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A 12-week digital care program for chronic non-specific low back pain involving exercise, education, and psychosocial support

Submission date
03/01/2017

Recruitment status
No longer recruiting

Registration date
04/01/2017

Overall study status
Completed

Last Edited
01/11/2019

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Lower back pain (LBP) is a common and costly problem, which affects most people at some point in their lives. When the pain has lasted for at least six weeks, it is known as chronic LBP. Chronic LBP is the leading cause of reduced quality of life in most countries. This is because the pain can persist over an entire lifetime and is severely debilitating, interfering with anything from sitting, standing, and sleeping, to performing activities. Despite its commonness, it is called 'non-specific' because for most people there is no clear, single cause that can be identified. It is therefore hard to treat with invasive methods such as surgery. Instead, it needs to be treated with a comprehensive approach of exercise therapy, education, and psychosocial support. This study is looking at a 12-week digital care program for people living with chronic LBP which has been developed by Hinge Health, Inc. This research is important because people living with long term disorders affecting their musculoskeletal (structural) system rarely receive all of the recommended treatment. The resulting pain, disability, and medical interventions generate avoidable suffering and significant unnecessary spending for healthcare systems. The aim of this study is to find out whether best-practice care for chronic LBP pain can be effectively and efficiently delivered digitally and remotely as part of a Digital Care Pathway.

Who can participate?
Adults with chronic low back pain

What does the study involve?
Participants are randomly allocated to one of two groups, with more participants being allocated to the first group. Those in the first group are invited to take part in a 12-week digital care pathway for chronic low back pain designed by Hinge Health. This involves taking part in a 12-week program delivered through a tablet computer with the help of a personal coach and digital sensors. As part of the treatment, participants will perform sensor-guided exercise, read education, perform cognitive behavioral therapy, be more active in their daily lives, and lose weight if necessary. Those in the second group receive three pieces of education on how to take care of their knee and reduce their symptoms. At the start of the study and then again after 11 weeks, participants in both groups have their level of knee pain assessed.

What are the possible benefits and risks of participating?
Participants may benefit from becoming more active in their daily lives due to a reduction of their low back pain of on average 50%. There are no known risks involved with participating in this study.

Where is the study run from?
Hinge Health, Inc. (USA)

When is the study starting and how long is it expected to run for?
November 2016 to October 2017

Who is funding the study?
Hinge Health, Inc. (USA)

Who is the main contact?
1. Mr Gabriel Mecklenburg (public)
2. Dr Peter Smittenaar (scientific)

Contact information

Type(s)
Public

Contact name
Mr Gabriel Mecklenburg

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A Digital Care Pathway for chronic non-specific low back pain: a randomised controlled trial on the efficacy of a 12-week comprehensive digital program to reduce low back pain and impact on daily life

Study objectives
A 12-week Digital Care Program that includes sensor-guided exercise therapy, education, cognitive behavioral therapy, and personal coaching - all delivered remotely - has significant positive effects on non-specific low back pain and disability compared to an active control group receiving education only.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Western Institutional Review Board, 01/06/2016, ref: #20160949

Study design
Multi-centre randomised actively controlled interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions

Participants are randomly assigned to the treatment or control group at a ratio of 3:2. This ratio is enforced by inviting batches of participants as applications for the program are received, and randomly allocating participants in each batch to treatment and control in a 3:2 ratio.

Treatment group: Participants will be invited to participate in a 12-week digital care pathway for chronic non-specific low back pain designed by Hinge Health. The "Digital Care Pathway" for chronic non-specific low back pain was developed following consensus recommendations by the American Pain Society and the National Institute for Health and Care Excellence (NICE), and reflect up-to-date medical consensus on best-practice care. The treatment group will undergo two weeks of screening and preparation, followed by a comprehensive twelve-week program delivered through a mix of tools, including: an Android-enabled tablet provided to participants with Hinge Health's mobile application pre-installed, wearable motion sensors designed to work with the mobile application during participants' exercise therapy, and remote coaching by Hinge Health staff. The treatment intervention combines the main components of best practice care: education, exercise therapy, and addressing of psychosocial factors. The program is designed to achieve high adherence to these components. Using the mobile application, participants will engage with a twelve-week program where their engagement and adherence will be monitored. First, to drive the adherence to the exercise therapy, a mix of measures will be taken. The biometric sensors offer real-time feedback that allows participants to immediately recognize when they are performing the exercises correctly during self-directed exercise therapy. In addition, each participant is assigned a personal coach from Hinge Health dedicated to supporting and monitoring their engagement with the program and shepherding them through the process. During the first week of the program, a coach will assist participants in tailoring the exercise regime during a remote onboarding session, including exercise selection and training volume, to their condition and goals. Coaches are available remotely on short notice to answer questions, offer feedback or resolve issues with the participant's mobile applications or biometric sensors.
A second component of the program is educational content delivered to participants through Hinge Health's mobile application. The content is delivered weekly and designed to coincide with the concurrent phase of the digital care program. Coaches will monitor engagement with the material, engaging participants who have not already done so to consume it and answering questions as they arise.
Third, to address psychosocial factors, each participant will be part of an electronically-mediated social support group comprising fellow employees who are part of the same treatment cohort. This socially oriented feature is delivered entirely through Hinge Health's mobile application. The social feed will be closely curated by coaches, who will also support the discussion by answering questions and addressing concerns that may arise.
In addition to this, participants will engage in bi-weekly cognitive behavioral therapy (CBT) modules designed to help participants confront, address and augment unhelpful thinking and behaviors. Decades of research, including multiple randomized control trials, demonstrate that CBT can be an effective treatment for individuals with a wide spectrum of chronic pain syndromes. Recent research has established its efficacy through digital and web-based formats as well as treatments delivered by non-psychologists.

Control group: Participants will be provided with three education articles of similar length to those provided to the treatment group. The education articles are titled "The importance of self-care", "Surviving setbacks in back health", and "Back pain, communication, and relationships". The control group is also reminded that their standard care - such as physical therapy and psychological support - remains available to them.

After study completion, participants in the treatment group retain access to the tablet computer and wearable sensors, and can continue to perform their exercises. The control group will be given the opportunity to participate in an upcoming roll-out of the 12-week program, pending their eligibility. Outcomes will be re-assessed at 24, 36, and 64 weeks following completion of the program, but given that many participants in the control group will have crossed over to the treatment arm these long-term outcomes are not part of the primary outcomes of the trial.

Intervention Type
Mixed

Primary outcome measure
1. Low back pain is assessed using the Modified von Korff pain scale at baseline and 11 weeks
2. Back disability is assessed using the Modified von Korff disability scale at baseline and 11 weeks
3. Back disability is assessed using the Oswestry Disability Index at baseline and 11 weeks

Secondary outcome measures
1. Low back pain is assessed using a visual analogue scale (VAS) from 0 to 10 at baseline and 11 weeks
2. Impact of low back pain on daily life is assessed using a visual analogue scale (VAS) from 0 to 10 at baseline and 11 weeks
3. Surgery interest and intent is assessed through self-reporting using an in-house questionnaire assessing likelihood and attitude at baseline and 11 weeks
4. Ability to self-manage as assessed through the question “Thinking about your symptoms, how well do you feel you understand your condition and your treatment options?” with answer options Not at all, Slightly, Moderately, Very well, Completely, at baseline and 11 weeks

Overall study start date
01/11/2016

Completion date
01/10/2017

Eligibility

Key inclusion criteria
1. Aged 18-65 years
2. Chronic non-specific low back pain for at least 6 weeks in the past 12 months
3. Provision of informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
200

Total final enrolment
177

Key exclusion criteria
1. Time in pain in last 12 months is <6 weeks
2. Surgery on the back less than 3 months ago
3. Injury to the back less than 3 months ago
4. Age below 18 years
5. Not on employer's insurance plan
6. Refusal to provide consent
7. Indicate they did not experience low back pain when asked about the location(s) of pain (other options are "upper back" and "neck")

Date of first enrolment
16/01/2017

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
United States of America

Study participating centre
Hinge Health, Inc.
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San Francisco
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CA 94107

Sponsor information

Organisation
Hinge Health, Inc.

Sponsor details
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San Francisco
United States of America
CA 94107

Sponsor type
Industry

Website
http://www.hingehealth.com

ROR
https://ror.org/00cztjn15

Funder(s)

Funder type
Not defined

Funder Name
Hinge Health, Inc.

Results and Publications

Publication and dissemination plan
Planned submission of a manuscript describing the results of this trial before 2018 in an international peer-reviewed journal that follows ICMJE and CONSORT guidelines for reporting randomized controlled trials.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The data are held on secure servers with Hinge Health, Inc. The data are not made available for reasons of participant privacy (given relatively small number of participants).

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	results	01/12/2019	01/11/2019	Yes	No