

# additional intervention for self-management in chronic pain patients

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Relapse after an intensive rehabilitation program is a problem, the additional intervention which is developed aimed to prevent this. The intervention is innovative and no alternatives are known in the literature. The following practical questions...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON47980

### Source

ToetsingOnline

### Brief title

Agrippa

### Condition

- Other condition

### Synonym

chronic pain

### Health condition

chronische musculo-skeletale pijn

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Hogeschool Utrecht

**Source(s) of monetary or material Support:** RAAK Publiek

## Intervention

**Keyword:** additional intervention, chronic pain, selfmanagement

## Outcome measures

### Primary outcome

1) The degree of relapse, relapse is defined here as the patient's inability to retain the profit made in the area of daily functioning during rehabilitation.

The Pain Disability Index and the Pain Self Efficacy Questionnaire (Van der Maas. 2012) from the Dutch Pain Rehabilitation Data Set are used as an outcome measure.

### Secondary outcome

Fear avoidance beliefs (FABQ), Self efficacy (PSEQ), illness perception (IPQ-k) and psychological flexibility (PIPS) are viewed as mediators. In addition, healthcare consumption is monitored by completing a cost diary.

## Study description

### Background summary

Chronic pain is defined as pain that lasts longer than three months, or lasts longer than the expected time for recovery from damage or illness. Compared to other chronic conditions, chronic pain is common. Chronic pain is a complex and expensive problem. Chronic pain has a major impact on quality of life, daily functioning, mood and absenteeism. One in 5 adult Dutch people (2.25 million ) experience chronic pain. With low back pain, for example, recurrent complaints are very common and regularly develop into a chronic problem (Hartvigsen J 2018). Chronic pain costs Europe billions of euros: almost  $\times$  300 billion or around 1.5-3% of GDP. There is currently no treatment that completely resolves

chronic pain. At the momentThe best treatment for chronic pain treatment aimed at self-management.. In the "Zorgstandaard Chronische Pijn (2016)", pain is defined as a multi-factorial problem in which the cooperation between primary care and secondary care is strongly advocated (Stepped Care model).

Effects of pain rehabilitation give positive results on pain perception and physical and mental functioning. However, these are described particular in the short term. In the longer term, 30-70% of patients appear to relapse and seek care for their pain problem again. Remarkably little scientific research has been done on the long-term effects of a pain rehabilitation program(Morley 2008). In a recent study in the Netherlands into the long-term effects of 15 weeks of pain rehabilitation, between 37% and 55% of patients reported a clinical improvement in the event of discharge, which after a year of follow-up appeared to be constant. However, some of the patients also experienced a relapse (Volker et al 2017). Currently a study is under construction on the long-term effects and relapse of three Dutch pain rehabilitation centers (SOLACE study).

The main goals of pain rehabilitation are learning to deal with pain differently (behavioral change) and promoting self-management. During the treatment, the patient is taught skills to ultimately "be able to do it himself." In addition, the rehabilitation centers have been reluctant to offer much aftercare because this could possibly have the opposite effect on the degree of self-management of a patient. That is why, up to now, often no or only limited formal aftercare has been arranged. At the same time, it is known that patients regularly return to rehabilitation centers with the request for help for renewed support or help with relapse. A new treatment process is then often started. The SOLACE study (SIA RAAK public 2014-02-23P) showed that patients need more support to perpetuate the results of their rehabilitation and prevent relapse.

The SOLACE consortium has developed two interventions with which relapse can be prevented. Both are elaborated in the form of a workbook that is used during the treatment and that facilitates and supports the application of acquired skills after the treatment.

- \* The first intervention, Do It Yourself (DIY), facilitates the registration of all important events and insights that the patient experiences during rehabilitation. These insights can then be used to a) check whether they are in line with the rehabilitation program; b) create a timeline to jointly evaluate progress; and c) to be used as a reference work after the rehabilitation.

- \* The second intervention consists of a scheme that helps patients formulate value-oriented goals (WD) and then plans and monitors these goals step by step. The applicability and user-friendliness of the workbook has been evaluated (feasibility). However, the long-term effectiveness of these prototypes has not yet been investigated. The question clearly emerged during the feasibility study, in addition to the question about the shape of the workbook, paper or digitally via an app.

The current application (Agrippa) combines both intervention modules and relates to the effectiveness of the additional intervention in the form of an

app.

## **Study objective**

Relapse after an intensive rehabilitation program is a problem, the additional intervention which is developed aimed to prevent this. The intervention is innovative and no alternatives are known in the literature.

The following practical questions were formulated in consultation with care professionals, rehabilitation institutions and patients' associations;

\* Are the interventions developed from SOLACE study that are used after an intensive rehabilitation period, in the long term, 6 to 12 months, effective to prevent relapse and medical shopping?

\* Is the digital application, Agrippa app, of the developed intervention as useful as it is effective?

By answering these two practical questions, the consortium aims to contribute to the development of an optimal rehabilitation process for chronic pain patients.

## **Study design**

A multi center randomized clinical trial. Randomisation is at group level.

## **Intervention**

Agrippa app; Application on the smartphone with the content developed in an earlier study (SOLACE) based on general self-regulation principles with the aim of transferring crucial treatment insights to the patient's personal context.

## **Study burden and risks**

The population undergoes the normal rehabilitation process, the intervention group receives an application for the smartphone, there are no risks involved.

The advantage of using the app is that patients themselves can reverse a relapse by easily retrieving the set goals and values via text, image and / or sound so that they can also retrieve the positive experiences within regular rehabilitation and later after the rehabilitation (themselves management).

The load depends on the usage, can be a daily or in a much lower frequency.

## **Contacts**

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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 Pain Patients qualified for a intensive rehabilitation program in the secondary care defined as patient with a classification WPN 3 and 4 ( Werkgroep Pijnrevalidatie Nederland); social and psychological factors are complex to very complex and play an important role

### **Exclusion criteria**

Chronic pain patient not classified as WPN 3 or 4. Patients with specific complaints like rheumatoid arthritis, carcinoma, stroke etc

## **Study design**

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	150
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	02-10-2019
Application type:	First submission
Review commission:	METC NedMec

## 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

CCMO

### ID

NL69066.041.19