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Psychological mechanisms in suicidal behaviour

Submission date	Recruitment status	[ ] Prospectively registered
03/03/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/11/2012	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims.
This study aimed to examine the acceptability and mechanisms of action of Mindfulness-based Cognitive Therapy (MBCT) delivered to patients in remission, but with a history of serious suicidal thoughts or behaviour. The aim of the study was to explore the feasibility of delivering MBCT to this population, and the extent to which treatment with MBCT could reduce vulnerability to suicidal thoughts and behaviour through an examination of its effects on psychological factors linked to of suicidal vulnerability.

Who can participate?
Participants aged between 18 and 65 who were currently well but reported at least one prior episode of major depression accompanied by serious suicidal thoughts were recruited from general practitioners and local psychologists/psychiatrists and from the community. All participants were required to be well (no more than one week of minimal depressive symptoms in the past 8 weeks), and to have experienced no episodes of mania for at least 6 months. Additional exclusion criteria included current psychosis, obsessive compulsive disorder or eating disorder as their main problem, current deliberate self harm on a regular basis, a neurological disorder or an inability to complete assessments due to language difficulties or cognitive impairment.

What does the study involve?
Participants were interviewed using the Mini International Neuropsychiatric Interview to establish psychiatric history. Following this, participants completed a number of other assessment measures assessing aspects of cognitive vulnerability to depression and suicidality. These measures included assessment of residual symptoms of depression, mood-related impairments in problem solving and future thinking, autobiographical memory deficits, tendency to suppress unwanted thoughts and self-discrepancy (perceptions of distance between how one currently sees themselves and how one would like to be). Participants were then randomly allocated to either immediate treatment with MBCT or a waitlist condition. The measures were completed again at the end of treatment or waitlist phase. Following this the waitlist group received treatment with MBCT.

What are the possible benefits and risks of participating?
Benefits included the fact that all participants were offered treatment with Mindfulness Based Cognitive Therapy, either immediately or at the end of the waitlist phase of the study. Potential

risks to participants related to the distress of reporting on prior psychiatric history and the inherent challenges of engaging in a therapeutic process designed to target vulnerability to recurrent depression and suicidality.

Where is the study run from?
Department of Psychiatry, University of Oxford

When is the study starting and how long is it expected to run for?
The study started in May 2005 and ended in December 2005

Who is funding the study?
The Wellcome Trust

Who is the main contact?
Professor Mark Williams
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PRG/06/01

Study information

Scientific Title

Study objectives
This is a preliminary (explanatory) trial to assess the immediate effects of Mindfulness-based Cognitive Therapy (MBCT) on cognitive reactivity (the tendency to react to small changes in mood with a catastrophic and rapidly escalating pattern of suicidal thinking).

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)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Suicidality

Interventions
Treatment:
Mindfulness-Based Cognitive Therapy (MBCT): manualised, eight week treatment combining stress reduction techniques and cognitive therapy and Treatment As Usual (TAU)

Control:
Waiting List control and Treatment As Usual (TAU)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Depression
2. Frequency of thought suppression
3. Change in problem solving and future thinking following experimental induction of mood
4. Self-rated mindfulness

5. Discrepancy between actual and ideal self-guides
6. Specificity of autobiographical memory

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/2005

Completion date
01/12/2005

Eligibility

Key inclusion criteria
1. Aged 18 to 64
2. History of major depression with suicidal ideation and/or suicidal behaviour
3. Not currently depressed or suicidal (at least eight weeks symptom free)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Visually impaired
2. Not fluent in English
3. Habitual self-damaging acts
4. Bipolar disorder
5. Schizophrenia
6. Active substance abuse
7. Eating disorder
8. Primary Obsessive Compulsive Disorder (OCD)

Date of first enrolment
01/05/2005

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University
Oxford
United Kingdom
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Sponsor information

Organisation
University of Oxford (UK)

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Sponsor type
University/education

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ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 067797)

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	preliminary results	01/04/2008		Yes	No
Results article	results	01/12/2008		Yes	No
Results article	results	01/06/2009		Yes	No