Postpartum care 2.0: do flexible distribution and intermission of postpartum care, without extension of hours, have a positive effect on the success rate of breastfeeding, experienced empowerment and quality of care by the mother during and after postpartum period?

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The aim of this reseach project is to gain insights into the effects of distribution and intermission of postpartum care hours on the success rate of breastfeeding and the experienced empowerment and quality of care by the mother during and after...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Postpartum and puerperal disorders
Study type	Interventional

Summary

ID

NL-OMON45871

Source
ToetsingOnline

Brief title
Postpartum care 2.0

Condition

- Postpartum and puerperal disorders

Synonym
puerperium and childbed

Research involving
Human

Sponsors and support

Primary sponsor: Verloskunde & Gynaecologie
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Breastfeeding, Clients' experience, Empowerment, Postpartum care

Outcome measures

Primary outcome

Our primary study outcome is successful breastfeeding (purely breastfeeding, no supplements) on day 1 after birth and at the end of the postpartum care period. Successful breastfeeding is considered as the most optimal surrogate outcome measure for health benefits of mother and newborn in the short and long term. Meta-analyses show that breastfeeding could protect children against health infections, increases childs' intelligence and possibly reduces chances of obesity and diabetes. Furthermore, breastfeeding could also protect women against breast cancer and ovarian cancer and diabetes type 2. It is even said that worldwide breastfeeding initiatives can reduces thousands of deaths among children under 5years and prevent thousands of deaths due to breastcancer among women.

SOURCE:

Victoria CG, Bahl R, Barros AJD, França GVA, Horton S, Krasevec J, Murch S,

Sankar MJ, Walker N, Rollins NC, for the Lancet Breastfeeding Series Group. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. Lancet. 2016; 387: 475-90.

Secondary outcome

- Experienced empowerment by the mother after childbed, based on the Maternal Empowerment Questionnaire (MEQ), which is part of the CLiK questionnaire and will be completed 4 weeks after childbirth. This questionnaire measures the empowerment of mothers.

- Experienced quality of postpartum care by mother, also based on CLiK questionnaire, which is completed four weeks after childbirth. We will specifically look at the evaluation questions / items related to postpartum care service (i.e. 5 items: general experience of postpartum care service, amount of hours received, experience health status today, experience of the maternity care assistant in the family and clients' choice for this specific postpartum care organisation).

- Successful breasfeeding (no supplements) at 4 weeks after birth; around 4 weeks mother will have her visit to the youth care.

- Experience with the intervention by clients and caregiver who accompanied and was medically responsible for parturition and childbed (e.g. midwife), postpartum care consultant, postpartum caregiver, lactation consultant and youth caregiver: focus on the barriers and possibilities of intervention.

- Cost-effectiveness of the intervention: based on the actual postpartum care hours and healthcare needs of client after postpartum care period until first visit to JGZ (youth care).

- Additional outcomes registred in the national Perinatale Registratie NL will be used in terms of the interventions' safety, like: complications, readmission and mortality mother/child during childbed (up to 28 days after birth).

SOURCE:

Factsheet CLiK (CLient Informatie Kraamzorg) en MEQ (Maternal Empowerment Questionnaire). Academische Werkplaats Kraamzorg in Geboortezorg, 2017.

Study description

Background summary

The Dutch maternity care model with home-based postpartum care is unique. This uniqueness results in little to no scientific knowledge on the effectiveness and efficiency of home-based postpartum care. Filling the knowledge gap and following the trend of personalized care are prerequisites in preserving this form of maternity care. Therefore this study researches the possibility of flexible distribution and intermission of postpartum care hours. It concerns a practice-based innovative research model which, without extension of postpartum hours, analyses whether distribution and intermission of postpartum care hours benefits the health of mother and child.
It is expected that this planning flexibility of postpartum care hours will have a positive effect on the success rate of breastfeeding and improve the experienced empowerment and quality of care by mothers (and their partners). Furthermore we hope to realise a better and more efficient cooperation between different health institutes and a smoother start for youth care organisations. Scientific evidence of essential and effective postpartum care can contribute to an improved maternity care system and its goal to give all mothers and newborns a perfect kick-off of life. To a greater extent, this new generated knowlegde can reduce maternal and perinatal mortality and morbidity in the long

run.

Study objective

The aim of this reseach project is to gain insights into the effects of distribution and intermission of postpartum care hours on the success rate of breastfeeding and the experienced empowerment and quality of care by the mother during and after childbed.

This intervention concerns the planning of postpartum care hours rather than the number of hours. The amount of postpartum care hours will always be restricted by the guidelines of the currently used LIP (as it is now) in order to make no additional medical expenses. However, it might be possible that distrbution and intermission of postpartum care hours limit medical costs. Furthermore, a prerequisite for the planning of hours is continuation of care.

In order to achieve abovementioned goals, the following questions are asked:
1. What effect has flexible distribution and intermission of (indicated) postpartum care hours on the success rate of breastfeeding, experienced empowerment and quality of care by the mother during and after childbed?
2. How do the client, responsible caregiver (who accompanies and is responsible during parturition and childbed) and postpartum caregiver experience the flexibility in planning postpartum care hours without the restriction of 8-10 consecutive days?
3. What effect has flexibility in planning of postpartum care hours on the actual used hours and the related cost of postpartum care?

Study design

Randomised controlled trial, randomisation on level of individual client.

Intervention

Intervention group:
Clients are offered the opportunity for flexible planning of their postpartum care hours (i.e. distribution and/or intermission), without making any additional health care costs. This means that the indicated 24-49 postpartum care hours may be distributed throughout the whole day and on noncontiguous days (to a maximum of 14 days). Additional indicated postpartum care (up to 80hrs) may also be distributed throughout the whole day and noncontiguous days (to a maximum of 14 days).
Furthermore, a decrease of the number of postpartum care hours is also possible. In this case, the guarantee of continuity of care is a vital condition.
(Re)distribution of postpartum care hours is always done in consultation with the client, the healthcare provider (who accompanies and is medically

responsible during parturition and childbed) and postpartum caregiver; in a similar manner as is done in the current situation using the LIP.

Control group:
Clients receive the current package of postpartum care hours (i.e. 24-49 hours in 8 continguous days), possibly followed by an additional indication of hours (up to 80hrs) within 10 contiguous days (i.e. 2 extra days).

SOURCE:
Landelijk Indicatieprotocol Kraamzorg. Instrument voor toekenning van kraamzorg: Partusassistentie en kraamzorg geurdende de kraamperiode. BTN, Z-org, STING, ZN en KNOV, 2008.

Study burden and risks

In our view, the risks of participation are negligible. Possible risks may only occur to those participants in the intervention group who receive less postpartum care hours per day than usually (i.e. since they prefer a longer postpartum care period instead of the amount of hours per day, e.g., 14 days x 3.5h). In that case one can think of potential risk factors like: higher change of falling or a delay in signaling (health) problems. We would like to emphasize that these risks are always taken into consideration by the health care providers when postpartum care hourse are (re)distributed.

The participation burden is considered minimal. The amount of postpartum care hours is always aligned with the statutory criteria (as indicated by the LIP); this accounts for both groups (intervention as well control). Besides the possibility for participants in the intervention group to a broader distribution and/or intermission of postpartum care hours (they always have the freedom to choose the 'regular' package), all participants are asked to fill out a questionnaire (ReproQ), to answer questions during brief phone interview (on self-reliance) and voluntary participation in focus group discussions (on self-reliance).

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 who have the intention (in week 30 of pregnancy, i.e. intake by postpartum care organisation) to breastfeed, who receive maternal care in the region of Nijmegen and who do not have an additional postpartum care insurance package (for example IZZ Zorg voor de Zorg + Extra 2/3)

Exclusion criteria

pregnant women who do not have the intention (in week 30 of pregnancy, i.e. intake by postpartum care organisation) to breastfeed OR who do not receive maternal care in the region of Nijmegen OR who have an additional postparum care Insurance package (for example IZZ Zorg voor de Zorg + Extra 2/3)

Study design

Design

Study phase:	4
Study type:	Interventional

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2017
Enrollment:	1114
Type:	Actual

Ethics review

Approved WMO Date:	12-06-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-07-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-10-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 25085
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61474.091.17
OMON	NL-OMON25085