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Author

Smith, S, Parkinson, J, Caitens, T, Sanders, A, Murphy, L, Hamilton, K

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BMJ Open Promoting adherence to stroke secondary prevention behaviours by imparting behaviour change skills: protocol for a single-arm pilot trial of Living Well After Stroke

Stephanie Smith ^{1,2}, Joy Parkinson ³, Thomas Caitens,¹ Andrea Sanders,¹ Lisa Murphy ⁴, Kyra Hamilton ^{2,5,6}

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For numbered affiliations see end of article.

Correspondence to

Dr Stephanie Smith;
ssmith@strokefoundation.org.au

ABSTRACT

Introduction Survivors of stroke have an elevated risk of recurrent stroke. Prompt intervention to support healthy lifestyle modification following an initial stroke is crucial for effective secondary prevention of stroke. However, many patients do not receive adequate postdischarge support for secondary prevention, particularly if not referred to inpatient rehabilitation. Living Well After Stroke is a health promotion programme based on the health action process approach (HAPA), which is designed to support this underserved group to improve and self-manage secondary prevention behavioural performance (eg, diet, exercise, medication-adherence) by equipping participants with a toolkit of theory-based and evidence-based behaviour change strategies and techniques that are transferable to different behavioural contexts.

Methods and analysis The target sample is 118 adults living in Queensland, Australia, with stroke or transient ischaemic attack not referred to inpatient rehabilitation. Adopting a prospective single-arm trial design, the intervention comprises five behaviour change sessions over an 8-week period. Participants will receive a mix of individual-based and group-based assessments and interventions, based on the HAPA theoretical framework, delivered via telehealth or in-person (eg, public library). Measures of primary (ie, goal behaviours 1 and 2) and secondary outcomes (intention, outcome expectancy, risk perception, self-efficacy, planning, action control, subjective well-being) will be taken at 2 weeks, 4 weeks, 8 weeks and 16 weeks. The primary outcomes of the trial will be behavioural performance and transferability of behaviour change skills at 16 weeks.

Ethics and dissemination The study has received ethical approval from the Griffith University Human Research Ethics Committee (Ref no: 2022/308). Informed consent is obtained via telephone prior to data collection. Findings will be presented in the form of peer-reviewed journal articles, industry reports and conference presentations, and will be used to inform the continued development and refinement of the programme for testing in a future fully powered trial.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A key strength of Living Well After Stroke (LWAS) is its strong theoretical basis and deliberate mapping of evidence-based behaviour change strategies and techniques proposed to affect change in the key theoretical constructs that predict behavioural initiation and maintenance; with interventions developed in partnership with people with lived experience of stroke and expert stakeholders.
- ⇒ LWAS uses an innovative approach of equipping individuals with a set of transferable skills and strategies which are designed to support ongoing self-management of stroke secondary prevention behaviours.
- ⇒ The main limitation of this pilot trial is the lack of a no-treatment control group, preventing examination of between-participant effects of the intervention.

INTRODUCTION

People who have had a stroke or transient ischaemic attack (TIA) have an elevated risk of recurrent stroke,¹ with the 5-year rate of stroke recurrence estimated to be as high as 41%.² The risk of death and disability significantly increases with recurrent stroke events.³ However, it is estimated more than 80% of strokes can be prevented.⁴ Secondary prevention of stroke refers to the implementation of strategies to reduce the risk of stroke recurrence among people who have previously had a stroke or TIA. International best practice guidelines recommend a multimodal approach to secondary prevention by addressing medication prescription in conjunction with active provision of information and education regarding stroke, lifestyle and behavioural risk factors, and medication adherence.^{5,6} Prompt intervention to support healthy lifestyle modification following an initial stroke, which involves patients being assessed and informed

of their risk factors for recurrent stroke and educated about strategies to reduce their risk as soon as possible following a stroke event, is crucial for supporting health behaviour change for effective secondary prevention.⁷ Modifiable behavioural factors recommended for reducing risk of stroke recurrence include medication adherence, maintaining a healthy diet, being physically active, stopping smoking and limiting or avoiding alcohol.^{6,8–17}

Recent significant improvements to diagnosis and acute management and treatment of ischaemic stroke have led to an increasing number of survivors of stroke who have a good outcome making up a significant proportion of the total survivors of stroke.^{18,19} Although the model of acute care for stroke has changed significantly, there has been little change in the provision of postdischarge services to support those who do not require inpatient care for their rehabilitation, which is now most stroke cases in Australia.²⁰ As such, many individuals do not receive adequate postdischarge support for health behaviour change for stroke secondary prevention. Moreover, people with TIA or ‘mild stroke’ still commonly experience ongoing symptoms such as fatigue, changes in cognition and communication, affected emotional, social and physical functioning, and other subtle problems in activities of daily living,^{21–25} and these are likely to serve as barriers to adopting a healthy lifestyle to prevent recurrent stroke.²⁶ This further highlights the need for postdischarge services to support this underserved group to make behavioural changes that will reduce their risk of recurrent stroke.

Systematic and meta-analytic reviews reveal the growing number of interventions targeting lifestyle modification for stroke secondary prevention,^{14,27–33} however, consensus about their efficacy is yet to be established. To ensure effectiveness and compliance, it is recommended that behavioural interventions are informed by theory, and incorporate behaviour change techniques that are directly relevant to the mechanisms of change outlined by the theory.^{34–36} Identification of the mechanisms of change and theoretical premises guiding intervention design is severely lacking in the current literature.^{14,37} Furthermore, there is growing need for interventions that incorporate self-management skills training^{37,38}—which is currently underused in the context of behavioural modification for stroke secondary prevention. For example, it is common for behavioural interventions to target health promotion by prescribing exercise regimens, or setting meal plans for participants to follow for the duration of a study.^{39,40} However, such approaches are often insufficient at producing meaningful and sustained lifestyle change beyond an intervention period,^{41,42} which may be due to a lack of self-management skills being imparted. Equipping individuals with self-management skills is needed to support people to achieve the sustained behavioural and lifestyle changes that are necessary for effective secondary prevention of stroke.

Moreover, interventions that prescribe or encourage the adoption of secondary prevention behaviours (eg,

physical activity, healthful eating) have often relied on changes in physiological outcomes (eg, body mass index, blood pressure, low-density lipoprotein) as indicators of intervention efficacy, rather than testing the efficacy of the intervention at changing behaviour—which is a more direct and relevant outcome. Evidence already suggests a path by which behaviour modification precedes changes to physiological risk factors.^{43–46} Meta-analytical evidence also shows that lifestyle modification interventions for stroke secondary prevention are effective at changing behavioural outcomes, but not physiological outcomes—which the authors attributed to the temporal precedence of behavioural change relative to physiological changes.³³ Therefore, while it is useful to research whether changes in the behaviour predicted by theoretical constructs has a concomitant effect on physiological outcomes indicative of reduced risk from chronic illness, it is arguably more appropriate for behavioural intervention research to focus on the direct effect that the theory-based intervention has on behaviour.

The present study

Effective secondary prevention requires that positive behavioural changes are not only adopted by individuals but sustained in the long term, highlighting the need for stroke secondary prevention interventions that improve behavioural performance, as well as equip individuals with the necessary skills for long-term self-management of the behavioural and lifestyle risk factors associated with recurrent stroke. To address the identified service gap and the limitations of the current literature, the secondary prevention programme Living Well After Stroke has been designed to support people with lived experience of stroke to implement and self-manage behavioural changes to reduce their risk of recurrent stroke. Specifically, the intervention is informed by the health action process approach (HAPA),^{36,47,48} which is a prominent theoretical framework that has widely been applied to understanding health behaviour and used to inform the development of behaviour change interventions,^{36,48,49} including behavioural interventions targeting people with other chronic illnesses and disabilities.⁵⁰

Theoretical background

The HAPA specifies theoretical constructs that represent two key phases relating to intentional action: a motivational phase, where intentions to perform a health behaviour are established; and a volitional phase, where intentions are translated into action. In the motivational phase, intention is posited as a primary predictor of behaviour, with outcome expectancy, task self-efficacy and risk perception proposed as factors influencing behavioural intention. The volitional phase outlines self-regulatory beliefs, skills and strategies which are believed to facilitate behavioural initiation and maintenance, including coping self-efficacy, recovery self-efficacy, action planning, coping planning and action control.^{47,48}

The content of the intervention was developed by matching evidence-based behaviour change strategies and techniques—such as verbal persuasion, focusing on past success, mental imagery, goal setting, planning and self-monitoring—which are proposed to affect change in the motivational and volitional determinants of intention and behaviour outlined by the HAPA.^{51 52} Best practice techniques guided the design and development of the behaviour change strategies embedded in the intervention.^{36 53–62} The HAPA-based intervention strategies and activities are designed to increase individuals' motivation towards changing their current behaviour to align more closely with the clinical guidelines for stroke secondary prevention, and subsequently support them to initiate and maintain behavioural change. Moreover, the set of motivational and volitional intervention strategies are delivered to participants in the form of a 'toolkit,' and participants will be taught to apply the toolkit in additional behavioural contexts, thus, equipping individuals with the skills for ongoing self-management of stroke secondary prevention behaviour/s, relative to their individual needs.

Aims and hypotheses

The aim of the research is to develop and test a HAPA-based intervention designed to facilitate initiation and maintenance of stroke secondary prevention behaviours, and to impart a set of transferable skills and strategies for ongoing self-management of stroke secondary prevention behaviour. Participants recruited to the single-arm open label trial will complete a total of five sessions with a trained facilitator over an 8-week period, with sessions comprising a mix of individual-based and group-based assessments and interventions delivered in-person and via telehealth. Participants will initially form a goal to change a single secondary prevention behaviour of their choosing (ie, goal behaviour 1) at the beginning of the programme, which will provide the behavioural context for the theory-based behaviour change strategies delivered throughout the programme. At the final intervention session, participants will be instructed to form a new goal to change an additional secondary prevention behaviour (ie, goal behaviour 2), and on exiting the intervention, they will be instructed to independently apply their toolkit of behaviour change strategies to the new goal behaviour. The primary research questions and respective pre-registered hypotheses are as follows:

1. Does the intervention lead to increased performance of participants' chosen stroke secondary prevention behaviour (goal behaviour 1)? Hypothesis: There will be a significant increase in participants' performance of their chosen secondary prevention behaviour (goal behaviour 1) from session 2 (baseline) to session 4 (4weeks) (H1a), session 5 (8weeks) (H1b), and follow-up at 16weeks (H1c).
2. Are the theory-based behaviour change skills and strategies transferable to new behavioural contexts? Hypothesis: There will be a significant increase in

participants' performance of an additional secondary prevention behaviour (goal behaviour 2) from session 5 (8weeks) to follow-up at 16weeks (H2).

The secondary research questions are as follows:

3. Does the intervention lead to changes in HAPA motivational and volitional beliefs and processes in relation to participants' chosen stroke secondary prevention behaviour/s? Exploratory analyses will be conducted to test whether the intervention leads to changes in intention, outcome expectancy, risk perception, self-efficacy, planning and action control in relation to goal behaviours 1 and 2, and subjective well-being.

METHODS AND ANALYSIS

The study protocol is reported in accordance with Standard Protocol Items: Recommendations for Interventional Trials standard protocol items for clinical trials.^{63 64}

Study design

The study will adopt a four-wave single-arm prospective open label trial design over 16weeks. The non-randomised trial will be conducted and reported in accordance with an adapted Consolidated Standards of Reporting Trials checklist for pilot studies.^{65 66} The trial is preregistered on Open Science Framework (<https://osf.io/ny8qa>) and has approval from the University Human Research Ethics Committee (Ref no: 2022/308). See [figure 1](#) for the flow of participants through the study.

Participants

Participants will include adults with stroke or TIA who (1) are ≥ 18 years, (2) reside in Queensland, (3) are between 3 months and 5 years post stroke or TIA and (4) were discharged home from hospital after their most recent stroke or TIA (ie, were not referred to in-patient rehabilitation). The 3-month cut-off is based on evidence for lower rates of participant retention in interventions among individuals recruited very soon after their stroke⁶⁷; and the 5-year cut-off is based on similar intervention studies for stroke secondary prevention⁶⁸ as well as evidence that the rate of stroke recurrence is similar at 1 and 5 years poststroke.^{1 69} Eligible participants will be recruited from the community and through hospital-based stroke clinics. The research team will contact prospective participants by telephone to screen for eligibility, obtain informed consent and enrol participants into the study. Anyone who does not meet the eligibility criteria will be referred to alternative Stroke Foundation postdischarge services and support for individuals with stroke.

Intervention

The intervention comprises five behaviour change sessions over 8weeks, with a mix of individual-based and group-based assessments and interventions delivered in-person and online. Sessions will be led by a group

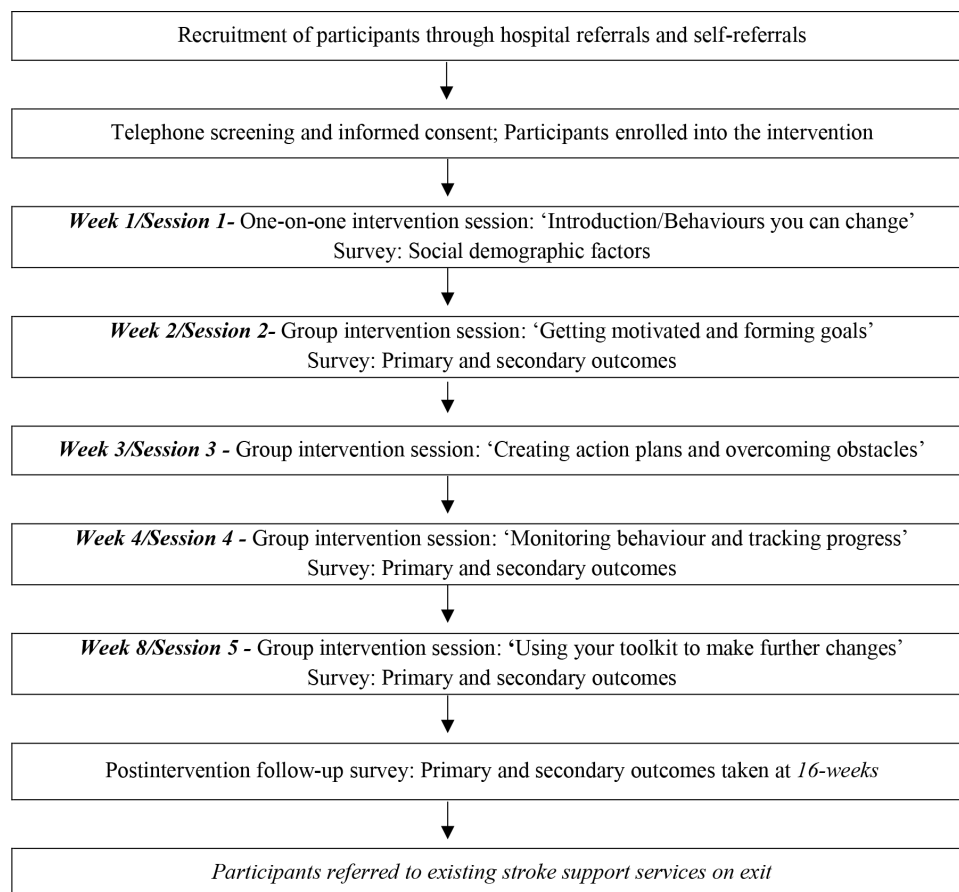


Figure 1 Flow of participants through the trial, and descriptions of the intervention content in each of the five sessions.

facilitator with appropriate experience and training delivering group-based behaviour change interventions to optimise effectiveness.⁷⁰ On enrolment, participants will receive a workbook containing health information on stroke secondary prevention, intervention activities, instructions for attending sessions and contact information for additional support services. Participants will also receive information (both hard copy and links to online resources) about recommendations for stroke secondary prevention behaviours: healthy eating, physical activity, medication adherence, smoking cessation and consuming alcohol within safe limits.⁶ Session scheduling information and reminders for the intervention sessions will also be delivered via email and text message. Furthermore, participants are informed that a support person is welcome to attend the sessions and participate in the intervention activities with them.

An initial one-on-one session (session 1) between participant and facilitator will be delivered online via 'Zoom' (Zoom Video Communications) and will run approximately 30 min. At the end of session 1, participants will be enrolled into a small group (n = ~8) with whom they will complete sessions 2–5. Sessions 2–5 (approximately 2 hours each) will be group-based sessions led by the facilitator and delivered online or in-person depending on participants' preference. Session 2, 3 and 4 are spaced 1 week apart, and sessions 4 and 5 spaced 4 weeks apart.

The intervention content was developed by the authors for this study, by mapping appropriate behaviour change strategies to the theoretical mechanisms of change outlined by the HAPA,^{51 52} and guided by best practice techniques for behaviour change strategies targeting change in the HAPA constructs they were mapped to.^{36 53–62}

Patient and public involvement

The Living Well After Stroke programme sessions and workbook were codesigned in partnership with people with lived experience of stroke and expert stakeholders to ensure acceptability of the interventions while retaining all evidence-based essential components. During development of the programme the study design, priority of study aims, educational and intervention content, choice of outcome measures and methods of recruitment were informed by discussions with a steering committee that included a person with lived experience of stroke and other expert stakeholders. Intervention materials were then independently reviewed and revised based on feedback from the National Stroke Foundation expert groups including the consumer council. Intervention prototypes were then delivered and revised based on feedback obtained during three unstructured focus

groups with a small group of people with lived experience of stroke.

Procedures

Session 1 (week 1)

The initial one-on-one session is designed to introduce participants to the programme, and to deliver educational information relating to stroke secondary prevention behavioural guidelines, which covers healthful eating, physical activity, smoking cessation, consuming alcohol within safe limits and medication adherence.⁶ Participants are then encouraged to consider their performance of the five health behaviours against the recommended guidelines, with the facilitator guiding them to identify the behaviour(s) relevant to them, to inform their selection of the single most salient behaviour they will focus on changing over the course of the programme.

Session 2 (week 2)

At the beginning of session 2, participants are instructed to select a single stroke secondary prevention behaviour (eg, physical activity, healthful eating, medication adherence) to focus on changing for the duration of the programme (ie, goal behaviour 1). Participants are then guided through a series of activities designed to build motivation towards changing their target secondary prevention behaviour by targeting self-efficacy, outcome expectancy and intention, as specified by the HAPA. The intervention strategies adopted in session 2 include goal setting, whereby participants set a goal defined in terms of the behaviour to be achieved (eg, 'I want to walk for 20 min, three times each week')⁵²; public commitment (ie, participants announce their goal to the rest of the group)⁵¹; focusing on past success (ie, participants think about or list previous successes in implementing their goal behaviour—or any new behaviour)⁵² and an outcome mental imagery task (ie, participants vividly imagine the likely or possible positive outcomes of regularly performing their goal behaviour).⁵²

Session 3 (week 3)

Session 3 comprises strategies designed to facilitate behavioural enaction by promoting the HAPA volitional construct planning in relation to participants' goal behaviour. The intervention strategies adopted in session 3 include action planning (ie, prompting detailed planning of performance of the behaviour by specifying 'when,' 'where' and 'how,' and the frequency and duration of performance)⁵²; preparatory planning (ie, prompting the formulation of plans that enhance the availability and accessibility of resources needed to obtain their goal)⁷¹ and coping planning (ie, formulation of plans to overcome important barriers when action initiation and/or maintenance is challenged).⁵² Self-efficacy is also targeted by instructing participants to focus on past success with respect to overcoming barriers (eg, participants think about or list previous successes in overcoming barriers to behavioural performance).⁵²

Session 4 (week 4)

Session 4 comprises strategies designed to facilitate behavioural maintenance by promoting the HAPA volitional construct action control in relation to participants' goal behaviour. The intervention strategies adopted in session 4 include self-monitoring of behaviour using a strategy tailored to participants' needs and preferences (ie, participants select a preferred self-monitoring strategy to track performance of their goal behaviour⁵¹; a goal setting activity, where participants set a goal defined in terms of the behavioural self-monitoring strategy to be implemented over the next 4 weeks (eg, 'I want to use a diary to keep record of my physical activity over the next 4 weeks')⁵²; and a process mental imagery task (ie, participants mentally rehearse tracking behavioural performance using their chosen self-monitoring strategy in relevant contexts over the next 4 weeks).⁵² Self-efficacy is also targeted by instructing participants to focus on past success with respect to recovering from setbacks (eg, participants think about or list previous successes in recovering from setbacks to behavioural performance).⁵²

Session 5 (week 8)

The primary objective of session 5 is to demonstrate how the programme strategies can be applied to make additional changes to health behaviour. Participants will be presented with a schematic representation of the programme content to enable the learner to activate relevant schemas so that new material can be associated,⁵¹ which will guide the demonstration of how the intervention strategies can be applied in additional behavioural contexts. A simplified checklist of the key intervention strategies delivered in sessions 2–4 will be presented to participants as a 'toolkit' of skills and strategies for self-managing health behaviour change. Participants will be instructed to review their initial behaviour change goal to include the performance of an additional secondary prevention behaviour (ie, goal behaviour 2).⁵² In addition to maintaining performance of their initial secondary prevention behaviour, participants will be instructed to use their toolkit of strategies and apply them to the new behaviour after the session has finished.

Measures

Measures of key social demographic factors will be taken at session 1. Data collection time points for the key social psychological and behavioural measures in relation to participants' goal behaviour (goal behaviour 1) will be at session 2 (2 weeks), session 4 (4 weeks), session 5 (8 weeks) and at the 16-week follow-up, to evaluate change over a 16-week period. Surveys at 8 weeks and 16 weeks will also include an additional set of measures of behaviour and HAPA constructs in relation to the additional secondary prevention behaviour selected by participants in session 5 (goal behaviour 2). Surveys will be completed at the beginning of the session, except for session 2 (2 weeks) where surveys will be completed immediately after participants select their 'goal behaviour 1' during the session.

Table 1 Outcome operationalisations, scale items and scoring for study measures of behaviour, HAPA constructs and subjective well-being

Outcome	Operationalisation	Measurement items	Scoring	Reference
Goal behaviour	Participants' chosen secondary prevention behaviour	<ol style="list-style-type: none"> 1. In the past [timeframe], how often did you generally perform your goal behaviour? 2. I performed my goal behaviour in the past (time frame). 	7-point scale from never (1) to always (7) 7-point scale from definitely false (1) to definitely true (7)	72 79
Intention	Intention to perform the chosen secondary prevention behaviour	<ol style="list-style-type: none"> 1. It is likely that I will perform my goal behaviour 2. I intend to perform my goal behaviour 3. I plan to perform my goal behaviour 	7-point scale from strongly disagree (1) to strongly agree (7)	72 79
Outcome expectancy	Outcome expectancy refers to the positive and negative expectations concerning the consequences of adopting a behaviour, ⁴⁷ akin to 'attitude' towards a behaviour	Performing my goal behaviour in the next week would be...	1=unpleasant, 7=pleasant; 1=bad, 7=good; 1=worthless, 7=valuable	72 79
Risk perception	Risk perception refers to the perceived severity and personal vulnerability to particular health conditions or outcomes ⁴⁷	<ol style="list-style-type: none"> 1. It would be risky for me to not perform my goal behaviour 2. If I did not perform my goal behaviour there would be risk involved 	7-point scale from strongly disagree (1) to strongly agree (7)	47
Self-efficacy	Self-efficacy refers to beliefs about personal capability and capacity to perform a given behaviour	<ol style="list-style-type: none"> 1. It is mostly up to me whether I perform my goal behaviour 2. I have complete control over whether I perform my goal behaviour 3. It would be easy for me to perform my goal behaviour 4. I am confident that I could perform my goal behaviour 	7-point scale from strongly disagree (1) to strongly agree (7)	72 79
Planning	Planning refers to the identification of salient cues that lead to action such as the situation parameters and the sequence of action ⁴⁷	I have a plan for... <ol style="list-style-type: none"> 1. When to perform my goal behaviour 2. Where to perform my goal behaviour 3. How often to perform my goal behaviour 4. How to perform my goal behaviour 	7-point scale from strongly disagree (1) to strongly agree (7)	80
Action control	Action control refers to beliefs about personal ability to self-monitor behavioural performance, and to self-regulate effort to ensure behaviour is performed to the intended standard ⁴⁷	<ol style="list-style-type: none"> 1. I have consistently monitored when, how often, and how to perform my goal behaviour 2. Performing my goal behaviour has always been on my mind 3. I have really tried hard to perform my goal behaviour 	7-point scale from strongly disagree (1) to strongly agree (7)	80
Subjective well-being	Current state of positive mental well-being	Over the past 2 weeks... <ol style="list-style-type: none"> 1. I have felt cheerful and in good spirits 2. I have felt calm and relaxed 3. I have felt active and vigorous 4. I woke up feeling fresh and rested 5. My daily life has been filled with things that interest me 	6-point scale from at no time (0) to all the time (5)	74

HAPA, health action process approach.

The psychological constructs will be measured on multi-item psychometric instruments developed using standardised guidelines.^{72 73} All items will be rated on a 7-point Likert scale (1=strongly disagree to 7=strongly agree), unless otherwise specified. See [table 1](#) for full details of all measures that will be used in the study.

Goal behaviour (1 and 2)

Participants will select their preferred secondary prevention behaviour (eg, physical activity, healthful eating, medication adherence), and specify a goal to change that behaviour (eg, 'I want to walk for 20 min, three times per week'). Participants will be instructed to think about their goal behaviour when responding to the survey items.

Two items will measure participants' goal behaviour: (1) 'In the past (time frame), how often did you generally perform your goal behaviour?' measured on a 7-point Likert scale (1=never to 7=always); (2) 'In the past (time frame), I performed my goal behaviour' measured on a 7-point Likert scale (1=false to 7=true).

Intention

Three items will measure intention to perform the goal behaviour (eg, 'I intend to perform my goal behaviour').

Outcome expectancy

Outcome expectancy toward the goal behaviour will be measured in response to the common stem: 'Performing

my goal behaviour would be....' With responses provided on three 7-point semantic differential scales (1=unpleasant to 7=pleasant; 1=bad to 7=good; 1=worthless to 7=valuable).

Risk perception

Two items will measure participants' perceived risk with respect to not performing the goal behaviour (eg, 'It would be risky for me not to perform my goal behaviour').

Self-efficacy

Four items will measure participants' confidence in their ability to perform their goal behaviour (eg, 'I am confident that I could perform my goal behaviour').

Planning

Four items will measure the extent to which participants have formed a plan to perform their goal behaviour (eg, 'I have a plan for when to perform my goal behaviour').

Action control

Three items will measure action control with respect to engaging in the goal behaviour (eg, 'I have consistently monitored when, how often, and how I perform my goal behaviour').

Subjective well-being

Subjective well-being will be measured using the WHO's 5-item Well-being Index (WHO-5).⁷⁴

Baseline participant characteristics

A range of participant characteristics will be measured at baseline to describe the sample: number of strokes/TIA, time since last stroke/TIA, type of stroke (most recent), gender, age, postcode, ethnicity, marital status, parental status, household makeup, socioeconomic status (eg, education, employment, income).

Power analysis

An a priori power analysis was conducted using G*Power V.3.1 for a single-arm repeated measures analysis of variance (ANOVA) model estimating main effects (ie, main effect of time on behaviour) with data collected on four occasions. The effect size was set to Cohen's $f=0.10$ to detect a conservatively small effect,⁷⁵ which was chosen due to the lack of previous research on HAPA-based behavioural interventions among survivors of stroke which could inform the expected effect size. Power was set at 0.80, alpha was set at 0.01 (adjusted to protect from inflation of type I error rate due to multiple tests), and the correlation between repeated measures set at 0.70, which was based on previous research that observed strong correlations between repeated measures of behaviour in a HAPA-based behaviour change intervention.⁷⁶ The analysis yielded a total minimum required sample size of 118.

Statistical analysis

Statistical analysis of the intervention data will be carried out using SPSS V.27. The efficacy of the intervention will

be tested using a series of repeated-measures ANOVAs with a Bonferroni correction applied to control for inflated type-1 error rate, with time (2 weeks, 4 weeks, 8 weeks, 16 weeks) as the within-participants variable, and the primary outcome (goal behaviour 1) and secondary outcomes (intention, outcome expectancy, risk perception, self-efficacy, planning, action control and subjective well-being) as separate dependent variables. Where an ANOVA indicates that there is a significant main effect of time for any of the outcome variables, pairwise comparisons will be conducted to explore within-group differences in the outcomes between time points. An independent samples t-test will be conducted to explore within-participant differences of goal behaviour 2 between 8 weeks and 16 weeks. Alpha will be set at 0.01 for the preregistered analyses (adjusted to protect from inflation of type I error rate due to multiple tests). Missing data will be imputed using the expectation-maximisation algorithm.

Ethics and dissemination

This study received ethical clearance from the Griffith University Human Research Ethics Committee (Ref. 2022/308). We anticipate that the rigorous development will ensure that no amendments to the protocol are required. However, if any amendments are required, they will be submitted as amendments to the Open Science Framework Registry record and reported in the final report of the study. We do not anticipate any risks greater than daily living. However, participants are provided with contact information for telephone support services, should they experience any discomfort due to undertaking the study. The findings will also inform the continued development and refinement of the programme for testing in a future fully powered trial.

Informed consent

Prospective participants are provided with a study information sheet on referral into the programme. A member of the research team will contact prospective participants by telephone to confirm eligibility and to obtain informed consent prior to the participant being enrolled into the study and prior to data collection. Participants are also advised in the information sheet that they are free to cease participation at any time without comment or penalty. See online supplemental material 1 for the participant information and consent materials for this study.

Confidentiality

Participants are informed in the study information sheet that the conduct of the research involves the collection, access, storage and/or use of their identified personal information, and provided assurances that personal information they provide will be treated confidentially, will be stored securely by the research team on a password-protected platform, and will not be disclosed to third parties without their consent, except to meet government,



legal or other regulatory authority requirements. Participants are also informed that a deidentified copy of this data may be used for other research purposes, including publishing openly (eg, in an open access repository), but their anonymity will at all times be safeguarded. Participants' data will not be identifiable in any publication or reporting.

Data deposition

Prior to publication of the results, data will be stored securely on the password protected Stroke Foundation OneDrive allocation which will be accessible only by authors SS, TC, AS and LM. Given the restrictions on access to the data, a data monitoring committee will not be required. Following publication, deidentified data and statistical code will be made available on Open Science Framework.

Dissemination

The findings will be presented in the form of peer-reviewed journal articles and industry reports and will be presented at scientific conferences. The authors of this protocol will author publications arising from this trial. Media releases and public statements about the research will also be made to disseminate the findings to the general public. The findings will also be made available to participants if requested. Contact details and procedure for requesting the results will be made available in the study information sheet.

DISCUSSION

The research addresses a major gap in stroke secondary prevention (ie, reducing the risk of stroke recurrence among people who have previously had a stroke or TIA), which is theory-based and evidence-based interventions that support people with stroke to modify their health behaviours and impart self-management skills for ongoing behavioural modification. The theoretical basis of the intervention is a key strength of the trial, along with the deliberate mapping of evidence-based behaviour change strategies and techniques proposed to affect change in the key theoretical determinants of behavioural intention and enactment. Furthermore, the intervention materials have been codesigned in partnership with people with lived experience of stroke and expert stakeholders. Another major strength of the programme is the innovative approach of imparting self-management skills in the context of health behaviour change, which is designed to equip individuals with a set of transferable skills and strategies to support ongoing self-management of stroke secondary prevention behaviours. In addition, the intervention has been developed for both in-person and online delivery, thus ensuring geographical location is not a prohibitive factor in accessing the programme.

The main limitation of this pilot trial is the lack of a no-treatment control group, which will prevent the examination of between-participant effects of the intervention.

Another limitation of this study is inadequate recruitment and retention of participants, which could lead to underpowered analyses or missing data points that would challenge the internal validity of reported results. Efforts to maximise enrolment and minimise loss to follow-up will include not recruiting participants too soon poststroke,⁶⁷ consideration of participants' needs regarding timing of the intervention, establishing consistent study procedures (eg, same time and location of intervention sessions), maintaining regular communication with participants including automated reminders about upcoming sessions or study tasks, and having the sessions delivered by an experienced and charismatic instructor who can readily establish good rapport with participants.⁷⁷

Another limitation is the lack of emotional, physical and mental health-related outcomes being examined in this study. The aim of this pilot trial is to obtain preliminary evidence for the effectiveness of the intervention at changing the health behaviours associated with risk of recurrent stroke. However, it is expected that mental health-related factors could influence the effectiveness of the intervention and should therefore be examined in this context in a future large-scale trial of the intervention. Finally, the current programme is being developed for ongoing delivery by National Stroke Foundation, Australia, however, it should be acknowledged that large scale adoption of the intervention internationally and across diverse healthcare systems may present challenges, thus, potentially limiting the generalisability of the intervention.

A full protocol for the process evaluation of the programme based on the RE-AIM framework (ie, reach, effectiveness, adoption, implementation, and maintenance),⁷⁸ and augmented to include feasibility, will be reported elsewhere. This pilot trial will provide formative evidence on the effectiveness of an engaging, personalised self-management programme which will inform the continued development and refinement of the programme for testing in a future fully powered trial. Living Well After Stroke has significant potential to improve secondary prevention of stroke, and reduce secondary stroke incidence, through positive behaviour change. Once validated, Living Well After Stroke is intended to be an ongoing support service provided by National Stroke Foundation, Australia, which will be delivered by trained group facilitators. This programme has the potential to transform models of care for people who have had a stroke in Australia by addressing this identified service gap, with future directions involving a digital adaption of the intervention to maximise reach and impact.

Author affiliations

¹National Stroke Foundation, Brisbane, Queensland, Australia

²School of Applied Psychology, Griffith University, Brisbane, Queensland, Australia

³Australian eHealth Research Centre, CSIRO, Herston, Queensland, Australia

⁴National Stroke Foundation, Melbourne, Victoria, Australia

⁵Menzies Health Institute Queensland, Griffith University, Gold Coast, Queensland, Australia

⁶Health Sciences Research Institute, University of California, Merced, California, USA

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ORCID iDs

Stephanie Smith <http://orcid.org/0000-0002-6892-4379>

Joy Parkinson <http://orcid.org/0000-0001-6265-0277>

Lisa Murphy <http://orcid.org/0000-0003-0248-0362>

Kyra Hamilton <http://orcid.org/0000-0001-9975-685X>

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