

List of all tests, outcomes, and time points for data collection, for the AU-ARROW study (includes some extra details not listed in the ANZ-CTR 40 outcomes listings). ANZ-CTR application number 382647.			
Primary and Secondary Outcomes For AU-ARROW (382647)	Outcome/test	Data collection time points	Extra information on outcome/measure
PRIMARY	<p>The Primary Outcome is a Global Cognitive composite Score.</p> <p>The global composite score will include scores from the Free and Cued Selective Reminding Test, Immediate and Delayed Visual Paired Associates, Number Span forward, backward and sequencing, Verbal Fluency by letters (F,A,S) and by Category (animals, vegetables, fruits), Digit Symbol Substitution Test, Immediate and Delayed Story Recall, and Trail making tests A and B.</p>	24 months after start of intervention, compared to baseline measurement (0 months).	

		SECONDARY OUTCOMES		
	1	<p>Global Cognitive Composite Score (at time points other than for Primary Outcome) The global composite score will include scores from the Free and Cued Selective Reminding Test, Immediate and Delayed Visual Paired Associates, Number Span forward, backward and sequencing, Verbal Fluency by letters (F,A,S) and by Category (animals, vegetables, fruits), Digit Symbol Substitution Test, Immediate and Delayed Story Recall, and Trail making test A and B.</p>	<p>Other time points for the Global Composite Score are at 6, 12 and 18 months after start of intervention.</p>	
	2	<p>Executive Function Composite. Composite score from tests: Verbal Fluency by Letter (F,A,S) Verbal Fluency by Category (animals, vegetables, fruits), Number span, Digit Symbol Substitution Test (DSST), Trail Making test B. Experimental measures include Cogstate One Back, and the Clock drawing Test.</p>	<p>All tests are administered at Baseline (0 months) as well as 6, 12, 18 and 24 months after start of intervention, (Except Cogstate One Back, which is administered at Baseline, as well as 12 and 24 months after the start of intervention)</p>	

	3	<p>Processing Speed Composite.</p> <p>Composite score from tests: the Digit Symbol Substitution Test (DSST), Trail Making test A.</p> <p>Experimental measures include Cogstate Detection and Identification and the Clock drawing test.</p>	<p>Tests are administered at Baseline (0 months) as well as 6, 12, 18 and 24 months after start of intervention, (except Cogstate Detection and Identification which is administered at Baseline as well as 12 and 24 months after intervention start)</p>	
	4	<p>Episodic Memory Composite</p> <p>Composite score from tests: Free and Cued Selective Reminding Test, Delayed Visual Paired Associates, Delayed Story Recall.</p> <p>Experimental measures include Cogstate One-Card Learning, Face Name Associative Memory Exam, Behavioral Pattern Separation of Objects</p>	<p>All tests are administered at Baseline (0 months) as well as 6, 12, 18 and 24 months after start of intervention, (Except for Cogstate One-Card Learning, Face Name Associative Memory Exam, Behavioral Pattern Separation of Objects, which are administered at Baseline, as well as 12 and 24 months after intervention start)</p>	
	5	<p>Clinical Dementia Rating: Clinical Dementia Rating Sum Of Boxes Score.</p>	<p>Administered at Baseline, as well as 12 and 24 months after start of intervention.</p>	
	6	<p>Risk of Type 2 Diabetes/metabolic syndrome Assessed by Blood Pathology tests - Fasting Blood glucose and Haemoglobin A1c tests</p>	<p>Data from fasting blood samples collected at Baseline as well as 6, 12, 18 and 24 months after start of intervention</p>	

	7	Hypertension Blood pressure measured using a blood pressure monitor (Sphygmomanometer)	Measures taken at Baseline then monthly up to 24 months following the start of the intervention for the Multidomain intervention group (ML participants). Blood pressure measured at Baseline then 3-monthly for the Health Education and coaching group (HC participants)	
	8	Risk of Cardiovascular disease Tests include: Blood Pathology from fasting blood samples : Lipid profile including LDL-cholesterol, HDL-cholesterol, Total Cholesterol, triglycerides.	Blood pathology tests are carried out at Baseline and then at 6, 12, 18 and 24 months after the start of the intervention.	
	9	Mindfulness, as measured using the Five-Facet Mindfulness Questionnaire.	Questionnaire completed by participants at Baseline, then 12 and 24 months after start of intervention	
	10	Loneliness Measured using the De Jong Gierveld Loneliness Scale	This questionnaire is completed by all participants at Baseline, then at 6, 12, 18 and 24 months after start of intervention.	
	11	Social Isolation, as measured using the Lubben Social Network Scale	This questionnaire is completed by all participants at Baseline, then at 6, 12, 18 and 24 months after start of intervention.	
	12	Psychological Wellbeing, as assessed using the Depression, Anxiety, and Stress Scale (DASS)	This questionnaire is completed by all participants at Baseline, then at 6, 12, 18 and 24 months after start of intervention.	

	13	Overall dietary changes, as measured using the Cancer Council of Victoria Food Frequency Questionnaire (CCV-FFQ)	This questionnaire is completed by all participants at Baseline, then at 6, 12, 18 and 24 months after start of intervention.	
	14	MIND diet adherence, as measured using the Cancer Council of Victoria Food Frequency Questionnaire (CCV-FFQ)	This questionnaire is completed by all participants at Baseline, then at 6, 12, 18 and 24 months after start of intervention.	
	15	Physical Function composite, as assessed using the Short Physical Performance Battery, 400 m walk test and Grip Strength Test (using a hand dynamometer)	This assessment is carried out on all participants at Baseline, and at 6, 12, 18 and 24 months following the start of the intervention.	
	16	Quality of Life, as measured using the Euroqol-5D test.	This questionnaire is administered at Baseline, and at 12 and 24 months after the start of the intervention	
	17	General Health Status, as measured using the Short Form Health Survey (SF-36)	This survey is completed by all participants at Baseline and at 12 and 24 months following the start of the intervention.	
	18	Subjective cognitive Impairment, as determined by the McCusker Subjective Cognitive Impairment Inventory (McSCI) and Everyday cognition (ECog) tests	Questionnaires are completed at Baseline and at 12 and 24 months following the start of the intervention.	
	19	Everyday Functional Status, as assessed by the Instrumental Activities of Daily Living (IADL) Scale (partner form)	Questionnaire is completed by the participant's study partner at Baseline, and at 12 and 24 months following the start of the intervention.	

20	Sleep quality, as assessed by the "Pittsburgh Sleep Quality Index" (PSQI)	This questionnaire is completed by all participants at Baseline, then at 6, 12, 18 and 24 months after start of intervention.	This questionnaire and 2 others listed at outcomes 39 and 40 assess different aspects of sleep: The "Insomnia Severity Index" measures difficulties falling and staying asleep as well as impact on daily life, the "STOP Bang Questionnaire" captures information concerning risk of obstructive sleep apnoea, and the "Pittsburgh Sleep Quality Index" is a self-reported measure of the previous month's sleep habits.
21	Cognition, as assessed by the BrainHQ tests	BrainHQ assessment is completed by all participants at clinic visits, at Baseline, then 6, 12, 18 and 24 months after start of intervention.	
22	Safety, as assessed by the Brief Medical Review Survey, and data from adverse event report forms.	The Brief Medical Review Survey is administered every 3 months up to 24 months following the start of the intervention. Adverse Event (AE) report forms will be completed as necessary, from recruitment up until the last clinic visit.	
23	Brain amyloid-beta deposition levels, provided as a Centiloid measure. Measured by Brain Positron Emission Tomography (PET), completed using one of the following Alzheimer's disease beta-amyloid-specific tracers: 18F-labelled Florbetaben, or 18F-NAV4694 (also known as flutafuranol F18)	PET scans are completed at Baseline and at 24 months following the start of the intervention.	

	24	Hyperspectral retinal imaging investigations. Retinal imaging completed with a hyperspectral eye camera	Retinal scans to be completed at Baseline and at 24 months following start of intervention.	
	25	Sleep Apnoea markers, measured using WatchPAT® devices worn for 2 consecutive nights.	WatchPAT® devices will be worn for 2 consecutive nights at Baseline, and at 12 and 24 months following start of intervention	
	26	Alzheimer's Disease preclinical blood biomarker investigations Assay systems include Single Molecular Array (SIMOA), and/or immunoprecipitation followed by mass-spectrometry. Biomarkers to be investigated include Plasma Alzheimer's disease amyloid-beta peptide isoforms, plasma tau (total and phosphorylated isoforms), glial fibrillary acidic protein, and neurofilament light.	Fasted blood samples collected at Baseline, and 12 and 24 months following start of intervention.	

	27	<p>Feasibility, The data for this outcome includes adherence data from gym attendance, BrainHQ login frequency, the Cancer Council of Victoria Food Frequency Questionnaire, group meeting attendance, Fitbit data, assessment completion (self-report and objective measures), and the Participant End of Study Feedback Survey.</p>	<p>The data for this outcome comes from multiple sources as listed, which will be collected throughout the study, and will be evaluated following the conclusion of the study.</p>	<p>The data for this outcome includes adherence data from gym attendance, BrainHQ login frequency, the Cancer Council of Victoria Food Frequency Questionnaire, group meeting attendance, and assessment completion (self-report and objective measures), also including results of online logs completed by ML participants (daily logs completed for one week/month, encompassing rate of perceived exertion, exercise type, reported heart rate (from Fitbit) during exercise, and number/type of social and cognitive activities for the week). Feasibility will also be determined from the answers to the Participant End of Study Feedback Survey (designed for this study) at 24 months after start of intervention, completed by all participants. Physical activity adherence will also be assessed from participant Fitbit data, which will include daily total steps, calorie expenditure, resting heart rate, minutes in peak, cardio and fat burn exercise zones, hours with 250+ steps, and total exercise time.</p>
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	28	<p>Urine analysis for potential early Alzheimer's disease biomarkers</p> <p>Samples will be investigated using liquid-chromatography mass spectrometry (LCMS), immunoassay, and/or nuclear magnetic resonance spectroscopy. The measurements may include, but are not limited to, inflammatory markers, biogenic amines, short chain fatty acids, cytokines, and small molecules such as organic acids, sugars and phenolics</p>	<p>urine samples will be collected at Baseline, and at 6, 12, and 24 months following start of intervention.</p>	
	29	<p>Changes in physical activities, as measured using the Physical and Mental Activities Questionnaire, (Modified "Community Healthy Activities Model Program for Seniors" CHAMPS questionnaire)</p>	<p>The Modified CHAMPS questionnaire is completed by all participants at Baseline and every 3 months up to 24 months, after the start of the intervention.</p>	<p>This questionnaire has coding algorithms that provide the following 4 assessments of physical activity levels: 1- Caloric expenditure/week in all exercise-related activities; 2- Caloric expenditure/week in moderate intensity exercise related activities; 3- Frequency/week of all exercise-related activities; and 4- Frequency/week of moderate-intensity exercise-related activities (https://cadc.ucsf.edu/champs)</p>
	30	<p>Changes to cognitive activities, as measured using the supplementary questions included in our modified Physical and Mental Activities Questionnaire, (Modified "Community Healthy Activities Model Program for Seniors" CHAMPS questionnaire)</p>	<p>The Modified CHAMPS questionnaire is completed by all participants at Baseline and every 3 months up to 24 months, after the start of the intervention.</p>	

	31	Pain severity, as measured using the Brief Pain Inventory	This questionnaire is administered to all participants at Baseline, and at 6, 12, 18 and 24 months following the start of the intervention.	
	32	Impact of pain on daily function, as measured using the Brief Pain Inventory	This questionnaire is administered to all participants at Baseline, and at 6, 12, 18 and 24 months following the start of the intervention.	
	33	Brain MRI measures, obtained following analysis of Brain MRI data	Participant brain MRI scans are to be completed at Baseline and at 24 months following the start of the intervention.	Brain MRI data will be analysed to provide (but may not be limited to) brain hippocampal volume, brain cortical volume, brain cortical thickness, Quantitative Susceptibility Mapping (QSM), Microbleed data, and White Matter Lesions.
	34	Motivation to change Lifestyle, as assessed by the Motivation to Change Lifestyle and Health Behaviours for Dementia Risk Reduction (MCLHB-DRR) questionnaire.	Questionnaire completed by all participants at Baseline and 24 months after start of intervention.	

	35	Dietary change monitoring, assessed from Easy Diet Diary app data and diet history information (ML participants only), and the 3-monthly MIND diet survey (all participants).	Easy Diet Diary app data is collected for 1 week/month from months 2 to 24 of the intervention (ML participants only), dietitian telehealth consultations will occur at least monthly from months 2 to 24 of the intervention (ML participants only). The MIND Diet Survey is completed online by all participants, during initial screening, then 3-monthly up to 24 months from the start of the intervention.	
	36	Changes in physical activity, using data obtained from Fitbit activity trackers.	All participants are provided with Fitbits at Baseline visits, and data will be collected continuously for 24 months from the start of the intervention.	Data will include total daily steps, resting heart rate, caloric expenditure, minutes in peak, cardio and fat burn exercise zones, hours with 250+ steps, total exercise time, and sleep data, as recorded by the Fitbits worn by all participants.
	37	Changes in the use of medical resources, as assessed in the 6-monthly (ML participants) or yearly (HC participants) clinician consultation reports, in combination with information from the online Brief Medical Review surveys.	Clinician consultation occurs every 12 months for HC participants and 6-monthly for the ML participants. The Brief Medical Review survey is completed online every 3 months by all participants.	This outcome will also cover changes to medication use, as documented in the Brief Medical Review surveys; data which is also reviewed by clinicians at the visits mentioned.
	38	Hearing, as assessed by the Speech, Spatial, and Qualities of Hearing Scale-short form (SSQ-12)	This questionnaire is administered to all participants at Baseline, and at 6, 12, 18 and 24 months following the start of the intervention.	This is a self-report on hearing loss and will be used to obtain information on participants' ability to understand speech in a variety of competing contexts.

39	Insomnia, as assessed by the Insomnia Severity Index (ISI)	This questionnaire is completed by all participants at Baseline, then at 6, 12, 18 and 24 months after start of intervention.	
40	Risk of Obstructive Sleep Apnoea, as assessed by the STOP Bang Questionnaire	This questionnaire is completed by all participants at Baseline, then at 6, 12, 18 and 24 months after start of intervention.	