The effectiveness of Serious Gaming during regular outpatient multidisciplinary rehabilitation for patients with complex chronic pain and fatigue complaints

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27485

Source
Nationaal Trial Register

Brief title
FSS: Functional Somatic Syndromes CP: Chronic Pain

Health condition

Chronic Pain (Chronische pijn)
Functional Somatic Syndromes (Functioneel Somatische Syndromen)
Medically Unexplained Physical Symptoms(Somatisch onvoldoende verklaarde lichamelijke klachten)

Sponsors and support

Primary sponsor: Tilburg University, Tilburg School of Social and Behavioral Sciences, Tranzo Scientific Center for Care and Welfare
Ciran Rehabilitation Centers, Venlo, the Netherlands
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Pain intensity (Current pain: 11-point Numerical Rating scale)

Pain coping and cognitions (Pain coping and cognitions list; PCCL)

Fatigue (Checklist Individual Strength; CIS)
Psychopathologic symptoms (Symptoms Checklist; SCL-90)

Secondary outcome

SECONDARY OUTCOME(S):
Patient Global Impression of Change; PGIC
General subjective health (1-item from the SF-36)

Treatment satisfaction (3 items Likert scales)

Study description

Background summary

Rationale
Video game technology is increasingly applied for restoring health, but yet seems to offer little solace for patients with complex chronic pain and fatigue complaints. Individuals are in chronic pain (CP) when complaints persist beyond a usual 3 to 6 month duration of organic recovery [3]. Functional somatic syndromes (FSS) are diagnosed in individuals that seek medical help for functional disturbance and chronic somatic symptoms without a satisfactory explanation by organ pathology or disease [4]. A high prevalence of complex chronic pain and fatigue complaints and current limitations in management come at high individual and societal costs. Meta-analyses conclude that therapeutics with evidently strong effects are lacking, and that (cognitive) behavioral intervention is weakly to moderately effective for patient symptom reduction and functioning. For patients with CP or FSS who are able and willing to use them, computer-based behavioral interventions will probably be (cost) effective. ‘Serious Games’ may engage patient users while improving their knowledge, behavior, and/or psychological outcomes. Therefore, Serious Gaming may conquer a place within an evidence based repertoire of modes for delivering (cognitive) behavioral intervention to patients with CP or FSS. At present, the deployment of immersive technology for the CP management is an important research area. Moreover, adequately powered clinical trials are required to determine the effectiveness of Serious Games for health.

Objectives

The primary aim of this study is to assess the effectiveness of a complementary blended Serious Gaming intervention, called 'LAKA', during regular multidisciplinary rehabilitation for patients with complex chronic pain and fatigue complaints. To our knowledge, LAKA is the first Serious Game that targets psychosocial adjustment in this target group, whereas its effectiveness has not been established yet. We question primarily to what extent outpatient multidisciplinary rehabilitation with an additional Serious Gaming component is more effective than such a program without Serious Gaming for the reduction of pain, fatigue, and psychological distress symptoms after treatment in patients with CP or FSS. In addition, we question for which patients, in what context, and how Serious Gaming is feasible and effective.

Methods

An embedded experimental mixed-methods design is used to evaluate the outcomes of a Serious Gaming intervention (LAKA) within the context of regular outpatient multidisciplinary rehabilitation. Quantitative methods are prioritized in this design for estimating patient level symptom reduction (pain, fatigue, and psychopathology) due to the addition of a Serious Gaming component. The implementation of blended serious gaming for all patients who are treated at two locations of an outpatient clinic (in a non-random order) provides this opportunity. Control over unobserved confounding factors by means of randomization is practically inhibited. Therefore, a two-armed pre-to-post controlled naturalistic quasi-experimental design is used. Quantitative and qualitative methods are embedded in the design for process analyses. Patient outcomes are determined from coded data, which will be extracted from patient records of the rehabilitation clinic. Outcomes are measured before treatment, intermediate after 8 weeks of treatment, and when the program is finished after the 16th treatment week.

Ethical approval for this study was obtained at the psychological ethical assessment committee of Tilburg School of Behavioral Sciences (EC-2016.25t).

LAKA is a Serious Game with metaphorical simulation elements (encounters) resembling situations that could occur at home, at work, or with family or friends, and with skills training in meditation practice. The game is designed to support recovery by positive changes in consciousness, regulation, and transcendence of self in adverse social situations. In accordance with suggestions raised during previous feasibility testing, patients are briefly introduced to playing the game LAKA (session 1), instructed to complete the game independently (session 2 and 3), and expected to participate in a “debriefing” session afterwards (session 4). The rehabilitation clinic provides scheduling of the 4 sessions (to be followed with 1- 6 patients simultaneously), suitable rooms with WIFI-connection, headphones, and tablets computers with LAKA installed.

Based on initial steps of qualitative research (step 1 and 2), as described in the published research protocol, the following expectations were formulated to be tested in subsequent steps of quantitative investigation:

- Differences in patient reported outcome change between multidisciplinary rehabilitation with versus without serious gaming are small.

- Rehabilitation with serious gaming improves patterns of outcome change in patient reported psychological fatigue and distress.

- Difference in outcome change between multidisciplinary rehabilitation with versus without serious gaming depend on adherence (exposure to the serious game, and debriefing).

- The effect of serious gaming on patient outcome change is mediated by improvement in learning results, and strengthened by gaming experiences (i.e. sense of presence and positive affect).

- Degree of acceptance, and/or impact of serious gaming on learning results or health outcome change of patients depend on; organizational factors (i.e. planning of serious gaming sessions within patients' rehabilitation programs, development in the quality of delivery over time), provider factors, patient factors (i.e. coping style, room for improvement in health outcome status, and/or demographic characteristics; higher with younger age).

Study objective

An outpatient multidisciplinary rehabilitation program with an additional Serious Gaming intervention component is more effective than an outpatient rehabilitation program without a Serious Gaming component for reducing health complaints in patients with chronic pain, fatigue, and functional disturbance. Health complaints concern pain (intensity, coping and cognitions), fatigue (subjective severity concentration problems and physical inactivity), and psychopathology.

Study design

1. Before rehabilitation program (baseline)

2. After 8 weeks (intermediate)

3. After the rehabilitation program (post-intervention)

Intervention

- An experimental group is constituted of study participants who follow a 16 week outpatient multidisciplinary rehabilitation with an additional blended serious gaming component planned during the second half (in week 9-12). The Serious Gaming component is incorporated in the program at two sites of a rehabilitation clinic.

- A control group is formed by patient participants who follow the same outpatient rehabilitation program without a scheduled Serious Gaming component in one of two other sites of the same clinic.

Contacts

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Eligibility criteria

Inclusion criteria

Included are all patients who received an indication of eligibility for outpatient multidisciplinary rehabilitation from a rehabilitation physician (and completed at least the first 8 weeks of an outpatient rehabilitation program). Indications are based on results of diagnostic tests (self-report), additional physical and psychological investigations, and a clinical interview. Patients:

- are between 18 and 67 years of age;

- report the presence of pain for more than 6 months, or fatigue complaints or a musculoskeletal disease for more than 3 months;

- have no (more) indication for another (cost-) effective medical treatment, and;

- report sustaining psychosocial problems

Exclusion criteria

The following exclusion criteria used by doctors

- Physically not able to follow an active treatment

- Psychiatric symptoms are not adequately controlled

- Significant risk of psychological decompensation through a rehabilitation treatment.

- Language or communication problems that make it impossible to follow rehabilitation.

- Not able to change behavior (due to personality disorders, 3rd party liabilities, or otherwise).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-07-2016
Enrollment:	220
Type:	Anticipated

Ethics review

Not applicable

Application type: Not applicable

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	NL5754
NTR-old	NTR6020
Other	: EC-2016.25t

Study results

Summary results
Vugts, Miel AP, et al. "Feasibility of Applied Gaming During Interdisciplinary Rehabilitation for Patients With Complex Chronic Pain and Fatigue Complaints: A Mixed-Methods Study." JMIR serious games 4.1 (2016).

Vugts, Miel AP, et al. "Serious gaming during multidisciplinary rehabilitation for patients with complex chronic pain or fatigue complaints: study protocol for a controlled trial and process evaluation." BMJ open 7.6 (2017): e016394.