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

Submission date
17/07/2018

Recruitment status
No longer recruiting

Registration date
20/07/2018

Overall study status
Completed

Last Edited
01/12/2023

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Low back pain is a common cause of disability and can cause pain and limitations in daily functioning such as shopping or working. In some people the low back pain lasts for a long time, or returns on a regular basis. A patient can do a lot to relieve his/her own low back pain, for example by doing exercises or being physically active.
The extent to which a patient recovers from low back pain depends on how the patient deals with low back pain. A physical therapist is able to provide a patient with guidance and support, but it is often difficult for patients to adhere to their advice completely.
An alternative to this is the use of an e-Exercise smartphone app, which can support the patients' adherence and improve self-management by providing information about low back pain and what the patient can do to promote recovery. In addition, the app offers support aimed at resuming daily activities, exercises and being physically active.
The aim of this study is to investigate whether the result of physical therapy can be improved by using the e-Exercise smartphone app.

Who can participate?
Males and females aged 18 years or older having non-specific low back pain can participate in this study

What does the study involve?
The study compares two different treatment programs. One group will receive physical therapy treatment in combination with the e-Exercise smartphone app. The other group will receive physical therapy without the app. Participants will be asked to complete questionnaires during and after the treatment (24 months follow-up) to assess the effects of the treatment.

What are the possible benefits and risks of participating?
It is expected that there will be benefits to participants in both groups, through improved physical function and reduced pain intensity. There are no known risks to participants of taking part.

Where is the study run from?
The trial is run from the University Medical Centre (UMC) Utrecht, the Netherlands

A total of 50 physical therapy practices throughout the Netherlands will be taking part in the study and treat the included patients with low back pain.

When is the study starting and how long is it expected to run for?
November 2017 to October 2021

Who is funding the study?
Dutch Organization for Scientific Research (NWO) (The Netherlands)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
SVB/RAAK.PRO02.063

Study information

Scientific Title
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.

Acronym
e-Exercise LBP

Study objectives
This study aims to examine 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Board of the University Medical Centre Utrecht, 11/04/2018, 18/085

Study design
Interventional prospective cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-specific low back pain

Interventions
Randomisation is done at the level of the participating physical therapy practices. Participating primary care physical therapy practices will be randomized by an independent researcher to either the intervention group or the usual care (control) group by a computer-generated random

sequence table generated using SPSS. Through cluster randomization, the possibility of professionals offering both experimental and usual care intervention is avoided and/or that professionals who offer the experimental or usual care intervention within one physical therapy practice will influence each other (contamination-effect).
Participants in the intervention group are stratified into 3 different groups based on the risk to develop persistent low back pain. All participants in the intervention group 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 - face-to-face care by a physical therapist, supported by a smartphone app. The stratification of the patients in this group means that the support of the app can differ based upon the risk profile of the patient - e-Exercise is tailored to the patients' individual needs, based on their prognostic risk for developing persistent LBP, as determined by the Keele STarT Back Screening Tool. 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. The online modules consist of (1) video-based LBP self-management information, (2) an individualized home-based exercise program including instruction videos and (3) a physical activity module to maintain or improve patients' individual level of physical activity, based on the principles of graded activity.
The control group receive usual care according to the recommendations of the guideline LBP of the Royal Dutch Association for Physical Therapy (KNGF) without the use of e-health applications.
Participants in both groups will be instructed to wear the Activ8 activity monitor for 5 consecutive weeks at baseline and 8 consecutive days at follow-up except during sleeping, showering, bathing or swimming, in order to measure time spent sitting/lying, standing, walking, running and cycling.

Intervention Type
Behavioural

Primary outcome(s)
1. Short-term improvement of low-back-related physical functioning assessed using the Oswestry Disability Index version 2.1a at the baseline, after 3 months, after 12 months and after 24 months
2. Long-term reduction of low-back-pain-related costs assessed using 8 retrospective cost questionnaires every 3 months from the baseline to the 24 months follow-up. Cost effectiveness is determined after 12 months and after 24 months, based on patient's healthcare utilisation and (unpaid) productivity losses due to LBP (based on responses to the cost questionnaires). Healthcare utilization will be valued using Dutch standards costs. If these are unavailable, prices reported by professional organizations will be used. Unpaid productivity losses will be valued in accordance with the "Dutch Manual of Costing". Paid productivity losses comprise of both sickness absence and presenteeism (i.e. reduced productivity while at work). Sickness absence will be valued in accordance with the "Friction Cost Approach" (FCA), with a friction period of 23 weeks and an elasticity of 0.8, using age- and gender-specific price weights. The FCA assumes that production losses are confined to the "friction period" (i.e. time needed to replace a sick worker) and that a 100 percent loss of labor input corresponds with an 80 percent reduction in productivity (i.e. an elasticity of 0.8)(63). The participants' level of presenteeism will be measured using the "World Health Organization – Work Performance Questionnaire" as well as the "Productivity and Disease Questionnaire", and valued using age- and gender specific price weights. The costs of e-Exercise LBP will be estimated using a bottom-up microcosting approach.

Key secondary outcome(s))

Current secondary outcome measures as of 26/04/2021:
The following will be assessed at the baseline, after 3 months, after 12 months and at the 24 months follow-up:
1. Pain intensity, assessed using the Numeric Pain Rating Scale (NPRS)
2. Physical activity, assessed using Activ8 activity monitor
3. Adherence to prescribed home exercises, assessed using Exercise Adherence Rating Scale (EARS) and Utrecht Home-based Exercise Adherence Questionnaire (UHAQ). EARS is a self-reported questionnaire and UHAQ is an interview-based questionnaire, which will be used by the physical therapist during face-to-face care, to determine qualitative performance of the recommended recommended home exercises and the agreement between recommended home exercises and patient reported adherence
4. Psychological function, assessed using the Fear-Avoidance Beliefs Questionnaire (FABQ) and the Pain Catastrophizing Scale (PCS)
5. Self-efficacy, assessed using the Generalized Self-Efficacy (GSE) scale
6. Self-management skills, assessed using the Dutch version of the Pain Activation Measure (PAM13-Dutch)
7. Health-related quality of life, assessed using the EQ-5D-5L
8. Number of recurrent low back pain episodes, assessed every 3 months from the baseline until the 24 months follow-up. This is measured using the number of self-reported LBP episodes during the follow-up period (a recurrent LBP episode is defined as return of LBP with a minimum duration of 24 hours with a minimum pain intensity of 3 or more on the NRS since the date of recovery. For recovery, a minimum duration of 4 weeks pain-free is used)

Previous secondary outcome measures:
The following will be assessed at the baseline, after 3 months, after 12 months and at the 24 months follow-up:
1. Pain intensity, assessed using the Numeric Pain Rating Scale (NPRS)
2. Physical activity, assessed using Activ8 activity monitor
3. Adherence to prescribed home exercises, assessed using Exercise Adherence Rating Scale (EARS) and Utrecht Home-based Exercise Adherence Questionnaire (UHAQ). EARS is a self-reported questionnaire and UHAQ is an interview-based questionnaire, which will be used by the physical therapist during face-to-face care, to determine qualitative performance of the recommended recommended home exercises and the agreement between recommended home exercises and patient reported adherence
4. Psychological function, assessed using the Fear-Avoidance Beliefs Questionnaire (FABQ) and the Pain Catastrophizing Scale (PCS)
5. Self-efficacy, assessed using the Generalized Self-Efficacy (GSE) scale
6. Self-management skills, assessed using the Dutch version of the Pain Activation Measure (PAM13-Dutch)
7. Health-related quality of life, assessed using the EQ-5D-5L
8. Risk of developing persistent low back pain, assessed using the STarT Back Tool (SBT)
9. Central sensitivity, assessed using the Central Sensitization Inventory (CSI)
10. Usability of the e-Exercise low back pain app, assessed using the System Usability Scale (SUS)

11. Number of recurrent low back pain episodes, assessed every 3 months from the baseline until the 24 months follow-up. This is measured using the number of self-reported LBP episodes during the follow-up period (a recurrent LBP episode is defined as return of LBP with a minimum duration of 24 hours with a minimum pain intensity of 3 or more on the NRS since the date of recovery. For recovery, a minimum duration of 4 weeks pain-free is used)

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Applying for physical therapy for LBP
2. Aged 18 years or older
3. Non-specific LBP, 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
4. Possessing a smartphone or tablet with access to the internet
5. Able to communicate in the Dutch language fluently

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
208

Key exclusion criteria
1. Diagnosed with LBP due to a possible specific cause trough medical imaging or a doctor (e.g. osteoporotic fractures, spinal nerve compromise, malignancy, ankylosing spondylitis, canal stenosis, or severe spondylolisthesis)
2. Serious comorbidities (i.e. malignancy, stroke)
3. Pregnant

Date of first enrolment
13/07/2018

Date of final enrolment
19/12/2019

Locations

Countries of recruitment
Netherlands

Study participating centre

Dept. of Rehabilitation, Physiotherapy Science and Sport, UMC Utrecht, Utrecht University
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Sponsor information

Organisation
UMC Utrecht

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Not defined

Funder Name
Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Alternative Name(s)
Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, The Dutch Research Council (NWO), Dutch Research Council, Netherlands, NWO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be valailable upon reasonable request from the principal reseacrher (Martijn Pisters, m.f.pisters@umcutrecht.nl)

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/02/2022	28/02/2022	Yes	No
Results article		24/11/2023	27/11/2023	Yes	No
Protocol article	protocol	22/04/2020	24/04/2020	Yes	No
Participant information sheet		19/07/2018	02/04/2019	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes