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

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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 a healthy lifestyle has direct benefits, sustaining and incorporating healthy activities into everyday life is a challenge. Engaging everyday activities have the potential to support lifestyle change and to 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 was to increase knowledge about the effects of a prevention programme and its feasibility to promote sustainable and healthy activity patterns among persons at risk of 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 patterns. 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 reference numbers 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.

Trial registration number NCT03730701.

Strengths and limitations of this study

- A major strength of the proposed study is the use 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 are 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, 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 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, have been found to be strongly related to well-being and longevity.[4 5] However, a recent focus-group study with general practitioners (GPs) 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 programme

The prevention programme 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 conceptualise 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 (eg, 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 (EEAs) that contribute to a healthy lifestyle. This might include changing the form of current EEAs or finding new health-promoting EEAs.

Engaging Everyday Activities: game changer

Although the benefits of a healthy lifestyle are clear,[3 12] the long-term effect and maintenance of a healthy lifestyle are not.[13–16] The effectiveness of a primary healthcare-based physical activity's interventions is 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. EEAs 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 that are done regularly and are 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] An example of how EEAs can be modified to increase health is, for example, to change a sedentary EEA to a more physically demanding activity, for example, a person who engages in listening to music, to regularly go out to dance or to listen to music while taking a walk or run. However, EEAs can also lead to ill health in cases where the EEA lead 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 of 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: (1) adults need to know why they are learning; (2) adults need to be motivated to learn by the need to solve problems; (3) adults' previous experiences must be respected and built on; (4) learning approaches should match adults' backgrounds and diversity; and (5) adults need to be actively involved in the learning process. The programme will be tailored to match the needs and competences of the individual and to 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 was 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 was 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 (PHCs) 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 randomised to the intervention group. It is estimated that a total of four PHCs will participate and deliver the intervention (two from rural and urban Stockholm, and two from rural and urban Gävleborg), each running an intervention group with 8–10 participants. A dropout rate of 20% is expected, resulting in a total of n=26 in the intervention and control groups, respectively.

Participant timeline

Participant enrolment will start in June 2019, and the last qualitative interview is scheduled 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, webpages and at PHCs. A stroke risk screening survey (potential participants are either self-screened online or screened by a professional at their PHCs) 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), interventions and controls, is estimated. Block randomisation will be used with a block size of four (two controls=A and two interventions=B, with blocks of four 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 the end of the study. Inclusion criteria are the following: (1) the participants should have a high risk of stroke according to the Stroke Risk Scorecard,[26] that is, at least three risk factors scored as high risk. The Stroke Risk Scorecard was developed as an easy-to-use self-assessment tool by the National Stroke Association in UK. 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 who have limited English language skills as the questions and answers are easy to understand; (2) the participants should be motivated for lifestyle change (asked about their motivation to take part in a lifestyle programme); (3) the participants should be motivated for participating in a digital lifestyle prevention (including user of a smartphone or tablet); and (4) the participants should be between 45 and 70 years old and without a diagnosis of dementia or cognitive impairment hindering participation. Exclusion criteria are having previously had a stroke or transient ischaemic attack (TIA) diagnosis and lack of understanding of 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 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 jeopardise that person's safety. Reasons for interruption will be recorded.

Active lifestyle: 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 interprofessional 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: (1) the incorporation of health-promoting EEAs, (2) the use of mobile phone technology to increase health literacy and awareness of current habits and to foster self-management, (3) forming new habits that prompt conscious decisions to make healthy choices and (4) 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 five 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 1 week after the last group session. During the intervention, participants will work actively with their self-chosen 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 contributing to psychological well-being, but a redesign of the activity could be walking or exercising at the gym while listening to an audio book, leading to health benefits that 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 (eg, to take the stairs).[30] The programme is expected

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

to foster self-management skills and the continuation a change process following the programme 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, a physiotherapist or a dietician. Each module will last 90 min and will be held at the participating PHCs, in their premises. To avoid contamination, the health professionals are instructed to not deliver the programme to other patients during the research period. The programme is new to the PHCs and has not been delivered before.

The mobile phone app

The app for the project was developed in close collaboration with ScientificMed Tech AB (http://www.scientificmed.com). ScientificMed Tech AB 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 preset goals and self-efficacy); physical activity (registering step counts, registering 24 hours' time use in relation to exercise, moderate intense activities, sleep, sedentary activities and other activities); EEAs (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 on 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 semistructured 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 the body mass index (BMI)) 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 EEAs.

Feasibility data

A combination of qualitative and quantitative data will be collected among the interventionists and the participants using surveys, logbooks and qualitative interviews. In order to investigate the 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 (eg, goal achievements, daily activities and dietary habits). Semistructured 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 the 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] *EuroQol-5D* will be used to measure quality of life.[40] The participants' level of occupational balance will be measured with the *Occupational Balance Questionnaire*, 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 min Walk Test* will be used to measure physical function.[45]

Data analysis plan

Feasibility of the intervention

Data collected from surveys, logbooks 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, dropouts, 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 will be presented. Qualitative interviews will be transcribed verbatim. All identifying factors will be removed (ie, 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 SPSS V.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 (RCT).

Patient and public involvement

A previous case study including six persons following 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 suggest that the participants highly valued the group meetings. Physical activities such as walking in nature and dancing were experienced as EEA. Experiences of the participants in the proposed pilot study of managing the app (eg, challenges, suggested changes, layout and period of use) and their experiences with 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 EEAs 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

semistructured interviews, logbooks, 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 of bias since reporting might not be accurate; therefore, observational measures such as the BMI and the 6 min 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 the effects of the protocol; however, the main aim of the pilot study was 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 of too small samples that do not provide sufficient diversity of the study population in relation to age, sex, rurality and socioeconomic 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 full-time. The risk of contamination between groups is assessed to be minimal, if any. Participants in 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 for 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 (reference numbers 2015/834-31, 2016/2203-32 and 2019/01444). In accordance with the general data protection regulation, 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 code 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.

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Contributors A-HP, 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 A-HP, EA and SG. AK, AB, CE and EÅ contributed to the design of the study. A-HP wrote the study protocol together with EA, SG and AB. All authors discussed and commented on draft versions and approved the final version.

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