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Staying Well After Depression: a randomised trial

Submission date	Recruitment status
04/01/2010	No longer recruiting
Registration date	**Overall study status**
05/01/2010	Completed
Last Edited	**Condition category**
24/02/2015	Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
http://www.staying-well.org/information-sheet

Study website
http://www.staying-well.org/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol version 5 (6/5/09); 067797

Study information

Scientific Title
Modifying risk and severity of relapse in patients with recurrent depression at high suicide risk: translational randomised controlled trial

Acronym
SWAD

Study objectives
That treatment with mindfulness-based cognitive therapy for depression, a novel form of treatment combining mindfulness meditation and cognitive therapy for depression, delivered in addition to treatment as usual (TAU), will:
1. Reduce risk of relapse to major depression in recurrently depressed patients compared with TAU alone and cognitive psycho-education (CPE), a treatment of equal plausibility, and
2. Reduce incidence of suicidal symptoms in those with a history of suicidality compared with TAU alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire Research Ethics Committee (REC) C, 27/06/2008, ref: 08/H606/56

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Can be found at http://www.staying-well.org/information-sheet (Oxford) and http://stayingwell.bangor.ac.uk/participant_info.php.en?menu=1&catid=7164&subid=0 (Bangor)

Health condition(s) or problem(s) studied
Recurrent depression

Interventions

Mindfulness-based cognitive therapy and cognitive psychoeducation as compared to ordinary care (treatment-as-usual).

Treatment duration: 8 weeks
Follow-up duration: 12 months

Intervention Type
Behavioural

Primary outcome measure
Time to relapse or recurrence meeting DSM-IV criteria for major depression, assessed using the Structured Clinical Interview for DSM-IV (SCID). Occurrence of relapse/recurrence is assessed at all follow-up assessments, and 'return to treatment' will be treated as a relapse/recurrence if, in the judgment of a blind assessor, the participant has experienced exacerbation of symptoms that would have met the criteria for major depression in the absence of immediate treatment. In addition to diagnostic status, we assess severity of depression and hopelessness using a number of interview and self-report measures including the Hamilton Rating Scale for Depression, the Beck Depression Inventory and the Beck Hopelessness Scale, at all time points. These quantitative measures complement the dichotomised outcome of diagnosis.

Outcomes measured pre-treatment, post-treatment and at 3, 6, 9, and 12 months follow-up.

Secondary outcome measures
1. Cognitive measures relevant to risk of relapse/recurrence (mindfulness, self-compassion, rumination, self discrepancy, autobiographical memory, and executive capacity) are assessed before and immediately after the treatment as well as at the end of the follow-up, and will be used in an explanatory analysis to examine factors that mediate and moderate efficacy
2. Severity of suicidal ideation/behaviour both within and between episodes of depression during the follow-up period

Outcomes measured pre-treatment, post-treatment and at 3, 6, 9, and 12 months follow-up.

Overall study start date
01/10/2008

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Aged 18 years or over, and not older than 70 years due to the fact that depression in old age has often been found to be related to different factors than depression in earlier stages of life. Male or female.
2. Meeting enhanced Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria for a history of recurrent major depression, i.e. history of at least three episodes of depression, two of which must have occurred within the last five years, of which one must have occurred within the last two years. Although previous suicidality is recorded in detail (which allows stratification to be carried out on this basis) participants are not included/excluded from the study on the basis of their prior experience of suicidality.
3. Meeting the National Institute of Mental Health (NIMH) guidelines for recovery or remission

at the time of baseline assessment. For the purposes of the trial participants are NOT deemed to be in recovery or remission (and hence are ineligible) if they report a week (or more) during the previous 8 weeks during which they experienced EITHER a core symptom of depression (depressed mood, anhedonia) or suicidal feelings AND at least one other symptom of depression, which together are not accounted for by bereavement or substances/general medical conditions, and which are accompanied by significant impairment in functioning.
4. Giving informed consent
5. Consent received from the participant's General Practitioner

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300 after allowing for attrition

Key exclusion criteria
Participants are excluded from the study if one or more of the following apply:
1. They have a history of schizophrenia, schizoaffective disorder, bipolar I disorder, current and severe substance abuse, organic mental disorder, pervasive developmental delay, a primary diagnosis of obsessive-compulsive disorder or eating disorder, or are currently regularly self-harming
2. They are showing a positive and continuing response to CBT
3. They have current psychotherapy or counseling more frequently than once per month
4. They are unable to complete the baseline research assessment (e.g. due to difficulties with English, visual impairment, or cognitive difficulties)

Date of first enrolment
01/10/2008

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Oxford
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Clinical Trials and Research Governance
Manor House
John Radcliffe Hospital
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England
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Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

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?
Protocol article	protocol	19/03/2010		Yes	No
Results article	results	01/02/2014		Yes	No
Results article	results	02/07/2014		Yes	No