The road to an integrated CenteringPregnancy: an effect evaluation.

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To evaluate the effect of CP in the Dutch setting on psychosocial- and health outcomes (concerning the pregnancy) and the success of implementation of CP (including a costanalysis)

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON38710

Source
ToetsingOnline

Brief title
Effects if CenteringPregnancy in the Netherlands

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Pregnancy outcomes

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: CenteringPregnancy, pregnancy, prenatal care, preterm birth

Outcome measures

Primary outcome

Infant morbidity, composite outcome: APGAR score <7 5 minutes postpartum or admission to the neonatal intensive care unit.

Secondary outcome

Prenatal care satisfaction

Proportion of initiating breastfeeding

Other study parameters:

1) Perinatal health indicators:

- Infant data (GA at delivery, birth weight, APGAR score, hospital admission, mortality)

- Maternal data (blood pressure, weight, weight change during/after pregnancy, health behaviors, psychosocial outcomes (stress, coping, depression) and social support, birth preparation, self-efficacy, health literacy).

- Care data (mode of birth, place of birth)

2) Process evaluations:

- Pregnant women: adequacy of care, care use, participation of partners, uptake interventions, perceived integration of care, satisfaction, attendance of group sessions.

- Health professionals: degree of implementation, provided information/activities to women during care, collaboration / integration with

partners, alterations made to the CP-program, satisfaction with provided care,

costs.

Study description

Background summary

In the Netherlands, the perinatal mortality and morbidity rate is relatively high, compared to surrounding countries. Pregnancy outcones are especiaaly worse for women with a low socio-economic background or for immigrants. Women could benefit greatly if we could lower the risk factors for perinatal mortality (a.o. pretem birth and low birth weight). Furthermore, we aim to optimalize the experience of pregnancy and child birth for women. This can be achieved by centering the pregnant woman within the provided care. A possible solution herefore, and for lowering the risk of perinatal mortality, is the approach of CenteringPregnancy, a different model of prenatal care.
CP in the US is primarily focused on immigrant and non-immigrant women with a low soci-economic background. Scientific research within this population shows that this type of care has a positive effect on health literacy and behavior, such as more prenatal and postnatal knowledge, better preparedness for delivery and higher breastfeeding percentages. Furthermore, women experience more social support, and are more satisfied with prenatal care. Women with higher stress-rates at the beginning of the pregnancy show a significant raise in selfesteem, significant less stress, and significant less social problems or depression postpartum. Having followed CP, women's risk for perinatal morbidity is lower than with individual care: 33% lower risk for preterm birth (in a high risk group), higher birth weight, end less sub-standard care. Despite these positive results, a more systematic approach is needed to support the effect op CP.
In 2011-2012 a feasibility study was performed in the Netherlands, in collaboration with three midwifery practices. In September 2012, already 160 women received prenatal care according to the CP program. The results of this study are promising. Pregnant women and their midwives are enthousiastic about CP. Women rate the care with an 8.4 on average on a scale 0-10. Further results are currently being analysed, but the feasibility of CP in the Netherlands is very plausible. This is an important fact, since the important differences in obstetrical systems between the Netherlands and the countries where CP was introduced so far (US, Canada, UK, Australia, Sweden).

Study objective

To evaluate the effect of CP in the Dutch setting on psychosocial- and health outcomes (concerning the pregnancy) and the success of implementation of CP

(including a costanalysis)

Study design

Randomised clustered trial, with a stepped wedge design. Participating clusters will be randomized to the moment they implement CP, the intervention. During the controlperiod of a cluster (the months between the start of the study and the start of implementation), control data will be collected. After implementing CP, the clusters collect intervention data, untill the end of the study period.

Intervention

In stead of the usual individual prenatal check-ups, prenatal care is provided in ten sessions for a group of women. During a session, the physical check is combined with education, interactive educational methods and conversation on what is important to women during their pregnancy. Groups consist of 8-12 women with the same gestational age. They get to know each others through the sessions and are stimulated to play a greater role in their own care process. This is achieved by interactive educational methods, theme sessions, a handbook wtih personal goals en reflection on these goals. Furthermore, women are actively involved in their medical care, by measuring their blood pressure and weighing, filling in their own pregnancy file. Sessions are supervised by a medically responsible care provider (midwife, gynaecologist), and an assistant.

Study burden and risks

Control period: women receive usual individual care, participants are asked to fill out questionnaires at four time points.
Intervention period: identical to control period, additionally women can choose at their intake for further individual prenatal care of group prenatal care according to CP.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- < 24 weeks of gestational
- able to communicate in Dutch or English
- given informed consent

Exclusion criteria

- physically or mentally unable to communicate in a group setting
- > 24 weeks of gestation

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-02-2014
Enrollment:	1600
Type:	Actual

Ethics review

Approved WMO

Date:	26-06-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	21-08-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 27178
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL44319.058.13
OMON	NL-OMON27178