

maandag, januari 16, 2023

Grant application form

Introduction

The ESC will provide funding to support an individual, group, institute or organisation with a project that has a scientific basis with a described relevant outcome(s) and is related to the aims of the ESC. Examples include: research into methods or provision of contraception, sexual and reproductive health; validated questionnaires to understand uptake or utilization of a method or procedure; or needs assessment within a community or locale.

The Internal Scientific Committee (ISC) retains the right to refuse an application if it feels the topic is not within the aims and objectives of the Society. For example, assisted reproductive technologies and projects on obstetric care would not be considered acceptable.

Application

- Please use this on line application form. Note sections with a maximum word count. Forms will be returned if the word count is exceeded. Please complete ALL sections of the form.
- If granted, the project MUST start within 12 months and MUST be completed within 3 years (if the project is to take longer, specific permission must be granted).
- A mentor will be allocated to each project. They are there to give advice if requested and will oversee progress.
- A short CV of the applicant (or the principal investigator) should be integrated into this application.
- If you or your department has been granted an ESC funded project or course before, this section of the form must be completed.

Who can apply?

Applicants must be paid up ESC European members with their membership paid within a European country. However, a European applicant is allowed to submit a project that will take place outside Europe. You must remain a paid-up ESC member until the project is complete and has been signed off by the ISC.

Funding

- Funding UP to a maximum of 10,000 euro per project can be requested. The money must be used for a definite project within a defined time period (usually up to 3 years) and with specified outcome measures. Part of the allocated funding is offered initially with the remainder being allocated on submission of an acceptable interim report(s). A final report MUST be sent to ESC within 6 months of completion.
- A detailed budget must be included in the application form. Example of costs include: staffing; involvement of a statistician; language editing; costs related to a questionnaire or obtaining relevant reference material. Costs for equipment may sometimes be accepted, dependant on reason given. Receipts may be requested. Grant money cannot be used for congress registration.
- The ESC may not be in a position to fully fund all applications; you must indicate whether / how part funding may impact your project.

Deadline

Applications MUST be received at ESC Central office by **31st December 2018**.

A. Name of the applicant requesting the funding

Name of applicant

Niklas Envall

Submission date of this form

zondag, januari 15, 2023

Job title

Dr.

Address

Högskolan Dalarna
Falun, 79188
Sweden

Phone Number

(+46) 704-090925

E-mail

nen@du.se

A short CV of the applicant (or the principal investigator) should be provided here. (Max 250 words)

Personal details:

Niklas Envall

Gamla Bromstensvägen 76H, 16864 Bromma,
Sweden

Telephone: +46704090925

E-mail: niklas.envall@ki.se, nen@du.se

Born: 2 April 1984

Nationality: Swedish

Languages: Swedish, English

Civil status: Married, three children, born 2011,
2014 and 2019

Current positions:

2020- Senior Lecturer, School of Health and
Welfare, Dalarna University

2019- Research affiliation with Karolinska
Institutet, dpt. of Women's and Children's Health

2020- Danderyd Regional Hospital and
Karolinska University Hospital Solna, Delivery
Wards, Registered Nurse Midwife (RNM)

Positions held:

2019-2020 Lecturer, School of Education,
Health and Social Studies, Dalarna University

2016-2019 PhD-student, Karolinska Institutet

2018-2019 Consultant Lecturer at the Midwifery
Programme, Dalarna University

2013-2019 The RFSU Clinic, Advisory on Sexual
and Reproductive health, contraception and health
care method development, RNM

2015-2017 Lecturer at the Midwifery
Programme, div. of Reproductive Health, dpt. of
Women's and Children's Health, Karolinska

Institutet

2008-2012 Neonatal Unit (NICU), Karolinska University Hospital (Danderyd), RNM and Registered Nurse (RN)

2011-2012 Delivery/Maternity ward, Danderyd General Hospital, RNM

2007 Local Emergency Ward Jakobsberg, telephone advisory, reception and Patient assessment, RN

2006-2007 Delivery/Maternity Ward, Södersjukhuset General Hospital, Nurse Assistant Education

University:

Dalarna University

2020 BHU I and II – qualifying courses in pedagogy in higher education, 7,5 ECTS

Karolinska Institutet

2022 Research ethics for postdocs and researchers in medicine

2021 Introductory doctoral supervision course

2021 Web course for supervisors

2019 PhD, Title of Thesis: Increasing uptake of long-acting reversible contraception—LARC.

Dissertation date: 6 Dec 2019.

Corresponds to 240 ECTS, including 35,6 ECTS in courses on a third-cycle level.

2016 Basic Pedagogy in higher education, 7,5 CME

2014 2 -day Course in Anticonception, awarded 0,6 CME

2010 Postgraduate Diploma in Midwifery

2007 Bachelor of Nursing

Graduated International Baccalaureate:

Nacka Gymnasium

2003 Natural Science Program

Other training

2013 Basics of Contact Tracing, One day, Authority of Infectious Diseases, Stockholm.

2009 Clinical Training, Three months midwifery at Mulago Hospital, Kampala, Uganda

Other merits

2022 Shair person, ESC Congress in Ghent

2022 Co-supervisor for doctoral student admitted to Örebro University

2021 Main Supervisor for doctoral student admitted to Karolinska Institutet

2020 Assistant Supervisor for doctoral student admitted to Karolinska Institutet

2016- Reviewer for journals in gynecology and reproductive medicine, such as

European Journal of contraception and Reproductive Health, BMJ, AMJPH, ACTA Obst. et Gyn. Scand and BMJ Sexual and Reproductive

Health.

2018- Lectures continuously on contraceptive methods in Sweden for Health Care Providers

2018 Invited speaker on Emergency contraception, ESC Congress 2018.

2018 Chairs person for free communication session, FIAPAC Conference 2018

2018 Member of scientific committee, FIAPAC Conference 2018

2017-2019 Project manager, Smartphone application development, Prev-appen (RFSU)

2013- Several appearances in the media (Swedish national television, Swedish national radio and printed media) regarding the subject of sexual and reproductive health and contraception.

B. Proposed project

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

No

C. Background of the project – narrative summary

Title of the project

Willingness to

Please provide a comprehensive description of your project. The application will be assessed under the following headings: Background and hypothesis; Specific aims and objectives; a Needs Analysis with evidence of unmet need and Innovation; Approach and Methodology; ie numbers recruited, ethical approval. inclusion & exclusion criteria; Expected outcomes; Impact it will or may have in the field of contraception, sexual and reproductive health; Feasibility (1000 words)

Background

The possibility to choose when and with whom you wish to have children are fundamental human rights, and knowledge about and access to contraception is key in the reproductive agency of women and their partners alike. Unwanted pregnancy and its consequences undermine women's health, education, social status, and future opportunities for work, contributing to further social inequity and gender inequality. Pregnancies resulting from unprotected sexual intercourse (UPSI) may be prevented by the use of emergency contraception (EC). The most effective EC method is the Cu-IUD which is approved for EC if inserted within 120 hours from UPSI. A recent study from the US has shown that the 52 mg LNG-IUS is non-inferior to the Cu-IUD, however, that trial did not only include women AT RISK of pregnancy, which is limiting the validity of the study.

Rationale

There is a high unmet need for contraception in Nigeria at 48% among unmarried and 19% among married women. Use of modern contraception is low, a mere 12% among married women and 28% among unmarried women, however, the unmet need for contraception among sexually active unmarried women is 48% and 19% among married women. In a Swedish trial, we gave structured contraceptive counselling, including method effectiveness, benefits and potential side-effects of the Cu-IUD and the Uliprisital Acetate-containing EC pill. The method of preference was then administered. We could see a significant difference in use of effective contraception 6 months after the EC visit, and more women were using LARC methods. Provision of unbiased information during contraceptive counselling and introducing new opportunities for ongoing and emergency contraception will increase women's ability to make informed decisions regarding contraceptive use and strengthen reproductive autonomy.

Aim

To, in a low-income setting, assess method preference for emergency contraception among women at risk of pregnancy from UPSI during the fertile window of their menstrual cycle, and to assess willingness to be randomized to either a Cu-IUD or LNG-IUS for EC. This is the first study in a planned larger project that aims to increase use of LARC methods among women in low-resource settings, and by such means decrease the impact of unintended pregnancies.

Methodology (include where will it take place - country/town, establishment, sample size, justification, ethical approval plans (inclusion & exclusion criteria);

Prospective observational trial of women at risk of pregnancy from UPSI during the fertile window of their menstrual cycle. They will receive oral and written information, and upon acceptance, sign an informed consent and then be provided with the method of choice. The study will be conducted in Nigeria. A local research group has already been established. It will be led by Prof. Akinyemi Akanni, together with the co-applicant Oluwaseun Ojomo, and aid in the provision of study information, enrolment of participants, data collection, and follow-up. The research group will ambulate between the participating clinics as needed. Should the participants not participate in follow-up through planned clinic visits, electronic surveys or phone, a representative will pay visits to participants and collect data to limit loss to follow-up. This is a common procedure to limit loss to follow-up in low-resource settings where internet and mobile phone access might be scarce. Data collection will be through electronic-CRFs using Research Electronic Data Capture (REDCap).

Sample size: There are to our knowledge no studies available on method preference regarding Cu-IUD or LNG-IUS for EC in low-income setting. We base our power calculation on one of our secondary outcomes, namely use of LARC 6 months after the EC visit. In a US trial a 10% difference in continued use in favor of the LNG-IUS was found. In this low-income setting we hypothesize that 80% will continue to use the LNG-IUD compared to 60% in the Cu-IUD. To show that difference we need 89 participants in each arm (80% power, $\alpha=0.05$). To allow for a 20-25% loss to follow up, we aim to include 220 participants.

Justification:

Method awareness among Nigerian women is low, especially awareness of highly effective LARC

methods. Almost 30% are not aware of the implant and more than 50% are not aware of the IUD. Evidence is lacking on method-specific knowledge among women and on factors associated with method choice and provision. Additionally, awareness of emergency contraception is estimated at a mere 36.7%. Furthermore, many family planning experts hypothesize that Nigerian women do not want the LNG-IUS, but this has not been adequately studied. This would be the first study of its kind in low-income settings, and needed to gather evidence regarding method preference for EC, and willingness of patients to be randomized into either Cu-IUD or LNG-IUS. The results will be used to assess the feasibility of the larger project, which will include an RCT on Cu-IUD vs LNG-IUS for EC among women at risk of pregnancy after UPSI and a Cluster RCT on Structured Contraceptive Counselling following the LOWE methodology. (Emtell Iwarsson et. Al, 2021). The study will seek to determine the basic characteristics of the study population in terms of who are they, age, socio-economic situation, previous pregnancies and their outcomes, abortions among others. The purpose of this is to locate suitable family planning clinics or health centers to conduct the scale up RCT. Upon acceptance, the baseline characteristics of the study population and the health facilities will be used to perform a stratified randomization.

Ethical approval: The study will be conducted in accordance with the WMA Declaration of Helsinki, and ethical clearance from the Swedish Ethical Review Authority as well as Nigerian authorities will be obtained prior to the study start.

Inclusion criteria (the most important):

- 18 years or older, regular menstrual cycle (21-35 days) and aware of their last menstrual period (± 3 days), at risk of pregnancy from UPSI within the fertile window of their menstrual cycle and within 5 days (120 hours) from the visit, no pregnancy desire within 12 months, no contraindication to IUD, negative pregnancy test.

Exclusion criteria (the most important):

- Vaginal bleeding of unknown etiology, signs of ongoing infection, untreated Sexually transmitted infection, exclusive breastfeeding of a child younger than 6 months.

Outcomes

Primary outcome: Method preference for EC (Cu-IUD/LNG-IUS).

Secondary outcomes:

- Willingness to be randomised (Cu-IUD or LNG-IUS);

Y/N),

Pregnancy at 1- and 6-months follow-up (low sensitive u-HCG test provided at EC visit), use of LARC at 6 months after the EC visit.

Statistical analysis:

Descriptive statistics, Mann-Whitney U-tests for non-normally- and normally distributed continuous variables, and Chi-Square tests and Fisher's exact tests as appropriate for categorical variables.

Impact:

This project will limit the impact of UIPs on women, their families and society, by increasing the use of LARC. This will be achieved by increasing knowledge about contraceptives to enable informed decision making, and by seizing novel opportunities to provide LARC for ongoing and emergency contraception. The negative impact of UIPs on women's finances and health, and on gender equality are well documented. We believe that the outcomes of this project will contribute to the development of Nigeria through multiple effects on the SDGs 1 (no poverty), 3 (good health and well-being), and 5 (gender equality).

Timeline: When will it start / finish? (Max 20 words)

Spring 2023 - Study meetings, recruiting clinics, start recruitment
2023-2024 recruitment
2025 Data analysis and manuscript submission

Is it a 'new' project?

Yes

D. Financial related information

How much will this project cost?

875000€

Are there other partners or organisations supporting this same project?

No

Have you already obtained any funding?

No

Details of your proposed budget

- **Example of costs include:** staffing; involvement of a statistician; language editing; costs related to a questionnaire or obtaining relevant reference material. Costs for equipment may sometimes be accepted, dependent on the reason given. Receipts may be requested. Grant money cannot be used for congress registration.
- List each item required for this project
- For each budgetary item, enter either the amount requested from the ESC or if there is also funding from another partner, list the amount & name of partner.

Budget

List each Item required for this project	Amount requested from ESC	Amount requested from additional partner	Name of partner	Any Comments
Travel	2000	25000	Swedish Research Council	
Staffing	8000	30000		
Ethical clearance		2500		
Ackommodation		20000		

Total amount requested from ESC

10000€

Total amount requested from partner(s)

77500

Who will oversee the budget & keep accounts?

Provide name, title, contact number and email address

Jesper Bengtsson, controller, +46(0)2377 86 67, jbn@du.se

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)

We will seek further funding from the Swedish Research Council.

Note: The ESC retains the right to be refunded any unspent money from the grant.

E. Previous funding from ESC

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

2016, P2016-B-02 - Larc Forward Counseling -
LOWE

F. Follow up

I/We, as responsible agents for this project, agree to the following 10 points:

I/We agree that all monies will be spent appropriately	yes
I/We agree to work with the nominated Mentor	yes
I/We agree to advise you at the earliest time if this project is delayed or cannot be completed	yes
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.	yes
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.	yes
I/We agree to provide receipts for monies spent if requested.	yes
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.	yes
I/We agree that any unspent money will be returned to the ESC	yes
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.	yes
I/We agree to remain fully paid up ESC member(s) until the final grant report is submitted	yes
I/ We agree that the reports get published on the ESC website	yes

Full Name

Niklas Envall

Questions? ESC Central Office: info@escrh.eu / Tel. 0032 2 582 08 52