

AuSCR Research Task Group approved projects

Title	Support After Stroke with group-based classes: The SASS study
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AuSCR role	Recruitment and data provision
Approved	6 April 2020
Status	In progress

Summary Stroke is the leading cause of disability from physical, social and mental health impacts (e.g. 1 in 3 survivors have depression after stroke. Community-based options for preventing comorbidity and supporting recovery after stroke are limited. MBIs are emerging to be a promising adjunct therapy to current rehabilitation strategies. Prior studies of MBIs in older adults, cardiac and cancer populations provide evidence of reduced stress, fatigue, mood disorders such as anxiety and depression, lower blood pressure and improved quality of life. Our objective is to test the feasibility and potential effectiveness of a purposefully designed MBI for people within 3-12 months of a stroke and living at home.

Our specific aims are:

1. Obtain data to report on the potential neural mechanisms of mindfulness development in the post acute phase of stroke (beyond first three months where most natural recovery has occurred) and whether there is any objective evidence of changes in brain structure for the intervention group compared to the control group (i.e. attention control).
2. Determine the acceptability, feasibility, and safety of the MBI in participants with stroke in preparation for a large-scale RCT.
3. Provide preliminary evidence of differences in health outcomes between the intervention and the attention control group to base the sample size calculations for a fully powered Phase III effectiveness trial.
4. Determine the optimal processes for conducting a complex intervention trial in the community for survivors of stroke.

Proposed methodology

Eligible participants will be identified via the AuSCR, and an invitation pack will be mailed out with a reply paid envelope addressed to the Monash University researchers. Upon receipt of consent and confirmation of eligibility, baseline assessments (i.e. questionnaires, biological samples, baseline MRI) be arranged by phone and will be administered by the project staff in person on the agreed date and time at the BrainPark and will coincide with the MRI scan appointment. Once baseline assessments have been completed the trained research officer will randomise the participant to: a) the intervention group with MBI for 12 weeks (group classes for 60 mins per week + home-based practice for 20 mins at least 3 times weekly) or, b) the active control group with social lifestyle group classes (60 mins per week).

After 12 weeks, the participants will be administered outcome assessments by a blinded assessor, ideally within 2 weeks of completing the intervention.

Predefined adverse and serious adverse events will be collected. Independent medical monitors will provide regular review. Intervention fidelity will be monitored throughout the trial by an independent member of the research team who will monitor group classes and procedures for baseline and outcome assessments. Focus groups will be conducted with up to 10 participants in either intervention group and a separate interview/semistructured survey will occur with the instructors involved in the group classes.