ISRCTN17065351 https://doi.org/10.1186/ISRCTN17065351

Motivational interviewing therapy after stroke

Submission date	**Recruitment status**	[X] Prospectively registered
17/01/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/02/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/07/2025	Circulatory System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A stroke occurs when the blood supply to the brain is cut off. A stroke can have a devastating effect on people, not only physically and mentally, but emotionally too. This research intends to help people who have had a stroke come to terms with their stroke and reduce depressive symptoms, a common problem after stroke. Depression affects about one in three stroke survivors. Depressed patients tend to be less motivated to take part in rehabilitation when they are in hospital, resulting in longer hospital stay and poorer recovery.
A type of talking therapy (counselling) called Motivational Interviewing-Based Intervention (MIBI) could be beneficial in helping stroke survivors adapt to life after a stroke. The aim of this study is to determine if MIBI is an effective and cost-effective approach for helping people who have had a stroke.
MIBI will be compared with a sham treatment (Attention Control) where participants spend time with a visitor, to mirror the additional social attention people receive through MIBI. This will help to determine if it is actually the MIBI, or if it is simply spending time with someone, that makes a difference.

Who can participate?
Adults aged 18 years and older who have had a stroke

What does the study involve?
Participants are randomly allocated to receive either: sessions of Motivational Interviewing-Based Intervention (MIBI) which is a talking therapy with a trained therapist plus usual care; or sessions of Attention Control (AC) which involves spending time with a trained AC provider having general conversations plus usual care; or only the usual care available. MIBI and AC sessions are 45 minutes long, and held weekly for up to four weeks, over telephone or video call. Participants complete questionnaires about how they are feeling when they enter the study, and twice more at 6 weeks and 3 months after their stroke.

What are the possible benefits and risks of participating?
Participants may benefit from engaging in either MIBI or AC sessions by being able to talk to someone individually. Participants may also value being involved in improving psychological support services for future patients. While engaging in MIBI, participants may become upset due to talking about their recent stroke and its impact. If MIBI therapists or healthcare staff feel concerned about participants' wellbeing, they will discuss this with participants, and participants

will be referred on to an appropriate person for help. Should participants disclose information that concerns staff regarding the health and safety of the participant or those around the participant, the staff member will report this to the person responsible for their care and the participant will be referred to an appropriate person.

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

When is the study starting and how long is it expected to run for?
September 2019 to December 2025

Who is funding the study?
1. National Institute for Health Research Collaborations for Leadership in Applied Health Research and Care North West Coast (UK)
2. National Institute for Health Research Senior Investigators Award (UK)
3. University of Central Lancashire (UK)

Who is the main contact?
Prof. Liz Lightbody
celightbody@uclan.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Catherine Elizabeth Lightbody

ORCID ID
https://orcid.org/0000-0001-5016-3471

Contact details
Stroke Research Team
University of Central Lancashire
Preston
United Kingdom
PR1 2HE
+44 (0)1772 893648
celightbody@uclan.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
261352

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
CPMS 45022, IRAS 261352

Study information

Scientific Title
COMMITS - Confirming the Mechanism of Motivational Interviewing Therapy after Stroke: a multi-centre randomised controlled trial

Acronym
COMMITS

Study objectives
The aim of the study is to determine the effect of Motivational Interviewing-Based Intervention (MIBI) on depressive symptoms in people post-stroke. It is hypothesised that MIBI (in addition to usual care) will reduce the number of people with depressive symptoms more so than attention control (in addition to usual care) and usual care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/01/2020, Welsh Research Ethics Committee 5, Bangor (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff CF11 9AB, UK; +44 (0)7970 422139; Wales.REC5@wales.nhs.uk), ref: 19/WA/0337

Study design
Randomized; Both; Design type: Treatment, Prevention, Psychological & Behavioural, Complex Intervention, Qualitative

Primary study design
Interventional

Study type(s)
Prevention, Treatment

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

Interventions
Current interventions as of 25/03/2024:

Following completion of baseline assessment, participants are randomly allocated to one of three groups. Random allocation is on a 1:1:1 ratio, and stratified by site, age (less than 65 years or 65 years and above), and baseline mood (PHQ-9 score of less than 10 or 10 and above).

The three groups are:
1. Motivational Interviewing-Based Intervention (MIBI) plus usual care [intervention arm]

2. Attention Control (AC) plus usual care [attention control arm]
3. Usual Care (UC) [control arm]

MIBI is a talking therapy that uses techniques to facilitate adjustment after stroke. Participants in the MIBI group receive up to four, 45-minutes long, individual sessions held weekly with a trained MIBI therapist, delivered remotely (telephone or video call).

AC is designed to provide participants with social attention of the same duration and intensity to the MIBI therapy. AC involves general conversation not focused on mood. Participants in the AC group receive up to four, 45-minutes long, individual AC sessions held weekly with a trained AC provider, delivered remotely (telephone or video call).

UC is available in accordance with national and local guidelines. Participants are not denied any treatment and receive whatever care is usual practice. All participants (in the MIBI, AC and UC groups) receive UC.

_____

Previous interventions:

Following completion of baseline assessment, participants are randomly allocated to one of three groups. Random allocation is on a 1:1:1 ratio, and stratified by site, age (less than 65 years or 65 years and above), and baseline mood (PHQ-9 score of less than 10 or 10 and above).

The three groups are:
1. Motivational Interviewing-Based Intervention (MIBI) plus usual care [intervention arm]
2. Attention Control (AC) plus usual care [attention control arm]
3. Usual Care (UC) [control arm]

MIBI is a talking therapy that uses techniques to facilitate adjustment after stroke. Participants in the MIBI group receive up to four, 45-minutes long, individual sessions held weekly with a trained MIBI therapist, delivered remotely (telephone or video call).

AC is designed to provide participants with social attention of the same duration and intensity to the MIBI therapy. AC involves general conversation not focused on mood. Participants in the AC group receive up to four, 45-minutes long, individual AC sessions held weekly with a trained AC visitor, delivered remotely (telephone or video call).

UC is available in accordance with national and local guidelines. Participants are not denied any treatment and receive whatever care is usual practice. All participants (in the MIBI, AC and UC groups) receive UC.

Intervention Type
Behavioural

Primary outcome(s)
Depressive symptoms measured with Patient Health Questionnaire (PHQ-9) at at baseline, 6 weeks and 3 months post-randomisation

Key secondary outcome(s))
1. Depressive symptoms measured using the Yale single item (“Do you often feel sad or depressed?” Yes or No) at 6 weeks and 3 months; self-reported anti-depressant use (Yes or No)

at 3 months; and self-reported psychological input (Yes or No) at 3 months
2. Survival measured using status (alive or dead) at 3 months
3. Anxiety disorder measured using General Anxiety Disorder 7-item at baseline, 6 weeks and 3 months
4. Quality of life measured using Stroke Impact Scale Short-Form at 3 months and the EuroQoL-5 Dimensions, five-level version (EQ-5D-5L) at baseline and 3 months
5. Patients' resource use measured with a resource use questionnaire at baseline and 3 months
6. Dependence measured using the Modified Rankin Scale at baseline and 3 months
7. Physical function measured using the Barthel Index at baseline and 3 months
8. Further stroke measured using self-report (Yes or No) at 3 months
9. Mediating factors including self-efficacy and confidence measured using the Stroke Self-Efficacy Questionnaire and Confidence after Stroke Measure at 6 weeks and 3 months

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 16/07/2025:
1. Aged ≥18 years
2. Admitted to a participating unit within 28 days of acute stroke
3. Able to provide informed consent
4. None, mild, moderate speech difficulties only (0, 1, 2 or 3 on the CoAT)
5. No known current psychiatric disorder (i.e. not receiving active treatment at the time of screening)
6. Not currently receiving a talk-based therapy
7. PHQ-9: Total Score ≤14 and Q9 Score = 0
8. No current alcohol/drug misuse or dependency
9. Able to converse in English
10. Access to online video conferencing or a telephone to participate in interventions via remote means
11. Does not have a life-threatening/terminal illness
12. Likely to adhere to follow-up procedures

Previous inclusion criteria:
1. Aged ≥18 years
2. Admitted to a participating unit within 28 days of acute stroke
3. Able to provide informed consent
4. Modified Rankin Score (mRS) of 0 – 4
5. None, mild, moderate speech difficulties only (0, 1, 2 or 3 on the CoAT)
6. No known current psychiatric disorder (i.e. not receiving active treatment at the time of screening)
7. Not currently receiving a talk-based therapy
8. PHQ-9: Total Score ≤14 and Q9 Score = 0
9. No current alcohol/drug misuse or dependency
10. Able to converse in English
11. Access to online video conferencing or a telephone to participate in interventions via remote means
12. Does not have a life-threatening/terminal illness
13. Likely to adhere to follow-up procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 16/07/2025:
1. <18 years
2. Not admitted to a participating unit within 28 days of acute stroke
3. Unable to provide informed consent
4. Moderately severe communication difficulties (4 or 5 on the CoAT)
5. Current psychiatric disorder (i.e. receiving active treatment at time of screening)
6. Currently receiving a talk-based therapy
7. PHQ-9: Total Score ≥15 and/or Q9 Score ≥1
8. Current alcohol/drug misuse or dependency
9. Not able to converse in English
10. No access to online video conferencing or a telephone
11. Has a life-threatening/terminal illness
12. Unlikely to adhere to follow-up procedures

Previous exclusion criteria:
1. <18 years
2. Not admitted to a participating unit within 28 days of acute stroke
3. Unable to provide informed consent
4. mRS of 5
5. Moderately severe communication difficulties (4 or 5 on the CoAT)
6. Current psychiatric disorder (i.e. receiving active treatment at time of screening)
7. Currently receiving a talk-based therapy
8. PHQ-9: Total Score ≥15 and/or Q9 Score ≥1
9. Current alcohol/drug misuse or dependency
10. Not able to converse in English
11. No access to online video conferencing or a telephone
12. Has a life-threatening/terminal illness
13. Unlikely to adhere to follow-up procedures

Date of first enrolment
01/03/2022

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Westmorland General Hospital
Burton Rd
Kendal
United Kingdom
LA9 7RG

Study participating centre
Royal Preston Hospital
Sharoe Green Ln
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Epsom General Hospital
Dorking Road
Epsom
United Kingdom
KT18 7EG

Sponsor information

Organisation
University of Central Lancashire

ROR
https://ror.org/010jbqd54

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NF-SI-0515-10116

Funder Name
NIHR Applied Research Collaboration North West Coast

Funder Name
University of Central Lancashire

Alternative Name(s)
UCLan

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Exact data sharing plans are unknown and will be made available at a later date.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes