

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	<input type="checkbox"/> Prospectively registered
Registration date 22/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/05/2011	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

Protocol serial number
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

Study type(s)

Treatment

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(s)

School attendance expressed as a percentage of what was expected.

Key secondary outcome(s))

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

Completion date

30/06/2005

Eligibility

Key inclusion criteria

1. Adolescents between 11 and 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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

11 years

Upper age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Department of Psychological Medicine

London

United Kingdom

SE5 9RJ

Sponsor information

Organisation

South London & Maudsley NHS Trust (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

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