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Organising Support for Carers of Stroke Survivors (OSCARSS): A Cluster Randomised Controlled Trial with embedded Process Evaluation

Submission date
26/07/2016

Recruitment status
No longer recruiting

Registration date
17/01/2017

Overall study status
Completed

Last Edited
17/02/2023

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Informal carers, typically partners and family, provide invaluable support for stroke survivors but this can affect their own health and well-being. Identifying and supporting the needs of informal caregivers is a national priority. The Carer Support Needs Assessment Tool (CSNAT) is a carer-led approach to individualised assessment of need and tailoring of support. Its components include a needs assessment tool; assessment review; action plan; plus guidance for how these should be implemented in practice. In previous research, the CSNAT approach was used with people caring for someone at end-of-life. The approach reduced self-reported caregiver burden and was valued by palliative care professionals as a framework for providing care. Preparation for this study involved working with informal carers of stroke survivors, researchers and stroke professionals to adapt the CSNAT approach to make it suitable for stroke (CSNAT-Stroke). The aim of this study is to explore clinical and cost-effectiveness of the CSNAT-Stroke intervention. In addition, the study will also look at the way CSNAT-Stroke is implemented to find out information about how the program itself operates in practice.

Who can participate?
Stroke Association services and staff and carers who have been referred to participating Stroke Association services.

What does the study involve?
Participating Stroke Association services are randomly allocated to one of two groups. In the first group, services use their standard methods for carer identification and support. This can vary between services. In the second group, staff are trained in the CSNAT-Stroke program. Participating carers are asked to complete some questions about themselves and their caring role entering the study and then asked about their health, well-being and experience of support and caring three and six months later. A sub-group of carers are also contacted by telephone at the start of the study about their experiences of support received and then again three months later to explore what they think about the impact of the support they received. The way that

CSNAT-Stroke is implemented is also examined by the research team in order to see if the the intervention has been offered and is working as it should do.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
The study is run by the University of Manchester and takes place in Stroke Association services across England, Wales and Northern Ireland (UK)

When is the study starting and how long is it expected to run for?
August 2015 to September 2019

Who is funding the study?
1. National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester (UK)
2. Stroke Association (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
OSCARSS v3 08.08.2017

Study information

Scientific Title
OSCARSS: a pragmatic cluster randomised controlled trial with embedded process evaluation exploring the clinical and cost effectiveness of an approach to needs assessment and support for carers of stroke survivors

Acronym
OSCARSS

Study objectives
The main research aim is to determine the effectiveness of the CSNAT-Stroke intervention for carers of stroke survivors, when compared to a control of standard practice. We will answer the following research questions using a mixed methodology, longitudinal, multi-site cluster randomised controlled trial with a health economic analysis and embedded process evaluation collecting quantitative and qualitative data:

Through the cluster randomised controlled trial (cRCT)
1. Does the intervention lead to less perceived burden by carers, when compared to standard practice?
2. Does the intervention lead to better carer perceptions of their health and well-being, when compared to standard practice?
3. Does the intervention lead to greater satisfaction with services from carer perspectives, when compared to standard practice?
4. Does the intervention lead to less economic burden for carers and society?

Through qualitative interviews nested within the cRCT
5. What are carers' experiences of the intervention and control?
6. What are carers' perceptions of the impact of the intervention and control for themselves and stroke survivors (and the mechanisms that might influence impact)?

Through the embedded process evaluation
7. What is 'standard practice' (control) within participating Stroke Association services, including any variation in such over time?
8. Is the staff training for the intervention deliverable, acceptable and effective?
9. Does the intervention affect the number and type of contacts with carers?
10. How does the intervention change practice within the Stroke Association?
11. What are Stroke Association staff experiences of the intervention, in terms of how it impacts their working practices and its relationship to carer outcomes?

The data collected through the study will also allow us to answer research questions that will be used to inform future service development:
12. What needs are identified and prioritised by carers?
13. What support inputs are available, recommended and acceptable to carers?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Lancaster NRES Committee, 29/09/2015, ref: 16/NW/0657
2. University of Manchester Research Ethics Committee approved component of Process Evaluation, 09/08/2016, ref: AMBS-2016-22

Study design
Pragmatic cluster randomised controlled trial with nested qualitative study and embedded process evaluation

Primary study design
Interventional

Study type(s)
Other

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

Interventions
Participating Stroke Association services across England, Wales and Northern Ireland form independent clusters (N=36) to be randomised to either intervention or control in a 1:1 allocation ratio. Randomisation is stratified by size of service using random block sizes of two.

Control group: Services will deliver standard practice for carer identification and support. Standard practice in Stroke Association services varies and the approach by which carers' own needs are identified and supported is not yet standardised.

Intervention group: Services will be trained to deliver the CSNAT-Stroke to carers referred to their service. The intervention does not prescribe the amount of support to be delivered; it is a carer-led, practitioner-facilitated framework for how individualised support should be provided. CSNAT-Stroke training and intervention covers: initial contact with carers; the use of a needs assessment tool; an assessment conversation; a shared action and review plan.

Carers will receive support from Stroke Association as per cluster allocation and will be invited to enrol in OSCARSS after the first face-to-face support visit.

Carers in both arms will be followed up three months after study entry (primary outcome) and again six months after study entry. Postal packs sent to carers' own home will be used to collect follow up data.

A sub-sample of carers (N=20-30 in each arm of the trial) will also be invited to take part in two qualitative telephone interviews. The first will be at the point of study entry to explore their experiences of support received. The second will take place after primary outcomes have been collected at three months to explore their perceptions of the impact of support received.

The embedded process evaluation in OSCARSS will explore intervention fidelity and service delivery closely and at multiple timepoints. Analysis of carer outcomes as they relate to intervention vs control, will only be meaningful if we have confidence that the intervention has been offered as intended and we know what is involved in 'standard practice' comparatively-speaking. Process evaluation will collect both quantitative and qualitative data including: cluster staff completing questionnaires and participating in qualitative interviews; intervention training being observed and evaluated; collecting data on all carer support contacts throughout the study.

Intervention Type
Other

Primary outcome(s)
Caregiver Strain is measured by the Caregiver Strain subscale of the Family Appraisal of Caregiving Questionnaire (FACQ) at 3 months.

Key secondary outcome(s))
All of the following relate to the cluster randomised controlled trial component of OSCARSS and are completed by carer self-report collected through postal questionnaires:
1. Caregiver Strain is measured by the Caregiver Strain subscale of the FACQ 6 months
2. Carergiver burden is measured using the Caregiver distress subscale of FACQ at 3 and 6 months
3. Positive impact of caring is measured using the Positive caregiving appraisals subscale of FACQ at 3 and 6 months
4. Satisfaction with stroke services provided is measured using the Pound Carer Satisfaction with Stroke Services Scale at 3 and 6 months
5. Mood is measured by the Hospital Anxiety and Depression Scale (HADS) at 3 and 6 months
6. Health is measured by the EQ-5D 5L questionnaire at 3 and 6 months
7. Economic burden of caring (for Health Economics evaluation), is measured using an adapted Service Receipt Inventory completed by carers to record healthcare services used and time spent caring at 3 and 6 months

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Clusters/Staff:
OSCARSS involves Stroke Association services and staff within those services whom:
1. Offer at least one face to face contact with carers as part of their service;
2. Have capacity to participate in the research;
3. For whom it would be meaningful and useful to perform a holistic carer needs assessment (some services only deliver a specific type of support)
4. Are likely to have at least five new client referrals per month. 'Clients' include both stroke survivors (who are likely to have associated carers) and carers directly;

5. Are considered ‘independent’ of other clusters. Some Stroke Association staff across several services work closely in terms of geography and shared client caseload. To reduce between-group contamination, these services will be aggregated to form one ‘cluster’ for OSCARSS.

Carers of stroke survivors:
1. Referred to participating Stroke Association clusters (either research intervention or control, as per randomisation);
2. Able to communicate in English;
3. ‘Active’ in their caring role at the time of study entry i.e. the stroke survivor being cared-for is alive
4. Aged 18 years and over

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
414

Key exclusion criteria
Not meeting inclusion criteria

Date of first enrolment
16/01/2017

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Manchester
Manchester Academic Health Sciences Centre
Oxford Road

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Study participating centre
Stroke Association
Stroke Association House
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Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Stroke Association

Alternative Name(s)
TheStrokeAssociation, TheStrokeAssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. Please contact Prof Audrey Bowen (Audrey.bowen@manchester.ac.uk) to discuss access to IPD, which may be made available on request on a case-by-case basis.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/01/2021	15/01/2021	Yes	No
Protocol article	protocol	07/01/2019		Yes	No
Abstract results		22/05/2019	17/02/2023	No	No
Abstract results	2 abstracts on page with this ISRCTN number	22/05/2019	17/02/2023	No	No
HRA research summary			28/06/2023	No	No
Other publications	value and learning from carer involvement	08/05/2020	25/06/2020	Yes	No
Other publications	process evaluation	12/01/2021	15/01/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	Statistical Analysis Plan. (DOCX 59 kb)		17/02/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes