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Peripartum pelvic pain during pregnancy and after delivery. A cohort and intervention study

Submission date	Recruitment status	[_] Prospectively registered
18/11/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/06/2008	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PPBS-study

Study information

Scientific Title

Acronym
PPGP - Peri-partal Pelvic Girdle Pain (PPBS - Peri Partaal Bekkenpijn Syndroom)

Study objectives
Pregnancy-related pelvic girdle and/or low back pain is a syndrome with an onset during pregnancy, characterized by pain in the lumbar-pelvic region and feelings of instability when standing and walking. After delivery most symptoms subside, but some women report persisting pain and a small group do not develop complaints until after delivery. Often symptoms have an impact on activities of daily life, participation in society and sometimes lead to a chronic disabling condition with considerable work absenteeism in the future.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Peripartum pelvic pain

Interventions
Experimental intervention: Theoretical concepts of self-management and fear-avoidance were integrated in the treatment protocol. It is an individualized approach of 7-9 sessions with a frequency of once a week. Standardized information is presented through a treatment protocol for the therapists and booklets for the patients. Generally, a time contingent policy is followed in which women set the pace.

Usual care: A pain contingent regimen of relative (bed) rest and avoiding and limiting several day-to-day activities. Goal setting focused on disease management with an accent on biomedical factors.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary domain for improvement of the intervention was limitations in activities. Other important domains were the severity of the main complaint and global feeling of recovery.

Secondary outcome measures
Pain was measured with two Visual Analog rating Scales (VAS) of the McGill Pain Questionnaire (MPQ-DLV) to record the intensity of pain the last week and day.

The impact on participation and autonomy (IPA) measured person-perceived restriction in participation and autonomy. The used subscales were self-care and appearance, mobility, leisure, social relationships and family role. Perceived participation is graded on a 5-point rating scale ranging from 0 (very good) to 4 (very poor).

Fear of movement was measured by the Dutch translation of the Tampa Scale for Kinesiophobia (TSK). We used the TSK and the both subscales 'fear avoidance' and 'harm'.

The Short-Form 36 (SF-36) evaluated health status. We used the subscale 'general health'.

Overall study start date
01/01/2001

Completion date
30/06/2005

Eligibility

Key inclusion criteria
The trial is embedded in a cohort study (n = 7526) that is designed as a longitudinal, prospective study which studies the prevalence, etiology, severity and prognosis during pregnancy until 1 year after delivery. Participants are included in the cohort when they are at least 18 years old, pregnant (about 14 weeks) and well versed in the Dutch language. Women are included in the intervention study out of the cohort at the time of three weeks after delivery.

Inclusion criteria are: pain in the pelvic girdle and/or low back pain with an onset during pregnancy and a delay in recuperation. The frame of reference for the inclusion criteria is a random sample of 100 women out of the cohort without complaints, examined with the same protocol three weeks after delivery.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
127

Key exclusion criteria
Women diagnosed with a relevant specific pathology are excluded.

Date of first enrolment
01/01/2001

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Epidemiology
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Sponsor information

Organisation
Dutch Health Care Insurance Board (College Voor Zorgverzekeringen) (The Netherlands)

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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Dutch Health Care Insurance Board (College voor Zorgverzekeringen) (PPBS-study)

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	Protocol	24/12/2004		Yes	No
Results article	Short-term results	27/02/2006		Yes	No
Results article	Long-tern results	30/05/2008		Yes	No