

Study protocol

TRIAL FULL TITLE	Development of an online mindfulness program for stroke survivors and their caregivers
PROTOCOL VERSION DATE	06-25-20
Clinical trial number	NCT04553679
Protocol Version	UP-20-00568 1.1
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Abstract

The incidence of depression and anxiety is much higher in stroke survivors and their caregivers compared to age-matched peers. Previous work suggests that mindfulness delivered in an online format is promising for both individuals with neurological disorders and caregivers to improve quality of life and psychological well-being.

The overall objective of this project is to develop and refine an online mindfulness program that is perceived as relevant and user-friendly for stroke survivors and their caregivers. This project also aims to determine the potential impact of the mindfulness program on psychological well-being for stroke survivors and caregivers to guide the development of a future intervention study.

The process of development of the online mindfulness program will be iterative and will involve three phases: one development phase, one usability testing phase with end-users and one refinement phase.

Phase 1) The 3-week online mindfulness program will be adapted from the program developed for individuals with amyotrophic lateral sclerosis by mindfulness and stroke experts to ensure suitability and relevance for individuals with stroke.

Phase 2) A testing phase will be conducted remotely for both technical and clinical verification with 5-10 stroke survivors and 5-10 caregivers. Self-reported questionnaires about psychological well-being will be administered prior to and after the participation to the program and at a 1-month follow-up. After the program, a usability questionnaire and a semi-structured interview will be conducted to assess the usability of the mindfulness program and gather participants' feedback. For each group, differences prior to and after the mindfulness program will be assessed using a repeated measure analysis of variance. The transcribed verbatim of the semi-structured interview will be analyzed independently using thematic content analysis by 2 members of the research team.

Phase 3) Based on the results from Phase 2, modifications will be made to the online mindfulness program. If warranted, the testing phase will be replicated with up to a second cohort of participants.

This project will lead to the development of an online mindfulness program suitable for stroke survivors and their caregivers to improve quality of life and psychological well-being. This project will help guide the development of a planned intervention study.

Background

Globally, the number of stroke survivors living with the consequences of stroke is estimated to almost 25.7 million, with the majority of global stroke burden being in low-income and middle-income countries (Feigin et al., 2014). Stroke is a complex and multifaceted medical condition. The consequences of stroke and the severity of the symptoms are heterogeneous with possible sensorimotor, cognitive, perceptual, social and psychological sequelae, impacting activity and participation (Mayo et al., 2002). At one-year post-stroke, evidence support that community-dwelling stroke survivors have poor perceived physical health (Patel et al., 2006), and high levels of dissatisfaction from life correlating with activity limitations and restricted participation (Hartman-Maeir et al., 2007). In the long-term, depression and cognitive impairments are strong predictors of reduced health-related quality of life (Haacke et al., 2006). Depression is common after stroke, with an incidence of 29-33% in different stages of stroke recovery and a cumulative incidence of up to 52% within 5 years (Ayerbe et al., 2013; Hackett et al., 2005). The occurrence of anxiety disorders and anxiety symptoms is also frequent, affecting 20-25% of stroke survivors (Campbell Burton et al., 2013).

The considerable psychosocial impact of stroke extends to spouse and family members, and close friends taking the role of caregivers (Low et al., 1999; Rigby et al., 2009). Caregivers play a crucial role in preserving rehabilitation gains and levels of independence, and maintaining stroke survivors in the community and the long-term well-being of stroke survivors (Rigby et al., 2009; Visser-Meily et al., 2006). However, the caregiver burden, which describes the weight or load carried by caregivers as a result of adopting the caregiving role, is estimated to 25-54% (Rigby et al., 2009). In caregivers of individuals who have had a stroke, diminished general health, vitality, and mental health are often reported (Anderson et al., 1995; Morimoto et al., 2003). The prevalence of depression amongst stroke caregivers is much higher than in older community-dwelling adults (Morimoto et al., 2003). The caregiver strain can be attributed to the caregivers' mood, increased patient disability, anxiety, and depression, and caregivers' negative affectivity (Blake et al., 2003; McCullagh et al., 2005).

To date, some of the most promising clinical treatments for the reduction of distress, the improvement of psychological well-being and help for people trying to cope with a chronic disorder are based on the concept of **mindfulness** (Francesco Pagnini & Philips, 2015). Mindfulness is defined as the process of actively making new distinctions about a situation and its environment, or its *current context*, rather than relying on previous categorizations (Langer, 2018; Langer, 2014; Langer & Moldoveanu, 2000). When mindful, we are actively engaged in the present and sensitive to both contexts (i.e., "What is our present situation?") and perspectives (i.e., "How are we viewing the situation, and how might others view it?"). A mindful perspective denotes the ability to assume multiple views about the present context, and to be aware of the current contextual details, which itself encourages greater engagement – the essence of mindfulness itself. Mindfulness can be seen as a mental state that includes awareness, flexibility, openness, and creativity. By contrast, mindlessness occurs when one considers only a single perspective about an event or a situation and reflects a reliance on automatic or repetitive thought processes, judgments and behavior. In this way, mindlessness is similar to being trapped in a rigid mindset and unaware of individual and contextual changes.

The mindless processing of information and experience does not allow for reconsideration and reinterpretation, maintaining a pre-determined perspective (Carson & Langer, 2006). The tendency to approach situations as if they were unchanging may be particularly problematic in physical health (Giardino et al., 2000), and particularly so in illnesses diagnosed as chronic or life-threatening. Previous studies indicate that many presumed physical or psychological limits are a result of mindlessness and may benefit by increasing mindfulness (Langer, 2012). While some exploration has begun, there is significant clinical potential to be explored in the construct of mindfulness as it relates to chronic disease. Through the practice of mindfulness, a more serene and balanced emotional and affective state can be achieved, which is a beneficial precondition for stress resistance and resilience (Teasdale et al., 1995). Mindfulness increases one's ability to cope with the challenges of the environment, and aids in developing the capability to accept one's own condition.

In a number of studies, mindfulness programs based on Langer's mindfulness theory have been shown to increase mindfulness in the general population or other cohorts (Alexander et al., 1989; Grant et al., 2004; Langer, 1993, 2000, 2009; Langer & Moldoveanu, 2000). One example is an online mindfulness intervention program for individuals with amyotrophic lateral sclerosis (ALS) and their caregivers. Following the treatment, people with ALS who participated in the online mindfulness program reported higher quality of life and a lower level of negative emotions, anxiety, and depressive symptoms, compared to the wait-list control group. Similarly, the caregivers reported lower levels of care burden, depression, and anxiety, and improved values of emotional well-being and social functioning (Pagnini et al., 2017). Most of these differences remained stable over time, indicating a stability of the effect, at least for the few months after that. Recently, it also been adapted for individuals with multiple sclerosis (Pagnini et al., in preparation). Given the favorable results for individuals with other neurological conditions and their caregivers, an online mindfulness program is promising for individuals post-stroke and their caregivers to increase mindfulness, decrease anxiety and depression and encourage stroke survivors to change their beliefs about their disability.

Aim

The aims of this project are: 1) to develop an online mindfulness program for stroke survivors and their caregivers, 2) to pilot test the online mindfulness program with potential users to evaluate the acceptability, ease-of-use, satisfaction, 3) to estimate the potential impact on quality of life, anxiety, depression and sleep quality in the short term, and 4) to obtain a final version suitable for individuals who have had a stroke with a wide range of impairments and their caregivers. It is hypothesized that the online mindfulness program will be well accepted and perceived as easy to use by stroke survivors and their caregivers. It is anticipated that minor modifications will be suggested to improve understandability and relevance for the participants.

Methods

The process of development of the online mindfulness program will be iterative and will involve three phases: one development phase, one usability testing phase with end-users and one refinement phase. An online program was selected to provide the opportunity for individuals

who may not be mobile enough to attend face-to-face classes in a rehabilitation, hospital or community settings or living in a remote area to participate.

Phase 1 – Development of the online mindfulness program

The first phase of the study focuses on the development of a three-week online mindfulness program, with distinct modules for individuals who have had a stroke and for caregivers. The modules are based on a mindfulness program initially developed for individuals with ALS and caregivers (Pagnini et al., 2017). To ensure suitability and relevance for individuals with stroke with a wide range of impairments and disabilities, a group of experts consisting of experienced therapists, stroke rehabilitation researchers, stroke survivors and mindfulness experts revised and adapted the content of the program. Stroke-specific exercises were also incorporated into the program to ensure the exercises *made sense* from stroke survivors' and caregivers' points of view. The purpose of the online mindfulness program is to increase participants' mindfulness and improve psychological state. The mindfulness program also encourages stroke survivors to change their beliefs about their disability. For caregivers, the program is designed to help caregivers better accept themselves and the individual who has sustained a stroke as autonomous and unique human beings rather than as a caregiver and a stroke survivor.

The online mindfulness will be hosted on the USC Biokinesiology and Physical Therapy continuing education platform named Desire2learn. Desire2learn is a user-friendly, commonly used platform in higher education. The content of the program will be accessible via a computer or a smartphone. Additional features of this platform include a discussion forum, exercise submission, ability to contact a member of the research team to ask questions about the program or to report any adverse events, and flexibility and ease to modify the content for the instructors.

For each of the three weeks, educational texts, exercises, audio recordings and videos will be available on the Desire2Learn platform. The general structure of the program will mix different mindfulness elements, with specific topics examined in depth and related exercises. The topics are: attention to variability, positive and negative events, unpredictability, sense making and novelty seeking and novelty producing (for detailed description of each topic, see Appendix 1). Exercises related to practical modifications to daily life activities will be provided across all weeks. During the program, participants will learn to experience new ways to engage in the present, increasing self-acceptance and learning to reduce their focus on the negative aspects of their disability. Specific exercises will be used to introduce the concepts of "negative" and "positive" point of views. Moreover, exercises in acceptance and positive communications between participants and caregivers will be introduced, in order to create a positive relationship between participants' psychological wellbeing and that of others. Each new concept related to mindfulness specifically targeted for stroke survivors living in the community and their caregivers will be introduced. The participant's acceptance of uncertainty will be addressed with reflections and exercises. To minimize the cognitive burden of reading while accomplishing the exercises, all exercises for the stroke survivors will have an audio track available, in addition to the written text.

Phase 2 – Beta-testing of the online mindfulness program

Data collection: A testing phase will be conducted for both technical and clinical verification. During this phase, we plan to recruit a convenience sample of 5-10 people with stroke and their caregivers from the Motor Behavior and Neurorehabilitation stroke database and community support groups. Participants will be purposefully selected to be representative of individuals who have had a stroke and caregivers (wide range of impairments, familiarity with computers, age, sex, gender, ethnicity, race and socio-economic backgrounds).

Inclusion criteria:

- Aged older than 18 years old
- Diagnosis of stroke (for stroke survivors)
- Ability to access Internet using a computer, a tablet and/or a smartphone
- Ability to provide informed consent
- Fluent in English

Exclusion criteria:

- Severe language impairments
- Regular meditation or participation in a mindfulness program in past 3months

The participation to this project will be done completely remotely using the HIPAA compliant platforms Zoom and REDCap for informed signed consent and patient-reported outcomes. The online mindfulness program will be offered continuously, so participants will be able to enroll in the study at any time during the data collection period. Prior to the start of the online mindfulness program, an online meeting will be scheduled with each participant. Each meeting will be done separately for stroke survivors and caregivers, even if participants are living together and are enrolled at the same time. During the first online meeting, participants will be informed of the procedures involved with the study and written consent will be obtained using the REDCap platform. Basic socio-demographic, stroke or caregiving-related information will be collected to characterize the study participants. A description of the mindfulness program and details on how to navigate the online platform will be offered. Participants will be also instructed on how to share their computer screen with the researcher for beta-testing of the online program.

While sharing their screen, participants will log in on the online mindfulness program website, watch the introductory videos and complete the exercises for the first day. A researcher will record of any difficulties experienced with accessing or navigating the online platform, assistance provided, technical issues, spontaneous feedback reported by participants, and time to complete the exercises (in minutes). Additional validated outcome measures will be given before, after the online mindfulness program and at a 1-month follow-up to guide a future intervention study (i.e. feasibility and preliminary effect of the online program). For stroke survivors, quality of life and impact of stroke, anxiety and depression, perceived stress, and sleep quality will be assessed: 1) Stroke Impact Scale (SIS) (Duncan et al., 2003), 2) Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), 3) NIH Perceived Stress Survey,

and 4) Single-Item Sleep Quality Scale (Snyder et al., 2018). For caregivers, quality of life, anxiety and depression, perceived burden, perceived stress and sleep quality will be assessed: 1) World Health Organization Quality of Life-BREF (WHOQOL-BREF; World Health Organization, 1998), 2) HADS, 3) Zarit Burden Interview (Zarit et al., 1980), 4) NIH Perceived Stress Survey, and 5) Single-Item Sleep Quality Scale. All outcome measures will be administered remotely using the REDCap platform. Specifically, a link to access the REDCap questionnaires will be sent by emails. With the guidance from the researcher, participants will complete each self-reported questionnaire.

For each week of the online mindfulness program (3 weeks total), participants will be instructed to connect to the platform and accomplish daily exercises a minimum of 5 days per week to optimize participation. Participants will be able to call or contact via the platform a member of the research team at any time to ask questions or report difficulties. Any difficulty reported will be recorded. At the end of the 3-week program, another Zoom meeting will be conducted with each participant to administer the self-reported questionnaires and conduct a semi-structured interview. In addition to the patient-reported outcome measures administered after the end of the program, an adapted version of the Post-Study System Usability Questionnaire (PSSUQ), will be administered to assess the usability of the mindfulness program. The adapted version of the PSSUQ consists of 5 questions on user's perceived satisfaction of a website or software. Each question is scored on a 7-point Likert scale ranging from Strongly Agree to Strongly Disagree. In a semi-structured interview lasting up to 30 minutes, participants will also be asked to provide feedback about technical issues (e.g., whether the website is fully accessible), program content and their feelings, beliefs, reactions and adherence to the program. In particular, the clarity of the lectures and other exercise communications, the duration of the program and the perception of the utility of the exercises will be verified. The interview will be video recorded.

Data analysis: See SAP

Phase 3 – Modifications to obtain a final version

Based on the feedback received by the users, recommendations to modify the content of the videos or the exercises, or the website will be drafted. Based on those recommendations, modifications will be made to the online mindfulness program. If warranted, the testing phase will be replicated with up to a second cohort of 10 participants (5 stroke patients and 5 caregivers).

Ethical considerations

Informed consent

Prior to providing informed consent, all participants (stroke survivors and caregivers) will be fully informed of the procedures involved and requirements for participation in the study. Participants will also be informed of the voluntary nature of participation in the project and the option to withdraw at any time without jeopardy. At the first online meeting, each participant will be asked to read the consent form at his or her own pace. A member of the research team will also explain every element of the consent form and answer any question or concern from the potential participant. Participants will be asked if they understand the nature of the study

and the procedures that will be employed. Then, participants will provide written consent on the REDCap platform should they agree to participate. A copy of the consent form will be printed, signed by the principal investigator, scanned and return to each participant by email. The HIPAA compliant Zoom platform will be used for all meetings.

Participant recruitment

A webpage was created using the Southern California Clinical and Translational Science Institute (CTSI) Clinical studies directory. The link to this webpage will be shared on social medias using a recruitment flyer. Specifically, stroke survivors support group will be targeted (e.g., Stroke Association of Southern California, American Heart Association Support Network). Interested individuals will be encouraged to contact a member of the research team. A member of the research team will contact potential participants to confirm eligibility, explain in more details the research project and answer questions. If difficulty arise with recruitment, participants will also be recruited by phone from an existing IRB-approved database, Registry for Aging and Rehabilitation Evaluation-RARE (HS-11-00413). Phone recruitment will be done using a phone script.

Participant privacy and data confidentiality

All information collected during this study will be coded in order to assure confidentiality and each participant will be assigned a random unique identification code. Once transcribed and verified for accuracy, the recordings of the semi-structured interviews will be destroyed. Electronic data will be stored on a secured drive and access to the drive will be password protected. Data will be stored for a period of seven years following the end of the study, after which, they will be destroyed. Only the members of the research team will have access to the data. The data identifier will be stored in a different location than the data generated during the study.

Potential risks and procedures for minimizing risks

The risks associated with this study are minimal and there are no expected adverse events. Risks include surveys or interview questions that may make participants feel uneasy or embarrassed, and a breach of confidentiality. During any self-reported or interview question, participants will be allowed to skip or stop answering any questions they wish not to. The HIPAA compliant REDCap platform will be used to obtain informed consent and collect all patient-reported outcomes (coded surveys). No identifier will be collected in REDCap. Study investigators will protect data against the privacy by storing data in locked cabinet, in password protected computers and files, and by using coded identifiers. If a participant scores over 11/21 on the HADS scale for depression and anxiety or if they experience any inconvenience during the study, they will be directed to their primary family physician to ensure they are receiving proper referral to mental health care.

Plan to disseminate findings

It is anticipated that the results from this study will be disseminated in a peer-review publication and at local, national and/or international conferences. To facilitate the knowledge

translation for students doing stroke research, the results will be presented at the Biokinesiology and Physical Therapy Division seminars at the University of Southern California.

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Appendix 1

Structure of the mindfulness program

- **Attention to variability:** The key concept is that world around us, and each one of us, is always changing. If you are able to notice subtle changes in the external world, as well as in how you feel, you will find that negative feelings, whether psychological or physical, are not always present. Thus, you can change the usual tendency to view things as if they are unchanging – a mindless construct of the world. Simple exercises can help to change this mindset. Two simple examples are:
 - Try to find 5 ways in which the weather is different today than yesterday.
 - Move one of your fingers and notice how it feels. Wait a minute and do it again. Think of 3 ways that it feels differently the second time.
- **Positive and negative events:** The same event may be seen as *either* positive or negative, depending on our perspective; that same event can be seen as *both* positive and negative. If we change our point of view then our perception about what we were certain is a negative event can, from that different perspective, be viewed as positive. That is, we can reframe a negative perception of an event by answering a simple question: “In what ways might this be good for me? Or “What about this situation could be seen as good?” With the disability following a stroke, we can try to find a different perspective about the illness. We see that our experience of the illness is a reflection of the view we take rather than of the illness itself. This may seem counterintuitive at first, but we can find many individuals who are able to reframe their experiences of their own illnesses by including views that express the positive experiences or opportunities the illness has brought to their lives (e.g., a focus on the important things they missed, whether it be family or philanthropy or art). This perspective shifting is a very mindful exercise and a very valuable coping resource. Examples of exercises could be:
 - You miss a bus to meet an important person in your life. Try to find 5 reasons how that could be positive.
 - If you have difficulty speaking or raising your arm or leg, think of 3 new positive opportunities that this difficulty provides.
- **Unpredictability:** a mindful view of the future acknowledges its ultimate unpredictability, as is the course of the participant’s disability. Such unpredictability opens up the possibilities for a more positive perception of the future than had been conceived. For example:
 - Find 3 possible reasons that explain why a certain event might occur, and then propose 3 reasons that it might not. For each of those reasons, describe the way in which it is both positive and negative.
- **Sense Making:** Disability and symptoms tend to be perceived as something that stays unchanging. However, it is unlikely that all symptoms are always present at the same

intensity or at the same level of impairment. Reflecting about symptoms and your ability to do things that are important to you allows for understanding their variability, and making sense of this can help develop an understanding that there are often many reasons for their variability. Once we can identify even a few reasons, feelings of increased control and awareness follow. One example of this is:

- Is today a better day than yesterday? What about compared to last week? In what ways is it better or worse? Can you think of 3 reasons why?
- **Novelty seeking and novelty producing:** The attitude of paying attention to new elements requires an open and curious orientation toward the world and towards oneself. Novelty producing actively creates new categories of thinking rather than relying on previously constructed categories and distinctions about the world (Langer, 1989). Novelty seeking is also related to the concept of flexibility, or using feedback from the environment to make any responsive adaptations to one's thinking and behavior. These attitudes may be improved in an effort to be more mindful. Examples of exercises with this purpose may be:
 - Imagine taking a new route to get from your house to any places to which you go very regularly. What new reactions occur to you?
 - What are five ways you could change your bathroom – even slightly - in order for it to make it easier for you to get in and out of the shower?