Wetenschappelijk Onderzoek Bevallingsbeleving.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23323

Source
NTR

Health condition

- Pregnant women
- Fear of childbirth
- Anxiety
- Childbirth
- Therapy
- Angst
- Bevalling
- Therapie
- Haptotherapy
- Treatment
- Zwangeren
- Bevallingsangst
- Haptotherapie
- Behandeling

Sponsors and support

Primary sponsor: Tilburg University
Warandelaan 2
5037 AB Tilburg
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

Fear of childbirth as measured by the WDEQ-A.

Secondary outcome

1. Distress as measured by the 4DSQ;

2. Anxiety as measured by the 4DSQ;

3. Depression as measured by the 4DSQ;

4. Somatization as measured by the 4DSQ;

5. Social support as measured by the SSQ;

6. Anxiety as measured by the HADS;

7. Depression as measured by the HADS;

8. Emotional bond as measured by the PRAM;

9. Trauma anxiety and PTSS as measured by the TES-B;

10. Pregnancy and childbirth complications as registered in the medical record;

11. Duration of delivery and birth weight as measured by the evaluation questionnaire;

12. Customer satisfaction as measured by the evaluation questionnaire.

Study description

Background summary

An identifiable group of pregnant women (6%) suffer from FOC (Areskog, Uddenberg and Kjessle 1981) (Saisto and Halmesmäk 2003). Women with FOC are at increased risk of birth interventions and pre- and postpartum complications, e.g., Post Traumatic Stress Disorder (Söderquist, et al. 2009) preterm births (Dole, et al. 2002), emergency cesarean section (Ryding, Wijma and Wijma 1998), and caesarean section at the request of the woman. Dutch

prevalence figures are not available. Research from England, Sweden and Finland shows that 7-22% of all caesarean sections are carried out because of FOC (Ryding 1991) (Atiba, et al. 1993) (Graham, et al. 1999) (I. MacKenzie 1999). Currently no effective therapeutic intervention for reduction FOC is scientifically analyzed. A Finnish study reported some positive effects of psycho-education and relaxation (Saisto, Salmela-Aro, et al. 2011). The present study is a randomized controlled trial (RCT). All participants will be tested by the WDEQ-A for FOC and those with a score > 84 will be randomly assigned to the treatment group or control group 1 or control group 2, and respectively receive haptotherapy (TrG), information (ContrG1), care as usual (ContrG2), according to the protocol. Those women with a score < 85 will be allocated to a comparison group and followed for the secondary objectives. All therapists involved in the trial know which kind of intervention must be given to each participating woman.

Study objective

1. In the TrG "Fear Of Childbirth" (FOC) will decrease from Time 1-3;

2. In the ContrG1 FOC will decrease from Time 1-3;

3. The decrease of FOC from Time 1-3 will be larger in the TrG than in the ContrG1 and ContrG2;

4. At Time 4 the mean scores of FOC will be TrG < ContrG1 < ContrG2;

5. FOC and bonding with their child during pregnancy and postpartum will correlate negatively;

6. Women in the TrG have less birth complications than women in the control groups (ContrG1 and ContrG2).

Study design

1. Admission to the study in week 20-24 of gestation;

2. In week 36 of gestation;

3. Six weeks postpartum;

4. Six months postpartum.

Intervention

The study has three groups:
1. Therapy group;

2. Control group with information;

3. Control group with Care as Usual.

The therapy group will receive haptotherapy. The control group with information will receive detailed information about pregnancy and delivery. The control group Care as Usual will receive the care usually given in the concerned practice.

Haptotherapy for pregnant women with FOC is a combination of skills, learned in eight sessions of one hour between week 16 and 35 of the gestation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Pregnant women;

2. WDEQ-A score > 84;

3. Age > 17.

Exclusion criteria

1. Multiparity;

2. Pregnant women who recently or in the past have experienced a psychotic episode;

3. Medical illnesses, which would severely interfere with haptotherapy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2012
Enrollment:	192
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-03-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39999
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3188
NTR-old	NTR3339
CCMO	NL34900.008.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39999

Study results

Summary results
N/A