

# 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

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

### Contact name

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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 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

## **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

## 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?
<a href="#">Results article</a>	results	01/08/2010		Yes	No