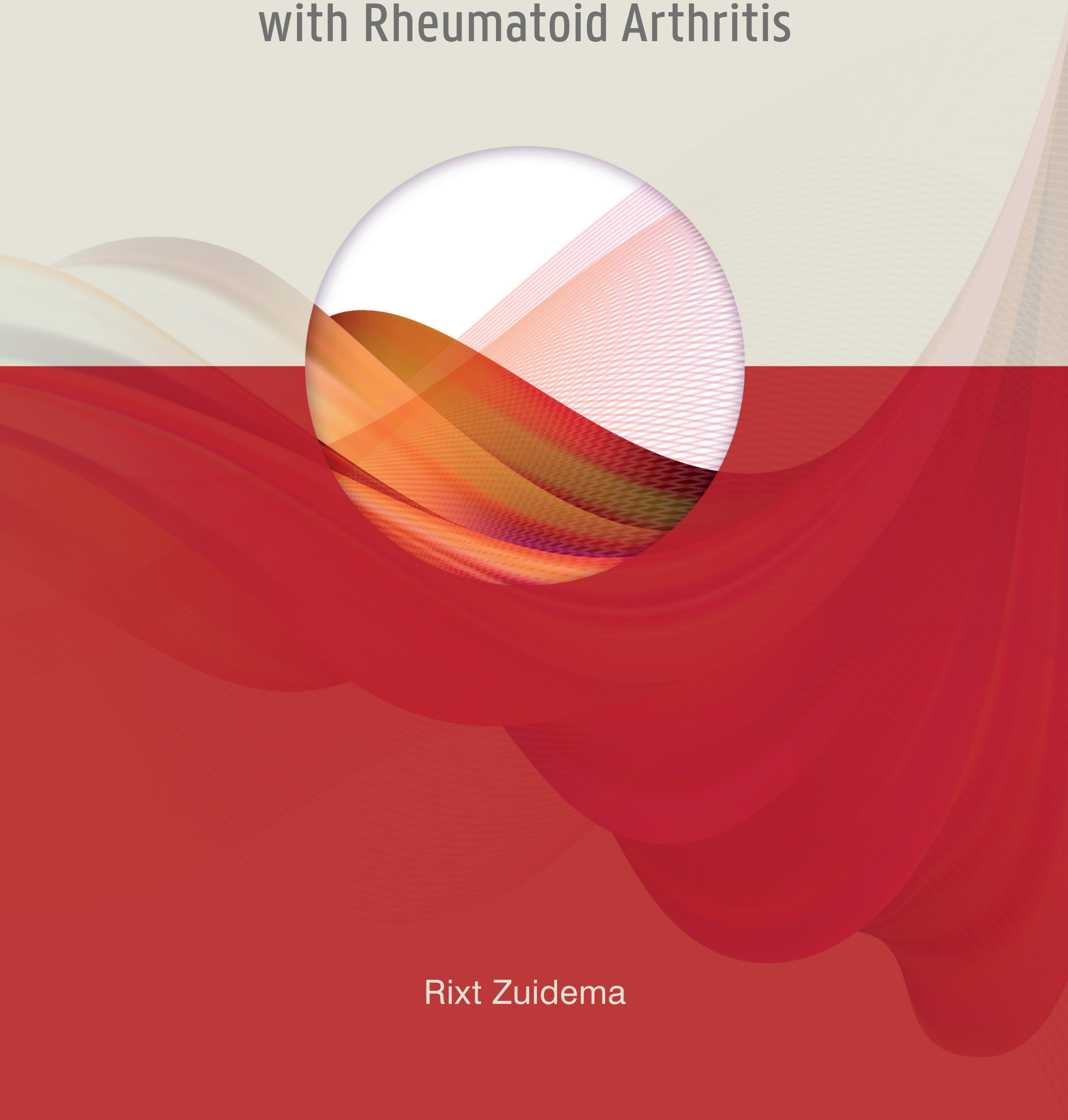
Participatory development and evaluation of an online self-management enhancing program for patients with Rheumatoid Arthritis



Rixt Zuidema

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For reasons of consistency within this thesis, some terms have been standardised throughout the text. As a consequence the text may differ in this respect from the articles that have been published. The studies presented in this thesis have been performed at the Scientific Center for Quality of Healthcare (IQ healthcare). The work presented was carried out within the Radboud Institute for Health Sciences, one of the approved research institutes of the Radboud university medical center.

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Contents

1

General introduction

Taking the role

In 2011 a new patient centred concept of health was proposed: 'Health as the ability to adapt and to self-manage, in the face of social, physical and emotional challenges' [1]. In this concept, health is considered as a dynamic ability of people who are living with or without a disease. It emphasises that people with a disease can have a good quality of life if they have the ability to adapt to their new situation and to cope with their illness. This implies that patients need to play an active role in their own health. Within this concept, the responsibility of the patient, their self-management behaviour, and a more equal relationship between the patient and health professional are crucial [1,2]. This active role of patients forces healthcare professionals to provide care in a different way. It creates greater collaboration between patients and healthcare professionals, where instead of caring for patients, healthcare professionals need to focus on supporting patients to manage their illness in daily life. Hubert et al. (2016) categorised the concept of health into six dimensions: 1) bodily functions, such as medical facts and physical functioning, 2) mental functions and perception, such as cognitive functioning and emotional state, 3) spiritual/existential dimensions such as acceptance and meaningfulness, 4) quality of life and perceived health, 5) social and societal participation, such as social and communicative skills and social contacts, and 6) daily functioning, such as performing daily activities and the ability to work. Studies show that better self-management behaviour of patients with a chronic disease is linked to several dimensions of the health concept of Hubert et al. (2016). Lorig et al. [3] found, for example, that better self-management is associated with fewer social/role activity limitations and better cognitive symptom management. Other studies show that better self-management behaviour is linked to several benefits in health status, such as lower functional disability and less pain and fatigue [4-8].

Self-management

Most definitions of self-management are focused on a (chronic) disease. A commonly used definition involves the ability to manage the symptoms, treatment, physical and psychosocial consequences, and lifestyle changes inherent in living with a chronic disease [9]. This means that patients play a central role in their own health, which requires active involvement in undertaking a wide range of activities. For example, a person who is diagnosed with a chronic disease needs to learn to take their medication on time, find ways to cope with physical and emotional symptoms and change their lifestyle so as to undertake physical activities. Self-management focuses on: (1) medical management, which refers to managing the illness, (2) emotional management, which involves the coping styles patients use to manage their emotional responses to the illness, and (3) role management, which refers to the way patients maintain their everyday life and their (social) roles [10,11]. Managing this range of activities is, however, difficult. Patients with a chronic disease try to maintain their daily lives, and at the same time they need to manage their disease [12-14]. Support for performing self-management behaviour is therefore essential. Every patient has their own support needs, so it is important to gain an understanding what these support needs are. We therefore undertook a study of self-management support needs in rheumatoid arthritis (RA) patients. Using our results, we developed, together with patients and healthcare professionals, an online self-management enhancing program for RA patients which was evaluated in an explorative RCT via process evaluation.

Rheumatoid arthritis

Rheumatoid arthritis (RA) is a chronic inflammatory disease which can lead to joint damage and bone destruction. Mortality rates in RA patients have been reported as higher than those of the general population [15]. The occurrence of RA varies between countries and areas of the world [16]. Several studies that have been conducted in North European and North American areas, and estimate a prevalence of 0.5 to 1.0% of people with RA [17].

New drug treatments (DMARDs and biologicals) for RA patients have proved to be effective in recent decades. Anti-inflammatory disease modifying drugs can slow down joint destruction and relieve symptoms such as stiffness and pain. Biologicals inhibit inflammation and immune cells, meaning inflammation decreases [18,19]. Early use of these medications is essential in controlling disease activity, and result in better daily functioning [20]. Despite these medications, patients with RA continue to experience fluctuations and uncertainty about their disease in daily life [21-24]. Pain, fatigue, stiffness and swollen joints are mentioned as physical consequences of RA, which mostly lead to functional disability [24,25]. Patients also experience psychological reactions to RA, such as frustration, anxiety and helplessness, and a depressed mood [26-29]. Many studies report the experienced difficulties that patients have in performing daily tasks due to RA. These difficulties range from those involving the simple daily tasks in household activities to limitations in social roles, such as work participation [30-32]. Patients need to manage the consequences of their disease to control and reduce the impact of RA in daily life.

Development and self-management interventions

Patient input

Patient input seems to be essential in developing online self-management enhancing programs [33,34]. It ensures that the program will be adapted to patient support needs for self-management and patient preferences for program usage. In this study, we composed a multidisciplinary panel of patients and health professionals who gave repeated input during the development of the program. As a starting point of the development, this panel helped us to assess support needs for self-management. Subsequently, the panel helped us to design and pre-test the intervention to ensure the program was clearly attractive and usable.

Theoretical basis

The theoretical basis of an intervention is important because it may influence the effectiveness of the intervention [35]. Behavioural theories explain (multiple) determinants of behaviour, and indicate which ones need to be changed (for example attitude or the level of self-efficacy) to perform self-management behaviour. Theories often used to develop interventions are the transtheoretical model (TTM), social cognitive theory (SCT), the health belief model (HBM) and the theory of planned behaviour (TPB) [4,36]. Behavioural change strategies (BCT) (for example modelling to increase self-efficacy) are specific strategies which can support behavioural change derived from above mentioned theories [37]. The use of standardised definitions of the BCT's for the replication of research is crucial, and therefore, a coding manual was developed to code 38 strategies used in interventions [38]. We used several BCTs strategies in the development of the online intervention, and translated them together with patients into practical applications (e.g. texts or videos). After this stage, we decided on the mode of delivery for the intervention.

E-Health

The internet has made an impact on healthcare in recent decades [39]. It has opened a means to empower patients to perform self-management and give them a central role in their own health. Online-based programs give patients the opportunity to adopt healthy behaviours by giving, for example, disease-specific information, monitoring behaviour and giving feedback [4]. With an online program, patients have the opportunity to receive support for self-management in addition to regular healthcare whenever they want. Recently, the number of online programs has grown rapidly for different groups of patients and various behaviours [40]. Reviews of these programs show positive, but small effects on various behaviours, such as physical activity in different patient groups [4,41].

Evaluating e-health interventions

Although most e-health interventions are evaluated via a randomised controlled trial (RCT), the Medical Research Council (MRC) recommends that a feasibility study be performed in advance [42]. In a feasibility study, important information will be gathered with which to design a larger trial, for instance: identifying appropriate outcome measures, or determining effect sizes, drop-out rates from the study or adherence rates from the intervention. The results of a feasibility study can lead to several recommendations in preparation for a larger trial, for example to refine the intervention so as to enhance usage, develop an appropriate questionnaire to measure outcomes, or to optimise the implementation process of the intervention.

Aims of this thesis

The aim of this thesis was firstly to develop an online self-management program for Dutch rheumatoid arthritis patients based on the framework of Intervention mapping (IM) [43]. Following the MRC Framework, this online program was tested in a feasibility study in preparation for a larger trial, including a qualitative interview study to assess reasons for usage and non-usage.

Outline of this thesis

Chapter 2 presents the results of a scoping review and gives an overview of self-management support needs based on the perspective of rheumatoid arthritis patients. The results of this scoping review, and input from the multidisciplinary panel of patients and professionals, gave input for the development of the online program, which is described in *Chapter 3*. This chapter reports on the use of the IM framework for development of the online program. An exploratory RCT is designed to evaluate the potential efficacy of the program. *Chapter 4* reports the results of this exploratory RCT. *Chapter 5* presents the results of a qualitative interview study. Insight into the (non-) usage of the program is given and patient experiences with the program are reported. In *Chapter 6*, experiences with another online self-management program, ‘Reumanet’, are described. Finally, *Chapter 7* discusses the findings of this thesis in a broader context. Suggestions for further research and recommendations for practice are also presented.

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2

What do we know about rheumatoid arthritis patients' support needs for self-management? A scoping review

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International journal of nursing studies 2015; 52; 10; 1617-1624

Abstract

Background: Self-management support is essential to perform self-management behavior. To provide this support in an effective way, insight in the needs for self-management support is necessary.

Objective: To give an overview of self-management support needs from the perspective of rheumatoid arthritis patients to help nurses to improve self-management.

Design: We conducted a scoping review for the period of January 2002 to May 2013 using the following inclusion criteria: 1) studies on adult patients aged 18 years and older, 2) studies from the perspective of rheumatoid arthritis patients, 3) studies reporting results on support needs, and 4) empirical studies using any design.

Data Sources: We searched in PubMed, CINAHL, and PsycINFO.

Review Methods: Following the steps of a scoping review, we 1) identified the research question, 2) identified relevant studies, 3) selected studies, 4) charted the data, and 5) collated, summarized, and reported results. We incorporated the optional sixth step of consultation of a multidisciplinary panel of professionals and patients to validate our findings.

Results: Seventeen articles were included. Our review shows that rheumatoid arthritis patients have informational, emotional, social and practical support needs. We found an information need for various topics, e.g. exercises and medication. Patients express a need for emotional support in daily life, given trough other RA patients, colleagues and supervisors and nurses. For information needs, emotional and social support it is important that it is tailored to the individual needs of the patient.

Conclusion: The most important support needs for self-management mentioned by rheumatoid arthritis patients are more informational, social and practical support and emotional support. Considering patients' perspective as a starting point for delivering support for self-management can lead to the development of nursing interventions tailored to the needs of rheumatoid arthritis patients.

Introduction

Rheumatoid arthritis is a chronic inflammatory and systemic disease which affects approximately 0.5 to 1.0% of the adult population worldwide [1]. Patients with rheumatoid arthritis face several challenging problems, such as pain, stiffness, fatigue, and decreased muscle strength which cause difficulties with daily activities [2]. Moreover, rheumatoid arthritis has been linked to various psychological challenges, such as depression, helplessness, and anxiety, and has a considerable impact on quality of life [1,3-5]. Because of the large impact of rheumatoid arthritis on health status and healthcare expenditures, there is a growing interest in self-management for rheumatoid arthritis patients [6-8].

There is no clear definition of self-management, a commonly used definition is: self-management refers to the individual's ability to manage the symptoms, treatment, physical and psychological consequences and life style changes inherent in living with a chronic condition [9]. Thus, self-management encompasses a variety of activities like making lifestyle changes to promote health, such as exercising, communicating with health professionals to improve treatment effects, making daily decisions on the basis of signs and symptoms of the illness, and coping with the impact of the disease to function in important roles and social relations with other people [10]. However, taking a central role in these various self-management activities can be a complex task for patients [11]. Therefore, support for self-management is essential [12]. Supporting self-management is effective when it engages informed patients, trained health professionals and health organization policies that support self-management behavior [12]. For this, insight in the support needs for self-management from RA patients' perspective is required. However, an overview of this is currently lacking. Therefore, the aim of this article is to identify the support needs for self-management of rheumatoid arthritis patients, from the available literature.

Materials and methods

Design

We conducted a scoping review, following the steps described by Levac [13]. A scoping review is an explorative method in which inclusion and exclusion criteria are based on relevance, rather than study quality. Besides that, this methodology has an optional consultation phase in which themes are discussed with professionals and stakeholders to share preliminary findings and validate findings from the literature [13]. The method contains five steps, namely 1) identifying the research question, 2) identifying relevant studies, 3) study selection, 4) charting the data, and 5) collating, summarizing, and reporting results. We incorporated the optional sixth step of consultation of a multidisciplinary panel of professionals and patients to validate our findings.

We started with the following research question: *What are the self-management support needs of rheumatoid arthritis patients from the patients' perspectives*? In the next step, we identified relevant studies. For this, we searched PubMed, CINAHL, and PsycINFO for the period between January 2002 and May 2013. We used both MeSH terms and free words texts. Table 1 provides the PubMed search string; equivalent search strings were used in the other databases.

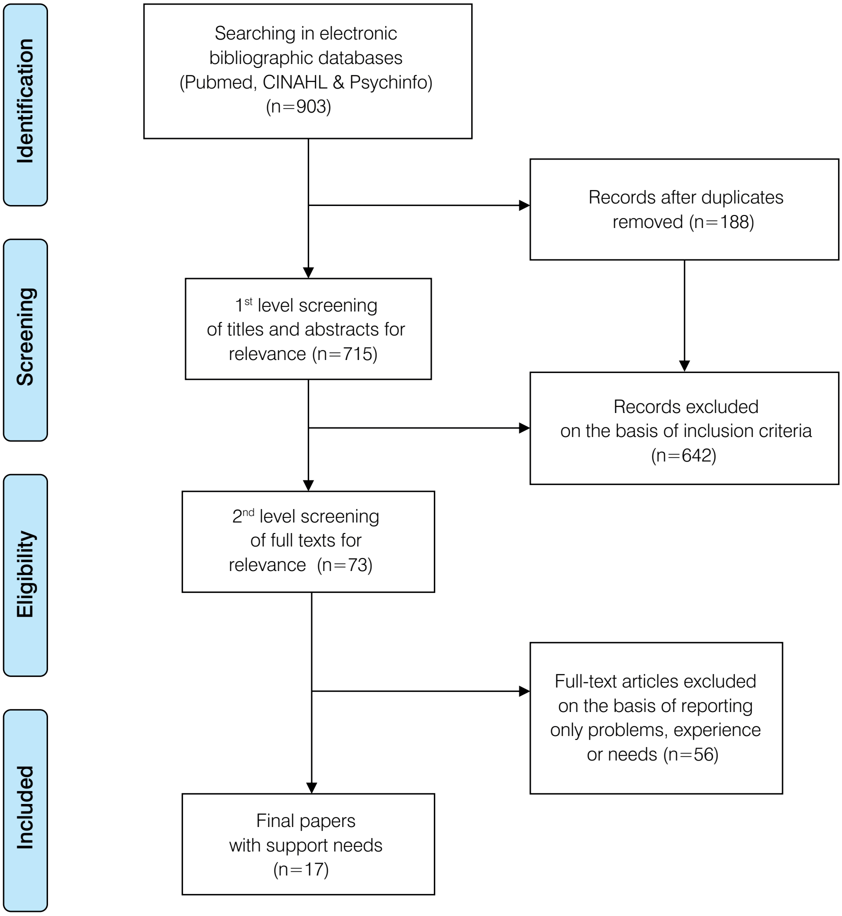
Table 1 Search string of scoping review

("Needs assessment"[MeSh] OR needs assessment[tiab] OR need assessment[tiab] OR needs assessment[tw] OR need assessment[tw] OR "needs assessment"[tiab] OR "healthcare needs"[tiab] OR "assessment of healthcare needs"[tiab] OR "assessing needs"[tiab] OR "assessed needs"[tiab] OR "needs assessed"[tiab] ***AND*** *perception[tw] OR perceptions[tw] OR satisfaction[tw] OR satisfied[tw] OR suggest[tw] OR prefer*[tw] support[tiab] ("Self Care"[MeSh] OR selfmanagement[tiab] OR "self management"[tiab] OR "self care"[tiab] OR "self support"[tiab] OR "self management support"[tiab] OR problem[tiab] OR problems[tiab] OR experien*[tiab])* ***AND*** *(Arthritis, Rheumatoid[MeSh] OR rheumatoid arthritis[tw]).*

In the third step we selected studies. The search strings for the three databases led to identification of 903 articles (PubMed n=549, CINAHL n=217, PsycINFO, n=137). After exclusion of duplicates, 715 articles were screened on title abstract. A researcher (RMZ) and a research assistant (LB) independently screened the titles and abstracts of 715 articles on the basis of the following inclusion criteria: 1) studies on adult patients aged 18 and older, 2) studies from the perspectives of rheumatoid arthritis patients, 3) studies reporting results on support needs, and 4) empirical studies using any design. Subsequently, 73 studies were considered full text by the same reviewers, and studies were excluded if the content did not meet the inclusion criteria. In case of disagreements, a third reviewer (HRW) was decisive in including or excluding the studies. Figure 1 shows the process of selecting studies.

In the fourth and fifth step, we collected and charted the data and subsequently analyzed and reported the results. Information regarding publication (year, country), target group (age, gender, disease duration, co-morbidity), sample size, study design, and methods were extracted and organized in a file. Besides the characteristics of the studies, we made an overview of patient-reported support needs described in the studies. We categorized them as support needs related to symptoms, treatment, physical consequences, psychological consequences and life style changes, based on Barlow's definition of self-management [9]. One researcher (RMZ) extracted the data, and a second researcher (BvG) independently reviewed the extracted data of 25% of randomly selected studies. Potential disagreements were discussed with a view to reaching consensus. Subsequently, we made an overview of the support needs. To validate the data in the last step, a multidisciplinary panel was formed, consisting of five rheumatoid arthritis patients, two rheumatologists, one psychologist, one physiotherapist, one specialized nurse, one occupational therapist, and three researchers (BvG, HRW, and RMZ). As an extra validation of our findings, the researchers provided the multidisciplinary panel a list of self-management support needs from the patients' perspectives, after which they discussed and validated the data on the basis of consensus.

Figure 1 Overall flow scoping review



Results

This review included 17 studies on self-management support needs of rheumatoid arthritis patients, presented in Table 2. Most of the studies have been performed in the western part of Europe and have a broad range of sample sizes (n=7 to n=683) and a broad range of age and disease duration. Study designs encompassed cross-sectional studies, and a single group longitudinal design. Four overarching themes were found, namely: information needs, social support needs, emotional support needs and practical support needs.

Information needs

Information needs about physical exercises

For exercise, patients want to have information about the purpose of the exercise and how to carry out the exercise [14], for example, what the best exercises are, how much they should practice, and when they have to stop [15]. With this knowledge, patients want to prevent joint damage and pain. Furthermore, they want to increase their muscle strength and mobility [14,15]. Patients mentioned that information about exercises should preferably be given in a group or video [14]. Another way to receive information about exercises are leaflets, which enable patients to read information afterwards [14]. When patients receive their information from professionals, they found it important that professionals are confident in giving the instructions [15].

Information needs about CVR

Since it is known that rheumatoid arthritis is related to cardiovascular risks (CVR), patients expressed the need for professional to listen to their concerns about cardiovascular risk and for receiving advice about their uncertainties about CVR, for example *"Doing exercises which could help the heart, but not hinder rheumatoid arthritis"* [16].

Information needs about fatigue

Patients mentioned that information and advice about fatigue from professionals, especially after diagnosis, is desirable [14,17]. Although patients found it difficult to identify what kind of information about fatigue they want to receive, they mention that the information must to be adjusted to their personal situations so they can use the information in their daily live [17].

Information needs about problems at work

To increase the support in work situations and to learn how to solve problems at work, patients need advice from health professionals [18,19]. For obtaining information about how to get access to equipment and finances, patients can learn from the experience of other rheumatoid arthritis patients [18].

Information needs about disease, treatment and medication

Firstly, patients want to have tailored information about their disease, which means that they are not interested in rheumatoid arthritis in general, but only in the consequences of rheumatoid arthritis specific to their own situation [14].

Secondly, information about the whole treatment is required. In the studies by Mäkeläinen et al., 2009 [20] and Jacobi et al., 2004 [21] patients mention that it is important that they receive information without asking for it, such as on the disadvantages and advantages of their treatment. Patients want to be able to ask for information freely and when they need it, and hope for clear answers, avoiding medical jargon. A way to do this is through oral explanations by professionals, in addition to written information [22].

Thirdly, patients want to receive information about medication from professionals so they know what they can expect. Important issues are: the purpose of the medication; the side-effects not only for the short-term, but also for the long-term and especially for ‘new’ medications; concomitant use of multiple medications; and adequate instructions on how and when to take the medication [14,21,23,24].

Furthermore, patients mention that professionals can help them in making decisions about the medication treatment through providing information and discussing the options [25]. The combination of information and help with decision-making can increase their medication adherence [23-25]. Additionally, patients find it important that their families receive information about their medication as well so they know what they can expect of rheumatoid arthritis and the possible side-effects of medications [14].

Social support needs

Social support can be seen as interactions between relationships, which can enable patients to manage their illness. Patients express a need for social support to maintain their everyday life. This social support should be given regularly, not only in times of increased disease activity [26]. Patients mention that this social support must be suited to their requirements, because too much support could feel like social control [26].

On a higher level, patients find it important that patients’ organizations and the government can make policies available which enable them to continue their work by receiving disability benefits [18].

Emotional support needs

Patients mention a need for emotional support about the impact of the disease.

> *“because it is quite hard to grasp the enormity of it [the disease]”* or “*your confidence goes down and because one of the causes is that you can’t do things you used to be able to. And the other thing that happens to me is that if I have a good day and I maybe do more than I should, then I suffer and go right down again*” [27].

Table 2 Overview of included studies

First author and year of publication	Aim of the study
Ahlmén, M. et al. (2005)	To determine the factors in relation to the treatment and satisfaction of patients
Barlow, J. (2002)	- To examine the levels and stability of psychological well-being at 12 months follow-up as an indicator of need - To investigate the associations between arthritis self-efficacy and physical and psychological health status. - To identify patients' preferences for psycho-educational interventions in terms of content and mode of delivery
Chilton, F. (2008)	To explore RA patient treatment preferences, their decision-making, and the treatment choices they would make when faced with three antitumour necrosis factor-a (TNF-a) therapy options.
Detaille, S. (2003)	To determine factors that help currently employed people with RA, diabetes mellitus, or hearing loss to continue working.
Hewlett, S. (2005)	To explore the experience of fatigue in patients with RA in the United Kingdom.
Jacobi, C.E. (2004)	To identify aspects of inadequate quality in RA health care, and to determine the usefulness of patients' quality ratings for quality improvement in health care by studying to what extent patients' ratings of quality of care were associated with patient characteristics.
John, H. (2009)	To qualitatively explore RA patients' perceptions about developing novel educational material to address their associated CVD risk.
Kirstianson, T.M. (2012)	To explore how people who were clinically regarded to be in remission experienced their everyday lives with RA. Secondly, to explore the experiences of people in early remission with healthcare provision and their perceived support needs.
Kristianson, T.M. (2012)	To integrate a sociological focus on chronic illness and everyday life with an empirical exploration of how everyday life is affected by RA in a Danish population, and to explore the implications for patient education and clinical practice. Secondly, the study aimed to explore whether RA affects individuals in different ways in the first years after diagnoses compared with later in the disease trajectory, and whether this might have any implications for patient education.
Law, R.J. (2010)	The overall objective was to enhance the information available to health professionals, allowing for a targeted, patient-centered approach to exercise prescription.
Makelainen,P. (2009)	To describe the content of patient education as portrayed and evaluated by RA patients.
Mitton, D.L. (2007)	To explore the health and life experiences of mothers with RA
Radford, S. (2008)	To explore what professional support patients felt they received at diagnosis, and what support system they felt would be most helpful.

Study design	Sample size	Age in years mean (sd)	Disease duration mean years (sd)	Country
Qualitative, cross-sectional	25	55 (31-77) [a]	14 (3-44) [a]	Sweden
Qualitative,single group longitudinal design	60	59.2 (11.30)	16.9 (13.65)	UK
Mixed methods, cross-sectional	190	65 [b]	Not reported	UK
Qualitative, cross-sectional	21	50 (23-65) [c]	Unclearly reported [d]	Netherlands
Qualitative, cross-sectional	15	55.6 (28-80) [c]	2.6 (8.6)	UK
Quantitative, cross-sectional	683	61.5 (23.4-92.1) [c]	10.7 (1.5-57.8) [c]	Netherlands
Qualitative, cross-sectional	18	56.7 (31-72) [c]	Not reported	UK
Qualitative, cross-sectional	11	Unclearly reported [d]	Unclearly reported [d]	Denmark
Qualitative, cross-sectional	32	Unclearly reported [d]	Unclearly reported [d]	Denmark
Qualitative, cross-sectional	18	59.1 (23-76) [c]	Unclearly reported [d]	UK
Quantitative, cross-sectional	173	57 (11.5)	11 (1-46) [a]	Finland
Qualitative, cross-sectional	7	36 (21-41) [c]	6.6 (3-11) [a]	UK
Qualitative, cross-sectional	12	Unclearly reported [d]	Unclearly reported [d]	UK

Table 2 Continued

First author and year of publication	Aim of the study
Repping-Wuts, H. (2008)	To explore the experience of fatigue in Dutch RA patients, including the concept, causes, and consequences of fatigue, patients' self-management strategies, and bottlenecks in professional care.
Ryan, S. (2003)	To identify the factors that patients perceive as prerequisites in obtaining a sense of control over living with the daily symptoms of their RA.
Van der Meer, M. (2011)	To investigate the experiences and needs of employees with RA treated with anti-TNF therapy with respect to work participation.
Ward, V.(2007)	To provide an understanding of what RA patients want and need from their outpatient care.

[a:] median (range), [b:] median, range unclearly reported, [c:] mean (range),
[d] Mean/median/s.d. or range reported only on focus group level

Emotional support could be provided by a buddy or peer with whom they could talk about medical and psychological issues, for example, about *"having a flare"* or "*being stressed"* [27]. Patients mention that meeting and talking to other peers is very helpful because 1) it gives rheumatoid arthritis patients a chance to mirror themselves and their own experience, 2) they can legitimize their experience with other rheumatoid arthritis patients, and 3) they can find role models showing it is possible to live a normal life with rheumatoid arthritis[16,28].

Furthermore, patients have a need for emotional support from colleagues and supervisors [18,19]. To receive the understanding and thus the emotional support of colleagues, it is important that colleagues are aware of the consequences of rheumatoid arthritis, so colleagues can deal with patients' physical and emotional states [18].

Studies show that the best way to deliver emotional support is for patients to be able to choose the support they need at the time they need it. At that moment, nurses need to have time to talk about patients' feelings in an unhurried way, so patients can express their psychological concerns [20,26,27].

Study design	Sample size	Age in years mean (sd)	Disease duration mean years (sd)	Country
Qualitative, cross-sectional	29	59 (6-80) [c]	12.6 (2-34) [a]	Netherlands
Qualitative, cross-sectional	40	56 (23-72) [c]	11 (0.5-38) [c]	UK
Qualtative, cross-sectional	14	47 (2.9)	7.7 (1.6)	Netherlands
Qualitative, cross-sectional	25	56.8 (37-76)	14.8 (2-32) [c]	UK

Practical support needs

Employers can deliver practical support to obtain adaptations at their workplace, such as a comfortable chair or a split-computer keyboard, flexible work hours, and possibilities for career development [18].

To continue daily activities and manage social roles, patients need information about coping strategies, how to find daily balance between activity and rest, how to manage fatigue how to use assistive devices in daily life, and the possibilities of home adjustments and aids at home [14,21,28,29]. Patients express that a useful way to provide this information about practical things is through leaflets [14].

Women, with rheumatoid arthritis who want to have children, have a specific need for pre- and postnatal pregnancy education, such as about the potential risks of pregnancy that can be more prevalent among women with rheumatoid arthritis. Further, they experience a lack of advice about practical things, such as on bathing the baby [30].

Validation by the multidisciplinary panel

The multidisciplinary panel validated the findings from the literature. All findings in the various domains were recognized as support needs by patients in the panel.

Discussion

To our best knowledge, this is the first review about support needs for self-management for rheumatoid arthritis patients. The aim of this study was to give an overview of support needs for self-management from the perspective of rheumatoid arthritis patients. Our review shows that rheumatoid arthritis patients have informational, emotional, social and practical support needs. We found an information need for various topics, e.g. exercises and medication. Patients express a need for emotional support in daily life, given trough other RA patients, colleagues and supervisors and nurses. For information needs, emotional and social support it is important that it is tailored to the individual needs of the patient.

The support needs for self-management of rheumatoid arthritis patients described in this study correspond with the support needs of patients with other chronic conditions as described in several studies. Patients with a coronary heart disease, stroke, or asthma express information needs with regard to taking their medications, such as information about side-effects, short- and long-term effects, and interaction effects [31-34]. Additionally, in the study by Pier et al., 2008 [32], patients express an information need in relation to performing physical exercises. Regarding social support, emotional support and practical support, the studies of Taylor et al., 2009 [35] and Reed et al., 2010 [36] showed the importance of peer support and support from family members in enabling stroke patients to continue their daily lives.

This scoping review has some limitations. Firstly, the included studies do not always describe the support needs explicitly, extensively, or clearly. This implies that to some extent bias may have been introduced by the interpretation of the reviewers. However, we reviewed the included studies with two researchers and discussed the support needs as described in the articles. In case of doubts or disagreements, we excluded the support need. As a result of this, overall we believe we distilled valid support needs for self-management, with the possibility that there is an incomplete list, because we excluded unclear descriptions of support needs for self-management [12].

Secondly, in a scoping review the quality of the studies is not assessed. Therefore, some studies of lesser quality could be included. However, to give an overview of all studies on support needs of rheumatoid arthritis patients, we gathered as much information as possible. Only single case studies were excluded, as results of such studies can be very specific for individuals. We included only studies which took the perspectives of rheumatoid arthritis patients into account, in contrast to other studies which were conducted from health professionals' perspective [37]. We expect that considering patients' perspectives as a starting point for delivering support for self-management may lead to best-suited and effective support for self-management. For nurses and healthcare organizations it is important to have insight in these needs, so professionals can be trained to deliver self-management support and healthcare organizations could support policies focused on enhance self-management behavior [38,39].

Conclusion

From rheumatoid arthritis patients' perspectives, there is a need for more informational, emotional, social and practical support for them to be able perform self-management behavior. These results can enable the development of patient-centered support for self-management. Considering patients' perspectives as a starting point for delivering support for self-management can lead to effective nursing interventions tailored to the needs of rheumatoid arthritis patients.

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3

An online tailored self-management program for patients with rheumatoid arthritis: a developmental study

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Abstract

Background: Every day Rheumatoid Arthritis (RA) patients make many decisions about managing their disease. An online, computer-tailored, self-management program can support this decision making, but development of such a program requires the active participation of patients. At present there is no well-designed online computer-tailored self-management program available for adult RA patients. Objective: To develop an online, computer-tailored, self-management program integrated with the nursing care, as nurses have an important role in support self-management behavior.

Methods: The Intervention Mapping (IM) framework was used to develop the program. Development was a multi-step process: 1) needs assessment, 2) developing program and change objectives in a matrix, 3) selecting theory-based intervention methods and practical application strategies, 4) producing program components, 5) planning and adoption, implementation and sustainability and, 6) planning for evaluation.

Results: After conducting the needs assessment (step 1) nine health-related problems were identified: 1) balancing rest and activity, 2) setting boundaries, 3) asking for help and support, 4) use of medicines, 5) communicating with health professionals, 6) use of assistive devices, 7) performing physical exercises, 8) coping with worries, 9) coping with RA. After defining performance and change objectives (step 2), we identified a number of methods which could be used to achieve them (step 3), such as provision of general information about health-related behavior, self-monitoring of behavior, persuasive communication, modeling, self-persuasion and tailoring. We described and operationalised these methods in texts, videos, exercises and a medication intake schedule. The resulting program (step 4) consisted of an introduction module and nine modules dealing with health-related problems. The content of these modules is tailored to the user's self-efficacy and patients can use the online program as often as they want, working through a module or modules at their own speed. After implementation (step 5) the program will be evaluated in a two-centre pilot trial involving 200 RA patients. Log-in data and qualitative interviews will used for a process evaluation.

Conclusions: The IM framework was used to guide development of an online computer-tailored self-management program via a process which could serve as a model for the development of other interventions. A pilot randomized controlled trial (RCT) will provide insight into the important outcome measures in preparation for a larger RCT. The process evaluation will provide insight into how RA patients use the program and the attrition rate.

Introduction

Rheumatoid arthritis (RA) is a chronic, autoimmune disease which predominantly affects the joints. Many RA patients face several physical problems, such as pain, stiffness and fatigue, which cause difficulties in everyday life [1]. RA has also been linked to depression, helplessness and anxiety, and has a considerable impact on quality of life [2-5]. As life expectancy increases and the number of people living with a chronic condition increases, there has been an increase in the number of RA patients [6].

Although healthcare professionals can give patients advice and support during visits and appointments, patients have to make day-to-day decisions about management of their disease by themselves. Self-management programs can help RA patients to take an active role in the everyday management of their disease [7-9]. Self-management has been defined as the tasks undertaken by patients to manage the symptoms, treatments, lifestyle changes and physical and psychological consequences associated with their illness [10]. Although self-management support programs are available, most programs are provided in clinical settings or in small groups [11] and not all RA patients are willing or able to participate. With the growing number of people with internet access and the increasing use of internet among RA patients [12] [13] an online self-management support program can be a sustainable way to support self-management behavior. Compared to face-to-face programs, online programs provide an easily accessible opportunity to reach the large group of RA patients. Also, online programs have the possibility to tailor information, and can provide more anonymity than face- to-face programs. Other advantages include avoiding waiting lists and a 24-hour availability [14,15].

In the Netherlands, two studies have shown that the use of self-management programs are feasible for specific groups of RA patients is feasible, one in adolescent RA patients [16], the other focusing on work related problems [17]. At this moment, there is no generic online self-management program for adult RA patients in the Netherlands. As nurses have an important role in supporting self-management behavior, such a program should preferably be integrated in the nursing care provided as part of the multidisciplinary RA care.

An online self-management program is a complex intervention. First, it should include a variety of components, such as information provision, management of symptoms, social support and communication strategies [18]. Second, because the target population can be diverse self-management programs should be extensive and tailored to patient needs. Within the population of RA patients there is variance in the need for self-management support, depending for example on age, level of education, gender or work status. Third, programs should enhance patient understanding of the behavioral change required for self-management. To develop such a program requires an understanding of the factors which influence self-management behaviors. To ensure that our development process took account of these three overarching requirements we used the Intervention Mapping (IM) framework. We chose to develop a tailored intervention because adapting communications and behavioral change strategies to patient needs [19] means that a higher proportion of the patients receive information that is personally relevant which increases their motivation to change their behavior [20].

This article describes the development of an online computer-tailored program and the design of an evaluation procedure using the IM framework; it could serve as a guide for the development and testing of other interventions.

Methods

The IM framework is designed to ensure that development work is focused on the most important determinants of behavior. IM has previously been used successfully to develop health programs related to, for instance, medication adherence [21], promoting physical activity [22], healthy lifestyles [23] and asthma-management [24]. The IM framework provides a way of systematically integrating theoretical research, empirical findings and data collected from the population [25]. IM provides a six-step framework for developing health education programs. The six steps are: 1) identifying problem behaviors and determinants through needs assessment, 2) developing a matrix of performance objectives and change objectives, 3) selecting theory-based intervention methods and practical application strategies, 4) producing program components, 5) planning and adoption, implementation and sustainability and, 6) planning for evaluation [25]. Active patient participation in the development process was secured by recruiting, during the first step, a multidisciplinary panel consisting of health professionals, researchers and patients who were involved in every step of the development process.

Step 1: needs assessment

First we recruited a multidisciplinary panel of five RA patients, two rheumatologists, one rheumatology nurse, a psychologist, a physiotherapist, an occupational therapist and three researchers (RMZ, HRW, BvG). The rheumatology nurse and rheumatologist played a crucial role in the development and implementation of the program.

Our needs assessment comprised two components: 1) a literature search for information on health problems, problems affecting health-related behaviors and determinants of problems and 2) input from two meetings of the multidisciplinary panel. During the first meeting we held a brainstorming session to identify the main health problems affecting RA patients. To select the most important health problems for RA patients, we coded health problems found in literature and discussed this among the multidisciplinairy panel . Selection was further based on recognizability and importance of the health problems. In the second meeting we identified problems affecting health-related behaviors and their determinants based on literature and discussed the following questions among RA patients and health professionals: *1) why do patients have problems 2) why do patients have problems with this behavior?* In the third meeting we asked the multidisciplinary panel whether the listed problems in health-related behavior were easily changeable or not. After these meetings, the researchers listed and coded the health problems, the problems affecting health-related behaviors and their determinants manually.

Step 2: developing a matrix of performance objectives and change objectives

In the second step, we organized the performance objectives and change objectives as a matrix to indicate which behaviors needed to change to achieve the overall goal of the program, which was to enhance patients' ability to self-manage their disease and thus improve their quality of life. The performance objectives formalized the behavioral changes RA patients needed to make to achieve the behavioral goals of the program. The change objectives were performance objectives linked to determinants and specified what needed to change in the determinants of behavior to achieve the performance objectives. A researcher (RMZ) constructed a matrix of the relationships between performance and change objectives which was subsequently validated by the multidisciplinary panel.

Step 3: selecting theory-based intervention methods and practical applications

After defining the matrix we selected theory driven methods on the basis of behavioral change theories. Two independent researchers linked methods from the classification of the Behavior Change Techniques to the problems affecting health-related behaviors and their determinants in order to select methods which could be used to achieve our overall goal. The Behavior Change Technique classification defines strategies used in supportive programs [26]. Using a summery produced by the 2 independent researchers, the multidisciplinary panel decided whether the methods were suitable for the RA patient population. We assessed the conditions under which the methods are shown to be effective to translate methods into practical applications, such as texts and videos.

Step 4: producing program components

Program development was based on the change objectives and the selected theory-driven methods and consisted of 1) composing program materials and 2) pre-testing these materials. Our research group worked with an information and communications technology (ICT) partner to produce the program materials. The research group developed the content, including textual material and our ICT partner incorporated this material into an online program.

Our pre-test of the online program comprised: 1) testing of the program materials by the multidisciplinary panel and 2) testing of the program by three RA patients who were not involved its development using the ‘think aloud’ method [27].

Step 5: planning for adoption, implementation and sustainability

IM steps 1 to 4 formed the basis of the implementation. Meetings of the multidisciplinary panel were held to identify and categories barriers and facilitators to implementation of the online program. The rheumatologist and specialist rheumatology nurse played a crucial role in the implementation process.

Step 6: planning for evaluation

In the final IM step we planned to evaluate the feasibility of the study design and the online self-management program by conducting an exploratory randomized controlled trial (RCT) and a process evaluation [28]. To do this we identified outcomes and process measures that were relevant to the program objectives. We also intend to conduct qualitative interviews with nurses, users and non-users of the program. Finally, we plan to monitor which topics related to the program components are discussed during nursing consultations and whether they are raised by the nurse or the patient.

Results

Step 1: needs assessment

Health problems and the underlying behavioral problems

We selected the most important eight health problems in daily life for RA patients, namely: pain, fatigue, stiffness, daily functioning, sexuality, work, social activities and coping with RA.

We identified nine general problems affecting health-related behavior from our literature review and through discussions among the multidisciplinary panel, namely: 1) balancing rest and activity, 2) setting boundaries, 3) asking for help and support, 4) use of medicines, 5) communicating with health professionals, 6) use of assistive devices, 7) performing physical exercises, 8) coping with worries, and 9) coping with RA.

Determinants of problem behaviors

Our literature search uncovered that the following factors were relevant to problems affecting health-related behavior: knowledge, awareness, risk perception, social influence, attitude, self-efficacy and habits. Patients confirmed the relevance of these determinants.

Step 2: developing a matrix of performance objectives and change objectives

The results of the needs assessment were used to draw up a matrix of performance and change objectives. One of the performance objectives was: *the patient is able to set her or his boundaries*. This performance objective was relevant to in the following health problems in daily life: pain, fatigue, social activities and work.

Next we formulated change objectives relevant to the determinants knowledge, attitude, self-efficacy and risk perception, for example *the patient knows the consequences of not setting his or her boundaries* (knowledge) and *the patient is conscious of the positive consequences of setting boundaries* (attitude).

Step 3: selecting theory-based intervention methods and practical applications

We used our matrix of change objectives to select a theory on which to base our intervention. The matrix placed most emphasis on self-efficacy, attitude and subjective norms. The Theory of Planned behavior (TPB) posits that these constructs are the most important determinants of behavior so we based our interventions on the TPB. We also emphasis on knowledge and awareness in our matrix, as these are pre-conditions for self-efficacy, attitude and subjective norms. We then made a list of techniques which could be used to improve self-efficacy, attitude, subjective norms and their pre-conditions.

For this, we derived the following methods per determinant from the coding manual for Behavioral Change Techniques [26]: *Determinant knowledge:* provide general information about health behavior, increase memory and/or understanding of transferred information. *Determinant awareness:* risk-communication, self-monitoring of behavior, self-report of behavior. *Determinant social influence:* provide information about peer behavior. *Determinant attitude:* Persuasive communications, belief selection, reinforcement on behavioral progress, provide contingent rewards. *Determinant self-efficacy:* modeling, practice, plan coping responses. *Determinant intention of behavior:* develop medication intake schedule. *Determinant action control:* use of social support, use of cues, self-persuasion. We operationalized these methods as follows: we used *texts* to increase knowledge, awareness, attitude, social influence and action control, we used *videos* and *exercises with feedback options* to increase self-efficacy, patients were encouraged to keep a *diary within the online program* to increase their awareness of their own health status and to use an *intake schedule* to increase intention of behavior. We also tailored the program to the user's self-reported level of self-efficacy, because self-efficacy has been found to predict changes in various health-related behaviors [29].

Step 4: producing program components

We used the change objectives and the practical applications as the basis for the online program 'Reuma zelf te lijf' which has 10 modules, consisting of two to five sessions each. Table 1 gives an overview of the content of the modules. The first module is the 'introduction module' and offers a short textual introduction to the other modules as well as providing information about how the program works. After this the user can respond to a series of statements; the responses are used to tailor recommendations about which module or modules the user is likely to find most helpful for improving his or her self-management. Examples of statements include: *'I want to learn to balance my daily schedule better', 'I want to learn how to ask for support and help', 'I want to learn how to say "no" to others, for example when I'm too tired to do something'.* Once the user has chosen a module he or she can work through it at his or her own pace, whenever he or she wants.

Every module starts with a text providing information about the topic of the module, what the patient can expect to learn from the module and how the module is structured. Most modules allow the user to respond to two questions to tailor the module to his or her self-efficacy. The responses to these questions are used to advise patients which session to move to next (session 2 for patients with a low level of self-efficacy; session 3 for patients with a high level of self-efficacy). Session 2 focuses on four determinants, knowledge, risk perception, awareness and attitude, and uses informative and persuasive texts, videos of peers, and exercises to improve patients' insight into their disease and behavior and change their attitudes. Session 3 focuses on self-efficacy and gives the user the opportunity to do exercises in familiar surroundings, for example doing an exercise to learn how to say "no" to others at home with a friend. Session 4 tells the user how to put the skills into practice in his or her daily life. After each exercise, the user is given the opportunity to evaluate his or her performance by responding to a set of questions. This evaluation exercise is used to help patients to identify the barriers and facilitators that are relevant to his or her behavior. In all exercises it is recommended that the user seeks support from his or her partner, family or friends. For an example of a module, see Table 2.

During the pre-test the collaborative multidisciplinary panel found that the information and the exercises provided in the modules were understandable/readable and applicable. The layout and the structure of the modules were described as attractive and clear. The three patients who tested the program using the 'think aloud' method found it difficult to navigate through the program. In response to this, we adjusted the program to make navigation easier.

Table 1 Overview of the modules in the online program

Modules	Number of sessions	Topics
1. Welcome	1	Short introduction to all modules and a questionnaire to assess the level of self-efficacy
2. Balancing activity and rest	4	Planning of activities
		Keeping a balance in daily life in the long term
3. Setting boundaries	4	Dare to set boundaries (say 'no')
		Setting boundaries (communicate saying 'no')
4. Asking for help and social support	4	Establishing and maintaining social contacts
		Asking for help or support
5. Use of medicines	4	How to collect information about medication
		Taking prescribed medication
6. Communication with health professionals	4	How to prepare for an appointment with a health professional
		Asking questions and/or expressing concerns during an appointment with a health professional
7. Use of assistive devices	4	Information on how to apply for assistive devices
		Deciding whether an assistive device can help you and if so, what assistive device
8. Performing physical exercises	4	Examples of physical exercises
		How to fit physical exercises into your daily life
9. Coping with worries	3	Insight into your worries
		Controlling your worries
10. Coping with RA	2	Information and tips on how to cope with RA

Table 2 Example module contents: setting boundaries

Change objectives	Methods	Practical applications	Session
Patient knows the consequences of not setting his/her boundaries (knowledge)	- Provide general information about health-related behavior	Texts providing information about the consequences of setting boundaries.	1
	- Increase memory and/or understanding of relevant information.		
	- Persuasive communication		
Patient knows why the consequences of not setting his/her boundaries arise (knowledge)	- Provide general information about health-related behavior.	Texts providing information about why setting boundaries is important	1
	- Increase memory and/or understanding of transferred information.		
	- Persuasive communication.		
Patient is conscious of the positive consequences of setting boundaries (attitude)	- Provide general information about health-related behavior.	Texts providing information about the positive consequences of setting boundaries which are designed to persuade the user of the benefits of setting boundaries	1
	- Increase memory and/or understanding of relevant information.		
	- Persuasive communication		
Patient says that he/she is able to set boundaries (self-efficacy)	- Provide instruction of how to perform behavior	Texts providing information on assertiveness and communicating verbal and non-verbal	2,3
	- Provide information about peer behavior	Quotes from other RA patients	2,3,4
		Videos with other RA patients.	2
	- Practice	- Exercises to identify helpful or not-helpful thoughts	2
		- Exercises focused on setting boundaries with 2 levels of difficulties	3,4
	- Use of social support	- Exercises focused on practice with partner, family or friends	3,4
	- Plan coping response	Using questions to let the patient identify barriers to set boundaries and overcome these barriers	3,4
	- Reinforcement on behavioral progress	Praise for behavioral progress	3,4

Step 5: planning for adoption, implementation and sustainability

We have planned a trial which will be conducted in two Dutch hospitals. The managers of the two Rheumatology departments met regularly with the researchers to discuss trial procedures. The multidisciplinary panel identified barriers and facilitators relevant for the implementation of the online program. This information was used to design an implementation plan for the two hospitals, which focus on dissemination of the online program and the user's experience of interacting with the online program. We asked the specialist nurses to bring the online program to the attention of their patients during appointments. For this, a researcher explained the modules and exercises in the program to specialist RA nurses to facilitate integration of the online program with nursing care. To try to ensure that users' first experiences of the program were positive we sent potential users a written instruction manual for the program. To encourage repeated use of the program, users will be sent reminders via e-mail.

Step 6: planning for evaluation

To evaluate the feasibility, we plan to do an exploratory RCT as advised by the Medical Research Council's framework for the development and evaluation of complex interventions [30]. The aims of our feasibility study will be to 1) evaluate the potential effectiveness of the online program for patients with RA and determine effect sizes for the various outcomes, 2) identify outcome measures most likely to capture potential patient benefits and 3) evaluate long-term participation and attrition rates for the online, computer-tailored self-management program [31]. Because the exploratory RCT is not expected to be powered to identify differences between groups, there is no sample size calculation. Considering the complexity of the intervention and the potentially large heterogeneity of the RA population, a total of 200 eligible RA patients, will be recruited by two hospitals in the eastern part of the Netherlands (TRIAL ID: NTR4871). Inclusion criteria will be: 1) diagnosis of RA, 2) aged 18 years or older, 3) ability to speak and read Dutch and 4) access to a computer with an internet connection. Patients receiving psychiatric or psychological treatment will be excluded. RA patients will be randomized to the intervention or control group. The control group will receive care as usual; the intervention group will additionally to the care as usual have access to the online program.

To evaluate the potential effectiveness of the online program – including effect sizes for outcome measures - and to identify outcome measures most likely to capture potential benefits, we selected the following outcome measures: the Patient Activation Measurement (PAM-13) which assesses the knowledge, skills and confidence for self-management [32], the health related quality of life survey (RAND-36) which assesses general health status in eight dimensions, namely: physical functioning, social functioning, role limitations (physical problems), role limitations (emotional problems), mental health, vitality and pain [33], the Rheumatoid Arthritis self-efficacy scale

(RASE), which measures the level of task specific self-efficacy for self-management [34], the Perceived Efficacy in Patient- Physician Interactions (PEPPI-5) [35], the short version of the self-management ability scale (SMAS-S) which measures the following dimensions: 1) taking initiatives, 2) invest in resources for long-term benefits, 3) maintain variety in resources, 4) ensure resource multifunctionality 5) self-efficacy, 6) maintain a positive frame of mind [36], the Modified Pain Coping Inventory scale (MPIC) which assesses both pro-active and passive coping of fatigue [37], and the Numeric Rating Scales (NRS), which measures pain and fatigue during the previous two weeks including at the moment of measurement. All instruments will be administered at baseline (T0) and after six (T1) and twelve months (T2). Data on the following patient characteristics will be gathered: age, gender, living situation, educational level, employment status, Disease Activity Score (DAS-28 score), physical ability using the Modified Health Assessment Questionnaire (MHAQ), time since diagnosis, current treatment, co-morbidity, usage of other support programs including online programs, date of last visit to a rheumatologist and date of last visit to a specialist nurse.

In the process evaluation we will use the framework of Saunders et al. 2005 [38] to evaluate feasibility of the online program. The key components of the process evaluation are: fidelity, dose received, dose delivered, reach, recruitment and context. Data for the process evaluation will be collected from multiple sources, namely: 1) data on log-ins to the online program, 2) a user questionnaire and 3) qualitative user interviews. The process analysis will make use of log-in data (exposure and continued use of the program), data on use of modules and data on performance of the exercises. The user questionnaire will ask about the 1) comprehensibility, 2) usefulness and length of the texts and exercises and 3) the layout and the login procedure. During the qualitative interviews the frequent users and those who have stopped using the program will be asked about their reasons for using or not using the online program, which will give us insight in potential limitations and yield ideas to improve the program. We will also interview nurses to elicit their views about how introduction of the online program might affect their professional role.

Finally, to get insight into whether the online program changes the roles of patients and nurses in management of RA we have made a checklist to be completed after nursing appointments with patients in both the control group and the intervention group, this covers 1) what topics were discussed during the nursing consultation and 2) whether it was the nurse or the patient who raised a particular topic.

Discussion

This article describes the systematically developed generic online, computer-tailored self-management supportive program for adult RA patients.

The process used to develop this program has several strengths, firstly, use of IM to structure the development process. In the needs assessment we successfully defined health problems, problems affecting health-related behaviors and determinants of problems with health-related behavior which were relevant to RA patients. Extending the needs assessment to encompass determinants of behavior gave us a good understanding of the causes of problems with health-related behaviors. The online program uses tailored behavioral change strategies to, which should improve the likelihood of RA patients' ability to manage their disease. Another strength of IM is the use which is made of input from patients and health professionals. Integrating the experiences, knowledge and visions of these diverse groups with scientific insights enabled us to develop a well-grounded intervention, tailored to the preferences and support needs of RA patients.

A second expected strength of the program is that the program is computer-tailored to the user's level of self-efficacy. This ensures that the RA patient receives material which is suited to his or her personal needs and this may increase motivation to persist with exercises and strategies recommended therein. The online format has the further advantage that patients can use the program as often as they want or need. They can choose which module(s) to work through and can do so at their own speed, whenever they want.

A third expected strength of the program is the extent to which the online program can be integrated with regular nursing care. All the topics covered in the program fall within the scope of a specialist RA nurse's expertise and can be discussed during appointments with a nurse. Specialist RA nurses can support RA patients to use the program and hopefully can benefit to continue to practice self-management.

The composition of the multidisciplinary panel might be considered a limitation of the study. All five RA patients had long disease duration and had found a way to cope with their illness and may not have been able to recall the problems they had in the early phase of the disease. However, in each meeting we asked the patients to try to remember how things had been when they were first diagnosed.

Another limitation might be the choice of the channel for communication relatively early in the development process. In the first IM step we decided to use an online program as the communication channel and this restricted our options at certain points in the development process which conflicted with the concept of IM as an iterative process. However, choosing to use e-health early on gave us the opportunity to learn about the pros and cons of e-health and how to deal with it during implementation.

Conclusions

This article describes how to develop an online tailored self-management program in a structured way and could serve as a guide for the development of similar interventions. The study yielded an online, computer-tailored self-management program suitable for all RA patients. In the planned exploratory RCT we will assess important outcomes and estimate the relevant effect sizes; this should be useful preparation for a larger RCT. The process evaluation will give us more insight into how RA patients use the program, which can be used to inform future development of the program. We hope that this online self-management program will become one of the treatment options available to RA patients as part of an integrated disease management plan.

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4

Efficacy of an online self-management enhancing program for patients with rheumatoid arthritis: explorative randomized controlled trial

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Abstract

Background: Online self-management enhancing programs have the potential to support patients with rheumatoid arthritis (RA) in their self-management; for example, improve their health status by increasing their self-efficacy or taking their prescribed medication. We developed an online self-management enhancing program in collaboration with RA patients and professionals as codesigners on the basis of the intervention mapping framework. Although self-management programs are complex interventions, it is informative to perform an explorative randomized controlled trial (RCT) before embarking on a larger trial.

Objective: This study aimed to evaluate the efficacy of an online self-management enhancing program for patients with RA and identify outcome measures most likely to capture potential benefits.

Methods: A multicenter exploratory RCT was performed with an intervention group and a control group. Both groups received care as usual. In addition, the intervention group received 12 months of access to an online self-management program. Assessment occurred at baseline, 6 months, and 12 months. Outcome measures included self-management behavior (Patient Activation Measurement, Self-Management Ability Scale), self-efficacy (Rheumatoid Arthritis task-specific Self-Efficacy, Perceived Efficacy in Patient-Physician Interaction), general health status (RAND-36), focus on fatigue (Modified Pain Coping Inventory for Fatigue), and perceived pain and fatigue (Numeric Rating Scales). A linear mixed model for repeated measures, using the intention-to-treat principle, was applied to study differences between the patients in the intervention (n=78) and control (n=79) groups. A sensitivity analysis was performed in the intervention group to study the influence of patients with high (N=30) and low (N=40) use of the intervention.

Results: No positive effects were found regarding the outcome measurements. Effect sizes were low.

Conclusions: Based on these results, it is not possible to conclude on the positive effects of the intervention or to select outcome measures to be regarded as the primary/main or secondary outcomes for a future trial. A process evaluation should be performed to provide more insight into the low compliance with and effectiveness of the intervention. This can determine for whom this sort of program will work and to fine-tune the inclusion criteria.

Introduction

Rheumatoid arthritis (RA) is one of the most prevalent chronic conditions, with a pervasive impact on daily life [1]. Despite the introduction of biological therapies and conventional disease-modifying antirheumatic drugs, RA patients experience a high level of pain [2] and fatigue [3,4], which leads to disabilities like restrictions in work participation [5,6] and leisure activities [7,9]. Moreover, many RA patients experience disease-related psychological problems, like depressive mood and helplessness [10,11].

To optimally manage the consequences of RA and reduce the impact of the disease on patients in daily life, effective self-management programs are needed. Online self-management programs can easily reach a large group of RA patients in their own place and time and provide more anonymity than face-to-face programs. Studies have shown that patients feel more comfortable sharing sensitive information like reports on daily activity or feelings online [12]. Other advantages are the possibility of tailoring information, avoiding waiting lists and 24-hour availability [13].

Studies about online self-management programs have shown to be effective in RA patients on several health outcomes, including increased self-efficacy, knowledge and physical activity [14], less pain, disability and depression, and a reduction in the overuse of medication and the number of visits to physicians [15-17]. However, many of the programs are developed without end-user involvement. Consequently, these programs may not suit patient support needs for self-management as patient preferences for program use are not well known [18,19].

To guarantee optimal patient involvement, we developed an online self-management programme based on intervention mapping (IM), called “Reuma zelf te lijf” [“Coping with RA”] [20-22]. According to the Medical Research Council (MRC), complex interventions such as this programme can be evaluated in a randomised controlled trial (RCT); however, it is advised to first perform an explorative study investigating potential outcome measurements to be used in a larger trial [23].

Therefore, the present explorative RCT study in patients with RA was aimed as follows: (1) to explore the potential efficacy of an online self-management enhancing program versus “usual care” on self-management behavior, self-efficacy, general health status, coping with fatigue and the level of pain and fatigue and to determine the effect sizes at 6 and 12 months after baseline, and (2) to identify outcome measures most likely to capture the potential benefits covered by the performance objectives, by exploring their floor and ceiling effects at baseline.

Methods

Design

A multicenter exploratory RCT was conducted in 2 Dutch hospitals, The Radboudumc (a University hospital) and the Sint Maartenskliniek (a specialized hospital in rheumatology, rehabilitation, and orthopedic surgery), both located in Nijmegen, the Netherlands. An intervention and a control group were compared at 6 and 12 months after baseline on 6 outcome measurements to explore the efficacy of the online program and to identify outcome measures [20]. The trial is registered at the Dutch Trial Register (ID: NTR4871).

Participants

Between December 2014 and June 2015, patients with a diagnosis of RA aged 18 years or older were invited by a letter to participate in this study, in collaboration with rheumatologists, until the required number of 190 patients was reached. Patients received the following: (1) information about the study, (2) a questionnaire for screening eligibility, and (3) an informed consent form. Eligibility criteria were the ability to speak and read Dutch and having access to a computer with an internet connection. Patients receiving psychiatric or psychological treatment were excluded. Patients willing to participate were asked to return the informed consent with the completed questionnaire. When patients agreed to participate and were eligible, the researcher sent the patient an email with the baseline questionnaire.

Randomisation

Eligible patients were stratified by the hospital and randomly assigned to the intervention or control group by an independent statistician using an automated randomization program. The researcher informed the patients by post if they were allocated to the control or intervention group. Patients in the control group continued with their care as usual, which comprised medical treatment at the outpatient clinic. The patients in the intervention group received, in additional to their care as usual, 12 months of access to the intervention directly after randomization.

Intervention

Online self-management enhancing programme

The intervention was developed between January 2013 and July 2014 in collaboration with RA patients and professionals as codesigners [20,24]. The theory of planned behavior was used as the underlying theory and essential behavioral change techniques were applied to induce behavioral change formulated as performance objectives, selected according to the IM steps [21,25,26]. The online self-management enhancing program comprises 9 modules with 13 performance objectives (Table 1) and a diary to track patients' fatigue and pain over time [20]. Each module comprises 2-5 sessions, with informational and persuasive texts, videos with instructions and role models, exercises, and assignments. The program is unguided, and patients need to choose a module by their own and can work through it at their own pace whenever they want.

Implementation of the online self-management enhancing programme

To implement the online programme and to increase use of the programme by patients, three implementation strategies were deployed during the study: 1) patients received a written instruction manual for the programme, 2) reminders to (re)-visit the programme were sent via e-mail two weekly, 3) nurses brought the programme to the attention of the intervention group participants during their consultation.

Table 1 Overview of the nine modules and their performance objectives

Module name	Performance objective: Patients need to…
1. Balancing activity and rest	- find balance between rest and activity - make choices when participating in daily life activities to keep balance
2. Setting boundaries	- set boundaries for their partner, relatives, colleagues and social environment
3. Asking for help and social support	- ask for social support or practical help from their partner, relatives, colleagues and social environment in daily life - ask for social support and practical help from colleagues - accept receiving social support or practical help from their partner, relatives, colleagues and social environment in daily life
4. Use of medicines	- take prescribed medication
5. Communication with health professionals	- prepare for a visit to a health professional - ask questions and/or express concerns during an appointment with a health professional
6. Use of assistive devices	- use, if necessary, assistive devices
7. Performing physical exercises	- perform daily physical exercises
8. Coping with worries	- cope with worries about RA
9. Coping with RA	- cope with RA

Measurements and outcomes

All included patients who filled in the baseline questionnaire between January 2015 and June 2015, received a questionnaire after six months (T1) and 12 months (T2). At baseline, demographic and disease characteristics were assessed. Patient-reported outcome measurements were assessed at baseline and during follow-up (T1 and T2). When patients preferred a paper questionnaire, a version was sent by post. When patients did not return the questionnaire at T1, but filled in the questionnaire at T2, this was indicated as a missing value at T1. Patients who did not return the T2 questionnaire are indicated as drop-outs.

Baseline characteristics

The following demographic and disease characteristics were assessed: age, gender, education level, employment status, disease duration, NRS pain/fatigue, physical disability and satisfaction with health status (M-HAQ-questionnaire). The M-HAQ consists of eight questions on difficulties in daily activities in the following domains: dressing, rising, eating, walking, hygiene, reach, grip and usual activities. Patients responded on a four-point scale, with a higher score indicating more difficulty in performing daily activities. Health satisfaction was assessed using one question about patient (dis) satisfaction about the course of their disease last week, with four response options, with a higher score meaning less satisfied than before and an *"I don't know"* option [27].

Outcome measurements

Based on the theory of planned behaviour, six outcome measures were relevant: self-management behaviour, self-efficacy, general health status, coping with fatigue and the level of pain and fatigue.

Self-management behaviour

The Patient Activation Measurement (PAM-13) includes statements about an individual's knowledge, confidence and skills for self-management of their chronic illness behaviour, and the level of activation. It includes 13 items on a five-point scale with a higher score indicating a higher level of patient activation. The scores of the 13 items are summarised as a total score. Total PAM scores were computed if at least 10 items were completed [28]. The short Self-Management Ability Scale (SMAS-S) consists of 18 items scored on a six-point scale with a higher score indicating better self-management behaviour [29].

Self-Efficacy

The Rheumatoid Arthritis task specific Self-Efficacy (RASE) questionnaire consists of 28 items scored on a five-point Likert scale. Higher scores reflect higher self-efficacy [30]. This questionnaire was translated into Dutch via forward-backward translation and decisions were based on consensus with a group of five researchers, four RA patients and one RA patient who was a native English speaker. The Perceived Efficacy in Patient-Physician Interaction (PEPPI-5) consists of a five-point Likert scale. A higher score reflects more confidence in patient interactions with their physician [31].

General health status

The RAND-36 consists of 36 questions measuring eight dimensions: physical functioning, social functioning, physical role limitations, emotional role limitations, mental health, vitality and pain, with various response options based on three- to six-point Likert scales, with a higher score indicating better perceived health related quality of life. Scores were transformed to a 0-100 point scale for each subscale[32].

Level of pain and fatigue

Pain and fatigue were measured with Numeric Rating Scales (NRS), ranging from 0-10 with 0 meaning no pain/fatigue and 10 meaning severe pain/very tired. For both outcomes, two questions were asked: the level of pain/fatigue today and the mean level of pain/fatigue during the last two weeks.

Coping with fatigue

The Modified Pain Coping Inventory for Fatigue (MPCI-F) was used. This questionnaire is based on a subscale of the Pain Coping Inventory (PCI) questionnaire, and modified to assess coping with fatigue instead of coping with pain [33]. The questionnaire consists of eight items to assess the focus on fatigue. A higher score reflects more focus on fatigue.

Statistical analysis

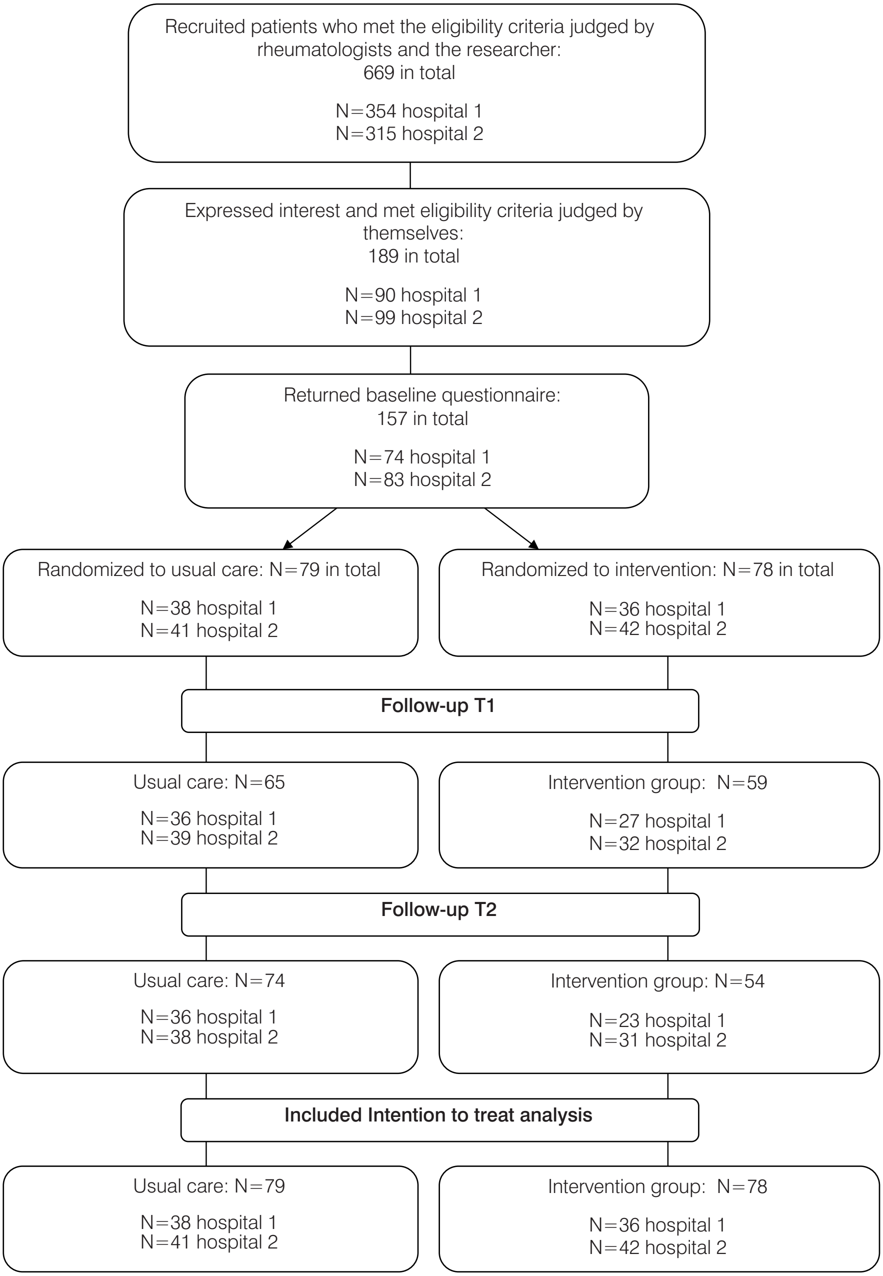
Descriptive statistics were used to describe the control and intervention groups at baseline. T-tests and chi-square tests were used to analyse baseline differences. It was analysed whether the patients who dropped out differed from the group that returned the questionnaire at T2 [34]. Between-group differences in outcomes were analysed using a linear mixed model to account for repeated measurements and to handle missing data under the missing-at-random assumption. Differences between the intervention and control group were analysed at baseline, after six months (T1) and twelve months (T2). The fixed variables in the model were: group (intervention/control), hospital (hospital 1 or hospital 2), age, gender, disease duration, education level, employment status, physical functioning (M-HAQ) and the interaction terms between measurement time points and groups. The first analysis was done using the intention-to-treat principle. Subsequently, a sensitivity analysis was performed to explore the influence of programme use within the intervention group. The intervention group was divided into three groups: 1) a group with low usage (0-1 visits), 2) a group with moderate usage (2-5 visits) and 3) a group with high usage (6 or more visits). In the analysis, the group with a moderate usage was left out to increase the contrast between the groups with low and high usage. T-tests and chi-square tests were performed to analyse between-group differences in demographics, disease-related characteristics and outcomes at baseline, T1 and T2. Statistical significance was defined as $p<0.05$.

For all outcome measurements, Cohen's D was used to quantify effect sizes by calculating the difference in means, divided by the pooled within-group standard deviation [38]. Following Cohen's definition of effect sizes, less than 0.4 was defined as a small effect, between 0.5 to 0.7 as moderate and ≥ 0.8 was considered as a large effect[35]. Floor and ceiling effects were explored for all outcome measures by examining the percentage of minimum and maximum scores, which reflects the extent that patients scored the lowest or the highest score. For a three- or five-point Likert scale, floor and ceiling effects were defined as more than 80% of the patients scoring lowest/highest. Statistical analyses were performed using SPSS V22 for Windows. For exploratory RCT such as these, sample sizes are not calculated based on formal power analyses. For this trial, a sample size of 200 patients was chosen, which was considered a sufficient size for a representation of the relevant variation in the target group.

Results

In total, 669 patients were eligible and invited. Of these, 191 patients expressed interest and 189 met the inclusion criteria (see Figure 1). In total, 157 patients completed the baseline questionnaire between January 2015 and June 2015. These patients were randomly assigned to the intervention group (n=78) and control group (n=79), stratified by hospital. At T1, 59 in the intervention group and 65 in the control group filled in the questionnaire. At T2, 54 patients in the intervention group and 74 patients in the control group completed the questionnaire. Overall, in the intervention group less patients (69% (54 of 78)) participated at T2 than in the control group (94% (74 of 79)). Most of these patients gave the burden of their illness as the reason for drop-out. Some patients refused to fill in the questionnaire at T1, but completed the questionnaire at T2, which explains the higher number of patients who filled in the questionnaire at T2 compared to T1. Differences in demographics and disease-related characteristics between the group of patients who refused to fill in the questionnaire at T2 and the group who returned the questionnaire at T2 were small (<10%), which indicated that drop-out did not influence the outcomes.

Figure 1 Patient flowchart



Baseline characteristics of patients

Demographics and disease-related characteristics at baseline were compared for the control group and intervention group, shown in Table 2. The only significant between-group difference in the patient characteristics was education level (p=0.003). Fewer patients in the intervention group had a lower education level (12.8% versus 35.4%) and more patients had a moderate (55.1% versus 35.4%) or higher education level (32.1% versus 29.1%). Some patients who filled in a paper questionnaire did not complete all items, which explains the missing data in Tables 3 and 4.

The outcome measurements at baseline and follow-up

Table 3 gives an overview of the mean scores of outcome measurements of the patients in the intervention and control group at baseline and after 6 and 12 months. The baseline scores of the two groups did not differ significantly.

Table 2 Demographics and disease-related characteristics at baseline

Demographics and disease-related characteristics at baseline	N	Control group	N	Intervention group
Age in years *(mean (SD))*		62.9 (10.2)		61.0 (11.3)
Gender				
Men	27	34.2 %	27	34.6 %
Women	52	65.8 %	51	65.4 %
Disease duration *(median (25th,75th percentiles))*	79	17 (6.0, 26)	77	9 (5.0, 19.5)
Education level				
Low	28	35.4 %	10	12.8 %
Medium	28	35.4 %	43	55.1 %
High	23	29.1 %	25	32.1 %
Employment status				
Not working	50	63.3 %	41	52.6 %
Part-time working	7	8.90 %	7	9.0 %
Working	22	27.80 %	30	38.5 %
Physical disability (M-HAQ) *(median (25th,75th percentiles))*	79	0.5 (0.1, 1.4)	78	0.6 (0.1, 1.1)
NRS pain today *(mean (SD))*	79	3.3 (2.3)	77	3.2 (2.2)
NRS mean pain last two weeks *(mean (SD))*	79	3.9 (2.3)	78	3.6 (2.3)
NRS fatigue today (NRS) *(mean (SD))*	79	4.1 (2.5)	78	3.8 (2.4)
NRS mean fatigue last two weeks *(mean (SD))*	79	4.3 (2.4)	78	4.3 (2.3)

* Values are %, unless otherwise indicated;
NRS= numerical rating scale (*higher score means more pain and fatigue*);
HAQ: Health Assessment Questionnaire (0-3 = *best possible functioning-worst functioning*)

Table 3 Mean scores of outcome measurements on baseline, T1 and T2 of Control (C) and Intervention (I) groups

Scales	Group	N	T0 mean (SD)	N	T1 mean (SD)	N	T2 mean (SD)
PAM (10-65)	C	57	46.9 (4.9)	49	47.7 (4.8)	45	47.8 (3.8)
	I	47	47.2 (3.7)	35	46.7 (6.9)	31	47.8 (2.9)
SMAS-S (0-60)	C	79	36.0 (6.3)	75	37.9 (6.8)	74	37.6 (6.8)
	I	78	36.7 (7.1)	57	39.4 (6.4)	54	38.8 (7.0)
RASE (28-140)	C	79	99.4 (12.7)	75	101.5 (10.6)	74	99.9 (11.6)
	I	78	102.9 (10.2)	57	101.9 (10.3)	54	102.0 (7.4)
PEPPI-5 (5-25)	C	79	21.6 (3.0)	75	21.0 (3.2)	73	20.6 (3.4)
	I	78	21.2 (3.3)	57	21.3 (3.1)	54	20.8 (3.1)
RAND physical functioning (0-100)	C	78	58.1 (27.0)	75	59.4 (26.5)	74	61.8 (25.9)
	I	77	61.7 (26.1)	57	65.9 (27.3)	54	65.9 (26.7)
RAND social functioning (0-100)	C	79	73.3 (2476)	75	72.7 (22.3)	74	73.1 (22.4)
	I	78	71.3 (20.8)	57	77.0 (19.6)	54	70.8 (24.3)
RAND physical role limitations (0-100)	C	79	49.1 (43.6)	75	51.11 (45.3)	74	49.0 (43.1)
	I	78	49.0 (43.3)	56	57.9 (42.0)	54	49.1 (44.2)
RAND emotional role limitations (0-100)	C	79	75.1 (40.5)	73	84.9 (35.2)	74	78.8 (39.2)
	I	77	80.1 (36.4)	54	85.2 (31.5)	54	78.4 (37.3)
RAND mental health (0-100)	C	78	54.7 (14.3)	75	72.6 (16.7)	74	76.1 (14.6)
	I	78	52.6 (13.4)	56	76.5 (12.0)	54	75.9 (13.8)
RAND vitality (0-100)	C	78	51.2 (22.7)	75	53.9 (21.6)	74	56.3 (21.2)
	I	78	53.1 (19.4)	56	61.2 (15.1)	54	62.5 (14.5)

Table 3 Continued

Scales	Group	N	T0 mean (SD)	N	T1 mean (SD)	N	T2 mean (SD)
RAND pain (0-100)	C	79	59.9 (21.3)	75	60.8 (22.2)	74	66.1 (21.8)
	I	78	64.3 (22.3)	57	67.1 (21.0)	54	63.9 (22.1)
RAND general health perception (0-100)	C	79	52.5 (18.7)	75	47.8 (18.3)	72	48.1 (17.5)
	I	77	52.7 (20.8)	57	52.3 (19.5)	48	50.4 (19.1)
RAND health change (0-100)	C	79	44.9 (21.2)	75	50.3 (19.9)	74	44.3 (19.7)
	I	78	47.8 (23.2)	57	51.3 (20.8)	54	43.5 (23.9)
NRS pain today (0-10)	C	79	3.3 (2.3)	75	3.2 (2.2)	72	3.0 (2.2)
	I	77	3.2 (2.2)	57	3.0 (2.3)	48	3.3 (2.3)
NRS mean pain last two weeks (0-10)	C	79	3.9 (2.3)	75	3.8 (2.1)	72	3.6 (2.2)
	I	78	3.6 (2.3)	57	3.4 (2.3)	48	3.9 (2.4)
NRS fatigue today (0-10)	C	79	4.1 (2.5)	75	3.8 (2.6)	72	3.7 (2.3)
	I	78	3.8 (2.4)	57	3.4 (2.4)	48	3.6 (2.4)
NRS mean fatigue last two weeks (0-10)	C	79	4.3 (2.4)	75	4.2 (2.6)	72	4.2 (2.4)
	I	78	4.3 (2.3)	57	3.7 (2.1)	48	4.0 (2.2)
MPCI-F (4-32)	C	79	14.1 (4.8)	75	14.1 (4.7)	74	13.6 (4.3)
	I	78	14.1 (3.9)	57	13.3 (3.3)	54	13.6 (3.2)

T1= six months after baseline, T2= twelve months after baseline.

PAM= Patient Activation Measurement; SMAS-S= short Self-Management Ability Scale; RASE= Rheumatoid Arthritis Self-Efficacy; PEPPI-5= Perceived Efficacy in Patient-Physician Interaction; RAND-36= General Health Status, NRS pain/fatigue= Numeric Rating scales pain/fatigue; Coping with fatigue= Modified Pain Coping Inventory for fatigue.

In Table 4, the estimated differences between the intervention and control groups of the intention-to-treat analysis at 6 and 12 months are presented. Overall, the scores show no significant differences and small effect sizes. Only the outcome measurement of the subscale RAND-36 vitality at T2 (5.41 95% CI: 0.16-10.65, p=0.04) showed a significant difference, with a small effect size (Cohen's D) of 0.01 in favour of the intervention group. Floor and ceiling effects were explored for all specified outcomes at baseline, but were not found.

Sensitivity analysis

Baseline characteristics of patients

High users of the intervention scored statistically significantly better than low users of the intervention on the following baseline characteristics: physical disability (M-HAQ) (p=0.031), RAND-36 subscale social functioning (p=0.016), RAND-36 subscale physical role limitations (p=0.029), RAND-36 pain (p=0.025), and all the NRS scales, i.e. pain today (p=0.002), mean pain last two weeks (p=0.020), fatigue today (p=0.001) and mean fatigue last two weeks (p=0.001) (Table 5).

After performing the sensitivity analysis, a statistically significant effect was found for the group with high usage on the subscale RAND-36 general health perception after 12 months (9.65, 95% CI: 0.83 -18.48, p=0.03), with a small effect size of 0.02 (Table 6). No floor and ceiling effects were found for any of the specified outcomes at baseline in the groups with low or high usage.

Table 4 The estimated group differences between intervention and control groups after intention-to-treat analysis at 6 months and 12 months after baseline

Scales	T0-T1 Δ	95% CI	P value	Cohens d	T0-T2 Δ	95% CI	P value	Cohens d
PAM (10-65)	-0.7	-3.4 to 1.5	0.44	0.0	-0.1	-1.6 to 1.5	0.93	0.00
SMAS-S (0-60)	0.3	-1.4 to 2.0	0.72	0.0	0.7	-1.1 to 2.5	0.43	0.03
RASE (28-140)	-2.1	-4.9 to 0.8	0.16	0.0	0.3	-2.2 to 2.9	0.81	0.00
PEPPI-5 (5-25)	0.4	-0.5 to 1.2	0.40	0.0	0.3	-0.7 to 1.3	0.51	0.03
RAND physical functioning (0-100)	2.5	-3.3 to 8.1	0.40	0.00	-0.2	-5.4 to 5.1	0.96	0.00
RAND social functioning (0-100)	4.1	-1.5 to 9.6	0.15	0.0	-2.7	-9.2 to 3.8	0.42	-0.01
RAND physical role limitations (0-100)	5.6	-7.0 to 18.2	0.38	0.00	-2.8	-14.9 to 9.3	0.65	0.00
RAND emotional role limitations (0-100)	-3.2	-14.1 to 7.6	0.56	0.00	-3.9	-16.0 to 8.3	0.53	0.00
RAND mental health (0-100)	2.8	-1.1 to 6.8	0.16	0.0	0.9	-3.0 to 4.7	0.66	0.00
RAND vitality (0-100)	3.4	-1.5 to 8.3	0.17	0.0	5.4	0.2 to 10.7	0.04*	0.01
RAND pain (0-100)	2.6	-3.7 to 8.9	0.42	0.0	-6.1	-12.5 to 0.4	0.06	-0.01
RAND general health perception (0-100)	2.2	-2.2 to 6.7	0.33	0.0	-0.1	-4.5 to 4.4	0.98	0.00
RAND health change (0-100)	0.1	-6.8 to 7.1	0.97	0.00	-1.4	-9.0 to 6.2	0.72	0.00
NRS pain today (0-10)	0.0	-0.6 to 0.7	0.97	0.00	0.5	-0.1 to 1.2	0.13	0.10
NRS mean pain last two weeks (0-10)	0.0	-0.7 to 0.6	0.97	0.00	0.7	0.0 to 1.4	0.60	1.13
NRS fatigue today (0-10)	0.2	-0.5 to 0.8	0.66	0.0	0.3	-0.4 to 0.9	0.46	0.01
NRS mean fatigue last two weeks (0-10)	-0.23	-0.9 to 0.4	0.45	-0.1	0.1	-0.6 to 0.7	0.81	0.00
MPCI-F (4-32)	0.1	-0.8 to 0.9	0.90	0.00	0.3	-0.7 to 1.2	0.58	0.01

*Significant differences ($P<0.05$) between control and intervention group

Values represent outcomes of the ITT analysis without confounders. After adding confounders, no changes in values appear.

PAM= Patient Activation Measurement; SMAS-S= short Self-Management Ability Scale; RASE= Rheumatoid Arthritis Self-Efficacy; PEPPI-5= Perceived Efficacy in Patient-Physician Interaction; RAND-36= General Health Status, NRS pain/fatigue= Numeric Rating scales pain/fatigue; Coping with fatigue= Modified Pain Coping Inventory for fatigue.

Table 5 Scores at baseline for the groups with a low and high usage of the intervention

Demographic characteristics, disease related characteristics and outcome measures at baseline	**N**	**Low usage**	**N**	**High usage**
Age in years	29	63.8 (10.5)	40	58.9 (10.8)
Gender men/women *(%)*				
Men	10	33.3%	14	35.0%
Women	20	66.7%	26	65.0%
Disease duration *(median (25th,75th percentiles))*	29	8,0 (4,5, 22,5)	40	8,5 (5,0, 18,7)
Education level (%)				
Low	3	10.0%	5	12.5%
Middle	19	63.3%	22	55.0%
High	8	26.7%	13	32.5%
Employment status (%)				
Not working	22	73.3%	23	57.5%
Working	8	26.7%	17	42.5%
Physical disability (M-HAQ) *(median (25th.75th percentiles))*	30	1.1 (0.2, 1.6)*	40	0.5 (0.1, 1,0)
PAM (10-65)	20	48.0 (3.3)	20	46.2 (3.8)
SMAS-S (0-60)	30	36.5 (7.3)	40	37.7 (7.0)
RASE (28-140)	30	102.1 (10.9)	40	103.4 (9.1)
PEPPI-5 (5-25)	30	21.5 (3.9)	40	21.2 (2.8)
RAND physical functioning (0-100)	29	54.3 (28.3)	40	66.3 (24.6)
RAND social functioning (0-100)	30	64.6 (24.8)	40	77.8 (17.1)*
RAND physical role limitations (0-100)	30	36.7 (43.9)	40	60.0 (42.7)
RAND emotional role limitations (0-100)	29	74.7 (41.5)	40	85.8 (33.7)*
RAND mental health (0-100)	30	72.1 (16.1)	40	78.7 (11.6)
RAND vitality (0-100)	30	53.1 (22.9)	40	61.7 (15.4)
RAND pain (0-100)	30	56.9 (25.5)	40	69.8 (19.2)*
RAND general health perception (0-100)	29	46.0 (19.4)	40	54.0 (17.6)
RAND health change (0-100)	30	43.3 (20.7)	40	52.5 (24.6)
NRS pain today (0-10)	29	4.3 (2.5)	40	2.5 (1.8)*
NRS mean pain last two weeks (0-10)	30	4.4 (2.5)	40	3.1 (2.1)*
NRS fatigue today (0-10)	30	4.8 (2.4)	40	3.0 (2.2)*
NRS mean fatigue last two weeks (0-10)	30	4.8 (2.4)	40	3.0 (2.2)*
MPCI-F (4-32)	30	15.0 (4.8)	40	13.2 (3.0)

*Significant differences (P<0.05) between the group low and high users
Values are means and SD, unless otherwise indicated; NRS= numerical rating scale (*higher score means more pain/fatigue*); HAQ= Health Assessment Questionnaire (0-3 = *best possible functioning- worst functioning*).
PAM= Patient Activation Measurement; SMAS-S= short Self-Management Ability Scale; RASE= Rheumatoid Arthritis Self-Efficacy; PEPPI-5= Perceived Efficacy in Patient-Physician Interaction; RAND-36= General Health Status, NRS pain/fatigue= Numeric Rating scales pain/fatigue; Coping with fatigue= Modified Pain Coping Inventory for fatigue.

Table 6 The estimated difference between the group with low and high usage of the intervention after sensitivity analysis at 6 months and 12 months after baseline

Scales	T0-T1 Δ	95% CI	*P*	Cohen's d	T0-T2 Δ	95% CI	*P*	Cohen's d
PAM (10-65)	2.4	-1.7 to 6.4	0.24	0.12	0.0	-2.9 to 2.9	0.99	0.00
SMAS-S (0-60)	-0.4	-3.4 to 2.7	0.82	0.00	1.3	-2.0 to 4.5	0.44	0.02
RASE (28-140)	-1.7	-6.8 to 3.4	0.52	-0.00	-0.6	-5.3 to 4.1	0.81	0.00
PEPPI-5 (5-25)	-1.0	-2.5 to 0.5	0.20	-0.11	-0.1	-1.9 to 1.7	0.93	0.00
RAND physical functioning (0-100)	9.2	-0.7 to 19.2	0.07	0.01	2.2	-7.4 to 11.8	0.65	0.00
RAND social functioning (0-100)	1.5	-8.4 to 11.4	0.76	0.00	5.3	-6.7 to 17.4	0.38	0.01
RAND physical role limitations (0-100)	7.4	-14.7to 29.5	0.51	0.00	3.7	-18.6 to 25.9	0.74	0.00
RAND emotional role limitations (0-100)	16.1	-3.6 to 35.7	0.11	0.01	-1.7	-24.5 to 21.0	0.88	0.00
RAND mental health (0-100)	0.8	-6.3 to 7.9	0.83	0.00	-4.2	-11.2 to 2.8	0.24	-0.02
RAND vitality (0-100)	2.9	-5.6 to 11.5	0.50	0.01	-1.2	-10.8 to 8.4	0.81	0.00
RAND pain (0-100)	1.7	-4.5 to 12.9	0.77	0.00	8.8	-3.0 to 20.6	0.14	0.02
RAND general health perception (0-100)	2.9	-5.1 to 10.8	0.48	0.01	9.7	0.8 to 18.5	0.03*	0.02
RAND health change (0-100)	8.3	-4.0 to 20.5	0.19	0.02	6.4	-7.9 to 20.6	0.38	0.01
NRS pain today (0-10)	0.0	-1.2 to 1.2	0.99	0.00	-0.6	-1.9 to 0.8	0.41	-0.11
NRS mean pain last two weeks (0-10)	-0.6	-1.8 to 0.5	0.29	-0.12	0.9	-2.3 to 0.6	0.24	-0.16
NRS fatigue today (0-10)	0.2	-1.0 to 1.3	0.73	0.03	-0.9	-2.2 to 0.5	0.22	-0.14
NRS mean fatigue last two weeks (0-10)	0.2	-1.0 to 1.3	0.78	0.03	-0.5	-1.7 to 0.8	0.51	-0.08
MPCI-F (4-32)	-0.2	-1.7 to 1.3	0.76	-0.01	-0.4	-2.1 to 1.3	0.67	-0.01

*Significant differences ($P<0.05$) between control and intervention group

Values represent outcomes of the ITT analysis without confounders. After adding confounders, no changes in values appear.

PAM= Patient Activation Measurement; SMAS-S= short Self-Management Ability Scale; RASE= Rheumatoid Arthritis Self-Efficacy; PEPPI-5= Perceived Efficacy in Patient-Physician Interaction; RAND-36= General Health Status, NRS pain/fatigue= Numeric Rating scales pain/fatigue; Coping with fatigue= Modified Pain Coping Inventory for fatigue.

Discussion

This study aimed to evaluate the efficacy of an online self-management enhancing program in patients with RA in an explorative trial on 6 outcomes: self-management behavior, self-efficacy, general health status, coping with fatigue, and the level of pain and fatigue. Results show no remarkable statistically significant difference between the intervention and control group. Moreover, effect sizes were low. Consequently, the results of this exploratory show no convincing trend regarding the efficacy of the program. This was unexpected as the theory-based intervention was carefully designed, according the IM steps, on the basis of patients support needs [36,37]. Also, the range of outcome measures were selected carefully and the study was well-performed. Randomisation was successful and the number of missing was limited. It is thought that the size was adequate for a pilot study (N=157).

Notably, the lack of a trend for a positive result is not in line with other studies, showing that self-management programs seem to be promising for patients with a chronic illness, including arthritis [15,38]. However, these studies cannot be compared with each other in a straightforward manner because of the various self-management approaches (eg, offering weekly vs nonweekly online courses, with face-to-face help or without), various contents of the self-management programs, and the different outcome measures used in these studies [15,39]. For example, it is unexpected that our online program yielded no results for RA patients, whereas the online program evaluated by Lorig and colleagues (2008) concluded that RA patients showed increased self-efficacy and improved health status for 4 of the 6 health status measures that were included[14]. These different results may be explained by the different questionnaires used for the same outcomes, that is, self-efficacy and health status. Moreover, differences in the content and delivery of the programs could be a reason for the different results. Other programs focused on different topics (eg, pain/stress management, problem solving and nutrition, which were not covered by our program). In our program, patients received no help with logging into the program or using the program in contrast to the program described by Lorig et al (2008), where patients received help and were encouraged to use the program. Patients could choose which modules to work through and follow it at their own speed. In the program described by Lorig et al (2008), peer moderators helped patients log in and encouraged them to use the weekly program and moderate posts that patients could leave on the program website [14].

There are potentially 5 reasons for the lack of efficacy of our online program: (1) the use of inappropriate outcome measures, (2) individual patients had no need for self-management support, (3) low usage of the program/high dropout of the intervention group, (4) inadequate embedding of the program in health care, and (5) not selecting the appropriate patients.

First, in the case of inappropriate outcome measures, it could be that the carefully selected validated questionnaires still did not exactly measure the pursued behavior changes formulated in the performance objectives. That is, the intervention aimed to result in specific self-management behaviors. The validated questionnaires comprised more generic questions and therefore did not exactly measure these specifically formulated behavioral changes in performance objectives (Table 1). However, it was expected that a positive significant result would be found on the RASE questionnaire, as this measures task-specific self-efficacy for patients with RA with items closely related to the specific formulated performance objectives. Finding no positive results suggests that it is possible that our intervention did not support patients in increasing their level of self-efficacy. This could mean that the absence of positive results is less driven by the choice of outcomes than by the other points discussed below.

Second, it could be that recruited patients did not have a perceived need for enhancing self-efficacy when they agreed to participate in the program. Although the program was developed on the basis of the support needs for self-management of RA patients, individual participating patients in this study were not asked whether, and if yes, what kind of support needs they had for self-management. It could be that patients differ in their needs and more tailoring toward individuals is needed, for example, preselection of the offered modules.

Third, the low usage of the program by patients in the intervention group could have resulted in finding only a significant effect on RAND-36 vitality, with a small effect size. The low usage of the program can have several reasons. As stated above, patients could have not felt a need for support. Another reason could be that patients were not motivated to change their behavior or had a negative attitude toward the online program. The program comprised several elements to stimulate patients' usage of the program, such as persuasive texts or modeling videos. It could be that these elements did not work or that elements were lacking in the program. Moreover, the characteristics of the online program, for example, attractiveness or the ease of logging in, are factors that could have influenced patient usage of the program. It was also notable that patients in the intervention group dropped out more than patients in the control group. A high dropout rate is a common finding in online programs [40,41]. Crutzen et al (2015), gave as possible explanation for these higher dropout rates that patients in an intervention group have several expectations of the intervention. In cases where these expectations are not met or if patients feel the intervention is not supporting them, patients will refuse to fill in the measurements and will not revisit the program [42]. In this study, patients in the intervention group were significantly higher educated than in the control group. It could be that higher educated patients use more resources that could support them (eg, support of health professionals), which could lead to lower usage of the program.

Fourth, this program was not adequately embedded in patient care. Although nurses brought the program to the attention of intervention group patients during their consultation, they did not discuss the self-management topics of the program with patients to continue the support for self-management during consultations. It has been shown that self-management programs with the possibility of interacting with health professionals (blended care) can lead to positive results [14,43].

Fifth, it could be that there was a selection bias in this study. Rheumatologists selected patients with diagnosis RA, aged 18 years, or were invited by letter to participate in this study, in collaboration with rheumatologists until the required number of 190 patients were reached. Probably, rheumatologists mainly selected the patients who had a low functional disability (health assessment questionnaire) as in their opinion, these patients would benefit of a self-management program the most.

Given the results of this study, relevant recommendations for future studies and practice can be given. First, using a questionnaire with questions referring to the program objectives is recommended to measure the effects in patient behavioral change [37]. For example, one of the performance objectives of this online program, *“set boundaries in their work situation,”* could be evaluated with an item like *“I’m able to set boundaries with my colleagues in my work situation”* (measuring skills). Patients can set their own objectives in the program, using goal setting as a strategy. Goal setting requires that patients set a clear, specific, and achievable goal to change their behavior. This concrete formulation of the goal ensures that the behavioral change is measurable [44].

Second, before inclusion, it is recommended to investigate whether patients have a need for self-management support and if so, what kind of support they need. A next step is to decide if patient support needs are handled in the program and to tailor the program to their support needs. This can avoid patients feeling that the program did not support them, which often results in no revisits. Investigation of support needs could take place over the telephone. This also offers the possibility of helping patients formulate their support needs, which is difficult to do in general.

Thirdly, to increase the usage of the programme and limit drop-out, during the development phase, it is important to pay attention to factors that could enhance usage of the programme (first visit, staying on the website, re-visits).

Third, to increase the usage of the program and limit dropout, during the development phase, it is important to pay attention to factors that could enhance usage of the program (first visit, staying on the website, revisits). Patients input, in combination with attention to dissemination, reach, adoption and implementation (emphasized in diffusion theory or RE-AIM theory), could be used to identify factors [45,46]. Moreover, qualitative research to explore the reasons for low usage should be conducted.

Fourth, to embed the program in regular health care, it is important that patient needs are also recognized by their rheumatologists or specialized rheumatology nurse and be used as a starting point during consultation. Nurses could also assist patients in performing exercises mentioned in the program, reminding patients to log on to the website and encourage patients to maintain their self-management behavior. Fifth, to increase the usage and efficacy of the program, a specific patient selection is needed. Further research is needed to assess which patient characteristics influence the use of an online program and the outcomes, for example, by performing subgroup analysis among groups with a low or high functional disability or by assessing their level of motivation to use the program. This can determine which inclusion criteria should be used to select patients likely to benefit most.

In conclusion, although there is external evidence in favor of the efficacy of online self-management interventions[14,15]. In conclusion, although there is external evidence in favor of the efficacy of online self-management interventions [47].

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Lessons learned from patients with access to an online self-management enhancing program for RA patients: qualitative analysis of interviews alongside a randomized controlled trial

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Abstract

Objective: this study aims to explain the earlier findings of a Randomized Controlled Trial (RCT) which showed that Rheumatoid arthritis (RA) patients did not benefit from an online self-management enhancing program and that patients used the program less frequently than expected.

Methods: As part of an explorative RCT, four patients group were interviewed to explore their (non)-usage of the program.

Results: The program failed to support patients because: 1) not all patients were motivated to use the program, 2) patients had no clear expectation or had differing expectations of the program, 3) there was a mismatch between individual patients' support needs and the needs included in the program, 4) reminders were only sent to fill in the diaries for pain and fatigue, not to use the program modules.

Conclusion: The study offers insights in the (non-)usage of online programs and how usage could be increased in practice.

Practical implications: nurses should be involved in the implementation of this online program.

Introduction

Over the past decade, online self-management enhancing programs have been developed for patients to better manage their chronic illnesses[1]. These programs can support patients in taking responsibility for improving their health status by strengthening self-management behaviours such as physical exercise and medication adherence [1,2,3].

Most online self-management enhancing programs are complex interventions characterised by a number of components to actively induce behavioural changes; these components differ in the underlying social theories used [1,4].

To be effective, online self-management programs need to be used regularly [5]. Research shows that currently, the actual usage (first visit, stay on the website and re-visits) of online self- management programs in experimental settings is quite low [6], and it is expected that usage may be even lower when these programs are implemented in real-life settings [4,7]. One explanation for the underuse of such programs could be that they are not developed with input from patients[8].

Knowing that, we developed, together with patients and professionals, an online self-management enhancing program targeting patients with Rheumatoid Arthritis (RA), based on the Intervention Mapping (IM) framework [9]. It was expected that patients' input would lead to high engagement, positive effects and higher usage. Surprisingly, our explorative Randomised Controlled Trial (RCT) showed that patients did not benefit from the program and used the program less often than expected [submitted]. Because of the importance of increasing usage, we interviewed non-users and users of the program evaluated in the explorative RCT to obtain insight into: 1) why patients used or disused the online program and 2) the experiences with the program among users. The results of this study can be regarded when performing future studies with this and other online programs.

Materials and methods

Design

Participants of the pre-planned qualitative study were patients who were randomised to the intervention group during the explorative RCT [10]. The study protocol was presented to the Medical Ethics Committee Arnhem-Nijmegen in the Netherlands, and the committee concluded that formal approval was not needed. The study is performed in conformity with the declaration of Helsinki. Details of the study are published elsewhere [9].

Intervention

Patients' input during the development of the intervention

The intervention was developed between January 2013 and July 2014, using the Intervention Mapping (IM) framework, and aimed to increase self-management behaviour of adult Dutch RA patients. The repeated inputs of five patients and six health professionals were used in each step of IM [9].

Content of the online program

The content of the program is shown in Table 1. For each module, performance objectives were formulated to specify the pursued behavioural change, shown in the first column in the table. The Behavioural Change Strategies (BCTs) and the practical applications are shown in the second column.

Patient recruitment

Patients were recruited by telephone, from the intervention group only and after they filled in the questionnaire at 6 months after baseline. Written informed consent had to be provided by the patient before inclusion in the qualitative study.

Procedure

Purposive sampling was used to select patients regarding the degree in which they used the program. Four patient groups were recruited: 1) non-users 2) low users: patients who logged in between 1-5 times, 3) moderate users: patients who logged in 6 or more times for mainly using the diary for pain and fatigue, 4) high users: patients who logged in 6 or more times, using the modules as well as the diary. The cut-off point between 'low users' and 'moderate' and 'high users' was arbitrarily set on 5 times as a reflection of active involvement. It was expected that 'moderate' users, who mainly used the diary for monitoring pain and fatigue, had different experiences than 'high users', who used both the diary and the modules. After giving written consent, each patient was interviewed once by telephone between February and May 2016 by the same researcher (sociologist/female). An interview guide was used to focus on three phases of (non) usage: 1) before using the online program, 2) while using of the program, 3) after using the program, i.e. to determine the outcomes of the program. The interview guide was pilot- tested; in addition, as test interview was held. The semi-structured interviews, lasting no longer than 30 minutes, were audio-recorded, anonymised and transcribed verbatim. After interviewing two participants per subgroup, members of the research team (RN, BvG, SvD) read the transcript of the interviews to optimise it and to add questions. The first 10 interviewed participants also received a summary of their own interview for a global check.

Table 1 Content of the program with the inserted BCT strategies and their practical applications

Content of the program
Based on needs assessment and patient input, we developed the following 10 modules* and a diary** with the following performance objectives: 0. Welcome (one session) 1. Balancing daily life activities (five sessions) - Finding balance between rest and activity - Making choices in participating in daily life activities 2. Setting boundaries (four sessions) - Setting boundaries to partners, relatives, colleagues and the social environment 3. Asking for help and support (four sessions) - Asking for social support or practical help from partners, relatives, colleagues and the social environment in daily life - Asking for social support and practical help from colleagues - Accepting social support or practical help from partners, relatives, colleagues and the social environment in daily life 4. Using medication (four sessions) - Taking prescribed medication 5. Communicating with health professionals (four sessions) - Preparing the visit to the health professionals - Asking questions and/or expressing concerns during an appointment with a health professional 6. Using assistive devices (four sessions) - Using, if necessary, assistive devices 7. Performing physical exercises (four sessions) - Performing daily physical exercises 8. Coping with worries (three sessions) - Coping with worries about RA 9. Coping with RA (two sessions) - Coping with RA An online diary to track the levels of mean pain and fatigue during the last 2 weeks and the levels of pain and fatigue today.

Table 1 Continued

Content of the program
Inserted BCTs and practical applications
The theory of planned behaviour [10] was the underlying theory, and the following BCTs were inserted [11]:
To enhance knowledge: Providing general information about health behaviour (informational texts) Increasing memory and/or understanding of transferred information (informational texts) To create awareness and insight: Risk-communication (text about positive consequences of behaviour) Self-monitoring of behaviour (diary pain and fatigue) Self-report of behaviour (e.g. assignment to fill in daily activities) To provide social influence:
Providing information about peer behaviour (quotes from patients and texts, with experiences of patients) To strengthen positive beliefs: Persuasive communication/belief selection (persuasive text) Reinforcement on behavioural progress (feedback) Providing contingent rewards (feedback) To enhance self-efficacy: Modelling (videos from other patients) Practicing (assignment to practice behaviour) Planning coping responses (evaluating questions) To encourage patient intention: Developing medication intake schedules (medication schedule to fill in) To encourage patient action control: Using social support (instructions on how to use social support) Using cues (instructions on how to use cues) Self-persuasion (instructions on how to increase patient motivation)

BCTs = behavioural change techniques
*Each module takes on average 25 minutes to complete. Patients can choose which module(s) to work through and can do this at their own speed at any time.
**Patients receive an email every other week with a hyperlink to the pain and fatigue diary.

Data analysis

Interview transcripts were uploaded to the software program AtlasTi for coding. The first six transcripts were independently coded by two researchers (RMZ and AOB), guided by a code tree which was developed in advance. After comparing the coded transcripts, code differences were resolved until the two researchers reached consensus. Codes were brought together in themes. Interviews were continued until data saturation was reached.

Results

In total, 78 patients were randomised to the intervention group. At month 6 (T1), 59 patients had returned the questionnaire. For the interviews, 49 patients were invited, 31 could be reached by telephone and 22 consented to participate, of whom 1 withdrew consent without providing a reason. The remaining five eligible patients were not recruited because data saturation was reached.

Consequently, 21 patients participated in the interviews, belonging to four user-groups (Table 2). Codes were combined according to the following themes: 'motivation', 'expectations of the program' and 'support needs for self-management' to analyse the phase before (not) using the program. The themes 'usability' and 'usage of the program' were used to analyse the phase of program use.

Table 2 Patients' demographic and disease-related characteristics

Group	N	Gender	Age (mean)	Disease duration in years (mean)	Education	Work
Non-users *0 times*	4	2 men 2 women	58	7	1 low 2 middle 1 high	2 yes 2 no
Low users *1-5 times*	4	4 women	64	4	4 middle	1 yes 1 part-time 2 no
High users basic *More than 6 times: mainly using the pain and fatigue diary*	7	3 men 4 women	53.5	14.3	4 middle 3 high	3 yes 3 part-time 1 no
High users plus *More than 6 times: using both the modules and the diary frequently*	6	3 men 3 women	67.8	11.5	1 low 4 middle 1 high	2 yes 1 part-time 3 no

Work "yes" means: more than 12 hours per week paid work or more than 8 hours unpaid work, "Part-time" work means 1 to 12 hours paid work or 1-8 hours unpaid work;" No" work means no paid or unpaid work.
Education "low" means no education or completed elementary school, education "medium" means completed preparatory secondary education, education "high" means completed a bachelor's degree in applied sciences or a university degree.

Subsequently, the themes 'experiences' and 'satisfaction with the program' were used to analyse the phase after using the program. The final transcript (n=21) yielded no new information and codes, indicating data saturation. The results are presented below under the four themes as described.

The results are presented under the themes as described in the method section. In this section, the group "high users" refers to both groups of high users (high users basic and high users plus). Different results between these two groups are indicated in the text.

Patient motivation

High users felt intrinsically motivated to use the self-management enhancing program. Patients wanted to be more responsible for their own health or used the online program to refresh their knowledge.

> *" A month after a visit to the website, I refreshed my knowledge. For example, how do I need perform my exercises".*

Also, curiosity whether the program could help them to find more information about RA or could support them to perform self-management behaviour was a reason to use the program. Low users felt eccentrically motivated by the advice of the rheumatologist or by the invitation letter of the research team. Improving healthcare was another reason to use the program.

> *"The rheumatologist asked me to participate and I thought this study could lead to improvements in healthcare".*

Reasons for not using the program were: finding the online program not important enough, laziness, lack of time and personal circumstances.

Expectations of the program

All patients were asked whether they have had a priori expectations of the program, and if so, which expectations they had. Most users had no specific expectations and started using the program without having a clear idea.

> *"I had no priori expectations of the program, i could not make an imagination of the program".*

Some high users hoped to find information about topics which were not discussed in the program, namely information about the causes of RA or new medicines and their effects. Also, some patients expected a possibility to interact with other patients, which was not the case. Non-users expected that the program could help them to find information about medications and the prevention of physical impairment.

Support needs for self-management

Users as well as non-users indicated a need for support in setting boundaries in daily life, finding balance in daily activities and prevention for physical impairment, which were all topics of the online program.

There were also patients who had support needs that were not met by the program. These patients, mostly suffering from a long-term disease, expressed a need for more (scientific) in-depth information about the newest developments in medication, nutrition in relation to RA, non-conventional medicines and an explanation of eye problems related to RA.

> *"That issue (about developments in medication) was in the media, that's one example, but I really have a need for this information about this issue. What is new about it and what could I do with it?".*

They mentioned that the information they read in the online program would be helpful when RA is just diagnosed.

> *"I think when someone gets rheumatism, I would recommend this as this program could be a guidance".*

The possibility to interact online with other patients to give each other advice in how to cope with RA, and an option to chat with a health professional, were also mentioned as a need for support. Even though the program did not fulfil the support needs for all patients with a long-term disease, they did re-visit the program several times due to curiosity, refreshing knowledge and a sense of obligation.

Among patients who experienced only few symptoms of RA, both users and non-users reported no support need. Should symptoms of RA arise, a visit to the rheumatologist and rheumatology nurse would suffice for them. Some patients, mostly with a long-term disease, had followed a course previously, had their own physical exercise program in the fitness centre or participated in a fitness group; the information provided in the online program was therefore not new for them. Moreover, they felt that the social support of family and friends was adequate.

Satisfaction with the online program

The attractive 'look and feel' of the online program, such as the clear lay-out, the possibilities to easily navigate through the program and to easily click on topics, a good overview of the content and the use of concise texts and ordered information were mentioned as attractive features. Patients were also satisfied with the every two weeks automatically sent emails to remind them to fill in the diary for pain and fatigue. The diary did encourage patients to think and evaluate why pain had occurred.

> *"And then, an e-mail and such a program, where you can automatically insert pain and fatigue, is very nice and I also find that you can evaluate yourself: How did it come that I had so pain in the elbow? What did I do? Those kinds of things are very nice.*

Other patients, high and low users, were unsatisfied with the program. For some of them, parts of the program were confronting, namely the modules worrying, coping with RA and the pain and fatigue diary. These topics forced them to think about their disease, even when they did not want to.

> *"I'm not a person who exactly knows how they feel every day; you need to fill in something and then you have too many thoughts about it while you are actually trying to minimise thinking" .*

Also, some patients found the problem was too long and found it difficult to figure out how the program works and to fill in certain components of the program.

Usage and usability of the program

With respect to the patients' first visit to the program, non-users reported that laziness, a lack of time due to their busy daily schedule, personal circumstances or ICT problems were reasons for not visiting the program. Log-in problems were the most important reasons for not using the program at all. The password, with a required number of letters, capital letters, signs and numbers, was experienced as difficult and forced patients to use an alternative password. To open the homepage on the IPad also appeared difficult. Only some high users, mainly those who visited the modules and diary, continued to return to the program despite the log-in problems.

The be-weekly reminders for the pain and fatigue diary were triggers to re-visit the program. A part of the high users visited modules of the program after filling in the diary because they were curious if there were any tasks in the modules for them.

> *"No, in the first instance, I visited the website when I wanted, but later, when I received emails....yes, then you visit the program more frequently".*

Other high users mentioned that the emails every two weeks were a reason to re-visit the diary (not necessarily the program).

> *"Because of my busy daily life, I forget it. You should have a pattern. I certainly would not have continued without receiving an email".*

Non-users and users gave various reasons for not re-visiting the program. High users did not take the initiative (after a while) to fill in the diary of daily activities or the pain and fatigue diary because this was not in their system.

> *"Yes, difficult if it is not in your system. Every day you check your email, but you don't visit the site to fill in [the diary of daily activities]".*

Reasons for not re-visiting the program for high users were: finding no new information, having physical problems, not having problems with RA or not needing any support. For low-users, problems with logging in, being unfamiliar with the internet and even finding the internet scary were reasons for no re-visit. Patients visited the modules 'finding daily balance', 'setting boundaries', 'assistive devices' for more information, learning skills about setting boundaries and applying for a wheelchair and domestic help. The reasons for not visiting the modules were as follows: experiencing no problems around these topics ('medication' and 'assistive devices'), already having the skills ('asking for social support', 'setting boundaries', 'coping with RA'). The module 'coping with worries' was too confronting for some patients.

Experienced support of the program

Some users, mainly high users, experienced support by the program, according to the drafted performance objectives of the program (Table 2) The module 'balancing daily life activities' supported them in finding more rest during the day, thereby gaining more energy. The module 'setting boundaries' supported patients in communicating their boundaries to others. Also, patients talked in their social environment about their illness to make sure the environment knew what to expect.

> *"After using the program, I started to communicate about my illness to others. I explained them what RA is and requested that they do not ask too much".*

The module 'physical exercises' gave patients insight into which exercises they could do and stimulated them to find a balance between daily activities. This ensured that patients performed physical exercises as part of their daily life. Patients were more physically active than prior to using the online program, and as a result of this, patients were less tired, had less pain, and their stiffness decreased.

> *"I learned which exercises I could do. I fit this in my daily schedule and take the time to stretch and strength my muscles every morning. I'm not tired anymore and do not have any pain anymore".*

One patient mentioned that the module 'taking medication' has led to a lower medication use. Some high users were also critical about the program; they did not find the program supportive because of their long-term diseases. A program could be supportive when it includes a group-based face-to-face approach to share needs with other RA patients and to obtain more information about new developments in the field of RA. Each module consisted of certain elements, the so-called "operationalised BCT's": texts, a number of modelling videos in which patients reported their experiences or gave an explanation on how to cope with a certain topic and with exercises. Patients were asked which of these elements supported them. Videos confirmed that patients adequately coped with RA or gave them the feeling they were not the only ones with RA. The diary for pain and fatigue gave patients an overview about their patterns of pain and fatigue over time, enabling them to reflect upon the course of the disease. As a result, the patients made better decisions about when to take more rest and also discussed their results with the rheumatologist. In some patients, however, the modelling videos had a negative effect on their mood.

> *"I feel bad that other people have RA, but do not focus on your limitations, but focus on the things you can do".*

The shown physical exercises were difficult to perform for older patients. The diary for daily activities required a lot of daily input, and for some patients, this was too time-consuming.

Discussion

The most important reasons our program failed to support patients in their self-management behaviour were as follows: 1) some patients were not (intrinsically) motivated to start using the program (first phase of behavioural change) and because the behavioural change strategies (BCTs) in the online program did not motivate them, 2) patients had no clear or a different expectation of the program, 3) there was a mismatch between individual support needs and the needs included in the program and 4) no triggers were sent to use the modules of the program.

Motivation

Non-users and low users were not motivated or felt (eccentrically) motivated by the advice of the rheumatologist or by the invitation letter of the research team. As a consequence, they did not re-visit the program. These patients experienced also log-in problems, which are barriers that are difficult to overcome when patients are not intrinsically motivated. These results are in line with the findings from other studies showing that being eccentrically motivated leads to non-usage or low usage of the intervention, and eccentrically motivated patients experienced more barriers related to log-in [12,13]. The BCTs in the online program aimed to change the behaviour of users, but patients who did not visit the program were not reached by the strategies. Thus, to reach less motivated patients, it is necessary to add strategies to increase the awareness that self-management can be supported by an online program. A part of the patients had already experienced support from the rheumatologist and the nurse, which was considered sufficient. It is also possible that patients were not aware of their active role in the management of their illness. In that case, the role of the nurse could be to explain in which ways they can actively manage their disease.

Expectations

Most patients did not know what to expect from the program, and some found that the program did not match with their expectations (they expected, for example, in-depth information about medication). A part of these patients expected to find information about various topics and were not aware that this online program could support them to change their behaviour. Considering the Technology Acceptance Model and the Unified Theory of Acceptance and Use of Technology, clear expectations are important in the decision to use the program [14]. That is, when patients have no expectation about the pursued effects of the program and the effort expected from them, they tend to use the program less frequently. When patients experience that the program did not meet their expectation, this could lead to a decreased motivation and underuse of the program Thus, it is crucial to clarify what patients can expect from the program, how much effort is needed and what effect can be reached.

Patient needs

Most patients had a need for more information and contact with other patients and health professionals. This result was unexpected, as we conducted a thorough need assessment, recommended by the Intervention Mapping framework, to receive insights into the support needs for the self-management of RA patients [15,16]. Therefore, it seems that a general need assessment is not sufficient to match the support needs with the program. Conducting an individual need assessment with the researcher or health professional and end-user could also be helpful.

Reminders

Reminders were linked to the pain and fatigue diary and not directly to the modules. Patients found reminders a trigger to re-use the program, but re-visited only the diary and not the modules. Earlier research showed that reminders can be effective to re-use the program [13,17]. It seems that the lack of a direct link between the diaries to the behavioural change techniques in the modules was a reason for not visiting the modules in the program.

Advances and limitations

Although we assumed that an interview study is the best approach to explore the use of the program, this study has some limitations. Firstly, patients were asked for an interview at the end of the 12 - month access period. Most of the patients had not used the program for a while, and as a consequence, some patients could not remember how to use the program correctly. Secondly, patients could be triggered to re-use the program after the interview, but our log-in data did not show that interviewed patients logged in directly after the interviews. The third limitation is that the program is delivered to patients without the involvement of nurses. Therefore, an individual need assessment was not performed, which is, however, essential to tailor the program to the individual needs of the patients. Also, nurses could educate patients in using the program, which is important in terms of expectations.

Implications for practice

Based on the results of this interview study, some implications can be made for further research and practice. It is recommended to deliver the online program in combination with face-to-face treatment (blended care), and therefore, the involvement of nurses is necessary to reach patients for this online program and to tailor the program to the patients' support needs. To reach patients, it is recommended to assess their motivation. Nurses can use the answers from a questionnaire according to the Trans Theoretical Model (TTM) to identify the behavioural change stage[1 8]. Depending on this stage, the nurses can decide to use Motivational Interviewing (MI) to increase patient motivation or give patients who are already motivated access to the program [19].

To clarify what the patients can expect from an online self-management program, instructions are needed in terms of the goals of the program, the expected outcomes and the effort expected from the patients.

To assess patients' needs, it would be helpful for patients to discuss their support needs with a nurse. Besides formulating a support need, a nurse can help to specify a support need to tailor the program to the needs of the patient. That is, an information need about treatment or medication might be too general and needs to be more specific. Based on patients' support needs, the program could be tailored to the individual patient (e.g. offer a specific module from the online program adjusted to individual needs). To improve the content of the program, more (scientific) in-depth information about the newest developments in medication, nutrition in relation to RA, non-conventional medicine and an explanation about the eye problems associated with RA could be added. Also, an interactive component, facilitating contact with other RA patients and health professionals, could be added as part of the program. Regarding the reminders, it is important to assess patients' preferences regarding reminders and to link reminders directly to the modules in the program.

Conclusion

This interview study contributes to our understanding of the (non-) usage of this online self- management enhancing program. The results show that the involvement of nurses is necessary in the implementation of the program. The program can be improved as follows 1) providing a more profound individual need assessment, 2) assessment of patients' motivational stage before usage, 3) providing a clear outline of realistic expectations from the program and 4) integrating reminders into program modules. Already effective proven online programs can use the results of this study as pre-conditions for a successful implementation.

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Appendix

Interview guide

The interviewer repeated briefly the information that the patient received and agreed with in the written consent. Also, she explained in short the aim of the interview and that answers of the patient are not considered as being right or wrong. Each question was introduced to the patient and described in this interview guide between brackets. [We want to receive more insight in why patients used the online program 'coping with RA' or not. Thus the reasons why you decided the use the program or not]

Question 1: What are the reasons for using the online program 'coping with RA' (or not)? [We also want to receive more information about patients' expectations of the program]

Question 2. What were your expectations of the program 'coping with RA'?
Did you're expectation met the program and can you explain why (not)?
[You could choose by yourself how many times you use the program]

Question 3. How many times do you visit the program and why do you (re-use) the program?
What is/are the reason(s) for re-using of the program
What is/are the reasons(s) for not re-using the program
What is the reason for non-usage of the program?

[The next questions are about the usage of the program. Can you remember how many time you logged-in until now? If patients did not remember, we explained to them how many times they used the program based on their user data].

Question 4. What is/are the reason(s) for re-use of the program, or what is/are the reason(s) for no re-use
What can help you to overcome barriers to use the program

[The next questions are about the usage of program components. The modules and diary of pain and fatigue. Can you remember which program components u used until now? If patients did not remember, we showed them which modules they had used based on their user data].

Question 5: Can you explain why you visit these components?
Why did you not visit the other program components
Did you finish the complete module? Why did you finish the module (not)?
[To optimize the program, it is important to know your user experiences with the program. The following questions are about your user experiences].

Question 6. Are you satisfied about the program?
About which program components are you satisfied? Why are you satisfied about this? About which program components are you unsatisfied? Why are you unsatisfied about this?

[The program 'coping with RA was developed to support you in daily life].

Question 7. Did the program you support in daily life?
How supports the program you (or) not? Why (not)?
Which support do you receive from the program?
From which components do you receive support?
If the program did not support you, need the program be change to support you? If yes, how need the program change. If the program did not support you, what kind of other support can help you?

6

Patient Self-Management and Tracking: A European Experience

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Abstract

The shift from a paternalistic model of health care (doctor with power versus passive patient) to a doctor-patient relationship where the doctor and patient make shared decisions, requires an actively-involved patient who takes responsibilities. This is the reason that self-management by the patient with a chronic disease plays more of an important role in patient care nowadays. However, the degree of self-management varies per patient. To help and stimulate patients in their self-management behavior, it is necessary to use an adequate tool, and to educate both patients as well as health professionals. In this chapter we will share experiences using a digital tool for this from the Netherlands.

Introduction

More than 2500 years ago the ancient Greeks like Hippocrates realized that maintaining good health and managing diseases depended on the natural causes and lifestyle issues like diet and exercise as well as on the environment [1]. Already at that time a lot of attention was being given to educate the population, to teach them that diseases are influenced by emotional factors and that human behavior has a strong influence on the course of diseases. Special educators went to villages to increase the so-called self-sufficiency of the population, which we now would call patient self-management. In the 20th century, due to the 1948 WHO definition of health, "health is a state of **complete** physical, mental and social well-being and not merely the absence of disease or infirmity", the focus was to find medical solutions to cure each disease. This fitted in the paternalistic approach which was the standard procedure for how medicine was practiced: the doctor is dominant and makes decisions for the patient.

In the past decade we moved from this paternalistic approach to a shared decision model in which the patient together with the health care professional make the decisions. This fits more in the new definition for positive health which "is the ability to **adapt** and to **self-manage**, in the face of social, physical and emotional challenges" [2]. In the same period it has been shown that lifestyle factors do influence the development of the disease, the course, and the response to treatments [3-7]. All these factors have caused more attention to be given to the role of the patient in the management of the disease. An important component of self-management is called self-monitoring, a patient undertakes self-measurement of, for instance, vital signs like weight and blood pressure or symptoms like pain, fatigue, and disease activity by Patient Reported Outcome Measures (PROM) [8,9].

The degree of self-management can vary per patient and depends for instance also of the situation the patient is facing. In an acute, life threatening situation like a myocardial infarction, the degree of self-management of a patient at the emergency department will be minimal, while for patients with a chronic disease the degree of self-management might vary between attending the outpatient clinic prepared with a list of their current medication usage to even suggesting to the health care professional to lower the dose of a prescribed medication because their disease activity is low. Several studies have shown that patients with a chronic disease who practice self-monitoring do have a better outcome of their disease [10]. This, together with an improved cost-effectiveness of this approach, is the reason that self-management should be stimulated in patients with chronic diseases. Different studies however have shown that the percentage of patients with Inflammatory Rheumatic Diseases

(IRD) that perform self-monitoring in daily clinical practice is still quite low [11]. In this chapter we will share our experiences with how we educated and motivated our patients with IRD to participate in a self-monitoring program.

Tool Reumanet

To stimulate patients in their self-management behaviour, a digital tool can be helpful in which the patient can monitor and manage their disease outcomes. For this purpose, we developed at the department of Rheumatology of Bernhoven, a teaching hospital in Uden, The Netherlands, Reumanet Bernhoven. This is an online two factor authentication protected- personal health environment with several functions to support patients with IRD in their self-management behaviour. This online personal health environment is available for the patient and the rheumatologist, but also the nurse, general practitioners and/or physiotherapist can have access (with permission of the patient). The online personal health environment includes all patient characteristics, questionnaires, graphical overviews, lifestyle advices, and feedback opportunities, which include e-health modules and other relevant information adjusted for the individual patient with an IRD. This information is summarized in the dashboard (Figure 1).

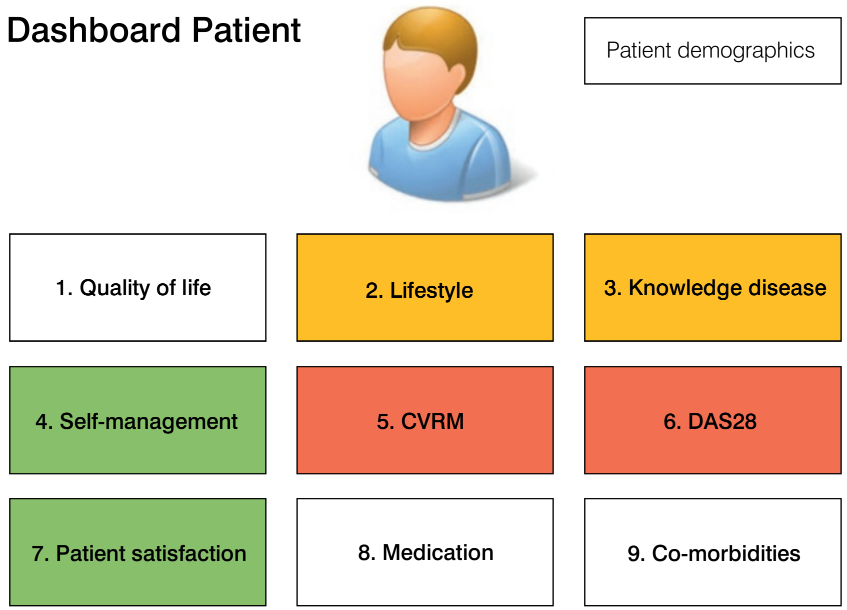
In more detail, firstly, patients can find an overview of their current and past medicines and blood values. Secondly, a monitoring function is available to track patients' disease activity. Patients can complete PROMs in this online system as preparation for the consultation with the rheumatologist and these scores are displayed in a graph. The patients can choose from scores such as the Rheumatoid Arthritis Disease Activity Index (RADAI) and the Rheumatoid Arthritis Impact Disease activity (RAID). These PROMs have shown to correlate well with objectively assessed measures and have good psychometric properties. In case the disease activity according to these PROMs and together with the patient set, exceeds a predetermined threshold, an alert appears in the online system. This enables identification of patients whose disease activity is not in line with the target and who might need further medical attention. Thirdly, patients can self-add measurements of body weight or blood pressure and the results are also visible in a graph. Fourthly, a chat function is available to send messages to health professionals. Lastly, patients can make use of the educational part of the program, called the library, which contains several leaflets and videos with information about various topics including information about their disease, medication use, fatigue, or working with RA.

Personalized dashboard

For the different health professionals involved in the management of IRD, it is mandatory to have an overview of the status of the different domains of disease management, see Figure 1. For example, the personalized dashboard contains the following domains: 1. Quality of life, in which different questionnaires will be filled in by

Figure 1 Example of a personalized dashboard for patients in Reumanet

Green button: under control, no action needed. Red button: not under control, further action is needed. CVRM, cardiovasculair risk management



patients about their current quality of life. 2. Lifestyle factors, such as physical activity behavior, smoking status and diet of the patient will be followed over time. 3. Knowledge of disease by the patient will be inquired by questionnaires. 4. Self-management, using the self-management questionnaire SEMAS, the different domains of self-management will be measured that can be used as a screening instrument for nurses to assess patients' individual capabilities or barriers for self-management. 5. Cardiovascular risk management (CVRM), the cardiovascular risk profile of the patient will be checked at least once a year. 6. Disease activity, such as the DAS28 in patients with rheumatoid arthritis, will be monitored. 7. Patient satisfaction and perceived quality of rheumatology care will be asked by questionnaires. 8. Medication use and adverse events will be documented in the system and 9. Co-morbidities.

It is very important for the patient to have an overview of the disease process as well and to get feedback about actions they have taken. For instance, to make sure that the patient will continue with an exercise program, it is important to set a target, to give feedback to the patient, and to encourage the patient to reach the target.

Therefore, it is important that in addition to the patient and the rheumatologist, the nurse, general practitioners, and/or physiotherapist also have access to this web-based program (only with patient permission). In this way both the patient and the rheumatologist and other health professionals are involved in managing the disease and are aware of each other's actions. In the case of a red button, the health professional or the patient should be aware that some action is needed in that domain. In the case of a green button, that domain is recently checked and under control and no further action is needed at this moment.

Education

To increase the number of patients participating in the self-management program education of both the patients as well as the health professionals is very important. Next to leaflets in the waiting room and general educational meetings, instruction classes have been organized to give patients a general instruction how to use Reumanet. Patients can call or email the help desk in case of any additional inquires. The staff at the outpatient clinic is also available to assist the patients in case they need so before or after their visit to the rheumatologist.

Chancing role of healthcare professionals

The introduction of a self-management outpatient clinic has, in addition to patients, also had consequences for the healthcare professionals (HCP). It requires a different approach, instead of the usual, old-fashioned paternalistic relationship –the role of the HCP has changed to one in which the patient is coached to manage their disease. Different skills are required for this role like for instance motivational interviewing to help and stimulate the patients to take their disease management role. For this purpose, a training program has been developed in which patients, HCPs, and students learn together by exchanging experiences, knowledge, and skills [12].

Self-management outpatient clinic

The traditional approach to monitoring IRD patients 2-4 times a year to assess disease activity is no longer necessary or appropriate but should be tailormade. As long as remission is not reached, frequent assessments need to be done to adapt the medication according to the Treat to Target guidelines. When the disease is under control, these measurements can be done less frequently and even remote self-monitoring would be feasible. Remote control by self-monitoring might also give important information about the disease course in between outpatient clinic visits, as it has been shown that this information might have an important impact on the outcome of the disease. Therefore, self-monitoring in IRDs as a first step towards personalized healthcare enables patients as well as healthcare providers to get insights in the disease activity course over time.

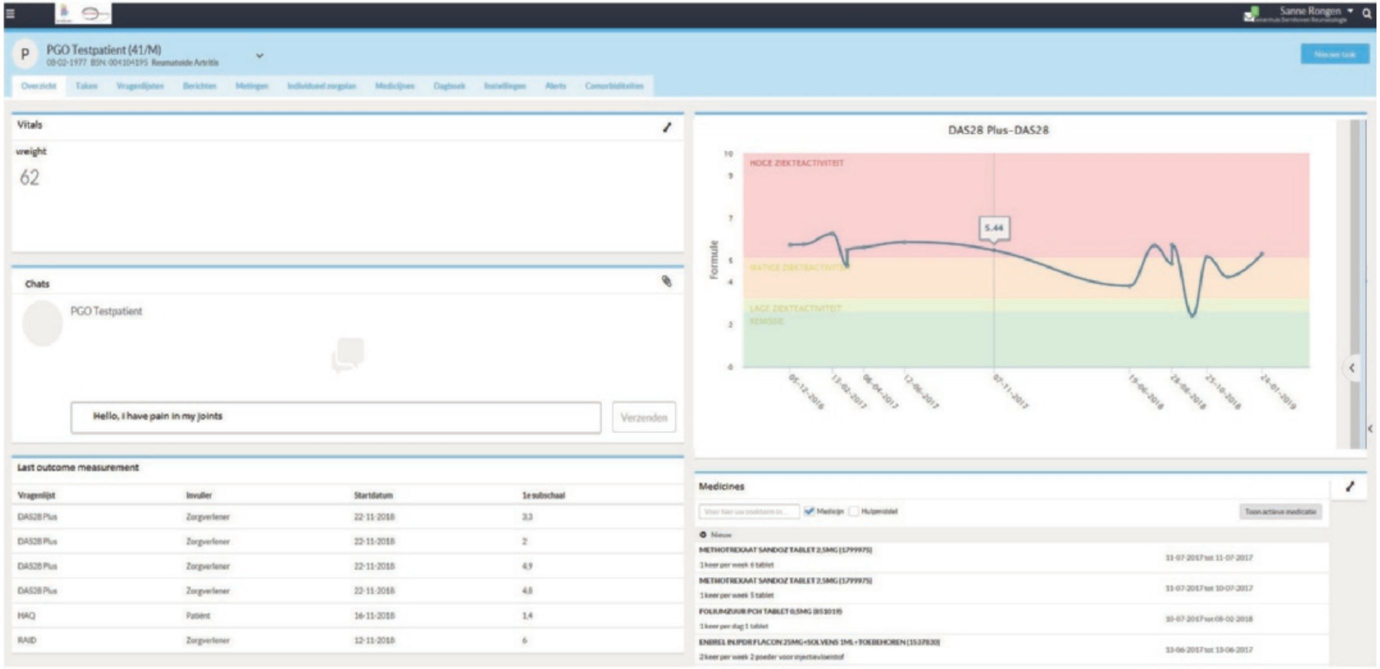
In November 2017 we started with a “self-management outpatient clinic” to find out if the monitoring frequency of patients can be decreased to 1 visit a year. Patients with IRDs are included if they fulfil the following inclusion criteria: 1) the patient is in remission or has low disease activity, 2) is motivated to take part in the self-management program, and 3) is able to use Reumanet. After consent, the patient receives information about 1) the aim of the self-management program and how to use Reumanet, 2) what the patient can expect from the health professionals, and 3) how to contact the outpatient clinic in case of questions. At the start, the self-management screening questionnaire (SeMAS) is filled out by the patients in order to get to know if the patient encounters barriers in self-management behaviour [13]. If appropriate these barriers are solved before the start of the program or, in case this is impossible, the patients will not be included.

The patients can choose to track their disease activity by filling in the RAID or RADAI questionnaire. Patients can decide by themselves the frequency to fill in the RAID, for example every week or every month. The results of the questionnaires are shown in a graph together with the DAS28 values performed by the health professional at the outpatient clinic visits (figure 2). To manage their disease, it is essential for them to perform self-management behaviour: they need to remind themselves to fill in the questionnaire multiple times and based on the insight they gain in the graph and the preset target, they need to decide when to make an in-between appointment for a visit to the outpatient clinic. After one year the rheumatologist and patient will evaluate the participation with a questionnaire to assess the patient’s satisfaction.

First Results

By November 2017, 1125 patients with an IRD were already active in Reumanet Bernhoven. The degree in which patients make use of Reumanet Bernhoven differed widely, and depended on patient needs, abilities, and skills. The results of Reumanet Bernhoven showed that 70% (n=790) of the patients used it at least once a year, but only 13% (n=100) of the patients used the self-monitoring tool. The remaining patients (n=335) were questioned for not using Reumanet at home. The most common reason for not using Reumanet were not having a computer or email address or the patient did not want to use a digital environment at home (Figure 3). To increase the chance that patients are using the self-monitoring tool, it is important that they find useful information in this digital environment and therefore it is important to involve patients in the development of such a tool. It is also important to teach patients how to use it; to enhance continuous usage patients need to receive feedback about it from their HCPs at the outpatient clinic visits. Therefore, to increase the usage of

Figure 2 Current dashboard



Hello, I have pain in my joints

Last outcome measurement

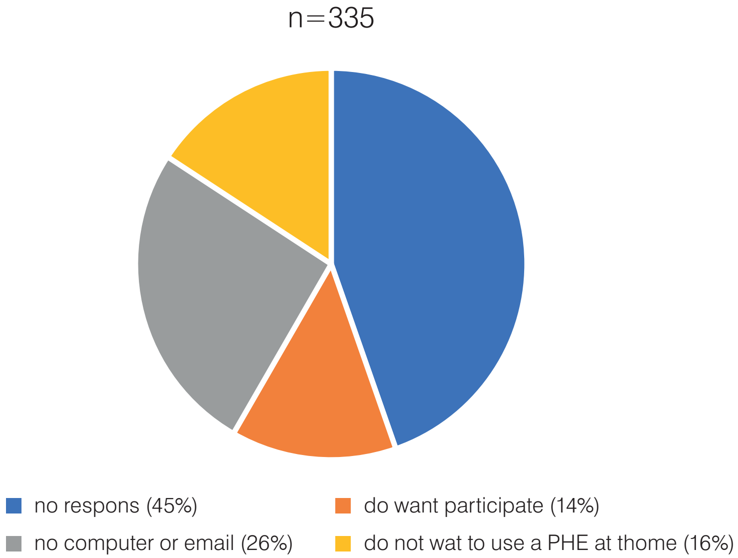
Vragenlijst	Invuller	Startdatum	1e subschaal
DAS28 Plus	Zorgverlener	22-11-2018	3,3
DAS28 Plus	Zorgverlener	22-11-2018	2
DAS28 Plus	Zorgverlener	22-11-2018	4,9
DAS28 Plus	Zorgverlener	22-11-2018	4,8
HAQ	Patiënt	16-11-2018	1,4
RAID	Zorgverlener	12-11-2018	6

METHOTREXAAT SANDOZ TABLET 2,5MG (1799975) 1 keer per week 6 tablet	11-07-2017 tot 11-07-2017
METHOTREXAAT SANDOZ TABLET 2,5MG (1799975) 1 keer per week 5 tablet	11-07-2017 tot 10-07-2017
FOLIUMZUUR PCH TABLET 0,5MG (851019) 1 keer per dag 1 tablet	10-07-2017 tot 08-02-2018
ENBREL INJPDR FLACON 25MG+SOLVENS 1ML+TOEBEHOREN (1537830) 2 keer per week 2 poeder voor injectievloeistof	13-06-2017 tot 13-06-2017

Reumanet, the program will be continuously optimized and extended in accordance with patients' support needs and preferences. Earlier research shows that the patients' input is essential in the development of online tools [14,15] and that patients have various educational support needs [16-18]. To assess patients' support needs and preferences regarding the educational part of the online tool in our patient population, patients filled out a questionnaire with questions about their usage and their opinion about optimizing the content of the program. For instance, patients were asked what kind of functions should be added to Reumanet (e.g. a newsletter, informational texts, or instructional videos). Also, patients were asked about which topics should be dealt within the program (e.g. new treatment options, the influence of nutrition on IRD, or medication usage).

Figure 3 Reasons Given by Patients for Not Using Reumanet

PHE, personal health environment.



The first results (n=35) showed that patients have several informational needs regarding physical impairments (pain, fatigue, and stiffness), and their treatment (how to prepare a visit to the outpatient clinic, improve their communication with health professional, usage of medicines, and being up to date on the newest treatment options). Informational texts, more graphical overviews, newsletters, instructional video's and exercises should be added as functions to support patients in their informational needs. In addition to the questionnaire, we will conduct qualitative interviews to explore what patients exactly want, for instance: what kind graphical overviews they may want and which topics should be discussed in newsletters. Based on the results of the questionnaire and qualitative interviews, program material will be developed and added to the program to provide patients support in their self-management.

Experiences of patients

The following quotes are from one of the patients who participated in the self-management program from the beginning of the program:

> *“After the diagnosis of Rheumatoid Arthritis (RA) was made, my biggest fear for the rest of my life was to be dependent on others, but nothing is less true. I am using Reumanet, on which I regularly fill out questionnaires. I do that at home at a time that suits me. I determine the frequency myself, the moment and the time, no pressure from outside or a planned ‘quarter of an hour’ ‘in the hospital where it has to be done. I have direct insight into my medication, laboratory results, a library full of useful information and there is room to add personal matters. Data from completed questionnaires are immediately processed and displayed in graphs that are readable and clear to me. The diagrams show progressive information in which I can set the period for which I want to look back”.*
>
> *“All of this really gives me the feeling to be in control of my own life and I don’t feel myself a patient anymore but a human being. Meanwhile I take the initiative to adjust the medication myself, of course under supervision and with the permission of my rheumatologist. If the disease activity values remain below the predefined target level, I don’t plan a visit to the outpatient clinic. Because I only use a consultation with the rheumatologist when it is really necessary, I can reduce the visits to the hospital to the minimum”.*
>
> *“Since last year I come to the hospital much more often than before I had RA, but not as a patient but to help others how to deal with it. With this I have given it a place, accepted and enjoy the nice things in life despite my chronic disease”.*

Experiences of health professionals

For the HCP the self-management program has changed the character of the outpatient visits significantly. Sometimes patients will start the consultation with a proposal to change their treatments based on their outcomes. The HCP will discuss the pros and cons of the proposal with the patient and a truly shared decision will finally be made. Of course, there is a wide range in the degree of self-management between the different patients, similar to a visual analogue scale it can vary from a situation in which the healthcare provider decides alone to a situation in which the patients tells the HCP what he or she decided. It is a continuous learning process for both the patients and HCPs, and because of this the discussions during the outpatient clinic become more and more well matched.

Conclusion

Currently in the management of patients with chronic diseases, more attention is being given to the patient's ability to adapt and self-manage their disease. The consequence of this is a change in the relationship between healthcare professional and patient: from a paternalistic to a shared decision approach. Currently the percentage of patients with chronic disease who practice self-management is still quite low. The rising health care costs and the decreasing number of available healthcare professionals in the near future compels us to find solutions in the short term. It would be very helpful if we are able to increase the percentage of patients who can manage and monitor themselves. In this respect the following aspects are important takeaways:

- an easy to understand electronic health record with a well-organized dashboard informing both the patient as well as the healthcare professional about the status of the different health domains
- attention should be paid to educate both patients as well as healthcare professionals
- use one electronic system for both the patient and healthcare professional
- the healthcare professional should discuss with the patient the results of the self-management and self-monitoring process.

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7

General discussion

General discussion

As outlined in the introduction, online self-management programs seem like a promising way to support patients in their active role in their own health. Ideally patient input and underlying social theories are used to increase acceptability and effectiveness when developing such programs, and therefore an online self-management enhancing program was developed in collaboration with rheumatoid arthritis (RA) patients and healthcare professionals, based on social theories [1,2].

This thesis was part of a larger project in which three online programs were developed and tested for patients with chronic diseases: rheumatoid arthritis, cardiovascular risk and severe mental Illness. The project involving cardiovascular risk patients is ongoing, and analysis of the exploratory trial is in progress. Results of the exploratory trial from the project involving patients with severe mental Illness are already published [3]. This thesis focuses on a research project for patients with RA, in which: 1) an online self-management program 'Coping with RA' was developed, aiming to increase self-management behaviour in RA patients; 2) this online program was tested in a feasibility study as preparation for a larger trial, including a qualitative interview study to assess reasons for usage and non-usage.

Developing the program

The online program was intentionally developed so that patients could use it independently, without the need for supervision or guidance. Intervention mapping (IM) was used as the underlying framework [4]. The three main development steps of IM are: 1) a needs assessment combined with a literature search (*Chapter 2*); 2) input into program development from a multidisciplinary panel of professionals and patients (*Chapter 3*); and 3) program evaluation (*Chapter 4*). Owing to the complexity of online self-management programs, the outcomes and feasibility of the program were evaluated in an exploratory 'pilot' study, in preparation for a larger trial [2].

A multidisciplinary panel of five RA patients, two rheumatologists, one rheumatology nurse, a psychologist, a physiotherapist, an occupational therapist, and three researchers shared knowledge, visions and experiences throughout the entire development process of 'Coping with RA', to ensure that the online program was tailored to the health problems and (support) needs of RA patients.

Development step 1 was thus a needs assessment, to gain insight into patient self-management support needs. This needs assessment was performed using input of the multidisciplinary panel from two brainstorm sessions, and was combined with a scoping review in which literature was selected based on relevance, rather than study quality. According to the assembled results, RA patients need information on various topics: performing physical exercises, medicine use, treatment options, fatigue, and problems at work. There also appears to be a need for social support, aiming to maintain everyday life. Patients furthermore appear to need emotional and practical support to cope with the impact of the disease and to receive understanding in their work situation. Practical support needs included adaptations at patient workplaces or help with housekeeping *(Chapter 2).*

This list of needs was the basis for the further development of the program. Based on the theory of 'planned behaviour' [5] several behavioural change techniques (BCTs) were fitted to the needs and inserted in the program. These BCTs were derived from an established manual to ensure that potentially effective techniques were included in behavioural change interventions and to ensure the use of standardised definitions of BCTs, which is crucial for the replications of research [6,7].

In Development Step 2, with the help of the multidisciplinary panel all BCTs were converted into practical applications, such as texts, diaries or videos of role models, which were consequently adapted to patient preferences. The result of this design phase was that the program consisted of 10 modules: a welcome module and nine modules focusing on the following behavioural change goals: balancing rest and activity, setting boundaries, asking for help and support, use of medicines, communicating with health professionals, use of assistive devices, performing physical exercises, coping with worries, and coping with RA. After logging-in, patients arrive at a starting page with access to all these 10 modules, presented as an overview with pictures (Figure 1). In the welcome module, a questionnaire was available with which the patient could gain insight into their own support needs and level of self-efficacy. This was followed by information about which module(s) treated these support needs. The patient was expected to choose any modules to engage with themselves *(Chapter 3)*.

Testing the program

To test the feasibility of the online self-management program and to gain insight into potential treatment effects, an explorative randomised controlled trial was performed (*Chapter 4*). In this trial, 157 outpatients with RA were randomised to either be given access to the online self-management enhancing program, or not to get access ('usual care'), with assessments at baseline and at six and twelve months. The outcome measures included self-management behaviour, self-efficacy, general health status, coping with fatigue and the level of pain and fatigue.

Given the results of the explorative study, we had to conclude that only a minority of the patients used the online self-management program and that the outcomes did not point to beneficial effects for patients with RA. Moreover, as there were virtually no between-group differences in any of the several outcomes, none of the outcome measures could be selected as a potential primary outcome for a follow-up trial. The pre-planned interview study with 21 intervention participants, users as well as non-users of the online program, revealed four main issues that may at least partly explain the lack of effect in the exploratory trial. Some patients were not intrinsically

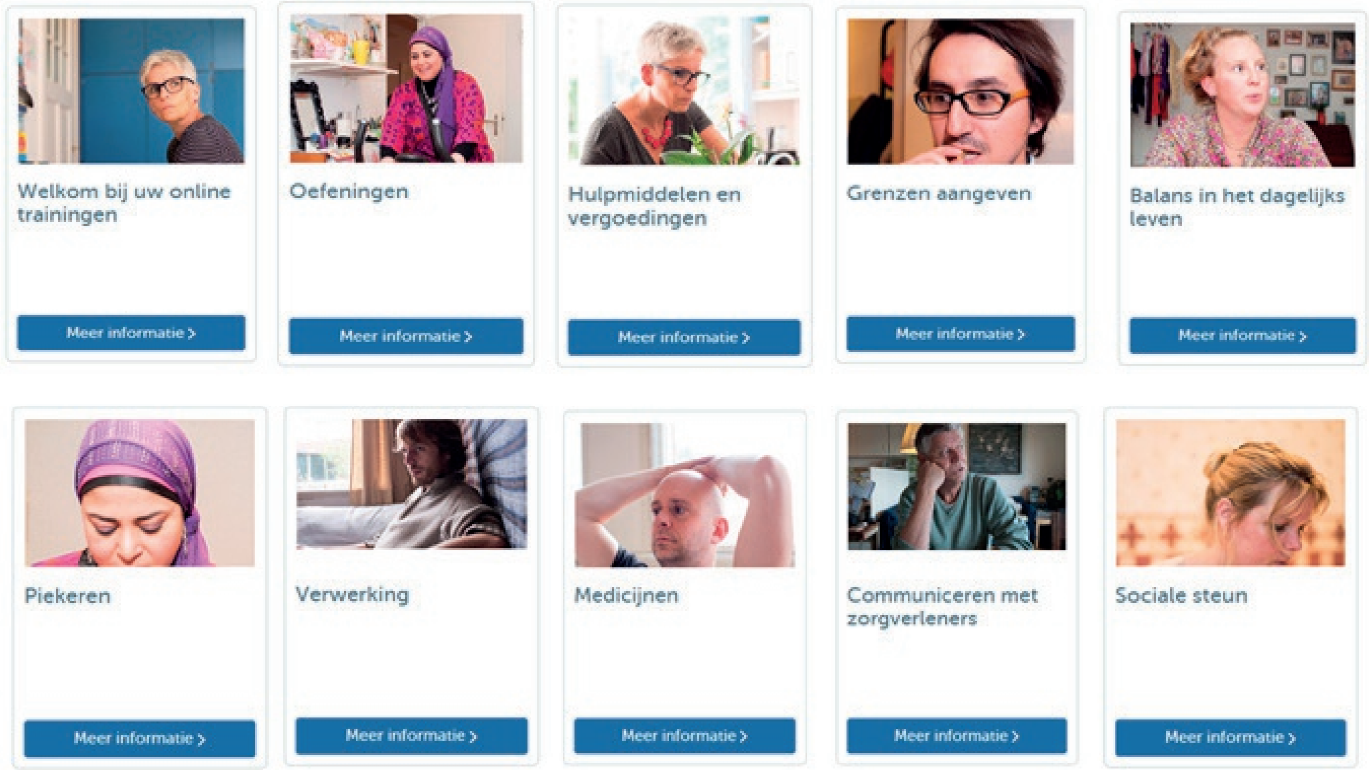


Figure 1 Overview of the 10 modules of the program

motivated to start and participate in the program at all (first phase of behavioural change). This may also be due to a second finding, that patients had no clear expectations of the program or had expectations that were not met by the program. Similarly, there appeared to be a mismatch between individual support needs and the needs included in the program. Lastly, no triggers or reminders were sent for use of the modules in the program. Some patients experienced IT problems (mainly log-in problems), and others stated that they needed more (online) support from a health professional during participation in the program.

Experience was collected in parallel with another online program, 'Reumanet', for patients with inflammatory rheumatic diseases, which includes RA (*Chapter 6*). The program was devised as a tool for patients to monitor and manage their disease outcomes and aimed to support self-management behaviour. Experience was collected from 1125 patients to whom the online program 'Reumanet' was offered. The evaluation showed that n=790 (70%) patients used the program at least once a year. Of them, n=100 (13%) used the self-monitoring tool. The remaining patients were questioned about not using the online program.

The most commonly reported reasons for not using the program were: not having a computer or email address, or unwillingness to use a digital environment at home.

In summary, the online self-management program for patients with rheumatoid arthritis was based on a social theory and developed together with patients and professionals. Despite thoughtful development, the pilot study did not suggest any effectiveness and the use of the program was disappointingly low. The project involving patients with severe mental illness had similar results [3]. In the explorative randomised controlled trial, 'E-IMR', an online program to enhance self-management behaviour, was tested against 'usual care' in n=60 patients meeting the Dutch severe mental Illness criteria. The online program was only used by n=14 users (34.1%), precluding definite conclusions on its potential efficacy. It appears that participation in an online self-management program is not self-evident or attractive for patients.

Reflections on the main findings

These findings may lead to a conclusion that the RA patients included in the exploratory trial comparing e-health versus 'usual care' were not 'ready' to engage on their own with a self-management program, however, as the results of the project involving e-health for severe mental illness also show, the issue is potentially larger. Online self-management programs can be seen as complex interventions, in which patient factors interact with the intervention itself and with the ICT background [2]. A range of possible outcome measurements are used and e-health is generally offered in a broad target population with a large variability.

Evaluation of such a program is not straightforward. Nevertheless, to gain insight into the potential effectiveness of the intervention, we evaluated the online self-management program in an explorative study after its development. Based on these results, it was decided not to perform a larger trial yet, because there is an unanswered question: why did we find no positive results? Although the interview study pointed to four factors resulting in a lack of effect, we will discuss other possible reasons below.

Methodological reflections

The strength of this online self-management enhancing program lies in its systematic development, with the input from the literature, patients and professionals, and theoretical underling strategies, as recommended in the intervention mapping (IM) framework [8]. The online program was adapted to patient support needs and patient preferences for the program features [9]. BCTs were carefully chosen and the program was pre-tested by RA patients [7]. Quite in contrast, the results of the explorative trial were disappointing because no clinical effects were found compared to the 'usual care', and the accompanying qualitative study even pointed to presence of unmet expectations. The main question is therefore: why did the program not work as expected? To answer that question it is worth taking a closer look at decisions made during the development phase.

Development phase of the intervention

Based on the belief that online self-management programs have various advantages in comparison to face-to-face or group self-management interventions for patients, a decision was made to develop an unsupervised online self-management program [10,11]. However, it was not assessed whether RA patients would find 'online programs' an appropriate way of self-management support. It may well be that not all patients endorse online self-management programs, and instead may prefer a group self-management program or a face-to-face session with a health professional. In future, an assessment about what RA patients think is the best way to improve self-management should be conducted as a first step.

It is possible that the multidisciplinary panel was not representative of the general RA population. The patients participating in the panel had a positive attitude towards online self-management programs and presumably were experienced in managing their disease, according to their long disease duration. The discussions suggested that they could mostly manage their life well, which made it difficult to remember their struggles in daily life after onset. As a consequence, the program was possibly developed with a focus on patients who were motivated to use an online self-management program. In future, it is recommended that a more heterogeneous multidisciplinary panel be composed, and should also include patients with a more 'average' attitude and/or less developed disease knowledge and level of experience. This same applies for testing the online self-management program. In our pre-test, patients with computer skills and a positive attitude towards online programs tested the online program, which is considered satisfactory for first tests but which may not have been a representative usability test.

It turned out that the behavioural change techniques (BCTs) that were inserted in the program required a lot from patients. For example, the 'giving feedback' BCT was included in the program, but not guided or explained by a health professional. Patients needed to convert this feedback on their own into behavioural change. The involvement of a health professional may ensure that patients can understand the feedback received, and could help them to apply the feedback to their situation.

Focus is recommended on the implementation of the online program during development [8]. Our strong focus on the content of the program may have meant that less attention was paid to the implementation. We did not explore possible barriers and facilitators to enhance patient use of the program, or to select patients to whom the intervention would be offered. This may have meant that the online self-management program was offered to a 'broad' target population with a different attitude than the patients in the 'development panel' and that consequently the program was generally not appreciated in the target population as helpful or meeting patient needs.

Several specific self-management behaviours were taken into account, by formulating performance objectives such as: *'the patient is able to take their described medication on time'* or *'the patients has knowledge about how to take their medication'*, however, we did not measure these specific formulated performance objectives, which could be a reason that no positive effects were found for patients on our selected outcome measurements. Although we selected our outcome measurements carefully, it were standardised questionnaires which did not measure our performance objectives exactly. Measuring these various behaviours, depending on the individual patient, is not possible with the standardised questionnaires on health outcomes and behaviour that we chose. On the other hand, it is assumed that the performance objectives indeed will translate in 'better health' or more 'satisfaction'. Despite this, it may be that these questionnaires contained items which were not very important to individual patient situations, or that these questionnaires did not contain items relevant to the patients. Based on this progressive insight, we could conclude that we did not measure patients' specific behavioural changes after participating in the online program and that measuring on a patient's individual level (using e.g. the goal attainment scale (GAS)) would be a better way to measure outcomes.

In conclusion, the developmental phase is a challenging process, in which many choices need to be made. The above described reflection on the development process gives insight into choices that could have influenced the effectiveness of the program negatively.

Online self-management programs targeting RA patients

It is generally accepted that conventional (not: online) self-management programs in RA can be beneficial [12,13]. While the online self-management program we developed did not suggest any effectiveness, it was considered useful to take a closer look at other recent trials of online self-management programs. The questions were: 1) is there sufficient evidence that other online self-management programs in RA are effective? and: 2) can something be learned about critical success factors from these trials?

Online self-management programs and trials

We performed a systematic literature search to find published randomised controlled trials of online self-management enhancing programs in patients with RA. Three such studies were found (Table 1), from Lorig [14], Cheryl [15] and Ferwerda [16]. There were thus four online programs tested in our study, which aimed to improve the self-management behaviour of RA patients. All four studies had a long term follow-up of nine or twelve months and compared the Dutch adult RA patients in an intervention group with a group who received care as usual. Ferwerda's study [16] included a specific patient population with an elevated level of distress. The durations of the intervention differed (from six weeks to twelve months) were guided by a peer or professional, except in our program. The content of the interventions partly corresponds (topics such as pain and fatigue were included), but there was a great variety of program features (personalised to-do-list, chat functions, diaries). Various outcomes were measured (Table 2).

Outcome measurements

Because the focus of self-management programs is on behavioural change, it is expected that behavioural change is an important outcome to measure. For RA patients, disease specific outcomes such as pain, fatigue, and functional disability are also important (secondary) outcomes (Table 2). It is notable that behavioural change is measured in only two of the four studies. All the outcome measurements for behavioural change, such as the Patient Activation Measurement (PAM-13) and the short Self-Management Ability Scale (SMAS-S) to assess self-management behaviour were general validated outcome measurements. None of the studies measured outcomes of behavioural change at the individual patient level. Impact on daily life and physical symptoms were measured in all studies(see Table 2, second column). Lorig measured role activities, and Cheryl measured role limitations and physical functioning. It can be concluded that a wide range of domains is measured in different ways in these four studies, which all aim to improve self-management in RA. Notably, no significant positive effects were found in behavioural change in the two trials where it was measured (Table 2). This could be a consequence of not measuring on an individual patient level. Significant positive effects in favour of

Table 1 References, study objective, number of participants target group, comparison, target group, intervention content and intervention delivery of selected studies.

References	Study objective	N=participants	Comparison
Lorig, K.R. et al. 2008 [14]	Testing an internet-based arthritis self-management program	Intervention group: N=233* Control group: N=227*	Care as usual vs. care as usual with the online program in addition
Cheryl L. et al. 2013 [15]	Testing an online self-management intervention with weekly telephone support	Intervention group: N=55 Control group: N=53	Care as usual vs. care as usual with the online program in addition
Ferwerda, M. et al., 2017 [16]	Testing an internet based tailoring cognitive-behavioural intervention	Intervention group: N=62 Control group: N=71	Care as usual vs. care as usual with the online program in addition
Zuidema, R.M. et al., 2018	Testing an online self-management enhancing program	Intervention group: N=78 Control group: N=79	Care as usual vs. care as usual with the online program in addition

*Lorig's study also included patients with fibromyalgia and osteoarthritis.
In this table, only the included RA patients are described.

Target group	Intervention content	Intervention delivery	Used underlying theory
Stable adult RA. Not participated in a self-management program. Access to a computer and agreement to participate in the program	A 6 week online program with an interactive component, a discussion board, tools for individual use (medication diaries) and 16 workshops	Trained peer moderators led each workshop and reminded patients to log on, offered encouragement and posted to the discussion board.	Social cognitive theory
Stable adult RA patients, no co- morbidities, not participated in a self-management program, willingness to participate in the online program.	The 10 online week program with ten educational modules and individual features, such as a personalised to-do list, a news feature and a resource library and self-monitoring.	A weekly contact with counsellor to encourage program use	Social cognitive theory
Adult RA patients with an elevated levels of distress	An internet-based cognitive behavioural intervention tailored to the individual's goals and characteristics with four modules consisting of assignments and psycho educational texts.	A therapist explored patients main issues during a face-to-face intake session and had a (bi-)weekly contact with patients to response with feedback on treatment assignments, explanation, explanation of the next assignments, practical tips and encouragement	Cognitive behavioural therapy
Adult RA patients, able to read/speak Dutch, access to a computer	A 12 month program consisting of nine modules targeting behavioural change and an online diary to track patient's level of fatigue and pain over time.	Nurses brought the programme to the attention of the intervention group participants during their consultation	Theory of planned behaviour

patients who participated in a self-management program were found in the following domains: health status/quality of life, impact of the disease in daily life, self-efficacy and psychological functioning (Table 2). Considering these significant positive effects and based on the Cohen D effect sizes of 0.2, 0.5 and 0.8 indicating a small, medium, and a large effect size, it should be noted that effect sizes in the studies of Lorig and Ferwerda were small to medium. Although the largest (thus medium-sized) effect sizes were reported by Ferwerda, for depressed and negative mood, anxiety and psychological functioning, the drop-out rate of the study was high. Of the 62 patients allocated to the intervention, only 38 completed it. Selective drop-out may thus have contributed to the effect size. Follow-up rates in Lorig's study were higher: of all patients (n=433) randomised to the intervention, only 24 patients did not participate in the program, and after 12 months, 44% of the patients who participated in the program had improvements of ≥ 0.30 effect size for three of the six health behaviours, compared with 30% of the usual care control group. The mean number of improvements at one year of ≥ 0.30 effect sizes among the six health behaviours was 2.4 for treatment participants and 1.8 for usual care control participants. These may be considered small favourable effects. Cheryl's study reported large effect sizes for self-efficacy and quality of life. In contrast to our study, the three other online programs all found positive effects in some of the outcomes. Two of the three programs reported only small effects, and there were no robust effects in common also outcomes. It can nevertheless not be excluded that online self-management programs can be effective for RA patients. These studies probably also give insight into factors that may determine the success/failure of the intervention.

Possible explanatory factors

The pre-planned interview study that we performed for our own study with RA patients showed four main issues that may at least partly explain the lack of effect: not all patients were motivated to start and use the program; patients had no clear expectations of the program; a mismatch between individual support needs and the needs included in the program; it was an intervention without 'live support'. The three additional trials in RA were evaluated to obtain insight into probable factors explaining the success or failure of the interventions, which is discussed below.

Being motivated to use the online program

Whereas Ferwerda selected a target group with an elevated level of distress, because the program focuses on patients with a psychological risk profile, the 'broadness' of the study population used by Lorig and Cheryl is comparable to our study. Both offered the program to a general population 18 years or older, with access to the internet and being able to speak and read the concerning language of the study) and added motivation to participate in the program as selection criteria as well, which

Table 2 An overview of domains in which the programs were effective after 9 months (Cheryl et al. 2013) and twelve months (all other studies)

Studies	**Health status/ Quality of life**		**Impact disease in daily life**								**Symptoms**		**Health behaviours**					**Self-efficacy**
	Future health status	Quality of life	Disability	Role limitations	Physical functioning	Role activities	Self-care	Mobility	Role limitations physical health problems	Role limitations emotional health problems	Fatigue	Pain	Aerobic exercises	Stretching and strength exercises	Communication with physician	Practice stress management	Self-management behaviour	Self-efficacy
Lorig	●		○			●					○	○	○	○	○	○		○
Cheryl		●		○	○							○						●
Ferwerda							○	○	○	●	○	○						
Zuidema		○									○	○					○	○

○ measured in the study

● Significant results after 9 or 12 months

Table 2 Continued

Studies	Health care utilisation					Disease activity	Compliance care	Social support			Psychological functioning					
	Physician visits	Emergency visits	Days in hospital	Chiropractic visits	Physical therapy visits	Patient reported disease activity	Compliance rheumatologic care	Social interactions	Social support	Loneliness	Negative mood	Anxiety	Depression	Health distress	Affective	Coping with fatigue
Lorig	○	○	○	○	○									○		
Cheryl								○	○	○			○		○	
Ferwerda						○	○				●	●	●			
Zuidema																○

○ measured in the study
● Significant results after 9 or 12 months

could be an essential inclusion criteria. In our study, it was implicitly assumed that patients were motivated to perform self-management if they agreed to participate in the study and we assumed that in the program itself barriers in the behavioural change process would be tackled, however, patient motivation to perform self-management was not formally assessed using, for instance, a needs assessment. The program was also offered to patients without the pre-planned use of implementation strategies, such as one-on-one education or using small media (e.g. printed materials and videos) to enhance patient motivation or to reduce barriers before or during use of the online program. In conclusion, the absence of a positive effect from the program could have been caused by the fact that we did not carefully select potential successful users at the right time. A self-management intervention may be appropriate for patients if they were already in the action stage or maintenance stage (intrinsic motivated) and perceived no external barriers to performing self-management behaviour. External barriers can be tackled by the insertion of implementation strategies.

Tailoring to individual patient support needs

Although each session in our program had its own goals, these goals were formulated based on the general needs assessment. It was therefore expected that the nine modules, diary pain and fatigue covered all the support needs that users had for self-management at that time, because the program was developed after a general needs assessment and a matrix of performance and change objectives (chapter 3, page 30). We assumed that patients were able to choose the appropriate module and session to support themselves in their self-management behaviour, after filling a questionnaire to receive insights into their support needs. Ferwerda's program was fully tailored to the individual goals of patients, which were assessed during a face -to-face intake session with the help of a health professional. The therapist selected relevant texts and assignments based on a patient's treatment goals, which meant the program was fully adapted to the patients. (Bi)-weekly contact with a health professional was also possible, for example for instruction or encouragement. In Lorig's program, patients could set their own goals, and made action plans based on their behavioural problems, which may make the program more relevant for the individual patients. In Cheryl's program, a personal display with tasks prompts patients to go through the self-management modules. Although patients did not set goals or make action plans, their activity was discussed via weekly telephone contact with a health professional.

In conclusion, a general needs assessment is not enough with which to assess individual patient support needs. Offering the whole program to patients without assessing individual needs across the care continuum and without any guidance for using the program or setting tailored goals with an action plan, may lead to suboptimal support from the program.

Guided or unguided program

In our program, there was only a questionnaire in the welcome module to help patients choose a module. Nurses had no role in guiding patients through the program, while all other programs were guided by a health professional or a peer. The lack of information and the divergent expectations of patients, the low motivation to start with, and the perceived need for contact with a health professional, could be solved by improved dissemination and implementation strategies. Health professionals can play an important role, such as offering education or motivational interviews (blended-care), or by supporting patients in goal setting. Our trial participants reported that contact with health professionals would have been an important in addition to online programs. In the online programs by Lorig and Cheryl, health professionals or peers had a ((bi)-weekly) contact with patients during the program to instruct, support or motivate them. The results of these studies yielded small positive effects, however, except for Cheryl's study. A reason for this could be that the health professionals in that study were trained in cognitive behavioural therapy, while Ferwerda's therapists were supervised by a senior clinical physiologist with post academic training in cognitive behavioural therapy. None of the studies gave insight into the tools that health professionals/ peer leaders used to motivate and support the patients, or whether health professionals were educated to guide patients in self-management behaviour. These findings suggest that the involvement of well-trained health professionals or peers has an added value in program performance. Several other studies also report that the involvement of health professionals could support and guide patients to overcome barriers, which leads to better results for patients [17-19]. In conclusion, it could be that patients in our intervention were unguided and unsupervised, and that the supporting care of a health care professional was lacking. It seems that a well-trained health professional plays an essential role in stimulating patients to change their behaviour. An online self-management program may be seen as a supportive tool, rather than the main instrument.

Based on the analysis of the other trials above, it can be concluded that there are four possible success factors: the outcome measurements, patient selection, the inclusion of dissemination and implementation strategies, and the (un)guidance. Apart from being 'outcome measurements', these factors were corresponding or related to the factors which were found in the interview study. While the purpose of an exploratory study is to learn, it is necessary to be explicit about the lessons learned. In the next section, recommendations for future developments in e-health interventions to increase self-efficacy (in patients with rheumatic disorders) will be given.

Recommendations

How to choose the program outcomes?

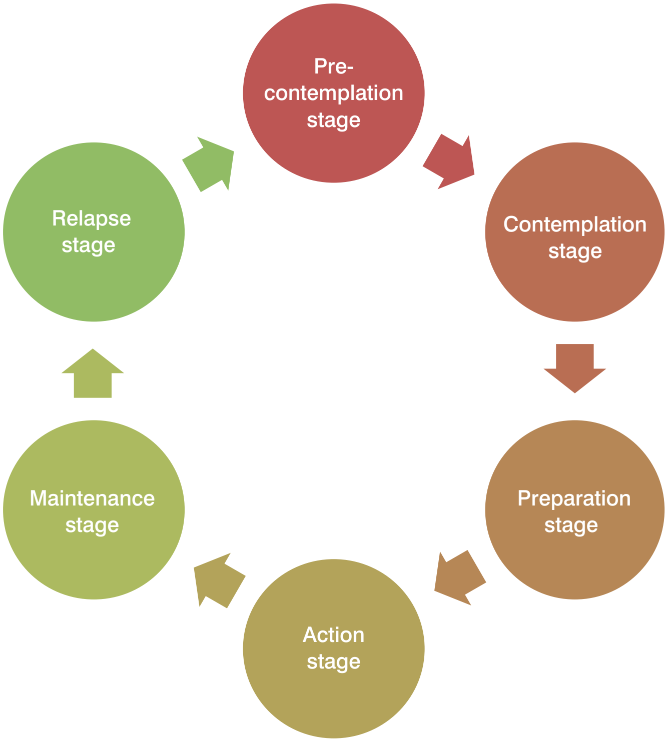
The goal attainment scaling (GAS) or Canadian Occupational Performance Measure (COPM), for example, can be used to measure individual patient behavioural change or treatment goals [20 21]. These methods score the extent to which a patient's individual goals are achieved during the course of the intervention. Patients identify their own goal and the level of these goals is determined by the patient's current or expected level of performance. For example, a patient can set the following goal: I'm prepared for my next visit to the rheumatologist. Depending on the patient's level of performance, 'prepared' means: being on time (more easy level) to 'writing my questions down'.

How to select and motivate potential users?

Patients should be screened in their stage of change, and a single online program offered only to patients in an action or maintenance stage. To increase the effectiveness of such single interventions and make the intervention appropriate for a larger general population, it is also useful to identify the determinants of (potential) barriers and facilitators that patients may experience, and to match implementation strategies to the identified barriers and facilitators [22,23]. According to the model of behavioural change, patients can adopt self-management behaviour depending on their stage of change. There are six stages of change in the process of behavioural change: 1) pre-contemplation stage in which the patient is unaware of the problem behaviour and their support needs for self-management (no change expected), 2) contemplation stage in which the patient is aware of the problem behaviour, but does not desired to change this behaviour, 3) preparation stage in which the patient intents to take action for behavioural change, 4) action stage in which patients practice their desired behaviour, 5) maintenance stage which means that the patient tries to sustain the behavioural change, and 6) the relapse stage which means that the patient falls back into their old patterns of behaviour [24].

These six motivational stages are affected by personal, including demographic, characteristics, disease-related characteristics and coping style and contextual factors such as work environment, support of the family and environmental quality of life [25]. The level of motivation can also differ between behaviours (e.g. someone can be motivated to take prescribed medication on time, while he/she is not motivated to perform physical exercises). The level of motivation can therefore be affected by various factors (stages can go both backwards and forwards), which can affect the use of an online program.

Figure 2 Stages of the process of behavioural change following the model by Prochaska and DiClemente [24]



How to tailor the program to patient needs?

Individual patient support needs for self-management should be assessed across their care continuum, and their progress in reaching individual goals over time should be measured. It may be also relevant to assess whether patients need an online program without any guidance, or whether they might prefer a blended care intervention, or only face-to-face contact with a health professional. After this assessment, a care plan can be made. To match online programs to a patient's individual support needs, it is necessary to pay attention to a patient's individual support needs and changes over time [26]. There is a growing number of studies that highlight the dynamic and changing nature of patient needs across the care continuum [26,27]. This also reflects the fluctuating nature of RA, such as disease activity, stiffness or fatigue that can lead to changing support needs and the different phases patients experience, such as diagnoses, stabilisation, and acceptance of illness [28-31].

How to implement the program in standard care?

Health professionals should be involved from the beginning in the online program, using motivational interviewing and shared decision making as tools to prepare patients to change their behaviour. Offering a tailored online program can support patients in making their behavioural change and maintaining that change. Health professionals need to be trained in supporting patients in their self-management; for example, they need to have the skills to use motivational interviewing and shared decision making as tools [23].

Implications for practice

The online self-management enhancing program did not support RA patients in their self-management behaviour. Offering the online program in the way it was done in this project is not feasible. Lessons learned in this project can be used in practice to enhance the use and effectiveness of existing programs or to improve this program. It is clear that patients need to be intrinsically motivated to participate in the program and need to be aware of their support needs for self-management. Health professionals can play an important role in the screening of appropriate (motivated) patients and in teaching patients to become aware of their support needs and use of online self-management programs, however, supporting patients in their self-management requires certain competencies in health professionals. They need to have a positive attitude towards online programs and the concept of self-management. The implementation of motivational interviewing (MI), combined with shared decision making (SDM) and goal setting is effective and thus advised in daily practice [32,33 34]. In this light, health professionals should be supported by their organisation to perform SDM and MI, and need to be trained regularly.

Implications for research

The feasibility study presented in this thesis was conducted in preparation for a larger trial. Based on the results of the study, a larger study is not recommended yet. Until now, it has been difficult to examine the modes of action and effectiveness of online self-management programs due to the various dimensions which influence the effectiveness. The program itself, and the active input of patients and health professionals, for example, can be reasons for a (non-) successful online program. The lessons learned from our study can be used in the future to optimise the online program and to select appropriate patients. The research design used in our feasibility study, an exploratory RCT, did not enable us to react to the shortcomings of the implementation during the study, for example to adapt selection criteria for the inclusion of patients. A feasibility study with an adaptive design (e.g. stepped wedge design) could be performed to overcome this. This will help to gain cumulative evidence for possible influencing factors, such as the contextual factors and working elements of the program.

Health professionals, stakeholders and patients should also be more involved during the implementation phase of the project. More studies about the efficacy of online programs with the involvement of health professionals (blended-care) should be conducted. These studies should report in a standardised way, reporting specific issues of blended care interventions in detail, for example the attitude of health professionals towards online self-management programs or the BCTs used by health professionals to motivate patients in program use.

Overall conclusion

Developing and implementing an online self-management enhancing program is a challenging process. Although a structured developmental approach was used in collaboration with patients and professionals, this thesis shows that it did not lead to positive outcomes for patients. The studies contributed to increased insight into the challenging developmental process and outcomes of an online self-management program for patients with rheumatoid arthritis. Although online programs seems to be a promising way to support patients with RA in their self-management, several barriers should be overcome in the development, daily practice and evaluation of online programs.

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Summary

Dankwoord

About the author

PhD portfolio

Summary

Chapter 1

This chapter introduced a new proposal for the concept of health from Huber: "'Health as the ability to adapt and to self-manage, in the face of social, physical and emotional challenges". This patient centred concept challenges patients to take an active role in their own health, which is also important for patients with rheumatoid arthritis (RA). Taking responsibility and performing self-management behaviour are therefore crucial. A commonly used definition of self-management behaviour is: "the ability to manage the symptoms, treatment, physical and psychosocial consequences, and lifestyle changes inherent in living with a chronic disease". Performing self-management behaviour means that patients need to undertake a wide range of actions, for example, to take medication on time, perform physical activities or to cope with the emotional consequences of the disease. Rheumatoid arthritis (RA) is a chronic inflammatory disease which can lead to joint damage and bone destruction. Despite the development of new drug treatments (DMARDs and biologicals), patients often experience physical symptoms such as pain, stiffness and fatigue, and psychological consequences, such as anxiety or a depressive mood, which leads to a loss of work productivity or difficulties performing daily activities. To control and reduce the impact of RA in daily life, patients need to self-manage the consequences of their disease, however, performing self-management behaviour is difficult and patients often struggle in daily life. Supporting self-management behaviour is therefore essential.

The aim of this thesis was to develop and test an online self-management enhancing program 'Coping with RA' for Dutch adult rheumatoid arthritis patients. The intervention mapping (IM) framework was used during the development of this intervention. The IM framework consists of three primary activities 1) a needs assessment combined with a literature search (Chapter 2), 2) input from a multi-disciplinary panel of professionals and patients in the program development (described in Chapter 3), and 3) program evaluation. The program evaluation was based on an exploratory randomised controlled trial to test the effectiveness and feasibility of outcome measures (described in Chapter 4) and a qualitative interview study to obtain insight into patients (non-) usage of the program (presented in Chapter 5. Chapter 6, describes an experience with an online self-management tool called 'Reumanet'. In Chapter 7 we reflect on the study outcomes and the lessons learned are discussed.

Chapter 2

This chapter describes a scoping review that was conducted for input from the literature. The results give an overview of self-management support needs from the perspective of rheumatoid arthritis patients. Seventeen articles were included for review. According the results, patients with RA had informational, emotional, social and practical support needs. Information was needed about various topics, such as exercises and medication. Patients expressed a need for emotional support in daily life, given through other RA patients, their colleagues and supervisors or nurses. It is important that information needs, emotional and social support are tailored to the individual needs of the patient. A multidisciplinary panel of professionals and patients validated the findings in the literature. The results of the scoping review, together with the patients' perspective were used as a starting point for the development of an online self-management enhancing program, tailored to RA patient needs.

Chapter 3

Based on the results of the scoping review in Step 1, the next step was used to develop the content of the self-management enhancing program which was focussed on behavioural change techniques (BCT). Together with patients and the multi-disciplinary panel of professionals, the eight most important health problems in daily life were selected: pain, fatigue, stiffness, daily functioning, sexuality, work, social activities, and coping with RA. Subsequently, nine needs were identified: (1) balancing rest and activity, (2) setting boundaries, (3) asking for help and support, (4) use of medicines, (5) communicating with health professionals, (6) use of assistive devices, (7) performing physical exercises, (8) coping with worries, and (9) coping with RA. Determinants relevant to the above mentioned needs were selected to tailor the BCTs: knowledge, awareness, risk perception, social influence, attitude, self-efficacy, and habits. Objectives were formulated, describing what should change in the patients' behaviour per determinant. For example, an objective of the knowledge determinant is "the patient knows the consequences of not setting boundaries; and for the determinant attitude, "the patient is aware of the potential positive consequences of setting boundaries". BCTs were translated into the following practical applications: informational and persuasive texts, videos, exercises with feedback options, assignments, an intake schedule and an online diary to track patients' levels of pain and fatigue over time (see table 2 page 30). The resulting program consisted of an introduction module and nine modules dealing with the nine needs. Patients could use the online program as often as they wanted, working through a module or modules at their own pace. An implementation plan was written, focusing on the dissemination of the online program and the user's experience of interacting with the online program. The following implementation strategies were deployed during the study: 1) a written instruction manual for the program for each patient, 2) reminders to (re)-use the programme were sent bi-weekly via e-mail to the patients during the period of 12 months access, 3) nurses brought the programme to the attention of the intervention group participants during their consultation. Nurses were informed that the patients in the intervention group could have questions about the program or their self-management behaviour. They were instructed to answer these questions, but did not guide patients actively to use the program. Patients could call the helpdesk when they experienced problems with the program (e.g. log-in problems) or had questions about the program (e.g. where they could find specific information). An evaluation plan was also written, explaining the aims of our feasibility study, inclusion criteria and outcome measurements.

Chapter 4

Chapter 4 reports on the exploratory RCT of the online self-management enhancing program. This study aimed to explore the potential efficacy of the online self-management enhancing programme versus ‘usual care’. Outcome measures focussed on self-management behaviour, self-efficacy, general health status, coping with fatigue and the level of pain and fatigue. Potential effectiveness was evaluated by determining the effect sizes at six and twelve months after baseline and 2) by identifying outcome measures most likely to capture the benefits covered by the performance objectives.. A multicentre exploratory randomised controlled trial was performed in two Dutch hospitals in Nijmegen, with an intervention and a control group. Both groups received care as usual, and in addition, the intervention group received 12 months access to the online self-management program. All patients were diagnosed with RA, aged 18 years or older, were able to speak and read Dutch and had access to a computer with an internet connection. Patients who received psychiatric or psychological treatment were excluded. A linear mixed model for repeated measures, using the intention-to-treat principle, was applied to study differences in the outcomes between the intervention (n=78) and control (n=79) groups. A sensitivity analysis was performed in the intervention group to study the influence of patients with high (N=30) and low (N=40) use of the intervention. No positive effects were found regarding the outcome measures and effect sizes were low. Fewer patients used the program than expected. Based on these results, it was not possible to conclude positive effects of the intervention or to select outcome measures to be regarded as the primary/main or secondary outcomes for the future trial.

Chapter 5

This chapter describes a qualitative interview study which aimed to explain the results of the exploratory randomised controlled trial (RCT) as described above. Patients who were randomised to the intervention group in the explorative RCT were interviewed to explore the reasons for their (non-) usage of the program. Purposive sampling (n=21) was used to select patients from four groups out of the total number of patients in the intervention group after filling in the T1 questionnaire (six months after baseline) (n=59): 1) non-users; 2) low users; 3) high users basic; 4) high users plus. Results demonstrated that the program supported only a small group of patients because: 1) Not all patients were motivated to use the program, and BCTs in the online program reached only patients who visited the program. Less motivated patients were thus not reached. 2) Patients had no clear expectations or had different expectations of the program, because less attention was paid to how to use the program and less on what the program could bring them. 3) Although a thorough need assessment was conducted, there was a mismatch between individual patient support needs and the needs included in the program. 4) Reminders were only sent to fill in the diaries for pain and fatigue, not to use the program modules, which was apparently not enough to motivate patients to re-use the program.

Chapter 6

This chapter describes the experiences with the online self-management program called 'Reumanet'. Reumanet is an online personal health environment that is in principle available for patients and rheumatologists. Patients can also decide to give access to their outpatient nurse, their general practitioner and/or physiotherapist. The online personal health environment includes all patient characteristics, questionnaires, graphical overviews, lifestyle advice and feedback opportunities, e-health modules and other relevant information adjusted for the individual patient with an inflammatory rheumatic disease (IRD). By November 2017, 1125 patients with an IRD had been invited to participate in Reumanet Bernhoven. The degree to which patients made use of Reumanet Bernhoven differed widely. According the Reumanet user data, 70% (n=790) of the patients used the online program at least once and only 13% (n=100) used the self-monitoring tool. The remaining patients (n=335) were questioned about not using Reumanet. The most common reason was not having a computer or email address, or not wanting to use a digital environment at home. To increase patients usage of the online program, it is expected that it is important that patients find useful information in this digital environment and therefore it is important to involve patients in the development of such an online program. It is also important to teach patients how to use it; to enhance their continuous usage patients need to receive feedback about it from their health professionals at outpatient clinic visits. Further development should thus focus on strategies to enhance patient motivation and the integration of Reumanet in daily practice in the outpatient clinic.

Chapter 7

This thesis demonstrated the complexity of developing and testing an online self-management enhancing program for patients with RA. Despite the structured development in collaboration with patients and professionals, no effects were found. Reflection on the development process suggested that several choices could have resulted in a lack of effect: 1) our assumption that online self-management support would be the way patients preferred to be supported in their self-management behaviour was probably not right, 2) the composition of our multidisciplinary panel, with patients with a positive attitude towards online self-management programs and a long disease duration, was not representative of the general population of RA patients, 3) offering the online program without any guidance requires intrinsically motivated patients with the knowledge and skills to perform self-management behaviour, and 4) there was a lack of focus on the implementation of the program during the development process. Not selecting the most appropriate patients could also have resulted in finding no effects. Selecting patients based on their stage of behavioural change (patients in the action or maintenance stage) would have been helpful to overcome barriers. It also seems that a general needs assessment was not enough to adapt our program to individual patient support needs. Assessing patient needs across their care continuum and formulating and evaluating a patient's individual goals can help to tailor the online program to the individual patient. The involvement of a health professional is needed to do this, and motivational interviewing (IM) and shared decision making (SDM) could be used as tools to guide the individual patient. To reach a large population, it is necessary to enhance patient motivation (patients in the pre-contemplation stage) to use the program. Implementing the online program as a single intervention does not seem to be enough to reach a larger group. Dissemination and implementation strategies are recommended. In conclusion, offering the online program as it was done in this project is not feasible. Lessons learned in this project can be used in practice to enhance the effectiveness of this program or other online programs. Both patients and professionals should be educated about their changed roles within the concept of 'patient centred care'. The research design used in our feasibility study, an exploratory RCT, did not enable us to react to the shortcomings regarding the implementation during the study, for example to adapt selection criteria for the inclusion of patients. To overcome this, a feasibility study with an adaptive design (e.g. stepped wedge design) could be performed. This will help to gain cumulative evidence of possible influencing factors, such as contextual factors and working elements of the program.

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Jorrit, 112 S.O.S hulplijn. Ik heb je heel wat gebeld voor hulp. Jouw relativerende adviezen helpen altijd goed.

Lieve Joep, wat is het toch leuk samen! Jij bleef altijd relaxt als ik weer eens ging werken en zocht dan ondertussen op je Ipad een mooie reis op om weer eens te gaan ontspannen. Vanaf nu hebben we meer tijd om samen te zijn en te genieten van Nore.

Ik kan niet wachten om weer te gaan reizen en dan nu met z’n drieën! Lieve Nore, ik kon soms moeilijk afstand doen van mijn laptop, maar voor jou ging dat zonder problemen. Nu kunnen we nog vaker samen van de glijbaan en op de wip-wap.

About the author

Rixt Zuidema was born in Drachten, Friesland on November 9th 1985. After finishing the secondary school in 2002, she studied nursing and worked as a trainee at the UMC Groningen (department cardiology and thorax surgery), Wilhelmina Ziekenhuis Assen (orthopaedics) and Nij Smellinghe, Drachten (neurology). Following her graduation in 2009, she started to study for her Master Degree in Sociology at the Rijksuniversiteit Groningen and graduated in 2012. In the mean time, she worked as research assistant at the Department of Social Psychology on a research project for quitting to smoke. After graduating she continued this position part-time and started also to work as research assistant at NIVEL (Netherlands Institute for Health Services Research) in a research project to optimize patient safety in Dutch hospitals. In 2013, she moved to Nijmegen to a research position at the Scientific Institute for Quality of Healthcare of the Radboud University Medical Center Nijmegen. She carried out the study “Participatory development and evaluation of an online self-management enhancing program for patients with Rheumatoid Arthritis”, described in this thesis. From 2016 she worked for about 1,5 year as project leader at OCE Nijmegen and coordinated projects aiming to improve elderly care in General Practices. Since, 2018 she is project leader at Bernhoven hospital in the Netherlands and coordinates projects related to self-management in patients with Rheumatoid Arthritis and shared decision making.

PhD portfolio

Radboudumc
university medical center

Name PhD candidate
R.M. Zuidema

Department
IQ healthcare

Graduate School
Radboud Institute for Health Science

PhD period
01-01-2013 – 28-02-2019

Promotor(s)
Prof. Dr. M.W.G. Nijhuis-van der Sanden
& Prof. A.M. van Dulmen

Co-promotor(s)
Dr. B.G.I. van Gaal & Dr. J. Fransen

	Year(s)	**ECTS**
TRAINING ACTIVITIES		
a) Courses & Workshops	e.g.	*e.g.*
- Pubmed basics, Radboud University Nijmegen	2013	0.1
- Pubmed advanced, Radboud University Nijmegen	2013	0.1
- Endnote workshop, Radboud University Nijmegen	2013	0.1
- NCEBP introduction course for PhD students, Radboud University Nijmegen	2013	1.5
- Advanced Conversation, Radboud University Nijmegen	2013	1.5
- Basis cursus regelgeving en organisatie voor klinisch onderzoekers (BROK), Radboud University Nijmegen	2014	1.5 1.5
- Intervision meetings	2013-2015	
- Summercourse Intervention Mapping, University Maastricht	2013	1.75
- Presenteren eigen onderzoek, Radboud University Nijmegen	2015	1.5
- Academic Writing, Radboud University Nijmegen	2015	3.0
- Multilevel analysis, VU medisch centrum	2016	1.0
b) Symposia & congresses		
- Association for researchers in psychology and health (ARPH congress)	2013	0.3
- The European Leage Against Rheumatism congress (EULAR) (poster presentation)	2014	1.0
- Nederlandse Vereniging Reumatologie (NVR) Najaarsdagen	2014	0.3
- IQ health congress Nijmegen	2016	0.3
- The European Leage Against Rheumatism congress (EULAR) (oral presentation)	2018	1.0
c) Supervision of internships / other		
- Refereerbijeenkomsten IQ healthcare	2013-2017	0.5
- PhD meetings Verplegingswetenschap	2013-2017	0.5
- Supervision of internships	2014-2017	1.0
- Member of RIHS PhD Council	2015	3.0
TOTAL		21.45