Lay Doula;A randomized intervention trial on the effect of lay doula in the Dutch obstetric system;A Pilot Study

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Looking at the extraordinary character of the Dutch Obstetric Care system, it is specific relevant to investigate the effect of a lay doula in a randomised trial in the Dutch setting. One group of women will deliver with a lay doula at her site...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON32407

Source
ToetsingOnline

Brief title
laydoula

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
delivery

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Achmea;ziektekostenverzekeraar

Intervention

Keyword: laydoula

Outcome measures

Primary outcome

Primary outcome measures:

• The percentage of referrals from primary to secondary care with no progress

of dilation or required pain medication.

• Length of labor, type of delivery, type and timing of analgesia/anesthesia,

and Apgar scores.

Secondary outcome

As Secondary measure the Quality of life will be assessed by validated

questionnaires. Each woman and her partner will complete a questionnaire

addressing health related quality of life HADS and WDQ (Wijma Delivery

Expectancy/Experience Questionnaire) [6].

These questionnaires will be filled in directly after randomisation (at 28-34

weeks gestational age) and 6 weeks postpartum

Study description

Background summary

The Dutch system of obstetric health care, with its special position of the uncomplicated birth based on a primary and a secondary care chain, is at present vulnerable.
The percentage of referrals from primary to secondary care with the indication non progressing dilatation or required pain medication did increase over the last 10 years. At the same time the amount of interventions in secondary

obstetric care has also increased: the number of caesareans, instrumental deliveries and need for pain medication.
In other countries, continuous support during labor by a trained labor coach, the so-called doula, next to the medical care giver, has proved to be very effective to reduce complications, medical interventions en psychological trauma during labor.
The short trained lay doula has also proven to be effective in increasing quality of life, and seems to be effective to prevent labor complications and to shorten the length of labor.

Study objective

Looking at the extraordinary character of the Dutch Obstetric Care system, it is specific relevant to investigate the effect of a lay doula in a randomised trial in the Dutch setting. One group of women will deliver with a lay doula at her site during labor; the other group of women will deliver with support during labor as usual given in the Dutch system.

Study design

Randomised controlled trial (pilot)

Intervention

Support by a lay doula versus usual care as practiced in the Netherlands.
• The doula group will be trained traditional doula supportive techniques in two 3-hour sessions.

The intervention group is called A, the controlled group B.
At group A the pregnant woman will be asked to identify a lay doula so a girlfriend, sister or mother to participate with her at a 2x4 hours training given by a professional doula trainer. The girlfriend, sister or mother is called *lay doula*. This lay doula will support the pregnant woman and her partner during labor continuously.

Group B will have *usual care*: the woman in labor will be visited and supported as usual during labor by her midwife, gynaecologist or nurse (or kraamzorg) and of course her partner.

Study burden and risks

Benefit: less referrals to secondary care i.e. less interventions such as epidural, artificial deliveries and caesarian section

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

Inclusion criteria:
• Nulliparous women who are able to identify a woman (friend or family member) who is willing to be lay doula.
• Maternal age > 18 years
• Signed informed consent

Exclusion criteria

Multiparous, twin pregnancies, antenatal care by obstetrician

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-01-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL22960.058.08