ISRCTN71091471 https://doi.org/10.1186/ISRCTN71091471

The prevalence and associations of fatigue in Systemic Lupus Erythematosus (SLE) and the effects of aerobic exercise on fatigue and sleep patterns in SLE

Submission date
18/07/2002

Recruitment status
No longer recruiting

Registration date
18/07/2002

Overall study status
Completed

Last Edited
05/01/2011

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
T0519

Study information

Scientific Title

Study objectives
To test the efficacy of a graded aerobic exercise programme in treating fatigue in systemic lupus erythematosus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was obtained from the district research ethics committee and all subjects gave valid and informed consent before entering the study.

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
Systemic lupus erythematosus (SLE)

Interventions
Allocation using a minimisation protocol to 12 weeks of either graded exercise therapy, relaxation therapy or no intervention

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Self-rated clinical global impression change score, measured at baseline and three months.

Secondary outcome measures
1. Assessments of symptoms, measured at baseline and three months
2. Functional capacity, measured at baseline and three months
3. Fitness, measured at baseline and three months

Overall study start date
01/01/2001

Completion date
01/01/2003

Eligibility

Key inclusion criteria
Female patients fulfilling American College of Rheumatology (ACR) classification for SLE

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
93

Key exclusion criteria
1. Evidence of active severe myositis, nephritis, neurological involvement or cardiac or pulmonary disease
2. Pregnant patients
3. Patients under 16 or over 55 years

Date of first enrolment
01/01/2001

Date of final enrolment
01/01/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Lupus Research Unit
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

Sponsor details
Copeman House
St Mary's Gate
Chesterfield
United Kingdom
S41 7TD
+44 (0)300 790 0400
enquiries@arthritisresearchuk.org

Sponsor type
Charity

Website
http://www.arc.org.uk

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (UK)

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	01/09/2003		Yes	No