

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

Submission date

12/09/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

31/10/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

16/06/2008

Condition category

Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Joseph McVeigh

Contact details

School of Health Sciences

University of Ulster

Jordanstown

Newtownabbey

Belfast

United Kingdom

BT37 0QB

+44 (0)28 90368148

j.mcveigh@ulster.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Fibromyalgia Impact Questionnaire.

Secondary outcome measures

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

Overall study start date

01/03/2003

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

156

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**

Northern Ireland

United Kingdom

Study participating centre

School of Health Sciences

Belfast

United Kingdom

BT37 0QB

Sponsor information**Organisation**

University of Ulster (UK)

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Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

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

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?
Abstract results	Abstract: McVeigh JG, Hurley DA, Basford JR, Sim J, Baxter GD, Finch MB 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