

# Development and evaluation of a fibromyalgia self-management programme

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/05/2009	<b>Condition category</b> 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

**Contact name**  
Dr A Hammond

**Contact details**  
Southern Derbyshire Acute Hospitals NHS Trust  
Department of Rheumatology  
Derbyshire Royal Infirmary  
London Road  
Derby  
United Kingdom  
DE1 2QY  
+44 (0)1332 347141 Ext 2418

## 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