Title: ACT for Post-Stroke Adjustment Via Telerehabilitation

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ACT for Post-Stroke Adjustment Via Telerehabilitation

Aims

The primary aim is to assess the preliminary efficacy of an adapted eight-week group of acceptance and commitment therapy (ACT), developed following Majumdar and Morris' 2019 study, that is delivered via telerehabilitation using idiographic methods.

The second aim is to explore the preliminary feasibility and acceptability of the intervention for adult stroke survivors.

Background

Stroke

With more than 1.3 million stroke survivors in the UK, stroke is considered one of the UK's main causes of disability (Stroke Association, 2017). The risk of stroke increases exponentially with age (Truelsen et al., 2006), but can have a detrimental impact on an individual's life regardless, affecting social interactions (Vickers, 2010), mood (Hilari, 2011) and activities of daily living (Hilari, 2011; Lazar & Boehme, 2017). Changes can be unexpected and difficulty adjusting could get in the way of rehabilitation (Mahmoud & Elaziz, 2016), affecting quality of life (QOL) (Bays, 2001; Jeong et al., 2012). Consequently, stroke survivors identify improvements to mental health services as an important research area (Weerasekara et al., 2021), and psychological intervention for wellbeing and adjustment is within the top 10 priorities for stroke rehabilitation (JLA, n.d.).

According to NICE (2023) Guidelines for psychological functioning in stroke rehabilitation, clinicians should assess changes to the way individuals adjust and cope, including monitoring of emotional functioning and behaviour. Specifically, Acceptance and commitment therapy (ACT) is recommended for those most at risk of anxiety or depression post-stroke (National Clinical Guideline for Stroke, 2023).

Acceptance and Commitment Therapy

ACT is a psychological intervention (Harris, 2019; McHugh, 2011) aiming to alter how individuals relate to distress following unexpected changes in circumstance, rather than change the distress itself (Hayes et al., 2006). ACT is therefore favoured for promoting wellbeing in adults living with long-term health conditions, including brain injury (Sander et al., 2021), chronic pain (Hughes et al., 2017), and multiple sclerosis (Han, 2021).

ACT incorporates the hexaflex model, referring to six core components of psychological flexibility (PF; Bond et al., 2015), where PF is the ability to act in line with our values (Doorley et al., 2020; Harris, 2019). The components include acceptance, contacting the present, values, committed action, self as context and defusion (Bond et al., 2015; Harris, 2019), which are grouped into a triflex of being present, opening up, and doing what matters (Harris, 2019).

In ACT, distress is considered normal due to the inevitability of adversity which prevents individuals from moving toward their goals and values (Harris, 2019). Cognitive therapies, however, argue a need to treat and therefore control distress (Hayes et al., 2006). This teaches clients to challenge their thoughts (Graham et al., 2015), undermining stroke survivors' understandably difficult circumstances (Gregg et al., 2007).

Consequently, ACT is preferred for addressing distress post-stroke because those with an acquired brain injury (ABI) must learn to accept their new difficulties/limitations and live with some uncertainty as part of moving forward with their life (Kangas & McDonald, 2011).

ACT Post-Stroke

The extent ACT reduces distress post-stroke is not yet known (Graham et al., 2015), possibly due to no consensus on the format/length of the intervention. However, many studies have started identifying the efficacy of ACT on wellbeing post-stroke and (more generally, ABI populations) using numerous methods, including case studies, bibliotherapy, and single-case experimental designs (Gladwyn-Khan & Morris, 2023; Graham et al., 2015; Niu et al., 2022; Ooi & Steverson, 2023; Rauwenhoff et al., 2023; Sathananthan et al., 2022).

Considering current waitlists in healthcare and the cost of implementing interventions into the NHS, group-based psychological therapies could be more practical. In 2019, Majumdar and Morris conducted a four-week, face-to-face ACT group intervention that was adapted for stroke survivors. They found that ACT led to clinically significant improvements in depression and increased self-reported ratings of health status and hopefulness, compared to controls receiving treatment as usual (Majumdar & Morris, 2019).

Further research comparing ACT to other psychological interventions (such as cognitive behavioural therapy) would be beneficial in establishing its true effectiveness, providing a potential topic for systematic review. However, a significant problem with research thus far, and in particular Majumdar and Morris' (2019) study, is the focus on wellbeing, QOL and mood, rather than the constructs of ACT (Doorley et al., 2020). While important to monitor wellbeing with any psychological intervention and its pertinent links with acceptance (Lander, 2009; Simione et al., 2021; Townend et al., 2010), it remains unclear whether ACT achieves its primary aim in supporting stroke survivors to accept and adjust to their circumstances.

Consequently, qualitative research using a grounded theory approach with Majumdar and Morris' (2019) participants, found preliminary evidence that ACT helps those experiencing psychological distress when adjusting post-stroke (Large et al., 2019). Notably, this study also proposed modifications for the four-week intervention to improve accessibility which has not yet been assessed experimentally (Large et al., 2019). These modifications included extending the intervention from four to eight weeks and is currently being rolled out in a stroke healthcare setting in Wales NHS. As an initial monitoring of outcomes in a clinical setting, the service uses the Short Warwick Edinburgh Mental Wellbeing Scale to monitor overall wellbeing and the UK Social Value Bank (HACT, 2017) to assess cost effectiveness of the intervention in regard to its impact on wellbeing and quality of life.

The literature therefore highlights a need for further research into the efficacy of ACT for post-stroke adjustment, including the empirical assessment of the modified ACT intervention from Majumdar and Morris' (2019) study.

Telerehabilitation

In addition to the benefits of group-based interventions in the NHS, the delivery of post-stroke healthcare via telerehabilitation (rehabilitation using technologies such as telephone, videoconferencing and web-based resources (Brennan et al., 2009; Signal et al., 2020)) is recommended in NICE (2023) Guidelines. Telerehabilitation improves accessibility of healthcare for those who cannot travel or access transport (Ostrowska et al., 2021). This is important given the risk of stroke increases exponentially with age (Truelsen et al., 2006) as older adults are more likely to have disabilities (Coleman, 2023) and/or live in rural or coastal areas far from healthcare services (Office for National Statistics, 2022).

To start assessing the efficacy of ACT via telerehabilitation, Ooi and Steverson (2023) conducted a case study, finding that six sessions improved psychological distress, depression and PF which was also maintained after six months. Given these findings, and a recent Cochrane review emphasising a need for more research into the efficacy of psychological therapy via telerehabilitation post-stroke (Laver et al., 2020), it is important to further explore the efficacy of ACT-based telerehabilitation for post-stroke adjustment.

Research Questions

Is group-based ACT delivered via telerehabilitation efficacious in managing post-stroke adjustment difficulties?

Is this intervention feasible and acceptable for adult stroke survivors?

Methods

Design

This is a single-case experimental design (SCED) using a small sample size and repeated collection of outcome measures (Krasny-Pacini & Evans, 2018).

In SCEDs, each participant serves as their own control (Tate & Perdices, 2019), but to improve validity and reliability, a multiple baseline design (MBD) will be adopted where participants are randomly allocated a baseline length before starting the intervention (Bouwmeester & Jongerling, 2020). This allows for longitudinal monitoring of stability in scores, improving confidence that changes observed are due to ACT and not other factors, evidencing “a potential treatment effect” (Slocum et al., 2022, p. 622).

According to Bouwmeester and Jongerling (2020), the MBD holds more power with groups of participants than single cases as outcomes in each phase are averaged. The revised “quality rating scale for [the] Risk of Bias in *N*-of-1 Trials” therefore argues a minimum of five datapoints at baseline (Tate et al., 2013, p. 619). This improves monitoring of the level, trend, and variability of data, which is important if attrition is high (Kratochwill et al., 2010). The baseline length will range from five to seven weeks.

Attrition is problematic when participant dropout causes less than five datapoints at baseline or occurs at a critical timepoint (e.g., during the intervention) (Kratochwill et al., 2010). Attrition at each stage will be reported in a flow chart, as per the Reporting Standards for Research in Psychology (APA, 2008).

The risk of attrition will be mitigated using a two-phase AB design, whereby A is the baseline (control), and B is the intervention (Levin et al., 2021). The longevity of change will be monitored three- and six-months post-intervention, reducing study demands compared to an ABA design where the second A acts as another control (Kazdin, 2021). Six-month follow-ups may occur after thesis submission for the purpose of publication if recruitment presents a challenge.

Participants

Nine adult stroke survivors will be recruited via NHS services (e.g., Early Supported Discharge Stroke Teams, IAPT services) and stroke charities. In SCEDs, six participants are recommended (Kratochwill et al., 2013), though nine will be recruited to account for attrition, with three being assigned to each baseline length (five, six, or seven weeks).

Inclusion

Adults (>18 years) will be included if they have:

- Suffered a stroke over three months ago.
- No other neurological illness.
- Not currently receiving any psychological intervention.
- No severe communication difficulties.
- No severe cognitive impairments.
- No current or historical suicidal ideation/self-harming behaviours.
- Not been diagnosed with major long-term health conditions in the last 12 months (except for stroke or trans-ischaemic attack; TIA).
- Access to a device with a camera, stable internet connection and private space.

Inclusion criteria ensure any changes are due to the intervention and not other factors such as spontaneous recovery from stroke which typically occurs within the first three months (Cassidy & Cramer, 2017; Zeiler, 2019); and other rehabilitative or psychological programmes. Criteria also ensures the monitoring of post-stroke adjustment rather than adjustment to other health conditions.

Exclusion

Participants will be excluded if they have:

- Had a TIA without the presence of a stroke.
- No current distress around adjusting to the consequences of stroke.

- Distress of a severity that it cannot be managed safely in a group therapy setting

Distress will be assessed using the Clinical Outcomes in Routine Evaluation – 10 (CORE-10) as it is considered valid and reliable in UK primary care populations (Barkham et al., 2013).

Measures

Outcome measures will be completed weekly, pre- and post-intervention or at three- and six-month follow-ups to reduce participant burden associated with frequent questionnaire completion. This is important as attrition is more likely amongst stroke survivors if studies are time-consuming (Weerasekara et al., 2021).

Less frequently collected measures were decided based on the secondary gains of ACT, the importance for between-study comparisons in assessing intervention efficacy and the second aim of feasibility and acceptability.

While some measures are not validated post-stroke, Bouwmeester and Jongerling (2020) suggest that the repeated collection of data in a SCED provides increased reliability in the test statistic.

CompACT-10

The Comprehensive assessment of Acceptance and Commitment Therapy Processes (CompACT) assesses PF (Francis et al., 2016) from the “three dyadic ACT processes”: openness to experience (OE), behavioural awareness (BA) and valued action (VA) (Golijani-Moghaddam et al., 2023, p. 60). The CompACT-10 (not attached due to copyright) has 10 items with acceptable to excellent internal consistency (Cronbach’s alpha, α, “total = 0.81, OE = 0.70, BA = 0.79, and VA = 0.75”), test-retest reliability (intraclass correlations, ICC, total = 0.83; OE = 0.86; BA = 0.76; VA = 0.89), convergent validity with the acceptance and action questionnaire-II (rs = -0.65 and -0.70) and concurrent validity with measures of wellbeing (rs = 0.66 and 0.67) amongst UK-representative samples (Golijani-Moghaddam et al., 2023, p. 64).

Higher scores indicate greater PF (Golijani-Moghaddam et al., 2023) and will be completed weekly during baseline/intervention phases and repeated at follow-up.

Community Integrated Questionnaire (CIQ)

The CIQ has 15 items assessing participation in relation to three subscales: home/social integration and productivity (Wilier et al., 1994). Each item has a three-point scale and is totalled for an overall score, whereby higher scores indicate greater independence for activities such as managing finances, housework, employment/volunteering and socialising (Dalemans et al., 2010). Data will be collected pre/post-intervention and at follow-up.

The CIQ has high test-retest reliability (ICC = 0.997) amongst geriatric populations (Singh & Sharma, 2015) and good internal consistency (α = 0.71 – 0.84) and test-retest reliability (ICC = 0.91-0.97) amongst adults with neurological conditions (Turcotte et al., 2019). The measure has also been extensively used in stroke research (Lee et al., 2015; Matos et al., 2020; Sathananthan et al., 2022).

Clinical Outcomes in Routine Evaluation-10 (CORE-10)

The CORE-10 is a 10-item questionnaire assessing psychological distress that is considered valid and reliable in UK primary care populations (Barkham et al., 2013). Each item is rated on a 5-point Likert scale from ‘not at all’ to ‘most or all of the time’ and provides a total clinical score where higher scores are indicative of more severe psychological distress (Barkham et al., 2013).

Amongst a post-acute stroke sample, the CORE-10 was considered to have high internal consistency (α = 0.80) and test-retest reliability (ICC = 0.81) as well as acceptable concurrent validity with measures of depression and anxiety (*r* = 0.49 – 0.89) (Steverson et al., 2024).

Aside from its validity and reliability, the CORE-10 was chosen due to its wide use in research and clinical settings, allowing for between-study comparisons and monitoring of wellbeing for early signposting (see ‘Ethics: Risk Management’). This data will be collected pre/post-intervention and at follow-up.

Stroke-Specific Quality of Life (SS-QoL)

SS-QoL measures health-related QOL amongst stroke survivors (Vincent-Onabajo et al., 2016). The 12-item version refers to domains of self-care, mobility/upper extremity, language, vision, thinking, work/family/social roles, personality and mood/energy which are rated on a five-point scale to generate a mean total score and physical and psychosocial sub-scores (Post et al., 2011). The measure has good internal consistency ($\alpha = 0.77 - 0.89$) (Post et al., 2011) and is validated in a bi-ethnic stroke population (Kerber et al., 2013).

Higher mean scores indicate better QOL (Vincent-Onabajo et al., 2016). Data will be collected pre/post-intervention and at follow-up.

Short Warwick Mental Wellbeing Scale (SWEMWBS)

SWEMWBS is a seven-item questionnaire that monitors mental wellbeing (Stewart-Brown et al., 2009). Each positively phrased item is ranked on a Likert-scale of one (none of the time) to five (all of the time) and totalled to provide an overall score, whereby higher scores indicate better mental wellbeing (Stewart-Brown et al., 2009). The scale has been validated across clinical (Shah et al., 2021; Vaingankar et al., 2017) and non-clinical populations (Ng Fat et al., 2017), and is comparable to the 14-item version (Ng Fat et al., 2017). SWEMWBS is also considered responsive to change following therapeutic intervention at a group and individual level (Shah et al., 2018).

Beyond assessing mental wellbeing, the scale also assesses cost effectiveness of an intervention in regard to its impact on wellbeing and quality of life (HACT, 2017). Therefore, data will be collected pre/post-intervention and at follow-up.

Feasibility and Acceptability

Immediately after the intervention, participants will complete a questionnaire created for the purpose of this study to address the second aim on intervention acceptability. No gold standards for satisfaction scales currently exist, but they typically include satisfaction and staff skills (Miglietta et al., 2018).

Feasibility will be assessed using six criteria monitoring attrition, attendance and homework completion, as per previous research (Sathananthan et al., 2022).

Procedure

A poster will be circulated via NHS services and stroke charities, containing a link to an online survey (JISC, 2021). Here, participants can view the information sheet, consent form, and eligibility questionnaire. A consent to contact form and researcher contact details will be available should anyone prefer discussing the study before consenting to participate. To ensure accessibility to the study, the consent to contact form can be signed by the individual themselves or, if unable to sign (for example, due to physical impairment following stroke preventing ability to write, or due to healthcare appointments being held remotely), they can provide verbal consent to be contacted by the researcher to their clinician. The clinician can then sign the consent to contact form on their behalf.

Those meeting the inclusion criteria will attend a 30-minute video call to confirm eligibility, including ability to use videoconferencing platforms as per guidance for remote research (McCarthy et al., 2021). Guidance for accessing video calls will be provided.

Once a group is identified, participants will be randomly allocated to a baseline length (five, six or seven weeks) and provided a start date. Visual calendars will mark the dates of each phase/task. Reminders and links to the questionnaire will also be sent weekly. During baseline and intervention phases, the CompACT-10 (Golijani-Moghaddam et al., 2023) will be completed weekly.

The intervention, delivered by the research team, lasts eight weeks. Each session is two hours, including breaks. Permission to access the protocol for the modifications to the intervention was granted (Large et al., 2019) and has been received. ACT training will be sought for the chief investigator prior to the study commencing.

Participants will have time at the end of each session for group reflections with reminders of where to access mental health support.

Immediately before and after the intervention phase and at three- and six-month follow-ups, participants will complete all questionnaires. At six-months, a 30-minute debrief will be offered.

As per the BPS Code of Human Research Ethics (BPS, 2021), all participants will receive a £10 gift card as reimbursement for their time.

For the purposes of this research, the end of the study will be defined as the date of the final data collection point from the last participant. This will mark the completion of all study-related procedures, including follow-up data collection. The study will be formally closed following data verification and any required reporting to the REC and HRA.

Patient and Public Involvement (PPI)

Patient and public involvement (PPI) was conducted with two older adults who have suffered a stroke. The purpose was to inform accessibility and readability of the research poster, information sheet and consent form. They were also asked to complete the questionnaires to ascertain how long it takes to complete and how many breaks would be required. They were also involved in discussions around the format of the questionnaires (online versus paper) and how to best remind participants at each stage of the study. This enabled assessment of potential participant burden of the study and for appropriate adaptations to be made.

The first stroke survivor was an older adult, who has been involved in a multitude of PPI over the last 20 years. They have supported various healthcare services, universities, charities, research groups and ethics committees to develop projects by participating in panels and focus groups, commenting on research materials such as advertisements and providing feedback on how to adapt procedures/interventions/designs to improve accessibility. This individual provided the perspective of a service user having suffered a stroke themselves; the perspective of a carer for someone with a physical health diagnosis; and the perspective of a healthcare professional who previously worked on a ward with patients who had suffered a stroke. This range of perspectives meant valuable insights were provided from multiple angles to improve the accessibility of each aspect of the study in the design stage. In particular, they offered insights into how we can best recruit via the NHS and provided creative suggestions for overcoming any potential barriers raised.

The second stroke survivor was an older adult who had suffered two strokes 12 years ago. They presented with mild aphasia and cognitive difficulties, which sometimes impacts word finding or problem solving/processing of complex information. This did not significantly impact their ability to communicate or understand information, but they did require some additional time for processing. Additional processing time is a common feature post-stroke, so they were selected to help us ascertain the potential burden the study materials may place on participants. This perspective was critical given the study does not plan to exclude those with mild language or cognitive difficulties. Below is a summary of the changes made following PPI.

Recruitment and Eligibility

For the poster, the feedback suggested that it was difficult to process due to being quite busy with no clear order of how to read the boxes. Therefore, the font within the main body was made bolder, the spacing and arrangement of boxes was improved (increasing blank space) and steps (1, 2, 3 etc.) were added to improve readability. Some of the language was simplified, including the description of background research and combining the two aims into one. There were suggestions of making the benefits to the study clearer, though this was not amended to manage expectations of the study. The possible benefits to taking part are included in the information sheet, alongside the potential risks, which provides a more balanced overview so the individual can feel confident they are making a fully informed decision.

For the information sheet and consent form, feedback overall was positive whereby comments referred to the layout, design and wording being clear. Within the information sheet, a description of what OneDrive is was added as suggested and the explanation of what research has shown was improved for coherence. Within the consent form, a line was added for participants to consent to the research team contacting them via the details provided as this was previously missed.

There were some suggestions to alter some of the wording within the information sheet. This included changing “you will” to “I need you to”. These changes were considered but not applied to reduce the likelihood of those reading feeling pressured into taking part. It was felt that “you will” conveys that there is structure to the study and may reduce the potential impact of demand characteristics by not applying too much emphasis onto each component. Moreover, depending on the sentence, the gunning-fog index of the text increased if the change was made, so this was avoided to ensure the information is simplified for accessibility and reducing the potential for distress when reading.

The eligibility questionnaire also received comments that it was easy to read and follow with a clear layout. Suggestions were made around reminding participants of why we are asking for specific personal details (e.g. NOK), so this has been made more explicit. There were some questions around whether the distress scale referred to post-stroke distress or distress more generally, so this has also been made more explicit at the time the question is asked.

Video Call Instructions

PPI agreed these were clear and helpful and that it was well set out and logical. It was suggested that those unfamiliar with Teams may find it harder to follow, so we discussed alternative support that could be provided and agreed that talking to the participant via telephone as they are logging into a videocall can be provided prior to the study. It is hoped this will improve accessibility to the study.

Questionnaire Completion

PPI suggested the questionnaires should be conducted online rather than in paper format. Given the group therapy will be held online, they said it can likely be assumed the individual can use the basic functions of a device to do the questionnaire online. Additionally, it was agreed that paper surveys would increase burden placed on participants, whereby paper copies may get lost in the post or at home; they would need to be posted back, and not all stroke survivors are independent or able to get out easily; and surveys may not be completed at the right time. Therefore, online surveys were considered more practical and accessible to a wider population.

The platform chosen for the online survey (JISC) was one that allows participants to pause and return to. This means they do not need to complete the survey in one sitting. If they need breaks, this can be done easily, and they will not lose their answers.

To assess the potential for participant burden, PPI were asked to time how long it takes to complete each questionnaire, including recording any breaks they required. The 10-item questionnaire took one person 2 minutes and another 45 minutes. The 48- item questionnaire took both individuals 5-10 minutes to complete. This led to discussions around the impact of fatigue and distraction post-stroke so information at the start of every questionnaire has been added to encourage participants to complete at a time when they are less tired/distracted and to seek support if required. My contact details have also been added to every page of the questionnaire so that if the individual requires support in completing the questionnaire, they can easily get in contact to discuss. It is hoped this will improve participant's experience of the study by making it easier to complete.

In regard to the feedback questionnaire, PPI found the questionnaire easy to understand and follow. It was suggested that greater emphasis on how the feedback will be used will improve the detail in responses. There was a suggestion that discussing the feedback with each participant may help to make it feel more personable and as though their individual comments are heard. We discussed the potential challenges of this, whereby some participants may not feel able to provide honest feedback if asked directly. The anonymity of the online questionnaire may help participants feel confident to provide critiques and suggestions for improvements. Therefore, it was agreed that giving participants the option to discuss the feedback with the research team directly was the next best solution. For this reason, this has been explicitly mentioned at the start of the questionnaire.

The final component PPI were asked to consider was how and when reminders to complete the questionnaire should be sent. It became clear that how people are reminded can come down to a matter of preference. However, PPI suggested that text messages are often more likely to be seen sooner than emails. For this reason, participants will be reminded via text (from a work phone) and via email. Links to the questionnaires will be provided in both messages, so that they can be accessed however the participant prefers. Discussions from PPI indicated that a reminder the day before and on the day would be most beneficial, given they must be completed within a certain timeframe. There were also suggestions around sending an additional reminder at 5pm on the day the questionnaire is due if the participant has not completed the questionnaire. To monitor who has completed the questionnaires, a box for participants to provide their initials has been added to the start of every questionnaire (except the feedback questionnaire). It is important the feedback questionnaire is anonymous, so participants feel able to disclose honest opinions on their experiences of the therapy. In assigning initials to each questionnaire, it will also be possible to monitor psychological risk throughout the study to ensure participant safety.

Ethics

NHS Research Ethics Committee approval will be sought.

Informed Consent

All recruiting avenues will have access to the poster, information sheet, inclusion/exclusion criteria and consent forms, outlining the study's purpose, possible benefits/risks and handling of data. Documentation produced is informed by the Health Research Authority Guidelines (HRA, 2020).

Full written informed consent is required to access the eligibility questionnaire and individuals will be reminded of their right to withdraw at any time without explanation, as per BPS (2021) Ethical Guidelines. To improve accessibility, a consent to contact form is available (which can be signed by the individual themselves or by their clinician on their behalf following verbal consent to be contacted) and researchers can be contacted directly prior to consenting to participate.

Mental Capacity

All participants must have capacity to consent to participating. In accordance with the Mental Capacity Act 2005 (Department of Constitutional Affairs, 2007), capacity will be assumed unless proven otherwise. Appropriate steps will be taken to support individuals to make and communicate their decision. If lacking capacity to consent to participating, individuals will be excluded as this may impact their ability to engage.

During the study, capacity to consent to participating will be assumed when questionnaires are completed (NHS, 2021). Capacity will be monitored throughout the intervention and if no longer stands, participants will be removed from the study given the possibility of discussing personal and/or sensitive topics with people they do not know.

Confidentiality, Anonymity and Data Protection

All information collected will be on a needs-to-know basis, in accordance with GDPR safeguards (ICO, 2020). Reasons for collecting personal information will be provided when requested. Data will be stored in a password protected file saved on University of East Anglia's OneDrive which is only accessible by the research team. All personal and identifiable information will be stored separately to questionnaire responses.

Participants will not be pressured into sharing personal details. Information shared during the intervention will be of their own volition, not discussed with others and anonymised in the final report with pseudonyms and all identifiable information removed.

While participants will be reminded of confidentiality at the start of each group, the sharing of information outside the group cannot be monitored. Participants will be informed of this risk prior to consenting to participate.

During the intervention, participants will be asked to join the videoconference platform from a safe/private space (McCarthy et al., 2021) and encouraged against using their full name for confidentiality reasons.

In accordance with the BPS (2021) Code of Human Research Ethics, confidentiality will be breached if participants are at risk of physical or psychological harm, including contacting their next of kin (NOK), GP, or emergency services. Participants will be informed of this prior to consenting to participate.

Coercion and Deception

Individuals will not be pressured into participating. All aims of the study will be provided prior to consenting. Participants will be reminded of their right to withdraw without explanation at the start of each questionnaire and intervention session.

Participant Distress and Burden

Questionnaires will be as short as possible and PPI will inform the accessibility of all supporting documents, reducing the potential for distress/burden from the point of advertisement and throughout.

While there is preliminary evidence of ACT improving mood post-stroke (Graham et al., 2015; Majumdar & Morris, 2019; Ooi & Steverson, 2023; Rauwenhoff et al., 2023; Sathananthan et al., 2022), potential risks will be highlighted during recruitment to improve feelings of preparedness and reduce the likelihood of distress.

Criteria of no severe cognitive impairments or communication difficulties will ensure participants can engage with the demands of the study, keeping distress and burden to a minimum. Excluding those without access to a private space during the intervention will reduce the likelihood of conversations being heard by those not participating and the associated distress this may cause for both participants and bystanders.

To minimise distress and burden during questionnaire completion and the intervention, breaks will be provided/encouraged. Group rules will encourage participants to be mindful of the sensitive nature of topics discussed and therefore how much they share with the group about their personal experiences.

Risk Management

Prior to consenting to participate, contact details for mental health services/charities/helplines will be provided at the end of the information sheet. This information will be re-sent with the questionnaires, during each session and at follow-up.

When assessing eligibility, individuals will be excluded if they have a history of complex mental health difficulties to ensure participants can engage with the content of the questionnaires and intervention. This will reduce the likelihood of sensitive topics of suicide in the group setting, further reducing the potential for participant distress.

As discussed under ‘Confidentiality, Anonymity and Data Protection’, participants must provide contact details for their NOK and GP at the time of consenting to participate to ensure appropriate steps can be taken if concerns for their wellbeing arise. If risk is identified during the intervention, as well as contacting the above, the individual(s) will be asked to stay on the call to discuss a safety plan. A risk management protocol will be followed.

Debriefing

Participants will have space for reflection in each group session. If risk is identified/disclosed in a session, participants will receive a 1:1 debrief with signposting as appropriate.

A 1:1 debrief will be given to all participants on study completion, outlining the aims/background, procedures taken place and why, and how to seek psychological support.

Analysis

Multiple methods of analysis are chosen to improve understanding and confidence in the results (Lane & Gast, 2014). These are outlined below.

Effect Size

Effect sizes estimate “the magnitude of a relationship”, irrespective of sample size (Tarlow & Penland, 2016, p. 228). To assess this, the percentage of non-overlapping data (PND) and percentage of data exceeding the median (PEM) are recommended for SCED’s with datasets smaller than 20 (Lenz, 2013).

The PND assesses the degree of change between baseline and intervention phases (Lenz, 2013) and can be easily interpreted due to its visual displays (Ma, 2006). It can be liable to Type II errors due to its focus on single data points (Ma, 2006; Tarlow & Penland, 2016), so Lane and Gast (2014) advise against using the PND alone.

To overcome this, Ma (2006) suggests using PEM which assesses the direction and magnitude of change. Scores range from zero to one (Ma, 2006), and while liable to Type I errors, is recommended in datasets that have outliers and/or variability (Lenz, 2013).

Due to their respective limitations, both the PND and PEM will be conducted to improve the validity and reliability of the analysis.

Visual Analysis (VA)

According to Kennedy (2005), VA is key for a SCED to demonstrate and interpret the effect of an intervention. It enables evaluation of the trend, level and stability of data (Lane & Gast, 2014).

Two types of VA will be conducted: a within-condition analysis assessing the pattern of data within each phase (Lane & Gast, 2014) and a between-condition analysis comparing data between each phase (Kennedy, 2005).

It is recommended that between-condition VA compares median rather than mean scores to minimise the influence of outliers (Lane & Gast, 2014). However, neither VA should be utilised in isolation (Lane & Gast, 2014) emphasising the importance of both for this project.

Reliable Change Index (RCI)

It is recommended that VA should be supported by statistical data analyses where possible (Bouwmeester & Jongerling, 2020; Morley & Adams, 1991). Therefore, RCI will be conducted to understand whether the change observed is significant and reliably exceeds what is expected from measurement error alone (Blampied, 2022; Jacobson & Truax, 1991).

Analyses will monitor changes between pre- and post-intervention scores and will be presented in a modified Brinley (scatter) plot (Blampied, 2022). Recommendations proposed by McAleavey (2024) will be considered.

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