ISRCTN11081163 https://doi.org/10.1186/ISRCTN11081163

A Swedish population-based reproductive life plan intervention

Submission date
01/11/2016

Recruitment status
No longer recruiting

Registration date
25/11/2016

Overall study status
Completed

Last Edited
12/10/2017

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 midwifes 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

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

Primary study design
Interventional

Study design
Randomized trial in primary care setting

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