Treatment of severe fear of childbirth with haptotherapy

Published: 08-11-2011
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Primary objective: - What is the effect of haptotherapy on fear of childbirth (FOC) in pregnant women with severe FOC?Secondary objectives:- Is there a negative correlation between FOC and emotional bonding of mother and child during pregnancy and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39999

Source
ToetsingOnline

Brief title
Treatment of severe fear of childbirth with haptotherapy

Condition

- Other condition

Synonym
Childbirth Fear / fear of childbirth

Health condition

Angst voor de bevalling tijdens de zwangerschap

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Alle kosten komen voor rekening van de onderzoeker G.A. (Gert) Klabbers

Intervention

Keyword: Childbirth Fear, Haptotherapy, Pregnant women, Treatment

Outcome measures

Primary outcome

Fear of childbirth as measured by the WDEQ-A

Secondary outcome

Distress as measured by the 4DSQ

Anxiety as measured by the 4DSQ

Depression as measured by the 4DSQ

Somatization as measured by the 4DSQ

Social support as measured by the SSQ

Anxiety as measured by the HADS

Depression as measured by the HADS

Emotional bond as measured by the PRAM

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

Pregnancy and childbirth complications as registered in the medical record

Duration of delivery and birth weight as measured by the evaluation

questionnaire

Customer satisfaction as measured by the evaluation questionnaire

Study description

Background summary

An identifiable group of pregnant women (6%) suffer from extreme fear of childbirth (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 more caesarean section at the request of the woman. Dutch 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 fear of childbirth is scientifically analyzed. A Finnish study reported some positive effects of psycho-education and relaxation (Saisto, Salmela*Aro, et al. 2011).

Study objective

Primary objective:
- What is the effect of haptotherapy on fear of childbirth (FOC) in pregnant women with severe FOC?

Secondary objectives:
- Is there a negative correlation between FOC and emotional bonding of mother and child during pregnancy and postpartum?
- Is there a negative correlation between haptotherapy and complications during delivery?

Study design

This 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 assign to the treatment group or control group 1 or control group 2, and respectively receive haptotherapy, information, care as usual, according to the protocol. Those women with a score < 85 will be allocated to the 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.

Intervention

The intervention group receives haptotherapy.
The control group 1 receives detailed information about pregnancy and childbirth.

The control group 2 receives care as usual.

Study burden and risks

There are no additional risks associated with participation in the study (a) since the treatment is a standard haptotherapeutical treatment already practiced in the some clinics, and (b) those participants in the treatment group have haptotherapy in addition to care as usual. Participants will additionally answer questionnaires with in total 120 questions, each time taking about 20 minutes. The research team has a long and extensive experience with similar studies with pregnant women. These studies have shown that participants have no problems to fill out such questionnaires without any detriment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Pregnant women with a WDEQ-A score > 84

Exclusion criteria

Respondents who are already in treatment for haptotherapy and / or haptonomic pregnancy counseling and / or there for other reasons during the research.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2012
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO

Date:	08-11-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	05-11-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	23-05-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	03-03-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23323
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL34900.008.11
OMON	NL-OMON23323