

# A randomised controlled trial of exercise prescription on Fibromyalgia (The Fibromyalgia Intervention Trial:- FIT)

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/01/2010	<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 Selwyn Richards

### Contact details

Kings Healthcare NHS Trust

Dept of Rheumatology

Poole NHS Trust

Poole

United Kingdom

BH15 2JB

+44 (0)20 7346 6195

selwyn.richards@kcl.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

## Acronym

FIT

## Study objectives

To evaluate the efficacy of a class based exercise prescription program for fibromyalgia (FM). The assessment was performed by a randomised controlled trial comparing the active treatment of graded aerobic fitness exercise to a control treatment of relaxation and flexibility.

## 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

Fibromyalgia

## Interventions

1. Graded aerobic fitness programme (intervention)
2. Programme of relaxation and flexibility

## Intervention Type

Other

## Phase

Not Applicable

**Primary outcome measure**

Participants' self assessment of improvement, tender point count, impact of condition measured by fibromyalgia impact questionnaire, and short form McGill pain questionnaire.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

30/09/1998

**Completion date**

30/12/2000

**Eligibility****Key inclusion criteria**

Fibromyalgia

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

132 (added 12/01/10, see publication)

**Key exclusion criteria**

Inability to attend classes

**Date of first enrolment**

30/09/1998

**Date of final enrolment**

30/12/2000

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Kings Healthcare NHS Trust**  
Poole  
United Kingdom  
BH15 2JB

## **Sponsor information**

### **Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

### **Sponsor details**

The Department of Health  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

### **Sponsor type**

Government

### **Website**

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

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

NHS Executive London (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	27/07/2002		Yes	No