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

Submission date 21/10/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/10/2010	**Overall study status** Completed	
Last Edited 11/05/2017	**Condition category** Signs and Symptoms	

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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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