

Relationships and sexual functioning in patients after stroke, a longitudinal observational study.

Published: 21-08-2013

Last updated: 26-04-2024

This study aims to determine the following: * What is the nature and extent of relational and sexual problems of stroke patients and their partners. * What is the time course of the relational and sexual problems of stroke patients and their...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39640

Source

ToetsingOnline

Brief title

BLOS-study

Condition

- Central nervous system vascular disorders

Synonym

seizure, stroke

Research involving

Human

Sponsors and support

Primary sponsor: Sophia Revalidatie

Source(s) of monetary or material Support: Sophia Revalidatie

Intervention

Keyword: Relationship, Sexuality, Stroke

Outcome measures

Primary outcome

Questionnaires focused on sexual / relational problems, general physical and mental functioning, quality of life, service use and care needs regarding sexual / relational problems, socio-demographic data and disease characteristics.

Secondary outcome

-

Study description

Background summary

Each year approximately 30,000 people in the Netherlands will have a cerebrovascular accident (CVA). A stroke can have major impact on the quality of life. Part of the quality of life are the relationship, intimacy and sexuality, for the patient as well as the partner. Experience shows that patients do not easily make their intimate relationship the subject of their rehabilitation goals.

Research into the effects of a stroke on the intimate relationship and sexual functioning is scarce. Because stroke patients and their partners are a significant group of patients in the care of Sophia Rehabilitation, it is important to understand the course of the relational and sexual problems they obtain, as well as understanding their need for care.

Study objective

This study aims to determine the following:

- * What is the nature and extent of relational and sexual problems of stroke patients and their partners.
- * What is the time course of the relational and sexual problems of stroke patients and their partners.

In addition, the researchers are trying to get answers to the following questions:

- * What are the determinants of relational and sexual problems in stroke patients and their partners.
- * In what extent is there a need for care on relational and sexual problems in stroke patients and their partners.

Study design

Longitudinal, observational, single-center study with a follow-up period of 1 year in adult patients within the care of Sophia Rehabilitation Center (inpatients and outpatients). The patients will be sent 3 times during the study a questionnaire: < 26, 26, 52 weeks after stroke. When the first questionnaire arrives with the respondent between week 22 and 26 after event, the second regular questionnaire will be canceled.

Study burden and risks

Burden for the patient and partner is limited to 2 or 3 times completing and returning a questionnaire, which takes 1 to 1.5 hours a time to complete. The study invites to reflect on their own relationship and sexuality. This can make people aware of personal loss or deprivation. The study can grow awareness of feelings that people usually prefer not to have (eg, sadness or frustration). The questionnaire can lead couples into talking about their intimate relationship. This can improve the relationship, but also can sharpen their focus on underlying conflicts.

This research is justified for its results will bring a better understanding of the specific problems of people with stroke and their partners both relationally and sexually. The results can incite to match these - often hidden - problems in a better way. The results of the study can contribute to improved care for the treatment of sexual and relational problems after stroke.

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

Patients in Sophia Revalidatie (at least 18 years old) and their partners, who have suffered a stroke in at most 26 weeks before.

Exclusion criteria

- Not sufficiently knowledge of Dutch language.
- Not able (also with help) to respond to the questionnaire, due to severe cognitive or fysical failure.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 15-01-2014
Enrollment: 0
Type: Actual

Ethics review

Approved WMO
Date: 21-08-2013
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO
Date: 15-04-2014
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

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

CCMO

ID

NL41572.058.12