e-Exercise: Stratified blended physical therapy in patients with non-specific low back pain

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To investigate the short-term (3 months) effectiveness on physical functioning, and the long-term (24 months) cost-effectiveness, of a personalized stratified blended care intervention (e-Exercise LBP) in comparison with usual physical therapy in...

Ethical review	Approved WMO
Status	Completed
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON50272

Source
ToetsingOnline

Brief title
e-Exercise low back pain

Condition

- Musculoskeletal and connective tissue disorders NEC
- Lifestyle issues

Synonym
low back pain, non-specific low back pain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: SIA-RAAK Pro (NWO)

Intervention

Keyword: E-health, Low back pain, physical therapy

Outcome measures

Primary outcome

The main study parameters are the short-term improvement of lower back related physical functioning and the long-term reduction of low back pain related costs.

Secondary outcome

Different secondary and other study parameters will be measured to describe the study population, to determine the (cost)-effectiveness of e-Exercise LBP and adjust the statistical analysis for potential confounders:

Secondary study parameters: Pain intensity, physical activity, adherence to prescibed home exercises, psychological functioning, self-efficacy, self-management skills, the number of reccurent low back pain episodes, and health related quality of life.

Other study parameters: Patient characteristics, the risk of developing persistent low back pain, central sensitization, the usability of the e-Exercise low back pain app, and the content and number of physical therapy sessions.

Experiences with selfmanagement behavior of patients with chronic low back pain

after following e-Exercise Low Back Pain.

Study description

Background summary

Non-specific low back pain is the most common cause of disability in western society. Physical therapy is recommended for patients with non-specific low back pain in national and international guidelines. Recently, research has shown that a stratified-care approach based on patients* prognostic risk profile led to similar outcomes, higher quality-adjusted life years for patients, and lower health costs. However, applying a stratified-care approach is currently not common practice in Dutch primary care. Furthermore, research has shown that the effectiveness of physical therapy highly depends on patients* adherence to physical activity and home-based exercise recommendations. Blended care, the integration of e-health technology into physical therapy care appears promising for improving physical therapy care outcomes and patients* adherence in the short- and long-term.

Study objective

To investigate the short-term (3 months) effectiveness on physical functioning, and the long-term (24 months) cost-effectiveness, of a personalized stratified blended care intervention (e-Exercise LBP) in comparison with usual physical therapy in patients with non-specific LBP.

Study design

Prospective cluster randomized controlled trial. Randomization will be done at the level of the participating physical therapy practices.

Intervention

In the intervention group patients with non-specific low back pain are stratified into three different groups based on the risk to develop persistent low back pain. Patients are treated using a blended care approach (e-Exercise) in which online e-health modules are an integral part of face-to-face physical therapy treatment. The e-Exercise low back pain program is an app containing information and self-management modules, a home-based exercise module and offers remote support to increase adherence to physical activity and exercise recommendations. Patients in the control group receive usual physical therapy care according to the Royal Dutch Association for Physical Therapy Guideline for the treatment of non-specific low back pain.

Study burden and risks

Patients are asked to complete a number of questionnaires at baseline, 3, 12 and 24 months. Additionally, the patients are asked to report on healthcare utilization and (unpaid) productivity losses retrospectively every 3 months for the duration of the trial. The content of the intervention is based on current literature, guidelines and focus groups with patients, physical therapists and experts. Therefore, risks for participating patients in the experimental group is expected to be similar to usual physical therapy care.

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

Patients with non-specific low back pain will be recruited within the participating physical therapy practices. In order to be eligible to participate in this study, a patient must meet all of the following criteria:
- being a patient applying for physical therapy for non-specific low back pain;
- aged 18 years or older;
- non-specific low back pain, defined as pain in the lumbosacral region (sometimes associated with radiating pain to the buttock or leg) in the absence of an identifiable underlying cause;
- possessing a smartphone or tablet with access to the internet;
- mastery of the Dutch language.

Exclusion criteria

A potential patient who meets any of the following criteria will be excluded from participation in this study:
- low back pain due to a possible specific cause trough medical imaging or a medical doctor (e.g. osteoporotic fractures, spinal nerve compromise, malignancy, ankylosing spondylitis, canal stenosis, or severe spondylolisthesis).
- serious comorbidities (e.g., malignancy, stroke);
- current pregnancy, due to the prevalence of pelvic girdle pain as a specific form of LBP.

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:	Completed
Start date (anticipated):	17-07-2018

Enrollment:	208
Type:	Actual

Ethics review

Approved WMO Date:	11-04-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	26-06-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-04-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-12-2020
Application type:	Amendment
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	ID
Other	ISRTCN: 94074203
CCMO	NL64425.041.18

Study results

Date completed:	31-12-2021
Results posted:	01-12-2023
Actual enrolment:	208

First publication
01-12-2023