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Family focused cognitive behaviour therapy versus behaviourally oriented psycho-education for chronic fatigue syndrome in 11 to 18 year olds: a randomised controlled treatment trial

Submission date
08/03/2007

Recruitment status
No longer recruiting

Registration date
22/05/2007

Overall study status
Completed

Last Edited
03/05/2011

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Cognitive Behaviour Therapy (CBT) will result in higher levels of school return than psycho-education at six months follow up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
King's College London Hospital (UK) on the 14/09/1999 (ref: 99/247)

Study design
A randomised controlled trial in which 13 sessions of family focused CBT was compared to 4 sessions of psycho-education over six months.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic Fatigue Syndrome (CFS) otherwise known as Myalgic Encephalomyelitis (ME)

Interventions
13 sessions of family focused CBT versus four sessions of psycho-education over six months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
School attendance expressed as a percentage of what was expected.

Secondary outcome measures
As a secondary outcome school attendance was dichotomised with a good outcome set at 70% or more, as at this age many healthy adolescents are not attending school or college full time. The following were recorded at six months:
1. Fatigue: Chalder Fatigue Scale - internal consistency in this sample was excellent with a Chronbachs alpha of 0.89
2. Functional impairment: physical functioning subscale of the 36-item Short Form health survey (SF-36) (range 0 to 100 higher scores denoting better health) - this measure is valid and reliable and has been used in adolescents with CFS
3. Degree to which fatigue interfered with adolescents life: Social Adjustment Scale - Chronbach s alpha was 0.91
4. Emotional and social responses: adolescents and their mothers completed the strengths and difficulties questionnaire - this measure has been shown to be valid and reliable in a number of studies
5. Global improvement and satisfaction: Global Outcome Scales - an assessor, blind to the group in which participants were randomised, carried out a semi-structured interview with the adolescent and rated degree of improvement in fatigue and disability on a nine-point scale from much better to much worse

Overall study start date
01/02/2000

Completion date
30/06/2005

Eligibility

Key inclusion criteria
1. Adolescents between 11and 18
2. Fulfill criteria for chronic fatigue syndrome
3. Have been investigated by a Paediatrician
4. If on anti-depressants, then had to be on a stable dose for three months

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
58 participants

Key exclusion criteria
1. Major depression
2. Somatisation disorder
3. Conversion disorder
4. History of self harm
5. Identifiable disease

Date of first enrolment
01/02/2000

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Psychological Medicine
London
United Kingdom
SE5 9RJ

Sponsor information

Organisation
South London & Maudsley NHS Trust (UK)

Sponsor details
Denmark Hill
London
England
United Kingdom
SE5 8AZ

Sponsor type
Hospital/treatment centre

Website
http://www.slam.nhs.uk/

ROR

https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
NHS Executive London Region Office (UK) (ref: RFG 640)

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?
Results article	results	01/08/2010		Yes	No