Returning to work after childbirth

Submission date	Recruitment status	Prospectively registered
20/12/2005	No longer recruiting	[X] Protocol
Registration date	Overall study status	Statistical analysis plan
20/12/2005	Completed	☐ Results
Last Edited	Condition category	Individual participant data
09/10/2014	Pregnancy and Childbirth	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.momatwork.nl

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR134

Study information

Scientific Title

Returning to work after childbirth: the effectiveness of the first contact by an executive with an employee during maternity leave on sick leave and work disability postpartum

Acronym

Mom@Work

Study objectives

Many women experience health problems during the first year after childbirth.

Common postpartum problems are fatigue, disturbed sleep, postpartum depression, back and pelvic pain. Those problems are often perceived as being unavoidable and 'all in the game'. However, frequently these problems lead to limitations in daily activities and to sick leave. In the Netherlands sick leave is higher during pregnancy and the first period postpartum than during other periods. About 30% of the women were absent from work due to health problems after maternity leave in 2002.

In the Netherlands, there is no contact with an occupational physician during maternity leave, not even when women experience health problems. Furthermore, women often wait for seeking medical care for their problems, frequently until their maternity leave is almost over. Therefore, the complaints may have existed for a considerable time before an intervention starts, while early intervention after complaints seems to be important for a good prognosis.

The aim of this study is to evaluate the effectiveness of an early consultation by an executive with an employee during maternity leave on health problems and sick leave, and to assess which factors contribute to return-to-work after maternity leave.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised active-controlled parallel-group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Pregnancy, neonatal disorders

Interventions

The women in the intervention group will be consulted 6 weeks postpartum during maternity leave by their executive, and in some cases by a case manager or a staff member of the personnel department. This executive will phone, or visit the women. Prior to this consultation the executive receives an information package. He or she will be instructed carefully to ask questions about the women's well-being, complaints, and return to work. They have to use a checklist when doing this consultation.

When a woman has the expectation that she will not return to work after maternity leave due to medical complaints, she will have the possibility to receive a consultation by a staff member of the Occupational Health Services (OHS). The executive will phone the OHS in case of need for medical intervention (or will follow the standard sick-listed procedure of the company). The OHS will call the woman to make an appointment within one week with an occupational physician or other consultant.

When a woman has no complaints and/or expects no problem to return-to-work, the executive will do nothing. When a woman has doubts or is uncertain if she is able to return-to-work, the executive will call again after 2 weeks. The executive uses the same checklist again.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. Sick leave (during pregnancy and after maternity leave; duration and frequency)
- 2. Costs (of the intervention, medical consumption, sick leave)
- 3. Stop working

Secondary outcome measures

- 1. Health status/quality of life
- 2. Complaints (pregnancy-related pelvic and back pain, fatigue and depressive complaints (postpartum depression, distress)
- 3. Satisfaction with intervention
- 4. Adaptation of working hours or work tasks

Overall study start date

01/01/2004

Completion date

01/06/2007

Eligibility

Key inclusion criteria

- 1. Voluntary participation (giving informed consent)
- 2. Age: between 18 and 45 years
- 3. Pregnant less than 32 weeks
- 4. Being employed before and after maternity leave, for a minimum of 12 hours per week
- 5. Good reading, writing and understanding of the Dutch language

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

600

Key exclusion criteria

- 1. Delivery before 34 weeks of pregnancy
- 2. Definitely not returning to work after delivery, meaning one has submitted ones resignation, or end of contract
- 3. Not returning to the same employer
- 4. Receiving a disability benefit or having submitted an application for a disability benefit

Date of first enrolment

01/01/2004

Date of final enrolment

01/06/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Department of Public and Occupational Health/EMGO Instituut

Amsterdam Netherlands 1081 BT

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details

EMGO-Institute and Department of Public and Occupational Health Van der Boechorststraat 7 Amsterdam Netherlands 1081 BT emgo@vumc.nl

Sponsor type

University/education

Website

http://www.vumc.nl

ROR

https://ror.org/00q6h8f30

Funder(s)

Funder type

Research organisation

Funder Name

Body@Work TNO - Vrije University Medical Centre (VUMC) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Protocol article 29/03/2007 Yes No