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Effect of a short teaching intervention on resident's care of women with fear of childbirth

Submission date
11/05/2015

Recruitment status
No longer recruiting

Registration date
20/05/2015

Overall study status
Completed

Last Edited
03/05/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Most pregnant women experience some level of anxiety about giving birth during their pregnancy. However, for some women these anxious feelings can develop into tokophobia, a fear of labour and childbirth. Fear of childbirth is considered to be a major factor in women choosing to have a caesarean section for non-medical reasons. Despite the fact that around 10% of women are thought to have a fear of childbirth, tokophobia is not well-recognised by the medical profession and there are no set guidelines on how treat affected patients. As a result, patients may not receive the necessary support from their GP or midwife in the run up to giving birth. The aim of this study is to see how well a short teaching intervention (programme) aimed at the care of women with a fear of childbirth works to improve the experience of patient-doctor interactions during routine appointments. The study will also track how participating women choose to give birth, i.e. by caesarean or vaginal delivery, and how they feel about their childbirth experience overall.

Who can participate?
Pregnant women fluent in Finnish with a referral for fear of childbirth.

What does the study involve?
Participating medical residents are given suggested guidelines on how to care for women fearful of childbirth. Medical residents follow the guidelines during consultations with women who have been referred to them due to their fear of childbirth. After each appointment, participants are asked to complete questionnaires evaluating the success of the appointment. Participating patients' records are used to assess how women give birth (caesarean delivery versus vaginal birth) and how successful the overall childbirth experience is.

What are the possible benefits and risks of participating?
A potential benefit of participating in this study is improved care for women fearful of childbirth. There are no risks associated with taking part in the study.

Where is the study run from?
University of Helsinki and Helsinki University Hospital (Finland)

When is the study starting and how long is it expected to run for?
November 2014 to March 2016

Who is funding the study?
University of Helsinki and Helsinki University Hospital (Finland)

Who is the main contact?
Dr S Forsell

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Assessment of a short teaching intervention effect on care by residents of women with fear of childbirth: a prospective single center study

Study objectives
A short teaching intervention for residents in treatment of women with fear of childbirth can reduce the anxiety and feelings of helplessnes in both doctor and patient. It can also improve care and thus reduce cesarean section rates and improve the experience of childbirth.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee for Gynecology and Obstetrics, Pediatrics and Psychiatry at The Hospital District of Helsinki and Uusimaa, 26/03/2015, ref: 93/13/03/03/2015.

Study design
Prospective interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Fear of labour in women giving birth

Interventions
Teaching material covering coping with fear of labour will be given to medical residents at the Helsinki University Hospital, Department of Gynecology and Obstetrics. The teaching material is a short, one-page check list containing brief guidelines and suggestions on how to care for patients with fear of labour during routine appointments. The medical resident will evaluate 10 appointments before and after the intervention.

Intervention Type
Behavioural

Primary outcome measure
Grade of anxiety, feelings of helplessness and opinion of overall success of the appointment, of both patient and doctor after the appointment using questionnaires (visual analog scale (VAS)) before and after intervention.

Secondary outcome measures
1. How the women gave birth (cesarean section or vaginal delivery)
2. Satisfaction with the childbirth experience (VAS scale)

Overall study start date
01/11/2014

Completion date
30/03/2018

Eligibility

Key inclusion criteria
Pregnant women sent to the maternity clinic with a referral for fear of childbirth, coming for their first appointment with a doctor.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200 patients.

Key exclusion criteria
Patients without fluency in Finnish.

Date of first enrolment
25/05/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Finland

Study participating centre
University of Helsinki and Helsinki University Hospital
Department of Obstetrics and Gynecology
Haartmaninkatu 2
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Sponsor information

Organisation
University of Helsinki and Helsinki University Hospital

Sponsor details
Department of Gynecology and Obstetrics
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
University/education

Funder Name
University of Helsinki and Helsinki University Hospital (Finland)

Results and Publications

Publication and dissemination plan
Dissemination of the trial results will be started in January 2016. Details of publication will be confirmed at a later date.

Intention to publish date
01/01/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available