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Improving follow-up care for people who have a mini stroke or minor stroke

Submission date
01/03/2021

Recruitment status
No longer recruiting

Registration date
03/03/2021

Overall study status
Completed

Last Edited
18/03/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
This study is for people who have experienced a mini stroke (transient ischaemic attack/TIA) or minor stroke.
After being diagnosed with a mini-stroke or minor stroke, it is important that people receive adequate healthcare and support. This includes:
• Understanding their diagnosis;
• Receiving medication and lifestyle advice to reduce risk of future strokes;
• Receiving support for other impacts from mini-stroke or minor stroke, such as anxiety or tiredness.
Follow-up care for people who have had a mini stroke or minor stroke is not currently standardised. Therefore, people have different experiences of care depending on what hospital or GP practice they attend.
We want to find out if healthcare could be improved by people having a follow-up appointment, with a nurse or therapist, one month after having a mini stroke. Before we do a large trial, we first want to see if it is feasible to have this follow-up appointment in a hospital and if patients find it acceptable.

Who can participate?
Adults aged 18 years or above, resident in the West Midlands, with a diagnosis of confirmed TIA or minor stroke by a stroke consultant.

What does the study involve?
Participants will be randomly allocated to the intervention (nurse/ therapist follow-up appointment) and the control (usual care)
We want to find out if healthcare could be improved by people having a follow-up appointment, with a nurse or therapist, one month after having a mini stroke. Before we do a large trial, we first want to see if it is feasible to have this follow-up appointment in a hospital and if patients find it acceptable.
To further explore if the study design and intervention are feasible and acceptable, we will conduct observations of the study procedures, such as recruitment and the intervention follow up appointment. In addition, we will interview a subset of participants and clinical staff who delivered the study.

What are the possible benefits and risks of participating?

The potential benefits are that this study will help us determine the best follow-up procedures for people who have experienced mini or minor stroke. Participants may find it rewarding to take part in research which may help us improve healthcare for people who have mini strokes (TIAs) in the future. Participants allocated to the intervention group will receive additional follow-up care, which they may not normally receive, to help identify and address your needs.
We anticipate minimal risks for participating in this study. However, some of the questions in the questionnaires completed at 1, 12 and 24 weeks contain sensitive questions which people may find upsetting. For example, the mood section includes questions about anxiety.
At the end of the study we will take a blood sample to measure cholesterol. This may cause discomfort and bruising at the site where the needle goes in. These complications usually are minor and go away shortly after the tests are done. Some people may feel anxious about giving a blood sample, the clinician who will take the sample will be happy to answer any questions and provide reassurance.
During this research we may invite participants to participate in an interview to discuss their experiences of follow-up care. Some people could find it distressing to talk about this.

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

When is the study starting and how long is it expected to run for?
March 2019 to April 2023

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

Who is the main contact?
Dr Grace Turner, G.Turner.1@bham.ac.uk

Study website
https://www.Birmingham.ac.uk/SupportTIA

Contact information

Type(s)
Scientific

Contact name
Dr Grace Turner

ORCID ID
https://orcid.org/0000-0002-9783-9413

Contact details
Murray Learning Centre
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT

+44 (0)121 414 5463
g.turner.1@bham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
267063

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42537, IRAS 267063

Study information

Scientific Title
Structured follow-Up Pathway to imProve management Of Residual impairmenTs and patients' quality of life after TIA and minor stroke: feasibility study

Acronym
SUPPORT TIA

Study objectives
After being diagnosed with a mini stroke (TIA) or minor stroke, it is important that people receive adequate healthcare and support. This includes:
• Making sure people understand their diagnosis;
• Giving medication and lifestyle advice to reduce risk of future strokes;
• Supporting other impacts of mini stroke (TIA) or minor stroke, such as anxiety or tiredness.
Follow-up care for people who have had a mini stroke (TIA) or minor stroke is not currently standardised. Therefore, people have different experiences of care depending on what hospital or GP practice they attend.
We hypothesise that healthcare could be improved by having a follow-up appointment to discuss healthcare needs and support, with a nurse or therapist, four weeks after having a mini stroke (TIA) or minor stroke. Before we do a large trial to see if the nurse/ therapist appointment is effective, we first need to do a smaller study to see if it is practical to have this follow-up appointment in a hospital and if patients' find it acceptable and helpful.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2021, Wales REC 1 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 230457; Wales.REC1@wales.nhs.uk) ref: 21/WA/0036

Study design

Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
This feasibility will be conducted in the West Midlands and recruit 60 participants, 30 will be randomised to the intervention (nurse/ therapist follow-up appointment) and 30 will be randomised to the control (usual care).
Each participant will be on the study for 6 months. Both groups will be asked to do the following:
1. Provide their medical history, demographic information (e.g. age, ethnicity, sex) and contact details.
2. Complete a questionnaire at 3 different time points: 1 week, 12 weeks and 24 weeks into the study. This contains questions about mood, fatigue (tiredness), quality of life, medication and healthcare/ support. Questionnaires can be completed electronically through a website (the link will be sent to participants) or paper copy which will be returned in the post.
3. Attend an appointment at the TIA clinic at the end of the study. At this appointment we will measure blood pressure and weight, record medications and take a blood test to measure cholesterol.
4. A subset of participants will be invited to attend an interview with a researcher to talk about their experience of taking part in the study.

Intervention group: The intervention group will be invited to attend a follow-up appointment with a nurse or therapist about 4 weeks into the study. The appointment will be at the TIA clinic or remotely, and last about 30 minutes. Before attending the appointment, participants will be asked to complete a checklist to identify any needs in relation to their mini stroke or minor stroke. At the appointment, the nurse/ therapist will discuss these needs and how to address them. Participants will agree on an action plan to address their needs and will be given a list of potentially relevant support services which may be helpful. The action plan will be shared with the participant's GP. The nurse/ therapist will also take the participant's blood pressure at the appointment.
There will be an option to have more follow-up appointments or phone calls if it is needed.
Participants will also receive usual care as normal. After the appointment(s) participants will be asked to complete a questionnaire to give feedback on their experience.
The intervention group will also receive treatment and care which is currently offered to people

after mini stroke or minor stroke. Participants will be sent a Stroke Association information sheet about mini strokes with the letter telling them which group they have been allocated to.

Control group: The Control group will receive treatment and care which is currently offered to people after mini stroke or minor stroke. Participants will also be sent a Stroke Association information sheet about mini strokes with the letter telling them which group they have been allocated to.

To further explore if the study design and intervention are feasible and acceptable, we will conduct observations of the study procedures, such as recruitment and the intervention follow up appointment. In addition, we will conduct interviews with about 3-6 healthcare providers who were involved in the study. The purpose of these interviews will be to get feedback on the acceptability of the trial design (including their experience of the training day) and acceptability of delivering the intervention.

Intervention Type
Not Specified

Primary outcome measure
Feasibility outcomes:
1. Number of eligible/ineligible patients and reasons for ineligibility measured using a recruitment log at baseline
2. Proportion of participants who consent face-to-face or postal measured using recorded method of consent at baseline
3. Willingness of clinical staff to randomise patients measured using qualitative interviews at 26 weeks
4. Recruitment and attrition rates measured using the recruitment log and questionnaire response rate at baseline, 1, 12 and 24 weeks
5. Response rates and frequencies of missing data: participant completed questionnaires and case report forms measured at 1, 12 and 24 weeks
6. End of study clinic appointment attendance rates measured using the clinic appointment CRF at 24 weeks
7. Acceptability of the trial design (patients and clinical staff) measured using qualitative interviews at 26 weeks
8. Standard deviations of continuous PROMs (HADS, FAS, EQ-5D, PROMIS-10, PAM-13, MARS 5) at 6 months

Secondary outcome measures
Process evaluation outcomes:
1. Participants' and clinical staff's opinion on acceptability of the intervention measured using qualitative interviews at 26 weeks
2. Intervention providers' understanding of the intervention components measured using qualitative interviews at 26 weeks
3. Participants' satisfaction with identification and management of needs measured using qualitative interviews at 26 weeks
4. Participants acting on agreed action plans and/or accessing support services measured using qualitative interviews at 26 weeks
5. Intervention providers' understanding of the intervention components measured using qualitative interviews at 26 weeks
6. Intervention providers' adherence to and deviations from the intervention manual measured using structured observations at 4 weeks

7. Control group contamination measured using qualitative interviews at 26 weeks
8. Intervention follow-up appointment: attendance, length of appointment and number of appointments measured using the intervention log at 4 weeks
9. Participants' perception of the intervention measured using qualitative interviews at 26 weeks
10. Participants acting on agreed action plans and/or accessing support services measured using qualitative interviews at 26 weeks

Overall study start date
01/03/2019

Completion date
01/04/2023

Eligibility

Key inclusion criteria
1. Adults (aged >=18 years)
2. Resident in the West Midlands (county)
3. Ability to converse in everyday English and read in English
4. Capacity to provide fully informed consent for participation in the trial
5. Diagnosis of confirmed TIA or minor stroke by a stroke consultant. TIA will be defined as a transient episode of neurological dysfunction caused by focal brain, spinal cord, or retinal ischemia, without acute infarction. Minor stroke will be defined as a modified Rankin scale score <=1 or no change in modified Rankin scale score from pre-event (to account for people who were disabled prior to their TIA/ minor stroke)
6. Attending the TIA clinic/ stroke ward for a new diagnosis of TIA/ minor stroke, rather than for a follow-up appointment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
54

Key exclusion criteria
1. History of full stroke
2. History of dementia
3. People who lack capacity to participate, such as if they have severe memory problems that

mean they would not remember giving consent or if they have severe communication problems not precluding patients who use electronic devices to communicate
4. Patients receiving early supported discharge or cardiac rehabilitation
5. Patients receiving any palliative care

Date of first enrolment
01/03/2021

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham

Sponsor details
Research Support Group Room 117
Aston Webb Building
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 415 8011
researchgovernance@contacts.bham.ac.uk

Sponsor type
University/education

Website
http://www.uab.edu/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: PDF-2017-10-047

Funder Name
National Institute for Health Research (NIHR) (UK)

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
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/10/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Grace Turner (G.Turner.1@bham.ac.uk). Type of data: reasonable requests for anonymised data. When the data will become available and for how long: after publication, for 5 years. By what access criteria data will be shared including with whom: reasonable requests for anonymised data (to be reviewed by the Chief investigator).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/06/2022	17/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		13/03/2025	18/03/2025	Yes	No