Effectiveness of a REhabilitation program to treat fatigue in patients who suffered from SubArachnoid Haemorrhage (RE-SAB); a pilot study

No registrations found.

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

Summary

ID

NL-OMON20856

Source
Nationaal Trial Register

Brief title
RE-SAB

Health condition

Subarachnoid Haemorrhage

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam
Source(s) of monetary or material Support: Erasmus MC Efficiency Research Pilot

Intervention

Outcome measures

Primary outcome

Fatigue, quality of life, feasibility in terms of patient satisfaction, compliance and practical

feasibility.

Secondary outcome

Self-efficacy, mood, cognition, coping style, (social) participation, physical fitness, physical activity

Study description

Background summary

A subarachnoid haemorrhage (SAH), a stroke subtype, has a major impact on the patient's life, with fatigue as one of the most commonly reported long-term symptoms. Fatigue leads to impairments in education/work and in social and personal activities and reduction in quality of life. Treating fatigue should therefore be an important part of rehabilitation after SAH. However, there is no suitable rehabilitation program available for these patients. Most of the patients are discharged from the hospital to their home, without receiving rehabilitation. Based on previous studies a rehabilitation program is developed, named RE-SAB, with the aim to reduce fatigue and improve quality of life. The primary aims of the pilot study are to examine whether and to what extent fatigue and quality of life of patients with SAH improve after participating in RE-SAB and whether RE-SAB is feasible . The secundary aim is to examine whether and to what extent physical activity level, physical fitness, coping style, cognition, mood, self-efficacy and social participation improve after participating in RE-SAB.

Study objective

It is expected that fatigue will decrease and quality of life will increase after participating in the RE-SAB program

Study design

0, 3 and 6 months

Intervention

The intervention consitst of three parts: (1) information sessions about fatigue and consequences of SAH by a rehabilition specialist and social worker; (2) session with an occupational therapist and (3) physical fitness trainingsessions

Contacts

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Eligibility criteria

Inclusion criteria

- Admitted and treated/controlled at the neurology of neurosurgery department of Erasmus MC;
- Diagnosed with subarachnoid haemorrhage (SAH);
- Between 3 - 9 months post SAH;
- Experience fatigue symptoms;
- At least 18 years of age;
- Living at home.

Exclusion criteria

- Previous stroke;
- Serious chronic disease (including neurological diseases);
- Insufficient mastery of the Duth language;
- Inability to understand verbal instructions and/or fill in the questionnaires (clinical judgement by neurologist).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2019
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-09-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48074
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8008
CCMO	NL68780.078.19
OMON	NL-OMON48074

Study results