Evaluating the co-designed "Kalmer" relaxation intervention for people with aphasia: a feasibility case series.

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Abstract:

People with aphasia are at increased risk of developing anxiety and depression. There is a need for accessible psychological interventions to be evaluated for this clinical group. Relaxation is a promising treatment option. This case series study aimed to assess the feasibility of the "Kalmer" relaxation intervention.

Twelve participants with aphasia were recruited via online social media/websites for people with aphasia. After 4 weeks of baseline assessment which included for mood the Behavioural Outcomes of Anxiety Scale (BOA) and Stroke Aphasic Depression Questionnaire – 10 item

(SADQ-10), participants accessed the relaxation intervention on Vimeo© for 5 weeks. Participants were encouraged to practice relaxation 5 times a week. Vimeo© analytics were collected to measure participants' preferences and use of the intervention. Immediately post intervention and at 3- and 6-month follow up time points, BOA and SADQ-10 scores were collected again. The Reliable Change Index was used to determine the impact of the intervention. Whilst recruitment was slow, once participants were enrolled the trial appeared feasible. Vimeo© analytics demonstrated participants engaged well in the treatment and preferred imagery-based relaxation recordings. Anxiety symptoms improved for 5/12 participants (42%) immediately post intervention and 7/11 participants (63%) at 3 and 6 month follow-up time points. Depressive symptoms improved for 6/12 participants (50%) immediately post intervention, 4/11 participants (36.3 %) at 3-month follow-up and 5/11 participants (45.5%) at 6-month follow-up. The Kalmer relaxation intervention appears feasible and shows potential to reduce anxiety and depressive symptoms in people with aphasia. Considerations for future trials include the need for expanding both recruitment (e.g. community and hospital rehabilitation services) and methods of delivery for the intervention (e.g. DVD and in person groups).

Introduction:

A stroke is a life altering medical event that 12.2 million people globally will experience this year [1]. Following stroke, it is not uncommon for people to experience significant mood disturbances [2, 3]. In fact, after stroke, people are more vulnerable to anxiety, depression and suicide when compared to the general population [2, 4, 5] Further, people after stroke can experience a broad range of physical and/or cognitive disabilities [6, 7]. Unfortunately, 30% of people after stroke will also be diagnosed with the communication disability aphasia[7, 8]. People with aphasia are highly vulnerable to developing anxiety, depression, and social

isolation, and have poorer rehabilitation outcomes, when compared to people without this stroke related impairment[8-13]. For instance, people with aphasia are 7.4 times more likely to develop depression after their stroke.[13]

Recent systematic reviews indicate that there is a lack of quality evidence for appropriate psychological interventions for people after stroke and that people with aphasia are typically excluded from clinical trials[14-18]. People with more severe aphasia may not be able to engage in talk-based psychological therapies given their disability and that psychologists are not formally trained in supportive communication strategies for this population[14, 19, 20].

There is some evidence that psychological interventions can be adapted for people with aphasia[21-24]. For example, modified Solution Focused Brief Therapy has been found to be highly acceptable to people after stroke and feasible[22, 25]. Additionally, peer befriending for people with aphasia has shown promising results for improving mental wellbeing and reducing social isolation of people with aphasia[23, 26]. More recently, a modified cognitive behavioural therapy (CBT)-based psychological intervention has been found to be both acceptable and promising for the treatment of depression[21]. Other interventions adapted for people who have had a stroke and shown to improve mood include behavioural activation therapy for those without [27], as well as those with aphasia after stroke [24]. These adapted interventions have primarily concentrated on treating depression[21, 24], whereas evidence for treatment of anxiety is scarce[14, 28].

For people after stroke with more severe communication and physical impairments, self-guided and cost-effective relaxation-based therapy has potential to be used, in both the acute and sub-acute stages of recovery in hospitals and later on in the community[29].

Relaxation is a state of low tension, anxiety, and stress in the mind and the body and can be achieved through a variety of different techniques for example, diaphragmatic breathing, progressive muscle relaxation, and guided imaginal meditation[30, 31]. Through training in relaxation, it is possible to reduce autonomic nervous system arousal and increase bodily awareness and results can be obtained over a short time period of time[30-32]. The literature suggests that relaxation is effective in reducing both anxiety and depressive symptoms in the general population[30, 33]. Preliminary research on relaxation for people after stroke supported efficacy in reducing anxiety symptoms when compared to no treatment controls, with benefits still present at 12-month follow-up[31, 32]. Most recently, a UK study has trialled a mixed mindfulness and relaxation DVD intervention for people after stroke where 38% of participants had mild to moderate aphasia[34]. Whilst the intervention was viewed positively and deemed feasible and acceptable for managing anxiety[34], the impact of the intervention on anxiety and depression symptoms and adherence was not objectively measured.

The literature suggests that technology based interventions are deemed highly acceptable by people after stroke and treatment adherence for digital interventions has also been found to be very high (up to 89%)[35]. People with aphasia have identified that technology based interventions have many applications and can be utilised to support self-management of aphasia rehabilitation[36]. Importantly, people with aphasia have an essential role to play in co-designing technology based interventions and should be supported with accessing and using such interventions[36]. Relaxation training as a digital health intervention could make treatment

accessible to people after stroke including those with aphasia as it can be completed at an individual's convenience via a phone, tablet, laptop or computer. This is the focus of the current research.

Aims and hypotheses:

The overarching aim of the current project was to examine the of a modified relaxation intervention to reduce anxiety and/or depressive symptoms in people with aphasia after stroke. Specifically, the study aimed to evaluate the feasibility of: a) Recruitment, b) the intervention c) Measures and d) Data collection. With respect to efficacy, it was hypothesised that there would be a reduction in symptoms of anxiety and depression from baseline to post-treatment.

Methods:

This study will be reported on following the Transparent Reporting of Evaluations with Nonrandomized Designs TREND[37] checklist of information to include when reporting a pilot or feasibility trial (see supplementary material). Note that the pre-print version of this study's protocol is available to read online[38].

Study design:

This multiple baseline case series study utilised a within-subject design.

Ethical considerations:

This project was approved by the Human Research Ethics Committees at the University of Technology Sydney (HREC REF NO. ETH22-7466) and received reciprocal approval from City University of London, (HREC REF NO. ETH2223-0400).

Participants:

Recruitment:

Potential participants with aphasia, were recruited online via convenience sampling in Australia and the UK. The study aimed to recruit 12 participants, a sample size that meets recommendations in the literature for pilot studies[39]. The researchers advertised extensively via online aphasia support groups, online social media groups for people with aphasia, online speech therapy social media pages, non-government organisations and research centres (See supplementary materials for a full list).

Inclusion Criteria:

Inclusion criteria required participants to be over 18, living in Australia or the UK, and have a formal diagnosis of aphasia post stroke. Participants aphasia was confirmed by either self-report or clinical opinion of and Speech and Language Pathologist. A score of 80% or below on the Carer Communication Outcome After Stroke Scale (Carer COAST)[40], a measure of communication ability, a score of 17 or more on the Behavioural Outcomes of Anxiety scale[41], and/or a score of 6 or more on the Stroke Aphasic Depression Questionnaire-10[40] were also required. A carer/family member who had regular contact with them was also necessary for participation.

Exclusion Criteria:

1. Medically unstable as indicated by the person with aphasia and/or carer.

2. The presence of any other significant psychiatric disorder apart from anxiety or depressive disorder as established by self-report.

3. Serious suicidal intent as assessed by the psychologist on the research team.

Consent:

All participants provided either written or verbal consent to participate in the study. Potential participants were emailed a participant information sheet and consent form. The information sheet and consent form were designed to be communicatively accessible for people with aphasia, by a speech language therapist on the research team[43]. In addition to this, the researcher, a psychologist, who had been trained in supportive communication strategies for people with aphasia, used phone calls to verbally explain the research and check participants' understanding and capacity to consent[43]. All participants were given the opportunity to have a family member or carer present during the consent phone calls. Participants could also choose to either sign and send back consent forms or give verbal consent during a phone call interview.

***Relaxation Intervention*:**

The Kalmer relaxation intervention was codesigned with people with aphasia[29].

It is comprised of a series of relaxation recordings and includes:

a) An introduction to the video by a co-design participant with aphasia

b) Progressive Muscle Relaxation MP3 recordings

c) Imaginal Relaxation MP3 recordings (fireplace, rainforest, and beach setting choices)

d) 3- part breathing also known as Diaphragmatic breathing MP3 recordings

e) Demonstration video of Progressive Muscle Relaxation by a member of the research team

All relaxation recordings were made available on Vimeo© in 2 versions, a higher communication support version where there was a lower complexity of spoken language

(LOW), and a lower communication support version where the complexity of spoken language was higher (HIGH). The Flesch-Kincaid readability analysis function in Microsoft Word along with the Grade Level test was utilised to ensure the readability of the scripts was at or below a Grade 7 level (see intervention development paper[29]). Participants had freedom to choose which of the videos to watch and how frequently they watched them however the recommended dose was to watch 5 times a week for the 5-week intervention period. Each recording was no longer than 10 minutes (for information regarding the length of each of the recordings, please see supplementary materials).

Prior to viewing the recordings participants received an information sheet on mood problems after stroke and the benefits of relaxation.

Outcome Measures:

Profiling measures

Demographic questionnaire:

A questionnaire was used to obtain demographic information on participants. Specifically, participants' age, living circumstances, education, language(s), marital status, date of stroke, type of stroke, disabilities following stroke, handedness, medications, other psychiatric diagnosis, and carer details including nature of relationship (e.g., spouse/sibling) were collected. The severity of participant's aphasia was rated by the lead author using the Aphasia Severity Rating scale[44]. A score between 0-4 was assigned to the participant where a higher score indicates greater impairment[44].

Nottingham Everyday Activities of Daily Living (NEADL) Scale:

The functional ability of participants was measured at baseline using the Nottingham Everyday Activities of Daily Living Scale[45, 46]. It was to describe the level of disability in the participant sample. It was competed by participants' carers, however participants who were

able to self-report on their daily functioning contributed to the rating. Scores on the NEADL range from 0-22, a higher score indicates greater independence.

Feasibility measures

Recruitment:

Feasibility of recruitment was measured by a) documenting the rate of recruitment over the course of the study b) keeping track of the different reasons participants opted not to participate and c) considering the proportion of participants who were not eligible for the study. The reasons why participants were ineligible for the study were also recorded.

Intervention:

Measuring feasibility of the intervention involved recording the number of participants who completed the intervention and adherence (use of the intervention) via video analytics on Vimeo©.

Measures:

Assessing the feasibility of measures included recording the number of incomplete questionnaires and any missing data.

Data collection/research process:

Withdrawal/drop-out rates from the study and any issues with the methodological design or other difficulties experienced were recorded.

Clinical outcome measures

Behavioural Outcomes of Anxiety scale (BOA):

The BOA was used to measure symptoms of anxiety[41]. It is an observer-rated instrument that was completed by the participants' carer or family member[41]. Observer-rated instruments were selected to ensure participants with more severe aphasia could participate. Participants who were able to self-report on their anxiety symptoms had the option of being present with their carer and discussing their symptoms with their carer. The BOA has been validated in people with aphasia and shown to be sensitive to change in relaxation intervention[41] The BOA was used to determine eligibility for the trial, cut off > 16. It was also administered at baseline, post intervention and at 3- and 6-month follow-up assessments. Scores on the BOA range from 0 -30 with higher scores indicating greater severity of anxiety symptoms.

The Stroke Aphasia Depression Questionnaire (SADQ-10):

The Stroke Aphasia Depression Questionnaire (SADQ-10) was utilised to measure depressive symptoms in participants[42]. The SADQ-10 is an observer-rated instrument that has been validated in people with aphasia[42]. It was completed by the participants' carer / family member. Participants who were able to self-report on their mood had the option of being present with their carer and discussing their depressive symptoms with their carer. The SADQ-10 was used to determine eligibility for the trial (cut off > 6). It was also administered at baseline, post intervention and at 3- and 6-month follow-ups. Scores on the SADQ range from 0 -30 with higher scores indicating greater severity of depressive symptoms.

The Carer Communication Outcome After Stroke Scale – (Carer-COAST):

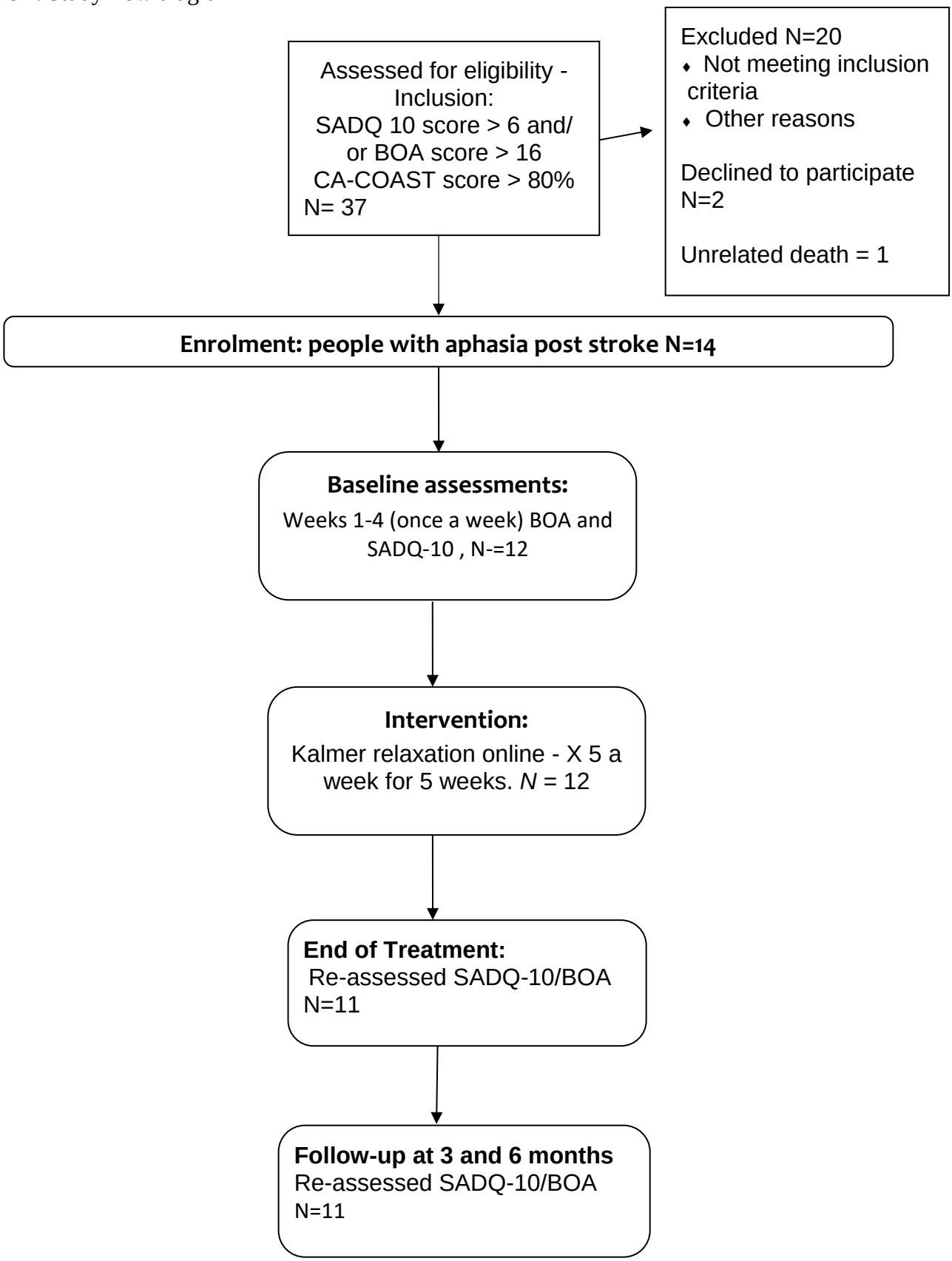
The Carer COAST scale is an observer-rated instrument and was utilised to describe the communication ability of each participant[42]. It was completed by the participant's carer or

family member. Participants who were able to report on their communication ability were involved in their carer/family members' ratings. Scores on the Carer COAST range from 0-100%, and a greater score indicates greater functional communication ability.

Procedure:

Following consent and prior to enrolment, participants' mood, functional and communication ability were assessed using the BOA, SADQ-10, NEADL and the CA-COAST questionnaires. If participants met inclusion criteria, they were enrolled into the study. Prior to starting the intervention, participants completed baseline assessments of their mood using the BOA and SADQ-10, once weekly for 4 weeks via a phone call by the first author, a psychologist trained in supportive communication for aphasia. Following these assessments, participants were asked to access the Kalmer relaxation recordings on Vimeo© for 5 weeks and encouraged to practice relaxation 5 days per week. During the intervention period, participants and their carers also received additional support via weekly phone calls from the psychologist (RE) on the research team. The phone calls involved supporting participants with using the intervention. No psychological therapy was provided by the psychologist. Vimeo© data analytics were collected during the intervention. The BOA and SADQ-10 were then administered immediately after the intervention period and at 3 month and 6-month follow-ups. Please see Figure 1 for study flow diagram.

Figure 1. Study flow diagram



Note. BOA = Behavioural Outcomes of Anxiety, SADQ-10 = Stroke Aphasic Depression Questionnaire – 10 item.

Data analysis:

Descriptive statistics were used to summarise participants characteristics and their scores on measures used. The Reliable Change Index (RCI)[47, 48] was used to consider whether a reliable baseline was established and determine intervention impact on anxiety and depressive symptoms. The RCI was used to evaluate whether the magnitude of change in participants' individual scores on the BOA or SADQ-10 pre to post treatment was sufficient to be deemed statistically reliable. To determine an RCI, the difference between 2 scores (i.e. pre and post intervention) is divided by the standard error of the difference between the 2 scores. If RCI value is greater than 1.96, then the difference is considered reliable [47, 48]. The first author was responsible for data analysis and no blinding methods were used.

Results:

Participants:

This study recruited 12 participants. There was diversity amongst the group of participants with regards, to age, gender, functional and communication abilities, and their living arrangements (please see Table 1 for participant demographic information and profiling measure results). Note that all 12 participants had access to a carer either a family member or a professional.

Table 1. Participant demographic information

Age	
Mean (SD)	61.4 (14.57)
Range	(34-82)
Gender	

Male	5
Female	7
Country of residence	
Australia	10
United Kingdom	2
Language	
English as first language	11
Additional language	3
English as a second language	1
Marital status	
Married	7
Unmarried	5
Living arrangements	
Living alone	2
Living with family	10
Mobility	
Reported physical disability (n=)	9
Type of stroke	
Ischemic	8
Haemorhaggic	4
Time from stroke	
Mean	3.6 years
Range	6 months – 8.5 years

Screened depression and anxiety symptoms	
Above cut off for depressive symptoms	11
Above cut off for anxiety symptoms	10
Education	
High school (year 9 – 12)	2
Tertiary education - TAFE	3
University degree e.g. Bachelors	7
Aphasia severity rating	
1	2
2	7
3	3
Handedness before stroke	
Left	11
Right	1
Handedness after stroke	
Left	3
Right	9
Other health conditions reported by participants:	8 participants reported other health conditions such as cancer, lupus, diabetes, spinal cord injury, epilepsy, asthma, high blood pressure, high cholesterol, history of previous stroke

Carer-COAST (SD)	
Mean (SD)	59.9% (10.8)
Range	45%-76%
NEADL	
Mean (SD)	14.7 (3.0)
Range	10-19

Feasibility of recruitment, measures and data collection:

Recruitment commenced in September 2020 and finished in May 2023 and there were several challenges faced by the research group with recruitment namely, the impact of COVID-19 on clinical services, and people with aphasia, as well as the stroke clinicians who would refer patients to research studies. Additionally, due to the pandemic, recruitment had to be moved online, and this put many people with aphasia who had poor computer literacy at a disadvantage. Whilst 12 participants did complete the intervention, 2 participants dropped out of the study after enrolling and 20 expressed interest in the study but did not participate for the following reasons: they did not meet inclusion criteria (e.g. no significant anxiety or depression symptoms, did not have aphasia, or had a traumatic brain injury or lived outside Australia or the UK), or they did not wish to enrol in the study, or did not wish to participate or complete any questionnaires. There was also 1 participant who expressed interest and passed away before enrolling in the study. Data collection and the measures used were feasible; only P2 had missing data, at 3 and 6 month follow-up time points, due to hospitalisation for serious illness.

Video analytics results:

Only combined data was available from Vimeo©. The device report analytics identified that 90 views in total occurred by phone, 10 views via tablet, and 51 via desktop computer (please see Table 2 for device report analytics). The total amount of time videos were watched was 8 hours and 56 minutes. The average view duration was 3 minutes and 33 seconds. In total, videos were viewed 151 times, and videos were finished to completion 95 times, the average time watched (i.e. the duration viewers stayed watching the videos before exiting the video) was 72%. The most viewed video was the imaginal relaxation video of the waterfall (LOW), and this was followed by the 3 part breathing video (LOW) and then progressive muscle relaxation (LOW). The higher complexity of language MP3s were the least played. The frequency of videos watched was not collected as Vimeo© does not allow for this analysis and the research team did not request that participants self-report on the frequency of their practice. Please see Table 3 for individual video view report. We would note here that many participants self-reported memorising the relaxation strategies and no longer needing to watch specific videos to practice.

Table 2. Devices analytics

Devices:	
Device type	Plays
mobile	90
desktop	51
tablet	10

Table 3. Individual video view report

Plays	Loads	Finishes	Name	Sum (minutes)
22	33	9	Imaginal relaxation - Waterfall setting - LOW	70
19	31	10	3 Part Breathing LOW	40
13	24	8	Progressive Muscle Relaxation – LOW	106
12	31	11	Psychoeducation and welcome by person with aphasia	16
11	19	8	Imaginal relaxation – Forest setting - LOW	49
10	18	4	Imaginal relaxation – Fireplace setting - LOW	35.6
9	89	5	Progressive Muscle Relaxation - HIGH	43.5
9	26	6	Imaginal relaxation – Beach setting - LOW	30
7	38	4	Imaginal relaxation – Waterfall setting HIGH	31.4
7	34	7	Imaginal relaxation - Beach setting - HIGH	26
6	41	5	Imaginal relaxation - Forest setting - HIGH	23.5
6	54	5	3 Part Breathing HIGH	7.5
5	28	3	Fireplace High (1).mp4	24.65
5	8	0	PMR- Demonstration video	24.5

Reliable Change Index for baseline assessments of anxiety and depression:

During the baseline period, 2 of the 12 participants' BOA scores did demonstrate reliable change across the 4 weeks (P4 [RCI= 4.92] and P6 [RCI= 2.65]. Notably for these 2 participants the score decreased at Week 2 but increased close to the first BOA score in Week 1 in the following assessments. For the SADQ-10, 2 out of the 12 participants demonstrated reliable change (P6 [RCI=2.7] and P12 [RCI=3.72]) over the baseline period. Notably participant 6 demonstrated a decrease in score across the baseline assessments and participant 12 increased at week 4 only and during the phone call interviews. It was observed that the presence or absence of various life stressors contributed largely to the changes in both

anxiety and depression symptoms reported over the weeks. These life stressors were disclosed over phone calls and were recorded by the researcher team as notes in excel.

Reliable change for immediate post intervention time point:

Impact of Kalmer Relaxation Intervention on BOA scores (i.e. Anxiety Symptoms):

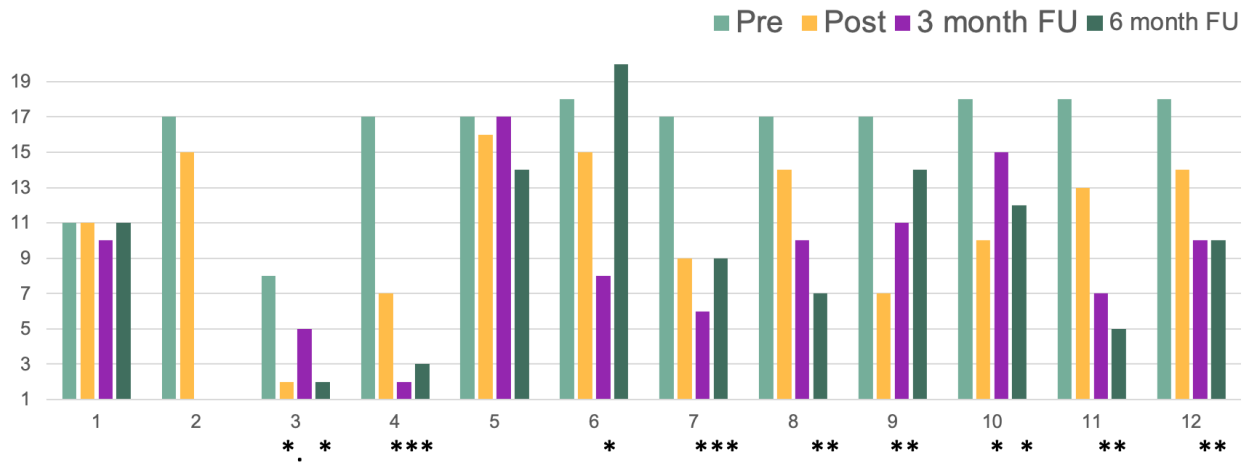
Relative to baseline,(i.e. the BOA and SADQ-10 score at enrolment), 5 participants' scores on the BOA decreased at the post intervention time point, i.e. 41.7% of participants, (P3 [RCI = 2.27]; P4 [RCI = 3.79]; P7 [RCI = 3.03]; P9 [RCI = 3.79]; P10 [RCI = 3.03]**.** At the post intervention time point, 7 participants did not demonstrate reliable change (P1[RCI = 0]; P2 [RCI = 0.76]; P5 [RCI = 0.38]; P6 [RCI = 1.14]; P8 [RCI = 1.14]; P11 [RCI = 1.89]**;** P12 [RCI = 1.52]).

Relative to baseline, 7 participants' scores on the BOA decreased at the 3-month follow up time point, ie.63.6% of participants, (P4 [RCI = 2.27]; P6 [RCI = 3.79]; P7 [RCI = 4.55] P8 [RCI =2.65]; P9 [RCI = 2.27]; P11 [RCI = 4.17] ; P12[RCI = 3.03])**.** At the 3-month follow-up time point, 4 participants did not demonstrate reliable change (P1[RCI = 0.38]; P3 [RCI = 1.14]; P5 [RCI = 0]; P10 [RCI = 1.14]). Relative to baseline, 7 participants' scores on the BOA decreased at 6-month follow up time point, i.e. 63.6% of participants, (P3 [RCI = 2.82]; P4 [RCI = 5.3]; P7 [RCI =3.03] P8 [RCI = 3.79]; P10 [RCI = 2.27]; P11 [RCI = 4.92]; P12[RCI =3.03]). The remaining 4 participants did not demonstrate reliable change at the 6-month follow-up time point, (P1[RCI = 0]; P5 [RCI = 1.14]; P6 [RCI = -0.76]; P9 [RCI = 1.14]). Please see Figure 2 for visual representation of the data. Following a reliable decrease in scores at 3-months follow-up, at 6-month follow up P6's anxiety scores increased however this was not considered reliable change. This was in the context of a significant life stressor.

Impact of Kalmer Relaxation Intervention on SADQ-10 scores (i.e. Depressive Symptoms):

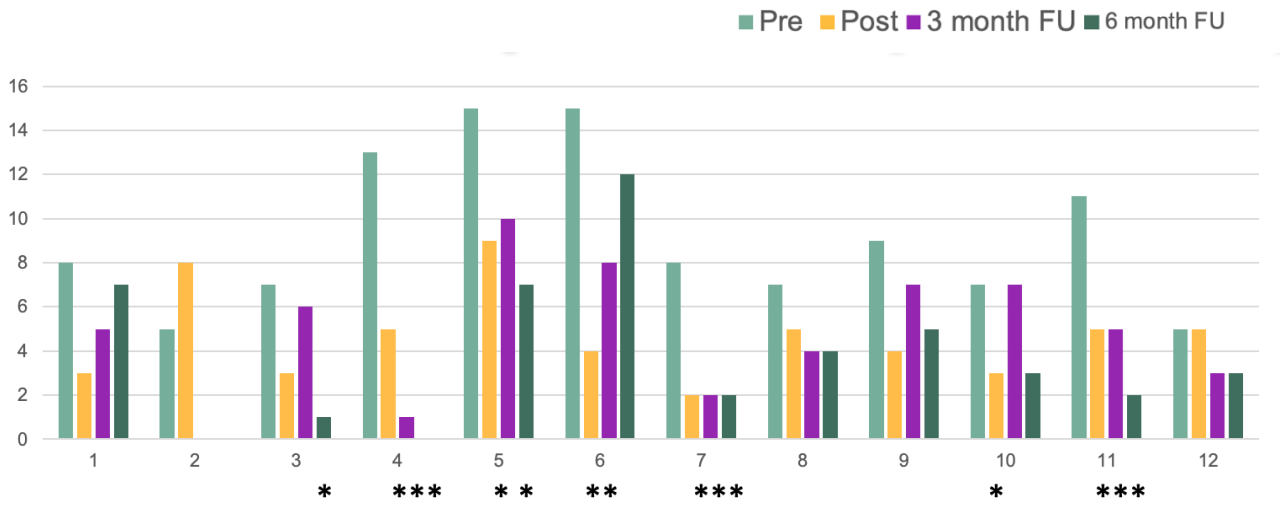
Relative to baseline, 6, participants' scores on the SADQ-10 decreased at the post intervention time point, i.e. 50% of participants, (P4 [RCI = 2.7]; P5 [RCI =2.03]; P6 [RCI = 3.72], P7 [RCI = 2.03]; P10 [RCI =2.03], P11 [RCI= 2.03]). At the post intervention time point, 6 participants did not demonstrate reliable change, (P1 [RCI = 1.7]; P2 [RCI = -1.01]; P3 [RCI = 1.34], P8 [RCI = .68]; P9 [RCI = 1.69], P12 [RCI= 0.34]). Relative to baseline, 4 participants' scores on the SADQ-10 decreased at the 3-month follow up time point, i.e. 36.3% of participants, (P4 [RCI = 2.82]; P6 [RCI = 2.36]; P7 [RCI = 2.03] P11 [RCI = 2.03]). At the 3-month follow-up time point, 7 participants did not demonstrate reliable change (P1 [RCI = 1.01]; P3 [RCI = 0.34]; P5 [RCI = 1.69], P8 [RCI = 0.68]; P9 [RCI = 1.01], P10 [RCI = 0], P12 [RCI= 0.68]). Relative to baseline, 5 participants' scores on the SADQ-10 decreased at the 6-month follow up time point (P3 [RCI = 2.82]; P4 [RCI = 4.39]; P5 [RCI = 2.7] P7 [RCI = 2.03]; P11 [RCI = 3.04]). At the 6-month follow-up time point 6 participants did not demonstrate reliable change (P1 [RCI = 0.34]; P6 [RCI = 1.01], P8 [RCI = 1.01]; P9 [RCI = 1.35], P10 [RCI = 1.35], P12 [RCI= 0.68]). Please see Figure 3 for visual representation of the data.

Figure 2. Impact of Kalmer intervention on anxiety symptoms (i.e. BOA scores)



***=reliable change, x-axis = participant number, y axis = BOA scores**

Figure 3. Impact of Kalmer intervention on depressive symptoms (i.e. SADQ-10)



*** = reliable change x-axis = participant number, y axis = SADQ-10 scores**

Discussion:

The literature highlights the high need for suitable and accessible interventions for both anxiety and depression that are adapted for people with aphasia[14, 19, 29]. The findings of this study demonstrate the feasibility of the research process and Kalmer intervention as well as its potential to reduce anxiety and depressive symptoms in some individuals after stroke. The study also provides insights into recruitment, intervention use, and data collection for future trials. Recruitment was notably slow, and this may have occurred for several reasons. Prominent among these is that people with aphasia struggle to seek professional help for their mental health concerns[49]. Further, the recruitment and data collection occurred online due to the COVID-19 pandemic and thus many potential participants who had poor computer literacy, or could not read or write, or did not have carers to support them with the trial, were unable to participate.

The video analytics results demonstrated that the participants of this study engaged well with the intervention and provided insight into the preferences of people with aphasia for relaxation therapy. Specifically, the results highlighted that people with aphasia may prefer relaxation recordings with lower complexity of language, particularly imagery-based relaxation.

Regarding changes in anxiety and depressive symptoms throughout the study, the majority of participants (n=9) demonstrated stable baselines. Notably, 5/12 participants (42%) demonstrated a reduction in anxiety symptoms on the BOA, immediately post intervention. At 3 and 6 month follow-up time points, 7/11 participants (63%) demonstrated a reduction in anxiety symptoms on the BOA. For depressive symptoms, 6/12 participants (50%) demonstrated a reduction in depressive symptoms on the SADQ-10, immediately post

intervention. At 3-month follow-up 4/11 participants (36.3 %) and at 6-month follow-up, 5/11 participants (45.5%) demonstrated a reduction in depressive symptoms. Importantly, no participant deteriorated during the trial.

The stepped psychological care model after stroke, was designed to support access to mental health care for people after stroke[20, 50]. There are 4 levels within the model, with the first level involving preventive treatments and the second level involving treatment for those with less severe mental health concerns[50]. Based on the findings of this study, the Kalmer relaxation intervention could be considered appropriate as a level 2 treatment i.e. as a first line treatment for those with less severe anxiety and depressive symptoms or as an additional component of current therapies[21, 24, 25, 27] already being used to treat psychological problems after stroke.

Limitations:

The authors acknowledge the limitations of this study which should be addressed in future research. Specifically, the baseline assessment showed reliable change for 2 participants in BOA scores and 2 participants in SADQ-10 scores. Thus, for some participants the reasons for change following the intervention may be unrelated to the use of the intervention and perhaps other variables need to be considered. These include the role of the phone calls from the lead author to the participants, or anticipatory effects prior to starting the intervention[51]. Another limitation of the study is that while participants were encouraged to use the intervention 5x per week, the dose of treatment for each participant remains unknown given the Vimeo© analytics grouped all participants together and many participants reported they practised relaxation without using the app.

Future directions:

Randomised controlled trials that are well powered and control for anticipatory and placebo effects might establish the efficacy of Kalmer. Future research may also wish to consider the impact of intervention dose, and any contribution of phone support to outcomes. More extensive data analytics should also be collected to further understand treatment adherence and participant preferences e.g. frequency of videos watched e.g. 2x per day, as well as individual vs grouped analytics. Qualitative interviews of participants experiences during the trial and with using the intervention should also be analysed in future as they may provide further information around the acceptability of the intervention. Additionally, future studies should look at providing the treatment in various formats, e.g. via DVD, in person via groups, as well as online and include self-report measures for participants who can report on their own mood.

Regarding future trials, researchers should consider recruiting not only from online social media groups for people with aphasia but also within hospital sites and speech pathology clinics as well as other community rehabilitation services. As regards, clinical implications, the Kalmer relaxation intervention could be trialled in rehabilitation wards where service provision is low[52]. Stroke clinicians in the community who often report poor self-efficacy with managing mood problems in people with aphasia[53] might find such a straightforward intervention easy to apply. Developing a treatment manual might support this. The findings of this study may also have implications for other clinical groups with challenges in communication and with cognition, for instance those with Traumatic Brain Injury (TBI), Multiple Sclerosis and Parkinson's Disease.

Conclusion:

Overall, the Kalmer relaxation intervention appears feasible and shows potential to reduce anxiety and depressive symptoms in people with aphasia after stroke. Large scale Randomized Controlled Trials are necessary to establish the efficacy of the intervention, however, challenges with recruitment need to be considered. Further research is also needed to establish the acceptability of this intervention to people with aphasia.

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Supplementary materials:

TREND Checklist

Paper Section/Topic	Item No.	Descriptor	Reported? X	Reported? Pg #
TITLE and ABSTRACT				
Title and Abstract	1	• Information on how units were allocated to interventions	X	1 -2
		• Structured abstract recommended	X	1-2
		• Information on target population or study sample	X	1-2
INTRODUCTION				
Background	2	• Scientific background and explanation of rationale	X	2-4
		• Theories used in designing behavioral interventions	NA	see El-Helou 2022
METHODS				

Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	X	5
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	X	5-6
		• Recruitment setting	X	5-6
		• Settings and locations where the data were collected	x	5-6
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	x	7
		○ Content: what was given?	x	7
		○ Delivery method: how was the content given?	x	7
		○ Unit of delivery: how were subjects grouped during delivery?	x	7
		○ Deliverer: who delivered the intervention?	x	7
		○ Setting: where was the intervention delivered?	x	7
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	x	7
		○ Time span: how long was it intended to take to deliver the intervention to each unit?	x	7
		○ Activities to increase compliance or adherence (e.g., incentives)	x	7
Objectives	5	• Specific objectives and hypotheses	x	4-5
Outcomes	6	• Clearly defined primary and secondary outcome measures	x	6-11
		• Methods used to collect data and any methods used to enhance the quality of measurements	x	6-12
		• Information on validated instruments such as psychometric and biometric properties	x	6-11
Sample size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	x	5-6
Assignment method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	x	5-11
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	NA	
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	NA	
Blinding (masking)	9	• Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed	x	13
Unit of Analysis	10	• Description of the smallest unit that is being analysed to assess intervention effects (e.g., individual, group, or community)	x	11-13
		• If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)	x	11-12
Statistical methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods for correlated data	x	13
		• Statistical methods used for additional analyses, such as subgroup analyses and adjusted analysis	x	13
		• Methods for imputing missing data, if used	NA	
		• Statistical software or programs used	x	13
RESULTS				

Participant flow	12	• Flow of participants through each stage of the study: enrollment, assignment, allocation and intervention exposure, follow-up, analysis (a diagram is strongly recommended)	x	12
		○ Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	x	12
		○ Assignment: the numbers of participants assigned to a study condition	x	12
		○ Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	x	12
		○ Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition	x	12
		○ Analysis: the number of participants included in or excluded from the main analysis, by study condition	x	12
		• Description of protocol deviations from study as planned, along with reasons	x	12
Recruitment	13	• Dates defining the periods of recruitment and follow-up	x	13-17
Baseline data	14	• Baseline demographic and clinical characteristics of participants in each study condition	x	13-17
		• Baseline characteristics for each study condition relevant to specific disease prevention research	NA	
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	x	11 -17
		• Comparison between study population at baseline and target population of interest	NA	
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	NA	
Numbers analyzed	16	• Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	x	16-17
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	NA	
Outcomes and estimation	17	• For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision		18-21
		• Inclusion of null and negative findings		18-21
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	NA	
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory		18
Adverse events	19	• Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)	NA	
DISCUSSION				
Interpretation	20	• Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study	x	
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	x	21-24
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	x	21-24
		• Discussion of research, programmatic, or policy implications	x	21-24

Generalizability	21	• Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues	x	23-24
Overall evidence	22	• General interpretation of the results in the context of current evidence and current theory	x	21-24

Additional recruitment information

This study was advertised in the following places:

a) Social media groups for people with aphasia
b) In person groups for people with aphasia via emails to group facilitators
c) The stroke foundation website and social media pages.
d) The Australian Aphasia Association website and social media pages.
e) At speech pathology clinic social media pages.
f) Emailing a database of Stroke Clinicians working with people with aphasia.
g) Advertising on Queensland Aphasia Research Centre newsletter.
h) The Aphasia Centre for Research Excellence newsletter and social media pages.
i) In conference presentations both nationally and internationally.
j) Through networking with academics and clinicians in Australia and United Kingdom
k) Twitter
l) Aphasia re-connect email list

Duration of each relaxation video/recording

Introduction to the intervention: 1 minute

Psycho-education on Relaxation video: 2 minutes

Progressive Muscle Relaxation (Demonstration video): 8 minutes

Diaphragmatic breathing (LOW) – 3 minutes

Progressive Muscle Relaxation (Low) – 10 minutes

Fireplace Guided Imaginal Relaxation (Low) – 7 minutes

Beach Guided Imaginal Relaxation (Low) – 5 minutes

Forest Guided Imaginal Relaxation (Low) – 6 minutes

Waterfall Guided Imaginal Relaxation (Low) – 6 minutes

Diaphragmatic breathing (HIGH) – 2 minutes

Progressive Muscle Relaxation (HIGH) – 8 minutes

Fireplace Guided Imaginal Relaxation (HIGH) – 5 minutes

Beach Guided Imaginal Relaxation (HIGH) – 4 minutes

Forest Guided Imaginal Relaxation (HIGH) – 4 minutes

Waterfall Guided Imaginal Relaxation (HIGH) – 6 minutes