Development of RehApp - an information and communication technology assisted intervention at home for patients with cervical radiculopathy based on principles from an innovation model

Rasmussen, Hanne; Boyle, Eleanor; Kongsted, Alice; Manniche, Claus; Sjøgaard, Gisela; Kjær, Per

Publication date: 2016

Document version
Other version

Citation for published version (APA):
Rasmussen, H., Boyle, E., Kongsted, A., Manniche, C., Sjøgaard, G., & Kjær, P. (2016). Development of RehApp - an information and communication technology assisted intervention at home for patients with cervical radiculopathy based on principles from an innovation model. Patient@home.

Terms of use
This work is brought to you by the University of Southern Denmark through the SDU Research Portal. Unless otherwise specified it has been shared according to the terms for self-archiving. If no other license is stated, these terms apply:

• You may download this work for personal use only.
• You may not further distribute the material or use it for any profit-making activity or commercial gain
• You may freely distribute the URL identifying this open access version

If you believe that this document breaches copyright please contact us providing details and we will investigate your claim. Please direct all enquiries to puresupport@bib.sdu.dk
Development of RehApp - an information and communication technology assisted intervention at home for patients with cervical radiculopathy based on principles from an innovation model

Authors: Hanne Rasmussen¹², Eleanor Boyle¹³, Alice Kongsted¹⁴, Claus Manniche², Gisela Sjøgaard¹, Per Kjær¹²

Affiliations
1 Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark
2 The Spine Centre of Southern Denmark, Lillebaelt Hospital, Middelfart, Denmark
3 Dalla Lana School of Public Health, University of Toronto, Toronto, Canada
4 Nordic Institute of Chiropractic and Clinical Biomechanics, Odense, Denmark

Context
The framework for this project is a large Welfare Technology Project entitled “Patient@home” that seeks to promote rehabilitative training at home in order to reduce the costs of hospitalization, transportation, improve patient healthcare and reduce the use of health care services. The development of the RehApp project was done in collaboration with researchers from the Department of Sports Science and Clinical Biomechanics at the University of Southern Denmark; engineers and students from The Maersk McKinney Moller Institute; the company ExorLive; and clinicians and patients from the Spine Centre of Southern Denmark. The work has been supported by grants from The Strategic Research Council, The Council for Technology and Innovation, and Vækstforum Fyn.

Odense 30th October 2015
Working group in Patient@home
Hanne Rasmussen, Alice Kongsted, Gisela Sjoegaard, Eleanor Boyle, Anne Marie Rosager, Berit Schiøttz-Christensen, Claus Manniche, Ulrik Pagh Schulz, Kenneth Kristensen, Maziar Taghiyar-Zamani, Jørgen Bondy, Per Kjaer (workpackage leader).

Working group at the Spine Centre
Per Kjaer, Hanne Rasmussen, Berit Schiøttz-Christensen, Claus Manniche
### Index

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall background and aim</td>
<td>5</td>
</tr>
<tr>
<td>The innovation process</td>
<td>6</td>
</tr>
<tr>
<td>Need</td>
<td>9</td>
</tr>
<tr>
<td>Screening of literature and best clinical practice</td>
<td>9</td>
</tr>
<tr>
<td>Descriptive and qualitative studies of patients with CR</td>
<td>10</td>
</tr>
<tr>
<td>Screening Technology</td>
<td>10</td>
</tr>
<tr>
<td>Concept</td>
<td>11</td>
</tr>
<tr>
<td>Partner identification</td>
<td>11</td>
</tr>
<tr>
<td>Idea generation</td>
<td>12</td>
</tr>
<tr>
<td>Mock-ups of prototypes</td>
<td>14</td>
</tr>
<tr>
<td>Testing and adjusting</td>
<td>16</td>
</tr>
<tr>
<td>Proof of concept</td>
<td>25</td>
</tr>
<tr>
<td>Background and aims of the feasibility study</td>
<td>25</td>
</tr>
<tr>
<td>Methods</td>
<td>27</td>
</tr>
<tr>
<td>Data analyses</td>
<td>30</td>
</tr>
<tr>
<td>Results</td>
<td>32</td>
</tr>
<tr>
<td>Discussion</td>
<td>38</td>
</tr>
<tr>
<td>Conclusion</td>
<td>41</td>
</tr>
<tr>
<td>References</td>
<td>42</td>
</tr>
<tr>
<td>Appendix 1</td>
<td>44</td>
</tr>
<tr>
<td>Interview guide (patients)</td>
<td>44</td>
</tr>
<tr>
<td>Appendix 2</td>
<td>45</td>
</tr>
<tr>
<td>Interviewguide til test af ‘Reh-app’ (Kliniker)</td>
<td>45</td>
</tr>
<tr>
<td>Kliniker information og spørgsmål om ‘Reh-app’</td>
<td>45</td>
</tr>
<tr>
<td>Appendix 3</td>
<td>46</td>
</tr>
<tr>
<td>Results of the patient interviews the concept phase</td>
<td>46</td>
</tr>
</tbody>
</table>
Appendix 4

Results from focus group interview with health care professionals

Appendix 5

Spørgeskema om RehApp
Andre kommentarer:

Appendix 6

Summary of suggestions and recommendations
Overall background and aim

It is estimated that between 8,000 and 10,000 Danes every year experience arm pain originating from their neck (ref). This pain may be the result of pressure on the nerve root by a herniated disk or degenerated joints in the neck. The condition is known as cervical radiculopathy (CR) [1]. About a quarter of the patients with CR are referred for surgery. While the vast majority are offered patient education and exercise therapy [2]. We know that exercises have a positive effect on patients with non-specific neck pain, but in terms of patients with CR, we do not know which type of exercise is the most effective [3].

Due to the severity of the CR symptoms and the associated pain-related activity limitation [4-6], patients with CR need monitoring and guidance as part of their care to detect worsening, to prevent development of chronic pain, and improve recovery. In some patients, sudden worsening of the condition requires fast medical attention that may result in the need to consult with a spinal surgeon. Also, it seems vital that patients experience control over their own situation and are able to maintain a normal life. Since the acute phase is generally characterized with severe pain, patients might be hindered in seeking timely healthcare because of their inability to travel to a healthcare provider. It is therefore relevant to identify and test new approaches and strategies to improve the healthcare management for this patient group. At the same time, there is an increasing demand in Denmark and in Western countries for interventions for common conditions that are less expensive and require less healthcare personnel.

The use of information and communication technology (ICT) such as telemedicine has been implemented for a variety of different conditions such as, heart failure [7], chronic obstructive pulmonary disease [8] and diabetes [9]. ICT assisted interventions at home might be beneficial for patients with CR, since it would be possible monitor their symptoms, introduce monitoring and interventions for CR that support patients in being able to manage their condition from their
home. In addition, this may reduce the need of services from the healthcare system and at the same time detect worsening that requires immediate medical attention.

The overall aim of this project was therefore by innovative procedures to develop and test an ICT assisted intervention that could improve health care management for patients with CR in an effective way.

**The innovation process**

*Patient@home* works according to an innovation model that forms the basis of the products and services being developed in the project. The innovation model has five phases: 1) Requirement/Need assessment; 2) Concept development; 3) Proof of concept; 4) Products/Services development; 5) Testing and Evaluation (see Figure 1). Depending on the individual innovation process, the various phases can be of different lengths and contain more, less, or other activities than the ones listed in Figure 1.

The innovation process may start at different stages. However, in general, all innovation projects start no later than phase 4 (Product/Services) in order to make room within the project period for testing and adaptation of the solution in question. Based on this innovation model, a prototype of an application for patients with cervical radiculopathy was developed and tested in a feasibility study. The general processes in the innovation and feasibility project is illustrated in Figure 2.
Figure 1. The Innovation Model from Patient@home
1. Literature reviews
   Clinical best practice
   Guidelines
2. Longitudinal and Qualitative studies of patients with CR
3. Screening of ICT

**Need**

**Concept**

- Partner identification
- Idea generation
- Mock-ups
- Testing and adjusting of ICT-intervention

**Proof of concept**

- Test of a prototype of RehApp in a feasibility study

**Product/service**

- Design and construction of a final version of RehApp as an ICT intervention

**Test and evaluation**

- Technology assisted intervention at home for patients with CR:
  - A randomized controlled trial

*Figure 1. The innovation process in the development of RehApp.*
Need

The demands and needs for developing /optimizing treatment approaches and care management strategies for patients with CR were identified by: 1) screening of literature regarding diagnostics [10, 11] and types of treatment [3], discussion of best clinical practice with researchers in the interdisciplinary working group in Patient@home, clinicians at the Spine Centre of Southern Denmark and through participation in developing a national clinical guideline [12]; 2) description of the patient cohort using a longitudinal observational study [4] and using two qualitative studies consisted of an intervention mapping study at the Spine Centre [13] and a master’s thesis about the “lived experience” for the patient [14]; and 3) screening of ICT technology in collaboration with researchers and engineers. This took place during the period from 2013 to 2015. Following needs and requirements were identified:

Screening of literature and best clinical practice

Diagnostics

The screening of the literature showed there was a variety in diagnostic criteria and they were all poorly described [10]. In an unpublished literature review of the diagnostic value of provocative and neurological tests it was found in a few and very heterogeneous studies that neurological tests (specifically tests for reflex impairment and muscle weakness) in combination with patient history and other physical findings, may be the most optimal method of diagnosing CR [15].

Treatment

There were a few studies with low evidence of effective interventions for CR [3]. In discussions with researchers and clinicians, it was recognised that the main focus in best clinical practice for patients experiencing signs of CR were in the first phase of the condition to inform about the condition, guide the patient in relation to appropriate coping strategies, and exercises and activities that would not increase radicular pain and symptoms. In addition, individual exercises
with focus on posture, neuromuscular and directional preferences could be relevant. This was also emphasized in the Danish national clinical guidelines for CR[12].

**Descriptive and qualitative studies of patients with CR**

The observational study of patients with neck pain with and without CR was conducted in the Spine Centre of Southern Denmark. At the first visit, CR patients had the most severe profile among all neck pain patients. The CR patient group had more pain, increased reporting of sick leave and more pain-related activity limitation [4] compared to other types of neck pain patients. These findings underpin the need for identifying and testing effective interventions that can address these problems. In the intervention mapping study, qualitative focus group interviews were conducted in patients with CR. Some of the major and repeated concerns/comments from the patients were about being more involved in their own care, receiving more education on their condition and achieve a greater degree of understanding from the outside world [13]. The results from the master thesis: ‘The 'un-just' Factor: Balancing Life in the Lived Experience of Cervical Radiculopathy’ - a qualitative study of patients’ experiences, revealed similar comments and concerns as in the intervention mapping study. In addition, patients expressed increasing sense of feeling isolated and not confident or anxious about their situation and condition.

**Screening Technology**

Based on the identified needs, the challenge was whether or not researchers, engineers and companies were capable of developing and delivering ICT technology that was able to: monitor patient progress, deliver information, guide exercise and register data for feedback to the user as well as for research purposes. Screening of the market for ICT technology and meetings with developers of ICT was initiated to identify an ICT solution that could support this.

In this process, several ICT technologies such as exercise applications, software programs, sensors for biofeedback, web-based-video platforms, headsets, elastic rubber bands with sensors were presented and discussed at meetings between companies, engineers and researchers. The collaborators in this phase were engineers, researchers and students from Maersk McKinney
Moeller Institute at the University of Southern Denmark, and small to medium size enterprises such as Digimovez, Mobile Fitness, iCura, DorsaVi, SportsSensor/Bandizer and ExorLive.

Concept

In this phase relevant collaborators/partners were identified and partnerships were formed. Time and financial limitations were taken were also taken into account.

Idea generation based on the identified needs and requirements in the first phase formed the concept and the first mock-ups of prototypes of the ICT intervention.

A user-involved iterative process with developing, testing and collecting feedback and responses on mock-ups and prototypes of different versions of the RehApp took place from January to April 2015.

Hanne Rasmussen (HR), physiotherapist in the Spine Centre and research assistant in the project was in charge of conducting the tests and interviews.

Partner identification

A partnership evolved between the Department of Sports Science and Clinical Biomechanics, Exorlive, and engineers and students from Maersk McKinney Moeller Institute to develop a web-based application platform with the option of adding other ICT supported interventions. A partnership with the Spine Centre of Southern Denmark was formed in order to give access to the potential users (patients and clinicians) of the ICT intervention.
Idea generation

Intervention

The result of the requirement/need phase was a need for developing an ICT supported intervention that could meet patient-expressed needs in terms of information and education in a way that the patient would feel involved with their healthcare and feel confident in handling their condition. It should be aligned with scientific evidence in literature, expressed focus areas from best clinical practice and recommendations from the clinical guidelines. Finally, the ICT supported intervention would need to be capable of collecting information about the course of CR and responses to the treatment strategies. Based on this it was decided to develop a web-based application platform with the option of adding other ICT options. The application was named RehApp.

The basis for developing the prototype of RehApp was a clinical decision algorithm developed in collaboration with researchers at the Department of Sports Science and Clinical Biomechanics. Based on knowledge about this patient group, it was decided that in the more sub-acute phase, exercises should be general and cardiovascular-related type as this would allow the patient to stay fairly active and maintain physical fitness without worsening their pain or CR symptoms. If the patient tolerated this, more specific exercises and activities would be initiated (Figure3). Therefore, the original intent was to develop an application that based on the patient’s pain level and severity of nerve root symptoms would direct the patient to the most appropriate action or exercise. When a patient reports increasing pain in their arm, they would be advised to stop doing their current exercise strategy and a different exercise strategy would be recommended and/or a pain relieving positions would be recommended. If the arm pain continued to increase over a two day period and/or they developed severe worsening of the condition in terms of loss of strength and sensitivity in the arm or legs, or loss of control over bladder and bowel function (so-called red
flags) (need to finish the thought). If the patient felt that their CR symptoms had improved, they would be advised to progress their exercises and activities.

Figure 2. Clinical decision algorithm for individualized exercise to patients with cervical radiculopathy
Outcome measures

It was discussed which methods to use for testing the feasibility and potential effects of the intervention. In relation to this, the use of individual and group interviews and questionnaires related to relevant patient outcomes such as pain and function were suggested.

In relation to relevant test methods, development of interview guides for interviews with patients and clinicians and a questionnaire for use in the feasibility study were planned. It was also decided to explore the possibility and value of adding questionnaires about disability in arm, shoulder and hand and pain (DASH) [16] and pain self-efficacy (PSEQ) [17] to the routine collection of patient demographics and bio-psycho-social profiles from the SpineData database used at the Spine Centre.

Design of interview guides and the RehApp questionnaire

Interview guides for patients and clinicians were prepared based on knowledge from the intervention mapping study and input from researchers at the Department of Sports Science and Clinical Biomechanics at the University of Southern Denmark. The RehApp questionnaire for the feasibility study was developed based on the responses to the interview guide during the testing of the RehApp prototypes.

Mock-ups of prototypes

The prototype RehApp underwent adjustments and changes according to input from the users, clinicians and researchers. These inputs and suggestions were discussed at meetings between researchers from the Department of Sports Science and Clinical Biomechanics, ExorLive and engineers from the Maersk McKinney Moeller Institute. If relevant, in relation to the identified needs as well as realistic and feasible within the budget and time frame, the adjustments to the application were made by the engineers, students and HR.
3 versions of prototypes of the RehApp were tested in a sample of patients aged 18 years or more, had at least one clinical sign of cervical nerve root compromise, pain equal to or above 3 on numeric pain rating scale (0-10) in one of their upper extremities [18] and were able to understand, speak and read Danish. The patients were invited to test RehApp at their first visit to the Spine Centre. HR introduced consenting patients to the RehApp. They were given verbal as well as written information and guidance. The study was presented for The Regional Committees on Health Research Ethics for Southern Denmark and did not require approval (project-ID s-201130116). The participants used the RehApp at home for the following two weeks. They could contact HR or the Spine Centre by phone during the entire test period in case of problems with the application or worsening CR symptoms. Participants were invited back at two weeks for a semi-structured interview about their opinions of the RehApp (Appendix 1). The interviews were performed by HR and were audiotaped and later on transcribed.

The first prototype of RehApp was presented to a multidisciplinary group of clinicians. HR demonstrated the prototype for the clinicians and they were given the option of testing before and after the presentation. A semi-structured focus group interview was performed based on an interview guide (Appendix 2).

In addition, the first and last version of prototypes were presented to all the staff, as part the routinely updating on projects in the Spine Centre, at a morning conference in the beginning and end of the prototype development. It was on those occasions possible for everyone to make comments and suggestions.
Testing and adjusting

User involvement (patients)

A total of five patients, three women and two men, age ranged between 45 and 59 years participated in testing of the three prototypes of RehApp.

The answers and responses from the five interviews are summarized in the following categories (Appendix 3):

1. Overall assessment

In general, all patients except one patient were positive.

Following feedback was expressed:

- It was nice that you could do the exercises when and where you wanted
- Helpful that you could read and see the exercises in a drawing or a video
- It would have been nice with more specific exercises for the neck

Quote from a patient ‘it was more like a warm-up exercise-pass for a soccer team…’

2. User-friendliness

In general all found the design of RehApp was logic and easy to understand but sometimes a little difficult to operate.

Following feedback was expressed:

- Sometimes hard to login
- Need for more flexibility in the exercise program

Quote from a patient: ‘Annoying that you couldn’t ignore an exercise and go to the next one or go back’

3. Positives

In general, patients expressed positive experiences with the RehApp.
Following feedback was expressed:

- The app helped with gaining more knowledge about the condition and how to handle it.
- It helped with understanding exercises since you could read and watch videos and repeat it.
- It allowed for flexibility in where and when to do exercise.
- It saved time and money since you didn't have to take time off from work and spent time and money on transportation to the clinic.
- It helped me to better understand the exercises and to remember to do them.

4. Deficiencies

All five also mentioned the need for an audio option in the RehApp that would make it possible to listen to instructions as an alternative or supplement to the written instructions.

Following feedback was expressed:

- Options of being able to go back and forwards or skip one of the exercises if needed.
- Option of drawing where the pain was.
- Receiving reminders about time for exercise.
- A type of exercise dairy where you could also see pain levels.
- More information about my condition.

5. Other Suggestions

- Ability to chat with the clinician or other patients would be nice.
- Option of uploading photos or videos for feedback.
**User involvement (clinicians)**

Seven clinicians including two physiotherapists, one chiropractor, one physician and two nurses participated in a focus group. The answers and responses from the focus group were summarized in the following categories (Appendix 4):

1. **Relevance**
   
   Everyone agreed that the use of an application would be relevant and helpful for this patient population
   
   Quote from one of the clinicians: *‘It would be helpful for patients that live far away from the Spine Centre and are working, they would be able to handle their situation from home including doing exercises instead of spending time driving to the spine centre’.*

2. **Requirements**
   
   Some of the requirements of the RehApp were that it should be very simple to use with short and clear information. Preferably with minimal text and use of symbols instead of text
   
   Quote from one of the clinicians: *‘Important with a simple technology and clear information to minimize misunderstandings and misinterpretation of exercises and guidelines’.*

3. **Challenges**
   
   It was stated it might not be appropriate for all patient groups due to lack of knowledge/familiarity with ICT technology, language and other psychosocial barriers, but at the same time these patients would also be those who could benefit from an inexpensive intervention, where they did not have to pay for visits at a clinic in primary care
   
   Quote from one of the clinicians: *‘It is not for all patients, some do not have experience and skills with the use of ICT technology. Some have issues and problems that cannot be handled in an app’.*
4. **Concerns**

The major concern among the clinicians was the risk of the patient developing more severe symptoms that would go unnoticed by them.

Quote from one of the clinicians: *‘I would be concerned of development of atrophy without noticing on time. Communication and dialog with other patients, which seem to be important in the group exercise program’.*

5. **Impact on clinical practice**

Everyone agreed it would be a different way to work, where you would have to change some of the clinical procedures and logistics. It could also probably improve the treatment.

Quote from one of the clinicians: *‘It would make it easier and probably improve treatment since you would be able to monitor and modify initiated exercise programs and advices’.*

6. **The most important contents of the app**

It was emphasized that the RehApp should be able to guide the patient not only based on pain and symptoms, but also based on their individual goals. In addition, the RehApp should be able to tailor the activities that are important to the patient.

Quote from one of the clinicians: *‘Important with individual goal setting at baseline that would guide choice of exercises and activities. It should also be possible to adjust goals and activities/exercises if needed during the course of treatment/rehabilitation’.*

7. **Most important outcomes of the use of the app**

The focus among the clinicians was on work-related outcomes, such as back-to-work and number of days on sick leave.

Quote from one of the clinicians: *‘Since this condition has a great impact on the patient but also on expenses in society, I would think it would be important to pick some outcomes such as back to work/sick leave that are important for both the patient and society’.*
Overall feedback from clinicians at the spine centre

The first and last prototypes of the RehApp were presented to all clinicians at morning-conferences where everyone could give their immediate feedback. There were only a few responses mainly due to limited time, but importance of selecting the right patient for the application and that there should be a form of diary for the patient in the app to assist the patient were brought up.

RehApp questionnaire

Based on results from the intervention mapping study, interview responses from the five test patients and input from the meetings, a RehApp questionnaire with 12 questions about feasibility, user friendliness and relevance was developed (Appendix 5).

The technical development of RehApp

The development of RehApp went through several adjustments based on the above input and after discussions with partners and researchers in the project. This resulted in four versions. Where the first version was a mock-up, just for exemplifying and the following three versions were the ones that were tested among the users and led up to the final prototype of RehApp.

1. Version

The first version was a simple mock-up that was developed to be able to decide on the visual design and the setup of the contents. In collaboration with engineer students, RehApp was developed using a decision algorithm that matched a clinical algorithm (Figure 3). This resulted in the ability to have the patient’s level of pain guide which intervention strategy would be most appropriate for him/her. It was also decided to register grip strength in order to monitor and register potential worsening of the condition
2. Version

Version 2 was simplified compared to Version 1. The patient would input their pain level and grip strength when they first used the application. The patient would continue inputting their pain level and RehApp would recommend what exercises to do. If pain level increased by more than 2 numbers, RehApp would suggest pain-relieving positions to the patient and contact the Spine Centre if there was still an issue with their pain level. Patients were asked to monitor their grip strength daily by using a dynamometer at home and enter the result in the app. RehApp provided information about ‘red flags’ (significant decrease in upper extremity strength, loss of sensation and / or bladder or bowel symptoms) and how to respond to these. The patient was advised to either use the cardio exercise program in the application or go for a walk 2-3 times a day for 20 minutes. The illustrations of the cardio- exercises and pain relieving exercises were copied from the ExorLive exercise platform with permission from company ExorLive. (Figure 4)

Figure 3. RehApp version 2

3. Version

Options of audio and video in relation to exercises were added. An information pamphlet about CR and a video podcast about CR were added to RehApp. It also became possible in this version for
the patient and clinician to see a history of the pain levels and completed exercises. Monitoring grip strength was dropped because it required an extra effort from the patient to do the measurement and enter the information to RehApp. It also did not add more relevant information for monitoring the red flags that could not be identified already by the red flags info in the app with warning and information about contacting the Spine Centre (Figure 5).

![Figure 4. RehApp version 3, Pain and exercise history.](image)

4. Version

The 4th version was the final prototype of RehApp. It was a web-based application that could be used on PCs, smartphones and tablets. The application consisted of two systems:

1) A customized front-end that could provide the ability to do the following tasks:
   a. Register pain levels and create a diary of pain level;
   b. Provide a set of fixed cardio exercises and create an exercise diary of completed exercises;
   c. Provide pain relieving positions;
d. Download an information pamphlet about CR;

e. Video-podcast about the condition; and

f. The custom front-end also had audio option so the patient could listen to the information in the app.

2) The commercial ExorLive exercise platform was added. This platform provided the ability for the clinician to tailor the exercise program to the patient and the ability to change or assign new sets of exercises to patients over time. The platform also includes instructional videos of how to do each exercise. The ExorLive platform did not offer audio output to instructional videos or instructions like the customized front-end of the app.

The systems were server-based and accessed using a personal account. The clinician was able to view the pain and exercise diaries (Figure 6).

On the final meeting between the developers and partners, it was decided that the 4th version would be the prototype that would go to a larger scale proof-of-concept because it met the needs of the clinicians and patients. A feasibility study would be conducted to evaluate the prototype.
Side 24 af 55

Figure 5. RehApp version 4 RehApp and ExorLive platform
Proof of concept

Test of the final prototype of RehApp in a feasibility study

Background and aims of the feasibility study

Based on the knowledge about the health problem and the possible value of using ICT as described in the background for the overall aim of the project, it was found to be relevant to develop and test the ICT intervention in a secondary health care setting, where there is an ongoing need for developing new ways of managing health care for patients with spinal pain in a safe and effective way, because of limited resources and increasing demands of involving patients in their own care. The start of the clinical pathway for patients with CR was chosen for the development and test, because patients with CR referred to the Spine Centre are assessed in order to determine if they need a surgical or conservative treatment approach. In this process, there is often a need for monitoring and guiding the patient over a few weeks in order to determine if they can improve with conservative treatment or they need surgery. That requires setup of appointments in the clinic for information, guidance and monitoring of the patient and potentially extra manpower in the clinic and at the same time for transport and possibly time off from work for the patient. It was relevant and suitable to test the prototype of RehApp in this part of the clinical pathway for the patient.

Before carrying out a larger study testing the effectiveness, it is important to test feasibility and user friendliness of the intervention, but also to get information about performance of questionnaires and explore testing of potential primary outcomes in a future trial as described by Lancaster et al. [19].

The specific study objectives and the list of questions within each objective are as follows:

1. To test feasibility and user-friendliness of RehApp
   a. What did the patients think about RehApp?
   b. What were the patients’ comments and experience?
2. To analyse the relationship between the patients assessment of RehApp and their actual use of RehApp
   a. How many times did the patients open RehApp?
   b. Was the use of RehApp different in patients who scored a low degree of satisfaction (below 5 in question 1-5 in RehApp questionnaire)?
3. To explore the potentials of RehApp and ExorLive strategies to influence pain level, pain self-efficacy and function
   a. How many times did the patients open the RehApp?
   b. How did pain change over time in each patient?
   c. Which RehApp-strategies were mostly used? (1. Cardio exercises, 2. Walking, 3. ExorLive individual exercises)
4. To test the feasibility and performance of Pain self-efficacy and DASH in this population at baseline, 2 weeks (three and six months)
   a. What was the variation in this population?
   b. How did the variation change over time?
   c. What were the patients’ comments and experience?
   d. How did pain and RehApp-strategies influence scoring of the PSEQ and DASH?
5. To compare change scores in the controls and intervention groups in PSEQ and DASH at 2 weeks
6. To report demographic, physical, social and psychological factors in the intervention and control group at baseline, (three and six months)
7. To map challenges in recruitment procedures
Methods

Patients

Testing of RehApp was done among patients referred to the Spine Centre with signs of CR between May 5th and June 30th 2015. The following inclusion criteria were used:

- Self-reported radiating pain in an arm of intensity four or more on a ten-point numerical pain rating scale [18]
- At least one clinical sign of nerve root involvement
- Able to understand, speak, and read Danish language.
- Above 18 years of age.

Patients were excluded if they needed acute referral to a surgical department, had serious pathology and co-morbid conditions or physical handicap, which may hinder the patient from doing the exercises.

Procedures at the Spine Centre

At the first visit, all patients completed the Spine Data questionnaire electronically. This questionnaire collects demographic information. In addition, the pain self-efficacy (PSEQ) [17] and the Spell DASH out (DASH) [16] were completed.

A physiotherapist, physician or chiropractor saw patients as part of the standard procedures in the Spine Centre. The clinicians involved in evaluating the patients referred with signs were given written and oral information about the project. They assessed if the patient met the inclusion criteria for the study. If the patient fulfilled the inclusion criteria, the clinician contacted HR for further assessment and possible participation in the feasibility study.

HR introduced patients, who provided written consent to participate in the study, to the RehApp. They received verbal and written information about RehApp and the app was demonstrated and reviewed with the patient. The participants used the RehApp at home for the following two
weeks. If their symptoms worsened or they had a problem with the RehApp, the participants could contact the physical therapist and Spine Centre.

In the same time period 11 control patients fulfilling the same criteria were enrolled.

**Measures**

All patients completed the SpineData questions electronically, as well as PSEQ and DASH at baseline and at 2 weeks. A follow-up with Spine Data, PSEQ and DASH questionnaires at six months were planned for both groups. In addition all the patients testing RehApp completed the RehApp questionnaire at two weeks.

The Spine Centre runs the ‘SpineData’ database in which patients’ self-reported data and clinical information is systematically collected at the first visit and after six and 12 months [20].

The DASH Outcome Measure is scored in two components: the disability/symptom section (30 items, scored 1-5) and the optional high performance Sport/Music or Work section (4 items, scored 1-5). In order to receive a score in the main section in the questionnaire, at least 27 of the 30 items must be completed for a score to be calculated and in the module section all four items must be completed for a score to be calculated.

In the PSEQ questionnaire patients were asked to rate their perceived ability to perform the 10 activities despite their pain on a 7-point numeric rating scale, where zero equals not at all confident and six equals completely confident, yielding a sum score ranging from 0 to 60. Higher scores indicate greater self-efficacy.

RehApp questionnaire was designed in the innovation process based on input from the relevant users as described in the ‘Concept’ section.

An overview of the measures is shown in Table 1.
Table 1. Data collection. List of variables and the timing of data collection. (w= weeks, m= months)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>2 w</th>
<th>6 m</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpineData</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Educational level</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of present episode</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of sick leave due to neck</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of sick leave not neck</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Full hours or modified duties at work*</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Recurrent or incident case</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain intensity neck</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Pain intensity arm</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Neck Disability Index</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>EuroQol 5D</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Depression</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catastrophizing</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Fear-avoidance beliefs</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Repetitive work</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical workload</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Leisure time activity</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Expectation about return to work</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Job satisfaction</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected of recovery</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain Self-efficacy (PSEQ)</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Disabilities of the Arm, Shoulder and Hand (DASH)</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>RehApp Questionnaire</td>
<td>x</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**RehApp intervention**

The users of RehApp received the same information as the control patients about their condition including signs of red flags (loss of strength and sensibility in the arm or legs or/and loss of control over bladder and bowel function) and how to contact the Spine Centre. They were informed that there might be a need for a surgical assessment if they were not responding to conservative treatment. They were assigned individual exercises in the ExorLive exercise platform in RehApp as describe on page 23 by HR. These individual exercises were based on the individual clinical assessment, the patient-expressed need and the clinical decision algorithm for individualized exercise to patients with cervical radiculopathy (fig. 3). Likewise advised about using general cardiovascular exercises, activities and pain relieving positions as suggested in RehApp. They were advised to follow the suggestions in RehApp if their pain level raised and contact the Spine Centre if no improvement.

**Standard care**

The control patients followed the Spine Centre’s standard protocol for patients with CR, where there might be a need for a surgical approach if they are not responding to conservative treatment. They would therefore be monitored for a shorter period typical not more than 2 weeks, where they would receive similar information and guidance as the intervention group, but by clinical appointments and phone calls.

Management and guidance in use of pain medication were the same in both groups, where both groups were seen and followed by a nurse if needed

**Data analyses**

1. Reported scores and answers on feasibility and user-friendliness of RehApp an ICT assisted intervention were presented as proportions. Comments and patients’ experiences were organized and presented in themes with quotes from the participants.
2. After examining the registered data in RehApp it was found that there were no closing of the individual registrations and therefore it was not possible to extract useful and valid data. Analyses of the following specific objectives were therefore dropped:
   a. Number of times RehApp was opened by each participant over two weeks was therefore dropped. Therefore no analyses were performed on frequency of RehApp-use in relation to scoring of RehApp in the RehApp
   b. Potentials of RehApp and ExorLive strategies to influence pain

3. Analyses of feasibility and performance of Pain self-efficacy and DASH were done by:
   a. Reported scores at baseline and two weeks in DASH and PSEQ questionnaires were presented as mean with standard deviations (SD), 95% confidence intervals (CI) and medians with maximums and minimums in the RehApp group and the control group.
   b. Changes in mean or median scores from baseline to two weeks in PSEQ and DASH were tested using Paired t-test within the 2 groups. Differences in mean or median change scores between the two groups were tested using un-Paired t-test between the two groups.
   c. Presentation of participant’s comments and experiences in themes with quotes.
   d. Scoring of PSEQ and DASH in relation to pain level and exercise strategies in RehApp, were not performed due to not useful RehApp data and, as earlier described.

4. Analyses of baseline characteristics including demographic, physical, social and psychological variables in the intervention and control group were not possible, since data was not available for the present reporting of the study. It will be added at a later time.

5. Recruitment procedures and challenges were reported in relation to clinicians, patients and clinical setting
Results

1. Feasibility and user-friendliness of RehApp

15 out of 16 invited patients (8 women) with a mean age of 51 years participated in the feasibility study and following completion of the RehApp-questionnaire.

A large proportion of the 15 patients rated RehApp positive in the first 5 questions about 1) the overall performance, 2-3) user-friendliness, 4) ability to help with feeling confident in handling their situation and 5) relevance of exercises, on a scale from 0-10 where 0 where poor and 10 was excellent. If classifying scores above 5 as positive in the 5 questions, the proportion of positive responses ranged from 65-85 %.

14 out of 15 patients read the information pamphlet about CR and 13 of them found it helpful.

13 out of 15 patients saw the informational video podcast about CR and 12 found it helpful.

Patients were asked more specifically about what were the positive aspects of RehApp. A total of 13 patients answered. The positive aspects that were mostly stated were that RehApp could help them with: 1) their neck problem (54 %), 2) with understanding their exercises better (62 %) and 3) with remembering doing their exercises (70 %). About 1/3 of the patients stated that reduced transportation was a positive and two patients stated it would be cost-effective.

On the question about what could be improved in RehApp, four patients stated they would like being able to communicate directly with a clinician through RehApp. Two patients suggested audio options in exercise videos in the ExorLive part of RehApp. Two patients felt that the information about their neck problem and choice of exercises could be improved. In addition, following individual suggestions for improvement were given:

- Ability to record and upload videos for feedback.
- Better information about how RehApp worked.
- Easier navigation in the app
- Improvement of the logon procedure.
• Cardio exercises should be more adjustable in time and intensity

53% of the patients preferred using RehApp instead of visits to the Spine Centre, and 47% of the patients felt they would have needed more visits to the clinic if they had not used RehApp. All except three patients would recommend RehApp for other patients with a similar problem.

2. Patients’ assessment of RehApp compared to registered information about use of exercises and information in RehApp.

The intention was to explore the relationship between how patients rated RehApp and how often they accessed and used RehApp for exercises and information. In the analyses of the data in RehApp it was found that since there were no closing-point to activities in RehApp, except for an optional registration, it was not possible to perform the analyses.

2a. Potentials of RehApp and ExorLive strategies to influence pain level, pain self-efficacy and function

As above

3. Feasibility and performance of Pain self-efficacy and DASH in this population at baseline and two weeks

All the participants in the feasibility study completed DASH at baseline and two weeks. 11 control patients completed it at baseline and seven at two weeks. In order for a score to be calculated at least 27 of the 30 items must be completed. This explains the variation in the total number of participants as seen in Table 3.

At baseline mean age were 55 in the RehApp groups and 44 in the control group, which was significantly lower. 12 RehApp patients and 11 control patients completed the disability/symptom section with an average DASH score of 37 and 45 respectively. The optional sport and work modules were answered by nine and one patients, respectively, in the RehApp group and one in the control group and were therefore dropped from the analysis due to small numbers (Table 3). There was a significant change in the RehApp group in the disability/symptom section with almost
10 % decrease in disability score from 37 to 27 at two weeks. Otherwise no significant changes within the groups were observed (Table 2).

All RehApp patients and 11 control patients also completed PSEQ at baseline and at 2 weeks except 4 control patients. The mean score at baseline were 34 and 26 respectively. Within the groups there were almost no changing scores after two weeks (Table 2.).

4. Change scores in the controls and intervention groups in PSEQ and DASH at 2 weeks

There were changes in DASH scores from baseline to two weeks for both groups both no significant differences between groups (Table 3). In the PSEQ, there were only small and no significant differences between the groups. (Table 3)

In general there were observed fairly wide CI’s large and SD’s in the mean scores for both groups especially in the DASH Questionnaire at both baseline and 2 weeks, indicating a large level of variance within the groups.
Table 2. Changes in DASH and PSEQ from baseline to 2 weeks within the groups.

<table>
<thead>
<tr>
<th></th>
<th>RehApp baseline</th>
<th>RehApp 2 weeks</th>
<th>Mean Change</th>
<th>P value</th>
<th>Control Baseline</th>
<th>Control 2 weeks</th>
<th>Mean Change</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DASH (n)</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>7</td>
<td>46</td>
<td>43</td>
<td>7</td>
<td>p&lt;0.05</td>
</tr>
<tr>
<td>Mean</td>
<td>37</td>
<td>27*</td>
<td>-10</td>
<td></td>
<td>19</td>
<td>21</td>
<td>5</td>
<td>p=0.10</td>
</tr>
<tr>
<td>SD</td>
<td>22</td>
<td>12</td>
<td>(-17 - -2)</td>
<td></td>
<td>(29-63)</td>
<td>(23-63)</td>
<td>(-8-1)</td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>(13-44)</td>
<td>(13-42)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSEQ (n)</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>7</td>
<td>23</td>
<td>23</td>
<td>7</td>
<td>p=0.72</td>
</tr>
<tr>
<td>Mean</td>
<td>34</td>
<td>35</td>
<td>1</td>
<td></td>
<td>11</td>
<td>11</td>
<td>4</td>
<td>p=0.86</td>
</tr>
<tr>
<td>SD</td>
<td>15</td>
<td>16</td>
<td>9</td>
<td></td>
<td>(12-34)</td>
<td>(13-33)</td>
<td>(-4-3)</td>
<td></td>
</tr>
<tr>
<td>CI</td>
<td>(26-42)</td>
<td>(26-44)</td>
<td>(-4-5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

n: Numbers of participants with complete scores; SD: standard deviations; CI: 95% confidence intervals; * = p<0.05

5. Presentation of participants’ comments and experiences in themes with quotes

In addition to completing the questionnaires, there was also an option of adding comments to both questionnaires. There were mainly only few comments, which were about details of their condition, other health problems and treatment. Quote from one of the patients: ‘I have started in physiotherapy and have received some exercises to do. I’ll see if they relieve my pain, which is increasing. I am going to see a shoulder specialist in September’.
Table 3. DASH and PSEQ at baseline and 2 weeks in and between the two groups.

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>2 weeks</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>2 weeks</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>2 weeks</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RehApp</td>
<td>Control</td>
<td>Value</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>RehApp</td>
<td>Control</td>
<td>Value</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>RehApp</td>
<td>Control</td>
<td>Value</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>15</td>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15</td>
<td></td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>Mean Age</td>
<td>55.15</td>
<td>44.13</td>
<td>P&lt;0.01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>44.13</td>
<td></td>
<td>31.08</td>
<td>P=0.28</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>42.74</td>
<td></td>
<td>42.74</td>
</tr>
<tr>
<td>(SD)</td>
<td>(9.90)</td>
<td>(4.13)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(4.13)</td>
<td></td>
<td>(23.18)</td>
<td>(15.59)</td>
<td></td>
<td></td>
<td></td>
<td>(21.50)</td>
<td></td>
<td>(21.50)</td>
<td></td>
</tr>
<tr>
<td>(CI)</td>
<td>(49.67-60.63)</td>
<td>(41.35-46.90)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(41.35-46.90)</td>
<td></td>
<td>(18.24-43.92)</td>
<td></td>
<td></td>
<td></td>
<td>(22.85-62.62)</td>
<td></td>
<td>(22.85-62.62)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median Age</td>
<td>56.3</td>
<td>43.8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>43.8</td>
<td></td>
<td>33.33</td>
<td></td>
<td></td>
<td></td>
<td>(8-71)</td>
<td></td>
<td>(8-71)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(min-max)</td>
<td>(41-78)</td>
<td>(38-51)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(38-51)</td>
<td></td>
<td>(2-78)</td>
<td>(20-70)</td>
<td></td>
<td></td>
<td></td>
<td>(20-70)</td>
<td></td>
<td>(20-70)</td>
<td></td>
</tr>
<tr>
<td>DASH N</td>
<td>12</td>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15</td>
<td></td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>Mean DASH</td>
<td>36.78</td>
<td>45.53</td>
<td>P=0.28</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>31.08</td>
<td></td>
<td>42.74</td>
<td>P=0.27</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>42.74</td>
<td></td>
<td>42.74</td>
</tr>
<tr>
<td>(SD)</td>
<td>(21.91)</td>
<td>(15.59)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(23.18)</td>
<td></td>
<td>(23.18)</td>
<td>(18.24-43.92)</td>
<td></td>
<td></td>
<td></td>
<td>(22.85-62.62)</td>
<td></td>
<td>(22.85-62.62)</td>
<td></td>
</tr>
<tr>
<td>(CI)</td>
<td>(22.86-50.70)</td>
<td>(35.05-56.00)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(35.05-56.00)</td>
<td></td>
<td>(18.24-43.92)</td>
<td>(18.24-43.92)</td>
<td></td>
<td></td>
<td></td>
<td>(18.24-43.92)</td>
<td>(18.24-43.92)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median DASH</td>
<td>39.17</td>
<td>44.17</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>44.17</td>
<td></td>
<td>33.33</td>
<td></td>
<td></td>
<td></td>
<td>(2-78)</td>
<td></td>
<td>(2-78)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(min-max)</td>
<td>(3-75)</td>
<td>(20-70)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(20-70)</td>
<td></td>
<td>(2-78)</td>
<td>(20-70)</td>
<td></td>
<td></td>
<td></td>
<td>(20-70)</td>
<td></td>
<td>(20-70)</td>
<td></td>
</tr>
<tr>
<td>PSEQ N</td>
<td>15</td>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15</td>
<td></td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>Mean PSEQ</td>
<td>34</td>
<td>26.18</td>
<td>P=.16</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>34.8</td>
<td></td>
<td>31.08</td>
<td>P=0.06</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>22.86</td>
<td></td>
<td>22.86</td>
</tr>
<tr>
<td>(SD)</td>
<td>(15.08)</td>
<td>(12.20)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(16.44)</td>
<td></td>
<td>(16.44)</td>
<td>(12.65-33.06)</td>
<td></td>
<td></td>
<td></td>
<td>(11.04)</td>
<td></td>
<td>(11.04)</td>
<td></td>
</tr>
<tr>
<td>(CI)</td>
<td>(25.65-42.35)</td>
<td>(17.98-34.38)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(17.98-34.38)</td>
<td></td>
<td>(25.69-43.90)</td>
<td>(25.69-43.90)</td>
<td></td>
<td></td>
<td></td>
<td>(12.65-33.06)</td>
<td>(12.65-33.06)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median PSEQ</td>
<td>32</td>
<td>26</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32</td>
<td></td>
<td>32</td>
<td></td>
<td></td>
<td></td>
<td>(9-41)</td>
<td></td>
<td>(9-41)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(min-max)</td>
<td>(18-59)</td>
<td>(7-51)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(7-51)</td>
<td></td>
<td>(8-58)</td>
<td>(8-58)</td>
<td></td>
<td></td>
<td></td>
<td>(8-58)</td>
<td></td>
<td>(8-58)</td>
<td></td>
</tr>
</tbody>
</table>

n: Numbers of participants with complete scores; SD: standard deviations; CI: confidence intervals; *= p<0.05
6. Scoring of PSEQ and DASH in relation to pain level and exercise strategies in RehApp

The intention was to explore PSEQ and DASH scores in relation to pain level and exercise strategies in RehApp. As described earlier, the collected data in RehApp is not usable for this analysis. It was therefore not possible to explore this objective further at this point.

7. Demographic, physical, social and psychological factors in the intervention and control group at baseline and 6 mo.

(This part of the results will be entered at a later time, when we have received data from SpineData database.)

8. Mapping of challenges in the recruitment procedures

Challenges in recruitment procedures were seen in relation to:

1. Clinicians

There was a large group of clinicians who were asked to be the first contact point for the study. They were responsible for initiating the recruitment process, but because it was not part of their normal workload they tended to forget to do it. The clinicians were well informed about the study and were motivated. They received daily reminders, emails and casual conversations.

2. Logistics

It was difficult to build a good routine in inclusion procedures in the clinical setting because of several major logistical and procedural processes were being applied at the same time. A new guideline for the clinical examination was implemented and a new medical IT system was installed. This resulted in an increase in their workload.

3. Patients

Recruiting the patients on the first day at the clinic was challenging and questionable because the patients had already been exposed to a large amount of examinations and information. They
would often express that they were not able to process more that day, both due to pain and feeling fatigued.

**Discussion**

This feasibility study investigated and explored the feasibility of a prototype of an information-and exercise-app called RehApp, in patients with CR. The overall strengths of the feasibility study were that it was carried out in a clinical setting with the daily routines and challenges, which improved the value of the observations and results for future development and design of the main study. Performing a feasibility study also allowed for exploring a wide range of objectives and questions related to the intervention and for collecting a large variety of informative observations and data.

The results showed in general very positive response in relation to both user friendliness and relevance of the app. There were several suggestions for improvements. They were especially related to technical improvements and to the content of the app. One of the focus areas was also audio and video options as well as communication. No one expressed a need for being able to communicate with other patients with CR. This was an important point in the master thesis about “lived experience for the patient and also the experience in the Spine Centre, where it was an important element of the group exercise sessions as expressed by the clinicians. This indicated that the results of this survey might not be covering all aspects. Since it was a questionnaire where most answers were given on a rating scale or in marked boxes it narrowed the variation and nuances in the answers and important aspects and issues could have been left out.

Being positive towards RehApp does not necessarily mean that the participants improved. The exploration of the DASH and PSEQ were to explore the performance, but it also informed of how the participants pain efficacy and function were during the test period. The mean scores in both questionnaires did not indicate worsening during the two weeks and in fact a slight but significant improvement in the RehApp group was noticed at two weeks. This should be noted with some
caution, since it is a very small sample size with no randomization or blinding. The improvement might therefore be due to bias, such as selection bias, potential influence of the investigator’s positive attitude towards the intervention and participants who were eager to please. The improvement in DASH scores was not reflected in the PSEQ scores. In other words the patients did improve their functional level but not their perceived ability to perform activities despite their pain. This seemed contradictory and might indicate problems with responsiveness and validity in the questionnaires in this population, but most likely it is due to the small sample size.

The wide confidence intervals and standard deviations in the questionnaires indicated first of all that this was a small sample sizes creating larger variation in the group. There were though similar variation within the groups over time and questionnaires would be relevant to test further in order to measure validity and responsiveness.

Objectives/questions of interest in the study were also to explore patients’ assessment of RehApp compared to registered information about use of exercises and guidance in RehApp as well as RehApp strategies potential influence on pain level and function. These objectives were dropped, since data in RehApp was not usable for further analyses, part of this was because of no closing points in the registered individual activity and only very few patients had registered start point of individual activities, and just left the app open after use. The original intentions with these objectives were to get more knowledge and understanding of patients’ compliance with exercises and their exercise and activity patterns in relation to their pain and disability. The positive responses and low/missing registration of exercises in RehApp were interesting and in some aspects they seemed conflicting. This could be due to different reasons; 1) the exercise part was not important to the patient and it was other elements in the app that was helpful for the patient 2) they exercised, but did not register and /or the programming of registration in RehApp was not sufficiently designed. In case it was the first reason, it made one wonder, what should be the implications for exploring the relation between patients’ improvement and exercise pattern. In case of the other reason, it would indicate that there might be some challenges with registration, since the patient might be doing their exercises, but are not using the app. As one the patients
reported: ‘After a couple of days I could remember my exercises, so I didn’t have to open the app every time’. This underlined the importance of making the research question clear and realistic to answer, in advance, and ensure that the programmed data registration in the app. were capable of answering this.

As brought up in the clinician interview in the innovation phase, there might be other or more outcomes than pain and function that are important. Since CR also causes economic burden on both the patient and society it would be relevant to have outcomes such as return to work and / or sick leave. It was also mentioned that it was important to measure outcomes based on more personal goals for the individual patient. Pain is on the other hand an important outcome measure in this population, since they often have severe pain and signs of nerve root affection.

The feasibility study also revealed challenges in the inclusion procedure related to information and collaboration with clinicians, logistical conditions as well as patient related challenges due to extensive information and communication with a various number of health care persons in the same visit. This informs of a need for timely planning with early information on staff-meetings. Smaller groups might be a solution as well, since it would make it easier to manage, even if it might increase the inclusion period. In relation to patients it might be important to split the inclusion process and introduction up in two sessions in order to decrease the information overload on the patient, who is already in a stress/overload situation due to their condition.

The results and information from the feasibility study suggests continuation of the innovative process with further adjustment and development of RehApp. In addition, development of a study protocol based on results and suggestions from the feasibility and innovative process for a future study testing the effectiveness of RehApp.

Besides having potential benefits for the patients, it might help the clinician in developing treatment approaches based on feedback from exercise history in RehApp and patients’ preferences and delivering a more tailored treatment approach. The results from this project may therefore provide basis for developing more sophisticated technologies that can improved the
treatment outcomes for not only patients with CR, but for other groups with musculoskeletal problems.

RehApp will also have potential of decreasing costs not only for the individual patient, but also in the health care system and society because of decrease in health care consultations and sick leave.

**Conclusion**

This feasibility study based on an innovative process showed that an ICT assisted intervention RehApp overall is a feasible and a potential intervention at home for patients with cervical radiculopathy in the sub-acute phase. The results, suggestions and information achieved in the innovation process should be taken into consideration if and when proceeding to the next two phases in the innovation process where a final version of RehApp is developed as the intervention in a larger comparative study (fig. 2).
References


4. Rasmussen H, Kent P, Kjaer P, Kongsted A: In a secondary care setting, differences between neck pain subgroups classified using the Quebec task force classification system were typically small - a longitudinal study. BMC musculoskeletal disorders 2015, 16:150.


15. Rasmussen H: The diagnostic value of provocative and neurological tests in relation to cervical radiculopathy, verified by advanced imaging or electro diagnostic testing: A systematic review. In.: University of Southern Denmark; 2013.


Appendix 1

Interview guide (patients)

1. Overordnet hvordan synes du app’en fungerede?
2. Var den anvendelig / nem at bruge?
3. Var vejledning og øvelser til at forstå?
4. Dækkede vejledning og øvelser nogle af de forventninger/ behov du har?
5. Hvad behøver du for at kunne overkomme sådanne udfordringer?
6. Var der noget der bekymrede dig ved at bruge app’en?
7. Hvis denne nye type træningsprogram og vejledning blev tilbudt, ville du så være interesseret i at deltage?
8. Tror du en app som denne ville hjælpe dig til at følge vejledninger og udføre dine øvelser?
9. Overordnet set, hvad ville du have behov for, for at få et positivt udbytte af en sådan app?
10. Har du andre kommentarer eller erfaringer du vil dele?
Appendix 2

Interviewguide til test af ’Reh-app’ (Kliniker)

Kliniker information og spørgsmål om ’Reh-app’

Vi er i øjeblikket i gang med at udvikle en ’app’, som kan informere patienter med nakkesmerter og udstråling til arm om hvordan man bedst muligt kan håndtere sine smertyver og træne uden at forværre smerter og symptomer.

Ligeledes vil app’en give behandleren mulighed for at kunne følge patienten i forhold til træning/aktivitetsniveau samt smerteniveau. App’en vil også kunne vejelede om patient skal tage kontakt til behandler.

’App’en er ikke færdigudviklet og indeholder ikke alle de elementer vi tænker vil være relevante. For at gøre app’en så relevant og brugervenlig som mulig, vil vi derfor gerne have dine input til udviklingen af app’en:

1. Med din kliniske erfaring/baggrund, er det så overordnet muligt at anvende en sådan ’app’ til denne patient gruppe?
2. Hvad skal der til for at gøre den succesfuld?
3. Er der nogen potentielle udfordringer?
4. Er der nogen betænkeligheder/problemer i at håndtere/behandle patienter med CR med denne tilgang?
5. Har du/I nogle løsningsforslag til disse udfordringer/betænkeligheder?
6. Uddyb hvordan anvendelsen af en ’app’ ville påvirke din kliniske praksis i rygcenteret?
7. Hvad ville din/jeres rolle være hvis en sådan intervention blev implementeret?
9. Hvad er efter din mening det vigtigste outcome/resultat for patienter med CR ved brug af en sådan ’app’?
Appendix 3

Results of the patient interviews the concept phase

Overall assessment

In general, all except one expressed that the app was relevant for their problem. The one that didn’t find it relevant stated it was because there was not enough specific exercises for the neck, ‘it was more like a warm-up pass for a soccer team...’ They found it helpful that you could do your exercises where and when you wanted and it was helpful and that it was nice with exercises that considered your pain

- Sometimes hard to login
- It was nice that you could do the exercises when and where you wanted
- Helpful that you could read and see the exercises in a drawing or a video
- It was nice that you could do the exercises when and where you wanted
- Helpful that you could read and see the exercises in a drawing or a video
- Not so much related to the neck. It seemed more like warm-up exercises for soccer

User-friendliness

- Sometimes hard to login
- A bit of a hassle in the beginning in the beginning
- Irritating that you couldn’t ignore an exercise or go back
- Easy to understand the directions
- Easy to use
- I learned to do the exercises, so I didn’t have to look in the app
- I couldn’t figure out how to use the exercise program, so didn’t do it
Positives

• It was nice that you could also print out your exercise program
• The app helped with gaining more knowledge about the condition and how to handle it
• It helped with understanding exercises since you could read and watch videos and repeat it
• It allowed for flexibility in where and when to do exercise
• It saved time and money since you didn't have to take time off from work and spent time and money on transportation the clinic
• It helped me to better understand the exercises and to remember to do them

Deficiencies

• Almost all five also mentioned the need for audio option in the app,
• Option of being able to go back and forwards or jump over one the exercises if needed.
• Option drawing where the pain was
• A sort of exercise dairy where you could also see pain levels

Suggestions

• Ability to chat with the clinician or other patients would be nice
• Option of uploading photos or videos for feedback
• More information about my condition
• It would be better if you could adjust exercises repetition and intensity in the app
• Receiving reminders about time for exercise
Appendix 4

Results from focus group interview with health care professionals

Relevance

- You have apps for everything, so why not. It would be helpful for patients that live far away from the spine centre and are working, they would be able to handle their situation from home including doing exercises instead of spending time driving to the spine centre
- It gives more security and reassurance for the patient to have this app
- It may help with compliance with exercises
- It fits into the new trends among especially young people where you expect healthcare to be a service that works around your schedule fits into your life

Needs/requirements

- Important with a thorough introduction so the patient knows the content of the app especially information about ‘red flags’
- Information and instructions need to be short and clear
- Important with a simple technology and clear information to minimize misunderstandings and misinterpretation of exercises and guidelines
- Helpful with option of video of exercises in app.
- Option of recording and uploading of patient videos for feedback
- Important that there are some easy guidelines/rules for the use of the app
- Helpful with a diary telling exercise and pain history

Challenges

- Not for all patients, some do not have experience and skills with the use of ICT technology. Some have issues and problems that cannot be handled in an app
• The patients who can’t afford treatment might benefit from this, but at the same time they are often a vulnerable group, that don’t have capability of using the app and manage their situation

**Concerns**

• Development of atrophy without noticing on time
• Not to many exercise sessions, this will stress the patient and they might quit exercises completely
• How about communication and dialog with other patients which seem to be important in the group exercise program
• Maybe those patients who can’t afford treatment would in one hand benefit from this inexpensive approach, but on the other hand thy might not have sufficient resources and skills to handle their situation by an app at home
• Need for some sort of safety or alarm that will inform the patient and clinician

**Impact on clinical practice**

• It will be a different way to work. It will require that you can schedule time for setup of the app and for answering questions and responding to questions and with feedback on videos etc.
• We will be more like a coach/consultant for the patient
• It might mean longer assessment and treatment-courses in the spine centre
• It would make it easier to monitor and tailor initiated exercise programs and advices

**The most important contents of the app**

• That it could summarise for the patient what they have done and how much
• Important with goal setting that should be the base for choice of exercises and activities
• Use of pacing principles in designing exercise/activity programs for the patient
Most important outcomes of the use of the app

- Back to work
- Sick days
- Specific functional goals for the patient
# Appendix 5

## Spørgeskema om RehApp

<table>
<thead>
<tr>
<th>NAVN: _______________________________</th>
<th>DATO: _______________</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPR: _______________________________</td>
<td></td>
</tr>
</tbody>
</table>

### 1. Din nuværende nakkesmerter

<table>
<thead>
<tr>
<th>Slet ingen</th>
<th>Værst mulige</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smerter</td>
<td>Smerter</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
</table>

### 2. Din nuværende armssmerter

<table>
<thead>
<tr>
<th>Slet ingen</th>
<th>Værst mulige</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smerter</td>
<td>Smerter</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
</table>
1. Hvad er din overordnede vurdering af Reh-App?

Dårlig | Nogenlunde | God
---|---|---
0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10

2. Hvordan var RehApp at bruge?

Meget Svær | Hverken eller | Meget nem
---|---|---
0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10

3. Var vejledningen i RehApp til at forstå

Slet ikke | Delvis | I høj grad
---|---|---
0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10

4. Har RehApp gjort dig mere tryg ved at håndtere dit nakkeproblem?

Slet ikke | Delvis | I høj grad
---|---|---
0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10

5. Dækkede RehApp øvelserne dine behov for træning?

Slet ikke | Delvis | I høj grad
---|---|---
0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10

6. Hvad er godt ved ReHApp? (sæt gerne flere krydser)
☐ Kan hjælpe mig med mit nakkeproblem
☐ Det er billigere
☐ Undgår transport
☐ Kan hjælpe mig til bedre at forstå øvelser
☐ Kan hjælpe mig til at huske at lave øvelser
☐ Andet
  Beskriv:

7. Hvad kunne være bedre ved RehApp? (sæt gerne flere krydser)

☐ At der var lyd på øvelsesinstruktion i ExorLive, så at man kunne høre i stedet for at læse instruktionen
☐ Mulighed for at kommunikere med behandler
☐ Mulighed for at kommunikere med andre der har lignende problem
☐ Mulighed for at optage video af øvelse og få feedback
☐ Informationen om mit nakkeproblem
☐ Valg af øvelser
☐ Andet
  Beskriv:

8. Læste du informationspjecen?
☐ Ja
☐ Nej

9. Hvis ja, var den nyttig?
☐ Ja
☐ Nej
10. Så du informations-videoen?
   □ Ja
   □ Nej

11. Hvis ja, var den nyttig?
   □ Ja
   □ Nej

12. Foretrækker du at komme til konsultation ved din behandler i Rygcenteret frem for at
    bruge RehApp?
   □ Ja
   □ Nej
   □ Ved ikke

13. Ville du have haft behov for flere fysiske besøg i rygcenteret, hvis du ikke havde haft
    RehApp?
   □ Ja
   □ Nej
   □ Ved ikke

14. Vil du anbefale RehApp til andre med nakkesmerter og udstråling til arm?
   □ Ja
   □ Nej
   □ Ved ikke

Andre kommentarer:
Appendix 6

Summary of suggestions and recommendations

RehApp

- Improvement of login procedures in RehApp
- Improved navigation in RehApp, including going back and forward between exercises.
  Skipping exercises
- Increased flexibility of the cardio exercises with option of adjusting time and intensity level
- Audio option in individual exercises
- Oploading of video/photo for clinician and patient feedback
- Communication function in the app between clinician and patient
- Improvement of exercise and pain history. Consider the use of symbols
- Minimal text more illustration and symbols
- Improvement/refinement of data registration in RehApp
- Formulation of research questions based on current information from feasibility study

Other related to future study

- Further tests of questionnaires (DASH, PSEQ)
- Consider more or other outcomes (sick leave, back to work, patient specific outcomes)
- Adjustment of inclusion procedures
  - Smaller group of clinicians
  - Early information
  - More time for introducing patients to RehApp