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Watching Pregnancy Project (WPP) Investigating pregnancy-related low back pain

Submission date
09/11/2016

Recruitment status
No longer recruiting

Registration date
24/11/2016

Overall study status
Completed

Last Edited
12/01/2023

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims

Many women are thought to experience low back pain (LBP) during their pregnancy, with symptoms typically increasing as pregnancy advances, and often continuing after birth. For many women, pain can become so severe that it leads to daily functional limitations, including time off work and disrupted sleep. There are some studies indicating that women often feel frustrated that their symptoms are not taken seriously, but we know little about the true extent of this problem in Northern Ireland, what treatments are available and how helpful women think these treatments are. Therefore, this study is taking place to find out the best ways to collect information from a group of pregnant women about whether, or not, they develop LBP between their 20-22-week anomaly scan until 6 months after their baby is born. Women taking part in the study will be asked to complete a series of secure online questionnaires (at four different time points, two during pregnancy and two after the birth), that include questions about any previous history and/or new episodes of LBP, types of treatment received and whether it was effective and the amount of pain, disability and avoidance of physical activity they experience, along with the effect on their quality of life. The findings will be used to inform the design of a larger study of this kind in the future aimed at improving the management of pregnancy-related LBP.

Who can participate?

Pregnant women attending the Ulster Maternity Unit for their anomaly scan. They do not have to have LBP to take part.

What does the study involve?

Midwives will direct potential participants to a member of the research team on the day of their 20- to 22-week scan for eligibility screening. This meeting will last for approximately 1 hour, and allows the researcher to check whether or not the participant is eligible to take part and to answer any questions they may have about the study. Eligible participants who give their verbal consent to participate will be asked to complete a study consent form, and complete the first of four secure online questionnaires, distributed by email (within 7 days of their eligibility screening). The second questionnaire will be emailed to consenting participants when they are between 31-34 weeks pregnant and then six weeks and six months after they have had their baby.

What are the possible benefits and risks of participating?
There will be no direct benefit to participants. However, they will have an important input to the future design of services to manage pregnancy-related LBP. Participation will involve a time commitment to complete the questionnaires at each of the follow-ups. Also, there is a risk of participants becoming upset, for example, when answering questions about previous pregnancies. Every step has been taken to minimise these risks.

Where is the study run from?
Ulster Hospital Maternity Outpatients Department (UK)

When is the study starting and how long is it expected to run for?
January 2016 to May 2018

Who is funding the study?
Chartered Society of Physiotherapy Charitable Trust (UK)

Who is the main contact?
1. Dr Sarah Dianne Liddle (public)
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2. Dr Julie McCullough (public)
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Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number
202189

ClinicalTrials.gov number

Secondary identifying numbers
16/NI/0072, IRAS 202189

Study information

Scientific Title
The Watching Pregnancy Project: An exploration of low back pain occurrence, symptoms and healthcare use in pregnant women

Acronym
WPP

Study objectives
Current study hypothesis as of 12/01/2023:
Aim: To conduct a prospective, observational cohort study exploring the low back pain (LBP) history, presentation, progression, healthcare use and subsequent patient-reported outcomes in a sample of pregnant women from initial presentation until 6 months after birth.

Objectives:
1. To determine the feasibility of recruiting pregnant women to the study and collecting the proposed outcomes using a bespoke online questionnaire, and to establish the rates of, and reasons for, attrition over four proposed timepoints.
2. To describe changes in pain, disability, days off work/early maternity leave, health-related quality of life and pain-related fear resulting from pregnancy-related LBP from 20 to 22 weeks' gestation until 6 months after birth.
3. To explore women's self-reported use of healthcare associated with pregnancy-related LBP.

Previous study hypothesis:
The aim of this study is to explore low back pain (LBP) history, presentation, progression, type(s) of treatment and subsequent patient-reported outcomes in a sample of pregnant women from initial presentation until 6 months after birth.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Updated 12/01/2023:
Approved 13/05/2016, HSC REC A, Office for Research Ethics Committees Northern Ireland (Unit 4, Lissue Industrial Estate West, Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 (0)28 95361400), ref: 16/NI/0072

Previous:
Office of Research Ethics Committees Northern Ireland (ORECNI), 12/08/2016, ref: 16/NI/0072

Study design
Single-centre prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Pregnancy-related low back pain

Interventions
Current interventions as of 12/01/2023:
Materials and methods:
Study design and setting:
A single-centre, prospective observational cohort study will be employed, recruiting eligible, consenting pregnant women attending a National Health Service (NHS) maternity outpatient department in a suburban hospital (study recruitment site) over a seven-month period (05/12/2016 to 06/07/2017). Eligible women will be invited to complete a series of online questionnaires throughout the pre- and post-natal period.

Recruitment and participants:
To ensure the study procedures adhere to all data protection issues the midwife will be the initial point of contact with potential participants attending their anomaly scan appointment (20 to 22 weeks gestation): all women deemed potentially eligible by their midwife will be informed of the study. Those expressing an interest in receiving more details with meet with the researcher in charge of recruitment (RA) to be screened for eligibility. Study inclusion and exclusion criteria are listed below;

Inclusion criteria:
1. Pregnant women booked to attend the study recruitment site for their routine 20 to 22-week anomaly scan

2. Fluency in English (verbal and written), access to the internet and basic online literacy (to complete follow-up questionnaires)
3. Willing to take part in the study at all timepoints

Exclusion criteria:
1. Serious spinal pathology, e.g. cancer, cauda equina lesion
2. Diagnosed with severe spinal stenosis, spondylolisthesis, fibromyalgia, scoliosis
3. History of systematic/inflammatory disease
4. Diagnosed with a urinary tract infection (that could manifest as LBP) or other reasons identified by the treating midwife, e.g. social services involved with the mother/family
5. Spinal surgery within the last 12 months
6. Women aged <18 years (as LBP in this subgroup is not representative of the typical LBP population)

All eligible women providing verbal consent to participate will be sent the baseline questionnaire (T0) within 7 days via a unique email link. Those women who provide written consent, and complete the first questionnaire, will be sent three follow-up questionnaires at the following data collection time points:
T1: between 31 to 34 weeks gestation
T2: 6 weeks after birth
T3: 6 months after birth
Of particular importance in any study following pregnant women is to prevent undue distress by ensuring that those women who develop complications at any point, e.g., miscarriage, are withdrawn in a timely manner. To achieve this the RA and trust midwifery team will arrange to meet immediately prior to the due date for sending follow-up questionnaires to confirm ongoing participant eligibility. Women deemed by the midwifery team to be no longer eligible will be withdrawn from the study and sent no further questionnaires.

Data collection:
The study questionnaire will be designed and distributed using Qualtrics software (https://www.qualtrics.com/uk/), which automatically generates a unique questionnaire link when sent to the participant. Access to the questionnaire will be predicated on the completion of written informed consent. Each participant will then be directed to sections covering general demographics (questionnaire 1 only), parity and risk factors for LBP such as; history of LBP, hypermobility and/or amenorrhea, and information about current LBP. For the purposes of this study, LBP is defined as 'pain or discomfort in the area between the lowest rib and the gluteal folds (+/- referral into the lower limb(s)) lasting 7 days or more since the beginning of pregnancy'. Women reporting LBP in questionnaire 1 (T0) will be asked whether they have already received, or been referred for treatment, along with data relating to the following outcomes;
1. Pain intensity and bothersomeness during the last 7 days, using an 11-point numerical rating scale (NRS), along with a brief description of symptoms; intensity and bothersomeness ratings will be averaged to provide a composite pain score. A change of 1.3 points is considered clinically important.
2. LBP-related functional disability measured using the Roland and Morris Disability Questionnaire (RMDQ) consisting of 24 items. The total score can range from 0 (no disability) to 24 (maximum disability). A change of 2 to 3 points has been reported as clinically important, with floor and ceiling effects occurring for baseline scores of <4 or >20 points.
3. Days off work/early maternity leave
4. LBP-related fear-avoidance of physical activity measured using the Fear-avoidance Beliefs Questionnaire Physical Activity Subscale (FABQ-PA). This subscale contains five items, with questions 2 to 5 (scaled from 0 = "completely disagree" to 6 = "completely agree") used to

generate scores ranging from 0 to 24. Higher scores indicate higher levels of fear and beliefs about avoiding activities. A score >14 indicates high avoidance of movement as a result of LBP, whilst a score of <12 is suggestive that fear avoidance is not a key contributor to the individual's LBP.
5. Health-related quality of life measured using EuroQol-5D-5L. A change of between 0.03 and 0.05 in the EuroQol Index and between 8 and 11 points in the EuroQol visual analogue scale (VAS) is considered clinically important.
6. Global perceived effect of treatment measured using the Global Perceived Change Scale (GPCS). A 7-point Likert scale, ranging from 'completely recovered'
to 'worse than ever' will be used and the results will be clustered into three categories; improved (1 or 2), unchanged (3, 4 or 5), and deteriorated (6 or 7).
A change of 2 points is considered clinically important.
It is anticipated that women may develop LBP at different stages of their pregnancy, therefore those women not experiencing LBP at T0 will be asked at each follow-up if they have developed LBP (lasting at least 7 days). Women reporting LBP will be asked to complete outcomes (a) to (f), and provide information about any treatment received or referral for treatment and/or medication used at all subsequent follow-ups. Women who do not report LBP during the course of the study will be asked to complete the EuroQol-5D-5L at each follow-up in order to compare health-related quality of life between participants with and without LBP.

As pregnancy typically introduces challenges to women's daily lives, our Patient, Carer and Public Involvement (PCPI) representative has emphasised the importance of evaluating the value of follow-up reminders to women taking part in the study. For this study, funding is only available to provide email reminders to participants. However, as text reminders are a popular method of follow-up with pregnant women, it is important to establish whether the lack of availability of text reminders in this study influences attrition. Therefore, each participant will be asked at the beginning of the study to identify their preferred method and number of follow-up reminders. At the end of the study, women will also be asked to comment on their experience of taking part in the study, via an exit questionnaire.

Previous interventions:
An online data collection tool (designed using Qualtrics software) will automatically generate a unique identifier for each participant and, once consent has been provided (at the beginning of the questionnaire), participants will be directed to sections on general demographic information, parity and risk factors for LBP such as; history of (low back pain) LBP, hypermobility and/or amenorrhea, and information about current LBP. For the purposes of this study, LBP will be defined using the standard criteria of 'pain or discomfort in the area between the lowest rib and the gluteal folds (+/- referral into lower limb) lasting 7 days or more since the beginning of pregnancy'. Women reporting LBP at baseline (T0) will be asked whether they have already received or been referred for treatment and/or out-of-pocket expenses incurred for treatment, along with data relating to:
1. Pain intensity and bothersomeness
2. LBP-related functional disability (using the Roland Morris Disability Questionnaire)
3. Days off work/early maternity leave
4. LBP-related fear
5. Health-related quality of life
6. Global perceived effect of treatment

The questionnaires will be completed at the anomaly scan between 20 to 22 weeks gestation; between 31 to 34 weeks gestation; 6 weeks postpartum; and 6 months postpartum.

Intervention Type

Other

Primary outcome measure

Current primary outcome measure as of 12/01/2023:
As this study will be the first of its kind to be carried out in a UK healthcare setting, a key outcome will be to determine the feasibility of recruiting pregnant women to the study over a 7-month recruitment period and to establish rates of, and reasons for, attrition over the four proposed study time points, i.e. 20-22 weeks gestation until 6 months after birth.

Previous primary outcome measure:
Feasibility of recruitment and retention of pregnant women is recorded using the online questionnaire within the timeframe of the study namely beginning at 20 to 22 weeks' gestation, again at 31 to 34 weeks' gestation, at 6 week's post-partum, and finally 6 month's post-partum.

Secondary outcome measures

Current secondary outcome measures as of 12/01/2023:
To describe women's lived experience of this condition in more detail than we are currently able to do (using the six patient-reported outcome measures listed below. To describe women's use of, and satisfaction with, healthcare associated with pregnancy-related LBP (including NHS and out-of-pocket expenses).
The following outcomes will be included in the online study questionnaire:
1. Pain intensity and bothersomeness measured using an 11-point numerical rating scale (NRS)
2. LBP-related functional disability assessed using the Roland Morris Disability Questionnaire
3. Days off work/early maternity leave
4. LBP-related fear-avoidance of physical activity using the Fear-Avoidance Beliefs Questionnaire Physical Activity Subscale
5. Health-related quality of life using the EuroQol-5d-5l
6. Global perceived effect of treatment using the Global Perceived Change Scale
All outcomes will be collected at T0 (20-22 weeks gestation), T1 (31-34 weeks gestation), T2 (6 weeks postpartum) and T3 (6 months postpartum)

Previous secondary outcome measures:
1. Pain intensity and bothersomeness are measured using an 11-point numerical rating scale (NRS)
2. LBP-related functional disability is assessed using the Roland Morris Disability Questionnaire
3. Days off work/early maternity leave is assessed using an online questionnaire
4. LBP-related fear is measured using the Fear-Avoidance Beliefs Questionnaire
5. Health-related quality of life is measured using the EuroQol-5d-5l
6. Global perceived effect of treatment is measured using the Global Perceived Change Scale
7. Use of and satisfaction with, health care (including NHS and out-of-pocket expenses) associated with pregnancy-related LBP are measured using an online questionnaire

All outcomes are assessed at T0 (20-22 weeks gestation), T1 (31-34 weeks gestation), T2 (6 weeks postpartum) and T3 (6 months postpartum)

Overall study start date

19/01/2016

Completion date

31/05/2018

Eligibility

Key inclusion criteria
Current inclusion criteria as of 12/01/2023:
1. Pregnant women attending the study recruitment site for their 20 to 22-week anomaly scan
2. Willing to take part in the study at all time points
3. Fluency in English (verbal and written)
4. Access to, and basic IT literacy (to complete follow-up questionnaires)
5. Aged >18 years

Previous inclusion criteria:
1. All pregnant women attending the South Eastern Health and Social Care Trust for 20 to 22-week anomaly scan
2. Willing to take part in the study at all time points
3. Fluency in English (verbal and written)
4. Access to, and basic IT literacy (to complete follow-up questionnaires)
5. Aged 18-65 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
600 pregnant women

Total final enrolment
477

Key exclusion criteria
Current exclusion criteria as of 12/01/2023:
1. Red flags indicating serious spinal pathology, e.g. cancer, cauda equina lesion
2. Diagnosed with severe spinal stenosis, spondylolisthesis, fibromyalgia, scoliosis
3. History of systematic/inflammatory disease
4. Spinal surgery within the last 12 months
5. Diagnosed with urinary tract infection (that may manifest as LBP) or other reasons identified by the treating midwife, e.g. social services involved with the mother/family

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1. Red flags indicating serious spinal pathology, e.g. cancer, cauda equina lesion
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3. History of systematic/inflammatory disease
4. Spinal surgery within the last 12 months
5. Diagnosed with urinary tract infection (that may manifest as LBP)

Date of first enrolment
05/12/2016

Date of final enrolment
06/07/2017

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Ulster Hospital
Maternity Outpatients Department
Upper Newtownards Road
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United Kingdom
BT16 1RH

Sponsor information

Organisation
Ulster University

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United Kingdom
BT37 0QB

Sponsor type
University/education

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Charity

Funder Name
Chartered Society of Physiotherapy Charitable Trust (CSPCT)

Results and Publications

Publication and dissemination plan
Dissemination of the study findings are planned for publication in a high-impact peer reviewed journal, internal reports, at national and international conferences and publication on Chartered Society of Physiotherapy and Ulster University Institute of Nursing and Health Research websites.

Intention to publish date
12/02/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository (Ulster University's research data repository).

Added 12/01/2023:
The name of the repository: Ulster University's Research Portal
A persistent weblink to the dataset (if applicable): https://doi.org/10.21251/a4072bc1-fae4-49f0-85e0-82df675bed7c
The type of data stored: SPSS format anonymised raw data
The process for requesting access (if non-publicly available): Not applicable
Date made available: 12/01/2023
Whether consent from participants was required and obtained: participants gave their consent for anonymised raw data to be made available as part of the publication of the study findings
Comments on data anonymization: all publicly available data related to the study is anonymised in line with standard ethical requirements
Any ethical or legal restrictions: none other than anonymisation
Any additional comments: none

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		12/01/2023	12/01/2023	No	No
Dataset		01/01/2023	12/01/2023	No	No
HRA research summary			28/06/2023	No	No