

# Group care exercise class vs individual physiotherapy care for the treatment of pelvic and back pain in pregnancy

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 24/03/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 24/03/2009	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**

N/A

## **Study information**

**Scientific Title**

Randomised controlled trial for the treatment of pelvic girdle pain in pregnancy

**Acronym**

GRIP trial (GRoup therapy verses Individual therapy for Pelvic girdle pain in pregnancy)

**Study objectives**

We aim to conduct a prospective open label randomised controlled trial to test the hypothesis that following initial assessment by a physiotherapist, group care exercise class is as effective in reducing pain as individual physiotherapy care.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Cork University Teaching Hospitals Clinical Research Ethics Committee, approved on 16/01/2009

**Study design**

Open-label randomised controlled single-centre trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Pelvic girdle pain in pregnancy

**Interventions**

Following initial assessment participants will be randomly allocated to one of two treatment groups (randomisation ratio 1:1). Patients will be asked to keep a pain score diary where they

will record their pain score using a visual analogue scoring system. Patients will be asked to record a score every morning and every evening during the treatment course. The first treatment in both treatment arms will be one week following initial assessment.

Individual care group: Three sessions/week, approximately 45 minutes/session

Group care group: Weekly group exercise classes for 4 weeks (1h/class), focusing on core stability and strengthening exercises.

In both treatment groups pain scores will be followed up for 1 week post last treatment.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

A reduction in the current intensity of PGP related to motion on a 100-point visual analogue scale (VAS) in the morning and in the evening recorded in the patient's diaries (0 represented no pain and 100 represented worst conceivable pain).

## **Secondary outcome measures**

1. Admission to hospital with PGP during the course of the current pregnancy
2. Frequency of sick leave from work due to PGP from initial diagnosis until delivery
3. Representation at the physiotherapy department during the trial period (From initial assessment and diagnosis until the last treatment session)
4. Representation at the physiotherapy department after the trial period (From last treatment session until delivery)
5. Number of patients requiring the combination of crutches and Tubigrip® (elasticated tubular support bandage) during the antenatal period
6. Number of patients induced or delivered earlier than their estimated date of delivery due to severe PGP
7. Patient satisfaction measured via the Client Satisfaction Questionnaire (CSQ-18B) following the third treatment
8. Patient specific functional scale (PSFS). This will be measured at initial assessment and following the third treatment. The PSFS will measure patient's ability to perform 3 out of the 4 following tasks. Each of the 3 tasks chosen by the patient is measured out of 10 and then an average score is taken. A drop of 2 in one of the tasks will be considered as indicating an improvement. A drop of 3 in the overall average of the 3 tasks will also be considered as indicating an improvement.

The 3 tasks will be chosen from:

- a. Turning over in bed
- b. Climbing stairs
- c. Sitting more than 10 minutes
- d. Standing more than 10 minutes

9. Active straight leg raise. This will be measured at initial assessment and following the third treatment. While lying supine with a wedge placed under the women's right side, the patient will be asked to alternatively raise her legs. The patient will be asked to give a score out of 5 for the difficulty level. Scores are indicated as follows

5 = Unable to perform

4 = Very Hard  
3 = Moderately Hard  
2 = Somewhat Hard  
1 = Minimal Difficulty  
0 = No Difficulty

The total score will be marked out of 10 (5 for each leg). A drop in the score of 3 will be considered as indicating an improvement.

- 10. Gestational age at delivery
- 11. Birthweight at delivery
- 12. Mode of delivery: Either normal vaginal delivery, instrumental delivery or caesarean section

**Overall study start date**

01/04/2009

**Completion date**

31/03/2010

## **Eligibility**

**Key inclusion criteria**

Pregnant women (primigravida and multigravida; no age limits) from 20-35 weeks of gestation attending Cork University Maternity Hospital (CUMH) low risk antenatal clinics who are referred to the physiotherapy department by their health care provider or following self referral with back pain or pelvic pain will be assessed for inclusion in the trial. Women referred to the physiotherapy department with symptoms of pelvic girdle pain (PGP) will be assessed on presentation by a one of six departmental physiotherapists specializing in women's health.

To make the diagnosis of PGP the following tests will be performed as per the European Guidelines on the diagnosis and treatment of Pelvic Girdle Pain and a pain history taken as detailed.

**Sacroiliac joint assessment:**

- 1. Posterior pelvic pain provocation test (P4)
- 2. Gaenslen's test
- 3. Compression of anterior superior iliac spines (ASIS)
- 4. Distraction Sacro-Iliac Joint (SIJ) pain provocation test
- 5. Assessment of Sulci depth in lumbar spine in neutral and extension

**Functional pelvic test:**

- 6. Active straight leg raise test (ASLR)

**Pain history (according to the criteria of Ostgaard):**

- 7. It is recommended that a pain history be taken with specific attention paid to pain patterns and irritability of PGP
- 8. There must be no nerve root syndrome
- 9. The severity of pain must be related to motion

The diagnosis of PGP will be made if the patient has two or more of criteria 1-4 (Laslett's criteria) in combination with a negative McKenzie and negative neurological examination. Criteria 5-9 will

be performed and assessed to try and improve diagnostic sensitivity and specificity as well as help exclude other pathologies that may cause pelvic and back pain.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

226

**Key exclusion criteria**

1. Women with other pain conditions, history of orthopaedic disease or surgery in the spine or pelvic girdle systemic disorders or if attending the high risk antenatal clinic in CUMH
2. Women who volunteered a history of sexual abuse at any point of the study
3. Women who do not speak English fluently
4. Women with non viable pregnancies
5. Women who have already received treatment for PGP outside of this trial
6. Pregnant women who present who will not be booking at CUMH for their pregnancy or are not resident in the South West of Ireland
7. Women with a history of severe PGP in previous pregnancies. Severe PGP will be defined as occurring less than 20 weeks gestation in a previous pregnancy or requiring crutches in a previous pregnancy or women with a history of PGP in two or more previous pregnancies.

**Date of first enrolment**

01/04/2009

**Date of final enrolment**

31/03/2010

**Locations****Countries of recruitment**

Ireland

**Study participating centre**

Anu Research Centre

Cork

Ireland

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**Sponsor information**

**Organisation**

Cork University Maternity Hospital (Ireland)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.ucc.ie/en/obsgyn>

**ROR**

<https://ror.org/04q107642>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Cork University Maternity Hospital (Ireland)

**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