

Pilot study 'Mindfulness for people with burns and parents of children with burns: feasibility and potential effect of a first mindfulness training'

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Aim of the study is exploring the feasibility and potential effect of a Mindfulness training for people with burns and parents of children with burns.

| | |
|------------------------------|---------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Other condition |
| Study type | Interventional |

Summary

ID

NL-OMON43498

Source

ToetsingOnline

Brief title

Mindfulness by burns

Condition

- Other condition

Synonym

Physical and psychosocial problems after burn

Health condition

Fysieke en psychosociale gevolgen van brandwonden

Research involving

Human

Sponsors and support

Primary sponsor: Vereniging Samenwerkende Brandwondencentra Nederland

Source(s) of monetary or material Support: Brandwondenstichting

Intervention

Keyword: Burns, Feasibility, Mindfulness, Parents

Outcome measures

Primary outcome

Main objectives are mindfulness capabilities such as, observation, describing, performing with attention, not judging and non-reactive, self-compassion and personal aims of the participants. Furthermore, the feasibility of the Mindfulness training will be studied.

Secondary outcome

There are no secondary parameters

Study description

Background summary

Despite good medical health care, people with burns can be hampered by stress, tensions, guilt feelings, anxiety, depression, and physical complaints such as pain, fatigue, and itch on the long term. Also parents of children with burns can continue to have post-traumatic stress symptoms and other psychological problems long after the burn accident. At the moment there is not an evidence based psychosocial group intervention for people with burns and for parents of children with burns. Mindfulness trainings, who stimulate attention for the present moment on a not-judging way, show positive effects on the quality of life and well-being of people with diverse diseases, such as Multiple Sclerosis, chronic pain, cancer, depression, and anxiety. It is not clear if a Mindfulness training is feasible and effective for people with burns and parents of children with burns.

Study objective

Aim of the study is exploring the feasibility and potential effect of a Mindfulness training for people with burns and parents of children with burns.

Study design

This is a prospective observational design. There will be 4 measurement moments: two times before the start of the training, directly after the training, and three months after the training.

Intervention

A Mindfulness training includes 8 sessions of 2,5 hours, a practice day of 6 hours, in which meditation, yoga, attention for body, feelings, and emotions are the most important ingredients. Participants will receive homework exercises for 1 hour a day.

Study burden and risks

The Mindfulness training will take a session of 2,5 each week, one practice day of 6 hours, and an 1 hour of practice each day at home. Furthermore, the participants have to fill out questionnaires at four moments, one intake before the training, and one interview by telephone after the training. The Mindfulness training could lead to extra tension at the beginning of the training, because participants have to pay attention to body sensations, cognitions, and feelings. After a few sessions we expect that tensions will decrease and that participants will benefit of this free Mindfulness training.

Contacts

Public

Vereniging Samenwerkende Brandwondencentra Nederland

Zeestraat 27-29 Zeestraat 27-29
Beverwijk 1940 EA
NL

Scientific

Vereniging Samenwerkende Brandwondencentra Nederland

Zeestraat 27-29 Zeestraat 27-29
Beverwijk 1940 EA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

People with burns: minimum of 1% total burned surface area, at least half year after the burn accident, 18 years or older, speaking the Dutch language, and mild to average physical and/or psychological problems.

Parents of children with burns: 18 years or older, at least 6 months after the burn accident of the child, speaking the Dutch language, and mild to average physical and/or psychological problems.

Exclusion criteria

People who have burns because of a suicide attempt, severe psychological or psychiatric problems (e.g. PTSD and depression), do not understand the Dutch language, have done a Mindfulness training before, and/or are in a psychosocial treatment at the moment.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 22-03-2016 |
| Enrollment: | 24 |
| Type: | Actual |

Ethics review

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|--------------------|------------------------------|
| Approved WMO | |
| Date: | 21-03-2016 |
| Application type: | First submission |
| Review commission: | METC Noord-Holland (Alkmaar) |

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 | NL56533.094.16 |