Information sheet for research participants

Research project for better public health

Participants in health dialogues for 40-year-olds in Skåne can also take part in a research project. The purpose is to develop new knowledge to improve public health. Your targeted health dialogue will not take longer if you participate in the research project.

In this project, we want to further the knowledge about health-related dialogues and identify new risk factors for various diseases. This is so that the healthcare service will be even better at preventing and treating serious diseases in the future.

The research project is led by the Center for Primary Health Care Research, which has been commissioned to support targeted health dialogues with scientific expertise and evaluation. Region Skåne is the main research authority for the project. The Ethics Review Authority has given its approval for the project.

How does the project work?

To participate in the research project, you must provide your written consent. It is completely voluntary to participate, and you can end your involvement at any time. Saying no or withdrawing consent does not affect your regular care or participation in the targeted health dialogue.

Researchers at the Center for Primary Health Care Research will monitor your health and any past and future diseases in national and regional registers. We will also collect the number and type of healthcare visits from two years before the health dialogue to two years after the health dialogue. Data that are documented in connection with the health interview (questionnaire responses, lifestyle habits, health parameters and results of blood tests and measurements) are also collected for analysis in the research project. If the health dialogue leads to you getting follow-up tests, we will collect these test results from the next two years after the health dialogue. To follow up on the direct effect on lifestyle habits and well-being, you may be invited to complete one or more follow-up questionnaires during the years following the health interview. The questionnaires are estimated to take 10-15 minutes to answer. Participation in these surveys is voluntary, as is the rest of the research project.

Research samples are taken at some healthcare centres. Participants in a healthcare centre where research samples are taken may give extra vials of blood, a total of 40 ml (approximately 2.5 tbsp), in connection with the blood sample before the health related interview. No extra jabs via needle will then be done. The blood is saved in Region Skåne's biobank for subsequent analyses. Otherwise, the health interview is carried out as usual and the research project requires no further efforts on your part.

All data are coded, analysed and presented anonymously, at group level, so that you as an individual cannot be identified. Targeted Health Dialogue interviewers or other staff at the healthcare centre do not have access to the information collected from research samples or registers.

Possible consequences and risks of participating in the project

There are no physical or psychological risks involved in participating in the research project, apart from the discomfort that could be experienced as the blood sample process takes a little longer. However, no extra needle insertion is needed, the research samples are taken in connection with the other blood samples.

A risk that must always be considered when handling personal data is breach of privacy. This risk is considered minimal because the Center for Primary Health Care Research has worked with the handling of research data for many years and has well-developed strategies that comply with current laws on confidentiality.

What happens to my information?

The project will collect and register information about you as follows:

- Regional quality register Targeted health dialogues in Skåne: all data from the health dialogues' web support (questionnaire responses, results of blood tests and measurements, comorbidities, health curve, actions), responses from follow-up questionnaires.
- Research-specific blood samples if these are to be taken: genetic and epigenetic data, proteins, metabolic molecules.
- The Swedish National Board of Health and Welfare's health data register: *Inpatient and Outpatient Register* (diagnosis date/diagnosis codes), *Cause of Death Register* (date of death/cause of death), *Cancer Register* (cancer diagnosis codes, date of diagnosis), *Medications register* (prescribed medicines, number of prescriptions/collected prescriptions), *Medical Birth Register* (information on health in connection with pregnancy and childbirth).
- Statistics Sweden's microdata: *Total Population Register* (marital status and citizenship), *Multigenerational Register* (information on familial blood relationships), *Longitudinal Integration Database* (socioeconomic data), *Geographical Coordinates* (SAMS, DeSO: neighbourhood-level information on housing and workplace. Geographical areas).
- Swedish quality register for cavities and periodontitis (SKaPa): information on dental health.
- The National Archives/Swedish Defence Conscription and Assessment Agency: Review data.
- Region Skåne's administrative register (PASiS, PRIVA, RSVD and Medical journal record): diagnostic codes and dates, referrals, healthcare visits (type and number) and test results.
- If you are participating in another research project called the Lifestyle Tool, we need to obtain information about it: participation yes/no, and how much you have used the project's digital tools. We will receive coded data about this, but not access to other data from the Lifestyle Tool.

All information collected about you in connection with the targeted health dialogue, blood tests and information retrieved from various data registers is coded so that the Swedish personal number is replaced with a serial number. The collected and coded information is stored on servers at Lund University. The server hall is fireproof, and access protected. Collected data are only available to a few data managers, statisticians and researchers working on the project. Researchers gain access to coded data after approval by a steering committee led by the researcher responsible for the project. A prerequisite is that the information is used in the way dictated by this research information.

We intend to start by analysing data and research samples over a ten-year period. The project is about diseases that often emerge later in life. Therefore, after the first ten years, we will apply for permission to extend the analysis period of collected data and research samples for a total period of 50 years, that is, until the youngest participants turn 90 years old.

The purpose of the processing of your personal data is to research risk factors linked to common and serious diseases. The legal basis under the EU General Data Protection Regulation is general interest as studies of this type can improve public health.
Your answers and your results will be processed so that unauthorised persons cannot access them. Region Skåne is responsible for your personal information. According to the EU General Data Protection Regulation, you have the right to access the information about you that is handled in the project free of charge and, if necessary, have any errors corrected.
You can also request that information about you be deleted and that the processing of your personal data be restricted. If you want to access your information, you must contact the researcher responsible for the project, see contact information below. Region Skåne's data protection representative can be reached by phone: 044-309 30 00, e-mail: region@skane.se. If you are dissatisfied with how your personal data is processed, you have the right to submit a complaint to the Swedish Authority for Privacy Protection, which is the regulatory authority.

What happens to my samples?

The research-specific blood samples taken in the project at certain healthcare centres are stored (coded) in Region Skåne's biobank, registration number 136, in Lund. Region Skåne is responsible for the biobank. You have the right to later withdraw your consent. In that case, your samples will be discarded or anonymised. If you want to withdraw your consent, you must contact the project manager, see contact information below. The samples may only be used in the manner for which you have given your consent. If there is additional research that is not yet planned, the Swedish Ethical Review Authority will decide whether you should be consulted again.

How do I get information about the results of the project?

The results will be published in scientific journals, press releases and other types of reports. In such publications, the results are presented at group level and your identity will not be revealed. The research project is linked to the targeted health dialogue. Any additional examinations or treatments due to the results of the health interview are handled by your healthcare centre.

Insurance and compensation

Participants in the targeted health dialogues for 40-year-olds in Skåne are covered by the patient injury insurance during all steps included in the health interview, i.e., questionnaire, examination, sampling and interviews. Compensation for lost earnings is not given.

Participation is voluntary

Your participation is voluntary, and you can choose to discontinue your participation at any time. If you choose not to participate or want to end your participation, you do not have to state why, nor will it affect your future care or treatment.
If you want to cancel your participation, contact the researcher responsible for the project, see below.

Contact information

Responsible for the project:
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