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Rehabilitation of memory following traumatic brain injury

Submission date	Recruitment status	[X] Prospectively registered
17/10/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/10/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/04/2019	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol

Background and study aims:
Currently, traumatic brain injury patients with memory problems do not routinely receive rehabilitation after the early intensive treatment, even though their abilities and needs may change once they have left the hospital. The aim of this study is to investigate how effective a group-based memory rehabilitation programme is for military personnel and civilians who have sustained a traumatic brain injury.

Who can participate?
Men and women, civilians and military personnel, aged 18 to 69, more than 3 months since a traumatic brain injury.

What does the study involve?
Participants are randomly allocated to receive either 10 group memory rehabilitation sessions or usual care, and are followed up for 12 months.

What are the possible benefits and risks of participating?
The exact benefits of the rehabilitation programme are not known, but it is hoped that participants will benefit from it. The information obtained from this study may help to improve the treatment of future patients with memory problems after a head injury. There are no particular risks involved in taking part in this study. However, participants may be made aware of memory problems that they did not know they had. The Assistant Psychologist is trained to be able to help with this.

Where is the study run from?
1. Nottingham University Hospitals NHS Trust (UK)
2. Birmingham Community Healthcare NHS Trust (UK)
3. Chester and Wirral Partnership NHS Foundation Trust (UK)
4. Central Surrey Health (UK)
5. The Walton Centre NHS Foundation Trust (UK)
6. Sheffield Health and Social Care NHS Foundation Trust (UK)

7. St George's Healthcare NHS Trust (UK)
8. North Bristol NHS Trust (UK)
9. South Tees Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2013 to April 2017

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
12944

Study information

Scientific Title
Rehabilitation of memory following traumatic brain injury: a Phase III randomised controlled trial

Acronym
ReMemBrin

Study objectives
Around 6% of patients are admitted to Accident and Emergency departments in the UK as a result of a head injury. A study in the United States also found that 25 per cent of soldiers will

experience a head injury during their army career. Following this type of injury a lot of these patients will find that they have long lasting problems with their memory affecting their life in a negative way. For example, some patients may not be able to return to work and notice that their memory problems have an effect on their social life and relationships. At the moment patients who have had a head injury are not always given any further therapy after they leave the hospital to help them deal with their memory problems. However, sometimes they find that their memory problems change or as their lifestyle changes.

The aim of this study is to compare a memory rehabilitation programme with current clinical care. The study will assess the usefulness of memory rehabilitation in reducing problems with memory and how much it would cost to the NHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands Nottingham Research Ethics Committee, 21/09/2012, ref: 12/EM/0324

Study design
Randomised interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Brain injuries and emergencies

Interventions
Memory rehabilitation
The intervention will be offered in a group setting. Each group will be led by an Assistant Psychologist (AP) and consist of 4-6 participants. The APs at the different centres will be trained. Participants will receive 10 group memory rehabilitation sessions (1.5 hours long, once a week for 10 weeks), following a treatment manual which was developed and tested in the pilot study. Follow up length: 12 months.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Frequency of memory failures in daily life, assessed using the Everyday Memory Questionnaire participant report (EMQ-p) at 6 months

Key secondary outcome(s))
Added 22/06/2017:
Assessed at 6 and 12 months after randomisation:

1. Individual goal attainment, evaluated on a 4-point Likert scale
2. Memory, assessed using the Rivermead Behavioural Memory Test, RBMT-3
3. Cognitive, emotional, and social wellbeing, measured using the European Brain Injury Questionnaire (EBIQ) patient and relative versions
4. Mood, assessed using the General Health Questionnaire (GHQ 30)
5. Health-related quality of life, assessed using the EQ5D
6. Frequency of memory failures in daily life, assessed using the Everyday Memory Questionnaire participant version (EMQ-p) at 12 months
7. Cost-effectiveness from an NHS perspective, assessed using the service use questionnaire. This cost data is compared to the Quality Adjusted Life Year scores (QALYs) calculated from the responses from the EQ-5D. This will be used to calculate an Incremental Cost-Effectiveness Ratio.
8. Frequency of memory failures in daily life, assessed using the Everyday Memory Questionnaire friend/relative report (EMQ-r)

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. Were admitted to hospital with a TBI more than 3 months prior to recruitment
2. Report having memory problems as assessed at baseline
3. Are 18 to 69 years of age
4. Are able to travel to one of the study centres and attend group sessions
5. Give informed consent.
6. Men and women

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
328

Key exclusion criteria
1. Unable or unsuitable to engage in group treatment if allocated
2. Are involved in other psychological intervention trials
3. Impairment of language, as assessed on the SST (cut-off score <17)

Date of first enrolment
01/03/2013

Date of final enrolment
22/12/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham University Hospitals NHS Trust
United Kingdom
NG5 1PB

Study participating centre
Birmingham Community Healthcare NHS Trust
United Kingdom
B7 4BN

Study participating centre
Chester and Wirral Partnership NHS Foundation Trust
United Kingdom
CH2 1BQ

Study participating centre
Central Surrey Health
United Kingdom
KT19 0DZ

Study participating centre
The Walton Centre NHS Foundation Trust
United Kingdom
L9 7LJ

Study participating centre

Sheffield Health and Social Care NHS Foundation Trust
United Kingdom
S10 3TH

Study participating centre
St George's Healthcare NHS Trust
United Kingdom
SW17 0QT

Study participating centre
North Bristol NHS Trust
United Kingdom
BS10 5NB

Study participating centre
South Tees Hospitals NHS Foundation Trust
United Kingdom
DL6 1JG

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Roshan das Nair (roshan.dasnair@nottingham.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2019	30/04/2019	Yes	No
Protocol article	protocol	06/01/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes