Should general practitioners manage chronic fatigue syndrome? A controlled trial

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date 23/01/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
29/10/2019	Signs and Symptoms			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PSI06-16

Study information

Scientific Title

Should general practitioners manage chronic fatigue syndrome? A controlled trial

Study objectives

A pragmatic randomised controlled trial was conducted in general practice to test the hypotheses that general practitioners could (a) diagnose and (b) treat patients with the Chronic Fatigue Syndrome (CFS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Other symptoms and general pathology

Interventions

The intervention we attempted to introduce was a form of brief behavioural therapy, offered to GPs as a management package. Control practices were invited to manage their patients as usual, which in many cases included referral to secondary care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The study suffered from both poor recruitment and high drop out. However, we were able to show that this intervention had no effect on the illness of the patients enrolled, and that patients with CFS remained highly disabled over the 12 month study period, whatever their treatment. The study suggests that general practitioners can diagnose CFS, but under the conditions of this study were unable to effectively treat the condition. This accords with the recent Royal Colleges' report, that early recognition in primary care is important, but that the only evidence for effective treatment thus far has come from specialist units. General practitioners do not yet generally have the skills nor the time to provide effective treatment programmes for CFS.

Secondary outcome measures

Not provided at time of registration

Overall study start date 01/04/1995

Completion date 01/02/1998

Eligibility

Key inclusion criteria

General Practices willing to take part.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/04/1995

Date of final enrolment

01/02/1998

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Public Health and Primary Care
Willerby
United Kingdom
HU10 6NS

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Primary and Secondary Care Interface National Research and Development Programme (UK)

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	01/01/2002	29/10/2019	Yes	No