The effect of an add-on treatment for sleep problems in the rehabilitation of patients with acquired brain injury and patients with chronic pain

No registrations found.

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

Summary

ID

NL-OMON24225

Source
NTR

Brief title
TBA

Health condition

acquired brain injury (traumatic brain injury, stroke, brain tumor, encephalitis, etc.) OR musculoskeletal chronic pain (pain lasting > 6 months).

Sponsors and support

Primary sponsor: No external sponsors. The study is facilitated internally by Rehabilitation Center Klimmendaal.
Source(s) of monetary or material Support: N.A. No external funding. The study is facilitated internally by Rehabilitation Center Klimmendaal.

Intervention

Outcome measures

Primary outcome

Pittsburg Sleep Quality Index (PSQI) - sleep quality

Secondary outcome

Dutch Multi-Factor Fatigue Scale (DMFS) - Fatigue
Dysfunctional Beliefs and Attitudes about Sleep Scale brief version (DBAS-16) - dysfuncitonal beliefs about sleep

Hospital Anxiety and Depression Scale (HADS) - anxiety and depression symptoms
Numeric Pain Rating Scale (NPRS) - pain score in the last 24 hours

Study description

Background summary

Sleep problems are common following acquired brain injury (ABI) and are very common in patients with chronic pain. Up to date, there is limited evidence for effective treatment of sleep problems in ABI patients, although CBT interventions are most promising. In chronic pain patients CBT for sleep problems has been found effective in prior research, although this is not part of the standard care in rehabilitation centers. A problem with the standard CBT interventions for insomnia is that there is a lot of overlap with interventions within the rehabilitation setting. Furthermore, the sleep problems in these patients are not always so severe that an entire CBT protocol for insomnia is necessary. Therefore, the aim of the present study is to examine whether a short add-on treatment for sleep problems is effective within the rehabilitation of patients with ABI and chronic pain. The main hypothesis is that sleep quality will significantly improve after a short add-on treatment for sleep problems, compared to a treatment as usual (rehabilitation) control group. Patients in the control group receive the add-on treatment for sleep problems als well, but after completing the assessment at T1 and T2.
The trial comprises of two identical studies in two common rehabilitaiton population groups. We aim to include 50 patients with ABI (25 per treatment arm) and 50 patients with chronich pain (25 per treatment arm). The trial is conducted in Rehabilitation Center Klimmendaal, Arnhem, the Netherlands.

Study objective

Sleep quality will significantly improve after a short add-on treatment for sleep problems, and improve more than treatment as usual (rehabilitation). Second, we expect fatigue and disfunctional beliefs about sleep to improve as well (but to lesser extent). Finally, we are interested in whether anxiety and depression symptoms and pain scores could improve

following a short add-on treatment for sleep problems.

Study design

Experimental condition: T1: baseline assessment at the start of session 1, T2 post-treatment assessment at the end of session 4 (last session) and a T3 follow-up assessment 3 months after completing the treatment. Between baseline and post-treatment is a period of 6 weeks. Control condition: T1 baseline assessment and T2 second assessment 6 weeks later (while participating in their usual rehabilitation treatment). No follow-up assessment is done, as control participants received the add-on sleep intervention as well following the second assessment. A third assessment was done post-treatment to evaluate their progression following treatment.

Intervention

Short add-on treatment for sleep problems (in addition to the regular rehabilitation program). The add-on treatment for sleep problems consists of cognitive behavioural therapy for insomnia (CBT-I) elements: psychoeducation, sleep hygiene, sleep restriction and stimulus control. The intervention has a duration of 4 sessions in a 6 week period and is given individually by trained professionals.

Contacts

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Eligibility criteria

Inclusion criteria

The treatment will be evaluated in patients with ABI and in patients with chronic pain. In order to be eligible to participate in this study, a patient must meet all of the following criteria:

- Self-reported sleep problems which are associated with disability in daily life.
- Following rehabilitation treatment for acquired brain injury (traumatic brain injury, stroke, brain tumor, encephalitis, etc.) in a specialized outpatient care. Patients are included if the injury is at least three months ago.
OR following rehabilitation treatment for musculoskeletal chronic pain (pain lasting > 6 months). Patients are included if any possible injury for their pain is at least 6 months ago.
- Fluent in Dutch.
- Age between 18 and 75
- Living independently at home.

Exclusion criteria

- Severe brain damage, such that patients are not able to follow this treatment or complete questionnaires (due to physical or severe cognitive problems), based on clinical judgement
- Neurodegenerative disorder (e.g., Parkinson, Multiple Sclerosis)
- Diagnosed sleep disorder prior to injury (e.g., apnea, restless legs syndrome)
- Serious psychopathology (e.g., risk for psychosis) or suicidality
- Alcohol or drug abuse or dependence (use of pain- and sleep medication are not exclusion criteria, unless patients started taking the medication < month ago). If necessary, the use of pain- and sleep medication will be taken into account in our analyses.
- Recently started taking pain- (e.g., opioids, analgesics) or sleep medication, less than a month ago

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-09-2018
Enrollment:	100

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

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	NL9368
Other	Research committee for local feasibility of Rehabilitation Center Klimmendaal : RCKLIM0007

Study results