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Graded Exercise Therapy guided SElf-help Treatment for CFS/ME

Submission date
24/05/2012

Recruitment status
No longer recruiting

Registration date
24/05/2012

Overall study status
Completed

Last Edited
27/06/2017

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic fatigue syndrome, also known as myalgic encephalomyelitis (CFS/ME), is a chronic disabling condition of no known cause. It affects about one in a hundred people. Guidelines recommend graded exercise therapy (GET) as one of only two treatments for which there is research evidence of benefit. In contrast most ME charities believe that GET can be harmful, and they do not recommend it; however, they do regard self-help strategies positively. This study will test the acceptability, effectiveness, cost-effectiveness and safety of graded exercise therapy delivered as a guided/supported self-help treatment for patients with CFS/ME attending hospital clinics.

Who can participate?
Patients with a diagnosis of CFS/ME attending two specialist clinics.

What does the study involve?
Participants will be randomly allocated to one of two study groups. In one group participants are guided, by a physiotherapist, through the graded exercise programme (GETSET) described in a self-help booklet, of which they will have a copy. Participants will follow the six steps described in the GETSET booklet that will inform them how to use graded exercise or physical activity to feel less tired and reduce disability in a planned and safe way. They will be given individual supportive guidance in how to apply the booklet over the next 8 weeks with up to 90 minutes of face-to-face/telephone and/or Skype support by a physiotherapist experienced in treating people with CFS/ME. In the other group participants continue to follow specialist medical advice as usual. We will ask people to rate their own health and disability at the end of the treatment period and also measure how much consequent face-to-face treatment they receive, to see if those who had the GETSET need less face-to-face treatment in the service afterwards.

What are the possible benefits and risks of participating?
The possible benefit is that the treatment we are offering may help you, although it is not guaranteed. The risk is that although GET appears to be safe when applied properly by trained staff, it has never been delivered as guided self-help before. Some patient surveys suggest GET

can make symptoms worse, but experts believe this happens when the therapy is not used properly or when there is not good professional supervision. We will carefully monitor patients progress through the GET with Skype/telephone contacts.

Where is the study run from?
The study is run from Barts and The London School of Medicine and Dentistry at Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
The study started in May 2012 and will continue until the end of 2014

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Peter D White (Principal Investigator)
p.d.white@qmul.ac.uk

Study website
http://www.wolfson.qmul.ac.uk/current-projects/getset-trial

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12053

Study information

Scientific Title
Graded Exercise Therapy guided SElf-help Treatment (GETSET) for patients with chronic fatigue syndrome/myalgic encephalomyelitis: a randomised controlled trial in secondary care

Acronym
GETSET

Study objectives
1. GETSET will be more effective at improving physical disability than usual specialist medical care alone as shown by a statistically significant difference between the two arms of the trial three months after randomisation.
2. GETSET will be acceptable to patients diagnosed as having CFS/ME in specialist secondary care clinics, as demonstrated by less than 25 per cent of eligible patients declining participation in the trial, and more than 75 per cent of those participating being satisfied with the approach.
3. There will be no statistically significant differences in the number of participants suffering serious adverse effects, serious adverse reactions, or a serious deterioration in their condition.
4. There will be no statistically significant difference in the cost-effectiveness between the two interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Bridge Research Ethics Committee, 23/11/2011, ref: 11/LO/1572

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Health services research

Interventions
Current interventions as of 28/02/2017:
Participants will be randomly allocated to one of two study groups. In one group participants are guided, by a physiotherapist, through the graded exercise programme (GETSET) described in a self-help booklet (http://www.wolfson.qmul.ac.uk/images/pdfs/getset/GET%20guide%20booklet%20version%201%2022062010.pdf), of which they will have a copy. Participants will follow the six steps described in the GETSET booklet that will inform them how to use graded exercise or physical activity to feel less tired and reduce disability in a planned and safe way. They will be given individual supportive guidance in how to apply the booklet over the next 8 weeks with up to 90 minutes of face-to-face/telephone and/or Skype support by a physiotherapist experienced in treating people with CFS/ME. In the other group participants continue to follow specialist medical advice as usual. Participants will be asked to rate their own health and disability at the end of the treatment period and also measure how much consequent face-to-face treatment they receive, to see if those who had the GETSET need less face-to-face treatment in the service afterwards.

The qualitative study will explore patient experiences of Guided graded Exercise Self-help (GES) delivered as part of the randomised controlled trial. The study will investigate the differences and similarities in treatment perceptions and experiences of guided graded exercise self-help (GES) among CFS/ME participants reporting an improvement compared to those reporting a deterioration in their condition.

Follow Up Length: 3 month(s); Study Entry : Single Randomisation only
Long Term Follow-up: 12 months from study entry

Previous interventions:
Guided support: A copy of the GETSET booklet, one 30 minute consultation face-to-face, by Skype or telephone, and 3 further Skype of telephone contacts. Intervention over 9 weeks.

Follow Up Length: 3 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. SF-36 physical function subscale (SF-36PF) measured at 12 weeks from randomisation

Added 21/07/2015:
2. Chalder fatigue scale measured at 12 weeks and 1 year

Updated 28/02/2017:
2. Chalder Fatigue Scale measured at 12 weeks

Secondary outcome measures
Clinical global impression change (CGI) score measured 12 weeks from baseline

Overall study start date
16/05/2012

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Patients attending two CFS/ME specialist clinics in London
2. Patients receiving a diagnosis of CFS/ME from a specialist doctor,and going onto a waiting list for clinic treatment
3. Patients must be 18 years or over
4. Speak and read English adequately to provide informed consent and read the guided support booklet.
5. Target Gender: Male & Female
6. Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 218; Actual Sample Size: 211

Key exclusion criteria
1. Not receiving a diagnosis of CFS/ME
2. Having a comorbid condition that requires exercise to be performed only in the presence of a doctor
3. Being under the age of 18
4. Having active suicidal thoughts

Date of first enrolment
16/05/2012

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wolfson Institute of Preventive Medicine
London
United Kingdom
EC1A 7BE

Study participating centre
Maidstone Hospital
Kent and Medway CFS/ME Service
Maidstone
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ME16 9QQ

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
School of Medicine and Dentistry
Clinical Sciences Research Centre
Rutland Place
Charterhouse Square
London
England
United Kingdom
EC1M 6BQ

Sponsor type
University/education

Website
http://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit Programme (UK)

Results and Publications

Publication and dissemination plan
The protocol has been published and the main paper, qualitative paper and long-term outcomes paper including health economics will be published in 2017.

Intention to publish date
01/04/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/06/2016		Yes	No
Results article	results	22/07/2017		Yes	No