

A Swedish population-based reproductive life plan intervention

Submission date 01/11/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/10/2017	Condition category 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

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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

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