ISRCTN54718796 https://doi.org/10.1186/ISRCTN54718796

Hemianopia Activity-Based InTervention (HABIT): refining and operationalising a rehabilitation intervention for visual field loss after stroke

Submission date
09/09/2020

Recruitment status
No longer recruiting

Registration date
06/10/2020

Overall study status
Completed

Last Edited
28/01/2021

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Visual field loss, the inability to see to one side (hemianopia), affects around a third of people with stroke; in the UK that's more than 30,000 people each year, and 5 million worldwide. Clinicians, patients and carers say treating visual problems after stroke is a top research priority. People with hemianopia have the impression of a complete visual world, yet often have severe difficulties because of their visual loss. Many people cannot find things or read easily, lose balance or bump into things and sometimes fall when walking, become overwhelmed by crowded spaces and cannot drive. This reduces confidence, independence and quality of life and increases loneliness. There is no standard treatment for stroke-related visual field loss; no treatment has enough evidence to be recommended for use across the NHS. Occupational therapists are the main people who treat visual field loss, but lack of knowledge about how to treat people limits what can be done. Best research evidence supports training people to compensate for visual field loss by "scanning" (looking repeatedly across into the affected area of vision), teaching them to search for and pay attention to the affected side of vision, and re-training them in reading. The researchers will work with people with visual loss after stroke, their carers and therapists to design a manual showing how to use the treatment, and videos for training and educating health professionals, patients and carers. They will then try out the training, manual and videos in several different NHS centres, and improve them based on feedback from therapists, stroke survivors and carers. People with hemianopia will be involved throughout the study. The aim of this study is to produce a treatment for loss of vision after stroke in adults that can be used in NHS services from early hospital-based rehabilitation to rehabilitation and care at home.

Who can participate?
1. NHS staff involved in providing therapy for visual rehabilitation after stroke at a participating centre.
2. Patients with visual field loss after stroke, recruited from a participating centre

What does the study involve?
The researchers will provide training for therapy staff on how to use the intervention with patients. They will collect feedback on this training session so it can be refined and improved as the study goes along. Once trained, Therapy Practitioners will use the intervention with patients recruited to the study. Both patients and therapists will provide feedback on the intervention to the study team. Feedback will be used to refine and implement these recommendations to work towards operationalising the intervention.

What are the possible benefits and risks of participating?
For patients who take part in the study, there are no serious side effects of this intervention on top of usual NHS care. However, some patients may find using the intervention tiring or that the intervention does not help them. For therapy practitioners, there is little anticipation of any significant risks to taking part, though it may take some time to use the tool.

Where is the study run from?
North Bristol NHS Trust, Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2019 to November 2021

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

Who is the main contact?
Dr Philip Clatworthy
Philip.Clatworthy@nbt.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Philip Clatworthy

Contact details
North Bristol NHS Trust
Southmead Hospital
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB
+44 (0)1174149330
habitresearchstudy@nbt.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
270718

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 270718, CPMS 45000

Study information

Scientific Title
Hemianopia Activity-Based InTervention (HABIT): refining and operationalising a rehabilitation intervention for visual field loss after stroke

Acronym
HABIT

Study objectives
To refine and operationalise a method of activity-based rehabilitation for people with visual field loss after stroke that can be delivered across the NHS. The resulting intervention will be called HABIT: the Hemianopia Activity-Based InTervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/04/2020, Wales Research Ethics Committee 4 Wrexham (Health and Care Research Wales Support Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0) 7976 982591; Wales.REC4@wales.nhs.uk), REC ref: 20/WA/0093

Study design
Refinement of an intervention, non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
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
Occupational therapy visual rehabilitation intervention (hemianopia activity-based intervention).

The main outcome from this study is the HABIT intervention itself which will comprise an online training, education and intervention tool with accompanying manual and description for replicating the intervention in future clinical studies. The researchers will provide training for therapy staff on how to use the intervention with patients. They will collect feedback on this training session so it can be refined and improved as the study goes along. Once trained, Therapy Practitioners will use the intervention with patients recruited to the study. Both patients and therapists will provide feedback on the intervention to the study team. Feedback will be used to refine and implement these recommendations to work towards operationalising the intervention.

The total duration of intervention and follow up is 12 months (plus a further 3 months for analysis and dissemination).

Intervention Type
Other

Primary outcome measure
The main outcome from this study is the HABIT intervention itself which will comprise an online training, education and intervention tool with accompanying manual and description for replicating the intervention in future clinical studies.

Secondary outcome measures
Secondary outcomes relating to future implementation and delivery in a clinical trial are detailed below:
1. Measuring recruitment and retention rates for a future clinical trial
2. Evaluating the feasibility of using the Canadian Occupational Performance Measure (COPM) as an outcome measure in a future evaluation
3. Evaluating the range of clients with whom HABIT can usefully be employed
4. Acceptability for patients, carers, therapists, therapy assistants and support workers

Overall study start date
14/10/2019

Completion date
12/11/2021

Eligibility

Key inclusion criteria
1. New stroke being managed on a stroke rehabilitation pathway
2. Presence of visual field defect on screening such as confrontation visual field testing e.g. as part of the NIHSS
3. Confirmation of visual field defect using perimetry
4. Visual field defect considered by a HABIT study trained OT to be causing difficulty with

meaningful goals for rehabilitation
5. Willing and have capacity to provide informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
34

Key exclusion criteria
1. Visual neglect severe enough to prevent any orientation beyond the midline to the affected side assessed by a treating clinician
2. Living outside of an area covered by the early supported discharge services or community providers associated with the recruiting centre if they are being discharged from inpatient services with ongoing therapy

Date of first enrolment
12/10/2020

Date of final enrolment
12/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Research & Innovation
Level 3, Learning & Research building
Southmead Hospital
Westbury on Trym
Bristol
England
United Kingdom
BS10 5NB
+44 (0)1174149330
researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.nbt.nhs.uk/research-innovation

ROR
https://ror.org/036x6gt55

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
Planned publication in high impact peer-reviewed journal. Protocol available on request.

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon reasonable request from Dr Philip Clatworthy (Philip.Clatworthy@nbt.nhs.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No