Development of a psychological expectancy training - phase 2: functionality and usability testing

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42999

Source
ToetsingOnline

Brief title
TRAIN-HEAL-TH-2

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 parameter of this pilot study is the usability of the eHealth

and serious gaming intervention, assessed by questionnaires and semi-structured

interviews using a think-aloud protocol during a single usability session at

Leiden University (duration: 2 hours).

Secondary outcome

Not applicable.

Study description

Background summary

Studies show that expectations about health and disease can directly 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 the current project, a prototype of this intervention will be further refined and improved.

Study objective

The primary study objective is to examine functionality and usability of a

newly developed eHealth and serious gaming intervention, to ensure that the intervention is user-friendly and fits the needs of potential users. Based on these functionality and usability tests, the intervention can be further improved prior to the proposed pilot feasibility study (fase 3 [TRAIN-HEAL-TH-3]: Protocol will be submitted to the CME shortly).

Study design

The proposed observational study consists of a user-based usability assessment in which targeted end-users will be asked to use the intervention based on a concurrent think-aloud protocol during a single meeting at Leiden University and to evaluate its user-friendliness. Both the healthy volunteers and the patients with a chronic pain or itch condition will be shown a psychological (non-pharmacological) eHealth and serious gaming intervention directing at optimizing health outcomes. The intervention is based on cognitive behavioural treatment in combination with automatic and conscious expectancy learning principles (see p. 15 for intervention description). The intervention is designed to be used by participants for 6-12 weeks. However, in this study participants will be shown the intervention once to examine functionality and usability.

Study burden and risks

There are no risks involved with participation in this study, only a time investment of 2 hours for the usability session. 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: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-08-2017
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	NL58186.058.16