

# Development and evaluation of a fibromyalgia self-management programme

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|--|---|--|
| <b>Submission date</b><br>12/09/2003   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>12/09/2003 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>12/05/2009       | <b>Condition category</b><br>Musculoskeletal Diseases | <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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N0077117143

# Study information

## Scientific Title

## Study objectives

Null hypothesis: there is no significant difference in health status between people with fibromyalgia attending a relaxation programme and self management programme incorporating psycho-educational approaches.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Fibromyalgia

## Interventions

91 patients with fibromyalgia will be recruited over a 1 year period and randomly allocated to attend either a self-management programme or a relaxation programme. The self-management programme uses educational and behavioural strategies to increase use of self management methods. Both consist of 10 meetings. Outcomes will be evaluated using a self-report questionnaire mailed out before and at 4 and 10 months after intervention.

## Intervention Type

Other

## Phase

Not Applicable

## Primary outcome measure

Measures of adherence with self-management strategies, functional, psychological and health status as well as demographic and health care utilisation information.

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/09/2002

### **Completion date**

31/05/2005

## **Eligibility**

### **Key inclusion criteria**

People with fibromyalgia (diagnosed by Consultant Physician) attending the Rheumatology Department, aged over 18 years, able to read English.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Not Specified

### **Target number of participants**

91

### **Key exclusion criteria**

People with severe disease/functional/psychological problems will be excluded.

### **Date of first enrolment**

01/09/2002

### **Date of final enrolment**

31/05/2005

## **Locations**

### **Countries of recruitment**

England

United Kingdom

**Study participating centre**  
Southern Derbyshire Acute Hospitals NHS Trust  
Derby  
United Kingdom  
DE1 2QY

## **Sponsor information**

**Organisation**  
Department of Health (UK)

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Southern Derbyshire Acute Hospitals NHS Trust (UK)

## **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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/10/2006   |            | Yes            | No              |