Title:	STAR-C (Sustainable behaviour change for health supported by person-Tailored, Adaptive, Risk-aware digital Coaching in a social context) Digital Coaching Intervention
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Abbreviations and Definitions of Terms

CVD	Cardiovascular Diseases
FGD	Focus Group Discussion
STAR-C	Sustainable behaviour changes for health supported by person-Tailored, Adaptive, Risk-aware digital Coaching in a social context
VIP	Västerbotten Intervention Programme

ABSTRACT

Context: The growth of digital and health information technologies provides an opportunity to tailor and personalise health promotion messages to promote behavioural change for the primary prevention of chronic diseases. STAR-C digital coaching intervention aims to increase the efficiency and outreach of the Västerbotten Intervention Programme (VIP) in Northern Sweden, one of the few long-term cardiovascular diseases (CVD) prevention programmes globally integrated into routine primary healthcare.

Objectives: The overall objective is to assess the effectiveness of the STAR-C digital coaching intervention for health-related lifestyle behavioural change. More specifically, the study aims to: (1) analyse the effectiveness of the digital tool in enhancing readiness for behavioural change (primary outcome) and adoption and maintenance of healthier behaviours, self-rated health and well-being, and use of the digital tool (secondary outcomes); (2) understand the barriers and facilitators for the adoption and maintenance of utilising the STAR-C digital coaching intervention among health professionals and the adult population.

Study Design: This intervention is designed as a two-arm individual pragmatic one-sided crossover randomised controlled trial, with participants receiving immediate access to the digital coaching intervention (Arm 1) and no digital coaching intervention (Arm 2, delayed access six months).

Setting/Participants: The intervention is integrated into the Västerbotten Intervention Programme (VIP) in Västerbotten Region. In total, we will recruit 1000 participants from all VIP-participating primary healthcare centres in Västerbotten, proportional to the size of the VIP participants in each centre. All participants will receive regular VIP intervention with the VIP nurse before recruitment into the STAR-C intervention study. The intervention is planned to run for 12 months, with in-person recruitment at the baseline and follow-up at 1, 3, 6 and 12 months. We exclude individuals who are bedridden, terminally ill or have severe communication problems and those who receive behavioural change treatment at the *Beteendemedicin* clinic.

Study Interventions and Measures: The primary outcome of the intervention is a change in the readiness for behaviour change. The secondary outcomes include: (i) actual changes in the behaviours, including use of tobacco cessation clinics, higher smoking and snus cessation rate, reduction in alcohol consumption, adoption of healthy food habits, increased level of physical activity and reduction of sedentary behaviours, self-rated health and well-being, comparing baseline and follow-up data; (ii) patterns and usage of the digital tool during the intervention period (for the intervention group). These outcomes will be measured quantitatively during the three follow-up periods using questionnaires. In addition, interviews and group interviews will be conducted to explore the barriers and facilitators for the adoption and maintenance of the STAR-C digital coaching intervention for VIP nurses and the adult population.

1. BACKGROUND INFORMATION AND RATIONALE

1.1. Introduction

As one of the very few long-term cardiovascular diseases (CVD) prevention programmes globally that is integrated into routine primary healthcare, the Västerbotten Intervention Programme (VIP) has been shown as a cost-effective intervention which combines low-risk population and high-risk individual approaches to reduce overall and CVD-specific premature mortality significantly (Blomstedt et al., 2015). However, little is known about how digital tools could be used to amplify the effect of VIP. The growth of digital and health information technologies provides an opportunity to tailor and personalise health promotion in the VIP while simultaneously widening its outreach to the population. STAR-C programme is designed to develop and evaluate a technical platform for personalised digital coaching to support behavioural changes to improve health (Ng et al., 2021).

1.2. Name and Description of Intervention

STAR-C Digital Coaching Intervention

1.3. Relevant Literature and Data

To understand individuals' propensity to engage in behaviour change, our work will be guided by the ***Health Belief Model*** and the ***Transtheoretical Model of Change***. We use the ***Diffusion of Innovations theory*** to explore how digital technology is being utilised in promoting behaviour change at the individual level.

The research field of health behaviour and behaviour change offers models and frameworks to explain and predict the mechanisms determining health behaviour (Davis et al., 2015). The ***Health Belief Model*** focuses on individuals' health attitudes and beliefs that predict health behaviours (Edberg, 2015). The model comprises six elements: (a) self-efficacy - an individual's belief in her own ability to take action; (b) a person's perceived susceptibility to a given health problem; (c) the perceived severity of the health problem; (d) the perceived benefits of engaging in efforts to avoid this problem; (e) perceived barriers to engaging in those efforts; and (f) cues to action, or external incidents motivating action. The ***Transtheoretical Model of Change*** is a biopsychosocial, integrative model aimed at conceptualising intentional behaviour change processes (Prochaska & Velicer, 1997). The model recognises change as a process that unfolds over time, involving progress through a series of five (temporal) stages reflecting the process of individual change: (a) pre-contemplation; (b) contemplation; (c) preparation; (d) action; and (e) maintenance. Certain principles and change processes work best at each stage to reduce resistance, facilitate progress, and prevent relapse. Those principles include decisional balance, self-efficacy, and processes of change. Guidance based on the *Transtheoretical Model* results in increased participation in the change process because it appeals to the whole population rather than the minority ready to take action (Prochaska &Velicer, 1997).

The ***Diffusion of Innovations Theory*** offers a systems approach to behavioural change and concerns the conditions and processes by which social system members adopt an innovation (Rogers, 2003). Innovation is more likely to be adopted if: (a) people perceive it as bringing relative advantages to their previous or current practice; (b) it is compatible with their existing values, norms and practices; (c) the results can be observed, and (d) it is perceived as being understandable and simple to use. The theory outlines five categories of 'adopters' of an innovation: innovators, early adopters, early majority, late majority, and

laggards. It recognises that while some people can adopt what they consider an interesting innovation, others who would like to do so face internal, external or innovation-related barriers and therefore are unable to do so.

The field of ***Behaviour Change Systems*** (BCS) and persuasive technology explores ***behaviour change techniques*** (BCT) (e.g., goal setting, feedback, personalisation) and their links to ***mechanisms of action*** (MoA) (e.g., motivation, readiness to change, self-efficacy, barriers) (Oinas-Kukkonen & Harjumaa, 2009; Connell et al., 2018). However, only a few studies base their system design and evaluation of behaviour change systems on theories of behaviour change (Taj et al., 2019). Further research aimed at exploring links between BCTs and MoAs is needed. The design of the STAR-C digital intervention is based on theories on behaviour change and BCS research (Lindgren et al., 2020; Lindgren & Weck, 2022). A theory-based conceptual model of the behaviour change process was developed (Lindgren & Weck, 2021) to tailor the intervention and study links between BCTs and MoAs and their effects over time. Further, ethical considerations relating to persuasive technology and artificial intelligence are considered in the design process, such as mechanisms for transparency and control (Lindgren et al., draft).

To address the gaps of knowledge identified in the field of behaviour change systems, the intervention will address and contribute to the following:

- STAR-C will test a digital coaching application that embeds a set of complementary behaviour change techniques to tailor the intervention to the individual and explore their effects over time on mechanisms of action, in particular, the level of readiness to change behaviour.
- STAR-C will explore how participants choose to use the BCTs over time regarding changes in the level of readiness to change behaviour and concerning different domains of lifestyle changes (physical activity, recovery activity, nutrition, alcohol intake, tobacco use).
- STAR-C will evaluate lived experiences of using the behaviour change application, the role of the application in influencing health beliefs, readiness for change and adoption of behaviour change, and healthcare professionals' experience of the application as a tool for a behaviour change intervention.

Two systematic reviews conducted with the STAR-C research programme assess the cost-effectiveness of digital health interventions for behavioural change (Kway, 2022) and medication adherence (Maria, 2022). Kway showed that all studies (n=20) included in the systematic review on the cost-effectiveness of digital health intervention for behavioural change originated from high-income countries. Most studies used telephone or text messaging, mobile health applications and online websites for the intervention. Of nine studies where full-scale economic evaluations were conducted, eight studies were identified as cost-effective. Six other studies indicated the potential cost-saving from such intervention (Kway, 2022). Similarly, Maria reviewed nineteen studies focusing on the cost-effectiveness of digital health interventions for medication adherence, and only one study was conducted in a low-income setting. The review indicates large heterogeneity in the design and outcomes of studies included in the systematic review. Most studies only conducted a partial economic assessment through cost-comparison analysis. Hence the results should be interpreted carefully (Maria, 2022). In the current STAR-C intervention, we will focus on using digital tool intervention to promote behaviour change.

To address the knowledge gaps identified in the systematic reviews, the current intervention will address and contribute to the following:

- STAR-C will test an integrated approach to behavioural change using a digital tool in a real-life primary healthcare setting, which is unique from other interventions identified in the systematic reviews.
- The cost-effectiveness analysis in STAR-C will focus on the differences in costs and outcomes comparing the intervention groups (i.e. compare against the ongoing VIP intervention as received by the control group).
- STAR-C will quantify the outcomes regarding changes in the readiness to change behaviour. A unique and novel contribution is methods to translate these outcomes into cost evaluation in the economic evaluation.
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2. STUDY OBJECTIVES

2.1. Overall objective

To evaluate the effectiveness of the STAR-C digital coaching intervention for health-related lifestyle behavioural change.

2.2. Specific objectives

The specific objectives are to

- Investigate to what extent STAR-C digital coaching intervention leads to change in the readiness for behavioural change (sub-study 1).
- Evaluate the effect of the digital intervention on behavioural change, including a visit to tobacco cessation clinics, higher smoking and snus cessation rate, reduction in alcohol consumption, adoption of healthy food habits, increased level of physical activity and reduction of sedentary behaviours (sub-study 1).
- Evaluate the effect of the digital intervention on self-rated health and well-being (sub-study 1).
- Evaluate the cost-effectiveness of STAR-C digital coaching intervention compared to the existing VIP intervention in promoting behavioural change among the adult population (sub-study 2).
- Evaluate barriers and facilitators for adopting and maintaining the utilisation of STAR-C digital coaching intervention among the adult population (sub-study 3) and health professionals (sub-study 5).
- Evaluate barriers and facilitators for adopting and maintaining health-related lifestyle behavioural change among the adult population (sub-study 4).
- Analyse the different patterns of digital tool usage that could explain the effectiveness of the different behaviour change techniques embedded in the intervention and their relation to the participants and their characteristics (readiness for change, motivation, barriers, etc.), observed across age groups, gender, education level and geographical area of residence (sub-study 6).

3. DESIGN, IMPLEMENTATION, AND EVALUATION OF THE STAR-C INTERVENTION

3.1. Intervention Plan

3.1.1. Study Design

This intervention is designed as a two-arm individual pragmatic one-sided crossover randomised controlled trial conducted within the ongoing Västerbotten Intervention Programme (VIP) in Västerbotten Region in Sweden. VIP is integrated into primary care and invites inhabitants in Region Västerbotten to a health survey, including a comprehensive questionnaire and a systematic screening for cardiovascular risk factors, followed by a single individual health counselling with a trained nurse every ten years, at ages 40, 50, and 60 years. During the counselling, a “star profile” is used to illustrate the interrelationships between risk markers and behaviours and options for health promotion (Norberg et al., 2010). Recently, a digital platform has been developed to support counselling, including a digital form, a decision support system, and a star profile. This digital platform is now being implemented and offered at all 38 healthcare centres, allowing the participant to provide the basis for a health consultation via the digital health form on 1177.se. The compilation of form responses and health examination results in the support system reduces the healthcare staff's time spent on oral questions, compilation, calculation, documentation, remittance, and follow-up. Instead, the VHU nurse can focus on the dialogue with the participant and contribute with various methods that support changing unhealthy lifestyles, focusing on assessing the examination and counselling results.

In the STAR-C intervention study, all participants will receive the regular VIP intervention (health survey and individual health counselling) before recruitment into the STAR-C intervention study. See Appendix 1 for the study flowchart and steps in the intervention.

In intervention arm 1 (intervention arm), the participant will receive immediate access to digital coaching with personalisation.

In intervention arm 2 (control arm), the participant will receive no digital coaching immediately but delayed access at six months.

3.1.1.1. Screening Phase

We will identify the intervention participants among those participating in the VIP. The VIP nurse will conduct the screening among VIP participants. If a participant fulfils the eligibility criteria, the participant will be invited to participate in the STAR-C digital coaching intervention. As recruitment occurs after the VIP participation, all participants will receive the standard VIP health dialogue with the nurse. See Section 3.1.4.1 for the inclusion criteria.

3.1.1.2. Baseline Phase

Upon receiving the participant's verbal consent, the VIP staff will help them download and install the STAR-C application on their mobile phones (by scanning a QR code or a link to a web page for instructions on how to download the software) or give instructions on how to install the application on a later occasion. All participants will receive the

application, with different functionalities according to their allocation to the intervention arms. Upon registration and login to the application, the participants will obtain detailed information about the intervention, and they have to provide their digital consent to participate. See Appendix 2 for the Informed Consent form. Finally, the nurse will make notes in the log book about the recruitment of the participants (simply by sticking the barcode label to the intervention register).

Upon consent, the participants will need to complete a baseline assessment through a digital questionnaire embedded in the application (See Appendix 3 for information collected in the baseline). In the baseline questionnaire, we will also ask if the VIP participants must come back for another visit at three months (usually for those with high blood pressure, blood glucose, or blood cholesterol). The participant can complete the assessment at their convenient time after the VIP visit. A few reminders will be sent, after which a research assistant will conduct the baseline assessment through a telephone interview. Relevant information collected in the VIP questionnaire will be linked to the baseline data later.

After completing the baseline assessment, the application will automatically randomise the participants into one of the intervention arms. We will use block randomisation to ensure a balanced number of participants recruited into the different arms in each intervention site. Participants in Arm 1 will have direct access to digital coaching applications. See Section 3.2 for the description of the digital coaching application and its functionality. Participants in Arm 2 will receive delayed access to the coaching functionalities of the application after six months. The application will show participants in the control group a page with information about the study and a list of follow-up checkpoints, which will be accessible when they reach each checkpoint, and a countdown that shows the number of days until they receive access to the full application.

3.1.1.3. Follow-up Phase

The follow-up phase will continue for one year, with follow-ups at one, three, six and twelve months. The application will send notifications two weeks before the follow-up time (a window period of plus and minus two weeks) for the participants to fill in an online follow-up questionnaire as in the baseline. Three reminders will be sent to the participants, after which a research assistant will conduct a follow-up using a telephone survey (See Appendix 3 for the questions collected in follow-up data collection).

In addition to the quantitative data, we will also conduct qualitative studies to understand the usage of digital coaching apps and the extent to which the use of the digital tool has influenced behaviour change among the study participants. The consent form will contain a question where the participant can indicate their interest in an individual or group interview. Those who indicate interest will be contacted and invited to participate in the qualitative study. See interview guides in Appendix 4.

3.1.1.4. Cost-effectiveness assessment

As the measure of the effectiveness of the intervention, we will use the primary and secondary outcomes described below. Information on the costs of application development and implementation of the intervention will be collected throughout the programme. We will also use the EQ 5D 5L tool to follow the potential differences between the groups. See Appendix 3.

3.1.2. Allocation to Treatment Groups and Blinding

Random allocation to treatment arms: The randomisation of study participants will be conducted by the digital system. As we are interested in studying differences in the treatment outcomes and digital literacy between population groups, the randomisation list will be stratified by gender (male/female) and age group (40, 50 and over). We will conduct block randomisation for the study site to ensure an approximately similar number of study participants in each treatment arm. An example of a stratified block randomisation list for a site that will recruit about 48 participants is as follows. In each block, six participants will be recruited and randomly allocated to one of the two research arms.

Male, 40 year			Male, 50 and 60 years			Female, 40 year			Female, 50 and 60 years		
Block	Sequence	Allocation	Block	Sequence	Allocation	Block	Sequence	Allocation	Block	Sequence	Allocation
1	1	Arm B	3	1	Arm B	**5**	1	Arm B	**7**	1	Arm A
1	2	Arm A	3	2	Arm A	**5**	2	Arm A	**7**	2	Arm B
1	3	Arm B	3	3	Arm A	**5**	3	Arm B	**7**	3	Arm A
1	4	Arm A	3	4	Arm A	**5**	4	Arm A	**7**	4	Arm B
1	5	Arm B	3	5	Arm B	**5**	5	Arm B	**7**	5	Arm A
1	6	Arm A	3	6	Arm B	**5**	6	Arm A	**7**	6	Arm B
2	1	Arm A	4	1	Arm B	**6**	1	Arm A	**8**	1	Arm A
2	2	Arm B	4	2	Arm A	**6**	2	Arm B	**8**	2	Arm A
2	3	Arm B	4	3	Arm A	**6**	3	Arm A	**8**	3	Arm B
2	4	Arm A	4	4	Arm B	**6**	4	Arm A	**8**	4	Arm B
2	5	Arm B	4	5	Arm A	**6**	5	Arm B	**8**	5	Arm B
2	6	Arm A	4	6	Arm B	**6**	6	Arm B	**8**	6	Arm A

Blinding: Upon their consent to participate in the study, baseline measurement will be conducted for each participant before their random allocation to different treatment arms. The research group will be blinded to the treatment assignment. The treatment assignment key will be revealed only after the intervention has been concluded and the analysis has been conducted.

3.1.3. Study Duration, Enrolment and Number of Sites

3.1.3.1. Duration of Study Participation

Duration of study: The participants are planned to be recruited from March 2023 – February 2024. For each participant, the intervention duration will be up to six months, with in-person recruitment at the baseline and follow-up at 1, 3, 6, and 12 months on the application or telephone survey as necessary.

3.1.3.2. Sample size and recruitment of participants

Sample size: We estimate the sample size for randomised controlled trials following Wittes (Hayes and Bennett 1999). We assume a control prevalence of populations with

readiness for behaviour change of 25% to yield a sample size of 328 participants in each arm that give 80% power at 95% confidence to detect a minimum of 40% increase (from 25% to 35%) in the prevalence of people with readiness for behaviour change in the intervention arm 1. After adjusting for a 50% oversample to allow for non-response, refusal or loss to follow-up, we obtained the minimum sample size of 492 participants per arm, yielding a total of approximately 1000 participants being recruited into the trial.

Recruitment of participants: We will recruit participants from all primary healthcare centres in Västerbotten which run the Västerbotten Intervention Programme. As COVID-19 has shut down the VIP in almost half of the primary healthcare centres during 2020-2022, we will work closely with Region Västerbotten to identify and involve primary healthcare centres with active VIP recruitment in 2023. We expect the primary healthcare centre to represent centres in urban and rural areas in Västerbotten.

3.1.4. Study Population

3.1.4.1. Inclusion Criteria

- VIP participants who have received the VIP intervention
- Has a smartphone

3.1.4.2. Exclusion Criteria

- Individuals who are bedridden, terminally ill, have severe vision/hearing problems, or with other hindrances to fulfilling the study protocol.
- Individuals who will be referred to the Behavioural medicine clinic for behavioural change treatment.

3.2. Intervention Tools

3.2.1. Development of the STAR-C person-tailored coaching application

The STAR-C coaching application is developed in a participatory design process involving experts from the domains of nursing, psychology, medicine, public health, nutrition, social work, ethnology, epidemiology, health economics, health informatics, human-computer interaction, and artificial intelligence, employed at Umeå University and/or Region Västerbotten. Further, tentative users and participants in VIP have been participating in the design process.

The theoretical foundation of the design includes behaviour change theories, activity theory, and argumentation theory. The basis for system design includes participatory design to include diverse views on purposes, values, and functionalities; value-based design taking ethical aspects into the design process of systems embedding artificial intelligence (AI) techniques; and behaviour change systems/persuasive technology design.

A combination of AI techniques is being developed, where the data collected through the version used in the study will be used to further refine and develop the models for personalisation during the study and future versions of the system.

3.2.2. The functionality of the STAR-C digital application

3.2.2.1. General functionalities

To access the application, a user account is needed to authenticate a user and to store data relating to the use of the application.

The system architecture consists of a mobile application communicating with a server at the Department of Computing Science at Umeå University. Storing data and computations are performed on the server with temporary storing of data in the mobile phone. The system architecture contains the following databases for storing participant information: a graph database for the generic content of the application, including the rule base for assessing adherence to national recommendations and generating person-tailored advice; a database for authentication; and a relational database for storing the person-specific information. This information is stored and coded by identifiers to questions and answers referring to corresponding objects in the knowledge base.

Besides specific functionalities described in the next sections, both versions of the mobile application also contain functionality that allows the participant to communicate with the project team to troubleshoot problems in using the application and provide suggestions for improvement, or in case the participant wants to withdraw from the study and to have their data erased.

3.2.2.2. STAR-C application with person-tailored coaching for the intervention group

The intervention version contains information about the study and a baseline assessment to create an initial user model, which can be used for tailoring the application's behaviour. The assessment is repeated at months 1, 3, 6, and 12. During daily use, the user model is updated with information about changed preferences

regarding activities, motives for changing behaviour, perceived barriers, and accomplishments related to short- and long-time goals.

The STAR-C intervention embeds a set of behaviour change techniques (BCT) that, according to earlier studies, have some links to mechanisms of action (MoA) such as motivation, readiness to change, beliefs about capability, and attitudes towards the behaviour in focus.

- Goal setting (long- and short-term) for each domain of behaviour the participant wants to address;
- Self-monitoring of behaviour:
    - List of chosen activities relating to short and long-term goals for logging accomplishments;
    - Visualisation of progress relating to particular selected behaviour(s) and the selected activities;
    - Visualisation of overall status (STAR profile);
- Evidence/knowledge-based information and person-tailored advice, including information about health consequences;
- Digital coach character with person-tailored behaviours to challenge and to support by providing reminders, feedback, and suggestions of goals, partly through text-based dialogues with the user.

How these BCTs are linked to MoAs is an open research question, which will be explored by allowing participants to use the behaviour change techniques that they prefer, which may also change over time.

3.2.2.3. STAR-C application without person-tailored coaching for the control group

The application for the control group contains information about the study and the participant's participation throughout the study, including the baseline questionnaire, which is followed up with questionnaires including a sub-set of questions at 1, 3, 6, and 12 months. The control group's version also embeds a countdown to when they can access the full version when completing the questionnaires after six months.

3.2.3. Data collection using the STAR-C application

Data collected is anonymous and transmitted securely through https, using encryption and stored in servers at the Department of Computing Science at Umeå University following national and local regulations for research at the University. The following data will be collected in the intervention study.

- Information necessary for setting up a user account and for the linkage to the VIP database: person number, email address, telephone number, age and gender.
- Participant's responses to baseline and follow-up assessments.
- Participant's defined goals, related activities and their characteristics, and logs of their activities relating to the goals.
- Information about when and how the participant responds to suggestions and reminders.
- Aggregated information about physical activity, psychological well-being, alcohol consumption, tobacco use, and nutrition habits. This information is numbers used to create a star profile and measure short- and long-term accomplishments.
- Information about the user's clicks on menus and buttons and time spent using the application.

- Information about the number of steps measured by sensors in the mobile phone.
- Participant's preferences regarding how the coaching functionalities should appear.
- Participant's suggestions about improvements of the application.

3.3. Study Evaluations and Measurements

3.3.1. Primary Endpoint

The primary endpoint will be the change in readiness for behavioural change between baseline and follow-ups at 1, 3, 6, and 12 months. The proportion of participants in different stages of behavioural change of (a) pre-contemplation; (b) contemplation; (c) preparation; (d) action; and (e) maintenance for different behaviours will be evaluated at different time points.

3.3.2. Secondary Endpoints

The secondary endpoints include the change in behaviours or adaptation of healthier behaviours in the form of:

- use of tobacco cessation clinics or smoking, snus and other tobacco products cessation
- reduction in alcohol consumption
- the adoption of healthy food habits (using the four index questions)
- increase level of physical activity, and reduction of sedentary behaviours.

We will also assess the following additional secondary outcomes:

- the use and pattern of use of the digital tools
- health-related quality of life using the EQ5D instrument
- WHO-5 well-being index (https://ogg.osu.edu/media/documents/MB%20Stream/who5.pdf).

We will identify all costs related to the intervention or non-intervention, value the costs and, in the end, measure the relevant costs. It will be important to distinguish between costs for the project and costs relevant to implementing ordinary VIP intervention. Identifying the effect in a health economic evaluation is as important since the costs must be related to an effect to assess the cost-effectiveness. More details about the cost-effectiveness measurement will be described in Section 3.4.3.

3.4. Data analysis

3.4.1. Baseline Data

We describe participants' characteristics at baseline and follow-up. Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g., means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender).

Stages of change will be compared for each behaviour at different time points and across population groups. We will conduct latent class analysis to group the participants

into several classes of readiness for behavioural change for different combinations of behaviours (using the baseline data).

3.4.2. Sub-study 1: Effectiveness Analysis

We will use an intention-to-treat approach in the analysis of the RCT data. We assess differences in the groups using ANOVA and Chi-square tests for continuous and categorical variables, respectively. We analyse the longitudinal data using generalised estimating equations (GEE) and mixed models to assess the effect of time and the intervention on the outcomes.

The primary effectiveness endpoint will be the change in readiness for behavioural change between baseline and follow-up visits at 1, 3, 6, 12 months. Using the follow-up data, we will conduct latent transition analysis to map different trajectories of readiness for behavioural change, comparing participants in different intervention arms. Similar methods will be adopted for the secondary endpoints, change in health behaviours and well-being.

3.4.3. Sub-study 2: Cost-Effectiveness Analysis

Identification of costs is the first step in health economic evaluation. Costs for the development of the digital solution (the app), the running costs for app maintenance, and costs for data storage in the server are regarded as fixed investment costs. The variable costs include costs for reimbursing the nurse’s time spent in the initial training to understand the intervention and get familiar with the apps' functionalities and time spent in implementing the intervention to the participants. When using a societal perspective in the analysis, the time used by the participants to participate in the intervention should also be accounted for as a cost. In the next step, the different costs are valued. When considering technically-related costs, it is important to distinguish between costs related to the project and costs related to the introduction of the regular VIP intervention. In the valuation of various costs identified, we will include costs from public material (average salaries x used time), and the participants’ time will be quantified with the opportunity cost approach. Based on published materials, we will also value future savings related to reduced morbidity.

The cost of developing the app will be measured by multiplying the estimated time by the current salaries. One hypothesis, however, is that the cost will be so low per user that this cost will be excluded from the analysis. Other continuous salary costs, time costs, and continuous update costs, however, become important to follow.

A cost-effectiveness analysis must also have a clear effect to measure. Alternative calculations will be carried out. A first analysis relates the cost to the number of users. At the second step, we can also relate the cost to users with positive readiness to change their behaviours. As the expected effect is multidimensional, it is difficult to do a complete cost-effect analysis without simplifying the reality. We will therefore carry out a number of scenario-based cost effect analyses, where we will ultimately use published risk equations to draw conclusions. Another way to simplify the analysis is to use indicators to measure health-related quality of life. We collected EQ5D 5L data and can calculate the number of gained QALY due to the intervention.

A result of scenario-based cost effect analysis based on our data could look like this, for example, the cost of the app is x kronor. If y number of people were to stop smoking, the intervention cost could be justified by this measure of effectiveness.

All these mean that we will have different CEAs to strive for; cost/user; cost/user with positive change; cost/smoke quitter, or cost per person with improved physical behaviour. The different analyses will together form the conclusion.

4. IMPLEMENTATION RESEARCH ON THE STAR-C INTERVENTION

We integrate the implementation of the intervention into the ongoing VIP in place; hence, this RCT is pragmatic and more scalable in the Swedish primary healthcare settings. We will use implementation research design throughout the STAR-C intervention to describe and understand the enabling factors and barriers to the implementation. We use the data to develop a theory about how the interventions impact health outcomes by assessing feasibility, acceptability, scalability, and replicability.

The implementation research consists of four sub-studies with different aims and is conducted among different participant groups as described below.

4.1. Sub-study 3: The lived experience of using the STAR-C application

Aim: to explore the lived experience of using the STAR-C application among the adult population, including barriers and facilitators for use.

Sample and selection: A sample of 8-10 STAR-C participants will be selected if they:
a) agreed to participate in the evaluation of the STAR-C application and
b) have downloaded the application with full functionalities.

The sample represents a variation in age, gender, geographical location, and experience using digital tools.

Methods: The sub-study is based on ethnographic research methods. Personal photo/text journals (Photovoice) and in-depth interviews will be used to explore the lived experience of using the STAR-C application, including barriers and facilitators for use. Study participants will be asked to document their use of the application visually and textually in a journal on three to five occasions (one week for each occasion), for six months. Visual and written journals allow individual participants to highlight matters they perceive to be important in long-term and day-to-day use of the application. Visual and textual journals will be complemented with in-depth interviews with study participants. In-depth interviews will allow participants to elaborate on matters identified and described in their visual and textual documentation, as well as for researchers to explore more specific matters related to participants' day-to-day use of the application, including barriers and facilitators for use. The study starts with an individual introduction where participants are informed about the purpose of the photo/text journal concerning their use of the STAR-C application. In-depth interviews will be conducted after three and six months of use of the application. Overall matters that will be explored are:

- How do participants experience using the STAR-C application, and what cultural, social and technological contexts are activated in their descriptions of their experiences?
- What are the potential barriers and facilitators for continuous use of the STAR-C application?
- What could be suggested for future interventions implementing similar digital tools?

Questions to interview guide: Given the study's methodological approach, including photo/text journals and in-depth interviews, questions discussed during interviews will be generated by both study participants and researchers. During in-depth interviews, participants will be asked to elaborate on the research material generated through their personal photo/text journals. The photo/text journals will also work as a base from which researchers identify important matters and ask questions for participants to elaborate further on during interviews. Given the semi-structured character of the interviews, researchers will ask questions that are centred around four general themes, aligning with the overall aim of the sub-study:

- In what ways are you using the application in your day-to-day life?
- When are you using the application in your day-to-day life?
- How is it like to use the application in your day-to-day life?
- What do you find to be barriers and facilitators for using the application?

Analysis: The research material will be analysed using an ethnographic explorative approach based on Discourse theory and Science and Technology Studies (STS). This methodological stance helps to explore how the cultural, social, and technological contexts in which participants are situated can influence experiences and uses of the STAR-C application, including barriers and facilitators for use.

4.2. Sub-study 4: Role of digital tool on behavioural change

Aim: To understand the role of a digital tool in influencing health beliefs, readiness for change, and adoption of behavioural change.

Sample: A sample will be selected based on participants that have:
a) responded to be in different stages of willingness for change at baseline
b) represent a variation in geographical residence, age, gender, and experience of using digital tools

The participants will be invited at 3 and 6 months after being included in the intervention, resulting in two rounds of interviews for those that agree upon this. Baseline data will be used as the foundation for the interview, where the participants will be asked to reflect upon the answers given at baseline. About 10-15 participants will be included in the study.

Methods: In-depth interviews will be used for the following study and if willing, interviewed at two occasions. Overall questions that will be explored are:

- How, what, and for whom can a digital tool complement the role of social networks and social environment in influencing health beliefs, readiness for change and adoption of behavioural change?
- What would be suggestions for future interventions using similar tools to further facilitate the adoption of and maintenance of health-related lifestyle behavioural change?

Questions to interview guide: Below are examples of the questions that will be included in the interview guide. Further questions are given in the Appendix. As the study is based on an emergent design, additional questions can be added during the study.

- Do you recall your reasoning when responding to questions on readiness for change?
- How would you rate yourself today about readiness for change?
- How do you experience the use of the app in influencing your readiness for change and any potential change between baseline and today?

- Have you made any changes since baseline, if yes please describe
- What do you see as the contributing factors for these changes?
- How do you utilize the app vs. your social networks for health-related behaviour change?

Analysis: The research material will be analysed using an inductive and deductive thematic analysis. In the deductive approach, the health belief model and the transtheoretical model of change will be used as frames of analysis.

4.3. Sub-study 5: Healthcare professionals' experiences of using digital tool

Aim: To explore healthcare professionals' experiences of using the STAR-C application as part of the VIP interventions, including perceptions of barriers and facilitators of using digital applications to help VIP participants to change and sustain health-related behaviours.

Sample and selection: Approximately 15 healthcare professionals (nurses, assistant nurses, etc.) working with VIP will be included in the sub-study. Participants will be selected based on having a variation in years of experience in working with the VIP, including health dialogues, and also experience in using digital tools for facilitating behavioural change. They will also represent a geographical variation in the location of healthcare centres.

Methods: The sub-study is based on group interviews with 15 participants, with 2-6 participants in each group interview. At least one group interview per the three broad geographical areas of the VIP (Lycksele, Umeå, Skellefteå) will be conducted. The group interviews aim to identify pivotal matters connected to the overall aim of the sub-study. The sub-study will be conducted at least six months into the intervention so that staff have experience introducing and using the STAR-C application as part of the VIP. Overall matters that will be discussed are:
- How do participants experience using the STAR-C application within the context of the VIP intervention?
- What are perceived to be potential barriers and facilitators for continuous use of the STAR-C application within the VIP intervention?
- What organisational, professional and technological contexts are activated in their descriptions of their experiences using the STAR-C application within the VIP intervention?
- What could be suggestions for future initiatives that want to implement similar digital tools in public health interventions?

Questions to use: Given the explorative approach of the sub-study, group interviews will be centred around four general themes, aligning with the overall aim of the sub-study:
- How do participants experience using the STAR-C application within the context of the VIP intervention?
- What are perceived to be potential barriers and facilitators for continuous use of the STAR-C application within the VIP intervention?
- What organisational, professional and technological contexts are activated in their descriptions of their experiences using the STAR-C application within the VIP intervention?
- What could be suggestions for future initiatives that want to implement similar digital tools in public health interventions?

Analysis: The research material will be analysed using an approach based on Qualitative content analysis. This methodological stance helps to identify potential barriers and facilitators and explore how organisational, professional and technological contexts can influence staff's experiences and uses of the STAR-C application within the context of the VIP intervention.

4.4. Sub-study 6: The role and effectiveness of behavioural change techniques

Aims: To understand the role of the different behaviour change techniques embedded in the digital tool in influencing health beliefs, readiness for change and adoption of behavioural change, and other mechanisms of action, and how different participants utilise these for promoting healthy behaviour. Furthermore, the design and implementation of the behaviour change techniques will be further evaluated and refined, partly based on the participants' suggestions provided through the application.

Methods: Data collection is done using the STAR-C digital application. Data includes answers to questions, defined activities to meet goals, logging of activities, experienced effects of logged activities, sensor data counting steps, and logs of usage of different functionalities in the application.

Analysis: We will employ several analytical approaches in this sub-study.

- Quantitative analysis of use patterns and links between behaviour change techniques, mechanisms of action and domains of behaviour change.
- Ontological analysis of how participants define and adjust baby-step goals in the different domains of behaviour change.
- Qualitative analysis of open-ended questions embedded in the application using thematic analysis.
- Case studies of usage and behaviour change patterns over time.

5. STUDY ADMINISTRATION

5.1. Data Collection and Management

All the quantitative and qualitative data collected during the study will be stored and catalogued using standard methods. All Investigators and study site staff involved with this study will conform to the General Data Protection Regulation (GDPR) 2018 concerning the collection, storage, processing and disclosure of personal information and uphold the Act's core principles.

5.2. Confidentiality

All participants will be informed that their information will be treated anonymously and will only be presented on an aggregate level. These data will be anonymised before sharing them with the collaborators. Only the research group will have access to the project data.

5.3. Ethical considerations

5.3.1. Risk Assessment

We are aware of potential ethical issues regarding asking sensitive questions concerning individuals' behaviours, perceptions and attitudes towards health, use of digital applications, and their encounters with healthcare. Interviews to explore the reasons for not changing behaviours might also be sensitive. However, none of our data collection methods poses any risk of harm to the participants, non-participants, or healthcare providers. Participants will be reassured that their withdrawal will not affect their future healthcare.

5.3.2. Potential Benefits of Trial Participation

Participation in the study may give valuable support for a healthy lifestyle, improved health and well-being.

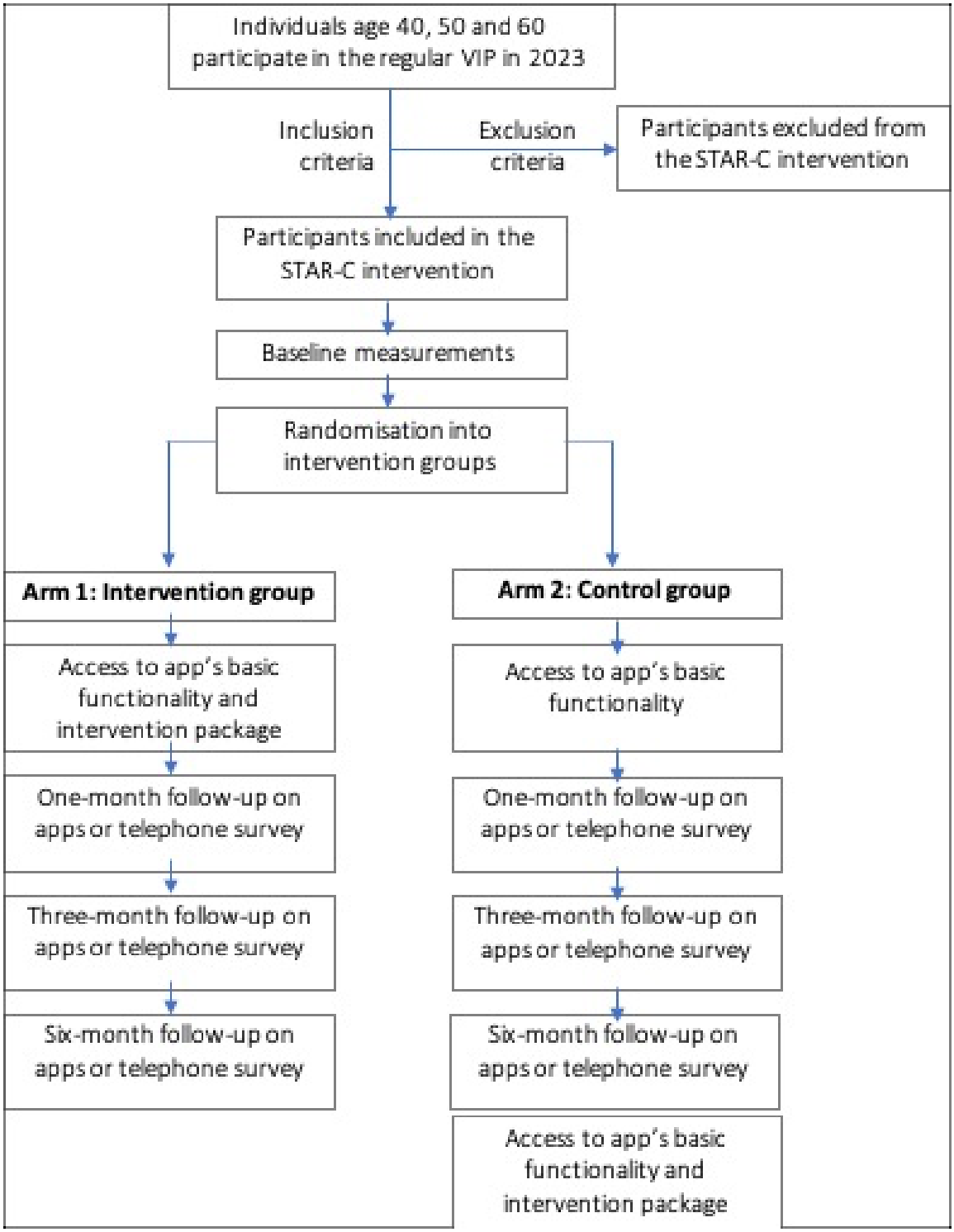
5.3.3. Risk-Benefit Assessment

The risk for participants is low and is outweighed by the scientific benefit of finding improved methods to enhance healthy lifestyles and improved health in the population.

This project aims to create equal opportunity and to ensure equitable access to high-quality health promotion activities at both societal and individual levels.

6. APPENDIX

Appendix 1. Study flowchart



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