Karin Emtell Iwarsson

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Datum Inzending	jun. 7, 2023 8:21 PM
Name of applicant (principal investigator or leader of the project team)	Karin Emtell Iwarsson
Job title	Registered nurse-midwife, PhD, Study coordinator/Research midwife
Name of the institution or society who will administer the grant if successful (if no responsible organization/ institution - please give justification for this)	Karolinska Institutet
Name of all other co-investigators and institutions. (Please provide name, affiliation, position, and country)	Professor Kristina Gemzell Danielsson, MD, PhD, Karolinska Institutet, Sweden Associate professor Elin Larsson, PhD, Karolinska Institutet, Sweden
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A short CV of the applicant (or the principal investigator or the team leader) should be provided here. (Max 2 pages)	CURRICULUM VITAE Name and title: Karin Emtell Iwarsson, RNM, MSc, PhD Address: Långseleringen 13 162 53 Vällingby Phone: +46 73 573 88 28 E-mail: karin.emtell.iwarsson@ki.se Date of birth: 24th September 1974 Education: • Upper secondary school - natural science, 3 year, Blackebergs gymnasium. 1993. • Degree of Bachelor of Science in Nursing, 120 credits, The Red Cross

University College. 1997.
• Behavioral Medical treatment of coronary artery disease, 5 credits, Uppsala University. 2002.
• Postgraduate Diploma in Midwifery, 60 higher education credits, Karolinska Institutet. 2004.
• Contraception course. Organon 2006 and MSD 2012.
• Natural Remedies, 7,5 Credits, Karolinska Institutet. 2011.
• Supervisor for midwifery students, 7,5 higher education credits, Uppsala University. 2013.
• Degree of Master (one year) of Science in Nursing - midwifery care - 2016.
• Doctor of Philosophy in Medical Science 240 hp. Karolinska Institutet. 17th June 2022 Thesis: Contraceptive counseling and use with a focus on migrant women in Sweden

Employment:
Karolinska University Hospital Reg. Nurse 970616 – 970803
Orthopaedic Ward

Danderyds Hospital Reg. Nurse 970908 - 980831
Orthopaedic Ward

S:t Görans Hospital Reg. Nurse 980901 – 040201
Cardiological Ward
Karolinska University Hospital Reg. Nurse 030609 – 030720
Maternity Ward

BB Stockholm Reg.Nurse-Midwife 040201 – 130531
Delivery Ward, Maternity Ward
Maternity Health Care Clinic, Youth Clinic

Youth Clinic in Solna Reg. Nurse-Midwife 120301- ongoing
part time

SESAM City Reg. Nurse-Midwife 130603-130915

Youth Clinic at Södermalm Reg. Nurse-Midwife 130916-140831

Karolinska Institutet Research Assistant 140901-150228
WHO-centre

Karolinska Institutet Study Coordinator /
WHO-centre Research Midwife 150301- ongoing
part time

Karolinska Institutet PhD-student
Dept. of Women´s and Children´s Health 170101-220831

Karolinska Institutet Post Doc
Dept. of Women´s and Children´s Health 220901- ongoing
part time

Additionally:
• Member of the FoU at Karolinska University Hospital /Karolinska Institutet Start 2020 – ongoing

• Member of the Science and Education Committee (SEC) within the European Society of Contraception and Reproductive Health (ESC), Start 2022 - ongoing

Is the person responsible for the project different to the person named in box A

No

Title of the project

Structured online contraceptive counseling at emergency contraception pharmacy provision - A cluster randomized crossover trial

Sector in the area of contraception, sexual and reproductive health:

Contraception

Please provide a comprehensive description of your project. The application will be assessed under the following headings: Background and rationale (with evidence of unmet need and innovation, the relevance of the proposed project with contraception, sexual and reproductive health); Aims/ Objectives; Methodology (include where will it take place - country/town, establishment, sample size, justification, ethical approval plans (inclusion & exclusion criteria); Main outcome measures, statistical analyses); Impact it will or may have in the field of contraception, sexual and reproductive health (also under consideration of the situation in your country); Patient/ public involvement (where relevant) (1200 words)

Background and Rationale

The emergency contraception pill (ECP) can be used when another contraceptive method has failed or not been used, and there is a risk for an unwanted pregnancy. Women who have unprotected sex in the same cycle after ECP use are up to three-times more likely to conceive than women who do not, due to postponed ovulation, and without contraception these women remain at risk of pregnancy in subsequent cycles (1). ECP is a good complement for urgent pregnancy prevention however, a regular hormonal contraceptive method is more effective (2). Therefore, facilitating initiation of an effective regular contraceptive method should be in focus for ECP users (3, 4).
Despite that all emergency contraceptive methods in Sweden can be provided for free at different clinics, most women prefer to buy ECPs at pharmacies. Since 2001 ECPs can be bought over-the-counter without a prescription. In Sweden the sale of ECPs has been reported to be among the highest in Europe possibly reflecting low use of regular contraception (5). In a Scandinavian population-based survey 34% of women reported ECP use at least once in their lifetime, and 50% of those reported repeat use (3). National and international guidelines recommend initiating regular contraception immediately after ECP, so called quick-starting. To achieve this, women in Sweden need to make an appointment to a contraceptive provider which takes time and requires knowledge of where to access this, hence leave women at risk for unintended pregnancy.
Findings from a recent cluster randomized controlled trial in the UK showed an increased rate (20%) of women who used an effective regular contraceptive method after ECP uptake, at 4-month follow-up, in the intervention compared to the control group (6). This when progestin-only-pills were provided at the time of the ECP uptake. However, only 19% in the intervention group used the rapid access card to attend a clinic for contraceptive counseling and provision (6). This indicates that women are willing to start a regular contraceptive method at the time of ECP uptake, and the importance of not only provide rapid but immediate access to contraceptive counseling.
We hypothesise that our intervention will result in increased subsequent use of an effective contraceptive method post ECP, hence preventing unwanted pregnancies.

Aims/Objectives

The aim of this study is to determine whether an intervention of online contraceptive counseling provided at the time of ECP pharmacy provision plus an invitation to a sexual and reproductive health clinic, will result in increased use of subsequent effective contraception compared with provision of ECP alone.

Primary outcome: The use of effective contraception (hormonal or intrauterine) at 1 month follow-up.

Secondary outcomes:
- Contraceptive use (including long-acting reversible contraception (LARC)) within 12 months follow-up
- Incidence of pregnancy and abortion within 12 months
- Participants´ satisfaction with the intervention package at 1 month
- Contraceptive use, pregnancy, abortion and satisfaction in vulnerable groups such as youths and migrants, compared to non-migrants and older participants

Methodology

We plan a cluster randomized controlled cross-over trial at 30 pharmacies and with 600 participants in Stockholm, Sweden. We will apply for ethical approval.

Inclusion criteria:
- Women >/=18 years visiting a pharmacy to buy ECP for her own use
- Has a smartphone with an electronic identification and ability to scan a QR code
- Ability to read Swedish or English or with the help of an interpreter
- Willing and able to provide informed consent
- Willing to participate in the follow-up

Exclusion criteria:
- Known allergy to the ECP
- Ongoing pregnancy

Study participation does not depend on the type of ECP choosen (ulipristal acetat or levonorgestrel). Eligible women will be allocated to intervention group or control group (ECP purchase without any contraceptive counseling or provision) depending on the visited pharmacy´s allocation. The order in which the pharmacies will provide the intervention or control will be randomly assigned at a ratio 1:1 by an independent statistician. A two-weeks-break when the pharmacies switch to the new group will be conducted (cross-over).

The intervention contraceptive counseling is an online modified version of our in-clinic structured contraceptive counseling previously developed and evaluated (7-9). The online contraceptive counseling consists of a;

1. seven-minute-long educational video
2. four key questions
3. an effectiveness chart
4. video clip displaying different contraceptive methods

all aiming to inform about different contraceptive methods and their effectiveness. After the contraceptive counseling the participants will receive an online invitation to book a digital- or physical appointment to a sexual and reproductive health clinic. The participant needs to complete the online contraceptive counseling and invitation for contraceptive provision within 24 hours. This is to ensure the uptake and possibly enable quick-start. However, the participant does not need to book an appointment unless wanted.

Main outcome measures, statistical analysis

The outcomes will be self-reported in an online follow-up questionnaire at 1 and 12 months post ECP provision. Additionally, for care related to pregnancy, data will be collected by electronic medical record if the participant is lost to follow-up or data is missing.
Effective regular contraception (i.e. short- and long-acting reversible contraception) will be defined as either hormonal contraception or copper intrauterine device. Hormonal contraception includes levonorgestrel intrauterine device, subdermal implant, injectable, pills, vaginal ring and patch.
The analysis will primarily be done by using cluster-level summary regression according to earlier recommendation (10). The study will have at least 80% power to be able to prove a relevant and meaningful effect. The assumed contraceptive use is 30% and 45% for control and intervention respectively, based on a previous study (6). To compensate for possible drop-out (20-25%) the study is planned to include 30 pharmacies with an average of 10 subjects per pharmacy and time-period. This gives a total of 600 subjects included. Based on completed subjects this will give a power in the range of 80%-90% (depending on the observed intraclass correlations). Calculations are based on the equation presented in Arnup (11). Additionally, background characteristics will be analysed by descriptive statistics.

Impact it will or may have in the field of contraception, sexual and reproductive health

Online counseling presents an alternative to in-person care as a type of self-care that may be more private and accessible for women. Self-care is a concept on the raise in the world which contributes to increased empowerment and in addition offer an efficient and cost-effective service. The results of this study could be of major importance to increase access to online services, to better allocate health care resources through a “task shift” from clinicians to women themselves and to empower and increase autonomy for women. Furthermore, online counseling caters to women´s choice and convenience. The intervention package can be used at a time and place appropriate to the woman and offer her time to fully understand the counseling process.

Patient/Public involvement

The Swedish pharmacy market consists of four large national retail chains which will collaborate in this trial. We will work in close collaboration with pharmacy personnel at included pharmacies in the Stockholm Region and also with the Swedish Pharmacy Association and their Chief Pharmacist.

References

1. Glasier A, Cameron ST, Blithe D, Scherrer B, Mathe H, Levy D, et al. Can we identify women at risk of pregnancy despite using emergency contraception? Data from randomized trials of ulipristal acetate and levonorgestrel. Contraception. 2011;84(4):363-7.
2. Swedish Medical Products Agency. Antikonception - behandlingsrekommendation. Uppsala: Swedish Medical Products Agency; 2014.
3. Guleria S, Munk C, Elfstrom KM, Hansen BT, Sundstrom K, Liaw KL, et al. Emergency contraceptive pill use among women in Denmark, Norway and Sweden: Population-based survey. Acta Obstet Gynecol Scand. 2020;99(9):1214-21.
4. Michie L, Cameron ST. Emergency contraception and impact on abortion rates. Best Pract Res Clin Obstet Gynaecol. 2020;63:111-9.
5. Lindh I, Skjeldestad FE, Gemzell-Danielsson K, Heikinheimo O, Hognert H, Milsom I, et al. Contraceptive use in the Nordic countries. Acta Obstet Gynecol Scand. 2017;96(1):19-28.
6. Cameron ST, Glasier A, McDaid L, Radley A, Baraitser P, Stephenson J, et al. Use of effective contraception following provision of the progestogen-only pill for women presenting to community pharmacies for emergency contraception (Bridge-It): a pragmatic cluster-randomised crossover trial. Lancet. 2020;396(10262):1585-94.
7. Emtell Iwarsson K, Envall N, Bizjak I, Bring J, Kopp Kallner H, Gemzell Danielsson K. Increasing uptake of long-acting reversible contraception with structured contraceptive counselling: cluster randomised controlled trial (the LOWE trial). BJOG. 2021.
8. Envall N, Emtell Iwarsson K, Bizjak I, Gemzell Danielsson K, Kopp Kallner H. Evaluation of satisfaction with a model of structured contraceptive counseling: Results from the LOWE trial. Acta Obstet Gynecol Scand. 2021;100(11):2044-52.
9. Emtell Iwarsson K, Larsson EC, Bizjak I, Envall N, Kopp Kallner H, Gemzell-Danielsson K. Long-acting reversible contraception and satisfaction with structured contraceptive counselling among non-migrant, foreign-born migrant and second-generation migrant women: evidence from a cluster randomised controlled trial (the LOWE trial) in Sweden. BMJ Sex Reprod Health. 2022.
10. Morgan KE, Forbes AB, Keogh RH, Jairath V, Kahan BC. Choosing appropriate analysis methods for cluster randomised cross-over trials with a binary outcome. Stat Med. 2017;36(2):318-33.
11. Arnup SJ, McKenzie JE, Hemming K, Pilcher D, Forbes AB. Understanding the cluster randomised crossover design: a graphical illustraton of the components of variation and a sample size tutorial. Trials. 2017;18(1):381.

Planned start date and end date	2024-01-01 to 2026-12-31
Timeline: Planned time for each phase of the project eg. approvals, recruitment, analysis, reporting, dissemination? (Max 50 words)	2023 Ethical approval application 2024 Study meetings, recruitment, data collection 2025 Recruitment, data collection, follow-ups 2026 Data analysis, manuscript, dissemination
Is it a ‘new’ project?	Yes
How much will this project cost?	385 000 euros

Are there other partners or organizations supporting this same project?	Yes
If YES - name the other partners who will support this project (Max 20 words)	We have applied for grants from The Swedish Research Council for Health, Work-life and Welfare (FORTE).
Have you already obtained any funding?	No

Budget

List each Item required for this project	Amount requested from ESC	Amount requested from additional partner	Name of partner	Any Comments
Staffing	6000	276777	FORTE	Project management, administration and assistance with study meetings, data collection, statistical analysis and dissemination of results
Operating costs	4000	30600	FORTE	Data management, tools, reimbursement pharmacies and participants, monitoring, regulatory fees, study meetings
Indirect costs	0	67623	FORTE	22%, Dept. of Women´s and Children´s Health at Karolinska Institutet

Total amount requested from ESC	10 000 euros
Total amount requested from partner(s)	375 000 euros
The ESC may not be in a position to fully fund all applications; you must indicate whether / how part-funding may impact your project. (Max 100 words)	Depending on the financial amount given some parts of the project may not be able to fulfill.
Who will oversee the budget & keep accounts? Provide name,	Mikaela Mati, Financial officer, +46 (0)8 524 82 361, mikaela.mati@ki.se

title, contact number, and email address

If you or your department has received grant funding from ESC for a project or course before, please give details of the date of funding, contact person, and title of the project or course.

2016, P2016-B-02 - Larc Forward Counseling – LOWE, Niklas Envall

I/We, as responsible agents for this project, agree to the following 11 points:

	yes
I/We agree that all monies will be spent appropriately	●
I/We agree to work with the nominated Mentor	●
I/We agree to advise you at the earliest time if this project is delayed or cannot be completed	●
I/We agree to provide an interim report(s) part way through the project and a final report to the ESC within 6 months of the end of the project.	●
I/We agree to provide the ESC with an interim budget(s) and a detailed budget at the end of the project. NOTE funding will be awarded in stages and will be dependent on appropriate reporting.	●
I/We agree to provide receipts for monies spent if requested.	●
I/We agree that if we need to make any significant changes to the duration, contents or funding of the project after it has been awarded, I/we will advise the nominated mentor.	●
I/We agree that any unspent money will be returned to the ESC	●
I/We (the applicant) agree to acknowledge the ESC as a donor in any publications, submission of abstracts and oral communications resulting from this project. Please inform the ESC Office where and when the data is to be presented and/or published and note that ideally any manuscript should be sent to the ESC journal in the first instance.	●
I/We agree to remain fully paid up ESC member(s) until the final grant report is submitted	●
I/ We agree that the reports get published on the ESC website	●

Full Name

Karin Emtell Iwarsson

Submission date of this form

jun. 7, 2023