The relation between post-stroke depression and insomnia

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27473

Source
Nationaal Trial Register

Brief title
RPDIA

Health condition

Stroke, depression, insomnia

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: Zuyderland MC

Intervention

Outcome measures

Primary outcome

depression

Secondary outcome

none

Study description

Background summary

Background: Post-stroke depression is a common neuropsychiatric consequence after stroke which develops in the first-year post-stroke. Post-stroke depression is known for its chronic or dynamic course in case it does not resolve spontaneously and can have severe consequences on disease process, quality of life and opportunities for rehabilitation. The development of post-stroke sleeping disorders is another and limiting problem that is frequently reported among stroke survivors. Insomnia is the most prevalent sleeping disorder. In non-stroke patients insomnia and the development of depression are convincingly related as shown by multiple studies. It is not clear yet whether this link also exists in post-stroke patients.
Objective and hypothesis: In this study we expect a relation between post-stroke insomnia and depressive symptoms. We expect a positive relation between level of post-stroke sleep insomnia and level of mood complaints, especially symptoms of depression.
Methods: This study is a cross-sectional study in which first stroke patients are assessed three months after their stroke to measure complaints of sleep and depression.
Subjects and procedure: outpatient stroke survivors are recruited via the neurology department, the rehabilitation department and the medical psychology department. A clinician attends the subject and the researcher provides information and enrolls subjects in the study after check on inclusion criteria and informed consent
Measurements: independent variables are the demographic variables (age, sex, level of education). Dependent variables are Hospital Anxiety Depression Scale (HADS), Pittsburgh Sleep Quality index (PSQI) and Insomnia Severity Index (ISI).
Statistics: We use a hierarchical regression method to predict level of depression after stroke with a regression model that consists of the following predicting variables (demographic variables, level of sleep insomnia).

Study objective

Severity of insomnia at three months post-stroke is correlated with severity levels of post-stroke depression.

Study design

After stroke patients have outpatient checkups with a nurse practitioner. In these checkups their health and wellbeing is monitored. For this study patients will be asked to complete three questionnaires after their regular check-up meeting with the nurse practitioner. There will be only one measurement. This will be at three months post-stroke.
By a short semi-structured interview every participant will be screened for in-and exclusion criteria, demographic and stroke-related variabilities. Independent variables are demographic variables (age, gender, level of education).
Furthermore, three questionnaires will be used in order to screen the dependent variables for sleep: the Pittsburgh Sleep Quality index (PSQI) and the Insomnia Severity Index (ISI). For mood: the Hospital Anxiety Depression Scale (HADS) will be used. The primary outcome is

mood.
The Pittsburgh Sleep Quality index (PSQI) is a subjective sleep questionnaire, that measures sleep quality and discriminates between ‘good’ from ‘poor’ sleepers. The Insomnia Severity Index (ISI) is a seven-item questionnaire assessing the nature, severity and impact of insomnia. By using two sleep questionnaires it is possible to separate the ‘good sleepers’ from the ‘bad sleepers’ and to distinguish whether there is an insomnia and to rate of the insomnia. The Hospital Anxiety Depression Scale (HADS) is a self-report questionnaire which measures symptoms of anxiety and depression. The HADS is validated for hospital settings and primary care and stroke patients.

Intervention

There is no intervention. This study is a cross-sectional research design in which participants are outpatient stroke patients from Zuyderland Medical Center. Variables are measured by using three questionnaires at three months post-stroke (HADS, PSQI, ISI). HADS is the dependent measure and independent measures are demographic variable and measures for insomnia (PSQI and ISI)

Contacts

Public
Zuyderland Medisch Centrum
Debbie van Tilburg

0884590570 / 0618658552
Scientific
Zuyderland Medisch Centrum
Debbie van Tilburg

0884590570 / 0618658552

Eligibility criteria

Inclusion criteria

1) Diagnosis of stroke, based on medical records and confirmed by a neurologist
2) Participating patients are outpatient stroke patients
3) Three until five months after stroke
4) Patients must be older than 18 years

Exclusion criteria

1) Hospitalized patients
2) Patients with severe aphasia
3) Patients with dementia
4) Patients with epilepsy
5) Patients with history of traumatic brain injury
6) Non-Dutch speaking patients
7) Patients using sleep medication

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-03-2020
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

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	NL8475
Other	METC Zuyderland : Z2020058

Study results