De effecten van CenteringPregnancy™ in Nederland

No registrations found.

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

Summary

ID

NL-OMON27178

Source
Nationaal Trial Register

Brief title
CONNECT-IN studie: Consortiumonderzoek Noordelijk Zuid-Holland naar effecten van Centering in Nederland

Health condition

The evaluated intervention is a prenatal care model, designed for pregnant women.

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Prenatal care satisfaction
Proportion of initiating breastfeeding
Infant morbidity, composite outcome: APGAR score <7 5 minutes postpartum or admission to the neonatal intensive care unit.

Secondary outcome

1) Perinatal health indicators:

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

- Maternal data (physical and mental health, blood pressure, weight, weight change during/after pregnancy, general well-being during pregnancy, health behaviors, psychosocial and social support, birth preparation, self-regulation, fetal health locus of control, health literacy).
- Care data (mode of birth, place of birth)

2) Process evaluations:

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

- Health professionals: provided information/activities to women during care, collaboration / integration, satisfaction with provided care, costs.

Study description

Background summary

Perinatal and maternal morbidity/mortality is relatively high in the Netherlands, compared to other European countries. The perinatal outcomes are especially worse for pregnant women from lower socio-economic groups and from non-western origin. In the US a customized care model has been developed for these groups of women: CenteringPregnancy™ (CP). CP consists of consultations in group setting aimed at empowering the pregnant women by integrating three major components of care: health assessment, education, and support. Studies have shown positive effects of CP in the US: amongst others a decrease in the number of preterm births. CP is now being adapted to the Dutch primary health care and its feasibility is being studied. In the region Northern South-Holland in the Netherlands CP will be strengthened by a) involving chain partners from public health care, other primary care professionals and specialized health care, and b) the development of additional support for pregnant women with complex needs.
We will use a wedged cluster randomized controlled trial to examine the effects of CP of infant outcomes, maternal outcomes, and care outcomes in 11 midwifery practices and 3 clinics. Instead of randomly allocating practices to the intervention or control condition, the midwifery practices and clinics are randomly allocated to the period in which they start with providing CenteringPregnancy™. Data registered in the Dutch Perinatal Registration is used to monitor infant outcomes, and some of the maternal and care outcomes. Next, pregnant women will complete questionnaires three times during and one time after pregnancy. During the study the key professionals will monitor the process of prenatal care such as participation

rate, uptake intervention, provided activities, and the costs of implementing group consultations. Professionals are also questioned (using a six monthly questionnaire) to assess their satisfaction with individual and group consultations and with the integration of care. Pregnant women and their partners will be asked about their satisfaction with care.
The project will be imbedded in our regional obstetric consortium group in which professionals and researchers in public health, primary, and specialized care are involved. The partners of our consortium are already collaborating in several networks: like the perinatal audits, obstetrics collaboration networks (verloskundig samenwerkingsVerband; VSV), and the Academic working place Public Health.

Study objective

Perinatal and maternal morbidity/mortality is relatively high in the Netherlands, compared to other European Countries. The perinatal outcomes are especially worse for pregnant women from lower socio-economic groups and from non-western origin. In the US a customized care model has been developed for these groups of women: CenteringPregnancy™ (CP), which consists of consultations in group setting aimed at empowering the pregnant women by integrating three major components of care: health assessment, education, and support. Studies have shown positive effects of CP in the US: amongst others a decrease in the number of preterm births. CP is now being adapted to the Dutch primary health care and its feasibility is being studied. In the region Northern South-Holland in the Netherlands CP will be strengthened by a) involving chain partners from public health care, other primary care professionals and specialized health care, and b) the development of additional support for pregnant women with complex needs. In the present study this adapted CP is developed and its effects are evaluated.

Study design

Mental health: Edinburg Postpartum Depression Scale, by Cox et al (28 weeks GA, 6 weeks postpartum)

Sociale Steun Lijst (Social Support), by van Eijk, van Sonderen (12 and 36 weeks GA)
Prenatal Distress Questionnaire, by Lobel et al (12 and 36 weeks GA)

Cambridge Worry Scale, by Green et al (12 and 36 weeks GA)
Parent Expectations Survey, by Reece et al (6 weeks postpartum)

Patient Participation and Satisfaction Questionnaire, by Littlefield and Adam (36 weeks GA)

Birth preparation: readiness for labor-delivery and infant scales, by Ickovics et al (36 weeks GA)

Health literacy: questionnaire measuring pre, peri and postnatal knowledge, based on Ickovics et al (12 and 36 weeks GA)
Adequacy of care: Kotelchuck index (36 weeks GA and 6 weeks pp, PRN)

Labor Agentry Scale, by Hodnett et al. (6 weeks postpartum)

Intervention

The intervention studied is group prenatal care according to the CenteringPregnancy™-model (https://www.centeringhealthcare.org/). The effect of the intervention will be studied performing a stepped-wedge clustered randomized controlled trial. Subsequently each cluster contributes some months of control data and some months of intervention data. The intervention is compared to usual (individual) prenatal care, provided during the control months.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria for the health care institute (cluster):

- the availability of group space

- population size: approximately 200 deliveries a year leads to one group starting each month

and is considered to be cost-effective

- provider involvement

- administrative participation and support

Inclusion criteria for participants within each cluster:

- Able to communicate in Dutch or English

- <24 weeks of gestational ages at first prenatal visit

Exclusion criteria

Physically or mentally unable to communicate with others in a group setting.

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):	31-10-2013
Enrollment:	1600
Type:	Anticipated

Ethics review

Positive opinion
Date: 17-09-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38710
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4006
NTR-old	NTR4178
CCMO	NL44319.058.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38710

Study results

Summary results
N/A