Pilot study: Using control systems engineering in smoking cessation to optimise a just-in-time adaptive intervention for relapse prevention

Participant information sheet

We are researchers at the Department of Psychology at Stockholm University. We would like to ask you if you would like to participate in a research project. In this document you will find information about the project and what participating in the study involves.

What is this project about and why do we want you to participate?

Cigarette smoking leads to illness and premature death. The best thing you can do for your health is to quit smoking, but it is difficult and the risk of relapse is high. Studies using mobile phones and smartwatches to measure various risk factors in the daily life show that smoking cessation is a dynamic process. Therefore, relapse prevention efforts need to have the ability to deliver the right type of psychological support to each individual, when and where they need it most ("just-in-time").

This interdisciplinary project aims to develop dynamic models that describe the mechanisms underlying lapse and relapse when trying to quit smoking. A further aim is to investigate what type of psychological support is optimal for preventing relapse, for application in a future individually tailored "just-in-time adaptive intervention".

Who can participate?

The study is aimed at people over 18 years of age who smoke cigarettes daily and are interested in trying to quit smoking. To participate, you need a smartphone with internet access. First, you will fill out a questionnaire. Then it will be decided whether you would benefit from the treatment in the study.

<u>Criteria for participation:</u>

- You are over 18 years of age.
- You live in Sweden and can speak, read and write in Swedish or English.
- You smoke cigarettes daily.
- You are willing to set a date to quit smoking (which means that you will try to never smoke a cigarette again).
- You are willing to wear a smartwatch and answer short, daily smartphone surveys for 28 days.

<u>You cannot participate if you:</u>

- Have a history of arrhythmias (e.g. atrial fibrillation).

- You regularly take beta-blockers (e.g. atenolol, bisoprolol).
- You have an implanted cardiac device.

What does participation involve?

We are investigating the effects of microinterventions in daily life. The study consists of the following steps:

1. You will receive written information about the study and we will ask you to sign a consent form.
2. You will answer a questionnaire online. Decisions regarding participation will be communicated via e-mail.
3. If you are eligible to be included in the study, you will be invited to an online meeting where the researcher will explain more about the study apps. A smartwatch will then be sent to your home via post.
4. You will use the study apps and answer short smartphone surveys online for 28 days.
5. You will complete a follow-up questionnaire online.

The research principal for the project is Stockholm University. Research principal means the organisation responsible for the project. The project is funded by the European Commission Horizon Europe Framework Programme (HORIZON), Grant No. 101065293 (PI: Dr. Olga Perski). The project has been approved by the Swedish Ethics Review Authority (registration number: 2025-01918-01).

What will happen if I take part in the study?

If you are interested in participating, you need to give your consent to participate. After you have given your consent to participate, you will be asked to fill out an online questionnaire. The questions are about your age and smoking habits. Once the investigators have reviewed these answers, an assessment will be made as to whether the study may be suitable for you. If the study is not considered suitable for you, we will contact you and inform you of the reasons for this decision. Here we may make recommendations for other help that may be a better fit. If your answers indicate that you are suitable for the study, you will be invited to an online call. During the call, we will explain how the different study apps and the smartwatch work. You will also be asked to set a date to quit smoking (which means that you will try to never smoke a cigarette again). You will then receive a smartwatch sent to you by post. The study will begin when you have received your smartwatch and reached your quit date. From the selected quit date, you will be asked to wear the smartwatch (which collects data on your heart rate variability) and complete short smartphone surveys several times a day for 28 days. The surveys will ask about, among other things, stressors, cravings, motivation, and whether you have smoked since the previous survey. Each

smartphone survey will take 2-3 minutes to complete. You will also receive daily, short "microinterventions" (i.e., short intervention messages) at various times. After 28 days, you will be asked to complete a short online survey about your experiences of participating in the study.

Possible consequences and risks of participating in the study

When trying to quit smoking, it is common to experience short-term withdrawal symptoms (e.g. cravings), which can be experienced as unpleasant. Despite this, quitting smoking leads to significant health improvements and increased quality of life in the long term. To prevent short-term discomfort, you will receive information about free, evidence-based psychological support and access to a new relapse prevention intervention that is not otherwise available. Even if you decide not to participate in the research, you will receive information about free, evidence-based psychological support.

In this study, we will collect a large amount of sensitive personal data (e.g. heart rate variability via smartwatches, smoking habits and motivation via short smartphone surveys). Data collection via smartwatches may reduce participant burden but risks feeling more intrusive and may lead to reduced awareness of what data is being collected about you. All data collected is necessary to answer the research questions. Your participation is voluntary and you can choose to withdraw from participation at any time without having to provide a reason.

What happens to my information?

If you choose to participate, the project will use certain information about you. This information is only that which you have entered yourself, i.e., gender, age and level of education. This information will be collected by you answering questions and questionnaires. No registry extracts will be made. The information or part of the information will be able to be linked to you, for example through your e-mail address and postal address. Information that can be linked to you in this way is considered personal data according to the EU Data Protection Regulation 2016/679 (GDPR).

The reason why the project needs to process such personal data is research. Stockholm University is the data controller for this processing. The legal basis for the processing of personal data is to perform a task of public interest pursuant to Article 6(1) of the EU General Data Protection Regulation. The personal data will be collected via secure software and stored on a password-protected and encrypted university network device together with a unique code (i.e. pseudonymised). This means that your data is linked to a code, for example 1234abcd, while your actual identity remains unknown. The only way to identify you as an individual is then through a so-called code key. No unauthorised person will have

access to the code key. The data will be processed in such a way that unauthorised persons cannot access them. After the study is completed, however, de-identified data will be made available by publishing them in a so-called data archive in accordance with the *FAIR principles*.

The Swedish Research Council recommends that research data be managed in accordance with the FAIR principles. FAIR is an internationally recognized concept that is built on 15 guiding principles for research data and data management. The aim is to make research data more accessible, reusable and interoperable. FAIR stands for "Findable, Accessible, Interoperable, and Reusable" (searchable, accessible, interoperable, and reusable for review and future projects). Potentially privacy-sensitive information will not be shared. For example, your exact wording, or other potentially sensitive or identifying information, will not be shared but will be replaced with a more general category. Here is an example of how we previously stored non-sensitive raw data to enable so-called open science according to the FAIR principle: https://doi.org/10.5281/zenodo.10472386. When the project is completed, what has been collected and processed within the project will be saved for at least 10 years. This includes pseudonymised personal data. If the material is deemed to have lasting value, it will be preserved for the future. According to the EU Data Protection Regulation and national supplementary legislation, you have the right to:

- Withdraw your consent without affecting the lawfulness of processing carried out in accordance with the consent before it was withdrawn.
- Request access to your personal data.
- Have your personal data corrected.
- Have your personal data erased.
- Have the processing of your personal data restricted.

Under certain circumstances, the General Data Protection Regulation and supplementary national legislation allow exceptions to these rights. For example, the right to access your data may be limited by confidentiality requirements, and the right to have data deleted may be limited by rules regarding archiving. However, the right to deletion and to restriction of processing of personal data does not apply when the data is necessary for the research in question. If you wish to invoke any of these rights, you should contact the responsible researcher or the Data Protection Officer at Stockholm University (see contact details below). If you are dissatisfied with how your personal data is processed, you have the right to complain to the Swedish Data Protection Authority. Information about this is available on the authority's website (www.imy.se).

How will you be informed about the results of the project?

You will receive regular emails with summaries of your smartphone survey responses (e.g. smoking cravings, motivation). In the final survey, we will ask if you would like a copy of the research results when they are ready. If you have any questions about the study, or if any questions arise after you have participated, please contact us via e-mail.

Insurance and compensation

You are not covered by any special insurance. No compensation will be paid for your participation. However, the treatment is free of charge.

Participation is voluntary

Your participation is voluntary and you may choose to withdraw at any time. If you choose not to participate or wish to withdraw, you do not need to state why, and it will not affect your future care or treatment. If you decide to withdraw, you will no longer be contacted with study-related information or questions, but the information you have provided up to this point will be retained to ensure the integrity of the research.

If you wish to withdraw, please contact the person responsible for the project (see below).

Responsible for the project

Responsible for the research project is Dr Olga Perski, Department of Psychology, Stockholm University. Email: olga.perski@su.se

Authorised representative of the research principal: Fredrik Jönsson, Head of Department, Department of Psychology, Stockholm University. Phone: 08-16 38 76. Email: fredrik.jonsson@psychology.su.se

Data Protection Officer at Stockholm University: Email: dso@su.se

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