De effecten van CenteringPregnancy™ in Nederland

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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…

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

Samenvatting

ID

NL-OMON27178

Bron
Nationaal Trial Register

Verkorte titel
CONNECT-IN studie: Consortiumonderzoek Noordelijk Zuid-Holland naar effecten van Centering in Nederland

Aandoening

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

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	31-10-2013
Aantal proefpersonen:	1600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-09-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38710
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A