Rehabilitation aimed at fatigue after subarachnoid haemorrhage: Determinants of physical behaviour.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular haemorrhagic disorders
Study type	Observational non invasive

Summary

ID

NL-OMON46677

Source
ToetsingOnline

Brief title
Determinants of physical behaviour after subarachnoid haemorrhage

Condition

- Vascular haemorrhagic disorders

Synonym
cerebral haemorrhage, subarachnoid haemorrhage

Research involving
Human

Sponsors and support

Primary sponsor: Rijndam Revalidatie
Source(s) of monetary or material Support: Vrije Beleidsruimte Rijndam Revalidatie

Intervention

Keyword: Fatigue, Physical behaviour, Rehabilitation, Subarachnoid haemorrhage

Outcome measures

Primary outcome

To examine determinants of physical behaviour, physical behaviour will be determined objectively and self-reported (accelerometry-based activity monitoring and electronic diary). As possible determinants the following outcomes will be assessed (questionnaires, semi-structured interview): fatigue (2 outcomes), sleep quality, activities, participation, health-related quality of life, social support, anxiety (2 outcomes), illness perception, depression, coping style, motivation (2 outcomes), self-efficacy and health condition (3 outcomes).

Secondary outcome

Secondary, preferences of patients for therapy to reduce fatigue will be explored regarding time investment, location, type, frequency and duration of therapy (semi-structured interview). In addition, physical fitness in terms of cardiorespiratory fitness (cardiopulmonary exercise test) and muscle strength (muscle strength test) will be assessed.

Study description

Background summary

With a prevalence ranging from 31% to 90%, fatigue is one of the most common long-term sequelae in both patients with aneurysmal and perimesencephalic subarachnoid haemorrhage (A-SAH and PM-SAH). Fatigue in these patients is strongly correlated with a decreased health-related quality of life and poorer

scores on cognitive functioning, depression and comorbidity. There is no rehabilitation program (either physical, cognitive, or multidisciplinary) that is specifically developed to treat fatigue in patients with SAH. Therapies aimed at fatigue in other neurologic conditions revealed inconsistent effects. This may be due to the multifactorial concept of fatigue, which makes it difficult to determine the best treatment procedure. Given previous studies indicating a physical origin of fatigue in patients with A-SAH, incorporating physical activity (including physical fitness training) in a rehabilitation program might be beneficial to treat fatigue. However, before developing such a rehabilitation program for people with SAH, insight in determinants of physical activity (PA) behaviour in this population is a prerequisite. Therefore, the primary aim of this study is to examine determinants of physical behaviour in patients with SAH. The study is based on *The Physical Activity for people with a Disability (PAD) model*, which captures determinants of PA behaviour in people with a disability. In addition, preferences of SAH patients for therapy to reduce fatigue will be explored regarding time investment, location, type, frequency and duration of therapy. To examine if a rehabilitation program (including physical activity) should also target patients with PM-SAH, physical fitness and physical behaviour, and their relation with fatigue will be explored in this subgroup.

Study objective

The main objective is to examine determinants of physical behaviour in patients with SAH (primary in patients with A-SAH and secondary in patients with PM-SAH). Secondary, preferences of patients for therapy to reduce fatigue will be explored in patients with SAH, and physical fitness and physical behaviour, and their relation with fatigue will be explored in patients with PM-SAH.

Study design

Cross-sectional design with measurements in the home-situation and in the clinical movement laboratory.

Study burden and risks

Patients will be visited at home once (2.5 hours), to fill in questionnaires and answer additional questions in a semi-structured interview. If necessary, patients will get rest between the questionnaires, therefore the burden is considered low. Comparable (numbers of) questionnaires have been conducted before in patients with SAH, this was found feasible. In addition, patients wear an accelerometer on the upper leg for seven consecutive days and fill out an electronic diary during those seven days. Wearing the accelerometer for seven consecutive days does not increase risk or burden for the patient, because the accelerometer is a small and light-weighted device and patients are not forced to perform other activities than in normal life. Filling out the

electronic diary has been found feasible in a comparable study from our research group with stroke patients. For testing physical fitness and physical behaviour, a subgroup of patients will perform a progressive cardiopulmonary exercise test (CPET) and a muscle strength test (MST). Patients will be screened by a physician prior to the CPET and MST to examine medical contraindications. If there is any suspicion of an underlying cardiovascular or pulmonary pathology, the tests will not be carried out. During the CPET, blood pressure and heart function will be monitored and a sport physician will provide emergency back-up. Patients will get enough rest between the tests. Both the CPET and MST test may cause temporary fatigue, but the risk is considered low. All tests have been performed before in A-SAH patients, without any adverse events. The patients will not benefit directly from participating in the study, they will gain insight in their physical behaviour and determinants and their physical functioning. The results will serve as input for the development of a rehabilitation program to reduce fatigue. When a rehabilitation program will be tested in a follow-up study, a subgroup of patients can be invited to participate.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Admitted and treated/controlled at the neurology or neurosurgery departments of Erasmus MC or Elisabeth-TweeSteden Ziekenhuis and/or receiving rehabilitation at Rijndam Revalidatie or Libra Revalidatie and Audiologie;
- Between 3 and 12 months post A-SAH onset;
- At least 3 months post PM-SAH onset;
- Living at home;
- Only for patients with A-SAH; experience and report fatigue symptoms;
- SAH diagnosed by computed tomography and if negative, by a lumbar puncture followed by a computed tomography angiography or digital subtraction angiography to detect the aneurysm (A-SAH). PM-SAH diagnosed by accumulation of blood around the mesencephalon on computed tomography and a normal four vessel angiogram;
- At least 18 years of age.

Exclusion criteria

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

Extra exclusion criteria regarding the cardiopulmonary exercise test and muscle strength test in patients with PM-SAH:
- Aged >= 70 years;
- Not eligible for maximal exercise testing, as determined by the treating physician, the Physical Activity Readiness Questionnaire (PAR-Q) and a checklist for medical contra-indications based on the ACSM guidelines for Exercise Testing and Prescription.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-10-2018
Enrollment:	91
Type:	Actual

Ethics review

Approved WMO

Date:	24-05-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL62745.078.17