BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031984
Article Type:	Protocol
Date Submitted by the Author:	28-May-2019
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Keywords:	Stroke < NEUROLOGY, Prevention, Mhealth, PRIMARY CARE, stroke risk, occupational therapy

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Word count: 3839 (excluding title page, abstract, references, and table).
Protocol version: 27th May 2019. Version 1.0

Trial Registration number: ClinicalTrials.gov Identifier: NCT03730701

Abstract

Introduction

Stroke is a globally common disease that has detrimental effects on the individual and, more broadly, on society. Lifestyle change can contribute to reducing risk factors for stroke. Although there are direct benefits of a healthy lifestyle, sustaining and incorporating healthy activities into everyday life is a challenge. Engaging everyday activities have the potential to support lifestyle change and promote sustainable activity patterns. Current healthcare is failing to reduce modifiable risk factors in people at risk, and in addition to current practice, there is a need for systematic and efficient non-pharmacological and non-surgical stroke prevention strategies. The aim of the pilot study is to increase knowledge about the effects of a prevention programme and its feasibility to promote sustainable and healthy activity patterns among persons at risk for stroke.

Methods and analysis

The proposed pilot study will be a two-armed randomised, assessor-blinded, parallel pilot trial. The study will include feasibility data, investigating acceptability and delivery of the intervention. Persons at risk of stroke (n=60) will be included in a mobile phone-supported prevention programme. The 10-week programme will be conducted at primary healthcare clinics, combining group meetings and online resources to support self-management of lifestyle change. Main outcomes are stroke risk, lifestyle habits and healthy activity pattern. Assessments will be performed at baseline and at follow-up (immediately following the end of the programme and at 6 and 12 months). Effects of the programme will be analysed using inferential statistics. Feasibility will be analysed using both qualitative and quantitative methods.

Ethics and dissemination

The study has been approved by the Regional Ethical Review Board in Stockholm, Sweden, being granted Ref. Nos. 2015/834-31, 2016/2203-32 and 2019/01444. Study results will be disseminated through peer-review journals and presentations to mixed audiences at regional and international conferences.

Article Summary

Strengths and limitations of this study

- A major strength of the proposed study is the utilisation of engaging everyday activities as a mediator for sustainable lifestyle change.
- The study is designed as a randomised controlled trial and will provide preliminary data on the effects of a prevention programme for persons at risk of stroke.
- Mobile phone technology will be used to support lifestyle change processes among participants.
- The combination of qualitative and quantitative data systematically collected before and after the intervention period will provide rich data, which is useful for analysing the feasibility of the programme and its impact on the health and well-being of persons at risk of stroke.
- A limitation of the study is a relatively small sample size, which can result in insufficient power to determine effects.

INTRODUCTION

Stroke is the third-leading cause of the global disease burden based on disability-adjusted life years (DALYs), which is a measure of years lost due to death, poor health or disability (1). The residual effects of stroke detrimentally impact on quality of life in terms of limiting physical, social, and emotional health both for persons with stroke and their caregivers (2). Subsequently, the economic impact of stroke is estimated at 76,000 Euros for the first 2 years after the event, not including indirect costs such as loss of income and family burden (1). The magnitude of the problem can be put into context, considering evidence that suggests that many of the risk factors for stroke and other cardiovascular events are modifiable: tobacco use, excessive alcohol consumption, type 2 diabetes, hypertension, physical inactivity and dietary intake leading to high cholesterol and/or obesity (1, 3). Meaningful and purposeful everyday activities combined with moderate physical activities and a healthy diet has been found to be strongly related to well-being and longevity (4, 5). However, a recent focus-group study with general practitioners in a Swedish primary healthcare context revealed that there was a lack of systematic screening of stroke risk and adherence to risk factor modification was rare (6).

Theoretical concept of the prevention program

The prevention program in this study is a theoretically grounded, complex intervention (7). The programme is based on activities in people's everyday lives and integrates health and well-being with what people do, as well as with what they want or need to do, in order to thrive and live well (8, 9).

In this protocol, the term lifestyle is used to conceptualize and define activity patterns (individual actions and behaviour) in everyday life that may or may not contribute to health. Lifestyle change refers to a conscious change of behaviour and everyday activities in order to promote health. The process of changing behaviour results from an interaction between the person (e.g. self-efficacy), the environment (support and material) and the action (10). In the project, the key behavioural change technique (11), is incorporating engaging everyday activities (EEA) that contribute to a healthy lifestyle. This might include changing the form of current EEAs or finding new health-promoting EEAs.

Engaging everyday activity – a game-changer

Although the benefits of healthy lifestyle are clear (3, 12) the long-term effect and maintenance of healthy lifestyle are not (13-16). The effectiveness of primary healthcare-based physical activity's interventions are inconclusive (17). There is evidence for short-term improvements, but there is a lack of evidence for long-term effects (14). Successfully and

sustainably incorporating healthy lifestyle patterns into everyday life is a challenge for many people. Engaging everyday activities (EEA) are seen as the means and goal for changing and sustaining a healthy lifestyle. EEAs occur in the interaction between the individual and the sociocultural setting (18). EEAs are personal activities done regularly and seen by the individual as valuable, meaningful and purposeful, as well as providing an intense sense of participation (19). EEAs can go beyond personal pleasure and can have a higher level of importance due to meaning for others such as family, friends or society at large. EEAs are the things that people do that make life worth living and that can contribute to well-being (9, 19, 20). Studies have shown that promoting EEAs can have positive health impacts for older adults (8, 18, 21, 22). However, EEAs can also lead to ill health in cases where the EAA contributes to the sedimentation of risk factors in everyday life. Although EEAs can be a key to incorporating change and sustainable healthy lifestyle choices to reduce the risk for stroke, there is a need to systematically explore this further.

Sharing personal experiences as part of a change process

The intervention in the present study espouses the idea that personal experiences should be the point of departure for a person-centred prevention programme, enabling individual autonomy in decisions regarding lifestyle change. Sharing experiences, shared activities and reflections lead to learning about one's own stroke risk, activity patterns and habits. Bryan and colleagues (23) have used theories to summarise five central principles for adult learning: a) adults need to know why they are learning; b) adults need to be motivated to learn by the need to solve problems; c) adults' previous experiences must be respected and built upon; d) learning approaches should match adults' backgrounds and diversity; e) adults need to be actively involved in the learning process. The programme will be tailored to match needs and competences of the individual and build on participants' previous experiences. In addition to increase literacy with regard to stroke risk and change, there is a need to learn how to use digital support systems efficiently. Participants in the study will be actively involved in setting their own goals because this is important in order to manage their health while following the programme.

Objectives of the proposed study

The aim is to gain knowledge concerning the effectiveness of a prevention programme in promoting sustainable and healthy activity patterns and enabling lifestyle change together with and among people at risk of stroke. The study's aim is also to gain knowledge about the feasibility and usefulness of a research protocol that includes a mobile phone application (app).

METHODS AND ANALYSIS

Design

The pilot study will be a two-armed randomised, assessor-blinded, parallel pilot trial. The protocol also includes a feasibility study combining qualitative interviews and descriptive quantitative data, investigating the acceptability and delivery of the intervention (24).

Study setting

The study will be conducted in close collaboration with Primary healthcare clinics (PHC) in the Stockholm area (different parts of Stockholm in order to reach a diverse population of healthcare seekers) and in PHCs in both urban and rural areas in the County Council of Gävleborg.

Sample size and power considerations

This study is an explorative pilot and feasibility study; no statistical power analyses have been calculated. It is estimated that a total of four PHCs will participate, (two from Stockholm, two from Gävleborg) each running an intervention group with 8-10 participants. A drop-out rate of 20% is expected, resulting in a total of n= 26 in the intervention and control groups, respectively.

Participant timeline

Participant enrolment will be started in June 2019 and the last qualitative interview is scheduled for before June 2020. During this period, 60 participants are expected to be enrolled in the study (30 controls and 30 in the intervention group).

Participants: Eligibility criteria

Persons at risk of stroke will be included in the project and recruitment will be by means of advertisements in local newspapers, webpage and at PHCs. A stroke risk screening survey (potential participants are either self-screened online or screened by a professional at their PHC) will be used to find eligible participants. A total sample of n=60 participants (persons at risk of stroke), divided into two arms (30+30) intervention and controls is estimated. Block randomisation will be utilised with a block size of four (2 control=A and 2 intervention=B, with blocks of 4 having random block orders: AABB, ABAB, ABBA, BABA, BAAB, and BBAA) to allocate patients to either the intervention or the control group (25). Inclusion criteria are that the participants a) have a high risk for stroke according to the Stroke Risk Score card (26), b) are motivated for lifestyle change and for participating in a digital lifestyle prevention (including the use of a smart phone or tablet), c) are between 45-70 years old and without a diagnosis of dementia or cognitive impairment hindering participation. Exclusion criteria are

having previously had a Stroke or TIA diagnosis and lack of understanding the Swedish language.

The researchers will encourage and guide any participant who experiences health-related problems during the programme to get in contact with his or her general practitioner, GP. Participants may choose to interrupt their participation in the study at any time. The researcher can also discontinue a participant's participation based on health issues or reasons that might jeopardize that person's safety. Reasons for interruption will be recorded.

Active Lifestyle – a stroke-prevention programme

The prevention programme is based on earlier research evidence and theoretical underpinnings as presented, and on preliminary studies conducted by the research group (6). The inter-professional research group together with health professionals and technicians had a total of four workshops during 2015-2017 with the aim of modelling the components and themes of the programme. A logic model (27) was created in order to plan and organise the intervention. The logic model was used to visualise possible conflicts, barriers, contradictions, needed resources, activities, outputs and impacts of the research process.

The Active Lifestyle prevention programme enables healthy activity patterns and aims to reduce the risk of stroke by means of four strategies: a) the incorporation of health-promoting EEAs, b) the use of mobile phone technology to increase health literacy and awareness of current habits c) forming new habits that prompt conscious decisions to make healthy choices, and d) setting realistic goals and sharing experience in a learning environment.

Duration and specific content of the intervention programme

The Active Lifestyle stroke-prevention programme is a 10-week programme. The intervention will include 5 sessions over 5 weeks with a booster session 5 weeks later. The programme starts with an individual meeting (baseline) and with a follow-up meeting one week after the last group session. The participants in the intervention group will set three self-chosen goals for lifestyle change formulated as daily goals based on an interview done at baseline using the Canadian Occupational Performance Measure (28). During the intervention, participants will work actively with both EEAs and habits in order to change behaviour and lifestyle. For example, a person may have reading as an EEA, an activity that is relatively neutral on a continuum of health-promotion. The activity might be experienced as engaging and meaningful, and contribute to psychological wellbeing, but a redesign of the activity could be walking or exercising at the gym while listening to an audio book, leading to health benefits which could be accepted and incorporated into the individual's activity patterns. During the

programme, the participants will become aware of their current lifestyle habits as well as new habits that are formed by the participants themselves. New habits may be cued by situations (such as seeing an escalator) prompting a health-promoting behaviour and making a conscious decision (e.g. to take the stairs) (29).

Each module has a theme and relevant activities. Group dynamics are used to reflect on experiences, doing and future goals. The modules, presented in table 1, are delivered by an interventionist/researcher together with a trained health professional (training during two half-days), for example an occupational therapist, physiotherapist or dietician.

Table 1: Summary of module themes, concepts and activities supporting a change process

Module theme	Concepts	Activity
1: Risk factors for stroke and engaging activities	Health literacy concerning stroke risk, engaging activities, change process, expectations	Peer interview on engaging activities. Learn how to register in the app. Set three lifestyle change goals
2: Physical activity	Physical activity, physical inactivity	Try a physical group exercise class at a gym
3: Diet and health	Dietary routines and change	Prepare and test a healthy sandwich
4: Balanced everyday life	Activity balance, stress	Relaxation, for example medical yoga
5: Sustained health: routines and activity patterns	Current and desired routines and activity patterns, revisiting goals	Walking session
Booster session: “Future horizon”, identity, self-management of health and social aspects of health	Self-management, view of the self, social support	Preparing healthy snacks and walking and talking in a park

The mobile phone app

The app for the project was developed in close collaboration with ScientificMed Tech AB (http://www.scientificmed.com). ScientificMed Tech has a solid track record with publications on similar platforms (30, 31). The digital platform includes several unique aspects in the data input logic, which contributes to immediate feedback on progress as well as tracking of personally tailored goals related to stroke risk in the context of everyday life. The app includes six domains for registering daily activities, experiences and behaviours: Goal achievements (questions on how well the person has achieved the three pre-set goals and self-efficacy), Physical activity (registering step counts, registering 24 hr time use in relation to exercise, moderate intense activities, sleep, sedentary activities and other activities), Engaging everyday activities (participating in EEAs and self-efficacy), Tobacco and alcohol use (registering consumption), Stress levels (questions about perceived time-pressure) and Dietary habits (registering consumption of fruits/vegetables, breakfast, fish and snacks). Registrations result in graphs and plots that inform the participant of current behaviours and which serve as feedback on habits. The six domains are based on modifiable risk factors for stroke as presented by the American Heart Association (3) with the addition of promoting EEAs and reducing stress. The purpose of the app is to support the participant's change process via registration, feedback and self-management of habits and behaviours that impact on health and risk of stroke. Novice technology users will have extra training in the use of the technology and the app.

The control group will be offered standard care by the PHCs. During baseline assessment, all participants will be informed of their stroke risk factors and given a leaflet with advice on how to manage modifiable risk factors.

Data collection

All of the instruments measuring primary and secondary outcomes will be collected at baseline, at follow-up and at 6 and 12 months. Demographic data will be collected at baseline. All qualitative interviews will be semi-structured and an interview guide will be used. Interviews will be digitally recorded.

Background and demographic data

Background data will include: weight, height (in order to calculate Body Mass Index) and blood pressure. Survey data will be gathered for health literacy of stroke risk (32), experiences of time pressure (stress), readiness and motivation for change (33), current mobile phone use and mapping out engaging everyday activities.

Feasibility data

A combination of qualitative and quantitative data will be collected among the interventionists and the participants using surveys, log books and qualitative interviews. In order to investigate acceptability of the programme, there will be analysis of patient recruitment, data collection, assessment tools, digital platforms and procedures. Items from the System Usability Scale (34) will be used to investigate ease of use of the Active Lifestyle app. In addition, usage-tracking tools and usage analytics will be used to obtain indicators of the feasibility and acceptability of the app. Data will include participants' daily self-reports and check-ins for ratings (e.g. goal-achievements, daily activities and dietary habits). Semi-structured qualitative exit interviews will be conducted by a researcher not involved in developing and delivering the intervention programme in order to investigate the acceptability of the programme. Participants (persons at risk of stroke) and healthcare professionals delivering the programme will be invited to participate in individual and focus-group exit interviews.

Outcome data

The primary outcome measures will be stroke risk, lifestyle habits and healthy activity patterns. Stroke risk is measured using the Stroke Risk Score card (26). The Stroke risk score card was developed as an easy to use self-assessment tool by the National Stroke Association in United Kingdom. The tool has been used in a few studies to detect risk factors for stroke (35, 36). The Stroke Risk Scorecard was chosen over other stroke risk screening tools as it includes modifiable risk factors for stroke and is easy to score for participants. Lifestyle habits will be measured using a lifestyle habits survey. The Swedish Lifestyle habits survey is based on guidelines for prevention by the National Board of Health and Welfare in Sweden (37), with the aim of registering and treating unhealthy lifestyle habits in primary healthcare. The survey includes questions in four domains: physical activity, alcohol consumption, tobacco use and dietary intake. Healthy activity patterns are measured using the Pleasure, Productivity and Restoration profile (38, 39) extended with a health domain and will map out the participants' everyday activity repertoire.

Secondary outcomes

Secondary outcomes will measure life satisfaction, quality of life, activity balance and activity performance and satisfaction. LiSat-11 measures life satisfaction (40). EQ-5D will be used to measure quality of life (41). The participants' level of occupational balance will be measured with the Occupational Balance Questionnaire (OBQ), giving insight into yet another perspective of the implications of how activities of everyday life can impact health (42). The

Canadian Occupational Performance Measure (COPM) measures subjective performance and satisfaction with individually chosen activities (28). COPM will be used to measure EEAs that the participants find difficult to perform and will guide the formulation of lifestyle change goals. The COPM scores importance, performance and satisfaction in chosen activities and upholds psychometric properties of validity and reliability (43, 44). The 6 Minute Walk Test will be used to measure physical function (45).

Data Analysis Plan

Feasibility of the intervention

Data collected from surveys, log books on recruitment and dropout, and logs from the app registrations will be entered, analysed and summarised. To promote data quality range checks for data values will be conducted. Descriptive statistical analyses will be conducted in order to report on feasibility of the study: recruitment, drop-outs, retention rate and adherence. Data from app registrations will be used to report on how the participants use the app, and on trends and goal achievements. Other app-related information of interest is the need for technical assistance. The investigators will assess patterns of app use over time. Conditions and events facilitating and/or hindering the delivery of the sessions and potential complications will be registered by the researchers and interventionists and presented. Qualitative interviews will be transcribed verbatim. All identifying factors will be removed (i.e. names) during transcription. Copies of the digital recordings will be destroyed after transcription is completed. Interview transcriptions will be stored in the university's database. Qualitative materials will be analysed using thematic qualitative analyses (46).

Evaluation of outcomes

The preliminary treatment effects will be analysed on an intention-to-treat basis, with randomised participants retaining their original allocated group, and measured as differences between groups at follow-up and at 12 months. The study data will be examined for outliers, normality and missing data. Analyses of covariance will be used for continuous outcomes with baseline values as covariates. Logistic regression analyses will be used for dichotomous outcomes. The level of significance will be set at $p \leq 0.05$ and the confidence level at 95%. We will use the SPSS (Version 22.0) to analyse the data. These analyses will provide preliminary results for the relative effectiveness of the intervention programme and will inform subsequent randomised controlled trials. Data from participants lost to follow-up will be used for descriptive purposes to describe the group, but removed from analysis of preliminary treatment effects.

Patient and Public Involvement

A previous case study including six persons following transient ischemic attack (TIA) and at risk of stroke was conducted in order to test the intervention model and to identify the needs and experiences of the participants. The content of the current intervention is based on the feasibility of the intervention given to the TIA group and adjusted in relation to the participants' experiences, needs and preferences. Experiences of the participants in the proposed pilot study of managing the app (e.g. challenges, suggested changes, layout, and period of utilisation) and their experiences of the research protocol and procedures will be used to inform and redesign any future version of the app and the study protocol (before a full scale RCT). The qualitative data from the interviews will report the participants' experiences of taking part in the programme.

Discussion

The theoretical base of the protocol is strong and based on EEA's as the mediator and goal for decreasing the risk of stroke and living a healthy life. Mobile phone technology is enabling the change process by offering individual feedback and an increasing awareness of current lifestyle and registration of new habits. This pilot study will provide preliminary data on the effects and feasibility of the Active Lifestyle prevention programme and its measures and procedures. Rich data on the impact and experiences of the programme will be provided from semi-structured interviews, log books, app registrations, outcome measures and surveys. The strength of the study lies in the robustness of the RCT design. The small sample size will limit the study's ability to determine effects of the protocol, however the main aim of the pilot study is not just to determine effects, but also to investigate procedures and feasibility, and so the sample size is considered to be sufficient in order to test the protocol in the primary healthcare setting.

ETHICS AND DISSEMINATION

The project invites and includes people at risk of stroke who, in different ways, may be faced with vulnerable situations due to their health and lifestyle. This invitation may be perceived as both an unwanted reminder of potential health complications such as stroke, while at the same time offering participation in developing a preventive programme with the aim of reducing the risk. The strength is that study participation is offered to the individual, who may or may not choose to respond. The potential participant will be informed both verbally and in writing and given a chance to ask questions before the researcher asks for written informed consent. An approval from the Regional Ethical Review Board in Stockholm, Sweden has been granted (Ref. Nos. 2015/834-31, 2016/2203-32 and 2019/01444). In accordance with the general data protection regulation, GDPR, the participants will be informed of their right

to withdraw at any time and of how their data will be managed. All data will be stored securely and all participant information will be stored and locked with limited access. All records will be identified by a coded number. The code number will be stored separately. All local databases will be password-protected. To ensure confidentiality, data shared to project team members will be blinded of any identifying participant information. Study participation is not expected to lead to risks or complications, although stroke risk factors will be monitored and possible health consequences will be transferred to the regional primary healthcare, it is expected to support the participating person's health self-management. The findings will be published in peer-reviewed journals. The results will also be presented to participants, staff and decision-makers involved in the study, other healthcare professionals and the general public through national and international conferences.

AUTHOR CONTRIBUTIONS

AHP, EA and SG conceived the original idea and outline of the study. EM is implementing the protocol in primary healthcare settings, with oversight and review by AHP, EA and SG. AK, AB, CE and EÅ contributed to the design of the study. AHP wrote the study protocol together with EA, SG and AB. All authors discussed and commented on draft versions and approved the final version. The group would also like to acknowledge Professor Kerstin Tham, Malmö University for initiating the project and for developing the conceptual ideas of EEA in stroke prevention.

FUNDING STATEMENT

This work was funded by grants from Vårdal Foundation, grant nr 2014-0108 and from the research school of Health Care Science, Karolinska Institutet. This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A a registration has not been done
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	13

Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	13
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/A, no trial sponsor
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	9
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	

Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	N/A
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10

Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A not been decided
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care	6

		providers, outcome assessors, data analysts), and how	
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate 6measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-10
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	7
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A

Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	12-13
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	12-13
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	None
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	13
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	13
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	None

Appendices

Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A the study was granted including consent forms, by national review board
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

BMJ Open

Primary prevention of stroke: engaging everyday activities promoting health – a randomised controlled pilot trial protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031984.R1
Article Type:	Protocol
Date Submitted by the Author:	30-Jul-2019
Complete List of Authors:	Patomella, Ann-Helen; Karolinska Institute, Department of Neurobiology, Care Sciences and Society Guidetti, Susanne; Karolinska Institutet, Neurobiology, Care Science and Society Mälstam, Emelie; Karolinska Institute, Department of Neurobiology, Care Sciences and Society Eriksson, Christina; Karolinska Institute, Department of Neurobiology, Care Sciences and Society Bergström, Aileen; Karolinska Institutet Department of Neurobiology Care Sciences and Society Åkesson, Elisabet; Karolinska Institute, Department of Neurobiology, Care Sciences and Society Kottorp, Anders; Malmö Universitet Asaba, Eric; Karolinska Institute, Department of Neurobiology, Care Sciences and Society
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	Stroke < NEUROLOGY, Prevention, Mhealth, PRIMARY CARE, stroke risk, occupational therapy

Primary prevention of stroke: engaging everyday activities promoting health – a randomised controlled pilot trial protocol

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Word count: 4121 (excluding title page, abstract and references).
Protocol version: 4th of July 2019. Version 2.0

Trial Registration number: ClinicalTrials.gov Identifier: NCT03730701

Abstract

Introduction

Stroke is a globally common disease that has detrimental effects on the individual and, more broadly, on society. Lifestyle change can contribute to reducing risk factors for stroke. Although there are direct benefits of a healthy lifestyle, sustaining and incorporating healthy activities into everyday life is a challenge. Engaging everyday activities have the potential to support lifestyle change and promote sustainable activity patterns. Current healthcare is failing to reduce modifiable risk factors in people at risk, and in addition to current practice, there is a need for systematic and efficient non-pharmacological and non-surgical stroke prevention strategies. The aim of the pilot study is to increase knowledge about the effects of a prevention programme and its feasibility to promote sustainable and healthy activity patterns among persons at risk for stroke.

Methods and analysis

The proposed pilot study will be a two-armed randomised, assessor-blinded, parallel pilot trial. The study will include feasibility data, investigating acceptability and delivery of the intervention. Persons at risk of stroke (n=60) will be included in a mobile phone-supported prevention programme. The 10-week programme will be conducted at primary healthcare clinics, combining group meetings and online resources to support self-management of lifestyle change. Main outcomes are stroke risk, lifestyle habits and healthy activity pattern. Assessments will be performed at baseline and at follow-up (immediately following the end of the programme and at 6 and 12 months). Effects of the programme will be analysed using inferential statistics. Feasibility will be analysed using both qualitative and quantitative methods.

Ethics and dissemination

The study has been approved by the Regional Ethical Review Board in Stockholm, Sweden, being granted Ref. Nos. 2015/834-31, 2016/2203-32 and 2019/01444. Study results will be disseminated through peer-review journals and presentations to mixed audiences at regional and international conferences.

Article Summary

Strengths and limitations of this study

- A major strength of the proposed study is the utilisation of engaging everyday activities as a mediator for sustainable lifestyle change.
- The study is designed as a randomised controlled trial and will provide preliminary data on the effects of a prevention programme for persons at risk of stroke.
- Mobile phone technology will be used to support lifestyle change processes among participants.
- The combination of qualitative and quantitative data systematically collected before and after the intervention period will provide rich data, which is useful for analysing the feasibility of the programme and its impact on the health and well-being of persons at risk of stroke.
- A limitation of the study is a relatively small sample size, which can result in insufficient power to determine effects.

INTRODUCTION

Stroke is the second leading cause of death globally and the disease burden based on disability-adjusted life years (DALYs), which is a measure of years lost due to death, poor health or disability has risen(1). The residual effects of stroke detrimentally impact on quality of life in terms of limiting physical, social, and emotional health both for persons with stroke and their caregivers (2). Subsequently, the economic impact of stroke in Sweden is estimated at 76,000 Euros for the first 2 years after the event, not including indirect costs such as loss of income and family burden (1). The magnitude of the problem can be put into context, considering evidence that suggests that many of the risk factors for stroke and other cardiovascular events are modifiable: tobacco use, excessive alcohol consumption, type 2 diabetes, hypertension, physical inactivity and dietary intake leading to high cholesterol and/or obesity (1, 3). Meaningful and purposeful everyday activities combined with moderate physical activities and a healthy diet has been found to be strongly related to well-being and longevity (4, 5). However, a recent focus-group study with general practitioners in a Swedish primary healthcare context revealed that there was a lack of systematic screening of stroke risk and adherence to risk factor modification was rare (6).

Theoretical concept of the prevention program

The prevention program in this study is a theoretically grounded, complex intervention (7). The programme is based on activities in people's everyday lives and integrates health and well-being with what people do, as well as with what they want or need to do, in order to thrive and live well (8, 9).

In this protocol, the term lifestyle is used to conceptualize and define activity patterns (individual actions and behaviour) in everyday life that may or may not contribute to health. Lifestyle change refers to a conscious change of behaviour and everyday activities in order to promote health. The process of changing behaviour results from an interaction between the person (e.g. self-efficacy), the environment (support and material) and the action (10). In the project, the key behavioural change technique (11), is incorporating engaging everyday activities (EEA) that contribute to a healthy lifestyle. This might include changing the form of current EEAs or finding new health-promoting EEAs.

Engaging everyday activity – a game-changer

Although the benefits of healthy lifestyle are clear (3, 12) the long-term effect and maintenance of healthy lifestyle are not (13-16). The effectiveness of primary healthcare-based physical activity's interventions are inconclusive (17). There is evidence for short-term improvements, but there is a lack of evidence for long-term effects (14). Successfully and

sustainably incorporating healthy lifestyle patterns into everyday life is a challenge for many people. Engaging everyday activities (EEA) are seen as the means and goal for changing and sustaining a healthy lifestyle. EEAs occur in the interaction between the individual and the sociocultural setting (18). The concept of EEA refers to an individual perception of personal activities that are valuable, meaningful and purposeful, as well as providing an intense sense of participation, EEAs are activities are done regularly and part of a person's life (19). EEAs can go beyond personal pleasure and can have a higher level of importance due to meaning for others such as family, friends or society at large. EEAs are the things that people do that make life worth living and that can contribute to well-being (9, 19, 20). Studies have shown that promoting EEAs can have positive health impacts for older adults (8, 18, 21, 22). Example of how EEAs can be modified to increase health is for example to change a sedentary EEA to a more physically demanding activity e.g. a person who engage in listening to music, to regularly go out to dance or listening to music while taking a walk or run. However, EEAs can also lead to ill health in cases where the EAA to the sedimentation of risk factors in everyday life such as sedentary behaviours or an unhealthy diet. Although EEAs can be a key to incorporating positive change and sustainable healthy lifestyle choices to reduce the risk for stroke, there is a need to systematically explore this further.

Sharing personal experiences as part of a change process

The intervention in the present study espouses the idea that personal experiences should be the point of departure for a person-centred prevention programme, enabling individual autonomy in decisions regarding lifestyle change. Sharing experiences, shared activities and reflections lead to learning about one's own stroke risk, activity patterns and habits. Bryan and colleagues (23) have used theories to summarise five central principles for adult learning: a) adults need to know why they are learning; b) adults need to be motivated to learn by the need to solve problems; c) adults' previous experiences must be respected and built upon; d) learning approaches should match adults' backgrounds and diversity; e) adults need to be actively involved in the learning process. The programme will be tailored to match needs and competences of the individual and build on participants' previous experiences. In addition to increase literacy with regard to stroke risk and change, there is a need to learn how to use digital support systems efficiently. Participants in the study will be actively involved in setting their own goals because this is important in order to manage their health while following the programme.

Objectives of the proposed study

The aim is to gain knowledge concerning the effectiveness of a prevention programme in promoting sustainable and healthy activity patterns and enabling lifestyle change together

with and among people at risk of stroke. The study's aim is also to gain knowledge about the feasibility and usefulness of a research protocol that includes a mobile phone application (app).

METHODS AND ANALYSIS

Design

The pilot study will be a two-armed randomised, assessor-blinded, parallel pilot trial. The protocol also includes a feasibility study combining qualitative interviews and descriptive quantitative data, investigating the acceptability and delivery of the intervention (24).

Study setting

The study will be conducted in close collaboration with Primary healthcare clinics (PHC) in the Stockholm area (different parts of Stockholm in order to reach a diverse population of healthcare seekers) and in PHCs in both urban and rural areas in the County Council of Gävleborg.

Sample size and power considerations

This study is an explorative pilot and feasibility study; no statistical power analyses have been calculated. A total sample of 60 participants will be enrolled of which 30 will be randomized to intervention group. It is estimated that a total of four PHCs will participate and deliver the intervention, (two from rural and urban Stockholm, two from rural and urban Gävleborg) each running an intervention group with 8-10 participants. A drop-out rate of 20% is expected, resulting in a total of n= 26 in the intervention and control groups, respectively.

Participant timeline

Participant enrolment will be started in June 2019 and the last qualitative interview is scheduled for before June 2020. During this period, 60 participants are expected to be enrolled in the study (30 controls and 30 in the intervention group).

Participants: Eligibility criteria

Persons at risk of stroke will be included in the project and recruitment will be by means of advertisements in local newspapers, webpage and at PHCs. A stroke risk screening survey (potential participants are either self-screened online or screened by a professional at their PHC) will be used to find eligible participants. A total sample of n=60 participants (persons at risk of stroke), divided into two arms (30+30) intervention and controls is estimated. Block randomisation will be utilised with a block size of four (2 control=A and 2 intervention=B, with

blocks of 4 having random block orders: AABB, ABAB, ABBA, BABA, BAAB, and BBAA) to allocate patients to either the intervention or the control group (25). Inclusion criteria are that the participants a) have a high risk for stroke according to the Stroke Risk Score card (26), b) are motivated for lifestyle change (asked about their motivation to take part in a lifestyle program) c) motivated for participating in a digital lifestyle prevention (including user of a smart phone or tablet), d) are between 45-70 years old and without a diagnosis of dementia or cognitive impairment hindering participation. Exclusion criteria are having previously had a Stroke or TIA diagnosis and lack of understanding the Swedish language.

The researchers will encourage and guide any participant who experiences health-related problems during the programme to get in contact with his or her general practitioner, GP. Participants may choose to interrupt their participation in the study at any time. The researcher can also discontinue a participant's participation based on health issues or reasons that might jeopardize that person's safety. Reasons for interruption will be recorded.

Active Lifestyle – a stroke-prevention programme

The prevention programme is based on earlier research evidence and theoretical underpinnings as presented, and on preliminary studies conducted by the research group (6). The inter-professional research group together with health professionals and technicians had a total of four workshops during 2015-2017 with the aim of modelling the components and themes of the programme. A logic model (27) was created in order to plan and organise the intervention. The logic model was used to visualise possible conflicts, barriers, contradictions, needed resources, activities, outputs and impacts of the research process.

The Active Lifestyle prevention programme enables healthy activity patterns and aims to reduce the risk of stroke by means of four strategies: a) the incorporation of health-promoting EEAs, b) the use of mobile phone technology to increase health literacy and awareness of current habits and to foster self-management c) forming new habits that prompt conscious decisions to make healthy choices, and d) setting realistic goals and sharing experience in a learning environment.

Duration and specific content of the intervention programme

The Active Lifestyle stroke-prevention programme is a 10-week programme. The intervention will include 5 sessions over 5 weeks with a booster session 5 weeks later. The programme starts with an individual meeting (baseline) and with a follow-up meeting one week after the last group session. The participants in the intervention group will set three self-chosen goals for lifestyle change formulated as daily goals based on an interview done at baseline using the Canadian Occupational Performance Measure (28). During the intervention, participants

will work actively with both EEAs and habits in order to change behaviour and lifestyle. For example, a person may have reading as an EEA, an activity that is relatively neutral on a continuum of health-promotion. The activity might be experienced as engaging and meaningful, and contribute to psychological wellbeing, but a redesign of the activity could be walking or exercising at the gym while listening to an audio book, leading to health benefits which could be accepted and incorporated into the individual's activity patterns. During the programme, the participants will become aware of their current lifestyle habits as well as new habits that are formed by the participants themselves. New habits may be cued by situations (such as seeing an escalator) prompting a health-promoting behaviour and making a conscious decision (e.g. to take the stairs) (29). The program is expected to foster self-management skills and the continuation a change process following the program period.

Each module has a theme and relevant activities. Group dynamics are used to reflect on experiences, doing and future goals. The modules, presented in table 1, are delivered by an interventionist/researcher together with a trained health professional (training during two half-days), for example an occupational therapist, physiotherapist or dietician. To avoid contamination, the health professionals are instructed to not deliver the program to other patients during the research period. The program is new to the PHCs and has not been delivered before.

Table 1: Summary of module themes, concepts and activities supporting a change process

Module theme	Concepts	Activity
1: Risk factors for stroke and engaging activities	Health literacy concerning stroke risk, engaging activities, change process, expectations	Peer interview on engaging activities. Learn how to register in the app. Set three lifestyle change goals
2: Physical activity	Physical activity, physical inactivity	Try a physical group exercise class at a gym
3: Diet and health	Dietary routines and change	Prepare and test a healthy sandwich
4: Balanced everyday life	Activity balance, stress	Relaxation, for example medical yoga
5: Sustained health: routines and activity patterns	Current and desired routines and activity patterns, revisiting goals	Walking session

Booster session: "Future horizon", identity, self-management of health and social aspects of health	Self-management, view of the self, social support	Preparing healthy snacks and walking and talking in a park

The mobile phone app

The app for the project was developed in close collaboration with ScientificMed Tech AB (http://www.scientificmed.com). ScientificMed Tech has a solid track record with publications on similar platforms (30, 31). The digital platform includes several unique aspects in the data input logic, which contributes to immediate feedback on progress as well as tracking of personally tailored goals related to stroke risk in the context of everyday life. The app includes six domains for registering daily activities, experiences and behaviours: Goal achievements (questions on how well the person has achieved the three pre-set goals and self-efficacy), Physical activity (registering step counts, registering 24 hr time use in relation to exercise, moderate intense activities, sleep, sedentary activities and other activities), Engaging everyday activities (participating in EEAs and self-efficacy), Tobacco and alcohol use (registering consumption), Stress levels (questions about perceived time-pressure) and Dietary habits (registering consumption of fruits/vegetables, breakfast, fish and snacks). Registrations result in graphs and plots that inform the participant of current behaviours and which serve as feedback on habits. The six domains are based on modifiable risk factors for stroke as presented by the American Heart Association (3) with the addition of promoting EEAs and reducing stress. The purpose of the app is to support the participant's change process via registration, feedback and self-management of habits and behaviours that impact on health and risk of stroke. Novice technology users will have extra training in the use of the technology and the app.

The control group will be offered standard care by the PHCs. During baseline assessment, all participants will be informed of their stroke risk factors and given a leaflet with advice on how to manage modifiable risk factors.

Data collection

All of the instruments measuring primary and secondary outcomes will be collected at baseline, at follow-up and at 6 and 12 months. Demographic data will be collected at baseline. All qualitative interviews will be semi-structured and an interview guide will be used. Interviews will be digitally recorded.

Background and demographic data

Background data will include: weight, height (in order to calculate Body Mass Index) and blood pressure. Survey data will be gathered for health literacy of stroke risk (32), experiences of time pressure (stress), readiness and motivation for change (33), current mobile phone use and mapping out engaging everyday activities.

Feasibility data

A combination of qualitative and quantitative data will be collected among the interventionists and the participants using surveys, log books and qualitative interviews. In order to investigate acceptability of the programme, there will be analysis of patient recruitment, data collection, assessment tools, digital platforms and procedures. Items from the System Usability Scale (34) will be used to investigate ease of use of the Active Lifestyle app. In addition, usage-tracking tools and usage analytics will be used to obtain indicators of the feasibility and acceptability of the app. Data will include participants' daily self-reports and check-ins for ratings (e.g. goal-achievements, daily activities and dietary habits). Semi-structured qualitative exit interviews will be conducted by a researcher not involved in developing and delivering the intervention programme in order to investigate the acceptability of the programme. Participants (persons at risk of stroke) and healthcare professionals delivering the programme will be invited to participate in individual and focus-group exit interviews.

Outcome data

The primary outcome measures will be stroke risk, lifestyle habits and healthy activity patterns. Stroke risk is measured using the Stroke Risk Score card (26). The Stroke risk score card was developed as an easy to use self-assessment tool by the National Stroke Association in United Kingdom. The tool has been used in a few studies to detect risk factors for stroke (35, 36). The Stroke Risk Scorecard was chosen over other stroke risk screening tools as it includes modifiable risk factors for stroke and is easy to score for participants, also for those that have limited English language skills as the questions and answers are easy to understand. Lifestyle habits will be measured using a lifestyle habits survey. The Swedish Lifestyle habits survey is based on guidelines for prevention by the National Board of Health and Welfare in Sweden (37), with the aim of registering and treating unhealthy lifestyle habits in primary healthcare. The survey includes questions in four domains: physical activity, alcohol consumption, tobacco use and dietary intake. Healthy activity patterns are measured using the Pleasure, Productivity and Restoration profile (38, 39) extended with a health domain and will map out the participants' everyday activity repertoire.

Secondary outcomes

Secondary outcomes will measure life satisfaction, quality of life, activity balance and activity performance and satisfaction. LiSat-11 measures life satisfaction (40). EQ-5D will be used to measure quality of life (41). The participants' level of occupational balance will be measured with the Occupational Balance Questionnaire (OBQ), giving insight into yet another perspective of the implications of how activities of everyday life can impact health (42). The Canadian Occupational Performance Measure (COPM) measures subjective performance and satisfaction with individually chosen activities (28). COPM will be used to measure EEAs that the participants find difficult to perform and will guide the formulation of lifestyle change goals. The COPM scores importance, performance and satisfaction in chosen activities and upholds psychometric properties of validity and reliability (43, 44). The 6 Minute Walk Test will be used to measure physical function (45).

Data Analysis Plan

Feasibility of the intervention

Data collected from surveys, log books on recruitment and dropout, and logs from the app registrations will be entered, analysed and summarised. To promote data quality range checks for data values will be conducted. Descriptive statistical analyses will be conducted in order to report on feasibility of the study: recruitment, drop-outs, retention rate and adherence. Data from app registrations will be used to report on how the participants use the app, and on trends and goal achievements. Other app-related information of interest is the need for technical assistance. The investigators will assess patterns of app use over time. Conditions and events facilitating and/or hindering the delivery of the sessions and potential complications will be registered by the researchers and interventionists and presented. Qualitative interviews will be transcribed verbatim. All identifying factors will be removed (i.e. names) during transcription. Copies of the digital recordings will be destroyed after transcription is completed. Interview transcriptions will be stored in the university's database. Qualitative materials will be analysed using thematic qualitative analyses (46).

Evaluation of outcomes

The preliminary treatment effects will be analysed on an intention-to-treat basis, with randomised participants retaining their original allocated group, and measured as differences between groups at follow-up and at 12 months. The study data will be examined for outliers, normality and missing data. Analyses of covariance will be used for continuous outcomes with baseline values as covariates. Logistic regression analyses will be used for dichotomous outcomes. The level of significance will be set at $p \leq 0.05$ and the confidence level at 95%. We will use the SPSS (Version 22.0) to analyse the data. These analyses will provide

preliminary results for the relative effectiveness of the intervention programme and will inform subsequent randomised controlled trials.

Patient and Public Involvement

A previous case study including six persons following transient ischemic attack (TIA) and at risk of stroke was conducted in order to test the intervention model and to identify the needs and experiences of the participants. The content of the current intervention is based on the feasibility of the intervention given to the TIA group and adjusted in relation to the participants' experiences, needs and preferences. For example in the TIA study, the preliminary results suggests that the participants highly valued the group meetings. Physical activities such as walking in the nature and dancing were experienced as EEA. Experiences of the participants in the proposed pilot study of managing the app (e.g. challenges, suggested changes, layout, and period of utilisation) and their experiences of the research protocol and procedures will be used to inform and redesign any future version of the app and the study protocol (before a full scale RCT). The qualitative data from the interviews will report the participants' experiences of taking part in the programme.

Discussion

The theoretical base of the protocol is strong and based on EEA's as the mediator and goal for decreasing the risk of stroke and living a healthy life. Mobile phone technology is enabling the change process by offering individual feedback and an increasing awareness of current lifestyle and registration of new habits. This pilot study will provide preliminary data on the effects and feasibility of the Active Lifestyle prevention programme and its measures and procedures. Rich data on the impact and experiences of the programme will be provided from semi-structured interviews, log books, app registrations, outcome measures and surveys. The strength of the study lies in the robustness of the RCT design. The small sample size will limit the study's ability to determine effects of the protocol, however the main aim of the pilot study is not just to determine effects, but also to investigate procedures and feasibility, and so the sample size is considered to be sufficient in order to test the protocol in the primary healthcare setting. A potential limitation is the risk for too small samples that does not provide sufficient diversity of the study population in relation to age, sex, rurality and socio-economic status (SES), therefore we have chosen to include PHCs from different areas (rural and urban and from different SES diverse areas) and to set the time for the group meetings to late in the afternoon to also facilitate participation from persons that work fulltime.

ETHICS AND DISSEMINATION

The project invites and includes people at risk of stroke who, in different ways, may be faced with vulnerable situations due to their health and lifestyle. This invitation may be perceived as both an unwanted reminder of potential health complications such as stroke, while at the same time offering participation in developing a preventive programme with the aim of reducing the risk. The strength is that study participation is offered to the individual, who may or may not choose to respond. The potential participant will be informed both verbally and in writing and given a chance to ask questions before the researcher asks for written informed consent. An approval from the Regional Ethical Review Board in Stockholm, Sweden has been granted (Ref. Nos. 2015/834-31, 2016/2203-32 and 2019/01444). In accordance with the general data protection regulation, GDPR, the participants will be informed of their right to withdraw at any time and of how their data will be managed. All data will be stored securely and all participant information will be stored and locked with limited access. All records will be identified by a coded number. The code number will be stored separately. All local databases will be password-protected. To ensure confidentiality, data shared to project team members will be blinded of any identifying participant information. Study participation is not expected to lead to risks or complications, although stroke risk factors will be monitored and possible health consequences will be transferred to the regional primary healthcare, it is expected to support the participating person's health self-management. The findings will be published in peer-reviewed journals. The results will also be presented to participants, staff and decision-makers involved in the study, other healthcare professionals and the general public through national and international conferences.

AUTHOR CONTRIBUTIONS

AHP, EA and SG conceived the original idea and outline of the study. EM is implementing the protocol in primary healthcare settings, with oversight and review by AHP, EA and SG. AK, AB, CE and EÅ contributed to the design of the study. AHP wrote the study protocol together with EA, SG and AB. All authors discussed and commented on draft versions and approved the final version. The group would also like to acknowledge Professor Kerstin Tham, Malmö University for initiating the project and for developing the conceptual ideas of EEA in stroke prevention.

FUNDING STATEMENT

This work was funded by grants from Vårdal Foundation, grant nr 2014-0108 and from the research school of Health Care Science, Karolinska Institutet. This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A a registration has not been done
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	13

Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	13
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/A, no trial sponsor
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	9
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	

Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	N/A
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10

Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A not been decided
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care	6

		providers, outcome assessors, data analysts), and how	
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate 6measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-10
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	7
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A

Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	12-13
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	12-13
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	None
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	13
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	13
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	None

Appendices

Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A the study was granted including consent forms, by national review board
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

BMJ Open

Primary prevention of stroke: engaging everyday activities promoting health – a randomised controlled pilot trial protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031984.R2
Article Type:	Protocol
Date Submitted by the Author:	10-Sep-2019
Complete List of Authors:	Patomella, Ann-Helen; Karolinska Institute, Department of Neurobiology, Care Sciences and Society Guidetti, Susanne; Karolinska Institutet, Neurobiology, Care Science and Society Mälstam, Emelie; Karolinska Institute, Department of Neurobiology, Care Sciences and Society Eriksson, Christina; Karolinska Institute, Department of Neurobiology, Care Sciences and Society Bergström, Aileen; Karolinska Institutet Department of Neurobiology Care Sciences and Society Åkesson, Elisabet; Karolinska Institute, Department of Neurobiology, Care Sciences and Society Kottorp, Anders; Malmö Universitet Asaba, Eric; Karolinska Institute, Department of Neurobiology, Care Sciences and Society
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	Stroke < NEUROLOGY, Prevention, Mhealth, PRIMARY CARE, stroke risk, occupational therapy

Primary prevention of stroke: engaging everyday activities promoting health – a randomised controlled pilot trial protocol

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Word count: 4121 (excluding title page, abstract and references).
Protocol version: 9th of September 2019. Version 3.0

Trial Registration number: ClinicalTrials.gov Identifier: NCT03730701

Abstract

Introduction

Stroke is a globally common disease that has detrimental effects on the individual and, more broadly, on society. Lifestyle change can contribute to reducing risk factors for stroke. Although there are direct benefits of a healthy lifestyle, sustaining and incorporating healthy activities into everyday life is a challenge. Engaging everyday activities have the potential to support lifestyle change and promote sustainable activity patterns. Current healthcare is failing to reduce modifiable risk factors in people at risk, and in addition to current practice, there is a need for systematic and efficient non-pharmacological and non-surgical stroke prevention strategies. The aim of the pilot study is to increase knowledge about the effects of a prevention programme and its feasibility to promote sustainable and healthy activity patterns among persons at risk for stroke.

Methods and analysis

The proposed pilot study will be a two-armed randomised, assessor-blinded, parallel pilot trial. The study will include feasibility data, investigating acceptability and delivery of the intervention. Persons at risk of stroke (n=60) will be included in a mobile phone-supported prevention programme. The 10-week programme will be conducted at primary healthcare clinics, combining group meetings and online resources to support self-management of lifestyle change. Main outcomes are stroke risk, lifestyle habits and healthy activity pattern. Assessments will be performed at baseline and at follow-up (immediately following the end of the programme and at 6 and 12 months). Effects of the programme will be analysed using inferential statistics. Feasibility will be analysed using both qualitative and quantitative methods.

Ethics and dissemination

The study has been approved by the Regional Ethical Review Board in Stockholm, Sweden, being granted Ref. Nos. 2015/834-31, 2016/2203-32 and 2019/01444. Study results will be disseminated through peer-review journals and presentations to mixed audiences at regional and international conferences.

Article Summary

Strengths and limitations of this study

- A major strength of the proposed study is the utilisation of engaging everyday activities as a mediator for sustainable lifestyle change.
- The study is designed as a randomised controlled trial and will provide preliminary data on the effects of a prevention programme for persons at risk of stroke.
- Mobile phone technology will be used to support lifestyle change processes among participants.
- The combination of qualitative and quantitative data systematically collected before and after the intervention period will provide rich data, which is useful for analysing the feasibility of the programme and its impact on the health and well-being of persons at risk of stroke.
- A limitation of the study is a relatively small sample size, which can result in insufficient power to determine effects.

INTRODUCTION

Stroke is the second leading cause of death globally and the disease burden based on disability-adjusted life years (DALYs), which is a measure of years lost due to death, poor health or disability has risen(1). The residual effects of stroke detrimentally impact on quality of life in terms of limiting physical, social, and emotional health both for persons with stroke and their caregivers (2). Subsequently, the economic impact of stroke in Sweden is estimated at 76,000 Euros per person for the first 2 years after the event, not including indirect costs such as loss of income and family burden (1). The magnitude of the problem can be put into context, considering evidence that suggests that many of the risk factors for stroke and other cardiovascular events are modifiable: tobacco use, excessive alcohol consumption, type 2 diabetes, hypertension, physical inactivity and dietary intake leading to high cholesterol and/or obesity (1, 3). Meaningful and purposeful everyday activities combined with moderate physical activities and a healthy diet has been found to be strongly related to well-being and longevity (4, 5). However, a recent focus-group study with general practitioners in a Swedish primary healthcare context revealed that there was a lack of systematic screening of stroke risk and adherence to risk factor modification was rare (6).

Theoretical concept of the prevention program

The prevention program in this study is a theoretically grounded, complex intervention (7). The programme is based on activities in people's everyday lives and integrates health and well-being with what people do, as well as with what they want or need to do, in order to thrive and live well (8, 9).

In this protocol, the term lifestyle is used to conceptualize and define activity patterns (individual actions and behaviour) in everyday life that may or may not contribute to health. Lifestyle change refers to a conscious change of behaviour and everyday activities in order to promote health. The process of changing behaviour results from an interaction between the person (e.g. self-efficacy), the environment (support and material) and the action (10). In the project, the key behavioural change technique (11), is incorporating engaging everyday activities (EEA) that contribute to a healthy lifestyle. This might include changing the form of current EEAs or finding new health-promoting EEAs.

Engaging everyday activity – a game-changer

Although the benefits of healthy lifestyle are clear (3, 12) the long-term effect and maintenance of healthy lifestyle are not (13-16). The effectiveness of primary healthcare-based physical activity's interventions are inconclusive (17). There is evidence for short-term improvements, but there is a lack of evidence for long-term effects (14). Successfully and

sustainably incorporating healthy lifestyle patterns into everyday life is a challenge for many people. Engaging everyday activities (EEA) are seen as the means and goal for changing and sustaining a healthy lifestyle. EEAs occur in the interaction between the individual and the sociocultural setting (18). The concept of EEA refers to an individual perception of personal activities that are valuable, meaningful and purposeful, as well as providing an intense sense of participation, EEAs are activities are done regularly and part of a person's life (19). EEAs can go beyond personal pleasure and can have a higher level of importance due to meaning for others such as family, friends or society at large. EEAs are the things that people do that make life worth living and that can contribute to well-being (9, 19, 20). Studies have shown that promoting EEAs can have positive health impacts for older adults (8, 18, 21, 22). Example of how EEAs can be modified to increase health is for example to change a sedentary EEA to a more physically demanding activity e.g. a person who engage in listening to music, to regularly go out to dance or listening to music while taking a walk or run. However, EEAs can also lead to ill health in cases where the EAA to the sedimentation of risk factors in everyday life such as sedentary behaviours or an unhealthy diet. Although EEAs can be a key to incorporating positive change and sustainable healthy lifestyle choices to reduce the risk for stroke, there is a need to systematically explore this further.

Sharing personal experiences as part of a change process

The intervention in the present study espouses the idea that personal experiences should be the point of departure for a person-centred prevention programme, enabling individual autonomy in decisions regarding lifestyle change. Sharing experiences, shared activities and reflections lead to learning about one's own stroke risk, activity patterns and habits. Bryan and colleagues (23) have used theories to summarise five central principles for adult learning: a) adults need to know why they are learning; b) adults need to be motivated to learn by the need to solve problems; c) adults' previous experiences must be respected and built upon; d) learning approaches should match adults' backgrounds and diversity; e) adults need to be actively involved in the learning process. The programme will be tailored to match needs and competences of the individual and build on participants' previous experiences. In addition to increase literacy with regard to stroke risk and change, there is a need to learn how to use digital support systems efficiently. Participants in the study will be actively involved in setting their own goals because this is important in order to manage their health while following the programme.

Objectives of the proposed study

The aim is to gain knowledge concerning the effectiveness of a prevention programme in promoting sustainable and healthy activity patterns and enabling lifestyle change together

with and among people at risk of stroke. The study's aim is also to gain knowledge about the feasibility and usefulness of a research protocol that includes a mobile phone application (app).

METHODS AND ANALYSIS

Design

The pilot study will be a two-armed randomised, assessor-blinded, parallel pilot trial. The protocol also includes a feasibility study combining qualitative interviews and descriptive quantitative data, investigating the acceptability and delivery of the intervention (24).

Study setting

The study will be conducted in close collaboration with Primary healthcare clinics (PHC) in the Stockholm area (different parts of Stockholm in order to reach a diverse population of healthcare seekers) and in PHCs in both urban and rural areas in the County Council of Gävleborg.

Sample size and power considerations

This study is an explorative pilot and feasibility study; no statistical power analyses have been calculated. A total sample of 60 participants will be enrolled of which 30 will be randomized to intervention group. It is estimated that a total of four PHCs will participate and deliver the intervention, (two from rural and urban Stockholm, two from rural and urban Gävleborg) each running an intervention group with 8-10 participants. A drop-out rate of 20% is expected, resulting in a total of n= 26 in the intervention and control groups, respectively.

Participant timeline

Participant enrolment will be started in June 2019 and the last qualitative interview is scheduled for before June 2020. During this period, 60 participants are expected to be enrolled in the study (30 controls and 30 in the intervention group).

Participants: Eligibility criteria

Persons at risk of stroke will be included in the project and recruitment will be by means of advertisements in local newspapers, webpage and at PHCs. A stroke risk screening survey (potential participants are either self-screened online or screened by a professional at their PHC) will be used to find eligible participants. A total sample of n=60 participants (persons at risk of stroke), divided into two arms (30+30) intervention and controls is estimated. Block randomisation will be utilised with a block size of four (2 control=A and 2 intervention=B, with

blocks of 4 having random block orders: AABB, ABAB, ABBA, BABA, BAAB, and BBAA) to allocate patients to either the intervention or the control group (25). The intervention group will participate in a stroke-prevention programme- Active Lifestyle. The controls will be offered standard care by the PHCs. All participants will be given a leaflet with advice on how to manage modifiable risk factors. Allocation will be done following baseline assessment. Allocation sequence will be done by an independent researcher not involved in data collection nor intervention. The researchers who are assessors of outcomes will be blinded to allocation until end of the study. Inclusion criteria are that the participants a) have a high risk for stroke according to the Stroke Risk Score card (26) i.e. at least three risk factors scored as high risk. The Stroke risk score card was developed as an easy to use self-assessment tool by the National Stroke Association in United Kingdom. The tool has been used in a few studies to detect risk factors for stroke (27, 28). The Stroke Risk Scorecard was chosen over other stroke risk screening tools as it includes modifiable risk factors for stroke and is easy to score for participants, also for those that have limited English language skills as the questions and answers are easy to understand, b) are motivated for lifestyle change (asked about their motivation to take part in a lifestyle program) c) motivated for participating in a digital lifestyle prevention (including user of a smart phone or tablet), d) are between 45-70 years old and without a diagnosis of dementia or cognitive impairment hindering participation. Exclusion criteria are having previously had a Stroke or TIA diagnosis and lack of understanding the Swedish language.

The researchers will encourage and guide any participant who experiences health-related problems during the programme (both intervention and control group) to get in contact with his or her general practitioner, GP. All participants may choose to interrupt their participation in the study at any time. The researcher can also discontinue a participant's participation based on health issues or reasons that might jeopardize that person's safety. Reasons for interruption will be recorded.

Active Lifestyle – a stroke-prevention programme

The prevention programme is based on earlier research evidence and theoretical underpinnings as presented, and on preliminary studies conducted by the research group (6). The inter-professional research group together with health professionals and technicians had a total of four workshops during 2015-2017 with the aim of modelling the components and themes of the programme. A logic model (29) was created in order to plan and organise the intervention. The logic model was used to visualise possible conflicts, barriers, contradictions, needed resources, activities, outputs and impacts of the research process.

The Active Lifestyle prevention programme enables healthy activity patterns and aims to reduce the risk of stroke by means of four strategies: a) the incorporation of health-promoting EEAs, b) the use of mobile phone technology to increase health literacy and awareness of current habits and to foster self-management c) forming new habits that prompt conscious decisions to make healthy choices, and d) setting realistic goals and sharing experience in a learning environment.

Duration and specific content of the intervention programme

The Active Lifestyle stroke-prevention programme is an 11-week programme. The intervention will include 5 sessions over 5 weeks with a booster session 6 weeks later. The programme starts with an individual meeting (baseline) and with a follow-up assessment one week after the last group session. During the intervention, participants will work actively with their self-chosen both EEAs and habits in order to change behaviour and lifestyle. For example, a person may have reading as an EEA, an activity that is relatively neutral on a continuum of health-promotion. The activity might be experienced as engaging and meaningful, and contribute to psychological wellbeing, but a redesign of the activity could be walking or exercising at the gym while listening to an audio book, leading to health benefits which could be accepted and incorporated into the individual's activity patterns. During the programme, the participants will become aware of their current lifestyle habits as well as new habits that are formed by the participants themselves. New habits may be cued by situations (such as seeing an escalator) prompting a health-promoting behaviour and making a conscious decision (e.g. to take the stairs) (30). The program is expected to foster self-management skills and the continuation a change process following the program period.

Each module has a theme and relevant activities. Group dynamics are used to reflect on experiences, doing and future goals. The modules, presented in table 1, are delivered by an interventionist/researcher (not involved in assessment) together with a trained health professional (training during two half-days), for example an occupational therapist, physiotherapist or dietician. Each module will last 90 minutes and will be held at the participating PHCs, in their premises. To avoid contamination, the health professionals are instructed to not deliver the program to other patients during the research period. The program is new to the PHCs and has not been delivered before.

Table 1: Summary of module themes, concepts and activities supporting a change process

Module theme	Concepts	Activity
1: Risk factors for stroke and engaging activities	Health literacy concerning stroke risk, engaging	Peer interview on engaging activities. Learn how to

	activities, change process, expectations	register in the app. Set three lifestyle change goals
2: Physical activity	Physical activity, physical inactivity	Try a physical group exercise class at a gym
3: Diet and health	Dietary routines and change	Prepare and test a healthy sandwich
4: Balanced everyday life	Activity balance, stress	Relaxation, for example medical yoga
5: Sustained health: routines and activity patterns	Current and desired routines and activity patterns, revisiting goals	Walking session
Booster session: “Future horizon”, identity, self-management of health and social aspects of health	Self-management, view of the self, social support	Preparing healthy snacks and walking and talking in a park

The mobile phone app

The app for the project was developed in close collaboration with ScientificMed Tech AB (http://www.scientificmed.com). ScientificMed Tech has a solid track record with publications on similar platforms (31, 32). The digital platform includes several unique aspects in the data input logic, which contributes to immediate feedback on progress as well as tracking of personally tailored goals related to stroke risk in the context of everyday life. The app includes six domains for registering daily activities, experiences and behaviours: Goal achievements (questions on how well the person has achieved the three pre-set goals and self-efficacy), Physical activity (registering step counts, registering 24 hr time use in relation to exercise, moderate intense activities, sleep, sedentary activities and other activities), Engaging everyday activities (participating in EEAs and self-efficacy), Tobacco and alcohol use (registering consumption), Stress levels (questions about perceived time-pressure) and Dietary habits (registering consumption of fruits/vegetables, breakfast, fish and snacks). Registrations result in graphs and plots that inform the participant of current behaviours and which serve as feedback on habits. The six domains are based on modifiable risk factors for stroke as presented by the American Heart Association (3) with the addition of promoting EEAs and reducing stress. The purpose of the app is to support the participant's change process via registration, feedback and self-management of habits and behaviours that impact on health and risk of stroke. Novice technology users will have extra training in the use of the technology and the app.

Data collection

All of the instruments measuring primary and secondary outcomes will be collected at baseline, at follow-up and at 6 and 12 months. Demographic data will be collected at baseline. During baseline assessment, all participants will be informed of their stroke risk factors and motivational interviewing techniques will be used to identify problem areas in relation to lifestyle habits. All qualitative interviews will be semi-structured and an interview guide will be used. Interviews will be digitally recorded.

Background and demographic data

Background data will include: weight, height (in order to calculate Body Mass Index) and blood pressure. Survey data will be gathered for health literacy of stroke risk (33), experiences of time pressure (stress), readiness and motivation for change (34), current mobile phone use and mapping out engaging everyday activities.

Feasibility data

A combination of qualitative and quantitative data will be collected among the interventionists and the participants using surveys, log books and qualitative interviews. In order to investigate acceptability of the programme, there will be analysis of patient recruitment, data collection, assessment tools, digital platforms and procedures. Items from the System Usability Scale (35) will be used to investigate ease of use of the Active Lifestyle app. In addition, usage-tracking tools and usage analytics will be used to obtain indicators of the feasibility and acceptability of the app. Data will include participants' daily self-reports and check-ins for ratings (e.g. goal-achievements, daily activities and dietary habits). Semi-structured qualitative exit interviews will be conducted by a researcher not involved in developing and delivering the intervention programme in order to investigate the acceptability of the programme. Participants (persons at risk of stroke) and healthcare professionals delivering the programme will be invited to participate in individual and focus-group exit interviews.

Outcome data

The primary outcome measures will be lifestyle habits and healthy activity patterns. Lifestyle habits will be measured using a lifestyle habits survey. *The Swedish Lifestyle habits survey* is based on guidelines for prevention by the National Board of Health and Welfare in Sweden (36), with the aim of registering and treating unhealthy lifestyle habits in primary healthcare. The survey includes questions in four domains: physical activity, alcohol consumption, tobacco use and dietary intake. Healthy activity patterns are measured using *the Pleasure, Productivity and Restoration profile (PPR)* (37, 38) extended with a health domain and will map out the participants' everyday activity repertoire.

Secondary outcomes

Secondary outcomes will measure life satisfaction, quality of life, activity balance and activity performance and satisfaction. *LiSat-11* measures life satisfaction (39). *EQ-5D* will be used to measure quality of life (40). The participants' level of occupational balance will be measured with the *Occupational Balance Questionnaire (OBQ)*, giving insight into yet another perspective of the implications of how activities of everyday life can impact health (41). The *Canadian Occupational Performance Measure (COPM)* measures subjective performance and satisfaction with individually chosen activities (42). COPM will be used to measure EEAs that the participants find difficult to perform and will also guide the participants to formulate three self-chosen goals for lifestyle change based on identified problem areas in relation to

lifestyle habits. The COPM scores importance, performance and satisfaction in chosen activities and upholds psychometric properties of validity and reliability (43, 44). *The 6 Minute Walk Test* will be used to measure physical function (45).

Data Analysis Plan

Feasibility of the intervention

Data collected from surveys, log books on recruitment and dropout, and logs from the app registrations will be entered, analysed and summarised. To promote data quality range checks for data values will be conducted. Descriptive statistical analyses will be conducted in order to report on feasibility of the study: recruitment, drop-outs, retention rate and adherence. Data from app registrations will be used to report on how the participants use the app, and on trends and goal achievements. Other app-related information of interest is the need for technical assistance. The investigators will assess patterns of app use over time. Conditions and events facilitating and/or hindering the delivery of the sessions and potential complications will be registered by the researchers and interventionists and presented. Qualitative interviews will be transcribed verbatim. All identifying factors will be removed (i.e. names) during transcription. Copies of the digital recordings will be destroyed after transcription is completed. Interview transcriptions will be stored in the university's database. Qualitative materials will be analysed using thematic qualitative analyses (46).

Evaluation of outcomes

The preliminary treatment effects will be analysed on an intention-to-treat basis, with randomised participants retaining their original allocated group, and measured as differences between groups at follow-up and at 12 months. The study data will be examined for outliers, normality and missing data. Analyses of covariance will be used for continuous outcomes with baseline values as covariates. Logistic regression analyses will be used for dichotomous outcomes. The level of significance will be set at $p \leq 0.05$ and the confidence level at 95%. We will use the SPSS (Version 22.0) to analyse the data. These analyses will provide preliminary results for the relative effectiveness of the intervention programme and will inform subsequent randomised controlled trials.

Patient and Public Involvement

A previous case study including six persons following transient ischemic attack (TIA) and at risk of stroke was conducted in order to test the intervention model and to identify the needs and experiences of the participants. The content of the current intervention is based on the feasibility of the intervention given to the TIA group and adjusted in relation to the

participants' experiences, needs and preferences. For example in the TIA study, the preliminary results suggests that the participants highly valued the group meetings. Physical activities such as walking in the nature and dancing were experienced as EEA. Experiences of the participants in the proposed pilot study of managing the app (e.g. challenges, suggested changes, layout, and period of utilisation) and their experiences of the research protocol and procedures will be used to inform and redesign any future version of the app and the study protocol (before a full scale RCT). The qualitative data from the interviews will report the participants' experiences of taking part in the programme.

Discussion

The theoretical base of the protocol is strong and based on EEA's as the mediator and goal for decreasing the risk of stroke and living a healthy life. Mobile phone technology is enabling the change process by offering individual feedback and an increasing awareness of current lifestyle and registration of new habits. This pilot study will provide preliminary data on the effects and feasibility of the Active Lifestyle prevention programme and its measures and procedures. Rich data on the impact and experiences of the programme will be provided from semi-structured interviews, log books, app registrations, outcome measures and surveys. The limitation of the study is the lack of a validated outcome measure on stroke risk, and there is a need to translate and validate an assessment such as the Stroke Riskometer (47) to a Swedish population. Self-reported measures will be used in the study and there is a risk for bias since reporting might not be accurate, therefore observational measures such as BMI, the 6-minute walk test are used as outcomes. The strength of the study lies in the robustness of the RCT design. The small sample size will limit the study's ability to determine effects of the protocol, however the main aim of the pilot study is not just to determine effects, but also to investigate procedures and feasibility, and so the sample size is considered to be sufficient in order to test the protocol in the primary healthcare setting. A potential limitation is the risk for too small samples that does not provide sufficient diversity of the study population in relation to age, sex, rurality and socio-economic status (SES), therefore we have chosen to include PHCs from different areas (rural and urban and from different SES diverse areas) and to set the time for the group meetings to late in the afternoon to also facilitate participation from persons that work fulltime. The risk for contamination between groups are assessed to be minimal if any. Participants to the control and intervention groups are recruited via newspaper advertisement and PHCs in a large city. Interventionists do not have any intervention activities with controls. The study design does not include an attention-control group and the dosage of attention is higher for the intervention group than the controls, although both groups do receive an analysis of stroke risks and will set three self-chosen lifestyle change goals at baseline.

ETHICS AND DISSEMINATION

The project invites and includes people at risk of stroke who, in different ways, may be faced with vulnerable situations due to their health and lifestyle. This invitation may be perceived as both an unwanted reminder of potential health complications such as stroke, while at the same time offering participation in developing a preventive programme with the aim of reducing the risk. The strength is that study participation is offered to the individual, who may or may not choose to respond. The potential participant will be informed both verbally and in writing and given a chance to ask questions before the researcher asks for written informed consent. An approval from the Regional Ethical Review Board in Stockholm, Sweden has been granted (Ref. Nos. 2015/834-31, 2016/2203-32 and 2019/01444). In accordance with the general data protection regulation, GDPR, the participants will be informed of their right to withdraw at any time and of how their data will be managed. All data will be stored securely and all participant information will be stored and locked with limited access. All records will be identified by a coded number. The code number will be stored separately. All local databases will be password-protected. To ensure confidentiality, data shared to project team members will be blinded of any identifying participant information. Study participation is not expected to lead to risks or complications, although stroke risk factors will be monitored and possible health consequences will be transferred to the regional primary healthcare, it is expected to support the participating person's health self-management. The findings will be published in peer-reviewed journals. The results will also be presented to participants, staff and decision-makers involved in the study, other healthcare professionals and the general public through national and international conferences.

AUTHOR CONTRIBUTIONS

AHP, EA and SG conceived the original idea and outline of the study. EM is implementing the protocol in primary healthcare settings, with oversight and review by AHP, EA and SG. AK, AB, CE and EÅ contributed to the design of the study. AHP wrote the study protocol together with EA, SG and AB. All authors discussed and commented on draft versions and approved the final version. The group would also like to acknowledge Professor Kerstin Tham, Malmö University for initiating the project and for developing the conceptual ideas of EEA in stroke prevention.

FUNDING STATEMENT

This work was funded by grants from Vårdal Foundation, grant nr 2014-0108 and from the research school of Health Care Science, Karolinska Institutet. This funding source had no

role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A a registration has not been done
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	13

Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	13
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/A, no trial sponsor
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	9
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	

Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	N/A
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10

Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A not been decided
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care	6

		providers, outcome assessors, data analysts), and how	
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate 6measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-10
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	7
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	11
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A

Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	12-13
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	12-13
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	None
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	13
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	13
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	None

Appendices

Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A the study was granted including consent forms, by national review board
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A