

# A Swedish population-based reproductive life plan intervention

<b>Submission date</b> 01/11/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/11/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/10/2017	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

From an international perspective, Swedish midwives have a unique role in family planning counseling and testing for sexually transmitted infections. They are responsible for about 90% of all prescription of contraceptives. Traditionally, midwives focus on counseling about contraceptive methods with emphasis on their effectiveness and safety. Other aspects of reproductive health are often not discussed and consequently women lack important information about fertility and reproductive health. The aim of this study is to find out whether structured information about reproductive health given by midwives improves women's knowledge about the importance of lifestyle for pregnancy planning.

### Who can participate?

Women aged 20-40

### What does the study involve?

Participants are randomly allocated to one of two groups. One group receives ordinary care at a midwife visit. The other group receives extended oral and written information (leaflet) at a midwife visit about lifestyle factors that affect fertility and pregnancy outcomes, including the effects of smoking, snuff, obesity, alcohol use and folic acid intake. Participants' knowledge is assessed by questionnaire before and after 2 months after the visit.

### What are the possible benefits and risks of participating?

Participants may benefit from better and more extensive information when planning pregnancies in the future. There are no risks involved in this study.

### Where is the study run from?

Uppsala University Hospital (Sweden)

### When is the study starting and how long is it expected to run for?

March 2016 to January 2017

Who is funding the study?

1. Region Örebro County (Sweden)
2. Bayer HealthCare (Germany)

Who is the main contact?

Prof. Tanja Tyden

## Contact information

### Type(s)

Scientific

### Contact name

Prof Tanja Tyden

### Contact details

Dept of Women's and Children's Health  
Akademiska sjukhuset  
Uppsala  
Sweden  
75185

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RFR-385381

## Study information

### Scientific Title

Reproductive life plan intervention - a Swedish randomized controlled trial

### Study objectives

This study evaluates the effect of structured information (reproductive life plan [RLP]) about reproductive health in maternal health care (primary care setting), on women's knowledge of reproductive health and pregnancy outcomes both long and short term.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Regional Ethics Board Uppsala, 20/08/2014, ref: 2012/101

### Study design

Randomized trial in primary care setting

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Prevention

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Reproductive health

**Interventions**

All women booking an appointment with the midwife regarding preconception care received general information about the study and filled a baseline questionnaire and consent before the visit. Before meeting the midwife the woman took a sealed envelope (the first one) from a box, and the midwife opened this and got the information to which group the patient was randomized. Then, depending on allocation, the patient had either:

1. A traditional visit about prepregnancy care or
2. An extended visit with oral and written information (leaflet) about lifestyle and factors affecting reproduction, including smoking, snuff, obesity, alcohol use and folic acid intake.

After the intervention (or control) the patient receives a questionnaire 2 months after the visit with three reminders. Follow up will be done later on through matching the cohort with the national pregnancy register to evaluate if the intervention actually had an effect on lifestyle entering a pregnancy.

**Intervention Type**

Behavioural

**Primary outcome measure**

Knowledge of reproduction, assessed by questionnaire at baseline and 2 months after visit

**Secondary outcome measures**

1. Knowledge of folic acids effect on reproduction, assessed by questionnaire at baseline and 2 months after visit
2. Knowledge of lifestyle effect on reproduction, assessed by questionnaire at baseline and 2 months after visit

**Overall study start date**

01/03/2016

**Completion date**

01/01/2017

## **Eligibility**

**Key inclusion criteria**

1. Females aged 20-40
2. Understand Swedish and able to communicate
3. Give written consent to participate in the study

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Sex**

Female

**Target number of participants**

2000, 1000 in each arm

**Key exclusion criteria**

Below 20 years old or over 40 years old

**Date of first enrolment**

01/03/2016

**Date of final enrolment**

30/09/2016

## **Locations**

**Countries of recruitment**

Sweden

**Study participating centre**

Örebro and Uppsala Region

Örebro

Sweden

70185

## **Sponsor information**

**Organisation**

Region Örebro County

**Sponsor details**

Box 1613  
Örebro  
Sweden  
70116

**Sponsor type**

Research council

**Website**

<https://www.regionorebrolan.se/>

**ROR**

<https://ror.org/00maqj547>

**Funder(s)**

**Funder type**

Research council

**Funder Name**

Region Örebro County

**Funder Name**

Bayer HealthCare

**Alternative Name(s)**

BHC

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

Germany

**Results and Publications**

Publication and dissemination plan

The study will generate at least two-three publications about baseline knowledge before the intervention and the results of the effect of the intervention on knowledge score. Time to be confirmed later date.

**Intention to publish date**

01/01/2018

**Individual participant data (IPD) sharing plan**

Basic data from the questionnaires are kept locked and safe by the researcher according to ethics approval.

**IPD sharing plan summary**

Not expected to be made available