

# A randomised controlled trial to evaluate the effectiveness of a combined education and pool-based exercise programme and usual care in the treatment of patients with fibromyalgia syndrome

|                                        |                                                       |                                                      |
|----------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>12/09/2005   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                       | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>31/10/2005 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                       | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>16/06/2008       | <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

### Contact name

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## Additional identifiers

### Protocol serial number

PRF/02/3; 02/04

# Study information

## Scientific Title

## Acronym

The NIFTY Trial (The Northern Ireland Fibromyalgia Therapy Trial)

## Study objectives

To determine the effectiveness of conventional treatment and a combined education and pool-based exercise programme for patients recently diagnosed with fibromyalgia syndrome (FMS).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval was granted prior to commencement of participant recruitment.

## Primary study design

Interventional

## Study design

Randomised controlled trial

## Study type(s)

Treatment

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

Fibromyalgia

## Interventions

Intervention Group: Patients allocated to the intervention group will receive a package of treatment consisting of:

1. A series of lectures/workshops aimed at addressing patients attitudes, beliefs and behaviours with respect to FMS
2. A 6 week programme of pool-based aerobic exercises

The education and exercise interventions will be provided by suitably qualified and experienced occupational therapists and physiotherapists.

Control: Usual care

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome(s)

Fibromyalgia Impact Questionnaire.

**Key secondary outcome(s)**

1. Tender point count and Total myalgic score
2. The 6-minute walk test
3. The Arthritis Impact Measurement Scales II (AIMS2)
4. McGill Pain Questionnaire

**Completion date**

01/03/2006

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

1. Women between the ages of 18 and 65 years. (If of childbearing age, state that they are not pregnant.)
2. Fulfil the 1990 American College of Rheumatology diagnostic criteria for fibromyalgia (i.e. at least a 3-month history of widespread pain in conjunction with tenderness at 11 of 18 specific tender points)
3. Able to attend and participate in a 6 week programme of moderate intensity exercise in a hydrotherapy pool
4. Diagnosed by a consultant rheumatologist with FMS within the previous 3 months
5. Give written informed consent to take part in the trial
6. Literate

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Key exclusion criteria**

1. Have concomitant medical illness (e.g. ischaemic heart disease, cerebrovascular accident) that would make participation in an exercise class unsafe
2. Are involved in ongoing litigation involving FMS
3. Score of less than 3 on a 10-point visual analogue scale (VAS) for pain (a low level cut off will avoid floor effects)
4. Have received physiotherapy within the last 3 months for FMS

**Date of first enrolment**

01/03/2003

**Date of final enrolment**

01/03/2006

## Locations

### Countries of recruitment

United Kingdom

Northern Ireland

### Study participating centre

School of Health Sciences

Belfast

United Kingdom

BT37 0QB

## Sponsor information

### Organisation

University of Ulster (UK)

### ROR

<https://ror.org/01yp9g959>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Physiotherapy Research Foundation (UK) (ref: PRF/02/3)

## 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? |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Abstract results</a> | Abstract: McVeigh JG, Hurley DA, Basford JR, Sim J, Baxter GD, Finch MB<br>Effectiveness of a combined pool-based exercise and education programme compared to usual medical care in fibromyalgia syndrome: a randomised, controlled trial. Physical Therapy Reviews, Volume , Number 3, September 2006, pp. 205-228(24) - | 01/06 /2006  |            | No             | No              |