Wetenschappelijk Onderzoek Bevallingsbeleving.

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23323

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: Tilburg University

Warandelaan 2
5037 AB Tilburg
Overige ondersteuning: initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Fear of childbirth as measured by the WDEQ-A.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Pregnant women;

2. WDEQ-A score > 84;

3. Age > 17.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2012
Aantal proefpersonen:	192
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-03-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39999
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A