PROTOCOL – PhD project

E-learning in patient education to patients with rheumatoid arthritis
- An evaluation of the effectiveness, the patient perspective and the implementation
Summary
Patient education is an important element in the treatment and care of patients with rheumatoid arthritis (RA). Today, there is a shift in the organisation of healthcare systems due to a demographic change towards ageing populations and an increasing use of technology. The aim of this study is to evaluate an e-learning patient education program based on self-management and targeting patients with RA.

Background
Patient education (PE), with the aim of supporting patients to self-manage their disease is considered an important part of the treatment and care offered to patients with rheumatoid arthritis (RA) (1, 2). According to recommendations from the European League Against Rheumatism (EULAR), PE enables patients to self-manage their illness, cope with their condition and thereby maintain a higher quality of life (2). RA is a chronic inflammatory disease with a rising prevalence due to the aging demographic (3, 4). This places new demands on the healthcare system, where time for sufficient PE may be limited. However, today, advancements in web-technology can offer alternative ways to provide PE, including e-learning programs.

Self-management, self-efficacy and behaviour change
Within the field of rheumatology, nurses play an important role in supporting patients to actively participate in the treatment of their chronic conditions and in achieving self-management skills (5). The Stanford Arthritis Self-Management Programme (ASMP) (6, 7, 8) is built on social cognitive theory (9) and implemented for many different chronic diseases (6, 7, 8). According to ASMP, self-management means having or being able to obtain the skills and resources necessary to best accommodate the chronic disease and its consequences (9). Self-efficacy, that is, the confidence a person feels about performing a particular activity, is considered a pre-condition of self-management (10). It has been shown that self-management education can lead to behaviour changes for patients with chronic diseases, and thereby improve outcomes, such as increased self-efficacy and treatment adherence, higher self-rated health, increased aerobic activity and decreased depression and anxiety (1). The way in which these behaviour changes take place is based on social cognition theory, such as the Common Sense Model of Health and Illness (CSM) (11, 12, 13).

The CSM is a hierarchically organized model and is an adaptive system featuring three main constructs: (i) ‘representation’ of the illness experience that might guide (ii) action planning or ‘coping’ responses and the performance of these, followed by (iii) ‘appraisal,’ or monitoring of the success or failure of coping efforts (12, 13). Hence, the CSM is a self-regulatory model that may explain how patients construct their own representations or models that help them make sense of their experiences of illness and treatment and provide a basis for their own coping response, that is, self-management (12, 13).

Patient education in RA
Educational needs vary among individuals and can change throughout the course of a disease (2). For this reason, it is recommended that PE in RA be individually tailored and include knowledge of the disease and treatment, non-pharmacological treatment, pain control, self-help methods, activity regulation, physical exercise, behaviour changes and emotional issues (2). At the minimum, PE must be offered at the time of diagnosis and when pharmacological treatment changes (2). PE can be provided face-to-face or on the web, supplemented by phone calls and written or multimedia material (2).

Thus far, only a small number of high-quality randomized controlled trails (RCT) have been conducted within the area of web-based PE targeting people with RA; most of the evidence comes from other chronic conditions. In an American RCT study, the effect of a web-based cognitive-behavioural self-management program was tested among 106 patients with RA. The study found beneficial effects in self-efficacy and quality of life (14). Another American RCT study among 855 patients with arthritis and fibromyalgia tested a web-based self-management program (15). This study showed improvements in health distress, activity level, self-reported global health, pain and self-efficacy (15). A German RCT study among 561 patients with diabetes or low-back pain showed that a web-based interactive health communication application enhanced patients’ knowledge and feelings of empowerment (16). In a Stanford study, a total of 761 patients with diabetes were randomized to a web-based self-management program of standard care. The study found an improvement in haemoglobin A1C-level, patient activation and self-efficacy for patients in the intervention group (17). Finally, a smaller RCT study in patients with atopic dermatitis found that web-based PE increased knowledge about the disease and reduced disease severity (18).
Patient education and web-technology

Today, approximately 90% of families and 79% of people over 65 in Denmark have access to the Internet (19), but variation is seen in health literacy and computer skills. In low-income groups, 17% have no access to the internet, and the use of health-related digital sources is lower among people with low educational levels (19, 20). Therefore, health literate principles, that is, the cognitive and social skills that enhance patient involvement in shared decision making with healthcare providers (21) must be taken into consideration when designing modern health information and services (22). Even so, PE based on web technology may have several advantages. First, a web-based PE program can be accessed repeatedly, and repetition of a performance increases the person's self-efficacy (10). Second, the integration of words and images in web-based PE can promote deeper understanding and learning since both auditory and visual channels are used (23). Moreover, it may be beneficial for patients to access the program at their time of convenience in familiar surroundings and possibly with relatives. A web-based PE program is expected to enhance the quality of care by standardisation of PE because of consistent program delivery (15) and individualisation simultaneously, as both the content and process are programmed (15). Furthermore, the program offers the possibility to move around based on individual need for information and repetition. Possible disadvantages may be related to the absence of face-to-face contact with healthcare professionals who may encourage and motivate patients through their interrelationship and communication.

Evidence shows that so-called entertainment education (EE) can improve self-efficacy by merging educational content with entertainment messages in order to increase knowledge, create favourable attitudes and change behaviour (24, 25). The main elements are narratives, stories and messages, combined with facts in an entertaining manner (24, 25). A web-based PE program based on EE has been pilot tested recently among patients with low HL skills who suffer from knee osteoarthritis, osteoporosis and RA (26). Preliminary results indicate that EE interventions may help patients better understand and manage their diseases (26).

Development of an e-learning PE program targeting RA patients

Given the need for alternative solutions to the standard face-to-face contact, we have developed an e-learning program targeting newly diagnosed patients with RA ahead of this study. We began the development in the spring of 2019, and it will be finished in the beginning of 2020.

Program theory

The e-learning program is based on a program theory inspired by Funnel and Rogers (27), who described how theories of change can explain the drivers by which behavior change occurs in individuals and where theories of action can explain the interventions that can activate these changes.

We use the Common Sense Model of Health and Illness (CSM) (12, 13) to explain how the e-learning program is expected to promote self-management behavior.

Theoretical framework of the e-learning PE program

The theoretical framework in the development and design draws on elements from the cognitive theory of multimedia learning (CTML) (23), which outlines the process through which people build coherent mental representations from words and images (23). It is based on the assumption that there are two separate channels (auditory and visual) for processing information and that channel capacity is limited. Further, CTML assumes that learning is an active process of paying attention, organizing and integrating information with existing knowledge (23). Elements from the theory of EE have also been included in the design (24, 25).

Focus groups

We have applied a focus group methodology (28) to inform and develop the content of the e-learning program. We wanted to explore the perspectives of both patients and professionals on the informational and educational needs related to RA and how this may be communicated in an e-learning program. Therefore, three focus groups were established; two for patients and one for healthcare professionals. Patient groups were divided into a group of patients who have been newly diagnosed with RA (< 1 year) and a group of more experienced patients with longer disease duration (> 1 year). The group of healthcare professionals consisted of two doctors and three nurses with various employment and experiences within the field of rheumatology. Literature covering educational needs among patients with RA and everyday life with RA (29, 30, 31, 32) were used to form the interview guide and data collection. Interviews were held for patients and for professionals separately, and thematic analysis was applied to analyze the data (33).
Four themes, covering experiences and needs emerged in the analysis of the interviews; ‘Knowledge of RA’, the disease course and prognosis’, ‘Medical treatment’, 'A new life situation' and ‘Daily living with RA’.

**Design of the e-learning program**

The program was developed through an iterative process between the project group, patient representatives, a communication consultant, graphic designers and an e-learning company (Guide2know).

The development of the different elements in the e-learning program all started by writing manuscripts of the content. This was done by LRK and ATH and subsequently this was adapted to storyboards by the e-learning company and graphic designers. The aim of this process was to ensure presentation in spoken language as well as consistency and a common thread in the tone, a logical and structured learning design, and appropriate amounts of content and continuously activating of participants. Subsequently, the content was recorded by a speaker, and graphic designers produced all graphic parts related to the spoken words. As the target group of the e-learning program is broader with respect to age, health qualifications and knowledge, we intended to avoid text-heavy presentations, and text was only applied in order to support the spoken words. The platform consists of a navigation site, which creates an overview of the program, and the progress of the program for the individual user.

The e-learning program is divided into three learning modules: (i) disease, medication and FAQ, (ii) additional information about disease, treatment and examinations, and (iii) daily living with RA, e.g. coping with emotions, pain, fatigue, work, education, travelling etc. Moreover, the platform contains supplementary information such as advice on physical activity, networking platforms, documents of medication and links about where to find more information etc. Documents for download were integrated, to support users with low functional health literacy or people who speak a foreign language. Further, quizzes were used for self-evaluation of understanding. Quizzes also provide feedback to the users about their understanding.

Module 1 consists of ‘need to know’ information about disease management, symptoms and medication. Thus, it is mandatory and must be completed before entering module 2 and 3. In module 2 and 3, patients can move around on the basis of their individual needs. The duration of the full program is approximately one and a half hour, but can vary dependent on the individual user needs. The program is targeted patients with early onset RA. However, the program also contains information which is relevant in later disease stages, and hence, the program is expected to be useful throughout the disease course as a supportive tool where patients can obtain information dependent on needs, interests and challenges.

In keeping with CTML and different ways of learning, the program offers a combination of animations, videos with patients and health professionals, graphics, podcasts, written text and spoken words. The intentions behind EE were implemented by personal patient stories, podcasts, animations and interactive quizzes.

Module 1 is available at the following link (confidentially).

An overview of the program theory and theoretical framework can be seen in Figure 1, and an overview of the development process can be seen in Figure 2.
Figure 1: The program theory of the e-learning program

The figure explains the construction of the program, that is, the theories, activities and interventions that are expected to promote self-management behavior in patients with RA attending PE through the e-learning program.
The development process was inspired by Elwyn et al. (34). The figure shows the development of the e-learning program from the clarifying and content specification phase to the design of the platform. The rectangles cover the content of the phases and the circles illustrate the involvement of collaborators and stakeholders throughout the development.

**Feasibility testing of the e-learning program**
The e-learning program is ready for feasibility testing this spring. Thus, we will test and assess patient’s acceptability and use of the PE program and its user interface before the beginning of the present PhD project. The results from the feasibility test will be used to make adjustments to the e-learning program if necessary and where possible.

The acceptability and usefulness of the content of the e-learning program and the user interface will be assessed through individual cognitive interviews with approximately ten patients with RA. Patients will be recruited in connection with an out-patient visit in the rheumatology clinic, Aarhus University Hospital (AUH), and will be selected purposively to ensure heterogeneity and diversity regarding gender, age and disease duration.

A study nurse will introduce patients to the program and the purpose of the test. The test will be conducted as a cognitive interview (35). Patients will be asked to go through the program and the study nurse will observe and make notes of questions and comments throughout the assessment.

Methodologically, the practice of cognitive interviewing falls into two general techniques: ‘think aloud’ and verbal probing following an interview protocol (36, 37). Through the think-aloud technique, informant-initiated rather than interviewer-initiated data can be collected as the technique allows examination of the informant’s perceptions with minimal interference from the interviewer. In the study, this technique will come into use by asking the patients: ‘What comes into your mind when you see/hear/read this?’

Subsequently, patients will be interviewed about their perceptions of using the program, comprehensibility of the content, reader-friendliness, layout, length of presentations, the amount of
presentation, etc. An interview guide will be formed. Systematic content analysis will be used to analyse the interviews by exploring recurring patterns and themes (38).

**Studies and objectives**
Given the limited evidence about the effectiveness and patient perspective of web-based PE in RA and the complexity of implementation of a new technology in clinical practice, the intention behind the present study is to evaluate the described e-learning program.

The project will be divided into three parts:

*Study I – A randomized controlled trial, evaluating the efficacy of an e-learning PE program.*
The objective is to assess the effectiveness of the e-learning PE program in improving self-efficacy, knowledge of RA and medication, medication adherence (medication taking), health literacy (HL) skills and quality of life in patients who have been newly diagnosed with RA.

*Study II – The patient perspective of an e-learning PE program.*
The objective is to explore the perceptions of receiving PE through the e-learning program from the perspective of patients with RA.

*Study III – The implementation of an e-learning PE program in clinical practice.*
The objective is to explore the complexities in the e-learning program and to improve chances of success in implementation of the technology in daily clinical practice.

**Hypothesis**
An e-learning PE program will be superior to standard face-to-face PE in improving self-efficacy.

**Material and methods**

**Study I – Assessing the effectiveness of e-learning in PE; a randomized controlled trial**

*Design*
A pragmatic randomized controlled trial will be carried out at four rheumatology clinics in the Central and North Denmark Region. In Denmark, approximately 1,300 patients are diagnosed with RA each year, and approximately 300-350 are diagnosed from the four clinics (39).

Patients who meet the inclusion criteria and have given written informed consent will be randomized 1:1 to either PE delivered through an e-learning program provided at home or standard face-to-face PE provided at the outpatient clinics. Due to the nature of the intervention, blinding is not possible. However, assessment of baseline data will be made before randomisation.

*Study population and recruitment*
Patients will be recruited in connection with an out-patient visit between October 2020 and February 2022 and will be considered eligible for the study if they have been diagnosed with RA according to the American College of Rheumatology 2010 criteria (40) within the past 3 - 4 months, are ≥ 18 years, able to speak and understand Danish and able to access the Internet. As methotrexate (MTX) is drug of choice in RA (41), patients must be treated with MTX as monotherapy or in combination with other disease modifying anti-rheumatic drugs (DMARDs) at baseline.

*Intervention*
Patients in the intervention group will have access to the e-learning program through a link send to them personally, by secure mail via e-Boks. They will be asked to accomplish the program within four weeks. A study nurse will introduce patients to the program and patients will be encouraged to go through the program as many times as necessary and involve family and relatives if they like.

*Control*
Patients in the control group will receive standard face-to-face PE from a nurse within four weeks after inclusion. Relatives can take part in the conversation.

Furthermore, patients in both the intervention and control group will be offered one individual educational session with a physiotherapist and one with an occupational therapist, if needed.
Outcomes
The primary outcome is the Danish version of the rheumatoid arthritis self-efficacy questionnaire (RASE) (42). This is used as the primary outcome as self-efficacy is considered a pre-condition of self-management (10, 42), and as RASE is developed specifically for measuring self-efficacy in RA. RASE is translated and validated into Danish and the study found specificity and sensitivity to detect self-efficacy in alignment with the original British version (42). Furthermore, RASE have been used as primary outcome in a RCT-study investigating the impact from different types of outpatient care on self-efficacy beliefs (43). Secondary outcomes will be health literacy level (44, 45), adherence to medication (46), quality of life (47), knowledge of RA (48) knowledge of treatment with MTX, socio-demographic data, disease activity (49), physical functioning, pain and fatigue (50). Patients will respond to questionnaires at baseline and follow up at 1, 3, 6 and 12 months.

During the study period, the number and content of telephone contacts from patients to the outpatient clinics will be measured to investigate possible causal relationships between the information provided through PE and the need for additional information or guidance related to self-management. Furthermore, we will measure the number of out-patient visits in the clinic. Information about contacts and visits will be retrieved through the medical records.

Sample size estimation
As mentioned above, self-efficacy (42) is considered a pre-condition of self-management (10, 42), which is why it is used as the primary outcome, and also the basis for the sample size estimation (42).

A RCT study on the effect of web-based patient education, found a mean (SD) RASE of 83.9 (SD 19.0) in the intervention group receiving web-based PE and 68.5 (SD 23.8) in the control group receiving standard PE (14). We want to see at least a difference of 10% between the groups. Given a statistical power of 90%, p-value 0.05, we will need a sample size of 113 patients in each group.

To account for attrition and loss to follow-up, we intend to recruit a total of approximately 250 participants.

Statistical analysis
For baseline data, differences between groups will be evaluated by Fisher’s exact test for dichotomous variables and the Kruskal-Wallis test for continuous variables. Data will be reported as mean with standard deviation for data with a normal distribution; otherwise, data will be reported as median and interquartile range (IQR). Data will be analyzed using intention-to-treat (ITT) analysis. In the ITT analysis, missing data will be imputed using a random intercept mixed model. PP analysis will be based on evaluation of all participants who completed the follow-up visits.

Study II – The patient perspective

Design
The patient’s perspective on PE delivered through an e-learning program will be explored through a qualitative interview study based on ‘interpretive description’ (51), which is a qualitative, inductive research strategy particularly suitable for studies in clinical practice. It implies an iterative process of data collection and analysis meant to extend the analysis to confirm, test, explore and expand on the conceptualisations that begin to form when entering the field (51).

Study population and recruitment
Approximately 20 patients from the intervention group will be included. Participants will be selected purposively after having finalised the program. The selection process will continue until diversity is achieved, including participants from both genders with various ages and disease severity to ensure information power.

Study III – The implementation in clinical practice

Design
We will do an implementation study, in order to evaluate the e-learning program and prepare this new technology for implementation into daily clinical practice. The evaluation will be based on elements from the NASSS (non-adoption, abandonment, scale-up, spread and sustainability) framework (52, 53, 54).

The purpose of the NASSS framework is to identify and analyse the complexities in technology projects in order to improve the chances of success and sustainability in the implementation of a new technology (52, 53, 54). It consists of 7 domains covering the different areas in a technology project; the disease (condition), technology, value proposition, adopters, organisation, wider
system, embedding and adaptation over time. Hence, used systematically, the NASSS may offer a framework for evaluation that can be used to produce a narrative that may help to explain its successes, challenges and failures. (52, 53, 54, 55).

Focus group interviews (28) with nurses and doctors involved in the project will be conducted. Four focus groups, i.e. one in each of the participating clinics, will be established. At least two doctors and two nurses will be included in each group. We will form a semi-structured interview guide based on questions covering the domains of the NASSS framework and inspired by the study of Abimbola et al. (55).

Furthermore, we will revisit the individual interviews with patients from study II in order to obtain information about the domains in the NASSS framework from the patient perspective.

The NASSS framework will be applied as a preliminary analysis of the implementation of the intervention, and form the basis of further analysis after the end of project period, e.g. by conducting a follow-up study assessing whether, how and why the e-learning program is used outside this project.

Ethical and data approval
The study will be conducted in accordance with the Helsinki Declaration. Approval of the study and permission to use the confidential data from the Danish Data Protection Agency has been given. According to Danish Law and the Central Denmark Region Committee of Health Research Ethics, this study does not require ethical approval. Verbal and signed written consent will be obtained from each participant before enrolment.

Perspectives and dissemination plan
The intention behind this project is to form the basis of an intervention that can promote self-management and safety in the everyday lives of patients with RA and thereby enable them to cope with their condition, maintain a high quality of life and strengthen patient involvement in their own care. We expect to expand on modes of delivering health information by offering different ways of learning and thereby accommodate different needs and competences among patients. This may also strengthen the education and guidance of people with reduced psychical and social resources and thereby contribute to reducing social inequality. Furthermore, a web-based PE program may potentially bridge the gap between the healthcare system and everyday life by being an available resource throughout the disease course.

The target group of the present study is adult patients who have been newly diagnosed with RA. Yearly, a total of approximately 300 - 350 patients are diagnosed with RA in the participating clinics and these patients will benefit from the program in the short run. However, as we expect the program to be a supportive tool throughout the course of the disease and as the prevalence of RA increases due to demographic changes, the program may have the potential to improve patient safety for a growing number of people living with RA in Denmark. If the e-learning program is shown to be effective, we assume that this mode of providing PE will be adopted and implemented on a national level. Thus, the program may target a broader group of patients and contribute to sustainable high-quality healthcare at the same time as it may potentially release staff resources.

There are three key audiences for this research: patients and the public, the rheumatology team staff and academia. In order to meet the first group, we will offer to give lectures in the Danish rheumatism organization and provide written communication to people with RA through the organization. Furthermore, some elements from the e-learning program will be disseminated to the public and thereby to a wider audience than patients in rheumatology clinics. Thus, animations, videos and podcasts, which may be meaningful as independent elements, will be disseminated through e.g. Facebook, YouTube and relevant websites. For the rheumatology team, we will take part in meetings with healthcare professionals to communicate and discuss the project results and guide with the implementation of the program. Finally, we will address the academic audience through publication of the research in peer-reviewed journals and seek to present results at national and international conferences.

At least three articles will be published in international peer-reviewed scientific journals:
- A randomized controlled trial testing the effectiveness of an e-learning PE program targeting patients with newly diagnosed RA.
- The experiences of receiving PE delivered through an e-learning program from the perspective of patients with RA.
- The implementation of an e-learning program into clinical practice: a new technology to provide PE.

Furthermore, an article on the development of the e-learning program in combination with results from the feasibility testing is currently under preparation.

Funding from The Tryg Foundation to the project will be mentioned and acknowledged in the academic dissertation as well as publications and presentations at national and international levels.

**Study organization and evaluation**
The present study is initiated by the Department of Rheumatology, Aarhus University Hospital, a highly specialized ward treating patients in all areas of rheumatology. To ensure the completion of this study and expertise within all phases of the study, a steering group with representation from relevant collaborators will be established. The steering group consists of the PhD student, supervisors, doctors and nurses from the participating clinics and patient research partners. Expertise within rheumatology, clinical epidemiology, patient education, qualitative research, and patient research partners will be represented. The objective of the steering group is to ensure the completion of the study by qualifying the project throughout the testing, evaluation, discussion and reporting of results. Furthermore, an advisory board consisting of international collaborators with great expertise in PE in inflammatory arthritis patients will be involved to qualify the analysis and discussion of results as a part of PE in a broader context.

To ensure the progress of the project, the project leader will provide close follow-up in all phases. Ongoing meetings within the steering group and frequently contact with clinicians will ensure an ongoing evaluation and adjustment of procedures to ensure the completion of the study. Effectiveness of the intervention will be evaluated through relevant outcome measures as described above.
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