

# 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

☐ Prospectively registered

☐ Protocol

**Registration date**  
18/07/2002

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
05/01/2011

**Condition category**  
Musculoskeletal Diseases

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr David D'Cruz

### Contact details

The Lupus Research Unit  
The Rayne Institute  
St Thomas' Hospital  
Lambeth Palace Road  
London  
United Kingdom  
SE1 7EH

## Additional identifiers

### Protocol serial number

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

### Study type(s)

Treatment

### 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(s)

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

### Key secondary outcome(s)

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

### Completion date

01/01/2003

## Eligibility

### Key inclusion criteria

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

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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**

United Kingdom

England

**Study participating centre**

The Lupus Research Unit

London

United Kingdom

SE1 7EH

## **Sponsor information**

**Organisation**

Arthritis Research Campaign (ARC) (UK)

ROR

https://ror.org/02jkpm469

## Funder(s)

### Funder type

Charity

### Funder Name

Arthritis Research Campaign (UK)

## Results and Publications

### 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