

# Early intervention in fatigue: a feasibility study

<b>Submission date</b> 17/05/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/05/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/05/2020	<b>Condition category</b> Nervous System 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

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## Additional identifiers

**Protocol serial number**  
11924

## Study information

**Scientific Title**  
Early intervention in fatigue: a feasibility study

**Study objectives**

The overall aim of this study is to investigate the feasibility and acceptability of conducting a randomised controlled trial (RCT) to investigate the effectiveness and cost effectiveness of early intervention for chronic fatigue syndrome (CFS)/myalgic encephalomyelitis (ME) compared with standard medical care in primary care.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Multicentre Research Ethics Committee (MREC), 19/01/2012, ref: 11/SW/0301

### **Study design**

Randomised; Interventional; Design type: Prevention, Treatment

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: Chronic fatigue syndrome (CFS)/ myalgic encephalomyelitis (ME)

### **Interventions**

Early intervention for fatigue. The intervention is based on the principles of cognitive, behavioural and graded exercise and is delivered by a trained therapist as an individual face to face session with telephone follow-up sessions. Follow up length: 6 month(s); Study entry: single randomisation only

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Recruitment, adherence and follow up. Timepoint(s): 3 and 6 months

### **Key secondary outcome(s)**

Not provided at time of registration

### **Completion date**

31/10/2014

## **Eligibility**

### **Key inclusion criteria**

1. Adult patients (over 18) presenting with an unexplained primary complaint of fatigue, as a new episode, lasting more than one month but less than four
2. Patient has given written informed consent
3. The participant has a Chalder Fatigue score >4 (screened by trial manager); target gender: male and female; lower age limit: 18 no age limit or unit specified

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

44

**Key exclusion criteria**

Patients where fatigue is due to another cause. This means that GPs will not refer patients with an active illness such as cancer, liver cirrhosis etc.

**Date of first enrolment**

05/05/2012

**Date of final enrolment**

31/10/2014

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Frenchay Hospital

Bristol

United Kingdom

BS16 1LE

# Sponsor information

## Organisation

North Bristol NHS Trust (UK)

## ROR

<https://ror.org/036x6gt55>

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research (Grant Codes: PB-PG-1010-23253)

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# 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	12/05/2020	26/05/2020	Yes	No
<a href="#">Basic results</a>		27/03/2019	27/03/2019	No	No