STAR-C (Sustainable behaviour change for health supported by person-Tailored, Adaptive, Risk-aware digital Coaching in a social context) Digital Coaching Intervention

NCT05864001

Statistical Analysis Plan, sub-study 1

Version 1
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Study objectives

The overall objective is to evaluate the effectiveness of the STAR-C digital coaching intervention for health-related lifestyle behavioural change (1).

The specific objectives are to

1. Investigate to what extent STAR-C digital coaching intervention leads to change in the readiness for behavioural change (sub-study 1).
2. 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).
3. Evaluate the effect of the digital intervention on self-rated health and well-being (sub-study 1).
4. 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).
5. Evaluate barriers and facilitators for adopting and maintaining the utilization of STAR-C digital coaching intervention among the adult population (sub-study 3) and health professionals (sub-study 5).
6. Evaluate barriers and facilitators for adopting and maintaining health-related lifestyle behavioural change among the adult population (sub-study 4).
7. 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).

This document describes the statistical analysis plan for sub-study 1.

Outcome variables

Primary outcome variables

The primary endpoint is the change in readiness for behavioural change between baseline and follow-ups at 1, 3, 6 (primary outcome time frame), and 12 months (post-trial follow-up). 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. This outcome is related to specific objective 1 above.

Secondary outcome variables

The secondary endpoints are changes 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

The other secondary outcomes include health-related quality of life and well-being.

Study design

The study 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 (2).

All participants will receive the regular VIP intervention (health survey and individual health counselling) before recruitment into the STAR-C intervention study (1).

In the intervention arm 1 (intervention arm), the participant will receive immediate access to digital coaching with personalisation.
In the intervention arm 2 (control arm), the participant will receive no digital coaching immediately but delayed access at six months.

Population

We will recruit participants from all primary healthcare centres in Västerbotten which run the Västerbotten Intervention Programme.

Inclusion criteria

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

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.

Samples 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 approximately 1000 participants being recruited into the trial.

Baseline characteristics and treatment group comparability

We will describe participants' characteristics at baseline. 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). The frequency of missing data will be presented in a separate column for all the variables. No statistical tests (p-value) will be estimated in the baseline table.

Primary analysis model

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. Stages of change will be compared for each behaviour at different time points and across population groups, with 6 months as the primary outcome time frame. We assess groups' differences using Chi-square tests for categorical variables. We will use an intention-to-treat approach in the analysis of the RCT data. We will assess the effect of STAR-C intervention on the changes in health behaviours using longitudinal analysis of covariance, also known as generalized estimating equations (GEE) and mixed models. More specifically, we will include the outcome variable at baseline and time as well as the interaction between the treatment variable and time to the regression model and control for other confounders.

We will also conduct latent class analysis (3) to group the participants into several classes of readiness for behavioural change for different combinations of behaviours (using the baseline data). Using the follow-up data, we will conduct latent transition analysis (4) 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, health-related quality of life, and well-being.

Subgroup analyses

We will conduct subgroup analyses based on: (i) sex (male and female), (ii) age (40, 50, and 60 years old), (iii) baseline level of readiness of change, (iv) level of e-health literacy, and (v) Framingham Risk Score risk groups (low risk: <10% of FRS, medium risk: 10-19% of FRS, and high risk: $\geq$20% of FRS) (5).

Handling of missing data

We will conduct all the analyses based on the intention-to-treat principle. We will conduct multiple imputations for missing data using chained equation (MICE) (6, 7).

Sensitivity analyses

For sensitivity analysis, we will conduct per-protocol analyses (8), using data from participants with complete data for the primary outcomes and no violation to the study protocol.

References

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