

Early intervention in fatigue: a feasibility study

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

05/05/2012

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 100; UK Sample Size: 100

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

England

United Kingdom

Study participating centre

Frenchay Hospital

Bristol

United Kingdom

BS16 1LE

Sponsor information

Organisation

North Bristol NHS Trust (UK)

Sponsor details

Trust Headquarters

Beckspool Road

Frenchay

Bristol

England

United Kingdom

B16 1JE

Sponsor type

Hospital/treatment centre

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

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?
Basic results		27/03/2019	27/03/2019	No	No
Results article	results	12/05/2020	26/05/2020	Yes	No