 6 wordt over de effectiviteit van de interventies gerapporteerd. De gecombineerde interventie (tool en ZOP) heeft geleid tot een significante verbetering van matige en intensieve beweging in vergelijking met gebruikelijke zorg. Direct na de interventieperiode bleek deze verbetering gemiddeld 12 minuten per dag. Drie maanden na de interventieperiode bleek deze vooruitgang nog steeds significant (11 minuten). Uit het onderzoek bleek tevens dat het gebruik van de tool in combinatie met het ZOP effectiever is dan alleen de toepassing van het ZOP (8 extra minuten). Het ZOP alleen had geen significant effect op beweging in vergelijking met de gebruikelijke zorg. De interventie bleek geen significant effect te hebben op de secundaire uitkomstmaten. Uit deze resultaten kan geconcludeerd worden dat de geautomatiseerde zelfcontrole en feedback component en/of het feit dat de praktijkondersteuner de beweegresultaten kan zien, de meest krachtige elementen van deze gecombineerde interventie zijn.

Hoofdstuk 7 doet verslag van de procesevaluatie van de *RCT It's LiFe!*, een onderzoek dat tot doel had om het bereik, de uitvoering en de tevredenheid aangaande de twee belangrijkste aspecten van de interventie te onderzoeken: het ZOP, dat werd uitgevoerd in beide groepen en de tool, die enkel gebruikt werd door patiënten in groep 1. Het bleek bijzonder moeilijk om voldoende praktijken en patiënten vinden die wilden deelnemen aan het onderzoek. Er moesten tien keer zoveel praktijken en binnen deze praktijken bijna drie keer zoveel patiënten benaderd worden. 17% van de patiënten viel uit tijdens het onderzoek. De uitvoering van de interventie was voldoende; het aantal en de planning van de consulten verliep zoals bedoeld (83%), patiënten herinnerden zich de verschillende aspecten van het Vijf A model (71%) en hoewel technische problemen vaak voorkwamen gebruikten de meeste patiënten (88%) de tool tot het einde van de interventieperiode. Zowel patiënten als praktijkondersteuners waardeerden het expliciet aandacht besteden aan stimuleren van meer bewegen met behulp van het Vijf A model. De technische problemen hadden weinig invloed op de tevredenheid; patiënten uit groep 1 waren significant meer positief over de interventie dan die in groep 2. De volledige interventie leidde tot meer bewustzijn en discipline ten aanzien van lichamelijke activiteit. Praktijkondersteuners vonden inzicht in beweging van hun patiënten via de objectieve metingen van de tool een nuttige aanvulling op hun begeleiding.

Hoofdstuk 8 van dit proefschrift geeft een overzicht van de belangrijkste bevindingen uit de individuele studies gevolgd door methodologische kanttekeningen bij het User Centred Design van een bewegingsinterventie gecombineerd met mobiele technologie. Daarnaast bevat dit hoofdstuk de discussie over de evaluatiemethode van een cluster gerandomiseerd onderzoek waarin effecten worden onderzocht van interventies die gedragsverandering beogen en daarbij gebruik maken van technologie. Vervolgens worden theoretische overwegingen beschreven die betrekking hebben op gedragsverandering en leefstijl coaching en de gevolgen daarvan voor de rol van de praktijkverpleegkundige. Dit hoofdstuk sluit af met implicaties voor onderzoek, praktijk en beleid. Gezien de positieve resultaten van de RCT en de procesevaluatie is het raadzaam dat verpleegkundigen lichamelijke (in)activiteit als een expliciet onderdeel beschouwen van de reguliere leefstijl risicofactor screening en indien nodig het gebruik van de *It's LiFe!* tool aanraden.

Tenslotte worden in hoofdstuk 9 de mogelijkheden nagegaan voor de valorisatie en verdere toepassing van de kennis die in dit proefschrift beschreven wordt.

Dankwoord

En dan is nu het moment aangebroken om iedereen persoonlijk te bedanken. Waarschijnlijk is het dankwoord het eerste en meest gelezen hoofdstuk van ieder proefschrift. Ik wil het kort houden en toch niemand overslaan. Dat wordt lastig want er hebben veel mensen bijgedragen aan het *It's LiFe!* project. En dan de volgorde, ook al een dilemma; eerst een lijstje maken en dan ad random, eerst werk en vervolgens privé, in de volgorde waarin ik ze ben tegengekomen, gewoon wie het eerste in me opkomt, of de allerliefste eerst.

Laat ik daar maar mee beginnen. Willem, als jij er niet bent, heeft ongeacht wat ik ook doe weinig betekenis. Als het even moeilijk is, dan zorg jij ervoor dat ik de dingen in een ander perspectief zie. Je hebt met eindeloze precisie alle beweegdata gecontroleerd, teksten meegelezen, feedback algoritmen mee opgesteld en commentaar gegeven op de congrespresentaties. Dankjewel voor je steun en begrip! En dan onze kinderen.
Leana, jij hebt met je ontwerp van het kaft een belangrijke stempel op dit proefschrift gedrukt. Fijn dat je dat voor me gedaan hebt. En Lucas, jij gaf commentaar op de technologie en de statistiek. Prima, want dan ging ik uitleggen waar ik mee bezig was en dat hield me scherp.

Dan nu een switch van privé naar werk. Soms is promoveren een eenzame klus, maar dat was niet zo in ons project. Sanne, ik wil je bedanken voor de jarenlange intensieve en fijne samenwerking! Jij brengt het beste in de mensen om je heen naar boven. Die eigenschap, gecombineerd met je positieve insteek, grote inzet, organisatietalent, perfectionisme en collegialiteit maakte het geheel tot een periode waar ik met veel plezier aan blijf terugdenken.

Ook wil ik graag het College van Bestuur, de faculteitsdirectie en teamleiders van Zuyd Hogeschool bedanken. Als jullie me niet in de gelegenheid gesteld hadden om aan dit project te beginnen dan had ik nu niets te melden gehad. Dat was een belangrijke voorwaarde voor de start van het project en daarop volgt logischerwijze een dank aan de mensen die betrokken zijn bij de afronding. Graag wil ik op deze plaats de leden van de beoordelingscommissie, Prof. dr. Dirk Ruwaard, Prof. dr. Stef Kremers, Prof. dr. Roland Friele en Prof. dr. Marieke Schuurmans, onder voorzitterschap van Prof. dr. Jean Muris, hartelijk danken voor het lezen en beoordelen van dit proefschrift.

De groep mensen die van dit project écht een succes gemaakt hebben zijn ongetwijfeld alle patiënten, praktijkondersteuners en huisartsen die bereid waren aan de onderzoeken deel te nemen. Bij aanvang was er soms gezonde twijfel, maar het is fijn

dat we uiteindelijk kunnen zeggen dat gebruik van de tool een positief effect heeft. Een mooi resultaat en dat bleek ook uit de vele positieve reacties van de deelnemers, iedereen hartelijk dank daarvoor!

Vervolgens wil ik graag de bij het project betrokken mensen van Maastricht Instruments en Sananet bedanken voor de samenwerking. Jullie hebben de tool en de monitor ontwikkeld en technische ondersteuning geboden gedurende het pilotonderzoek en de trial. Ook de samenwerking met Jos Donkers en Ina van Opstal was heel waardevol, jullie maakten de eerste jaren onderdeel uit van het onderzoeksteam bij de UM om te zorgen dat het patiënt perspectief centraal stond. Hartelijk dank voor jullie betrokkenheid bij het project en bij ons.

Van de UM nog even terug naar Zuyd Hogeschool, en dan speciaal Marielle en Joyce. We hadden vast veel vertraging opgelopen als jullie niet zonder enige twijfel ‘ja’ gezegd hadden toen ik vroeg om mee te werken aan het pilot onderzoek. Dank voor jullie bereidwilligheid en enthousiasme. Bij Zuyd denk ik ook aan de collega's van de master Advanced Nursing Practice, het lectoraat Technologie in de Zorg en de bachelor Verpleegkunde, de opleiding waar ik oorspronkelijk vandaan kom en de meeste jaren van mijn loopbaan gewerkt heb. Bedankt voor jullie oprechte belangstelling. Ik kon nooit over de D1 gang of bij de Zorgacademie Parkstad rondlopen of er vroeg wel iemand naar hoe het met mijn onderzoek ging, vooral Magda en Albine deden dat vaak. Jammer dat ik een autootje kocht, want daarna was meeliften niet meer nodig en moest ik de ritjes Maastricht- Heerlen in jullie gezelschap missen.

Over goed gezelschap gesproken, Sylvia wat waren de uitjes en zeiltochtjes met jou in al die jaren toch een heerlijke afwisseling. Dankjewel voor vriendschap. En ook Ingrids vriendinnen (en ook een beetje de mijne) wil ik bedanken. Ik geniet van alle mails/apps waarin we zin/onzin en lief/leed delen. Bij jullie kan ik de focus op het werk (en die heb ik soms tot vervelens toe) even helemaal loslaten. En Annette, wij hebben 25 jaar geleden in Sittard als verpleegkunde docent samengewerkt en bespreken sindsdien, behalve de ontwikkelingen in ons vak, vooral ook alle andere zaken die het leven de moeite waard maken. Je bent een geweldige vriendin!

Nog één keer een switch van privé naar werk. Bij Zuyd denk ik ook aan Luc de Witte, hoewel, niet alleen bij Zuyd, ook bij de UM en EIZT, overal heb jij die ‘technologie-in-de zorg-pet’ op. Vanaf de start van het lectoraat stimuleerde je mij om me te ontwikkelen. Je hebt me de 'wereld van het onderzoek' binnengeloodst, de laatste jaren in de rol van promotor. Altijd een overvolle agenda, maar ik wist zeker dat ik bij je terecht kon als dat nodig was. En Trudy van der Weijden, al was je iets meer op afstand betrokken, zo voelde dat toch niet, want op belangrijke momenten stuurde je altijd een mailtje met bruikbare adviezen. Ook de copromotoren Huibert Tange en Marieke Spreeuwenberg

wil ik graag bedanken. Huibert, jouw gedegen feedback op de artikelen vond ik heel waardevol. En Marieke, mede door jouw geduldige en duidelijke uitleg (en Twisk en Field binnen handbereik) is het goed gekomen met de statistiek en werd dat zelfs nog leuk ook! Maar het ging niet alleen over data, ook voor alle andere zaken kon ik goed bij jou terecht.

Nu ik het toch over data heb, dan is dit een mooi moment om April Boessen de hemel in te prijzen. Jij hebt met een ongelofelijke precisie de data van de trial ingevoerd. Je hebt ons heel veel werk uit handen genomen, dankjewel. Intussen ben ik bij de collega's van de UM aanbeland. Joan, vanaf het allereerste begin was jij een gezellige kamergenoot. Je hebt me wegwijs gemaakt op de UM en samen hebben wij vijf jaar lang ins en outs en ups en downs gedeeld. Dat ga ik vast en zeker missen! En niet te vergeten de andere technologie dames, Laura en Martine, met jullie erbij was het een geweldige afsluiting tijdens het eTELEMED congres in Lissabon. Nog even terug naar de kamer, Tom wij hebben regelmatig de 'wereld van de wetenschap' op de korrel genomen, ik wens je veel succes in je nieuwe baan. En natuurlijk wil ik ook alle andere collega's van de vakgroep HSR bedanken. Het was altijd gezellig om even naar de Lidl te lopen voor een broodje, om lekker buiten in het zonnetje ervaringen uit te wisselen over werk, vakantie, en andere leuke dingen. Ik ga mijn werkplek op Duboisdomein zeker missen!

Teruglezend lopen werk en privé nogal door elkaar heen, kenmerkend… Ik sluit af met het bedanken van de paranimfen, Annette en Joan. Fijn dat jullie op deze dag dicht bij me in de buurt willen zijn!

About the author

Renée Verwey was born in Ede, the Netherlands on the 10th of May, 1961.

After secondary school (HAVO) at the Marnix College, she obtained a bachelor degree in Nursing at the Hogeschool Arnhem Nijmegen (HAN) in Nijmegen (1980). She worked until 1988 as a psychiatric nurse at the Mondriaan, an institution for mental health in Maastricht.

In 1988 she attended a first grade teacher training at Maastricht University. From that moment onwards she worked at Zuyd University of Applied Sciences as a teacher at the Bachelor of Nursing and the Master Advanced Nursing Practice. She also worked for educational innovation programs called EDICTO and MAATWERK, where she focused on ICT and testing in higher education.

Alongside her work, she received two master degrees, in 2001 she attended a distance learning course Master Online Education and Training (OET) at the Institute of Education, University of London and in 2008 a blended learning course Master of Public Health, with a specialization Health Services Innovation, at Maastricht University.

Since 2008 Renée is the secretary of V&VN VZI (nurses and healthcare informatics), a specific task force within the professional association.

From the establishment of the 'Lectoraat Technologie in de Zorg' at Zuyd in 2006, Renée was a member of this unit. She worked as a project leader in several projects concerning the use of Electronic Health Records.

Finally, from September 2010 until March 2015 she had an honorary appointment at Maastricht University, at the department Health Services Research and within CAPHRI, the School for Public Health and Primary Care, to work as a PhD student on the project *It's LiFe!.*

Since March 2015 Renée works at Zuyd, as a teacher at the Faculty of Health and as a researcher at EIZT, the Centre of Expertise for Innovative Care and Technology.

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Mensen met een chronische ziekte zoals COPD en diabetes type 2 vinden het over het algemeen moeilijk om meer te gaan bewegen. Tevens is de huidige manier van leefstijladvisering door de praktijkondersteuner vaak niet toereikend om deze gedragsverandering te bewerkstelligen. De Universiteit Maastricht heeft daarom in het project *It's LiFe!* in samenwerking met twee bedrijven (Maastricht Instruments en Sananet) een tool ontwikkeld die gebruikers stimuleert om te gaan bewegen. De tool bestaat uit een bewegingsmeter, die draadloos is verbonden met een smartphone en een online coaching systeem. Via een app is te zien hoeveel minuten er bewogen zijn in relatie tot persoonlijke doelen. Gebruik van de tool is ingebed in een zorgprogramma dat bestaat uit extra consulten bij de praktijkondersteuner. In de huisartsenpraktijk kan de praktijkondersteuner de beweegresultaten van gebruikers van de tool via het coaching systeem monitoren.

In dit proefschrift beschrijft Renée Verwey de ontwikkeling en het testen van het zorgprogramma, het coaching systeem en het testen van het gebruik van de tool in combinatie met dit zorgprogramma in de praktijk. De resultaten van het evaluatieonderzoek bij 24 huisartsenpraktijken wijzen uit dat deze gecombineerde interventie effectief is en door patiënten en praktijkondersteuners gewaardeerd wordt. Dit proefschrift is relevant voor mensen met een chronische aandoening die meer willen bewegen en voor zorgprofessionals die deze patiënten begeleiden. De uitkomsten van het project zijn eveneens van belang voor wetenschappers en beleidsmakers die zich bezig houden met een gezonde leefstijl en geïnteresseerd zijn in de ontwikkeling van een mHealth interventie.

Renée Verwey (1961) heeft een achtergrond in de verpleging en is als senior docent en onderzoeker werkzaam bij Zuyd Hogeschool bij het Expertisecentrum voor Innovatieve Zorg en Technologie (EIZT). Gedurende het *It's LiFe!* project was zij verbonden aan de vakgroep Health Services Research binnen CAPHRI School for Public Health and Primary Care aan de Universiteit Maastricht.