ISRCTN21012555 https://doi.org/10.1186/ISRCTN21012555

A randomised trial of group-delivered cognitive behavioural therapy versus standard pain clinic treatment for chronic pelvic pain

Submission date
24/02/2011

Recruitment status
No longer recruiting

Registration date
31/03/2011

Overall study status
Completed

Last Edited
06/11/2019

Condition category
Urological and Genital Diseases

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

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2010UROL02

Study information

Scientific Title
Self Management Activation Randomised Trial for Prostatitis (SMART-P)

Acronym
SMART-P

Study objectives
The main objective of the study is to show that a programme of group-directed cognitive behavioural therapy for men with chronic pelvic pain is more effective than standard therapy (pain relief and coping mechanisms delivered by the pain clinic). This will be evaluated by changes in the National Institute of Health Chronic Pelvic Pain Score (NIH-CPPS), a validated scoring system for assessing the severity of the condition which will be measured before and after the intervention.

Chronic prostatitis is a severe, debilitating chronic illness suffered by a considerable number of men. A universally effective treatment is lacking which can be frustrating for clinicians and distressing for patients. We aim to improve the treatment of these patients by combining cognitive behavioural therapy, which has been shown to be effective for chronic pain conditions including chronic prostatitis, with group-directed self management which has been shown to be effective for a number of other chronic diseases.

We propose to randomise patients to either a self management health and care education programme or to pain clinic referral alone (standard care). We believe that a randomised controlled trial is the most robust method of evaluation of our approach, and will allow us to compare to current available treatment in a scientific manner.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norfolk Research Ethics Committee approved on 19th January 2011, ref: 11/H0310/6

Study design
Randomised controlled 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
Chronic prostatitis/Chronic pelvic pain syndrome

Interventions
Men will be randomised to attend either a self management health and care education programme or to pain clinic referral alone.

Standard care
After exclusion of a treatable bacterial cause for CP/CPPS, referral to pain clinic will be as a result of agreement between clinician and patient. Pharmacological agents such as gabapentin, pregabalin and antidepressants are the mainstay of standard care at present.

Intervention
This group will take part in a course of six weekly small group sessions (five to eight men) developed in conjunction with experts in psychology, pain management and urology, each lasting one hour with a focus on:
1. Understanding physiology of pain
2. Psychological contributors
3. Pain-coping mechanisms
4. Behavioural responses
5. Prevention, rehabilitation and re-enablement
6. Relationships between symptom distress, emotion and pain

We will design the sessions to enable the participants to learn techniques of problem solving and goal setting. Supported self care and co-production will be the underlying principles of this programme. The initial session is an introduction to the programme requirements, the rationale and the value of the approach. In early sessions , patients are instructed in the use of the Reaction Record for self-identifying and modifying catastrophic cognition and in understanding how such thinking is associated with greater negative affect, how there is little supportive evidence for such thinking, and how it can lead to poor choices in behavioural coping. During following sessions, patients identify and modify deficits in social support by practicing self-assertion communication exercises with their instructor and then later with significant others in their lives while using the Reaction Record to examine how to better negotiate distressing episodes. Further sessions use the Reaction Record tool to identify and modify illness-focused behavioural coping strategies and also to help re-engage the patient in physical and social activities that they may have abandoned. In the final session, patients are provided with a detailed review of their acquired behavioural modifications. Following this discussion, patients are instructed on continued problem-solving skills and future self-management challenges are discussed.

At 2, 6, and 12 months, clinicians not involved in the conduct of the trial will review participants in the urology outpatient departments and perform NIH-CPPS assessment (a validated pain-score for chronic pelvic pain).

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
1. Changes in the National Institute of Health Chronic Pelvic Pain Score (NIH-CPPS), a validated scoring system for assessing the severity of the condition which will be measured before and after the intervention.

Secondary outcome measures
1. Assess functional status (Hospital Anxiety and Depression (HAD) and SF-36 score)
2. Changes in requirements for pain-relief medication will also be used as a measure of effectiveness
3. Patients degree of self-management/activation will be assessed by the PAM questionnaire

The outcomes will be measured before and after the intervention.

Overall study start date
25/03/2011

Completion date
24/03/2012

Eligibility

Key inclusion criteria
1. Men with chronic prostatitis (CP)/chronic pelvic pain syndrome (CPPS) refractory to simple pharmacological manipulation from general urology clinics at Norfolk and Norwich University hospitals (NNUH)
2. All patients aged over 18 with a diagnosis of CP/CPPS made by a urologist referred for the first time by their GP
3. Patients must be refractory to antibiotic treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
120

Key exclusion criteria

1. Abnormal serum prostate specific antigen (PSA) level
2. Suspected prostate cancer on digital rectal examination
3. Active urinary tract infection
4. Alternative cause for pain found by urologist (e.g. ureteric calculus)

Date of first enrolment
25/03/2011

Date of final enrolment
24/03/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Urology
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Sponsor information

Organisation
Norfolk and Norwich University Hospitals NHS FoundationTrust (UK)

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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/01wspv808

Funder(s)

Funder type
Government

Funder Name
Health Enterprise East Ltd (UK)-Regional Innovation Fund

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	study protocol	26/09/2011		Yes	No