# **Evaluation of the Online Exercise Coach**

Published: 19-03-2009 Last updated: 06-05-2024

The primary objective is to investigate if the use of the Online Exercise Coach enhances compliance with the follow-up exercise program. Therefore the primary objective is: 1. Are patients who used the OEC during their follow-up exercise treatment...

Ethical reviewApproved WMOStatusWill not startHealth condition typeOther conditionStudy typeInterventional

## **Summary**

#### ID

NL-OMON34003

Source

ToetsingOnline

**Brief title** 

Online Exercise Coach

#### Condition

• Other condition

#### **Synonym**

chronic pain, non-acute pain

#### **Health condition**

chronic pain (low back pain, RSI, whiplash)

#### **Research involving**

Human

### **Sponsors and support**

**Primary sponsor:** Revalidatiecentrum Het Roessingh **Source(s) of monetary or material Support:** WOR

#### Intervention

Keyword: Compliance, Preferences, Satisfaction, Webbased exercise

#### **Outcome measures**

#### **Primary outcome**

The main study parameter of this study is compliance with the exercise follow-up program. Patients are asked to fill out a weekly diary to log the frequency and duration of their exercise sessions and the type of exercises they performed. In addition compliance is logged by means entries of the Online Exercise Coach by the patient.

#### **Secondary outcome**

Secondary parameters:

- b) Patients\* preferences towards exercise follow-up treatment A preference elicitation questionnaire is used to investigate preferences for follow-up care. These are explicit measures of benefit valuation for assessing alternative health care interventions (Gerard et al, 2007). In this research we investigate so called \*stated preferences\*; individuals\* stated preferences in hypothetical (or virtual) markets.
- c) Patients\* satisfaction with follow-up treatment User satisfaction will be measured by means of a self-constructed questionnaire since no standardized and validated questionnaires are available to assess user satisfaction of teletreatment services like the Online Exercise Coach. The Theory of Planned Behaviour (TPB) (Ajzen, 1991) and the Technology Acceptance Model (TAM) (Davis, 1989; Davis, Bagozzi, & Warshaw, 1989), two models widely used and

well-supported in the uptake of ICT based services, are used as underlying theoretical framework. The models suggest that behavioural intention is preceded by a patient\*s perceived usefulness, perceived ease of use, attitude, social norm and self-efficacy. The items of the questionnaire will assess these determinants and their intention to use the OEC.

#### d) Effectiveness of follow-up treatment

Pain intensity (assessed by means of VAS scales)/ the level of subjectively experienced disability due to pain (assessed with the PDI, a self-rating scale that contains 7 items for the domains: 1) family and home responsibilities, 2) recreation - sports and leisure time activities, 3) social activity - participation with friends and other acquaintances, 4) occupation - activities partly or directly related to working, 5) sexual behaviour - frequency and quality of sex life, 6) self-care - basic life-supporting behaviours and 7) daily activities)/ the level of pain-related anxiety (assessed with the PASS20, a scale that assesses self-reported levels of pain related anxiety) and hysical and mental health (assessed by the SF36 that measures eight domains of health)

e) Technical feasibility will be measured by means of automatic data logging of the Online Exercise Coach website. In addition, technical complaints of both patients and health care professionals will be registered and analysed.

Therefore the professionals and patients are asked to log technical problems and failures they encounter and report this to the researcher by email or telephone.

# **Study description**

#### **Background summary**

At present, physical exercises are a principal part of every multidisciplinary programme for the treatment of chronic low back pain (Guzman et al, 2002). A recent systematic review of Henchoz & Kai-Lik So (2008) found exercise to be effective in the primary and secondary prevention of low back pain. Reviews and randomised controlled studies inspected by the Cochrane Group also underscore the importance of exercise training in the treatment of subjects with persistent pain (Van Tulder et al.,1997, 2000; Ostelo et al., 2005). Results from Rainville, Hartigan & Martinez (2004) underline these results. In addition, Rossy et al (1999) found that those with chronic pain benefit greatly from increased aerobic conditioning. Results from literature reviews are in line with these results.

However, adherence to exercise programs remains problematic. Dropout rates have ranged from 10% to 36% and many patients\* exercise adherence levels decline even further once they complete their program (Blanchard et al, 2003). Moore et al (1998) showed that only 30% of their sample was engaging in regular exercise.

As ICT makes it possible to deliver alternative models of service delivery, home-based treatment becomes possible. Home-based exercise programs have to potential to better meet preferences of patients and in this way enhance exercise treatment compliance. For example, travel times is reduced, an important barrier to compliance of regular outpatient exercise programs. In addition, home based exercise programs offer the benefit of flexible exercise hours and the advantage that a patient can fit the program within his/her daily routine. Both benefits were greatly valued by the patient sample in the research of Ruland et al (2000). Other research investigating perceived barriers by patients to adhere to exercise programs confirm these results (Van Baar et al, 2006; Jones et al, 2007) and underscore the benefits home exercise could offer tot the patient. In addition, home-based programs foster patient-empowerment and self-management, especially important in chronic diseases. The patient learns to take own responsibility for his or her own health and in this way there is a bridge between the \*gap\* of treatment and no treatment at all, which may prevent a sudden relapse of the patient when treatment stops. This so called \*empowerment\* of the patient fits in with the current trend in healthcare. In summary, ICT based exercise programs have the potential to overcome patients\* perceived exercise barriers.

Online Exercise Coach (OEC)
In the present study, the Online Exercise Coach, an online tailored exercise

program, developed by Roessingh Research & Development and Roessingh en Roessingh Revalidatie Centrum (in Dutch: Online Bewegings Coach) will be subject of research. The OEC is deployed as six weeks follow-up care. After patients completed their clinic-based treatment, each policlinic therapist selects exercises suitable for the follow-up treatment for his patient, by logging onto the website www.r-motion.nl. Following, the patient logs onto the website and is able to compose his own weekly exercise schedule by selecting exercises from the list of exercises his therapist selected. In addition patients have the opportunity to view the exercises on their computer by playing the video-files on the website. Also they are offered an email function on the website where they can contact their therapist in case they have questions about their exercises.

#### Treatment preferences

As ICT home-based exercise programs are hypothesized to be cheaper, more easily performed and efficient compared to regular exercise programs, they may be preferable for the treatment of chronic pain. But is it something patients want? Patient preferences are of great importance as they offer the possibility to select treatment that best matches the needs and expectations of the patients. Gan et (2004) al state this improves compliance, treatment outcomes, and ultimately satisfaction. Patients who receive their preferred treatment might be better motivated and comply better with the treatment programmes and report better outcomes (King et al, 2005). McPherson et al (1997) also suggest a moderating effect of preferences on treatment effect.

However, the effect of patients\* preferences on treatment outcomes remains uncertain. A systematic review of King et al (2005) concludes that participant or physician preferences influenced outcome results. But, evidence for moderate or large preference effect on outcome was much weaker when only large trials were taken into analyses and when baseline differences were taken into account. When preference effects where evident, they were inconsistent in direction. On the contrary, a recent meta-analysis of eight musculoskeletal trials proved that patients\* preferences were associated with treatment effects. Patients who were randomised to their preferred treatment had showed a greater effect size those who were indifferent to the treatment assignment.

In the field of telemedicine, preferences are not yet studied. In order to develop new interventions that better suit the needs of patients and in this way enhance compliance rates, treatment outcomes and patients satisfaction, it is important to investigate patients\* preferences regarding telemedicine interventions.

#### Study objective

The primary objective is to investigate if the use of the Online Exercise Coach enhances compliance with the follow-up exercise program. Therefore the primary objective is:

1. Are patients who used the OEC during their follow-up exercise treatment more compliant than patients who did not use the OEC?

#### Secondary objectives:

#### **Preferences**

- 2. What are the preferences of chronic pain patients regarding exercise follow-up treatment?
- a) Do chronic pain patients prefer the OEC or the traditional advice as exercise follow-up treatment?
- b) Which attributes of OEC and traditional advice exercise follow-up treatment are considered as most important by chronic pain patients?
- 3. Do exercise follow-up treatment preferences change after patients completed their follow-up treatment?

#### Satisfaction

- 4. How satisfied are patients on the factors of the intention-based models (such as the TPB and TAM model: attitude, self-efficacy and/or social support, perceived ease of use and perceived usefulness)?
- 5. Is the technical performance of the OEC sufficient for clinical use from the end user perspective?

#### Clinical Effectiveness

- 6. Do patients\* interference of pain, actual pain levels, pain related fear of movement and general health change after six weeks of exercise follow-up treatment?
- 7. Do patients who used the OEC during their follow-up score better on interference of pain, actual pain levels, pain related fear of movement and general health than patients who did not use the OEC?

#### Study design

The study design is a 'randomized controlled trial' (RCT) in which the intervention group receives the Online Exercise Coach. The control group receives the traditional follow-up treatment.

#### Intervention

Subjects in the experimental group will receive six weeks of OEC follow-up treatment. Patients have access to their online tailored exercise programs by logging onto the website www.r-motion.nl. Patients\* former policlinic therapist will select a broad range of exercises from which the patient can choose from to create his own exercise programme. The exercises consist of mobilizing, muscle strengthening and conditional exercises. In addition patients have the opportunity to view the exercises on their computer by playing the video-files on the website. Also they are offered an email function on the website where

they can contact their therapist in case they have questions about their exercises.

The control group comprises of a six week exercise follow-up program by means of once-only instruction by word of mouth at the end of the policlinic treatment at \*Het Roessingh\*. If patients experience problems during their six weeks of follow-up treatment they are instructed to call their therapist. Patients in both the intervention and control group are asked to exercise for 30 minutes 3 times a week.

#### Study burden and risks

The OEC is estimated to have minimal risk as patients are trained in the exercises presented during the follow-up treatment and learned to recognize their own boundaries. In addition, the exercises patients will perform during follow-up treatment are approved by the clinical physicians. The burden to the patients exists of filling in questionnaires and investing time to learn to operate the OEC. Potential risks and burden outweigh the potential benefit patients receive, as they have the opportunity to receive detailed information on what and how to execute exercises during their follow-up treatment. In addition, patients contribute to the development of better follow-up treatment for future patients. The ultimate goal is to develop a follow-up treatment that serves the needs and preferences of chronic pain patients.

### **Contacts**

#### **Public**

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## **Trial sites**

#### **Listed location countries**

**Netherlands** 

## **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

#### Inclusion criteria

Chronic low back pain, RSI, whiplash Age of 18 years or older Successful completion of policlinic treatment at 'Het Roessingh'

#### **Exclusion criteria**

Insufficient control of the Dutch language

# Study design

### **Design**

Study type: Interventional

Intervention model: Other

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Treatment

#### Recruitment

NL

Recruitment status: Will not start

Enrollment: 56

Type: Anticipated

## **Ethics review**

Approved WMO

Date: 19-03-2009

Application type: First submission

Review commission: METC Twente (Enschede)

# **Study registrations**

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register ID

Other in behandeling bij NTR

CCMO NL25915.044.08