

# Motivational interviewing therapy after stroke

<b>Submission date</b> 17/01/2022	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/02/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/07/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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**

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celightbody@uclan.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

261352

**ClinicalTrials.gov number**

Nil known

## **Secondary identifying numbers**

CPMS 45022, IRAS 261352

# **Study information**

## **Scientific Title**

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

## **Acronym**

COMMITTS

## **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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Prevention, Treatment

## **Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet.

## **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.

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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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/09/2019

## **Completion date**

31/12/2025

# **Eligibility**

## **Key inclusion criteria**

Current inclusion criteria as of 16/07/2025:

1. Aged  $\geq 18$  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  $\leq 14$  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  $\geq 18$  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  $\leq 14$  and Q9 Score = 0
9. No current alcohol/drug misuse or dependency
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**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 1334; UK Sample Size: 1334

**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  $\geq 15$  and/or Q9 Score  $\geq 1$
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  $\geq 15$  and/or Q9 Score  $\geq 1$
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**

England

United Kingdom

**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

## Sponsor details

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Preston

England

United Kingdom

PR1 2HE

+44 (0)1772893393

SCrean@uclan.ac.uk

## Sponsor type

University/education

## Website

<http://www.uclan.ac.uk/>

## 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**

### **Publication and dissemination plan**

A protocol will be available once published. The final results of the study will be published in a peer-reviewed journal following the end of the study and within a year of the overall study end date. Results will also be disseminated widely to participants, patients and the public through social media and lay reports; clinical staff through final reports and presentations; academic community through publication in journals and presentations at conferences; and policy by feeding into the next update of the Intercollegiate Stroke Working Party National Clinical Guideline for Stroke.

### **Intention to publish date**

31/12/2025

### **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?
<a href="#">HRA research summary</a>			28/06/2023	No	No