

Development and evaluation of a fibromyalgia self-management programme

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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

Southern Derbyshire Acute Hosptials NHS Trust

Derby

United Kingdom

DE1 2QY

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Southern Derbyshire Acute Hospitals NHS Trust (UK)

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 | 01/10/2006 | | Yes | No |