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MAST evaluation of a pilot study**

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Information and communication technology (ICT) assisted intervention at home for patients with Cervical Radiculopathy

MAST evaluation of a pilot study

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Health problem and technology

It is estimated that 8-10,000 Danes experience arm pain originating from their neck. The pain may be caused by compression of the nerve root by a herniated disk or degenerated joints in the neck, then called cervical radiculopathy (CR) [1]. About a quarter of these patients are being referred for surgery, while the vast majority is 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 their symptoms and disabilities [4], patients with CR need monitoring and guidance as part of their care in order to detect worsening, prevent development of chronic pain, and to obtain a possible quicker recovery. Also, it seems vital that the patients experience control over their own situation and are able to maintain a normal life. Since the acute phase is generally marked with severe pain, patients might be hindered in seeking timely health care because of their inability to travel to a healthcare provider.



Information and communication technology (ICT) assisted intervention at home might therefore be beneficial for patients with CR, since it is a way to introduce monitoring and interventions for CR that support patients in being able to manage their condition from their home. In addition, reduce the need of services from the health care system and at the same time detect worsening that requires immediate medical attention.

RehApp is a web-based app for PCs, smartphones and tablets that puts the patient at the center of care and mainly takes place in the patient's home. The development of the app is based on patient preferences, scientific evidence and clinical experience. The focus has been on the development of technologies that can deliver and support monitoring, guidance and information for the individual patient. The application consists of two systems:

1) A custom front-end that registers pain levels, provides a set of fixed cardio exercises and pain relieving positions tailored to the specific case, written information and a video-podcast about the condition and a diary registering pain level and exercises. The custom front-end also allows the patient to listen to the information in the app.

2) The commercial ExorLive exercise platform with options of designing specific exercise programs for the individual patient. It is also possible to view the exercises in an attached video. Furthermore, ExorLive provides a wide range of options, including the possibility for the clinician to change or assign new sets of exercises to patients. Both systems are server-based accessed using a personal account, and both systems allow the physiotherapist to monitor pain level and the activities of the patient.

Testing of RehApp was done among patients referred to the Spine Centre with signs of CR between May 5th and June 30th 2015. 15 patients out 16 invited patients participated in the pilot test. The following inclusion criteria were used in the selection of patients:

- Self-reported radiating one arm where arm pain intensity greater than three on a zero to ten numeric pain rating scale
- 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.

Patients who gave consent to participate in the study were introduced to RehApp by the clinician who were also in charge of the pilot study. They were given verbal as well as written information and guidance. The participants used the app at home for the next 2 weeks. They could contact the physical therapist and Spine Centre by phone during the entire test period in case of problems with the application or in case of worsening of their condition.

Safety

The applied technology is safe to use for the patient, since there is no invasive procedures.

Even though the risk is low, CR requires close monitoring and quick medical response in case of developing severe worsening of the condition in terms of loss of strength and sensibility in the arm or legs and loss of control over bladder and bowel function (so-called red flags). Patients in the pilot study were monitored by RehApp and had the same access to a dedicated clinician at the Spine Centre as patients in usual care. In addition they were given information about signs of the condition worsening such as strange feeling in the feet, unstable gait, problems controlling bladder/bowel function, arm or neck pain increase to intractable, sudden loss of power or paralysis in the hands or arms and how they should contact the Spine Centre for additional assessments.

Data from questionnaires was gathered in the 'Spine Data Database' that has been approved by the Danish Data Protection Agency. Other data from RehApp will be stored in a joint database after approval by the relevant authorities. Information about the participants is protected by the law of personal data and the Health Act. The study will be reported to the Region of Southern Denmark's contact person who is in charge of the reporting of regional health research projects within to the national data protection agency.



Clinical efficacy

It is the project's hypothesis that by using motivational technologies to deliver relevant information, exercises and monitoring in the patient's own home it will be possible to reduce pain and improve pain coping strategies and functions in patients with CR to a level that is, at least, similar to that of the traditional treatment. If this kind of approach proves as efficient as traditional care or treatment in a specialized unit, considerable savings can be achieved through reduced travel and consultation costs.

In this pilot study the focus has not been on clinical efficacy, but on feasibility and user friendliness. Clinical efficacy of this intervention will require longitudinal studies or randomized controlled trials. As part of the standard procedures all the participating patients completed questionnaires regarding their condition. Preliminary results from questionnaires relating to pain and pain self-efficacy indicated that the participating patients on average did not get worsening of their arm pain and their ability to cope with the pain during the 2 week test period.

The patient's perspectives

In development of the prototype of RehApp, an intervention-mapping study was done initially, where the focus was to identify important themes and issues for patients with CR. Some of the important themes identified, was: 1) getting information about the condition 2) feeling safe and involved in their own care 3) minimizing travel/transportation [5]. The information and knowledge from the intervention-mapping were included in the development and testing of 3 prototypes of RehApp, where 6 patients with CR gave feedback. Individual interviews of these patients were performed. Some of the statements that were repeated among the participants were that it was positive with information about the condition and access to information, guidance and exercises from their home. As one of the patients stated: 'The more knowledge you have the better you can handle your situation'

The patients also asked for audio-options, a reminder-function and an option of chatting and uploading pictures or videos in RehApp. This information was considered in the development of the final prototype of RehApp that was tested in the present pilot study



The patients experience using the final prototype of RehApp was examined in the pilot study with 14 questions about the contents, user-friendliness as well as negative and positive aspects of the application. It was also possible for the patient to add additional comments.

15 out of 16 invited patients participated in the survey.

Based on preliminary results from the survey, the overall rating of RehApp was average 8 on a Likert-scale, where 10 were good and 0 was poor. In terms of user-friendliness, guidance and improving the patient's sense of security, the patients on average graded RehApp to 7. All the participants found the written information useful. All the participants except one found the video podcast useful. In the comments-section, 7 out of 13 stated that RehApp could help them with their neck problem. 9 out of 13 stated that RehApp could help reminding them of doing their exercises. One pointed out that RehApp was a good help in managing the condition. One asked for the option of making the cardio-exercises more adjustable in time and contents. A few (2) stated that it was too difficult to use or it didn't serve their needs.

Economic aspects

A comprehensive economic evaluation of the consequences of implementation of the RehApp to manage patients with CR in the acute stage is challenging and has not yet been done. Some reasons are; 1) we do not know the exact one-year prevalence of CR in Denmark (10.000 is an estimate based on the incidence rate in other countries [6, 7], 2) we do not know the exact costs of health care utilisation for these patients in primary care, and 3) in the secondary care setting, diagnostic coding is a challenge. But we do know that surgeons are allowed to perform 2000 surgical procedures a year on the neck and that the major part of these are delivered to patients with CR [2]. Whether a new service like the RehApp would affect the rate of surgical procedure, hospitalisation or health care utilisation in primary care or sick-leave can only be detected by longitudinal studies or randomized controlled trials.

The Spine Centre of Southern Denmark sees on average 800 patients with CR on a yearly basis according to the official Danish patient registry (LPR). The mean number of visits is five. The costs per visit vary with between 767- 1682DKK. In the Spine Centre, approximately 200 patients with



CR had surgery since 2009, but at the moment, the number of patients referred to other departments for surgery is unknown. For a full economic evaluation, data on the average time spend in the Spine Centre, hours and distances on transportation travelling xx kilometres, and days of work has to be systematically collected.

The development of the new intervention has been costly in terms of hours spend by the researchers, research assistants and students from IoB and MMMI at SDU as well as time spend by health care professionals at the Spine Centre and the time spend by the involved company ExorLive as well as the value of their software. The hardware required for the patient to use RehApp is a smart phone, tablet or PC. A smartphone or tablet has to be provided for patients who do not have their own.

Using the Spine Centre as a business case, the ReHapp may potentially:

1. reduce the number of consultations
2. reduce the travel costs and the time spend by the patient in the SpineCentre
3. improve the patients self-management of pain
4. reduce the use of medication
5. reduce the use of primary care health services
6. reduce days of work

The cost for the prototype ReHapp is currently low because the development has been paid elsewhere. But for the future, the cost will be limited to smartphones or tablets for the patients, setting up infrastructure to manage communication and to buy the RehApp licence for patients. The potential cost savings are for the patient and at societal level. As a paradox, The Spine Centre will probably have a smaller income due to the fewer consultations.

The potential market for the RehApp is not only outpatient clinics but also Physiotherapy and Chiropractic clinics and rehabilitation centres in the municipalities managing the estimated 10.000 patients a year.



Organizational aspects

A qualitative focus group interview was conducted in spring 2015 in a group of 6 clinicians representing physical therapists, chiropractors, nurses and physicians in the Spine Center. Among the topics discussed were clinician's perspectives on the applications possible effect on clinical procedures and workflow.

Some of the general statements were that this type of intervention would be relevant for some of the patients. It would require some introduction and training of the clinicians in the setup and use of the technology. On the other hand this intervention might free up some time for more complex patients that require a more 'person to person' and interdisciplinary approach.

Some of the points from the clinician were also that it could help them in individualizing and optimizing treatment, since they would be able to get more detailed information from registered data about the patients' exercise-habits and pain patterns in the application.

Experience during the pilot study also indicates that the workflow in the clinic will change for this patient group and result in less time spent on physical visits and more time required for online consultation and monitoring for the health care professional.

It will also require some education and training of the health professionals in designing, updating and monitoring the application

Socio-cultural, ethical and legal aspects

Some concerns about the social and cultural aspects are that some people might benefit from this intervention, but due to ICT illiteracy it is not an option. Also patients, who do not understand Danish, will not be able to use the application. There will therefore be a need to translate the application into other languages if it proves to be feasible.



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