**TITLE**

Helping Ease Anxiety and Depression after Stroke, a pilot Randomized Controlled Trial to test feasibility and acceptability of the HEADS: UP Online self-management Mindfulness Based Stress Reduction course [27 words]

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**KEY WORDS**

stroke, anxiety, depression, mindfulness, MBSR, online, pilot RCT, mixed methods, feasibility, acceptability, process evaluation, self-management

**ABSTRACT**

**Trial Design**

A mixed-methods two-arm parallel pilot RCT, with 1:1 allocation ratio, of HEADS: UP versus Treatment as Usual (TAU) conducted in miniature of a definitive trial, assessing feasibility and acceptability of conducting a future full-scale trial of effectiveness.

**Methods**

Participants were eligible if they were stroke survivors, aged ≥18 years, had ≥1 stroke at least 3 months previously, able to speak and understand conversational English, could follow a two-stage command, and scored ≥3 on PHQ-4. Participants were recruited online and had to be living in any constituent nation of the UK. Participants could opt to nominate a family member to support their participation. The trial had two arms, comparing HEADS: UP MBSR course versus TAU. HEADS: UP is a 9-week course, delivered on Zoom©, by experienced MBSR trainers. MBSR completion was defined as attending ≥4 sessions in an 8-week course; intervention feasibility was defined as 70% of participants attending ≥4 sessions. Trial objectives were 1) to test trial procedures, candidate outcome measures, randomisation, and check direction of effect is in the expected direction, 2) identify potential resource use implications and 3) determine whether to proceed to a full-scale trial of effectiveness. Candidate primary outcome measures were Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Depression Anxiety Stress Scales (DASS-21). Secondary outcome measures were Stroke impact scale (SIS-SF); EQ-5D-5L. Data settings were UK and data captured via online survey or paper. Data was collected from all participants at four time points: Baseline T0; Post-intervention T1; Follow-up T2; Follow-up T3. Eligible individual participants were randomised (1:1 ratio) to trial arms (intervention or TAU). Randomisation was conducted by an independent statistician who assigned participants stratified by participant status i.e. lone participant or participant with a partner (dyad). Neither the researchers not the participants were blinded to allocation. The statistician who did the analysis was blinded to group allocation.

**Results**

From 120 expressions of interest, 83 were screened for eligibility, and 64 enrolled (50 as lone participants; 14 with a partner). Sixty-two participants completed baseline questionnaires at T0 and were randomised to HEADS: UP (n=30) or TAU (n=32) to address trial objectives.

The unit of analysis was the stroke survivor. Participants analysed for HEADS: UP versus TAU at T0 numbered n=30 versus n=32; for T1 n=25 (83.3%) versus n=25 (78.1%); for T2 n=24 (80%) versus n=26 (81.3%); and for T3 n=20 (66.7%) versus n=25 (78.1%), respectively.

Mean age, gender split and time post-stroke of the HEADS: UP and TAU groups were 56.0 and 56.8; 30% and 56% male; and 15 and 24 months, respectively. Data completion for online measures was acceptable by numbers analysed, although attrition was higher in the HEADS: UP group (33.3%) compared with TAU (21.9%) by T1.

From T0 to T1, the DASS total mean score for HEADS: UP improved from 46.2 (SD=24.0) to 24.0 (SD=16.1), a change score of 22.2 and indicative of ‘recovery’ and in the direction of expected effect. This compared with TAU 36.1 (18.7) to 31.6 (20.4), change score of 4.5, indicative of ‘no reliable change’. Both group scores continued to improve by T2 and T3. BDI scores for HEADS: UP at T0 and T1 were 24.7 (SD=12.6) and 12.4 (SD=8.2), compared with TAU of 21.3 (SD=9.9) and 17.6 (SD=9.2), which corresponded to a shift from ‘moderate’ to ‘minimal’ symptoms for HEADS: UP and no improvement in ‘moderate’ symptoms from baseline for TAU. BAI scores for HEADS: UP at T0 and T1 were 23.1 (SD=11.9) and 11.6 (SD=8.9), compared with TAU of 16.3 (SD=10.0) and 14.1 (SD=9.5), which corresponded to a shift from moderate to mild symptoms for both groups.

Two participants chose not to provide data at two timepoints due to mental health distress. This was deemed to be unrelated to the trial and participants elected to provide data at other timepoints**.**

**Conclusions**

The pilot trial was feasible and acceptable, and the outcome measures demonstrated greater mean score changes in the HEADS: UP intervention arm compared with the TAU arm. Whilst TAU participants continued to struggle with mental health issues and lack of engagement HEADS: UP participants described benefits that positively impacted diverse aspects of daily life including social engagement.

[685 words; 250 allowed]

**Strengths and Limitations of this study** 5 bullet points relating specifically to study methods

* Weexceeded our recruitment target and recruited quickly (2.9 participants per week)
* Most participants completed the outcome measures online
* Retention tactics including clear explanation about randomisation and group allocation, frequent communication and reiteration of the importance of every individual’s contribution were effective
* The sample lacked representativeness in terms of ethnic diversity
* Groups were not evenly distributed in terms of time post-stroke, gender and educational attainment

**Trial registration:** This pilot trial was registered at Clinicaltrials.gov: NCT04985838**.**

**Ethics:** School of Health and Life Sciences Ethics Committee, Glasgow Caledonian University:HLS/NCH/20/038 HEADS: UP, awarded 31.01.2022

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**Competing interests statement**: See the Mindfulness submission guidelines

**MANUSCRIPT**

**INTRODUCTION**

Stroke is a chronic and complex long-term condition (Jones, 2006). Approximately 100,000 new events are reported annually in the UK (https://www.strokeaudit.org/results/Clinical-audit/National-Results.aspx); 12.2 million globally (GBD 2019 Stroke Collaborators). Advances in stroke treatments and interventions, such as mechanical thrombectomy and tPA (tissue plasminogen activator) (Campbell and Nguyen 2022) whilst reducing rates of mortality and incidence of severe disability, are resulting in more people living longer, often with the complex disabling effects of stroke (King et al. 2020). Mood disorders are common after stroke (Devereux et al. 2023) especially anxiety (20-29%; Broomfield et al. 2014) and depression (25% 1-5 years; Hackett and Pickles 2014), and persist in the long-term. Incidence of depression at 5 years post-stroke 23% (Hackett and Pickles 2014); anxiety 17-24% up to 10 years post-stroke (Ayerbe et al 2014). Post-stroke mood disorder is associated with increased mortality, higher rates of disability and dependency, reduced quality of life (QoL), and reduced social participation (West et al 2010; Kutlubaev and Hackett 214; Kirkevold et al 2018). Service provision is limited and varies geographically (e.g. Thompson et al 2022). Stroke professionals are not necessarily equipped to provide psychological support, and interventions tend to focus on supporting individuals in the short-term, rather than taking a longer-term family-orientated approach. Over several decades, stroke survivors and their families have persistently reported an unmet need for long-term support (The Stroke Priority Setting Partnership 2021).

Mindfulness Based Stress Reduction (MBSR) a structured, group-based self-management course uses meditation to increase levels of mindfulness for people coping with physical, psychological, or emotional distress (Kabat-Zinn, 1982; Kabat-Zinn 2013). The effectiveness of MBSR has been demonstrated in a wide range of conditions, including anxiety and depression comorbid with long-term conditions (Chiesa et al. 2010; Gotink et al., 2015). Our systematic review revealed positive psychosocial benefits, indicating potential for effectiveness in self-managing symptoms of anxiety and depression following stroke (Lawrence et al 2013).

In earlier funded research we worked with people affected by stroke to co-develop HEADS: UP (Helping Ease Anxiety and Depression after Stroke), an adapted version of a standardised Mindfulness Based Stress Reduction (MBSR) course (Lawrence et al 2023). The 9-week HEADS: UP intervention and research processes were subsequently tested for feasibility and acceptability in two non-randomised studies (in-person, pre-covid; online post-covid) (Lawrence et al in submission). In this paper, using the CONSORT Extension for pilot and feasibility studies (Eldridge et al. 2016), we report a mixed methods pilot randomised controlled trial (RCT), conducted in miniature of a future definitive large-scale study (https://classic.clinicaltrials.gov/ct2/show/NCT04985838).

**METHODS**

The pilot RCT aimed to test feasibility and acceptability of research and intervention processes. Three objectives were described: 1) to test trial procedures, candidate outcome measures, randomisation, and check direction of effect is in the expected direction (in favour of the intervention), 2) identify potential resource implications for NHS (National Health Service) utilisation and 3) determine whether to proceed to a future full-scale trial of effectiveness. See supplementary material Appendix 1 for full list of research questions.

**Trial design**

This was a mixed-methods two-arm parallel pilot RCT, with 1:1 allocation ratio, of HEADS: UP versus Treatment as Usual (TAU) conducted in miniature of a definitive trial, assessing feasibility and acceptability of conducting a future full-scale trial of effectiveness. There were no major changes to trial procedures after pilot trial commencement.

**Participants**

Participants were eligible if they were stroke survivors, aged ≥18 years, had ≥1 stroke at least 3 months previously, able to speak and understand conversational English, could follow a two-stage command (Maruya et al 2018), and scored ≥3 on PHQ-4 (Löwe et al. 2010). Participants were recruited online and had to be living in any constituent nation of the UK. Participants could opt to nominate a family member to support their participation i.e. a supportive partner (Lawrence et al 2023; Morris et al 2023).

**Participant identification**

We used a UK-focused community-based recruitment strategy comprising social media (e.g. Twitter (now ‘X’), Facebook) and third sector organisations (e.g. Stroke Association, Chest, Heart & Stroke Scotland), to recruit community-dwelling stroke survivors. We posted short recruitment videos (1-1.5 mins) on social media featuring past participants (https://www.youtube.com/@headsup6765). When recruiting through third sector organisations we sent gatekeepers project information leaflets (PILs); and consent forms for dissemination to relevant (e)mail distribution lists. When recruiting online we emailed/posted PILs, consent forms, and data privacy notices in response to expressions of interest to each of which assigned an ID.

**Consent processes**

Informed consent, given electronically, was obtained before proceeding to screening. If potential participants were unable/unwilling to complete and return the Word version of the consent form we asked them to reply to a standard email which included two statements, one indicating consent and one declining consent. The recipients were invited to reply to the email, inserting a copy of one of the two statements into the body of the email. After obtaining informed consent, a researcher conducted screening (phone/or online video platform) using a bespoke screening and enrolment questionnaire, incorporating the Modified Telephone Interview for Cognitive Status (TICSm; Brandt et al. 1988) and the Patient Health Questionnaire-4 (PHQ-4; Kroenke et al. 2009). The TICSm was used to provide participant profile data rather than as an inclusion criterion. Stroke survivors who met the inclusion criteria were eligible to participate. Potentially eligible participants were asked whether they wanted to identify someone (e.g. a family member) to take part with them in a supportive role; this was not an inclusion criterion. (Lawrence et al 2023; Morris et al 2023). The nature of this supporting role would vary across dyads, with some family members simply assisting the participant to get online, whilst others attended the sessions along with the participant. During screening and enrolment, the researchers also collected details pertaining to course attendance e.g. availability for planned sessions and any potential internet access issues; details of any assistance required to complete questionnaires; and any accessibility issues e.g. requiring paper copies of questionnaires. The researcher ended by explaining what was required of the participants regarding participation in the study. The screening process took approximately 45 minutes. If individuals became fatigued a break was offered.

**Interventions**

The pilot trial had two arms, comparing HEADS: UP MBSR course versus TAU. Details of the HEADS: UP course and processes have been reported elsewhere (Lawrence et al 2023; Lawrence et al in submission). Most studies define MBSR completion as attending ≥4 sessions in an 8-week course; most do not achieve this (15-27% drop out rates have been reported; Crane and Williams 2010; Marjani 2017) Note: originally we said 30% dropped out of MBSR courses (as opposed to research studies!) - but I don't have a reference for this – does anyone?. In this RCT wedefined intervention feasibility (as opposed to trial feasibility) as 70% of participants who did not drop out i.e. attended ≥4 sessions. HEADS: Online was delivered on Zoom©, by experienced MBSR trainers who had completed HEADS: UP Train the Trainer training prior to course commencement. Trainers were supplied with session plans and fidelity logs, as well as templates for pre- and post-session emails.

**Data Collection**

Candidate primary outcome measures for the future trial were Beck Depression Inventory (BDI) (Beck et al 1961), Beck Anxiety Inventory (BAI) (Beck et al 1988), and Depression Anxiety Stress Scales (DASS-21) (Lovibond and Lovibond, 1995). Secondary outcome measures were the Stroke Impact Scale (SIS-SF) (Duncan et al, 1999) and EQ-5D-5L (Feng et al. 2021). Data were collected at four time points: baseline (T0); post-intervention (T1); 3-month follow-up (T2); and 6-month follow-up (T3). There were no changes to pilot trial assessments or measurements after commencement. Data were collected online, using REDcap® survey software (https://projectredcap.org/software/) unless individuals requested paper questionnaires to be posted to them. If necessary, we sent reminders (phone calls; texts) after 3 days and, if required, a member of the research team assisted participants to complete measures over the phone. During and after intervention delivery we asked participants to keep weekly mindfulness practice logs. These were simple check-box forms (supplementary material Appendix 2) hosted in REDcap®. We made paper copies available on request. Consent was reaffirmed before completion of the measures. To support long-term engagement with the data collection process, we maintained intermittent contact with all participants, principally by sending seasonal greetings cards.

**Sample size**

Typically, MBSR is delivered to groups (15-20 individuals). To promote adherence, we aimed to deliver HEADS: UP to dyads (a participant plus family member in a supportive role), where possible. Based on the results from earlier feasibility and testing work we estimated attrition at 23%-44% (Lawrence et al 2023). Originally, we aimed to enroll at least n=90 participants to 6 groups i.e. 15 stroke survivors (who may/may not be partnered by a family member) per group, in 2 cohorts. Cohort 1 to be recruited by September 2021 (n= 30 stroke survivor participants); Cohort 2 to be recruited by mid-January 2022 (n= 60 participants). Allowing for attrition, this would leave 8-12 participants per group (i.e. n=48-72) by the end of the study, fulfilling the recommendation for a feasibility study sample size of n=50 participants, minimum (Sim and Lewis, 2012). However, acknowledging the restrictions faced by the research team (time; personnel) following the restructuring of the study design in response to covid-19, a pragmatic decision was taken to end recruitment after enrolling n=60 participants. This would leave an estimated n=40 participants in the study at Time 3, a number still in keeping with National Institute for Health Research recommendations (Julious 2005).

**Randomisation**

Following collection of baseline data, eligible individual participants were randomised (1:1 ratio) to trial arms (intervention or TAU). Randomisation was conducted by the NMAHP Research Unit, University of Stirling (<https://www.nmahp-ru.ac.uk>) by an independent statistician who used a randomisation generator on Microsoft Excel to assign participants, stratified by participant status i.e. lone participant or participant with a partner (dyad). This aimed to achieve between-group equivalence for lone participants vs. those with a supportive partner; important because of the anticipated non-specific effects of sharing the experience with another. The research team were not blinded to allocation; neither were the participants who self-reported their outcome measure assessments. The statisticians (ND; MR) who conducted the pilot trial analysis were blind to allocation.

**Health economic assessment**

A resource use questionnaire (RUQ) designed for this study was used to collect data about participants’ use of stroke-related health care treatment during the study period, including use of hospital services, community health services, and prescription medication (see supplementary material Appendix 3). Health-related QoL data was collected using the EQ-5D-5L (Herdman et al. 2011) and scored using the EuroQol crosswalk (van Hout et al 2012).For participants completing RUQ and EQ-5D-5L online, all questions were set as required response, in line with licensing requirements. Paper or telephone alternativesfor all measures were made available, according to individual preference. Data collected over the phone was entered directly into REDCap® and all data entry was checked for accuracy by a second researcher, working independently.

**Data analysis**

A Statistical Analysis Plan was developed and approved before commencing quantitative analysis. The unit of analysis was the participant i.e. the stroke survivor. We used descriptive statistics to summarise characteristics of participants, their outcome measures, and any adverse events, using R statistical software. There were no formal tests of statistical significance as this pilot trial was not powered to detect effectiveness. Analysis was conducting using intention to treat. CONSORT guideline extension for pilot trials informed the data analysis (Eldridge et al. 2016). There was no sub-group analysis. Qualitative data were entered into NVivo version 12. Framework analysis (Gale et al. 2013) was conducted using the Template for Intervention Description and Replication (TIDieR; Hoffman et al. 2014) checklist, supplemented by inductive themes.

**Adverse events**

Two standard operating procedures (SOPs) were developed for the reporting of any adverse events. (SOP) 1addressed probable mood disorder in participants with high scores on any of the mood disorder questionnaires used in the study. Any such participants were referred to their General Practitioner (GP), Stroke Nurse Specialist, or other relevant specialist, and remained in the trial. SOP 2 addressed suicidal ideation. Any participant expressing suicidal thoughts was referred, as per SOP 1, and excluded from the trial.

**Trial management and conduct**

The conduct of the pilot RCT was overseen by a Trial Advisory Group (TAG) comprising stroke survivors, senior stroke academic researchers, senior members of the HEADS: UP research team, and a representative from the funding organisation, the UK Stroke Association. We also established a Project Advisory Group (PAG) comprising stroke survivors, stroke clinicians, and MBSR trainers who contributed to the conduct of the research by collaborating with the research team to develop accessible recruitment materials and to critically review intervention and dissemination materials.

**Data management**

Procedures for handling, storing, and destroying research data conformed to General Data Protection Regulation (2016) requirements, and were documented in the project Data Management Plan. Anonymity was ensured in all dissemination.

**PROCESS EVALUATION**

Once data analysis was completed, we conducted a mixed methods process evaluation (Craig et al. 2008). We used 12 methodological questions (Shanyinde et al., 2011) to systematically interrogate study data and identify what worked well and to identify any design issues encountered which would need to be addressed before conducting a definitive trial (Scobbie et al. 2013; Grant et al., 2020). See Davis et al. (in draft) for full details of the process evaluation.

**RESULTS**

The 10-week period of recruitment (October – December 2021) generated 120 expressions of interest. Eighty-three were screened for eligibility; 64 enrolled (50 as lone participants; 14 with a supportive partner); 62 participants completed baseline questionnaires (T0) and were randomised to HEADS: UP (n=30) or TAU (n=32). Of the n=30 randomised to HEADS: UP n=25 (83.3%) received the intended treatment, compared with n=27 of n=32 (84.4%) who received TAU, and were analysed for the objectives (see Figure 1).

Figure 1 HEADS: UP Pilot Trial CONSORT flow chart

A flowchart of a patient

Description automatically generated

Unrelated to the trial process n=1 participant died, n=2 participants withdrew because of mental health reasons (one in each arm; one returned at T2, and one withdrew at T3), n=1 withdrew because their dyadic partner could no longer support them, n=1 withdrew because of work commitments, and the remainder dropped out and were lost to follow-up. Related to the trial process were n=2 participants allocated to TAU (6.3%) who withdrew because they were not randomised to the HEADS: UP arm. The RCT stopped in September 2022, following collection of 6-month follow-up data (T3). At baseline mean age, gender split and time post-stroke of the HEADS: UP and TAU groups were 56.0 and 56.8; 30% and 56% male; and 15 and 24 months, respectively (Table 1). Participants analysed for HEADS: UP versus TAU at T0 numbered n=30 versus n=32; at T1 n=25 (83.3%) versus n=25 (78.1%); at T2 n=24 (80%) versus n=26 (81.3%); and for T3 n=20 (66.7%) versus n=25 (78.1%), respectively (Figure 1).

Table 1 Demographic data

|  |  |  |  |
| --- | --- | --- | --- |
| **Baseline - time 0** | | | |
|  | | Group A  N=30 (100%) | Group B  N=32 (100%) |
| Age | Mean, SD | 56.0, 11.8 | 56.8, 10.6 |
| Gender | n, % | Female 21 70.0%  Male 9 30.0% | Female 14 43.8%  Male 18 56.2% |
| Time post-stroke (months) | Median (IQR) | 15 (19.5) | 24 (46.5) |
| Living arrangements | n, % | Alone 8 26.7%  Live w/ family 13 43.3%  Live w/ partner 9 30.0% | Alone 9 28.1%  Live w/ family 11 34.4%  Live w/ partner 12 37.5% |
| Ethnicity | n, % | White 28 93.3%  Other 2 6.7% | White 30 93.8%  Other 2 6.3% |
| Employment status | n, % | Economically active 6 20.0%  Economically inactive 24 80.0% | Economically active 11 34.4%  Economically inactive 21 65.6% |
| Highest educational attainment | n, % | Secondary school 11 36.7%  College 4 13.3%  University 15 50.0% | Secondary school 6 18.8%  College 14 43.8%  University 12 37.5% |
| Fatigue | n, % | No 3 10.0%  Yes 27 90.0% | No 2 6.3%  Yes 30 93.8% |
| Dyad status | n, % | No 23 76.7%  Yes 7 23.3% | No 25 78.1%  Yes 7 21.9% |
| Recruitment source | n, % | TSA 13 43.3%  NHS 5 16.7%  Social media 12 40.0% | TSA 9 28.1%  NHS 3 9.4%  Social media 20 62.5% |
| Key  SD: Standard deviation; IQR: interquartile range; TSA: the Stroke Association; NHS: National Health Service | | | |
| *% does not always add to 100% because of round-up* | | | |

**Outcomes**

From T0 to T1, the DASS total mean score for HEADS: UP improved from 46.2 (SD=24.0) to 24.0 (SD=16.1), a change score of 22.2 and indicative of ‘recovery’ and in the direction of expected effect. This compared with TAU 36.1 (18.7) to 31.6 (20.4), change score of 4.5, indicative of ‘no reliable change’. Both group scores continued to improve by T2 and T3 (supplementary materials, Tables 2 & 3; see also supplementary materials, Table 4 for outcomes measures’ symptom severity). BDI scores for HEADS: UP at T0 and T1 were 24.7 (SD=12.6) and 12.4 (SD=8.2), compared with TAU of 21.3 (SD=9.9) and 17.6 (SD=9.2), which corresponded to a shift from ‘moderate’ to ‘minimal’ symptoms for HEADS: UP and no improvement in ‘moderate’ symptoms from baseline for TAU. At T2 and T3, HEADS: UP mean BDI symptom scores improved further and remained ‘minimal’ at 13.2 (SD=7.4) and 12.5 (SD=7.1), respectively. This compared with TAU mean BDI scores at T2 and T3 of 18.11 (SD=9.3) and 18.0 (SD=9.0), representing worsening scores at each timepoint but still in the ‘mild’ symptom category (supplementary material, Tables 2-6). BAI scores for HEADS: UP at T0 and T1 were 23.1 (SD=11.9) and 11.6 (SD=8.9), compared with TAU of 16.3 (SD=10.0) and 14.1 (SD=9.5), which corresponded to a shift from moderate to mild symptoms for both groups (see supplementary material, Table 2). Both groups remained ‘mild’ symptoms at T2 and T3 (see supplementary material, Tables 2-7). Data completion for online measures was acceptable by numbers analysed, although attrition was higher in the HEADS: UP group (33.3%) compared with TAU (21.9%) by T1 despite two withdrawals (6.3%) in the TAU arm because they were not randomised to HEADS: UP.

**Harms**

Two participants chose not to provide data at two timepoints due to mental health distress. This was deemed unrelated to the trial and participants elected to provide data at other timepoints. There were no other noted important unintended participant consequences.

**QUALITATIVE RESULTS**

At Time 1 (post-intervention), 39 people (Intervention n=23; TAU n=16) participated in focus groups or interviews; at Time 3 (6-month follow up), 22 people participated (Intervention n=12; TAU n=10). Results from the framework analysis are reported below, illustrated with verbatim quotes.

**Time 1 interviews and focus groups**

Intervention and TAU

**Research procedures:** Participants described recruitment and screening as *“sensitively done”* and *“straightforward, it was pretty slick in its operation and execution.”* Participants felt that they could complete the Outcome Measure (OM) questions *“honestly”* and using REDCap, the online platform, was straightforward, *“the online questionnaires are really quick and easy,”* although a small number still preferred to use postal questionnaires.

Intervention group

**Mode of delivery:** Overall participants liked being online *“I wouldn’t have been able to do this [face to face] geographically, I live so remotely,”* although others would have liked more group interaction *“I would have liked everyone to have been able to talk more, it’s not like when you are there in person.”* But in general participants enjoyed the supportive environment within the group, *“I think from the very first session we felt like a group … because we were all there for the same reason.”*

**Personal practice:** Personal practice often proved challenging, but with support it was possible, *“At the beginning I did really struggle to kind of put [mindfulness] into my daily life and commit to it, but definitely having that kind of reinforcement from everybody else every week helped.”* Following participant feedback, revisions to personal practice logs proved successful, *“Yeah [the practice log] was pretty easy, you just enter it in and submit, yeah really easy to use.”*

**Perceived benefits:** Participants expressed the positive effect the HEADS: UP course had on their lives *“It’s really helping with my anxiety, and I don’t get as stressed, I am not as snappy with people,*” and *“I can honestly say, and it is not dramatic, this course has helped me with my mental health so much.”* Again, offering HEADS: UP online has benefitted people, *“I would never have a chance to do this, and I think this is very, very important for people who have had a stroke. I think it has the potential to have real benefits.”*

TAU

**Being involved in research is important:** Despite some disappointment at their allocation control group participants expressed their altruistic desire to help others affected by stroke *“I’m pleased to be part of the research because what bit we do now hopefully will benefit people in the future,”* and *“I have had a lot of support from the NHS and I’m very keen to give a little bit back and to help in research for stroke.”* We aimed to ensure control participants felt valued and this was acknowledged, *“You have had a very personal approach… you actually come across as people that care and are passionate about your research,*” and participants enjoyed being involved in the focus groups, *“Because I am meeting people who are in the same situation as me.”*

**Time 3**

Intervention

**Perceived benefits:** Participants described the impact of mindfulness on their lives, *‘But the key is “Take care of you”, because we can’t give from an empty vessel … filling up and feeling healthy inside [so that] what comes out is love and healthiness’*. Key aspects arising from the data included a better acceptance of stroke, leading to improved engagement with rehabilitation, and an increase in confidence in many areas of life, *‘it gave me the confidence to walk properly,’* and *‘it's provided me with the confidence to live positively’.* Six months on people described the HEADS: UP course as ‘a turning point’ to move on to starting a new job or learning a new skill. However, some people had found it difficult to maintain regular practice ‘*It’s the work lifestyle that’s stopped me doing it,’* and missed the support and prompting they had experienced during the course, ‘*I have been lazy actually doing the practices without being prompted … [on the course] we always got reminders.’*

TAU

**Six months on:** The control group described continuing low mood, low confidence, lack of motivation, and other health issues, with a distrust of the NHS, ‘*I have not got my confidence back [following stroke] … medics look at the physical, they don’t look at the emotional, I am not happy with the NHS.’* Participants also described searching online for mindfulness apps ‘*I have tried apps* … *but you start to … you just drift off in different directions,’* although others continued with anti-depressants, *‘I don’t know whether they work but I take them anyway’* or had tried private counselling *‘it just wasn’t long enough.’* Others focused on their physical health in the hope that it would have a positive effect on their mood ‘*if you can move around and your strength [improving], of course, you are going to feel better about yourself.’*

**HEALTH ECONOMIC ASSESSMENT**

At baseline 52 participants completed questionnaires online, 7 completed paper copies and 3 participants completed questionnaires by telephone. See Table 2 for completion rates data.

Table 2 Number of participants (percentage) completing economic measures

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Timepoint | Participants (prior to end of study) | Participants (following close of study, accounting for LTFU) | EQ5D-5L completed  (in full) | RUQ completed\* |
| T0 | 62 | 62 | 62 (100%) | 62 (100%) |
| T1 | 57 | 52 | 50 (96%) | 50 (96%) |
| T2 | 54 | 51 | 50 (98%) | 50 (98%) |
| T3 | 54 | 47 | 45 (96%) | 45 (96%) |
| *Footnote: \*not necessarily all questions within tool* | | | | |

**Feasibility**

Most participants (n=5, 83.9%) reported they did not require help to complete the RUQ. Of those that did, 7 (11.3%) participants noted they required “a little” help to complete the RUQ and 3 (4.8%) “a lot” of help. See Fenocchi et al 2024 (in review) for full details of HEA methods and outcomes.

**Adverse events**

After intervention start in early 2022, a SUSAR was completed to record the sudden and unexpected death of one of the MBSR trainers and its impact on the research i.e. last minute cancellation of a session and restarting the sessions 2 weeks later with another MBSR trainer.

**PROCESS EVALUATION**

Issues identified by the process evaluation included strengths i.e. recruitment (weekly rate), outcomes completion, participant retention and synergy of research process components, and limitations i.e. recruitment (ethnic diversity) and randomisation (see supplementary material, Table 7 for full details). Weexceeded our (revised) recruitment target and recruited quickly (2.9 participants per **week,** cf 1-2 stroke survivors recruited to stroke rehabilitation trials per **month** (McGill et al., 2020)). This may be in-part attributed to the provision of in-house training which ensured the research team had both competence and confidence in applying the research protocols. Most participants completed outcome measures online. Completion rates were bolstered by provision of timely email and SMS prompts. Retention of TAU participants was particularly successful. Retention tactics included providing clear and honest explanation from the outset about randomisation and what allocation would entail for each group, maintaining frequent communication e.g. seasonal greetings cards (Christmas and Spring), and reiteration of the importance of every individual’s contribution. Previous robust development and feasibility work (Lawrence et al 2023; Lawrence et al in peer review) ensured strong synergy between components. Tactics to counter identified limitations in study design will be developed ahead of a subsequent large-scale trial. This will include implementation of an augmented recruitment strategy to enhance sample representativeness and a revised randomisation strategy to ensure even between-groups distribution of time post-stroke, gender and educational attainment.

**DISCUSSION**

The mixed methods pilot trial of a stroke–specific adaptation of a standardised MBSR intervention, HEADS: UP, was found to be feasible and acceptable. Quantitative analysis showed that outcome measures demonstrated greater mean score changes in the HEADS: UP intervention arm compared with the TAU arm. Participant decisions to not provide data for mental health reasons was unrelated to the trial processes and the individuals concerned provided data at other time-points. Qualitative analysisfound that at 6-month follow-up TAU participants continued to struggle with low mood and low levels of social engagement. Conversely, Intervention group participants felt that symptoms of anxiety and depression were improved and described improvements to confidence, which in turn seemed to have positively impacted social participation, including return to work. This finding echoes findings from a previous pilot RCT (n=32 partisans) which found a 9-week MBSR programme to be feasible and acceptable for people following a stroke (Baldo et al 2021). Eleven intervention group participants in that study reported having ‘made changes to their lifestyle’ compared with 27% of the active control group participants, although there is no detail is provided regarding the nature of those changes. Neither confidence nor social participation were measured in our pilot RCT; inclusion of such measures will be considered for future stages of the research.

*Feasibility and Acceptability issues*

*Recruitment*

We had aimed to recruit a study sample representative of the stroke population of the UK across a range of characteristics, including geographic location, socioeconomic profile, and ethnic diversity. We had hoped, for example, that recruiting online for an online intervention might see greater representativeness from remote and rural locations. Whilst we did have some island participants most participants lived in or close to major conurbations. And, whilst sample characteristics did reflect those of populations typically associated with the uptake of mindfulness, yoga, and other complementary therapies in terms of age and educational attainment, they did not reflect the demographic profile of the wider UK stroke population. Similarly, we recruited a largely white study population, despite efforts to appeal to people from other ethnic groups. As a result of this, even as we were actively recruiting, we were devising an augmented recruitment strategy incorporating early community engagement activity, to implement in any future work.

*Randomisation*

Between group differences were evident in relation to gender, time post-stroke, employment status and educational attainment, indicating the need to make improvements to the randomisation process. Two participants dropped out of the TAU arm after not being randomised to HEADS: UP. In a future trial we will explore means of improving trial equipoise to minimise participant perception of a favoured intervention.

*Blinding*

Other than the independent statistician conducting the analysis, the research team and participants were not blinded to allocation, a potential source of bias. However, participants self-reported their own outcomes online with only a few being supported by the research team using telephone contact. Members of the research team had close contact with participants throughout the study, and this was perceived to be a strength of the study design in terms of participant retention. However, the same researchers also moderated the focus groups and conducted the interviews and analysed and reported the qualitative data, which may have introduced an element of bias into the data collection process. In future work we will employ independent researchers to collect and analyse the qualitative data to help minimise bias and maximise the validity of the results (Karanicolas et al., 2010).

*Collection of health economic data*

In this study, we used the EQ-5D-5L and a project-specific resource use questionnaire (RUQ)to test the feasibility and acceptability of collecting health economic data in a future trial. Participants completing paper copies encountered some challenges in understanding how to fully complete the questionnaire, which resulted in missing data. This, coupled with participants’ free text responses within the RUQ, indicates that refinements are required to improve accessibility (e.g. formatting, wording of completion instructions). Conversely, completion of the RUQ, accessed through the REDcap online survey platform, was unproblematic, due in part to the use of the ‘forced answers’ feature. Ahead of a future large-scale trial some refinements are required to improve accessibility and associated completion rates.

**Strengths and limitations**

*Recruitment*

Using a well-developed community-based recruitment strategy, which incorporated utilising social media channels, we were able to recruit quickly. However, because we had no researcher with a dedicated recruitment role, it is unlikely that the success of the social media recruitment routes would have been sustained overtime. Even within the short recruitment window for the study, we observed the social media routes to be collapsing in on themselves as we found we were posting to ever diminishing circles of stroke academics and researchers. In a future large-scale trial, we will fund a fully resourced recruitment role to enable ongoing production of new and engaging content and to implement proactive strategies to extend our networks (followers) and reach wider target audiences.

*Retention*

Still to write this: Retention tactics including clear explanation about randomisation and group allocation, frequent communication and reiteration of the importance of every individual’s contribution were effective

*Synergy*

Still to write this:

*Online delivery/restricted NHS provision*

Still to write this: Online delivery was feasible and acceptable and may be a way of improving service provision in a cost-effective was

This pilot RCT’s methods and findings are generalisable to other studies of online mindfulness interventions. Future large-scale research is warranted to assess effectiveness and identify any implementation and scalability issues

**CONCLUSION**

HEADS: UP intervention and research processes are feasible and acceptable. Intervention participants reported a positive impact on symptoms of anxiety and depression and described improved confidence and levels social engagement.

Manuscript: 5,170 words

**Author's contributions**

*this section may also include contributors who do not qualify as authors. Please visit the ICMJE website for more information on authorship*

**Data sharing statement**

"Technical appendix, statistical code, and dataset available from the Dryad repository, DOI: [include DOI for dataset here].

**Tables**

Table 1 Demographic data

Table 2 Number of participants (percentage) completing economic measure

**Figures**

Figure 1: HEADS: UP Pilot Trail CONSORT flow chart

**Supplementary Material**

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Appendix 2 Participant Practice logs

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Appendix 4 Table 2 Baseline outcome measures

Appendix 5 Table 3 Outcome measures post-intervention (T1)

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Appendix 7 Table 5 Outcome measures at first follow-up (T2)

Appendix 8 Table 6 Outcome measures at second 6-month follow-up (T3)

Appendix 9 Table 7 Outcome measures mean change scores and effect sizes

Appendix 10 Table 8 Process Evaluation

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**SUPPLEMENTARY MATERIAL**

**Appendix 1**

Table 1 Full list of research questions

|  |
| --- |
| **RESEARCH QUESTIONS**   1. Can we recruit sufficient stroke survivors within the recruitment period? |
| 1. Will stroke survivors identify family members/peers to take part in the study with them? |
| 1. How many participants adhere to the adapted online course? (course attrition) |
| 1. Can participants complete the online outcomes measures? |
| 1. How many people drop out? (study attrition) |
| 1. What are participants' perceptions of barriers/facilitators and any changes required? |
| 1. What are MBSR trainers' perceptions of barriers/facilitators and any changes required? |
| 1. Can we identify the main resource implications and how to measure these in a future economic evaluation, as part of a future Phase III trial? |
| 1. Are the trial processes, including data collection in the intervention and control group, and randomisation, appropriate for up-scaling to a large-scale trial? |
| 1. What is the magnitude and variability of changes in primary and secondary outcome measures? |

**Appendix 2**

Participant Practice logs

v.1; 29 MAY 2021

This is your personal practice log. Please keep a record of your mindfulness practice here.

You don’t have to write a lot – only tick the boxes on the days you practice and make a note of how long you practice for. Your practice can be anything you did to help you practice mindfulness.

If you did not practice on a day, please write ‘0’ in both boxes.

Each week we will ask you to tell us how much you practiced. This is not to assess you. This is to find out how we could improve HEADS: UP.

**Try to remember to keep this log up to date every day,** rather than relying on memory at the end of the week!

You may like to keep a separate log for yourself, where you can reflect on your practice experiences.

|  |  |  |
| --- | --- | --- |
| **Day** | **Practice** (please **tick** the days you practiced) | **Duration** (minutes, best guess) |
| **Tuesday**  (HEADS: UP day)  Date – Session No. |  |  |
| **Wednesday** |  |  |
| **Thursday** |  |  |
| **Friday** |  |  |
| **Saturday** |  |  |
| **Sunday** |  |  |
| **Monday** |  |  |

**Appendix 3**

Resource Use Questionnaire

**Resource Use Questionnaire**

v.2 29 MAY 2021

This questionnaire will ask you about your use of health services in relation to your **anxiety and/or depression** over the **last 3 months.**

You will also be asked about your use of health services for **other health problems** in general.

There will be 6 questions. **Please make a note of when you start a questionnaire**. We will be asking how long it took you to complete it as part of your feedback.

Please answer **‘Yes’ or ‘No’** to each question.

If you answer ‘No’, move on to the next question.

If you answer ‘Yes’, please complete the relevant section next to your answer.

You will also be asked about any medication you have been prescribed for anxiety and/or depression.

**PLEASE NOTE:** **We do NOT need to know about any COVID-19 related treatment or vaccinations.**

**1.** In the last **3 months**, have you been to hospital because of your depression and/or anxiety?

Please tick **'Yes' or 'No'** for each line. If you answer 'Yes' to any of them, please tell us how many times you used the service.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** |  | **Number** |
| Been to Accident and Emergency (casualty) |  |  | Total number of visits |  |
| Stayed in hospital overnight |  |  | Total number of nights |  |
| Had a hospital outpatient appointment |  |  | Total number of appointments |  |

**2.** In the last **3 months**, have you been to hospital for **other health problems**? This does **NOT** include any COVID-19 related health care.

Please tick **'Yes' or 'No'** for each line. If you answer 'Yes' to any of them, please tell us how many times you used the service.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** |  | **Number** |
| Been to Accident and Emergency (casualty) |  |  | Total number of visits |  |
| Stayed in hospital overnight |  |  | Total number of nights |  |
| Had a hospital outpatient appointment |  |  | Total number of appointments |  |

**3.** In the last **3 months**, have you received care from any of the services below because of your anxiety and/or depression?

Please tick **'Yes' or 'No'** for each line. If you answer 'Yes' to any of them, please tell us how many times you used the service.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Number of times** |
| GP at the surgery |  |  |  |
| GP via telephone or video call |  |  |  |
| GP at your home |  |  |  |
| Practice nurse at the surgery |  |  |  |
| Practice nurse via telephone or video call |  |  |  |
| Practice nurse at home |  |  |  |
| Home visit from district nurse |  |  |  |
| Psychologist |  |  |  |

**4.** In the last **3 months**, have you received care from any of the services below for **other health problems?** This does **NOT** include any COVID-19 related health care.

Please tick **'Yes' or 'No'** for each line. If you answer 'Yes' to any of them, please tell us how many times you used the service.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Number of times** |
| GP at the surgery |  |  |  |
| GP via telephone or video call |  |  |  |
| GP at your home |  |  |  |
| Practice nurse at the surgery |  |  |  |
| Practice nurse via telephone or video call |  |  |  |
| Practice nurse at home |  |  |  |
| Home visit from district nurse |  |  |  |
| Other |  |  |  |

**5. Medication Usage**

a) Over the last 3 months have you been prescribed any medications **for your anxiety or depression** by a GP or hospital doctor? If no, please go to question 6.

Yes

No

b) If **Yes**, were you taking this medication before you had your stroke?

Yes

No

We would like to know what medication you take for **anxiety or depression**. We would also like to know how much you take and how often.

We have listed a number of common medications to help you, if you take any of the medications listed here, please tick the box.

If you don’t see your medication listed, please write this into the space named **‘Other medication.’**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Medication you take for anxiety or depression** | **YES** | **NO** | **How much do you take?** | **How often do you take it?** |
| Sertraline |  |  |  |  |
| Citalopram |  |  |  |  |
| Amitriptyline |  |  |  |  |
| Mirtazapine |  |  |  |  |
| Fluoxetine |  |  |  |  |
| Venlafaxine |  |  |  |  |
| Duloxetine |  |  |  |  |
| Paroxetine |  |  |  |  |
| Escitalopram |  |  |  |  |
| Trazodone |  |  |  |  |
| Other medication: |  |  |  |  |

**6.** Have you incurred any other costs in the last 3 months because of your **anxiety or depression or** from taking part in this study that you would like to tell us about?

Yes

No

If **Yes**, please give details in the box below:

|  |
| --- |
|  |

**Thank you for completing this questionnaire.**

Please take a moment to check you have answered all questions.

**Appendix 4**

Table 2 Baseline outcome measures

|  |  |  |  |
| --- | --- | --- | --- |
| **Baseline** | | | |
|  | | Group A  N=30 | Group B  N=32 |
| BAI score | Mean, SD | 23.13, 11.85 (moderate) | 16.34, 10.04 (moderate) |
| BDI score | Mean, SD | 24.70, 12.56 (moderate) | 21.31, 9.87 (moderate) |
| DASS total | Mean, SD | 46.20, 24.00 | 36.06, 18.70 |
| DASS -A | Mean, SD | 11.73, 8.66 (moderate) | 6.69, 5.02 (minimal) |
| DASS -D | Mean, SD | 17.00, 10.90 (moderate) | 15.38, 10.59 (moderate) |
| DASS -S | Mean, SD | 17.47, 8.79 (mild) | 14.00, 7.48 (minimal) |
| EQ5D5L index | Mean, SD | 0.519, 0.28 | 0.613, 0.20 |
| EQ5D5L VAS | Mean, SD | 54.5, 22.6 | 64.0, 16.6 |
| SIS Strength | Mean, SD | 3.70, 1.15 | 3.72, 0.92 |
| SIS memory | Mean, SD | 3.37, 1.10 | 3.44, 1.01 |
| SIS Emotion | Mean, SD | 3.43, 1.22 | 3.53, 0.95 |
| SIS communication | Mean, SD | 4.13, 0.97 | 4.13, 0.91 |
| SIS ADL | Mean, SD | 3.23, 1.14 | 3.63, 1.29 |
| SIS mobility | Mean, SD | 3.63, 1.10 | 3.94, 1.24 |
| SIS hand function | Mean, SD | 3.43, 1.48 | 3.41, 1.56 |
| SIS Social participation | Mean, SD | 2.80, 1.24 | 3.34, 1.31 |
| Key  BAI: Beck Anxiety Inventory; BDI: Beck Depression Inventory; DASS-A: Depression Anxiety Stress Scales; DASS-D: Depression Anxiety Stress Scales; DASS-S: Depression Anxiety Stress Scales: EQ5D5: European xxx; EQ5D5L VAS: European xxx Visual Analogue Scale; SIS: Stroke Impact Scale; SIS ADL: Stroke Impact Scale Activities of Daily Living  *Footnote: Group A were on average higher on all BAI, BDI and DASS scores at baseline; Group A were worse than Group B on symptom severity category for DASS-A and DASS-S.* | | | |

**Appendix 5**

Table 3 Outcome measures post-intervention (T1)

|  |  |  |  |
| --- | --- | --- | --- |
| **Post-intervention (T1)** | | | |
|  | | Group A  N=25 | Group B  N=25 |
| BAI score | Mean, SD | 11.64, 8.90 (mild from mod) | 14.12, 9.54 (mild from mod) |
| BDI score | Mean, SD | 12.36, 8.22 (minimal from mod) | 17.64, 9.22 (no change mod) |
| DASS total | Mean, SD | 24.00, 16.07 | 31.60, 20.43 |
| DASS -A | Mean, SD | 6.00, 5.60 (minimal from mod) | 6.80, 6.71 (no change minimal) |
| DASS -D | Mean, SD | 8.72, 7.30 (minimal from mod) | 12.00, 9.66 (mild from moderate) |
| DASS -S | Mean, SD | 9.28, 5.80 (minimal from mild) | 12.80, 7.30 (no change minimal) |
| EQ5D5L index | Mean, SD | 0.617, 0.288 | 0.598, 0.223 |
| EQ5D5L VAS | Mean, SD | 65.5, 20.1 | 67.7, 14.6 |
| SIS Strength | Mean, SD | 3.76, 1.234 | 3.56, 0.96 |
| SIS memory | Mean, SD | 3.48, 1.122 | 3.84, 0.90 |
| SIS Emotion | Mean, SD | 4.00, 0.866 | 3.84, 1.07 |
| SIS communication | Mean, SD | 4.28, 0.792 | 4.32, 0.75 |
| SIS ADL | Mean, SD | 3.72, 1.173 | 3.72, 1.14 |
| SIS mobility | Mean, SD | 3.96, 1.098 | 3.88, 1.17 |
| SIS hand function | Mean, SD | 3.64, 1.381 | 3.20, 1.58 |
| SIS Social participation | Mean, SD | 3.72, 1.021 | 3.40, 1.19 |
| Key: BAI: Beck Anxiety Inventory; BDI: Beck Depression Inventory; DASS-A: Depression Anxiety Stress Scales; DASS-D: Depression Anxiety Stress Scales; DASS-S: Depression Anxiety Stress Scales: EQ5D5: European xxx; EQ5D5L VAS: European xxx Visual Analogue Scale; SIS: Stroke Impact Scale; SIS ADL: Stroke Impact Scale Activities of Daily Living  *Footnote: DASS total deterioration (increase in scores by 5 or more); no reliable change (scores changed by 4 or less); reliable improvement (scores reduced by 5 or more); recovery (scores reduced by 5 or more and most recent score is 6 or less, putting them in the Mild/Subclinical range). HEADS: UP DASS total score improved: 46.2 to 24.0 (mean change score=22.2 or ‘recovery’), compared with 36.1 to 31.6 (mean change score= 4.5 and ‘no reliable change’. At T2, HEADS: UP score 21.0; TAU 29.8, both indicating no reliable change since T1.* | | | |

**Appendix 6**

Table 4 Outcome measures symptom severity

Table

Description automatically generated

*Footnote: These data scores for symptom severity were obtained from each published validated*

*outcome measure*

**Appendix 7**

Table 5 Outcome measures at first follow-up (T2)

|  |  |  |  |
| --- | --- | --- | --- |
| **Follow-up - time 2** | | | |
|  | | Group A  N=24 | Group B  N=26 |
| BAI score | Mean, SD | 10.80, 7.53 (mild) | 13.50, 7.93 (mild) |
| BDI score | Mean, SD | 13.24, 7.41 (minimal) | 18.11, 9.28 (mild) |
| DASS total | Mean, SD | 20.96, 14.14 | 29.77, 16.14 |
| DASS -A | Mean, SD | 4.75, 5.00 (minimal) | 6.38, 4.83 (minimal) |
| DASS -D | Mean, SD | 6.92, 6.78 (minimal) | 11.69, 8.38 (mild) |
| DASS -S | Mean, SD | 9.04, 5.08 (minimal) | 11.69, 6.37 (minimal) |
| EQ5D5L index | Mean, SD | 0.702, 0.157 | 0.647, 0.208 |
| EQ5D5L VAS | Mean, SD | 66.6, 16.6 | 65.4, 19.2 |
| SIS Strength | Mean, SD | 3.833, 1.007 | 3.808, 1.021 |
| SIS memory | Mean, SD | 3.708, 0.806 | 3.769, 0.863 |
| SIS Emotion | Mean, SD | 4.250, 0.847 | 3.769, 0.992 |
| SIS communication | Mean, SD | 4.417, 0.881 | 4.346, 0.689 |
| SIS ADL | Mean, SD | 3.708, 1.268 | 3.808, 1.234 |
| SIS mobility | Mean, SD | 4.000, 0.978 | 4.000, 0.938 |
| SIS hand function | Mean, SD | 3.583, 1.472 | 3.423, 1.554 |
| SIS Social participation | Mean, SD | 3.500, 1.142 | 3.577, 1.137 |

**Appendix 8**

Table 6 Outcome measures at second 6-month follow-up (T3)

|  |  |  |  |
| --- | --- | --- | --- |
| **Follow-up - time 3** | | | |
|  | | Group A  N=20 | Group B  N=25 |
| BAI score | Mean, SD | 9.65, 7.96 (mild) | 14.16, 9.50 (mild) |
| BDI score | Mean, SD | 12.45, 7.05 (minimal) | 18.00, 8.97 (mild) |
| DASS total | Mean, SD | 19.20, 17.93 | 31.85, 19.50 |
| DASS -A | Mean, SD | 3.80, 5.15 (minimal) | 7.08, 6.36 (minimal) |
| DASS -D | Mean, SD | 7.80, 8.13 (minimal) | 12.69, 8.76 (mild) |
| DASS -S | Mean, SD | 7.60, 5.97 (minimal) | 12.08, 7.39 (minimal) |
| EQ5D5L index | Mean, SD | 0.686, 0.182 | 0.642, 0.194 |
| EQ5D5L VAS | Mean, SD | 66.7, 17.7 | 64.0, 17.9 |
| SIS Strength | Mean, SD | 3.75, 1.020 | 3.625, 0.875 |
| SIS memory | Mean, SD | 4.10, 0.641 | 3.840, 0.898 |
| SIS Emotion | Mean, SD | 4.25, 1.020 | 3.600, 1.155 |
| SIS communication | Mean, SD | 4.35, 0.813 | 4.280, 0.891 |
| SIS ADL | Mean, SD | 3.85, 0.933 | 3.680, 0.988 |
| SIS mobility | Mean, SD | 4.15, 0.933 | 3.880, 1.054 |
| SIS hand function | Mean, SD | 3.35, 1.565 | 3.375, 1.527 |
| SIS Social participation | Mean, SD | 3.45, 1.191 | 3.280, 1.339 |

**Appendix 9**

Table 7 Outcome measures mean change scores and effect sizes

|  |  |  |
| --- | --- | --- |
| **Mean change scores or Effect sizes with 95% CI (within group)** | **Group A (HEADS: UP)** | **Group B (TAU)** |
| Mean change score BAI T0 to T1 | 11.49333 | 2.22375 |
| Effect size BAI T0 to T1 | 1.08 | [0.51, 1.65] | 0.23 | [0.30, 0.75] |
| Mean change score BAI T1 to T2 | 0.84 | 0.62 |
| Effect size BAI T1 to T2 | 0.10 | [0.45, 0.66] | 0.07 | [0.48, 0.62] |
| Mean change score BAI T0 to T2 | 12.33333 | 2.84375 |
| Effect size BAI T0 to T2 | 1.22 | [0.63, 1.79] | 0.31 | [0.21, 0.83] |
| Mean change score BDI-II T0 to T1 |  |  |
| Effect size BDI-II T0 to T1 |  |  |
| Mean change score BDI-II T1 to T2 |  |  |
| Effect size BDI-II T1 to T2 |  |  |
| Mean change score BDI-II T0 to T2 |  |  |
| Effect size BDI-II T0 to T2 |  |  |
| Mean change score Short Form Stroke Impact Scale (SF-SIS): for each of the 8 items T0 to T1 | Strength: -0.06  Memory: -0.1133333  Emotion: -0.5666667  Communication: -0.1466667  ADL: -0.4866667  Mobility: -0.3266667  Hand Function: -0.2066667  Social Participation: -0.92 | Strength: 0.15875  Memory: -0.4025  Emotion: -0.30875  Communication: -0.195  ADL: -0.095  Mobility: 0.0575  Hand Function: 0.20625  Social Participation: -0.05625 |
| Effect size SF-SIS for each of 8 items T0 to T1 | Strength: 0.05 | [0.58, 0.48]  Memory: 0.10 | [0.63, 0.43]  Emotion: 0.53 | [1.06, 0.02]  Communication: 0.16 | [0.69, 0.37]  ADL: 0.42 | [0.96, 0.12]  Mobility: 0.30 | [0.83, 0.24]  Hand Function: 0.14 | [0.67, 0.39]  Social Participation: 0.80 | [1.35, 0.25] | Strength: 0.17 | [0.36, 0.69]  Memory: 0.42 | [0.94, 0.11]  Emotion: 0.31 | [0.83, 0.22]  Communication: 0.23 | [0.76, 0.29]  ADL: 0.08 | [0.60, 0.45]  Mobility: 0.05 | [0.48, 0.57]  Hand Function: 0.13 | [0.39, 0.65]  Social Participation: 0.04 | [0.57, 0.48] |
| Mean change score Short Form Stroke Impact Scale (SF-SIS): for each of the 8 items T1 to T2 | Strength: 0.05166667  Memory: -0.2283333  Emotion: -0.25  Communication: -0.1366667  ADL: 0.01166667  Mobility: -0.04  Hand Function: 0.05666667  Social Participation: 0.22 | Strength: -0.2476923  Memory: 0.07076923  Emotion: 0.07076923  Communication: -0.02615385  ADL: -0.08769231  Mobility: -0.12  Hand Function: -0.2230769  Social Participation: -0.1769231 |
| Effect size SF-SIS for each of 8 items T1 to T2 | Strength: 0.05 | [0.51, 0.61]  Memory: 0.23 | [0.79, 0.33]  Emotion: 0.29 | [0.85, 0.27]  Communication: 0.16 | [0.72, 0.40]  ADL: 9.56e-03 | [0.55, 0.57]  Mobility: 0.04 | [0.60, 0.52]  Hand Function: 0.04 | [0.52, 0.60]  Social Participation: 0.20 | [0.36, 0.76] | Strength: 0.25 | [0.80, 0.30]  Memory: 0.08 | [0.47, 0.63]  Emotion: 0.07 | [0.48, 0.62]  Communication: 0.04 | [0.59, 0.51]  ADL: 0.07 | [0.62, 0.48]  Mobility: 0.11 | [0.66, 0.44]  Hand Function: 0.14 | [0.69, 0.41]  Social Participation: 0.15 | [0.70, 0.40] |
| Mean change score Short Form Stroke Impact Scale (SF-SIS): for each of the 8 items T0 to T2 | Strength: -0.008333333  Memory: -0.3416667  Emotion: -0.8166667  Communication: -0.2833333  ADL: -0.475  Mobility: -0.3666667  Hand Function: -0.15  Social Participation: -0.7 | Strength: -0.08894231  Memory: -0.3317308  Emotion: -0.2379808  Communication: -0.2211538  ADL: -0.1826923  Mobility: -0.0625  Hand Function: -0.01682692  Social Participation: -0.2331731 |
| Effect size SF-SIS for each of 8 items T0 to T2 | Strength: 0.12 | [0.66, 0.42]  Memory: 0.35 | [0.89, 0.19]  Emotion: 0.76 | [1.31, 0.20]  Communication: 0.30 | [0.84, 0.24]  ADL: 0.40 | [0.94, 0.15]  Mobility: 0.35 | [0.89, 0.19]  Hand Function: 0.10 | [0.64, 0.44]  Social Participation: 0.58 | [1.13, 0.03] | Strength: 0.09 | [0.61, 0.43]  Memory: 0.35 | [0.87, 0.17]  Emotion: 0.25 | [0.76, 0.27]  Communication: 0.27 | [0.79, 0.25]  ADL: 0.14 | [0.66, 0.37]  Mobility: 0.06 | [0.57, 0.46]  Hand Function: 0.01 | [0.53, 0.51]  Social Participation: 0.19 | [0.71, 0.33] |
| DASS -A mean change score T0 to T1 | 5.733333 | -0.1125 |
| DASS -D mean change score T0 to T1 | 8.28 | 3.375 |
| DASS -S mean change score T0 to T1 | 8.186667 | 1.2 |
| DASS total mean change score T0 to T1 | 22.2 | 4.4625 |
| DASS -A mean change score T1 to T2 | 1.25 | 0.4153846 |
| DASS -D mean change score T1 to T2 | 1.803333 | 0.3076923 |
| DASS -S mean change score T1 to T2 | 0.2365217 | 1.107692 |
| DASS total mean change score T1 to T2 | 3.043478 | 1.830769 |
| DASS -A mean change score T0 to T2 | 6.983333 | 0.3028846 |
| DASS -D mean change score T0 to T2 | 10.08333 | 3.682692 |
| DASS -S mean change score T0 to T2 | 8.423188 | 2.307692 |
| DASS total mean change score T0 to T2 | 25.24348 | 6.293269 |
| EQ5D5L index | See economic report |  |
| EQ5D5L VAS | See economic report |  |
| SIS Strength mean change score T0 to T1 | -0.06 | 0.15875 |
| SIS memory mean change score T0 to T1 | -0.1133333 | -0.4025 |
| SIS Emotion mean change score T0 to T1 | -0.5666667 | -0.30875 |
| SIS communication mean change score T0 to T1 | -0.1466667 | -0.195 |
| SIS ADL mean change score T0 to T1 | -0.4866667 | -0.095 |
| SIS mobility mean change score T0 to T1 | -0.3266667 | 0.0575 |
| SIS hand function mean change score T0 to T1 | -0.2066667 | 0.20625 |
| SIS Social participation mean change score T0 to T1 | -0.92 | -0.05625 |
| SIS Strength mean change score T1 to T2 | 0.05166667 | -0.2476923 |
| SIS memory mean change score T1 to T2 | -0.2283333 | 0.07076923 |
| SIS Emotion mean change score T1 to T2 | -0.25 | 0.07076923 |
| SIS communication mean change score T1 to T2 | -0.1366667 | -0.02615385 |
| SIS ADL mean change score T1 to T2 | 0.01166667 | -0.08769231 |
| SIS mobility mean change score T1 to T2 | -0.04 | -0.12 |
| SIS hand function mean change score T1 to T2 | 0.05666667 | -0.2230769 |
| SIS Social participation mean change score T1 to T2 | 0.22 | -0.1769231 |
| SIS Strength mean change score T0 to T2 | -0.008333333 | -0.08894231 |
| SIS memory mean change score T0 to T2 | -0.3416667 | -0.3317308 |
| SIS Emotion mean change score T0 to T2 | -0.8166667 | -0.2379808 |
| SIS communication mean change score T0 to T2 | -0.2833333 | -0.2211538 |
| SIS ADL mean change score T0 to T2 | -0.475 | -0.1826923 |
| SIS mobility mean change score T0 to T2 | -0.3666667 | -0.0625 |
| SIS hand function mean change score T0 to T2 | -0.15 | -0.01682692 |
| SIS Social participation mean change score T0 to T2 | -0.7 | -0.2331731 |

**Appendix 10**

Table 8 Summary of Process Evaluation

|  |  |  |
| --- | --- | --- |
| **Methodological considerations in the context of an RCT** | **Findings** | **Evidence**  **(I=Intervention group, TAU (Treatment as Usual)=Control group)** |
| 1. Did the feasibility study allow a sample size calculation for the main trial? | Yes | Target n=60 (min 40); achieved n=64 |
| 1. What factors influenced eligibility and what proportion of those approached were eligible? | Ineligibility was due to expressions of interest from people who were: not UK-based (n=3); scored ≤3 PHQ4 (n=6); had severe aphasia (n=4); had not had a stroke (n=2); had attended an MBSR course within 3 years (n=2); had cognitive impairment (n=1); were not available (n=1) | Expressions of interest n=120, screened n=83, ineligible n=19 |
| 1. Was recruitment successful? | Yes, and supported by in-house staff training and support. | Target n=60; consented participants n=64; randomised n=62 |
| 1. Did eligible participants consent? | High conversion to consent | Consented participants n=62 |
| 1. Were participants successfully randomised and did randomisation yield equality in groups? | Randomisation was successful; but groups were not entirely equivalent | Groups were unequal in terms of **time post-time stroke**, median (months) I n=15; TAU n=24; **gender** (male): I n=9 (30%); TAU n=18 (56.2%); **educational attainment** (secondary school): I n= 11(36.7%); TAU n=6 (18.8%) |
| 1. Were blinding procedures adequate? | Partially, given the context and low research staff numbers | All hands-on researchers were blinded to the quantitative data and the quantitative data analysts were blinded to allocation. Researchers known to the participants collected, analysed, and reported qualitative data. |
| 1. Did the participants adhere to the intervention? | Good adherence to the intervention and mindful practice | Intervention:24/26 attended ≥4 of 8 intervention sessions (92.3%)  Median intervention attendance = 8 sessions  4 treatment participants withdrew (partially or completely) before course start (13.3%)  2 participants attended ≤4 sessions.  Practice: 24 participants returned at least 1 weekly log (92.3%). Practice days per week, median =6 days (IQR 5-7), participation mean (across practice days) =22.7 mins/practice day (SD 14.6 mins) |
| 1. Was the intervention acceptable to the participants? | Yes | Qualitative data supports this; ‘*the course really helped me focus. The breaks were great, the content was perfect, …You know, it was good to adapt to you personally’* (*Intervention group participant);*  ‘*I didn’t get anxious about doing it [on Zoom], I just kind of felt quite comfortable’ (TAU participant).* |
| 1. Was it possible to calculate intervention costs and duration? | Yes | Collection of HEA data feasible, although the data collection requires refinement; participants reported they found HEA measure difficult to complete (n=9), required help with reading (n=6), and needed assistance with online completion (n=5). |
| 10. Were outcome assessments completed? | Yes | Overall, completing outcomes on REDcap was very successful; people receiving paper copies returned mainly by post. |
| 11. Were outcomes measured those that were most appropriate? | Yes; but we should consider measuring additional outcomes in the next stage of the research | Qualitative evidence of improved confidence that, at 6 months participants were able to return to work, learn new skills, and felt able to engage better in physical activity. Consider measuring confidence and social participation/social engagement |
| 12. Was retention to the study good? | Yes | Participation and completion at Time 3: Intervention n=20/30, TAU n=25/32 |
| 13. Were the logistics of running an online trial assessed? | Yes | Capped online group size 10 (-12); understaffed (research staff/time: dedicated qualitative researcher (for blinding); also require PPI person; IT support; EDI person; limited access to additional trainers; good IT support/licenses (communications platform, REDcap, Padlet etc); admin support |
| 14. Did all components of the protocol work together? | Components had strong synergy | All components demonstrated high synergy. There were no difficulties identified in the various processes and the researchers’ ability to implement them. |
| KEY  EDI: equality, diversity, inclusivity; HEA: Health Economics Assessment; I: Intervention; IQR: interquartile range; IT: information technology; MBSR: Mindfulness Based Stress Reduction; PHQ4: Patient Health Questionnaire-4; PPI: Patient and Public Involvement; SD: Standard deviation; TAU: Treatment as Usual | | |
|  | | |