

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

<b>Submission date</b> 18/07/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/07/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/01/2011	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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](mailto: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?
<a href="#">Results article</a>	results	01/09/2003		Yes	No