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To investigate the effectiveness of (manualised) reattribution therapy in the treatment of medically unexplained symptoms (MUS) within the General Hospital

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/11/2014	**Condition category** Signs and Symptoms	[_] Individual participant data [_] Record updated in last year

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

N0156093329

Study information

Scientific Title
To investigate the effectiveness of (manualised) reattribution therapy in the treatment of medically unexplained symptoms (MUS) within the General Hospital

Study objectives
To determine the effectiveness of reattribution therapy for patients with medically unexplained symptoms. Previous studies in primary care have indicated that there are beneficial outcomes in training general practitioners in reattribution therapy. This study aims to establish the effectiveness of the treatment itself.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Medically unexplained symptoms (MUS)

Interventions
The research will be conducted in two phases:

Phase 1 - The development of a client manual that will be used as an adjunct to therapy. This will be achieved by running a small case series, interviewing 2-4 patients with medically unexplained symptoms undertaking four sessions of reattribution therapy. The manual will be developed by utilising current knowledge from the literature and the lessons learned from the case series.

Phase 2 - Randomised Trial. The trial will compare a group undertaking reattribution therapy with a control group receiving treatment as usual. A baseline assessment will be taken. The

treatment group will receive four sessions of reattribution therapy and will also receive an assessment 6 months after the baseline assessment.

The groups will be compared according to changes in social adjustment and symptom ratings.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Modified Social Adjustment Scale (primary outcome measure)
2. Illness Perception Questionnaire
3. Hospital Anxiety and Depression Scale
4. Economics Questionnaire
5. SCL-90-R (Measures psychological and somatic symptoms)
6. Number of contacts with primary and secondary health care services (derived from patient questionnaire and case notes)

From the study it is anticipated that the researcher will:
1. Devise a client centred treatment manual
2. Show effectiveness of reattribution therapy

Secondary outcome measures
Not provided at time of registration

Overall study start date
15/11/2000

Completion date
30/11/2004

Eligibility

Key inclusion criteria
Four patients in initial case series and then 186 patients aged 16-64 of whom 50% (n=93) will be randomised into the treatment group and 50% into the control group (n=93).

These participants will be selected from people of this age group who are referred to the Liaison Mental Health Service with medically unexplained symptoms according to physicians or surgeons.

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
186

Key exclusion criteria
Clients presenting with Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM IV) organic or psychiatric mental disorders, alcohol and drug dependance or abuse, borderline personality disorder, inability to converse fluently in English will not be included in the research.

Date of first enrolment
15/11/2000

Date of final enrolment
30/11/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool University Hospital
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
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
Mersey Care NHS Trust (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