

Efficacy of Acupuncture in the Treatment of Fibromyalgia

Submission date 20/08/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/08/2011	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R01 AT00003

Study information

Scientific Title

Study objectives

Not provided at time of registration

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)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Fibromyalgia (FM)

Interventions

One hundred FM patients will participate in a 12-week trial.

These patients will be randomized into 3 control groups and 1 "true" acupuncture group. The control groups will consist of a group receiving acupuncture treatment for an unrelated condition (morning sickness), a group receiving needle insertion at non-channel, non-point locations, and a "true" placebo group.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The primary outcome was subjective pain as measured by a 10-cm visual analogue scale ranging from 0 (no pain) to 10 (worst pain ever). Measurements were obtained at baseline; 1, 4, 8, and 12

weeks of treatment; and 3 and 6 months after completion of treatment. Participant blinding and adverse effects were ascertained by self-report. The primary outcomes were evaluated by pooling the 3 sham-control groups and comparing them with the group that received acupuncture to treat fibromyalgia.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2001

Completion date

01/09/2002

Eligibility

Key inclusion criteria

Male or Female, aged 18 and over with Fibromyalgia

Participant type(s)

Patient

Age group

Not Specified

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2001

Date of final enrolment

01/09/2002

Locations

Countries of recruitment

United States of America

Study participating centre
University of Washington
Seattle
United States of America
98101

Sponsor information

Organisation

National Center for Complementary and Alternative Medicine (NCCAM) (USA)

Sponsor details

6707 Democracy Blvd room 401
Bethesda
United States of America
20892

Sponsor type

Research organisation

ROR

<https://ror.org/00190t495>

Funder(s)

Funder type

Government

Funder Name

National Center for Complementary and Alternative Medicine (NCCAM) (USA)

Alternative Name(s)

NCCAM

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

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?
Results article	Results	05/07/2005		Yes	No