Project: Telemedicine for Contraceptive Counselling – A Randomized Controlled Study of Structured Contraceptive Counselling via Digital Consultation Compared to In-Person Visits

Background and Purpose

Sweden has a high rate of unintended pregnancies, an increasing unmet need for contraception, and the highest proportion of repeat abortions in the European Union. Increased use of the most effective contraceptive methods—such as intrauterine devices (IUDs) and contraceptive implants—reduces the risk of unintended pregnancy and decreases the number of abortions. Despite the availability of several highly effective contraceptive methods, many individuals do not use them even when pregnancy is not desired.
Studies on Structured Contraceptive Counselling (SCC) have previously been conducted at youth clinics, midwifery clinics, and abortion clinics in Stockholm. These studies showed increased use of the most effective contraceptive methods among those who received structured counselling and fewer pregnancies after 12 months among abortion patients.

To improve access to healthcare and counselling—especially during the COVID-19 pandemic—telemedicine (digital consultation) has rapidly developed. Previous studies have shown that telemedicine can enhance healthcare capacity by increasing the number of available appointments and reducing physical barriers. However, there are few studies on telemedicine in contraceptive counselling, and no studies comparing telemedicine with traditional in-person counselling.

With this project, we aim to compare contraceptive counselling via telemedicine—specifically, video consultations—with traditional in-person counselling. All participants will receive the same structured contraceptive counselling to determine whether the mode of counselling affects the uptake and use of the most effective contraceptive methods.
In this project, telemedicine refers to video-based consultations.

Invitation to Participate

Since you are seeking contraceptive counselling and have contacted a participating clinic, you are being invited to take part in this research project.

How Does the Project Work?

The project consists of two parts, and you can choose to participate in either one (Part 1 only) or both (Part 1 and Part 2).

Part 1:

If you choose to participate, you will be randomly assigned to receive counselling either digitally via a video consultation or in person at the clinic. The counselling will follow a structured format, ensuring that the content is the same regardless of whether it takes place in person or online. The session will provide information on different contraceptive methods and help you make an informed decision about whether and which contraceptive method to use.

If you choose not to participate in the study, you will receive counselling according to the clinic's standard routine, which is an in-person visit.

During the consultation (either in person or via video), your healthcare provider will review information from your medical record and, together with you, answer a set of questions regarding your medical history, previous illnesses, medications, and reproductive history (e.g., number of pregnancies, childbirths, abortions, and prior contraceptive use). You will also complete a digital questionnaire about your background, current relationship, and previous contraceptive experiences.

Participation in this part of the project will take approximately 30 minutes, whether the counselling is conducted online or in person.

Afterward, you will be followed up for 24 months and asked to complete additional surveys at 3 and 12 months. You will receive a link to the surveys via email. Completing each survey will take about 5 minutes and will include questions about contraceptive use and any pregnancies. If you cannot respond via the email link, we will attempt to contact you by phone to collect your answers.

Additionally, researchers will retrieve relevant data from your medical records regarding pregnancy, abortion, or childbirth. All medical record data will be anonymized.

Part 2:

You may also choose to participate in a more in-depth interview about your experience with digital contraceptive counselling. The interview will cover your thoughts on the consultation, potential improvements, and your perception of the healthcare provider's approach. The interview will be recorded (audio and video) and will last approximately 30–60 minutes.

Risks and Benefits

Are there any risks?
Your care and treatment at the clinic will not be affected by your decision to participate or not. Participating in the project is not expected to pose any risks, though some of the questions asked may feel personal. However, all collected information will be anonymized.

Are there any benefits?
Participants assigned to digital counselling may save time and travel costs by avoiding a clinic visit. You will receive structured contraceptive counselling and gain increased knowledge about contraceptive options. Additionally, your participation will help evaluate and improve contraceptive counselling methods in healthcare.

Data Handling and Confidentiality

The project will collect and store personal data, including information directly from you and your medical records. This data includes your age, ethnicity, relationship status, contraceptive history, prior diagnoses, and prescribed medications.

Your information will be handled anonymously using a secure electronic data collection system, Smart Trial, managed by Region Örebro County. Data will be linked to you only through a coded identifier (study ID), which is connected to your personal identification number in a separate document. This code key will be securely stored for 17 years on a protected server managed by Region Örebro County, with access restricted to the responsible researcher.

Interview recordings will also be securely stored for 17 years.

Region Örebro County is responsible for your personal data, which will be processed in accordance with the General Data Protection Regulation (GDPR) for research purposes (public interest). Under GDPR, you have the right to access your data, request corrections if necessary, and, in some cases, request deletion or restricted processing of your personal data. However, deletion may not be possible if the data is essential to the research.

If you wish to access your data, please contact the research team (contact details below).

Data Protection Officer:
Email: dso@regionorebrolan.se
Phone: +46 (0)19-6027310
Address: Dataskyddsombudet, Box 1613, 701 16 Örebro, Sweden
Alternatively, you may contact the Data Protection Officer via the 1177 Healthcare Guide.

If you are dissatisfied with how your personal data is handled, you have the right to file a complaint with the Swedish Authority for Privacy Protection (IMY), which oversees personal data processing.

Only participating researchers and authorized personnel will have access to your responses. Your responses and results will be anonymized and presented only at the group level, making it impossible to identify individual participants.

Your medical records will remain confidential, with access restricted to healthcare providers and midwives involved in the study. An independent representative from relevant authorities may review the data to ensure the project is conducted correctly. All information regarding your participation is confidential and cannot be shared with unauthorized individuals.

Project Results

The findings from this project will be published in peer-reviewed scientific journals (in English) and presented in Swedish reports. You have the right—but no obligation—to access the results. If you wish to receive the results, please contact the lead researcher after the project's completion.

Insurance and Compensation

As a participant, you are covered by Sweden's standard public healthcare insurance in case of any unforeseen events. If needed, you may contact the lead researcher for assistance. Any unexpected issues will be addressed by the responsible researcher, and if necessary, you may seek support through the healthcare or insurance system. Alternatively, you can report any claims via www.lof.se.

No financial compensation will be provided for participation.

Voluntary Participation

Participation is entirely voluntary, and you can withdraw at any time without providing a reason. Withdrawing will not affect your future healthcare or treatment. Data collected before withdrawal may still be used unless you request its deletion.

To withdraw, contact:
Maria Åkesson (maria.akesson2@regionorebrolan.se)
or
Lead Researcher Jan Brynhildsen (jan.brynhildsen@oru.se)

Consent Form

I have received both oral and written information about the study:
"Telemedicine in Contraceptive Counselling – A Randomized Controlled Study of Structured Contraceptive Counselling via Digital Consultation Compared to In-Person Visits."
I have had the opportunity to ask questions and will keep the written information.

I consent to participating in:
(Please check the applicable option)
☐ Both the intervention (structured contraceptive counselling via digital or in-person consultation with follow-up for 24 months) and the in-depth interview.
☐ Only the intervention.

I consent to my personal data being processed as described.
I understand that I can withdraw at any time without explanation.

Location and Date:
Signature:
Printed Name: