

Guided self-help for women with chronic pelvic pain (CPP) in primary care

Submission date 21/10/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/05/2017	Condition category Signs and Symptoms	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8336

Study information

Scientific Title

An exploratory randomised controlled trial of guided self-help for women with chronic pelvic pain (CPP) in primary care

Acronym

SUPPORT

Study objectives

This is a pilot trial of an evidence-based self-care guide for women with chronic pelvic pain that will be facilitated by their GP. The trial aims to assess the effects of the guide on: pain and symptom severity; psychological wellbeing (anxiety and depression); health-related quality of life; self-efficacy; sexual relationships; work life; use of healthcare services. Participating GPs will receive training to use the guide within their consultations. Women will be randomised to either receive the facilitated self-care guide or usual care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Northwest 2 Liverpool Central REC, 04/05/2010, ref: 10/H1005/24

Study design

Single-centre randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

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

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

This is a pilot trial of an evidence-based self-care guide for women with CPP that will be facilitated by their GP.

The guide contains information about chronic pelvic pain, what it is, how it presents, possible causes, and potential treatment and management strategies. Assessment, investigations and common diagnoses are explained. A specific section of the guide addresses the possibility that no diagnosis will be found to account for the woman's pain. The guide provides advice on pain management, lifestyle and social factors and coping with psychological distress. The guide uses positive language and encourages partnership between the woman and her GP.

Delivery of the intervention:

Group 1: women in Group 1 will receive the self-help guide from their GP. The GP will facilitate the guide in a consultation, focussing on issues which the patient identifies as priority areas.

Group 2: patients allocated to Group 2 will continue to receive their routine care as defined by their GP.

Assessments - timing and administration:

Women who consent to participate in the trial will have data collected on entry to the trial, at 6 months and 1 year later. Initial data collection (baseline and 6 months) will be conducted pre- and post-delivery of the guide. Questionnaires will be administered by post with telephone support (if required) from the Trial Coordinator. Data collection at 1 year will assess longer term outcomes.

Study entry:

Single randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Reduction in pain and symptom severity, measured at 6 months and 12 months

Secondary outcome measures

1. Health-related quality of life, measured at 6 months and 12 months
2. Psychological wellbeing (anxiety and depression), measured at 6 months and 12 months
3. Self-efficacy, measured at 6 months and 12 months
4. Sexual relationships, measured at 6 months and 12 months
5. Use of healthcare services, measured at 6 months and 12 months
6. Work life, measured at 6 months and 12 months

Overall study start date

01/11/2010

Completion date

31/12/2011

Eligibility

Key inclusion criteria

1. Aged 18 years and above, female
2. Pelvic pain greater than 3 months duration

3. Pain not necessarily related to menstrual cycle or sexual activity
4. Has a common diagnosis which falls under the umbrella of CPP
5. Has a symptom profile attributed to CPP, in the absence of a diagnosis

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

Planned sample size: 140

Key exclusion criteria

1. Pregnancy or within 12 months of delivery
2. Serious underlying pathology
3. Insufficient English to engage in self-help
4. Participation in other pain management research

Date of first enrolment

01/11/2010

Date of final enrolment

31/12/2011

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

School of Nursing, Midwifery and Social Work

Manchester

United Kingdom

M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

School of Nursing, Midwifery and Social Work
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Manchester
England
United Kingdom
M13 9PL

Sponsor type

University/education

Website

<http://www.manchester.ac.uk/>

ROR

<https://ror.org/027m9bs27>

Funder(s)**Funder type**

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB)
Programme (ref: PB-PG-0408-16192)

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