ISRCTN71789677 https://doi.org/10.1186/ISRCTN71789677

Clinical pilot study of inference based psychological therapy for body dysmorphic disorder

Submission date
10/09/2019

Recruitment status
No longer recruiting

Registration date
23/10/2019

Overall study status
Completed

Last Edited
12/10/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Body Dysmorphic Disorder (BDD) is a debilitating condition characterized by an intense preoccupation with a slight or imagined defect in physical appearance leading to significant impairment in functioning. BDD is very similar to Obsessive-Compulsive Disorder (OCD) but is considered a more complex disorder than OCD, because it is associated with much higher levels of overvalued ideation (OVI) and is associated with poor treatment outcomes.
Inference-based cognitive therapy (IBCT) is a proven, evidence-based cognitive therapy originally developed for OCD with high OVI. A comprehensive pilot study directly comparing IBCT with CBT is needed in order to determine the promise and feasibility of larger-scale RCT.

Who can participate?
Patients with BDD who are over the age of 18 and fluent in French

What does the study involve?
Participants will be evaluated to confirm a primary BDD diagnosis. Then, if the diagnosis is confirmed, they will participate in 24 psychotherapy sessions with a trained psychologist as well as to complete several questionnaires. They will be assessed on the primary outcomes at pretreatment, mid-treatment, post-treatment and at six-month follow-up

What are the possible benefits and risks of participating?
Benefits: Participants will have access to psychotherapy with a trained psychologist without fee. They may see a decrease in BDD symptoms as the treatment was successful in the past.
Potential risks are similar to those that can be encountered in psychotherapy. Participants could feel shyness, anxiety, shame or frustration, and some may feel that they are wasting their time

Where is the study run from?
Centre de recherche de l'Institut universitaire en santé mentale de Montréal, Canada

When is the study starting and how long is it expected to run for?
August 2019 to December 2023 (updated 07/04/2021, previously: November 2022 (updated 10 /11/2020, previously: November 2020))

Who is funding the study?
Centre de recherche de l'Institut universitaire en santé mentale de Montréal

Who is the main contact?
Dr Frederick Aardema, faardema@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Frederick Aardema

ORCID ID
http://orcid.org/0000-0003-1589-7511

Contact details
7331 Hochelaga Street
Montreal
Canada
H1N 3V2
1-514-251-4015 ext.
faardema@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluating the effectiveness of inference-based cognitive therapy for body dysmorphic disorder: a 24-session randomized controlled pilot study

Acronym

IAB-BDD

Study objectives
The main objective of this pilot study is to establish the promise and feasibility of a large-scale randomized controlled trial. We are thus primarily interested in the selection of the most appropriate outcome measures, and obtaining precise estimates of outcome on the basis of the results. To this end, we will compare effect sizes confidence intervals on our outcome measure in each treatment modality, which will guide our power calculations for a larger, sufficiently powered RCT trial. In addition, given the important role of overvalued ideation in predicting negative treatment outcome we will also conduct subgroup analyses comparing both treatments among those with very high levels of overvalued ideation utilizing a cut-off point based on previous studies among those with BDD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/07/2019, Ethical research committee of the Centre Intégré Universitaire de Santé et de Services Sociaux de l'Est-de-l'île-de-Montréal (Maisonneuve-Rosemont Hospital, 5415 Assumption Blvd, Montreal, Quebec H1T 2M4, Canada; +1 514-252-3400; cer.cemtl@ssss.gouv.qc.ca), ref: 2019-1841

Study design
Pilot study of a randomized clinical 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
Randomization.
Following diagnosis and baseline assessment, participants who meet eligibility criteria will be randomly allocated to one of two treatment modalities at point of entry into the study using a computerized random number generator with a randomization ratio of 1:1, performed by an independent statistician. Allocation Concealment Mechanism: The allocation sequence will be concealed from the evaluators.

Modality 1.
Cognitive behavioral therapy (CBT) will be based on a standard, commonly-used manual for BDD that contains standardized forms for exercises and homework assignments. Core treatment components include: a) psychoeducation, b) motivational enhancement strategies, c) cognitive restructuring that addresses negative thoughts and maladaptive beliefs about appearance (e.g. the importance of appearance or self-worth), d) exposure and response prevention to avoided situations as guided by a hierarchy, e) mindfulness interventions and perceptual retraining (e.g., observing one's body without selective attention to details and flaws and approach oneself in a non-judgemental manner) and f) relapse prevention focused on the consolidation and maintenance of gains.
Beyond these core elements, the treatment program also includes several optional modules therapists can utilize to tailor the treatment to symptoms that occur in some, but not all BDD patients, including: a) skin picking and hair pulling, b) weight, shape and muscularity, c) cosmetic treatment and d) depression. To conform with previous studies and guidelines, specific criteria will be applied to guide the use of these optional modules, based on scores on the BDD-Symptom Scale (BDD-SS); 2) level of depression as assessed by the BDI, 3) participant preferences and 4) clinician judgement. For all patients, treatment ends with relapse prevention strategies and booster sessions focused on helping patients maintain their gains.

Modality 2.
inference based psychological therapy (IBCT) will be delivered in a manualized, step-by-step format utilizing worksheets, exercise sheets and training cards in accordance with published guidelines. The treatment primarily targets the dysfunctional reasoning that gives rise to overvalued ideas related to appearance. IBCT does not include exposure in vivo, but instead, aims to bring resolution to the initial obsession or overvalued idea about appearance and imagined physical defects by showing the client that the obsession is the result of incorrect reasoning. The first learning point is that the compulsions, anxiety and discomfort are driven by the overvalued idea. (Sessions 1-4). The next crucial step in therapy is to show that the doubt is 100% irrelevant in the here and now. The client is taught that the justification behind the obsession or overvalued idea is generated subjectively and goes against actual sense and perceptual data (Sessions 4-8). This step covers the essence of the inferential confusion process where the person confuses an imagined possibility with a probability that is based in reality. Following an explanation of the reasoning process leading up to the overvalued belief, the entire reasoning narrative giving rise to obsessional doubts and overvalued ideas is identified, while simultaneously, an alternative more reality-based narrative is introduced to the client. (Sessions 9-12). Next, the client is taught how they leave reality behind as soon as they engage with their doubts and beliefs about their appearance. This cross-over point can be identified, as it is initiated by thoughts that lead the client away from reality and beyond common sense (Sessions 13-15). The next step is the identification of various reasoning devices, which give credibility to the overvalued idea (incl. "selective use of facts", "category errors", "inverse inference" and "distrust of normal perception") (Sessions 16-19). The selective nature of the obsession is further underlined by showing the client how under most everyday circumstances his/her reasoning is entirely different from the obsessional situation (Sessions 19-21). This stage also educates the client in the thematic nature of their beliefs about appearance and how personal themes dictate the idiosyncratic nature of the person's obsession. The final stage of therapy consists of training the client in the proper use of the senses, as well as a focus on relapse prevention (Session 22-24). Beyond these core elements, IBCT will include one optional module specifically targeting depressive symptoms. This module and the criteria for its application will be identical to modality 1, including scores on the BDD-II > 20, 2) patient input and 3) clinician judgement. No other manualized optional modules will be included in the IBCT modality. Specific symptoms requiring special attention will solely be addressed within the

context of the core treatment components of IBCT focused on the reasoning and overvalued beliefs that give rise to these behaviors.

Intervention Type
Behavioural

Primary outcome measure
BDD symptoms assessed using the Yale-Brown Obsessive-Compulsive Scale Modified for BDD (BDD-YBOCS) at pre and post-treatment

Secondary outcome measures
1. BDD symptoms assessed pre and post-treatment by self-report with the Body Dysmorphic Symptom Scale (BDD-SS)
2. Overvalued ideation - Level of OVI will be assessed pre and post-treatment with the Over-Valued Ideas Scale (OVIS)
3. Anxiety will be assessed pre and post-treatment with The Beck Anxiety Inventory (BAI)
4. Depression will be assessed pre and post-treatment with the Beck Depression Inventory (BDI)
5. Obsessive beliefs will be measured at pre- and post-treatment with the 20-item version of the Obsessive Beliefs Questionnaire (OBQ-TRIP)
6. Level of inferential confusion will be formally assessed at pre-treatment, post-treatment and follow-up by the validated Inferential Confusion Questionnaire — Expanded Version (ICQ-EV)
7. Feared self-perceptions will be assessed pre- and post-treatment with the expanded version of the Fear of Self Questionnaire (FSQ-Expanded Version).
8. Dissociative Absorption will be assessed pre and post-treatment with an adapted version of the Selves Questionnaire
9. Obsessive-compulsive symptoms will be assessed pre and post-treatment with the Vancouver Obsessive-Compulsive Inventory (VOCI)
10. Dissociation will be assessed pre and post-treatment with the Dissociative Processes Scale (DPS)
11. Disability and impairment in work, social life and family responsibilities will be measured pre and post-treatment with the Sheehan Disability Scale (SDS)
12. Quality of life will be assessed pre and post-treatment with the Brunsviken Brief Quality of Life Scale
13. Social self-esteem will be assessed pre and post-treatment with the Social Self-Esteem Inventory (STI)
14. Global self-esteem will be assessed pre and post-treatment with the Rosenberg's Self-Esteem Scale (RSES)
15. Self-report measures to measure treatment acceptability and satisfaction will be administered immediately following the 1st, 8th and 16th treatment session:
15.1 Distress/Endorsement Validation Scale (DEVS)
15.2 The Treatment Acceptability/Adherence Scale (TAAS)
15.3 The Credibility and Expectancy Questionnaire (CEQ)
15.4 Evaluation of Treatment Questionnaire (ETQ)
These questionnaires will be provided to patients in a sealed envelope and returned by mail to the project manager to minimize potential bias. In addition, we will ask each patient that refuses or drops out of treatment to list the reasons they refused or discontinued treatment utilizing an inventory with a list of potential reasons developed by Hansen, Hoogduin, Schaap & De Haan (1992)

Overall study start date
30/11/2018

Completion date
30/12/2023

Eligibility

Key inclusion criteria
1. Age >18 years
2. A primary diagnosis of BDD according to DSM-5 criteria
3. No change in medication during the 12 weeks before treatment for antidepressants (4 weeks for anxiolytics)
4. Willingness to keep medication stable while participating in the study (g) not undergoing a current psychological treatment
5. Willingness to undergo active psychological treatment
6. Willingness to undergo randomization into treatment modality
7. Fluency in French

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Total final enrolment
16

Key exclusion criteria
1. Evidence of suicidal intent
2. Evidence of current substance abuse
3. Past or present psychotic or bipolar disorder
4. Neurocognitive, developmental disorder or intellectual disability

Date of first enrolment
31/07/2019

Date of final enrolment
30/09/2023

Locations

Countries of recruitment

Canada

Study participating centre
Centre de recherche de l'Institut universitaire en santé mentale de Montréal
7331 Hochelaga Street
Montréal
Canada
H1N 3J4

Sponsor information

Organisation
Centre de recherche de l'Institut universitaire en santé mentale de Montréal

Sponsor details
7331 Hochelaga
Montreal
Canada
H1N 3V2
1-541-251-4015
criusmm.cemtl@ssss.gouv.qc.ca

Sponsor type
University/education

Website
https://criusmm.ciusss-estmtl.gouv.qc.ca/fr

Funder(s)

Funder type
University/education

Funder Name
Centre de recherche de l'Institut universitaire en santé mentale de Montréal

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author upon reasonable request. Data will be provided for meta-analysis or for serious requests from researchers with research privilege. They will be available for 7 years, participants' information will be anonymised

IPD sharing plan summary
Available on request