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ORIGINAL PAPER

A Pilot Randomized Controlled Trial Testing the Feasibility and Acceptability of Helping Ease Anxiety and Depression after Stroke (HEADS: UP): An Online Mindfulness-Based Intervention for Stroke Survivors

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Abstract

Objectives The purpose of this study was to assess feasibility and acceptability of a stroke-specific mindfulness-based intervention called Helping Ease Anxiety and Depression after Stroke (HEADS: UP).

Method This study was a mixed-methods pilot randomized controlled trial comparing HEADS: UP to treatment as usual (TAU). HEADS: UP is a 9-week mindfulness intervention for stroke survivors. UK (United Kingdon)-based stroke survivors were recruited and attended HEADS: UP Online. Psychological functioning outcomes measures and other data were collected online at pre-intervention (Week 0), post-intervention (Week 9), and follow-up (months 3 and 6). Participants were randomized 1:1 to either HEADS: UP or TAU.

Results Sixty-two participants completed baseline questionnaires and were randomized to HEADS: UP ($n=30$) or TAU ($n=32$). Retention rates were as follows: HEADS: UP ($n=25$, 83.30%) versus TAU ($n=25$, 78.10%) at post-intervention, HEADS: UP ($n=24$, 80%) versus TAU ($n=26$, 81.30%) at 3-month follow-up, and HEADS: UP ($n=20$, 66.70%) versus TAU ($n=25$, 78.10%) at 6-month follow-up. The mean age for HEADS: UP was 56.0 years versus 56.80 for TAU. The HEADS: UP group was 30% male, while the TAU group was 56% male. Depression Anxiety Stress Scales (DASS)-21 total mean score for HEADS: UP improved in the direction of expected effect (baseline 46.20, *SD* (standard deviation) = 24.00; post-intervention 24.00, *SD* = 16.10) indicating *recovery* versus *no reliable change* for TAU (baseline 36.10, *SD* = 18.70; post-intervention 31.60, *SD* = 20.40). HEADS: UP and TAU scores continued to improve over time. Between-group effect sizes (Cohen's *d*) at post-intervention were large for BAI (Beck Anxiety Inventory) ($d=0.91$), DASS-21 total ($d=0.89$), and BDI (Beck Depression Inventory)-II ($d=0.86$), highlighting the potential of HEADS: UP for improving depression and anxiety symptoms. At the six-month follow-up, the attrition rate was higher in the HEADS: UP group (33.30%) compared with TAU (21.90%).

Conclusions HEADS: UP is feasible and acceptable and has potential to improve depression and anxiety symptoms for stroke survivors.

Preregistration ClinicalTrials.gov: NCT04985838.

Keywords Stroke · Anxiety · Depression · Online MBSR (Mindfulness Based Stress Reduction) · Pilot RCT

Stroke is a chronic and complex long-term condition (Katan & Luft, 2018; Soto et al., 2020). Approximately 100,000 new events are reported annually in the UK (https://www.strokeaudit.org/results/Clinical-audit/National-Results.aspx), and 12.2 million globally (GBD, 2019). Advances in stroke treatments and interventions, such as mechanical thrombectomy and tPA (tissue plasminogen activator) (Campbell & Nguyen, 2022) have reduced mortality and severe disability, resulting in more people living longer with the complex effects of stroke (King et al., 2020). Long-term mood

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disorders can occur after stroke (Devereux & Berns 2023) with depression (25% 1–5 years; Hackett & Pickles, 2014) and anxiety (19–24%; Knapp et al., 2020) being common. Incidence of depression at 5 years post-stroke is 23% (Hackett & Pickles, 2014) and anxiety can persist at 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, reduced quality of life (QoL), and reduced social participation (Kirkevold et al., 2018; Kutlubaev & Hackett, 2014; West et al., 2010). Promoting mental health and wellbeing is a global public health priority (e.g. Patel et al., 2018; World Health Organization, 2001), but clinical service provision varies with disparity in access to psychological support services in some disadvantaged populations and geographical locations (Oman, 2025; Thompson et al., 2022). Stroke healthcare 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 psychological support (Stroke Priority Setting Partnership, 2021).

Mindfulness-Based Stress Reduction (MBSR) and other mindfulness-based interventions (MBIs) are structured self-management programs using meditation to increase levels of mindfulness for people coping with physical, psychological, or emotional distress (Kabat-Zinn, 1982, 2013). MBIs can be delivered either in-person or online and are effective with non-clinical populations (e.g. Barcaccia et al., 2024; Galante et al., 2021) and for people with long-term health conditions and comorbid depression and anxiety symptoms (e.g. Blankespoor et al., 2017; Cash et al., 2016; Gotink et al., 2015). A systematic review (Lawrence, et al., 2013) and a scoping review (Mak et al., 2023) of MBIs with stroke survivors have shown tentative psychosocial benefits for self-managing symptoms of depression and anxiety after stroke. Helping Ease Anxiety and Depression after Stroke (HEADS: UP) is a co-developed stroke-specific adaptation of MBSR (Lawrence et al., 2023). HEADS: UP recently underwent feasibility and acceptability testing in two (in-person and online) non-randomized studies (Lawrence et al., 2024).

Using the CONSORT Extension for pilot and feasibility studies (Eldridge et al., 2016), this paper reports the quantitative findings from a mixed-methods two-arm pilot randomized controlled trial (RCT) with 1:1 allocation ratio to HEADS: UP or TAU, conducted in miniature of a planned definitive large-scale trial, to test the feasibility and acceptability of research and intervention processes. The three main objectives were to (1) test trial procedures, candidate outcome measures, randomization, and assess whether the direction of effect favored the intervention; (2) identify potential resource implications for UK NHS (United Kingdom National Health Service) utilization; (3) determine whether to proceed to a future full-scale effectiveness RCT (see Online Resource 1 for details of the 10 research questions). This paper addresses Objectives 1 (in detail) and 2 (in summary). The results of the economic evaluation feasibility (Objective 2) and the process evaluation, which draws on data from the quantitative and qualitative elements of the study, (Objective 3) will be reported separately.

Method

Participants

Participants were community-dwelling stroke survivors recruited using a UK-focused strategy comprising social media (e.g. Twitter (now X), Facebook) and non-governmental organizations (e.g. Stroke Association; Chest, Heart & Stroke Scotland). Social media adverts included short recruitment videos (1–1.5 min) featuring past participants and members of the project advisory group (https://www.youtube.com/@headsup6765). Potential participants who responded to social media adverts were sent (by mail or email) a project information pack (a project information leaflet (PIL), consent form and data privacy notice). When recruiting through third sector organizations gatekeepers disseminated the project information pack to their members. MBSR is often delivered to groups (15–20 individuals), but to promote adherence the plan was to deliver HEADS: UP to dyads (a participant plus a supportive partner) where possible. The initial plan was to enroll participants ($n = 90$) into six groups, but COVID-19 restrictions and changes to the research design (moving to online delivery) limited recruitment time (Lawrence et al., 2024). A pragmatic decision was made to reduce the number of participants ($n = 60$) across four groups in two cohorts (i.e. 15 stroke survivors per group). Cohort 1 was recruited by September 2021. Cohort 2 was recruited by mid-January 2022. Attrition was estimated at 44% by six months (Lawrence et al., 2024) which would leave 10 participants per group by 6-month follow-up. This was in keeping with UK National Institute for Health Research recommendations for pilot and feasibility studies (Julious, 2005) and depending on the standard deviation of the main outcome measures, would fulfill a recommended minimum number of $n = 40$ (Sim & Lewis, 2012).

The 10-week period of recruitment (October–December 2021) resulted in 120 expressions of interest. Potential participants were eligible if they were: living in the UK, stroke survivors, aged ≥ 18 years, at least 3 months post-stroke, able to speak and understand conversational English, and to follow a two-stage command (Maruya et al., 2018) and scored ≥ 3 on the Patient Health Questionnaire-4 (PHQ-4). The PHQ-4 is a brief screening tool addressing anxiety and

depression, selected to reduce participant burden (Lawrence et al., 2023; Löwe et al., 2010); an elevated score indicates that further investigation is warranted (Kroenke et al., 2009). Eighty-three people were screened for eligibility; 64 enrolled (50 as lone participants; 14 (22%) with a supportive partner) and were successfully randomized evenly across the two arms; see Fig. 1 for enrollment flowchart. Sixty-two participants completed baseline questionnaires (T0) and were randomized to HEADS: UP ($n=30$) or TAU ($n=32$). At baseline mean age, gender split, and time post-stroke of the HEADS: UP and TAU groups were 56.00 and 56.80; 30% and 56% male; and 15 and 24 months, respectively (see Table 1 for full demographic data). Of the $n=30$ randomized to HEADS: UP, $n=25$ (83.30%) received the intended treatment, compared with $n=27$ of $n=32$ (84.40%) who received TAU, and were analyzed for the study objectives (see Fig. 1). Unrelated to the trial process one participant died and two participants withdrew because of mental health reasons (one in each arm; one returned at T2, and one withdrew at T3), one participant withdrew because their partner could no longer support them, and another withdrew because of work commitments. The remainder dropped out and were lost to follow-up. Related to the trial process were two participants allocated to TAU (6.30%) who withdrew because they were not randomized to the HEADS: UP arm. Participants analyzed for HEADS: UP versus TAU at T0 numbered $n=30$ versus $n=32$; at T1 $n=25$ (83.30%) versus $n=25$ (78.10%); at T2 $n=24$ (80%) versus $n=26$ (81.30%); and for T3 $n=20$ (66.70%) versus $n=25$ (78.10%), respectively (Fig. 1). The RCT stopped in September 2022, following collection of 6-month follow-up data.

Procedure

After obtaining informed consent, confirmed by email, a researcher conducted screening by phone or on Zoom© (an online video platform) using a bespoke screening and enrolment questionnaire, which incorporated the Modified Telephone Interview for Cognitive Status (TICSm; Brandt et al., 1988) and the PHQ-4. Stroke survivors who were eligible to participate were asked whether they wanted to nominate another person (e.g. a family member) to take part with them (Lawrence et al., 2023; Morris et al., 2023). This was not an inclusion criterion, and the role varied, according to participant preference (e.g. some family members simply assisted the participant to get online, others attended sessions with the participant). Participants were also asked for "logistics" data: availability on pre-set dates, internet access issues, help (if any) to complete questionnaires; accessibility requirements e.g. paper study materials. Finally, the researchers reminded participants of the study requirements, including completing repeated questionnaires and taking part in focus groups, irrespective of group allocation. Screening took approximately 45 min; breaks were offered.

Following collection of baseline data, individual participants were randomized (1:1 ratio) to HEADS: UP or TAU. Randomization was conducted by an independent statistician who used a randomization generator (Microsoft Excel) to assign participants, stratified by participant status i.e. lone participant or participant with a partner. This aimed to achieve between-group equivalence for lone participants vs. those with a partner; important because of the anticipated non-specific effects of sharing the experience with another. To minimize bias, participants self-completed the patient reported outcomes measures (PROMs) unless they requested assistance; the researchers recorded details of any assistance given. One researcher (NC) entered all PROMs data, which were independently checked by a second researcher (BD or ML). The statisticians who conducted the analysis were blind to allocation (ND; MJ). HEADS: UP participants received a course manual and had access to downloadable audio practices. Participants (HEADS: UP and TAU) did not receive any financial or other incentive to participate.

HEADS: UP was delivered online, to groups, over nine weeks using Zoom. The first week was an introductory session which was followed (Weeks 2–9) by the eight core MBSR sessions (Santorelli et al., 2017). The core sessions cover a range of mindfulness techniques including body-focused meditation, gentle movement (yoga), and breathing meditations. Students learn about, practice, and then discuss each technique within the group. Weekly sessions were 2.5 hr and include two 15-min breaks. In week seven the session is longer (6 hr) to accommodate a silent retreat. Full details of course content, development and optimization have been reported previously (Lawrence et al., 2023, 2024). The course was delivered by experienced MBSR trainers who fulfilled the British Association of Mindfulness-Based Approaches (2011) good practice requirements and had completed bespoke HEADS: UP Train the Trainer training. Trainers' audio-recorded the individual weekly practices and uploaded the recordings to an online repository (Padlet). The TAU treatment was not structurally equivalent to HEADS: UP and was not intended to augment any therapeutic intervention typically received by individual participants during the course of the study. TAU participants remained under the care of their GP (General Practitioner) with no specific recommendations on prescription of medication, psychological interventions, or referral to a mental health professional.

Each person expressing interest in the study was assigned an identity number (ID), so they could be tracked throughout the various stages of the study. Demographic data (gender, age, time post-stroke, ethnicity, marital status, living arrangements, educational attainment, employment status, dyadic versus lone participation, recruitment

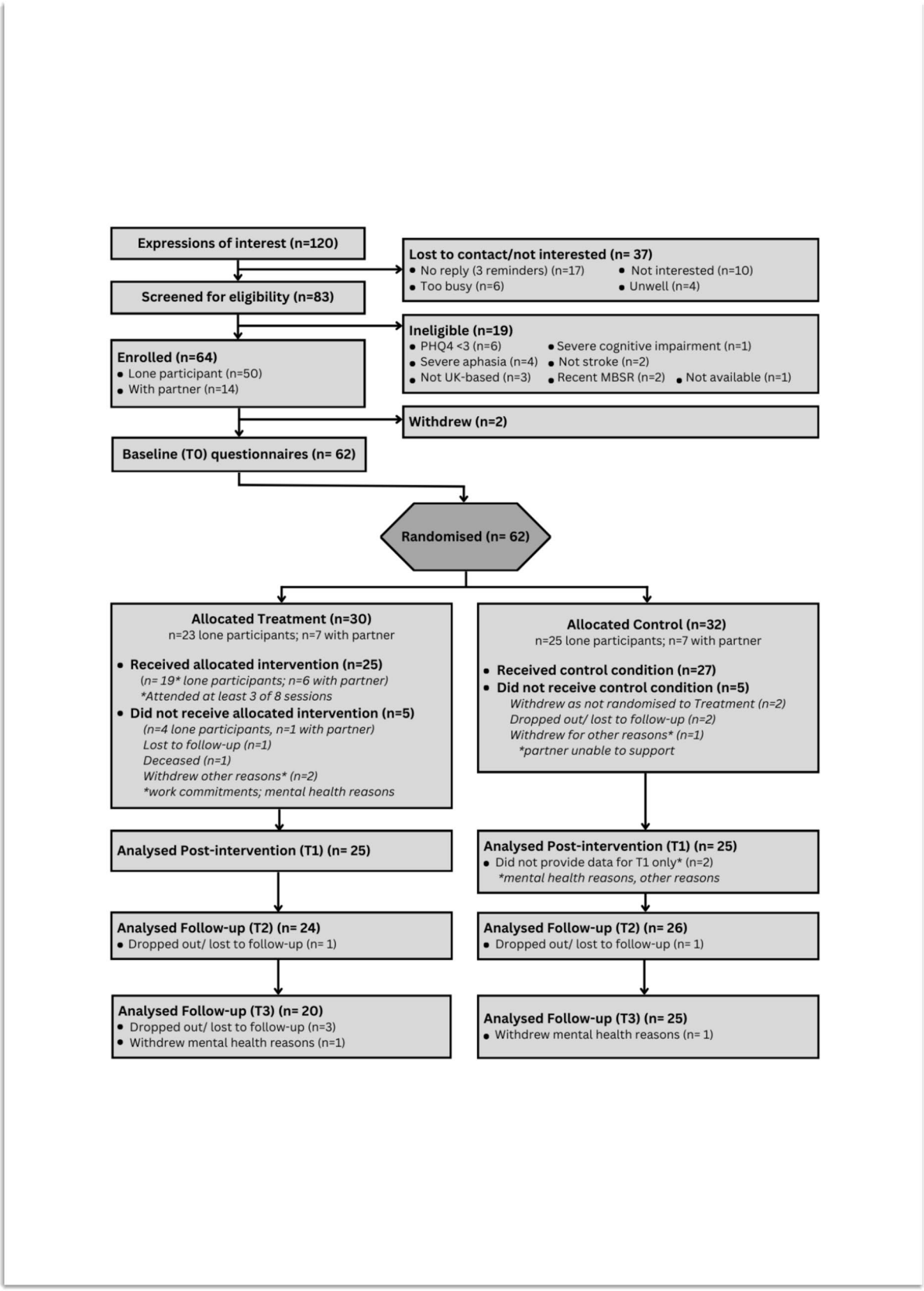

Fig. 1 HEADS: UP Pilot Trial CONSORT flow chart

Table 1 Demographic data

Baseline—time 0					
		HEADS: UP $n=30$ (100%)		TAU $n=32$ (100%)	
Age	Mean, *SD*		56, 11.80		56.80, 10.60
Gender	*n*, %	Female Male	21 70.00% 9 30.00%	Female Male	14 43.80% 18 56.20%
Time post-stroke (months)	Median (*IQR*)		15 (19.50)		24 (46.50)
Living arrangements	*n*, %	Alone Live w/family Live w/partner	8 26.70% 13 43.30% 9 30.00%	Alone Live w/ family Live w/ partner	9 28.10% 11 34.40% 12 37.50%
Ethnicity	*n*, %	White Other	28 93.30% 2 6.70%	White Other	30 93.80% 2 6.30%
Employment status	*n*, %	Economically active Economically inactive	6 20.00% 24 80.00%	Economically active Economically inactive	11 34.40% 21 65.60%
Highest educational attainment	*n*, %	Secondary school College University	11 36.70% 4 13.30% 15 50.00%	Secondary school College University	6 18.80% 14 43.80% 12 37.50%
Fatigue	*n*, %	No Yes	3 10.00% 27 90.00%	No Yes	2 6.30% 30 93.80%
Dyad status	*n*, %	No Yes	23 76.70% 7 23.30%	No Yes	25 78.10% 7 21.90%
Recruitment source	*n*, %	TSA NHS Social media	13 43.30% 5 16.70% 12 40.00%	TSA NHS Social media	9 28.10% 3 9.40% 20 62.50%

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

origin) was used to assess whether randomization had been successful. Recruitment origin (e.g. X; Stroke Association) data allowed assessment of the various strands of our recruitment strategy. Most studies have defined MBSR completion as attending ≥ 4 of the eight core sessions; most have not achieved this with reported dropout rates of 15–30% (e.g. Cash et al., 2016; Marjani, 2017; Wang et al., 2019). In this study, intervention feasibility was defined as ≥ 70% of participants attending ≥ 4 core sessions. Of $n=26$ HEADS: UP participants, $n=24$ (92.30%) attended at least four core sessions. Participants with a supportive partner attended an average (median) of seven sessions (median; *IQR* 6–8); lone participants attended eight (*IQR* 7–8). Participants practiced on 6 days of the week (*IQR* 5–7) for 22.70 (*SD* 14.60) mins per practice day. Across 16 core sessions, the Cohort 2 trainer recorded nine incidences of deviation from session plans (minor overruns $n=5$; breakout rooms not used $n=3$; one practice omitted $n=1$). HEADS: UP participants were invited to keep personal practice logs (PPLs, simple check-box forms submitted weekly; Online Resource 2) to record their home practice. Reminder SMS (Short Message Service) prompts were sent, as required. Weekly session plans and fidelity logs, completed by the trainers, allowed assessment of fidelity.

PROMs data were collected at four time points: baseline (T0); post-intervention (T1); 3-month follow-up (T2); and 6-month follow-up (T3). Changes to study design made as a consequence of COVID-19 restrictions meant that the planned 12-month follow-up was no longer possible (Lawrence et al., 2024). Reminders (phone calls; SMS texts) were sent after three days and a member of the research team assisted participants with completing the measures via phone. Sixty-two (96.90%) participants completed all baseline PROMs (completion time 40 min approx.). Eleven (17.20%) participants requested paper copies of all research materials including PROMs. Eleven participants (17.20%) required assistance to complete the PROMs, whether online or on paper: reading the questions $n=5$ (8.10%); explaining the questions $n=1$ (1.60%); clicking on/writing the answer $n=5$ (8.10%). At 3-month follow-up two participants returned only partially complete PROMs. Twenty-four (92.30%) HEADS: UP participants returned PPLs; 23 (88.50%) returned ≤ 4 PPLs. Some paper copies returned included omissions (e.g. "practice duration" was incomplete: $n=15$ logs, at least 1 missing item), illegible handwriting,

and contradictory information ($n = 2$ logs). Long-term engagement with data collection processes was maintained through intermittent contact with all participants (e.g. sending seasonal greetings cards).

Measures

Primary PROMS Measuring Depression and Anxiety

Beck Depression Inventory-II (BDI-II): The BDI-II measures severity of depression with 21 items scored from 0 to 3. The total score ranges from 0 to 63 with 0–13 representing minimal, 14–19 mild, 20–28 moderate, and ≥ 29 severe depression. The BDI-II manual reports high internal reliability for outpatients, (0.92) and high retest (0.93) for outpatients tested one week apart; Chronbach's alpha $\alpha = 0.89$ (Beck et al., 1996; Sacco et al., 2016).

Beck Anxiety Inventory (BAI): The BAI measures severity of anxiety with 21 items scored from 0–3. The total score ranges from 0–63 with 0–9 representing normal or no anxiety, 10–18 mild to moderate anxiety, 19–29 moderate to severe anxiety, and ≥ 30 severe anxiety. The BAI exhibits convergent validity, test–retest reliability, and very good internal consistency; Chronbach's alpha $\alpha = 0.94$ (Beck et al., 1988; Fydrich et al., 1992).

Depression Anxiety Stress Scales (DASS-21): The DASS-21 measures depression, anxiety and stress in 42 items across 7 subscales, with scores ranging from 0 to 21 for each subscale; higher scores indicating greater symptomatology (Lovibond & Lovibond, 1995). The scale has shown convergent, discriminant and construct validity and high reliability in a large sample ($n = 1{,}794$) of the UK general population; Chronbach's alpha for Anxiety $\alpha = 0.87$, Depression $\alpha = 0.92$, Stress $\alpha = 0.89$ (Henry & Crawford, 2005; Thiyagarajan et al., 2022).

Secondary PROMs (quality of life (QoL) and economic evaluation)

Stroke Impact Scale Short Form (SIS-SF): The SIS-SF, derived from the SIS (Duncan et al., 1999), measures the impact of stroke on health and wellbeing with 8 items scored on a metric of 0–100, with higher scores indicating better self-reported health. Testing demonstrated content, convergent, and discriminant validity; Cronbach's alpha $\alpha = 0.89$ (Coppers et al., 2021; MacIsaac et al., 2016).

EQ-5D-5L: EQ-5D-5L is a generic preference-based outcome measure that can be used to define an individual's health state using the dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (Herdman et al., 2011). Each dimension has five levels which, together, provide a health state utility value. Scores range from −0.59 hsuv to 1.00 hsuv. Testing demonstrated good internal consistency; Cronbach's alpha $\alpha = 0.79$ (Seng et al., 2020).

EQ Visual Analogue Scale (EQ-VAS): The EQ-VAS is a vertical analogue scale which measures self-rated health on a scale from 0 to 100, where 100 is "the best health you can imagine" (Feng et al., 2014).

To test feasibility of collecting resource-use data to estimate costs associated with accessing other stroke-related healthcare treatment over time, a bespoke resource use questionnaire (RUQ) was used (Online Resource 3). Additional quantitative and qualitative data were collected from various sources (e.g. practice and fidelity logs; focus groups and interviews) to inform the process evaluation (to be reported elsewhere). Two standard operating protocols (SOPs) were developed for reporting any adverse events. SOP One addressed probable mood disorder in participants with high scores on mood disorder PROMs; SOP Two addressed suicidal ideation. The SOPs directed the researcher to refer participants to their GP or other appropriate mental health specialist. SOP One participants remained in the trial; SOP Two required participants to be excluded.

Data Analyses

A statistical analysis plan was developed and approved before commencing analysis of the PROMs data and the unit of analysis was the participant—i.e., the stroke survivor. Descriptive statistics and R statistical software (RStudio Team 2020.03.0 + 454, "Chocolate Cosmos", running R 4.3.2) were used to summarize participant characteristics, their outcome measures, and any adverse events. There were no formal tests of statistical significance as this pilot trial was not powered to detect effectiveness. Analysis was conducted using intention to treat. CONSORT guideline extension for pilot trials informed the data analysis (Eldridge et al., 2016). There was no sub-group analysis. EQ-5D-5L was scored using the EuroQol crosswalk (van Hout et al., 2012). Mean change in utility scores and EQ-VAS scores were reported with estimates of precision (standard deviation (SD), min and max scores). Self-reported healthcare resource use during the study period was summarized and presented by trial arm. Components of intervention delivery were itemized and unit costs from the Personal Social Services Research Unit were attached to each item of resource (Jones & Burns, 2021).

Results

The T0 to T1 DASS total mean score for HEADS: UP improved in the direction of expected effect (i.e. in favor of HEADS: UP) from 46.20 ($SD = 24.00$) to 24.00 ($SD = 16.10$)

which suggests "recovery". This compared with a "non-reliable change" of 36.10 (18.70) to 31.6 (20.40) for TAU. Both HEADS: UP and TAU continued to improve by T2 and T3 (Online Resources 5, 7, 8 & 9; 6 for PROMs' symptom severity). BDI-II scores for HEADS: UP at T0 and T1 were 24.70 ($SD = 12.60$) and 12.40 ($SD = 8.20$) which corresponded to a shift from "moderate" to "minimal" symptoms for HEADS: UP. The BDI-II scores for TAU at T0 and T1 were 21.30 ($SD = 9.90$) and 17.60 ($SD = 9.20$) which suggests symptoms remained in the "moderate" category. At T2 and T3 HEADS: UP mean BDI-II symptom scores improved further and remained "minimal" at 13.20 ($SD = 7.40$) and 12.5 ($SD = 7.10$). Whilst TAU mean BDI-II scores at T2 and T3 were 18.11 ($SD = 9.30$) and 18.0 ($SD = 9.00$), representing worsening scores at each timepoint but still in the "mild" symptom category (Online Resources 5, 7 & 8). BAI scores for HEADS: UP at T0 and T1 were 23.10 ($SD = 11.90$) and 11.60 ($SD = 8.90$) versus 16.30 ($SD = 10.00$) and 14.10 ($SD = 9.50$) for TAU, which corresponded to a shift from "moderate" to "mild" symptoms for both groups (Online Resources 4 & 5). Both HEADS: UP and TAU BAI scores remained "mild" at T2 and T3 (Online Resources 7 & 8).

The HEADS: UP group had an attrition rate of 33.3% by 6-month follow-up (T3), lower than the estimated 44%, which ensures sufficient participants for the pilot trial objectives (Julious, 2005). However, HEADS: UP attrition was higher than TAU (21.90%). Males in the HEADS: UP group were more likely to drop out than females, and participants longer post-stroke appeared more likely to discontinue.

While this pilot trial was not designed or powered to test the effectiveness of HEADS: UP, exploratory between-group comparisons were conducted to inform the selection of a candidate primary outcome measure for a future definitive trial. As shown in Table 2, effect sizes (Cohen's d) were calculated using mean change scores and standard deviations for the BAI, BDI, and DASS subscales. All three measures demonstrated were deemed to have "large" (> 0.80) effect sizes (BAI Cohen's $d = 0.91$; DASS: $d = 0.89$ BDI: 0.86), with BAI showing the largest. Among the DASS subscales DASS-S (stress) and DASS-A (anxiety) produced large effect sizes (Cohen's $d = 0.94$ and $d = 0.88$, respectively) while DASS-D (depression) produced a 'moderate' (> 0.50) effect size (Cohen's $d = 0.51$). Although the BAI appeared less favorable due to both HEADS: UP and TAU groups improving from "moderate" to "mild" symptoms, it had the largest effect size and may be the most sensitive measure for detecting change between T0 and T1. There were two occasions when participants ($n = 2$) chose not to provide data due to mental health distress unrelated to the trial. A Serious Adverse Event was recorded when one HEADS: UP trainer died suddenly during the study and this unrelated event had an impact on participants, a fellow trainer, researchers, and research processes. High PROMs scores (SOP One) were recorded fourteen times (HEADS: UP $n = 4$, 13.30%; TAU $n = 10$, 31.30%) and suicidal ideation (SOP Two) four times (HEADS: UP $n = 1$, 3.30%; TAU $n = 3$, 9.40%).

Health economic assessment

The economic evaluation feasibility study findings are summarized here. For full details of health economic assessment methods and results see Fenocchi et al., (in peer review). Most participants (> 95% at each timepoint) provided data about health outcomes measured using EQ-5D-5L and about health care resource use. Completion of RUQ and EQ-5D-5L are presented in Table 3. From the EQ-5D-5L, no statistically significant difference in health-related QoL was observed between groups cross-sectionally at any timepoint (Online Resource 9). Both groups indicated improvement over time (utility scores for the HEADS: UP group

Table 2 Between group effect sizes

Outcome measure	Group	Mean change score	Pretest *SD*	Posttest *SD*	*N* (at T1)	*N* (at T0)	Cohen's *d* (*n* at T0)	Interpretation
BAI	HU	11.49	11.85	8.90	25	30	0.91	Large effect
	TAU	2.22	10.04	9.54	25	32		
BDI	HU	12.34	12.56	8.22	25	30	0.86	Large effect
	TAU	3.67	9.87	9.22	25	32		
DASS-A	HU	5.73	8.66	5.60	25	30	0.88	Large effect
	TAU	−0.11	5.02	6.71	25	32		
DASS-D	HU	8.28	10.90	7.30	25	30	0.51	Moderate effect
	TAU	3.38	10.59	9.66	25	32		
DASS-S	HU	8.19			25	30	0.94	Large effect
	TAU	1.20			25	32		
DASS-T	HU	22.20	24.00	18.70	25	30	0.89	Large effect
	TAU	4.46	16.07	20.43	25	32		

Table 3 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%)

Key LTFU Loss to follow up; *not necessarily all questions within tool

ranged from −0.04 to 1.00 at T0 ($n=25$), and 0.32 to 1.00 at T3 ($n=20$), compared with TAU from 0.08 to 0.85 at T0 ($n=25$), and 0.16 to 1.00 at T3 ($n=25$)) although small numbers preclude conclusions. The highest reported categories of health care resource use were for hospital outpatient appointments and GP appointments (telephone, online and in person combined). A few participants reported appointments with a psychologist about their anxiety or depression symptoms, or both. Healthcare resource use at each time point is presented in Online Resources 10, 11, 12. Estimates of the costs of delivering HEADS: UP indicated a time commitment of 70.5 hr from a single practitioner for training specifically in HEADS: UP course delivery (10.5 hr) and online course delivery (60 hr, ranging 22.5 hr to 26 hr), plus central resources (time of trial team at university to train-the-trainer, and provision of materials) necessary for ensuring fidelity to the HEADS: UP delivery model.

Discussion

Helping Ease Anxiety and Depression After Stroke (HEADS: UP) is a stroke–specific adaptation of MBSR and proved feasible and acceptable in this mixed-methods pilot RCT. Outcome measures demonstrated greater mean score improvement with HEADS: UP compared to TAU. [Note: qualitative outcomes are to be reported elsewhere.] The revised recruitment target was achieved, and the community-based recruitment strategy exceeded the recruitment rate normally seen in stroke trials (2.9 participants per week versus 1–2 stroke survivors per month (McGill et al., 2020)). Shorter recruitment windows have been reported elsewhere when using social media to recruit to healthcare research studies (Whitaker et al., 2017). A recent review reported "early signs of effectiveness" of social media recruitment strategies across a range of clinical trials (Zimmerman et al., 2022). In this study, the recruitment strategy relied predominantly on pre-existing networks and on social media platforms. However, as the study progressed the reach of the online posts was diminishing, and it is unlikely the initial success using social media would have been sustained over time. In a future large-scale trial, a fully resourced recruitment plan would be needed to bolster long-term recruitment (Schoultz et al., 2015).

Using TAU as the control condition in the RCT prompted two participants to drop out when they were not being randomized to HEADS: UP. This design of RCT is known to be challenging and risks drop-out due to reluctance at being denied a potentially therapeutic intervention. To minimize this risk of dropouts from the TAU arm all participants were provided with an explanation of the study design and the value of both the HEADS: UP group and the TAU group. This approach highlighted the importance of research and the altruistic value of participation to help other stroke survivors (Calitri et al., 2021). Future trials may need to explore ways of reducing the perception of a favored intervention to ensure trial equipoise (Chard & Lilford, 1998).

Adherence rates with MBIs vary considerably (20%−81%) across different cohorts with chronic disease/co-morbidities (Blankespoor et al., 2017; Cash et al., 2016; Lawrence et al., 2013; Parkinson et al., 2019; Simpson et al., 2014). A recent study of MBSR in stroke reported 93% adherence to weekly sessions and personal practice times of 3.1 h per week (Baldo et al., 2021) although variability was considerable across the small cohort ($n=16$). Another recent study with stroke survivors used a modified MBSR intervention and reported 83% adherence (Wrapson et al., 2021). This study achieved a high rate of session adherence and participants practice logs indicated frequent home practice. This suggests that condition-specific adaptations of MBIs may be more accessible and acceptable to participants, as has been suggested in studies of the standardized MBSR course in cohorts with chronic conditions (e.g. Wrapson et al., 2021; Cash et al., 2016; Schoultz et al., 2015). Whilst participants in this study did not record practicing for the 45 min per day originally recommended by Kabat-Zinn (1982), they did approximate 20 min of daily practice, a finding which echoes that of other studies and is perhaps a more realistic aim for people starting out on their mindfulness journey (Cash et al., 2016; Parkinson et al., 2019). Interestingly, previous studies of MBSR in people with chronic disease have found frequency of practice rather than duration to be associated with improved outcomes (Merkes, 2010), indicating, perhaps that interventions and applications to support frequency and duration of practice, tailored to the needs of stroke survivors

are required to supplement HEADS: UP and other MBSR courses.

Although this pilot trial was not designed to evaluate the effectiveness of HEADS: UP, exploratory between-group comparisons were undertaken to provide insights into the suitability of candidate outcome measures for a future RCT. Effect size calculations using Cohen's *d* highlighted notable differences between the intervention and control groups. All three measures—BAI, BDI, and DASS—demonstrated "large" (Cohen's $d > 0.8$) effect sizes, with the BAI showing the largest ($d = 0.91$). These results highlight the potential sensitivity of BAI in detecting changes over time, even if both groups showed improvement. Such comparisons, while exploratory, contribute valuable preliminary data to guide the selection of a primary outcome measure in a definitive RCT.

This study considered whether attending the HEADS: UP course with another person would support adherence to the weekly sessions and home practice. However, contrary to expectation, most participants elected to take part alone and those participants attending with a partner attended fewer sessions than lone participants. Similarly, Cash et al., (2016) in their study of MBSR with participants with Parkinson's Disease (PD) and their caregivers, found that only 30% of PD participants elected to take part along with a caregiver. Of the stroke survivors who took part with another person in the current HEADS: UP RCT study, some only required assistance to get online and then continued unaccompanied, others completed the course together. Earlier studies of stroke survivors using online MBIs found that in some instances, participants and their supportive partner were working together—often offline – discussing session content and supporting each other's practice (Lawrence et al., 2024; Parkinson et al., 2023). It appears that modes of participation with another person vary from dyad to dyad suggesting that MBSR courses need to be sufficiently flexible to accommodate the varying support requirements of stroke survivors and to accommodate those who choose to attend either with or without a supportive partner.

Findings from previous studies indicated that participants thought online completion of PROMs would be less burdensome than having to complete paper copies and somehow get them back to the researchers, most typically by mail (Lawrence et al., 2024). Whilst most participants in this study did complete the measures online, some participants, particularly those with cognitive problems, required email and SMS reminders to ensure timely completion of PROMs. Similarly, other studies with stroke survivor participants have found supportive tactics such as the ones reported here similarly effective in improving rates of compliance with intervention and research processes (e.g. Atkinson et al., 2023).

The BAI demonstrated the largest effect size from the three candidate PROMs (BAI, BDI, DASS). The DASS subscales revealed differences, in that the stress and anxiety subscales had "large" effect sizes compared with a "moderate" depression subscale effect size. This suggests that improvements in anxiety and stress were most frequently reported, and that using the BAI may be a sensible choice for a future trial. However, the BAI initially appeared the least favorable as both HEADS: UP and TAU groups shifted from "moderate" symptoms at T0 to "mild" symptoms at T1. Therefore, in the planning for a future definitive trial, this decision should be made with an Expert Advisory Group (including experts by experience) and the trial statistician, informed by updated evidence review of clinically and statistically significant changes in definitive RCT primary outcome measures, in any relevant reported studies.

Determining the economic value of interventions depends on the collection of costs and outcomes data to inform estimates of potential cost-effectiveness (Drummond, et al., 2015). When determining clinical guideline recommendations, the paucity of published stroke intervention cost-effectiveness data may be limiting (Cadilhac, et al., 2020). Therefore, ensuring the feasibility of collecting health economic data ahead of a definitive trial is important. In this study, the opportunity to pilot instruments used to collect costs and outcomes data confirmed the feasibility of collecting EQ-5D and resource-use data for use in economic evaluation. Also, additional participant costs were identified that should be considered for collection in future work, including travel costs and impacts on employment (time off work, change in employment status) and other economic activities.

Limitations and Future Research

The exclusion of people with aphasia is a limitation frequently noted in stroke intervention research (Shiggins et al., 2024) and may, at least in part, be related to the additional time and resources required to ensure meaningful involvement of people with moderate to severe communication impairment. An additional concern for people with aphasia in the context of a standardized MBSR course is that course content increases in difficulty, both in terms of the concepts being explored and the language used to describe them as the course progresses (Pieri et al., 2022a). Therefore, we determined that further adaptation of HEADS: UP would be required to ensure its accessibility for people with moderate-severe aphasia, and a PhD study commenced concurrently with this RCT, to develop HEADS: UP Aphasia (Pieri et al., 2022a, 2022b).

The study aimed to recruit a representative sample of the stroke population of the UK across a range of characteristics, including geographic location, socioeconomic profile, and ethnic diversity. Whilst the sample included some island-dwelling participants, most lived in or close to major conurbations. 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. It is acknowledged that in Western societies MBIs are typically accessed by well-educated, White populations, so future research will need to develop recruitment strategies to enhance inclusivity across social groups and cultures (Oman, 2023). Such strategies include expanding networks to include community-based faith groups and partnerships and working collaboratively with such groups to consider how best to "brand" HEADS: UP to enhance perceptions of relevance across diverse populations, ahead of and during a future definitive trial (Zimmerman et al., 2022).

The observed attrition rate in the HEADS: UP group at six-month follow-up was lower than the anticipated 44% benchmark, aligning with UK NIHR recommendations for pilot and feasibility studies. However, attrition was higher in the HEADS: UP group (33.3%) than in the TAU group (21.9%). Analysis of participant characteristics revealed that fewer males (9) than females (21) were randomized to the HEADS: UP group, whereas the TAU group had a higher proportion of males (18) than females (14). This imbalance may have influenced the attrition patterns observed, although the extent to which this was directly related to the intervention remains unclear. Additionally, participants further post-stroke were more likely to discontinue. A large, definitive RCT would allow for a more robust randomization to better account for time-post stroke differences and ensure balanced group characteristics. Conversely, the relatively low attrition rate in the TAU group, often harder to retain due to the absence of an active intervention, may reflect the effectiveness of recruitment and retention strategies, such as regular participant contact and emphasizing the altruistic value of participation.

Whilst the independent statistician conducting the analysis was blinded to allocation, the research team and participants were not—a potential source of bias. In a future definitive RCT, independent researchers will manage data collection, analysis, and reporting processes. Randomization was effective in ensuring equal distribution of participants attending with a supportive partner between the two trial arms. However, between group differences were evident in relation to gender, time post-stroke, employment status and educational attainment, reflecting the pilot trial's smaller sample size and the associated increased likelihood of random imbalances in baseline characteristics (Netz et al., 2019). In a future definitive RCT a larger sample size will help eliminate these imbalances, and a more robust randomization strategy will be used. Specifically, variable-sized permuted blocks could be used to maintain allocation concealment and flexibility, while stratification could incorporate key variables such as gender, time-post stroke, and baseline anxiety and depression severity to maintain group balance. These measures will support more equitable group characteristics and strengthen validity of trial outcome data.

In conclusion, HEADS: UP Online intervention and research processes are feasible and acceptable. Results indicate a positive impact on mood and quality of life outcomes. Future large-scale research is warranted to assess effectiveness and cost-effectiveness and to identify any implementation and scalability issues.

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All authors read and approved the final manuscript

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Data Availability The results of the analysis of all quantitative PROMs collected during this study are included in this published article and its supplementary information files. However, the datasets generated during the study are not publicly available because, in line with

contemporaneous conventions and university policies, participants in the HEADS: UP Online pilot RCT gave consent for us to store their data for five years, after which time the data will be securely destroyed (September 2027).

Declarations

Ethical Approval This study was approved by the Department of Nursing and Community Health Research Ethics Committee at Glasgow Caledonian University, Scotland, UK. (24.06.2021; HLS/NCH/20/038 HEADS: UP).

Conflict of Interests The authors declare no conflicts of interest with respect to the research, authorship, or publication of this article.

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