My Active and Healthy Aging (My-AHA)

Randomized Control Trial Study

Protocol

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1 Protocol Flowchart

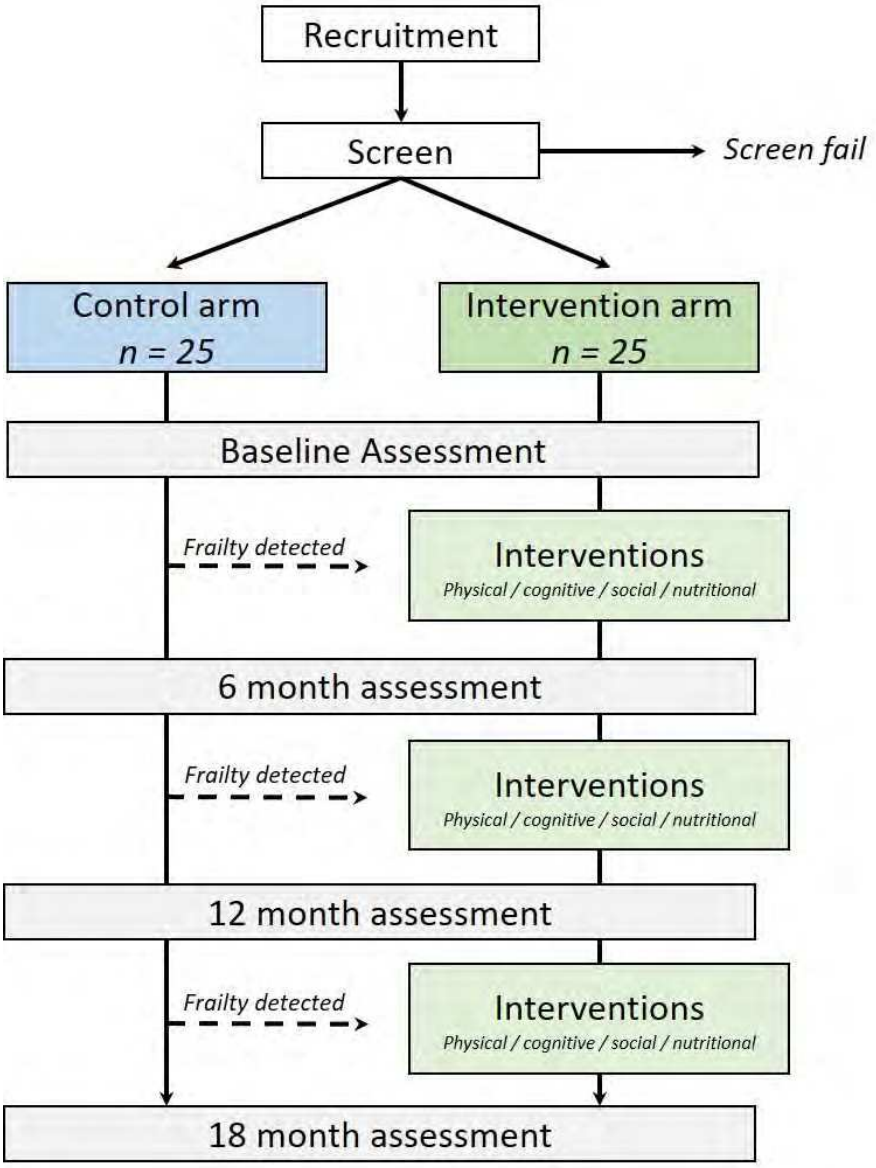


Figure 1: *Protocol flowchart*

The My-AHA RCT protocol comprises 6 elements that will be described in detail below:

1. Participant recruitment
2. Participant screening
3. Randomised allocation to control or intervention arm
4. Periodic assessments
5. Interventions
6. My-AHA User Platform interface

2 Recruitment

2.1 Type and Number of Participants

Participants will be adults aged 60 years and older meeting study inclusion criteria for pre-frailty (Table 2) and not meeting study exclusion criteria for clinically significant cognitive and/or mood disturbance (Table 4) or for concomitant diseases (see Section 3.2).

A total of 50 participants will be recruited from the Sunshine Coast region. Participants will be community residing older adults, residing either in their own home/unit, retirement community, or residential aged care (non-secure). The majority are likely to be living in a semi-supported independent living setting receiving some aged care support services in own home/residence but otherwise fully independent.

Participants who volunteer to participate in the RCT must be screened to ensure that each participant meet all inclusion criteria (Table 1) and do not meet any exclusion criteria (Table 3).

3 Participant Screening

3.1 Inclusion Criteria

Table 1: *My-AHA RCT inclusion criteria for participant screening*

INCLUSION CRITERIA
1. Age: over 60 yrs
2. Familiar with use of smartphones and/or tablet computers
3. Have access to WiFi connection and existing internet data plan and provider
4. Able to stand and walk unassisted
5. Free of significant cognitive impairment (age-corrected MMSE ≥ 24) (Table 4)
6. Free of clinically significant mood disturbance (HADS-Anxiety <15; HADS-depression < 15) (Table 4)
7. Free of any acute or unstable medical conditions
8. Meet criteria for pre-frail status (Table 2)
9. Able to understand directions and participate in the protocol
10. Able to sign informed consent

Table 2: *Pre-frail inclusion criteria for participant screening*

Clinical sign/symptom	Measure	Cutoff values	
PHYSICAL DOMAIN ***Pre-frail = 1 or 2 of the following criteria are met***			
1. Shrinking, evidenced by weight loss (unintentional)	≥ 4.5 kg unintentional in prior 12 months; or at follow-up assessment ≥ 5% of body weight in prior 12 months	Self-reported weight loss (not due to dieting or fasting) in preceding 12 mo ≥ 4.5 kg Follow-up: K = (weight in previous year - current measured weight)/(weight in previous year). If K ≥ 0.05, meets weight loss frailty criteria	
2. Weakness	Grip strength in lowest 20% at baseline adjusted for gender and BMI	**BMI** Men BMI ≤ 24 Men BMI 24.1 - 26 Men BMI 26.1 - 28 Men BMI > 28 Women BMI ≤ 23 Women BMI 23.1 - 26 Women BMI 26.1 - 29 Women BMI > 29	**Grip strength cutoff (kg)** ≤ 29 ≤ 30 ≤ 30 ≤ 32 ≤ 17 ≤ 17.3 ≤ 18 ≤ 21
3. Poor endurance and energy	Self-report of exhaustion as indicated by responses to 2 questions on CES-D scale	Using the CES–D Depression Scale, response of "2" (a moderate amount of the time, 3-4 days) or "3" (most of the time) to either of the following 2 items: (a) I felt that everything I did was an effort; and/or (b) I could not get going.	
4. Slowness	Time to walk 15ft (4.57m) ≤ slowest 20% adjusted for gender and standing height	**Gender/Height (cm)** Men Height ≤ 173 cm Men Height > 173 cm Women Height ≤ 159 cm Women Height >159 cm	**Cutoff time to walk 4.00 m)** ≥ 6.13 sec ≥ 5.25 sec ≥ 6.13 sec ≥ 5.25 sec

5. Low physical activity level	Energy expenditure per week below established cutoff	Short version of the IPAQ questionnaire assesses activity levels for walking, moderate-intensity and vigorous-intensity activities for work, transportation, domestic chores, gardening and leisure-related activities.	IPAQ Activity level measures as MET-min units). Convert IPAQ Met-min units to kcal using following formula adjusting for participants weight in kg: [kcal = MET-min x (weight kg/60)] Gender specific cutoff values: ▪ Men: < 383 kcal ▪ Women: <270 kcal

3.2 Exclusion Criteria

Potential participants will be excluded if they meet one or more of the following exclusion criteria:

Table 3: *My-AHA RCT exclusion criteria for participant screening*

EXCLUSION CRITERIA	**Participant excluded if meets 1 or more of below:**
Mobility problems	1. cannot stand and ambulate unassisted 2. painful arthritis, spinal stenosis, amputation, or painful foot lesions that limits balance and mobility,
Concurrent chronic disease independently contributing to frailty	1. suffers from a significant neurodegenerative CNS disorder, e.g. a. Alzheimer's disease b. Lewy body dementia c. Frontotemporal Lobar Degeneration, Fronto-Temporal Dementia d. Parkinson's disease e. multiple sclerosis f. progressive supranuclear palsy g. amyotrophic lateral sclerosis h. hydrocephalus i. Huntington's disease j. prion diseases 2. affected by severe peripheral nervous system and/or neuromuscular disorders, e.g. a. CIDP b. myasthenia gravis c. multiple sclerosis d. polymyositis
Concomitant injury or disease known to impact independently, cognitive psychological or physical function	1. clinical evidence or history of stroke (within 2 yrs) 2. clinical evidence or history of transient ischemic attack (within 6 months) 3. significant head injury with associated loss of consciousness, skull fracture or persisting cognitive impairment (2 years) 4. epilepsy (a single prior seizure is considered acceptable) 5. if meet DSM-5 criteria for: a. major depressive disorder (current) b. schizophrenia or other psychotic disorders (lifetime) c. bipolar disorder (within the past 5 years d. substance (including alcohol) related disorders (within the past 2 years)
Presence of cognitive, sensory or perceptual deficits that interfere with assessment tasks	1. have language deficits that impair testing 2. have significant visual impairment 3. have a significant hearing loss

Presence of other conditions or diseases that will compromise participants' ability to undertake interventions (especially physical)	1. have clinically significant cardiovascular disease, i.e: a. hospitalization for acute coronary syndrome (acute myocardial infarction or unstable, angina) b. symptoms consistent with angina pectoris, within the 12 months c. signs or symptoms of clinical heart failure within the 12 months d. evidence of uncontrolled atrial fibrillation e. a cardiac pacemaker 2. preexisting or current signs or symptoms of respiratory failure, e.g. a. chronic obstructive pulmonary disease b. bronchial asthma c. lung fibrosis d. other respiratory disease 3. untreated hypertension 4. metastatic cancer or immunosuppressive therapy 5. concurrent acute or chronic clinically significant immunologic, hepatic (such as presence of encephalopathy or ascites), or endocrine disease (not adequately treated).
Unacceptable Test/Laboratory Values	1. Postural hypotension (fall in systolic blood pressure of greater than 30 mmHg or fall in diastolic blood pressure of greater than 20 mmHg on standing compared to sitting) at the time of screening. Participants who present at the time of screening with postural hypotension yet have no known history of postural hypotension, nor underlying medical condition related to hypotension, may be rescreened

Table 4: *Exclusion criteria for **clinically significant deficits** in Cognitive and Psychological function*

Clinical sign/symptom	Measure	Cutoff values	
COGNITIVE DOMAIN	**Must NOT *meet 1 or more of the EXCLUSION CRITERIA***	**INCLUSION CRITERIA**	**EXCLUSION CRITERIA**
1. Evidence of lowered general cognitive function	Mini Mental State Examination test (MMSE) screens for deficits across several cognitive functions.	Age-adjusted MMSE • 24-30 (no cognitive impairment)	Age-adjusted MMSE score • 18-23 = MCI • 0-17 = severe clinical deficit
2. Evidence of lower than age-appropriate learning and recall of verbal information	Hopkins Verbal Learning Test (HVLT) is a brief test of verbal list learning and memory. Comprises 12 words, organized into three semantic categories, and presented over three consecutive learning trials.	HVLT-total recall score • Score ≥ 25	HVLT-total recall score • Score ≤ 24
PSYCHOLOGICAL DOMAIN	**Must NOT *meet any EXCLUSION CRITERIA***	**INCLUSION CRITERIA**	**EXCLUSION CRITERIA**
1. Increased levels of anxiety and/or lowered mood experienced over the preceding week	HADS – Hospital and Depression Scale, a 14-item scale to which participant indicates degree of agreement/frequency of experience in previous week on a 4 point scale. Seven of the items relate to anxiety and seven relate to depression.	Scores are computed separately for the Anxiety scale (7 items – HADS-a) and the Depression scale (7 items – HADS-d): 0-7 = normal mood 8-10 = mild symptoms 11-14 = moderate symptoms	• Scores ≥ 15 - HADS-d and/or • Scores ≥ 15 - HADS-a

3.3 Screening Failures

Screen Failures are defined as participants who sign a Screening Participant Informed Consent Form (PICF-Screen) for My-AHA study but are not subsequently randomized and who do not enter the RCT. Participants who are Screen Failures may be rescreened once only after approval by the study Medical Supervisor (University of Torino, Italy).

3.4 Withdrawal Criteria

3.4.1 Reasons for Withdrawal

- Any clinical AE, laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant in the opinion of the investigator
- Significant protocol violation
- Participant requests to discontinue for any reason; it is important to determine whether the withdrawal of consent is primarily due to an AE, lack of efficacy, or other reason

The above reasons do not automatically lead to withdrawal from the study in all cases. The final decision will be based on consultation between the Principal Investigator and the study Medical Supervisor (University of Torino, Italy), with the ultimate decision by the principal investigator or participant. Participants may discontinue from treatment with study intervention but may agree to continue to be followed for additional safety evaluation.

If a participant meets discontinuation criteria during treatment, the participant will undergo the Participant Withdrawal process (Section 3.4.2).

3.4.2 Participant Withdrawal Procedures

If a participant is prematurely discontinued from the intervention, the investigator must make every effort to perform the evaluations scheduled for the next assessment phase scheduled for that participant.

4 Participant randomization

Participants will be randomized into 2 study arms, with 50% of participants allocated to each arm:

- Study Arm 1: Control group (n = 25)
- Study Arm 2: My-AHA intervention group (n = 25)

Randomization will occur at each study site independently.

Initial randomization of participants at each site will occur on a 1 (control) : 1 (intervention) ratio, with allocation of participants to each treatment arm being undertaken using on alternating allocation sequence based on order of entry into the study (i.e. participant 1 – study arm 1; participant 2 – study arm 2; participant 3 – study arm 1; participant 4 – study arm 2, and so on).

Once recruitment and allocation to study arms of 20 participants has occurred at each site. The study site PI will submit to the RCT Study Coordinator basic demographic information on the 20 participants recruited and allocated to study arms. The demographic information required for each of the 20 participants is:

- Gender
- Age
- Highest education level

The RCT study coordinator will review the balance of participants across study arms for these demographic variables within each study site and advise the Principal Investigator of any adjustment to the allocation procedures for remaining participant assignment to treatment arms to ensure equivalence of study arms within each site.

5 Devices

Participants in the intervention group will require the following devices and access requirements:

Table 5: *Devices required for participants in intervention group*

1	Android based smartphone and/or tablet computer	Preferably participant's own device. Can be supplied by site if participant does not own Android compliant device
2	Internet access – WiFi	Participant's own internet plan and WiFi modem in place of residence.
3	Mobile phone data	Participant's existing mobile phone plan and SIM card with appropriate level of data access
4	Medisana ViFit MX3 wristband	Site to provide one ViFit activity tracking wristband per participant in the intervention group
5	Personal computer (optional)	Participant's own PC can be used an optional additional device for connection to My-AHA portal

6 Assessment protocol

6.1 Overall Design

The design of the assessment phases is illustrated in Figure 2, with a detailed list of individual measures at each assessment phase described in Table 6.

Figure 2: *Schematic of Study Design*

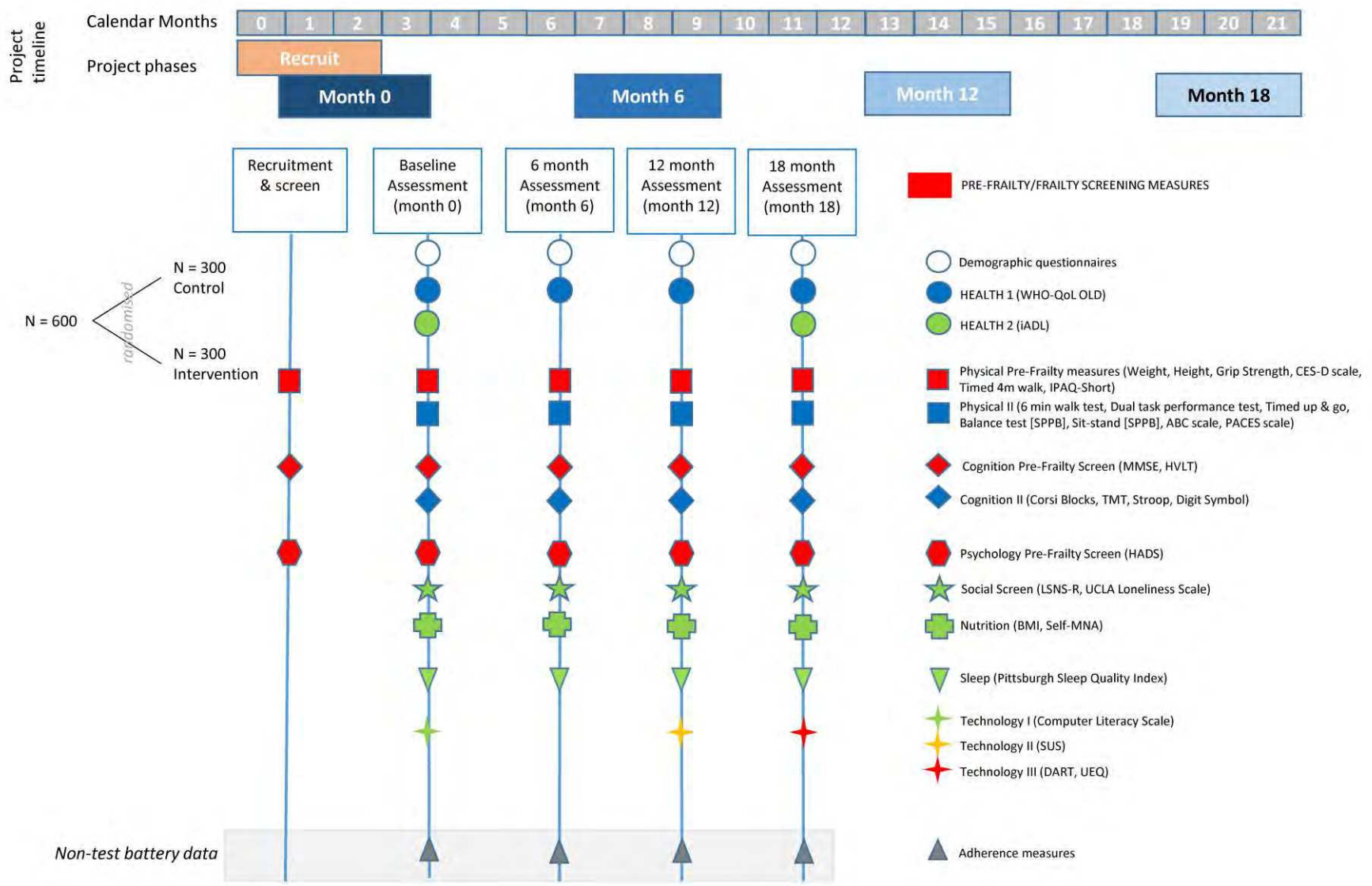


Table 6: *Assessment battery for the My-AHA RCT assessment points*

DOMAIN	Test name	Screening	Baseline	6mth	12mth	18mth
Consent process	Information sheets and consent forms (Appendix 1, Appendix 2, Appendix 3)	✓Appendix 1	✓			
Screening questionnaire	Screening for inclusion and exclusion criteria; including pre-frail assessment	✓				
Demographic	Standard questionnaire • Date of birth • Gender • Education (years completed) • Residential status (live alone, with other etc.) • Fear of falls • Falls history • Cognitive activities (mental activity) • Medical history (diseases/diagnoses past and current, medication history) • Continence		✓			
	Brief demographic update questionnaire (to track demographic variables than can change over time): • Change in residential status since prior assessment • Fear of falls • Falls history since previous assessment • Continence • Cognitive activities (mental activity) since previous assessment • Medical since previous assessment point (diagnoses existing and new, medication prescription current)			✓	✓	✓
RCT Adherence	Cognitive games (in My-AHA platform) time spend in game, time scheduled		✓	✓	✓	✓
	iStoppFalls – time spent/time scheduled		✓	✓	✓	✓
	FAME – calendar with diary		✓	✓	✓	✓
	OTAGO – calendar with diary		✓	✓	✓	✓
	Endurance training (heart rate monitor, calendar with diary)		✓	✓	✓	✓
	VitalinQ – time spent/recipes used		✓	✓	✓	✓
	Technology – duration and frequency of app use		✓	✓	✓	✓
Health	WHO-QoL OLD		✓	✓	✓	✓
	Lawton-Brody iADL scale		✓		✓	✓
Physical	Weight (kg)	✓	✓	✓	✓	✓
	Height (cm)	✓	✓	✓	✓	✓
	Grip strength	✓	✓	✓	✓	✓
	CES-D (2 items assessing exhaustion)	✓	✓	✓	✓	✓
	Time to walk 4m (SPPB)	✓	✓	✓	✓	✓
	IPAQ-Short version	✓	✓	✓	✓	✓

	6-minute walk test		✓	✓	✓	✓
	Short Physical Performance Battery (SPPB)		✓	✓	✓	✓
	Dual-Task Performance (repeat of gait speed test of the SPPB)		✓	✓	✓	✓
	Timed up and Go test		✓	✓	✓	✓
	ABC (self-efficacy for physical function)		✓	✓	✓	✓
	PACES (Physical Activity Enjoyment Scale)					✓
Cognitive	MMSE	✓	✓	✓	✓	✓
	HVLT	✓	✓	✓	✓	✓
	WMS-III Spatial Span (SSP)		✓	✓	✓	✓
	Trail Making Test (TMT-A & TMT-B)		✓	✓	✓	✓
	Stroop test (24 item Victoria Version)		✓	✓	✓	✓
	WAIS-III Digit Symbol substitution (DSS)		✓	✓	✓	✓
Psychological	HADS	✓	✓	✓	✓	✓
Social	LSNS-R (Lubben Social Network Scale, Short form)		✓	✓	✓	✓
	UCLA Loneliness Scale		✓	✓	✓	✓
Nutrition	BMI (*derived from height/weight data in Physical battery*)		✓	✓	✓	✓
	Self-MNA		✓	✓	✓	✓
Technology	Evaluation of Usability Scale (SUS)				✓	
	DART questionnaire					✓
	Computer Literacy Scale (CLS)		✓			
	User Experience Questionnaire (UEQ)					✓
	*Measures used to determine pre-frailty status of participants (*see Table 2)					

Estimated maximum protocol duration:

- Screening assessment – 60 min (1hr)
- Baseline assessment – 155 min (2hr 35min)
- 6 month assessment – 130 min (2hr 10 min)
- 12 month assessment – 135 min (2hr 15 min)
- 18 month assessment – 155 min (2hr 35min)

6.2 Screening questionnaire

Persons expressing an interest in participating in the My-AHA RCT will undergo formal screening to ensure that they meet inclusion criteria and do not meet any of the identified exclusion criteria (see Section 3 Participant Screening, Table 1, Table 2, Table 3, Table 4). A standard questionnaire for participant screening will be used (Appendix 4) along with standard forms for the MMSE, HVLT, IPAQ, and HADS which will be administered to confirm each participant meets pre-frailty criteria for inclusion in the RCT. It is estimated that the screening process will take a maximum of 60 minutes to complete.

6.3 Adherence assessment

Adherence to the intervention packages (see Section 6) are recorded automatically through the platform (Section 8). The system records all complete and incomplete sessions of intervention and can confirm whether a scheduled training session has been completed or not, which is then registered in the calendar.

6.4 Demographic measures

6.4.1 Standard demographic questionnaire

At baseline assessment, all participants will be required to complete the *Standard Demographic Questionnaire* (Appendix 5).

This questionnaire collects information from each participant regarding:

- Date of birth
- Gender
- Education (years completed)
- Residential status (live alone, with other etc.)
- Fear of falls
- Falls history
- Cognitive activities (mental activity)
- Medical history (diseases/diagnoses past and current, medication history)
- Continence/incontinence

6.4.2 Brief demographic questionnaire

At follow-up assessment time points (6, 12, 18 months) the *Brief Demographic Questionnaire* (Appendix 6) is to be completed by each participant. This questionnaire is designed to collect data on demographic variables that may change across the duration of the RCT, specifically information regarding changes in:

- Change in residential status since last assessment
- Current fear of falls
- Falls history since last assessment
- Cognitive activities (mental activity) engaged in since last assessment
- Medical since last assessment point (diagnoses existing and new, medication prescription current)
- Continence/incontinence

6.5 Health assessment

6.5.1 WHOQol-OLD

The *World Health Organisation Quality of Life – OLD extension* (WHOQol-OLD) is a 24-item self-administered scale, assessing quality of life in older adults (Appendix 7).

Responses are recorded on Likert-scaled items assigned to six facets: "Sensory Abilities" (SAB), "Autonomy" (AUT), "Past, Present and Future Activities" (PPF), "Social Participation" (SOP), "Death and Dying" (DAD) and "Intimacy" (INT). Each of the facets has 4 items, thus for all facets the score of possible values can range from 4 to 20, provided all items of a facet have been completed (see **Error! Reference ource not found.**). The scores of these six facets or the values of the 24 single items of the WHOQOL-OLD module can be combined to produce a general ("overall") score for quality of life in older adults, denoted as the WHOQOL-OLD module "total score". As empirically supported by analyses of the measurement model via structural equation modelling (see below), quality of life is conceived as a higher-order factor, underlying the structure of the WHOQOL-OLD module.

6.5.2 Instrumental Activities of Daily Living (iADL)

The *Lawton-Brody Instrumental Activities of Daily Living (iADL)* Scale is an 8-item examiner administered scale, assessing the highest level of functional capacity of the participant across 8 areas of daily activity (Appendix 8):

1. Ability to use a telephone
2. Shopping
3. Food preparation
4. Housekeeping
5. Laundry
6. Mode of transportation
7. Responsibility for own medications
8. Ability to handle finances

6.6 Physical assessment

6.6.1 Weight

Participants weight (in kg) will be recorded at each assessment point on a standard set of calibrated digital scales. Each site will use the same digital scale for all participants.

Additionally, participants will be screened to ascertain if they meet Fried criteria for weight loss (unintentional) of more than 4.5kg in the preceding 12 months.

6.6.2 Height

Participant's height will be measured (in cm) using standardized stadiometer measurements. A stadiometer is constructed from a vertical ruler with a sliding horizontal headpiece which is adjusted to rest on top of the head. Each site will utilise the same stadiometer for all participant assessments at each visit. The stadiometer will be portable to enable assessment visits to occur at the participant's place of residence.

6.6.3 Grip Strength

Dominant hand grip strength (kg) is to be assessed using a **Jamar Hand Grip Dynanometer (Model 5030J1**). The participant is asked to sit upright in a chair without placing his/her forearms on armrests. With dynamometer handle held in their dominant hand., the participant is instructed "to squeeze your hand with all your power, give everything you have." The examiner will provide verbal encouragement to the participant to squeeze harder during the assessment. The hand dynamometer is to be cleaned with alcohol disinfectant wipes after each participant.

6.6.4 Exhaustion (CES-D)

Two (2) items from the CES-D Depression scale will be completed by each participant. Participants respond on a 4-item Likert scale ranging from "rarely or none of the time (less than 1 day)" to "most or all of the time (5-7 days) for how often they have felt the following during the past week (Appendix 9):

Item 7 I felt that everything I did was an effort

Item 20 I could not get "going".

CES-D Response Key:

Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
☐	☐	☐	☐

6.6.5 IPAQ-short version

The *International Physical Activity Questionnaire (IPAQ)* short form is a standardized and validated self-administered questionnaire comprising 7 items that assess a person's level of physical activity in the preceding 7 days across vigourous, moderate and gentle levels of activity (Appendix 11).

IPAQ scores are converted to a standard energy consumption metric of MET-minutes/week. This metric is then converted to a kilocalorie (kcal) unit of energy expenditure adjusted for the participant's weight using the following formula:

kcal = (Total physical activity MET-min/week) x (weight kg/60)

Gender specific cutoff values for PRE-FRAIL are based on kcal cutoffs:

- Men: < 383 kcal
- Women: <270 kcal

6.6.6 6 minute walk test

Description: The 6-Minute Walk test is a **sub maximal measure of aerobic capacity**. Participants may use an ambulation aid and oxygen if they do so normally. The 6MWT is a useful measure of **functional capacity** suitable for frail older adults. The test has been widely used for preoperative and postoperative evaluation and for measuring the response to therapeutic interventions for pulmonary and cardiac disease.

Equipment: pulse oximeter, Blood Pressure cuff, Borg RPE, dyspnea scale, stopwatch, tape measure, portable chair

<u>Absolute contraindications</u> (test not to be administered):

- unstable angina during the previous month
- myocardial infarction during the previous month.

Relative contraindications (test only administered with medical clearance):

- Resting HR > 120
- SBP > 180 mm Hg
- DBP > 100 mm Hg

Terminate exercise IMMEDIATELY if and of the following symptoms exhibited:

Angina, light-headedness, confusion, ataxia, staggering unsteadiness, pallor, cyanosis, nausea, marked dyspnea, unusual fatigue, claudication or other significant pain, facial expressions signifying distress.

Notify treating medical practitioner if test is terminated for any of the above reasons.

Instructions to the Participant:

"The objective of this test is to **walk as far as possible** for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time to walk, so maybe you will be exerting yourself. You will possibly get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall (or at chairs which are places throughout the course) while resting, but resume walking as soon as you are able.

You will be walking back and forth around the cones. You should pivot briskly around the cones and continue back the other way without hesitation. Now I'm going to show you. Please watch the way I turn without hesitation. "We will avoid having a conversation so that you can save your wind for walking. You can begin when I say 'go'.

At the end of the 6 minutes:

- Have participant sit down (portable chair)
- Have patient rate their Borg Rate of Perceived Exertion (RPE), and dyspnea
- Calculate and record the distance walked, as well as the RPE, heart rate and dyspnea values.
- Ask: "What, if anything, kept you from walking farther?"

Safety:

Monitor vital signs before after the test. If there is an unexpected vital sign response, continue monitoring and documenting every 5 minutes until SBP and HR returns to within about 10-20 of pre-exercise values. Note heart rhythm, especially if it changes from a regular rhythm in pre-exercise to an irregular rhythm in post-exercise.

6.6.7 Timed up and go test

Equipment: arm chair, tape measure, tape, stop watch.

Begin the test with the participant sitting correctly (hips all of the way to the back of the seat) in a chair without arm rests. The chair should be stable and positioned such that it will not move when the participant moves from sit to stand. The participant is not allowed to use the arm rests during the sit – stand and stand – sit movements.

Place a piece of tape or other marker on the floor 3 meters away from the chair so that it is easily seen by the participant.

Instructions: "On the word GO you will stand up, walk to the line on the floor, turn around and walk back to the chair and sit down. Walk at your regular pace. (While giving the verbal instructions, the examiner performs the test once himself to ensure the participants understood the task)

Start timing on the word "GO" and stop timing when the participant is seated again correctly in the chair with their back resting on the back of the chair.

The participant wears their regular footwear, may use any gait aid that they normally use during ambulation, but may not be assisted by another person. There is no time limit. They may stop and rest (but not sit down) if they need to.

The participant should be given a practice trial that is not timed before testing.

6.6.8 Short Physical Performance Battery (SPPB)

Equipment required:

- Chair with arms (46-18 cm high)
- Stopwatch
- Tape measure
- tape to mark 4m

SBBP subtests are administered in the following order (Appendix 10).

6.6.8.1 Balance test

Comprises 3 measures of balance. The examiner provides a verbal instruction with accompanying physical demonstration of the movement to be performed by the participant. If the participant is unable to perform the movement, then the next measure of balance is performed.

The participant must be able to stand unassisted without the use of a cane or walker.

(i) Side-by-Side Stand

Participant is instructed to stand with feet together (side-by-side) for 10 seconds. The participant may use their arms, bend their knees, or move their body (but not their feet) to maintain balance. Examiner provides sufficient support of the participant's arm to prevent any sudden loss of balance.

If participant passes this test, proceed to test (ii).

If participant unable to pass this test, proceed to test (b – Gait Speed Test)

(ii) Semi-Tandem Stand

Participant is instructed to stand with one foot in front and side of the other foot, such that the heel of one foot is touching the big toe of the other foot for 10 seconds. The participant may use their arms, bend their knees, or move their body (but not their feet) to maintain balance. Examiner provides sufficient support of the participant's arm to prevent any sudden loss of balance.

If participant passes this test, proceed to test (iii).

If participant unable to pass this test, proceed to test (b – Gait Speed Test)

(iii) Tandem Stand

Participant is instructed to stand with one foot in front and side of the other foot, such that the heel of one foot in in front of the other foot and the heel of one foot is touching the toes of the other foot (in a straight line) for 10 seconds. The participant may use their arms, bend their knees, or move their body (but not their feet) to maintain balance. Examiner provides sufficient support of the participant's arm to prevent any sudden loss of balance.

6.6.8.2 Gait Speed Test

The examiner observes how the participant walks normally. Participant may use a cane or other walking aid if normally used.

(i) First Gait Speed Test

Participant walks a distance of 4m in a straight line – marked by a tape measure. Examiner demonstrates first, then follows behind the participant as they walk the course. Time to travel 4m is recorded.

(ii) Second Gait Speed Test

Participant repeats walking a distance of 4m in a straight line – marked by a tape measure. Examiner demonstrates first, then follows behind the participant as they walk the course. Time to travel 4m is recorded.

(iii) Dual-task performance

Participant repeats walking a distance of 4m in a straight line – marked by a tape measure. However, this time the participant is instructed to count backwards by 7 from 200 while walking (e.g. "200, 193, 186 …."). The participant counts aloud from when they start walking and stops counting once both feet have crossed the finish line.

6.6.8.3 Chair Stand Test

Examiner assesses the participant's ability to stand from sitting on a chair and to repeatedly sit-stand-sit.

(i) Single Chair Stand

Participants is instructed to stand from sitting in a chair. They must keep their arms crossed/folded across their chest from seated to standing position.

If unable to do so, they are instructed to use their arms to stand (do not proceed to next test).

(ii) Repeated Chair Stands

Participants is instructed to stand from sitting in a chair without using their arms, for 5 repetitions as quickly as they can. They must keep their arms crossed/folded across their chest from seated to standing position and from standing to seated position.

6.6.9 The Activities-specific Balance Confidence (ABC) scale

The ABC is a self-rated 16 item questionnaire in which the participant indicates their level of confidence in doing a physical activity without losing their balance or becoming unsteady from choosing one of the percentage points on the scale form 0% to 100% (Appendix 12).

Where the participant does not currently do the activity in question, they are asked try and imagine how confident they would be if they had to do the activity. If the participant normally uses a walking aid to do the activity or hold onto someone, they are asked to rate their confidence as though they were using these supports.

6.6.10 Physical Activity Enjoyment Scale (PACES)

The PACES is an 18 item questionnaire asking the participants to respond to questions relating to their enjoyment in undertaking physical activity at the moment (Appendix 13).

Responses are provided on a 7 item Likert scale, with items 1, 4, 5, 7, 9, 10, 11, 13, 14, 16 and 17 being reverse scored (i.e. if participants select 1 score = 7; 2 = 6; 3 = 5; 4 = 4; 5 = 3; 6 = 2; 7 =1).

Total score is the sum of scores of the 18 items, following reverse scoring of the 11 reversed items. Total score range is 18 – 126.

6.7 Cognitive assessment

6.7.1 Mini-Mental State Examination (MMSE)

The MMSE is an 11-item brief screening assessment of basic cognitive functions [1] (Appendix 14). The MMSE is a clinical test, and will be administered by a trained and experienced researcher under the supervision of A/Prof Summers, APHRA registered Psychologist endorsed for practice as a Clinical Neuropsychologist.

The 11 items on the MMSE assess:

1. Orientation to time
2. Orientation to place
3. Registration of 3 objects
4. Attention and calculation
5. Recall of 3 objects
6. Language and praxis

Scores on the MMSE range from 0-30, and are corrected for level of education.

Abnormal cutoff scores are:

- < 24 – university/college education
- < 23 – high school education (9-12 years formal education)
- < 21 – junior high school education or less (fewer than 9 years of formal education)

6.7.2 Hopkins Verbal Learning Test (HVLT)

The Hopkins Verbal learning test (HVLT) [2] assesses verbal list-learning and memory through immediate recall, delayed recall and delayed recognition (Appendix 15). The test is commonly used to detect dementia and cognitive decline among respondents and allows insight into individuals' memory function. This is a widely-used word learning test which consists of three immediate recall trials followed by a delayed recall 20 minutes later. During this gap, other, non-memory-based cognitive tests may be performed. Parallel forms will be used across different assessment points to minimize potential practice effects.

6.7.3 Spatial Span (WMS-III)

A subtest of the Wechsler Memory Scale, 3rd edition (WMS-III) [3]. The test assesses a participant's visual short term memory capacity. The examiner touches an increasingly long sequence of blocks (mounted on a board – see Figure 3) at 1 second intervals, which the participant then repeats. The trial ceases when the participant fails to correctly duplicate the sequence twice at the same length. The second trial involves the participant repeating the reverse sequence of the sequence demonstrated by the examiner. This backward span trial ceases when the participant fails to correctly duplicate the sequence twice at the same length (Appendix 16).

Both trials commence with a 2 block sequence, and two sequences are presented at each sequence length before increasing sequentially to the next sequence length.

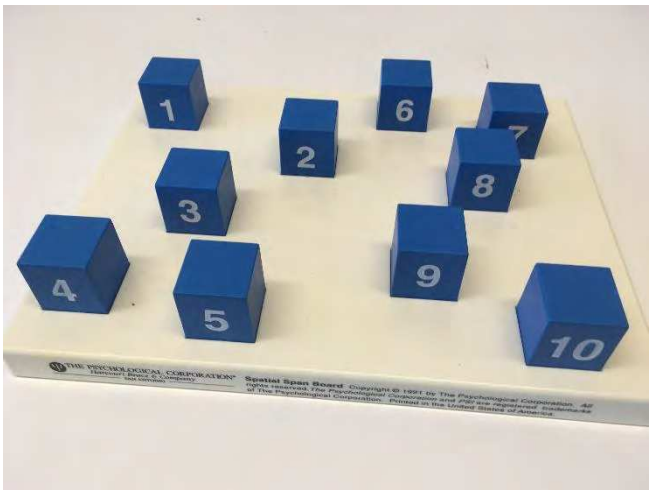


Figure 3: *WMS-III Spatial Span board*

6.7.4 Digit Symbol Coding test (WAIS-III)

This subtest of the Wechsler Adult Intelligence Scale – 3rd edition (WAIS-III) [4] requires participants to correctly copy symbols that represent numbers and assesses visuomotor information processing speed and attention. Participants complete as many items as they can within a 120 second time limit (Appendix 19).

6.7.5 Trail Making Test (TMT)

A "join-the-dots" paper and pencil test consisting of two trials [5, 6]. The first trial requires participants to connect a series of numbers from 1 to 25 in numerical order as fast as possible. The second trial requires participants to connect a series of letters (A to L) concurrently with a series of numbers (1-13), such that the connections made are number-letter-number-letter, and so on, in alphabetical and numerical order (Appendix 17). Time taken to complete each trial and number of errors made are recorded

6.7.6 Stroop Test (24 item Victoria Version)

The 24-item Victoria version of the Stroop test requires subjects to name the ink colour of the print in three separate trials [6]. The first trial requires participants to name the ink colour of clusters of X's. The second trial requires subjects to name the ink colour of simple nouns (e.g., car). The third trial requires subjects to name the ink colour of colour words (e.g., red), subjects must not name the word, but the colour of the ink in which the word is printed. The complexity on this trial is that the ink colour does not match the word, for example the word "red" might be printed in blue ink and the participant is required to say "blue" not "red". Time taken to complete each trial and the number of errors made are recorded (Appendix 18).

6.8 Psychological assessment

6.8.1 Hospital Anxiety and Depression Scale (HADS)

The HADS [7] is a self-report 14 item scale assessing symptoms of depression (7 items) and anxiety (7 items) experienced in the **preceding 7 days**. Responses are given on a 4-item scale, relating to frequency or intensity of symptoms experienced – each item has a score of 0-3 (Appendix 20).

Anxiety scale and Depression scale are scored separately, each scale has a range of 0-21.

For both Anxiety and Depression scales, the following cutoff values apply:

Score	***Interpretation***
0 – 7	Normal
8 – 10	Mild symptoms
11 – 14	Moderate symptoms
15 – 21	Severe symptoms

6.9 Social functioning

6.9.1 Lubben Social Network Scale, Short Form (LSNS-R)

The LSNS-R scale is a 12-item questionnaire on which participants respond on a 6 item Likert scale [8]. Of the 12 questions, 6 relate to familial relationships and 6 relate to friendships. There are no reverse scored items (Appendix 21).

LSNS-R Total score is the sum of scores across the 12 items, with subscores for family and friendships being the sum of scores for the 6 items in each. Scores range from 0-60 for LSNS-R Total Score, and from 0-30 for each of the Family and Friendships subscores.

6.9.2 UCLA Loneliness Scale

The UCLA Loneliness scale is a 20-item questionnaire on which participants respond on a 4-point Likert scale regarding how frequently they experience feelings of social isolation and loneliness [9]. Of the 20 items, 9 items are reverse scored (i.e. a score of 1 is counted as 4, 2 as 3, etc.). Total score is the sum of scores of the 20 items, following reverse scoring of the 9 reversed items. Total score range is 40-80 (Appendix 22).

6.10 Nutrition

6.10.1 BMI

The Body Mass Index (BMI) for each participant will be calculated from weight and height data collected at each assessment phase using the following formula:

BMI = [height(m) / weight (kg)] / [height(m)]

6.10.2 Self-MNA

The Self Mini Nutritional Assessment (Self-MNA) [10] is a brief questionnaire assessing the nutritional status of adults aged 65 years and older (Appendix 23). The Self-MNA is produced and licensed by Nestle Nutrition Institute, with permission to use this scale in the my-AHA project having been received.

The Self-MNA comprises:

1. 5 items relating to food intake, weight change, mobility, illness, dementia/depression
2. Height and weight measures
3. Circumference measurement of the left calf

Preferably, the scale is investigator administered to ensure consistency of measurement of physical data.

6.11 Technology use

6.11.1 Computer Literacy Scale (CLS)

The CLS is a brief screening test to assess an individual's level of familiarity with computer based interfaces.

The CLS comprises 2 parts:

- Part 1 – captures basis demographic information and items relating to experience with computers
- Part 2 – assesses a participant's familiarity with the meaning of various icons used by computer based systems as well as the meaning of basic menu options for computer programs.

The CLS will be administered only at baseline assessment.

6.11.2 Evaluation of Usability Scale (SUS)

The SUS is a brief 10 item scale assessing a participants experience with the usability of the My-AHA platform. The participant responds to each of the 10 items on a 5 point scale from "strongly disagree" to "strongly agree"

The SUS will be administered at a single assessment point (12 months) in the RCT protocol.

6.11.3 DART Questionnaire

The DART questionnaire surveys the participant's responses to the use of application in the health care sector and their experiences in using the My-AHA application.

- The survey comprises 3 parts:
- Part 1- collects basis demographic information and responses to the value of the My-AHA application
- Part 2 – comprises 19 items in which the participant rates the level of importance of different features of smartphone or tablet applications in the health care sectors
- Part 3 – comprised the same 19 items repeated, but the participant is asked to respond with reference specifically to the My-AHA application.

6.11.4 User Experience Questionnaire (UEQ)

The UEQ is a 26 item scale assessing the participant's description of the attributes of the My-AHA application.

Participants are presented with a series of 26 paired (and opposing) attributes, to which they indicate their level of response on a 7 point scale.

The UEQ will be administered at a single assessment point (18 months) at the completion of the RCT.

7 My-AHA Interventions

The intervention in this study is defined as the My-AHA platform. Participants randomized into the intervention arm will have access to the full My-AHA intervention platform (see also Section 8 My-AHA User Platform interface). Participants in the control group will not have access to the intervention package (no treatment control). All participants recruited into the study have no active disease state being treated. All participants meet study criteria for pre-frail status, a non-clinical disease state.

The protocol in the intervention arm is designed to prevent deterioration from a non-clinical state (pre-frail) into the disease state (frail).

The no-intervention control arm will not receive any element of the My-AHA intervention, a no-intervention non-disease control group. Participants in both study arms undergo formal assessment of clinical frailty status at 4 timepoints (baseline, 6 mo, 12 mo, 18mo). **Development of clinical frailty is considered an adverse endpoint for the participant in this study.**

Where a control group participant displays evidence of clinical decline at 6 or 12mo assessment points (defined a meeting clinical criteria for frailty) they will be offered access to the My-AHA intervention suite. We cannot estimate or predict what proportion of the control participants may develop frailty during the 18 month trial as there is no published data on incidence, age-dependent prevalence, or on average rate of decline into frailty from pre-frail states.

Participants randomly allocated to the intervention group will be provided with access to tailored intervention packages. Intervention packages will target domains of pre-frailty (e.g. physical, social, cognitive, nutrition) identified at baseline assessment for each participant. The intervention packages will be revised following each assessment point to accommodate for changes in domain specific areas of pre-frailty.

IMPORTANT NOTE: For participants in the control group access to interventions will not be provided – this is a no-treatment control group. **The exception is when a control participant is found to meet clinical criteria for physical frailty at any of the post-baseline assessment points (6 month or 12 month). If progression to physical frailty is detected in a control group participant, that participant will be provided with immediate fully supported access to the physical intervention package to meet ethical obligations to the participant.**

7.1 Physical Interventions

As the key physical markers of frailty are: weight loss, physical weakness, reduced endurance and energy, motor slowing, and reduced physical activity [11]; interventions have been selected to target these key physical indicators of frailty. With falls being the most likely consequence of increasing physical frailty [12], prevention of falls through balance training to enhance gait pattern and postural control is a key approach to be employed in the My-AHA project. In addition to fall prevention, endurance training will also be provided to increase physical activity levels, improve cardiovascular-fitness and therefore increase energy levels and endurance capacity.

The multicomponent physical intervention deployed in the My-AHA project involve activities that combine strength, balance and endurance training over and extended duration (≥5 months), with high frequency repetition (performed three times per week) for 30–45 minutes per session. Such physical interventions have been found to result in superior outcomes compared to other exercise programs [13] and that exercise interventions combining strength, endurance and balance training display the greatest reduction in falls rate and improvement in gait, balance, and strength performance in physically frail older adults [14, 15].

For the strength and balance domains, the OTAGO (OEP) home-based exercise program [16], the Fitness and Mobility Exercise program FAME [17], and endurance training will be applied. Guidelines for endurance training will be provided based on the participants' maximum heart rate (HRmax), with participants being able to choose the type of endurance activity from a range of options (e.g., walking, Nordic walking, bicycling, stationary bicycling, treadmill).

7.1.1 Otago home-based exercise program (OED)

The OEP [16] will be deployed as a home-based exercise programme used by older adults in their own homes without expert's supervision. Prior to commencing the OEP program each participant will have a home visit from an exercise instructor who will prescribe an individually tailored set of exercises according to the participant's clinical history and fitness level. The instructor will also provide each participant with detailed instructions regarding the correct implementation of each exercise. Participants will be provided with a booklet listing the exercises including short description and repetitions for each set as well as adjustable ankle cuff weights, which must be easy to take on and off. For participants, unable to exercise from a standing position, a chair-based exercise programme will be provided resistance-based training using ankle weights being replaced with resistance-bands.

Participants will undertake the OEP program one session per week, as each participant will engage in one additional group-based exercise session that targets the same domains as in the OEP. In addition, the OEP advice of undertaking a walking activity will be replaced with a recommendation of undertaking some form of endurance training for one additional session per week. This modified OEP program, including group exercise and endurance training, will result in a total of 3 hours of physical training per week.

7.1.2 Fitness and Mobility Exercise program (FAME)

FAME is a standardised group-based exercise programme [17] which participants will complete one session per week under the supervision of a physical exercise instructor (appropriately qualified and trained fitness instructors, physical therapists or occupational therapists). Each group session will be undertaken with a ratio of no greater than 1 instructor per 5 participants.

7.1.3 Endurance exercise programs

The endurance training exercise programs will be delivered in accordance with the guidelines of the American Heart Association and the American College of Sports Medicine for endurance training for older adults [18] and aims to reach the proposed recommendations of physical activity (150 min/week) by Month 9 of the RCT. The walking part of the OEP will be replaced by an endurance training suggested to be undertaken for one session per week, with the endurance training activity to be selected by each participant to increase compliance (e.g. walking, Nordic walking, bicycling, treadmill or stationary bicycling). Intensity of the endurance training will start at a moderate level the first few months before gradually increasing to vigorous level activity adjusted for the participants' estimated maximum heart rate (HRmax = 220bpm - age). The intensity rate (HRMax) to training duration is specified in Table 7. Participants are able to halt intensity increases if they perceive the level of intensity is too difficult. However, participants will be required to maintain a minimum of 65% of the HRmax for at least 150 Min per week.

Table 7: *Intensity and duration of endurance training over 18 month RCT as determined by HRMax*

Month	Intensity (%HR max)	Min/session
1-2	50%	30
3-4	55%	35
5-8	60%	40
9-12	65%	40
13-16	65%	45
17-18	70%	45

7.2 Cognitive Interventions

Cognitive interventions in the My-AHA project will comprise working memory training (N-back task), cognitive bias modification therapy (CBMT). As with physical interventions, the type of cognitive intervention offered to each participant will be individually tailored as determined by their individual areas of strength and weakness identified at each assessment point.

7.2.1 Working memory training (N-back task)

The main target group for n-back training is healthy elderly individuals. To achieve maximum adherence, self-efficacy, and engagement the n-back task will use graded difficulty whereby task difficulty is continuously adjusted to match participant level of performance.

Two versions of the n-back task will be used: a letter-based and a visuospatial version. In the letter-based n-back task, letters are capitalised at 20% of the monitor height and appear in black Arial font on a white background in the centre of the screen. For the visuospatial n-back task a 3 by 3 blue grid (11.5 cm x 11.5 cm) is displayed on a white background size with a blue fixation cross is constantly visible in the centre slot. For the visuospatial n-back task, the stimulus is a blue square (3.5 cm x 3.5 cm) that appears in different positions inside the grid slots, except the centre position containing the fixation cross, hence 8 positions. For both letter-based and visuospatial n-back tasks, 8 combinations of presentation time (fixed 2000 ms; variable starting at 2000ms decreasing by 100 ms each successful block or increasing 100 ms each unsuccessful block; variable starting at 500 ms decreasing by 50 ms each successful block or increasing 50 ms each unsuccessful block) and inter-stimulus intervals (ITI; 0 ms or 2000 ms) will be used. Participants are instructed to respond by pressing a response key/button as to whether the letter currently on screen matches the letter presented n letters previously. The ratio of non-targets and targets is 2:1, presented in a random order. During a 'lure' trial the current stimulus matches the one n + 1 or n – 1 stimuli previously. Each block contains two lures (e.g., 2-back targets in a 3-back block), which constitutes 10% of all trials. Each block consists of 20 + n trials, such that a 3-back block would comprise 23 letters with 20 possible pairs. Participants begin their first trial with n = 2 (regardless of previous performances), while adjustments are continuously made, based on participants' performance. Upon a successful block (at least 90% correct responses) n increases by 1, upon a non-successful block (below 75%), n decreases by 1. The level of n is maintained when participants give between 75% and 89% correct responses. A session comprises 15 blocks of n-back training (approximately 15 to 20 minutes). Participants will be provided with real-time feedback following each relevant trial, which is done using a stop-light paradigm. Two small circles (1.5 cm diameter, arranged green above red) are placed in the bottom left corner of the screen. All size measurements are relative to a 17-inch screen. The feedback is triggered directly following a response or in the case of a 'miss' during the ITI. In case of a match, the green circle lights up for 200 milliseconds. If participants' response is incorrect (false positive, miss, or false negative) the red circle lights up for 200 milliseconds. At the end of the training session participants are provided with an overview of their performance, e.g.: correct hits, and misses, as well as average level of n. Au and colleagues [19] have reported a dose-dependent relationship between working memory training and positive outcomes. Reliable effects have been achieved using n-back training daily on weekdays for 20 days for 25 minutes (roughly 15 blocks). The training will be delivered via the My-AHA app directly (PC, Tablet or Mobile phone) but can also be installed on the participant's home computer and operated with a keyboard or computer mouse.

7.2.2 Cognitive Bias Modification Therapy (CBMT)

CBMT works by training anxious or depressed individuals to disengage from threat-related stimuli and redirecting their attention towards other 'positive' stimuli [20]. Such training has been found to lead to increased mood and lower stress reactivity [21, 22]. Essentially, during CBMT participants select 'good' or 'positive' options over 'bad' or 'negative' ones. By consciously selecting the 'positive' option repeatedly, the negative bias becomes overridden and, over time, replaced by a novel, more adaptive habit. There are two common variants of CBMT, namely 'attention bias modification' (ABM) and 'interpretative bias modification' (CBM-I), which both have been reported to be effective in reducing anxiety and depression pathology [23]. ABM will be used in the My-AHA intervention package. In ABM participants learn to direct their attention towards relatively positive stimulus, which can be a word or a picture, and away from threat-related stimuli.

ABM is a modified computerized visual-probe procedure in which a pair of stimuli of different valences (e.g. a happy and a sad face, happy and neutral face, or neutral and sad face) are presented simultaneously then followed by presentation of a probe (one or two dots) behind one of the stimuli. Stimuli are presented for either 500 or 1000 ms before the probe is displayed. Randomization is set such that 500 and 1000 ms trials occur at the same frequency throughout a session. The presentation of a one-dot or two-dot probe is also randomized. Participants are instructed to press a button according to the number of dots presented. The appearance of the dots is manipulated, such that the dots always appear in place of the more positive stimulus. Participants learn implicitly to direct attention towards the happy stimuli and away from the negative ones, which constitutes a shift in attentional bias. A session of ABM comprises 96 trials and participants are recommended to complete two sessions daily for 28 sessions in total.

7.3 Psychosocial Interventions

Three social interventions will be implemented in the My-AHA project: group activity interventions; group support interventions, and a social media platform.

Group activity interventions will increase participant engagement in social interaction by provision of targeted group based activities including: group physical activity classes, group cooking classes, and group excursion based activities (e.g., visiting a museum). The My-AHA platform will match participant's preferences for type of activity and will create digital activity groups for participants with common preferences. The My-AHA platform then matches appropriate group activity proposals and presents the demand for specific group activities to secondary stakeholders as providers of group activities.

Group support interventions will provide an opportunity for participants to find targeted help and support (e.g., bereavement support, disease support such as cancer support groups). My-AHA participants can set corresponding parameters in their profile to indicate their need for support. The My-AHA platform will match support groups to individual participants, based on the parameters and preferences set by the participant.

The social media platform will address technology literacy of elderly people and allow digital interaction with all My-AHA participants. The social media platform will encompass the exchange and sharing of information as well as communication with other participants. It will provide a digital space for participants to interact with each other and share information, opinions, recommendations, etc.

7.4 Nutritional Interventions

Nutritional interventions will be implemented using a nutrition application (**VitalinQ** - https://www.vitalinq.nl/) for mobile devices. The interventions to be deployed include: individual meal plan generation, and tailored nutritional advice and education.

7.4.1 Meal plan generation

With meal plan generation, users will be able to plan meals ahead. In My-AHA application, meal plans and recommendations will be generated and presented to the user. The application will check in the database which recommendations and preferences fit the profile. The recommendations are official guidelines, which have been determined by official nutritional institutions in every participating country. The preferences (such as known allergies, lifestyle (e.g. vegetarian) and/or kitchen type) can be entered into the profile by the user. These recommendations and preferences will be compared to the recipes in the database. The recommendation engine should be able to generate meal plans that fit the needs of each user, based on their user profile. The nutritional application will consider the anthropometric data, lifestyle, activity level, nutritional status of the user, and on user preferences in creating individually tailored meal plans. The application will generate plans for all different types of meals (breakfast, lunch, dinner and snacks), as well all meals for one day or all meals for one week.

7.4.2 Nutritional advice and education

7.4.2.1 Nutritional advice and education

Participants will receive nutritional advice based on the food intake they log into their food diary [24]. Users will be educated on what they eat and get advice on how to improve their intake to meet their requirements. Educating the user on their food intake is important to ensure an improved eating pattern in the future. Therefore, the nutritional advice will be given in short passages of text, these feedback passages are derived from the nutritional database of VitalinQ and provide information as to whether the intake of a specific nutrient is high, low or as required and (if necessary) how to improve that intake and in most cases why.

8 My-AHA User Platform interface

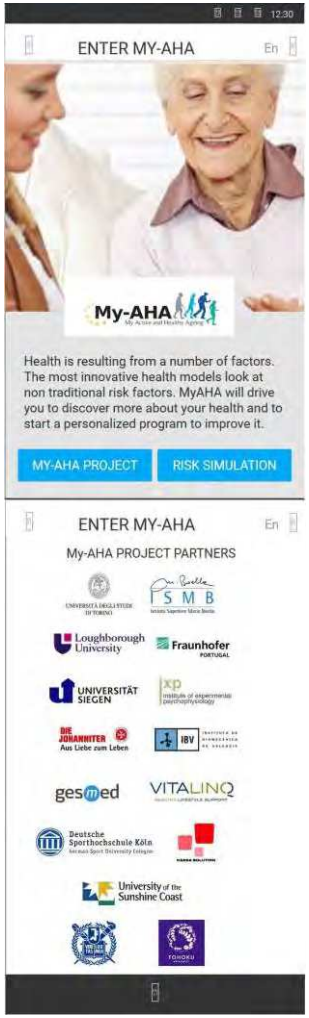
The My-AHA platform is a web-based interface that has been designed for use via computer, tablet PC, and/or smart mobile telephone.

The platform interface covers the following areas:

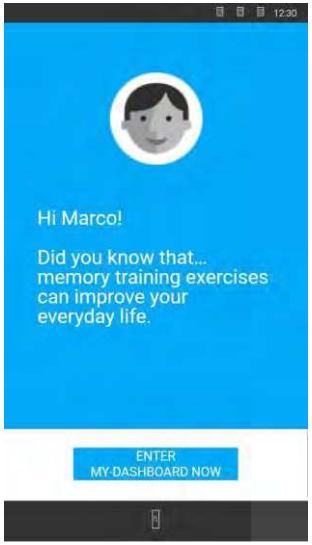
1. Language selection (multi-language platform)
2. User login (password secured)
3. Menu interface enabling access to the User Dashboard, under which the user can select from 3 different options
    a. Goals
    b. Interventions
    c. Results
4. An a risk analysis page, which enables the user to identify their current level of risk for diseases such as dementia. The risk analysis page also enables the user to model the effect of changing different modifiable risk factors (e.g. increasing their level of exercise) and how these lifestyle changes result in measureable change to their risk of chronic diseases in the future. This provides the user with both a simple informational tool that also provides motivation to undertake a change to lifestyle which decreases risk for disease.

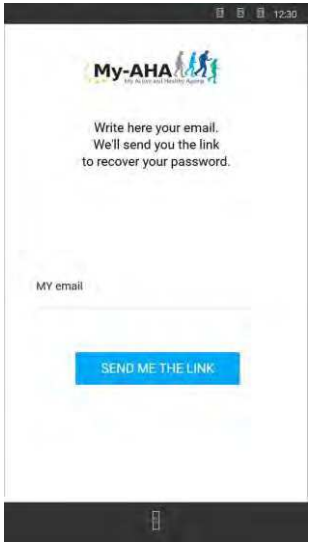
The purpose built My-AHA Platform is illustrated in the Figures below.

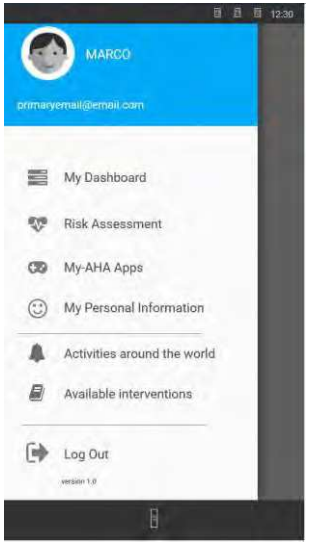

ENTER MY-AHA
EN: Please, choose your language.
IT: Scegli la tua lingua.
DE: Bitte wählen Sie Ihre Sprache.
ES: Elije tu idioma.
English
Italiano
Deutsch
Español

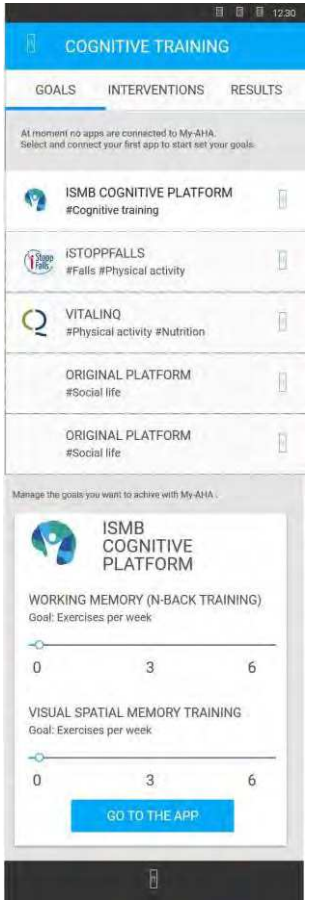

ENTER MY-AHA
My-AHA
Health is resulting from a number of factors. The most innovative health models look at non traditional risk factors. MyAHA will drive you to discover more about your health and to start a personalized program to improve it.
MY-AHA PROJECT
RISK SIMULATION
ENTER MY-AHA
My-AHA PROJECT PARTNERS

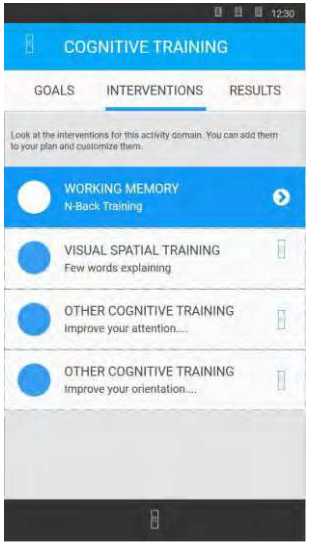

ENTER MY-AHA
My-AHA
User ID
Password
I forgot the credentials
ENTER
Not yet registred?
Sign up here.

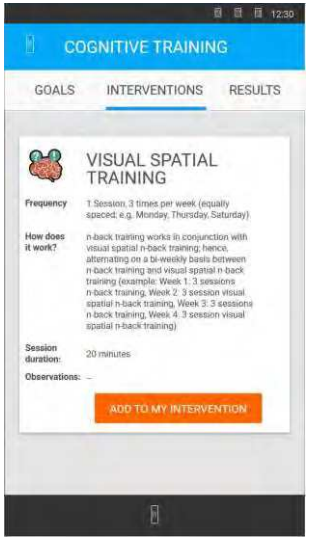

Hi Marco!
Did you know that... memory training exercises can improve your everyday life.
ENTER MY-DASHBOARD NOW


My-AHA
Write here your email. We'll send you the link to recover your password.
MY email
SEND ME THE LINK

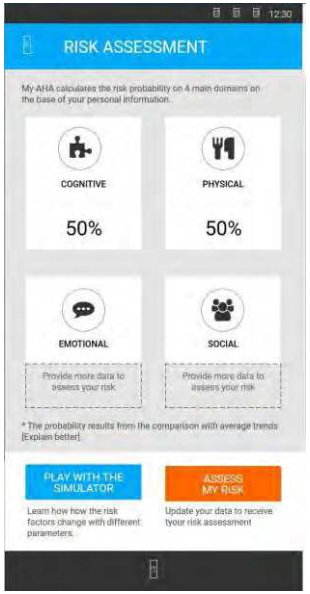

MARCO
primaryemail@email.com
My Dashboard
Risk Assessment
My-AHA Apps
My Personal Information
Activities around the world
Available interventions
Log Out

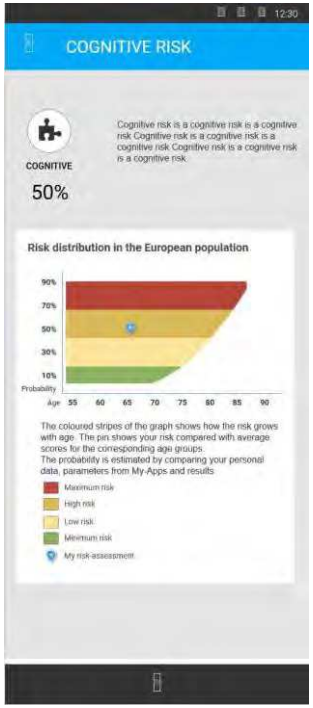

COGNITIVE TRAINING
GOALS
INTERVENTIONS
RESULTS
ISMB COGNITIVE PLATFORM
#Cognitive training
iSTOPPFALLS
#Falls #Physical activity
VITALINQ
#Physical activity #Nutrition
ORIGINAL PLATFORM
#Social life
ORIGINAL PLATFORM
#Social life
ISMB COGNITIVE PLATFORM
WORKING MEMORY (N-BACK TRAINING)
Goal: Exercises per week
0
3
6
VISUAL SPATIAL MEMORY TRAINING
Goal: Exercises per week
0
3
6
GO TO THE APP


COGNITIVE TRAINING
GOALS
INTERVENTIONS
RESULTS
WORKING MEMORY
N-Back Training
VISUAL SPATIAL TRAINING
Few words explaining
OTHER COGNITIVE TRAINING
Improve your attention....
OTHER COGNITIVE TRAINING
Improve your orientation....


COGNITIVE TRAINING
GOALS
INTERVENTIONS
RESULTS
VISUAL SPATIAL TRAINING
Frequency
How does it work?
Session duration:
20 minutes
Observations:
ADD TO MY INTERVENTION


COGNITIVE TRAINING
GOALS
INTERVENTIONS
RESULTS
FREQUENCY
Monitor activities you've done per week.
RESULTS
Look at your progresses!
WORKING MEMORY
VISUAL SPATIAL MEMORY
REACTION TIME


12:30
RISK ASSESSMENT
My-AHA calculates the risk probability on 4 main domains on the base of your personal information.
COGNITIVE
50%
PHYSICAL
50%
EMOTIONAL
Provide more data to assess your risk
SOCIAL
Provide more data to assess your risk
* The probability results from the comparison with average trends [Explain better]
PLAY WITH THE SIMULATOR
Learn how how the risk factors change with different parameters
ASSESS MY RISK
Update your data to receive tyour risk assessment


12:30
COGNITIVE RISK
COGNITIVE
50%
Cognitive risk is a cognitive risk is a cognitive risk Cognitive risk is a cognitive risk is a cognitive risk Cognitive risk is a cognitive risk is a cognitive risk
Risk distribution in the European population
90%
70%
50%
30%
10%
Probability
Age 55 60 65 70 75 80 85 90
The coloured stripes of the graph shows how the risk grows with age. The pin shows your risk compared with average scores for the corresponding age groups.
The probability is estimated by comparing your personal data, parameters from My-Apps and results
Maximum risk
High risk
Low risk
Minimum risk
My risk assessment

9 Safety and Screening Assessments

9.1 Adverse Events

The Principal Investigator or site staff are responsible for detecting, documenting, and reporting events that meet the definition of an Adverse Event (AE) or Serious Adverse Event (SAE).

9.1.1 Definition of Adverse Events (AE)

An AE is any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related. Therefore an AE can be **ANY** unfavorable and unintended sign, symptom, or disease temporally associated with the use of a product, without any judgment about causality.

Events meeting the definition of an AE **include**:

- Exacerbation of a chronic or intermittent pre-existing condition including either an increase in frequency and/or intensity of the condition.
- New conditions detected or diagnosed after product administration even though it may have been present prior to the start of the study.
- Signs, symptoms, or the clinical sequelae of a suspected intervention interaction.
- Clinically significant abnormal findings should be recorded as AEs. A "clinically significant" finding is one that affects clinical management, including additional visits, monitoring or referrals, diagnostic tests, or alteration of treatment, or that is considered clinically significant by the investigator. A clinically significant finding may be a change in a test that has previously been abnormal but now requires additional action.

Events that **do not** meet the definition of an AE include:

- Anticipated day-to-day fluctuations or expected progression of pre-existing disease(s) or condition(s) present or detected at the start of the study unless judged by investigator to be more severe than expected for the participant's underlying condition.
- Abnormal clinical measurements that are not labelled clinically significant (see definition above).
- Situations where an untoward medical occurrence did not occur (social and/or convenience admission to a hospital).
- Overuse of the intervention in the absence of other AEs will not be reported as an AE in its own right.
- Adverse events are recorded from the time that informed consent is signed.

9.1.2 Definition of Serious Adverse Event (SAE)

An SAE is considered serious if, in the view of either investigator or medical supervisor, it results in any of the following outcomes:

- Death,
- A life-threatening AE (an AE is considered "life-threatening" if, in the view of either the investigator or medical supervisor, its occurrence places the participant at immediate risk of death. It does not include an AE that, had it occurred in a more severe form, might have caused death. The determination of whether an AE is life-threatening can be based on the opinion of either the investigator or medical supervisor. Thus, if either believes that it meets the definition of life-threatening, it must be considered life-threatening for reporting purposes).
- Inpatient hospitalization,
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or
- Important medical events that may not result in death, be life-threatening-, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or a fall requiring hospitalisation.

This definition of an SAE permits either the medical supervisor or the investigator to decide if an event is serious. Because SAEs are critically important for the identification of significant safety problems. For example, the investigator's perspective may be informed by having actually observed the event, and the medical supervisor is likely to have broader knowledge of the intervention and its effects to inform its evaluation of the significance of the event. If either the medical supervisor or investigator believes that the event is serious, the event must be considered serious and evaluated by the sponsor for possible expedited reporting.

9.1.3 Time Period and Frequency for Collecting Adverse Event and Serious Adverse Event Information

Collection of AEs and SAEs will begin at the time a participant signs informed consent and continues until the follow-up contact.

All SAEs will be recorded and reported to Project Management Board (PMB) within 24 hours of the investigator becoming aware of the SAE.

Investigators are not obligated to actively seek AEs or SAEs in former study participants. However, if the investigator learns of any SAE, including a death, at any time after a participant has been discharged from the study, and he/she considers the event reasonably related to the intervention or study participation, the investigator must promptly notify the PMB.

9.1.4 Assessment of Adverse Events

The severity of each AE will be assessed by the investigator, or designee approved and documented for this study, as mild, moderate, or severe based on the below definitions:

- **Mild**: Event that is usually transient and may require only minimal treatment or therapeutic intervention. The event does not generally interfere with usual activities of daily living
- **Moderate**: Event that is usually alleviated with additional specific therapeutic intervention. The event interferes with usual activities of daily living, causing discomfort, but poses no significant or permanent risk of harm to the participant.
- **Severe**: Event that interrupts usual activities of daily living or significantly affects clinical status, or may require intensive therapeutic intervention.

Note that severity is not the same as "seriousness". Outcome will be assessed using the following categories: recovered/resolved, not recovered/not resolved, recovered/resolved with sequelae, fatal, or unknown.

9.1.5 Method of Detecting Adverse Events and Serious Adverse Events

Care will be taken not to introduce bias when detecting AEs and/or SAEs. Open-ended and non-leading verbal questioning is the preferred method to inquire about AE occurrence. Appropriate questions include:

- "How are you feeling?"
- "Have you had any (other) medical problems since your last visit/contact?"
- "Have you taken any new medicines, other than those provided in this study, since your last visit/contact?"

9.1.6 Follow-up of Adverse Events and Serious Adverse Events

After the initial AE/SAE report, the investigator is required to proactively follow each participant at subsequent visits/contacts. All AEs and SAEs will be followed until resolution, until the condition stabilizes, until the event is otherwise explained, or until the participant is lost to follow-up.

9.1.7 Reporting of Serious Adverse Events

All new SAEs must be reported in English to the Project Management Board within 24 hours of the investigators first knowledge of the event regardless of relationship to the study procedures. All deaths must be reported within 24 hours of the investigator's first knowledge of the event. It is recognized that complete information may not be available at the time of the initial SAE report. Additional information should be supplied on subsequent Serious Adverse Event Forms as it becomes available.

For the initial SAE notification report, the investigator must provide, at minimum, basic information such as the protocol number, participant's initials and date of birth, participant identification number, period of investigational product intake, event term, nature of the event, the seriousness criteria, and the investigator's attribution regarding relatedness to investigational product. In addition, the initial SAE report should

include all pertinent known information about the SAE and the affected participant. In addition, the investigator should provide a narrative to describe the course of events including any treatments or relevant procedures. Follow-up information, which may include copies of relevant participant records and other documents not available at the initial SAE report must be sent to the Project Management Board as soon as available. Follow-up SAE reports may describe the evolution of the reported event and any new assessment of outcome and/or relationship to investigational product. Full supporting documentation should be solicited by the investigative site even if the SAE occurred at another institution. Such documentation may include copies of relevant medical/hospital records, pathology, or autopsy reports where available.

9.1.8 Regulatory Reporting Requirements for Serious Adverse Events

Prompt notification by the investigator to the medical supervisor of all SAEs and non-serious AEs occurring during a clinical trial is essential so that legal obligations and ethical responsibilities towards the safety of participants are met.

An investigator who receives an investigator safety report describing an SAE(s) or other specific safety information (e.g., summary or listing of SAEs) will file it with the Investigator Brochure and will notify the Institutional Review Board/Institutional Ethics Committee (IRD/IEC), if appropriate according to local requirements.

10 Data Management

10.1 Site specific

Each site PI is responsible for the management and storage of data collected at the site. All data will be collected using standard de-identification procedures:

1. Each participant will be allocated a unique identifier code
2. A master key matching the identifier code to the identity of the participant will be retained as a secured, encrypted data file; separate in location to all data collected in this study. The master key file can only be access by the site PI and authorized research personnel at the site.
3. All data collected from each participant will be identified only by the unique identifier code.
4. Data storage and security is the responsibility of the site PI
5. The site PI will transfer de-identified data the study coordinator using secure, encrypted HTTPS transfer protocol. Only de-identified data can be transferred to the study coordinator for combining with data from all study sites to enable data analysis.
6.

10.2 Project wide

The study coordinator is responsible for the management and storage of multi-site de-identified data collected across the multiple sites involved in the RCT.

1. Data from each participant will only be identified by a unique identifier code indicating the study site from which the data was collected
2. No persons will be able to identify the identity of the individual from the identifier code used. Only the site PI will retain the master key for participant identities specific to their site.
3. Data storage and security of the combined multi-site data is the responsibility of the study coordinator

11 Responsibilities

11.1 Investigator Responsibilities

11.1.1 Good Clinical Practice

The investigator will ensure that this study is conducted in accordance with the principles of the National Health and Medical Research Council (NHMRC) of Australia, as well as the "Declaration of Helsinki" (as amended in Edinburgh, Tokyo, Venice, Hong Kong, and South Africa), International Conference on Harmonisation (ICH) guidelines, or with the laws and regulations of the country in which the research is conducted, whichever affords the greater protection to the study participant. The investigator will ensure that the basic principles of "Good Clinical Practice," as outlined in 21 Code of Federal Regulations (CFR) 312, subpart D, "Responsibilities of Sponsors and Investigators," 21 CFR, part 50, 1998, and 21 CFR, part 56, 1998, are adhered to. These standards are consistent with the requirements of the European Community Directive 2001/20/EC, which shall be adhered to fulfil the contractual requirements of this European Commission funded research project.

11.1.2 Institutional Review Board/Independent Ethics Committee Approval

This protocol and any accompanying material to be provided to the participant and caregiver (such as advertisements, participant information sheets, or descriptions of the study used to obtain informed consent) will be submitted by the investigator to an IRB or IEC. Approval from the IRB or IEC must be obtained before starting the study and should be documented in a letter to the investigator specifying the protocol number, protocol version, protocol date, documents reviewed, and date on which the committee met and granted the approval.

Any modifications made to the protocol or other documents described in the above paragraph after receipt of IRB or IEC approval must also be submitted to the IRB or IEC for approval before implementation.

11.1.3 Informed Consent

The investigator is responsible for obtaining written informed consent from each individual participating in this study after adequate explanation of the aims, methods, objectives, and potential hazards of the study and before undertaking any study-related procedures. The investigator must utilize an IRB- or IEC-approved consent form for documenting written informed consent. Each informed consent will be appropriately signed and dated by the participant or the participant's legally authorized representative and the person obtaining consent. Consent from both the caregiver representative and participant will be obtained.

11.1.4 Inspections

The investigator should understand that source documents for this trial should be made available to IRBs or IECs, or to regulatory authority or health authority inspectors.

11.1.5 Protocol Compliance

The investigator is responsible for ensuring the study is conducted in accordance with the procedures and evaluations described in this protocol.

11.1.6 Study Report and Publications

A clinical study report will be prepared and provided to the regulatory agencies.

11.2 Joint Investigator/Consortium Responsibilities

11.2.1 Access to Information for Monitoring

In accordance with ICH Good Clinical Practice (ICH GCP) guidelines, the Study Coordinator must have direct access to the investigator's source documentation in order to verify the data recorded for consistency.

The Study Monitor is responsible for routine review of the data collected at regular intervals throughout the study to verify adherence to the protocol and the completeness, consistency, and accuracy of the data being entered on them. The monitor should have access to any de-identified participant records needed to verify adherence. The site PI agrees to cooperate with the study coordinator to ensure that any problems detected in the course of these monitoring visits are resolved.

11.2.2 Study Discontinuation

The Consortium reserves the right to terminate the study at any time. Should this be necessary, both parties will arrange discontinuation procedures and notify the appropriate regulatory authority(ies), IRBs, and IECs.

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Appendix 1. PICF (Screening)

PARTICIPANT INFORMATION SHEET – Screening

Screening to participate in the My Active and Healthy Ageing (My-AHA) – Randomised Control Trial

This information sheet is for you to keep. The information sheet is long, but it is important that you read it carefully before you agree to participate in this study.

You have expressed an interest in participating in randomised control trial study aiming to identify individuals at risk for frailty and to assess different interventions to reduce your risk for frailty. Before we can enrol you in the 18 month long randomised control trial, we will need to screen you to ensure that you are a suitable candidate for the study and that you meet the selection criteria for participating in the study.

It is important to note, that if you meet the entry requirements for the study, you will then be formally invited to participate in the 18 month randomised control trial. If you accept this invitation you will then be randomly allocated to one of two groups:

1. A control group, in which you will undergo routine assessments at 6 month intervals but will not undertake any of the interventions being used in this study
2. An intervention group, in which you will undergo routine assessments at 6 month intervals and will undertake tailored interventions between each assessment point.

Participants invited into the study will be allocated randomly and evenly across both groups. This means you have a 1 in 2 chance (50%) of being allocated to either the control or the intervention group.

If you are happy with these conditions, please continue reading this information sheet. Once you have read this information sheet, if you wish to participate in this study please complete the attached consent form. If you have any questions, or would like additional information about the trial, please speak with **Associate Professor Mathew Summers** either in person, or by telephone on **5456 3758**. A/Prof Summers is the Principal Investigator and trial site coordinator for the Australian trial.

The My-AHA randomised control trial is a multi-site, multi-national study. The Australian trial site is being conducted by:

- **Associate Professor Mathew Summers** (Principal Investigator and Trial Site Coordinator - Australia), *Associate Professor of Neuropsychology & Mental Health, Sunshine Coast Mind and Neuroscience – Thompson Institute, University of the Sunshine Coast*

There are other trial sites involved in this study from:

- Italy
- Austria
- Spain
- Germany
- United Kingdom
- Belgium
- Sweden

The Australian trial site is being coordinated from the Sunshine Coast Mind and Neuroscience - Thompson Institute; a research institute of the University of the Sunshine Coast which is located at 12 Innovation Parkway, Birtinya.

1. 'What is the purpose of this study?'

Older adults with physical frailty are at increased risk of falls and other secondary complications. Frail older adults experience a loss of independence and increasing need for residential care. There is evidence to suggest that it is possible to reverse this risk by targeting a person's risk factors for developing frailty before frailty appears. The aim of this study is to test a new platform that we have developed to monitor an individual's risk for frailty in physical function (e.g. balance), cognition (e.g. memory), mood (e.g. depression), social activity (e.g. isolation), and nutrition (e.g. healthy eating). We will then develop a risk profile for each individual that recognises their specific areas of risk across these domains. This will results in our platform recommending specific activities (e.g. physical exercises, social activities in groups, diet changes) that will target the specific areas of risk for that individual participant. We believe that this approach will lead to a significant reduction in an older adult's risk for frailty, thereby promoting ongoing independence for the older adult in the community.

2. 'Why have I been invited to participate in this study?'

You have been invited to this screening because you have expressed an interest and are:

(a) Aged over 60-75 years;
(b) Able to stand and walk unassisted
(c) Do not suffer from a significant cognitive impairment (e.g. dementia)
(d) Do not suffer from a psychological or psychiatric condition (e.g Depression)
(e) Do not current have an acute (i.e. current or recent) or unstable (i.e. not well-controlled) medical condition
(f) Able to understand directions and participate in this study
(g) Able to give fully informed consent

3. 'What does participation in this screening study involve?'

To assess your eligibility to take part in this study, we will first ask you a series of questions about your:

- Mobility
- Medical history
- Psychological and psychiatric history
- Medication history

In addition, we will measure your blood pressure and screen your basic cognitive functions.

If you meet eligibility requirements and are willing to participate in this study, we will contact you to formally invite you to participate in the randomised control trial study. Should you accept you will be randomly allocated to either the control group or the intervention group for an 18 month long study trial.

When you are invited to participate in the study trial we will again fully explain all aspects of the study trial and ask you to consent to participate in that trial.

4. 'Is information about me confidential and can I withdraw from the study?'
It is important that you understand that your involvement in this screening study is voluntary. While we would be pleased to have you participate, we respect your right to decline. There are no consequences to you if you decide not to participate. If you decide to discontinue participation at any time, you may do so without providing an explanation. All information will be treated in a confidential manner, and your name will not be used in any publication arising out of the research. All of the research will be kept as secure computer files by A/Prof Summers, and only A/Prof Summers will have full access to re-identifiable information.

5. 'Are there any possible benefits from participation in this study?'
The information collected from you at screening will determine your suitability to participate in the randomised control trial to assess the capacity of interventions to reduce a person's risk for frailty.

6. 'Are there any possible risks from participation in this study?'
There are no significant harms or risk associated with participating in this study. You will be asked to disclose information regarding your personal life (e.g. education, family, occupation) and medical history. Some people may feel discomfort in disclosing personally sensitive information. We require this information to ensure that you are eligible to participate in the randomised control trial and that participating in the randomised control trial will not result in harm to yourself due to another condition. It is therefore important that you disclose all information that we request so that we can ensure you are safe to participate.
All information we collect from you is treated as strictly confidential and will be de-identified to protect your privacy. No individual information will be presented in any papers coming from this project, only summary data from the entire group will be reported, ensuring that your personal information cannot be identified.

7. 'How is this research funded?'
The Australian study site at the Sunshine Coast Mind and Neuroscience – Thompson Institute is funded by a *National Health and Medical Research Council (NHMRC) European Union Project Grant (1115818)* awarded to A/Prof Mathew Summers as Chief Investigator.
The European trial sites are funded by a *European Commission HORIZON2020 Consortium GHrant*, on which A/Prof Summers is a Principal Investigator.

8. 'What if I have questions about this research?'
If you would like to discuss any aspect of this research please feel free to contact **A/Prof Mathew Summers on 5456 3758, or email** msummers@usc.edu.au. A/Prof Summers would be happy to discuss any aspect of the research with you. You are welcome to contact A/Prof Summers at any time to discuss any issue relating to the research study.

This study has been approved by the Human Research Ethics Committee (Ethics approval number: ********). If you have concerns or complaints about the conduct of this study you can raise them with the Principal Investigator (A/Prof Mathew Summers). If you prefer an independent person, contact the Chairperson of the Human Research Ethics Committee at the University of the Sunshine Coast: (c/- the Research Ethics Officer, Office of Research, University of the Sunshine Coast, Maroochydore DC, 4558; telephone (07) 5459 4574; email humanethics@usc.edu.au. You will need to quote **HREC project HREC **** My Active and Healthy Ageing (My-AHA) randomised control trial study.**

On behalf of A/Prof Mathew Summers, the European Consortium partners, and the University of the Sunshine Coast, we thank you for taking the time to consider participating in this study.

If you wish to participate in this screening study, please sign the attached consent form. This information sheet is for you to keep.

CONSENT FORM

TITLE OF PROJECT:

The relationship between vascular processes and neurocognitive function in non-stroke cardiovascular disease: A prospective longitudinal investigation

1. I have read and understood the 'Information Sheet' for this project.
2. The nature and possible effects of the study have been explained to me.
3. I understand what my participation in this study involves as outlined in the 'Participant Information Sheet'
4. I understand that I will be asked to provide information regarding my demographic information, mobility, medical history, psychological and psychiatric history, and medication history.
5. I understand that I will have my blood pressure assessed.
6. I understand that I will have my cognitive functions screened.
7. I understand that information that identifies me will be removed and all information will be retained as confidential and will only be used for the purposes of the research project.
8. I understand that the results of my participation in this screening assessment will be used to determine if I am eligible to participate in the randomised control trial. I agree to being invited to participate in the randomised control trial if I am found to meet the eligibility criteria.
9. Any questions that I have asked have been answered to my satisfaction.
10. I agree that the research data gathered from me for the study may be published provided that I cannot be identified as a participant.
11. I agree that my de-identified data from this research can be used in future research projects.
12. I agree that my data (de-identified) can be shared with other researchers.
13. I agree to participate in this investigation and that I may withdraw at any time without any effect or explanation, and if I so wish, may request that any data I have supplied to date be withdrawn from the research.

Name of Participant:

Signature: Date:

Statement by Investigator

☐ I have explained the project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

Name of Investigator:

Signature: Date:

Appendix 2. PICF (RCT Intervention Group)

PARTICIPANT INFORMATION SHEET – Intervention Group

The My Active and Healthy Ageing (My-AHA) Randomised Control Trial to detect pre-frailty in older adults and provide individually tailored interventions to reduce risk for frailty.

This information sheet is for you to keep. The information sheet is long, but it is important that you read it carefully before you agree to participate in this study.

You have successfully completed the screening assessment for this study and we have found that you meet all inclusion criteria for participation in the 18 month long randomised control trial study aiming to identify individuals at risk for frailty and to assess different interventions to reduce your risk for frailty.

You have been randomly allocation to the **intervention group**. As a member of the intervention group you will be asked to undergo routine assessment every 6 months for 18 months. In between each assessment you will provided with an individually tailored intervention package. The intervention package will be tailored to target areas of relative weakness identified at each assessment across physical, cognitive, mood, social or nutrition. The interventions selected are safe and have been shown to improve function in these areas. Some of the interventions are performed individually in your own home, some will be performed in group settings. We will provide individual training and support before you undertake any of the interventions we recommend.

If you are happy with the above, please continue reading this information sheet where we provide more detailed information regarding what participation in this study will require. Once you have read this information sheet, if you wish to participate in this study please complete the attached consent form. If you have any questions, or would like additional information about the trial, please speak with **Associate Professor Mathew Summers** either in person, or by telephone on **5456 3758**. A/Prof Summers is the Principal Investigator and trial site coordinator for the Australian trial.

The My-AHA randomised control trial is a multi-site, multi-national study. The Australian trial site is being conducted by:

- **Associate Professor Mathew Summers** (Principal Investigator and Trial Site Coordinator - Australia), *Associate Professor of Neuropsychology & Mental Health, Sunshine Coast Mind and Neuroscience – Thompson Institute, University of the Sunshine Coast*

There are other trial sites involved in this study from:

- Italy
- Austria
- Spain
- Germany
- United Kingdom
- Belgium
- Sweden

The Australian trial site is being coordinated from the Sunshine Coast Mind and Neuroscience - Thompson Institute; a research institute of the University of the Sunshine Coast which is located at 12 Innovation Parkway, Birtinya.

1. 'What is the purpose of this study?'

Older adults with physical frailty are at increased risk of falls and other secondary complications. Frail older adults experience a loss of independence and increasing need for residential care. There is evidence to suggest that it is possible to reverse this risk by targeting a person's risk factors for developing frailty before frailty appears. The aim of this study is to test a new platform that we have developed to monitor an individual's risk for frailty in physical function (e.g. balance), cognition (e.g. memory), mood (e.g. depression), social activity (e.g. isolation), and nutrition (e.g. healthy eating). We will then develop a risk profile for each individual that recognises their specific areas of risk across these domains. This will results in our platform recommending specific activities (e.g. physical exercises, social activities in groups, diet changes) that will target the specific areas of risk for that individual participant. We believe that this approach will lead to a significant reduction in an older adult's risk for frailty, thereby promoting ongoing independence for the older adult in the community.

2. 'Why have I been invited to participate in this study?'

You have been invited to participate in this study as you have been screened as meeting all of the eligibility criteria for being a participant in the study. You have been randomly allocated to the **intervention group** for the study.

3. 'What does participation in this study involve?'
Your participation in this study will involve the following basic elements:

1. Participation in an 18 month long study

2. Undergoing comprehensive assessment on 4 occasions each spaced 6 months apart. These assessment will take a maximum of 3 hours to complete on each occasion. These assessment will occur:
    - Before you start the interventions
    - 6 months later
    - 12 months later
    - 18 months later (completion of the intervention study)

3. Undertaking recommended interventions over 18 months. You can choose how many or how few interventions as you like. You can do these interventions when you prefer and can space them out over the entire week.

The Comprehensive Assessments every 6 months

From your commencement in this study and every 6 months for the next 18 months we will ask you to undergo comprehensive assessment. Each assessment will take less than 3 hours to complete including regular rest breaks.
This assessment is designed to examine your strengths and weaknesses across different aspects of: medical health; general health; physical functions; cognitive functions (e.g., memory); your mood; your social activity; your diet and nutrition; your sleeping patterns; and your experience with using technology (e.g. mobile telephones).

These assessment are very important for two reasons:

1. Your performances on these assessment will be used to determine your relative areas of strength and weakness so that we can provide an individually tailored package of interventions, designed specifically for you.
2. Your performances will be monitored over time to measure how effective these interventions were in improving your performances in both your areas of weakness and strength.

For the assessment of each area of function, we will ask you to do the following:

a. Medical and general health
    - Complete a short questionnaire in which we will collect information regarding you recent medical health, medication prescriptions, educational history, residential status, relationship status, your history of falls, and the mental activities you have undertaken
    - Complete a questionnaire assessing how you feel your quality of life is
    - Complete a questionnaire regarding how well you perform daily activities (e.g., cooking, cleaning etc)

b. Physical function will be assessed by a variety of questionnaires and physical function assessments
    - We will measure your weight and height
    - We will measure the strength of your hand grip with each hand
    - We will assess how long it takes for you to:
        i. Walk 4 meters
        ii. Walk for 6 minutes

iii. Stand up and sit down
iv. Perform two tasks at once

- We will assess how well you can balance, and how well you can stand from sitting
- Complete a series of questionnaires that assess your level of physical tiredness, the enjoyment you have when doing physical activity, and how good you feel about yourself when doing physical activities

c. Cognitive performances will be assessed using a variety of paper-and-pencil and computer based tasks:
   - We will screen your general cognitive functions – such as naming things and short term memory
   - We will assess your capacity to learn and recall a list of 12 words that we will read out to you
   - We will assess your capacity to remember the location of objects to measure your short term memory
   - We will assess how fast you can perform a join-the-dots task
   - We will assess you reading speed for words and colours
   - We will assess how fast you can transcribe in writing shapes for numbers

d. Mood
   - We will ask you to complete a questionnaire to assess your mood have been feeling over the preceding week.

e. Social activity
   - Complete a questionnaire that asks you about your network of friends and family
   - Complete a questionnaire that asks you to describe how you feel about your social relationships

f. Nutrition
   - Complete a short questionnaire that asks you about your diet

g. Sleep
   - Complete a short questionnaire that asks you about how you have been sleeping recently.

The Interventions

Once we have examined the results of your first assessment, we will provide you with a individually tailored intervention package for you to undertake until the next assessment point. Following each assessment we will reconfigure the intervention package; meaning that the interventions you are provided may change from assessment to assessment. These changes will be a response to changes in the areas of strength and weakness we identify at each assessment point.
There are a wide range of interventions we will make available to you. These interventions have strong research indicating that they are safe and effective to use. Precisely which intervention(s) you will receive will depend on your individual assessment results; but your intervention(s) will be selected from the following range of options and you can choose how much or little you do of these recommended interventions:

a. **Physical interventions** will be selected from
   - A home-based exercise program, we will provide individual training after whgich you can undertake these exercises in your own home without assistance.
     i. Strength training
     ii. Balance training
     iii. Endurance and fitness training where you can choose your preferred form of activity (e.g. walking, bicycling, stationary bicycle, treadmill etc)
   - A group-based exercise program. We will invite you to a group exercise class at a central location which will be conducted by a trained and experienced fitness and exercise instructor. All activities will be tailored to your own level of fitness and ability and will be supervised at all times. Exercising in a group of other participants in this study can be a great social activity as well.
   - An endurance exercise program which you will undertake once per week and can choose your own activity to perform for up to 150 minutes per week (e.g. walking, bicycling, treadmill, stationary bicycling, etc).

b. **Cognitive interventions** are all based on computer training or computer game type activities. As your performances improve the tasks increase in difficulty – ensuring that the mental challenge increases to further improve your cognitive performance:
   - N-Back training – is a computer training program that requires you to remember a series of visual pictures and to match against ones that you have previously seen. This is a powerful, but challenging, method of training your working memory and attention and concentration.
   - Attention bias modification training is a computer training program that trains your brain to direct attention to a positive visual picture and to ignore a negative picture.

c. **Psychosocial interventions** are all based on participating in group activities, wither in person or through an online platform
   - Group activities can be selected from a range of options such as: group physical exercise classes; group cooking classes; or group excursions.
   - Support groups will be connected for specific personal issues you may be experiencing, e.g. bereavement support, or support groups for specific diseases
   - An online social platform will enable you to share information and chat with other participants in the My-AHA study from across the multiple study sites over Europe as well as the local site on the Sunshine Coast.

d. **Nutritional interventions** will be provided through a nutrition application on your mobile telephone. This application generates individual meal plans as well as nutritional advice and education which are tailored to meet your needs. When you record what you eat on the nutritional application, new meal plans and advice are generated to match your preferences.

4. 'Is information about me confidential and can I withdraw from the study?'
It is important that you understand that your involvement in the study is voluntary. While we would be pleased to have you participate, we respect your right to decline. There are no consequences to you if you decide not to participate. If you decide to discontinue participation at any time, you may do so without providing an explanation. All information will be treated in a confidential manner, and your name will not be used in any publication arising out of the research. All of the research will be kept as secure computer files by A/Prof Summers, and only A/Prof Summers will have full access to re-identifiable information.

5. 'Are there any possible benefits from participation in this study?'
You were selected to participate in this study as you were identified as meeting the eligibility criteria for participation. One of the key eligibility criteria for all participants is that they display evidence of "pre-frailty". Pre-frailty is a state in which a person displays some (but not all) of the features of frailty, and the features the person displays are mild in nature not meeting the diagnosis of frailty. Pre-frailty can be considered to be a state of increased risk for developing frailty – but being pre-frail does mean a person will always become frail.

The study you are participating in is designed to deliver individually tailored interventions targeting your areas of risk for frailty. These interventions have been shown to be effective and safe in other research, however this is the first time that we will tailor your interventions based on your individual risk for frailty. A major benefit of participation in this study is the potential to significantly reduce your risk for develop frailty and potentially to prevent you developing frailty in later life.
Further, the data we collect during this research will be used to develop a final My-AHA platform for detecting and treating older adults with pre-frail risk across Australia and Europe. Your participation is essential to ensure that the final My-AHA platform developed is effective and easy to use.

6. 'Are there any possible risks from participation in this study?'
There are no significant harms or risk associated with participating in this study. The interventions were will recommend have been selected for their safety and effectiveness. We will provide individual training on each intervention that is recommended to you and modify the interventions to suit your own level of ability and preferences.

The assessment tasks used at 6 monthly intervals include measures that are challenging and designed to push you to your level of best performance. Consequently, you may find that each test becomes more difficult and harder to complete. While this may be frustrating, it is necessary for our testing to push you so that we can determine what your best performance is. In addition you will be asked to complete some questionnaires relating to your emotions and feelings. Some people may experience some discomfort reporting their emotional states.

Disclosing personal information

- You will be asked to complete some questionnaires relating to your personal life (e.g. education, family, occupation) and medical history. Some people may feel discomfort in disclosing personally sensitive information. We require this information as these factors are known to contribute to your performance,

so our knowledge of whether these factors are present will enable us to more accurately interpret your results.

- Your information will be treated as confidential and will be de-identified to protect your privacy. Your de-identified data will be combined with de-identified data from all the other study sites o that we can analyse the effectiveness of our intervention program across counties. No individual information will be presented in any papers coming from this project, only summary data from the entire group will be reported, ensuring that your personal information cannot be identified. Only A/Prof Mathew Summers is able to re-identify your data, no other research personnel will be able to identify which data belongs to you, or who you are.

7. 'How is this research funded?'

The Australian study site at the Sunshine Coast Mind and Neuroscience – Thompson Institute is funded by a *National Health and Medical Research Council (NHMRC) European Union Project Grant (1115818)* awarded to A/Prof Mathew Summers as Chief Investigator.
The European trial sites are funded by a *European Commission HORIZON2020 Consortium GHrant*, on which A/Prof Summers is a Principal Investigator.

8. 'What if I have questions about this research?'

If you would like to discuss any aspect of this research please feel free to contact **A/Prof Mathew Summers on 5456 3758, or email** msummers@usc.edu.au. A/Prof Summers would be happy to discuss any aspect of the research with you. You are welcome to contact A/Prof Summers at any time to discuss any issue relating to the research study.

This study has been approved by the Human Research Ethics Committee (Ethics approval number: ********). If you have concerns or complaints about the conduct of this study you can raise them with the Principal Investigator (A/Prof Mathew Summers). If you prefer an independent person, contact the Chairperson of the Human Research Ethics Committee at the University of the Sunshine Coast: (c/- the Research Ethics Officer, Office of Research, University of the Sunshine Coast, Maroochydore DC, 4558; telephone (07) 5459 4574; email humanethics@usc.edu.au. You will need to quote **HREC project HREC **** My Active and Healthy Ageing (My-AHA) randomised control trial study.**

On behalf of A/Prof Mathew Summers, the European Consortium partners, and the University of the Sunshine Coast, we thank you for taking the time to consider participating in this study.

If you wish to participate, please sign the attached consent form. This information sheet is for you to keep.

CONSENT FORM

TITLE OF PROJECT:

The My Active and Healthy Ageing (My-AHA) Randomised Control Trial to detect pre-frailty in older adults and provide individually tailored interventions to reduce risk for frailty

1. I have read and understood the 'Information Sheet' for this project.
2. I understand that I have been randomly allocated to the intervention group and consent to being a participant in the intervention group.
3. The nature and possible effects of the study have been explained to me.
4. I understand what my participation in this study involves as outlined in the 'Participant Information Sheet'
5. I understand that involvement in this study involves undergoing 4 assessment sessions spaced 6 months apart over 18 months, and that each session will take no more than 3 hours to complete including regular rest breaks.
6. I understand that in these assessment sessions I will be asked to provide information regarding my demographic information, medical history, occupational and educational history, quality of life, sleep habits, social activity, and diet and nutrition. I understand that my physical functions (e.g balance), cognitive functions (e.g. memory) and psychological wellbeing (e.g. mood) will be assessed.
7. I understand that I will be provided with an individually tailored intervention program which I can choose to do as much or as little of as I want. These interventions will be selected from physical exercises, cognitive training games, group activities, and/or nutritional advice. I understand that these interventions will be performed at home by myself, in a group class setting, in a group-based activity, or by using an application on my mobile telephone.
8. I understand that the assessment measures as well as the interventions I am asked to perform are designed to become increasingly difficulty as my abilities improve and that I may experience some frustration as the difficulty increases.
9. I understand that should I experience any discomfort, dizziness, faintness, breathlessness or illness during the either the assessments or while undertaking the intervention I must notify the researcher immediately, so that they can stop the procedure immediately.
10. I understand that information that identifies me will be removed and all information will be retained as confidential and will only be used for the purposes of the research project.
11. I understand that throughout the course of this study I will be provided with feedback as to how I am performing and how the interventions I have completed have modified my risk for developing frailty.
12. Any questions that I have asked have been answered to my satisfaction.
13. I agree that the research data gathered from me for the study may be published provided that I cannot be identified as a participant.
14. I agree that my de-identified data from this research can be used in future research projects.

15. I agree that my data (de-identified) can be shared with other researchers involved in the My-AHA consortium.
16. I agree to participate in this investigation and that I may withdraw at any time without any effect or explanation, and if I so wish, may request that any data I have supplied to date be withdrawn from the research.

Name of Participant:

Signature: Date:

Statement by Investigator

☐ I have explained the project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

Name of Investigator:

Signature: Date:

Appendix 3. PICF (RCT Control Group)

PARTICIPANT INFORMATION SHEET – Control Group

The My Active and Healthy Ageing (My-AHA) Randomised Control Trial to detect pre-frailty in older adults and provide individually tailored interventions to reduce risk for frailty.

This information sheet is for you to keep. The information sheet is long, but it is important that you read it carefully before you agree to participate in this study.

You have successfully completed the screening assessment for this study and we have found that you meet all inclusion criteria for participation in the 18 month long randomised control trial study aiming to identify individuals at risk for frailty and to assess different interventions to reduce your risk for frailty.

You have been randomly allocation to the **control (no treatment) group**. As a member of the control group you will be asked to undergo routine assessment every 6 months for 18 months. In the event that you develop clinical symptoms of frailty during this 18 month trial we will immediately offer you the opportunity to transfer to the intervention group which is assessing the ability of an individually tailored intervention package to reduce signs and symptoms of frailty. However, as this is a randomised control trial designed to test whether the intervention package has efficacy in helping older adults manage changes in physical, cognitive, social, and psychological function, it is imperative that we have a comparison group who do not receive this intervention package. Note, you may continue to do any or all of the activities you currently do which you may have chosen improve your health and fitness; we do not require you to cease any activities you are currently doing and will not ask you to not undertake any other activities you choose to do in the future.

At the conclusion of the study, we will determine if our intervention package is successful and aim to make this a commercially available product. As a participant in this study you will be the first to be informed of these results and whether the intervention package has been developed for people to obtain and use.

If you are happy with the above, please continue reading this information sheet where we provide more detailed information regarding what participation in this study will require. Once you have read this information sheet, if you wish to participate in this study please complete the attached consent form. If you have any questions, or would like additional information about the trial, please speak with **Associate Professor Mathew Summers** either in person, or by telephone on **5456 3758**. A/Prof Summers is the Principal Investigator and trial site coordinator for the Australian trial.

The My-AHA randomised control trial is a multi-site, multi-national study. The Australian trial site is being conducted by:

- **Associate Professor Mathew Summers** (Principal Investigator and Trial Site Coordinator - Australia), *Associate Professor of Neuropsychology & Mental Health, Sunshine Coast Mind and Neuroscience – Thompson Institute, University of the Sunshine Coast*

There are other trial sites involved in this study from:

- Italy
- Austria
- Spain
- Germany
- United Kingdom
- Belgium
- Sweden

The Australian trial site is being coordinated from the Sunshine Coast Mind and Neuroscience - Thompson Institute; a research institute of the University of the Sunshine Coast which is located at 12 Innovation Parkway, Birtinya.

1. 'What is the purpose of this study?'

Older adults with physical frailty are at increased risk of falls and other secondary complications. Frail older adults experience a loss of independence and increasing need for residential care. There is evidence to suggest that it is possible to reverse this risk by targeting a person's risk factors for developing frailty before frailty appears. The aim of this study is to test a new platform that we have developed to monitor an individual's risk for frailty and to provide recommended interventions to reduce the risk for frailty in physical function (e.g. balance), cognition (e.g. memory), mood (e.g. depression), social activity (e.g. isolation), and nutrition (e.g. healthy eating).

As a member of the control group we will monitor your health and function over 18 months without providing you access to the intervention package. We will provide your results to you following each assessment which you can discuss with us and your medical practitioner if you choose. It is important to note, we will not ask you to stop doing any activities that you currently are doing, or intend to do in the future, to improve your health or fitness.

If we detect a significant change in your functions over the 18 month trial that indicate you are developing signs of frailty, we will immediately offer you the opportunity to join the intervention and have full access to the intervention package. We do yet not know whether these interventions are effective in reducing symptoms of frailty as this is the purpose of this study.

2. 'Why have I been invited to participate in this study?'

You have been invited to participate in this study as you have been screened as meeting all of the eligibility criteria for being a participant in the study. You have been randomly allocated to the **control (no treatment) group** for the study.

3. 'What does participation in this study involve?'

Your participation in this study will involve the following basic elements:

1. Participation in an 18 month long study

2. Undergoing comprehensive assessment on 4 occasions each spaced 6 months apart. These assessment will take a maximum of 3 hours to complete on each occasion. These assessment will occur:
    - Before you start the interventions
    - 6 months later
    - 12 months later
    - 18 months later (completion of the intervention study)

The Comprehensive Assessments every 6 months

From your commencement in this study and every 6 months for the next 18 months we will ask you to undergo comprehensive assessment. Each assessment will take less than 3 hours to complete including regular rest breaks.

This assessment is designed to examine your strengths and weaknesses across different aspects of: medical health; general health; physical functions; cognitive functions (e.g., memory); your mood; your social activity; your diet and nutrition; your sleeping patterns; and your experience with using technology (e.g. mobile telephones).

These assessment are very important for two reasons:

1. Your performances on these assessment will be used to determine your relative areas of strength and weakness so that we can provide an individually tailored package of interventions, designed specifically for you.
2. Your performances will be monitored over time to measure how effective these interventions were in improving your performances in both your areas of weakness and strength.

For the assessment of each area of function, we will ask you to do the following:

a. Medical and general health
    - Complete a short questionnaire in which we will collect information regarding you recent medical health, medication prescriptions, educational history, residential status, relationship status, your history of falls, and the mental activities you have undertaken
    - Complete a questionnaire assessing how you feel your quality of life is
    - Complete a questionnaire regarding how well you perform daily activities (e.g., cooking, cleaning etc)

b. Physical function will be assessed by a variety of questionnaires and physical function assessments
    - We will measure your weight and height
    - We will measure the strength of your hand grip with each hand
    - We will assess how long it takes for you to:
        i. Walk 4 meters
        ii. Walk for 6 minutes
        iii. Stand up and sit down
        iv. Perform two tasks at once
    - We will assess how well you can balance, and how well you can stand from sitting
    - Complete a series of questionnaires that assess your level of physical tiredness, the enjoyment you have when doing physical activity, and how good you feel about yourself when doing physical activities

c. Cognitive performances will be assessed using a variety of paper-and-pencil and computer based tasks:
   - We will screen your general cognitive functions – such as naming things and short term memory
   - We will assess your capacity to learn and recall a list of 12 words that we will read out to you
   - We will assess your capacity to remember the location of objects to measure your short term memory
   - We will assess how fast you can perform a join-the-dots task
   - We will assess you reading speed for words and colours
   - We will assess how fast you can transcribe in writing shapes for numbers

d. Mood
   - We will ask you to complete a questionnaire to assess your mood have been feeling over the preceding week.

e. Social activity
   - Complete a questionnaire that asks you about your network of friends and family
   - Complete a questionnaire that asks you to describe how you feel about your social relationships

f. Nutrition
   - Complete a short questionnaire that asks you about your diet

g. Sleep
   - Complete a short questionnaire that asks you about how you have been sleeping recently.

h. Technology
   - Complete occasional questionnaire that ask you to describe how you feel about using different technologies (e.g. mobile telephones, computers etc).

4. 'Is information about me confidential and can I withdraw from the study?'
It is important that you understand that your involvement in the study is voluntary. While we would be pleased to have you participate, we respect your right to decline. There are no consequences to you if you decide not to participate. If you decide to discontinue participation at any time, you may do so without providing an explanation. All information will be treated in a confidential manner, and your name will not be used in any publication arising out of the research. All of the research will be kept as secure computer files by A/Prof Summers, and only A/Prof Summers will have full access to re-identifiable information.

5. 'Are there any possible benefits from participation in this study?'
You were selected to participate in this study as you were identified as meeting the eligibility criteria for participation. One of the key eligibility criteria for all participants is that they display evidence of "pre-frailty". Pre-frailty is a state in which a person displays some (but not all) of the features of frailty, and the features the person displays are mild in nature not meeting the diagnosis of frailty. Pre-frailty can be considered to be a state of increased risk for developing frailty – but being pre-frail does mean a person will always become frail.

The study you are participating in is designed to deliver individually tailored interventions targeting your areas of risk for frailty. As a member of the control group you will not have access to the intervention

package. However, should we detect a significant change in your functions across assessments indicating that you may be developing clinical frailty, we will immediately offer you the opportunity to transfer to the intervention group where you will be provided with full access to the intervention package. This may help reduce symptoms of frailty, however, we cannot be sure that this will occur as the purpose of this study is to test whether the intervention package actually does reduce symptoms of frailty.
Further, the data we collect during this research will be used to develop a final My-AHA platform for detecting and treating older adults with pre-frail risk across Australia and Europe. Your participation is essential to ensure that the final My-AHA platform developed is effective and easy to use.

6. 'Are there any possible risks from participation in this study?'
There are no significant harms or risk associated with participating in this study. The assessment tasks used at 6 monthly intervals include measures that are challenging and designed to push you to your level of best performance. Consequently, you may find that each test becomes more difficult and harder to complete. While this may be frustrating, it is necessary for our testing to push you so that we can determine what your best performance is. In addition you will be asked to complete some questionnaires relating to your emotions and feelings. Some people may experience some discomfort reporting their emotional states.

<u>Disclosing personal information</u>

- You will be asked to complete some questionnaires relating to your personal life (e.g. education, family, occupation) and medical history. Some people may feel discomfort in disclosing personally sensitive information. We require this information as these factors are known to contribute to your performance, so our knowledge of whether these factors are present will enable us to more accurately interpret your results.
- Your information will be treated as confidential and will be de-identified to protect your privacy. Your de-identified data will be combined with de-identified data from all the other study sites o that we can analyse the effectiveness of our intervention program across counties. No individual information will be presented in any papers coming from this project, only summary data from the entire group will be reported, ensuring that your personal information cannot be identified. Only A/Prof Mathew Summers is able to re-identify your data, no other research personnel will be able to identify which data belongs to you, or who you are.

7. 'How is this research funded?'
The Australian study site at the Sunshine Coast Mind and Neuroscience – Thompson Institute is funded by a *National Health and Medical Research Council (NHMRC) European Union Project Grant (1115818)* awarded to A/Prof Mathew Summers as Chief Investigator.
The European trial sites are funded by a *European Commission HORIZON2020 Consortium GHrant*, on which A/Prof Summers is a Principal Investigator.

8. 'What if I have questions about this research?'
If you would like to discuss any aspect of this research please feel free to contact **A/Prof Mathew Summers on 5456 3758, or email** msummers@usc.edu.au. A/Prof Summers would be happy to discuss any aspect of the research with you. You are welcome to contact A/Prof Summers at any time to discuss any issue relating to the research study.

This study has been approved by the Human Research Ethics Committee (Ethics approval number: ********). If you have concerns or complaints about the conduct of this study you can raise them with the Principal Investigator (A/Prof Mathew Summers). If you prefer an independent person, contact the Chairperson of the Human Research Ethics Committee at the University of the Sunshine Coast: (c/- the Research Ethics Officer, Office of Research, University of the Sunshine Coast, Maroochydore DC, 4558; telephone (07) 5459 4574; email humanethics@usc.edu.au. You will need to quote **HREC project HREC **** My Active and Healthy Ageing (My-AHA) randomised control trial study.**

On behalf of A/Prof Mathew Summers, the European Consortium partners, and the University of the Sunshine Coast, we thank you for taking the time to consider participating in this study.

If you wish to participate, please sign the attached consent form. This information sheet is for you to keep.

CONSENT FORM

TITLE OF PROJECT:

The relationship between vascular processes and neurocognitive function in non-stroke cardiovascular disease: A prospective longitudinal investigation

TITLE OF PROJECT:

The My Active and Healthy Ageing (My-AHA) Randomised Control Trial to detect pre-frailty in older adults and provide individually tailored interventions to reduce risk for frailty

1. I have read and understood the 'Information Sheet' for this project.
2. I understand that I have been randomly allocated to the control (no treatment) group and consent to being a participant in the control group.
3. I understand that I will not be asked to cease any activities I am currently doing or choose to do in the future, and that these choices will not affect my participation in this study.
4. I understand that should a significant decline in my function be detected, suggesting development of clinical frailty, I will be offered the opportunity to transfer into the intervention group where I will receive access to the full intervention package being tested.
5. I understand that there is no guarantee that the intervention package will reduce symptoms of frailty.
6. The nature and possible effects of the study have been explained to me.
7. I understand what my participation in this study involves as outlined in the 'Participant Information Sheet'
8. I understand that involvement in this study involves undergoing 4 assessment sessions spaced 6 months apart over 18 months, and that each session will take no more than 3 hours to complete including regular rest breaks.
9. I understand that in these assessment sessions I will be asked to provide information regarding my demographic information, medical history, occupational and educational history, quality of life, sleep habits, social activity, and diet and nutrition. I understand that my physical functions (e.g balance), cognitive functions (e.g. memory) and psychological wellbeing (e.g. mood) will be assessed.
10. I understand that the assessment measures I am asked to perform are designed to become increasingly difficulty as my abilities improve and that I may experience some frustration as the difficulty increases.
11. I understand that information that identifies me will be removed and all information will be retained as confidential and will only be used for the purposes of the research project.

12. I understand that throughout the course of this study I will be provided with feedback as to how I am performing and how the interventions I have completed have modified my risk for developing frailty.
13. Any questions that I have asked have been answered to my satisfaction.
14. I agree that the research data gathered from me for the study may be published provided that I cannot be identified as a participant.
15. I agree that my de-identified data from this research can be used in future research projects.
16. I agree that my data (de-identified) can be shared with other researchers involved in the My-AHA consortium.
17. I agree to participate in this investigation and that I may withdraw at any time without any effect or explanation, and if I so wish, may request that any data I have supplied to date be withdrawn from the research.

Name of Participant:

Signature: Date:

Statement by Investigator

☐ I have explained the project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

Name of Investigator:

Signature: Date:

Appendix 4. Screening Assessment Checklist

To be completed by Investigator interview of potential participant:

1	Date of Birth	DD / MM / YYYY	
2	Age (years)		If 60 years or older **proceed** If <60 yrs - **EXCLUDE**
3a	Able to stand and walk unassisted	YES / NO	If YES – **proceed** If NO - **EXCLUDE**
3b	Painful arthritis, spinal stenosis, amputation, or painful foot lesions that limit balance and mobility.	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
4a	suffers from a significant neurodegenerative CNS disorder, *e.g. Alzheimer's disease, Lewy body dementia, Frontotemporal Lobar Degeneration, Fronto-Temporal Dementia, Parkinson's disease, multiple sclerosis, progressive supranuclear palsy, amyotrophic lateral sclerosis, hydrocephalus, Huntington's disease, prion diseases*	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
4b	affected by severe peripheral nervous system and/or neuromuscular disorders, *e.g. CIDP, myasthenia gravis, multiple sclerosis, polymyositis*	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
5a	clinical evidence or history of stroke (within 2 yrs)	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
5b	clinical evidence or history of transient ischemic attack (within 6 months)	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
5c	significant head injury with associated loss of consciousness, skull fracture or persisting cognitive impairment (2 years)	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
5d	epilepsy (a single prior seizure is considered acceptable)	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
5e	if meet DSM-5 criteria for: *major depressive disorder (current), schizophrenia or other psychotic disorders (lifetime), bipolar disorder (within the past 5 years), substance (including alcohol) related disorders (within the past 2 years)*	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
6a	have language deficits that impair testing	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
6b	have significant visual impairment	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
6c	have a significant hearing loss	YES / NO	If YES – **EXCLUDE**

			If NO - **proceed**
7a	have clinically significant cardiovascular disease, i.e: *hospitalization for acute coronary syndrome (acute myocardial infarction or unstable, angina), symptoms consistent with angina pectoris (within the 12 months)*, *signs or symptoms of clinical heart failure within the 12 months, evidence of uncontrolled atrial fibrillation, a cardiac pacemaker*	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
7b	preexisting or current signs or symptoms of respiratory failure, e.g. *chronic obstructive pulmonary disease, bronchial asthma, lung fibrosis, other respiratory disease*	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
7c	untreated hypertension	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
7d	metastatic cancer or immunosuppressive therapy	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
7e	concurrent acute or chronic clinically significant immunologic, hepatic (such as presence of encephalopathy or ascites), or endocrine disease (not adequately treated).	YES / NO	If YES – **EXCLUDE** If NO - **proceed**
8	Prescription medication other than for treating conditions in 3b to 7e		Confirm participant can proceed into RCT with medical monitor if other medications are reported
9	Postural hypotension at the time of screening. Participants who present at the time of screening with postural hypotension yet have no known history of postural hypotension, nor underlying medical condition related to hypotension, may be rescreened	BP sitting Sys = _____ Dias = _____ BP standing Sys = _____ Dias = _____	Standing systolic BP >30mgHG lower than sitting systolic BP - **EXCLUDE** and/or Standing diastolic BP >20mmHg lower than sitting diastolic BP - **EXCLUDE** If does not meet above - **proceed**
10	Legally able to consent	YES / NO	If YES – **proceed** If NO - **EXCLUDE**
11	Gender	Male / Female	
12	Height	_____ m	

13	Weight	_____ kg	
14	BMI	_____	[height(m)/weight (kg)] / [height(m)]
15	Able to use smartphone and/or tablet computer		If YES – **proceed** If NO – **EXCLUDE**
15a	Owns own smartphone/tablet computer	YES / NO	Model: _____ OS: Android / Win / Mac
15b	Has existing mobile plan and provider?	YES / NO	Provider: _____ Data/mth: _____
15c	Has WiFi access at place of residence?	YES / NO	
15d	Has existing internet provider and plan?		Provider: _____ Data/mth: _____

PHYSICAL FRAILTY ASSESSMENT

1	Self-reported weight loss (not due to dieting or fasting) in preceding 12 mo ≥ 4.5 kg		YES / NO
2	Grip strength measured using dynanometer	**Sex** / **BMI** / **Grip strength cutoff (kg)** Male: ≤ 24 / ≤ 29; 24.1 - 26 / ≤ 30; 26.1 - 28 / ≤ 30; > 28 / ≤ 32 Female: ≤ 23 / ≤ 17; 23.1 - 26 / ≤ 17.3; 26.1 - 29 / ≤ 18; > 29 / ≤ 21	Is grip stength **below** cutoff for sex/age? YES / NO
3a	Ask participant "How often over the past week have you felt that everything you did was an effort?"	0 = rarely or none of the time (<1 day) 1 = Some or a little of time (1-2 days) 2 = Occaisionally or a moderate amount of time (3-4 days) 3 = Most or all of the time (5-7 days)	Score 2 or 3 YES / NO
3b	Ask participant "How often over the past week have you felt that you could not get "going""?"	0 = rarely or none of the time (<1 day) 1 = Some or a little of time (1-2 days) 2 = Occaisionally or a moderate amount of time (3-4 days) 3 = Most or all of the time (5-7 days)	Score 2 or 3 YES / NO
4	Time to walk 15ft (4.57m) ≤ slowest 20% adjusted for gender and standing height	**Sex** / **Height (cm)** / **Cutoff time to walk 15ft** Male: ≤ 173 / ≥ 7 sec; > 173 / ≥ 6 sec Female: ≤ 159 / ≥ 7 sec; >159 / ≥ 6 sec	Is time to walk **greater** than cutoff for sex/height? YES / NO
5	IPAQ Short Version Activity Level _____ MET-min	Kcal [kcal = MET-min x (wight kg / 60)] Cutoff: Men < 383 kcal; Women < 270 kcal	Is activity level (kcal) **below** cutoff for gender? YES / NO
		TOTAL NUMBER OF "YES"	**/ 5**
		If 1 or 2 YES	Include
		If 0 or >2 YES	**EXCLUDE**

COGNITIVE FRAILTY ASSESSMENT

1	MMSE Raw Score = _____ / 30 MMSE Age-adjusted Score = _____ / 30	Age-Adjusted Score ≤ 26	YES / NO
2	Hopkins Verbal Learning Test (HVLT) HVLT total recall score = _____ / 36	HVLT total recall score ≤ 24	YES / NO
		TOTAL NUMBER OF "YES"	**/ 2**
		If 0 YES	Include
		If 1 or 2 YES	**EXCLUDE**

PSYCHOLOGICAL FRAILTY ASSESSMENT

1	HADS Anxiety Score = _____ / 21	HADS Anxiety Score ≥ 15	YES / NO
2	HADS Depression Score = _____ / 21	HADS Depression Score ≥ 15	YES / NO
		TOTAL NUMBER OF "YES"	**/ 2**
		If 0 YES	Include
		If 1 or 2 YES	**EXCLUDE**

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

(IPAQ)

PARTICIPANT SCREEN NUMBER: _____
STUDY SITE: _____
TEST PHASE: Screening

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **days per week**

☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **hours per day**
_____ **minutes per day**

☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week**

☐ No moderate physical activities → ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**
_____ **minutes per day**

☐ Don't know/Not sure

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

(IPAQ)

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking → ***Skip to question 7***

1. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**
_____ **minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

2. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**
_____ **minutes per day**

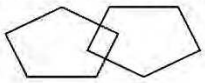
☐ Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

Mini-Mental State Examination (MMSE)

Patient's Name: _____ Date: _____

***Instructions:* Ask the questions in the order listed. Score one point for each correct response within each question or activity.**

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day of the week? Month?"
5		"Where are we now: State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: _____
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, ...) Stop after five answers. Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 
30		TOTAL

(Adapted from Rovner & Folstein, 1987)

Instructions for administration and scoring of the MMSE

Orientation (10 points):

- Ask for the date. Then specifically ask for parts omitted (e.g., "Can you also tell me what season it is?"). One point for each correct answer.
- Ask in turn, "Can you tell me the name of this hospital (town, county, etc.)?" One point for each correct answer.

Registration (3 points):

- Say the names of three unrelated objects clearly and slowly, allowing approximately one second for each. After you have said all three, ask the patient to repeat them. The number of objects the patient names correctly upon the first repetition determines the score (0-3). If the patient does not repeat all three objects the first time, continue saying the names until the patient is able to repeat all three items, up to six trials. Record the number of trials it takes for the patient to learn the words. If the patient does not eventually learn all three, recall cannot be meaningfully tested.
- After completing this task, tell the patient, "Try to remember the words, as I will ask for them in a little while."

Attention and Calculation (5 points):

- Ask the patient to begin with 100 and count backward by sevens. Stop after five subtractions (93, 86, 79, 72, 65). Score the total number of correct answers.
- If the patient cannot or will not perform the subtraction task, ask the patient to spell the word "world" backwards. The score is the number of letters in correct order (e.g., dlrow=5, dlorw=3).

Recall (3 points):

- Ask the patient if he or she can recall the three words you previously asked him or her to remember. Score the total number of correct answers (0-3).

Language and Praxis (9 points):

- Naming: Show the patient a wrist watch and ask the patient what it is. Repeat with a pencil. Score one point for each correct naming (0-2).
- Repetition: Ask the patient to repeat the sentence after you ("No ifs, ands, or buts."). Allow only one trial. Score 0 or 1.
- 3-Stage Command: Give the patient a piece of blank paper and say, "Take this paper in your right hand, fold it in half, and put it on the floor." Score one point for each part of the command correctly executed.
- Reading: On a blank piece of paper print the sentence, "Close your eyes," in letters large enough for the patient to see clearly. Ask the patient to read the sentence and do what it says. Score one point only if the patient actually closes his or her eyes. This is not a test of memory, so you may prompt the patient to "do what it says" after the patient reads the sentence.
- Writing: Give the patient a blank piece of paper and ask him or her to write a sentence for you. Do not dictate a sentence; it should be written spontaneously. The sentence must contain a subject and a verb and make sense. Correct grammar and punctuation are not necessary.
- Copying: Show the patient the picture of two intersecting pentagons and ask the patient to copy the figure exactly as it is. All ten angles must be present and two must intersect to score one point. Ignore tremor and rotation.

(Folstein, Folstein & McHugh, 1975)

Interpretation of the MMSE

Method	Score	Interpretation
Single Cutoff	<24	Abnormal
Range	<21	Increased odds of dementia
	>25	Decreased odds of dementia
Education	21	Abnormal for 8th grade education
	<23	Abnormal for high school education
	<24	Abnormal for college education
Severity	24-30	No cognitive impairment
	18-23	Mild cognitive impairment
	0-17	Severe cognitive impairment

Sources:

- Crum RM, Anthony JC, Bassett SS, Folstein MF. Population-based norms for the mini-mental state examination by age and educational level. *JAMA*. 1993;269(18):2386-2391.
- Folstein MF, Folstein SE, McHugh PR. "Mini-mental state": a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res*. 1975;12:189-198.
- Rovner BW, Folstein MF. Mini-mental state exam in clinical practice. *Hosp Pract*. 1987;22(1A):99, 103, 106, 110.
- Tombaugh TN, McIntyre NJ. The mini-mental state examination: a comprehensive review. *J Am Geriatr Soc*. 1992;40(9):922-935.

HOPKINS VERBAL LEARNING TEST

LIST 1 (HVLT-1)

PARTICIPANT SCREEN NUMBER: _____
STUDY SITE: _____
TEST PHASE: Screening

Instructions: Read the list of 12 words in Part A (at a rate of 1 word every 2 seconds), then have the participant repeat as many of the words as s/he can recall. Do this for 3 trials. Do not warn the participant that they will be asked to remember these words later on.

After 20-25 minutes delay continue to Part B (participant undertakes remainder of assessment for this visit). Complete the **Delayed Recall** trial by asking the participant to recall the words you read to them at the beginning of the test. Then complete the **Recognition** trial by saying each word to the participant and asking the participant to respond with "Yes" if the word was on the list or "no" if it was not.

Part A	Trial 1	Trial 2	Trial 3	Part B	Delayed Recall
LION					
EMERALD					
HORSE					
TENT					
SAPPHIRE					
HOTEL					
CAVE					
OPAL					
TIGER					
PEARL					
COW					
HUT					
TOTAL CORRECT					

Part B – RECOGNITION TRIAL

	Y	N		Y	N		Y	N		Y	N
HORSE			EMERALD			Balloon			Apartment*		
House*			mountain			Boat			COW		
HUT			CAVE			Dog*			LION		
TENT			TIGER			HOTEL			PEARL		
Ruby*			SAPPHIRE			Coffee			Penny		
OPAL			Cat*			Scarf			Diamond*		

Participant Screening number: _____

Study Site: _____

Test Phase: Screening

Hospital Anxiety and Depression Scale (HADS)

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings he or she will be able to help you more.

This questionnaire is designed to help your clinician to know how you feel. Read each item below and **underline the reply** which comes closest to how you have been feeling in the past week.

Ignore the numbers printed at the edge of the questionnaire.

Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long, thought-out response.

A	FOLD HERE D			FOLD HERE A	D
		I feel tense or 'wound up'	**I feel as if I am slowed down**		
3		Most of the time	Nearly all the time		3
2		A lot of the time	Very often		2
1		From time to time, occasionally	Sometimes		1
0		Not at all	Not at all		0
			I get a sort of frightened feeling like		
		I still enjoy the things I used to enjoy	**'butterflies' in the stomach**		
	0	Definitely as much	Not at all	0	
	1	Not quite so much	Occasionally	1	
	2	Only a little	Quite often	2	
	3	Hardly at all	Very often	3	
		I get a sort of frightened feeling as if something awful is about to happen	**I have lost interest in my appearance**		
3		Very definitely and quite badly	Definitely		3
2		Yes, but not too badly	I don't take as much care as I should		2
1		A little, but it doesn't worry me	I may not take quite as much care		1
0		Not at all	I take just as much care as ever		0
		I can laugh and see the funny side of things	**I feel restless as if I have to be on the move**		
	0	As much as I always could	Very much indeed	3	
	1	Not quite so much now	Quite a lot	2	
	2	Definitely not so much now	Not very much	1	
	3	Not at all	Not at all	0	
		Worrying thoughts go through my mind	**I look forward with enjoyment to things**		
3		A great deal of the time	As much as I ever did		0
2		A lot of the time	Rather less than I used to		1
1		Not too often	Definitely less than I used to		2
0		Very little	Hardly at all		3
		I feel cheerful	**I get sudden feelings of panic**		
	3	Never	Very often indeed	3	
	2	Not often	Quite often	2	
	1	Sometimes	Not very often	1	
	0	Most of the time	Not at all	0	
			I can enjoy a good book or radio or		
		I can sit at ease and feel relaxed	**television programme**		
0		Definitely	Often		0
1		Usually	Sometimes		1
2		Not often	Not often		2
3		Not at all	Very seldom		3

Now check that you have answered all the questions

A	D

Appendix 5. Standard Demographic Questionnaire

Participant Code number: _____

Study Site: _____

Test Phase: Baseline / 6mo / 12mo / 18 mo

My-AHA Demographic Questionnaire - BASELINE

Demographic Information

Date of birth : DD / MM / YYYY

Age (years): _____

Gender: Male / Female *(circle one)*

Handedness Right / Left *(circle hand you write with)*

Height _____ cm

Weight _____ kg

Marital Status: Single / Married / Defacto / Widowed *(circle one)*

Describe your living situation

- ☐ Alone
- ☐ With a partner/spouse
- ☐ With children/grandchildren

Where do you live?

- ☐ Own home (house / apartment / unit)
- ☐ Residential village (e.g. retirement community)
- ☐ Supported accommodation (e.g. aged care facility)
- ☐ Nursing home

Are you currently living

- ☐ Independently with no support services
- ☐ Semi-independently – receive some support services (e.g. meals on wheels, cleaning support, etc)
- ☐ Fully dependent care (e.g. nursing home with meals and medical care provided)

Prior education history

A. _____ Total number of years at school (primary + high)

B. _____ Total number of years of post-school formal education (e.g. University/College)

C. _____ TOTAL EDUCATION YEARS (A+B)

Have you ever fallen over? Yes / No

If YES describe when and what occurred (e.g. injury) _____

_____

_____

_____

_____

_____

How fearful are you of falling?	0	1	2	3	4	5
	Never	Rarely	A little	Moderately	Often	Always

Are you currently continent? Urinary Yes / No
Bowel Yes / No

What type of events or entertainment have you undertaken in the last 2 months?
(tick all that apply)

- ☐ Movies
- ☐ Plays / drama productions
- ☐ Pub / Club
- ☐ Concert / Recital
- ☐ Special Performances
- ☐ Dancing
- ☐ Visiting Friends
- ☐ Attending a sporting event
- ☐ Meal at a restaurant

How would you spend a typical day
(tick all that apply)

- ☐ Sleep / nothing
- ☐ House work
- ☐ TV
- ☐ Radio
- ☐ Listening to music
- ☐ Walking
- ☐ Gardening
- ☐ Crosswords
- ☐ Pet care
- ☐ Socialising
- ☐ Reading
- ☐ Writing
- ☐ Studying
- ☐ Teaching
- ☐ Volunteering
- ☐ Paid work
- ☐ Strategy games (e.g. chess, bridge, cards)
- ☐ Helping friends/family
- ☐ Artistry (e.g. drawing, painting, sculpture, creative writing, acting, etc.)
- ☐ Prayer / religious activity
- ☐ Playing music
- ☐ Brain training games (on a computer, ipad etc)
- ☐ Learning something new
- ☐ Hobby or past-time
- ☐ Intellectual/professional

How often do you make an outing to see a family member, friend or a group of friends?

- ☐ Never
- ☐ Less than monthly
- ☐ Monthly
- ☐ Fortnightly
- ☐ Weekly
- ☐ Daily

Are you currently diagnosed with a medical condition? Yes / No

IF YES
What diagnoses have you been given?

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

Are you currently diagnosed with a psychological or psychiatric condition? Yes / No

IF YES
What diagnoses have you been given?

1. _____
2. _____
3. _____
4. _____
5. _____

Are you taking any prescription medication? Yes / No

List all medications	*Medication name*	*Dose (mg)*	*How often (e.g twice daily)*
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Are you taking any other supplements or vitamins? Yes / No

If so what? _____

Do you drink alcohol? Yes / No

On average, how much alcohol do you consume?

_____ Standard drinks per DAY

_____ Standard drinks per WEEK

1 standard drink = 10 gm of alcohol = 285ml beer / 100 ml wine or champagne / 30 ml spirits

Do you smoke tobacco? Yes / No

On average, how much do you smoke PER DAY?

_____ cigarettes per DAY

_____ cigars/pipes per DAY

Do you consume recreational (illicit) drugs? Yes / No

What drug / how often

1 _____ Daily / Weekly / Fortnightly / Monthly

2 _____ Daily / Weekly / Fortnightly / Monthly

3 _____ Daily / Weekly / Fortnightly / Monthly

4 _____ Daily / Weekly / Fortnightly / Monthly

5 _____ Daily / Weekly / Fortnightly / Monthly

6 _____ Daily / Weekly / Fortnightly / Monthly

~ Thankyou ~

Appendix 6. Brief demographic questionnaire

Participant Code number: _____

Study Site: _____

Test Phase: Baseline / 6mo / 12mo / 18 mo

My-AHA Demographic Questionnaire – FOLLOW-UP

Demographic Information

TEST PHASE : 6 month / 12 month / 18 month *(circle one)*

Height _____ cm

Weight _____ kg

Marital Status: Single / Married / Defacto / Widowed *(circle one)*

Describe your living situation

- ☐ Alone
- ☐ With a partner/spouse
- ☐ With children/grandchildren

Where do you live?

- ☐ Own home (house / apartment / unit)
- ☐ Residential village (e.g. retirement community)
- ☐ Supported accommodation (e.g. aged care facility)
- ☐ Nursing home

Are you currently living

- ☐ Independently with no support services
- ☐ Semi-independently – receive some support services (e.g. meals on wheels, cleaning support, etc)
- ☐ Fully dependent care (e.g. nursing home with meals and medical care provided)

Have you fallen over since your last assessment? Yes / No

If YES describe when and what occurred (e.g. injury) _____

_____

_____

_____

_____

_____

How fearful are you of falling?	0	1	2	3	4	5
	Never	Rarely	A little	Moderately	Often	Always

Are you currently continent? Urinary Yes / No
Bowel Yes / No

What type of events or entertainment have you undertaken in the last 2 months?
(tick all that apply)

- ☐ Movies
- ☐ Plays / drama productions
- ☐ Pub / Club
- ☐ Concert / Recital
- ☐ Special Performances
- ☐ Dancing
- ☐ Visiting Friends
- ☐ Attending a sporting event
- ☐ Meal at a restaurant

How would you spend a typical day
(tick all that apply)

- ☐ Sleep / nothing
- ☐ House work
- ☐ TV
- ☐ Radio
- ☐ Listening to music
- ☐ Walking
- ☐ Gardening
- ☐ Crosswords
- ☐ Pet care
- ☐ Socialising
- ☐ Reading
- ☐ Writing
- ☐ Studying
- ☐ Teaching
- ☐ Volunteering
- ☐ Paid work
- ☐ Strategy games (e.g. chess, bridge, cards)
- ☐ Helping friends/family
- ☐ Artistry (e.g. drawing, painting, sculpture, creative writing, acting, etc.)
- ☐ Prayer / religious activity
- ☐ Playing music
- ☐ Brain training games (on a computer, ipad etc)
- ☐ Learning something new
- ☐ Hobby or past-time
- ☐ Intellectual/professional

How often do you make an outing to see a family member, friend or a group of friends?

- ☐ Never
- ☐ Less than monthly
- ☐ Monthly
- ☐ Fortnightly
- ☐ Weekly
- ☐ Daily

Are you currently diagnosed with a medical condition? Yes / No

IF YES
What diagnoses have you been given?

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

Are you currently diagnosed with a psychological or psychiatric condition? Yes / No

IF YES
What diagnoses have you been given?

1. _____
2. _____
3. _____
4. _____
5. _____

Are you taking any prescription medication? Yes / No

List all medications	*Medication name*	*Dose (mg)*	*How often (e.g twice daily)*
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Are you taking any other supplements or vitamins? Yes / No

If so what? _____

Do you drink alcohol? Yes / No

On average, how much alcohol do you consume?

_____ Standard drinks per DAY

_____ Standard drinks per WEEK

1 standard drink = 10 gm of alcohol = 285ml beer / 100 ml wine or champagne / 30 ml spirits

Do you smoke tobacco? Yes / No

On average, how much do you smoke PER DAY?

_____ cigarettes per DAY

_____ cigars/pipes per DAY

Do you consume recreational (illicit) drugs? Yes / No

What drug / how often

1 _____ Daily / Weekly / Fortnightly / Monthly

2 _____ Daily / Weekly / Fortnightly / Monthly

3 _____ Daily / Weekly / Fortnightly / Monthly

4 _____ Daily / Weekly / Fortnightly / Monthly

5 _____ Daily / Weekly / Fortnightly / Monthly

6 _____ Daily / Weekly / Fortnightly / Monthly

~ Thankyou ~

Appendix 7. WHOQoL-OLD

WHOQOL-OLD

PARTICIPANT ID: _____

STUDY SITE: _____

TEST PHASE: Baseline / 6 month / 12 month / 18 month *(circle one)*

Instructions

This questionnaire asks for your thoughts and feelings about certain aspects of your quality of life and addresses issues that may be important to you as an older member of society.

Please answer all the questions. If you are unsure about which response to give to a question, please choose the one that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life in the last two weeks.

For example, thinking about the last two weeks, a question might ask:

How much do you worry about what the future might hold?

Not at all	A little	A moderate amount	Very much	An extreme amount

You should circle the number that best fits how much you have worried about the future over the last two weeks. So you would circle the number 4 if you worried about your future "Very much", or circle number 1 if you have worried "Not at all" about your future. Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

Thank you for your help

The following questions ask about **how much** you have experienced certain things in the last two weeks, for example, freedom of choice and feelings of control in your life. If you have experienced these things an extreme amount circle the number next to "An extreme amount". If you have not experienced these things at all, circle the number next to "Not at all". You should circle one of the numbers in between if you wish to indicate your answer lies somewhere between "Not at all" and "Extremely". Questions refer to the last two weeks.

1. **To what extent do impairments to your senses (e.g. hearing, vision, taste, smell, touch) affect your daily life?**

Not at all	A little	A moderate amount	Very much	An extreme amount

2. **To what extent does loss of for example, hearing, vision, taste, smell or touch affect your ability to participate in activities?**

Not at all	A little	A moderate amount	Very much	An extreme amount

3. **How much freedom do you have to make your own decisions?**

Not at all	A little	A moderate amount	Very much	An extreme amount

4. **To what extent do you feel in control of your future?**

Not at all	Slightly	Moderately	Very	Extremely
1				

5. **How much do you feel that the people around you are respectful of your freedom?**

Not at all	Slightly	Moderately	Very	Extremely
1				

6. How concerned are you about the way in which you will die?

Not at all	Slightly	Moderately	Very	Extremely
1	-	-	.	-

7. How much are you afraid of not being able to control your death?

Not at all	Slightly	Moderately	Very	Extremely
1	-	-	.	-

8. How scared are you of dying?

Not at all	Slightly	Moderately	Very	Extremely
1	-	-	.	-

9. How much do you fear being in pain before you die?

Not at all	Slightly	Moderately	Very	Extremely
1	-	-	.	-

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks, for example getting out as much as you would like to. If you have been able to do these things completely, circle the number next to "Completely". If you have not been able to do these things at all, circle the number next to "Not at all". You should circle one of the numbers in between if you wish to indicate your answer lies somewhere between "Not at all" and "Completely". Questions refer to the last two weeks.

10. To what extent do problems with your sensory functioning (e.g. hearing, vision, taste, smell, touch) affect your ability to interact with others?

Not at all	A little	Moderately	Mostly	Completely

11. To what extent are you able to do the things you'd like to do?

Not at all	A little	Moderately	Mostly	Completely

12. To what extent are you satisfied with your opportunities to continue achieving in life?

Not at all	A little	Moderately	Mostly	Completely

13. How much do you feel that you have received the recognition you deserve in life?

Not at all	A little	Moderately	Mostly	Completely

14. To what extent do you feel that you have enough to do each day?

Not at all	A little	Moderately	Mostly	Completely

The following questions ask you to say how **satisfied, happy or good** you have felt about various aspects of your life over the last two weeks . For example, about your participation in community life or your achievements in life. Decide how satisfied or dissatisfied you are with each aspect of your life and circle the number that best fits how you feel about this. Questions refer to the last two weeks.

15. How satisfied are you with what you have achieved in life?

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied

16. How satisfied are you with the way you use your time?

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied

17. How satisfied are you with your level of activity?

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied

18. How satisfied are you with your opportunity to participate in community activities?

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied

19. How happy are you with the things you are able to look forward to?

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied

20. How would you rate your sensory functioning (e.g. hearing, vision, taste, smell, touch)?

Very poor	Poor	Neither poor nor good	Good	Very good

The following questions refer to any **intimate relationships** that you may have. Please consider these questions with reference to a close partner or other close person with whom you can share intimacy more than with any other person in your life.

21. To what extent do you feel a sense of companionship in your life?

Not at all	A little	A moderate amount	Very much	An extreme amount

22. To what extent do you experience love in your life?

Not at all	A little	A moderate amount	Very much	An extreme amount

23. To what extent do you have opportunities to love?

Not at all	A little	Moderately	Mostly	Completely

24. To what extent do you have opportunities to be loved?

Not at all	A little	Moderately	Mostly	Completely

Do you have any comments about the questionnaire?

THANK YOU FOR YOUR HELP

Appendix 8. Lawton-Brody IADL Scale

LAWTON-BRODY

INSTRUMENTAL ACTIVITIES OF DAILY LIVING SCALE (I.A.D.L.)

PARTICIPANT CODE: _____

STUDY SITE: _____

TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo *(circle one)*

Scoring: For each category, circle the item description that most closely resembles the client's highest functional level (either 0 or 1).

A. Ability to Use Telephone	**E. Laundry**
1. Operates telephone on own initiative-looks up and dials numbers, etc. 1	1. Does personal laundry completely 1
2. Dials a few well-known numbers 1	2. Launders small items-rinses stockings, etc. 1
3. Answers telephone but does not dial 1	3. All laundry must be done by others 0
4. Does not use telephone at all 0	
B. Shopping	**F. Mode of Transportation**
1. Takes care of all shopping needs independently 1	1. Travels independently on public transportation or drives own car 1
2. Shops independently for small purchases 0	2. Arranges own travel via taxi, but does not otherwise use public transportation 1
3. Needs to be accompanied on any shopping trip 0	3. Travels on public transportation when accompanied by another 1
4. Completely unable to shop 0	4. Travel limited to taxi or automobile with assistance of another 0
	5. Does not travel at all 0
C. Food Preparation	**G. Responsibility for Own Medications**
1. Plans, prepares and serves adequate meals independently 1	1. Is responsible for taking medication in correct dosages at correct time 1
2. Prepares adequate meals if supplied with ingredients 0	2. Takes responsibility if medication is prepared in advance in separate dosage 0
3. Heats, serves and prepares meals, or prepares meals, or prepares meals but does not maintain adequate diet 0	3. Is not capable of dispensing own medication 0
4. Needs to have meals prepared and served 0	
D. Housekeeping	**H. Ability to Handle Finances**
1. Maintains house alone or with occasional assistance (e.g. "heavy work domestic help") 1	1. Manages financial matters independently (budgets, writes checks, pays rent, bills, goes to bank), collects and keeps track of income 1
2. Performs light daily tasks such as dish washing, bed making 1	2. Manages day-to-day purchases, but needs help with banking, major purchases, etc. 1
3. Performs light daily tasks but cannot maintain acceptable level of cleanliness 1	3. Incapable of handling money 0
4. Needs help with all home maintenance tasks 1	
5. Does not participate in any housekeeping tasks 0	
Score	**Score**
	Total score

A summary score ranges from 0 (low function, dependent) to 8 (high function, independent) for women and 0 through 5 for men to avoid potential gender bias.

Appendix 9. CES-D 2 item questionnaire

Participant Code number: _____

Study Site: _____

Test Phase: Baseline / 6mo / 12mo / 18 mo

CES-D

Statement	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. How often in the past week have you felt that everything you did was an effort?	1	2	3	4
2. How often in the past week have you felt that you could not get going?	1	2	3	4

Total Score _____

Appendix 10. Short Physical Performance Battery (SPPB)

Short Physical Performance Battery Protocol and Score Sheet

Participant Name: _____ Date: _____

All of the tests should be performed in the same order as they are presented in this protocol. Instructions to the participants are shown in bold italic and should be given exactly as they are written in this script.

1. BALANCE TESTS

The participant must be able to stand unassisted without the use of a cane or walker. You may help the participant to get up.

Now let's begin the evaluation. I would now like you to try to move your body in different movements. I will first describe and show each movement to you. Then I'd like you to try to do it. If you do it, tell me and we'll move on to the next one. Let me emphasize that I do not want you to try to do any exercise that you feel might be unsafe.

Do you have any questions before we begin?

A. Side-by-Side Stand

1. ***Now I will show you the first movement.***
2. (Demonstrate) ***I want you to try to stand with your feet together, side-by-side, for about 10 seconds.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the side-by-side position.
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say, ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.
9. If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

B. Semi-Tandem Stand

1. ***Now I will show you the second movement.***
2. (Demonstrate) ***Now I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the semi-tandem position
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.
9. If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

C. Tandem Stand

1. ***Now I will show you the third movement.***
2. (Demonstrate) ***Now I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the tandem position.
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say, ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.

SCORING:

A. Side-by-Side stand

Held for 10 sec	❒1 point
Not held for 10 sec	❒0 points
Not attempted	❒0 points

If 0 points, end Balance Tests

Number of seconds held if less than 10 sec:

____.___ Sec

If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not hold position unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (specify)	6
Participant refused	7

B. Semi-Tandem Stand

Held for 10 sec	❒1 point
Not held for 10 sec	❒0 points
Not attempted	❒0 points

(circle reason to the right)

If 0 points, end Balance Tests

Number of seconds held if less than 10 sec:

____.___ Sec

If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not hold position unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (specify)	6
Participant refused	7

C. Tandem Stand

Held for 10 sec	❒2 point
Held for 3 to 9.99 sec	❒1 points
Held for < than 3 sec	❒0 points
Not attempted	❒0 points

(circle reason above)

Number of seconds held if less than 10 sec:

____.___Sec

If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not hold position unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (specify)	6
Participant refused	7

D. Total Balance Tests score _____ (sum points)

Comments:_____

_____

_____

_____

2. GAIT SPEED TEST

Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it.

A. First Gait Speed Test

1. ***This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.***
2. Demonstrate the walk for the participant.
3. ***Walk all the way past the other end of the tape before you stop. I will walk with you. Do you feel this would be safe?***
4. Have the participant stand with both feet touching the starting line.
5. ***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***
6. Press the start/stop button to start the stopwatch as the participant begins walking.
7. Walk behind and to the side of the participant.
8. Stop timing when one of the participant's feet is completely across the end line.

B. Second Gait Speed Test

1. ***Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course.***
2. Have the participant stand with both feet touching the starting line.
3. ***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: "Ready, begin."
4. Press the start/stop button to start the stopwatch as the participant begins walking.
5. Walk behind and to the side of the participant.
6. Stop timing when one of the participant's feet is completely across the end line.

GAIT SPEED TEST SCORING:

Length of walk test course: Four meters ❒ Three meters ❒

A. Time for First Gait Speed Test (sec)

1. Time for 3 or 4 meters ____.___ sec
2. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not walk unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify) _____	6
Participant refused	7

Complete score sheet and go to chair stand test

3. Aids for first walk..... None ❒ Cane ❒ Other ❒

Comments:_____

_____

_____

B. Time for Second Gait Speed Test (sec)

1. Time for 3 or 4 meters ____.___ sec
2. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not walk unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify)	6
Participant refused	7

3. Aids for second walk..... None ❒ Cane ❒ Other ❒

What is the time for the faster of the two walks?

Record the shorter of the two times ____.___ sec

[If only 1 walk done, record that time] ____.___ sec

If the participant was unable to do the walk: ❒ 0 points

For 4-Meter Walk:		For 3-Meter Walk:	
If time is more than 8.70 sec:	❒1 point	If time is more than 6.52 sec:	❒1 point
If time is 6.21 to 8.70 sec:	❒2 points	If time is 4.66 to 6.52 sec:	❒2 points
If time is 4.82 to 6.20 sec:	❒3 points	If time is 3.62 to 4.65 sec:	❒3 points
If time is less than 4.82 sec:	❒4 points	If time is less than 3.62 sec:	❒4 points

3. CHAIR STAND TEST

Single Chair Stand

1. ***Let's do the last movement test. Do you think it would be safe for you to try to stand up from a chair without using your arms?***
2. ***The next test measures the strength in your legs.***
3. (Demonstrate and explain the procedure.) ***First, fold your arms across your chest and sit so that your feet are on the floor; then stand up keeping your arms folded across your chest.***
4. Please stand up keeping your arms folded across your chest. (Record result).
5. If participant cannot rise without using arms, say "Okay, try to stand up using your arms." This is the end of their test. Record result and go to the scoring page.

Repeated Chair Stands

1. ***Do you think it would be safe for you to try to stand up from a chair five times without using your arms?***
2. (Demonstrate and explain the procedure): ***Please stand up straight as QUICKLY as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. I'll be timing you with a stopwatch.***
3. When the participant is properly seated, say: ***"Ready? Stand"*** and begin timing.
4. Count out loud as the participant arises each time, up to five times.
5. Stop if participant becomes tired or short of breath during repeated chair stands.
6. Stop the stopwatch when he/she has straightened up completely for the fifth time.
7. Also stop:
    - If participant uses his/her arms
    - After 1 minute, if participant has not completed rises
    - At your discretion, if concerned for participant's safety
8. If the participant stops and appears to be fatigued before completing the five stands, confirm this by asking ***"Can you continue?"***
9. If participant says "Yes," continue timing. If participant says "No," stop and reset the stopwatch.

SCORING

Single Chair Stand Test

	Yes	No	
A. Safe to stand without help	❒	❒	
B. Results:			
Participant stood without using arms	❒		→ Go to Repeated Chair Stand Test
Participant used arms to stand	❒		→ End test; score as 0 points
Test not completed	❒		→ End test; score as 0 points
C. If participant did not attempt test or failed, circle why:			
Tried but unable	1		
Participant could not stand unassisted	2		
Not attempted, you felt unsafe	3		
Not attempted, participant felt unsafe	4		
Participant unable to understand instructions	5		
Other (Specify)	6		
Participant refused	7		

Repeated Chair Stand Test

	Yes	No
A. Safe to stand five times	❒	❒
B. If five stands done successfully, record time in seconds. Time to complete five stands ____.___ sec		
C. If participant did not attempt test or failed, circle why:		
Tried but unable	1	
Participant could not stand unassisted	2	
Not attempted, you felt unsafe	3	
Not attempted, participant felt unsafe	4	
Participant unable to understand instructions	5	
Other (Specify)	6	
Participant refused	7	

Scoring the Repeated Chair Test

Participant unable to complete 5 chair stands or completes stands in >60 sec:	❒0 points
If chair stand time is 16.70 sec or more:	❒1 points
If chair stand time is 13.70 to 16.69 sec or more:	❒2 points
If chair stand time is 11.20 to 13.69 sec:	❒3 points
If chair stand time is 11.19 sec or less:	❒4 points

Participant ID: _____ Date: _____ Tester Initials: _____

Scoring for Complete Short Physical Performance Battery

Test Scores

Total Balance Test score _____ points

Gait Speed Test score _____ points

Chair Stand Test score _____ points

Total Score _____ **points** (sum of points above)

Appendix 11. IPAQ – Short Form

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (August 2002)

SHORT LAST 7 DAYS SELF-ADMINISTERED FORMAT

FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS (15-69 years)

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health–related physical activity.

Background on IPAQ

The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken across 12 countries (14 sites) during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages, and are suitable for national population-based prevalence studies of participation in physical activity.

Using IPAQ

Use of the IPAQ instruments for monitoring and research purposes is encouraged. It is recommended that no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments.

Translation from English and Cultural Adaptation

Translation from English is supported to facilitate worldwide use of IPAQ. Information on the availability of IPAQ in different languages can be obtained at www.ipaq.ki.se. If a new translation is undertaken we highly recommend using the prescribed back translation methods available on the IPAQ website. If possible please consider making your translated version of IPAQ available to others by contributing it to the IPAQ website. Further details on translation and cultural adaptation can be downloaded from the website.

Further Developments of IPAQ

International collaboration on IPAQ is on-going and an ***International Physical Activity Prevalence Study*** is in progress. For further information see the IPAQ website.

More Information

More detailed information on the IPAQ process and the research methods used in the development of IPAQ instruments is available at www.ipaq.ki.se and Booth, M.L. (2000). *Assessment of Physical Activity: An International Perspective.* Research Quarterly for Exercise and Sport, 71 (2): s114-20. Other scientific publications and presentations on the use of IPAQ are summarized on the website.

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

   _____ **days per week**

   ☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

   _____ **hours per day**

   _____ **minutes per day**

   ☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

   _____ **days per week**

   ☐ No moderate physical activities → ***Skip to question 5***

SHORT LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised August 2002.

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

SHORT LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised August 2002.

Appendix 12. Activities specific Balance Confidence (ABC) Scale

The Activities-specific Balance Confidence (ABC) Scale*

Instructions to Participants:
For each of the following, please indicate your level of confidence in doing the activity without losing your balance or becoming unsteady from choosing one of the percentage points on the scale form 0% to 100%. If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as it you were using these supports. If you have any questions about answering any of these items, please ask the administrator.

The Activities-specific Balance Confidence (ABC) Scale*

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale:

0% 10 20 30 40 50 60 70 80 90 100%
no confidence completely confident

"How confident are you that you will not lose your balance or become unsteady when you…

1. …walk around the house? ____%
2. …walk up or down stairs? ____%
3. …bend over and pick up a slipper from the front of a closet floor ____%
4. …reach for a small can off a shelf at eye level? ____%
5. …stand on your tiptoes and reach for something above your head? ____%
6. …stand on a chair and reach for something? ____%
7. …sweep the floor? ____%
8. …walk outside the house to a car parked in the driveway? ____%
9. …get into or out of a car? ____%
10. …walk across a parking lot to the mall? ____%
11. …walk up or down a ramp? ____%
12. …walk in a crowded mall where people rapidly walk past you? ____%
13. …are bumped into by people as you walk through the mall? ____%
14. … step onto or off an escalator while you are holding onto a railing? ____%
15. … step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? ____%
16. …walk outside on icy sidewalks? ____%

*Powell, LE & Myers AM. The Activities-specific Balance Confidence (ABC) Scale. *J Gerontol Med Sci* 1995; 50(1): M28-34

Appendix 13. Physical Activity Enjoyment Scale (PACES)

PHYSICAL ACTIVITY ENJOYMENT SCALE (PACES)

From Kendzierski & DeCarlo (1991)

Participant Code number: _____

Study Site: _____

Test Phase: Baseline / 6mo / 12mo / 18 mo

Please rate how you feel *at the moment* about the physical activity you have been doing

Circle one number for each item

*1**	I enjoy it	1	2	3	4	5	6	7	I hate it
2	I feel bored	1	2	3	4	5	6	7	I feel interested
3	I dislike it	1	2	3	4	5	6	7	I like it
*4**	I find it pleasurable	1	2	3	4	5	6	7	I find it unpleasurable
*5**	I am very absorbed in this activity	1	2	3	4	5	6	7	I am not at all absorbed in this activity
6	It's no fun at all	1	2	3	4	5	6	7	It's a lot of fun
*7**	I find it energizing	1	2	3	4	5	6	7	I find it tiring
8	It makes me depressed	1	2	3	4	5	6	7	It makes me happy
*9**	It's very pleasant	1	2	3	4	5	6	7	It's very unpleasant
*10**	I feel good physically while doing it	1	2	3	4	5	6	7	I feel bad physically while doing it

1

PHYSICAL ACTIVITY ENJOYMENT SCALE (PACES)

From Kendzierski & DeCarlo (1991)

My-AHA

*11**	It's very invigorating	1	2	3	4	5	6	7	It's not at all invigorating
12	I feel very frustrated by it	1	2	3	4	5	6	7	I am not at all frustrated by it
*13**	It's very gratifying	1	2	3	4	5	6	7	It's not at all gratifying
*14**	It's very exhilarating	1	2	3	4	5	6	7	It's not at all exhilarating
15	It's not at all stimulating	1	2	3	4	5	6	7	It's very stimulating
*16**	It gives me a strong sense of accomplishment	1	2	3	4	5	6	7	It does not give me any sense of accomplishment at all
*17**	It's very refreshing	1	2	3	4	5	6	7	It's not at all refreshing
18	I felt as though I would rather be doing something else	1	2	3	4	5	6	7	I felt as though there was nothing else I would rather be doing.
	TOTAL SCORE								

* reverse scored items

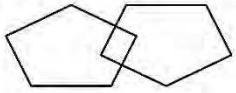
2

Appendix 14. Mini Mental State Examination (MMSE)

Mini-Mental State Examination (MMSE)

Patient's Name: _____ Date: _____

***Instructions:* Ask the questions in the order listed. Score one point for each correct response within each question or activity.**

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day of the week? Month?"
5		"Where are we now: State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: _____
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, ...) Stop after five answers. Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 
30		TOTAL

(Adapted from Rovner & Folstein, 1987)

1

Source: www.medicine.uiowa.edu/igec/tools/cognitive/MMSE.pdf

Provided by NHCQF, 0106-410

Instructions for administration and scoring of the MMSE

Orientation (10 points):

- Ask for the date. Then specifically ask for parts omitted (e.g., "Can you also tell me what season it is?"). One point for each correct answer.
- Ask in turn, "Can you tell me the name of this hospital (town, county, etc.)?" One point for each correct answer.

Registration (3 points):

- Say the names of three unrelated objects clearly and slowly, allowing approximately one second for each. After you have said all three, ask the patient to repeat them. The number of objects the patient names correctly upon the first repetition determines the score (0-3). If the patient does not repeat all three objects the first time, continue saying the names until the patient is able to repeat all three items, up to six trials. Record the number of trials it takes for the patient to learn the words. If the patient does not eventually learn all three, recall cannot be meaningfully tested.
- After completing this task, tell the patient, "Try to remember the words, as I will ask for them in a little while."

Attention and Calculation (5 points):

- Ask the patient to begin with 100 and count backward by sevens. Stop after five subtractions (93, 86, 79, 72, 65). Score the total number of correct answers.
- If the patient cannot or will not perform the subtraction task, ask the patient to spell the word "world" backwards. The score is the number of letters in correct order (e.g., dlrow=5, dlorw=3).

Recall (3 points):

- Ask the patient if he or she can recall the three words you previously asked him or her to remember. Score the total number of correct answers (0-3).

Language and Praxis (9 points):

- Naming: Show the patient a wrist watch and ask the patient what it is. Repeat with a pencil. Score one point for each correct naming (0-2).
- Repetition: Ask the patient to repeat the sentence after you ("No ifs, ands, or buts."). Allow only one trial. Score 0 or 1.
- 3-Stage Command: Give the patient a piece of blank paper and say, "Take this paper in your right hand, fold it in half, and put it on the floor." Score one point for each part of the command correctly executed.
- Reading: On a blank piece of paper print the sentence, "Close your eyes," in letters large enough for the patient to see clearly. Ask the patient to read the sentence and do what it says. Score one point only if the patient actually closes his or her eyes. This is not a test of memory, so you may prompt the patient to "do what it says" after the patient reads the sentence.
- Writing: Give the patient a blank piece of paper and ask him or her to write a sentence for you. Do not dictate a sentence; it should be written spontaneously. The sentence must contain a subject and a verb and make sense. Correct grammar and punctuation are not necessary.
- Copying: Show the patient the picture of two intersecting pentagons and ask the patient to copy the figure exactly as it is. All ten angles must be present and two must intersect to score one point. Ignore tremor and rotation.

(Folstein, Folstein & McHugh, 1975)

Interpretation of the MMSE

Method	Score	Interpretation
Single Cutoff	<24	Abnormal
Range	<21	Increased odds of dementia
	>25	Decreased odds of dementia
Education	21	Abnormal for 8th grade education
	<23	Abnormal for high school education
	<24	Abnormal for college education
Severity	24-30	No cognitive impairment
	18-23	Mild cognitive impairment
	0-17	Severe cognitive impairment

Sources:

- Crum RM, Anthony JC, Bassett SS, Folstein MF. Population-based norms for the mini-mental state examination by age and educational level. *JAMA*. 1993;269(18):2386-2391.
- Folstein MF, Folstein SE, McHugh PR. "Mini-mental state": a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res*. 1975;12:189-198.
- Rovner BW, Folstein MF. Mini-mental state exam in clinical practice. *Hosp Pract*. 1987;22(1A):99, 103, 106, 110.
- Tombaugh TN, McIntyre NJ. The mini-mental state examination: a comprehensive review. *J Am Geriatr Soc*. 1992;40(9):922-935.

Appendix 15. Hopkins Verbal Learning Test (HVLT)

HOPKINS VERBAL LEARNING TEST
LIST 1 (HVLT-1)

My-AHA

PARTICIPANT CODE: _____
STUDY SITE: _____
TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo *(circle one)*

Instructions: Read the list of 12 words in Part A (at a rate of 1 word every 2 seconds), then have the participant repeat as many of the words as s/he can recall. Do this for 3 trials. Do not warn the participant that they will be asked to remember these words later on.

After 20-25 minutes delay continue to Part B (participant undertakes remainder of assessment for this visit). Complete the **Delayed Recall** trial by asking the participant to recall the words you read to them at the beginning of the test. Then complete the **Recognition** trial by saying each word to the participant and asking the participant to respond with "Yes" if the word was on the list or "no" if it was not.

Part A	Trial 1	Trial 2	Trial 3	Part B	Delayed Recall
LION					
EMERALD					
HORSE					
TENT					
SAPPHIRE					
HOTEL					
CAVE					
OPAL					
TIGER					
PEARL					
COW					
HUT					
TOTAL CORRECT					

Part B – RECOGNITION TRIAL

	Y	N		Y	N		Y	N		Y	N
HORSE			EMERALD			Balloon			Apartment*		
House*			mountain			Boat			COW		
HUT			CAVE			Dog*			LION		
TENT			TIGER			HOTEL			PEARL		
Ruby*			SAPPHIRE			Coffee			Penny		
OPAL			Cat*			Scarf			Diamond*		

HOPKINS VERBAL LEARNING TEST
LIST 2 (HVLT-2)

PARTICIPANT CODE: _____
STUDY SITE: _____
TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo *(circle one)*

Instructions: Read the list of 12 words in Part A (at a rate of 1 word every 2 seconds), then have the participant repeat as many of the words as s/he can recall. Do this for 3 trials. Do not warn the participant that they will be asked to remember these words later on.

After 20-25 minutes delay continue to Part B (participant undertakes remainder of assessment for this visit). Complete the **Delayed Recall** trial by asking the participant to recall the words you read to them at the beginning of the test. Then complete the **Recognition** trial by saying each word to the participant and asking the participant to respond with "Yes" if the word was on the list or "no" if it was not.

Part A	Trial 1	Trial 2	Trial 3	Part B	Delayed Recall
FORK					
RUM					
PAN					
PISTOL					
SWORD					
SPATULA					
BOURBON					
VODKA					
POT					
BOMB					
RIFLE					
WINE					
TOTAL CORRECT					

Part B – RECOGNITION TRIAL

	Y	N		Y	N		Y	N		Y	N
Spoon*			RUM			Whiskey*			PAN		
Harmonica			Lemon			Pencil			Beer*		
Knife*			Doll			BOMB			POT		
WINE			SWORD			BOURBON			VODKA		
PISTOL			Trout			FORK			Gold		
Can opener*			SPATULA			Gun*			RIFLE		

HOPKINS VERBAL LEARNING TEST
LIST 3 (HVLT-3)

PARTICIPANT CODE: _____
STUDY SITE: _____
TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo *(circle one)*

Instructions: Read the list of 12 words in Part A (at a rate of 1 word every 2 seconds), then have the participant repeat as many of the words as s/he can recall. Do this for 3 trials. Do not warn the participant that they will be asked to remember these words later on.

After 20-25 minutes delay continue to Part B (participant undertakes remainder of assessment for this visit). Complete the **Delayed Recall** trial by asking the participant to recall the words you read to them at the beginning of the test. Then complete the **Recognition** trial by saying each word to the participant and asking the participant to respond with "Yes" if the word was on the list or "no" if it was not.

Part A	Trial 1	Trial 2	Trial 3	Part B	Delayed Recall
SUGAR					
TRUMPET					
VIOLIN					
COAL					
GARLIC					
KEROSENE					
VANILLA					
WOOD					
CLARINET					
FLUTE					
CINNAMON					
GASOLINE					
TOTAL CORRECT					

Part B – RECOGNITION TRIAL

	Y	N		Y	N		Y	N		Y	N
Pepper*			Basement			Drum*			Electricity*		
Bell			VANILLA			Chair			Piano*		
TRUMPET			WOOD			FLUTE			SUGAR		
KEROSENE			Priest			Sand			CLARINET		
GARLIC			CINNAMON			Oil*			Moon		
Salt*			GASOLINE			COAL			VIOLIN		

Appendix 16. WMS-III Spatial Span (SSP) test

PARTICIPANT CODE: _____

STUDY SITE: _____

TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo *(circle one)*

My-AHA

Spatial Span (WMS-III)

DISCONTINUE RULE	SCORING RULE
Spatial Span Forward & Backward Score 0 on both trials of any item. For both Spatial Span Forward & Backward, administer both trials of each item even if Trial 1 is passed.	Each Trial: 0 or 1 pt for each response. Item score = Trial 1 + Trial 2

Spatial Span Forward			Trial Score (0 or 1)	Item Score (0, 1, or 2)	Spatial Span Backward			Trial Score (0 or 1)	Item Score (0, 1, or 2)
Trial		Item/Response			Trial		Item/Response		
1	1	3 - 10			1	1	7 - 4		
	2	7 - 4				2	3 - 10		
2	1	1 - 9 - 3			2	1	8 - 2 - 7		
	2	8 - 2 - 7				2	1 - 9 - 3		
3	1	4 - 9 - 1 - 6			3	1	10 - 6 - 2 - 7		
	2	10 - 6 - 2 - 7				2	4 - 9 - 1 - 6		
4	1	6 - 5 - 1 - 4 - 8			4	1	5 - 7 - 9 - 8 - 2		
	2	5 - 7 - 9 - 8 - 2				2	6 - 5 - 1 - 4 - 8		
5	1	4 - 1 - 9 - 3 - 8 - 10			5	1	9 - 2 - 6 - 7 - 3 - 5		
	2	9 - 2 - 6 - 7 - 3 - 5				2	4 - 1 - 9 - 3 - 8 - 10		
6	1	10 - 1 - 6 - 4 - 8 - 5 - 7			6	1	2 - 6 - 3 - 8 - 2 - 10 - 1		
	2	2 - 6 - 3 - 8 - 2 - 10 - 1				2	10 - 1 - 6 - 4 - 8 - 5 - 7		
7	1	7 - 3 - 10 - 5 - 7 - 8 - 4 - 9			7	1	6 - 9 - 3 - 2 - 1 - 7 - 10 - 5		
	2	6 - 9 - 3 - 2 - 1 - 7 - 10 - 5				2	7 - 3 - 10 - 5 - 7 - 8 - 4 - 9		
8	1	5 - 8 - 4 - 10 - 7 - 3 - 1 - 9 - 6			8	1			
	2	8 - 2 - 6 - 1 - 10 - 3 - 7 - 4 - 9				2			
Spatial Span Forward Total Score (Range =0 to 16)					**Spatial Span Backward Total Score (Range =0 to 16**				

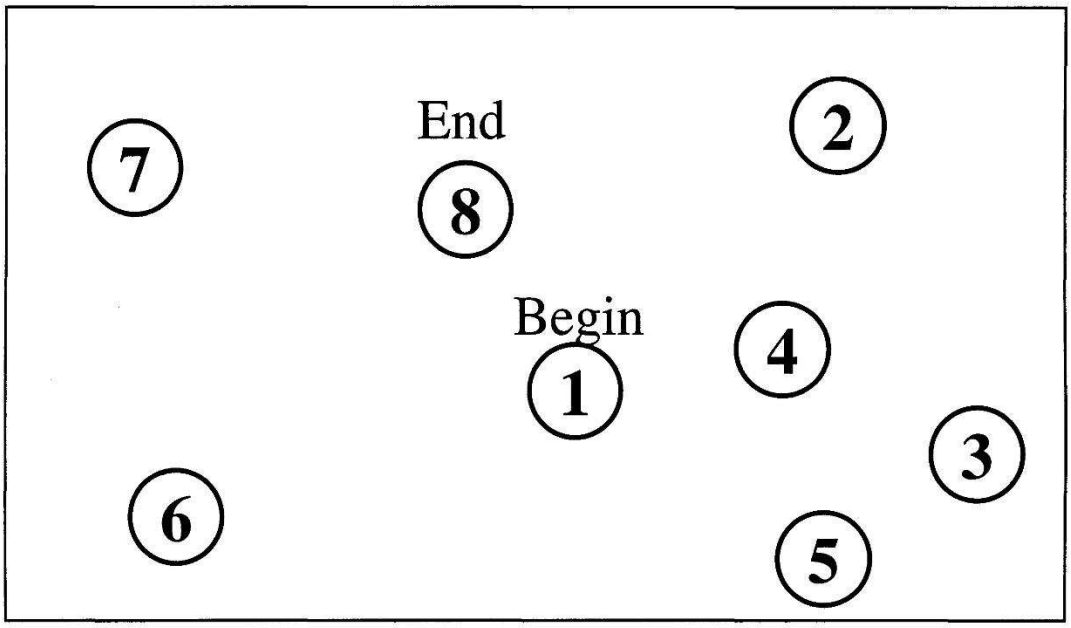
Spatial Span Total Score (Range =0 to 32)	

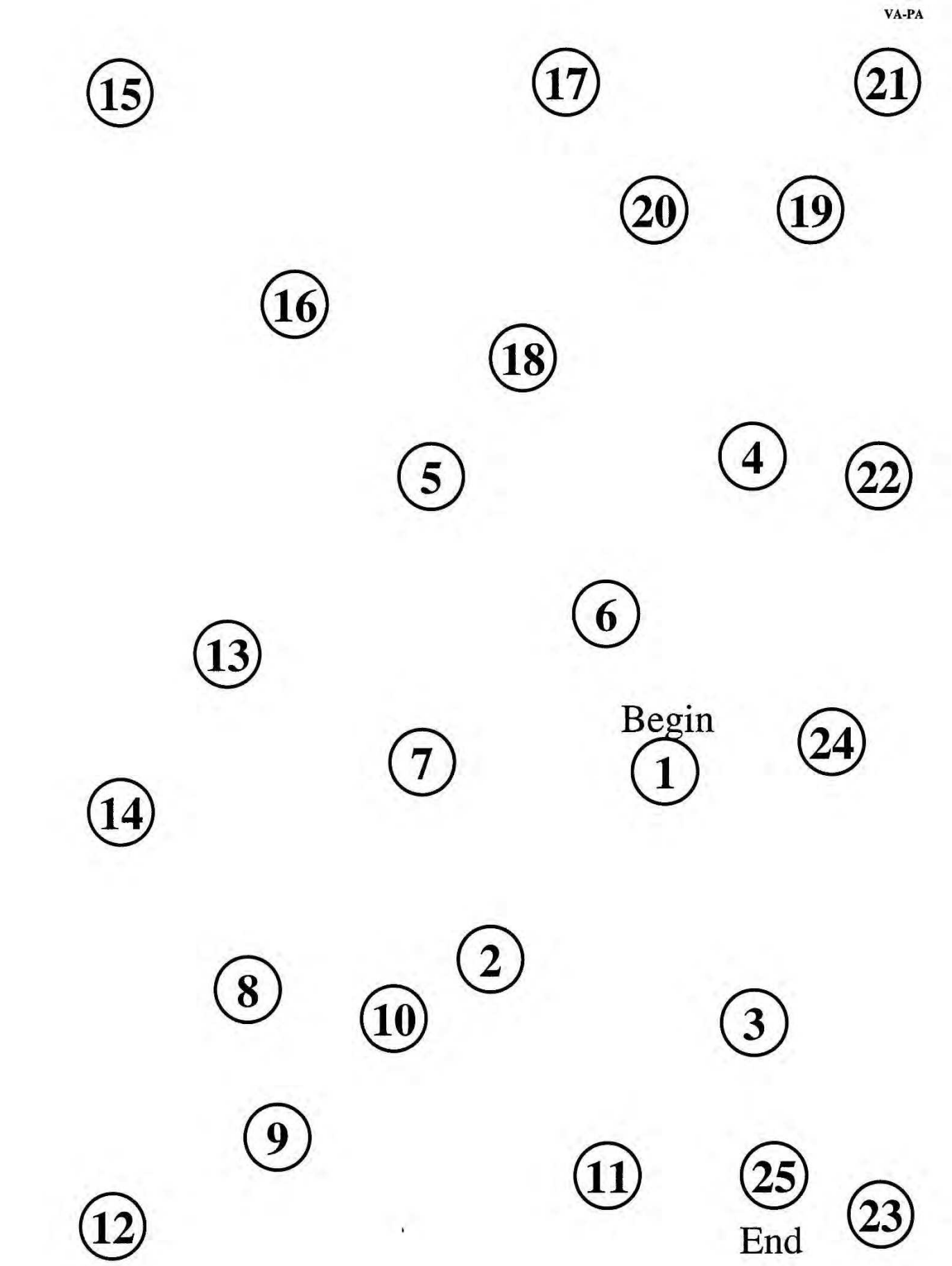
Appendix 17. Trail Making Test (TMT)

PARTICIPANT CODE: _____
STUDY SITE: _____
TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo (circle one)

Total Time (seconds) _____ Errors _____

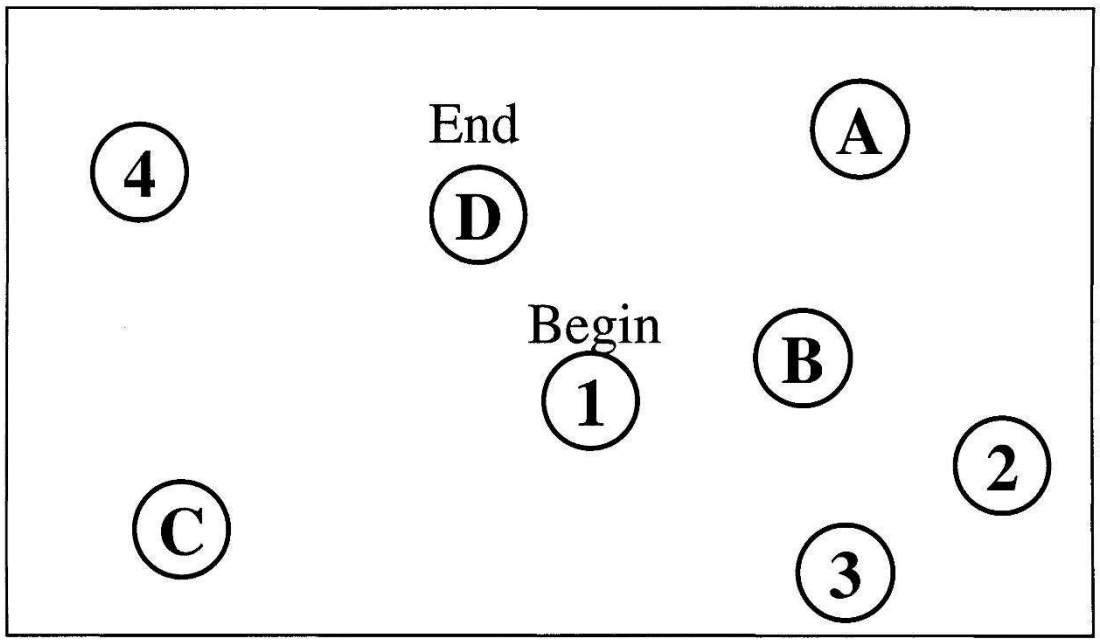
Trail Making Test
Part A

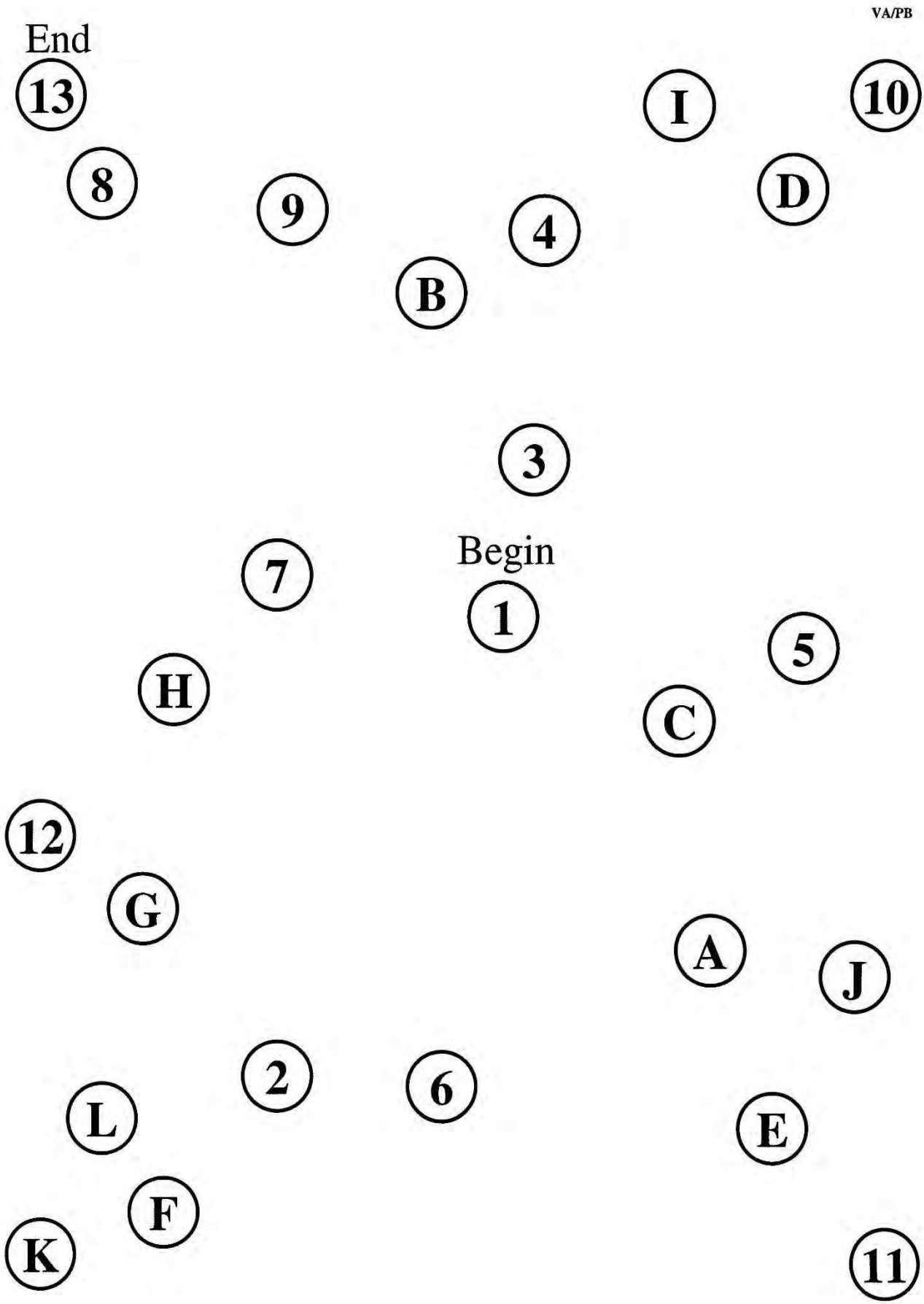



VA-PA
15
17
21
20
19
16
18
4
5
22
6
13
Begin
24
7
1
14
2
8
10
3
9
11
25
23
12
End

PARTICIPANT CODE: _____
STUDY SITE: _____
TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo (circle one) Total Time (seconds) _____ Errors _____

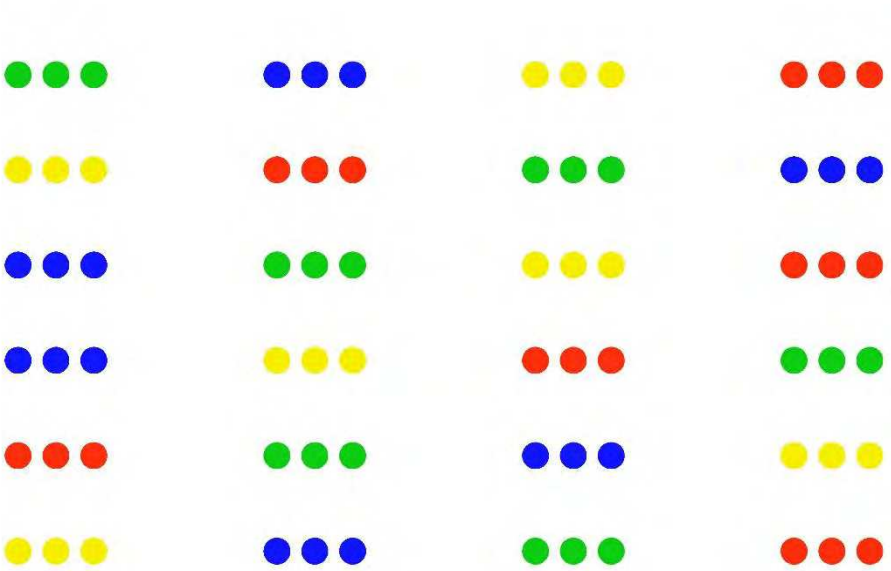
Trail Making Test
Part B




VA/PB
End
13
I
10
8
D
9
4
B
3
Begin
7
1
5
H
C
12
G
A
J
2
6
L
E
F
K
11

Appendix 18. 24-item Victoria Version Stroop Test

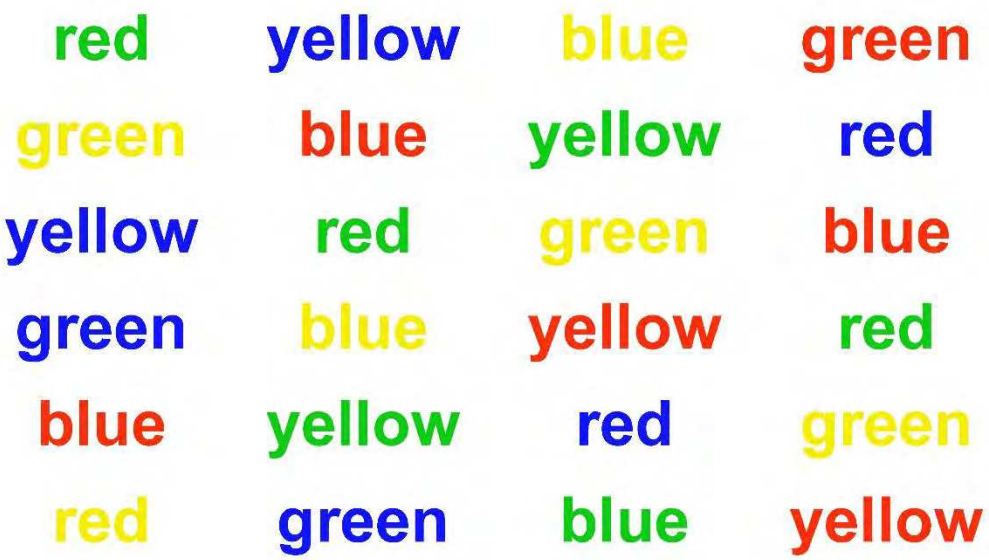
Colour



Colour - Word


when and hard over
hard over when and
and when hard over
and hard over when
over when and hard
hard and when over

Colour – Word Incongruent



STROOP COLOUR WORD TEST – 24-ITEM VICTORIA VERSION

My-AHA

PARTICIPANT CODE: _____

STUDY SITE: _____

TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo *(circle one)*

A. Colours of Dots

G	B	Y	R
Y	R	G	B
B	G	Y	R
B	Y	R	G
R	G	B	Y
Y	B	G	R

B. Colours of nonsense words

G	B	Y	R
Y	R	G	B
B	G	Y	R
B	Y	R	G
R	G	B	Y
Y	B	G	R

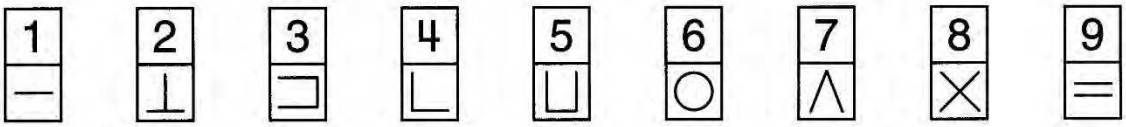
C. Incongruent Colour-Word trial

G	B	Y	R
Y	R	G	B
B	G	Y	R
B	Y	R	G
R	G	B	Y
Y	B	G	R

	Time (sec)	Errors
A		
B		
C		
C/A ratio		

Appendix 19. WAIS-III Digit Symbol Coding (DSC) test

Digit Symbol—Coding



Sample Items

2	1	3	7	2	4	8	2	1	3	2	1	4	2	3	5	2	3	1	4

5	6	3	1	4	1	5	4	2	7	6	3	5	7	2	8	5	4	6	3

7	2	8	1	9	5	8	4	7	3	6	2	5	1	9	2	8	3	7	4

6	5	9	4	8	3	7	2	6	1	5	4	6	3	7	9	2	8	1	7

9	4	6	8	5	9	7	1	8	5	2	9	4	8	6	3	7	9	8	6

2	7	3	6	5	1	9	8	4	5	7	3	1	4	8	7	9	1	4	5

7	1	8	2	9	3	6	7	2	8	5	2	3	1	4	8	4	2	7	6

Appendix 20. Hospital Anxiety Depression Scale (HADS)

Participant Code number: _____

Study Site: _____

Test Phase: Baseline / 6mo / 12mo / 18 mo

My-AHA

Hospital Anxiety and Depression Scale (HADS)

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings he or she will be able to help you more.

This questionnaire is designed to help your clinician to know how you feel. Read each item below and **underline the reply** which comes closest to how you have been feeling in the past week.

Ignore the numbers printed at the edge of the questionnaire.

Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long, thought-out response.

A	FOLD HERE D			FOLD HERE A	D
		I feel tense or 'wound up'	**I feel as if I am slowed down**		
3		Most of the time	Nearly all the time		3
2		A lot of the time	Very often		2
1		From time to time, occasionally	Sometimes		1
0		Not at all	Not at all		0
			I get a sort of frightened feeling like		
		I still enjoy the things I used to enjoy	**'butterflies' in the stomach**		
	0	Definitely as much	Not at all	0	
	1	Not quite so much	Occasionally	1	
	2	Only a little	Quite often	2	
	3	Hardly at all	Very often	3	
		I get a sort of frightened feeling as if something awful is about to happen	**I have lost interest in my appearance**		
3		Very definitely and quite badly	Definitely		3
2		Yes, but not too badly	I don't take as much care as I should		2
1		A little, but it doesn't worry me	I may not take quite as much care		1
0		Not at all	I take just as much care as ever		0
		I can laugh and see the funny side of things	**I feel restless as if I have to be on the move**		
	0	As much as I always could	Very much indeed	3	
	1	Not quite so much now	Quite a lot	2	
	2	Definitely not so much now	Not very much	1	
	3	Not at all	Not at all	0	
		Worrying thoughts go through my mind	**I look forward with enjoyment to things**		
3		A great deal of the time	As much as I ever did		0
2		A lot of the time	Rather less than I used to		1
1		Not too often	Definitely less than I used to		2
0		Very little	Hardly at all		3
		I feel cheerful	**I get sudden feelings of panic**		
	3	Never	Very often indeed	3	
	2	Not often	Quite often	2	
	1	Sometimes	Not very often	1	
	0	Most of the time	Not at all	0	
			I can enjoy a good book or radio or		
		I can sit at ease and feel relaxed	**television programme**		
0		Definitely	Often		0
1		Usually	Sometimes		1
2		Not often	Not often		2
3		Not at all	Very seldom		3

Now check that you have answered all the questions

A	D

Appendix 21. Lubben Social Network Scale – Revised (LSNS-R)

LUBBEN SOCIAL NETWORK SCALE – REVISED (LSNS-R)

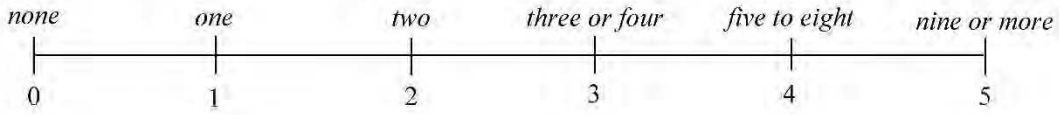
Participant Code number: _____

Study Site: _____

Test Phase: Baseline / 6mo / 12mo / 18 mo

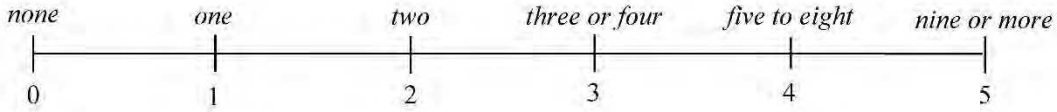
FAMILY *Considering the people to whom you are related either by birth or marriage…*

1. How many relatives do you see or hear from at least once a month?

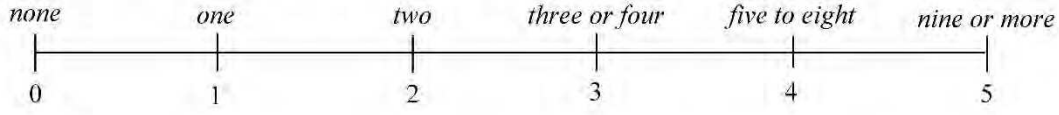


2. How often do you see or hear from relative with whom you have the most contact?

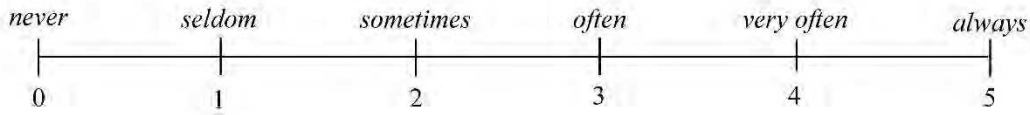
3. How many relatives do you feel at ease with that you can talk about private matters?



4. How many relatives do you feel close to such that you could call on them for help?

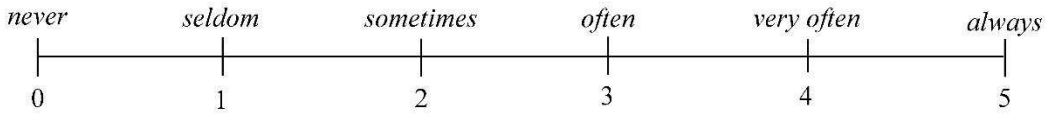


5. When one of your relatives has an important decision to make, how often do they talk to you about it?



1

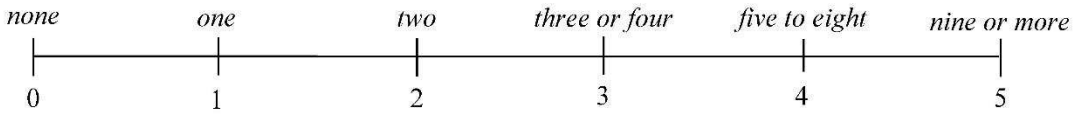
6. **How often is one of your relatives available for you to talk to when you have an important decision to make?**



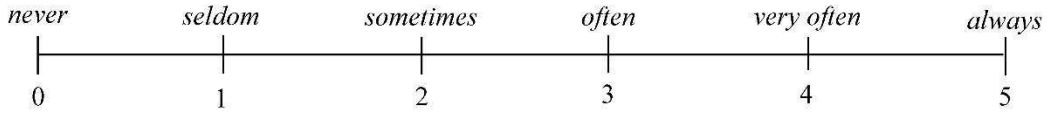
Family Raw Score ☐ **Family Scaled Score** ☐

FRIENDSHIPS: *Considering your friends who do not live in your neighbourhood….*

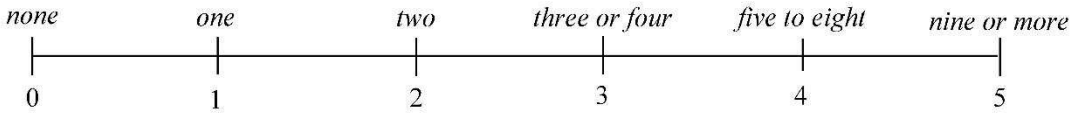
7. **How many of your friends do you see or hear from at least once a month?**



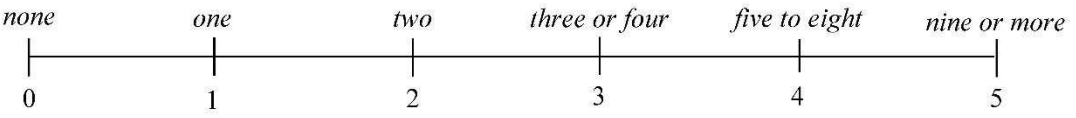
8. **How often do you see or hear from the friend with whom you have the most contact?**



9. **How many friends do you feel at ease with that you can talk about private matters?**

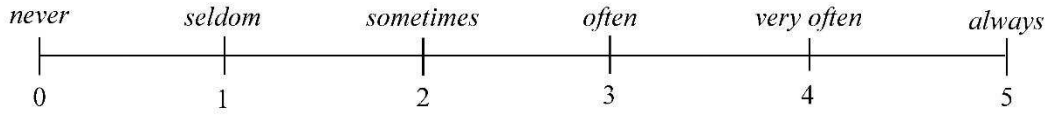


10. **How many friends do you feel close to such that you could call on them for help?**

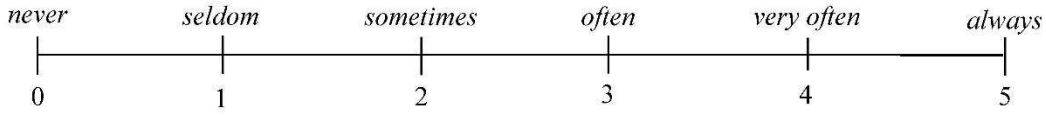


2

11. When one of your friends has an important decision to make, how often do they talk to you about it?



12. How often is one of your friends available for you to talk to when you have an important decision to make?



Friendship Raw Score ☐ **Friendship Scaled Score** ☐

LSNS-R Total Score ☐

3

Appendix 22. UCLA Loneliness Scale

Participant Code number: _____

Study Site: _____

Test Phase: Baseline / 6mo / 12mo / 18 mo

My-AHA

UCLA Loneliness Scale

	Statement	Never	Rarely	Sometimes	Often
*	1. How often do you feel that you are "in tune" with the people around you?	1	2	3	4
	2. How often do you feel that you lack companionship?	1	2	3	4
	3. How often do you feel that there is no one you can turn to?	1	2	3	4
	4. How often do you feel alone?	1	2	3	4
*	5. How often do you feel part of a group of friends?	1	2	3	4
*	6. How often do you feel that you have a lot in common with the people around you?	1	2	3	4
	7. How often do you feel that you are no longer close to anyone?	1	2	3	4
	8. How often do you feel that your interests and ideas are not shared by those around you?	1	2	3	4
*	9. How often do you feel outgoing and friendly?	1	2	3	4
*	10. How often do you feel close to people?	1	2	3	4
	11. How often do you feel left out?	1	2	3	4
	12. How often do you feel that your relationships with others are not meaningful?	1	2	3	4
	13. How often do you feel that no one really knows you we11?	1	2	3	4
	14. How often do you feel isolated from others?	1	2	3	4
*	15. How often do you fee1 you can find companionship when you want it?	1	2	3	4
*	16. How often do you feel that there are people who really understand you?	1	2	3	4
	17. How often do you feel shy?	1	2	3	4
	18. How often do you feel that people are around you but not with you?	1	2	3	4
*	19. How often do you feel that there are people you can talk to?	1	2	3	4
*	20. How often do you feel that there are people you can turn to?	1	2	3	4

Total Score (* = reverse) _____

Appendix 23. Self-MNA scale

Nestlé Nutrition Institute

Self-MNA®

Mini Nutritional Assessment

For Adults 65 years of Age and Older

Last name: First name:

Date: Age:

Complete the screen by filling in the boxes with the appropriate numbers. Total the numbers for the final screening score.

Screening		
A Has your food intake declined over the past 3 months? [ENTER ONE NUMBER] *Please enter the most appropriate number (0, 1, or 2) in the box to the right.*	0 = severe decrease in food intake 1 = moderate decrease in food intake 2 = no decrease in food intake	☐
B How much weight have you lost in the past 3 months? [ENTER ONE NUMBER] *Please enter the most appropriate number (0, 1, 2 or 3) in the box to the right.*	0 = weight loss greater than 3 kg 1 = do not know the amount of weight lost 2 = weight loss between 1 and 3 kg 3 = no weight loss or weight loss less than 1 kg	☐
C How would you describe your current mobility? [ENTER ONE NUMBER] *Please enter the most appropriate number (0, 1, or 2) in the box to the right.*	0 = unable to get out of a bed, a chair, or a wheelchair without the assistance of another person 1 = able to get out of bed or a chair, but unable to go out of my home 2 = able to leave my home	☐
D Have you been stressed or severely ill in the past 3 months? [ENTER ONE NUMBER] *Please enter the most appropriate number (0 or 2) in the box to the right.*	0 = yes 2 = no	☐
E Are you currently experiencing dementia and/or prolonged severe sadness? [ENTER ONE NUMBER] *Please enter the most appropriate number (0, 1, or 2) in the box to the right.*	0 = yes, severe dementia and/or prolonged severe sadness 1 = yes, mild dementia, but no prolonged severe sadness 2 = neither dementia nor prolonged severe sadness	☐
Please total all of the numbers you entered in the boxes for questions A-E and write the numbers here:		☐☐

Now, please CHOOSE ONE of the following two questions – F1 or F2 – to answer.

Question F1

Height (cm)	Body Weight (kg)			
147.5	Less than 41.1	41.1 – 45.3	45.4 – 49.6	49.7 or more
150	Less than 42.8	42.8 – 47.2	47.3 – 51.7	51.8 or more
152.5	Less than 44.2	44.2 – 48.7	48.8 – 53.4	53.5 or more
155	Less than 45.6	45.6 – 50.4	50.5 – 55.2	55.3 or more
157.5	Less than 47.1	47.1 – 52.0	52.1 – 57.0	57.1 or more
160	Less than 48.6	48.6 – 53.7	53.8 – 58.8	58.9 or more
162.5	Less than 50.2	50.2 – 55.4	55.5 – 60.6	60.7 or more
165	Less than 51.7	51.7 – 57.1	57.2 – 62.5	62.6 or more
167.5	Less than 53.3	53.3 – 58.8	58.9 – 64.4	64.5 or more
170	Less than 54.9	54.9 – 60.6	60.7 – 66.4	66.5 or more
172.5	Less than 56.5	56.5 – 62.4	62.5 – 68.3	68.4 or more
175	Less than 58.2	58.2 – 64.2	64.3 – 70.3	70.4 or more
177.5	Less than 59.9	59.9 – 66.1	66.2 – 72.4	72.5 or more
180	Less than 61.6	61.6 – 67.9	68.0 – 74.4	74.5 or more
182.5	Less than 63.3	63.3 – 69.8	69.9 – 76.5	76.6 or more
185	Less than 65.0	65.0 – 71.8	71.9 – 78.6	78.7 or more
187.5	Less than 66.8	66.8 – 73.7	73.8 – 80.8	80.9 or more
190	Less than 68.6	68.6 – 75.7	75.8 – 82.9	83.0 or more
192.5	Less than 70.4	70.4 – 77.7	77.8 – 85.1	85.2 or more
Group	**0**	**1**	**2**	**3**

Please refer to the chart on the left and follow these instructions:

1. Find your height on the left-hand column of the chart.
2. Go across that row and circle the range that your weight falls into.
3. Look to the bottom of the chart to find out what group number (0, 1, 2, or 3) your circled weight range falls into.

Write the Group Number (0, 1, 2, or 3) here: ☐

Write sum of questions A-E (from page 1) ☐

Lastly, calculate the sum of these 2 numbers. This is your SCREENING SCORE: ☐

Question F2

DO NOT ANSWER QUESTION F2 IF QUESTION F1 IS ALREADY COMPLETED.

Measure the circumference of your LEFT calf by following the instructions below:

1. Loop a tape measure all the way around your calf to measure its size.
2. Record the measurement in cm: _____
   - If less than 31cm, enter "0" in the box to the right.
   - If 31cm or greater, enter "3" in the box to the right.

☐

Write the sum of questions A-E (from page 1) here: ☐☐

Lastly, calculate the sum of these 2 numbers. This is your SCREENING SCORE: ☐☐

Screening Score (14 points maximum)

12–14 points:	Normal nutritional status	
8–11 points:	At risk of malnutrition	
0–7 points:	Malnourished	**Copy your SCREENING SCORE:** ☐☐

If you score between 0-11, please take this form to a healthcare professional for consultation.

Appendix 24. Computer Literacy Scale (CLS)

COMPUTER LITERACY SCALE (CLS)

PARTICIPANT CODE: _____

STUDY SITE: _____

TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo *(circle one)*

The purpose of this questionnaire is to ask about your experience with computers. It begins with general questions about your use of computers (part A) and continues with a task of assigning meanings to computer-related symbols and terms (part B). It will take about 10 minutes to complete. Please read the instructions carefully. It is very important that you answer all questions. Thank you!

Part A: Experience with computers

1. For how many years have you been using computers? _____ years

   If you have never used a computer, please skip to part B

2. How many hours per week do you typically use a computer? _____ hrs/week

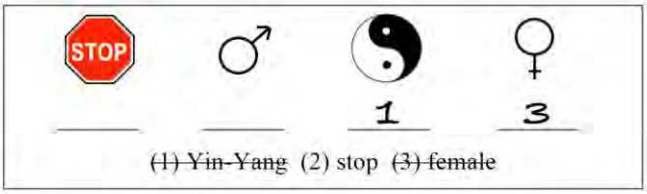
3. How often do you use a computer for the following tasks?

	never	seldom	sometimes	often
Word processing	☐	☐	☐	☐
Spreadsheet analysis	☐	☐	☐	☐
Presentations	☐	☐	☐	☐
Image (Photo or Video) editing	☐	☐	☐	☐
Computer games	☐	☐	☐	☐
Programming	☐	☐	☐	☐
E-mail	☐	☐	☐	☐
Internet surfing	☐	☐	☐	☐
Systematic information seeking	☐	☐	☐	☐
Online shopping	☐	☐	☐	☐
Online banking	☐	☐	☐	☐

Part B: Assignment of symbols and terms

On the next page, you will see different symbols that are relevant to the use of electronic equipment and computers. Please assign them to their respective meanings by writing the appropriate number under each symbol as illustrated by this example using common symbols:

Please keep in mind that there is not a matching meaning for every symbol so that, in each box, there will be one symbol left over. To make this task easier, cross out the meanings after you have assigned them to their respective symbols.



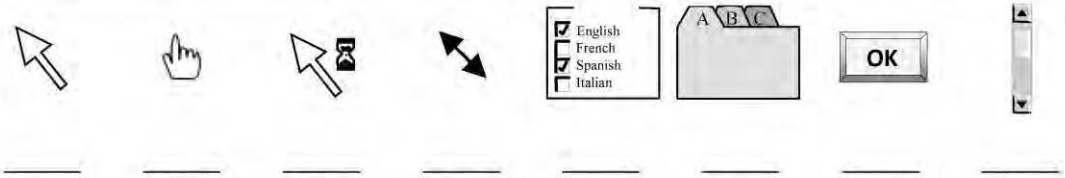
COMPUTER LITERACY SCALE (CLS)

It is only natural that you will not know all the answers. However, please try to assign <u>all</u> meanings to a symbol. If you are not sure, just guess which symbol is most likely to fit.

If you have further questions, please do not hesitate to ask. If not, you may begin now.

(1) fast-forward (2) save (3) attachment (4) delete
(5) play / start (6) eject (7) switch on / off

(1) backspace (2) escape (3) OK / confirm (4) tabulator
(5) help (6) delete (7) undo



(1) tabs (2) button (3) resize object (4) scrollbar
(5) background activity / please wait (6) check boxes (7) cursor (standard)

Please assign the following terms to their respective meanings

File Cancel Tooltip Browser Hyperlink Icon

(1) A computer program used to view websites on the World Wide Web (www)
(2) A short explanatory text that can be shown if the mouse remains on an icon for some time
(3) Data that has been saved as a self-contained document under a shared name
(4) Cross reference in hypertext documents that points to another page or place
(5) Abort the current operation

Appendix 25. Evaluation of Usability Scale (SUS)

EVALUATION OF USABILITY SCALE (SUS)

PARTICIPANT CODE: _____

STUDY SITE: _____

TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo *(circle one)*

The following section related to your ***feelings and thoughts*** that may occur while using the My-AHA application.
Please circle one response number for each of the following statements. Only circle one number for each statement.

	Statement	**Strongly disagree**				**Strongly agree**
1	I think that I would like to use the system more often	1	2	3	4	5
2	I found the system unnecessarily complex	1	2	3	4	5
3	I found the system was easy to use	1	2	3	4	5
4	I think I would need the help of a technical person to be able to use the system	1	2	3	4	5
5	I found the different functions in the system were well integrated	1	2	3	4	5
6	I think the system was too unstable	1	2	3	4	5
7	I can imagine that most people can easily learn to use the system very quickly	1	2	3	4	5
8	I found the system very uncomfortable to use	1	2	3	4	5
9	I felt safe while using the system	1	2	3	4	5
10	I needed to learn a lot of things before I could start using this system	1	2	3	4	5

Appendix 26. DART Questionnaire

ACCEPTANCE OF HEALTH CARE SECTOR APPLICATION (MY-AHA) FOR SMARTPHONES/TABLETS QUESTIONNAIRE (DART)

PARTICIPANT CODE: _____

STUDY SITE: _____

TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo *(circle one)*

Over the last few months, you have been using the My-AHA Dashboard app on your smartphone or tablet. During this time, you used the dashboard to monitor your results and other data; you established your risk of disease and you managed your devices. The following questions and statements are designed to address both your personal attitude towards the app as well as the experiences you had with the app. This questionnaire is in 2 parts:

In the **first part** of the questionnaire, we would like you to answer a few general questions about yourself and your attitudes.
In the **second part** of the questionnaire, we would like to know the experiences you had while using the My-AHA Dashboard application during the last few months and what your attitude toward the application is.

Part 1: General questions about yourself and your attitudes

1. Are you
   - ☐ Female
   - ☐ Male

2. How old are you? _____ years

3. What is your highest level of education? *(select only one option)*
   - ☐ Primary school
   - ☐ Year 10 of secondary school (O-levels)
   - ☐ Completed secondary schools (Year 12, A-levels)
   - ☐ University/college degree
   - ☐ A different qualification _____

4. What is/was your occupation? *(select only one option)*
   - ☐ Farmer/agriculturalist
   - ☐ Independent professional (e.g., doctor, lawyer)
   - ☐ Self-employed
   - ☐ Civil servant/public official
   - ☐ Employee
   - ☐ Manual worker
   - ☐ Different occupation, namely _____

ACCEPTANCE OF HEALTH CARE SECTOR APPLICATION (MY-AHA) FOR SMARTPHONES/TABLETS QUESTIONNAIRE (DART)

Part II: Questions regarding your use of My-AHA during the last few months

		Non-existent / very poor					*Very Good*
1.	How do you rate your skill with smartphones/tablets	☐	☐	☐	☐	☐	☐
2.	How do you rate your knowledge of smartphone applications from the health care sector? (*e.g., nutrition assistant, movement assistant etc?)*	☐	☐	☐	☐	☐	☐

3. How often did you use the My-AHA application in the last few months?

- ☐ Not at all
- ☐ Once a week
- ☐ More than once a week
- ☐ Daily

ACCEPTANCE OF HEALTH CARE SECTOR APPLICATION (MY-AHA) FOR SMARTPHONES/TABLETS QUESTIONNAIRE (DART)

5. Would you be prepared to pay a **monthly** fee for using the My-AHA application? If so, how much would you be prepared to pay? *(select one option only)*

- ☐ Less than $5
- ☐ Less than $10
- ☐ More than $10
- ☐ I would not be prepared to pay a monthly fee to use the application

6. Would you be prepared to pay a **one-off** fee for using the My-AHA application? If so, how much would you be prepared to pay? *(select one option only)*

- ☐ Less than $5
- ☐ Less than $10
- ☐ More than $10
- ☐ I would not be prepared to pay a one-off fee to use the application

7. Would you buy the My-AHA application if it were partially financed by your health insurance fund?

- ☐ Yes
- ☐ No

ACCEPTANCE OF HEALTH CARE SECTOR APPLICATION (MY-AHA) FOR SMARTPHONES/TABLETS QUESTIONNAIRE (DART)

Now please rate the importance of the following statements regarding smartphone/tablet applications in the health care sector

The application should ….	Totally unimportant					Very important
help me improve my own personal fitness levels	☐	☐	☐	☐	☐	☐
allow me an adequate level of self-control	☐	☐	☐	☐	☐	☐
give me advance warning of health risks, thus improving my safety	☐	☐	☐	☐	☐	☐
reward me appropriately for healthy behavior	☐	☐	☐	☐	☐	☐
help me expand my knowledge of health issues	☐	☐	☐	☐	☐	☐
enable me to talk about health-related topics with my family and friends	☐	☐	☐	☐	☐	☐
enable my family and friends to support me with health issues	☐	☐	☐	☐	☐	☐
enable the creation of groups of people with similar, health-related interests	☐	☐	☐	☐	☐	☐
support me in making new contacts and getting to know them	☐	☐	☐	☐	☐	☐
be modern, and designed according to the current state of the art	☐	☐	☐	☐	☐	☐

ACCEPTANCE OF HEALTH CARE SECTOR APPLICATION (MY-AHA) FOR SMARTPHONES/TABLETS QUESTIONNAIRE (DART)

Please rate the extent to which the My-AHA application that you have been using over the past few months corresponds to the statements below						
The application ….	Not at all					Fully
helps me to improve my personal fitness level	☐	☐	☐	☐	☐	☐
allows me an adequate level of self-control	☐	☐	☐	☐	☐	☐
improves my safety by warning me at an early stage of health risks	☐	☐	☐	☐	☐	☐
rewards me appropriately for healthy behavior	☐	☐	☐	☐	☐	☐
helps me expand my knowledge of health issues	☐	☐	☐	☐	☐	☐
enables me to talk about health-related topics with my family and friends	☐	☐	☐	☐	☐	☐
enables my family and friends to support me with health issues	☐	☐	☐	☐	☐	☐
enables the creation of groups of people with similar, health-related interests	☐	☐	☐	☐	☐	☐
supports me in making new contacts and getting to know them	☐	☐	☐	☐	☐	☐
is modern, and designed according to the current state of the art	☐	☐	☐	☐	☐	☐

ACCEPTANCE OF HEALTH CARE SECTOR APPLICATION (MY-AHA) FOR SMARTPHONES/TABLETS QUESTIONNAIRE (DART)

Once again, please rate the importance of the following statements regarding smartphone/tablet applications in the health care sector						
The application should ….	Totally unimportant					Very important
be adaptable and individually adjustable to my needs	☐	☐	☐	☐	☐	☐
be easy to understand	☐	☐	☐	☐	☐	☐
react quickly and have a short charging time	☐	☐	☐	☐	☐	☐
be robust with no malfunctions / as few malfunctions as possible	☐	☐	☐	☐	☐	☐
be displayed large enough on the screen so that I can see everything	☐	☐	☐	☐	☐	☐
be inexpensive to buy	☐	☐	☐	☐	☐	☐
be easy to learn to use, without a great deal of effort	☐	☐	☐	☐	☐	☐
be easy to maintain, without a great deal of effort (e.g., updating the app to a newer version)	☐	☐	☐	☐	☐	☐
treat my personal details confidentially	☐	☐	☐	☐	☐	☐
not patronize me or restrict my autonomy in any way	☐	☐	☐	☐	☐	☐

ACCEPTANCE OF HEALTH CARE SECTOR APPLICATION (MY-AHA) FOR SMARTPHONES/TABLETS QUESTIONNAIRE (DART)

Once again, please rate the extent to which the MyAHA application you have been using during the last few months corresponds to the statements below

The application ….	Totally unimportant					Very important
is adaptable and individually adjustable to my needs	☐	☐	☐	☐	☐	☐
is easy to understand	☐	☐	☐	☐	☐	☐
reacts quickly and has a short charging time	☐	☐	☐	☐	☐	☐
is robust and never / hardly ever malfunctions	☐	☐	☐	☐	☐	☐
is displayed on the screen large enough so that I can see everything	☐	☐	☐	☐	☐	☐
is inexpensive to buy *(optional question)*	☐	☐	☐	☐	☐	☐
can be learned easily, without a great deal of effort	☐	☐	☐	☐	☐	☐
can be maintained, without a great deal of effort (e.g., updating the app to a newer version)	☐	☐	☐	☐	☐	☐
gives me the feeling that my personal details are treated confidentially	☐	☐	☐	☐	☐	☐
does not patronize me or restrict my autonomy in any way	☐	☐	☐	☐	☐	☐

Appendix 27. User Experience Questionnaire (UEQ)

USER EXPERIENCE QUESTIONNAIRE (UEQ)

PARTICIPANT CODE: _____

STUDY SITE: _____

TEST PHASE: Baseline / 6 mo / 12 mo / 18 mo *(circle one)*

For the assessment of the My-AHA application, please complete the following questionnaire.
The questionnaire consists a series of paired contrasting attributes that may apply to the My-AHA application. The circles between each paired attribute represent graduations between opposing attributes. You can express your agreement with the attributes by ticking the circle that most closely reflects your impression.

For example:

attractive	○	⊗	○	○	○	○	○	unattractive

This response would mean that you rate the application as more attractive than unattractive.

Please decide spontaneously. Don't think too long about your decision to ensure that you convey your initial impression.

Sometimes you may not be completely certain about your agree with a particular attribute or you may find that the attribute does not apply completely to the My-AHA application. Nonetheless, please select a response for every statement.

It is your personal impressions that count, there are no right or wrong answers.

USER EXPERIENCE QUESTIONNAIRE (UEQ)

Please assess the My-AHA application by ticking one circle in each line:

	1	2	3	4	5	6	7		
annoying	○	○	○	○	○	○	○	enjoyable	1
not understandable	○	○	○	○	○	○	○	understandable	2
creative	○	○	○	○	○	○	○	dull	3
easy to learn	○	○	○	○	○	○	○	difficult to learn	4
valuable	○	○	○	○	○	○	○	inferior	5
boring	○	○	○	○	○	○	○	exciting	6
not interesting	○	○	○	○	○	○	○	interesting	7
unpredictable	○	○	○	○	○	○	○	predictable	8
fast	○	○	○	○	○	○	○	slow	9
inventive	○	○	○	○	○	○	○	conventional	10
obstructive	○	○	○	○	○	○	○	supportive	11
good	○	○	○	○	○	○	○	bad	12
complicated	○	○	○	○	○	○	○	easy	13
unlikable	○	○	○	○	○	○	○	pleasing	14
usual	○	○	○	○	○	○	○	leading edge	15
unpleasant	○	○	○	○	○	○	○	pleasant	16
secure	○	○	○	○	○	○	○	not secure	17
motivating	○	○	○	○	○	○	○	demotivating	18
meets expectations	○	○	○	○	○	○	○	does not meet expectations	19
inefficient	○	○	○	○	○	○	○	efficient	20
clear	○	○	○	○	○	○	○	confusing	21
impractical	○	○	○	○	○	○	○	practical	22
organized	○	○	○	○	○	○	○	cluttered	23
attractive	○	○	○	○	○	○	○	unattractive	24
friendly	○	○	○	○	○	○	○	unfriendly	25
conservative	○	○	○	○	○	○	○	innovative	26