Evaluation of a randomized controlled trial on the effect on return to work with light therapy/magnetic field therapy and coaching for workers with burnout

No registrations found.

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

Summary

ID

NL-OMON26701

Source
NTR

Brief title
ROX

Health condition

work-related chronic stress
burnout, fatigue

Sponsors and support

Primary sponsor: Coronel Instituut voor Arbeid en Gezondheid, Academisch Medisch Centrum / UvA
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FLUXPlus

Intervention

Outcome measures

Primary outcome

Return to work

Secondary outcome

- Fatigue

- Stress

- Quality of life

Study description

Background summary

Burnout (work-related chronic stress) is a problem that is common in the workplace, and implies that the employee feels exhausted. It is not only an attack on health, well-being and functioning of the employee, also for the employer and for society it is costly as an employee is absent due to absenteeism costs, lost productivity and medical expenses. The usual treatment of burnout is the cognitive-behavioral approach (coaching) which induced factors that have contributed to the onset of the problem. With this treatment reduction in symptoms and increasing the reintegration of work is the main goal.

Objective:

Letec developed a technique that utilizes the light therapy / magnetic field therapy treatment platform Xentix besides coaching. In order to demonstrate the effectiveness of this method, a "proof of concept" is necessary. This can be obtained by means of a scientific study in which the research question is whether the therapy using light / magnetic field therapy can contribute return to return to work, reducing stress and fatigue and improve the quality of life. The intention is to implement the proven efficacy of the treatment within the care of people with burnout.

Intervention:

Light therapy / magnetic field therapy / coaching treatment for 12 weeks, 2 times a week for 40 minutes on the treatment platform (group 1). A placebo group receives the same treatment which the light therapy / magnetic field therapy is not activated (group 2) and a control group receives only coaching (group 3).

Study design:

The study is a randomized placebo-controlled study and will take approximately one year in burnout patients (n = 90). Subjects with the aforementioned problems are treated in three groups namely: group 1 receives light therapy / magnetic field- therapy and coaching, group 2 receives the same treatment with the light therapy / magnetic field- therapy which is not activated and Group 3 will only receive coaching.

Study population:

The population consists of employees (18yr -65yr) from the South of the Netherlands with burnout complaints with at least 50% absenteeism

Main study parameters / endpoints:

Return to work score between baseline (week 0) and endpoint (week 12)

Study objective

Combination of light therapy / magnetic field therapy can increase return to work by patients suffering from burnout.

Study design

baseline week -1

T1 week 6

T2 week 12

T3 week 24

Intervention

Participants will be treated for 12 weeks, 2 times a week for 40 minutes on the treatment platform with light therapy / magnetic field therapy / coaching (group 1). A placebo group receives the same treatment which the light therapy / magnetic field therapy is not activated (group 2) and a control group receives coaching only (group 3).

Contacts

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Eligibility criteria

Inclusion criteria

- Employees with burnout symptoms between 18 and 65 years with at least 50% sickness absenteeism

- Diagnostic criteria for overstrain (symptoms 0-6 months)

- Not be able to perform total or part of daily work

- Speaking Dutch language

Exclusion criteria

- Pregnancy

- Serious somatic problems such as diabetes and epilepsy

- Serious ocular diseases

- Presumption of confusion or severe gloom

- Use of psychotropic drugs other than selective serotonin reuptake inhibitors SSRIs

- Pacemaker / neurostimulators

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2014
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-09-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41105
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4651
NTR-old	NTR4794
CCMO	NL49345.018.14
OMON	NL-OMON41105

Study results

Summary results
N/A