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Biopsychosocial Intervention for Stroke Carers

Submission date
11/03/2015

Recruitment status
No longer recruiting

Registration date
12/03/2015

Overall study status
Completed

Last Edited
23/09/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
The trend for earlier discharge from hospital means that more stroke survivors than ever are now living in the community with support from their spouse or other informal carer. The transition from hospital to home can be seen as both demanding and complex, which can have an adverse impact on the health and quality of life of both the stroke patient and carer. Currently services do not provide specific support to carers to adjust to the caregiving role and its demands. The first phase of this study will be to develop, tailor and target the delivery of a biopsychosocial intervention that satisfies the unique needs and difficulties experienced by carers of stroke patients. The second phase of the study is to examine whether the group intervention programme is both feasible and well tolerated by stroke carers. The ultimate aim of this study is to find out whether a group biopsychosocial intervention improves adjustment and mood outcomes in carers of stroke survivors. However, a large definitive study cannot be carried out until further information is collected to inform the design of such a study.

Who can participate?
The study aims to recruit 30 participants (20 stroke carers and 10 research/clinical experts) for the first phase of the study, and 40 stroke patients and their carers from primary and secondary care settings for the second phase.

What does the study involve?
The first phase of the study involves running focus groups with carers of stroke survivors and a panel of national clinical and research experts to determine and inform the content of the intervention. The second phase involves testing the feasibility of the newly developed intervention. Stroke survivors and their carers are recruited from Nottingham University Hospitals and Community Stroke Teams. About 20 patients and carers are randomly allocated to receive standard care. About 20 patients and carers are assigned to the group intervention. Stroke survivors are not invited to participate in the group intervention, however we intend to complete outcome measures with stroke survivors, to monitor the impact of the intervention on their mental and physical wellbeing and quality of life. The group intervention consists of weekly 2 hours sessions for a period of 6 weeks. The sessions focus on topics and exercises informed by the focus groups e.g. ‘roles and relationships following stroke’ and ‘managing anxiety post-stroke.’ The sessions are based on a biopsychosocial framework. They are designed to teach individuals to identify and deploy skills to reduce current and future distress, thus aiding coping and adjustment. Participants in both trial arms are asked to complete measures assessing their

wellbeing and quality of life at the start of the study and then after 6 months later. Purposefully selected carers are invited to participate in qualitative feedback interviews post final follow-up questionnaires which are completed face to face, to obtain feedback on all aspects of the study in addition to the intervention – procedures, assessments, intervention (if received) and perceived outcomes. For those in the control group the interviews provide confirmation of the nature of usual care received.

What are the possible benefits and risks of participating?
There may well be no direct benefit to those taking part. However, the information obtained from this study may help improve the treatment and support of stroke carers in the future. There are no particular risks involved in taking part in this study. However, carers might begin discussing or exploring sensitive issues, recollecting unpleasant memories and feelings around the stroke during the focus groups or group intervention. Carers are free to stop at any time and are directed to appropriate support services (GP) should they feel access for further support is required.

Where is the study run from?
University of Nottingham (UK)

When is study starting and how long is it expected to run for?
July 2015 to March 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Prof. Marion Walker
marion.walker@nottingham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Marion Walker

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18589

Study information

Scientific Title
Biopsychosocial Intervention for Stroke Carers (BISC) Study

Acronym
BISC

Study objectives
Current hypothesis as of 09/06/2017:
As this is a feasibility trial, we are not in a position to make predictions about outcomes at this stage. The aim of this feasibility trial is to:
1. Develop a biopsychosocial intervention for carers of stroke patients
2. Undertake a feasibility randomised controlled trial of a stroke specific biopsychosocial intervention for carers of stroke patients to explore whether it is both feasible and well tolerated.

Previous hypothesis:
As this is a feasibility trial, we are not in a position to make predictions about outcomes at this stage. The aim of this feasibility trial is to:
1. Develop a Cognitive Behavioural Therapy (CBT) intervention for carers of stroke patients
2. Undertake a feasibility randomised controlled trial of a stroke specific CBT intervention exploring whether CBT for carers of stroke patients is both feasible and well tolerated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands – Nottingham 2, 04/12/2014, ref: 14/EM1264

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Stroke; Subtopic: Rehabilitation; Disease: Therapy type, Community study

Interventions
Current interventions as of 09/06/2017:
1. Treatment intervention group: There will be 4 intervention groups of approximately 5 participants. Groups will be held in a non-clinical environment in Nottinghamshire. An research psychologist will facilitate the group sessions. Each session will last approximately 2 hours and will include a 15-minute tea/coffee break, allowing participants to socialize. Each session will end with a 15-minute relaxation exercise. The intervention group programme will focus on adjustment to illness. For each session there will be a presentation containing information about a topic and practical exercises to aid discussion. The precise content of the sessions will be formalized following the findings of the focus groups with carers and nominal groups with experts. Homework will be set to encourage participants to practise exercises from the group sessions in their own time. The sessions are based on a biopsychosocial framework. They are designed to teach individuals to identify and deploy skills to reduce current and future distress, thus aiding coping and adjustment.
2. Control group: Participants in the control group will not receive the group biopsychosocial intervention but will have access to all other usual services.

Previous interventions:
1. Treatment intervention group: There will be 4 intervention groups of 5 participants. Groups will be held in a non-clinical environment in Nottinghamshire. An assistant psychologist will facilitate the group sessions. Each session will last approximately 2 hours and will include a 15-minute tea/coffee break, allowing participants to socialize. Each session will end with a 15-minute relaxation exercise. The intervention group programme will focus on adjustment to illness. For each session there will be a presentation containing information about a topic and practical exercises to aid discussion. The precise content of the sessions will be formalized following the findings of the focus groups with carers and nominal groups with experts. Homework will be set to encourage participants to practise exercises from the group sessions in their own time. The sessions are based on a cognitive behavioural and psycho-educational framework. They are designed to teach individuals to identify and deploy skills to reduce current and future distress, thus aiding coping and adjustment.
2. Control group: Participants in the control group will not receive the group CBT intervention but will have access to all other usual services.

Intervention Type
Behavioural

Primary outcome measure
As this is a feasibility trial, we have no pre-defined outcome measure at present. The measures will pertain to the feasibility aims of the study. We will test the feasibility, tolerability and acceptability of delivering the intervention and will record data on study completion and attrition.

At baseline the following measurement data will be collected with stroke patients:
1. At baseline we will collect demographic details of patients including age, gender, ethnicity and employment.

2. Language and Cognitive Abilities (Montreal Cognitive Assessment)
3. Personal Activities of Daily Living (Barthel Index)
4. Stroke severity (National Institute of Health Stroke Scale)
5. Which service (if any) the patient is discharged to (e.g. ESD, intermediate care)
6. Number and percentage of participants who meet eligibility criteria
7. Number of eligible participants who give consent

Questionnaires to be completed face-to-face, with both patients at baseline, 6 months after recruitment include:
1. To assess levels of anxiety and depression: Hospital Anxiety and Depression Scale
2. To assess functional health and wellbeing: Rand SF36
3. To assess Quality of Life: EuroQol to assess quality of life

Additional questionnaires to be completed with just patients include:
To assess level of dependence: Modified Rankin Scale

Measures at two and four months:
1. Number and percentage of people who completed each outcome measures at 6 month follow-up
2. Number of times RA is unblinded to intervention and description of how this occurred
3. Number and percentage of patients who died, including date of death and cause of death
4. Number and percentage of hospital readmissions (whether general or stroke-specific)
5. Number and percentage of participants for whom outcome data at 6 months is collected
6. Other reasons for loss to follow-up

Outcome data will be utilised to inform a sample size calculation for the definitive trial by assessing variability and completeness of data. In terms of actual time participants will be involved in this phase is approximately 30 minutes during each assessment period.

At baseline the following measurement data will be collected with stroke carers:
1. At baseline we will collect demographic details of stroke carers including age, gender, ethnicity and employment.
2. Number and percentage of participants who meet eligibility criteria
3. Number of eligible participants who give consent

Questionnaires to be completed face-to-face, with carers at baseline, 6 months after recruitment include:
1. To assess levels of anxiety and depression: Hospital Anxiety and Depression Scale
2. To assess functional health and wellbeing: Rand SF36
3. To assess Quality of Life: EuroQol to assess quality of life

Additional questionnaires to be completed with just carers include:
To assess levels of carer strain: Carer Burden Scale

We will also collect data on the composition of intervention groups.

Measures at 6 months:
1. Number and percentage of people who completed each outcome measures at 6 month follow-up
2. Number and percentage of people who attended the intervention/number of sessions they attended
3. Number of times RA is unblinded to intervention and description of how this occurred

4. Number and percentage of patients who died, including date of death and cause of death
5. Number and percentage of hospital readmissions (whether general or stroke-specific)
6. Number and percentage of participants for whom outcome data at 6 months is collected
7. Other reasons for loss to follow-up

Updated 09/06/2017: Follow up timepoints were changed from 2 and 4 months to 6 months.

Secondary outcome measures
N/A

Overall study start date
01/01/2015

Completion date
31/03/2018

Eligibility

Key inclusion criteria
Current inclusion criteria as of 09/06/2017:
Phase 1: Development of Intervention
Carer Focus Groups:
1. Adult carers of stroke patients who have a confirmed diagnosis of stroke
2. Carers able to provide informed consent
Stroke expert clinicians and researchers:
1. Researchers and clinicians with significant experience (>3 years) of either working clinically or conducting research with stroke carers
Expert panellists have already been identified by the steering committee for invitation for this phase of study.

Phase 2: Feasibility Trial
Stroke patients:
1. Adult stroke patients who have a confirmed diagnosis of stroke
2. Stroke patients within one year of their stroke onset
3. Willingness of stroke survivor to be included in follow up assessments
4. Both patients and their carers must consent for their carer to take part in the study.
Stroke carers:
1. Adult carers of stroke patients who have a confirmed diagnosis of stroke
2. Carers of patients within one year of their stroke onset
3. Carers who are able to provide informed consent
4. Willingness to attend a behavioural programme of 6 weeks duration
5. Willingness of stroke survivor to be included in follow up assessments
6. Both patients (or their consultee) and their carers must consent for their carer to take part in the study.

Previous inclusion criteria:
Phase 1: Development of Intervention
Carer Focus Groups:
1. Adult carers of stroke patients who have a confirmed diagnosis of stroke
2. Carers able to provide informed consent
Stroke expert clinicians and researchers:

1. Researchers and clinicians with significant experience (>3 years) of either working clinically or conducting research with stroke carers
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5. Both patients and their carers must consent for their carer to take part in the study.
Stroke carers:
1. Adult carers of stroke patients who have a confirmed diagnosis of stroke
2. Carers of patients within one year of their stroke onset
3. Carers who are able to provide informed consent
4. Willingness to attend a behavioural programme of 6 weeks duration
5. Willingness of stroke survivor to be included in follow up assessments
6. Both patients and their carers must consent for their carer to take part in the study.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Total final enrolment
35

Key exclusion criteria
Current exclusion criteria as of 09/06/2017:
Phase 1: Development of Intervention
Carer Focus Groups:
1. People who do not speak English
Stroke expert clinicians and researchers:
1. People who do not speak English

Phase 2: Feasibility Trial
Stroke patients:
1. People who do not speak English
2. People engaged in other research involving behavioural interventions
Stroke carers:
1. People who do not speak English

2. People engaged in other research involving behavioural interventions
3. People with visual (blindness) or auditory (deafness) impairments that would preclude them from participating in the therapy sessions.

Previous exclusion criteria:
Phase 1: Development of Intervention
Carer Focus Groups:
1. People who do not speak English
Stroke expert clinicians and researchers:
1. People who do not speak English

Phase 2: Feasibility Trial
Stroke patients:
1. People who do not speak English
2. People engaged in other research involving behavioural interventions
3. People with visual (blindness) or auditory (deafness) impairments that would preclude them from participating in the therapy sessions.
Stroke carers:
1. People who do not speak English
2. People engaged in other research involving behavioural interventions
3. People with visual (blindness) or auditory (deafness) impairments that would preclude them from participating in the therapy sessions.

Date of first enrolment
01/06/2015

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham University Hospitals NHS Trust
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
Nottingham
United Kingdom
NG3 6AA

Sponsor information

Organisation
University of Nottingham

Sponsor details
Research Innovation Services
Kings Meadow Campus
Lenton Lane
Nottingham
England
United Kingdom
NG7 2NR

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ee9ar58

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

Results and Publications

Publication and dissemination plan
Findings arising from the research will be disseminated via presentation to Nottinghamshire Community Stroke Teams and inpatient settings to promote and facilitate implementation in the NHS. The trialists intend to publish the findings of this study in peer-reviewed journals and present findings at appropriate local and national conferences to optimise and maximise impact on practitioners and service managers such as the UK Stroke Forum and the European Stroke Conference. No personable identifiable information will be included in either publications or presentations.

All people interested or involved in the study will also be invited to the yearly patient-led stroke research conference at the East Midlands Conference centre to disseminate the results. This will include the service user groups who have collaborated with the project, academics, practitioners, service commissioners and family members.

The lay members of the consumer group will be involved in preparing a lay summary of the key research findings that will be enclosed with thank you letters to all participants and family members who have given consent to take part.

The trialists will continue to work closely with researchers and clinicians from other organisations, NHS, Universities and Professional Societies so helping research move forward by learning from each other.

Intention to publish date
31/03/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/10/2017	23/09/2020	Yes	No
Results article	results	01/10/2020	23/09/2020	Yes	No