

Managing Unexplained Symptoms (chronic widespread pain) In primary Care: Involving traditional and Accessible New approaches

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Registration date 10/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/10/2015	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Arthritis Research Campaign (ARC) ID number: 17292

Study information

Scientific Title

Managing Unexplained Symptoms (chronic widespread pain) In primary Care: Involving traditional and Accessible New approaches

Acronym

MUSICIAN

Study objectives

Chronic Widespread Pain (CWP) is the cardinal feature of the fibromyalgia syndrome. It has a population prevalence of approximately 13% in the UK and is amongst the most common reasons for referral to a rheumatologist. Managing patients with chronic widespread pain is difficult. No individual management modality (pharmacological, physical, psychological therapies) has been demonstrated to be effective in relieving symptoms. Treatment is often prolonged and improvement likely to occur slowly. There is a need therefore to develop interventions at a primary care level that are potentially available to a large number of patients, which result in an improvement of symptoms, are acceptable and convenient to patients, and ideally which are inexpensive to provide.

Hypothesis:

Amongst patients with "unexplained" chronic widespread musculoskeletal pain that in addition to usual care:

1. A telephone-based Cognitive Behavioural Therapy (CBT) programme
2. Prescribed exercise
3. A combination of both treatments

will improve pain and disability in the short (6 months) and medium (9 months) term, in comparison to patients receiving "usual care" only.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cheshire Research Ethics Committee, 04/07/2007, REC ref: 07/Q1506/61

Study design

Multicentre 2 x 2 factorial design randomised controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic Widespread Pain (CWP)

Interventions

When eligibility is established and consent is obtained, subjects will be randomly allocated into one of four treatment groups, stratified by two important predictors of outcome: initial chronic pain grade score (I/II/III/IV) and by psychological distress (high/low). The four groups, which will be of equal size are:

Group 1: telephone-based CBT intervention (10 sessions in total)

Group 2: prescribed exercise intervention in a local leisure facility under the supervision of a

fitness instructor (2 - 3 times a week)

Group 3: telephone-based CBT and prescribed exercise intervention

Group 4: treatment as usual

Each patient will receive the intervention for a period of 6 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The primary outcome of the trial will be a self-rated clinical global impression change score at 6 (end of intervention) and 9 months post-randomisation. This is a seven-point scale measuring how participants feel that their health has changed since the period prior to entering the trial. It ranges from "I feel much worse" (score 1) to "I feel better" (score 6) and "I feel much better" (score 7).

Key secondary outcome(s)

1. Pain
2. Fatigue
3. Coping
4. Psychological distress
5. Sleep problems
6. Fear of movement
7. Quality of life
8. Treatment side-effects

This corresponds to the recommendations of core outcome domains for chronic pain clinical trials, and outcomes considered by the Outcome Measures in Rheumatology Clinical Trials initiative. All secondary outcomes will be measured at 6 and 9 months post-randomisation.

Completion date

30/09/2010

Eligibility

Key inclusion criteria

1. Satisfy the American College of Rheumatology (ACR) definition of Chronic Widespread Pain (CWP) as used in the criteria for fibromyalgia
2. Symptoms have an impact on physical function as assessed by the Chronic Pain Grade Questionnaire
3. Consulted their general practitioner because of these symptoms within the past year
4. Have access to a landline telephone
5. Age above 25 years (both genders will be included)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients who have contraindications for prescribed exercise or cognitive behavioural therapies, as determined by their GPs or the research nurse.

Date of first enrolment

01/10/2007

Date of final enrolment

30/09/2010

Locations**Countries of recruitment**

United Kingdom

Scotland

Study participating centre

University of Aberdeen

Aberdeen

United Kingdom

AB25 2ZD

Sponsor information**Organisation**

University of Aberdeen (UK)

ROR

<https://ror.org/016476m91>

Funder(s)**Funder type**

Charity

Funder Name

Arthritis Research Campaign (UK) (ref: MUSICIAN ID number: 17292)

Results and Publications

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?
Results article	results	09/01/2012		Yes	No
Results article	results	18/02/2015		Yes	No