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Cognitive training as a facilitated self-help intervention for depression: a Medical Research Council (MRC) experimental medicine trial

Submission date 31/03/2010	**Recruitment status** No longer recruiting
Registration date 31/03/2010	**Overall study status** Completed
Last Edited 19/07/2013	**Condition category** Mental and Behavioural Disorders

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4580

Study information

Scientific Title
Cognitive training as a facilitated self-help intervention for depression: a randomised interventional single centre treatment trial

Study objectives
1. Can concreteness cognitive training facilitated self-help produce robust and stable shifts in thinking style in dysphoric and moderately depressed individuals, relative to a no training control condition (treatment-as-usual) and relative to an active intervention controlling for non-specific factors (relaxation)?
2. Can cognitive training facilitated self-help in addition to treatment-as-usual significantly reduce rumination and depression in depressed patients relative to treatment-as-usual and relative to an active intervention controlling for non-specific factors (relaxation) in a primary care setting?
3. Does the shift in thinking style causally mediate the effects of cognitive training on rumination and depression? To investigate mediation using Baron and Kenny's criteria, we will investigate a series of supplementary research questions:
3.1. Does treatment condition have a significant effect on outcome?
3.2. Does treatment condition influence changes in the given cognitive process from before to after therapy?
3.3. Does change in the given cognitive process predict outcome?
3.4. Does change in the given cognitive process remain a significant predictor of outcome when controlling for treatment condition
3.5. Is the effect of treatment condition on outcome attenuated when controlling for change in the given cognitive process? A given cognitive process could be said to function as a mediator of facilitated self-help on outcome if all the above questions are answered "yes".
4. Is cognitive training feasible and acceptable as a potential self-help intervention?
5. What patient factors might predict response to the psychological intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Devon and Torbay REC approved in September 2006 (ref: 06/Q2102/66)

Study design
Randomised interventional single centre treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network, Primary Care Research Network for England; Subtopic: Depression, Not Assigned; Disease: Depression, All Diseases

Interventions
1. Cognitive training self-help in addition to treatment-as-usual
2. Relaxation training self-help in addition to treatment-as-usual
3. Treatment-as-usual

The cognitive training facilitated self-help intervention will consist of an initial meeting lasting approximately 1.5 hours (subject to modification as the project progresses), during which the researcher will explain the rationale for why cognitive training is helpful and then practice relaxation or the cognitive training paradigm.

Follow Up Length: 6 month(s)
Study Entry: Single Randomisation only

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Hamilton Rating Scale for Depression - 17 item version (HRS-D). Timepoints were assessed at baseline pre-treatment, 2 months post-baseline assessment (post-treatment), after 3 months follow-up (i.e., after 5 months post-baseline) and after 6 months follow-up (i.e., 8 months post baseline assessment).

Secondary outcome measures
Depressive symptoms: the Beck Depression Inventory (BDI-II). Timepoints were assessed at baseline pre-treatment, 2 months post-baseline assessment (post-treatment), after 3 months follow-up (i.e., after 5 months post-baseline) and after 6 months follow-up (i.e., 8 months post baseline assessment).

Overall study start date
01/03/2008

Completion date
31/08/2009

Eligibility

Key inclusion criteria

1. Aged 18 years or older, either sex
2. Currently depressed patients, whether they are currently taking antidepressant medication or not

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria
1. Current co-morbid diagnosis or history of bipolar disorder, schizophrenia or other psychotic disorders
2. Current and clinically significant drug or alcohol dependence
3. Persistent anti-social behaviour
4. Persistent self-injury requiring clinical management/therapy
5. Learning disability (intelligence quotient [IQ] less than 70)
6. Organic brain damage
7. Current formal face-to-face psychotherapy/counselling (does not include computer-based cognitive behavioural therapy [CBT], psychoeducation, or bibliotherapy)
8. Unable to engage with facilitated self-help treatment for physical, practical or other reasons (e.g. unable to comprehend materials)

Date of first enrolment
01/03/2008

Date of final enrolment
31/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Mood Disorders Centre
Exeter

United Kingdom
EX4 4QG

Sponsor information

Organisation
University of Exeter (UK)

Sponsor details
The Queen s Drive
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United Kingdom
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Sponsor type
University/education

Website
http://www.exeter.ac.uk/

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: 72156)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/07/2012		Yes	No