Development of a psychological expectancy training - phase 3: pilot feasibility testing

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With this pilot feasibility study, the feasibility of and satisfaction with an eHealth and serious gaming training based on psychological expectancy mechanisms are evaluated.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43322

Source
ToetsingOnline

Brief title
TRAIN-HEAL-TH-3

Condition

- Other condition
- Autoimmune disorders
- Cornification and dystrophic skin disorders

Synonym
chronic pain or chronic itch

Health condition

Het onderzoek wordt uitgevoerd onder patiënten met chronische aandoeningen die gepaard gaan met jeuk (zoals psoriasis of eczeem) en/of pijn (zoals reumatoïde artritis of fibromyalgie), en onder gezonde mensen.

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: European Research Counsil Proof of Concept Grant

Intervention

Keyword: Conditioning, eHealth, Expectancies, Health

Outcome measures

Primary outcome

The main study parameters of this pilot feasibility study are the feasibility

of the online intervention satisfaction with the online intervention and the

satisfaction with the intervention, assessed by questionnaires (see page 19 of

the protocol for measurement details).

Secondary outcome

Not applicable.

Study description

Background summary

Studies show that expectations about health and disease may directly and positively affect health and treatment outcomes, for example by inducing anti-inflammatory effects. In this project, knowledge on the effects of implicit and explicit expectancy mechanisms such as conditioning and verbal suggestions is applied in a psychological eHealth and serious gaming intervention aimed to optimize health outcomes. In this project, a prototype of this intervention will be further refined and improved. In phase 2 (see CME submission NL58186.058.16), the intervention will be examined regarding its functionality and usability. In the next phase (phase 3, described in this CME submission), the improved intervention will be subjected to pilot feasibility

testing.

Study objective

With this pilot feasibility study, the feasibility of and satisfaction with an eHealth and serious gaming training based on psychological expectancy mechanisms are evaluated.

Study design

Pilot study to evaluate the feasibility of and satisfaction with the newly developed eHealth and serious gaming training.

Intervention

Both the healthy volunteers and the patients with a chronic pain or itch condition will participate in a psychological (non-pharmacological) eHealth and serious gaming training directing at optimizing health outcomes. The intervention has a duration of 6 to 12 weeks and is based on cognitive behavioural treatment in combination with automatic and conscious expectancy learning principles (see page 15 of the protocol for intervention description).

Study burden and risks

There is a negligible risk involved with participation in this study. The burden for participants consists of a time investment of two times approximately 45 minutes for the questionnaire assessment before and after the intervention, 1 hour for the face-to-face appointment with the therapist, and a time investment of approximately 15-30 minutes per day during the 6-12 week intervention. There are no direct benefits for subjects participating in this study. The major contribution of this study is that an innovative non-pharmacological treatment aimed at optimizing health outcomes without pharmacological drugs could be useful as an addition, or ultimately replacement of, current drug treatments. This may lead to new therapeutic possibilities for patients with chronic somatic conditions requiring long-term pharmacological treatment.

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

For healthy volunteers:
- age * 18 years
- sufficient understanding of the Dutch language;For patients with a chronic pain or chronic itch condition:
- age * 18 years
- sufficient understanding of the Dutch language
- confirmed diagnosis of chronic pain condition or chronic itch condition

Exclusion criteria

For healthy volunteers:
- confirmed diagnosis of chronic pain condition or chronic itch condition
- severe physical or mental conditions (e.g., malignancy, psychosis, DSM-V diagnosis [American Psychiatric Association, 2013]) that interfere with the study protocol
- pregnancy;For patients with a chronic pain or chronic itch condition:
- severe physical or mental conditions (e.g., malignancy, psychosis, DSM-V diagnosis [American Psychiatric Association, 2013]) that interfere with the study protocol
- pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-09-2017
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	17-10-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	14-11-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL58192.058.16