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Cognitive behavioral analysis system of psychotherapy for treatment-resistant depression: adaptation to a group modality

Submission date
28/05/2020

Recruitment status
No longer recruiting

Registration date
22/07/2020

Overall study status
Completed

Last Edited
02/12/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Severe, recurrent depression is a debilitating mood disorder with long-term impacts on social and professional functioning requiring specific psychosocial treatments concurrent with medication. The Cognitive Behavioral Analysis System of Psychotherapy (CBASP), developed by J. McCullough, Jr. is specifically designed to treat social withdrawal and maladaptive coping strategies to help depressed individuals reestablish meaningful interpersonal interactions with others during the depressive episode. Administering CBASP in a group format is a cost-effective way of providing mental health services in an outpatient setting and provides as well as direct exposure to a social setting in which adaptive learning takes place.
The study was designed to test the feasibility of a group adaptation to the CBASP therapy model as it was designed by its author J. McCullough Jr., Ph.D. to be administered individually. The duration of the group treatment recommended in this study was extended to 20 weeks, which is longer than the initial 12 weeks reported in the large multi-site study of the effectiveness of CBASP as an individually administered treatment. This extended duration reflected empirical evidence indicating that 12 weeks is not sufficient for chronic depression. The aim of this study is to observe the benefits gained by both bipolar and unipolar depressed patients in an outpatient psychiatric setting who agree to undertake CBASP in a 20-week group format.

Who can participate?
Adults aged 18 - 65 with a primary diagnosis of persistent depressive disorder or major depressive disorder

What does the study involve?
The study involves meeting each patient individually for one or two sessions prior to beginning group therapy in order to carry out a psychological assessment, invite the patient to the group therapy if it is deemed an appropriate treatment, explain the CBASP model, present the research study, and obtain informed consent from the patient. The next step involves identifying with each patient the salient social domain that he or she recognizes to be important to work on in group therapy and formulate what is called a “transference hypothesis” according to the CBASP model. Each participant is engaged and informed about the therapeutic goals that he or

she will work on for the duration of group therapy. Once all 6 participants, needed to constitute one group, have been met individually, the group can begin with one 2-hour session per week, for 20 consecutive weeks. Participants complete self-report questionnaires before the start of group, 10 weeks into group therapy and at the end of 20 weeks of group therapy. All participants are followed by their treating psychiatrist for the medical follow-up which remains stable throughout group therapy.

What are the possible benefits and risks of participating?
Benefits of CBASP in a group format are numerous. A group setting provides an environment that is more enabling and empowering and that succeeds from the start at breaking the cycle of isolation and despair which these patients report on a continual basis at the start of therapy. In addition, the group setting helps to counter the individual therapist's temptation to want to rescue the depressed patient. Instead, group members tend to make recommendations to each other on how to resolve certain difficulties. A group modality places individuals in an interactive, communicative mode. The group is a social network in which members can influence each other intentionally, therefore exercising personal agency and enhancing self-efficacy. Group members' beliefs in their capabilities develop through their experience of mastery by working together on Situational Analyses that are challenging social problem-solving exercises described in CBASP. Through social modeling, group members learn to persevere and observe how others in the group with similar depressive symptoms succeed at reaching their interpersonal goals. Finally, learning occurs through the effects of social persuasion with group members influencing and encouraging each other. The group also provides a naturally rewarding environment resembling the one patients left behind, being on disability from work or having withdrawn from family and friends. The group is a form of simulation or "social laboratory" replicating to some extent reality-based, expected levels of functioning for each individual. For example, group members are expected to attend each and every group session or to notify of their absence in case of an emergency. Group members are also asked to respect a limited set of rules covering issues of confidentiality and acceptance to work on individual objectives.
Depressed patients are usually reluctant to participate in group therapy because it places them in an exposure situation to what they most fear, which is interacting with others. There are no risks in participating in the group due to the voluntary participation of each group member and the assurance that no negative impact on their treatment at the clinic will result from their decision to discontinue the group. The task-focused and structured content of group sessions also provides assurance to patients of the treatment objectives and of what to anticipate.

Where is the study run from?
Douglas Mental Health University Institute (Canada)

When is the study starting and how long is it expected to run for?
August 2010 to March 2017

Who is funding the study?
Douglas Mental Health University Institute (Canada)

Who is the main contact?
Liliane Sayegh
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Contact information

Type(s)

Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IUSMD-10-19

Study information

Scientific Title
Group Cognitive Behavioral Analysis System of Psychotherapy (CBASP): a pilot study of feasibility for persistent depression

Study objectives
CBASP administered in a 20-week group intervention is expected to be beneficial for chronically depressed patients in diminishing self-reported depressive symptoms and improving social functioning

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/08/2010, Douglas Institute Research and Ethics Board (6875 LaSalle boulevard, Montréal, H4H1R3, Canada; +1 (0)514 761 6131 extension 3405; bruno.debruille@douglas.mcgill.ca), ref: IUSMD-10-19

Study design
Single-center non-randomized single-arm prospective longitudinal (interventional) study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

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
Severe depression

Interventions
Cognitive Behavioral Analysis System of Psychotherapy - group format
Behavioral Activation - group format
No randomization.
Group format, 20 weeks duration, 2 hours per session each week.
Administered by a CBASP certified psychologist and experienced clinical staff

Participants experiencing severe depression, referred by their treating psychiatrist, chose to undergo group therapy and were sequentially included in the group until a sufficient number

was reached to begin that group (5 or 6 individuals per group). Primary data was collected using self-report questionnaires at the start of group therapy, 10 weeks into group therapy and at the end (20 weeks) of group therapy.

Intervention Type
Behavioural

Primary outcome measure
Depressive symptoms measured using the Inventory of Depressive Symptoms, Self-Report (IDS-SR) at approximately 10-week intervals: at the beginning of group treatment (baseline: time 1), at the 10th week of treatment (mid-treatment: time 2), and at the 20th week of treatment (termination: time 3)

Secondary outcome measures
Three times over the course of treatment at approximately 10-week intervals: at the beginning of group treatment (baseline: time 1), at the 10th week of treatment (mid-treatment: time 2), and at the 20th week of treatment (termination: time 3):
1. Social functioning (Social Adjustment Scale self-report, SAS-SR)
2. Interpersonal distress (Inventory of Interpersonal Problems, IIP-32)
3. Dispositions (Circumplex Scales of Interpersonal Values, CSIV and of Interpersonal Self-Efficacy, CSIE)
4. Coping strategies (Coping Inventory of Stressful Situations, CISS),
5. Perceived stress (Perceived Stress Scale, PSS)
6. Self-reported treatment improvements (self-report measure of health improvements)
7. Satisfaction (Satisfaction Questionnaire)

Overall study start date
06/08/2010

Completion date
15/03/2017

Eligibility

Key inclusion criteria
1. Ages 18 to 65 years
2. A primary diagnosis of persistent depressive disorder, chronic depression, or major depressive disorder

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
107

Key exclusion criteria
1. Current psychosis
2. Primary diagnosis of schizophrenia, anxiety disorder, eating disorder, substance use disorder
3. Debilitating medical diagnosis
4. High suicide risk
5. Current substance use while attending group
6. Acting-out, or self-destructive behaviors while attending group
7. Bipolar disordered patients with a high risk of switch to mania

Date of first enrolment
08/06/2012

Date of final enrolment
07/09/2016

Locations

Countries of recruitment
Canada

Study participating centre
Douglas Mental Health University Institute
6875
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.douglas.qc.ca

ROR
https://ror.org/05dk2r620

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
In-kind contributions from the Douglas Mental Health University Institute

Results and Publications

Publication and dissemination plan
We would like to publish the results of the pilot study regarding the feasibility of administering CBASP in a group format with depressed patients. We would like to submit results of the primary outcome measure to a special edition of Frontiers in Psychology that is focused on CBASP studies (deadline for manuscript submission is September 2020). We have been invited to submit an article and have had the abstract accepted. However, it is necessary to register the study with an appropriate registry as a condition to proceeding further with the manuscript submission.

A second article summarizing the secondary outcomes of this study is also almost ready to be submitted but the journal is not chosen. Acceptance of this non-randomized trial's registration with ISRCTN will certainly determine where the study will be submitted for publication.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Liliane Sayegh (liliane.sayegh@douglas.mcgill.ca). Data is entered in Research Electronic Data Capture (REDCap). The data is already entered and available upon request to L. Sayegh. The data will be

available for as long as needed. Consent from participants was not obtained for subsequent analyses beyond the scope of the study described to participants. Data does not identify individual patients included in the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			23/07/2020	No	No
Results article	results	23/09/2020	02/12/2020	Yes	No