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

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| **Submission date**<br>12/09/2007 | **Recruitment status**<br>No longer recruiting |
| **Registration date**<br>10/10/2007 | **Overall study status**<br>Completed |
| **Last Edited**<br>29/10/2015 | **Condition category**<br>Musculoskeletal Diseases |

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### 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 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 measure
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).

## Secondary outcome measures
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.

## Overall study start date
01/10/2007

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
552 patients

### 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
Scotland

United Kingdom

### Study participating centre
**University of Aberdeen**
Aberdeen
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# Sponsor information

**Organisation**
University of Aberdeen (UK)

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**Sponsor type**
University/education

**Website**
http://www.abdn.ac.uk/r&i/

**ROR**
https://ror.org/016476m91

# Funder(s)

**Funder type**
Charity

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

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