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Effects of a meditation program on symptoms of illness in fibromyalgia

Submission date	Recruitment status	[ ] Prospectively registered
15/04/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/06/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/12/2014	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
N/A

Study information

Scientific Title
Effects of a meditation program on symptoms of illness in fibromyalgia

Study objectives
Participation in a mindfulness-based stress reduction will reduce symptoms of illness in fibromyalgia

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Louisville; full ethical approval details not yet received as of 22/06/06

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 syndrome

Interventions
Mindfulness-based stress reduction (MBSR) versus usual care

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Pain, sleep, impairment, depressive symptoms and neuroendocrine function

Secondary outcome measures
Quality of life

Overall study start date
01/01/2000

Completion date
01/01/2003

Eligibility

Key inclusion criteria
1. Over age 18
2. Confirmed American College of Radiology (ACR) diagnosis of fibromyalgia
3. Available to participate in a weekly group program for eight weeks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
91

Key exclusion criteria
Active psychosis

Date of first enrolment
01/01/2000

Date of final enrolment
01/01/2003

Locations

Countries of recruitment
United States of America

Study participating centre
University of Louisville
Louisville, KY

United States of America
40292

Sponsor information

Organisation
University of Louisville Intramural Research Program (USA)

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Sponsor type
University/education

ROR
https://ror.org/01ckdn478

Funder(s)

Funder type
University/education

Funder Name
University of Louisville (intramural research grant) - USA

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	15/02/2007		Yes	No
Results article	results	01/06/2015		Yes	No