An evaluation of a game for the rehabilitation of pain patients (Pilot Study).

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22384

Source
Nationaal Trial Register

Brief title
Gaming and rehabilitation

Health condition

chronic pain:
- chronic low back pain (CLBP)
- chronic neck-/ shoulder pain

Sponsors and support

Primary sponsor: Roessingh Research and Development
Source(s) of monetary or material Support: Europese Unie

Intervention

Outcome measures

Primary outcome

The main study parameters are user experience (satisfaction, usability and emotional

engagement) with the Playmancer game and the clinical changes (complaints and disability) induced by playing the Playmancer game. Satisfaction is assessed by a self-constructed questionnaire based on UTAUT (unified theory of acceptance and use of technology). The usability will be assessed by the system usability scale (SUS) and the emotional engagement will be assessed by items of the core element of game experience questionnaire (CEGEQ). Clinical change will be assessed by a Vas for pain intensity and different disability questionnaire (PDI, NDI and RDQ). The obejective clinical changes will be assessed by the six minutes walking test (6mwt) and different outcomes logged by the game (walking velocity, walking distance, reaching ability, time of relax etc.)

Secondary outcome

A secundairy study parameter is game performance.

Study description

Background summary

Rationale:

The growing popularity of motion-based games, like Nintendo's Wii, is not limited to the youth and gamers but slightly entering the professional field of physical rehabilitation as well. Games have the potential to be an attractive alternative for therapy. The challenging game environment is considered to be motivating for patients thereby potentially increasing exercise compliance. Besides games challenge participants to play a game over and over to beat their personal high score and thereby increase their treatment intensity and performance. Motion-based games have an additional advantage in that they are controlled by the movement of a person captured by a controller (Nintendo's Wii) or by a digital camera device (Sony EyeToy) and as such have the potential to positive influence physical performance.

Although promising, practice shows there are a number of limitations when applying these existing games into professional rehabilitation settings. First, not all games can be adjusts to the level of the impaired patient and become too hard to play which often leads to frustration. It would be an advantage when a game could be adapted to the capabilities of an impaired patient. Second, the level of energy expenditures reported for the motion-based games cannot be compared to levels of energy expenditures reached during physical therapy as only limited movements with a controller held in the patient's hand are requested from the patient for controlling the game. Desirable would be a game controlled by those motions the patient's need to train. As a consequence of these limitations games are more used as a pleasurable alternation in stead of being a proper tool to use for the treatment during rehabilitation.
A game with the possibility to personalize for different patients and controlled by the relevant motions of the patient's body has been developed by different European partner's expert on

the field of rehabilitation, motion capturing and game design. The aim of this pilot study is to investigate the user experience with this game and clinical changes induced by playing this game. As, the experience of patients and clinical changes associated with game-based pain rehabilitation in literature are scarce. Therefore, this study will have an explorative nature.

Objective:

The two objectives of this pilot study are: [1] What are the experiences of pain patient with the Playmancer game after training with the game for 8 sessions during four weeks? [2] Does the Playmancer game induce an improvement in subjectively perceived health status (complaints & disability) and in objective measured health status (physical fitness outcome) in patients with pain when training with the game for 8 sessions during four weeks?

Study design:

The study design of this pilot study is: a prospective cohort study.

Study population:

The research sample exists of a group of chronic pain patient suffering from low back pain or pain in the neck-shoulder region without specific pathological causes for at least 12 weeks during the past.

Intervention:

The participants are asked to visit Roessingh Research and Development and to train with the game during 8 sessions performed in a period of 4 – 8 weeks with a (average) frequency of 1-2 times a week. During the game, consisting of three different mini games, patients will have to wear a motion capturing suit which needs to be calibrated to the individual body of the patient during a 10 minute calibration period in the first session. Subsequently, the individual baseline values are assessed and individual goals are set for each mini game. The 3 mini-games focus on; walking, reaching overhead, relaxation of the muscles of the neck-/shoulder region and mobility of the head. Before and after the first session (Baseline) and after the last session (T0) the participant will fill in the same questionnaires to assess outcome.

Main study parameters/endpoints:

The main study parameters are user experience (satisfaction, usability and emotional engagement) with the Playmancer game and the clinical changes (complaints and disability) induced by playing the Playmancer game.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The burden associated with participations comprises several visit (8 in total) of approximately 30-60 minutes at Roessingh Research and Development. The Playmancer game challenges participant to train daily live movements; walking, reaching overhead and turning the head. Potential risks considered to be minimized.

Study objective

N/A

Study design

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Intervention

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Eligibility criteria

Inclusion criteria

1. Be aged 18 years or older;

2. Have a length between 1m50 and 1m95 (task layout requirement);

3. Physical capable of playing a motion-based game;

4. Patients have back pain or pain in the neck-shoulder region without specific pathological causes for at leas 12 weeks during te past.

Exclusion criteria

1. An insufficient understanding of the Dutch language;

2. A visible impairment that inhibits the perception of the screen were the play is on projected.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2010
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-08-2010
Application type:	First submission

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
NTR-new	NL2364
NTR-old	NTR2471
Other	METC Medische Spectrum Centrum (Enschede) : P30-10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A