Trial of an individualised intervention for the prevention of stroke (**TIIPS**)

Study Protocol &
Manual of Procedures
2022
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Document History

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1.0	12th May 2022	Rita Krishnamurthi	Draft 1 For submission to ethics

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BACKGROUND AND RATIONALE

1. THE IMPACT OF TIA/MINOR STROKE

Patients with Transient Ischaemic Attack (TIA) and minor (non-disabling; (NIHSS ≤ 3)[1] stroke are at high risk of secondary vascular events, including major stroke, myocardial infarction (MI), cognitive deficits and death, with population-based studies reporting incidence of adverse outcomes as high as 25% within 90 days.[2] New vascular events, including fatal strokes, MI, and other cardiovascular deaths, occur in up to 26% of patients within four years post-TIA.[3, 4] Increased risk is associated with an unhealthy lifestyle and poor adherence to medications to treat elevated blood pressure, diabetes mellitus, and previous vascular disease.[3] ARCOS-IV[5] showed that the age-standardised incidence of first-ever TIA in NZ is one of the highest among developed countries at 50 [95%CI 46-55] per 100,000 persons in 2011-2012.[6] TIA occurred at a younger mean age in Māori and Pacific people (60 years) and Asian and other (including Middle Eastern and African) people (68 years) compared to Europeans (74 years).[6] ARCOS-IV also found a high prevalence of cardiometabolic risk factors (e.g. 65% had hypertension, 47% had elevated lipids, and 27% had atrial fibrillation).

2. SECONDARY PREVENTION AFTER TIA/MINOR STROKE

There is ample evidence that modifying health behaviours for stroke and cardiovascular disease (CVD) prevention is feasible, improves health outcomes, reduces healthcare costs, can reduce individual risk of stroke by about 80%,[7][8] and can reduce stroke incidence by about 50%.[9] Addressing health behaviours, including the use of multifactorial lifestyle interventions,[10] can lead to clinically meaningful reductions in CVD and stroke.[11] Both TIA and minor stroke are highly preventable with medical management,[12-14] combined with education about stroke/TIA and the importance of medication adherence and support for lifestyle behaviour change.[15-18] Current NZ stroke guidelines recommend behavioural counselling for diabetes, diet, exercise and smoking cessation for long-term self-management of risk factors.[19] However, in NZ, management of TIA/minor stroke *remains inadequate*.[20] In addition, due to the transient nature of symptoms, *patients do not recognise TIA as a significant medical event* with long-term health implications. Resultant delays in seeking medical treatment, low adherence to healthy lifestyle and prescribed medications, lead to *preventable major secondary events*.[21-23]

3. EFFICACY OF LIFESTYLE INTERVENTIONS IN STROKE/TIA

A recent systematic review including 15 trials on lifestyle interventions for secondary prevention following TIA or ischemic stroke, with the majority based on educational material, lifestyle advice, or exercise training,[24] showed a significant lowering of systolic blood pressure, but no significant effect on cholesterol or mortality. The authors recommended that future trials test interventions with at least 8 contact points, using a theoretical framework,[25] including educational and behavioural interventions with at least a four-month follow-up, and considering factors such as self-efficacy to facilitate health behaviour change.[24] Well-designed health coaching interventions improve physical and mental health, and sustain changes in lifestyle-related behaviours in people with diabetes[26, 27] myocardial infarction,[28] and other chronic conditions.[103] Resultant health behaviour changes have the potential to be long-lasting.[29]

4. MEASURING CARDIOVASCULAR RISK.

Testing an intervention that targets brain and heart health requires an evidence-based, relevant and reliable measure to determine its efficacy. Hypertension or high blood pressure is the most significant risk factor for stroke. The landmark INTERSTROKE study conducted in over twenty-six thousand participants in 32 countries showed that a history of hypertension increased the risk of stroke by 2.64-fold, and was the most significant risk factor for stroke. [30] Moreover the Global Burden of Diseases studies have shown that high systolic blood pressure is the leading risk factor contributing to the burden of stroke with 79.6 million disability adjusted life years lost (DALYs), which equated to 55% of DALYs. [31, 32]. A meta-analysis of 48 randomised trials evaluating the effects of blood pressure lowering in the risk of major CVD events (including stroke) found that a reduction of 5 mm Hg systolic blood pressure was associated with an 11% reduction in major cardiovascular events in people with previous cardiovascular disease.[33]

A recent study from Finland examined the association of the LS7 with the risk of stroke men without a history of stroke. In terms of absolute blood pressure, the study found that average blood pressures were 138.2 ± 16.6 mm Hg in the poor, 132.0 ± 16.5 mm Hg in the average and 118.6 ± 12.4 mm Hg in the optimum categories of the LS7.[34] Thus, an improvement from poor to ideal blood pressures could reduce systolic blood pressure by up to 13 mm Hg. Th Novel Approach to Cardiovascular Health By Optimizing Risk Management (ANCHOR) trial demonstrated a 4.5 mm Hg reduction in systolic blood pressure using a behaviour change intervention in people with an increased risk of CVD. [35] While the incidence of stroke and new vascular events would be ideal primary outcomes, this outcome would require long term follow-up and a prohibitively large sample size [18, 24, 36]. Blood pressure is also considered as a practical paradigm for preventing cardiovascular disease and improving total health. [33]

Given the increased risk of secondary events in this population, a 6 mm Hg difference in systolic blood pressure is plausible with an effective intervention.[37]

As well as improving blood pressure, a key secondary aim of the trial is to address multifactorial modifiable risk factors as a way to lower the risk of stroke and CVD. The INTERSTROKE study also found that overall there were ten potentially modifiable risk factors are collectively associated with about 90% of the population-attributable risk of stroke.[30] including lifestyle related risk factors such as physical activity, diet, and smoking. The Life's Simple 7 (LS7) was developed by the American Heart Association, (AHA), to predict ideal cardiovascular health using seven domains or metrics.[37-39] These are; blood pressure, cholesterol, glucose, body mass index, smoking, physical activity, and diet.[37] The LS7 is a simple scoring system to assess cardiovascular health with scores ranging from 0 to 14, with the overall LS7 score categorised as inadequate (0–4), average (5–9), or optimum (10–14) cardiovascular health (see Table 1). Inadequate and average scores on the LS7 have a high association with increased CVD/stroke risk and mortality.[38] Ideal levels of the Life's Simple 7 factors are defined as: non-smoker or quit >1 year ago; body mass index (BMI) of <25 kg/m2; ≥150 min/week of moderate+vigorous physical activity; 4 to 5 components of a healthy diet pattern; untreated total cholesterol of <5.2 mmol/L; untreated blood pressure of <120/80 mm Hg; and untreated fasting glucose of <5.6 mmol/L. The Reasons for Geographic and Racial Differences in Stroke study (REGARDS) found that in 22,914 people with no previous history of CVD, an improvement by one category (from inadequate to average or average to optimum) or of the LS7 score was associated with a 25% lower risk of stroke**,** and that a 1-point higher LS7 score was associated with an 8% lower risk of stroke.[37] In the Atherosclerosis Risk in Communities (ARIC) study of 1277 individuals who experienced a MI, adverse outcomes were inversely related to mid-life LS7 scores using the LS7 scoring where two-points are given for each optimum domain.[40] A recent review suggested that "an integrated socio-behavioural and medical intervention to improve LS7 factors was a potent and likely cost-effective approach to cardiovascular and general health promotion and disease prevention".[41]

HEALTH AND WELLNESS COACHING.

Health and Wellness coaching (HWC) is a multidimensional psychological behaviour change intervention aimed at improving self-management of lifestyle behaviour and maintaining health and wellbeing.[42] HWC is a goal-oriented, theory based,[25] client-centred partnership that has produced positive effects on health and enhanced well-being of patients with chronic disease.[43-45] HWC is a widely accepted and established intervention in the community,[46] and is of particular relevance to stroke prevention as it can address multiple risk factors. HWC fosters ongoing self-directed learning,[43] delivers a cost-effective[47] intervention in person or by telephone, and by medical or non-medical personnel,

thus saving cost and increasing the scope of implementation. Individuals who receive HWC have increased perceived health status, improved medication adherence, and physical activity,[48, 49] with significantly improved health outcomes shown in patients following myocardial infarction.[50-52]

5. THEORETICAL FRAMEWORK FOR HWC

In the context of this study the health and wellness coaching intervention is aimed at behaviour change which improves and physical health as well as the mental wellbeing of participants. However, behaviour change is challenging, and influenced by of physical, psychological and psychosocial factors, which may change over time. Motivating individuals to change unfavourable health behaviours is a challenge for health professionals, but growing evidence suggests that involving people in their own decision-making results in more favourable outcomes.[53]

There are several theoretical models for health behaviour change that support the HWC intervention. These include the concept of self-efficacy [54] in the health belief model, which focuses on attitudes and beliefs as a way to explain behaviour for improving lifestyle changes. Fostering a sense of self-determination, self-responsibility and ownership enhances motivation, satisfaction and adherence to healthier lifestyle choices.[55]The transtheoretical model proposed by Prochaska suggests that health behaviour is an interaction of five stages of change, processes of change and self-efficacy.[56] In this model, it is suggested that individuals move through stages of change: pre-contemplation, contemplation, preparation, action, maintenance and termination. Change may occur at different rates for individuals, and they may even move back and forth between stages, before achieving the final stage of termination. Self-change is a product of individuals doing the right thing (processes) at the right time (stages).

The HWC intervention is underpinned by a combination of these theoretical models, as HWC also encompasses the whole person and their beliefs, but it also considers the dynamic interaction between the person and their environment and all the factors that influence them.

6. PREVIOUS EVIDENCE FOR HWC FOR STROKE PREVENTIONS

We have recently completed (publication underway) a phase III randomised controlled trial (RCT) using HWC (PREVENTS study, n=320) [57] for ***primary*** stroke prevention in those with moderate and high risk of CVD (prior stroke or TIA excluded).

The study showed a significant difference in the change in LS7 score in the HWC group between baseline (7.08 [2.03]) and 9- months (7.39 [2.00]) compared to controls (baseline 7.15 [2.20], 9-months 7.15 [2.39]) (p=0.044). Among LS7 domains, regression analyses adjusting for age, sex and ethnicity showed statistically

significant increases in scores (indicating a positive change) for blood pressure (p=0.005), and cholesterol (p=0.04). The absolute blood pressure increased in both groups, but the increase was greater in the control group (10.58mmHg) than the HWC group (4.36mmHg). Cholesterol, blood glucose and BMI values also showed greater decreases in the HWC group compared to controls. The trial also demonstrated high acceptability and feasibility of the HWC intervention, positive feedback from participants and low dropout.

TRIAL DESIGN

The **T**rial of an **I**ndividualised **I**ntervention for the **P**revention of **S**troke (TIIPS) is a phase III, prospective, open-label, single-blinded end-point randomised controlled trial of 360 participants. The participants will be recruited from Auckland based public hospitals, including outpatient TIA clinics. The recruitment of participants from the existing health system will maximise the uptake of the intervention.

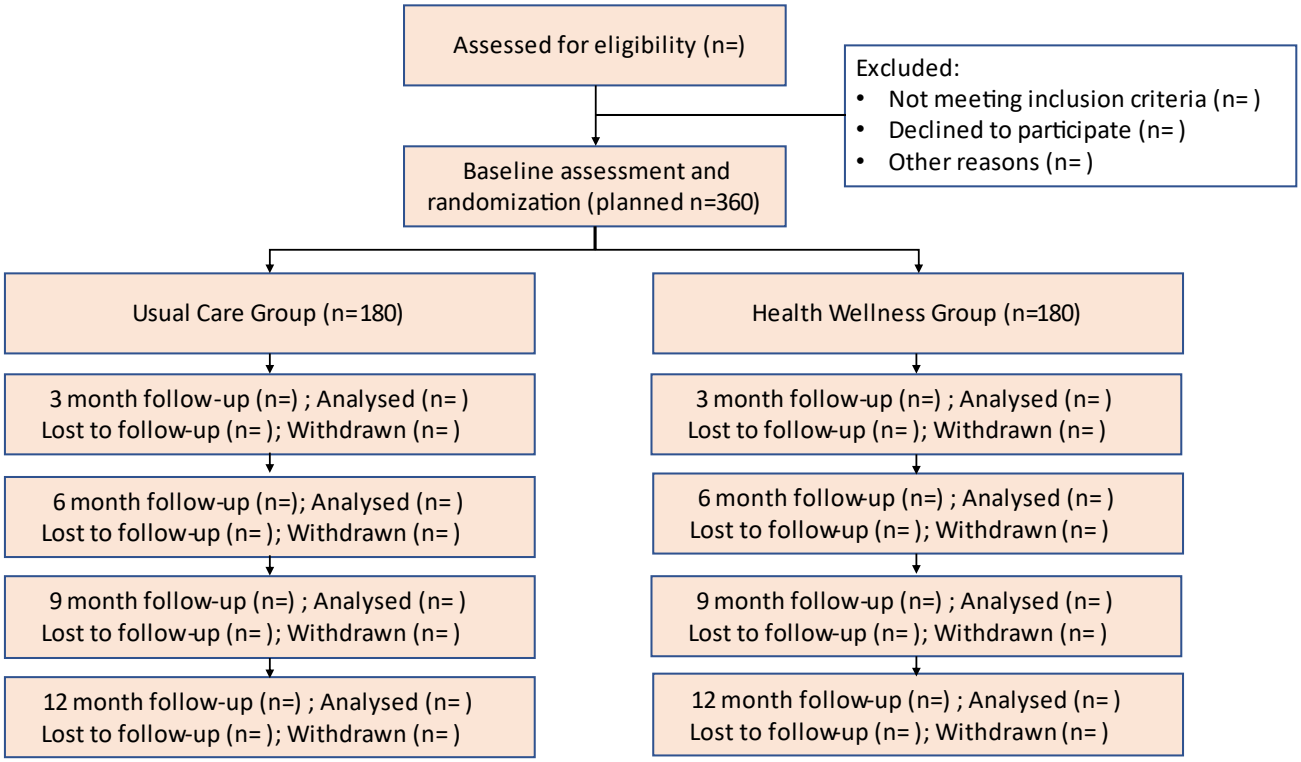
7. SAMPLE SIZE CALCULATION AND POWER ANALYSIS:

360 participants are required to provide 85% power (two sided α=0.05) to detect at least a 6 mm Hg clinically significant difference in systolic BP (SBP) changes at 6 months from baseline, between the HWC and UC groups. This estimation assumes a 20% non-compliance/loss to follow-up. Based on our previous HWC trial (Prevents RCT on HWC for primary stroke prevention, publication in preparation) [57] data in NZ stroke patients (n=251, 9- month BP change in HWC patients is 4.4 mm Hg (SD:18) and in usual care patients is 10.6 mm HG (SD 22).

The sample size estimations used the proc power procedure of SAS – a statistical analysis software. Using the means of the SBP changes in the two groups and the pooled standard deviation (SD 20) from the previous HWC trial, the calculation indicates n=352. R software was also used for simulating changes in BP for the two groups and yielded a simulated type II error < 0.10 (statistical power > 0.90) when n=300 (simulation of 1000 and 10000 times). We adopted the simulated results because it uses two different group standard deviations, and it is under the budget limit control. After adjusted 20% attrition rate, the proposed sample size is n=360. The power calculation is also informed by literature that a 5mmHg reduction in SPB is clinically meaningful and leads to a 11% reduction in the incidence of stroke.

The results of the trial will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement as outlined in the below flowchart. If required, we will apply The CONSERVE 2021 Statemen; Guidelines for Reporting Trial Protocols and Completed Trials Modified, in the case of the study being affected COVID-19 Pandemic and Other Extenuating Circumstances.

8. CONSORT CHART



9. AIMS AND HYPOTHESES

10. PRIMARY AIM

The **primary aim** is to determine the effectiveness of HWC in improving blood pressure at 6 months post-randomisation.

The primary hypothesis is that HWC initiated one-month post (± two weeks) of the onset of first-ever in a lifetime minor stroke or onset of TIA will lead to clinically meaningful improvements in lifestyle behaviours resulting in a mean difference of 6 mm Hg change in blood pressure from Baseline to 6 months post-randomisation in the HWC compared to usual care. Recurrent TIA onset is included.

The primary end-point is the difference in the mean change from Baseline in systolic blood pressure at 6 months post-randomisation between UC and HWC. The study is powered to detect a mean difference in change of 6 mm Hg (SD±20 mm Hg) between HWC and UC groups at 6 months post-randomisation.

11. SECONDARY AIMS

The **secondary aims** are to determine are to determine the effectiveness of HWC in improving

1. Overall cardiovascular disease (including stroke) risk at 6 months post-randomisation based on the LS7 compared to Baseline

2. Individual LS7 behavioural risk factors at 3-, 6- 9- and 12- months post-randomisation compared to Baseline
3. Awareness about stroke symptoms, risk factors and their management 6- and 12- months post-randomisation compared to Baseline
4. Quality of life, at 6- and 12- months post-randomisation compared to Baseline
5. Cognitive outcomes at 6-, and 12- months post-randomisation compared to Baseline
6. Mood outcomes compared to Baseline
7. Adherence to CVD medications at 3, 6-, and 9 and 12- months compared to Baseline
8. CVD/adverse outcomes at 12 months post randomisation.
9. Health and service costs at 12 months post randomisation
10. Productivity status at 12 months post randomisation

Secondary outcomes are:

1. systolic blood pressure, total cholesterol, blood glucose at 6-months post randomisation
2. change in proportion of participants in 'high' and 'intermediate' to 'low' risk on LS7 at 6-months post randomisation
3. Stroke risk from Stroke Riskometer – 5- year absolute and relative risk at 6- and 12-months post randomisation
4. Quality of life (EQ5D) at 6-months post randomisation
5. Stroke awareness at 6- and 12-months post randomisation
6. Cognitive assessment score (Montreal Cognitive Assessment)
7. Medication adherence (Self-Efficacy For Appropriate Medication Use Scale (SEAMS)
8. CVD adverse outcomes (fatal and nonfatal stroke, TIA, myocardial infarction and heart failure, death attributable to CVD and all-cause mortality)
9. Healthcare and community service costs assessed as self-reported service use questionnaire at follow up. Productivity status will be self-reported and will include items regarding status (e.g., paid work, voluntary work, homemaker, student, unemployed), hours (e.g., full/part time), compared to hospitalisation pre-stroke status.

PARTICIPANT RECRUITMENT

12. INCLUSION CRITERIA

1. People aged between18 years to 75 years diagnosed with TIA or first-ever minor stroke (excluding subarachnoid haemorrhage (SAH)) (National Institutes of Health Stroke Scale (NIHSS) score ≤ 4) and/or modified Rankin Scale (mRS) score 0-2 at discharge [1] in the past 6 weeks

2. Admitted to one of the three Auckland based hospitals or identified via primary care for minor stroke or TIA
3. Who can converse in English
4. Provides written informed consent
5. Exclusion criteria
6. History of major stroke or myocardial infarction (verified through Clinical Portal medical records)
7. Planned carotid endarterectomy
8. Life-threatening conditions with a life-expectancy <5 years
9. Current (in the past year) significant clinical depression/anxiety (Hospital Anxiety and Depression questionnaire (HADS) ≤ 11 in either or both the depression and anxiety domains) (either in clinical records or at screening) OR psychiatric conditions (based on medical records),
10. History (past year) of alcohol or drug/substance abuse
11. Dependent on others (living in a rest-home/care facility)
12. Significant cognitive impairment or pre-existing diagnosis of dementia e.g. ACE-R ≤82 (from clinical records), or at screening (MoCA (<26))
13. Participation in another RCT

The majority of the inclusion and exclusion criteria will be determined by means of medical record/clinical portal screening, completed by hospital based research staff. If all the relevant information is not available, the initial section of the Baseline assessment will allow further screening to check for remaining criteria (e.g. cognitive impiarment or abnormal mood). Exclusion due to significant anxiety and depression [58, 59] or cognitive impairment [60] are necessary in order to recruit participants who will be able to engage effectively with the study over a period of 12 months.

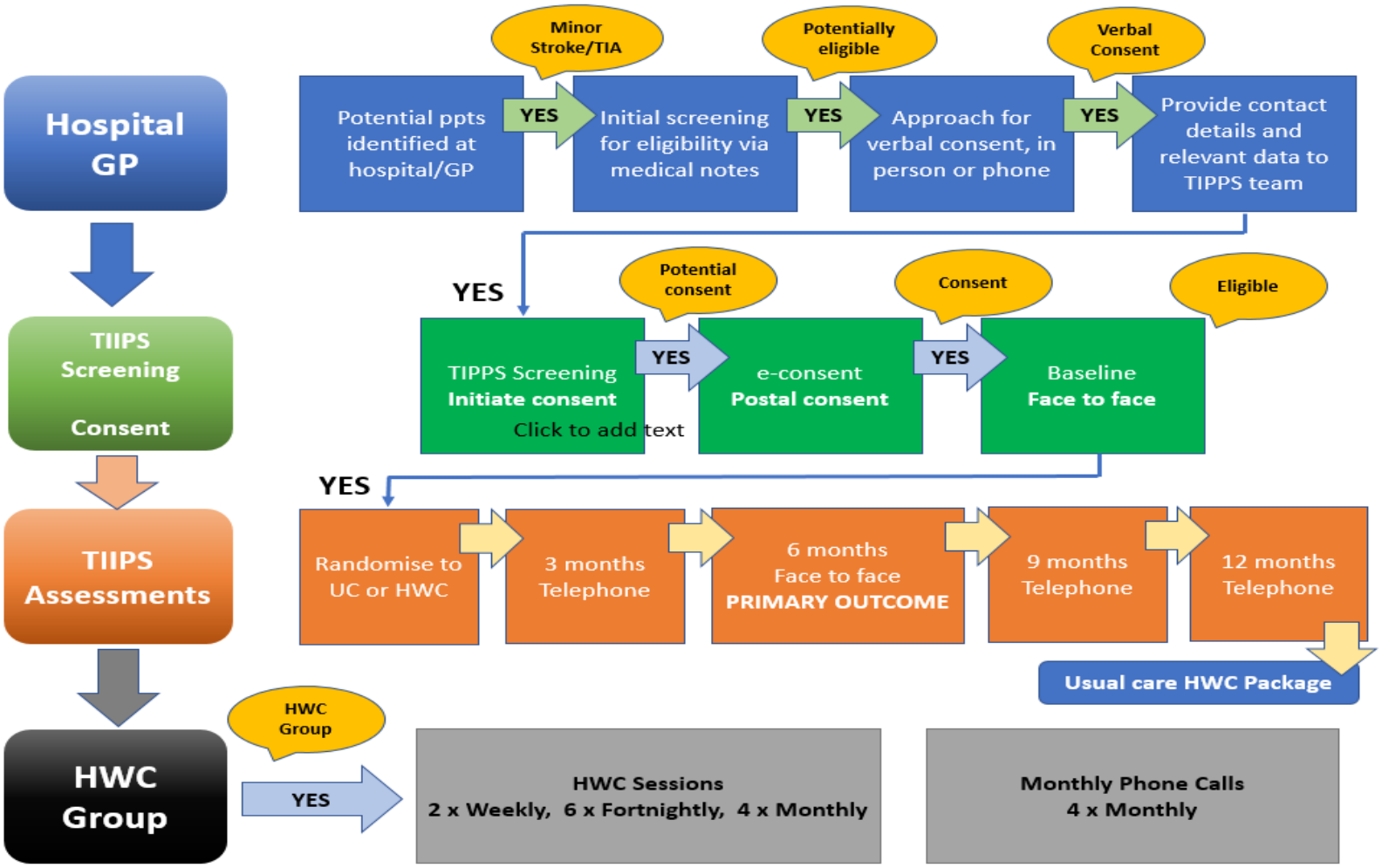
13. SCREENING

Screening will happen in two stages (see Flowchart Figure 1).

Potential participants initially screened for eligibility based on the study inclusion and exclusion criteria (See **Appendix C** Case Record Forms, Screening Form) from hospital admission information at the public hospitals in Auckland. Those deemed to be potentially suitable will contacted by a hospital-based research assistant to briefly explain the study and for verbal consent to be contacted by a study research assistant.

Those who agree to be contacted will be telephoned by a study research assistant (RA). The RA will provide a brief description of the study, and the screening form will be reviewed to confirm eligibility based available information. If a person is found to be ineligible, the reason will be explained and the participant thanked for their interest in participating in the trial.

14. STUDY PROCESSES FLOWCHART



STUDY PROCESSES

15. RECRUITMENT SITES

1. Auckland City Hospital, Grafton, Auckland City
2. Middlemore Hospital, Otahuhu, Auckland
3. Northshore Hospital, Takapuna, Auckland
4. Waitakere Hospital, Henderson, Auckland
5. GP clinics, Auckland Supercity

16. PARTICIPANT RECRUITMENT PROCEDURES

Trial participants will predominantly be recruited through hospital referrals. **H**ospital based RAs (**H**RA) based in the stroke wards and HRAs who have access to the Clinical portal and patient medical records will conduct daily searches of presentations and admissions to hospital with any diagnoses suggestive of stroke and/or TIA. For those patients with a diagnosis of stroke or TIA as confirmed by their treating physician, the RA will further search their records for the main eligibility criteria as listed in section 2.1. Those who meet the criteria will be approached either in-person if still in hospital or by telephone if discharged, by the HRA, for verbal consent to be contacted by a study RA for further information about the study. The HRA will provide the name and contact details (usually a landline or mobile number) of those who agree to be contacted to the **c**ommunity RA (**C**RA). The number of people who meet the initial screening criteria will be registered in the study database. Potential participants who are identified through GP practices will be approached by the GP or clinic nurse for verbal consent to approach the patient for their interest in the study. Those who consent to be contacted will be telephoned by a CRA in a similar manner as for hospital referrals. Confirmation of TIA/stroke diagnoses will be conducted by checking medical records and/or by the study neurologists.

17. CONSENTING

The CRA will contact those who have provide verbal consent for initial contact, will be telephoned by a CRA to explain the study in detail and to answer any questions. Participants will be informed of their choice to participate and to withdraw at any time, will have a chance to ask any questions. Following this, those who agree to participate will be asked to send a signed copy of the PISC to the research team via post, e-mail or electronic scanning (e-consent). The signed consent form will be

countersigned by a research assistant as the person who explained the study to the participant. A copy of the signed consent form will be retained by the study participant, and an e-copy will be retained by the study team in the REDCap database. Eligible participants will be registered on the TIIPS REDCap database and assigned a unique participant ID.

18. ASSESSMENTS

There will be a total of five assessments: baseline, 3, 6, 9 and 12 months. Eligible participants will be contacted by CRAs to book appointments for assessments. The baseline and 6- month assessments will be conducted face to face to allow the measurement of the primary outcome metrics for the LS7 (height, weight, blood pressure, blood glucose and blood cholesterol) as well as cognitive assessments. The 3-, 9- and 12-months assessments will be conducted over telephone, at a suitable time.

For face-to-face assessments, the participant will have the option of attending a clinic at one of the three locations at the AUT campuses (AUT North, City or South). Participants travelling to clinics will be provided a petrol or supermarket voucher (NZ $20) for parking or travel costs.

Participants who are unable to travel to clinic sites will be offered a home visit to conduct the baseline and 6-month assessments.

19. COVID-19 OUTBREAK RELATED RESTRICTIONS

The research Protocol may need to be amended should there be a COVID outbreak and government-imposed restrictions. The pandemic may result in the reduced ability to recruit participants, and conduct face to face assessments. The trial will follow the NZ government guidelines and AUT policies. The ethics committees will be informed of any significant changes and approvals for amendments will be sought as required.

COVID-10 Protection Framework Requirements

Research guidelines at AUT at the Red level of the Protection Framework are outlines at the weblink https://auti.aut.ac.nz/resch/duringcovid-19/Pages/default.aspx. All RAs who will be contacting participants in-person will be required to be fully vaccinated against COVID-19, and will

be required to wear medical masks during all in-person assessments. Gloves and eye protection will be worn during blood sample collection.

3.5 CASE RECORD FORMS AND QUESTIONNAIRES

20. LIST OF QUESTIONNAIRES

Table 1. List of outcome measures

Outcome measure	Baseline	3	6	12
Demographic Factors: Age, sex, ethnicity, employment, education, marital status	✓			
Event type - stroke and pathological subtypes, or TIA and event date (physician diagnosed)	✓			
Hospitalization details: hospital, date of admission, date of discharge	✓			
Event details (revascularization and planned procedures) from medical records	✓			
Hospital Anxiety and Depression Scale	✓	✓	✓	✓
Stroke awareness (recognition of risk factors, knowledge of actions) [61]	✓	✓	✓	✓
Quality of life (EQ-5D-5L) [62]	✓		✓	
Cognitive functioning by MoCA [63]	✓		✓	
Medication adherence and self-efficacy (SEAMS) REF)	✓	✓	✓	✓
Physical measurements (non-fasting blood test, SBP/DBP, BMI, HR)*	✓		✓	
Absolute and relative 5-year risk of stroke (as measured by Stroke Riskometer app)	✓		✓	
Lifestyle factors (Diet score, physical activity, smoking, alcohol)	✓	✓	✓	✓
CVD outcomes, recurrent events, hospitalisation (stroke, CVD events) self-report and/or from clinical records	✓	✓	✓	✓
Health and Service costs: NMDS (NZ)			✓	✓
Productivity level NMDS (NZ)	✓	✓	✓	✓
Participant feedback questionnaire – Intervention group only	✓	✓	✓	✓

Items will include demographic factors, medical history, lifestyle risk factors, awareness of stroke risk factors, warning signs, symptoms and actions;[64] depression screening test (Hospital Anxiety and Depression Scale) health related quality of life (EQ-5D-5L),[62] health-care resource

use questionnaire, cognitive assessment (Montreal Cognitive Assessment MoCA) and participant satisfaction questionnaires. See 2 for details of measures collected at each timepoint. Life's Simple 7 score will be calculated from corresponding measurements of smoking, BMI, physical activity, healthy diet score, blood total cholesterol, glucose level and BP.[37]

Table 2. Life's Simple 7

Modifiable factors	**Poor health**	**Intermediate health**	**Ideal health**
Smoking status	Current smoker	Former ≤ 12 months	Never or quit > 12 months
Body mass index	≥ 30 kg/m^2	25–29.9 kg/m^2	< 25 kg/m^2
Physical activity	No physical activity	1–3 times, less than 2.5 hours per week	≥ 4 times per week, 2.5 hours or more
Healthy diet score	0–1 component	2–3 components	4–5 components
Total cholesterol	≥ 240 mg/dL	200–239 mg/dL or treated to goal	< 200 mg/dL
Blood pressure	SBP ≥ 140 mm Hg or DBP ≥ 90 mm Hg	SBP 120–139 mm Hg or DBP 80–89 mm Hg or treated to goal	SBP < 120 mm Hg and DBP < 80 mm Hg
Blood glucose	≥ 126 mg/dL	100–125 mg/dL or treated to goal	< 100 mg/dL

ASSESSMENT INFORMATION

The Primary Outcome measure of **blood pressure** will be collected as part of the LS7 questionnaire. The LS7 is a simple scoring system to assess cardiovascular health with scores ranging from 0 to 14, with the overall LS7 score categorised as inadequate (0–4), average (5–9), or optimum (10–14) cardiovascular health. These are; blood pressure, cholesterol, glucose, body mass index, smoking, physical activity, and diet.[37] The total LS7 score as well as individual LS7 items apart from blood pressure are secondary outcomes.

The Life's Simple 7 scale

Table 3. Definitions of the LS7 categories *

Life's Simple 7	Level of Cardiovascular Health		
	Poor	Intermediate	Ideal
Lifestyle Factors			
Body mass index, kg/m^2	≥30	25.0–29.9	<25
Physical activity, min/day	0 MVPA	>0 – <150 MPA or MVPA >0 to <75 VPA	≥150 MPA or MVPA ≥75 VPA
Healthy diet score	0–1 components	2–3 components	4–5 components
Cigarette smoking	Current	Quit <12 months ago	Never or quit >12 mo
Medical risk factors			
Blood pressure, mmHg	≥140/≥80	120 – 139/80–89 or <120/<90 with med	<120/<80 no med
Total cholesterol, mg/dL	≥240	200–239 or <200 with medication	<200
Fasting blood glucose, mg/dL	≥126	100–125	<100
Glycosylated Hemoglobin, %	≥6.5 or taking diabetes med	5.7–6.4	<5.7

M, moderate; V, vigorous; PA, physical activity.

(i) Fruits and vegetables ≥4.5 cups/day; (ii) Fish 3.5-oz servings (preferably oily fish) ≥2 servings/week; (iii) Sodium <1500 mg/day; (iv) Sweets/sugar-sweetened beverages ≤450 kcal (36 oz)/week; (v) Whole grains (1.1 g of fiber in 10 g of carbohydrates), 1-oz-equivalent servings ≥3 servings/day.

*Note: Fasting blood glucose in mmol/l is ≥7.00 (poor), 5.55–6.99 (adequate) and <5.55 (optimum). Plasma total cholesterol, mmol/l≥ 6.22(poor), 5.18–6.21 (adequate) < 5.18(optimum).

Hospital Anxiety and Depression Scale (HADS)

The HADS is a commonly used scale to identify anxiety and depression disorders, including stroke and TIA patients [65-67]. The scale has seven items for depression and seven items for anxiety, with a total possible score of 0-21 for each, with 0-7 being = normal, 8-10 – borderline abnormal, and 11-21 = abnormal. As part of the screening for TIIPS, those who score ≥11 on either the depression or anxiety items will not be eligible to participate in the trial.

Stroke Awareness questionnaire

Stroke awareness is an essential aspect of stroke prevention. Being aware of stroke risk factors allows individuals to make lifestyle changes. Being aware of stroke signs and symptoms allows individuals to recognise the signs if they or someone they know experience stroke and action a call to emergency services/healthcare. The stroke awareness questionnaire is adapted from an Australian telephone community survey [68] to determine baseline knowledge regarding stroke risk factors, symptoms, treatment, and information resources.[64]

Montreal Cognitive Assessment

The Montreal Cognitive Assessment (MoCA) [63] was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. Time to administer the MoCA is approximately 10 minutes. The total possible score is 30 points; a score of 26 or above is considered normal.

Modified Rankin Scale (mRS).

The modified Rankin Scale (mRS) is commonly used in the stroke setting as a scale for assessing the level of disability or dependence in daily activities.[69] It is widely used in stroke clinical trials to assess improvements in disability levels. The scale ranges from 0 to 6, with 0 denoting no symptoms at all, to 6 for death. The Figure below shows the individual items of the mRS. In this study, those participants with an mRS score of 0-2, denoting independence in all personal activities without assistance, will be eligible for the trial.

Self-Efficacy For Appropriate Medication Use Scale (SEAMS)

SEAMS is a self-efficacy scale for medication adherence in chronic disease management that can be used in patients with a broad range of literacy skills.[70] It is a reliable and valid instrument for assessing medication self-efficacy in chronic disease management. Participants are asked to choose their level of confidence in taking medications correctly under different circumstances (1 = not confident, 2 = somewhat confident, and 3 = very confident). It was designed for patients with low literacy. The total score ranges from 13 to 39 where low scores indicate a low level of confidence and high scores indicate a high level of confidence. The SEAMs questionnaire has been used in a range of chronic condition settings such as secondary prevention of cardiovascular diseases. [71-73]

Participant Satisfaction with Life

The Cantril's ladder[74] is a self-reported subjective measure of Satisfaction with life two item scale is a simple ladder scale asks respondents to think of a ladder, with their best possible life being a 10, and the worst possible life being a 0. They are then asked to rate their own current lives on that 0 to 10 scale. Participants are also asked to imagine their life in the best possible light and to describe their hopes and wishes for the future. Scoring: Low <6 points, Medium 6–7 points, and

High 8 points. This is used in several studies including older populations as a measure of life satisfaction. [75, 76]

The Satisfaction with Life Scale [77] [78]is a five item scale to measure general life satisfaction and subjective well-being, and is used in chronic conditions such as Parkinson's disease. [79]

Stroke Riskometer stroke risk assessment

The validated Stroke Riskometer is a mobile application that is free to download from App stores. The Stroke Riskometer App [80] is a novel, evidence-based app for the primary prevention of stroke. The App incorporates several evidence-based tools to promote behaviour change aligned with internationally recognised stroke prevention guidelines.[81] These include:

- Provision of feedback on *absolute* risk of stroke within the next 5 to 10 years *and* compares a person's *relative* risk with those of a person of the same age and sex without risk. This approach has been demonstrated to motivate behaviour change when used in conjunction with other methods.[82]
- Employs *tailored self-management* strategies including goal setting to engage the person in behaviour modification
- Includes *information on stroke risk factors and warning signs* aligned with the internationally relevant Face, Arm, Speech, Time (FAST) international mass media campaign.
- Uses *reminders*, known as "push notifications", to prompt users to achieve their goals. Such reminders have been shown to increase adherence to programs.[83]

Health and Service Use and Productivity level

The net costs and benefits of the intervention compared to the control will be described and reported in accordance with the Consolidated Health Economic Evaluation Reporting Guidelines (CHEERS).[84] For each intervention arm, the probability of resource use and associated costs will be reported. Cost estimates will be presented in terms of direct costs (e.g. healthcare), indirect costs (e.g. lost productivity) and out-of-pocket costs. Unit prices for resources utilised will be sourced from the most appropriate and up-to-date source (PHARMAC). Costs will be measured in real prices for the reference year (e.g. 2023). Where prices in 2023 are unavailable, adjustment to the real price will be made using the published health sector specific deflator/inflators.

RANDOMISATION

Randomisation will be conducted in REDCap. On completion of the baseline assessment, the study manager will randomise participants into HWC (n=180) or UC (n=180). Stratified minimisation randomisation will be used to balance prognostic factors: age (<55, ≥55 years, sex (Male, Female), ethnicity (European, Pacific, Māori, Asian and MELAA (Middle Eastern, Latin American and African).

Randomisation Procedure

The randomisation form in REDCap will be a hidden form, visible only to the study managers and data manager. The research assistants will not have access to the randomisation form. The randomisation parameters will be predefined, the stratified randomisation module will be selected, and the strata will be selected as: age (<55, ≥55 years), sex (M, F); and four ethnicity categories (1) European, (2) Pacific, (3) Māori, (4) Asian and MELAA (Middle Eastern, Latin American and African). The Dashboard display will show the allocation as HWC or Usual Care.

PROCESS FOR PHYSICAL MEASUREMENTS

21. STUDY EQUIPMENT:

- Cardiocheck blood test kit
- Omron Blood pressure monitor
- Stadiometer
- Weight scales
- Gloves
- Medical Masks
- Hand sanitizers and wipes
- Biohazard waste bins

Participants will be requested to come in light clothing and will be asked to remove their shoes for height and weight measurement. Measures will include, in this order, BP measured after 10 minutes of rest using a Omron digital blood pressure monitor and European Society for Cardiology guidelines,[85] height with a stadiometer, weight with Omron digital scale, a capillary blood sample using a single use lancet and capillary tube will be used with a Cardiochek point of care monitor to

obtain non-fasting glucose, total, HDL and LDL cholesterol and triglyceride levels. Assessments should take 30 minutes.

People identified as having high risk levels of BP will be encouraged to seek medical attention for further management. Please refer to the Blood Pressure Assessment section in Appendix A for further information (systolic BP reading over 220 mmHg or diastolic BP reading over 140 mmHg requires immediate medical attention: systolic reading over 180 or diastolic reading over 110 require the participant to seek medical advice in the next 48 hours).

THE HEALTH AND WELLNESS COACHING INTERVENTION

22. TRAINING THE COACHES

Research staff will attend an intensive 4-week coaching course, at Momentum Coaching (www.coachmomentum.co.nz), with two sessions in the first two weeks and 4 which includes training in core coaching competencies and code of ethics, developed by the International Coach Federation (ICF) to support greater understanding of the skills and approaches used in the coaching profession. ICF coaching is an internationally recognized approach effectively used in various settings,[86] including our previously accomplished primary stroke prevention trial.[87] Coaches will receive regular group supervision, facilitated by a registered ICF coach, using a small group approach.[87] This model increases the capacity of the team to think from multiple perspectives, translating diverse experiences and issues to the group.

23. TRAINING MATERIALS

The coaches will be provided with relevant materials during training. The training is outlined as below:

Day 1:

1. Establish group rapport, practicalities e.g. Paperwork and safety procedures. Each person introduces themselves, share their interest in the project.

2. Develop the group contract

3. a. Define Life Coaching, increase understanding of differences between Coaching, Counselling, Psychotherapy, Mentoring and Consulting

4. Recognise coaching attributes

5. Explain and discuss the elements of the Co-Active, give group feedback.

6. a. Identify and be able understand the 3 levels of listening. Practice new listening skills.

7. a. Explain and demonstrate the Circle of Life tool, practise coaching in pairs, in whole group acknowledge each coach for the competencies done well in coaching practice, each person identify one competency that could be done better.

Day 2:

1. Demonstrate coaching by listening and responding in a coach-like manner in response to group members' sharing of breakthroughs and challenges of the week. Participate in group discussions, giving and receiving feedback. Engage in clearing personal issues that could otherwise prohibit full participation in session.

2. Discuss the importance of the Core Competencies and how we use them as the Foundation in coaching.

3. Recognise and identify various types of coaching questions, define specific types of questions and explain the effect of various questions types, differentiate effective and ineffective question types.

4. Explain, discuss and demonstrate Coaching Skills such as: paraphrasing, reframing, clarifying, analogy and metaphor, distinctions, bottom-lining, intruding, metaview, championing and challenging.

5. Practise coaching in pairs. In whole group acknowledge each coach for the competencies done well in coaching practice. Each person identify one competency that could be done better.

Day 3:

1. Define Personal Values. Understand the importance of Values in a coaching forum in order to facilitate learning and results from a deep understanding of self. Practise coaching in pairs using Personal Values Card Sort. Acknowledge each other for competencies demonstrated and name where improvement is possible.

2. Introduce a variety of Assessment tools and discuss the benefits of each. Discuss how to interpret the information attained and how to create a coaching plan most relevant to each specific clients' needs.

3. Name and demonstrate examples of the SMARTPP GOALS components. Establish a variety of goal-setting tools for use in coaching sessions. Become practiced at utilising a variety of methods/tools for goal- setting.

Day 4:

1. Experience the psycho-geometric profiling exercise (Susan Dellinger PhD). Identify and recognise own preferences in relation to psycho-geometric profiling, apply this tool in coaching session, gain awareness of uses of this tool in coaching sessions.

2. Demonstrate the use of the Focus Framework as a goal-setting Strategy, Remediation resource for under-achievement or Time-management resource.

3. Introduce the Decisional Balance framework as a resource for ambivalence or indecision. Practise coaching each other, give feedback on coaching.

Day 5:

1. Gain knowledge and understanding of the MOMENTUM Model of Coaching. Explain how it aligns with the Core Competencies.

2. Introduce the Coaching Evaluation Form. Discuss the use of it in conjunction to ongoing supervision.

3. Discuss the importance of identifying beliefs in coaching in the context of how they can help or hinder achievement. Introduce brainstorming as a useful resource in uncovering hidden beliefs.

4. Extend the topic of Beliefs into the concept of Self-Talk, The Inner Critic / Ally. Demonstrate the use of the resources. In pairs, practice coaching using the Self-Talk concept. Group feedback.

5. Understand the powerful impact of 'metaview' coaching by identifying and coaching PATTERNS (instead of separate scenarios). Demonstrate the process by using the Recurring Pattern Intervention concept, using one of the trainees' personal examples. Group feedback.

6. Coaching practice in 3's. Coach, coachee, observer.

Day 6:

1. Brainstorm all coaching knowledge covered on the course to-date. (Including the 8 Main Competencies)

2. Introduce the Relationship Overview resource. Recap Momentum Model.

3. Coaches practise coaching in 3's, feedback as a group. Practise filling out Coaching Evaluation Form

4. Introduce the Time Management resources: DDDS, Ideal Weekly Planner, Daily Prioritising, Weekly Prioritising, Weekly Planner with roll-over.

5. Discuss and agree upon Consistency of Coaching Structures and Toolkit for measurement, Supervision Structure.

24. OUTLINE OF SESSIONS

Topic	Aims/Strategies for the first session (in-person)
Session opening	Introductions, setting expectations, discussing the study and confidentiality, setting agenda
Health risk assessment	Focus on positive and strengths, values and readiness to change for participant, make appropriate referrals
Wellness vision	Dreams and vision of self and wellbeing in 3-5 years, identify values and motivators
Three month goals	Mid-term goals for consistent behaviours to be doing in three months' time, consider barriers and supports
Weekly goal(s)	First experiment and short-term step forward in an area that the participant is motivated and ready to change
Session close	Affirm belief in the participant and their autonomy, review how the process can be improved, schedule next session
Topic	Aims/Strategies for the first session (over the telephone or in-person, if required)

Session opening	Check in, highlight of the week, set the agenda
Review weekly goals	Focus on positive, explore full experience, reflect participant's strengths and values. Review vision and three month goals. Confirm the vision and three month goals are still where the client is heading, only done once per month
General moment	Participant identifies a target behaviour to address, explore ideal situation, best past experience, values and strengths, and brainstorm ideas
Set weekly goals	Next step in behaviour change in an area the participant is motivated and ready to change, SMART (Specific, Measurable, Action-based, Realistic and Time-bound) goals
Session close	Affirm belief in the participant and their autonomy, review how the process can be improved, schedule next session (if relevant)

Data from the ARCOS V study on stroke risk factor prevalence and significance by age, sex and ethnicity, life satisfaction and other measures will guide the emphasis of the intervention on which particular health behaviours to focus on. As such, providing/referring to educational material is relevant to this model, including information booklets from the Heart and Stroke Foundation (https://www.heartfoundation.org.nz/resources) which include recommendations and guidelines on duration and frequency of exercise, weight loss, healthy eating, smoking cessation, and reducing alcohol intake,[88] and information about the free Stroke Riskometer mobile app (for stroke awareness and risk assessment, https://nisan.aut.ac.nz/Stroke-Riskometer). This is also in line with recent evidence recommending that RCT's for secondary disease prevention in TIA/minor stroke should include a combination of educational and behavioural interventions.[89-91]

25. COACHING TRACKING AND COMPLIANCE WITH SESSION ATTENDANCE

The compliance with health coaching will be assessed by completion of records on session attendance on REDCap. Sessions will be recorded as completed or missed and reasons for missed sessions will be recorded.

Coaching evaluation

At the completion of each session, health coaches will self-evaluate the session using the Coaching Evaluation questionnaire on REDCap. In addition, a random 10% of recordings will be evaluated by the coach trainer and supervisor to track the quality of coaching and identify any potential areas of improvement. This will be used to guide ongoing supervision of the coaches.

Addition Information to track study procedures on study completion
Feedback from health coaches on implementation of intervention
Number of participants who are (1) eligible, (2) recruited, (3) randomised, (4) withdrawn or lost to follow-up
Number of coaching sessions carried out in intervention group
Completion rate of case record forms; (1) number of forms completed; (2) average completion of individual forms

26. ONGOING SUPERVISION

On completion of the initial 6 sessions, coaches will be asked to practice coaching with each other, and friends and family. Once coaching with study participants commences, the coaching trainer will provide regular supervision and advice by way of a monthly coaching supervision meeting. Here coaches will share their experiences and receive feedback and advise on handling various scenarios. The meetings will be audio-recorded for training purposes (to be shared withing the coaching team only).

27. REPORTING AND COMPLIANCE OF INTERVENTION DELIVERY

At the end of each coaching session, coaches will complete the coaching compliance questionnaire on REDCap. This will record when the session took place, the length of the session, the coaches self-rating of how well they judged the session to have gone, and any relevant notes as free text. In addition, a random 10% of interviews will be reviewed by the health coach trainer and given a rating for compliance. If a session was missed, the reasons for this and the plans to make up for this missed session will be recorded.

The intervention will combine educational material and intensive HWC coaching. Participants allocated to the HWC group will have 12 individual coaching sessions over 6 months with trained HWC coaches, of which 4 sessions are carried out weekly, 6 sessions fortnightly and the remaining two sessions monthly. The initial two sessions and the final session will be conducted face-to-face and remaining coaching sessions via telephone. Between the final coaching session and the 12-month assessment, HWC participants will receive a short monthly telephone call from their coach to encourage maintenance of behaviour change. Coaching sessions will take up to 1 hour initially, with later sessions lasting about 30 minutes. IG participants will be provided with tools to assist with behaviour changes.

28. ASSESSMENT OF COACHING AGAINST ICF CORE COMPETENCIES

The coaching sessions will be evaluated by the coaching trainer against the following competencies (as listed in the case record forms):

Demonstrates Ethical Practice. Definition: Understands and consistently applies coaching ethics and standards of coaching

Embodies a Coaching Mindset. Definition: Develops and maintains a mindset that is open, curious, flexible and client-centered

Establishes and Maintains Agreements. Definition: Partners with the client and relevant stakeholders to create clear agreements about the coaching relationship, process, plans and goals. Establishes agreements for the overall coaching engagement as well as those for each coaching session.

Cultivates Trust and Safety. Definition: Partners with the client to create a safe, supportive environment that allows the client to share freely. Maintains a relationship of mutual respect and trust.

Maintains Presence. Definition: Is fully conscious and present with the client, employing a style that is open, flexible, grounded and confident

USUAL CARE

Participants in the UC group will be informed of their group assignment post randomisation. UC participants will receive telephone assessments at 3, 9 and 12 months, and a face-to-face assessment at 6 months post randomisation. They will not be informed about the HWC intervention.

DATA COLLECTION AND FOLLOW-UP

Research assistants (RAs) will be provided training and ongoing supervision to conduct assessments. All assessments will be conducted in a standardised manner in accordance the Protocol. The Project Manager will conduct the randomisation and assign cases to the RAs. RAs will be blinded to the treatment group.

29. OUTCOME ASSESSMENTS (SEE TABLE 1 FOR THE FULL LIST OF OUTCOMES)

Baseline: The baseline assessment will be conducted prior to randomisation, and within 6 weeks of the index event. The Baseline assessment will be conducted in-person. The initial part of the assessment will be used to determine the full eligibility of the participant for the TIIPS trial. The full assessment will be completed for eligible participants only, and will include all measures required to analyse the primary and secondary outcomes

3 months (plus or minus 2 weeks from date of randomisation): The assessment will be conducted by telephone only, and will assess secondary outcomes.

6 months (primary outcome) (plus or minus 2 weeks from date of randomisation): The 6- month assessment be conducted in-person and will re-assess the primary outcome as well as secondary outcomes.

9 months (plus or minus 2 weeks from date of randomisation): The assessment will be conducted by telephone only, and will assess secondary outcomes.

12 months (plus or minus 2 weeks from date of randomisation): The assessment will be conducted by telephone only, and will assess secondary outcomes.

30. PRIMARY END POINTS

The primary end-point will be measured at 6 months post randomisation. The primary end-point will be the difference in the mean change in systolic blood pressure at 6 months post-randomisation between UC and HWC.

31. SECONDARY END POINTS

Secondary outcomes include: (1) difference in the mean change in the LS7 scale score at 6 months post-randomisation between UC and HWC (2) the change in individual lifestyle components of the LS7 scale (BMI, smoking, physical activity, and diet) at 6 and 12 months; (2) diastolic BP (mmHg); (3) quality of life (EQ-5D-5L, (4) awareness of stroke risk factors and warning signs, (5) medication adherence (6) cognitive outcomes (7) adverse events including hospitalisations; and (6) health service use and costs.

The LS7 scale includes BP, cholesterol, blood glucose, BMI, smoking, physical activity, and diet. The score of LS7 will be calculated by providing 2 points for ideal, 1 point for intermediate, and 0

points for poor status of each of the 7 individual factors.[92, 93] Ideal levels of health factors were: non-smoker or quit >1 year ago; BMI <25 kg/m2; BP <120/80 mm Hg; total cholesterol <200 mg/dL; fasting blood glucose <100 mg/dL; ≥150 min/week of physical activity; and a healthy diet score (≥4 components). Study participants who were treated to target levels for hypercholesterolemia, hypertension, or diabetes mellitus were classified as intermediate for the respective health factor. Thus, the LS7 summary score will range from 0 to a maximum of 14 points, with a higher score indicating healthier status.

WITHDRAWAL

Participants will be able withdraw at any time during the trial without needing to provide a reason. Once a participant has withdrawn, there will be no further follow-up phone calls and data collection. The RA will record the withdrawal and the approximate date of withdrawal, and the reasons for withdrawal if provided. Participants will be informed that any information about them has already been collected, analysed and/or included in a publication by the study, will not be able to be destroyed. This will be outlined in the Participant Information Sheet and Consent Form. A participant may be withdrawn from the TIIPS trial if:

1. The participant makes a voluntary decision to withdraw from the trial.
2. The trial is terminated.

PROTOCOL VIOLATIONS

Any significant protocol violation must be documented and reported to the Study Manager and Operations Committee. A protocol violation is defined as a failure to adhere to the pre-specified trial protocol. Examples are ineligible participants who were included in the trial by mistake and those for whom the intervention or other procedure differed from that outlined in the protocol.

The study manager will maintain all protocol violations, and amendments/changes to the study protocol and operational decisions about the study.

STATISTICAL ANALYSES

32. POWER CALCULATION

The sample of 360 participants will provide a simulated 90% statistical power (two sided α=0.05 , β =0.10) to detect a clinically significant 6 mmHg (SD±20) difference in systolic blood pressure change at 6 months post-randomisation, assuming 20% non-compliance/loss to follow-up.

Based on our RIBURST data (a observational stroke risk study)[94] data in NZ general population (n=1265, with 0.07% incident stroke or TIA), the required sample size (n=360) will also provide 90% power (2-sided alpha) to detect 20% relative risk reduction in 5-year absolute risk of stroke. The estimated 5-year risk of stroke after TIA and minor stroke in NZ appeared to be greater than that in Europe,[4] likely due to greater risk of stroke in Māori and Pacific people constituting 20% of the NZ RIBURST Study population.

33. DESCRIPTIVE ANALYSES

These will be reported overall and compared between HWC and usual care groups using parametric and non-parametric techniques, depending on the distribution of the data. Means (95% CI), standard deviations, medians and quartiles will be reported for continuous risk factor variables while cross-tabulations will be reported for categorical risk factor variables.

34. INFERENTIAL ANALYSES

Intention to treat (ITT)[95] analyses and per protocol analysis will be used. To address the primary hypothesis ANCOVA will be used to compare the difference in systolic blood pressure at 6-months post randomisation between the HWC and usual care groups, accounting for baseline stratification factors: (age, gender and ethnicity), referral centres, geographical region and known influential clinical characteristics (e.g., comorbidities). To address the secondary hypotheses linear mixed effects (LME) repeated measures models will be used to investigate the differences in (1) adherence to medication (2) health-related quality of life (3) incidence of new vascular events including death (4) life satisfaction (5) cognition (6) mood) and (7) health service utilisation costs between the HWC and Usual care groups, and by ethnicity (sub-group analysis) at 6-months (plus

life-style and adherence at 1-year post-randomisation. These LMEs will model effect of time (baseline, 3-, 6- 9- and 12-months (medication adherence, lifestyle and awareness at only 12 months), post-randomisation whilst accounting for key demographic stratification factors known to confound with outcomes. Any data not collected within 6-weeks of the follow-up points will be classified as missing data. Baseline covariates of age, sex, most recent blood pressure measure and any additional variables predictive of outcome data will be included in the imputation model.[46] The reasons for missingness and the reasons will be recorded and accounted for. Sensitivity analyses will be conducted to test the assumptions of the model (including a complete case analysis in which only subjects with complete data are included). Familywise error control will be used to account for the multiplicity of tests. Inferences will be based on a 5% significance level and two-sided alternatives.

For the analysis of - CVD adverse outcomes (fatal and nonfatal stroke, TIA, myocardial infarction and heart failure, death attributable to CVD and all-cause mortality), we will use Kaplan-Meier life-test and estimate the hazard ratios (HR) and adjusted HR using time-to-event Cox regression analysis. Time to event analysis will include recurrent events and time-dependant variables where appropriate.

Competing risk method will also be applied to compare the CVD adverse outcomes between the two interventional groups, accounting for mortality outcome.

35. INTERIM ANALYSES

The need for interim analysis will be the trial SC based on the recruitment rate or if advised by the independent DSMC using stopping guidelines for an effectiveness trial.[96]

SERIOUS ADVERSE EVENTS

All hospitalisations (for any reason) are classified as Serious Adverse Events (SAEs), whether or not they are considered related to the heath coaching intervention and should be reported to TIIPS study Manager or PI by the Research Assistant as soon as possible by completing a serious adverse event form (Appendix C Form S). If a participant is admitted to hospital, they should notify hospital staff that they are in the TIIPS trial. As this is an open label trial, clinical management should continue as usual.

All serious adverse events will be reported regularly to the Data Safety Monitoring Committee (see below). If at any time the DSMC considers there to be definite evidence of an excess of SAEs they will notify the TIIPS Trial Steering Committee of the findings. The Steering Committee will discuss the issues arising and determine the action to be taken. Copies of the reports issued by the DSMC will be available to Coordinating Centre staff.

An adverse event (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Inter-current illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal
- is associated with a serious adverse event
- is associated with clinical signs or symptoms
- leads to additional treatment or to further diagnostic tests
- is considered by the investigator to be of clinical significance

All adverse events that do not meet any of the criteria for serious should be regarded as non-serious adverse events.

DATA SAFETY MANAGEMENT COMMITTEE

An independent Data Safety Monitoring Committee (DSMC) will be established to oversee the overall conduct of the study and ensure the safety of the trial and review of all serious adverse events (SAEs). SAEs will include all hospitalisation, new stroke, heart attack, death, and significant mood issues. Given the low-risk (non-pharmacological, no medical procedures, low-level researcher contact) nature of the intervention, a DSMC will be established and will meet quarterly to ensure safety of the participants and integrity and efficacy of the trial. Members will include clinical experts in stroke and an independent statistician, with an independent Chair appointed. Significant reporting of SAEs will be notified to the Trial Steering Committee of the findings who will discuss the issues arising and determine the action to be taken. A formal DMC charter outlining the remit and role of the DMC and the details of stopping rules for the trial will be drawn before the study commences and will signed off by the DMC before the trial (Appendix B).

HEALTH ECONOMIC EVALUATION

The net costs and benefits of the intervention compared to the control will be described and reported in accordance with the Consolidated Health Economic Evaluation Reporting Guidelines (CHEERS). [97] For each intervention arm, the probability of resource use and associated costs will be reported. Cost estimates will be presented in terms of direct costs (e.g., healthcare), indirect costs (e.g. lost productivity) and out-of-pocket costs. Unit prices for resources utilised will be sourced from the most appropriate and up-to-date source (e.g., PHARMAC). Costs will be measured in actual prices for the reference year (e.g., 2023). Where prices in 2023 are unavailable, adjustment to the actual price will be made using the published health sector specific deflator/inflators. The overall 'Program Costs' (i.e., non-research related costs associated with providing the intervention) will be deducted from the potential cost-offsets from fewer readmissions or other resource savings. Sensitivity and uncertainty (probabilistic multivariable [Monte-Carlo simulated]) analyses to account for variability in point estimates will be performed to assess the robustness of results.

The analysis will include modelling the potential opportunity cost savings from future strokes averted based on changes in risk profile (e.g., change in absolute 5-year risk of stroke or clinically relevant change in LS7 score). An incremental cost/ quality-adjusted life year (QALY) gained will also be calculated. The EQ5D is the most commonly used in economic evaluations to estimate preference-based outcome measure and will be used to calculate QALYs for the cost utility analysis.[62, 98] Threshold and willingness-to-pay analyses, illustrated using cost effectiveness acceptability curves, will be performed to assess uncertainty in the model parameters or a range of different scenarios, to explore under what conditions HWC could be cost effective and yield potential cost offsets/savings. Potential savings will be calculated using a "case-adverted" approach, which estimates the direct and indirect costs savings if the use of HWC leads to annual reduction in stroke incidence. These estimates will be extrapolated to the overall New Zealand population.

TRIAL ORGANISATIONAL STRUCTURE

The TIIPS trial host centre is The National Institute for Stroke and Applied Neurosciences, Auckland University of Technology, Auckland, New Zealand.

36. TRIAL COMMITTEES

The Steering Committee of TIIPS, consists of investigators on the grant with additional invited members. This Committee will view and comment on essential study documents and comment on major changes to the study protocol. This committee has an advisory role and due to its membership including staff from the District Health Boards, ensures liaison with stakeholders. The Committee will meet monthly (or as needed) and has the opportunity to approve all study documentation and procedures, but this does not require a mandate. The Steering Committee is responsible for the overall management of the trial including all aspects of trial design, conduct, analysis and publication, including:

- Trial design and recruitment
- Data management
- Committee coordination
- Ethics committee and Locality applications
- Initiation visits to participating centres
- Monitoring of data quality and adherence to applicable guidelines and regulations
- Statistical analysis
- Preparation of the final report and manuscript of main findings

The Operations Committee will be under the guidance of the Study Co-PI and study Project Manager, and will oversee the day-to-day management of the trial, including

- Participant consent and recruitment
- Protocol and procedures training
- Data entry and management
- Participant communication and queries
- Preparation of reports for the Steering Committee

37. STAFF TRAINING

Research assistants who will be conducting assessments will attend online and in-person training sessions on all aspects of their role, including,

- the design and aims of the TIIPS trial

- Informed consent processes, participant recruitment, and booking appointments
- Data collection and entry on REDCap
- Assessment processes, including physical, cognitive and psychological measures, and completion of individual questionnaires, cultural considerations
- Reporting of adverse events
- Regular attendance of research assistant meetings

ETHICAL CONSIDERATIONS

The study will seek ethical approval for research in human participants through the Health and Disability Ethics Committees (HDECs) (https://ethics.health.govt.nz/). The processes of Informed consent and confidentiality will by informed by the National Ethical Standards for Health and Disability Research and Quality Improvement.

In addition, the study will seek institutional ethical approval from the AUT ethics committee (AUTEC) (https://www.aut.ac.nz/research/researchethics)

Locality Approvals will be sought for each of the District Health Boards (DHBs): Auckland, Waitemata and Counties Manukau, according to their guidelines.

Māori and Pacific cultural consultations will be conducted via the AUT Vision Mātauranga Committee and DHB Māori advisory teams.

DATA MANAGEMENT

The data will be managed by NISAN and stored at AUT University. Physical information (i.e. paper copies) will be kept in locked cabinets in secure offices at AUT. Computerised data will be kept on secure AUT servers. No identifiable data will be stored on cloud or shared via emails. AUT University follows a rigorous process where the data is stored, retained, and disposed in an ethical manner. The information is required to be protected under the NZ Health Information Privacy Code 1994 and NZ Privacy Act 1993. Information will not be shared with any third party.

The data will be kept for a period of 10 years. This is so that we can analyse this data and report it to the participants, agencies, and communities effectively. After 10 years all information will be destroyed by the study manager by deleting records on the REDCap database and shredding the

paper copies. De-identified and aggregated data will be retained to conduct secondary analyses and for data pooling.

Although the participants will share some identifiable information, it will be stored on REDCap in an anonymised fashion and not shared outside the small research team. The participants will also be providing information about their estimated risk of having a stroke in the future. However, this information will not be linked to their identifiable information.

Data capture will be facilitated using REDCap (Research Electronic Data Capture) – a secure web-based application designed specifically for this purpose in a research study setting. REDCap provides 128-bit encryption from client to server, audit trails, easy-to-use forms with real-time field validation, ability to export to a variety of statistical packages, and security features (including user permissions). Two-factor authentication (2FA) is mandated system wide. AUT's ICT department manages and performs daily backups of the local REDCap installation, and appointed research data managers will develop, support and maintain the project's database structure and content.

Although data collection will be conducted via face-to-face manner at specified AUT clinics, data capture will be performed by Research Assistants (RA) using the web-based interface of REDCap. Each RA will have their own REDCap account and will be required to re-authenticate via Google Authenticator or email verification (presently the re-authentication window is 6.5 days). All direct identifiers will be marked accordingly in REDCap – only those users with appropriate training and permissions will be able to export these variables.

REDCap has a comprehensive user rights module that allows the ability to define user roles with specific rights to access forms and functionality and then assign users to each role. Once assigned user roles, the user can only interact with forms and records in a controlled environment. This feature protects unauthorised users from accessing identifiable participant information such as National Health Index (NHI) number, Date of birth (DoB).

Data collected and resulting publications from this study are the property of the National Institute for Stroke and Applied Neurosciences, AUT University.

CASE REPORT FORMS

The study Case Report Form (CRF) is the primary data collection instrument for the study. All data requested on the CRFs must be recorded on REDCap. All missing data must be explained. CRFs are used to record clinical study data and are an integral part of the study and subsequent reports. CRFs must be kept current to reflect subject status at each phase during the course of the

study. The investigator will be responsible for retaining all records pertaining to the study. The CRFs for the TIIPS study as designed in REDCap are listed in Appendix C.

VISION MATAURANGA STATEMENT FOR PROJECT

Vision Mātauranga provisions for this project will ensure that Māori have access to their spiritual realm, their language and protocols throughout the consultation, implementation and reporting phases of this project.

AUT researchers have obligations under the Treaty of Waitangi and AUT's Vision Mātauranga policies to engage with iwi in a culturally safe manner. The values outlined in the AUT Vision Mātauranga policies require all staff to foster a culturally safe environment that promotes whānau support values. All whānau of Māori decent within this study will be able to opt into or out of the Vision Mātauranga provisions.

PUBLICATION POLICIES AND DISSEMINATION PROCESSES

This trial will be registered with https://www.anzctr.org.au/, (Australian New Zealand Trials Registration Number: TBA) an organisation that maintains a database of trials in progress to assist with the synthesis of controlled trials. The main results will be published as a journal article in a relevant journal as well as an internal report for NISAN.

In this context 'publication' refers to all work for intended for dissemination, as well as any poster or oral presentations of materials. The project lead refers to the person wishing to produce material for dissemination.

Steps to take:

As the Principal Investigator has ultimate responsibility for all aspects of the study performance and presentations, the Project Lead needs to discuss a preliminary idea about the proposed publication with the Principal Investigator.

The Project Lead will email their idea(s) to a person responsible for circulation of the Steering Committee agenda or PA of Prof. Valery Feigin (cc'd to the Principal Investigator and Co-Directors of the ARCOS V Programme TIIPS trial) to be added to the agenda for the next Steering Committee

meeting. The email should include a brief title/description of the topic so that committee members unable to attend the meeting can comment.

For programme related works, The Project Lead will discuss the nominated publication(s) with Trial Steering Committee to agree the publication is in keeping with the key objectives of the programme, nominate junior researchers who they recommend be contributors to the publication and, ensure potential conflict with existing work are managed. The decision of the Programme Co-Directors will be entered in the minutes.

The proposed idea is to be discussed at the next Steering Committee meeting. At this stage the core individuals to contribute to the paper/presentation are to be identified (this is the *Writing Committee* for that particular work) and the most suitable forum for the work is to be discussed.

Authorship will include those on the writing committee as well as any other members of the Steering committee who make a significant contribution. In the case of extensive multiple authorship being appropriate, the Writing Committee will be named authors and others will be represented in an agreed collective title

All decisions relating to proposed dissemination ideas are to be minuted. The minutes should include an invitation to any Steering Committee members who were unable to attend the meeting to contact the primary author taking responsibility for the work before the next Steering Committee meeting if they also wish to contribute.

All project team members will be advised of the proposed publication, and can at this point indicate if they would like to contribute.

Once the publication is nearing completion, and has had input from all Writing Committee members, it is then to be circulated with the agenda for the next Steering Committee meeting before submission.

At this stage, discussion should pertain to ensure that the Authorship is appropriate and the targeted forum for the publication is the most appropriate (rather than manuscript content). At the end of this discussion, the decision of the Steering Committee should be minuted.

The Steering Committee should be informed of any editorial decisions made through presentation at the Steering Committee meeting. This includes acceptances as well as rejections, and in the case of rejections should contribute to any decisions about further submissions. All such developments should be minuted.

If the work is restricted by a tight timeframe (e.g. conference abstract submission deadline before the next steering committee meeting), the work may be approved for submission by the

Principal Investigator and Co-Directors and the Steering Committee members informed of the decision.

STUDY ACKNOWLEGEMENT

By signing below, I confirm that I have received, read and understood the protocol, dated 5/13/2022, for the Auckland Regional Community Stroke Study V (ARCOS V) study.

Name:_____

Signature: _____

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APPENDICES

38. APPENDIX A: PHYSICAL MEASURES AND EQUIPMENT

Requirements for face-to-face visit

The Participant File with information and consent form.

MoCA hardcopy for cognitive screening.

Tablet or laptop within REDcap database open to ‘baseline assessment – physical measurements’ (can be used offline if no internet)

Completion of questionnaires in REDCap.

Reminder sheet about blinding of the Research Assistants so that participants do not disclose if they are in the HWC group.

The following will occur at each visit:

Any questions regarding the information sheet or consent form will be addressed, ensuring that the participant received an electronic copy of the consent form to keep and reassured that they can withdraw at any time.

Before the baseline assessment the Research Assistant should review the completed online questionnaires. This will confirm eligibility in terms of medical history before completing further eligibility checks.

The first eligibility check will be the physical measurement of blood pressure (See below under PHYSICAL MEASUREMENTS). If participants have met this criterion, the assessment will continue. The clinical testing will confirm how many biomedical items are in the unhealthy range.

PHYSICAL MEASUREMENTS

All measurements are made according to International Standards for Anthropometric Assessment.

Measurement of Blood Pressure and Heart Rate

Three seated blood pressure (BP) measurements and heart rate will be taken using an OMRON model T9P automatic blood pressure monitor obtained at least 3 minutes apart, as required in Form B1.

If a participant is identified as having high risk blood pressure, they will be directed to seek further medical attention. A systolic blood pressure reading over 220 mmHg or diastolic blood pressure reading over 140 mmHg requires immediate medical attention. A systolic reading over 180 or diastolic reading over 110 requires the participant to seek medical advice in the next 48 hours. This advice will be given to participants during their study visit along with a copy of their results.

Instruction for Using the Omron T9P Automatic Blood Pressure Monitor

The Research Assistant is required to read the accompanying instruction manual carefully (a copy should be filed in the Trial Documentation File). The accuracy and reliability of BP measurements will be improved by following these standardised steps.

Ensure that the participant has not eaten, consumed alcohol, smoked or exercised for at least 30 minutes before blood pressure measurement.

The participant should rest for at least 5 minutes in the seated position.

Remove tight-fitting clothing from the upper arm.

The participant's feet should be flat on the floor with their arm supported on a table with the cuff at the same level as their heart.

The arm goes through the cuff loop making sure that the bottom edge of the cuff is approximately 1-2 cm above the elbow and that the Green Marker on the cuff is above the brachial artery. (The tube should run down the centre of the arm approximately even with the middle finger)

Pull the end of the cuff so that the entire cuff is evenly tightened around the arm and press the hook material firmly against the pile side of the cuff.

Connect the printer to the monitor with the circle (●) symbol upper most.

Press the ON / OFF button.

Ask the participant to remain still and not talk until the measurement is completed.

After the heart symbol (♥) appears on the digital panel, press the Start button.

When the measurement is complete, the monitor displays the blood pressure and heart rate, and automatically deflates the cuff.

Enter blood pressure readings into items in REDCap form 'baseline assessments – physical measurements'

Special Pitfalls and Problems

The Auscultatory Gap

In some participants, particularly in those with hypertension, the sounds heard over the brachial artery when the cuff pressure is high disappear as the pressure is reduced and then reappear at some lower level. This early, temporary disappearance of sound is called the auscultatory gap. Because this gap may extend over a range as great as 40 mmHg, it is possible to seriously underestimate the systolic pressure or overestimate the diastolic pressure, unless its presence is excluded by first palpating for disappearance of the radial pulse as the cuff pressure is raised.

Effect of Arm Position

The pressure in the arm increases as the arm is lowered from the level of the heart; conversely, raising the arm above this position lowers the pressure measurement. The effect is explained mainly by hydrostatic pressure or by the effect of gravity on the column of blood. Therefore, when measuring indirect blood pressure, the participant's arm should be positioned so that the midpoint of the cuff is at the level of the heart. This location of the heart is arbitrarily taken to be at the junction of the fourth intercostal space and the lower left sternal border.

Participants with Large Arms

In participants with large upper arms, a longer and broader cuff is needed for adequate compression of the brachial artery. A cuff with a bladder width of 40-50% of the arm circumference should be used in all participants to assure adequate BP measurements. In participants with moderately large arms, a 15 cm wide cuff will generally be adequate. Determination of forearm blood pressure should not be used because of the falsely elevated diastolic readings, which occur with this technique.

Measurement of blood sugar and lipids

Non-fasting blood test will be performed using certified Cardiochek PA Analyser (Figure). Cardiochek point of care system allows determination of the full lipid panel within 2 minutes.

Medication should not be stopped

Measurement of Height

Seca model 214 stadiometer, with a maximum 2 metre range, will be supplied for height measurement.

Assemble the stadiometer by placing the baseplate on the floor, selecting as firm a level as possible. Insert the measuring stick components into the baseplate.

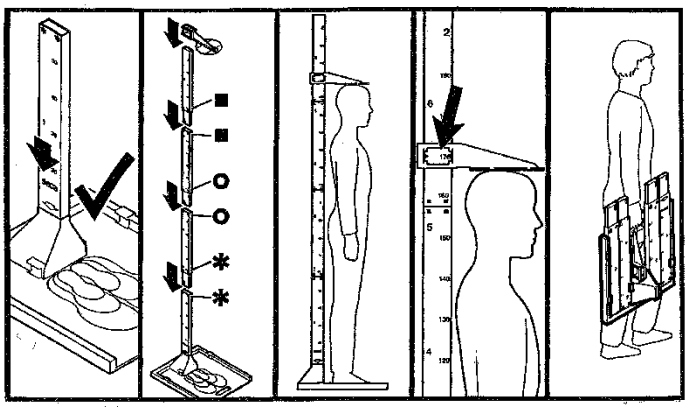
Ask the participant to remove their shoes and stand on the base plate with their back to the measuring stick. The participant should be told to stand as tall and straight as possible with feet on the “feet outline” of the baseplate and arms held loosely at the side and shoulders relaxed. Heels, buttocks and shoulders should be against the measuring stick.

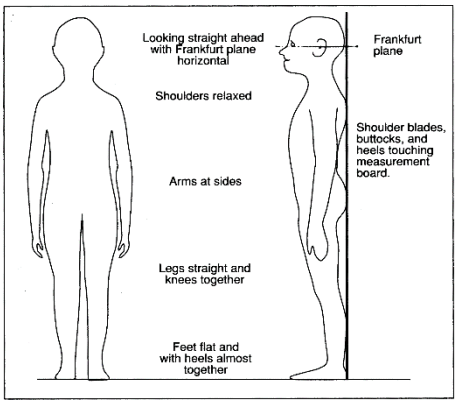
Ask the participant to breathe in and look straight ahead.

Read the height to the nearest cm. Make one measurement of height. Record the value on the PRF.

Record to nearest cm (round 0.1- 0.4 downwards and 0.5 - 0.9 upwards to the nearest whole number).

NB: If the participant is unable to stand, estimate the height by asking the participant.





Measurement of Weight

Salter bathroom scales model 9175

with a maximum 200kg range, will be supplied for weight measurement as required in relevant section of REDCap 'baseline assessments – physical measurements'. The scales have been calibrated and will be recalibrated annually.

All weight measurements are to be in kilograms. Ensure that the weight mode switch on the underside of the scales is set to KG.

Weigh the participant without their shoes. The participant should ideally *wear light indoor clothing* only. Remove any heavy items of clothing, heavy items from pockets, and heavy jewellery.

Place the scales on a flat level surface.

Press the centre of the scale platform firmly with your foot to activate the scales.

Remove foot and wait for the display to show a '0.0' reading.

When zero is displayed ask the participant to step onto the scales and stand still.

The participant should stand on the centre of the scales without support. Weight should be evenly distributed on both feet and the participant should look straight ahead.

Make one measurement of weight – the weight display will appear after 2-3 seconds.

Record weight to nearest 0.1kg.

Warning indicators are: Err = overload (maximum load is 200kg) and picture of a battery = replace batteries.

Batteries: when necessary replace with 4 new AA size batteries. Ensure +/- terminals are the correct way round.

Measurement of Waist Circumference

A 2-meter tape measure will be supplied for the measurement of waist circumference as required in question 'baseline assessments – physical measures'.

The waist circumference is to be measured with the participant wearing light indoor clothing. The participant should remove heavy outer garments and belts, loosen tight clothing and empty their pockets.

Measure in a standing position with participant breathing normally. (Ask the participant a question as you are about to take the measurement).

Participant should stand sideways to the Research Assistant in order to check that tape is horizontal.

Measure waist half way between lower border of ribs and iliac crest.

There should be no indentation of the skin due to the tape.

Record waist measurement to nearest cm (round 0.1- 0.4 downwards and 0.5 - 0.9 upwards to the nearest whole number).

Waist measurement

Use the circumference at the level of the noticeable waist narrowing located approximately half way between lower border of ribs and iliac crest.

In participants where the waist is not apparent, an arbitrary waist measurement is made at this level.

Confirmation of non-medical inclusion & exclusion criteria:

Participants that have proceeded to this stage will have met the cut-off for blood pressure score.

Following this, the Research Assistant will use a hard copy of the MoCA© and enter results directly into the REDCap form. This will calculate total score. If participant scores <26 they will need to be excluded. The Research Assistant performing the MoCA© should complete the online MoCA© Training and Certification Program at https://www.mocatest.org/.

If the inclusion criteria are met, the participant will proceed to complete the Hospital Anxiety and Depression (HADs) questionnaire. If the score for HADS is greater than 11 in either the Anxiety or Depression domains, the participant is ineligible to continue.

If participants are ineligible at this stage they will be notified of not meeting the study requirements and thanked for their interest in the study. They should be offered reimbursement for their time, if requested, in line with local ethics approvals.

The RAs conducting the assessments will be provided with the study Manual of Procedures, outlining all the day to day processes for conducting the study, safety information, contact details of senior study staff, as well as a field manual for easy reference. They will also be provided with iPads for data entry, mobile phones and stationary for data collection and record keeping.

39. APPENDIX B: DATA SAFETY MONITORING CHARTER

A DSMC charter will be developed according to the below guidelines at the commencement of the study.

Data Monitoring Committee Charter *(to be completed post ethics review)*

TITLE OF PROTOCOL: TRIAL OF AN INDIVIDUALISED INTERVENTION FOR THE PREVENTION OF STROKE (TIIPS)

PROTOCOL NUMBER: 1

SPONSOR OF PROTOCOL: Auckland University of Technology

DATE OF DOCUMENT: 04/05.2022

1. Introduction

This Charter is for Data Monitoring Committee (DMC) for:

Trial name: TRIAL OF AN INDIVIDUALISED INTERVENTION FOR THE PREVENTION OF STROKE (TIIPS)

Trial Registration Number: TBA

The purpose of this document is to define the primary roles and responsibilities of the DMC, its relationship with other trial committees, its membership and the purpose, format and timing of its meetings. The Charter will also provide the procedures for ensuring confidentiality and proper communication, the statistical monitoring guidelines to be implemented by the DMC, and an outline of the content of the Open and Closed Reports that will be provided to the DMC.

2. Primary Responsibilities of the DMC

The DMC will be responsible for safeguarding the interests of trial participants, assessing the safety and efficacy of the interventions during the trial, and for monitoring the overall conduct of the clinical trial. The DMC will provide recommendations about stopping or continuing the trial. To contribute to enhancing the integrity of the trial, the DMC may also formulate recommendations relating to the selection/recruitment of participants, their management, improving adherence to protocol-specified regimens and retention of participants, and the procedure for data management and quality control.

The DMC will be advisory to the clinical trial leadership group, hereafter referred to as the Steering Committee (SC). The SC will be responsible for promptly reviewing the DMC recommendations, to decide whether to continue or terminate the trial, and to determine whether amendments to the protocol or changes in study conduct are required.

3. Organisational Diagram

The following diagram shows the relationships between DMC and other committees and functional areas involved in the trial.

[*An Organisational Diagram should be inserted here*]

4. Membership of the DMC

4.1 Members

The DMC is an independent multidisciplinary group consisting of biostatisticians, clinicians and ethicists that, collectively, has experience in the management of patients with [fill in disease] and in the conduct and monitoring of randomised clinical trials.

DMC Chair (TBA)

DMC Members (TBA)

4.2 Conflicts of Interest

The DMC membership has been restricted to individuals free of apparent significant conflicts of interest. The source of these conflicts may be financial, scientific or regulatory in nature. Thus, neither study investigators nor individuals employed by the sponsor, nor individuals who might have regulatory responsibilities for the trial products, are members of the DMC.

The DMC members should be independent of the trial, and should not serve on DMCs of similar concurrently active trials. They should not own stock in companies having products being evaluated by the clinical trial. Any competing interest, whether actual or potential, should be declared. The DMC will be responsible for deciding whether these competing interests materially impact their objectivity.

The DMC members will be responsible for advising fellow members of any changes in competing interests that occur during the course of the trial. Any DMC members who develop significant conflicts of interest during the course of the trial should resign from the DMC.

DMC membership is to be for the duration of the clinical trial. If any members leave the DMC during the course of the trial, the SC will promptly appoint their replacements.

5. Terms of reference and specific roles of the DMC

**Terms of reference*

The DMC should receive and review the progress and accruing data of this trial and provide advice on the conduct of the trial to the SC.

Specific roles of the DMC

To undertake to review the trial's progress by

- Assessing data quality, including completeness (thereby encouraging collection of high quality data
- Monitoring recruitment figures and losses to follow-up
- Monitoring compliance with the protocol by participants and investigators

- Monitoring evidence for treatment differences in the primary efficacy and safety outcome measures – and thus recommending action when/whether the main trial question has been answered
- Monitoring evidence for treatment harm (eg toxicity, SAEs, deaths) in a timely way, receiving prompt reports of SUSARs and taking appropriate action to ensure patients' safety.
- Recommending whether the trial should continue to recruit or follow-up (see section on decision making)
- Recommending any significant changes to the protocol where necessary (eg changes to recruitment procesdures, inclusion criteria, endpoints, data collection)
- Advising on and/or endorsing any major protocol modifications suggested by the investigators or sponsors
- Assessing the impact and relevance of any external evidence provided
- Monitoring the compliance with previous DMC recommendations
- Considering the ethical implications of any recommendations made by the DMC

The DMC will report its recommendations to the SC.

6. Timing and Purpose of the DMC Meetings

6.1 Organisational Meeting

The initial meeting of the DMC will be an Organisational Meeting. It will be held during the final stages of protocol development, to provide advisory review of scientific and ethical issues relating to study design and conduct, to discuss the standard operating procedures for the role and functioning of the DMC, and to discuss the format and content of the Open and Closed Reports that will be used to present trial results at future DMC meetings.

The Organisational Meeting will be attended by the DMC, the lead trial investigators, the trial statistician, and the data manager. Representatives of the sponsors may also attend. Before the meeting, the DMC will be provided with the drafts of the clinical trial protocol, the Statistical Analysis Plan, the DMC Charter, and the current version of the case report forms. The DMC will also receive the initial draft templates of the Open and Closed Reports. Agreement on the format and content of reports wil ensure the DMC is receiving the necessary data on the trial progress.

(Note that all DMC members will have sight of the protocol/outline before agreeing to join the DMC. DMC members should be constructively critical of the ongoing trial, but supportive of the aims and methods of the trial.)

5.2 Monitoring meetings

Timing:

It is recommended that the DMC meet at least ** and will otherwise depend on the wishes of the DMC. The needs of the trial office will be considered when planning each meeting.

The first meeting of the DMC should take place during the early stage of recruitment, to review early safety information, to review factors relating to quality of trial conduct, and to review information provided to the DMC.

Meetings will continue until the trial has ** months left to completion.

Format:

The first meeting will be face-to-face. It is recommended that all subsequent meetings should be face-to-face too, with teleconference as a second option.

Attendance:

The Principal Investigator (PI) should attend open sessions of the DMC meetings. It may also be helpful for other members of the SC and the trial manager to attend the open sessions.

The trial statistician provides the link between the database and the DMC, and they are the only person outside the DMC to have access to unblinded data (data from closed reports, see below) during the trial. They are responsible for the production of the DMC reports, will attend both the open and closed sessions of the DMC meeting to talk the DMC through the reports. They may also participate in some DMC discussions.

Every effort should be made for all DMC members, the trial PI and the trial statistician to attend meetings. The DMC administrator will attempt to ensure a date is chosen to allow this. If, at short notice, any DMC member cannot attend, the meeting may still take place as long as at least three people are present, including one statistician, one clinician and the DMC Chair. If the DMC is considering recommending a significant action after such a meeting the DMC Chair should talk to the absent members as soon after the meeting as possible to check whether they agree. If they don't a further meeting by teleconference with the full DMC should be held.

6. Procedures to Ensure Confidentiality and Proper Communication

To enhance the integrity and credibility of the trial, procedures will be implemented to ensure the DMC has exclusive access to evolving information from the clinical trial regarding comparative efficacy and safety data, aggregated by treatment arm. An exception will be made to permit access for the trial statistician who will be responsible for serving as a liaison between the database and the DMC. A nominated member of the DMC will be provided immediate access on an ongoing basis to patient-specific information on SUSARs (Suspected Unexpected Serious Adverse Reactions).

At the same time, procedures will be implemented to ensure proper communication is achieved between the DMC and the trial investigators and sponsor. To provide a forum for exchange of information among various parties who share responsibility for the successful conduct of the trial, a format for Open Sessions and Closed Sessions will be implemented. The intent of this format is to enable the DMC to preserve confidentiality of the comparative efficacy results while at the same time providing opportunities for interaction between the DMC and others who have valuable insights into trial-related issues.

6.1 Closed Sessions

Sessions involving only DMC members and the independent statistician who generated the Closed Reports (called Closed Sessions) will be held to allow discussion of confidential data from the clinical trial, including information about the relative efficacy and safety of interventions. In order

to ensure that the DMC will be fully informed in its primary mission of safeguarding the interest of participating patients, the DMC will be unblinded in its assessment of safety and efficacy data.

At a final Closed Session, the DMC will develop a consensus on its list of recommendations, including that relating to whether the trial should continue.

6.2 Open Session

In order to allow the DMC to have adequate access to information provided by study investigators, a joint session between these individuals and DMC members (called an Open Session) will be held between the Closed Sessions. This session gives the DMC an opportunity to query these individuals about issues that have arisen during their review in the initial Closed Session. With this format, important interactions are facilitated through which problems affecting trial integrity can be identified and resolved. These individuals will either be present in person at the DMC meeting or be provided a telephone link.

Identification and circulation of external evidence (eg from other trials or systematic reviews) is not the responsibility of the DMC. The PI will take responsibility to collate such information and provide it to the DMC.

6.3 Open and Closed Reports

For each DMC meeting, Open and Closed Reports will be provided (See Section 8 for outlines of the content of these reports). The trial statistician, [provide name of statistician] will prepare these reports.

Open Reports, available to all who attend the DMC meeting, will include data on recruitment and baseline characteristics and pooled data on eligibility violations, completeness of follow-up and compliance.

Closed Reports, available only to those attending the Closed Sessions of the DMC meeting, will include analyses of primary and secondary efficacy endpoints, subgroup and adjusted analyses, analyses of AEs and symptom severity, analyses of laboratory data, and Open Report analyses that are displayed by intervention group.

The Open and Closed Reports should provide information that is accurate, with follow-up that is complete to within two months of the date of the DMC meeting. The Reports should be provided within *** working days before the date of the meeting.

6.4 Minutes of the DMC Meeting

The DMC will prepare minutes of their meetings. Two sets will be prepared: the Open Minutes and the Closed Minutes.

The Open Minutes will describe the proceedings in the Open Session of the DMC meeting, and will summarise all recommendations by the DMC. These minutes will be circulated immediately to the Principal Investigator and the Study Manager, therefore it is necessary that these minutes do not unblind the efficacy and safety data if the DMC is not recommending early termination.

The Closed Minutes will describe the proceedings from all sessions of the DMC meeting, including the listing of recommendations by the Committee. Because it is likely that these minutes will contain unblinded information, it is crucial that they are not made available to anyone outside the DMC. The study statistican will receive minutes of the sections of the closed sessions they attend, and it is vital that these are kept confidential. Copies will be archived by the Chair and by the study Statistician, for distribution to the Principal Investigator, sponsor, and regulatory authorities at the time of study closure.

6.5 Recommendations to the Steering Committee (SC)

At each meeting of the DMC during the conduct of the trial, the DMC will make a recommendation to the Steering Committee to continue or to terminate the trial. This recommendation will be based primarily on safety and efficacy considerations and will be guided by statistical monitoring guidelines defined in the Charter.

The SC is jointly responsible with the DMC for safeguarding the interests of participating patients and for the conduct of the trial. Recommendations to amend the protocol or conduct of the study made by the DMC will be considered and accepted or rejected by the SC. The SC will be responsible for deciding whether to continue or to stop the trial based on the DMC recommendations.

The DMC will be notified of all changes to the protocol or to study conduct. The DMC concurrence will be sought on all substantive changes to the protocol or study conduct prior to their implementation.

The SC may communicate information in the Open Report to senior management and may inform them of the DMC recommended alterations to study conduct or early trial termination in instances in which the SC has reached a final decision agreeing with the recommendation. The SC will maintain confidentiality of all information it received other than that contain in the Open Reports until after the trial is completed or until a decision for early termination has been made.

7. Statistical Monitoring Guidelines

[The DMC Charter should specify the statistical monitoring procedures that will be used by the DMC to guide their recommendations regarding termination or continuation of the trial. These procedures should include guidelines relating to early termination for benefit, as well as guidelines for termination when evidence indicates the experimental intervention has an unfavourable benefit-to-risk profile.]

[The DMC may also be asked to ensure procedures are appropriately implemented to adjust study sample size or duration of follow-up to restore power, if protocol specified event rates are inaccurate. If so, the algorithm for doing this should be clearly specified.]

8. Content of DMC's Open and Closed Reports

8.1 Open Statistical Report: An Outline

- One-page outline of the study design, possibly with a schema
- Statistical commentary explaining issues presented in Open Report figures and table
- DMC monitoring plan and summary of Open Report data presented at prior DMC meetings

- Major protocol changes
- Information on patient screening
- Study accrual by month and by institution
- Eligibility violations
- Baseline characteristics (pooled by treatment regimen)
- Demographics
- Laboratory values and other measurements
- Previous treatment usage and other similar information
- Days between randomisation and initiation of treatment
- Adherence to medication schedule (pooled by treatment regimen)
- Attendance at scheduled visits (pooled by treatment regimen)
- Reporting delays for key events (pooled by treatment regimen)
- Length of follow-up data available (pooled by treatment regimen)
- Participant treatment and study status (pooled by treatment regimen)
- Completeness of data (pooled by treatment regimen)

8.2 Closed Statistical Report: An Outline

- Detailed statistical commentary explaining issues raised by Closed Report figures and tables (by coded treatment group, with codes sent to DMC members by a separate mailing)
- DMC monitoring plan and summary of Closed Report data presented at prior DMC meetings
- Repeat of the Open Report information, in greater detail by treatment group
- Analyses of primary and secondary efficacy endpoints
- Subgroup analyses and analyses adjusted for baseline charactersistics
- Analyses of adverse events and overall safety data
- Analyses of lab values, including basic summaries and longitudinal analyses
- Discontinuation of medications
- Information on crossover patients.

40. APPENDIX C CASE RECORD FORMS

List of TIIPS study case record forms

	Form Name	Purpose
1	Form A NHI number	Confidential record of NHI number
2	Form B Baseline and Screening	Screening for eligibility, and Baseline demographic and health related information
3	Form C Contact Details	Record of participant contact details, alternate contact and GP contact
4	Form F Follow-up	Follow-up assessments at 3, 6, 9 and 12 months
5	Form R Randomisation	Completion of data entry for randomisation, and record of group allocation
6	Form S Serious adverse events	Record of stroke/TIA/MI recurrent events, death and hospitalisation
7	Form Z Coaching assessment and compliance	Record of coaching sessions, compliance, and assessment of coaching quality

A - NHI List

Participant Registration Number

_____

TIIPS **Trial of an Individualised Intervention for the Prevention of Stroke**

RA initials

- ◯ Akbar
- ◯ Akbar
- ◯ Amanda
- ◯ Bala
- ◯ Blake
- ◯ Devaki
- ◯ Jennifer
- ◯ Jesse
- ◯ Karen
- ◯ Karolina
- ◯ Kylee
- ◯ Lily
- ◯ Rita
- ◯ Shaheena
- ◯ Viv Kelly

Participant NHI

_____
(Put participant NHI here.)

Date of entry

_____

B - Screening and Baseline

Participant Registration Number _____

Trial of an Individualised Intervention for the Prevention of Stroke

RA initials

- ◯ Akbar
- ◯ Akbar
- ◯ Amanda
- ◯ Bala
- ◯ Blake
- ◯ Devaki
- ◯ Jennifer
- ◯ Jesse
- ◯ Karen
- ◯ Karolina
- ◯ Kylee
- ◯ Lily
- ◯ Rita
- ◯ Shaheena
- ◯ Viv Kelly

Section 1: Screening (Note: Collect the following information from Clinical Portal)

Inclusion Criteria

1.1. Admitted to one of the three Auckland based hospitals or primary care for first-ever minor stroke or TIA

◯ Yes ◯ No
(Note: recurrent TIA can be included)

1.1.1. If yes, then which hospital?

☐ Auckland ☐ North Shore
☐ Waitemata ☐ Counties

1.1.2. If not, then referred from:

☐ Primary Care (specify)
☐ Stroke Foundation, ☐ Other (specify)

1.1.3. Specify here:

_____

1.2. Planning to live in Auckland for the next 12 months?

◯ Yes ◯ No
(The HRA may have to call the participant to confirm.)

1.3. Confirmed stroke or TIA by hospital physician	◯ Yes ◯ No (Note: A GP is unable to confirm a stroke or TIA)
1.4. Age 18 to 75 years	◯ Yes ◯ No
1.5. Date of birth	_____
1.6. Sex	◯ Male ◯ Female ◯ Non-binary
1.7. Event Type	◯ Stroke ◯ TIA
1.8. Event Date	_____
1.9. Ethnicity	☐ New Zealand European ☐ Maori ☐ Samoan ☐ Cook Island Maori ☐ Tongan ☐ Niuean ☐ Chinese ☐ Indian ☐ MELAA* ☐ Other Europeans ☐ Other (More than one option can be ticked)
1.10. If Other, please specify	_____
1.11. NIHSS < = 4 and/or mRS score 0-2 at discharge	◯ Yes ◯ No (From medical notes or discharge summary OT/PT notes)
1.12. Is the participant's hearing good enough for a phone assessment?	◯ Yes ◯ No
1.13. Can converse in English	◯ Yes ◯ No

If No to any of the above, this participant is not eligible. Stop here.

Exclusion Criteria

1.14. Participation in another RCT which overlaps with this study?	◯ Yes ◯ No
1.15. History of major stroke or myocardial infarction (self-report and verification through medical records)	◯ Yes ◯ No
1.16. Planned carotid endarterectomy	◯ Yes ◯ No
1.17. Life-threatening conditions with a life expectancy < 5 years	◯ Yes ◯ No

1.18. Significant co-morbidities (pre-stroke/TIA mRS >2)	◯ Yes ◯ No
1.19. Current (in the past year) significant clinical depression/anxiety either in clinical records or at screening) or psychiatric conditions (based on medical records)	◯ Yes ◯ No ◯ Unknown ((If unknown, check unknown, to be completed by RA at Baseline screening).)
1.20. History (past year) of alcohol or drug/substance abuse	◯ Yes ◯ No
1.21. Dependent on others (living in a rest-home/care facility)	◯ Yes ◯ No
1.22. Significant cognitive impairment or pre-existing diagnosis of dementia e.g., ACE-R < = 82 (from clinical records), or at screening (MoCA) (If unknown, check unknown, to be completed by RA at Baseline screening.	◯ Yes ◯ No ◯ Unknown

If YES to any of the above, this participant is not eligible. Stop here.

Section 2: Screening measures from Medical Notes.
(Note: Collect the following information from Clinical Portal)

2.1. Was the NIHSS recorded at admission?	◯ Yes ◯ No
2.1.1. Put the NIHSS score here. NIHSS at admission (1 digit) or unavailable.	_____
2.1.2. Date of assessment	_____
2.2. Was the NIHSS recorded at discharge (or post revascularization procedure)?	◯ Yes ◯ No
2.2.1. NIHSS at discharge (or post revascularization procedure)	_____
2.2.2. Date of assessment	_____
2.3. mRS at discharge (If MRS score is not available, please respond based on the ADL information in the discharge summary)	◯ Completed ◯ Not completed
2.3.1. Please choose one of the following; whether independent or dependent?	◯ 0-2 independent ◯ 3-5 dependent ((If MRS score is not available, please respond based on ADLs from the discharge summary))
2.3.2. Date of assessment	_____

2.4. Mood assessment	◯ Completed ◯ Not completed
2.4.1. If completed, write name of the assessment.	_____
2.4.2. Was there a diagnosis of anxiety?	◯ Yes ◯ No
2.4.3. Was there a diagnosis of depression?	◯ Yes ◯ No
2.4.4. Date of assessment	_____
2.5. Cognitive assessment	◯ Completed ◯ Not completed
2.5.1. If completed, write name of the assessment.	_____
2.5.2. Was there a diagnosis of cognitive impairment?	◯ Yes ◯ No
2.5.3. Date of assessment	_____

Section 3: Initial Assessment

3.1.1. Did the assessment take place?	◯ Yes ◯ No ◯ Unknown
3.1.2. If no, please choose the appropriate response.	◯ Withdrawn ◯ Not contactable ◯ Unwell/deceased ◯ Other (specify)
3.1.2.1 Specify	_____
3.2. Date of assessment	_____
3.2.1. RA conducting assessment	◯ Lily ◯ Blake ◯ RA3 ◯ RA4
3.2.1 Place of assessment	◯ AIH North Clinic ◯ AUT South Campus ◯ AUT City ◯ Participant Home ◯ Phone assessment ◯ Via video ◯ Other (specify)
3.2.2 If Other, please specify	_____

Section 4: Verification (Baseline only)

4.1. Has the participant provided informed consent?	◯ Yes ◯ No
If NO, please stop here. Check consent status	

Section 5: Case ascertainment (Baseline only)

5.1. Date of hospitalisation	_____
5.2. Date of discharge	_____
5.2.1 Was the participant discharged to rest home or managed facility?	◯ Yes ◯ No
5.2.2. If yes, the participant is not eligible for the study.	
5.3. Revascularization procedure	◯ Yes ◯ No
5.3.1 Provide date	_____
5.4. Thrombolysis	◯ Yes ◯ No
5.4.1. Provide date	_____
5.5. Clot retrieval	◯ Yes ◯ No
5.5.1. Provide date	_____

Section 6: Demographic Information

6.1. Employment Status prior to stroke/TIA	◯ Full-time: Paid employment for >=30 hrs a week ◯ Part-time: Paid employment for 1 to less than 30 hrs a week ◯ Not in Paid Employment OR Paid employment for less than 1 hour per week ◯ Retired
6.2. Current marital status	◯ Married, civil union or de facto relationship ◯ Single ◯ Separated, divorced, or widowed
6.3. Usual dwelling place of participant prior to stroke/TIA	◯ Own home ◯ Rented ◯ Living with friends or family ◯ Retirement village or similar ◯ Boarding house ◯ Other ◯ Unavailable
6.3.1 If other dwelling, specify	_____

6.4. Participant's highest qualification. Degree e.g.: MA, PhD, BA, BSc, Medicine	◯ Degree e.g.: MA, PhD, BA, BSc, Medicine ◯ Diploma or Certificate ◯ Trade: or Technical qualification ◯ High school: at least upto Form 5 or Year 11 ◯ Less than High School or Year 11
6.5. Participant's income level.	◯ 0-19k ◯ 20-50k ◯ 51-80k ◯ 81-100 ◯ 101 + (Optional, participant may refuse)

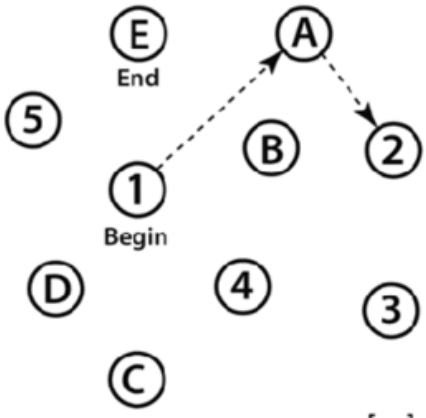
Section 7: Montreal Cognitive Assessment

MONTREAL COGNITIVE ASSESSMENT (MOCA)

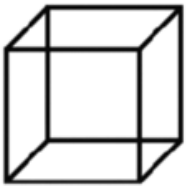
Version 7.1 Original Version

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE



Copy cube



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POINTS ___/5

NAMING

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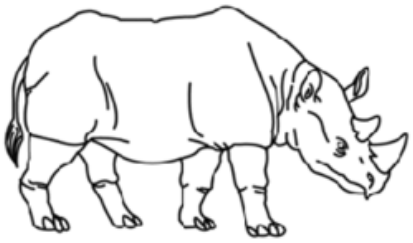
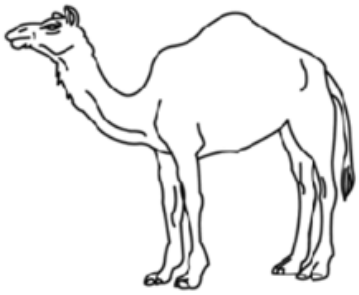


[ ]



[ ]

___/3

MEMORY

Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION

Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

___/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

___/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

___/3

LANGUAGE

Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

___/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

___/1

ABSTRACTION

Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

___/2

DELAYED RECALL

	FACE	VELVET	CHURCH	DAISY	RED
Has to recall words WITH NO CUE	[ ]	[ ]	[ ]	[ ]	[ ]
Optional: Category cue					
Optional: Multiple choice cue					

Points for UNCUED recall only

___/5

ORIENTATION

[ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

___/6

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Normal ≥ 26 / 30

TOTAL ___/30

Add 1 point if ≤ 12 yr edu

Administered by: _____

((Upload the image of printed and completed MoCA for this participant.))

7.1.1. Visualspatial/Executive score

_____

7.1.2. Naming score

_____

7.1.3. Attention score

_____

7.1.4. Language score

_____

7.1.5. Abstraction score

_____

7.1.6. Delayed Recall score

_____

7.1.7. Orientation score

_____

7.1.8. MoCA total score

_____

(If MOCA < =25, the participant is not eligible for the study.)

Cognitive Impairment WARNING !!!! STOP HERE !!!!

Section 8. Hospital Anxiety and Depression Scale (HADS)

Please indicate which of the following options best describes how you have been feeling during the last week.

8.1. I feel tense or wound up

- ◯ Most of the time
- ◯ A lot of the time
- ◯ From time to time, occasionally
- ◯ Not at all

8.2. I still enjoy the things I used to enjoy

- ◯ Definitely as much
- ◯ Not quite as much
- ◯ Only a little
- ◯ Hardly at all

8.3. I get a sort of frightened feeling as if something awful is about to happen

- ◯ Very definitely and quite badly
- ◯ Yes, but not too badly
- ◯ A little, but it doesn't worry me
- ◯ Not at all

8.4. I can laugh and see the funny side of things	◯ As much as I always could ◯ Not quite so much now ◯ Definitely not as much now ◯ Not at all
8.5. Worrying thoughts go through my mind	◯ A great deal of the time ◯ A lot of the time ◯ From time to time, but not too often ◯ Only occasionally
8.6. I feel cheerful	◯ Not at all ◯ Not often ◯ Sometimes ◯ Most of the time
8.7. I can sit at ease and feel relaxed	◯ Definitely ◯ Usually ◯ Not often ◯ Not at all
8.8. I feel as if I am slowed down	◯ Nearly all the time ◯ Very often ◯ Sometimes ◯ Not at all
8.9. I get a sort of frightened feeling like 'butterflies' in the stomach	◯ Not at all ◯ Occasionally ◯ Quite often ◯ Very Often
8.10.. I have lost interest in my appearance	◯ Definitely ◯ I don't take as much care as I should ◯ I may not take quite as much care ◯ I take just as much care as ever
8.11. I feel restless as if I have to be on the move	◯ Very much indeed ◯ Quite a lot ◯ Not very much ◯ Not at all
8.12. I look forward with enjoyment to things	◯ As much as I ever did ◯ Rather less than I used to ◯ Definitely less than I used to ◯ Hardly at all
8.13. I get sudden feelings of panic	◯ Very often indeed ◯ Quite often ◯ Not very often ◯ Not at all
8.14. I can enjoy a good book or TV programme	◯ Often ◯ Sometimes ◯ Not often ◯ Very seldom

8.15. Anxiety Score (Sub Total)

_____

(Advise the participant and study manager to contact GP if the score is equal to or more than 11.)

Anxiety warning

8.16. Depression Score (Sub Total)

_____

(Advise the participant and study manager to contact GP if the score is equal to or more than 11.)

Depression warning

8.17. Has the mental health record form sent to the GP?

◯ Yes ◯ No

Upload Mental Health Record Form.

Any comments.

_____

8.18. Have all the screening questions been completed?

◯ Yes ◯ No

If NO, please complete all screening questions before proceeding.

Section 9: Comorbidities.

9.1. Does the participant have any of the following? (tick all that apply, if previously ticked it won't display again)

☐ Previous TIA
☐ Elevated blood lipids (cholesterol),
☐ Hypertension (elevated blood pressure)
☐ Type 1 diabetes
☐ Type 2 diabetes
☐ Coronary artery disease, angina
☐ Previous irregular pulse (arrhythmia), atrial fibrillation,
☐ Valvular heart disease,
☐ Heart failure,
☐ Peripheral vascular disease (pain in legs when walking),
☐ Epilepsy/seizures
☐ Migraine,
☐ Previous head injury (resulting in loss of consciousness),
☐ Patent Foramen Ovale defect (PFO)
☐ Renal/kidney disease,
☐ COPD (obstructive cardiopulmunary disease)
☐ Cancer
☐ Arthritis

9.1.1. If yes to TIA, add the date

_____

9.2. Have you experienced any significant stress in the last year?

◯ Yes ◯ No

9.2.1. If YES, please rate your level of stress over the last 2 weeks (0= No stress; 10 = extremely stressed)	_____
9.2.2. Please comment in case the participant wants to share the reason e.g. bereavement.	_____
9.3. Have you experienced memory problems in the past year?	◯ Yes ◯ No
9.4. Have you ever been diagnosed with COVID19?	◯ Yes ◯ No
Date of diagnosis for COVID?	_____ (approximate date acceptable)
How was the diagnosis done?	◯ Home RAT test ◯ PCR test ◯ Unknown (medical records only)

Section 10: Current Medications.

10.2. CVD Medications prescribed at discharge (Tick all that apply)	☐ Aspirin ☐ Dipyridamole ☐ Clopidogrel ☐ Warfarin ☐ Dabigatran ☐ Rivaroxaban ☐ Blood pressure lowering medication(s) ☐ Lipid lowering therapy (statins) ☐ Diabetes medication(s), ☐ Mood modification therapy ☐ Oral contraceptives ☐ Supplements (herbal or vitamins) ☐ Other ☐ None of the above (Complete Section 11 only if medications medications are taken (Q10.1))

Section 11: Self-Efficacy For Appropriate Medication Use Scale [SEAMS]

How confident are you that you can take your medications correctly:

	Not At All Confident	Somewhat Confident	Very Confident
11.1. When you take several different medicines each day?	◯	◯	◯
11.2 When you are away from home?	◯	◯	◯
11.3 When no one reminds you to take the medicine?	◯	◯	◯
11.4 When you take medicines more than once a day?	◯	◯	◯

11.5 When the schedule to take the medicine is not convenient?	◯	◯	◯
11.6 When your normal routine gets messed up?	◯	◯	◯
11.7 When you get a refill of your old medicines and some of the pills look different than usual?	◯	◯	◯
11.8 When you are not sure how to take the medicine?	◯	◯	◯
11.9 When you are not sure what time of the day to take your medicine?	◯	◯	◯
11.10 When a doctor changes your medicines?	◯	◯	◯
11.11 When they cause some side effects?	◯	◯	◯
11.12 When you are feeling sick (like having a cold or the flu)?	◯	◯	◯

11.13 SEAMS Score Total _____

11.14 Do you have trouble remembering to take your medication? ◯ Yes ◯ No

11.15 How often do have difficulty remembering to take all your medication?
◯ Never/Rarely ◯ Once in a while
◯ Sometimes ◯ Usually
◯ All the time

12. EQ-5D - 5L

Under each heading, please tick the ONE box that best describes your health TODAY

12.1. Mobility
◯ I have no problems in walking about
◯ I have slight problems in walking about
◯ I have moderate problems in walking about
◯ I have severe problems in walking about
◯ I am unable to walk about

12.2. Self-Care
◯ I have no problems washing or dressing myself
◯ I have slight problems washing or dressing myself
◯ I have moderate problems washing or dressing myself
◯ I have severe problems washing or dressing myself
◯ I am unable to wash or dress myself

12.3. Usual Activities (e.g. work, study, housework, family or leisure activities)
◯ I have no problems doing my usual activities
◯ I have slight problems doing my usual activities
◯ I have moderate problems doing my usual activities
◯ I have severe problems doing my usual activities
◯ I am unable to do my usual activities

12.4. Pain/Discomfort

- ◯ I have no pain or discomfort
- ◯ I have slight pain or discomfort
- ◯ I have moderate pain or discomfort
- ◯ I have severe pain or discomfort
- ◯ I have extreme pain or discomfort

12.5. Anxiety/Depression

- ◯ I am not anxious or depressed
- ◯ I am slightly anxious or depressed
- ◯ I am moderately anxious or depressed
- ◯ I am severely anxious or depressed
- ◯ I am extremely anxious or depressed

12.6. EQ VAS - Health State Score

_____

(We would like to know how good or bad your health is TODAY. 100 means the best health you can imagine. 0 means the worst health you can imagine.)

12.7. Any comments.

_____

Section 13: Risk Factor Awareness

13.1. Which of the following best describes a stroke? (please tick one or more boxes)

- ◯ A heart attack
- ◯ A brain attack
- ◯ When blood supply to the brain is stopped or blocked
- ◯ Not sure, but has something to do with the brain
- ◯ Not sure, but it is like a heart attack
- ◯ Don't know

13.2. What may be signs that someone is having a stroke? (please ticke one or more boxes)

- ◯ Chest pain
- ◯ Rash
- ◯ Drooping face
- ◯ Coughing
- ◯ Slurred speech
- ◯ Not able to lift one or both arms
- ◯ Stress

13.3. What causes you to be at higher risk of stroke? (please tick one or more boxes)

- ◯ High blood pressure
- ◯ High cholesterol
- ◯ Diabetes
- ◯ Smoking
- ◯ Asthma
- ◯ Being tired
- ◯ Family history of stroke
- ◯ Excessive alcohol intake
- ◯ Stress
- ◯ Poor diet
- ◯ Being overweight (obesity)
- ◯ Lack of excessive/fitness
- ◯ Irregular heart beat

13.4. What is the most important thing to do if you or someone else experiences any of the following?

	Advise them to rest	Contact a doctor	Call a family member	Call an ambulance	Go to the hospital	Do nothing
13.4.1. Paralysis or weakness of the face	○	○	○	○	○	○

	Advise them to rest	Contact a doctor	Call a family member	Call an ambulance	Go to the hospital	Do nothing
13.4.2. Not able to lift one or both arms, or one arm paralysed	○	○	○	○	○	○

	Advise them to rest	Contact a doctor	Call a family member	Call an ambulance	Go to the hospital	Do nothing
13.4.3. Slurred speech, or unable to understand what someone else is saying	○	○	○	○	○	○

Section 14: Life Satisfaction

14.1. On a scale of 1 to 10 indicate where you stand right now. (Note: 10 represents the best possible life and the 1 represents the worst possible life.)

0 5 10

(Place a mark on the scale above)

14.2. On a scale of 1 to 10 indicate where in the ladder you stand right now. (Note: 10 represents the best level of satisfaction with your life and 1 represents the worst level of satisfaction.)

0 5 10

(Place a mark on the scale above)

14.3. Satisfaction with Life Scale

Below are five statements with which you may agree or disagree. Using the scale below, indicate your agreement with each item by checking the appropriate radio button preceding that item. Please be open and honest in your response.

	Strongly Disagree	Disagree	Slightly Disagree	Neither Agree or Disagree	Slightly Agree	Agree	Strongly Agree
In most ways my life is close to my ideal.	○	○	○	○	○	○	○
The conditions of my life are excellent.	○	○	○	○	○	○	○

I am satisfied with life.	○	○	○	○	○	○	○
So far I have gotten the important things I want in life.	○	○	○	○	○	○	○
If I could live my life over, I would change almost nothing.	○	○	○	○	○	○	○

14.3.1 Satisfaction with life total score _____

Section 15. LS7 Questionnaire

Part A: Blood Pressure

15A.1. Systolic blood pressure (mm Hg) Reading 1 _____

15A.2. Diastolic blood pressure (mm Hg) Reading 1 _____

15A.3. Systolic blood pressure (mm Hg) Reading 2 _____

15A.4. Diastolic blood pressure (mm Hg) Reading 2 _____

15A.5. Systolic blood pressure (mm Hg) Reading 3 _____

15A.6. Diastolic blood pressure (mm Hg) Reading 3 _____

15A.7. Average Systolic blood pressure (mm Hg) _____

If the average systolic blood pressure is less than 130, please stop here. Participant is not eligible.

15A.8. Average Diastolic blood pressure (mm Hg) _____

15A.9. LS7 BP Score _____

Part B: CardioChek Screening for Blood tests - Cholesterol

15B.1. Is this a fasting test?
◯ Yes ◯ No

15B.2. Last meal taken (number of hours ago)
◯ 2 hours ago or less
◯ 2 to 6 hours ago
◯ 6 -11 hours ago
◯ 12 hours ago or more

15B.3. Blood lipids LDL (mmol/l)
_____

15B.4. Blood lipids HDL (mmol/l)
_____

15B.5. Total Cholesterol (mmol/l)
_____

15B.6. LS7 Cholesterol Score
_____

Part C: CardioChek Screening for Blood tests - Blood Glucose

15C.1. Blood Glucose (mmol/l)
_____

15C.2. LS7 Blood Glucose Score
_____

Part D: BMI

15D.1. Height (cms)
_____

15D.2. Weight (kgs)
_____

15C.3. BMI (Formula: Calculated BMI weight(kg)/height2(m2))
_____

15C.4. BMI LS7 Score (Formula: BMI < 25kg/m2 LS7 score = 2, BMI 25-29.99 kg/m2 LS7 score = 1, BMI 30+ kg/m2 LS7 score = 0)
_____

Part E: Smoking

15E.1. Which of this best describes your current smoking status?
◯ Current smoker
◯ Ex-smoker, quit smoking within the last 12 months
◯ Never smoked, or last smoked more than 12 months ago (cigarettes, ready-made or roll your own; cigars cigarillos or pipe)

15E.2. If current smoker, average number of cigarettes smoked per day?
_____

15E.3. LS7 Smoking score

_____

Part F: Recreational Drugs: Additional Section (Not a part of LS7 scoring)

15F.1. Smoked any of the following products in the past year.

☐ Tobacco Vapes
☐ Hookah/Shisha Cannabis
☐ Other recreational drugs

15F.2. If consumed recreational drugs, please specify.

_____

15G.1 Alcohol: Additional Section (Not a part of LS7 scoring)

15G.1. Have you had anything alcoholic to drink in the last 12 months?

◯ Yes ◯ No

15G.2. If yes, total years of alcohol consumption.

_____

15G.3. Which of the following best describes how often you CURRENTLY drink alcohol?

◯ Less than 1 drink a day (occasional)
◯ 1-2 drinks a day
◯ 3 or more drinks a day

Part H: Diet

15H.1. How many portions of fresh fruit and vegetables do you eat per day on average?

_____

Note: 1 portion = 1 pc of fruit, or 1 cup of vegetables e.g., 1 apple and 1 cup of mixed salad= 2 portions.

15H.2. LS7 healthy diet component met? Tick if more than 4 portions per day

◯ Yes ◯ No

15H.3. How many times per week do you eat fish (100g or more) including canned or frozen fish?

_____

15H.4. LS7 healthy diet component met? Tick if more than 2 servings per week

◯ Yes ◯ No

15H.5. Do you add salt to your food AFTER it has been cooked?

◯ Yes ◯ No

15H.6. How often do you eat highly processed foods (such as sausages, ham, chips, crisps etc) and/or fast food/takeaways per week?

◯ Never
◯ Less than once per week
◯ 1-2 times per week
◯ 3+ times per week

15H.7. LS7 healthy diet component met?

◯ Yes ◯ No

Note: Tick if NEVER or LESS than once per week.

15H.8. During the past month, how often did you eat sweets/chocolates etc or drink fruit juices, soft drinks or energy drinks?	◯ Never ◯ Less than once per week ◯ 1-2 times per week ◯ 3+ times per week (Note: Do not include diet varieties. Soft drinks are often carbonated/ fizzy and include Coca-Cola, Pepsi, lemonade, ginger beer, energy drinks (Red Bull, Lift plus), Powerade, E2, G-force. Excludes diet varieties, flavoured waters, and sports waters.)
15H. 9. LS7 healthy diet component met? Tick if less than 3 times per week	◯ Yes ◯ No
15H.10. How often would you have 100g of whole grains (e.g., wholegrain cereal, millet, buckwheat, rye, brown rice, quinoa, rolled oats, 3 slices of wholegrain bread, beans, dhal etc) per day?	◯ Never ◯ Less than once per week ◯ 1-2 times per week ◯ 3+ times per week
15H.11. LS7 healthy diet component met? Note: Tick if less than 3 times per week	◯ Yes ◯ No
15H.12. LS7 Healthy Diet score	◯ if 4 to 5 components are ticked. ◯ if 2 to 3 components are ticked ◯ if 0-1 components are ticked

Part I: Physical activity

15I.1. How often do you perform moderate to vigorous physical activity for at least 10 minutes that makes you breathe harder/break into a sweat?	◯ 4 times a week or more ◯ 1-3 times a week ◯ Never
15I.1.1. How many hours per week would you spend performing these physical activities?	◯ Less than 2.5 hours per week ◯ 2.5 hours per week or more
15I.2. LS7 Activity score	_____
15J. Total LS7 Note: Score out of 14.	_____

Section 16: Stroke risk by the Stroke Riskometer App (Baseline only)

16.1. Risk assessment date	_____
16.2. Riskometer assessment done by	☐ CRA ☐ HWC ☐ Participant
16.3. Father or mother had a stroke or heart attack before reaching the age of 65.	◯ Yes ◯ No ◯ Unknown

16.4. 5- year Stroke risk (%)

_____

16.5. 5- year Relative risk (%)

_____

16.6. 10- year Stroke risk (%)

_____

16.7. 10- year Relative risk (%)

_____

Section 17. Health Service Use (3, 6, 9 and 12 months)

17.1. Have you visited your GP since your stroke/TIA

◯ Yes ◯ No

17.1.1. If Yes, how often since your TIA/stroke?

☐ Once
☐ Twice
☐ Three times
☐ Four times
☐ More than 4 times
☐ Can't remember

17.2. Have you visited your GP since the last assessment

◯ Yes ◯ No

17.2.1. If Yes, how frequently have you visited your GP?

◯ Once
◯ Twice
◯ Three times
◯ Four times
◯ More than 4 times
◯ Can't remember/unknown

17.3. Have you received other healthcare services since your stroke/TIA?

◯ Yes ◯ No

17.3.1. Which services have you received?

☐ visiting nurses
☐ speech therapy
☐ psychologist
☐ physiotherapy
☐ social worker
☐ counsellor
☐ occupational therapist
☐ other health provider (e.g. neurologist)
☐ other

17.4.1. For the above services, how many visits did you receive per week?

◯ 1 ◯ 2 ◯ 3 ◯ 4
◯ 5 or more

17.4.2. For the above services, how many visits did you receive per week?

◯ 1 ◯ 2 ◯ 3 ◯ 4
◯ 5 or more

17.4.3. For the above services, how many visits did you receive per week?

◯ 1 ◯ 2 ◯ 3 ◯ 4
◯ 5 or more

17.4.4. For the above services, how many visits did you receive per week?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 or more
17.4.5. For the above services, how many visits did you receive per week?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 or more
17.4.6. For the above services, how many visits did you receive per week?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 or more
17.4.7. For the above services, how many visits did you receive per week?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 or more
17.4.8. For the above services, how many visits did you receive per week?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 or more
17.4.9. For the above services, how many visits did you receive per week?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 or more
17.5. Have you received other healthcare services since the last assessment ?	◯ Yes ◯ No
17.5.1 If Other, please state	_____
17.6 Have you received other healthcare services since the last assessment	◯ Yes ◯ No
17.7 State what other services you have received	_____
17.8.1 Have you received any personal care/home help since your last assessment?	◯ Yes ◯ No
17.9.2 How often have you received home help?	◯ Daily ◯ 2 to 3 times per week ◯ once a week ◯ once a fortnight ◯ once a month or less
17.10.1 Do you receive any other type of help?	◯ Yes ◯ No
17.11.2. State what other help you receive.	_____
17.12 Has there been a change in your employment status since your TIA/stroke?	◯ Yes ◯ No
17.12.1 What changes have occurred since your last assessment?	◯ Newly employed ◯ No longer employed ◯ Reduced hours ◯ Changed job or type of work ◯ Now self-employed ◯ Other
17.12.2 Please explain answer to 17.12.1	_____

17.13 Are you currently in paid employment?	◯ Yes ◯ No
17.13.1. If Yes to 17.13., what number of hours have you usually worked in the past 2 weeks?	_____
17.14. Are you currently paying for any private health or support services?	◯ Yes ◯ No
17.14.1. If Yes to 17.14, what services?	_____

C - Contact Details

Participant Registration Number _____

Trial of an Individualised Intervention for the Prevention of Stroke

1. Contact Information

'This form is for TIIPS [registration_number].'

1.1. RA initials

- ◯ Akbar
- ◯ Akbar
- ◯ Amanda
- ◯ Bala
- ◯ Blake
- ◯ Devaki
- ◯ Jennifer
- ◯ Jesse
- ◯ Karen
- ◯ Karolina
- ◯ Kylee
- ◯ Lily
- ◯ Rita
- ◯ Shaheena
- ◯ Viv Kelly

1.2 Date of contact form filling. _____

1.3 Title _____

1.4 First name(s) _____

1.4.1. Preferred Name _____

1.5 Last name _____

1.6 Address	_____
1.7 Email address	_____
1.8 Home phone number (including area code)	_____
1.9 Work phone number (including area code)	_____
1.10 Mobile phone number	_____
1.11. Preferred Phone number	☐ Home phone ☐ Work phone ☐ Mobile phone
1.12. Preferred day/time to receive follow up call.	☐ Weekdays ☐ Weekends ☐ Mornings ☐ Afternoons ☐ Evenings
1.13. Any other preferential information ?	_____
1.14. How would participant like to receive the information sheet?	☐ Post ☐ Email ☐ Text
1.15. Has the study manager checked the receipt of the information sheet?	☐ Yes ☐ No

2. Post Discharge Contact

2.1. Are the contact details after discharge from hospital different from above ?	◯ Yes ◯ No
2.1.1. First name(s)	_____
2.1.2. Last name	_____
2.1.3. Address	_____
2.1.4. Phone Number	_____
2.1.5. Mobile Number	_____

3. Alternate Contact (friend or relative)

3.1 First name(s)

_____

3.2 Last name

_____

3.3. Address

_____

3.4. Home phone number (including area code)

_____

3.5. Work phone number (including area code)

_____

3.6. Mobile phone number

_____

3.7. Email address

_____

3.a. Alternate Contact 2 (friend or relative)

3.1a First name(s)

_____

3.2a Last name

_____

3.3a. Address

_____

3.4a. Home phone number (including area code)

_____

3.5a. Work phone number (including area code)

_____

3.6a. Mobile phone number

_____

3.7a. Email address

_____

4. General Practitioner

4.1 Title

_____

4.2 First name(s)

_____

4.3 Last name

_____

4.4. Name of GP practice

_____

4.5. Address

_____

4.6. Work phone number (including area code)

_____

4.8. Email address

_____

R - Randomization

Participant Registration Number _____

Trial of an Individualised Intervention for the Prevention of Stroke

On the date that participant's demographics were recorded, the age of the participant (in years) was: _____

From the age calculated above, please select the age bracket (in years) that the participant falls into:

- ◯ 18-54
- ◯ 55-75
- ◯ The participant falls outside of the required ages of 18-75 years

Sex

- ◯ Male
- ◯ Female

Ethnicity

- ◯ NZ Euro
- ◯ Maori
- ◯ Pacific
- ◯ Asian
- ◯ MELAA
- ◯ Other

Please randomize the participant now into either the HWC group or the UC group, now that their age, sex and ethnicity has been entered.

- ◯ HWC - Group A
- ◯ UC - Group B

F - Follow Up

Participant Registration Number

_____

TIIPS Trial of an Individualised Intervention for the Prevention of Stroke

RA initials

- ◯ Akbar
- ◯ Akbar
- ◯ Amanda
- ◯ Bala
- ◯ Blake
- ◯ Devaki
- ◯ Jennifer
- ◯ Jesse
- ◯ Karen
- ◯ Karolina
- ◯ Kylee
- ◯ Lily
- ◯ Rita
- ◯ Shaheena
- ◯ Viv Kelly

Section 3: Initial Assessment

3.1. Which assessment is this? (tick one only)

◯ 3 months ◯ 6 months
◯ 9 months ◯ 12 months

3.1.1. Did the assessment take place?

◯ Yes ◯ No ◯ Unknown

3.1.2. If no, please choose the appropriate response.

◯ Withdrawn ◯ Not contactable
◯ Unwell/deceased ◯ Other (specify)

3.1.2.1 Specify

_____

3.2. Date of assessment

_____

3.2.1. RA conducting assessment	◯ Akbar ◯ Akbar ◯ Amanda ◯ Bala ◯ Blake ◯ Devaki ◯ Jennifer ◯ Jesse ◯ Karen ◯ Karolina ◯ Kylee ◯ Lily ◯ Rita ◯ Shaheena ◯ Viv Kelly
3.2.1 Place of assessment	◯ AIH North Clinic ◯ AUT South Campus ◯ AUT City ◯ Participant Home ◯ Phone assessment ◯ Via video ◯ Other (specify)
3.2.2 If Other, please specify	_____

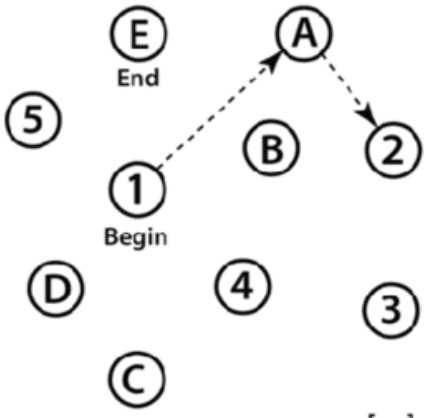
Section 7: Montreal Cognitive Assessment

MONTREAL COGNITIVE ASSESSMENT (MOCA)

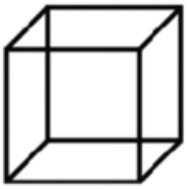
Version 7.1 Original Version

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE



Copy cube



[ ] [ ]

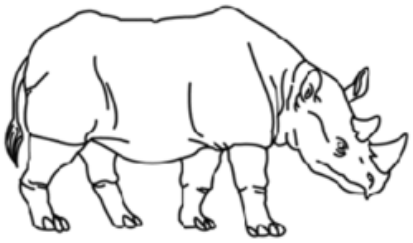
Draw CLOCK (Ten past eleven)
(3 points)

[ ] Contour [ ] Numbers [ ] Hands

POINTS ___/5

NAMING

[ ]



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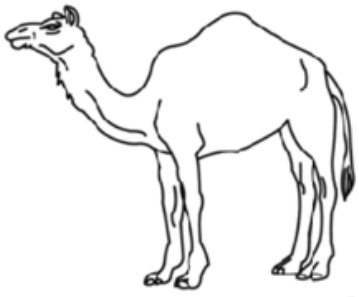

[ ]

___/3

MEMORY

Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION

Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

___/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

___/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

___/3

LANGUAGE

Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

___/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

___/1

ABSTRACTION

Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

___/2

DELAYED RECALL

	FACE	VELVET	CHURCH	DAISY	RED
Has to recall words WITH NO CUE	[ ]	[ ]	[ ]	[ ]	[ ]
Optional: Category cue					
Optional: Multiple choice cue					

Points for UNCUED recall only

___/5

ORIENTATION

[ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

___/6

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Normal ≥ 26 / 30

TOTAL ___/30

Add 1 point if ≤ 12 yr edu

Administered by: _____

	((Upload the image of printed and completed MoCA for this participant.))
7.1.1. Visualspatial/Executive score	_____
7.1.2. Naming score	_____
7.1.3. Attention score	_____
7.1.4. Language score	_____
7.1.5. Abstraction score	_____
7.1.6. Delayed Recall score	_____
7.1.7. Orientation score	_____
7.1.8. MoCA total score	_____ (If MOCA < =25, the participant is not eligible for the study.)
Cognitive Impairment WARNING !!!!	

Section 8. Hospital Anxiety and Depression Scale (HADS)

Please indicate which of the following options best describes how you have been feeling during the last week.

8.1. I feel tense or wound up	◯ Most of the time ◯ A lot of the time ◯ From time to time, occasionally ◯ Not at all
8.2. I still enjoy the things I used to enjoy	◯ Definitely as much ◯ Not quite as much ◯ Only a little ◯ Hardly at all
8.3. I get a sort of frightened feeling as if something awful is about to happen	◯ Very definitely and quite badly ◯ Yes, but not too badly ◯ A little, but it doesn't worry me ◯ Not at all

8.4. I can laugh and see the funny side of things	◯ As much as I always could ◯ Not quite so much now ◯ Definitely not as much now ◯ Not at all
8.5. Worrying thoughts go through my mind	◯ A great deal of the time ◯ A lot of the time ◯ From time to time, but not too often ◯ Only occasionally
8.6. I feel cheerful	◯ Not at all ◯ Not often ◯ Sometimes ◯ Most of the time
8.7. I can sit at ease and feel relaxed	◯ Definitely ◯ Usually ◯ Not often ◯ Not at all
8.8. I feel as if I am slowed down	◯ Nearly all the time ◯ Very often ◯ Sometimes ◯ Not at all
8.9. I get a sort of frightened feeling like 'butterflies' in the stomach	◯ Not at all ◯ Occasionally ◯ Quite often ◯ Very Often
8.10.. I have lost interest in my appearance	◯ Definitely ◯ I don't take as much care as I should ◯ I may not take quite as much care ◯ I take just as much care as ever
8.11. I feel restless as if I have to be on the move	◯ Very much indeed ◯ Quite a lot ◯ Not very much ◯ Not at all
8.12. I look forward with enjoyment to things	◯ As much as I ever did ◯ Rather less than I used to ◯ Definitely less than I used to ◯ Hardly at all
8.13. I get sudden feelings of panic	◯ Very often indeed ◯ Quite often ◯ Not very often ◯ Not at all
8.14. I can enjoy a good book or TV programme	◯ Often ◯ Sometimes ◯ Not often ◯ Very seldom

8.15. Anxiety Score (Sub Total)

_____

(Advise the participant and study manager to contact GP if the score is equal to or more than 11.)

Anxiety warning

8.16. Depression Score (Sub Total)

_____

(Advise the participant and study manager to contact GP if the score is equal to or more than 11.)

Depression warning

8.17. Has the mental health record form sent to the GP?

◯ Yes ◯ No

Upload Mental Health Record Form.

Any comments.

_____

8.18. Have all the screening questions been completed?

◯ Yes ◯ No

If NO, please complete all screening questions before proceeding.

Section 9: Comorbidities.

9.1. Does the participant have any of the following? (tick all that apply, if previously ticked it won't display again)

☐ Previous TIA
☐ Elevated blood lipids (cholesterol),
☐ Hypertension (elevated blood pressure)
☐ Type 1 diabetes
☐ Type 2 diabetes
☐ Coronary artery disease, angina
☐ Previous irregular pulse (arrhythmia), atrial fibrillation,
☐ Valvular heart disease,
☐ Heart failure,
☐ Peripheral vascular disease (pain in legs when walking),
☐ Epilepsy/seizures
☐ Migraine,
☐ Previous head injury (resulting in loss of consciousness),
☐ Patent Foramen Ovale defect (PFO)
☐ Renal/kidney disease,
☐ COPD (obstructive cardiopulmunary disease)
☐ Cancer
☐ Arthritis

9.1.1. If yes to TIA, add the date

_____

9.2. Have you experienced any significant stress in the last year?

◯ Yes ◯ No

9.2.1. If YES, please rate your level of stress over the last 2 weeks (0= No stress; 10 = extremely stressed)	_____
9.2.2. Please comment in case the participant wants to share the reason e.g. bereavement.	_____
9.3. Have you experienced memory problems in the past year?	◯ Yes ◯ No
9.4 Have you ever been diagnosed with COVID19?	◯ Yes ◯ No
Date of diagnosis for COVID?	_____ (approximate date acceptable)
How was the diagnosis done?	◯ Home RAT test ◯ PCR test ◯ Unknown (medical records only)

Section 10: Current Medications.

10.2. CVD Medications prescribed at discharge (Tick all that apply)	☐ Aspirin ☐ Dipyridamole ☐ Clopidogrel ☐ Warfarin ☐ Dabigatran ☐ Rivaroxaban ☐ Blood pressure lowering medication(s) ☐ Lipid lowering therapy (statins) ☐ Diabetes medication(s), ☐ Mood modification therapy ☐ Oral contraceptives ☐ Supplements (herbal or vitamins) ☐ Other ☐ None of the above (Complete Section 11 only if medications medications are taken (Q10.1))

Section 11: Self-Efficacy For Appropriate Medication Use Scale [SEAMS]

How confident are you that you can take your medications correctly:

	Not At All Confident	Somewhat Confident	Very Confident
11.1. When you take several different medicines each day?	◯	◯	◯
11.2 When you are away from home?	◯	◯	◯
11.3 When no one reminds you to take the medicine?	◯	◯	◯
11.4 When you take medicines more than once a day?	◯	◯	◯

11.5 When the schedule to take the medicine is not convenient?	◯	◯	◯
11.6 When your normal routine gets messed up?	◯	◯	◯
11.7 When you get a refill of your old medicines and some of the pills look different than usual?	◯	◯	◯
11.8 When you are not sure how to take the medicine?	◯	◯	◯
11.9 When you are not sure what time of the day to take your medicine?	◯	◯	◯
11.10 When a doctor changes your medicines?	◯	◯	◯
11.11 When they cause some side effects?	◯	◯	◯
11.12 When you are feeling sick (like having a cold or the flu)?	◯	◯	◯

11.13 SEAMS Score Total _____

11.14 Do you have trouble remembering to take your medication? ◯ Yes ◯ No

11.15 How often do have difficulty remembering to take all your medication?
◯ Never/Rarely ◯ Once in a while
◯ Sometimes ◯ Usually
◯ All the time

12. EQ-5D - 5L

Under each heading, please tick the ONE box that best describes your health TODAY

12.1. Mobility
◯ I have no problems in walking about
◯ I have slight problems in walking about
◯ I have moderate problems in walking about
◯ I have severe problems in walking about
◯ I am unable to walk about

12.2. Self-Care
◯ I have no problems washing or dressing myself
◯ I have slight problems washing or dressing myself
◯ I have moderate problems washing or dressing myself
◯ I have severe problems washing or dressing myself
◯ I am unable to wash or dress myself

12.3. Usual Activities (e.g. work, study, housework, family or leisure activities)
◯ I have no problems doing my usual activities
◯ I have slight problems doing my usual activities
◯ I have moderate problems doing my usual activities
◯ I have severe problems doing my usual activities
◯ I am unable to do my usual activities

12.4. Pain/Discomfort

- ◯ I have no pain or discomfort
- ◯ I have slight pain or discomfort
- ◯ I have moderate pain or discomfort
- ◯ I have severe pain or discomfort
- ◯ I have extreme pain or discomfort

12.5. Anxiety/Depression

- ◯ I am not anxious or depressed
- ◯ I am slightly anxious or depressed
- ◯ I am moderately anxious or depressed
- ◯ I am severely anxious or depressed
- ◯ I am extremely anxious or depressed

12.6. EQ VAS - Health State Score

_____

(We would like to know how good or bad your health is TODAY. 100 means the best health you can imagine. 0 means the worst health you can imagine.)

12.7. Any comments.

_____

Section 13: Risk Factor Awareness

13.1. Which of the following best describes a stroke? (please tick one or more boxes)

- ◯ A heart attack
- ◯ A brain attack
- ◯ When blood supply to the brain is stopped or blocked
- ◯ Not sure, but has something to do with the brain
- ◯ Not sure, but it is like a heart attack
- ◯ Don't know

13.2. What may be signs that someone is having a stroke? (please ticke one or more boxes)

- ◯ Chest pain
- ◯ Rash
- ◯ Drooping face
- ◯ Coughing
- ◯ Slurred speech
- ◯ Not able to lift one or both arms
- ◯ Stress

13.3. What causes you to be at higher risk of stroke? (please tick one or more boxes)

- ◯ High blood pressure
- ◯ High cholesterol
- ◯ Diabetes
- ◯ Smoking
- ◯ Asthma
- ◯ Being tired
- ◯ Family history of stroke
- ◯ Excessive alcohol intake
- ◯ Stress
- ◯ Poor diet
- ◯ Being overweight (obesity)
- ◯ Lack of excessive/fitness
- ◯ Irregular heart beat

13.4. What is the most important thing to do if you or someone else experiences any of the following?

	Advise them to rest	Contact a doctor	Call a family member	Call an ambulance	Go to the hospital	Do nothing
13.4.1. Paralysis or weakness of the face	○	○	○	○	○	○
13.4.2. Not able to lift one or both arms, or one arm paralysed	○	○	○	○	○	○
13.4.3. Slurred speech, or unable to understand what someone else is saying	○	○	○	○	○	○

Section 14: Life Satisfaction

14.1. On a scale of 1 to 10 indicate where you stand right now. (Note: 10 represents the best possible life and the 1 represents the worst possible life.)

0 5 10

(Place a mark on the scale above)

14.2. On a scale of 1 to 10 indicate where in the ladder you stand right now. (Note: 10 represents the best level of satisfaction with your life and 1 represents the worst level of satisfaction.)

0 5 10

(Place a mark on the scale above)

13.3. Satisfaction with Life Scale

Below are five statements with which you may agree or disagree. Using the scale below, indicate your agreement with each item by checking the appropriate radio button preceding that item. Please be open and honest in your response.

	Strongly Disagree	Disagree	Slightly Disagree	Neither Agree or Disagree	Slightly Agree	Agree	Strongly Agree
In most ways my life is close to my ideal.	○	○	○	○	○	○	○
The conditions of my life are excellent.	○	○	○	○	○	○	○
I am satisfied with life.	○	○	○	○	○	○	○
So far I have gotten the important things I want in life.	○	○	○	○	○	○	○
If I could live my life over, I would change almost nothing.	○	○	○	○	○	○	○

14.3.1 Satisfaction with life total score _____

Section 15. LS7 Questionnaire

Part A: Blood Pressure

15A.1. Systolic blood pressure (mm Hg) Reading 1

_____

15A.2. Diastolic blood pressure (mm Hg) Reading 1

_____

15A.3. Systolic blood pressure (mm Hg) Reading 2

_____

15A.4. Diastolic blood pressure (mm Hg) Reading 2

_____

15A.5. Systolic blood pressure (mm Hg) Reading 3

_____

15A.6. Diastolic blood pressure (mm Hg) Reading 3

_____

15A.7. Average Systolic blood pressure (mm Hg)

_____

If the average systolic blood pressure is less than 130, please stop here. Participant is not eligible.

15A.8. Average Diastolic blood pressure (mm Hg)

_____

15A.9. LS7 BP Score

_____

Part B: CardioChek Screening for Blood tests - Cholesterol

15B.1. Is this a fasting test?

◯ Yes ◯ No

15B.2. Last meal taken (number of hours ago)

◯ 2 hours ago or less
◯ 2 to 6 hours ago
◯ 6 -11 hours ago
◯ 12 hours ago or more

15B.3. Blood lipids LDL (mmol/l)

_____

15B.4. Blood lipids HDL (mmol/l)

_____

15B.5. Total Cholesterol (mmol/l)

_____

15B.6. LS7 Cholesterol Score

_____

Part C: CardioChek Screening for Blood tests - Blood Glucose

15C.1. Blood Glucose (mmol/l)

_____

15C.2. LS7 Blood Glucose Score

_____

Part D: BMI

15D.1. Height (cms)

_____

15D.2. Weight (kgs)

_____

15C.3. BMI (Formula: Calculated BMI weight(kg)/height2(m2))

_____

15C.4. BMI LS7 Score (Formula: BMI < 25kg/m2 LS7 score = 2, BMI 25-29.99 kg/m2 LS7 score = 1, BMI 30+ kg/m2 LS7 score = 0)

_____

Part E: Smoking

15E.1. Which of this best describes your current smoking status?

- ◯ Current smoker
- ◯ Ex-smoker, quit smoking within the last 12 months
- ◯ Never smoked, or last smoked more than 12 months ago (cigarettes, ready-made or roll your own; cigars cigarillos or pipe)

15E.2. If current smoker, average number of cigarettes smoked per day?

_____

15E.3. LS7 Smoking score

_____

Part F: Recreational Drugs: Additional Section (Not a part of LS7 scoring)

15F.1. Smoked any of the following products in the past year.

- ☐ Tobacco Vapes
- ☐ Hookah/Shisha Cannabis
- ☐ Other recreational drugs

15F.2. If consumed recreational drugs, please specify.

_____

15G.1 Alcohol: Additional Section (Not a part of LS7 scoring)

15G.1. Have you had anything alcoholic to drink in the last 12 months?	◯ Yes ◯ No
15G.2. If yes, total years of alcohol consumption.	_____
15G.3. Which of the following best describes how often you CURRENTLY drink alcohol?	◯ Less than 1 drink a day (occasional) ◯ 1-2 drinks a day ◯ 3 or more drinks a day

Part H: Diet

15H.1. How many portions of fresh fruit and vegetables do you eat per day on average? Note: 1 portion = 1 pc of fruit, or 1 cup of vegetables e.g., 1 apple and 1 cup of mixed salad= 2 portions.	_____
15H.2. LS7 healthy diet component met? Tick if more than 4 portions per day	◯ Yes ◯ No
15H.3. How many times per week do you eat fish (100g or more) including canned or frozen fish?	_____
15H.4. LS7 healthy diet component met? Tick if more than 2 servings per week	◯ Yes ◯ No
15H.5. Do you add salt to your food AFTER it has been cooked?	◯ Yes ◯ No
15H.6. How often do you eat highly processed foods (such as sausages, ham, chips, crisps etc) and/or fast food/takeaways per week?	◯ Never ◯ Less than once per week ◯ 1-2 times per week ◯ 3+ times per week
15H.7. LS7 healthy diet component met? Note: Tick if NEVER or LESS than once per week.	◯ Yes ◯ No
15H.8. During the past month, how often did you eat sweets/chocolates etc or drink fruit juices, soft drinks or energy drinks?	◯ Never ◯ Less than once per week ◯ 1-2 times per week ◯ 3+ times per week (Note: Do not include diet varieties. Soft drinks are often carbonated/ fizzy and include Coca-Cola, Pepsi, lemonade, ginger beer, energy drinks (Red Bull, Lift plus), Powerade, E2, G-force. Excludes diet varieties, flavoured waters, and sports waters.)
15H. 9. LS7 healthy diet component met? Tick if less than 3 times per week	◯ Yes ◯ No

15H.10. How often would you have 100g of whole grains (e.g., wholegrain cereal, millet, buckwheat, rye, brown rice, quinoa, rolled oats, 3 slices of wholegrain bread, beans, dhal etc) per day?	◯ Never ◯ Less than once per week ◯ 1-2 times per week ◯ 3+ times per week
15H.11. LS7 healthy diet component met? Note: Tick if less than 3 times per week	◯ Yes ◯ No
15H.12. LS7 Healthy Diet score	◯ if 4 to 5 components are ticked. ◯ if 2 to 3 components are ticked ◯ if 0-1 components are ticked

Part I: Physical activity

15I.1. How often do you perform moderate to vigorous physical activity for at least 10 minutes that makes you breathe harder/break into a sweat?	◯ 4 times a week or more ◯ 1-3 times a week ◯ Never
15I.1.1. How many hours per week would you spend performing these physical activities?	◯ Less than 2.5 hours per week ◯ 2.5 hours per week or more
15I.2. LS7 Activity score	_____
15J. Total LS7 Note: Score out of 14.	_____

Section 16: Stroke risk by the Stroke Riskometer App

16.1. Risk assessment date	_____
16.2. Riskometer assessment done by	☐ CRA ☐ HWC ☐ Participant
16.3. Father or mother had a stroke or heart attack before reaching the age of 65.	◯ Yes ◯ No ◯ Unknown
16.4. 5- year Stroke risk (%)	_____
16.5. 5- year Relative risk (%)	_____
16.6. 10- year Stroke risk (%)	_____
16.7. 10- year Relative risk (%)	_____

Section 17. Health Service Use (3, 6, 9 and 12 months)

17.1. Have you visited your GP since your stroke/TIA
◯ Yes ◯ No

17.1.1. If Yes, how often since your TIA/stroke?
☐ Once
☐ Twice
☐ Three times
☐ Four times
☐ More than 4 times
☐ Can't remember

17.2. Have you visited your GP since the last assessment
◯ Yes ◯ No

17.2.1. If Yes, how frequently have you visited your GP?
◯ Once
◯ Twice
◯ Three times
◯ Four times
◯ More than 4 times
◯ Can't remember/unknown

17.3. Have you received other healthcare services since your stroke/TIA?
◯ Yes ◯ No

17.3.1. Which services have you received?
☐ visiting nurses
☐ speech therapy
☐ psychologist
☐ physiotherapy
☐ social worker
☐ counsellor
☐ occupational therapist
☐ other health provider (e.g. neurologist)
☐ other

17.4.1. For the above services, how many visits did you receive per week?
◯ 1 ◯ 2 ◯ 3 ◯ 4
◯ 5 or more

17.4.2. For the above services, how many visits did you receive per week?
◯ 1 ◯ 2 ◯ 3 ◯ 4
◯ 5 or more

17.4.3. For the above services, how many visits did you receive per week?
◯ 1 ◯ 2 ◯ 3 ◯ 4
◯ 5 or more

17.4.4. For the above services, how many visits did you receive per week?
◯ 1 ◯ 2 ◯ 3 ◯ 4
◯ 5 or more

17.4.5. For the above services, how many visits did you receive per week?
◯ 1 ◯ 2 ◯ 3 ◯ 4
◯ 5 or more

17.4.6. For the above services, how many visits did you receive per week?
◯ 1 ◯ 2 ◯ 3 ◯ 4
◯ 5 or more

17.4.7. For the above services, how many visits did you receive per week?
◯ 1 ◯ 2 ◯ 3 ◯ 4
◯ 5 or more

17.4.8. For the above services, how many visits did you receive per week?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 or more
17.4.9. For the above services, how many visits did you receive per week?	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 or more
17.5. Have you received other healthcare services since the last assessment ?	◯ Yes ◯ No
17.5.1 If Other, please state	_____
17.6 Have you received other healthcare services since the last assessment	◯ Yes ◯ No
17.7 State what other services you have received	_____
17.8.1 Have you received any personal care/home help since your last assessment?	◯ Yes ◯ No
17.9.2 How often have you received home help?	◯ Daily ◯ 2 to 3 times per week ◯ once a week ◯ once a fortnight ◯ once a month or less
17.10.1 Do you receive any other type of help?	◯ Yes ◯ No
17.11.2. State what other help you receive.	_____
17.12 Has there been a change in your employment status since your TIA/stroke?	◯ Yes ◯ No
17.12.1 What changes have occurred since your last assessment?	◯ Newly employed ◯ No longer employed ◯ Reduced hours ◯ Changed job or type of work ◯ Now self-employed ◯ Other
17.12.2 Please explain answer to 17.12.1	_____
17.13 Are you currently in paid employment?	◯ Yes ◯ No
17.13.1. If Yes to 17.13., what number of hours have you usually worked in the past 2 weeks?	_____
17.14. Are you currently paying for any private health or support services?	◯ Yes ◯ No
17.14.1. If Yes to 17.14, what services?	_____

S - Recurrent Events and SAE

Participant Registration Number

_____

Trial of an Individualised Intervention for the Prevention of Stroke

1.1. Date of this assessment

_____

1.2. RA Name

- ◯ Akbar
- ◯ Akbar
- ◯ Amanda
- ◯ Bala
- ◯ Blake
- ◯ Devaki
- ◯ Jennifer
- ◯ Jesse
- ◯ Karen
- ◯ Karolina
- ◯ Kylee
- ◯ Lily
- ◯ Rita
- ◯ Shaheena
- ◯ Viv Kelly

2. Specific Diagnosis

_____

3. Hospital Admissions

3.1. Was the participant admitted to hospital?

- ◯ Yes (completed formal admission procedures)
- ◯ No (go to question 4)

3.2. If yes, date admitted to hospital

_____

3.2.1. Which hospital?

- ◯ Auckland
- ◯ Middlemore
- ◯ North Shore
- ◯ Waitakere
- ◯ Other

3.2.2. If other, please specify.	_____
3.3. ICD Code for reason for admission	_____
3.4. Date discharged from hospital (leave blank if still in hospital)	_____

4. Stroke / TIA Related Outcomes

4.1. Is this a stroke related outcome?	◯ Yes ◯ No
4.2. Is this a TIA related outcome?	◯ Yes ◯ No
4.3. Recurrent stroke?	◯ Yes ◯ No
4.3.1. If Yes, Date	_____
4.4. Recurrent TIA?	◯ Yes ◯ No
4.4.1. If Yes, Date	_____
4.5. Myocardial Infarction?	◯ Yes ◯ No
4.5.1. If Yes, Date	_____
4.5.2. Could you explain the event?	_____

5. Information about death.

5.1. Has the participant died?	◯ Yes ◯ No
5.2. If yes, date of death	_____
5.3. If yes, Primary cause of death.	_____
5.4. ICD Code for Primary cause for death taken from medical record (write all that apply)	_____
5.5. Secondary contributing factors	_____
5.6. ICD code for Secondary contributing factors.	_____

6. Sources of Information related to death

6.1. NZHIS	◯ Yes ◯ No
6.2. Medical records	◯ Yes ◯ No
6.3. Death certificate	◯ Yes ◯ No
6.3.1. If yes, attach a copy of report	
6.4. Autopsy performed	◯ Yes ◯ No
6.4.1. If yes, attach the copy of report	
6.5. Information given by attending doctor	◯ Yes ◯ No
6.6. Information given by family/friend	◯ Yes ◯ No
6.7. Other	◯ Yes ◯ No
6.7.1. If other, please specify	_____

7. SAE due to any aspects of the study protocol intervention

7.1. Was SAE due to any aspects of the study protocol intervention?	◯ Yes ◯ No
7.2. If yes, how was the SAE due to the study protocol?	_____
8. RA initials	◯ Blake ◯ Anjali ◯ Ann

Z - Coach Compliance Assessment Feedback

Participant Registration Number

_____

TIIPS Trial of an Individualised Intervention for the Prevention of Stroke

1. Coaching evaluations

Name of person completing this form

- ◯ Akbar
- ◯ Akbar
- ◯ Amanda
- ◯ Bala
- ◯ Blake
- ◯ Devaki
- ◯ Jennifer
- ◯ Jesse
- ◯ Karen
- ◯ Karolina
- ◯ Kylee
- ◯ Lily
- ◯ Rita
- ◯ Shaheena
- ◯ Viv Kelly

Date assessed

_____

1. Which coaching session is this?

_____

1.1. If more than 12, please give the reason

_____

1.2. Date of Session

_____

1.3. Name of health coach	◯ Akbar ◯ Akbar ◯ Amanda ◯ Bala ◯ Blake ◯ Devaki ◯ Jennifer ◯ Jesse ◯ Karen ◯ Karolina ◯ Kylee ◯ Lily ◯ Rita ◯ Shaheena ◯ Viv Kelly
1.4. Did the session take place?	◯ Yes ◯ No
1.4.1. Reason for missed session	◯ Participant withdrew ◯ Not contactable ◯ Unwell ◯ Deceased ◯ Other
14.1.1. If other, state here	_____
1.5. Length of session in minutes:	_____
1.5.1. Please provide comments of possible reasons for this session length	_____
1.6. Type of session delivery	◯ Face to face ◯ Video call ◯ Telephone call
1.7. Were there any barriers to conducting today's session?	◯ Distractions (TV noise, other people) ◯ Participant not responsive or engaged ◯ Other_state ◯ None
If Other, state the reasons.	_____
1.8. How do you feel today's session went?	◯ Very well, could not have been much better ◯ Somewhat well, some things could have improved ◯ Not too well, many things could have improved ◯ Very badly
1.8.1. Give a further explanation of the above response.	_____
1.9. Please list the actions the participant has committed to achieving after this session.	_____

2. Coaching Competencies

Meeting ethical guidelines and professional standards: Understanding of coaching ethics and standards and ability to apply them appropriately in all coaching situations.	◯ Understands and exhibits in own behaviours the ICF Standards of Conduct. ◯ Understands and follows all ICF Ethical Guidelines. ◯ Clearly communicates the distinctions b between coaching, consulting, psychotherapy and other support professions. ◯ Refers client to another support professional as needed, knowing when this is needed and the available resources.
Establishing the coaching agreement: (INITIAL session): Ability to understand what is required in the specific coaching interaction and to come to agreement with the prospective and new client about the coaching process and relationship. WHAT, IMPACT, VISION, AGREEMENT	◯ Understands and effectively discusses with the client and specific parameters of the coaching relationship (e.g., logistics, fees, scheduling, the inclusion of others if appropriate) ◯ Reaches agreement about what is appropriate in the relationship and what is not, what is and is not being offered, and about the client's and coach's responsibilities. ◯ Determines whether there is an effective match between his/her coaching method and the needs of the prospective client.
Establishing trust and intimacy with the client:? Ability to create a safe, supportive environment that produces ongoing mutual respect and trust.	◯ Shows genuine concern for the client's welfare and future. ◯ Continually demonstrates personal integrity, honesty and sincerity. ◯ Establishes clear agreements and keeps promises ◯ Demonstrates respect for client's perceptions, learning style, personal being. ◯ Provides ongoing support for and champions new behaviours and actions, including those involving risk taking and fear of failure. ◯ Asks permission to coach the client in sensitive new areas.
Coaching presence: Ability to be fully conscious and create spontaneous relationship with the client, employing a style that is open, flexible and confident.	◯ Is present and flexible during the coaching process dancing in the moment. ◯ Accesses own intuition and trusts one's inner knowing - goes with the gut. ◯ Is opened to not knowing and takes risks. ◯ Sees many ways to work with the client and chooses in the moment what is most effective. ◯ Uses humour effectively to create lightness and energy. ◯ Confidently shifts perspectives and experiments with new possibilities for own action. ◯ Demonstrates confidence in working with strong emotions and can self-manage and not be overpowered or enmeshed by client□s emotions.

Active listening: Ability to focus completely on what the client is saying and is not saying, to understand the meaning of what is said in the context of the client's desires, and to support the client's self-expression.	◯ Attends to the client and the client□s agenda, and not to the coach's agenda for the client. ◯ Hears the client□s concerns, goals, values and beliefs about what is and is not possible. ◯ Distinguishes between the word, the tone of voice, and the body language. ◯ Summarizes, paraphrases, reiterates and mirrors back what the client has said to ensure clarity and understanding. ◯ Encourages, accepts, explores, and reinforces the client□s expression of feelings, perceptions, concerns, beliefs, suggests, etc. ◯ Integrates and builds on client□s ideas and suggestions. ◯ □Bottom-lines□ or understands the essence of the client□s communication and helps the client get there rather than engaging in long descriptive stories. ◯ Allows the client to vent or □clear□ the situation without judgement or attachment in order to move onto next steps.
Powerful questioning: Ability to ask questions that reveal the information needed for maximum benefit to the coaching relationship and the client.	◯ Ask questions that reflect active listening and an understanding of the client's perspective. ◯ Asks questions that evoke discovery, insight, commitment or action (e.g., those that challenge the client's assumptions). ◯ Asks open-ended questions that create greater clarity, possibility or new learning. ◯ Asks questions that move the client towards what they desire, not questions that ask for the client to justify or look backwards.
Direct communication: Ability to communicate effectively during coaching sessions, and to use language that has the greatest positive impact on the client.	◯ Is clear, articulate and direct in sharing and providing feedback. ◯ Reframes and articulates to help the client understand from another perspective what he/she wants or is uncertain about. ◯ Clearly states coaching objectives, meeting agenda, purpose of techniques or exercises. ◯ Uses language appropriate and respectful to the client (e.g. non-sexist, non-racist, non-technical, non-jargon) ◯ Uses metaphor and analogy to help illustrate a point or paint a verbal picture.

Creating awareness: Ability to integrate and accurately evaluate multiple sources of information, and to make interpretations that help the client to gain awareness and thereby achieve agreed-upon results.	◯ Goes beyond what is said in assessing the client's concerns, not getting hooked by the client's description. ◯ Invokes inquiry for greater understanding, awareness, and clarity. ◯ Identifies for the client his/her underlying concerns, typical and fixed ways of perceiving himself/herself and the world, differences between the facts and the interpretation, disparities between thoughts, feeling and action. ◯ Helps clients to discover for themselves the new thoughts, beliefs, perceptions, emotions, moods, etc. that strengthen their ability to take action and achieve what is important to them. ◯ Communicates broader perspectives to clients and inspires commitment to shift their viewpoints and find new possibilities for action. ◯ Helps clients to see the different, interrelated factors that affect them and their behaviours (e.g., thoughts, emotions, body, background). ◯ Expresses insights to clients in ways that are useful and meaningful for the client. ◯ Identifies major strengths vs. major areas for learning and growth, and what is most important to address during coaching. ◯ Asks the client to distinguish between trivial and significant issues, situational vs. ◯ recurring behaviours, when detecting a separation between what is being stated and what is being done.
Designing actions: Ability to create with the client opportunities for ongoing learning, during coaching and in work/life situations, and for taking new actions that will most effectively lead to agreed-upon coaching results.	◯ Brainstorms and assists the client to define actions that will enable the client to demonstrate, practice and deepen new learning. ◯ Helps the client to focus on and systematically explore specific concerns and opportunities that are central to agreed-upon coaching goals. ◯ Engages the client to explore alternative ideas and solutions, evaluate options, and make related decisions. ◯ Promotes active experimentation and self-discovery, where the client applies what has been discussed and learned during sessions immediately afterwards in his/her life setting. ◯ Celebrities client successes and capabilities for future growth. ◯ Challenges the client s assumptions and perspectives to provoke new ideas and find new possibilities for action. ◯ Advocates and brings forward points of view that are aligned with client goals and, without attachment, engages the client to consider them. ◯ Helps the client 'Do It Now' during the coaching session, providing immediate support. ◯ Encourages, stretches and challenges but also a comfortable pace of learning.

Planning and goal setting: Ability to develop and maintain an effective coaching plan with the client.	◯ Consolidates collected information and establishes a coaching plan and development goals with the client that address concerns and major areas for learning and development. ◯ Creates a plan with results that are attainable, measurable, and specific and have target dates. ◯ Makes plan adjustments as warranted by the coaching process and by changes in the situation. ◯ Helps the client identify and access different resources for learning (e.g. books, other professionals) ◯ Identifies and targets early successes that are important to the client.
Managing progress and accountability: Ability to hold attention on what is important for the client, and to leave responsibility with the client to take action.	◯ Clearly requests of the client actions that will move the client toward their stated goals ◯ Demonstrates follow through by asking the client about these actions that the client committed to during the previous session(s) ◯ Acknowledges the client for what they have done, not done, learned or became aware of since the previous session(s) ◯ Effectively prepares, organises and reviews with client information obtained during sessions ◯ Keeps the client on track between sessions by holding attention on the coaching plan and outcomes, agreed-upon courses of action, and topics for future sessions ◯ Focuses on the coaching plan but is also opened to adjusting behaviours and actions based on the coaching process and shifts in direction during sessions ◯ Is able to move back and forth between the big picture of where the client is heading, setting a context for what is being discussed and where the client wishes to go ◯ Promotes client's self-discipline and holds the client accountable for what they say they are going to do, for the results of intended action or for a specific plan with related timeframes ◯ Develops the client's ability to make decisions, address key concerns and develop himself/herself (to get feedback, to determine priorities and se4t the pace of learning, to reflect on and learn from experiences) ◯ Positively confronts the client with the fact that he/she did not take agreed-upon actions.
Total Competency Score	_____
General Comments and Recommendations:	_____

3. Coaching participant feedback

Today's date

_____

Including the last session, how many coaching sessions have you had so far?

_____

Participant session rating: On a scale of 1-10 with 10 being the best and 1 being the worst, please rate how you felt today's' session went for you?

1 5 10

(Place a mark on the scale above)

Please explain your reasons for this rating

_____

How well do you thing the coaching sessions have been responsive to you as an individual, keeping in mind your age, gender, ethnicity and any other characteristics?

- ◯ Excellent
- ◯ Very good, but could be improved
- ◯ Neutral
- ◯ Poor, much to be improved

Please explain your answer to the above

_____

Please add your feedback about the coaching, the coach, and any suggestions or comments.

_____