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Early intervention in fatigue: a feasibility study

Submission date
17/05/2013

Recruitment status
No longer recruiting

Registration date
17/05/2013

Overall study status
Completed

Last Edited
26/05/2020

Condition category
Nervous System 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
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 efffectiveness 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 telelphone 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