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Cognitive therapy for body dysmorphic disorder

Submission date
26/04/2017

Recruitment status
No longer recruiting

Registration date
12/05/2017

Overall study status
Completed

Last Edited
14/10/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Body Dysmorphic Disorder (BDD) is an obsessive-compulsive disorder where a person is preoccupied with perceived defects or flaws in their appearance. These defects often appear slight to others. People with BDD believe that specific features of their face, skin or body are disfigured or ugly, and report that the "defect" is on their mind many hours a day. Preoccupation with the "defect" is experienced as uncontrollable, includes recurrent mental images and memories (e.g., teasing), negative emotions, thoughts, beliefs, time-consuming ritualistic behaviors (e.g., mirror checking) and avoidance. People with BDD experience marked distress, handicap, and psychosocial impairments, have high rates of suicide, are often housebound and /or socially isolated, and have difficulties with relationships. They are often too ashamed to reveal their main BDD symptoms and report symptoms of depression and social anxiety. BDD is regarded as rare, but evidence suggests rates of 0.7-2.9% in the community, and higher rates in cosmetic surgery and dermatology settings. One way of treating BDD is through cognitive therapy (CT), a type of therapy which works on changing emotions, thoughts, beliefs, attention, perception, images, memories and behaviors. However, so far there is only one study showing how well some of the CT interventions work for adults. Therefore, the aim of this study is to find out how well CT interventions help people with BDD by reducing BDD symptoms and improving their mental health.

Who can participate?
Patients aged 18-70 with BDD

What does the study involve?
Participants are randomly allocated to either receive 20 sessions of CT treatment (25x50 units) over 9 months, or to be put on a waiting list. CT involves six phases that explore different processes that maintain the disorder, change their cognitive and emotional processes (attention, perception, images, memories, emotions, thoughts and beliefs), promote healthy behaviors and relationships, and prevent relapsing. Those in the waiting list group have to wait for 3 months. After this period they also receive CT. Participants are assessed during treatment (12 weeks, 24 weeks), after treatment, and are followed up 3 and 6 months after the treatment to assess their symptoms and overall mental health.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in BDD symptoms. There are no direct risks of participating.

Where is the study run from?
Goethe University Frankfurt (Germany)

When is the study starting and how long is it expected to run for?
March 2016 to March 2021

Who is funding the study?
German Research Foundation (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DFG project number: 287331963

Study information

Scientific Title
Cognitive Therapy for Body Dysmorphic Disorder (CT-BDD): a randomized controlled trial

Acronym

CT-BDD

Study objectives
Efficacy of cognitive therapy (CT) vs. waitlist (WL) in body dysmorphic disorder concerning improvements in BDD symptom severity and associated features (e.g., insight, depression, psychological functioning) – named hypothesis A1.

The first add-on study (named B1) of this randomized controlled trial will be studying changes in emotion regulation, and attachment characteristics as differential predictors of treatment outcome in patients with body dysmorphic disorder who are treated with cognitive therapy (resp. waitlist).

The second add-on study (named C1) of this randomized controlled trial will be studying implicit and explicit shame and social pain in patients with body dysmorphic disorder who are treated with cognitive therapy (resp. waitlist).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Faculty of the Goethe University of Frankfurt, 25/10/2015, ref: 239/15

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Body dysmorphic disorder

Interventions
Current interventions as of 17/08/2021:
Thirty-eight adults with a primary diagnosis of BDD will be randomized to 20 sessions (25x50 units) of individual CT-BDD over 9 months or to a 3-month waitlist control group in a ratio of 1:1.

The random allocation sequence is generated by an urn randomization program (Stout et al., 1994; Wei, 1978). Randomization is stratified by pretreatment delusionality (as assessed by the BABS).

Cognitive therapy for BDD (CT-BDD) includes interventions that aim at modifying biased appearance-related cognitive and emotional processes such as attention, perception, mental imagery, memory, interpretation and dysfunctional behaviors (e.g., rituals, safety behaviors). CT-BDD utilizes interventions for BDD patients (Attentional Training, Perceptual Retraining with Mirror Feedback, Video Feedback, Imagery Rescripting, Behavioral Experiments and Cognitive Restructuring) and additional modules (e.g., Skin Picking, Surgery Seeking).

Outcome measures will be completed at pretreatment, every 3 months at intervention phase (at 12- and 24-week), at post treatment (resp. post-waitlist), and at 3- and 6-month follow-up. Treatment response is defined by a BDD-YBOCS reduction ≥30% from baseline.

Previous interventions:
Thirty-eight adults with a primary diagnosis of BDD will be randomized to 25 (+5) sessions of individual CT-BDD over 10 months or to a 3-month waitlist control group in a ratio of 1:1. The random allocation sequence is generated by an urn randomization program (Stout et al., 1994; Wei, 1978). Randomization is stratified by pretreatment delusionality (as assessed by the BABS).

Cognitive therapy for BDD (CT-BDD) includes interventions that aim at modifying biased appearance-related cognitive and emotional processes such as attention, perception, mental imagery, memory, interpretation and dysfunctional behaviors (e.g., rituals, safety behaviors). CT-BDD utilizes interventions for BDD patients (Attentional Training, Perceptual Retraining with Mirror Feedback, Video Feedback, Imagery Rescripting, Behavioral Experiments and Cognitive Restructuring) and additional modules (e.g., Skin Picking, Surgery Seeking).

Outcome measures will be completed at pretreatment, every 3 months at intervention phase (at 12- and 24-week), at post treatment (resp. post-waitlist), and at 3- and 6-month follow-up. Treatment response is defined by a BDD-YBOCS reduction ≥30% from baseline.

Intervention Type
Other

Primary outcome measure
For A1:
1. BDD symptom severity, measured using the clinician-administered Body Dysmorphic Disorder Modification of the Yale-Brown Obsessive-Compulsive Scale (BDD-YBOCS)
2. BDD diagnosis, measured using the clinician-administered BDD Diagnostic Module (BDDDM)
Measured at pretreatment, 12 weeks/post-WL, 24 weeks, post treatment, 3- and 6-months follow-up

Secondary outcome measures
For A1:
1. Insight, measured using the Brown Assessment of Beliefs Scale (BABS) at pre, 12-weeks/post-WL, 24 weeks, post, 3- and 6-month follow-up
2. Depression, measured using the Quick Inventory of Depressive Symptoms (QUIDS-C), Beck Depression Inventory-II (BDI-II) at pre, 12-weeks/post-WL, 24 weeks, post, 3- and 6-month follow-up
3. Psychosocial functioning, measured using the Global Assessment of Functioning Scale (GAF) at

pre, 12-weeks/post-WL, 24 weeks, post, 3- and 6-month follow-up
4. Body dysmorphic concerns, measured using the Body Dysmorphic Symptoms Symptoms Inventory, Fragebogen körperdysmorpher Symptome (FKS) at pre, 12-weeks/post-WL, 24 weeks, post, 3- and 6-month follow-up
5. General symptomatology, measured using the Brief Symptom Inventory (BSI) at pre, 12-weeks /post-WL, 24 weeks, post, 3- and 6-month follow-up
6. Quality of life, measured using the EUROHIS Quality-of-Life Index (EUROHIS-QOL) at pre, 12-weeks/post-WL, 24 weeks, post, 3- and 6-month follow-up

For B1:
1. Emotion regulation, measured using the clinician-administered Operationalized Skills Assessment Inventory, Emotion Regulation adapted for BDD (OFD-ER-BDD) at pre, 12 weeks /post-WL, post
2. Attachment characteristics, measured using the clinician-administered Adult Attachment Interview, Erwachsenen-Bindungsprototypen-Rating (EBPR-BI) at pre
3. Self-reported attachment, measured using the self-report questionnaire Experiences in Close Relationships-Revised (ECR-R) at pre, 12 weeks/post-WL, 24 weeks, post, 3- and 6-months follow-up

For C1:
1. Implicit shame, measured using an Implicit Association Test (IAT) at pre, post-WL, post
2. Explicit shame, measured using the Body-Focused Shame and Guilt Scale (BFSGS) at pre, post-WL, post
3. Social pain, measured using the Cyberball Paradigm and the self-report questionnaire Social Pain Questionnaire (SPQ) at pre, post-WL, post

Overall study start date
01/03/2016

Completion date
01/03/2021

Eligibility

Key inclusion criteria
1. Primary diagnosis of body dysmorphic disorder (BDD) according to the Body Dysmorphic Disorder Diagnostic Module (BDDDM adapted for DSM-5), the Structured Interview for Diagnostic and Statistical Manual of Mental Disorders – Fifth Edition (SCID-I DSM-5) and the Yale-Brown Obsessive-Compulsive Scale Modified for BDD (BDD-YBOCS) ≥ 20
2. BDD symptoms for at least 6 months prior to participation
3. Age 18-70 years
4. Either no psychotropic medication or, if taking psychotropic medication, be on a stable dose for at least 2 months prior to initial evaluation and agreement not to change the medication during the study
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
38

Total final enrolment
40

Key exclusion criteria
1. Acute suicidality
2. Psychotic disorder (excluding delusional BDD)
3. Bipolar disorder
4. Alcohol or substance dependence within the last 3 months
5. Borderline personality disorder
6. Prominent risk of self-harm
7. Body image/weight concerns accounted primarily by an eating disorder
8. Organic mental disorder
9. Severe medical conditions
10. Concurrent psychotherapeutic treatment (e.g., psychodynamic)

Date of first enrolment
01/09/2016

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
Germany

Study participating centre
Clinical Psychology and Psychotherapy
Varrentrappstr. 40-42
Frankfurt
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60 486

Sponsor information

Organisation
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Sponsor type
Research organisation

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ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer review journal.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/07/2022	14/10/2022	Yes	No