Study protocol

Tele-health for contraceptive counselling – a randomized controlled trial of contraceptive counselling via tele-health compared to standard routine on the effects of choice and uptake of LARC

Maria Åkesson, Reg. Nurse Midwife, PhD Student

Jan Brynhildsen, MD, PhD, Professor, Örebro University

Niklas Envall, Reg. Nurse Midwife, PhD, Dalarna University, Karolinska Institutet

Yvonne Skogsdal, Reg. Nurse Midwife, PhD, Örebro University

Abbreviations:

LARC, long-acting reversible contraceptives

CC, Contraceptive counselling

MHC, Maternal health clinic

YHC, Youth health clinic.

Protocol summary:

Sweden has a high rate of unintended pregnancies, an increasing rate of unmet need of contraception and the highest rate of repeat abortion in the European Union. Effective and respectful contraceptive counselling may result in higher patient satisfaction and may also give empowerment to use the method correctly. This may ultimately lead to higher rates of continuation, higher uptake of contraceptive methods with the highest efficacy, long-acting reversible contraceptives (LARC), and potentially a reduction of unintended pregnancies.

Several studies have been carried out in order to find better ways of contraceptive counselling to increase contraceptive uptake, and especially the use of high effective LARC methods. Interventions that have increased access, removed financial barriers, and increased the method-specific knowledge, with focus on contraceptive effectiveness, have led to higher use of LARC and lower the rate of unintended pregnancies and abortion.

The World Health Organization (WHO) describes tele-health as "the delivery of health care services, where patients and providers are separated by distance". Tele-health may include the use of telephones, computers, mobile applications, or email.

The use of tele-health for contraceptive counselling significantly increased during the covid-19 pandemic. Previous studies support telehealth as an option for health systems to improve capacity and access by increasing the total number of available appointments, as well as reducing barriers to reproductive health care and also suggest that telemedicine addresses geographic barriers and improves health care service delivery in low-resource populations. During the pandemic, many health care providers were forced to rapidly expand tele health services to ensure the provision of care. In the context of contraception, several studies have examined the use of a text message to improve uptake, adherence, and continuation of contraceptives.

However, few studies describe tele health, focused on contraceptive counselling and no RCT has been undertaken in order to study uptake and satisfaction compared to in person visits, in a Swedish context. Little is known about patients and providers experience of tele health for contraceptive counselling. Before tele-health can be established as an option in improving access to family planning services, the quality of the counselling and the impact of the uptake of LARC must be studied.

In the present study, we aim:

- To study if the *choice* of long-acting reversible contraception (LARC) after counselling via tele-health (video calls) is equal to the *choice* after counselling in person with a midwife, using structured contraceptive counselling. Structured contraceptive counselling will be used in both groups.
- To study if the *uptake* of a LARC method 3 months after the counselling is equal between the women who have received the different methods of counselling

- To study the number of pregnancies after 1-year and 2-year, and the risk of pregnancy in relation to initiated contraceptive method and mode of counselling.

Area Overview:

Unintended pregnancies and the related unmet need for contraception are fundamental reproductive health issues worldwide (1). Sweden has a high rate of unintended pregnancies and highest rate of repeat abortion in the European Union (2). During 2021 approximately 33 700 abortions were reported in Sweden, corresponding to 18 abortions in 1000 women in the age 15-44 years (3). Unintended pregnancy is associated with difficulties for the individual (4) but also influence health care-costs. The yearly costs of unintended pregnancies in Sweden are estimated to be approximately SEK 448 million (1, 5).

The mean age in women giving birth to their first child is now (2023) over 30 years in most European countries (6). Therefore, most women and couples have a need for effective contraception for many years during their most fertile years.

The effectiveness of contraceptive methods is measured as Pearl Index (PI). PI measures pregnancy in 100 women per year with ”perfect use” and ”typical use”. “Typical use” describes how a contraceptive method is commonly used in a “real-world” setting. Failure rates associated with typical use take into account incorrect and inconsistent use. The PI for “perfect use”, on the other hand, is based on the results from clinical trials. The PI vary significantly between different contraceptive methods, especially when it comes to PI during “typical use”. Long-active reversible contraception (LARC) includes intrauterine devices (IUD) and contraceptive implants. LARC has similar low PI for ”perfect use” and ”typical use”, as these methods are unrelated to user compliance (7). LARC methods are the most effective methods for contraception and have the highest user satisfaction (7, 8). It has been estimated that if 5% of women who use non-LARC switched to LARC it could prevent more than 3500 unintended pregnancies in Sweden yearly and save more than SEK 70 million (4).

Consequently - increasing the prevalence of contraceptive use and the use of the most effective contraceptive methods- LARC, have the potential to reduce the risk of unintended pregnancies (6).

In 2014, the updated Swedish national guidelines for contraception issued by the Swedish Medical Products Agency, pointed out the importance of protecting fertility and prevent an unintended pregnancy (9). In 2020, the reference group for family planning in the Swedish association for obstetrics and gynaecology (SFOG), issued recommendations and goals for contraceptive counselling in Sweden. The recommendation states that the goal should be 40% of women choose LARC after counselling at primary care visits and 60% of women who had an abortion should choose these methods (10).

A nationwide survey of women of fertile ages in Sweden in 2017 showed that 71% of the participants were using contraception. LARC was used by 30.9%, which was an increase since previous survey in 2013 (11). The unmet need for contraception had increased from almost 9 percent in 2013, to 15 % in 2017 (11, 12). Participants using contraceptive pills, patches or vaginal rings had a 20 times higher risk of contraceptive failure, 4.55 per 100 participant-years, as compared with 0.27 for those who used LARC (4). Another, internet-based survey from Sweden, published in 2022, showed lower use of LARC (19.8%) but confirmed the high unmet need of contraception. In a prospective cohort study of 5000 women, Peipert at al reported that satisfaction after 1 year was 84% for women using LARC versus 53% with non-LARC methods (13).

Structured contraceptive counselling:

There are no consistent recommendations for contraceptive counselling and there are no reported models for providing contraceptive counselling that have been reported to result in fewer unintended pregnancies. Information from the provider may be affected by provider bias and previous studies show that some patients may express coercion-like experiences and feel forced to choose a certain contraceptive method (14, 15). Surveys conducted in Sweden have shown that patients rated contraceptive effectiveness as the most important characteristic for a contraceptive method (11, 12). Despite this, the most prevalent contraceptive method in Europe and the United States, is the contraceptive pill (16, 17).

Several studies have been carried out to find better way of contraceptive counselling in order to increase contraceptive uptake, and especially the use of LARC. Interventions that removed financial barriers and increased the method-specific knowledge, with focus on contraceptive effectiveness, led to higher use of LARC and lowered the rate of unintended pregnancies and abortion (18-20).

A cluster-randomised trial including 1,364 participants in Stockholm, Sweden, conducted at youth clinics, abortion clinics, and maternal health clinics, evaluated the effect of a structured contraceptive counselling package "The LOWE method". The LOWE method include a 7-minute-long educational video about contraceptive methods, four key questions, a modified tiered effectiveness chart for contraceptive methods, and a demonstration box with contraceptive models (22). Women who received the structured counselling were more likely to choose LARC compared to standard counselling. The uptake of LARC was 40.6 % in the intervention group and 30.3 % in the control group (22). The effect of the structured contraceptive counselling was equally good when controlled for migrant background. (21). Women at abortion clinics who received the intervention also had significantly fewer further unintended pregnancies (22). Satisfaction of the structured counselling method was evaluated with both participants and health care providers in the intervention group. Health care providers found that the method was supportive and was also time neutral, compared to regular counselling. Participants found the structured method helpful when choosing contraception (23).

Tele-health:

The World Health Organization (WHO) describes tele-health as "the delivery of health care services, where patients and providers are separated by distance" (24). Tele-health may include the use of telephones, computers, mobile applications, or email.

Previous studies support telehealth as an option for health systems to improve capacity by increasing the total number of available appointments, as well as reducing barriers to reproductive health care (25). Prior studies also suggest that tele-health addresses geographic barriers and improves health care service delivery in low-resource populations (26). In one study including over 18 000 women, pre-abortion contraceptive counselling provided through tele-health, resulted in higher uptake of LARC compared to integrated in-person counselling during the abortion consultation (27).

In the context of contraceptive counselling, several studies have examined the use of text messaging to improve uptake, adherence to use and continuation of a contraceptive method. One study evaluated the

effect of daily educational text messages with oral contraceptive continuation in 6 months. The intervention groups had significantly higher continuation rates compared to the control group (28). Two randomized controlled trial investigated the use of text messaging to support contraceptive continuation in oral contraceptives and injectable depo contraceptives. These studies support the beneficial effect of daily interactive text message reminders on oral contraceptive and injectable contraceptive continuation (29, 30).

The Covid-19 pandemic intensified barriers to reproductive health care. According to one survey, one-third of respondents reported delaying reproductive health care or difficulty getting birth control due to the pandemic (31).

The use of tele-health for contraception care increased significantly during the pandemic. Tele-health helped bridge gaps in contraceptive health care, deepened by the pandemic (32-34). In a mixed method study in New York City, patient's experience of tele-health for contraceptive counselling were studied in the context of covid-19. Eighty six percent of respondents reported to be very satisfied with tele-health visit and 63% stated that the visit completely met their needs. In-Depth interview with respondents reported similar findings. Patients generally reported that tele-health visits saved time compared to having to travel to a clinic. Most patients stated that tele-health visit was comparable with in person visits. The issue of privacy concerns was stated by some patients in in-depth interview, if the tele-health visit was conducted from work or at home (35). Similar results were shown in a study from the US where the quality of contraceptive counselling via tele-health versus in person visits were compared. The results showed that when patients self-selected the type of visits, their assessment of quality were similar in both groups. Tele-health respondents identified ease of communication and less difficulty in scheduling, as positive factors for tele-health use. Rates of the contraceptive methods chosen between patients receiving counselling through tele-health, and patients receiving counselling through regular visit were also similar, including LARC. Rates of long-acting reversible contraceptive selection between groups were 22 of 52 (42%) telemedicine-visit respondents vs 21 of 58 (36%) office-visit respondents. No specific counselling intervention Was used (36).

A vast majority of family planning providers in the US, reported that tele-health visits was an effective way to provide contraceptive counselling (33,37) and 84% of the providers believed that tele-health visits for contraceptive counselling should be expanded after the pandemic. A total of 172 providers completed the survey and most of them, 78%, were new to tele-health as a method for contraceptive counselling. Some concerning issues was raised by the providers: tele-health may exacerbate health disparities due to less access to technology and may also be experienced as less personal connection with the patient, but it could also increase the access for geographically isolated patients (33).

The procedural nature of LARC, insertion and removal, has posed challenges during the pandemic due to lockdowns and patients could experience difficulties accessing these methods (38). This may remain a challenge when using tele health in the post pandemic era.

In conclusion, more research is needed to study if tele-health can be used in general settings and not only in selected groups. There is also a need to further understand patient´s experience of tele-health for contraceptive counselling to determine whether it can meet patients' needs and if contraceptive counselling through tele-health, effects the uptake of LARC in a Swedish context.

Study design: An open randomized, controlled, non-inferiority trial.

Study objects: Women contacting maternal health clinics (MHC) or youth health clinics (YHC) for contraceptive counselling.

Inclusion criteria:

- Women aged 16-40 years
- Primary reason for use of contraception being pregnancy prevention
- Not having pregnancy intentions within 6 months.
- Sufficient language skills to understand the study information available in Swedish and English.

Exclusion criteria:

- Women in need for contraceptive method for medical reasons other than protection against unintended pregnancy.

Sample size: 772 participants.

Time plan:

2023	Summer – Ethics application
2024	August – Recruitment start
2025	Recruitment
2026	Recruitment complete, analysis

Data will be collected from August 2024-May 2026. Inclusion time- 2 years.

Method:

Randomized controlled non-inferiority trial.
All data collection will be performed using the electronic data collection program Smart Trial®.

Eligible women who contact a midwife at a MHC or YHC for CC will be informed about the study verbally and invited to participate. Interested patients will get written information about the study sent by email or through 1177. The written study information will include contact information to the responsible researchers to answer any questions, as well as a link to the informed consent form. Women who consent to participate will get an appointment, not specifying if the appointment will be digital or in person during a regular visit. After written consent, the Smart Trial® randomization plug-in will automatically allocate participants in a 1:1 ratio to receive structured contraceptive counselling

either via telehealth video (intervention) or via in-person visit (control). Thereafter, the participants will be informed about their group allocation in 1177.
Before the counselling session, the participant will receive a first survey of background variables including socio-demographic variables such as BMI, educational level, country of birth, and contraceptive and reproductive history. Women who are randomized to tele-health (video counselling) and choose combined pill/ patch will be asked to register blood pressure after the appointment. The blood pressure can be checked at home, in the pharmacy or in a health clinic. Participants with blood pressure over 140/90 will be asked to contact a health care clinic according to standard guidelines.

After completing the first survey, the participants will be linked to the educational video which is to be seen prior to the rest of the counselling (see description of structured contraceptive counselling above). visit.
The tele-health counselling will be provided using "Visiba Care" a virtual care platform. Visiba Care is CE-marked as a medical technology product (Class I) and is certified according to the information security standards ISO 27001 and DCB 0129. All patient data is handled following GDPR and the Patient Data Act (PDL).

At the end of the counselling, the midwife will complete a survey to register the contraceptive choice. Participants in both the intervention and control group, choosing LARC will receive a second, in person appointment for placement of the method.

After the counselling, participants will receive a second survey with questions regarding the experience with the contraceptive counselling, questions about participant autonomy, and also questions about the LOWE methodology.

Follow-up surveys will be sent to participants at 3 and 12, months after the counselling, to collect data on method initiation continued use satisfaction, method switching, pregnancies and outcomes of pregnancies. Medical records will be scrutinized for pregnancies and pregnancy outcomes within 24 months. Data will be collected pseudonymized.

<u>Primary outcome:</u>

- Difference in proportion of women choosing LARC among participants receiving structured contraceptive counselling via telehealth (intervention) compared to in-person visit (control).

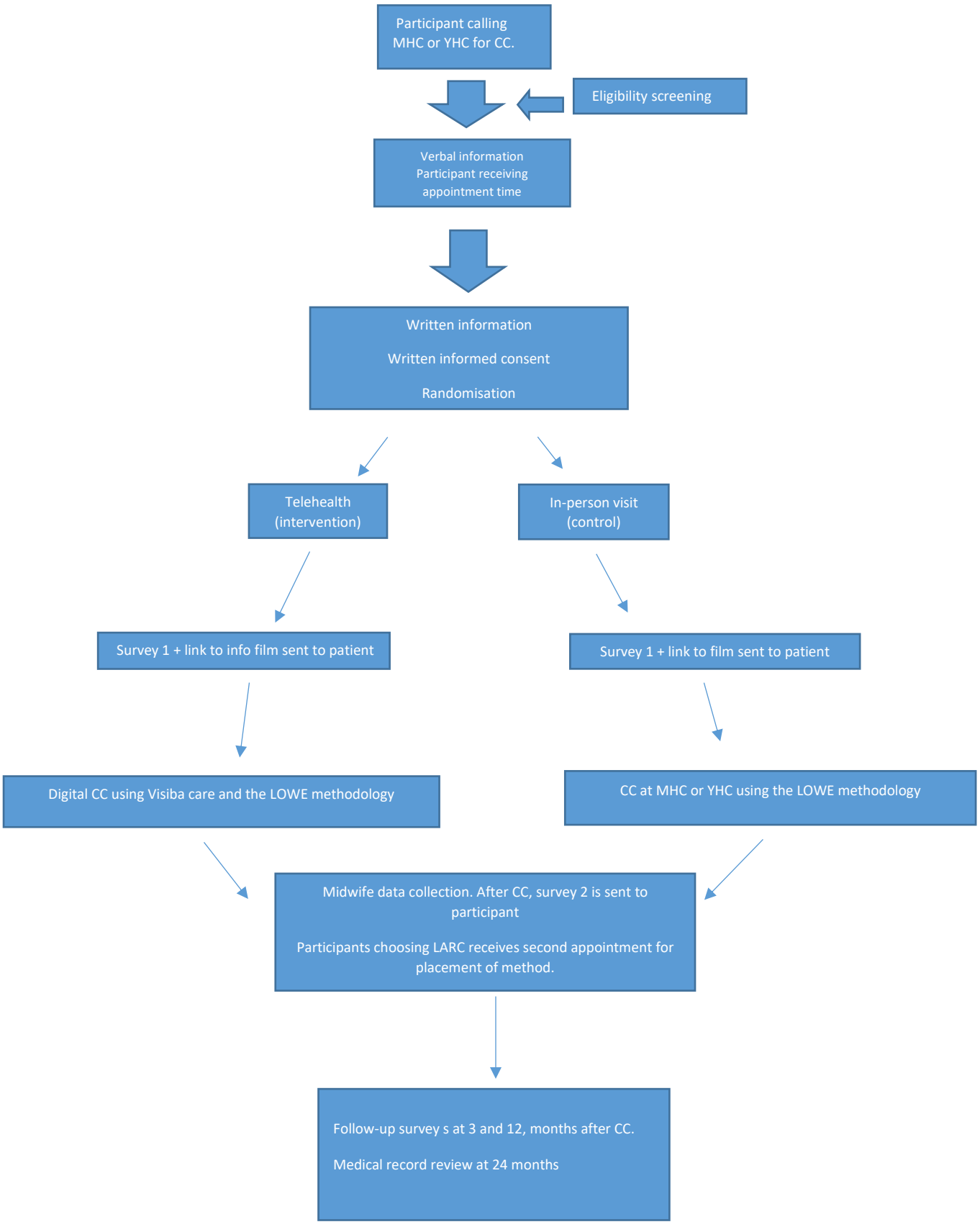
<u>Secondary outcomes</u>

- Satisfaction with received contraceptive counselling (participants)
- Satisfaction with the different parts of the structured contraceptive counselling package (participants and providers)
- Perceived level of contraceptive automy
- Method initiation and time to initiation (3 months follow-up)
- Continued use, method shifting and method satisfaction (12 months follow-up)
- Number of pregnancies and odds/risk of pregnancy depending on initiated contraceptive method (24 months follow-up)

- Number of abortions and risk of abortion depending on initiated contraceptive method (24 months follow-up)

FLOW CHART

Flow chart describing the structure of the study. Participants in both the intervention and control group will receive a 30-minute appointment, during which they will receive structured contraceptive counselling using the LOWE methodology.



Analyses:

Data will be analyzed using descriptive statistics. T-test and Mann-Whitney u-test will be used where appropriate. Logistic regression models will be used to assess association between demographic characteristics and LARC choice and to assess factors related to use of contraception and risk of subsequent pregnancy and abortions.

Statistical power

RCT with non-inferiority design.

The number of users of LARC vary widely between studies. Two recent Swedish publications have reported substantially different figures; 19.8% vs 30.7% and consequently it is difficult to adequately estimate the number of women who will chose LARC. Several other studies have reported similar figures.

We hypothesize that 25% of all women will chose LARC and that the number not is lower in the intervention group. Given a non-inferiority limit of 10% (Δ), 90% power ($1-\beta$) and 5% significance level (α) we need to include 644 women, 322 in each group. To compensate for an estimated 20% loss to follow-up we aim to include 772 participants.

Ethical considerations:

Contraceptive use and personal characteristics such as demographic background and educational level are sensitive information and personal issues. It could be considered problematic to register this type of information. In the present study, the data will be handled and analysed psudonymised and the results will not be presented on an individual level. The code key will be stored locked and only available for the responsible researcher. Consequently, during analyses no information can be linked to individuals.

Scrutinizing patient records in order to follow-up pregnancies and abortions might be considered as sensitive and could be considered as questionable. However, this information will be retrieved by administrators and coded with the individual study code before the information will be available for the researchers (appendix 1). Thus, no information can be linked to individuals. Written consent for the use of medical records will be obtained in accordance with the Personal Data Act.

The study will be performed according to the Declaration of Helsinki. Patients will receive oral and written information emphasising that participation is voluntary, before giving their consent to participate. They will also have the opportunity to stop the participation whenever they want, without it affecting their planned healthcare.

One concern that could be raised about telehealth is whether it may exacerbate health disparities for those who have limited access to technology. However, most adults living in Sweden in age 18-40 years, own a computer or smartphone. Privacy is also a concern, using telehealth, compared to in person visits. However, recent studies during the early stages of the pandemic describes an overall

positive experience of tele health, from both patients and providers, and privacy was not raised as a major concern.

Importance of the study:

Effective and respectful contraceptive counselling may result in higher patient satisfaction and empowerment to use the method correctly. Participants in the LOWE trial reported high user satisfaction with the package for structured contraceptive counselling, and patients felt supported in their contraceptive choice. This may ultimately lead to higher rates of continuation, higher uptake of long-acting reversible contraceptives (LARC), and potentially a reduction of unintended pregnancies, but remains to be evaluated also in counselling provided via telehealth.

The Covid-19 pandemic has significantly increased the use of telehealth and prompted the rapid integration of telehealth services. In the context of contraception, several studies have examined the use of a text message to improve uptake, adherence, and continuation of contraceptives. However, few studies describes tele health, focused on contraceptive counselling and no RCT has been undertaken in order to study uptake and satisfaction. Previous studies support telehealth as an option for health systems to improve capacity by increasing the total number of available appointments, as well as reducing barriers to reproductive health care. Prior studies also suggest telemedicine addresses geographic barriers and improves health care service delivery in low-resource populations. However, little is known about patients and providers experience of tele health for contraceptive counselling. Before we can consider tele health´s role in improving access to family planning services, we must assess the quality of telehealth counselling and the impact on the uptake of LARC in a Swedish context.

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