DClinPsy: Maladaptive cognitive processes during exposure in people with OCD (checking subtype)

Submission date	Recruitment status	Prospectively registered
28/09/2007	No longer recruiting	∐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Completed	☐ Results
Last Edited	Condition category	Individual participant data
01/09/2015	Mental and Behavioural Disorders	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

DClinPsy: Maladaptive cognitive processes during exposure in people with OCD (checking subtype)

Study objectives

The research aims to identify covert cognitive strategies that are used by individuals with Obsessive Compulsive Disorder (checking subtype) (OCD) when they are exposed to fear provoking stimuli. The principle objective is to increase our understanding of OCD and to refine and improve cognitive treatments for OCD.

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

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

Health condition(s) or problem(s) studied

Mental and Behavioural Disorders: Obsessive compulsive disorder (OCD)

Interventions

HYPOTHESIS 1

Asking a participant with OCD (checking subtype) to search for a perfect memory will lead to an increase in anxiety, urge to check and belief that the item was not properly checked compared to a condition in which a participant is asked to abandon a memory search.

HYPOTHESIS 2

Asking a participant with OCD (checking subtype) to consider a series of Socratic questions

about the likelihood that an item was not checked properly will lead to an increase in anxiety, urge to check and belief that the item was not checked properly will lead to an increase in anxiety, urge to check and belief that the item was not checked properly compared to a condition in which the participant uses detached mindfulness.

The study will use two ABC single-case series experimental designs. Conditions B and C will be counterbalanced: Half of the participants will be randomly assigned to receive condition B before C; the other participants will receive condition C and then B. This is to ensure that the effects of the experimental manipulations are not due simply to the order in which they were given.

STAGE 1: BASELINE (CONDITION A)

In the baseline experiment participants will be exposed to their fear provoking stimuli, which may differ between participants. For example, one participant may need to switch off an electrical appliance and walk away without checking whilst another may need to lock a car door. The participant will then spend five minutes doing what they normally do when they have just checked something (with the exception of going back to check) and will fill in their visual analogue scales.

STAGE 2: EXPERIMENT 1 (CONDITION B)

Participants will be given a rationale about the use of memory searching as a technique people sometime use to prevent them from checking. Once the Principal Investigator is confident that the participant understands how to do a memory search, the participant will repeat their exposure to the fear producing stimuli and then return to the research room to engage in a five minute memory search whilst completing the visual analogue scale.

STAGE 3: EXPERIMENT 1 (CONDITION C)

Participants will be given a rationale which suggests why memory searching may not be useful. The participant will then be asked to think of ways to abandon doing a memory search. Once the Principal Investigator is confident that the participant is able to abandon the memory search, the participant will repeat their exposure to the feared stimuli and then return to the research room to engage in five minutes of deliberately not searching their memory whilst completing the visual analogue scales.

EXPERIMENT 2

Experiment 2 will take place approximately one week after the first experimental session. The design of the experiment will be exactly the same as experiment 1 except that it will test hypothesis 2. The rationales will therefore be on the use of Socratic questioning and the use of detached mindfulness.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Visual analogue scales used standardly in CBT

Secondary outcome measures

- 1. MINI International Neuropsychiatric Interview
- 2. Yale-Brown Obsessive Compulsive Scale
- 3. Padua Inventory
- 4. Maudsley Obsessive-Compulsive Inventory
- 5. Beck Depression Inventory 1st and 2nd editions

Overall study start date

01/09/2006

Completion date

30/06/2007

Eligibility

Key inclusion criteria

- 1. Referred to Leeds Clinical Psychology services
- 2. Aged between 16-65
- 3. Meets diagnostic criteria for OCD
- 4. OCD is the main presenting problem
- 5. Checking symptoms are the primary presenting symptom of the disorder

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

15 as of February 2007

Key exclusion criteria

- 1. The assessment reveals a suicide or self-harm risk
- 2. Alcohol or drug dependence
- 3. Learning disability
- 4. Psychosis

Date of first enrolment

01/09/2006

Date of final enrolment

30/06/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Leeds

Leeds United Kingdom LS2 9LT

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

South West Yorkshire Mental Health NHS Trust

Funder Name

NHS R&D Support Funding

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration