EXTENDING HEALTH EXAMINATION AND LIFESTYLE HEALTH DIALOGUE IN PRIMARY CARE WITH A DIGITAL MULTIPLE HEALTH BEHAVIOUR CHANGE INTERVENTION: PROTOCOL FOR THE *COACH PRIMARY CARE* RANDOMISED CONTROLLED TRIAL

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INTRODUCTION

Behavioural risk factors, such as harmful alcohol consumption, unhealthy diets, insufficient physical activity, and smoking, contribute to about a third of global disability adjusted life years, and are leading causes of non-communicable diseases (NCDs), including cardiovascular disease, respiratory disease, cancer, and diabetes [1,2]. The World Health Organization has determined that reducing the prevalence of behavioural risk factors should be a priority in many societies to reduce the incidence of NCDs and disability adjusted life years [3]. It is therefore important that effective and scalable means of helping individuals to improve their health behaviours are established.

The Public Health Agency of Sweden's national public health survey from 2020 [4] (n = 16 947) reports data on lifestyle behaviours of Swedish citizens aged 16-84. According to the survey, 16% of respondents report hazardous or harmful alcohol consumption, 35% report being insufficiently physically active, 12% report smoking occasionally or daily, and 93% report eating less fruit and vegetables than recommended. Additionally, 52% of individuals report being obese or overweight. Unfortunately, with the exception of smoking, the prevalence rates of these behaviours have not decreased markedly over the past 10 years, with some increasing, witnessing of a lost decade for prevention efforts. Unhealthy lifestyle behaviours also tend to cluster and interact [5,6], e.g. those who are overweight are more likely to be physically inactive, and excessive alcohol consumption may lead to weight gain. Risks from multiple unhealthy lifestyle behaviours may be multiplicative [7]; thus, it is of value to not only extend the reach of interventions, but to also investigate tools designed to support change of multiple health behaviours.

In the county of Östergötland in Sweden, health examinations followed by a lifestyle-directed health dialogue have been a part of the primary health care since 2012. The aim of the health dialogue is to promote health, prevent cardiovascular disease and premature deaths from non-communicable diseases in the population. Previous research points out that the approach may contribute to reduce both mortality from cardiovascular disease and all-cause deaths. The health dialogue offers the possibility to systematically raise awareness regarding participants lifestyle, and the possibility to support participants to change their lifestyle behaviours.

The health dialogue consists of a visit at the local primary care clinic. Before the visit, participants are asked to complete surveys on health, lifestyle, heredity for cardiovascular disease, and to leave a blood sample at the laboratory that will be analysed for biological biomarkers (blood sugar and lipids). During the visit, before the health dialogue, a health examination of body measurements (weight, height, hip, and waist measures) and blood pressure examination are conducted. All of participants health data, from surveys, the health examination and blood samples are compiled on a graphic health profile and the health dialogue is conducted using the person-centred conversation technique motivational interviewing.

One way of extending the face-to-face health promotion activities that are already ongoing in primary care is to offer digital support tools. This is especially promising in Sweden, since the internet is used daily by approximately 90% of the population, and the same proportion use smartphones on a regular basis [8,9]. Studies evaluating digital interventions addressing *multiple* health behaviours have shown promising results [10–13]. However, the evidence of these types of interventions in more general populations is lacking, as the majority of studies have been conducted among university students, employees within specific fields, or patients with specific health conditions. Increasing our understanding of the effects of a digital multiple health intervention as an extension to face-to-face health promotion is therefore important to support their adoption more widely in primary care.

OBJECTIVES

This study aims to estimate the effects of a digital multiple health intervention (alcohol, physical activity, diet, and smoking) as an extension to face-to-face health promotion within primary care. The primary objectives of the study are to:

1. Estimate the effects of a digital multiple health intervention on individual health behaviours:
    a. Weekly alcohol consumption and number of episodes per month of heavy drinking.
    b. Average daily fruit and vegetable consumption.
    c. Weekly moderate to vigorous physical activity.
    d. Four-week point prevalence of smoking.

2. Estimate the degree to which the effects of the intervention are mediated through perceived importance, confidence, and know-how.

3. Evaluate the cost versus consequences of extending face-to-face health promotion within primary with a digital health intervention.

METHODS

A randomised controlled trial will be employed to address the objectives of the study. A Bayesian sequential design will be used to periodically make decisions to continue or stop recruitment [14–16]. This protocol contains relevant items from the *Standard Protocol Items: Recommendations for Interventional Trials* (SPIRIT) [17].

STUDY SETTING, RECRUITMENT AND ELIGIBILITY

Individuals aged 40, 50 and 60 years old, living in the county of Östergötland (in the south-east part of Sweden) will be invited to a health dialogue with a health-care professional at their primary health care clinic. Participants will be recruited from approximately 30 primary health care clinics. Since conducting health dialogues just recently became part of the clinical routine within the primary health care, the number of conducted examinations and lifestyle health dialogues per year has varied greatly, between on average 10-100 per clinic. Approximately 30-35% of those invited to a health dialogue accept and attend, resulting in around 2000 health dialogues each year in Östergötland.

After completing the health dialogue, all individuals will be given brief verbal information about the Coach Primary Care study, and written material with instructions on how to register interest. Those interested in taking part in the study will be asked to send a text message to a dedicated phone number.

Individuals registering interest will receive a text message with a hyperlink that takes them to a web page with informed consent materials. Consent will be given by clicking on a button on the bottom of the page. All individuals giving informed consent will be asked to complete a baseline questionnaire, which will also assess eligibility for the trial (please see Appendix A). Individuals will be included in the trial if they fulfil at least one of five conditions:

-   **Weekly alcohol consumption:** Consumed 10/15 (female/male) or more standard drinks of alcohol the past week. A standard drink of alcohol is in Sweden defined as 12 grams of pure alcohol.

-   **Heavy episodic drinking:** Consumed 4/5 (female/male) or more standard drinks of alcohol on a single occasion at least once the past month.

- **Fruit and vegetables:** Consumed less than 500 grams of fruit and vegetables on average per day the past week.

- **Moderate to vigorous physical activity:** Spent less than 150 minutes on moderate to vigorous physical activity the past week.

- **Smoking:** Having smoked at least one cigarette the past week.

Individuals will be explicitly excluded if they do not fulfil any of the criteria or if they are less than 18 years of age. The trial information and intervention will be entirely in Swedish and delivered to participants' mobile phones, thus, not comprehending Swedish well enough to sign up or not having access to a mobile phone will implicitly exclude individuals.

INTERVENTIONS

CONTROL

Individuals randomised to the control condition will be recommended to read more about how to achieve a healthy lifestyle on a nationally adopted website containing information about health and wellbeing (https://www.1177.se). They will be advised to motivate themselves and attempt to change their behaviour and that access to the digital intervention will be made available to them at a later stage.

INTERVENTION

Individuals randomised to the intervention condition will be recommended the same website as in the control condition (https://www.1177.se), and in addition, immediate access to the digital intervention.

The digital intervention, which is called *Coach Primary Care*, consists of six components which users access using their mobile phone, based on an intervention design we have used previously [18,19]. The intervention is designed around social cognitive theories of behaviour change, with a focus on modifying environment, intention, and skills [20,21]. The intervention's components are intended to be used as a toolbox, allowing users to choose which parts of the intervention to interact with and tailor the support to their needs. The intervention materials can be accessed at participants' discretion over a 4-month period, and each Sunday afternoon participants will receive a text message with a link and a reminder to access the intervention materials. A summary of the components of the intervention is presented in Table 1, and a detailed description of the intervention is available in Appendix B.

Table 1 - Brief description of the components of the *Coach Primary Care* intervention

Screening and feedback
Every Sunday afternoon, participants will receive a text message with a hyperlink which takes them to a questionnaire regarding their current health behaviours. Once complete, feedback on their current behaviour is given in relation to national guidelines. Thereafter users are given access to the rest of the components (depending on allocation).
Goalsetting and planning
This component let participants set a goal for their future behaviour and plan for what to do when they struggle and succeed. Participants can also accept challenges for the coming week, e.g., to walk for 15 minutes each day, or to not drink any alcohol this week. Self-composed challenges are also available. Reminders are sent via texts to participants about their goals and challenges throughout the week.

Motivation
This component contains information and tools to increase participants' motivation for change. This includes information on negative health consequences, costs induced from certain behaviours, and reflective tasks. If participants choose, they can also activate motivational text messages which are sent to them throughout the week.

Skills and know-how
Concrete tips on how to initiate and maintain change in everyday life is offered in this component. This includes giving participants strategies they can use to say no to alcoholic beverages at parties, how to increase the nutritional value of their breakfast, etc. If participants choose, they can also activate text messages with tips sent to them throughout the week.

Mindfulness
This component aims to increase users' awareness of their own lived experience and strengthen their capacity for non-reactive, compassionate, and less stressful way of being in the world. Mindfulness exercises are offered to participants, including guided meditations.

Self-composed text messages
Participants are given the opportunity to compose messages and have them sent to themselves throughout the week (on days and times of their own choosing). A participant may for instance write a message to themselves reminding them to eat two fruits each day, to not drink anything on Wednesdays, or to go for a walk with a friend.

OUTCOMES

MEASURES

Outcomes are listed here and subsequently explained. All questionnaires (baseline, and follow-up) used in the trial can be found in Appendix A.

Primary outcome measures

- **Alcohol:** Weekly alcohol consumption; monthly frequency of heavy episodic drinking.

- **Diet:** Average daily consumption of fruit and vegetables.

- **Physical activity:** Weekly moderate to vigorous physical activity (MVPA).

- **Smoking:** Four-week point prevalence of smoking abstinence.

Secondary outcome measures

- Perceived stress.

- Weekly consumption of sugary drinks.

- Weekly consumption of candy and snacks.

- Body mass index (BMI).

- Weekly number of cigarettes smoked.

- Quality of life (QoL).

Mediation measures

- Importance of change.

- Confidence in one's ability to change.

- Knowledge of how to change.

PRIMARY AND SECONDARY OUTCOMES

Weekly alcohol consumption will be assessed by asking participants the number of standard drinks of alcohol they consumed last week (short term recall method [22]). Frequency of heavy episodic drinking will be assessed by asking participants how many times they have consumed 4/5 (female/male) or more standard drinks of alcohol on one occasion the past month. These two outcomes are both part of the proposed core outcome set for brief alcohol interventions [23–25], and represent different risk behaviours which are sometimes found in the same individual and sometimes not. For instance, one may have a high weekly alcohol consumption, and thereby be at risk for negative health consequences, without consuming 4/5 or more drinks on the same occasion. Similarly, having one episode of heavy episodic drinking increases the risk of short-term consequences (such as injury) and long-term health consequences, but does not fulfil the criteria for total weekly consumption.

Diet and physical activity will be measured utilising a questionnaire based on the previously published questionnaire by the National Board of Health and Welfare in Sweden [6], and was further modified to also include portion sizes. The consumption of fruit and vegetables will be measured using two questions concerning the number of portions (100 g) of fruit and vegetables (respectively) the participants ate on average per day during the past week. Sugary drinks consumption will be measured by a question regarding the number of units (33 cl) of sugary drinks participants consumed the past week, and candy and snacks will be measured using a single question regarding number of servings consumed last week. MVPA will be estimated by summing responses to two questions regarding the number of minutes spent on moderate and vigorous physical activity, respectively, during the past week.

Body mass index will be measured by asking participants to report their weight and height.

Four-week point prevalence of smoking abstinence (no cigarettes the past four weeks) will be asked as a binary question. This is a suggested measure by the Society of Research on Nicotine and Tobacco [26]. Participants who have smoked any cigarette the past four weeks will be asked for the number of cigarettes smoked the past week.

QoL will be measured using PROMIS Global 10 [27] and perceived stress will be assessed using the short form perceived stress scale (PSS-4) [28].

MEDIATION MEASURES

Participants will be asked to report on confidence, importance, and know-how; which are three psychosocial factors believed to be important markers of behaviour change [20,21,29–31]. To reduce participant burden, we will use single face-valid items, acknowledging the limitation of such measures.

PARTICIPANT TIMELINE AND FOLLOW-UPS

A trial participant timeline is presented in Figure 1. The intervention (depending on allocation) will be made available to participants at their own discretion throughout the 4-month period (with weekly reminders). There are 4 follow-up stages: 1-, 2-, 4-, and 6-months post randomisation. All follow-ups will be initiated by sending text messages to participants with hyperlinks to questionnaires. The following additional attempts will be made to collect data:

1. A total of two text reminders will be sent two days apart to those who have not responded.

2. If there is no response to the mediator questions at the 1-month follow-up, then the questions will be sent in a text message and participants are asked to respond directly with a text.

3. If there is no response to the 2-, 4-, and 6-month follow-ups, then we will call participants to collect responses for the primary outcome measures only. A maximum of 5 call attempts will be made.

			STUDY PERIOD				
	Enrolment	Allocation	Post-allocation				Close-out
TIMEPOINT	0	0	0	1 month	2 months	4 months	6 months
ENROLMENT:							
Informed consent	X						
Eligibility screen	X						
Allocation		X					
INTERVENTIONS:							
Digital intervention		X	◆———————————————◆				
Control condition		X	◆———————————————◆				
ASSESSMENTS:							
Baseline questionnaire	X						
Mediator questionnaire	X			X	X	X	X
Lifestyle outcomes questionnaire					X	X	X
Perceived stress	X				X	X	X
QoL							X
Intervention group experience						X	
Control group experience							X

Figure 1 - SPIRIT figure showing participant timeline throughout the study

ASSIGNMENT OF INTERVENTIONS

Randomisation will be fully automated and computerised. Block randomisation will be used to allocate participants to the two conditions (random block sizes of 2 and 4). Neither research personnel nor participants will be able to influence allocation.

Research personnel will be blind to allocation throughout the trial. Participants will be aware of having immediate or delayed access and will therefore not be blind to allocation.

PATIENT AND PARTICIPANT INVOLVEMENT STATEMENT

Outcome measures used in the trial are informed by national guidelines in Sweden, as well as those set by the WHO. The Swedish National Board of Health and Welfare [6] have reported that research regarding multiple health behaviour change interventions is lacking. No patients or participants were involved in the planning of this trial or design of the intervention; however, both have been informed by our previous research involving individuals looking for help to change health related behaviours.

ANALYSIS

All analyses will be done keeping all participants in the groups to which they were randomised. Analyses will be done using both available data and imputation. Imputation will be done using multiple imputation with chained equations [32]. The implicit missing at random (MAR) assumption underlying this approach will be investigated by two attrition analyses: (1) if data is missing systematically then it may be the case that early responders (answering without reminders) differ from non-responders (requiring several attempts), and in extension that late responders are more alike non-responders. Therefore, one attrition analysis will regress primary outcomes against number of attempts to collect follow-up before a response was recorded; (2) we will further explore the MAR assumption by investigating if responders and non-responders are different with respect to baseline characteristics.

Groups will be contrasted using multilevel regression models with participant level and clinic level adaptive intercepts. Models of longitudinal data (primary outcomes and perceived stress) will include group by time by component interactions. Bayesian inference will be used to estimate the parameters of the models [33–35] (see Sample Size for priors). For each coefficient of interest, we will report the marginal posterior probability of effect, and the median will be used as a point estimate of the magnitude of the effect. We will also report on 50% and 95% compatibility intervals.

MODELS

PRIMARY AND SECONDARY OUTCOMES

Analyses of primary outcomes will be conducted among those fulfilling the respective criteria for inclusion at baseline, e.g., weekly alcohol consumption will be analysed among those who reported having consumed 10/15 (female/male) or more units of alcohol the past week. BMI, sugary drinks, candy/snacks, QoL, and perceived stress will be analysed among all participants, and number of cigarettes smoked weekly among baseline smokers.

Weekly alcohol consumption, frequency of heavy episodic drinking per month, weekly intake of candy and snacks, number of sugary drinks per week, and cigarettes smoked per week are all count variables that are likely skewed and over dispersed. Therefore, these outcomes will be analysed using negative binomial regression. If found not to be over dispersed, we will consider using normal regression (possibly log

transformed). Average intake of fruit and vegetables per day, MVPA minutes per week, BMI, QoL, and perceived stress will be analysed using linear regression (possibly log transformed). Point prevalence of smoking abstinence will be analysed using logistic regression.

All models will be adjusted for age, sex, and mediators (importance, confidence, and know-how) at baseline. Primary outcomes and perceived stress will be adjusted for their respective baseline values, except for smoking prevalence which will be adjusted by the weekly number of cigarettes smoked at baseline. BMI, sugary drinks, and candy/snacks will be adjusted for baseline MVPA minutes per week and average intake of fruit and vegetables per day. Number of cigarettes smoked last week will be adjusted by its baseline value. QoL will be adjusted for perceived stress at baseline.

Effect modification will be explored in all models to assess if any of the baseline characteristics moderate the effects of the intervention.

MEDIATOR OUTCOMES

Mediators will be explored using a causal inference framework [36–38], using Bayesian inference to estimate the natural direct effect and natural indirect effect (as per the definitions of Pearl [38]). We will report on the posterior distributions of these two estimates. Four models will be created for each primary outcome measure, three which investigate the mediating factors on their own, and a fourth which incorporates all mediators at once.

COST-CONSEQUENCE ANALYSIS

A health economic study will be conducted to estimate the relative cost versus consequences of a wider dissemination of a digital health intervention as an extension to face-to-face health promotion in primary care. Both a healthcare and societal perspective will be taken, with outcomes including incidence of common NCDs, quality adjusted life years, and life years gained.

INTERACTIONS AMONG HEALTH BEHAVIOURS

Outcome interactions, and determinants of such, will be investigated in an exploratory analysis. For instance, those who quit smoking may also be more likely to reduce their alcohol consumption, and this interaction may be moderated by baseline characteristics. In addition, we will investigate interactions between changes in perceived stress, QoL, and behaviour change. Models to detect such interactions will be explored and findings will be used to create hypotheses for future research.

SAMPLE SIZE

The trial will use a Bayesian sequential design [14–16] to monitor recruitment. Each of the primary outcomes will be modelled according to the analysis plan (see Analysis), and coefficients for group allocation at each follow-up interval will be assessed for effect, harm, and futility with respect to each outcome. We let $ß_{I,i}$ represent the regression coefficient for group allocation, at time I, for outcome i, and D all the data currently accumulated, then the target criteria will be:

- **Effect (fruit/veg. and physical activity):** $p(ß_{I,i} > 0 \mid D) > 97.5\%$ and $p(ß_{I,i} > 0.25 \mid D) > 50\%$
- **Harm (fruit/veg. and physical activity):** $p(ß_{I,i} < 0 \mid D) > 97.5\%$ and $p(ß_{I,i} < -0.25 \mid D) > 50\%$
- **Futility (fruit/veg. and physical activity):** $p(-0.15 < ß_{I,i} < 0.15 \mid D) > 95.0\%$

- **Effect (alcohol):** $p(ß_{I,i} < 0 \mid D) > 97.5\%$ and $p(ß_{I,i} < \log(1/1.2) \mid D) > 50\%$

- **Harm (alcohol):** $p(\beta_{l,i} > 0 \mid D) > 97.5\%$ and $p(\beta_{l,i} > \log(1.2) \mid D) > 50\%$
- **Futility (alcohol):** $p(\log(1/1.1) < \beta_{l,i} < \log(1.1) \mid D) > 95.0\%$

- **Effect (smoking):** $p(\beta_{l,i} > 0 \mid D) > 97.5\%$ and $p(\beta_{l,i} > \log(1.5) \mid D) > 50\%$
- **Harm (smoking):** $p(\beta_{l,i} < 0 \mid D) > 97.5\%$ and $p(\beta_{l,i} < \log(1/1.5) \mid D) > 50\%$
- **Futility (smoking):** $p(\log(1/1.4) < \beta_{l,i} < \log(1.4) \mid D) > 95.0\%$

Outcomes analysed using normal regression will be standardised when checking the above criteria. We will use a standard normal prior for group allocation covariates (mean = 0, sd = 1.0). The criteria should be viewed as targets, thus at each interim analysis we will evaluate each criterion and decide if we believe that recruitment should stop or continue. Note that the Bayesian approach allows us to make unlimited looks at the data without worrying about multiplicities and error rates, as would be necessary using a frequentist approach [39]. Also, since no fixed effect size is pre-specified, we reduce the risk of stopping recruitment both too early and too late [16].

While the final sample size is not determined a-priori, a traditional power calculation can give an indication of what the final sample size will be. Using effect sizes at the minimal value of the above criteria (0.25 Cohen's d for fruit/veg and physical activity, 1.2 incidence rate ratios for alcohol, and 1.5 odds ratios for smoking), and a significance level of 0.05 and power of 0.8, power calculations indicate that: approximately 504 individuals need to be analysed for fruit/veg, physical activity, and alcohol outcomes, and 584 for smoking. While this suggests that 2600 individuals need to be analysed, this assumes that each individual in the study has only one unhealthy behaviour. We know from previous studies that this is false, meaning that the estimated 2600 analysed individuals should be viewed as an upper bound on the sample size.

DISCUSSION

Maintaining a healthy diet and adequate physical exercise are proven ways to decrease the risk of many NCDs such as cancer and type II diabetes. More specifically, evidence suggests that the risk of many types of cancer is reduced by a diet which, among other things, includes vegetables and fruits and limits high-calorie foods and sugary drinks [40]. Smoking has been identified as the most prominent risk factor for developing many types of cancer, however, there are indications that more complex connections are in effect. For instance, alcohol consumption is a strong risk factor for cancer in and of itself, however, it has a synergetic relation with smoking in the context of developing certain types of cancer, meaning that a combination of these health behaviours amounts to bigger risks than their individual effects [41,42]. Research has provided strong evidence that risk factors for disease such as smoking, alcohol, physical inactivity and poor diet tend to have a clustered and co-occurring pattern in populations [43,44]. Swedish data shows a similar tendency, increasing the risk of poor health outcomes in the population and hence providing additional incitement for future studies to utilise a multi-behaviour approach. Furthermore, previous research concludes the need for future research to use a holistic approach, focusing on multiple and simultaneous interventions for behavioural change [11,43,45–48]

Two meta-analyses reported modest effects of multiple health behaviour interventions in non-clinical [46] and clinical populations [49], with various suggested reasons, including poor implementation. Some of the limitations of past efforts may be difficult to overcome with traditional face-to-face interventions, due to the large demand on staff and other resources. Only 4 of the 69 trials in one of the meta-analyses [46] investigated the use of interventions delivered via digital technology (e.g., email, text messages or websites). These trials were however limited by low power or engagement, targeted university students or young individuals, and had questionable external validity. All in all, despite the extended reach which digital interventions may have, there is a lack of evidence for digital multiple health behaviour interventions targeting a more general population.

GENERALISABILITY AND LIMITATIONS

We have adopted a pragmatic recruitment strategy for this trial which closely mimics the way the intervention would be disseminated in a real-world context. The trial should therefore be viewed as estimating effectiveness of the intervention, rather than an efficacy. However, careful consideration should be taken due to the trial context creating expectations of and from participants [50,51], and those who take part in trials may be systematically different from those who do not. In addition, several limitations of the trial should be considered when interpreting findings.

Since conditions are known to participants we do not consider them blinded to allocation, which increases the risk of bias [52,53]. In particular, social desirability bias may be induced, as those who are positive to the treatment received may want to support its dissemination by reporting more positive outcomes than actual [54]. Compensatory rivalry bias could exacerbate this issue [55]. We will ask questions with respect to participants' perceptions about the support received and allocation procedures to support reasoning about the strength of these threats to validity.

Condition allocation may be revealed to research personnel when participants are called to collect follow-up data. This may be a source of bias, as non-blinded assessment of subjective measures have been found to bias estimates [56]. Personnel are instructed to not ask about anything else than the follow-up data, and not to ask about allocation. Using phone calls is a strategy employed to reduce the risk of attrition bias, which we believe outweighs the risk of detection bias.

Finally, we use single face-valid items for mediators to reduce participant burden, which means that any marked mediation effect should be carefully interpreted to relate to the full concept of importance, confidence, and know-how.

ETHICS AND DISSEMINATION

The study was approved by the Swedish Ethical Review Authority on 2022-10-11 (Dnr 2022-04776-01). It was registered in the ISRCTN registry on 2023-01-11 (ISRCTN18001653). Participants are likely to have been motivated to sign up for the trial by the potential of receiving novel support, leading to a risk of opportunity cost if the intervention only exerts small effects on behaviour. However, considering that current prevention efforts seem to not be enough to reduce the prevalence of unhealthy behaviours, and the potential effects and reach a digital multiple health behaviour change intervention could have among those seeking help online, this risk was deemed acceptable.

Recruitment will begin in January 2023, and we anticipate that recruitment will last no more than 24 months. A final dataset will therefore be available in June 2025, and findings will be subsequently submitted for peer-review in open access journals.

STATEMENTS

FUNDING

COMPETING INTERESTS

MB and PB own a private company (Alexit AB) that develops and distributes lifestyle behaviour interventions for use in healthcare settings. Alexit AB had no part in funding or planning of this trial but is relied upon for a service to send text messages.

DATA AVAILABILITY STATEMENT

Data will be made available to researchers upon reasonable request, after approval of a research proposal and signing of data transfer agreements.

REFERENCES

1.   World health organization. Fact sheet Noncommunicable diseases. 2018.

2.   Stanaway JD, Afshin A, Gakidou E, Lim SS, Abate D, Abate KH, et al. Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Stu. The Lancet. 2018 Nov;392(10159):1923–94.

3.   World Health Organization. Global action plan for the prevention and control of noncommunicable diseases 2013-2020. 2013.

4.   Folkhälsomyndigheten. Bilaga 1 till "Folkhälsans utveckling – Årsrapport 2021" - Resultat i tabellform [Internet]. 2021. Available from: https://www.folkhalsomyndigheten.se/globalassets/publicerat-material/publikationer/folkhalsan-arsrapport-2021/folkhalsans-utveckling-arsrapport-2021-bilaga-1-21014-1.pdf

5.   Schuit AJ, Van Loon AJM, Tijhuis M, Ocké MC. Clustering of lifestyle risk factors in a general adult population. Prev Med. 2002;35(3):219–24.

6.   Socialstyrelsen. Nationella riktlinjer för prevention och behandling vid ohälsosamma levnadsvanor. 2018.

7.   Myint PK, Luben RN, Wareham NJ, Bingham SA, Khaw K tee. Combined effect of health behaviours and risk of first ever Norfolk cohort of European Prospective Investigation of Cancer (EPIC Norfolk): prospective population study. 2009;338(1):b349.

8.   Befolkningens it-användning 2020. SCB; 2020.

9.   Svenskarna och internet. Internet Stiftelsen; 2021.

10.   Deitz D, Cook RF, Hersch RK, Leaf S. Heart healthy online: an innovative approach to risk reduction in the workplace. J Occup Environ Med. 2014;56(5):547–53.

11.   Schulz DN, Kremers SPJ, Vandelanotte C, Van Adrichem MJG, Schneider F, Candel MJJM, et al. Effects of a web-based tailored multiple-lifestyle intervention for adults: A two-year randomized controlled trial comparing sequential and simultaneous delivery modes. J Med Internet Res. 2014;16(1):e26.

12.   Duncan MJ, Vandelanotte C, Trost SG, Rebar AL, Rogers N, Burton NW, et al. Balanced: a randomised trial examining the efficacy of two self-monitoring methods for an app-based multi-behaviour intervention to improve physical activity, sitting and sleep in adults. BMC Public Health. 2016 Dec;16(1):670.

13.   A O, J B, A D, de Weerdt I, de Vries H, Oenema A, et al. Efficacy and use of an internet-delivered computer-tailored lifestyle intervention, targeting saturated fat intake, physical activity and smoking cessation: a randomized controlled trial. Ann Behav Med. 2008;35(2):125–35.

14.   Gsponer T, Gerber F, Bornkamp B, Ohlssen D, Vandemeulebroecke M, Schmidli H. A practical guide to Bayesian group sequential designs. Pharm Stat. 2014;13(1):71–80.

15. Berry DA. Bayesian clinical trials. Nat Rev Drug Discov. 2006 Jan;5(1):27–36.

16. Bendtsen M. The P Value Line Dance: When Does the Music Stop? J Med Internet Res. 2020;22(8):e21345.

17. Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Ann Intern Med. 2013 Feb 5;158(3):200.

18. Bendtsen M, McCambridge J. Reducing Alcohol Consumption Among Risky Drinkers in the General Population of Sweden Using an Interactive Mobile Health Intervention: Protocol for a Randomized Controlled Trial. JMIR Res Protoc. 2019;8(4):e13119.

19. Åsberg K, Lundgren O, Henriksson H, Henriksson P, Bendtsen P, Löf M, et al. Multiple lifestyle behaviour mHealth intervention targeting Swedish college and university students: protocol for the *Buddy* randomised factorial trial. BMJ Open. 2021 Dec;11(12):e051044.

20. Fishbein M, Triandis HC, Kanfer FH, Becker M, Middlestadt SE, Eichler A. Factors influencing behaviour and behaviour change. In: Handbook of Health Psychology. Psychology Press Taylor & Francis Group; 2001. p. 3–17.

21. Conner M, Norman P. Predicting Health Behavior: Research and Practice with Social Cognition Models. 2005.

22. Rehm J. Measuring Quantity, Frequency, and Volume of Drinking. Alcohol Clin Exp Res. 1998;22(s2):4s–14s.

23. Shorter GW, Heather N, Bray JW, Giles EL, Holloway A, Barbosa C, et al. The 'Outcome Reporting in Brief Intervention Trials: Alcohol' (ORBITAL) framework: protocol to determine a core outcome set for efficacy and effectiveness trials of alcohol screening and brief intervention. Trials. 2017 Dec;18(1):611.

24. Shorter GW, Bray JW, Giles EL, O'Donnell AJ, Berman AH, Holloway A, et al. The Variability of Outcomes Used in Efficacy and Effectiveness Trials of Alcohol Brief Interventions: A Systematic Review. J Stud Alcohol Drugs. 2019 May;80(3):286–98.

25. Bendtsen M, Garnett C, Toner P, Shorter GW. The Effect of Question Order on Outcomes in the Core Outcome Set for Brief Alcohol Interventions Among Online Help-Seekers: Protocol for a Factorial Randomized Trial. JMIR Res Protoc. 2020 Nov 26;9(11):e24175.

26. SRNT Subcommittee on Biochemical Verification. Biochemical verification of tobacco use and cessation. Nicotine Tob Res. 2002 May;4(2):149–59.

27. Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. Qual Life Res. 2009 Sep;18(7):873–80.

28. Vallejo MA, Vallejo-Slocker L, Fernández-Abascal EG, Mañanes G. Determining Factors for Stress Perception Assessed with the Perceived Stress Scale (PSS-4) in Spanish and Other European Samples. Front Psychol. 2018 Jan 26;9.

29. Ajzen I. The theory of planned behavior. Organ Behav Hum Decis Process. 1991;50(2):179–211.

30. Bandura A. Self Efficacy: the exercise of control. Worth Publishers; 1997.

31. Rogers R. Cognitive and physiological processes in fear appeals and attitude change: A revised theory of protection motivation. In: Social Psychophysiological: A Sourcebook. 1983.

32. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. Stat Med. 2011;30(4):377–99.

33.   Bendtsen M. A Gentle Introduction to the Comparison Between Null Hypothesis Testing and Bayesian Analysis: Reanalysis of Two Randomized Controlled Trials. J Med Internet Res. 2018;20(10):e10873.

34.   Bendtsen M. Electronic Screening for Alcohol Use and Brief Intervention by Email for University Students: Reanalysis of Findings From a Randomized Controlled Trial Using a Bayesian Framework. J Med Internet Res. 2019;21(11):e14419.

35.   Bendtsen M. An Electronic Screening and Brief Intervention for Hazardous and Harmful Drinking Among Swedish University Students: Reanalysis of Findings From a Randomized Controlled Trial Using a Bayesian Framework. J Med Internet Res. 2019;21(12):e14420.

36.   Imai K, Keele L, Tingley D. A General Approach to Causal Mediation Analysis. Psychol Methods. 2010;15(4):309–34.

37.   Pearl J. Causality. Causality: Models, Reasoning, and Inference, Second Edition. Cambridge: Cambridge University Press; 2009.

38.   Pearl J. Interpretation and identification of causal mediation. Psychol Methods. 2014;19(4):459–81.

39.   Harrell F. Continuous Learning from Data: No Multiplicities from Computing and Using Bayesian Posterior Probabilities as Often as Desired [Internet]. 2020 [cited 2020 May 10]. Available from: https://www.fharrell.com/post/bayes-seq/

40.   Norat T, Scoccianti C, Boutron-Ruault MC, Anderson A, Berrino F, Cecchini M, et al. European Code against Cancer 4th Edition: Diet and cancer. Cancer Epidemiol. 2015 Dec;39:S56–66.

41.   Leon ME, Peruga A, McNeill A, Kralikova E, Guha N, Minozzi S, et al. European Code against Cancer, 4th Edition: Tobacco and cancer. Cancer Epidemiol. 2015 Dec;39:S20–33.

42.   Scoccianti C, Cecchini M, Anderson AS, Berrino F, Boutron-Ruault MC, Espina C, et al. European Code against Cancer 4th Edition: Alcohol drinking and cancer. Cancer Epidemiol. 2016 Dec;45:181–8.

43.   Noble N, Paul C, Turon H, Oldmeadow C. Which modifiable health risk behaviours are related? A systematic review of the clustering of Smoking, Nutrition, Alcohol and Physical activity ('SNAP') health risk factors. Prev Med. 2015 Dec;81:16–41.

44.   Berrigan D, Dodd K, Troiano RP, Krebs-Smith SM, Barbash RB. Patterns of health behavior in U.S. adults. Prev Med. 2003 May;36(5):615–23.

45.   Bendtsen M, Bendtsen P, Henriksson H, Henriksson P, Müssener U, Thomas K, et al. The Mobile Health Multiple Lifestyle Behavior Interventions Across the Lifespan (MoBILE) Research Program: Protocol for Development, Evaluation, and Implementation. JMIR Res Protoc. 2020;9(4):e14894.

46.   Meader N, King K, Wright K, Graham HM, Petticrew M, Power C, et al. Multiple Risk Behavior Interventions: Meta-analyses of RCTs. Am J Prev Med. 2017;53(1):e19–30.

47.   Prochaska JJ, Spring B, Nigg CR. Multiple health behavior change research: An introduction and overview. Prev Med. 2008;46(3):181–8.

48.   De Vries H, Kremers S, Smeets T, Reubsaet A. Clustering of diet, physical activity and smoking and a general willingness to change. Psychol Health. 2008;23(3):265–78.

49.   Alageel S, Gulliford MC, McDermott L, Wright AJ. Multiple health behaviour change interventions for primary prevention of cardiovascular disease in primary care: systematic review and meta-analysis. BMJ Open. 2017 Jun;7(6):e015375.

50.   McCambridge J, Kypri K, Elbourne D. Research participation effects: a skeleton in the methodological cupboard. J Clin Epidemiol. 2014 Aug;67(8):845–9.

51.	McCambridge J, Witton J, Elbourne DR. Systematic review of the Hawthorne effect: New concepts are needed to study research participation effects. J Clin Epidemiol. 2014 Mar;67(3):267–77.

52.	Higgins JPT, Altman DG, Gotzsche PC, Juni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ. 2011 Oct 18;343(oct18 2):d5928–d5928.

53.	Bendtsen M, McCambridge J, Åsberg K, Bendtsen P. Text Messaging Interventions for Reducing Alcohol Consumption Among risky drinkers: Systematic Review and Meta-Analysis. Addiction. 2020;

54.	Miles LM, Elbourne D, Farmer A, Gulliford M, Locock L, McCambridge J, et al. Bias due to MEasurement Reactions In Trials to improve health (MERIT): protocol for research to develop MRC guidance. Trials. 2018 Dec 26;19(1):653.

55.	McCambridge J. From question-behaviour effects in trials to the social psychology of research participation. Psychol Health. 2015 Jan 2;30(1):72–84.

56.	Hrobjartsson A, Thomsen ASS, Emanuelsson F, Tendal B, Hilden J, Boutron I, et al. Observer bias in randomised clinical trials with binary outcomes: systematic review of trials with both blinded and non-blinded outcome assessors. BMJ. 2012 Feb 27;344(feb27 2):e1119–e1119.

BASELINE QUESTIONNAIRE

1. Sex:
   a. Female
   b. Male

2. Age (numerical measure)

3. How many standard drinks of alcohol did you consume last week? (numerical measure)

4. How often, during the past month, have you consumed four/five (female/male) or more standard drinks of alcohol on one occasion? (numerical measure)

5. How many cigarettes did you smoke last week? (numerical measure)

6. How much time in total did you spend on moderate physical activity (e.g. bicycling or walking for transport or leisure) **last week**?
   a. 0
   b. Less than 30 minutes
   c. 30-60 minutes
   d. 1 hours
   e. 1.5 hours
   f. 2 hours
   g. 2.5 hours
   h. 3 hours
   i. 3.5 hours (i.e. 30 minutes per day)
   j. 4 hours
   k. 5 hours
   l. 6 hours
   m. 7 hours (i.e. 1 hour per day)
   n. 10.5 hours (i.e. 1.5 hours per day)
   o. 14 hours (i.e. 2 hours per day)

7. How much time in total did you spend on vigorous physical activity (i.e. producing increases in breathing or heart rate), for instance running, aerobics, etc. **last week?**
   a. 0
   b. Less than 30 minutes
   c. 30-60 minutes
   d. 1 hours
   e. 1.5 hours
   f. 2 hours
   g. 2.5 hours
   h. 3 hours
   i. 3.5 hours (i.e. 30 minutes per day)
   j. 4 hours
   k. 5 hours
   l. 6 hours

m. 7 hours (i.e. 1 hour per day)

n. 10.5 hours (i.e. 1.5 hours per day)

o. 14 hours (i.e. 2 hours per day)

8. How many 100g portions (equivalent to an average sized banana or one large apple) of fruit did you consume **last week**?

    a. 0

    b. 1-2 portions **per week**

    c. 3-4 portions **per week**

    d. 5-6 portion **per week**

    e. 1.0 portion **per day**

    f. 1.5 portions **per day**

    g. 2.0 portions **per day**

    h. 2.5 portions **per day**

    i. 3.0 portions **per day or more**

9. How many 100 g portions (equivalent to an average handful) of vegetables did you consume **last week**?

    a. 0

    b. 1-2 portions **per week**

    c. 3-4 portions **per week**

    d. 5-6 portion **per week**

    e. 1.0 portion **per day**

    f. 1.5 portions **per day**

    g. 2.0 portions **per day**

    h. 2.5 portions **per day**

    i. 3.0 portions **per day or more**

10. How tall are you? (numerical measure)

11. What is your current body weight? (numerical measure)

12. In the last month, how often have you felt that you were unable to control the important things in your life?

    a. Never

    b. Almost never

    c. Sometimes

    d. Fairly often

    e. Very often

13. In the last month, how often have you felt confident about your ability to handle your personal problems?

    a. Never

    b. Almost never

    c. Sometimes

    d. Fairly often

    e. Very often

14. In the last month, how often have you felt that things were going your way?

a. Never
b. Almost never
c. Sometimes
d. Fairly often
e. Very often

15. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?
    a. Never
    b. Almost never
    c. Sometimes
    d. Fairly often
    e. Very often

16. How important is it for you to improve your lifestyle behaviours? (10-point scale ranging from 1 = "Not important" to 10 = "Very important")

17. How confident are you that you will be able to improve your lifestyle behaviours? (10-point scale ranging from 1 = "Not at all" to 10 = "Very confident")

18. To what degree do you have the know-how and strategies to improve your lifestyle behaviours? (10-point scale ranging from 1 = "Not at all" to 10 = "Very high degree")

1-MONTH FOLLOW-UP (MEDIATORS ONLY) QUESTIONNAIRE

1. How important is it for you to improve your lifestyle behaviours? (10-point scale ranging from 1 = "Not important" to 10 = "Very important")

2. How confident are you that you will be able to improve your lifestyle behaviours? (10-point scale ranging from 1 = "Not at all" to 10 = "Very confident")

3. To what degree do you have the know-how and strategies to improve your lifestyle behaviours? (10-point scale ranging from 1 = "Not at all" to 10 = "Very high degree")

2-, 4-, AND 6-MONTH FOLLOW-UP QUESTIONNAIRE

1. How many standard drinks of alcohol did you consume last week? (numerical measure)

2. How often, during the past month, have you consumed four/five (female/male) or more standard drinks of alcohol on one occasion? (numerical measure)

3. Have you smoked any cigarettes the past four weeks?
   a. Yes
   b. No

4. (Smokers only) How many cigarettes did you smoke last week? (numerical measure)

5. How much time in total did you spend on moderate physical activity (e.g. bicycling or walking for transport or leisure) **last week**?
   a. 0
   b. Less than 30 minutes

  c. 30-60 minutes

  d. 1 hours

  e. 1.5 hours

  f. 2 hours

  g. 2.5 hours

  h. 3 hours

  i. 3.5 hours (i.e. 30 minutes per day)

  j. 4 hours

  k. 5 hours

  l. 6 hours

  m. 7 hours (i.e. 1 hour per day)

  n. 10.5 hours (i.e. 1.5 hours per day)

  o. 14 hours (i.e. 2 hours per day)

6. How much time in total did you spend on vigorous physical activity (i.e. producing increases in breathing or heart rate), for instance running, aerobics, etc. **last week?**

  a. 0

  b. Less than 30 minutes

  c. 30-60 minutes

  d. 1 hours

  e. 1.5 hours

  f. 2 hours

  g. 2.5 hours

  h. 3 hours

  i. 3.5 hours (i.e. 30 minutes per day)

  j. 4 hours

  k. 5 hours

  l. 6 hours

  m. 7 hours (i.e. 1 hour per day)

  n. 10.5 hours (i.e. 1.5 hours per day)

  o. 14 hours (i.e. 2 hours per day)

7. How many 100g portions (equivalent to an average sized banana or one large apple) of fruit did you consume **last week**?

  a. 0

  b. 1-2 portions **per week**

  c. 3-4 portions **per week**

  d. 5-6 portion **per week**

  e. 1.0 portion **per day**

  f. 1.5 portions **per day**

  g. 2.0 portions **per day**

  h. 2.5 portions **per day**

  i. 3.0 portions **per day or more**

8. How many 100 g portions (equivalent to an average handful) of vegetables did you consume **last week**?

  a. 0

  b. 1-2 portions **per week**

  c. 3-4 portions **per week**

    d. 5-6 portion **per week**

    e. 1.0 portion **per day**

    f. 1.5 portions **per day**

    g. 2.0 portions **per day**

    h. 2.5 portions **per day**

    i. 3.0 portions **per day or more**

9. How many cans (33 cl, one standard can) of sugary drinks (e.g. soft/fizzy drinks, "energy drinks") did you consume **last week**?

    a. 0 cans

    b. 1 can **per week**

    c. 2-3 cans **per week**

    d. 4-6 cans **per week**

    e. 1 can **per day**

    f. 1.5 cans **per day**

    g. 2.0 cans **per day**

    h. 2.5 cans **per day**

    i. 3.0 cans **per day or more**

10. How many portions of sweets, chocolate, pastry (e.g. buns, muffins, biscuits), ice cream and salty snacks (e.g. crisps, nuts, cheese doodles) did you eat **last week**? *One portion is 50 g sweets (9 pieces), 40 g chocolate (6 pieces/squares), 1 bun, 2 dl (scoops) of ice cream or 2 dl snacks (40 g).*

    a. 0 portions

    b. 1 portion **per week**

    c. 2-3 portions **per week**

    d. 4-6 portions **per week**

    e. 1 portion **per day**

    f. 1.5 portions **per day**

    g. 2.0 portions **per day**

    h. 2.5 portions **per day**

    i. 3.0 portions **per day**

    j. 3.5 portions **per day**

    k. 4.0 portions **per day or more**

11. What is your current body weight? (numerical measure)

12. In the last month, how often have you felt that you were unable to control the important things in your life?

    a. Never

    b. Almost never

    c. Sometimes

    d. Fairly often

    e. Very often

13. In the last month, how often have you felt confident about your ability to handle your personal problems?

    a. Never

    b. Almost never

c. Sometimes
        d. Fairly often
        e. Very often

14. In the last month, how often have you felt that things were going your way?
        a. Never
        b. Almost never
        c. Sometimes
        d. Fairly often
        e. Very often

15. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?
        a. Never
        b. Almost never
        c. Sometimes
        d. Fairly often
        e. Very often

16. How important is it for you to improve or maintain healthy lifestyle behaviours? (10-point scale ranging from 1 = "Not important" to 10 = "Very important")

17. How confident are you that you will be able to improve or maintain healthy lifestyle behaviours? (10-point scale ranging from 1 = "Not at all" to 10 = "Very confident")

18. To what degree do you have the know-how and strategies to improve or maintain healthy lifestyle behaviours? (10-point scale ranging from 1 = "Not at all" to 10 = "Very high degree")

6-MONTH FOLLOW-UP ONLY

1. In general, would you say your health is: (Poor, Fair, Good, Very good, Excellent)

2. In general, would you say your quality of life is: (Poor, Fair, Good, Very good, Excellent)

3. In general, how would you rate your physical health: (Poor, Fair, Good, Very good, Excellent)

4. In general, how would you rate your mental health, including your mood and your ability to think? (Poor, Fair, Good, Very good, Excellent)

5. In general, how would you rate your satisfaction with your social activities and relationships? (Poor, Fair, Good, Very good, Excellent)

6. In general, please rate how well you carry out your usual social activities. This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.: (Poor, Fair, Good, Very good, Excellent)

7. To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?
        a. Not at all

b. A little
    c. Moderately
    d. Mostly
    e. Completely

8. In the past 7 days, how often have you been bothered by emotional problems such as feeling anxious depressed or irritable?
    a. Always
    b. Often
    c. Sometimes
    d. Rarely
    e. Never

9. In the past 7 days, how would you rate your fatigue on average?
    a. Very severe
    b. Severe
    c. Moderate
    d. Mild
    e. None

10. In the past 7 days, how would you rate your pain on average (where 0 is No Pain, and 10 is Worst Pain Imaginable)?

INTERVENTION GROUP EXPERIENCE (4-MONTH FOLLOW-UP)

- Overall, how well suited do you believe that the support was to your needs?
    o I did not receive any support at all
    o I received some support, but it did not suit my needs
    o I received some support, and it suited my needs to some degree
    o I received the support I needed

- You have answered that you did not receive any support or that the support you received did not suit your needs. What was your reaction:
    o I decided to find other support to change my lifestyle behaviours
    o I decided to not change my lifestyle behaviours
    o Other, please leave a comment:

- Please leave a comment describing your needs and how the intervention matched or did not match them:

- To what degree do you believe that Coach can help people who want to change their lifestyle behaviours? (1 = "Not very helpful" to 5 = "Very helpful")

- Would you recommend Coach to a friend who expresses a wish to change their lifestyle behaviour?
    o Yes
    o No

- o I do not know

- If you were to continue using Coach, for how much longer would you want to use it?
  - o I would use it for one to two more months
  - o I would use it for three to six more months
  - o I would use it for more than six months
  - o I do not want to use it any more
  - o I do not know

CONTROL GROUP EXPERIENCE (6-MONTH FOLLOW-UP)

Questions asked to the control group at the end of the trial.

You were part of the group that was given access to information before being given access to the mobile phone-based support. Out of the options listed below, which best describes your immediate reaction and your later actions. Please also leave a comment to explain your response.

- Immediate response:
  - o Interested to check out the information.
  - o Frustration, irritation, or disappointment. I was ready for extra support to reduce my consumption.
  - o Neither positive or negative. It did not really matter for me.
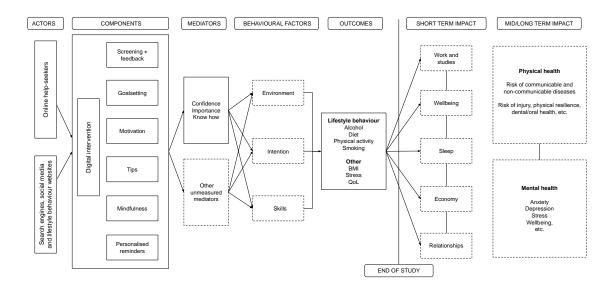 - o I do not know.

- Actions:
  - o I decided to motivate myself and change my lifestyle behaviours.
  - o I decided to continue living as normal, and to change my behaviours once the initial phase was over.
  - o I found other support that I used to change my lifestyle behaviours (please leave a comment on which support you used).
  - o I gave up on the idea of changing my lifestyle behaviours.

- Did you look at the information given, and did you find it useful?
  - o I looked at the information and found it useful to think about my lifestyle behaviours.
  - o I looked at the information and found that it was not useful.
  - o I did not look at the information.
  - o I do not know.

APPENDIX B – DIGITAL INTERVENTION DESCRIPTION

This appendix describes the content of the *Coach Primary Care* intervention, which is based on an intervention design we have used previously [1,2]. The intervention targets alcohol, diet, physical activity, and smoking.

The intervention was developed with inspiration from the first four steps of the Intervention Mapping (IM) approach [3]. The intervention is based on social cognitive models for behaviour change where environment, intentions and skills often are highlighted as important for change [4,5]. Therefore, we identified and designed components which intended to affect these factors. This was based on our previous research in Sweden [1,6–12] and the research literature more widely (see specific descriptions below). The logic model in Supplementary Appendix Figure 1 gives an overview of the reasoning behind the intervention, including outcomes and potential short-, mid- and long-term impact.

Supplementary Appendix Figure 1 - Logic model showing actors, intervention components, mediators, behavioural factors, outcomes, and short-, mid- and long-term impacts
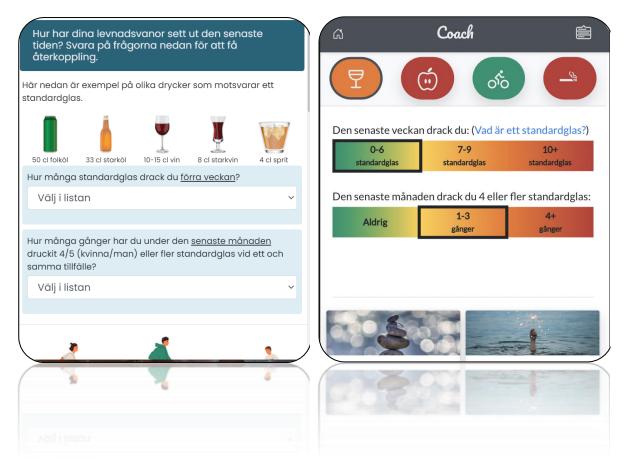
INTERVENTION DESIGN AND COMPONENTS

The intervention is intended to be used as a toolbox, enabling users to decide which intervention content they want to interact with and when. As can be seen in the screenshot in Supplementary Appendix Figure 2, the design of the intervention allows for each component to be presented to participants in a menu. Follows does a description of each component, using the BCTTv1 93-item taxonomy [13] to specify techniques included when appropriate.

Supplementary Appendix Figure 2 - A screenshot of the digital intervention showing the main menu

COMPONENT 1: SCREENING AND FEEDBACK

The first component consists of screening and feedback. Every Sunday afternoon, participants will receive a text message with a hyperlink. When pressing the link, participants will be asked to respond to a questionnaire regarding their current lifestyle behaviours, after which they are shown feedback on their current behaviour in contrast to national guidelines (see screenshots in Supplementary Appendix Figure 3). They will subsequently be given access to the rest of the components appropriate for their randomised allocation. Self-monitoring has been shown to be a potentially effective strategy for reducing excessive alcohol consumption [14–17] and to promote healthy eating and physical activity [18,19]. BCTs used: Discrepancy between current behaviour and goal (BCT 1.6), Feedback on behaviour (BCT 2.2), Self-monitoring of behaviour (BCT 2.3), and Social comparison (BCT 6.2).

Supplementary Appendix Figure 3 – Screenshots of the digital intervention showing screening and feedback based on national guidelines

COMPONENT 2: GOALSETTING AND PLANNING

The second component supports enhanced self-regulatory capacity and skills via goalsetting and planning. This includes setting goals for future behaviour, preparing for triggers, and accepting both custom and ready-made challenges. Intervention content designed around goalsetting, action planning, practicing behaviour, and habit formation have, amongst other planning related activities, been shown to be important among effective lifestyle interventions [18,20–25]. Participants will be reminded of the goals that they have set, including any challenges they have accepted, via text message prompts throughout the week (up to 4 messages). BCTs used: Goal setting (behaviour) (BCT 1.1), Problem solving (BCT 1.2), Action planning (BCT 1.4), Prompts/cues (BCT 7.1), Behaviour practice/rehearsal (BCT 8.1), Behaviour substitution (BCT 8.2), Habit formation (BCT 8.3), Graded tasks (BCT 8.7).

COMPONENT 3: MOTIVATION

The third component aims to increase users' awareness of their own motivation, prompt commitment, and boost motivation. This is supported via texts, videos and exercises relating to health, economics, and motivation awareness. Digital behaviour change interventions have been shown to have the capacity to increase self-efficacy, however, there is lack of consensus across reviews with regards to which content works to facilitate an increase of self-efficacy [26]. The component will also allow participants to sign up for text messages with motivational content sent to them throughout the week. Participants choose which behaviours they wish to have messages for, with a maximum of 8-10 messages per week. The content of the messages has been derived from previously developed and evaluated interventions [6–12]. BCTs used: Information about

health consequences (BCT 5.1), Credible source (9.1), Pros and cons (BCT 9.2), Comparative imagining of future outcomes (BCT 9.3).

COMPONENT 4: SKILLS AND KNOW-HOW

The fourth component aims to increase user's skills and know-how of how to make lasting behavioural changes. This will include concrete tips on how to initiate and maintain change in everyday life. For instance, participants are given strategies they can employ when going to parties where alcohol is served, or how to introduce vegetables to their meals. As with the third component, participants will be able to sign up for text messages with tips sent to them throughout the week (maximum 8-10 per week) – the content of which has also been derived from previously developed and evaluated interventions [6–12]. BCTs used: Social support (unspecified) (BCT 3.1), Instructions on how to perform a behaviour (BCT 4.1), Self-incentive (BCT 10.7), and Self-reward (BCT 10.9).

COMPONENT 5: MINDFULNESS

The fifth component aims to increase users' awareness of their own lived experience and strengthen their capacity for a non-reactive, compassionate, and less stressful way of being in the world. The practices thus help participants to build the mental resources needed for behaviour change. A set of mindfulness exercises, including guided meditations, will be available in the component. The exercises are based on previous research, and are considered evidence-based methods to improve the mental well-being of clinical populations, while effects in non-clinical settings and behaviour change are less studied [27–31].

COMPONENT 6: SELF-COMPOSED TEXT MESSAGES

The sixth component consists of self-composed text messages sent to participants throughout the week. Participants will be allowed to author up to three messages to themselves and have them sent at specified intervals. For instance, a participant can write a message about their commitment to increase their physical activity and decide to have it sent to them every Monday and Wednesday at 5pm. This type of activity seems generally under-studied in the literature, but has shown preliminary interesting results in an ongoing trial [32].

REFERENCES

1. Bendtsen M, McCambridge J. Reducing alcohol consumption among risky drinkers in the general population of Sweden using an interactive mobile health intervention: protocol for a randomized controlled trial. JMIR Res Protoc. 2019;8(4):e13119.

2. Åsberg K, Lundgren O, Henriksson H, Henriksson P, Bendtsen P, Löf M, et al. Multiple lifestyle behaviour mHealth intervention targeting Swedish college and university students: protocol for the *Buddy* randomised factorial trial. BMJ Open. 2021 Dec;11(12):e051044.

3. Bartholomew Eldredge LK. Planning health promotion programs: an intervention mapping approach. Fourth edition. San Francisco, CA: Jossey-Bass & Pfeiffer Imprints, Wiley; 2016. 1 p.

4. Fishbein M, Triandis HC, Kanfer FH, Becker M, Middlestadt SE, Eichler A. Factors influencing behaviour and behaviour change. In: Handbook of Health Psychology. Psychology Press Taylor & Francis Group; 2001. p. 3–17.

5. Conner M, Norman P. Predicting health behaviour: research and practice with social cognition models. Open University Press; 2005.

6.   Müssener U, Bendtsen M, Karlsson N, White IR, McCambridge J, Bendtsen P. Effectiveness of Short Message Service Text-Based Smoking Cessation Intervention Among University Students. JAMA Intern Med. 2016;176(3):321.

7.   Müssener U, Bendtsen M, Karlsson N, White IR, McCambridge J, Bendtsen P. SMS-based smoking cessation intervention among university students: study protocol for a randomised controlled trial (NEXit trial). Trials. 2015;16(1):140.

8.   Thomas K, Bendtsen M, Linderoth C, Karlsson N, Bendtsen P, Müssener U. Short message service (SMS)-based intervention targeting alcohol consumption among university students: study protocol of a randomized controlled trial. Trials. 2017;18(1):156.

9.   Thomas K, Müssener U, Linderoth C, Karlsson N, Bendtsen P, Bendtsen M. Effectiveness of a Text Messaging–Based Intervention Targeting Alcohol Consumption Among University Students: Randomized Controlled Trial. JMIR MHealth UHealth. 2018;6(6):e146.

10.   Müssener U, Bendtsen M, McCambridge J, Bendtsen P. User satisfaction with the structure and content of the NEXit intervention, a text messaging-based smoking cessation programme. BMC Public Health. 2016;16(1):1179.

11.   Mussener U, Thomas K, Linderoth C, Leijon M, Bendtsen M. A Text Message-Based Intervention Targeting Alcohol Consumption Among University Students: User Satisfaction and Acceptability Study. JMIR Hum Factors. 2018;5(3):e23.

12.   Thomas K, Linderoth C, Bendtsen M, Bendtsen P, Mussener U. Text Message-Based Intervention Targeting Alcohol Consumption Among University Students: Findings From a Formative Development Study. JMIR MHealth UHealth. 2016;4(4):e119.

13.   Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. Ann Behav Med. 2013 Aug;46(1):81–95.

14.   Michie S, Whittington C, Hamoudi Z, Zarnani F, Tober G, West R. Identification of behaviour change techniques to reduce excessive alcohol consumption. Addict Abingdon Engl. 2012 Aug;107(8):1431–40.

15.   Bendtsen P, McCambridge J, Bendtsen M, Karlsson N, Nilsen P. Effectiveness of a Proactive Mail-Based Alcohol Internet Intervention for University Students: Dismantling the Assessment and Feedback Components in a Randomized Controlled Trial. J Med Internet Res. 2012 Oct 31;14(5):e142.

16.   McCambridge J, Bendtsen M, Karlsson N, White IR, Nilsen P, Bendtsen P. Alcohol assessment and feedback by email for university students: Main findings from a randomised controlled trial. Br J Psychiatry. 2013;203(5):334–40.

17.   Bendtsen P, Bendtsen M, Karlsson N, White IR, McCambridge J. Online Alcohol Assessment and Feedback for Hazardous and Harmful Drinkers: Findings From the AMADEUS-2 Randomized Controlled Trial of Routine Practice in Swedish Universities. J Med Internet Res. 2015;17(7):e170.

18.   Michie S, Abraham C, Whittington C, Mcateer J. Effective Techniques in Healthy Eating and Physical Activity Interventions : A Meta-Regression. 2009;28(6):690–701.

19.   Murray JM, Brennan SF, French DP, Patterson CC, Kee F, Hunter RF. Effectiveness of physical activity interventions in achieving behaviour change maintenance in young and middle aged adults: A systematic review and meta-analysis. Soc Sci Med 1982. 2017 Nov;192:125–33.

20.   Knittle K, Nurmi J, Crutzen R, Hankonen N, Beattie M, Dombrowski SU. How can interventions increase motivation for physical activity? A systematic review and meta-analysis. Health Psychol Rev. 2018 Sep;12(3):211–30.

21. Howlett N, Trivedi D, Troop NA, Chater AM. Are physical activity interventions for healthy inactive adults effective in promoting behavior change and maintenance, and which behavior change techniques are effective? A systematic review and meta-analysis. Transl Behav Med. 2019 Jan;9(1):147–57.

22. Ashton LM, Sharkey T, Whatnall MC, Williams RL, Bezzina A, Aguiar EJ, et al. Effectiveness of Interventions and Behaviour Change Techniques for Improving Dietary Intake in Young Adults: A Systematic Review and Meta-Analysis of RCTs. Nutrients. 2019 Apr;11(4).

23. Garnett C V, Crane D, Brown J, Kaner EFS, Beyer FR, Muirhead CR, et al. Behavior Change Techniques Used in Digital Behavior Change Interventions to Reduce Excessive Alcohol Consumption: A Meta-regression. Ann Behav Med Publ Soc Behav Med. 2018 May;52(6):530–43.

24. McCrabb S, Baker AL, Attia J, Skelton E, Twyman L, Palazzi K, et al. Internet-Based Programs Incorporating Behavior Change Techniques Are Associated With Increased Smoking Cessation in the General Population: A Systematic Review and Meta-analysis. Ann Behav Med Publ Soc Behav Med. 2019 Feb;53(2):180–95.

25. Ek A, Alexandrou C, Söderström E, Bergman P, Delisle Nyström C, Direito A, et al. Effectiveness of a 3-month mobile phone based behavior change program on active transportation and physical activity in adults: A randomized controlled trial. JMIR MHealth UHealth. 2020;8(6).

26. Newby K, Teah G, Cooke R, Li X, Brown K, Salisbury-Finch B, et al. Do automated digital health behaviour change interventions have a positive effect on self-efficacy? A systematic review and meta-analysis. Health Psychol Rev. 2020 Jan 20;1–19.

27. Crane RS, Brewer J, Feldman C, Kabat-Zinn J, Santorelli S, Williams JMG, et al. What defines mindfulness-based programs? The warp and the weft. Psychol Med. 2017 Apr 29;47(6):990–9.

28. Creswell JD. Mindfulness Interventions. Annu Rev Psychol. 2017 Jan 3;68(1):491–516.

29. Wong SYS, Chan JYC, Zhang D, Lee EKP, Tsoi KKF. The Safety of Mindfulness-Based Interventions: a Systematic Review of Randomized Controlled Trials. Mindfulness. 2018 Oct 2;9(5):1344–57.

30. Galante J, Friedrich C, Dawson AF, Modrego-Alarcón M, Gebbing P, Delgado-Suárez I, et al. Mindfulness-based programmes for mental health promotion in adults in nonclinical settings: A systematic review and meta-analysis of randomised controlled trials. Patel V, editor. PLOS Med. 2021 Jan 11;18(1):e1003481.

31. Neff KD, Germer CK. A Pilot Study and Randomized Controlled Trial of the Mindful Self-Compassion Program. J Clin Psychol. 2013 Jan;69(1):28–44.

32. Bendtsen M, McCambridge J. Reducing Alcohol Consumption Among Risky Drinkers in the General Population of Sweden Using an Interactive Mobile Health Intervention: Protocol for a Randomized Controlled Trial. JMIR Res Protoc. 2019;8(4):e13119.