**PROTOCOL**

**Title: Exploring the impact of attention training on attention difficulties experienced by older adults with or without Mild Cognitive Impairment (MCI).**

**Attention and Older Adults**

**Version 7**

1. **Investigators:**

*Name, position, contact information, team role.*

* ***Principal Investigator/Researcher-***

Name: Mousumi Singh

MPsych (Health), Clinical endorsements (APS and AHPRA)

Position: Psychologist-Senior

Geriatric Adult Rehabilitation and Stroke Services (GARSS), Toowoomba Hospital, Darling Downs Health (DDH).

*Role in the study team:*

* Dissemination of information on the research in research sites and people managing those sites.
* All correspondence with participants
* Conducting both consent interviews
* Design of the study
* Preparation and delivery of interventions to treatment and control groups
* Data entry and analysis
* Report writing or writing the thesis
* Completing applications for grants and progress reports for various organisations (USQ and HREC) at regular periods of time
* Preparing articles for journal submissions.
* Organising and facilitating post-trial intervention for control group of participants with MCI.
* Supervision and guidance to research assistant/s.
* Dissemination of research results
* ***Associate Investigators-***

1. ***Primary Supervisor***

Name: Professor Bob Knight

Position: Professor (Psychology)

School of Psychology and Counselling,

University of Southern Queensland (USQ)

1. ***Secondary Supervisor***

Name: Associate Professor Gavin Beccaria

Position: Associate Professor (Psychology)

School of Psychology and Counselling (USQ)

*Roles of the Primary and Secondary supervisors (Associate Investigators) in the study team:*

* Provide guidance and direction to the principal researcher through hourly face to face sessions fortnightly delivered till the completion and submission of the thesis.
* Provide guidance and direction in preparation of all submissions including research grants and publications.
* Provide guidance and supervision in design of the study, data analysis, preparation of the research intervention, and thesis writing.
* Independently address any concerns raised by the participants or any other parties regarding the research.
* Ensure that the research timelines are maintained.
* Ensure that the research is carried out in an ethical manner.

1. **Study Sites:**

*Name each site individually (not just DDH).*

1. ***Memory Clinic, Toowoomba Hospital, DDH***

Memory Clinic patients newly diagnosed by the Geriatrician with Mild Cognitive Impairment (MCI) will be one of the sample population group (Group 1).

1. ***Psychology Clinic, University of Southern Queensland (USQ)***

Toowoomba Campus.

Healthy older adults living in the community will be recruited from University 3rd Age (U3A) and through advertisements posted in the Toowoomba Library, but they will receive the interventions at the Psychology Clinic, USQ, Toowoomba. They will form Group 2 participants.

For both these sites, research assistants will conduct the eligibility assessments and pre-post training assessments of all eligible participants. They will also facilitate the post-trial intervention to interested participants of the control group (for Group 2 only), once the research has concluded. The primary researcher will conduct the consent interviews and facilitate the research intervention (training) to the treatment groups as well as the training to the control groups. Pre-post assessment data will be forwarded by the research assistant to the principal researcher for analysis and reporting.

1. **Contents:**
   1. **Introduction / Background**

The current study wants to explore difficulties in cognition in older adults, specifically difficulties with attention and concentration that may exist among older adults including those that have been diagnosed with Mild Cognitive Impairment (MCI). It also wants to investigate the impact of a structured attention training program on participants’ attention abilities and general cognitive capacity.

* 1. **Rationale and purpose of the study**

***Benefits to individuals and families- both for people with Mild Cognitive Impairment (MCI) and healthy older adults (without MCI):***

-Detection of the specific cognitive domain/s that show significant decline may be identified early and targeted cognitive training can be offered to individuals.

-Individuals showing improved post-training results can be offered individualised cognitive rehabilitation program that may help maintain their cognitive gains.

***For the Treatment groups:***

*-*Psychoeducation on aging and cognition.

-Process-based cognitive training for the treatment group to learn and expand on

their attention skills.

-Strategy-based cognitive training to learn compensatory techniques to improve

performance on cognitive tasks that increase in difficulty with age

-Functional activities training or the practise of the skills learned in peoples’

daily lives as well as use of real-life activities to work on underlying attention

skills.

-Additional benefits of face to face group learning are:

 Direct observation and learning from others’ experiences –real life experiences

 Boost self-esteem and self-confidence. Help refocus on one’s functionality in a realistic manner

 Explore new meaning in life

 Alleviate unnecessary fears and concerns.

 Increase willingness to try tasks in a group than individually.

 Learning can be fun

***For the Control groups:***

-Benefits include increased awareness and knowledge around cognitive decline with

age and options to improve cognitive health.

-Relaxation training has multiple benefits, possible reduction of stress in

daily life that in turn may help improve cognitive health.

-Moreover, the control group has the option of obtaining the same training after the

research is completed.

-Participation of the control group is necessary in order to demonstrate significant

differences (if any) resulting from the research intervention. Hence the control group

participation is vital for their contribution to the increased knowledge in this field of

research.

***For research and advancement of knowledge:***

-Early intervention programmes can be developed and adopted as standard practise that promote active aging.

***For Clinicians:***

-Understanding of the specific attention domains or areas of general cognition that differentiate older adults with and without Mild Cognitive Impairment (MCI).

***For Community:***

-If this research intervention is proven to be effective, it can be adopted as a standard practise that will benefit the larger community of mature-aged individuals who inevitably experience cognitive decline due to aging.

-Finally, older adults may be able to stay in their own homes longer if they maintain their cognitive health. This may address the growing demand of increased hospitalisation and supported living arrangements for an aging population, which can be reserved for rapidly declining individuals.

***For Research Assistant/s:***

-Research assistant/s contribution to the study will be acknowledged in the final thesis as well as in publications

-Research assistants will obtain increased knowledge and practise of specific clinical assessments with older adults.

**3.2 Literature review**

According to World Population Prospects data: the 2015 Revision (Department of Economic and Social Affairs, Population Division, 2015), older people (60 years and above) has increased considerably in recent years and this growth is expected to continue in the coming years. The absolute number of people aged 60 years and over is projected to increase from 1.4 billion by 2030 to 2.1 billion by 2050. Considering this rate of growth in the aging population, it is predicted that by 2030, older persons (60 years and above) will outnumber children aged 0-9 years (1.4 billion versus 1.3 billion) and by 2050, will outnumber adolescents and youth aged 10-24 years (2.1 billion versus 2.0 billion) (Department of Economic and Social Affairs, Population Division, 2015). This necessitates actions to improve trajectories of healthy ageing at multiple levels and in multiple sectors (World Health Organisation, 2017). Whilst it is often assumed that increasing life expectancy implicates extended period of good health, there is little evidence to suggest this (World Health Organisation, 2017).

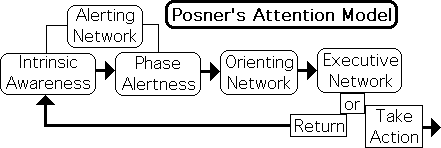
Active ageing as defined by the World Health Organisation (2002) is “the process of optimizing opportunities for health, participation and security to enhance quality of life as people age” (p12). Aging brings about varied patterns of cognitive changes (The Australian Psychological Society, 2000). The term cognition comes from the word “Cognoscere” meaning “to know”. Hence cognition refers to the workings of the mind that enable us to make sense of the world (Malia & Brannagan, 2007). It has been well documented that increased age is associated with lower performance on various measures of cognitive functions such as attention, processing speed, and reaction time among others (Craik & Salthouse, 2008).

Attention is a central constituent of cognitive ability. It is the ability to focus on certain aspects of the environment that are considered important and interesting by the individual, and flexibly manipulate this information. Alertness and arousal are essential components of attention. Attention is not a unitary function but is composed of several different processes. Through attention, information is selected, hence if attention is impaired, the brain will not receive information needed for further processing be it language, memory or any other cognitive faculty. If attention is compromised, the information received will not be processed accurately in the brain and this may possibly lead to reduced and faulty understanding. Hence, attention problems can impact on other cognitive abilities such as thought processes, social judgement, self awareness and communication. (Malia & Brannagan, 2007).

The Diagnostic and Statistical Manual (DSM) fifth edition describes 'mild neurocognitive disorder (mNCD)' formerly known as Mild Cognitive Impairment, as a “modest cognitive decline from a previous level of performance in one or more cognitive domains” and “the cognitive deficits do not interfere with capacity for independence in everyday activities” and is not explained by “delirium” or “any other mental disorders” (American Psychiatric Association, 2013, p605). Bharath et al. (2017) found that people with MCI presented mainly with memory disturbances, and deficits in more than one cognitive domain namely attention and executive functions.

Increased cognitive and brain reserve that facilitates neuroplasticity and promotes healthy aging can be stimulated through cognitive training (Shah, Weinborn, Verdile, Sohrabi, & Martins, 2017). Though cognitive impairment in the form of attention deficits among older adults has been well established, attention training programs for this population are limited. Understanding the various frameworks or models of attention will assist in designing and implementing theoretically grounded cognitive training programs. Several scientific frameworks for attention have been proposed that are based on cognitive processing theories, factor analysis of psychometric tests, neuro-anatomic theories, and clinically based models (Sohlberg & Mateer, 2010).

The model that best describes the deficits in attention due to aging is Posner and Rothbart’s model of attention (Posner & Rothbart, 2007). Their neuro-anatomical model of attention discusses a system of anatomic structures involved in the attentional processing system. Their attention model describes three separate but fully integrated systems in the brain, namely 1) alerting or arousal network, 2) orienting network, and 3) executive network. Alerting is the process of achieving and maintaining a state of high sensitivity to incoming stimuli; orienting allows the selection of information from sensory input; and executive attention involves mechanisms for evaluation, decision making and responding. (Posner & Rothbart, 2007).



The executive network was further explained by Baddeley, in his models of working memory (Baddeley, 2001). He defined the concept of the central executive control of attention (Baddeley, 2001; Sohlberg & Mateer, 2010). Our ability to focus, divide and switch attention is directed by the attentional control system which is identified as the central executive in Baddeley’s model (Baddeley, 2001; Sohlberg & Mateer, 2001). This type of attention that is part of an executive control is called a “top-down” phenomenon because it is based on acquired knowledge. Research lends relatively strong support for age-related declines in executive types of attention (Andrés and Van der Linden, 2000; Braver and West, 2008; Lustig and Jantz, 2015).

The model of attention by Sohlberg and Mateer (2001) provides a good basis for evaluation and treatment of attentional impairments in the aging population and hence was chosen as a clinical framework for the current study. It consists of five levels of attention: focused attention, sustained attention, selective attention, alternating attention, and divided attention (Sohlberg & Mateer, 2001, 2010). Impairments in these five components are seen with aging (Nobre & Kastner, 2014). Focused attention is the basic momentary response to external or internal stimuli and lasts for milliseconds (Sohlberg and Mateer, 2001). Sustained attention is the ability to maintain focused attention over a period of time. Though sustained attention abilities are affected in aging, the onset of this decline may be later than other forms of attention deficits (Nobre and Kastner, 2014). Selective attention is the ability to select the most important stimuli/stimulus in the environment at the exclusion of irrelevant distractions, at any point in time. Deficits in selective attention in older adults were found regardless of age-related slowing of information processing and decline in bottom-up sensory processes (Nobre and Kastner, 2014). Alternating attention is the ability to switch attention between different stimuli steadily, smoothly and rapidly. (Malia and Brannagan, 2007). Age-related declines were noted in task switching ability that required a global shift in the cognitive set (Clapp, Rubbens, Sabharwal, & Gazzaley, 2011; Callaghan, Holland and Kessler; 2017). Finally, divided attention is the ability to share sustained attention between two or more stimuli at the same time. Harada, Natelson Love, and Triebel (2013) reported noticeable age effects on selective and divided attention. Age-related decline in divided attention may increase the risk of personal injury in older adults when performing a cognitive task concurrently while executing a motor response such as driving as well as engaging in a meaningful conversation (Nobre and Kastner, 2014).

In summary, the theories of attention discussed above, complement each other: Posner and Rothbart’s model of attention (2007), fundamentally discussed the neural pathways and processes involved in attention. Baddeley furthered the importance of attention in his models of working memory by defining the concept of the central executive control of attention (Baddeley, 2001; Sohlberg & Mateer, 2010) -these two models will assist in understanding the mechanisms in age-related changes in attention, whilst, Sohlberg and Mateer (2001) discussed the varied interactive levels of attention functions that can be improved through cognitive training. The latter model will assist in formulating a specific attention training program for the current study.

Despite age-related decline in attentional abilities and processing mechanisms, the brain has the ability to compensate for these deficits. This is explained by the Scaffolding Theory of Aging and Cognition (STAC) (Park and Reuter-Lorenz 2009). The brain responds to neural insults or structural deficiencies by engaging in continuous functional reorganization and repairs. This homeostatic phenomena by the brain throughout life is explained by the STAC model.

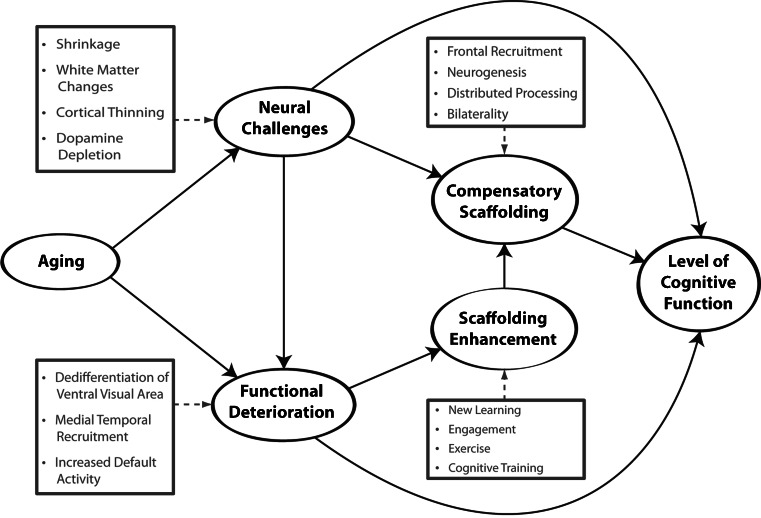


Fig 1. The Scaffolding Theory of Aging and Cognition (Park and Reuter-Lorenz 2009)

STAC model concludes that structural or neural changes and functional degradation of the brain occur as a result of aging. The level of cognition in an individual is the combination of this negative structural and functional degradation in the brain, and “compensatory scaffolding.” Compensatory scaffolding involves the formation of additional circuitry or the use of remaining circuitry differently with age that compensates for declining structures whose function has become noisy, inefficient, or both. With progressive age and absence of appropriate intervention, the brain’s ability to provide effective compensation can weaken over time. This necessitates the initiation of scaffolding that can be achieved through cognitive engagement. Though the basic hardware of cognition significantly deteriorates with age, knowledge and expertise are relatively protected from this age-related decline, which may enhance the level of compensatory scaffolding. It was also confirmed that long term severe deterioration can weaken the brain’s ability to provide effective compensation, this necessitated the determination of the inclusion of the minimum age criteria in the current study which was 60 years.

The recognition of the influence of lifestyle, experience, genetics, and environment in the course of aging and level of cognitive function (Bender and Raz 2012; de Frias, Schaie, & Willis, 2014; Zanjani, Downer, Kruger, Willis, & Schaie, 2013) led to the development of the revised STAC model (STAC-r). The STAC-r model (Reuter-Lorenz and Park, 2014) includes the life-course variables which implicate the accumulation of experiences and states experienced from birth to death (Mayer, 2003). This revised model states that both life-span (aging) and life-course (experience) factors influence the structure and function of the brain and directly affect the development of compensatory scaffolding. STAC-r model introduces two new concepts namely Neural Resource Enrichment and Neural Resource Depletion. Neural resource enrichment factors enhance brain structure or function. Some of these factors are engagement in leisure and cognitive activities in middle and late adulthood (Reed et al., 2011; Wilson et al., 2013) as well as physical exercise (Head et al., 2012 and Erickson, Gildengers, & Butters, 2013). STAC-r posits two pathways for this protective effect to occur: firstly by enhancing and preserving brain structure and function (Erickson, Miller, Weinstein, Akl, & Banducci, 2012, and Chapman et al., 2015) and secondly through life course enrichment factors by increasing the capacity for compensatory scaffolding (Reuter-Lorenz and Park, 2014). The second construct- “neural resource depletion,” are negative influences on brain structure, neural function and cognition and may range from genetic factors to health and lifestyle choices (de Frias et al., 2014; Bender and Raz, 2012). Different domains of cognition may age differently within and across individuals (Mungas et al., 2010; Boyle et al., 2013). For example this nonlinearity may be evident in an individual who showed little change in cognition from ages 52-64 years, and then may undergo treatment (chemotherapy, rehabilitation) for a serious illness that leads to a sharp, nonlinear decline in function. Thus, cognitive intervention is a powerful scaffolding tool that mediates between neural resource enrichment and neural resource depletion.

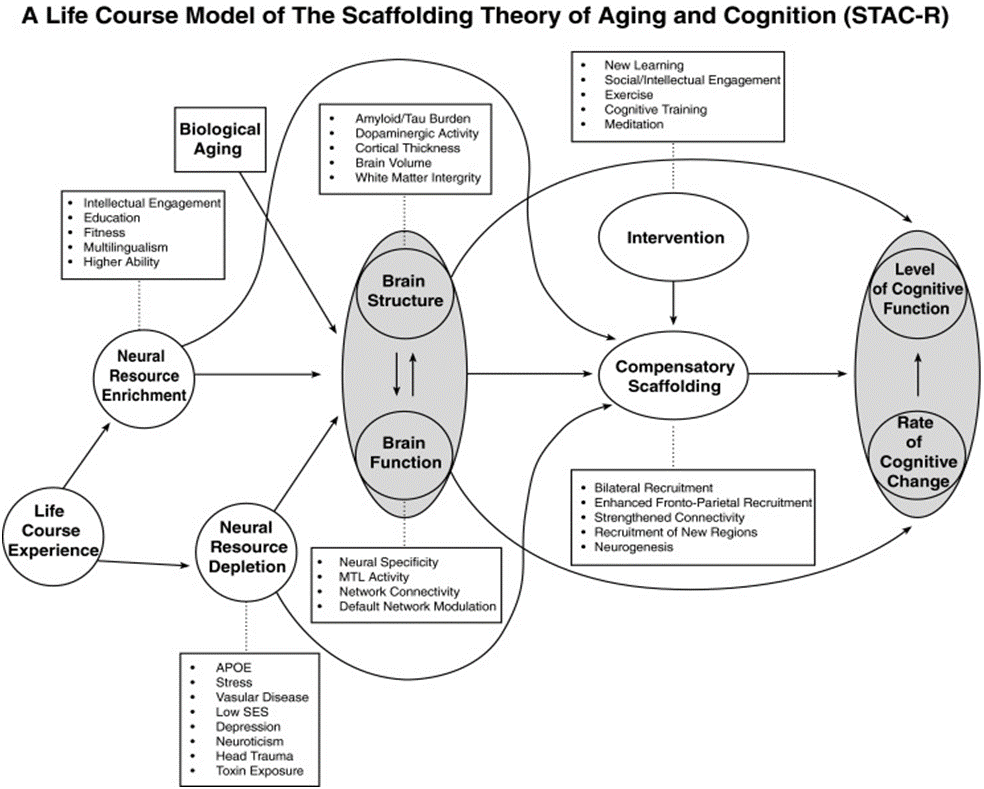


Fig 2. The revised Scaffolding Theory of Aging and Cognition (Park and Reuter-

Lorenz, 2014).

Cognitive training, a type of compensatory scaffolding technique refers to repetitive practice of a set of standard tasks with varying levels of difficulty (Kallio et al., 2018). Cognitive training (CT) is mainly restorative and targets cognitive impairment through structured tasks that can be delivered in person or via technology (computerised), individually or in a group format (Bahar-Fuchs, Clare and Woods, 2013). The following paragraphs discuss some computerised cognitive training programs and opinion on it from the scientific committee. Computerised CT was found to be a practical intervention for improving global cognition, memory, working memory, attention, and psychosocial functioning, including depressive symptoms in people with mild cognitive impairment (MCI) (Hill et al., 2017).

A computerized cognitive stimulation (CCS) program was shown to improve inhibitory control, mental flexibility, free recall as well as self esteem among participants. A computerized cognitive engagement (CCE) program showed improvement in processing speed, greater acceptance of technology and improved self esteem (Djabelkhir et al., 2017). A meta-analysis examining the efficacy of commercially available, computerized cognitive training programs to improve cognition in older adults and transfer to everyday functioning, found significant small to medium training effects for the cognitive domains of attention (d = 0.651, p < .001), processing speed (d = 0.294, p = .002), and visuospatial memory (d = 0.252, p = 0.016), as well as far transfer to self-reported measures of everyday function (d = 0.277, p < 0.001). (Tetlow & Edwards, 2017). The largest effect of CT was found for attention (d = 0.651), which is a commonly targeted cognitive domain by commercially available CT programs. 26 clinical trials including follow-up studies of commercial computerised brain training programs (such as Posit science, Cognifit, Cogmed, Brain age 2, My brain trainer, Dakim and Lumosity) showed improvement in varying degrees (small to large effect sizes) in memory, processing speed, executive functions and reasoning capabilities in older adults (Shah et al., 2017). Some limitations of these computerised CT studies were inconsistencies in designs, variations in measurement tools and statistical analyses for measuring cognitive domains- all these made comparison among studies difficult. Brief training duration in some studies, and the inability to learn through observation, feedback and reward most possible in face to face training were also lacking in these studies.

In addition, leading cognitive psychologists and neuroscientists from the Stanford Centre on Longevity, Max Planck Institute for Human Development (2014) concluded that the results obtained from commercially available computerised brain games are often exaggerated and misleading. Such studies fail to establish the enduring positive effects of participants’ performance that were reported during the actual training. Moreover, the transfer effect of such exercise to other domains of cognition as well as in everyday life remains questionable. The effects of motivation and expectations of participants that can influence results have also not been separately investigated in the studies on commercially available computerised brain exercises. In addition, it is well established that any stimulating cognitive exercises have a positive impact on cognitive health, therefore the superiority of such programs over other cognitive challenges undertaken by participants as claimed by the authors of these programs, is questionable. Considering these limitations, research on face to face cognitive training was also explored.

The Promoting Aging with Cognitive Exercise (PACE) study – a randomized control trial, examined 160 older adults with MCI and found no effect of intervention (5-week Cognitive Activity Training Strategies (CATS) program) on participants’ primary outcome measure, the Cambridge Cognitive Examination Revised (CAMCOG-R) that assessed global cognition (Vidovich et al., 2015). However, Digit Span and Quality of Life in Alzheimer’s Disease (QoL-AD)- two of the secondary measures favoured the intervention, although the effect sizes were small and clinical significance was questionable. Digit Span was used as a measure of attention. The authors suggested that the imbalance in the male to female ratio among the participants and excess of amnestic MCI in the CATS group could have biased the outcomes despite statistical adjustment. Lack of monitoring of the MCI status may have also affected the results. CAM-COG-R as a sensitive measurement tool was also questioned by the authors. The improvement in immediate attention associated with the intervention did not influence other cognitive domains positively (memory recall), hence the authors suspect that this improvement could be a result of Type 1 error. They found that participants receiving the active intervention reported improved quality of life (QoL) and less dependence on the use of mnemonic strategies to improve memory in daily situations. This led the authors to conclude that this improvement could be due to a modest increase in confidence and wellbeing as a result of participation in the intervention, however such conclusion could not be validated as no quantitative measures were obtained. The nature of the CATS program and the information delivered during its short duration was considered insufficient to influence any noticeable quantitative gains in cognition.

The largest randomised controlled single blind study with healthy older adults was the Advanced Cognitive Training for Independent and Vital Elderly (ACTIVE) study (Rebok et al., 2014). Their 2,802 healthy adults aged 65 years and older (mean age of 74 years) were assigned to one of three intervention groups- memory, reasoning and speed of processing or to a control group receiving no research intervention. Interventions were conducted in small groups in ten 60–75minute sessions over 5 to 6 weeks. Manualised intervention sessions 1–5 focused on strategy instruction and exercises to practice the strategy while sessions 6–10 provided additional practice exercises. Booster training (four 75-minute sessions) was provided at 11 and 35 months to participants who completed initial training (attended a minimum of 8 out of 10 sessions). Outcomes were obtained following 1, 2, 3, 5 and 10 years. The results promisingly demonstrated that the training had immediate and long-term effects lasting up to five years on memory abilities and up to 10 years on reasoning and speed of processing. Transfer effects were also evident: 60% of participants from all three training groups reported less difficulty in the instrumental activities of daily living (e.g., medication management, meal preparation) than the control group after 10 years, in comparison to 49 percent of control group participants. After 10 years, 60 to 70 percent of participants indicated that they were as good as or better than when they started the ACTIVE study. This indicated that interventions can be designed to maintain cognitive function. In addition, researchers found that the interventions were less effective on adults who progressed to developing MCI. Hence, it is recommended that early work with adults showing signs of minor cognitive problems may assist in maintaining their cognitive health in the long-term. In addition, the authors projected financial gains that demonstrated decreased predicted medical expenditures by 3.2 percent between baseline and the one-year follow-up after the training. Some limitations highlighted were the characteristics of the sample who were advantaged in age, education and Mini Mental State Examination (MMSE) over the general population, hence the results cannot be fully generalised and the design of the booster sessions made it difficult to examine dose effects. Attrition was present at the follow-up interval (retention at the 5-year assessment was 67%). This was brought about by participants who had increasing health problems and lowered cognitive function as they aged. However, through 5 years, the authors did not find differential attrition by condition. Therefore, they concluded that the attrition did not affect the between group comparisons of intervention effects.

In summary, cognitive decline is inevitable with aging. Cognitive assessment facilitates the diagnosis of cognitive disorders, it also helps to understand the nature and extent of cognitive impairment and allows for more accurate estimation of functional ability (Woodford & George, 2007). However, research in identifying the best predictor of cognitive decline in the elderly has been lacking. This could be due to varied reasons including high cost of cognitive testing, lack of trained clinicians to conduct testing, lack of perceived benefits of testing the elderly. Attention is undoubtedly one of the core cognitive domains, central to a number of cognitive functions required for daily living. Studies investigating the impact of attention deficits on other cognitive domains in older adults are lacking. There is no study to date which investigated the individual impact of attention training for older adults on their attention ability. The gamut of research has identified non-specific cognitive interventions that address different cognitive domains as well as global cognition, and attention ability in this context has also been investigated. Comparatively there is a dearth of literature investigating specific cognitive interventions and their impact on the targeted cognitive domain/s. The ACTIVE study can safely be regarded as one such study, but attention was not one of the targeted cognitive domains investigated in this study.

**3.3 Research Question**

Considering the above-mentioned gaps in literature, the research questions are:

1. What is the relationship between attention deficits and deficits in other cognitive domains in both groups of participants (with MCI and Healthy Older Adults)?
2. Does a structured attention training program influence change or address the deficits in attention in these groups studied? (people with MCI and healthy older adults)? If so
3. Which group of participants (with MCI or healthy older adults) show greater improvement?
4. Understand the difference (if any) in performance among the participants of the treatment group (participants receiving attention training only), the participants of the control group who receive the relaxation training followed by the attention training, and the participants of the control group who participate in the relaxation training only?

**4 Aims/Objectives:**

**4.1 Aims:**

The main aims are:

1. To investigate the nature of age-related decline in attention and other cognitive abilities of older adults with or without Mild Cognitive Impairment (MCI).

2. With the above knowledge this study will investigate changes in attention ability resulting from participants’ engagement in a structured attention training program.

**4.2 Objectives:**

In relation to **Aim 1**, this study will investigate:

a) As well as compare the predictive efficacy of the various subscales of the Test of Everyday Attention (TEA) and the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) being utilised in this study

b) It will also investigate the relationship between attention deficit and deficits in other examined cognitive domains in both the groups (people with MCI and healthy older adults).

In relation to **Aim 2**, this study will:

c) Explore changes in attention abilities of the two groups (people with MCI and healthy older adults) once they have completed their training in the research intervention namely Attention Training.

d) Explore the changes in attention abilities of participants receiving the attention training only and the control group of participants receiving the relaxation training only and the other control group of participants receiving relaxation training followed by the attention training?

**4.3 Research Question:**

(Please see above answer to question 3.3)

**4.4 Hypothesis**

H1. People with Mild Cognitive Impairment (MCI) are hypothesized to have greater attentional difficulties and are expected to perform poorly than healthy older adults, on standardised measures of attention and general cognition.

H2. Attention Training program is expected to influence positive changes in attention ability and general cognition among older adults with and without MCI.

H3. Attention Training in program is expected to influence greater improvement in attention abilities and general cognition among older adults with MCI than the same population without MCI. (This hypothesis is based on the assumption that greater gains might be possible in the group that shows greater deficits in all areas of cognition).

H4. The control groups of participants receiving relaxation training followed by attention training is hypothesized to show similar improvement to that of the intervention group (participants receiving the attention training only).

**5 Method:**

**5.1 Includes study design, setting and who the target participants are, interventions**.

This study has a mixed design. 1. A quasi-experimental design with data collected pre and post intervention training offered to the sample of participants with Mild Cognitive Impairment (MCI- Group 1). 2. Randomized control trial with data collected pre and post trainings offered to both the treatment and control groups of the sample of healthy older adults (Group 2).For Group 1, participants with a new diagnosis of Mild Cognitive Impairment (MCI) recruited from the Memory Clinic, GARSS, Toowoomba Hospital, and from Geriatricians in their private practises as well as General Practitioners from the community will be recruited. All participants will be aged between 60-80 years.

Geriatricians in private practise and GPs who mainly work with the older adult population will be approached by the principal researcher through phone contact, emails or in person if necessary. (Please see attached letter to Geriatricians and GPs in private practice in Appendix XI). Please also see attached recruitment and consent flowchart (Appendix -XII).

Interested participants will contact the principal researcher by phone or by email. Alternatively, after receiving the reply slips from participants, the principal researcher will contact the prospective participants. During that contact, the principal researcher will answer queries the participants may have on the research and if they wish, then proceed with scheduling an eligibility and pre-assessment session (if eligible) with the research assistants at the USQ Psychology Clinic (for community participants with or without MCI) and with research assistants at the Memory Clinic (for participants with MCI recruited from the Memory Clinic).

Potential participants will be given Participant Information Sheet. The inclusion-exclusion criteria will be adhered to during recruitment (please view Appendix I at the end of this document). Participants from the community (MCI and Healthy Older Adult participants) will have their assessments and training at the University of Southern Queensland and participants from the Memory Clinic will have their assessments and training at the Toowoomba Hospital.

After consent interviews and eligibility assessment with the aid of the Repeatable Battery for the Assessment of Neuropsychological Status- RBANS Update (Form A), the participants will be administered the additional pre-training measure - Test of Everyday Attention (TEA). Eligible participants’ RBANS Update A scores will be included as a pre-training measure.

After completion of the pre-training assessments, eligible participants of Group 1 (people with MCI) will be offered the intervention training (Attention Training) individually or in groups of 2-3 participants maximum depending on the number of participants recruited. On the other hand, after completion of pre-training assessments, participants of Group 2 (healthy older adult participants) will be randomly assigned to either the Attention Training group or the Relaxation Training group using a computer-generated randomization numbers available at random.org, with each group receiving equal number of participants (Haahr, M., 1999 and Snippe, et al., 2016).

To maintain confidentiality, each eligible participant of the Group 2 (healthy older adults) will be coded with a number (1-64) based on the order of their recruitment to the study. As 16 participants will be recruited at a time, their corresponding codes will be fed into the “List Randomiser” program from “Random org”. This program will generate a randomised sequence of numbers for a block of 16 participants at a time.

For Example: “P” indicates participant who are given a random allocation in this example.

P 4

P11

P 13

P3

P 16 (TREATMENT GROUP- ATTENTION TRAINING)

P10

P 7

P 8

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P 5

P 14

P 1

P 15 (CONTROL GROUP- RELXATION TRAINING)

P 9

P 6

P 2

P 12

The first 8 randomly numbered participants will receive the Attention Training and the rest of 8 randomly numbered participants will receive the Relaxation Training. This tool will be used for all 64 coded Group 2 participants (Healthy Older adults) in blocks of 16 maximum, as they are recruited for the study.

Participants in the treatment groups (both healthy older adults and people with MCI groups) will receive 10 weeks, 2 hrs per week session of structured Attention Training program (please view Appendix VI at the end of this document). Each treatment session will consist of: psychoeducation, an individual attention training task, a group attention training task- both of which primarily targets one or more aspects of attention namely selective, sustained and alternating attention but not divided attention, followed by discussion and feedback. The group facilitator (Principal Researcher) will keep a record of the individual participants’ performance on each individual task completed for the entire 10 weeks program.

Participants of the control group of Group 2 (only healthy older adults) will be offered group Relaxation training (10 sessions each 2 hourly, please see Appendix VII at the end of this document) in groups of maximum 8 participants. This comparison group will allow us to understand whether the attention training tasks help improve attention abilities of the treatment groups but not the control groups, keeping other factors constant. All participants will be offered catch-up sessions in a timely manner in the event they miss any of the 10 sessions.

After completion of the group or individual training programs (Attention training program for the treatment groups and Relaxation Training program for the control groups), each participant will be re-administered the alternate form of the TEA and the RBANS- Update Form B.

Control group of healthy older participants (Group 2 ) who would like to obtain the Attention Training program after completion of their relaxation training, will be contacted and offered the same Attention Training Program (10 weekly sessions x 2 hrs each) in groups of 8 participants maximum. Upon completion of the Attention Training program by these control group participants, they will be assessed using the RBANS and the TEA, in line with best practise.

**5.2 Participants:**

***5.2.1: Sample size***

Sample size was determined by G power analysis. This was calculated for medium effect size (.20 to .50) for 4 groups (namely two- treatment and control groups of participants with MCI and two- treatment and control healthy older adult groups), and with one repeated measure. Hence total number of participants was calculated to be 128: 32 in the treatment group of participants with MCI, 32 in the control group of participants with MCI, 32 in the treatment group of healthy older adults and finally 32 in the control group of healthy older adults.

If the above sample size cannot be obtained despite every effort utilised to do so, the following options will be explored:

1. For Group 1 participants (participants with MCI), a repeated measure t-test will be used. A sample of 44 participants was calculated from G-power for medium effect size (.20 to .50), for this to take place. The G-power calculated for medium effect size (.20 to .50) for Group 2 participants (healthy older adults) remain the same that is 64 participants.
2. As a last option if this sample number of 44 participants cannot be obtained for Group 1 (participants with MCI), then Reliable Change Index (RCI) will be calculated from individual measures obtained from this sample population.

***5.2.2: Inclusion/Exclusion criteria*** (Please view Appendix I at the end of this document)

***Inclusion Criteria***

1. **Group 1: Participants with a diagnosis of MCI**

Participants will be recruited from the Memory Clinic, Geriatric Adult Rehabilitation and Stroke Services, GARSS, Toowoomba Hospital, from Geriatricians in their private practise as well as General Practitioners (GPs) from the community. All participants will have a confirmed diagnosis of MCI. MCI status need to be recent within 3 months of recruitment to this study. The MCI status in GARSS is determined by the consultant geriatrician after the patient goes through a thorough clinical assessment by the Memory Clinic team formed of the consultant geriatrician, psychologist, pharmacist and the geriatric clinical nurse consultant. Additional to their MCI status, all MCI participants, within 3 months of recruitment to this study, will be screened by the research assistant for their eligibility by using RBANS (Update form A). Their RBANS score should be between 1 and 2 SD below the mean or between 3rd and 16 percentiles for their age and education matched peers on culturally appropriate normative data (American Psychiatric Association, 2013). Cognitive impairment maybe seen in one or more cognitive domains measured by the RBANS. However, participants will be independent with all their activities of daily living as reported by them, significant others or their GP. Participants of this group will be assessed with the RBANS at regular intervals of 3 months during their participation period, to ensure that they continue to hold their eligibility status. This 3 months’ time frame is followed because a) test-retest of RBANS is 3 months b) for a review in the Memory clinic for MCI status, a minimum of 3 months interval is maintained only if the clients have not had any rapid cognitive decline in the interim c) As MCI status is variable over time, regular monitoring of MCI status is also recommended in the practice guidelines update summary for MCI (Petersen et al., 2018).

Age of the sample population was determined to be between 60-80 years. This is based on the recommendations obtained from the STAC (revised model- 2014) that states scaffolding needs to be provided in a timely manner. With, progressive age and absence of appropriate intervention, the brain’s ability to provide effective compensation can weaken over time. Though the basic hardware of cognition significantly deteriorates with age, knowledge and expertise are relatively protected from this age-related decline, which may enhance the level of compensatory scaffolding.

1. **Group 2: Healthy Older Adults (without MCI diagnosis):**

Participants will be recruited from the community and should be aged between 60 years and 80 years, do not hold a diagnosis of Mild Cognitive Impairment (MCI) and/or Dementia in the last 3 months prior to recruitment. On the RBANS Update Form A, participants’ scores should be at least equal or above the mean, for their age and education matched peers on culturally appropriate normative data (APA, 2013). No reports of functional or cognitive decline as noted by client, significant other or GP. Participants will be re-assessed of their eligibility status by using RBANS, if they or their significant other or their GP report any rapid cognitive decline, during their participation period.

***Exclusion criteria:***

People with a current or predicted diagnosis of Dementia (for both groups 1 and 2) and a predicted or current diagnosis of MCI (for healthy older adult group 2) will be excluded from the study. If healthy older adults’ scores are found to be suggestive of the possibility of either MCI or Dementia (2 or more SD or 3rd percentile or below appropriate norms, APA, 2013), they will be provided a letter addressed to their GP, detailing their assessment results and they will be encouraged to consult their GP with that letter. The participants with MCI whose assessment scores are suggestive of the possibility of Dementia, will be re-referred to their referrer (geriatrician or GP) at the (Memory Clinic or community). Their geriatrician or GP may then like to review or consult these participants and provide them and/or their family with further treatment options. At this point they will also be excluded from the study.

Other exclusion criteria for both Groups 1 & 2 include severe sensory impairment that could potentially impact on their performance, acute medical condition or a severe medical condition needing intensive treatment, and intellectual impairment. These people are excluded as such conditions will hinder their ability to participate in the interventions.

***5.2.3 Participant Information***

After ethics approval from DDH ethics committee and the USQ ethics committee, the principal researcher will hold presentations on this research for recruitment of participants from the Memory Clinic GARSS, Toowoomba Hospital, GP and private geriatricians (please view Appendix 9- pamphlet for people with MCI), the University 3rd Age (U3A, Toowoomba branch) and Toowoomba Regional Council (for dissemination of information to community groups organised by the council).

Group 1 participants (older adults with MCI) will be informed of the research by their geriatricians or GPs, after patients are given the diagnosis. Interested participants will then obtain the Participant Information Sheet from the reception of the Memory Clinic or from the receptionist of their private physicians.

Recruitment of Group 2 participants (healthy older adults from the community)- The principal researcher will advertise about the research through pamphlets (please view Appendix 10) in various community centres (University 3rd Age-U3A, Toowoomba branch, Toowoomba library, Toowoomba Regional Council to disseminate information to community groups for older adults). Interested participants will then obtain the Patient Information Sheet from the reception office of U3A and information desk of the Toowoomba Library.

Participants will have 2 months’ time to register their interest. Interested participants will complete the relevant section of the Participant Information Sheet and post it to the Memory Clinic (Group 1 participants) and to the Psychology Clinic, University of Southern Queensland (USQ, Toowoomba Campus, for Group 2 participants), through the reply-paid envelope supplied with the Participant Information Sheet. They may also choose to email the Principal Researcher the Reply Slip if that is more convenient to them**.** At this point, the principal researcher will collate the responses of participants and contact the interested participants to invite them for the consent interviews, eligibility assessments (please view Appendix 11 and 12), pre-training assessments, randomisation, participation in the interventions and post training assessments.

Participants begin the initial face to face session with the 1st consent interview for eligibility assessment with the principal researcher (Please view Appendix 3 and 7). Then they proceed to complete the eligibility assessment conducted by the research assistant. After eligibility assessment, the principal researcher will conduct the 2nd consent interview for obtaining participant’s consent for participating in the rest of the research (Appendix 4 and 8). Participants will then complete a second pre-training assessment (Test of Everyday Attention, TEA) only if they are deemed eligible to participate in the study. If deemed ineligible for participation, they will be excluded from the study.

Eligible participants of Group 1 (participants with MCI) will be offered the Attention training program individually or in groups of 2-3 participants as and when they are recruited to the study. They will be re-assessed by the research assistant/s using the RBANS update form B and the TEA (alternate form) (Please view Appendix 17 and 18) after completion of their Attention Training program (10 sessions, 2 hourly weekly sessions.

Eligible participants of Group 2 (healthy older adult participants) will be randomly allocated to treatment and control groups by the research assistant. Participants will be invited to the training programs through letters sent to them within 2 months from their initial assessment session (please view appendices: 13, 14, 15, 16). At any one time a maximum of 8 participants will be provided the training programs. The training groups will be continued until the sample of 64 participants is reached.

Treatment groups will receive 10, 2 hourly weekly sessions of structured Attention Training program. Control groups will receive 10, 2 hourly weekly sessions of Relaxation training. Both training programs will be provided by the principal researcher.

After completion of the respective training programs, participants of Group 2 (Healthy Older Adults-treatments and controls) will be re-assessed by the research assistant/s using the RBANS update form B and the TEA (alternate form) (Please view Appendix 17 and 18). In addition, participants of the Control group from Group 2 only (healthy older adults) who wish to obtain the Attention Training Program, after they have completed their Relaxation Training will be contacted by the principal researcher and offered the same Attention Training program in groups of 8 participants maximum for 10 weekly sessions – 2 hrs each, by the principal researcher. At the completion of this training program, participants will be re-assessed using the RBANS and the TEA, in line with best practise.

***5.3 Data Collection – procedures and tools***

*What data will you collect? How frequently will it be collected and how will it be collected?*(please view Appendix IX at the end of this document)

1. A clinical/demographic questionnaire will be administered by the research assistant (Please view appendix V attached at the end of this document), to eligible participants after eligibility screens.
2. Psychometric assessment tools (pre-post training assessment tools) will be administered by the research assistants before and after participants’ participation in the interventions/trainings (for both groups 1 & 2 treatment and control groups).
3. In addition, the principal researcher/group facilitator will keep a record (please view appendix VIII at the end of this document) of each treatment group participants’ individual performance on the individual task completed for the entire 10 weeks attention training program.
4. In addition, research assistants will also collect post training data using the RBANS and the TEA from the control group participants who participates in the Attention Training program, once they have completed the Relaxation Training.

Please view Appendix IX at the end of this document.

***5.4 Psychometric Tools/Pre-post training assessments tools:***

**a) Test of Everyday Attention (TEA)**

Robertson, I.H, Nimmo-Smith, I., Ward, T., & Ridgeway, V (1994).

TEA is an individual measure of three important clinical and theoretical aspects of attention: selective attention, sustained attention, and attentional switching. As such it can detect the specific areas of deficits in attention that can be improved through a defined program in this study. It is used for adults 18-80 years old. It is sensitive to show normal age effects in the general population and is validated with patients with closed head injury, stroke, and Alzheimer's disease, and including those with low educational level. The subtests of the TEA use everyday skills to examine various aspects of attention namely: Map Search (selective attention), Elevator Counting, Elevator counting with distraction and lottery (sustained attention), Elevator Counting using Visual or Auditory Stimulus (attentional switching), and Telephone Directory (divided attention). Coefficients for the test-retest reliability of versions A to B of the TEA ranged from 0.59 to 0.86. For versions B to C, test-retest reliability coefficients ranged from 0.61 to 0.90. TEA has high face validity for individuals with intact auditory and sensory acuity.

1. **Repeatable Battery for the Assessment of Neuropsychological Status** (**RBANS Update Form A and B)** Randolf, C (2012).

The RBANS is a brief 30 minutes individual assessment to measure cognitive decline or improvement across 5 domains namely immediate and delayed memory, attention, visuospatial/constructional and language, in people aged 18-89 years. It has shown sensitivity of 84% and specificity of 97% for cognitive impairment in Alzheimer’s disease (AD). This test can track recovery during rehabilitation and can also track progression in degenerative diseases such as Dementia. Alternate forms are available for evaluating progression or improvement of neuropsychological symptoms which helps eliminate content practice effects.

***5.5 Data Analysis***

The pre-training assessment data namely the RBANS- Update Form A and the TEA scores will be analysed using the correlation analysis and the logistic regression discussed below:

**1.Correlation analysis:**

The correlation between the various attention measures (selective attention, sustained attention, attentional switching, and divided attention and various domains of the RBANS Update A namely immediate and delayed memory, visuospatial and language measures and overall cognition will be investigated by completing a correlation matrix. This will measure and describe the strength and direction of the relationship existing among these variables.

**2.Logistic Regression**:

This analysis will determine what subscales of the Test of Everyday Attention (TEA) namely (selective attention, attentional switching, divided attention, and sustained -four subtests in total) and what subtests/domains of the RBANS (namely attention, immediate memory, delayed memory, language or visuospatial) best predict the group of participants with MCI.

**The above two analyses will be conducted after collection of pre-training assessment data.**

**3.Regression Slope and Correlation**

For treatment groups only for both Groups 1 (people with MCI) and 2 (healthy older adult groups), each participant’s score for tasks completed on each session (10 sessions) will be recorded. For each individual session, each participant’s score on the allocated task is the number of correct responses out of the total number of items to be completed within the specified time limit. Individual participant’s score on treatment intervention is the sum of the scores obtained from each individual session (10 in total).

Regression slopes will be calculated for each participant and these regression slopes will be correlated with the TEA (alternate form) change scores.  This would allow the quantification of change as well as map the direction of change. Participants will receive training in 3 aspects of attention namely selective, sustained and alternating attention but not divided attention. This record of task performance and the measures of the TEA share the same aspects of attention. In addition, TEA also measures divided attention, but the treatment group participants will not receive any training in it. This will help us to determine whether training in the specific tasks of attention influence participants’ attentional abilities in the 4 examined aspects of attention.

**4. Paired t-test ONLY FOR GROUP 1 (Participants with MCI)-**

Continuous outcome is measured for each participant at the start and end of their training program (Attention Training program). For each subject, the change between the start (pre-training data) and end (post-training data) is measured. The mean values and standard deviations between the above data (pre-post training) is obtained. Comparison between the mean values is completed.

**5. 2X2 Two by two repeated Analysis of Variance (ANOVA) ONLY FOR GROUP 2 (Healthy Older adults’ sample):**

The pre and post training assessment data (RBANS and TEA) will be analysed using the 2 X 2 repeated ANOVA. The independent variable in this study is the Attention Training Program. Independent variable groups are: 1. Treatment group of healthy older adults and 2. Control group of healthy older adults. Control group of participants will be offered an unrelated relaxation training program during the research.

There are 4 dependent variables that will be assessed namely selective attention, sustained attention, divided attention and attentional switching – the four components of the Test of everyday Attention (TEA- alternate form) and the total score of the Repeatable battery for the Assessment of Neuropsychological Status (RBANS Update Form B). Delta scores will be used here.

Statistical comparisons will focus on determining the following:

* Differences noted between treatment groups versus control groups.
* Whether there will be reliable changes pre-versus post-intervention?

Data will be analysed using the SPSS version 25. Principal supervisor will be assisted by her supervisors/associate investigators for analysis and interpretation of the data.

**6. Data Management: Storage, access destruction and confidentiality**

***6.1 Storage***

All original data will de-identified before analysis and reporting.

***DDH Storage***

DDH will only be responsible for storage of data obtained from participants with MCI, recruited from the Memory Clinic.

***USQ Storage***

USQ will only be responsible for storage of data obtained from participants with MCI recruited from the community and healthy older adults recruited from the community.

De-identified data will be entered directly into the secure USQ U Drive which can be accessed from Queensland Health premises.

***6.2 Access and Confidentiality***

The raw data will be accessed by the research assistant/s (RA) and the principal researcher for identification, coding, re-identification and de-identification purpose.

RA will be responsible for coding of pre-training and post-training assessment data. The principal researcher will enter individual participant’s data set obtained from their group participation in the Attention Training program. The associate researchers will only have access to de-identified data sets. De-identified data will be shared between DDH and USQ.

***6.2.1 DDH Secure document storage***

***DDH***

Hard copy files will be stored in a designated research only locked filing cabinet in the work space of principal researcher (GARSS Memory Clinic) with restricted access during the duration of the research. Hard copy files will be stored in a designated research only locked filing cabinet in the DDH library after the completion of the research for a minimum of 5 years (according to DDH policies). The DDH Senior Librarian, Research Fellow and the HREC Coordinator are gatekeepers to the research filing cabinet in the Library and access is dependent on their authorisation. De-identified data for the participants with MCI recruited from the Memory Clinic will be stored digitally on the DDH secure network drive Data 7 (W:), with restricted access to the researchers. For digital documents only, researchers listed on this HREA application will be able to access the subfolder assigned to the research project.

***USQ***

A research data management plan will be completed when applying for USQ research ethics. Hard copy files for the community participants (Participants with MCI diagnosis from the community and healthy older community adults) will be stored in the locked filing cabinet in the USQ Psychology Clinic with restricted access**.** Digital data will be stored in a system called the Research Data Bank Storage Application (ReDBank). Application to set up and access this system will be obtained after USQ ethics approval. With ReDBank, it can be assured that data is stored in Australia in a way aligned with USQ’s Research Data Management Policy. Responsibility for research data management resides with the principal researcher and the research (HDR) supervisors (associate investigators) for this study.

***6.3 Secure Transfer of confidential information:***

De-identified data from participants with MCI from the memory Clinic will be entered directly into the secure USQ U Drive which can be accessed from QHealth premises.

***6.4 Destruction:***

Once this research is completed the de-identified data will be stored in the listed above sites (DDH and USQ, Psychology Clinic) for a maximum of 7 years as per Australian Psychological Society (APS guidelines). For DDH, the library will create alerts for when the documents need to be reviewed for destruction. The Director of Psychology will receive the alert in the absence of the Primary Researcher listed in this document. Hard copy documents and electronic files will be destroyed according to DDH confidential document destruction protocols. For data stored with USQ Psychology Clinic, the coordinating Operational Support Officer, Faculty of Health, Engineering and Sciences, will create alerts for when the documents need to be reviewed for destruction. In the absence of the primary researcher, the head of the Department of Psychology will be alerted. Hard copy documents and electronic files will be destroyed according to USQ confidential document destruction protocols.

**7.1 Research related risks:**

As the training is a mental exercise there are no medical side effects from it. There are no risks from attending the Attention Training or Relaxation Training. It is possible that some participants may become upset if their test results show a decline in their mental abilities. In those situations, the researchers will be able to arrange for free counselling by trained people from the Psychology Clinic, USQ. These counsellors will not be members of the research team. The geriatrician in the Memory Clinic will be notified immediately when any participant with MCI have progressed to having Dementia, as indicated by the results of his/her cognitive testing. If significant cognitive decline is detected in the healthy older adults or participants with MCI recruited from the community, they will be provided with a letter stating their assessment results addressed to their geriatrician or their GP, and they will be encouraged to have further follow-ups. Additionally, lists of community psychological services will be provided to them.

Another predicted issue could be that the difficulty level of intervention tasks (for the attention training program) may challenge some participant/s of the treatment groups. The Attention Training program will be designed keeping in mind the general groups' level of cognitive ability. Despite efforts made to suit the difficulty levels of the intervention tasks with participants' levels of cognitive ability, and predicted gains expected, such tasks may at times be more challenging for some participants. As such, every effort will be made by the principal researcher (PR) to support the individual participant to develop their skills at their own pace. They will be encouraged to complete tasks and not coerced in doing so. PR will be available to discuss difficulties encountered and suggest varied ways to work out the intervention tasks. Practise worksheets will be provided as well as information booklet on the psychoeducation topics discussed during the sessions, so assist the participants work through their skills in between sessions and after the end of the program, if they wish to.

***7.2 Duty of Care:***

Coincidental health concerns identified in the course of the research that do not relate to the research will be managed through standard referral pathways.

***7.3 Participants in non-intervention arms:***

Control group participants of Group 2 (Healthy older adults) only, not receiving the research intervention during the initial part of the research will indicate their interest to receive this intervention, upon completion of their Relaxation Training. Such interested control group participants will be contacted via letters (please view Appendix 19) by the principal researcher (PR) at both sites and offered a list of dates, the research intervention will be offered. Interested participants will then indicate their availability through completed replies via reply-paid envelope posted to the PR. PR will then collate this information and inform the interested participants of the details of the upcoming program (please view Appendix 20 and 21), through letters. The same Attention Training groups will be offered to interested control group participants (healthy older adults) in groups of 8 maximum, for 10 weekly sessions- 2 hours each, by the principal researcher.

**8. Dissemination of results:**

***8.1 Dissemination to healthcare community:***

* The outcome of the project will be submitted as a PhD thesis under the University of Southern Queensland.
* A final report will be submitted to the HREC, DDH.
* Dissemination of results will take place for staff in the Memory Clinic, GARSS through a presentation.
* The project will be registered as a clinical trial via Prospero and therefore the research results will be published through accepted journals.
* The principal researcher will also share the findings through various clinical and peer reviewed publication, conferences and poster presentations.

***8.2 Feedback to participants:***

Interested participants will indicate their wish to obtain a copy of the outcome of the research, during the 2nd consent interview. Upon completion of this research, a paper copy outlining the summary of the outcome of this research in simple English will be posted to interested participants.

**9. Translation to practice:**

-Focused assessments for detection of MCI for patients who are referred to the Memory Clinic. This will positively influence the accuracy of diagnosis.

-If the results are favourable, future plans will be made for a targeted follow-up treatment pathway for people diagnosed with MCI at the Memory Clinic as well as in the community

-Improvement of the existing cognitive rehabilitation group (attention training group) run at GARSS by having a more structured, evidenced-based program.

-Expansion of the existing cognitive rehabilitation group and incorporation of other related domains of cognition and collaboration with other disciplines (mainly occupational therapists) to deliver such group programs. This may increase cost-effectiveness of the service by being able to cater to patients in groups rather than individuals, having similar problems.

-Sharing of knowledge obtained with other co-professionals so that they can consider incorporating such programs in their work with people diagnosed with MCI and healthy older adults in the community.

**10. Duration of the project:**

This project is expected to complete by June 2022. (Please view Appendix X at the end of this document)

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**APPENDIX I**

**INCLUSION/EXCLUSION CRITERIA (Section 4.2.2)**

**Inclusion Criteria: GROUP 1**

1. 60-80 years of age.
2. New diagnosis of Mild Cognitive Impairment (MCI)
3. Repeatable Battery for the Assessment of Neuropsychological Status RBANS (Update) score: 1 and 2 SD below the mean or between 3rd and 16 percentiles for their age and education matched peers on culturally appropriate normative data.

Cognitive impairment in one or more cognitive domains as reflected by the RBANS score.

1. Independent with all their activities of daily living as reported by them, significant others or their GP.

**Inclusion Criteria: GROUP 2**

1. 60-80 years of age.
2. RBANS Update score at least equal or above the mean, for their age and education matched peers on culturally appropriate normative data.
3. No reported cognitive or functional impairment.

**Exclusion criteria: BOTH GROUPS**

1. Current or predicted diagnosis of MCI or Dementia (2 or more SD or 3rd percentile or below appropriate norms) for healthy older adult group 1.
2. Current or predicted diagnosis of Dementia for participants with MCI (Group 1)
3. Severe sensory impairment
4. Acute medical condition or a severe medical condition needing intensive treatment
5. Intellectual impairment.

**APPENDIX II: RECRUITMENT AND CONSENT FLOWCHARTS (Section 4.2.4)**

***Study Design for People with MCI (Group 1)***

|  |  |  |
| --- | --- | --- |
| **WEEK 1 RECRUITMENT** | NOT INTERESTED  Geriatrician newly diagnose patients with Mild Cognitive Impairment (MCI) and selects patients    INTERESTED: Participants obtain Participant Information Sheet from Memory Clinic reception  2 MONTHS RESPONSE TIME  Clinic) | **NO FURTHER CONTACT** |
| **WEEK 10**  **ELIGIBILITY/**  **SCREENING**  **CONSENTS**  **AND**  **PRE-TRAINING**  **ASSESSMENTS** | **ALL THIS TAKES PLACE IN ONE SESSION**  Appointment with Principal Researcher (PR) for consent interview 1 – for eligibility assessment  DOES NOT CONSENT  CONSENTS TO SCREENING:  Research Assistant (RA) administers Repeatable Battery for Assessment of Neuropsychological Status (RBANS Update Form A)  INELIGIBLE  OR  NOT INTERESTED  **BREAK**  If eligible then consent interview 2 with PR for participation in the rest of the study.  Administration of the Test of Everyday Attention (TEA, pre-training assessment) by RA  DOES NOT CONSENT |  |
| **TREATMENT**  **AND**  **FOLLOW-UP** | Eligibility checks by RA every 3 months during the duration of participant’s engagement in the study  Participants receive 10,  2 hourly weekly  sessions of Attention  Training Program by PR,  individually or in groups of 2-3  participants | Ineligible  OR  Withdrawal |

**APPENDIX III: RECRUITMENT AND CONSENT FLOWCHARTS (Section 4.2.4)**

***Study Design for Healthy Older Adults (Group 2)***

|  |  |  |
| --- | --- | --- |
| **WEEK 1 RECRUITMENT** | Pamphlets distributed to catchment areas – U3A (Toowoomba Branch) and the Toowoomba Library.  NOT INTERESTED  INTERESTED: Participants obtain Participant Information Sheet from reception of U3A and Toowoomba Library  2 MONTHS RESPONSE TIME  Clinic) | **NO FURTHER CONTACT** |
| **WEEK 10**  **ELIGIBILITY/**  **SCREENING**  **CONSENTS**  **AND**  **PRE-ASSESSMENTS** | **ALL THIS TAKES PLACE IN ONE SESSION**  DOES NOT CONSENT  Appointment with Principal Researcher (PR) for consent interview 1 – for eligibility assessment  INELIGIBLE  OR  NOT INTERESTED  CONSENTS TO SCREENING:  RA administers Repeatable Battery for Assessment of Neuropsychological Status (RBANS Update Form A)  **BREAK**  If eligible then consent interview 2 with PR for participation in the rest of the study.  RANDOMIZATION: Advised of Group membership  Administration of the Test of everyday Attention (pre-training assessment) by RA  DOES NOT CONSENT |  |
| **TREATMENT**  **AND**  **FOLLOW-UP** | Eligibility checks by RA if concerns raised by participant, family or GP  Treatment group- 10, 2 hourly weekly sessions of Attention Training Program by PR  Control group- 10, 2 hourly weekly sessions on Relaxation Training by PR.  Eligibility checks by RA  If required  Post-training assessments (RBANS Update Form B and TEA (Alternate form) administered by RA | Ineligible  OR  Withdrawal  Ineligible  OR  Withdrawal |
| **ATTENTION TRAINING INTERVENTION**  **FOR CONTROL GROUP ONLY** | NOT INTERESTED  Participants will be re-assessed (RBANS and TEA) administered by RA after completion of their Attention Training Group  Interested control group participants after completion of relaxation training will be offered the attention training program facilitated by the PR.  NOT INTERESTED |  |

**APPENDIX IV**

***Study Design***

***Quasi-Experimental Design Randomised Controlled Trial***

GROUP 2: 64 Healthy older adults

GROUP 1 : **44 participants with MCI**

Treatment Group-Attention Training

Control Group (Healthy Older Adults)-32

Treatment Group (Healthy Older Adults)-32

**Interested Participants receive Attention Training Program**

**APPENDIX V**

**CLINICAL INFORMATION SHEET**

Date:

Identifying No:

Age:

Gender: Male/ Female/indeterminate

Marital Status: Married/Divorcee/widow/never married/ in a relationship/other – please specify

Cognitive status: Healthy Older adults /MCI; if MCI, date of diagnosis:

Highest educational level achieved: Primary/secondary/tertiary/trade (specify: ).

Current employment status: Employed/Retired

Sensory deficits (if any):

a) Vision: Intact/using aids/ not using prescribed aids/ no prescribed aids given.

b) Hearing: Intact/using aids/ not using prescribed aids/ no prescribed aids given.

Main medical condition/s:

Prescribed medication: please specify type:

**APPENDIX VI**

**ATTENTION TRAINING PROGRAM OUTLINE** (2 hours per week for 10 weeks).

**Session 1**

Psychoeducation – 30 mins. The brain and the importance of neuroplasticity.

Individual Attention Training Task- 20 mins. “Paced random numbers” task that primarily targets selective attention.

Break:10 mins

Group Attention Training Task- 30 minutes on “Get to know the group” task primarily targeting selective attention and retention in short term memory and recognition.

Feedback, discussion and in-session task allocation: 30 mins.

**Session 2**

Psychoeducation – 30 mins. General cognitive functions of the brain

Individual Attention Training Task- 20 mins on “Sound targeting” task that primarily targets selective attention.

Break:10 mins

Group Attention Task- 30 minutes “Simon says” task on selective attention and sustained attention

Feedback, discussion and in-session task allocation: 30 mins.

**Session 3**

Psychoeducation – 30 mins. What is attention and its role in the varied cognitive functioning needed in everyday life

Individual Attention Training Task- 20 mins. “Categorizing” task that primarily targets selective and alternating attention

Break:10 mins

Group Attention Training Task- 30 minutes on the task of “Action in numbers” which primarily targets selective and alternating attention

Feedback, discussion and in-session task allocation: 30 mins.

**Session 4**

Psychoeducation – 30 mins. Types of Attention and how they are interrelated.

Individual Attention Training Task- 20 mins. “Reverse counting” task that primarily targets sustained attention

Break:10 mins

Group Attention Training Task- 30 minutes on “Lego” task that primarily targets sustained attention

Feedback, discussion and in-session task allocation: 30 mins.

**Session 5**

Psychoeducation – 30 mins. Difficulties in attention and personal challenges faced in functioning that relate to the different types of attention discussed in the last session.

Individual Attention Training Task- 20 mins on “Addition/subtraction” task that primarily targets alternating, sustained and selective attention

Break:10 mins

Group Attention Training Task- 30 mins on “Variable numbers, letters and sounds” tasks that primarily targets alternating, sustained and selective attention

Feedback, discussion and in-session task allocation: 30 mins.

**Session 6**

Psychoeducation – 30 mins. How does this attention training hope to facilitate Neuroplasticity. Individual Attention Training Task- 20 mins on “Alphabet addition” task that primarily targets sustained attention

Break: 10 mins

Group Attention Training Task- 30 mins on “Two back” task on sustained attention

Feedback, discussion and in-session task allocation: 30 mins.

**Session 7**

Psychoeducation – 30 mins. Psycho-social factors impacting on peoples’ ability to attend and how can those factors be addressed

Individual Attention Training Task- 20 mins on “Task maintenance” task that primarily targets sustained attention

Break:10 minutes

Group Attention Training Task- 30 mins on “Puzzles” task that primarily targets sustained attention

Feedback, discussion and in-session task allocation: 30 mins.

**Session 8**

Psychoeducation – 30 mins. Psycho-social factors impacting on peoples’ ability to attend and how can we address those factors (continued from session 7).

Individual Attention Training Task- 20 mins on the task of “Number Blocks” task that primarily targets selective and sustained attention

Break:10 minutes

Group Attention Training Task- 30 mins on “Mindful Drawing” task that primarily targets selective and sustained attention

Feedback, discussion and in-session task allocation: 30 mins.

**Session 9**

Psychoeducation – 30 mins. Normal aging versus not so normal aging in terms of varied cognitive functioning of the brain.

Individual Attention Training Task- 20 mins on “Random dot to dot pictures” task primarily targeting sustained attention

Break:10 minutes

Group Attention Training Task- 30 mins on “finding places on a map” task that primarily targets selective and sustained attention

Feedback, discussion and in-session task allocation: 30 mins.

**Session 10**

Psychoeducation – 30 mins. Recapitulating topics covered.

Individual Attention Training Task- 30 mins on “Decoding” task that primarily targets sustained attention

Break: 10 minutes

Group Attention Training Task- 50 mins on overall feedback and discussion on take home skills and messages.

*It is to be noted that although the tasks for both individual and group attention training primarily targets a specific component of attention yet all the varied components of attention (selective, sustained and alternating) are quite interrelated and participants will often use more than one component in the varied attention training tasks identified above as well as in their daily life. Also, to note no specific training is provided for divided attention.*

**APPENDIX VII**

**RELAXATION TRAINING GROUP OUTLINE (Control participants)**

**Duration: 2 hours per week for 10 weeks.**

**Session 1**

Psychoeducation – 1 hour. The brain and the importance of neuroplasticity.

Break:10 mins

Relaxation session- 1 hour

**Session 2**

Psychoeducation – 1 hour. General cognitive functions of the brain

Break:10 mins

Relaxation session- 1 hour

**Session 3**

Psychoeducation- Stress, its role in health and well-being and management of stress

Break:10 minutes

Relaxation session- 1 hour

**Session 4**

Psychoeducation – 1 hour. What is attention and its role in the varied cognitive functioning needed in everyday life

Break:10 mins

Relaxation session-1 hour

**Session 5**

Psychoeducation – 1 hour. Memory and its role in everyday functioning

Break:10 mins

Relaxation session-1 hour

**Session 6**

Psychoeducation – 1 hour. Visuospatial awareness and its importance in everyday functioning

Break:10 mins

Relaxation session- 1 hour

**Session 7**

Psychoeducation – 1 hour. Language and its importance in everyday functioning

Break: 10 mins

Relaxation session- 1 hour

**Session 8**

Psychoeducation – 1 hour. What other psycho-social factors impact on people’s health and well being

Break:10 minutes

Relaxation session- 1 hour

**Session 9**

Psychoeducation – 1 hour. Normal aging versus not so normal aging in terms of varied cognitive functioning of the brain.

Break:10 minutes

Relaxation session-1 hour

**Session 10**

Psychoeducation – 1 hour. Recapitulating topics covered, feedback, discussion.

Break: 10 minutes

Relaxation session 1 hour.

**APPENDIX VIII: RECORD SHEET (ATTENTION GROUP TASKS)**

(For each participant)

|  |  |  |  |
| --- | --- | --- | --- |
| **Session** | **ATTENTION TARGET AREAS**  **(Outcome Measured)** | **TASK**  **(Timed- 20 minutes)** | **SCORE**  **(for each session)** |
| 1 | Selective | Paced Random Numbers | \_\_\_\_/69 |
| 2 | Selective | Sound Targeting | \_\_\_/7 |
| 3 | Alternate, selective | Categorising | \_\_\_/64 |
| 4 | Sustained | Reverse Counting | \_\_\_/60 |
| 5 | Alternate, sustained, selective | Addition/subtraction | \_\_\_\_/56 |
| 6 | Sustained | Alphabet Addition | \_\_\_\_/210 |
| 7 | Sustained | Task Maintenance | \_\_/20 minutes |
| 8 | Selective, sustained | Number Blocks | \_\_\_/32 |
| 9 | Sustained | Random Dot to Dot Pictures | \_\_\_/34 |
| 10 | Sustained | Decoding | \_\_\_\_/42 |

**APPENDIX IX DATA COLLECTION TABLE**

|  |  |  |  |
| --- | --- | --- | --- |
| **DATA COLLECTED** | **TIME COLLECTED** | **OUTCOME MEASURED** | **PERSON COLLECTING DATA** |
| Clinical Information Sheet | After eligibility assessment | Clinical and demographic information | Research Assistants/s |
| Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) Update Form A | Data collected using RBANS Update Form A during eligibility is used as a pre-assessment data for eligible participants. This data is collected before intervention is provided. | Overall Cognition  Specific Domains:  1.Attention  2.Immediate Memory  3. Delayed Memory  4. Visuospatial/Constructional  5. Language | Research Assistant/s |
| Test of Everyday Attention (TEA) | After recruitment, before intervention. | Everyday overall Attention  Specific Domains:  1.Selective Attention  2.Sustained Attention  3.Switching Attention (alternating)  4.Divided Attention | Research Assistant/s |
| Attention Training Program tasks (Treatment Group ONLY) | Each session of Attention Training Program (total of 10 sessions). | Please see Record Sheet for outcome measured  1.Selective Attention  2.Sustained Attention  3.Switching Attention (Alternating) | Principal Researcher |
| RBANS Update Form B | Completion of Interventions | Changes in:   * Overall Cognition * Specific Domains:   1.Attention  2.Immediate Memory  3. Delayed Memory  4. Visuospatial/Constructional  5. Language | Research Assistant/s |
| Test of Everyday Attention (TEA) | Completion of Interventions | Changes in:   * Everyday overall Attention * Specific Domains:   1.Selective Attention  2.Sustained Attention  3.Switching Attention (alternating)  4.Divided Attention | Research Assistant/s |

**APPENDIX X TIME FRAME**

|  |  |  |  |
| --- | --- | --- | --- |
| **ACTIVITY** | **START DATE** | **COMPLETE /**  **INCOMPLETE** | **EXPECTED**  **COMPLETION**  **DATE** |
| Literature Review | July 2016 | Incomplete | June 2022 |
| Preparation for Confirmation of Candidature | January 2018 | Complete | June 2018 |
| Confirmation of Candidature submission | - | Complete | June 2018 |
| Confirmation of Candidature Seminar preparation | June 2018 | Complete | June 2018 |
| Confirmation of Candidature amendments | June 2018 | Complete | July 2018 |
| DDHHS HREA preparation | Aug 2018 | Complete | Sept 2018 |
| DDHHS HREA submission | Sept 2018 | Complete | HREA outcome finalised-Nov 2018 |
| USQ ethics preparation | Oct 2018 | Complete | Oct 2018 |
| USQ ethics submission | Oct 2018 | Complete | USQ Ethics outcome finalisation-Dec 2018 |
| Consultation with sources of recruitment | Jan 2019 | Complete | Feb 2019 |
| Preparation of research intervention manuals, Application for grants | July 2018 | Complete | Dec 2018 |
| Eligibility Assessments (ongoing) | Mar 2019 | Incomplete | Jan 2021 |
| Consent interviews (ongoing) | Mar 2019 | Incomplete | Jan 2021 |
| Randomisation (ongoing) | Mar 2019 | Incomplete | Jan 2021 |
| Pre-training Assessment administration (ongoing) | Mar 2019 | Incomplete | Jan 2021 |
| Delivery of Interventions (ongoing) | April 2019 | Incomplete | June 2021 |
| Post training Data collection (ongoing) | July 2019 | Incomplete | Nov 2021 |
| Dissertation write up | Dec 2021 | Incomplete | June 2022 |
| Submission of Thesis | **-** | Incomplete | 15 July 2022 |
| Post-Trial Intervention to interested Control Group Participants  Summary of the outcome posted to interested participants |  | Incomplete | After PhD confirmation |

**APPENDIX XI- Letter to Geriatricians and GPs in Private practise.**

Dear Dr \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Thank you for assisting me in recruiting participants for my research.

I am a psychologist at the Toowoomba Hospital. I am currently doing a research on “Attention and Older Adults” which is a joint venture between USQ (Where I am enrolled as a PhD candidate) and DDH (as I work there and am also collecting data from the Memory Clinic at the hospital).

The inclusion criteria for my study are:

• Older adults aged 60-80 years

• Has a clinical diagnosis of Mild Cognitive Impairment (MCI).

• Participants need to be reasonably fit (no sensory deficits example visual impairment), no intellectual impairment and not having any acute medical condition or a severe medical condition needing intensive treatment. These people are excluded as such conditions will hinder their ability to participate in the interventions provided as part of the study.

I have attached the following documents for you to use as necessary:

• Pamphlet

• Participant Information Sheet and Reply Slip

• Protocol of the study for reference.

Kind Regards

Mousumi Singh

Principal Researcher

**APPENDIX XII- RECRUITMENT AND CONSENT FLOWCHART**

***Study Design for Community participants with MCI***

|  |  |  |
| --- | --- | --- |
| **WEEK 1**  **RECRUITMENT** | NOT INTERESTED  Geriatrician and GPs inform newly diagnosed patients with Mild Cognitive Impairment (MCI) about the research.    INTERESTED: Participants obtain Participant Information Sheet and Reply Slip from receptionist of the respective clinic. 2 MONTHS RESPONSE TIME  Clinic) | **NO FURTHER CONTACT** |
| **WEEK 10**  **ELIGIBILITY/**  **SCREENING**  **CONSENTS**  **AND**  **PRE-TRAINING**  **ASSESSMENTS** | **ALL THIS TAKES PLACE IN ONE SESSION**  Principal Researcher (PR) makes contact with prospective participants after receiving the Reply Slips.  DOES NOT WANT TO PARTICIPATE  Interested participants are scheduled appointments for consent, eligibility and preassessment with Research Assistant (RA) at USQ clinic.  INELIGIBLE  OR  NOT INTERESTED  Participants go through consent interview 1-consent to take part in the eligibility assessment. Then they take the eligibility assessment.  **BREAK**  If eligible then they go through the consent interview 2 for participation in the rest of the study.  Administration of the Test of Everyday  Attention (TEA, pre-training assessment) by RA  DOES NOT CONSENT |  |
| **TREATMENT**  **AND**  **FOLLOW-UP** | Participants receive 10, 2 hourly weekly sessions of Attention Training Program by PR,  Individually or in groups of 2-3  participants                Post-training assessments (RBANS Update Form B and TEA (Alternate form) administered by RA | In eligible  or  Withdrawal |