A pilot study on app-based treatment, combining physical exercise, graded activity, and pain journaling for patients with spinal complaints.

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Primary Objective: To assess the effectiveness of an app-based treatment combining physical therapy, graded activity, and pain journaling, in improving health-related quality of life measured with the EuroQol 5 dimensions (EQ-5D-5L) in patients with...

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON57321

Source
ToetsingOnline

Brief title
SPINAPP Study

Condition

- Joint disorders

Synonym
back pain, chronic back pain, Spinal complaints

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: The eHealth Project B.V.,Wetenschapsgelden Zuyderland MC

Intervention

Keyword: App-based, eHealth, Pilot study, Spinal complaints

Outcome measures

Primary outcome

8.1.1 Main study parameter/endpoint

The primary outcome is change in QoL measured from baseline to three-month follow-up using the EQ-5D-5L. With interval measurements at baseline and after one, two and three months of treatment.

Secondary outcome

o Demographics

o Change in pain, measured with the Visual Analogue Scale (VAS).

o Change in disability, measured with the Oswestry Disability Index (ODI).

o Change in lost productivity, measured with missed working days.

o Change in Body Mass Index, measured using patients* input on length and weight.

o Adherence of participants measured using frequency of patients* input in the mobile application.

o Patients* experience and satisfaction qualitatively, measured using semi-structured face-to-face interviews.

o Safety measured using the (serious) adverse events ((S)AE).

Adverse events: increased pain or discomfort for which the patient visits the

hospital, neurological deficits, technology-related issues. Adverse events will

be followed up to 30 days after completion of the treatment period.

Study description

Background summary

The incidence of spinal complaints is increasing in our ageing population. Back pain is amongst the conditions with the highest burden of disease in terms of years lived with disability (YLD), with a global lifetime prevalence of about 80%. The global prevalence of spine-related complaints is 9.4%, and this increases with age, reaching 19-23% by the age of 80 [1, 2]. Besides age, spine-related disorders are also associated with a sedentary lifestyle and obesity [3]. Consequently, as our population ages and rates of obesity and physical inactivity increase, the number of patients with spine-related disorders is rising exponentially [3-5]. Besides causing significant pain and impairment, spinal complaints also impose an economic burden on healthcare systems worldwide. This economic burden is reflected by considerable healthcare-related costs and indirect costs such as loss of productivity [6-8]. Traditional conservative interventions, such as physical therapy, pharmacological management, and lifestyle modifications are the most widely used modes of treatment for most spinal complaints, mainly back pain [9-11]. It should be noted that there is conflicting evidence on the effect of most of these treatments, although there might be evidence for their effectiveness in the short term. It is apparent that physical therapy and lifestyle modifications focused on physical activity are the most successful options to achieve long term results [12, 13].
The digital revolution in the healthcare sector, characterized by rapid proliferation of health apps, offers promising avenues for innovative treatment modalities. These app-based interventions have potential to deliver personalized treatment regimens, provide real-time feedback, and enhance patient engagement, from the convenience of a patient's mobile device [14]. Another possible benefit of app-based treatments is the wide availability and scalability at relatively low costs, especially when compared to traditional treatments [15, 16].
While these digital tools hold promise, there remains a critical need to assess their efficacy. Studies of healthcare apps in other fields have shown mixed results, with most indicating promising outcomes from app-based interventions, while some suggest only small benefits, like traditional treatment modalities [17, 18]. As evidence within spinal care is limited, our study seeks to provide a comprehensive evaluation of the efficacy of an app-based treatment for spinal complaints that do not require a specific intervention.

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Study objective

Primary Objective:
To assess the effectiveness of an app-based treatment combining physical therapy, graded activity, and pain journaling, in improving health-related quality of life measured with the EuroQol 5 dimensions (EQ-5D-5L) in patients with spinal complaints who would receive physical therapy, general lifestyle advice, or an expectant treatment in current practice.

Secondary Objectives:
1. To assess the change in pain, measured with the Visual Analogue Scale (VAS).
2. To assess the change in disability, measured with the Oswestry Disability Index (ODI).
3. To assess the change in catastrophizing of pain, measured with the Pain Catastrophizing Scale (PCS).
4. To assess the change in lost productivity, measured with missed working days.
5. To assess change in Body Mass Index, measured using patients* input on length and weight.
6. To evaluate the adherence of participants, measured using frequency of patients* input in the mobile application.
7. To evaluate the patients* experience and satisfaction qualitatively, using semi-structured face-to-face interviews.
8. To evaluate the safety of the intervention, measured based on the occurrence of (serious) adverse events. Adverse events reported spontaneously by the subject or observed by the investigator or medical staff will be recorded.

Hypothesis:
An app-based treatment combining physical therapy, graded activity, and pain journaling is effective in increasing health-related quality of life in the studies population.

Study design

A prospective pilot study with a treatment and follow-up duration of three months will be conducted in Zuyderland Medical Centre Heerlen, the Netherlands. The follow-up period of three months is chosen, as it is deemed appropriate to allow for a comprehensive evaluation of the app's usability, acceptance, and initial efficacy in managing spinal complaints. Moreover, a short study period reduces recall bias in qualitative data. A longer follow-up period, e.g. one year, would provide more data on long-term effects, but is beyond the scope of this pilot study.
This study includes patients with spinal complaints who would receive physical therapy, general lifestyle advice, or an expectant treatment, in current

practice and do not require another specific treatment or surgical intervention. Patients eligible for inclusion will be referred to the researchers. The researchers will inform the patient, and when they are willing to participate and meet the inclusion criteria, include them. Patients will provide informed consent when first logging into the treatment app.

Intervention

5.1 Investigational product/treatment
The app-based treatment consists of a combination of physical therapy, graded activity, and pain journaling. The app will be installed on the participant's mobile device. The app will be used anonymously, and patients use their unique study code to activate the app.

Physical therapy
Patients are instructed to perform several stretches daily. It is advised to perform each stretch for 20-30 seconds. Patients will receive information on how to properly perform these stretches through text, images, and optional videos. The included stretches are:
1. Cat-cow stretch or a combination of pelvic tilts and knees to chest stretch.
2. Seated or standing hamstring stretch.
3. Kneeling or standing hip flexor stretch.
4. Seated or lying thoracic rotations.

Graded activity
In the graded activity section of the app, patients chose either walking or bicycling, based on their own preferences. Both graded activity programmes have the same structure. The program starts with a baseline self-assessment. Patients determine how many minutes they can perform the activity before the pain reaches VAS 7 (significant pain). This number of minutes is then applied in the graded activity program. Pain scores are monitored during and after activity.

Frequency: Once every day. If the duration of the activity exceeds 10 minutes, the frequency is adjusted to once every two days.
Duration: Start with a duration that 70% of the baseline assessment. For instance, if the patient can walk for 10 minutes before pain intensifies to a level at which the patient has to stop, start with 7 minutes.
Pain Score Monitoring: If the planned activity is not reached due to pain, the duration of activity is not adjusted.
Incremental Increase: Increase the duration by 10% after each activity without significant pain, with a minimal increase of one minute.
Steady State: If the patient is able to walk for longer than half an hour without significant pain, no adjustments are made.

Pain Journaling
The app incorporates pain and symptom journaling. The app uses graphics to

provide patients with insight on the symptoms, exercise frequency and activity. The following components are included:
1. Daily: Exercises logging, VAS back pain score & analgesics used (paracetamol, NSAIDs, opioids, neuropathic analgesics, other).
2. Seven - three times a week, depending on level of activity: activity (minutes) and VAS back pain during and after activity: activity (minutes) and VAS back pain during and after activity.
3. Monthly: Health-related quality of life (EQ-5D-5L), disability (Oswestry Disability Index), pain catastrophizing (PCS), weight (kilograms), work absenteeism (days, including unpaid work).

Study burden and risks

The nature and extent of the burden associated with participation in our app-based treatment program primarily involve adherence to the recommended activities and inputting relevant health data. Adherence to the prescribed activity and inputting data will take several minutes per day. Based on tolerance to activity, this may amount to a maximum of three hours per week. Given that we are integrating existing treatment modalities such as physical therapy, graded activity, and pain journaling, the risks associated with participation are minimal, as these interventions are already deemed safe and widely practiced. Participants can expect benefits such as improved pain management, enhanced physical function, and better overall well-being. Additional educational information such as frequently asked question and red flags included in the app are based on professional guidelines. Moreover, we refer to professional and reliable information, specifically developed for Dutch patients (thuisarts.nl).

Contacts

Public
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL
Scientific
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

o Patients visiting the spine-centre at Zuyderland Medical Centre.
o Suffering from spinal complaints for which in current practice physical therapy, general lifestyle advice, or an expectant treatment would be advised.
o Minimum age of 18 years.
o Psychosocially, mentally, and physically able to fully comply with this study protocol.
o Informed consent prior to this study.

Exclusion criteria

o Requiring a specific intervention (e.g., surgery, pain treatment, rehabilitation, bracing)
o Inadequate command of the Dutch language.
o Digitally illiterate or otherwise unable to use an application on a mobile phone.
o Active spinal infection.
o Immature bone (ongoing growth).
o Active malignancy.
o Pregnancy.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	De Rug App
Registration:	No

Ethics review

Approved WMO

Date:	20-02-2025
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
CCMO	NL87666.000.24