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A feasibility trial of digital support for mental and sexual wellbeing after brain injury

Submission date
02/02/2023

Recruitment status
No longer recruiting

Registration date
01/03/2023

Overall study status
Completed

Last Edited
15/10/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Every 90 seconds in the UK, someone has an injury to their head. This is known medically as acquired brain injury (ABI) and can include stroke, traumatic brain injury, tumour and meningitis. ABI can cause long-term issues for survivors: a common problem is a low mood, which can affect how someone feels about themselves and others. These feelings can cause sexual and relationship troubles. Over one million people with ABI have long-term depression, sexual problems, or both. There are clear links between mental and sexual wellbeing - if one gets worse, so does the other. The researchers of this study want to break this cycle, but topics like sex are not easy to discuss – for patients, their partners, or healthcare staff. Many patients prefer to discuss sensitive issues with people who are 'in the same boat', that is, 'peer support'. Another means of support is self-management where patients learn to look after their own health and wellbeing. Research has shown that peer-supported self-management programmes help people to live with the effects of ABI. However, to date, sexual wellbeing support has never been included in such programmes.

Who can participate?
Adults over the age of 18 years, who have had any type of ABI at least 3 months ago

What does the study involve?
The team have worked with people living with ABI to co-design a new online course to support mental and sexual wellbeing and wants to invite people with ABI to test this course. Half the enrolled people will join a peer-supported course, where there are options to interact with others on the course and be guided by a peer facilitator. The other half of the enrolled people will join a self-directed course, with no peer support or options to interact. The course lasts for 8 weeks and the content can be accessed flexibly at a convenient time. Participants will be asked to fill in questionnaires 3 times - once before the course, once afterwards, and then again 6 months later. Participants will receive a £10 gift voucher for each of the questionnaires completed after the course. The whole study takes place online.

What are the possible benefits and risks of participating?
The HOPE4ABI course may help you to manage your own mental and sexual wellbeing. You may meet new friends, learn new skills, or find out something new about yourself. The study is online

and there is a little physical risk of taking part. However, mental and sexual wellbeing can be sensitive issues. You can decide how much to participate in topics that you might find uncomfortable. If you feel emotional or psychological distress at any time, you are welcome to leave the activity or withdraw from the research entirely.

Where is the study run from?
Coventry University (UK)

When is the study starting and how long is it expected to run for?
November 2023 to October 2024

Who is funding the study?
National Institute of Health and Care Research (NIHR), Research for Patient Benefit Scheme

Who is the main contact?
Dr Hayley Wright, ab7764@coventry.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
325598

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR203600, IRAS 325598, CPMS 55391

Study information

Scientific Title
Digital self-management for mental and sexual wellbeing after acquired brain injury (HOPE4ABI): feasibility randomised controlled trial

Acronym
HOPE4ABI

Study objectives
Acquired brain injury (ABI) is a rapidly growing global public health concern, and a major cause of disability and disruption to families and society. Reducing the burden and impact of ABI is imperative, yet neurorehabilitation provision remains inadequate and inconsistent.

There is a complex interplay of neurological damage and biopsychosocial changes (e.g. depression, anxiety, self-esteem) following ABI. Biopsychosocial changes can cause – and be caused by - sexual concerns. The bidirectional relationship between mental wellbeing and sexuality highlights the overdue need for holistic, person-centred support post-ABI.

Self-management and peer-support approaches in neurorehabilitation have shown promising benefits, but have not been tested in combination to support sexual wellbeing after ABI.

Our proposed intervention - HOPE4ABI - will provide digital self-management support for psychological and sexual wellbeing issues that are common after ABI. A target number of 60 participants will be randomly assigned to a peer-supported HOPE4ABI course or a self-directed HOPE4ABI course (n=30 per group).

A feasibility randomised controlled trial will address specific uncertainties, including willingness to be randomised, recruitment and retention rates, and acceptability of the peer-supported or self-directed, sexual and mental wellbeing intervention, before conducting a definitive trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 14/03/2023, Coventry University Ethics Committee (Coventry University, Priory Street, Coventry, West Midlands, CV1 5FB, UK; +44 (0)24 7765 7688; ethics.uni@coventry.ac.uk), ref: P147535
2. Approved 22/06/2023, West Midlands - Edgbaston Research Ethics Committee (3rd Floor, Barlow House, Minshull Street, M1 3DZ, UK; +44 (0)2071048083; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0089

Study design
Mixed-methods feasibility study with a parallel group randomized (1:1) control design

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Mental and sexual wellbeing after acquired brain injury

Interventions
The HOPE4ABI intervention will be hosted on a digital platform owned by Hope for The Community (H4C) Community Interest Company, a research social enterprise spinout company from Coventry University (https://www.h4c.org.uk). The HOPE4ABI content has the same structure and format across the 8 weeks, consisting of videos, educational content, activities with homework suggestions and suggested additional resources. The content comprises text, images, downloadable documents, and links to external websites, and is configured into interactive activities (e.g., quizzes, self-monitoring tools, journals), supporting participants to learn and consolidate the content. The peer-supported HOPE4ABI course (Intervention Group; 'IG') uses forums and messaging facilities that act as a conduit for communication between participants, peers and facilitators. The self-directed HOPE4ABI course (Control Group; 'CG') contains all the same material but does not include peer support or interaction with other participants. HOPE4ABI is asynchronous, and content is released at set times over the 8 weeks, e.g., at 11 am every Monday. Trained peer facilitators with lived experience with ABI moderate the peer-supported HOPE4ABI course. Facilitators are trained in both health coaching (provided by a QISMET accredited trainer), and sexual wellbeing coaching (provided in collaboration with The

Stroke Association) and are scored throughout the course against checklists to monitor fidelity of delivery.

The participants will be randomly assigned to the IG or CG using a 1:1 allocation ratio using minimization to ensure balance. Randomisation is initiated automatically on completion of the baseline questionnaires, through the bespoke algorithm embedded within the eNgage research management platform. The research team will be unable to influence any aspect of the randomisation procedure.

Upon completion of baseline questionnaires, participants will be notified of their allocated group (IG or CG), via an email generated by eNgage. Within the email, participants will also receive a link to join the HOPE4ABI course they have been randomly assigned to. The research team will be blind carbon-copied into this email confirmation, thus making them aware of participant allocation at this point.

Participants will complete study questionnaires digitally (via the bespoke research management platform 'eNgage'), at baseline, 8 weeks, and 6 months. A sample of completers and non-completers will be randomly selected after the intervention has finished (i.e., 8 weeks) and invited to complete an online interview with a researcher to discuss their experiences of the study.

Intervention Type
Behavioural

Primary outcome(s)
1. Referral rate measured using the responses on the screening log by Research Nurse (for NHS referrals) and responses on an automated screening questionnaire on the study website (for self-referrals)

2. Refusal rate for NHS referrals, defined as the proportion of eligible participants who explicitly declined information about the study when approached by the Research Nurse, measured using data recorded in the screening log

3. Recruitment rate, defined as the proportion of eligible/referred participants who went on to provide consent and complete baseline questionnaires (see below for questionnaire details)

4. Enrolment rate, defined as how many of the participants recruited log into the HOPE4ABI course on the platform, measured using H4C platform analytics

5. Engagement rate, defined as how many of those enrolled go on to access at least 4 modules, measured using H4C platform analytics

6. Follow-up rate, defined as how many of those recruited went on to complete the follow-up questionnaires at T1 and T2, measured using the number of responses on Qualtrics

7. Retention rate, defined as the proportion of participants recruited who engaged with the intervention AND completed follow up questionnaires, measured by combination of Engagement and Follow Up rates described above

8. Withdrawal rate, defined as how many recruited participants explicitly withdrew their consent to take part in the study, measured using the number of email requests to withdraw

9. Acceptability addressing elements of the intervention such as usability, usefulness, relevance of the content, appropriateness of the content, format and delivery, and participants' overall satisfaction with the intervention measured using quantitative and qualitative methods comprising:
9.1. A multiple choice or Likert-scale format feedback survey at the end of the 8-week intervention. This is a bespoke questionnaire developed by H4C for evaluating participant experience on various Hope programmes.
9.2. Semi-structured acceptability interviews will be carried out with randomly selected study completers (n=8) and non-completers (n=8), to gain a balanced overview of the intervention and study procedures, across both study arms.

10. Usage patterns measured using data that is routinely collected on the H4C digital platform, such as pages viewed, login frequency and duration.

Key secondary outcome(s))
Participant wellbeing outcomes measured using standardised validated questionnaires, at baseline, 8 weeks (T1), and 6 months (T2):
1. Mental wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)
2. Sexuality following brain injury measured using the Brain Injury Questionnaire of Sexuality (BIQS)
3. Health-related quality of life measured using the Quality of Life after Brain Injury – Overall Scale (QOLIBRI-OS)

Participants' mental wellbeing is also monitored across the 8-week intervention period by the Short Version of The Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS) embedded within the digital intervention at week 1, week 4 and week 7.

Completion date
31/10/2024

Eligibility

Key inclusion criteria
1. Ages ≥18 years old
2. UK-based
3.1. Diagnosed ABI (including head injury, stroke, meningitis, brain tumour, encephalitis, hydrocephalus, cerebral abscess, anoxic brain injury, carbon monoxide poisoning, encephalopathy, cerebral oedema, compression of the brain) ≥3 months prior to trial entry, category B/C/D on Patient Categorisation Tool
3.2. OR suspected ABI, with corresponding self-reported history of brain injury, behavioural, psychological, physical, or emotional difficulties (reported at self-referral / research nurse screening phase), ≥3 months prior to trial entry
4. Capacity to give informed consent
5. Ability to communicate in English, participate in the intervention and complete outcome measures
6. Internet connection and an internet-enabled device

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
73

Key exclusion criteria
1. Self-reported severe mental illness (e.g. schizophrenia)
2. Diagnosis of dementia or other neurodegenerative disorder
3. Drug- or alcohol-dependency
4. Actively suicidal or attempted suicide in the last 3 months

Date of first enrolment
28/06/2023

Date of final enrolment
04/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
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Study participating centre
Torbay and South Devon NHS Foundation Trust
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Sponsor information

Organisation
Coventry University

ROR
https://ror.org/01tgmhj36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitive nature of the data. Anonymised data that underpin outputs that result from the research will be deposited in the institutional repository, PURE. Readme files will accompany dataset records, to aid the understanding of the openly shared data and the

processes and methodologies that were used during the project. Raw data will not be published openly but will be made available for audit purposes as required. Data will be archived in the long term utilising the Preservica archive, which is attached to the institutional repository.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/11/2023	01/12/2023	Yes	No
Participant information sheet	version 1	23/01/2023	10/02/2023	No	Yes
Participant information sheet	version 2		24/01/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1	23/01/2023	02/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes