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

PROTOCOL

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Introduction

Background and rationale

Acquired brain injury (ABI) is an umbrella term referring to brain injury sustained after birth. Traumatic brain injury (TBI) and stroke account for the majority of UK ABIs (46% and 36%, respectively (1)), but other causes include brain tumour, encephalitis, meningitis, and aneurysm. The UK prevalence of ABI is an estimated 2.5million (2,3) costing £41 billion per year (2,4) in health and social care, lost work contributions, and continuing disability (2). ABI is a major cause of disability and disruption to families and society (5). There are national campaigns in the UK to highlight the hidden impact and reduce the burden of ABI for patients and families (1,6,7), yet neurorehabilitation provision remains inadequate and inconsistent (1).

Sexual and reproductive health is integral to person-centered healthcare (8,9) but is often neglected in neurorehabilitation (10–13). This is commonly attributed to a lack of training opportunities and hence professional confidence and competence of healthcare practitioners (8), as well as patients' reluctance to initiate discussions with healthcare professionals (12–14). Entrenched social discourses attribute sexuality to the idealised 'young, heterosexual, able-bodied male', and subsequently denying sexuality to those not fitting this model (14). As such, discussions surrounding sexuality have become stigmatized (15), particularly for older adults and those with disabilities. In healthcare, this results in limited opportunities for sexual (re)education and the formation and maintenance of intimate and social relationships after ABI (16).

Sexual health is inextricably bound to both physical and mental health (13,15,17,18). The World Health Organization (WHO) definition of human sexuality encompasses gender identities and roles, eroticism, sexual orientation, and intimacy, alongside sexual activity and reproduction (19). Yet, public health campaigns are dominated by messages of preventing sexual ill-health and adverse outcomes (e.g., underage / unplanned pregnancy, sexually transmitted infections and HIV (15)). Academics have called for a paradigm shift, one which promotes the positive, normative, and pleasurable dimensions of sexuality. Normalising discussions around sex, sexuality and intimacy is the first step to reducing the taboo, enabling discussions, and promoting sexual wellbeing – particularly following ABI.

Up to 75% of ABI survivors experience sexual problems (16,20), totalling ~1.6 million people in the UK alone. Further, one in two report depression at 6months (21), totalling ~1.2million UK patients. There are complex interrelationships between neurological damage (22) and biopsychosocial

changes (e.g. depression, anxiety, self-esteem (23)) following ABI. That is, biopsychosocial changes can cause – and be caused by - sexual issues (13,15,17,18). Depression has a profound impact on health and quality of life for people with ABI, resulting in more hospitalizations, less societal participation, reduced return-to-work rates, greater burden on caregivers, and negative effects on social relationships (24). Given the interrelationship between sexual health and mental health (13,15,17,18), it is feasible that supporting sexual wellbeing will benefit psychological wellbeing.

Supported self-management is central to the NHS Long Term Plan (25), and involves professionals and patients jointly identifying needs, priorities, and goals (26). This process empowers patients with skills, knowledge and confidence to manage their own health and wellbeing. After stroke, people who engage in self-management interventions have significantly improved quality of life, self-efficacy, engagement in health-related behaviours, recovery from disability and participation in activities of daily living (27–31). However, to date, no self-management interventions have focussed on sexual wellbeing following any type of brain injury.

Peer-to-peer support approaches in neurorehabilitation have shown promising benefits, including increased behavioural control (32), self-efficacy and self-confidence; positive effects on quality of life by improving depressive symptoms, mood, psychological health, and coping mechanisms; and increased knowledge, awareness, service engagement (12). Mutual sharing with peers who experience similar challenges is central to the success of peer support approaches in this area (33). Educational resources for sex and relationships are available from many UK brain injury related charities (10,11,34,35), but lack interactive content and peer-peer exchange. There are currently no peer support programmes for sexual wellbeing after brain injury (12).

Patients generally attempt sexual activities 3-6 months post-ABI (20,36), and post-3 months (37) is on average, patients' preferred time to receive sexuality information and support (38). Digital technologies can support sexual education for patients, and provide a solution to time constraints experienced by rehabilitation professionals (16). For stigmatised topics such as sexuality, digital delivery allows autonomy, privacy, and anonymity for the participant.

Our proposed intervention - HOPE4ABI - will provide digital self-management support for psychological and sexual wellbeing issues that are common across different types of brain injury (10,11). HOPE4ABI is a novel offering, compiled of repurposed elements of an existing self-management intervention - The HOPE Programme© - alongside new, co-designed sexual wellbeing

support. HOPE stands for 'Help to Overcome Problems Effectively', and The HOPE Programme© is built on the principles of positive psychology, cognitive behaviour therapy, acceptance commitment therapy and mindfulness. It has a unique focus on hope and gratitude to create an upward spiral of positivity (39) and embeds group curative factors, such as instilling hope, universality, and altruism (40), to support self-management of health and wellbeing of long-term conditions.

Owing to the novelty and sensitivity of the research area, we do not yet know whether a peer supported intervention is an appropriate or acceptable forum for discussing sexual wellbeing after ABI. Owing to the personal nature of the topic, a self-directed intervention may be more suitable. With no comparative interventions to draw upon from research or practice, we propose a randomised controlled trial of the HOPE4ABI intervention, in two delivery formats: i) peer-supported, and ii) self-directed. A feasibility RCT of HOPE4ABI will address specific uncertainties (including willingness to be randomised, recruitment and retention rates, and acceptability of a sexual and mental wellbeing intervention) (41–44) before conducting a definitive trial. As part of the acceptability assessment, we will also explore the appropriateness of mixed peer cohorts (e.g., whether participants would prefer peers to be of a similar age, ABI-type, and/or gender).

For the purpose of the feasibility study, participants attending at least half of the intervention (>4 sessions) will be categorized as intervention completers (45,46). Studies show a non-linear relationship between time spent on an intervention, the number of sessions completed, and outcomes (45). For example, the amount of usage needed to obtain desired outcomes varies across groups, and individuals may stop using the intervention once personal goals are achieved (47). Therefore, the completion cut-offs serve as a pragmatic progression criterion, rather than a proxy measure of acceptability or relevance. Concepts such as these will be addressed via acceptability interviews with research participants across the trial, to explore acceptability, usefulness, and appropriateness of the intervention content and delivery.

This protocol has been prepared in accordance with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines for clinical trials (48).

Aim and objectives

The aim of this study is to assess the feasibility and acceptability of a digital peer-delivered intervention (HOPE4ABI) to support people with acquired brain injury to self-manage their mental and sexual wellbeing.

The primary objective relates to assessing trial feasibility:

Recruitment & refusal

1. How many participants screened?
2. How many participants meet eligibility criteria?
3. What proportion of eligible participants are willing to be referred to the study website?
4. What proportion of eligible participants consent/enrol in the study?

Retention & engagement

5. How many participants complete outcome questionnaires at baseline and follow up points (8-weeks and 6 months)?
6. What proportion of participants complete ≥75% of the content across ≥50% (i.e. at least 4) of the HOPE4ABI modules (45,47)?

Acceptability

7. What feedback do participants provide after the 8-week HOPE4ABI intervention (T1)?
8. Are there differences in feasibility/acceptability for intervention and control groups?

The secondary objective is to assess a preliminary signal of efficacy, via pre-post change in scores on validated measures of mental wellbeing, quality of life and sexual wellbeing.

Trial Design

This study will employ a feasibility randomised active control design, with two parallel trial arms: i) peer supported HOPE4ABI (intervention group); ii) self-directed HOPE4ABI without peer support (control group). HOPE4ABI is an 8-week digital self-management programme. Quantitative monitoring of participant progress through the online programme will be undertaken through remote engagement, adherence and usage monitoring via the digital platform. Participants wellbeing will be monitored via responses to standardised questionnaires at baseline, embedded within the intervention at weeks 1, 4 and 7, after the intervention at 8 weeks (T1), and at 6 months (T2) post-randomisation.

Methods: Participants, interventions, and outcomes

Study setting

The feasibility RCT will be conducted online with UK-based participants. The study will be hosted on Coventry University's secure bespoke online research management platform, eNgage; see (49). Participant information, research update pages, study recruitment, consent, randomisation, notification of allocated condition, questionnaire data collection, and research team contact details,

are all integrated within eNgage, thus acting as a study website. eNgage has been developed to work seamlessly with other web applications, such as Qualtrics Survey Software for questionnaire data collection. On joining a project, participants provide their full name and email address, on which a unique participant ID is created. Participants are then directed to Qualtrics to complete questionnaires, and back to eNgage where they are randomised to intervention groups. Once randomised, the participants will be sent a notification of which group they have been allocated to, along with a weblink to join the relevant course. Hope for The Community (H4C) Community Interest Company, a spinout social enterprise from Coventry University, will host HOPE4ABI on their digital platform (https://www.h4c.org.uk). The H4C platform is hosted on Coventry University servers as part of collaboration agreement, ensuring compliance with all GDPR, data protection and cybersecurity. Analytics data on participant use of the HOPE4ABI courses is collected routinely by the H4C platform and will be used to inform engagement and usage patterns. All data from the research platforms and software (e.g., Qualtrics, H4C) is linked by the unique participant ID within eNgage.

Eligibility criteria

Inclusion criteria:

- Age ≥18 years, UK-based
- 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 (20,36,38) prior to trial entry, category B/C/D on Patient Categorisation Tool (50,51)
    - 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
- Capacity to give informed consent
- Ability to communicate in English, to participate in the intervention and complete outcome measures
- Internet connection and an internet-enabled device

Exclusion criteria:

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

Participants meeting any exclusion criteria will be signposted to relevant services listed on the study website.

Intervention

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 uses forums and messaging facilities that act as a conduit for communication between participants, peers and facilitators. The self-directed HOPE4ABI course 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 11am every Monday. The peer supported HOPE4ABI course is moderated by trained peer facilitators with lived experience of ABI. 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.

Outcomes

We will administer a sociodemographic and health questionnaire at baseline, requesting the following personal information from participants: name, address, email address, telephone number, gender, date of birth, ethnicity, marital and cohabiting status, sexual orientation, highest level of education, employment status, details about their ABI, and their name and address of their GP.

Primary outcome measures (trial feasibility objectives)

Referral and recruitment phase:

Referral rate will show how many of those screened were eligible and thus referred onto the study (either by Research Nurse or automated screening questionnaire)

Refusal rate can only be calculated for NHS referrals and will be represented by the proportion of eligible participants who explicitly declined information about the study when approached by the Research Nurse (as recorded on the screening log)

Recruitment rate will be calculated as the proportion of eligible/referred participants who went on to provide consent and complete baseline questionnaires

Intervention phase:

Enrolment rate will show how many of the participants recruited log into the HOPE4ABI course on the platform

Engagement rate how many of those enrolled go on to access at least 4 modules

Post-intervention (months 2-6):

Follow up rate illustrates how many of those recruited went on to complete the follow up questionnaires at T1 and T2

Retention rate will be calculated as the proportion of participants recruited who engaged with the intervention AND completed follow up questionnaires

Withdrawal rate will show how many recruited participants explicitly withdrew their consent to take part in the study

Acceptability will be assessed using quantitative and qualitative methods. At the end of the 8-week intervention, a short feedback **survey** will be emailed to all participants. Questions will be in a multiple choice or Likert-scale format, for ease of response, and will address elements of the intervention such as usability, usefulness, relevance of the content, appropriateness of the content, format and delivery, and participants' satisfaction with the intervention overall. 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 (52).

Usage patterns will be summarised from data that is routinely collected on the H4C digital platform, such as pages viewed, login frequency and duration. Such data can be utilized during the intervention period to assist the moderators in monitoring participant experience. For example, reminders can be sent to participants who have not logged in initially, or for an extended period across the intervention. We will analyse usage patterns for the 8-week intervention period, as well as for the total 6 months that participants will have access to the course materials. The data will generate overall group-level usage patterns in the intervention and control groups.

Secondary outcome measures

Participants will complete a set of validated questionnaires at baseline and follow ups, to give an indication of changes pre-post HOPE4ABI on mental wellbeing, quality of life, sexual wellbeing (**see Appendix 1** for full questionnaire and response items). Whilst changes cannot be determined with any statistical significance in this study, we can assess the feasibility of administering this set of questionnaires with particular focus on acceptability and participant burden.

Mental wellbeing

The Warwick Edinburgh Mental Wellbeing Scale (WEMWBS; (53)) is a scale of 14 positively worded feelings and thoughts, used to assess mental wellbeing within the adult population. The scale includes statements relating to experiences of positive affect, satisfying interpersonal relationships and positive functioning over the last two weeks. Participants rate each of the 14 items on a scale of 1 to 5, with a total positive mental wellbeing score ranging from 14-70, where higher scores represent greater positive mental wellbeing. A change in total score of ≥ 3 points is considered a clinically meaningful change (54).

The short 7-item version of WEMWBS (SWEMWBS (55)) will be embedded within the HOPE4ABI intervention in weeks 1, 4 and 7, so participants can monitor their own mental wellbeing throughout the course. This also allows researchers to monitor participants wellbeing and escalate any concerns promptly and appropriately (e.g. sudden decline in mental wellbeing score; see **Appendix 1:** Distress Protocol).

Quality of life

Quality of Life after Brain Injury – Overall Scale (QOLIBRI-OS; (56,57)) is a 6-item health-related quality of life measure (HRQoL) specifically tailored to patients with brain injury. QOLIBRI-OS is preferable to the full 37-item QOLIBRI (58) in this feasibility study, since a global assessment of HRQoL is sufficient, interference from fatigue and cognitive impairment are reduced (59,60) and participant response burden is low. Items related to satisfaction with physical, cognitive, and emotional health, daily activities, social life, and future prospects, are scored on a 5-point scale: 'Not at all', 'Slightly', 'Moderately', 'Quiet', and 'Very'. Total score is calculated by calculating the mean for the 6 items (provided no more than two responses are missing) and converting to a percentage by subtracting one and multiplying by 25. QOLIBRI-OS scores range from 0-100, with 100 being the optimal score indicating best possible quality of life. A minimal clinically important change is a difference score of 12 (57). QOLIBRI-OS is validated for TBI and stroke (57), meets standard psychometric criteria for reliability (Cronbach's α=0.86, test-retest reliability =0.81) and has good construct validity in TBI populations (56).

Sexual wellbeing

Brain Injury Questionnaire of Sexuality (BIQS; (61)) asks participants to compare post-injury aspects of their sexuality with their pre-injury status on a 5-point Likert scale (1 = greatly decreased, to 5 = greatly increased). Fifteen questions cover changes in sexual functioning, relationship quality and self-esteem, and mood (reverse-scored). Scores across all items are summed, with higher total scores indicating more improvement. Additional questions that are not scored, provide insights such as relationship status and possible reasons for changes in sexual functioning, such as pain, fatigue,

and low confidence. Internal consistency (Cronbach's α=0.92), and convergent and divergent validity between the BIQS subscales and another established scale measuring sexual function (62) are good.

Participant timeline

Participants will be referred to the study via three main routes, as detailed below. This information is summarised in the Participant Flow diagram below (see Figure 1).

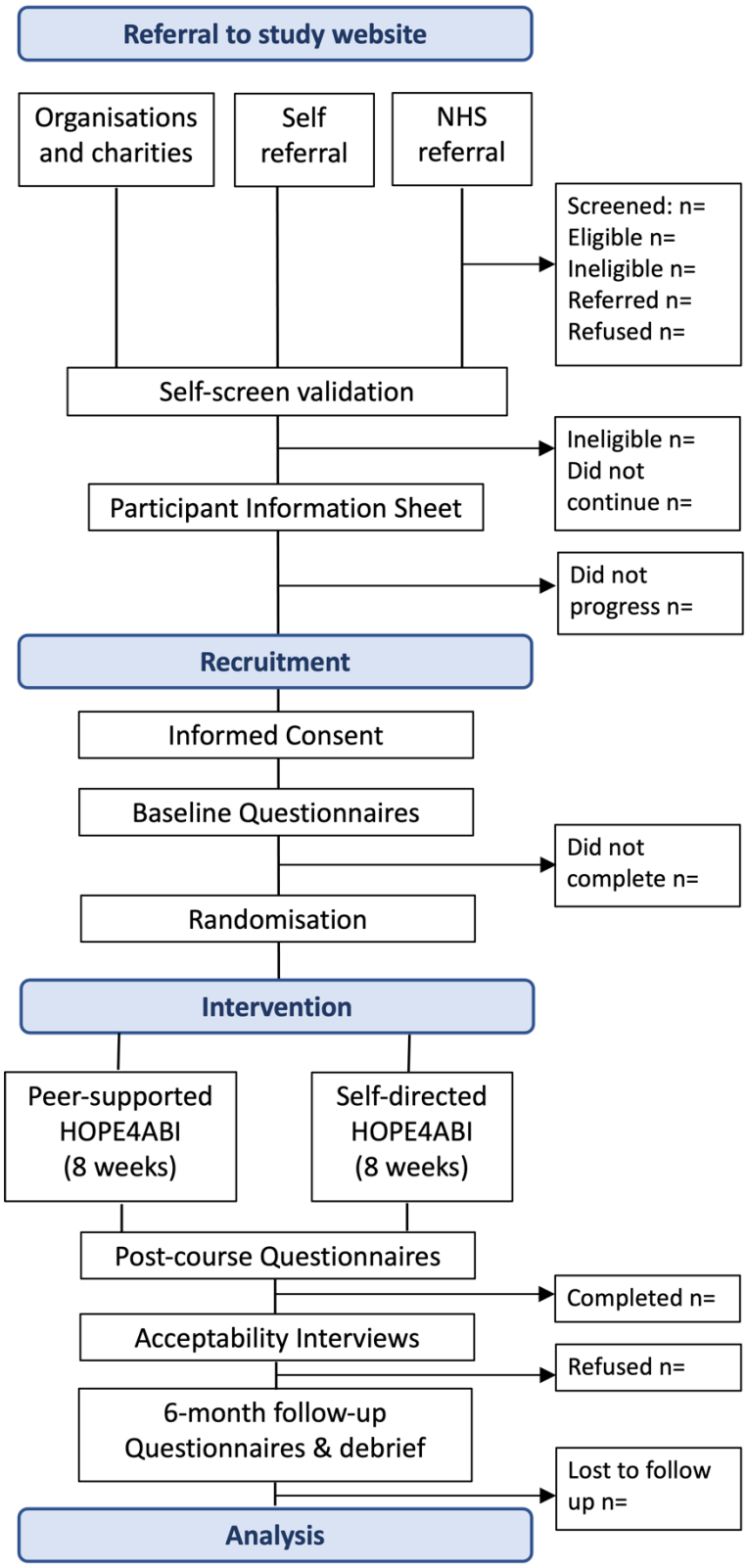

Figure 1. Participant flow diagram showing possible routes through the study

1. Self-referrals

The trial will be advertised by the research team via multiple routes including social media (e.g., Facebook, Twitter), partnering organizations' websites, newsletters, and events, and the NIHR 'Be Part of Research' network. People with ABI may be exposed to these adverts through deliberate search (e.g., via 'Be Part of Research') or simply through newsfeeds on their social media channels. A standard advert (**see Appendix 2**) will be distributed amongst the relevant channels. Adverts will contain brief information about the trial and a link/QR code to access the study website for further information self-screening questionnaire, and digital consent form (**see Appendix 2**).

2. Organization referrals

Many partnering organisations (e.g. Headway, Brainstrust) have existing groups of research volunteers who are themselves living with brain injury. Partner organisations may distribute our trial adverts amongst their own networks of volunteers via email, social media, newsletters, meetings or events, in a more targeted approach than self-referral described above. The referral and recruitment process will be the same as above, where adverts will contain brief information about the trial and a link/QR code to access the study website containing a self-screening questionnaire, participant information sheet, and digital consent form (**see Appendix 2)**.

3. NHS referrals

The trail has been adopted by the NIHR Portfolio and will receive screening support from a Research Nurse (RN), or other appropriate member of the clinical team, at each participating NHS Trust site. Trusts currently participating in referrals are University Hospitals Coventry and Warwickshire NHS Trust, and Torbay and South Devon NHS Foundation Trust. Further Trusts may be added as the study progresses, for example, if participant recruitment rate is slow. Patients attending relevant outpatient Neurology / Stroke / TBI clinics will be screened against the eligibility criteria using a combination of medical notes and consultation with the clinical team. The anonymized screening log (see Figure 2 and **Appendix 2**) will be completed by the RN, scanned, and emailed to the CU research team on a weekly basis. In case of technical issues, screening logs can be photocopied and posted to the research team. All eligible patients will be ***referred*** (i.e., not recruited) to the study website by the RN/clinical team, via an information leaflet (**Appendix 2**). For consistency, the leaflet is the same as the advert distributed on social media. It will contain brief information about the trial, including a link/QR code to access the study website containing a self-screening questionnaire, participant information sheet, and digital consent form (**see Appendix 2)**.

HOPE4ABI Screening Log
UHCW

Please assess all outpatients attending neurology clinics by the following criteria:
{*Study inclusion and exclusion criteria to be presented here*}

If patient is eligible, please give them HOPE4ABI study information leaflet.

Scan and email the completed screening log to CU Research Team at the end of every week.

Please record details for all clinic outpatients in the log below:

Patient ID	Age	Gender	Ethnicity	Screened? Y/N	Eligible? Y/N	Referred? Y/N	Reason for refusal
1							
2							
3							
4							
…							
…							
…							

Figure 2. Example screening log to be completed by the Research Nurse at NHS referring sites

After providing informed consent to take part in the study, all participants will be guided through a process of completing the online baseline questionnaires (Time 0; hereafter referred to as T0). Upon completion of T0 questionnaires, participants will be randomised to the peer-supported HOPE4ABI course (intervention group; IG) or the self-directed HOPE4ABI course (control group; CG). Participants will be notified which group they have been randomised to at the end of the survey and will be emailed a link to join the relevant programme. There will be approximately 30 participants in each group. After the 8-week course (T1) all participants will receive an email link to the follow up questionnaires, including feedback questionnaire (**see Appendix 2**).

A subset of participants will be randomly selected from the IG and CG to take part in post-course interviews with a member of the research team, to explore acceptability of the HOPE4ABI courses. We will aim to interview participants who completed all or most of the intervention, as well as those who completed fewer than half of the sessions, to gain a balanced evaluation to inform future co-design. An example of the semi-structured acceptability interview schedule can be found in **Appendix 2.**

All participants will be asked to complete the wellbeing questionnaires after 6 months (T2), along with follow up questions relating to whether they have used any of the techniques or skills they learned on the course. Participants will receive a £10 voucher at each timepoint (T1 and T2) for completing follow-up questionnaires, to incentivize timely completion (total compensation amount: £20).

Sample size

For a feasibility trial, it is not necessary to conduct sample size calculations to power the study (63). A randomised sample size of n=60 (n=30 per arm) was deemed appropriate for this feasibility study, informed by similar studies in this area (64) and National Institute of Health and Care Research (NIHR) Research Design Service (RDS) guidelines (65).

Recruitment

If enrolment is <50% (i.e. <30 participants) halfway through the recruitment period (i.e. after 3 months), AD (co-I) will implement amendments to the recruitment strategy (e.g. recruiting more NHS referral sites and/or primary care settings, local and national brain injury charities and organisations). If the recruitment target is met <3months, the intervention period will commence ahead of schedule. For patients who have been recruited but are awaiting intervention commencement, we will send regular short updates about the study (e.g., 'places are filling up fast', 'we look forward to meeting you', 'only one week to go', etc.) via text, email, social media, etc. to maintain participant interest and prevent drop-out/attrition.

Methods: Assignment of interventions

Sequence generation

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.

Allocation concealment mechanism

Participants will be notified of their allocated group (IG or CG) upon completion of baseline questionnaires, via an email generated by eNgage. 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.

Blinding

It will not be possible to blind participants to allocation past the point of randomisation, due to the notable differences in the intervention delivery between the IG and CG (i.e., peer-supported or self-directed). Analysis of quantitative outcome measures will be conducted by a researcher who is blinded to participant allocation (e.g., IG and CG data will be arbitrarily renamed 'Group A' and 'Group B' for purposes of analysis).

Methods: Data collection, management and analysis

Data collection methods

Screening data (i.e., age, gender and ethnicity) will be recorded on a trial screening log by the Research Nurse / clinical team at participanting NHS sites. Screening logs will be sent to the research team on a weekly basis, and will be transferred to an SPSS data file.

Primary outcome data relating to feasibility measures will be collected automatically through the digital research management software (eNgage) and the digital intervention platform (H4C).Acceptability interviews will be carried out by a trained member of the research team, over Microsoft Teams.

Participant wellbeing data (i.e., secondary outcomes) will be collected digitally via online questionnaires administered through eNgage and Qualtrics. Where participants do not complete questionnaires within 10 days, and do not reply to automatic email nudges, a member of the research team will try to contact participants via phone, text, email, or post, depending on availability of contact details provided at enrollment. If preferred by the participant, the researcher will read out the questions over the phone and record the participants' responses directly onto a digital data file. To ensure inclusivity and convenience and maximise response rates, participants are permitted to complete and return questionnaires via their preferred medium (e.g., online, post, email, screenshot, scan, photo of the completed questionnaires).

Data management

Participant wellbeing data will be collected through Qualtrics, and routinely downloaded to an SPSS file (.sav) for analysis. Engagement and usage data files (.xls) will be downloaded from the H4C platform routinely and added to the SPSS file alongside participants' questionnaire data, matched by the unique ID generated by the eNgage platform. Acceptability interview data will be audio/video recorded (.mp4) and transcribed (.docx) automatically via Microsoft Teams. Please see attached Data Management Plan, v1, 23/01/2023 in **Appendix 3**.

Statistical methods

This feasibility trial data is not appropriate, nor sufficiently powered, for inferential statistical analyses. All quantitative data from the study will be analysed descriptively in concordance with the CONSORT extension for pilot and feasibility trials (66). Screening data representing age, ethnicity and gender of all participants screened, referrerd, or refused, will be presented as proportions at group level. This data may indicate trends in demographic groups that the HOPE4ABI study does or does not appeal to, and inform future recruitment strategies to widen participation.

Primary outcome data (i.e. feasibility measures) will be used to examine whether progression to a definitive trial is justified, based on the following cut-offs:

i. Recruitment: ≥50% of eligible participants consent to take part
ii. Retention: ≥75% of participants complete all questionnaires
iii. Engagement: ≥75% of participants view ≥75% of content in ≥50% (i.e. 4) modules (45,47)
iv. Acceptability: ≥80% of participants 'satisfied' or 'very satisfied' with HOPE4ABI delivery, content, and ease-of-use

A 'traffic light' system will be implemented to establish progression in the following categories:

- Red (stop): i not met
- Amber (modify): i is met; AND either ii/iii/iv reach at least 70%
- Green (proceed): all criteria met

Measures of mean and variance, including confidence intervals and standard deviations, and number and percent for categorical variables, will be used to describe the full range of secondary outsome data (i.e., participant wellbeing questionnaire scores) at baseline, T1 and T2 follow up. All quantitative analyses will be performed using SPSS Statistics [IBM Corp, Armonk, NY: IBM Corp.].

Qualitative data will be analysed by thematic content analysis (67). Interview transcripts will be read multiple times by two researchers, and coded independently by each researcher. An inter-rater reliability score (Cohen κ) of <.70 will indicate all data should be coded by a third researcher. The researchers will generate, review, and refine themes and any sub-themes emerging from the data, for each of the IG and CG groups. Qualitative data analysis may be supported using NVivo software [QSR International Pty Ltd. (2020) NVivo].

Methods: Monitoring

Data monitoring

In this feasibility trial, it is not necessary to employ an independent data monitoring committee. However, participant questionnaire scores will be screened at T0, T1 and T2 by the research team to check for decline in wellbeing scores. Similarly, scores on the SWEMWBS questionnaire embedded within the HOPE4ABI course at weeks 1, 4 and 7 will be monitored by the facilitators (IG) and research team (CG). During the intervention period, the facilitators and research team will periodically check participants forum posts, journal or gratitude entries, and comments on the digital platform for signs of distress.

Harms

The Participant Information Sheet explains that mental and sexual wellbeing can be sensitive issues, and that participants can decide how much to engage with topics that might be uncomfortable. Participants who feel any emotional or psychological distress at any time are welcome to leave the activity or withdraw from the research entirely. They are advised to discuss any sexual or psychological wellbeing concerns with a professional by contacting their GP or NHS 111.

If the research team suspect a participant may be at risk of harm to themselves or others, we will advise them to contact their GP, NHS 111, or call 999 (in an emergency) for further support. We will contact the participant's GP using the details provided at enrollment (e.g., post, email) to inform of their patient's participation in the study, and to alert them of any welfare concerns during the trial. We may also contact emergency services on the participants behalf if we feel there is an immediate risk to life.

Mental wellbeing data will be screened at T1 (8 weeks) and T2 (6 months) for a clinically meaningful *decrease* in scores since T0 (e.g., a *reduction* in WEMWBS score of 3 or more (54)). Responses to the SWEMWBS during the intervention phase (i.e., at week 1, 4, and 7) will also be monitored. Participants indicating a clinically meaningful decrease on WEMWBS will be contacted by the research team and encouraged to visit their GP. Participant distress during the intervention will be managed according to the **Distress Protocol** (see **Appendix 1**) by the trained peer facilitators and/or research team. Any significant deterioration in participant wellbeing will be recorded and listed within the final report(s) as possible adverse effects of the HOPE4ABI intervention. The research team includes a clinical neuropsychologist (GY), who will be consulted if participants display concerning behaviour. Discussions will remain anonymous, and the research team will refer or

signpost participants to their GP or other sources of support, according to the professional guidance of GY.

All research is conducted online so physical risks are minimal. However, there is a chance that researchers and/or peer facilitators may become emotionally burdened or distressed by the discussions they witness firsthand, through discussion forums, or through analyzing data. Mitigation strategies to minimise these risks include sharing the data collection and analysis across team members to reduce burden, and briefing and debriefing researchers, as described in the Distress Protocol (**see Appendix 1**).

Auditing

Auditing of trial conduct will not be necessary. Many versions of the Hope Programme have been developed for long-term conditions and have been tested safely in various studies. The current feasibility trial of the HOPE4ABI programme will assess recruitment and randomisation procedures and retrospective acceptability.

Ethics and dissemination

Research ethics approval

This study was reviewed and approved by Coventry University Ethics Committee (Reference number: P147535) and NHS Research Ethics Committee (IRAS Project ID: 325598).

Protocol amendments

Any amendments to the protocol will be submitted to Coventry University Ethics Committee and NHS Research Ethics Committee for review, and research study activities will be suspended until the respective ethics committees have been consulted and approval to continue is granted.

Consent

Informed consent will be taken digitally through our bespoke research management platform (eNgage) and Qualtrics Survey Software. Participants will be required to answer yes to all consent statements before proceeding to the study questionnaires. If participants answer 'no' to any consent statements, they will be directed to the end of the survey and no data will be collected. Separate PIS and consent forms will be used for the overall trial, and the post-course acceptability interviews (**see Appendix 2**). This gives participants a fair opportunity to consider taking part in the interviews at the time, rather than >2 months in advance.

Confidentiality

At the point of consent, participants will be assigned a unique Participant Identifier (PID) through eNgage, which will be used to link study data from a single participant across multiple timepoints (T0, T1, T2) with usage and engagement data from the HOPE4ABI course. Participant data will be identifiable via this unique ID for the duration of the study.

Declaration of interests

AT is a non-executive director of Hope for The Community (H4C) CIC.

Access to data

HW, AWC, AD, LK, CC, PK, and AT will have access to the final, anonymized dataset. HW, AWC and AT (CU research team), peer facilitators and H4C, will have access to participant names and contact details, which will be kept in separate files to the research data.

Ancillary and post-trial care

A follow-up questionnaire is scheduled at the end of the study (6 months; T2) to measure mental and sexual wellbeing and quality of life. An email will be sent from the study team to every participant at the end of the study, explaining the purpose of the study and next steps for the research and providing a reminder of additional sources of support that participants can contact if needed (**see Appendix 2** for debrief information).

Dissemination policy

The results of the feasibility RCT will be submitted for open access publication in a relevant journal (e.g., Journal of Medical Internet Research), and a Plain English summary of the findings will be presented in blogs, newsletters and brief updates on the CU website, study webpage (eNgage), H4C website, partnering organisations and social media channels. Trial participants will also be emailed directly with study updates and findings.

Appendices

Appendix 1

- Distress Protocol

Appendix 2

- Participant recruitment advert
- Self-screening questions
- Screening Log for NHS referrals
- Participant Information Sheets
- Consent forms
- Study questionnaires
- Interview schedules
- Debrief

Appendix 3

- Data Management Plan

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