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Efficacy of Acupuncture in the Treatment of Fibromyalgia

Submission date	Recruitment status	[ ] Prospectively registered
20/08/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/08/2011	Musculoskeletal Diseases	

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