Screening and patient-tailored care for Emotional and COgnitive problems in patients discharged home after ischemic stroke (ECO-stroke)

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

Summary

ID

NL-OMON28988

Source
Nationaal Trial Register

Brief title
ECO-stroke

Health condition

ischemic stroke, after-care, societal participation, quality of life, cost-benefit analysis, cognition, emotion beroerte, herseninfarct, CVA-nazorg, nazorg, (maatschappelijke) participatie, kosteneffectitiveit, cognitie, emotie

Sponsors and support

Primary sponsor: OLVG Amsterdam
Source(s) of monetary or material Support: ZonMw (projectnumber: 843004122)

Intervention

Outcome measures

Primary outcome

The primary outcome will be the level of participation measured with the Restriction subscale of the Utrecht Scale for Evaluation of Rehabilitation on the level of Participation (USER-P Restriction) at 1 year.

Secondary outcome

1. The following secondary outcome measures for clinical effectiveness will be used: cognitive complaints (Checklist for Cognitive and Emotional Consequences following stroke (CLCE-24)), depression and anxiety (Hospital Anxiety and Depression Scale (HADS)), quality of life (Six-Dimensional EuroQol (EQ-6D-5L)), patient-reported global health (PROMIS Global-10), physical disability (modified Rankin Scale (mRS)) and self-efficacy (General Self-Efficacy Scale (GSES)) at 1 year. Data will be collected at six weeks (T1), three months (T2) and 12 months (T3) after stroke. Besides, patient satisfaction will be measured by a customized version of the SASC-19 and will be completed at 3 months. 2. With regard to the economic evaluation, the quality of life will be measured with the EQ-5D-5L and the use of care and health-related costs will be assessed with the Medical Consumption Questionnaire (MCQ) and the Productivity Cost Questionnaire (PCQ). Data will be collected at 6 weeks, 3 months (T2) and 12 months (T3). 3. A process evaluation by a mixed methods study will be conducted parallel to the randomized controlled trial to establish the feasibility of the intervention by assessing performance according to protocol, attendance and adherence, and the opinion of patients, and professionals about the intervention. In this prospective mixed methods study, data will be gathered using questionnaires for patients, registration forms for professionals and by carrying out semi-structured interviews with patients and professionals. All materials will be developed specifically for this study and intervention.

Study description

Background summary

A multicenter, single blinded, cluster randomized controlled trial will be performed in order to examine the effect of an intervention focused on screening and patient-tailored care for emotional and cognitive problems as compared to usual care in subjects with ischemic stroke who are discharged home. Centers will be randomized in stratified blocks of two in a 1:1 ratio to the protocol group or the usual care group; centers will be stratified into two groups by the level of screening for emotional and cognitive problems (either 'medium' or 'high' level of screening). Subjects (>18 years old) with a diagnosis of ischemic stroke that resolves sufficiently to discharge subjects to their homes without follow-up care at the physiatry

outpatient clinics will be included. The intervention encompasses a short, individualized, semi-structured consultation, focused on emotional and cognitive problems. The consultation will be executed at the outpatient clinics by a specialized nurse six weeks after the index event. This consultation includes 1) a structured screening for emotional and cognitive problems, 2) a structured screening for restrictions in societal participation, 3) self-management support and 4) a guideline for referall to rehabilitation services when indicated. In the control group patients will receive care as usual. The primary outcome will be the level of participation measured with the Restriction subscale of the Utrecht Scale for Evaluation of Rehabilitation on the level of Participation (USER-P Restriction) at 1 year.

Study objective

Patients with good outcome in terms of motor functioning and communication are likely to be discharged home without referral to further rehabilitation services. A substantial amount of these patients experience emotional and cognitive problems, resulting in decreased quality of life and decreased societal participation. Therefore, this study examines the effect of screening and patient-tailored care for emotional and cognitive problems in patients discharged home after ischemic stroke.

Study design

T0 baseline - index event T1 6 weeks: follow-up moment and intervention for the intervention group T2 3 months: follow-up moment T3 12 months: follow-up moment

Intervention

A short, individualized, semi-structured consultation, focused on emotional and cognitive problems executed by a nurse (either a specialized nurse, nurse specialist, nurse practitioner or physician assistant) at the outpatient clinics six weeks after the index event. The consultation will take about one hour. A maximum of one follow-up session after the initial assessment may be proposed by the nurse when needed, but this is not obligatory. When more follow-up sessions seem to be needed, referral for specialized care will be advised. If a nurse is not available in an eligible center, one of the researchers will perform the intervention. All nurses will attend a single, four hour training to perform the intervention. Besides, a detailed manual on the intervention will be provided. The main elements of the protocol are: 1. a structured screening for emotional and cognitive problems using sensitive instruments, i.e. the Checklist for Cognitive and Emotional Consequences following stroke (CLCE-24), the Montreal Cognitive Assessment (MoCA) and the Hospital Anxiety and Depression Scal (HADS); 2. a structured screening for restrictions in societal participation by the Restriction subscale of the Utrecht Scale for Evaluation of Rehabilitation on the level of Participation (USER-P Restriction); 3. self-management support: a) providing timely and individualized active oral and written information about stroke and its possible emotional and cognitive consequences, b) measuring self-efficacy by the Dutch adaptation of the General Self-Efficacy Scale (GSES) and providing patient-tailored guidance, c) shared-decision making and d) providing contact details for possible additional questions or problems; 4. a guideline for referall to rehabilitation services based on the results of the screening instruments

Contacts

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Eligibility criteria

Inclusion criteria

- clinical diagnosis of ischemic stroke as diagnosed by a neurologist after anamnesis, neurological examination and CT-brain or MRI-brain; - signs and symptoms resolve sufficiently to discharge subjects to their homes without the need for inpatient rehabilitation or follow-up care at the physiatry outpatient clinics.

Exclusion criteria

- age below 18 years; - any serious comorbidity that 1) presumably interferes with the study outcomes (e.g. a psychiatric disorder wherefore supervision of an psychiatrist is needed), 2) has a progressive course (e.g. cancer, multiple sclerosis, and a diagnosis of mild cognitive impairment or dementia) or 3) has a life expectancy of less than 6 months; - transient ischemic attack defined as symptoms of a stroke that last less than 24 hours and are not accompanied with ischemic lesions in the corresponding vascular territory on CT-scan or MRI; - hemorrhagic stroke; - unable to understand questionnaires due to insufficient Dutch language proficiency or aphasia based on clinical judgement; ; - legally incompetent adults; - no informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2019
Enrollment:	516
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
1. Will individual participant data be available (including data dictionaries)?
Yes
2. What data in particular will be shared?
Individual participant data that underlie the results reported in the published articles after deintification (text, table, figures, and appendices).
3. What other documents will be available?
Study Protocol, Statistical Analysis Plan.
4. When will data be available (start and end dates)?
Beginning 9 months and ending 36 months after the first article publication
5. With whom?
Investigators 1) whose proposed use of the data has been approved by a review committee and 2) who signed the data acces agreement (“Overeenkomst Gemeenschappelijke Verantwoordelijkheid”).
6. For what type of analyses?
To achieve aims in the approved proposal.
7. By what mechanism will data be made available?
Proposals may be submitted up to 36 months following article publication and should be directed to j.p.l.slenders@olvg.nl. After 36 months the data will be available in our hospital’s data warehouse but without investigator support other than deposited metadata.

Ethics review

Positive opinion

Date:	25-09-2018
Application type:	First submission

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	NL7295
NTR-old	NTR7504
Other	Medical Research Ethics Committees United (MEC-U), Nieuwegein : W18.169 (niet-WMO verklaring)

Study results