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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

Registration date
12/09/2003

Overall study status
Completed

Last Edited
28/11/2014

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Mersey Care NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration