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Oxford Cognitive Screen (OCS)-care: a study for developing and evaluating a care pathway for cognitive problems after stroke

Submission date
14/02/2014

Recruitment status
No longer recruiting

Registration date
27/03/2014

Overall study status
Completed

Last Edited
12/01/2018

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cognitive problems (in memory, language, attention, action planning) can affect more than 90% of the stroke survivors, but currently there is no standardised care pathway to advise on the treatment of these problems and little evidence on whether diagnosis and advising on cognitive deficits improves outcome for survivors. The aim of this project is to assess whether a recently developed stroke-specific cognitive screen (the Oxford Cognitive Screen) can diagnose cognitive problems after stroke more accurately than competitor instruments, and whether this leads to improved outcome. This project builds on the recent completion of the Birmingham University Cognitive Screen trial (BUCS) by the research team, funded by the Stroke Association, which produced and validated a clinical screen (the Birmingham Cognitive Screen, BCoS) for cognitive problems in sub-acute stroke. The BCoS is more inclusive and less language-weighted than other screens, and gives a unique cognitive profile for survivors, predictive of longer-term outcomes. The Oxford Cognitive Screen (OCS, which will be used here, has been developed to cover similar ground but takes only 15 min to administer. The present study will ask whether initial data can be collected in order to assess whether there are contrasting outcomes for survivors who either (a) receive cognitive screening using the OCS and enter the proposed case pathway, or (b) are given assessment and treatment current in the NHS practice (e.g., screening using the Montreal Cognitive Screen, MOCA).

Who can participate?
Stroke patients up to 90 years of age, plus their main carer

What does the study involve?
Participants will be randomly allocated to one of two groups: standard care group or cognitive assessment group. There will be a number of tests/questionnaires.
Standard care arm group (within 2 months of stroke):
- MOCA: this is a 15min paper-and-pencil test currently used as a cognitive screening tool in dementia and as a short screen in acute stroke units (www.moca-test.org)
- Barthel index: this consists of 10 items that measure a person's daily functioning specifically the activities of daily living and mobility. The items include feeding, moving from wheelchair to

bed and return, grooming, transferring to and from a toilet, bathing, walking on level surface, going up and down stairs, dressing, continence of bowels and bladder.
- NIHSS: this is a questionnaire with 11 questions covering cognitive and motor problems after stroke. The questions cover motoric ability (including eye gaze), sensory deficits (including visual field tests), the presence of aphasia and neglect.
Cognitive assessment group (within 2 months of stroke):
- The OCS. This is a 15-min paper-and-pencil test that measures: attention and executive function, language, memory, praxis and number processing (see the Appendix for the Protocol)
- Barthel index
- NIHSS
All patients (at follow-up, 6 months post-initial assessment):
- OCS and MOCA
- Barthel index
- NIHSS
- Nottingham extended ADL (a 22 point scale assessing everyday activities)
- HADS (anxiety and depression measure)
- ICECAP (5 point scale assessing quality of life)
- Stroke Impact Scale
Carers (at the follow-up session):
- Carer strain index (a 13 point scale evaluating carer strains)

What are the possible benefits and risks of participating?
There are no known or potential risks. A benefit would occur if patients given a cognitive screen have better outcome. Patients entering the study will receive an assessment of their cognition and both they and their carer may benefit from this information which is currently not provided systematically. There are no side effects.

Where is the study run from?
The study is run from the University of Oxford but will have participating sites are the UK. Currently around 100 sites have expressed an interest.

When is the study starting and how long is it expected to run for?
The developmental phase of the study, establishing the OCS instrument, has been completed (started in January 2012). The study will now run from March 2014 until end of December 2015. Participants will be recruited throughout this period.

Who is funding the study?
Stroke Association (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol v2.0

Study information

Scientific Title
A randomised controlled pilot study for developing and evaluating a care pathway for cognitive problems after stroke (the OCS-care project)

Acronym
OCS-care

Study objectives
That systematic screening for cognitive problems after stroke will improve outcome for patients and carers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands Coventry & Warwickshire, 09/10/2012, REC ref: 12/WM/0335

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

GP practice

Study type(s)
Quality of life

Participant information sheet
'Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
Standard care arm only (within 2 months of stroke):
1. MOCA. This is a 15min paper-and-pencil test currently used as a cognitive screening tool in dementia and as a short screen in acute stroke units (www.moca-test.org)
2. Barthel index The Barthel Index consists of 10 items that measure a person's daily functioning specifically the activities of daily living and mobility. The items include feeding, moving from wheelchair to bed and return, grooming, transferring to and from a toilet, bathing, walking on level surface, going up and down stairs, dressing, continence of bowels and bladder.
3. NIHSS. This is a questionnaire with 11 questions covering cognitive and motor problems after stroke. The questions cover motoric ability (including eye gaze), sensory deficits (including visual field tests), the presence of aphasia and neglect.

Cognitive assessment arm (within 2 months of stroke):
1. The OCS. This is a 15-min paper-and-pencil test that measures: attention and executive function, language, memory, praxis and number processing (see the Appendix for the Protocol)
2. Barthel index
3. NIHSS

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
NIHSS score measured at baseline, at 6 months post stroke

Secondary outcome measures
Oxford Cognitive Screen and the Montreal Cognitive Assessment measured at baseline, at 6 months post stroke

Overall study start date
01/03/2014

Completion date
31/12/2015

Eligibility

Key inclusion criteria
Stroke patients up to 90 years of age, plus their main carer

Patients:
1. Having had a stroke
2. Sufficient concentration to take part in paper and pencil tests for 1 hour (judged by the multi-disciplinary team in the hospital)
3. Sufficient language comprehension to pass the first orienting tests in the OCS. Within 2 months of the stroke
4. Male or female adults up to 90 years of age
5. Willing and sufficiently able to give informed consent to take part in the study

Carers:
1. Being the primary carer of stroke patient enrolled in the study
2. Willing and able to give informed consent

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Too unwell to take part (judged by the multi-disciplinary team in the hospital)
2. Insufficient concentration to take part in paper and pencil tests for 1 hour (judged by the multi-disciplinary team in the hospital)
3. Insufficient language comprehension to pass the first comprehension tests in the OCS (picture pointing)
4. Outside of 2 months of the stroke

Date of first enrolment
01/03/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University
Oxford
United Kingdom
OX1 3UD

Sponsor information

Organisation
University of Oxford (UK)

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Sponsor type
University/education

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ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Stroke Association (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration