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Accelerating delivery of psychological therapies after stroke

Submission date
03/02/2016

Recruitment status
No longer recruiting

Registration date
04/02/2016

Overall study status
Completed

Last Edited
14/04/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery (ischaemic stroke) or a bleed (haemorrhagic stroke). A large proportion of stroke victims suffer from long-term complications depending on the area of the brain that is affected, which can affect their ability to move, speak or even their cognitive function (memory loss, difficulty reasoning and confusion). Psychological problems, such as depression, are common after stroke and can have negative effects on stroke survivors and their carers. Although general psychological services exist (e.g. Improving Access to Psychological Therapies (IAPT) services), there is a lack of psychological support available for stroke survivors. This may be because of the range of difficulties that stroke survivors might have, such as communication problems, which make it more challenging for services to provide effective support. This study aims to find out whether existing IAPT services can be adapted so that they are useful for stroke survivors.

Who can participate?
Adults who have suffered from a stroke and their carers, as well as staff working in the hospital and community settings at each of the sites.

What does the study involve?
At the start of the study, interviews will be held with stroke survivors to find out about their experience and views of psychological services. Staff of stroke services and psychological services staff are also interviewed in order to assess the current psychological care offered. Following this, notes of patients who have previously been admitted to hospital are reviewed in order to find out whether the initial stages of the study (i.e. the process mapping and the development of the implementation package) even before the main part of the study has started, has an effect on the psychological support patients receive, for example by raising staff awareness of unmet needs. The main trial involves stroke services being randomly allocated to one of two dates to begin the implementation package, spaced three months apart. The implementation package is adopted into normal care and involves training the staff of stroke teams and IAPT teams in order to provide psychological help to stroke survivors when needed. After 6 weeks and 6 months, patients are asked to complete a number of questionnaires in order to find out if the package has had any effect on their mood and general wellbeing. At the end of

the study, patients, carers and staff are interviewed in order to give their opinions about their experiences.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Four stroke services in NHS trusts based in the North-West of England

When is the study starting and how long is it expected to run for?
November 2015 to December 2016

Who is funding the study?
1. National Institute for Health Research (UK)
2. MQ: Transforming Mental health (UK)

Who is the main contact?
Dr Elizabeth Lightbody
CELightbody@uclan.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Elizabeth Lightbody

Contact details
University of Central Lancashire
Clinical Practice Research Unit (CPRU)
Department of Nursing
Fylde Road
Preston
United Kingdom
PR1 2HE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20096

Study information

Scientific Title
Accelerating Delivery Of Psychological Therapies after Stroke (ADOPTS)

Acronym
ADOPTS

Study objectives
The aim of this study is to explore the feasibility and acceptability of providing psychological support to stroke survivors in the NHS through exploring the operationalisation of an Implementation Package using a stepped-wedge trial design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire and The Humber - Leeds East, 20/08/2015, ref: 15/YH/0343

Study design
A feasibility stepped-wedge cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life

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

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

Interventions
At the start of the study, stroke survivors are interviewed in order to find out about their experience and views of psychological services. In addition, staff at stroke services and psychological services staff are interviewed in order to inform the design of the implementation package (developed in earlier phases of the project).

The Implementation Package itself will establish a care pathway for patients with psychological needs after stroke, based on a stepped care model. The pathway will focus on the collaborative work between the stroke teams and IAPT teams, allowing psychological needs after stroke to be identified, treated and where necessary, for more complex cases, referred on to appropriate

services. The Implementation Package will be individualised for each site, taking into consideration the staff and service user views, current practices and pathways, and available resources at each site.

While delivery will vary slightly across sites, the core aspects of the implementation strategies will be consistent across all sites and will include the care pathway, training, a manual and a model of supervision. The research team is experienced in developing intervention implementation packages and will use a co-design approach where stroke patients and carers are involved in its conception and design. The rationale for such a partnership is to maximise the "potential fit" of the intervention with the local context in which the intervention will be implemented thus maximising buy-in from clinical staff.

The trial will include exploring the usual practice before the study begins, delivery plan for the main intervention, and capturing the experiences of participants after the study has finished. The trial comprises of the following three elements: casenote review,main trial and process evaluation.

Casenote Review
Retrospective review of patient hospital casenotes to explore feasibility of stepped-wedge design. It is important to know whether the initial stages of the study (i.e. the process mapping and the development of the Implementation Package), even before the main intervention has started, has impacted on the psychological support patients receive, for example by raising staff awareness of unmet needs. This will inform the feasibility and suitability of the stepped wedge design for a future trial.

Main Trial
A stepped-wedge cluster randomised trial in 4 stroke services (clusters) which will be randomised to one of two dates to begin the roll-out period (3 months apart). Randomisation will be performed by an independent statistician in the Lancashire CTU using computer-generated pseudo-random numbers. All clusters start in a usual care phase (no intervention delivered at any site), then sequentially crossover to the roll-out phase, until all sites are receiving the intervention. The Implementation Package will be rolled out over a 3 month period to embed the pathway in the services prior to the start of formal data collection for the intervention phase.
The Implementation Package consists of providing a care pathway for psychological support after stroke. This pathway will be adopted as part of usual care, patients consent to data collection and follow up only. While delivery will vary slightly across sites, the core aspects of the implementation strategies will be consistent across all sites.
All recruited patients will receive a postal questionnaire at 6-weeks and 6-months post-stroke to collect outcome data

Process Evaluation
In order to understand the experiences of those involved in the study, process evaluation interviews will be held with both patients and staff. The interviews will establish what participants thought worked well, as well as areas they felt could be improved.
Through semi-structured interviews, patients and their carers will be asked to describe their experience of psychological support since their stroke, including whether they found their experience acceptable and suitable. Participants will be asked to comment on a proposed service model for future psychological support services for patients after stroke.
Following roll-out of the implementation package, staff will be interviewed about their experiences. The interview will aim to understand staff feelings towards implementing the intervention package, including the training and supervision they received, what they felt

worked well, and what they felt could be improved. This will provide ideas for refinement of trial procedures and protocol should a large scale trial be conducted in future.

Intervention Type
Behavioural

Primary outcome measure
Patient Health Questionnaire 9 item (PHQ-9) at baseline, 6 weeks and 6 months.

Secondary outcome measures
1. Behavioual Outcomes of Anxiety Scale (BOA) at baseline, 6 weeks and 6 months
2. Generalised Anxiety Disorder 7 item (GAD-7) at baseline, 6 weeks and 6 months
3. Impact of Events Scale 6-items at 6 weeks and 6 months
4. Stroke Aphasia Depression Questionnaire 10 item (SADQ-10) at baseline, 6 weeks and 6 months
5. Work and Social Adjustment Scale 5-items at 6 weeks and 6 months

Overall study start date
04/11/2015

Completion date
30/11/2017

Eligibility

Key inclusion criteria
Case note review
All stroke patients on the acute stroke unit will be identified over one week during the usual care period (prior to process mapping and development of the implementation package), and one week during the period of rolling out the implementation package.

Main Trial
Consecutive stroke patients admitted to the acute stroke units will be identified who:
1. Survive to day 3 post-stroke or being discharged prior to day 3
2. Lives within catchment area of trust
3. Aged 18 or over

Process Evaluation
Stroke patients and carers
Stroke patients and carers will be purposely selected (12 per site) to recruit a balance in sex, age (younger and older), stroke severity (mild, moderate and severe), communication abilities and time since stroke.

Staff
Staff working within the stroke hospital settings within each of the sites. This may include nurses, doctors, OTs, physiotherapists, allied health professionals, reflecting the range of staff involved in the care pathway at each site.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Casenote review: Approximately 20 patients per site (total of 80 patients). Main Trial: Approximately 20-30 patients from each centre in each period (total of 320-480). Process Evaluation: Stroke patients and carers - Approximately 12 per site (total of 48)

Key exclusion criteria
The participant exclusion criteria is the same for all three elements (casenote review, main trial and process evaluation) and are as follows:
1. Living outside area catchment area of trust
2. Aged under 18
3. Lacks capacity AND has no friend/relative/carer

Date of first enrolment
04/11/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
Arrowe Park Road
Upton, Wirral
Merseyside

United Kingdom
CH49 5PE

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Countess of Chester Hospital NHS Foundation Trust
The Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Sponsor information

Organisation
University of Central Lancashire

Sponsor details
Fylde Road
Preston
England
United Kingdom
PR1 2HE

Sponsor type
University/education

ROR
https://ror.org/010jbqd54

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
Not provided at time of registration

Intention to publish date
30/11/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		04/04/2025	14/04/2025	Yes	No