New York State Psychiatric Institute

Institutional Review Board

September 3, 2021

To: Dr. Ronit Kishon

From: Dr. Edward Nunes, Co-Chair
Dr. Agnes Whitaker, Co-Chair

Subject: Approval Notice*: Continuation

Your protocol # **6806R** entitled: **PSYCHOLOGICAL MINDEDNESS AS A PREDICTOR OF COGNITIVE BEHAVIOR THERAPY OUTCOME (FORMERLY #5768)** Protocol version date 09/03/2021 and consent forms have been approved by the New York State Psychiatric Institute - Columbia University Department of Psychiatry Institutional Review Board from **September 9, 2021 to September 8, 2022.** (Reviewed at the Full Board meeting on August 23, 2021.)

Consent requirements:
☐ Not applicable:
☐ 45CFR46.116 (f)(3) waiver of consent
√ Signature by the person(s) obtaining consent is required to document the consent process
☐ Documentation of an independent assessment of the participant's capacity to consent is also required.

Approved for recruitment of subjects who lack capacity to consent: √ No ☐ Yes

Field Monitoring Requirements: √ Routine ☐ Special: _____

✓ Only copies of consent documents that are currently approved by the IRB may be used to obtain consent for participation in this study.
✓ A progress report and application for continuing review is required 2 months prior to the expiration date of IRB approval.
✓ Changes to this research may not be initiated without the review and approval of the IRB except when necessary to eliminate immediate hazards to participants.
✓ All serious and/or unanticipated problems or events involving risks to subjects or others must be reported immediately to the IRB. Please refer to the PI-IRB website at http://irb.nyspi.org for Adverse Event Reporting Procedures and additional reporting requirements.

*Approved under 45CFR46.204

Cc: RFMH Business Office (NIMH 1R21 MH121915-01A1)

Encl: CF, recruitment materials, HIPAA

EN/AHW/alw

Signed copy on file at IRB

Protocol Title:
Psychological Mindedness as a Predictor of Cognitive Behavior Therapy Outcome (formerly #5768)

Version Date:
09/03/2021

Protocol Number:
6806R

First Approval:
09/10/2013

Expiration Date:
09/08/2022

Contact Principal Investigator:
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Co-Investigator(s):
Jurgen Kayser, PHD
Maren Westphal, PHD

Research Chief:
B. Timothy Walsh, MD

Cover Sheet

Choose ONE option from the following that is applicable to your study
If you are creating a new protocol, select "I am submitting a new protocol." As 5 Year Renewals are no longer required, this option remains for historical purposes.
I am submitting an annual continuation without modifications

Department & Unaffiliated Personnel

Department

What Department does the PI belong to?
Clinical Therapeutics
Within the department, what Center or group are you affiliated with, if any?
Depression Evaluation Services

Unaffiliated Personnel

List investigators, if any, who will be participating in this protocol but are not affiliated with New York State Psychiatric Institute or Columbia University. Provide: Full Name, Degrees and Affiliation.

None

Application for Continuation of Research

Status

Current Status of Study:
Subject enrollment is ongoing.

Summary of Experiences to Date

Please provide a summary of scientific progress of the study and the experience of research participants, to date. This requirement is designed to allow for the investigator and the IRB to reassess the study's risks and benefits in terms of developments in the field, changing practice patterns, and new IRB policies and procedures.
The first 3 months, we were challenged by COVID, and recruitment was sparse; however, after 6 months, we were actively recruiting patients as expected. Patients come to PI only for blood work and EEG tests at baseline and the end of the study. Therefore, they come to PI only 3 times during the study and are not at risk besides the usual risk of being currently going outside due to COVID. In addition, they receive 12 CBT sessions on Zoom, and they fill the self-report measure on RedCap. These procedures are running well and seem to be as effective as they were when done in person. We are looking forward to continuing another year of the R21.

Funding

Have there been any changes in funding status since the prior approval?
No
Have the principal investigator and other investigators made all required disclosures of financial interest in the study sponsor/product?
Yes

Summary

Have there been any study findings, recent literature, or untoward events occuring here or at other sites in the past year which might affect the analysis of the safety, risks or benefits of study participation?
No
Have there been any serious adverse events (serious and/or unanticipated problems involving risks to subjects or others at this site which occured in the past year)?
No
Have all study staff with a significant role in the design or implementation of the human subject components of this study received required training in human research subject protections?
Yes
Is the study covered by a certificate of confidentiality?

No

Overall Progress

Approved sample size
150
Total number of participants enrolled to date
124
Number of participants who have completed the study to date
116
Have there been any significant deviations from the anticipated study recruitment, retention or completion estimates?
No
Comments / additional information

Sample Demographics

Specify population
18-70
Total number of participants enrolled from this population to date
126
Gender, Racial and Ethnic Breakdown

Adults	White (not Hispanic origin)	Black (not Hispanic origin)	Hispanic	Asian or Pacific Islander	American Indian/Alaskan Native	other	Total
Female	53	4	5	6	0	2	72
Male	37	6	5	6	0	0	54
Total	92	10	10	12	0	2	126

Summary of Current Year's Enrollment and Drop-out

Number of participants who signed consent in the past year
16
Number of participants currently enrolled
10
Did the investigator withdraw participants from the study?
No
Did participants decide to discontinue study involvement?
No

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures

✓ Psychiatric Assessment
✓ Neuropsychological Evaluation
✓ Psychotherapy Trial
✓ Audio or Videotaping
✓ Internet-based Data Collection or Transmission

Population

Indicate which of the following populations will be included in this research

✓ Pregnant Woman
✓ Adults
✓ Adults over 50

Research Support/Funding

Will an existing internal account be used to support the project?
No
Is the project externally funded or is external funding planned?
Yes
Select the number of external sources of funding that will be applicable to this study

Funding Source #1

Is the PI of the grant/contract the same as the PI of the IRB protocol?
Yes
Select one of the following
The grant/contract is currently funded
Source of Funding
Federal
Institute/Agency
NIMH
Grant Name
R21
Grant Number
1R21MH121915 - 01A1
Select one of the following
Single Site
Business Office

RFMH
Does the grant/contract involve a subcontract?
No

Study Location

Indicate if the research is/will be conducted at any of the following
✓ NYSPI
This protocol describes research conducted by the PI at other facilities/locations
No

Lay Summary of Proposed Research

Lay Summary of Proposed Research

Psychological Mindedness (PM) is viewed as the ability and motivation to achieve a psychological understanding of the self. A person is considered to be psychologically minded if she or he can access their feelings, is willing to try and understand oneself and others, and has an interest in the meaning and motivation of his or her own and others' behavior. Historically, interest in PM grew out of attempts to identify patients best suited for psychoanalytically oriented psychotherapy. There has been limited attention regarding its potential impact on other therapeutic approaches. In recent years different theorists (Conte, Ratto, and Karusa, 1996; Grant, 2001) have noted that PM may have particular relevance for cognitive behavioral therapy (CBT) because PM includes self-monitoring and self-evaluation of one's cognitions, emotions, and behaviors which are central to the successful practice of CBT. This study aims to see if PM is a component in the mechanism of change that is activated in CBT treatment for depression. As such, it may be related to change of symptoms during CBT, and at post-treatment. Mindfulness is another construct of self-awareness that is related to PM and yet distinct. We are studying to see its role in CBT for depression, and its relationship with PM. We will be administrating a few self-report measures of PM that have been used in other studies. We will also begin validating a structured interview of PM that we created in our lab. We also measure other concepts found to be related to PM and mindfulness, rumination, alexithymia, and self-compassion.

Our studies and those of other researchers have found evidence that pretreatment resting EEG, event-related brain potentials (ERPs), and performance on neurocognitive tests show promise of being predictors of subsequent clinical response to antidepressants or CBT. However, the extent to which these tests predict response to specific treatments for depression or the mechanisms underlying successful response to CBT is not known. We propose to test depressed patients before they begin a treatment study as well as after treatment (pre-post design) to confirm the value of resting EEG, ERPs, dichotic listening, and neuropsychological tests for predicting treatment response in MDD. Patients will be randomized between 12 sessions of CBT and a control condition of non-specific supportive therapy for 12 weeks so to match the experimental condition of CBT with respect to receiving support by a professional, creating an alliance with the therapist, length of sessions, and duration of treatment.

Background, Significance and Rationale

Background, Significance and Rationale

Depression is one of the most common psychiatric conditions in the United States. It is a chronic and disabling disorder associated with substantial impairment, decreased quality of life, and psychiatric comorbidity. The two standard treatments for depression are pharmacotherapy and cognitive behavior therapy (CBT). Both treatment modalities are similar in that they are only moderately effective, with a large proportion of patients remaining symptomatic after the initial intervention. Possibly the primary reason for the substantial individual differences in treatment responsiveness is heterogeneity within current psychiatric disease categories, which are present at all levels (i.e.genetic, neurobiological, and psychological levels) (Hollon et al., 2006). In the present study, we measure the changes in self-awareness and specific biomarkers through 12 weeks of CBT for depression and a control condition of 12 weeks of psychoeducation for depression. Psychological mindedness (PM), an aspect of self-awareness, has long been considered to be an essential psychological mediator for therapy outcome. Through the history of clinical psychology, PM was mostly used intuitively by clinicians to evaluate the psychotherapy process, and more specifically, in predicting a patient's ability and motivation in psychotherapy (Farber & Golden, 1977). However, most definitions and measures of PM have approached the task from a psychodynamic perspective, thus limiting the use of this construct by clinicians and researchers from evidence-based psychological perspectives, such as CBT (Grant 2001). Two measures presently being used in studies, the Psychological Mindedness Scale (PMS) (Conte, Ratto, & Karasu 1996), and the more recent measure, Balanced Index of Psychological Mindedness (BIPM) (Nyklíček & Denollet, 2009), have shown some predictive value in different studies of treatment in mentally ill patients. They have not though been thoroughly investigated as predictors in evidence-based psychotherapies such as CBT for depression. A third measure, the Self-Reflection Index Scale (SRIS; Grant, Franklin, & Langfirm) is an evolved form of the Private Self- Consciousness Scale (PrSCS; Fenigstein, Scheier, & Buss, 1975) which is another method to assess PM, and also recommended in RDoC as a measure of self- knowledge. SRIS is compromised of two separate factors labeled Self-Reflection (SRIS-SR) and Insight (SRIS-IN) which are parts of self-awareness but differently correlate with depression: in studies, the SRIS-SR correlated positively with anxiety and stress, but not with depression and alexithymia. The SRISIN was negatively correlated with depression, anxiety, stress, and alexithymia, and positively correlated with cognitive flexibility and self-

regulation (Grant at el. 2002). In addition to PM we examine other concepts that relate to self-awareness so to capture the whole spectrum of one's ability and will to observe oneself. Mindfulness has been found to relate to the construct of PM in a nonclinical sample (Beitel, Ferrer, & Cecero, 2005), yet no study has examined its relationship with PM in a clinical sample despite a growing body of research supporting the role of mindfulness in facilitating clinical improvement in CBT. We measure facets of mindfulness that are particularly relevant to PM and examine their interactions and relative contribution to predicting CBT outcomes in depressed patients. We added a rumination measure because it is a core process in the development and maintenance of depression. Consistent with research indicating a distinction between rumination as a maladaptive form of self-attentiveness, and reflection as an adaptive intellectual form of self-attentiveness thought to underlie PM (Trapnell & Campbell, 1999), we examine the added value of the level of rumination in predicting CBT outcome and its longitudinal relationship with PM through the CBT. Another important construct that has been lately related to different forms of self-awareness and self-observation is self-compassion (Neff, 2003). This is a third construct that may be important for understanding the proposed relationship between increases in PM and symptomatic improvement in depression throughout treatment. There is increasing evidence that self-compassion is a robust predictor of lower psychopathology (for reviews, see Barnard & Curry, 2011; MacBeth & Gumley, 2012). A recent controlled treatment study suggests that self-compassion is a particularly salutary form of emotion regulation in individuals with high levels of depressed mood (Diedrich, Grant, Hofmann, Hiller, &Berking, 2014). To our knowledge, no published research has yet examined the relation between PM and self-compassion. Individuals high in PM may be more likely to develop greater self-compassion throughout CBT treatment as PM taps qualities that may be essential to developing self-compassion. We examine potential interaction effects for self-compassion and PM in the prediction of depression levels pre and post CBT treatment, for example, PM-related symptomatic improvement in depression may be more pronounced for individuals scoring high in self-compassion. Studies have found evidence that pre-treatment resting EEG, event-related brain potentials (ERPs), and performance on neurocognitive tests show promise of being predictors of subsequent clinical response to antidepressants or CBT (Bruder, Kayser, & Tenke, 2012). However, the extent to which these tests predict response to specific treatments for depression or the mechanisms underlying successful response to CBT are not known. We propose to test depressed patients, under Dr. Kayser's protocol (#6559) before they begin a treatment study, both in the CBT condition and control condition, as well as after treatment (pre-post design) to confirm the value of resting EEG, ERPs, dichotic listening, and neuropsychological tests for predicting treatment response in MDD. Patients are retested after the successful completion of CBT, which will take 12 weeks and at the end of psychoeducation treatment (12 weeks). The development of biomarkers for predicting treatment response would be important for personalizing treatment in depression (i.e., determining who will and who will not respond to CBT).

Specific Aims and Hypotheses

Specific Aims and Hypotheses

Study aims: (1) to examine whether pre-treatment PM scores predict the reduction of depressive symptoms at the end of treatments, (2) to determine whether an increase in PM during therapy is associated with a

decrease in symptom levels during 12 weeks in both treatments (3) to examine the relationship between PM and conceptually related and distinct concepts: self-reflection, insight, rumination, mindfulness, and self-compassion, and if and how they are related to a reduction of symptoms in CBT and in the control condition, (4) to obtain neurocognitive and electrophysiologic (EEG and ERP) measures so as to further evaluate hypotheses that depressive disorders involve abnormalities of frontal and temporoparietal function (Dr. Jürgen Kayser's protocol (#6559); (5) to evaluate the prediction that treatment with CBT will result in acute and chronic changes in neurocognitive, EEG and ERP measures; (6) measures of left hemisphere processing will be predictive of clinical response to cognitive behavioral therapy; (7) to evaluate any interactions between psychological measures and brain variables in predicting change in symptoms during treatments.

Description of Subject Population

Sample #1

Specify subject population
Adults who suffer from depression
Number of completers required to accomplish study aims
130
Projected number of subjects who will be enrolled to obtain required number of completers
150
Age range of subject population
18 to 70

Gender, Racial and Ethnic Breakdown

Gender breakdown: 60% Female/40% Male

Ethnicity breakdown: The composition of the sample is likely to be 10% non-Hispanic African American, 30% Hispanic/Latino, 5% other minority, and 55% non-Hispanic white.

Description of subject population
This pilot study will enroll 150 subjects between the ages of 18 and 70 with primary DSM-V-TR diagnosis of major depression.

Recruitment Procedures

Describe settings where recruitment will occur

Recruitment will occur via referral from other mental health care professionals and physicians, and via self-referral prompted by advertising.

How and by whom will subjects be approached and/or recruited?

A DES research assistant will conduct a 20-minute telephone screening interview, performed under the DES'#6669R to determine likely diagnostic suitability. It includes subject's name, address, demographic information, source of referral, presenting problem, psychiatric history, past treatment, social history, family history, medical history, mental status, provisional diagnosis, and disposition. Potentially eligible participants will be invited to the DES Clinic at NYSPI for a psychiatric intake evaluation and structured clinical interview, which will be performed under the DES's Consent # 6669R. Informed consent will be obtained prior to any procedure after a subject has been found qualified both medically and diagnostically to participate. A full explanation of all research procedures, risks, benefits, and rights of the subject will be given before proceeding. **Recruitment to this protocol will be restricted to those who enroll in protocol #6559. Participansts in this study will need need to have EEG measures (#6559) before 12 sessions of CBT and control group, and at the end of of the 12 weeks.**

How will the study be advertised/publicized?

Online advertisements will be placed on websites that may include RecruitMe (recruit.cumc.columbia.edu, a CU research site aimed at aiding recruitment of study participants), Craigslist, in sections including volunteers, gigs, and jobs, Google AdWords, Facebook, Research Match, academic listserv, radio, and others. We will advertise this study to Columbia-affiliated clinicians on the Columbia University PsychoPharmacology (CUPP) list-serve. We will approve through the IRB any future advertisement material.

Do you have ads/recruitment material requiring review at this time?
Yes
Does this study involve a clinical trial?
Yes
Please provide the NCT Registration Number
NCT01868711,

Concurrent Research Studies

Will subjects in this study participate in or be recruited from other studies?
Yes

Describe concurrent research involvement
Patients recruited for current protocol will also participate in protocol # 6559R.

Inclusion/Exclusion Criteria

Name the subject group/sub sample
Depressed adults
Create or insert table to describe the inclusion criteria and methods to ascertain them

Males or females between ages 18-70 (inclusive)	Screening interview
Primary diagnosis of Major Depression	SCID and clinical review
Beck Depression Inventory	BDI ≥13 BDI
Hamilton Rating Scale for Depression	HRSD ≥ 14

Participation in protocol #6559

No psychotropic medication or over-the-counter antidepressant for at least one month prior to recruitment and three months for fluoxetine.	Clinical interview
Ability to give inform consent	Interview, the capacity to consent
Fluent in English Intake interview	Self-Report

Create or insert table to describe the exclusion criteria and methods to ascertain them

Disorder or organic mental disease	Clinical interview
DSM-V substance abuse or dependence within 6 months (except nicotine or caffeine).	Toxicology, screen, intake
Currently taking psychotropic medication.	Clinical interview
Currently receiving another type of psychotherapy or any other therapeutic intervention.	Clinical interview
Participants who have used any of the psychedelic drugs (Ketamine, Psilocybin, LSD, MDMA) for the current episode of depression.	Clinical interview

Waiver of Consent/Authorization

Indicate if you are requesting any of the following consent waivers
Waiver of consent for use of records that include protected health information (a HIPAA waiver of Authorization)
No
Waiver or alteration of consent
No
Waiver of documentation of consent
No
Waiver of parental consent
No

Consent Procedures

Is eligibility screening for this study conducted under a different IRB protocol?
Yes
Indicate NYSPI IRB #
6669R
Describe Study Consent Procedures

Consent procedures are the following:

When subjects are eligible for the study, they will be scheduled to meet Dr. Kishon via Webex (HIPAA-compliant teleconference) before signing *a study consent form*. A copy of the consent form will be provided to the participant before consent is obtained via encrypted email. Subjects will be accessible to an electronic consent form via REDCap and join a HIPAA-compliant teleconference with Dr. Kishon to discuss consent. Afterward, they will digitally sign the consent form with the e-signature function in REDCap.

Indicate which of the following are employed as a part of screening or main study consent procedures
✓ Consent Form

Persons designated to discuss and document consent

Select the names of persons designated to obtain consent/assent
Kayser, Jurgen, PHD
Kishon Ph.D., Ronit
Type in the name(s) not found in the above list

Study Procedures

Describe the procedures required for this study

Baseline visits

Subjects will be briefed on the newly implemented COVID-19 safety protocol to reassure them precautions are being taken. This protocol is based on NYSPI COVID19 Amendment guidelines for research on April 20 and NYSPI Remote communication guidelines for clinical care and research 3.30.20). In the current study, all procedures will be done remotely.

Subjects who sign the DES screening consent will be contacted within two weeks after the screening call; they received the diagnoses of major depressive disorder. The DES psychiatrist will approve their medical tests. An evaluator will rate the HRSD-17, CGI-Severity, and Beck Depression Inventory. If still eligible, subjects will be presented with the study consent form via REDCap and have their questions answered by Dr. Kishon via Webex. Once they signed the study consent form via REDCap, subjects will complete a battery of self-report measures in REDCap. Patients will also take part in EEG and cognitive tests administered under Jurgen Kayser's protocol #6559R**.** The patients will be randomized to the experimental condition of 12 sessions of CBT for depression and 12 sessions of control condition of nonspecific supportive treatment. CBT and supportive therapy are provided by Ph.D. student psychologists who are screened and interviewed by Dr. Kishon and approved and credentialed by Dr. Laura Mufson. All sessions will be administered via Webex. Dr. Kishon will supervise all therapists every week via Webex. **Psychotherapy sessions will be audiotaped unless the subject does not consent; audiotaping of sessions is optional**. The audio recording will not include the subject's full name and will be reviewed by Dr. Kishon, who will evaluate the treatments provided by therapists in this study. The audio recordings will be kept for no more than ten years, after which they will be destroyed.

If the patient withdraws his or her consent, audio recordings can be destroyed during or after the procedure. The patient reserves the right to withdraw this consent at any time before or during the audiotaping. Ph.D. students in psychology supervised by Dr. Kishon will provide nonspecific treatment. Sessions in the control group will be audio recorded

CBT Treatment Protocol

CBT protocol represents incorporation and integration from several sources. These include (a) prior experience of the therapist with the treatment of depression and (b) published cognitive therapy (CBT) manual published by Emery (2000). The present protocol encourages therapist's flexibility in approach, yet during the treatment, specific tools and methods of coping with depression are given to each subject. The subject will learn to use the following basic cognitive-behavioral techniques for the treatment of depression: constructing an 'Action Schedule', setting goals, doing 'behavioral experiments,' and creating a Distorted Thought Record (DTR). The patient is expected to experiment with the tools between sessions.

A nonspecific treatment control condition

Therapists will provide 12 sessions of support focused on the three facilitative conditions (warmth, genuine, and empathy). They will provide support and will assess the patients for levels of depression and suicidality in each session. Approved DES evaluators will administer to all patients in both groups the Hamilton Rating Scale for Depression (HRSD-17) via Webex, and the CGI Severity and Improvement Scales at baseline via REDCap. The HRSD-17 will be administered every three weeks and at post-treatment via Webex. The CGI will be filled every week and at posttreatment. If there is no improvement in depressive symptoms at week 6, the study PI will conduct an informal interview in which she will discuss with the participant alternative treatments. The discussion will be documented in the participant's chart.

Post-Treatment Assessment Visit

Post-treatment assessment visits will occur within 12 days of the subject's last therapy session. All baseline rating scales will be administered (HRSD-17, CGI) via Webex and REDCap, as well as all self-report measures (BDI-II, Work and Social Adjustment, TAS-20, PM, BIPM, SRIS, Treatment Credibility and The Expectancy of Improvement Scale, Reasons for Living, Ruminative Response Scale (RRS), The Mindful Attention Awareness Attention Scale(MAAS), Five-Facet Mindfulness Questionnaire (FFMQ), and Self-Compassion Scale (SCS) via REDCap. The SCIP -M will be done via Webex. Patients will also take part in EEG and cognitive tests administered under Jurgen Kayser's protocol #6559R. If a patient terminates before completing the entire 12-session protocol, in each of the groups, this visit will be conducted as close as possible to the last session. Study participants who do not remit (end treatment HDRS-17 > 7, BDI-II>13) at the end of the trial will be offered a referral for psychotherapy or medications per subject's preference, or if in the control group will be offered CBT based on the availability of therapists.

I attest to follow the COVID-19 Safety Guidelines for Columbia Psychiatry and NYSPI Re-Entry outlined in the NYSPI Director's June 1st memo, which includes but are not limited to:
• Infection Control/PPE – Guidelines
• Research participants will only come on-site if absolutely necessary for the study procedures.
• No volunteers/externs on-site during Stage 1.
• Clinical research teams will screen their participants for COVID symptoms (night before and day of the onsite visit, documenting this in the chart), and escort them in and out of the building.
• COVID/COVID-like symptoms in participants will be reported to the IRB via PRISM as an SAE.

You can upload charts or diagrams if any

Criteria for Early Discontinuation

Criteria for Early Discontinuation

Criteria for Early Discontinuation

The subject will be withdrawn and prematurely terminated from the study under any of the following circumstances:

1. The subject requests to withdraw from the study.

2. The subject exhibits a clear-cut worsening of anxiety or mood symptoms, e.g., subject whose CGI Improvement score rating increases to 6 (much worse) or 7 (very much worse).

3. The subject reports suicidal ideation of sufficient concern to require hospitalization. Visit the emergency room without admission will be judged on a case-by-case basis erring on the side of ending study participation.

4. The appearance of a new or undercurrent illness that prevents the patient from complying with the protocol.

5. The subject has missed four sessions or is not responding to repeated attempts to contact him or her. Careful medical and psychiatric screening would be conducted to identify patients with risk for potential adverse events if they were to participate in the study treatments. As examples, patients for whom suicide is considered a significant risk will be excluded from all study participation, and subjects with uncontrolled mental impairment.

Any patient who evidences significant clinical deterioration, such as unusually high levels of distress or suicidality at significant risk during the treatments will be removed from the study and treated with alternative and appropriate clinical care at the DES until referred to another treatment. Signs of deterioration will be monitored weekly by the protocol therapist and PI of the study. At each visit during the 12 weeks of the treatments, the clinician will monitor, via clinical interview and various assessment measures for signs of increased severity of depression or the emergence of a major depressive episode. If in the judgment of the clinician and the PI removal of a participant from the study is indicated due to increased severity of depression, the patient will be removed and treated by the study PI (Ronit Kishon) until appropriate referrals will set in place. The threshold for mandatory removal from the study is a CGI Global Improvement score of 6 or 7 (worse to very much worse). Such ratings at any evaluation would prompt premature termination. However, clinicians and patients can end the study at any time; i.e. a CGI-GI score > 6 is not required to remove a patient from the study.

Assessment Instruments

Create a table or give a brief description of the instruments that will be used for assessment

Screening Visit:
Structured Clinical Interview for DSM-V (SCID-V) (2 hours)
Iowa Personality Disorder Screen (7 minutes)
Global Impressions Index: Severity Scale (CGI) (5 minutes)

Total time = 2 hours 12 minutes

Baseline Visit
HAM-D (15 minutes)
CGI - Severity (1 minute)
Beck Depression Inventory-II (BDI-II) (5 minutes)
Twenty Item Toronto Alexithymia Scale (TAS-20) (5 minutes)
Work and Social Adjustment Scale (5 minutes)
Reasons for Living Scale (5 minutes)
Psychological Mindedness Scale (PM Scale) (5 minutes)
The Balanced Index of Psychological Mindedness (5 minutes)
The Self Reflection and Insight Scale (5 minutes)
The Ruminative Response Scale (RRS) (5 minutes)
The Mindful Attention Awareness Scale (MAAS) (5 minutes)
Five Facet Mindfulness Questionnaire (FFMQ) (5 minutes)
Self Compassion Scale (SCS) (5 minutes)
Structured Clinical Interview for Psychological Mindedness (SCIP-M). (45 min)
Parental socioeconomic status (SES) (15 min)
Emotional Regulations Questionnaire (ERQ) (15 min)
Brunel Lifestyle Physical Activity Questionnaire (10 min)
The Pittsburgh Sleep Quality Index (10 min)
Social Adjustment Scale (10 min)
EEG and cognitive tests were administered under Jurgen Kayser's protocol #6559R (2.5 hrs).

Total time = 4 hours and 30 minutes.

During-Session Process Measures (week 2, 6, 12)
Treatment credibility and Expectancy of Improvement Scale (3 minutes)
The Working Alliance Inventory (7 minutes)

Total time =10 minutes.

Evaluation of depressive symptoms every 3 weeks:
HAM-D (10 minutes)

Mid and Post-treatment Assessments (week 6, 12)
HAM-D (10 minutes) CGI - Severity (2 minutes)
Beck Depression Inventory-II (BDI-II) (5 minutes)

Twenty Item Toronto Alexithymia Scale (TAS-20) (5 minutes)
Work and Social Adjustment Scale (5 minutes)
Reasons for Living Scale (5 minutes)
Psychological Mindedness Scale (PM Scale) (5 minutes)
The Balanced Index of Psychological Mindedness (5 minutes)
The Self-reflection and Insight Scale (5 minutes)
The Ruminative Response Scale (RRS) (5 minutes)
The Mindful Attention Awareness Scale (MAAS) (5 minutes)
Five Facet Mindfulness Questionnaire (FFMQ) (5 minutes)
Self-Compassion Scale (5 minutes)
Structured Clinical Interview for Psychological Mindedness (SCIP-M). (45 min)
Parental socioeconomic status (SES) (15 min)
Emotional Regulations Questionnaire (ERQ) (15 min)
Brunel Lifestyle Physical Activity Questionnaire (10 min)
The Pittsburgh Sleep Quality Index (10 min)
Social Adjustment Scale (10 min)
EEG and cognitive tests were administered under Jurgen Kayser's protocol #6559R (2.5 hrs).

Total time = 4 hour 30 minutes

Please attach copies, unless standard instruments are used

Research Related Delay to Treatment

Will research procedures result in a delay to treatment?
No
Treatment to be provided at the end of the study
At the end of study participation, non-remitters will be offered appropriate referrals as clinically indicated. They will discuss it with their therapist, and after the end of sessions will continue to meet Dr. Kishon as needed, until an appropriate referral will put in place.
Remitters will discuss potential referrals with the therapist in the last 3 weeks of treatment. During this period, and at the end of treatment, Dr. Kishon will be available to meet with the patient to consult on the nature of the referral. After the subject concludes where to be referred, the project coordinator of the study will provide a list of referrals to the patient and will remain in contact so as to follow how the patient integrates with the new treatment place.

Clinical Treatment Alternatives

Clinical treatment alternatives
CBT is an accepted and empirically supported form of treatment for depression, and thus is not considered

experimental. Non-specific supportive treatment was also found to be effective for depression through in smaller percentages than CBT. Subjects may want to be medicated for their depression in which case they will appropriately be referred to during the screening/evaluation process.

Risks/Discomforts/Inconveniences

Risks that could be encountered during the study period
Assessment procedure: Subjects could develop mild to moderate emotional discomfort or frustration associated with psychiatric interviewing, or filling out questionnaires. Only experienced clinicians will administer these interviews; they are well trained and experienced in recognizing and dealing with emotional discomfort. Also, subjects will be informed that they can end the meeting at any time, or skip uncomfortable questions. Unless such skipped questions prevent a diagnosis or other clinical issues from being adequately assessed, the subject will remain study eligible. Subjects' mood symptoms may also worsen during treatment. See procedures for minimizing risk in the next section.

CBT and nonspecific supportive treatments: Subjects may exhibit subjective distress during CBT or supportive treatment, which, if it occurs, is likely to be mild and transient. We will closely monitor reactions and address them therapeutically. In the unlikely event that a subject manifests unusually high levels of distress, the PI will withdraw him or her from the study and provide the necessary support until a referral will be in place.
Describe procedures for minimizing risks
Careful medical and psychiatric screening will be conducted to identify subjects with elevated risk for potential adverse effects. For example, participants for whom suicide is considered a significant risk will be excluded from the study.

Any subject who evidences significant clinical deterioration, such as unusually high level of distress or suicidality at significant risk during CBT or supportive treatment, will be removed from the study and treated with alternative and appropriate clinical care at the DES until a referral plan is set in place. Signs of deterioration will be monitored weekly by the protocol therapist, study PI, and a psychiatrist at the DES as needed. In addition, at each visit during the 12 weeks of CBT and control group, the treating clinician will monitor various assessment measures for signs of increased severity of depression via clinical interview. If in the judgment of the clinician and the PI, the removal of a participant from the study is indicated due to increased severity of depression, the patient will be removed and treated until the referral is in place or clinically indicated. The threshold for mandatory removal from the study is a CGI Global Improvement score of 6 or 7 (worse to very much worse). Such ratings at any evaluation would prompt premature termination. However, clinicians and subjects can end the study at any time; i.e., a CGI-GI score > 6 is not required to remove a subject from the study.

Precautionary measures will be taken to prevent the transmission of COVID-19 in experimental processes. The changes we proposed in the amendment section will minimize the subjects' infection risk for COVID-19. We are minimizing risks of in-person visits by conducting 12 virtual CBT sessions and 12 virtual control group therapy sessions. All self-report measures and interviews measures will be done remotely.

Methods to Protect Confidentiality

Describe methods to protect confidentiality

All collected data will be kept confidential and used for research purposes only. Patient charts and hard copy data will be held in locked file cabinets and identifiable only by number and a naming code of initials. Access to research records is restricted to research staff and regulatory authorities. No research participant's identifying data will be published. All electronic records will be kept confidential to the extent permitted by law. Participant's names and other personal identifying information will be stored in an electronically secure database at the New York State Psychiatric Institute on a registered password-protected computer. The information may be accessed only by the PI and the research coordinator. The study Data Manager will manage a data file on SPSS that has all study data without identifying information. Patients' names will not be entered into the study database, and each will be uniquely identified only by the ID number. All data will be entered once but checked and audited by two different staff members. When data entry is complete, all data will be cleaned and rechecked for accuracy before being backed up on an encrypted flash drive. Any data that is transmitted electronically will be fully encrypted and password protected.

Due to remote administration of intake evaluation procedure, therapy sessions, clinical interviews through sessions, and self-report measures at pretreatment, mid-treatment, and post-treatment, confidentiality is protected through HIPAA-compliant videoconferencing and web-based platforms, and encrypted email communication.

Will the study be conducted under a certificate of confidentiality?
No

Direct Benefits to Subjects

Direct Benefits to Subjects
All participants will receive a complete medical and psychiatric evaluation, and the PI will share the necessary information with the participant.
Benefits to participants are direct (i.e., treatment of depression; amelioration of symptoms). Also, some participants may experience relief of their depressive symptoms.

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?
No

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Uploads

Upload the entire grant application(s)
Upload copy(ies) of unbolded Consent Form(s)
Consent form non bolded 8_27_2021docx.pdf
Upload copy(ies) of bolded Consent Form(s)
Consent form bolded 8_27_2021docx.pdf
Upload copy(ies) of recruitment materials/ads to be reviewed

Recruit me non bolded blurb 8_27_21_.pdf
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HIPPA Form October , 2017.pdf
Upload any additional documents that may be related to this study
Consent form undbolded 8_21_2021docx.pdf

Twelve Weeks of Cognitive Behavior Therapy (CBT) vs. Supportive Therapy for Depression

Sponsor: National Institute of Mental Health
Enrolling: Male and Female Patients
Study Length: 15 Weeks
Clinic Visits: 3 visits in person
Age Range: Between 18 and 65 years old
IRB Number: 6806R
US Government ID: NCT01868711
Contact: Ronit Kishon Ph.D.: 646 724 4171 Tayler.Wilson@nyspi.columbia.edu

Additional Study Information:

This study offers 12 individual free sessions of Cognitive Behavior Therapy (CBT) or Supportive Therapy to people who suffer from depression. All sessions will be administered virtually using HIPAA-compliant video teleconferencing. Participants must have access to the internet and have video conferencing capabilities. During the study, participants can't be on psychotropic medications nor attend any other psychotherapy**.** Participants will need to come in person once for a urine & blood test (protocol #6669) and twice for an electroencephalogram (EEG) (protocol #6559). Please exercise caution when traveling in public and follow public health guidelines, such as wearing masks in public and avoiding crowds. It is important for you to stay informed of public health recommendations and guidelines regarding COVID-19, such as those issued by the Centers for Disease Control (CDC.gov) and local governments. If you have questions or do not feel safe traveling, please let us know, and know that you can call to reschedule visits.

CBT is a well-established psychotherapy for depression. CBT's primary goal is to provide specific tools and methods of depression management. The primary goal of supportive psychotherapy is to strengthen the patient's ability to cope effectively with various life stressors. The purpose of this research study is to learn which psychophysiological and psychological variables predict who will benefit from each treatment and how these variables may change throughout therapy.

Participants are randomized to one of these groups and are required to fill out measures that assess various psychological variables at three-time points through 12 weeks of treatment in addition to shorter measures throughout the treatment. These measures will be filled out online using HIPPA-compliant platforms. We will assist you in accessing and filling out those measures online. We plan to recruit 60 participants with depression who will complete the psychotherapy, study forms, and EEG.

Twelve Weeks of Cognitive Behavior Therapy (CBT) vs. Supportive Therapy for Depression

Sponsor: National Institute of Mental Health
Enrolling: Male and Female Patients
Study Length: 15 Weeks
Clinic Visits: 3 visits in person
Age Range: Between 18 and 65 years old
IRB Number: 6806R
US Government ID: NCT01868711
Contact: Ronit Kishon Ph.D.: 646 724 4171 Tayler.Wilson@nyspi.columbia.edu

Additional Study Information:

This study offers 12 individual free sessions of Cognitive Behavior Therapy (CBT) or Supportive Therapy to depressed adults. All sessions will be given virtually using Zoom. Participants must have internet access and video conferencing capabilities. During the study, participants can't be on psychotropic medications or attend any other psychotherapy. Participants will need to come in person before receiving sessions for a urine & blood test (protocol #6669) and once before and once after sessions for an EEG (protocol #6559). Please exercise caution when traveling in public and follow public health guidelines, such as wearing masks in public and avoiding crowds. In addition, you need to stay informed of public health recommendations and guidelines regarding COVID-19, such as those issued by the CDC (CDC.gov) and local governments. If you have questions or do not feel safe traveling, please let us know, and know that you can call to reschedule visits. CBT is well-established psychotherapy for depression. CBTs primary goal is to provide specific tools and methods of depression management. Supportive Psychotherapy's primary goal is to strengthen the patient's ability to cope effectively with various life stressors. **The purpose of this research study is to learn which variables predict who will benefit from each treatment and how these variables may change throughout therapy. Participants are randomly assigned to receive one of the two therapies and are required to fill out forms weekly through the 12 weeks of treatment. These forms will be filled out online using HIPPA-compliant platforms. We plan to recruit 60 participants with depression who will complete the psychotherapy, study forms, and EEG.**

NYSPI IRB Approved
6806R
9/9/2021 -> 9/8/2022

Research Study Psychotherapy for Depression at Columbia University

We offer 12 free online psychotherapy sessions focused on treating depression

We are seeking adult study participants that 1) are depressed,
2) not on antidepressants (prescribed or over-the-counter),
3) not currently receiving psychotherapeutic treatment.

Participants will attend 12 therapy sessions over 12 weeks, and come to our laboratory three times: once for a blood and urine screen, and twice for EEG (brainwave) testing. There are no costs for the psychotherapy sessions nor is there any financial compensation for study participation.

For full details please call or email:

646 774 8030 Ronit.Kishon@nyspi.columbia.edu

08/20/2021

Consent Summary Page

- **Overview**

Below is a summary of the study that you are asked to participate in. This outline is meant to be a guide for you to use while considering the study and reading the consent form. It is not meant to replace the consent form, which you will have to sign if you decide to participate in the study. The consent form contains detailed information about the study and about the risks which you will need to consider before making your decision. Read the consent form carefully and discuss it with others before deciding to take part. And remember that, even if you agree to participate, you can change your mind at any time.
The purpose of the study is to compare two forms of therapy for depression *Cognitive Behavior Therapy (CBT)* and *Nonspecific supportive treatment*, and examine whether their effectiveness relates to concepts about self and others. In each therapy you will receive 12 individual sessions. You will not be able to choose which therapy you will receive but both are considered effective for treating depression. Precautionary measures will be taken to prevent the transmission of COVID-19 in experimental processes. Most of your visits will be conducted remotely using the telephone or HIPAA-compliant video teleconferencing.

- **Voluntary**

As with all research, this is a voluntary study, and you do not have to participate if you do not want to. Also, you may stop participating at any time.

- **Alternative Treatments/Alternatives to Participation**

Medications, interpersonal psychotherapy (IPT), dialectic behavior therapy (DBT), group therapy.

- **Procedures**

1. Evaluation for Major Depression Disorder (remote session).
2. Self-report study measures (beginning, midpoint, end) done online**.**
3. EEG and cognitive tests (beginning and end) done in the lab at NYSPI.
4. 12 weekly sessions of Cognitive Behavior Therapy for Depression or 12 weekly sessions of Supportive Therapy for Depression(remote sessions).
5. Participants cannot be on psychotropic medications during the study. Medicating for depression will not be part of this study.
6. Participants will be interviewed about symptoms of depression every 3 weeks, and will fill a self-report measure on their symptoms every week (remote sessions, and measures done online).

- **Risks and Inconveniences**

This study includes some risks and discomforts (please refer to the consent form for further details and explanations of these risks). These include no change of your depressive symptoms. Sometimes psychotherapy might increase sadness and anxiety.
You should exercise caution when traveling in public and follow public health guidelines, such as wearing masks in public and avoiding crowds. It is important for you to stay informed about public health recommendations and guidelines regarding COVID-19, such as those issued by the Centers for Disease Control (CDC.gov) and local government guidelines and directives. If you have questions about how you will travel for appointments, or do not feel safe traveling, please let us know, and be advised that you can call to reschedule visits

- **Benefits**

Although some benefit is possible such as reduction of depressive symptoms, you may not have any benefit if the treatment is not effective.

- **Questions**

You may contact the study principal investigator, Ronit Kishon, at 646 724 4171 with any question

CONSENT FORM Study # 6806R
Cognitive Behavior Therapy for Depression

Purpose and Overview

The purpose of the study is to compare two forms of therapy for depression since we still can't predict which one will be more helpful for a particular person. Previous studies suggested that *Cognitive Behavior Therapy (CBT)* is an effective treatment for depression in nearly half of the individuals who do it, however there are others who do not benefit from it. *Nonspecific supportive treatment* focuses on meeting with a therapist, receiving support, having one's hope restored, and overcoming demoralization. In each of the treatments you will receive12 virtua**l** sessions. You will be randomly assigned to one or the other. The purpose of this study is to explore whether your concepts about yourself and others are related to the effectiveness of each of the treatments. Also, **you must enroll** in Dr. Kayser's study (#6559) for the purpose of behavioral and electrophysiological tests at two time points that will contribute to our study. The aim is to learn more about brain function in people who are depressed and receive different types of talk therapy.

Voluntary

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate or withdraw your participation will not affect your current or future treatment at the New York State Psychiatric Institute or Columbia University Medical Center. If you are determined to be eligible for the study and later stop your participation for any reason, the study principal investigator, Dr. Kishon will treat you until the appropriate referral will be in place**.** You will be notified of significant new findings that may relate to your willingness to continue to participate in the study.

Alternative Treatments/ Alternatives to Participation

You do not have to participate in this study to receive treatment for your depression. CBT and nonspecific supportive therapy can be obtained outside of study participation. There are medications that have been shown to be effective for depression and can be prescribed by your regular physician. There are also other non-medication treatments for depression beside CBT such as interpersonal psychotherapy, or group therapy.

Procedures

Precautionary measures will be taken to prevent the transmission of COVID-19 in experimental processes. All your visits in this protocol will be conducted remotely using the telephone or HIPAA-compliant video teleconferencing. In this study most of the evaluation process and all psychotherapy sessions will be done virtually. We will discuss with you the technology HIPAA-compliant platforms to be used and any concerns you may have, such as access to a private space in which to take calls, or accessibility—access at home to adequate devices, cell signal, or Wi-Fi. In the CBT treatment, you will receive 12 weekly remote psychotherapy sessions that last about 50 minutes each. The treatment involves being asked questions about your thoughts and feelings, as well as learning skills to manage

them. In nonspecific supportive therapy you will also receive 12 sessions that last 50 minutes each. In the sessions you will receive support and understanding for your problems, so to have your hope restored and to overcome demoralization.

Study measures:
You will be interviewed remotely and you will fill some self-report measures online for a total of an hour and 15 minutes before treatment, in week 6, and after 12 weeks when the treatment is completed. We will also ask you before each session to fill a self-report measure that takes 5 minutes so we can monitor your symptoms. Every 3 weeks we will interview you for 15 minutes, again with the intention of monitoring your level of symptoms. The brain tests will be administered in Dr. Kayser's study(#6559).

Medications during the study:
You can participate in the study if you did not take prescribed antidepressant, or over the counter antidepressant medications, in the past month (three months for fluoxetine). You will be able to continue receiving psychotherapy sessions in the study if your clinical condition will initiate your outside physician to prescribe psychotropic medications.

The study doctors will end your study participation if they determine it is no longer in your best interest. In addition, you may stop participating in this study at any time for any reason. If you stop participating in the study before 12 weeks end**,** the study principal investigator, Dr. Kishon, will continue to see you for sessions until an appropriate referral will be made. Completion of the study is not required for you to receive these sessions by Dr. Kishon.

Cognitive Behavior Therapy and Nonspecific Supportive Therapy – Audiotaping:
You will be audiotaped during your treatment visits. **The audiotaping is optional**. The audio recording will be used for education, research or training purposes only. Any audio recording will not include your full name, and will be reviewed by Dr. Kishon who will evaluate the treatment provided by therapists in this study. The audio recordings are kept for no more than 10 years after which they will be destroyed. If you withdraw your consent, audio recordings can be destroyed during or after the interview or procedure.

Treatment After the End of the Study:
After the study is over, the Principal Investigator, Dr. Kishon, will meet with you, and answer any questions you may have. If after completion of the study you have not improved, you will receive referrals for continuation of psychotherapy and/or medications. You will be able to see Dr. Kishon for weekly sessions until the referral is in place.

Investigator Initiated Discontinuation of Study:
There may be times when the investigator carrying out this study decides to stop the study even though you may wish to continue to participate. Examples include missing 4 number of sessions or not responding to repeated attempts to contact you.

Risks and Inconveniences
The primary risk of participating in this study is that the treatment may not help your symptoms. If you do not improve it may be up to 12 weeks from the time you enter the study until you would be provided with another type of treatment. Therefore, if you do not improve, participating in this study will delay your receiving treatment for up to 12 weeks with medications and other psychotherapies known to be helpful. The risks of psychotherapy treatment include the possibility of increased anxiety or sadness, and the therapists will try to help you with that if it occurs. We anticipate that the risks of study participation are

no greater than those encountered in routine clinical treatment. However, you may be withdrawn from the study and offered other treatment.

Benefits:
A direct benefit to you is the possibility that the treatments will help your symptoms of depression. In addition, your participation may help researchers learn more about how to treat depression. There may be no benefit to you if the treatment is not effective.

The knowledge gained from this study may contribute to a better understanding of psychiatric disorders, and it may contribute to the development of objective measures for diagnosis and treatment selection.

Confidentiality
All records will be stored in locked files and will be kept confidential to the extent permitted by law. Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits).

Your name and other personal identifying information will be stored in an electronically secure database at New York State Psychiatric Institute. Research data that is entered into the computer will be stored according to study ID. A master list linking the patient name to the assigned ID is kept in a separate file. In order to access, the computer and appropriate data files, the staff member must know have knowledge of the password and be given rights to access the data by the data manager.
All data that is transmitted via computer is encoded and identifying information is removed.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your private information could be used for future research studies or distributed to another investigator for future research studies, with or without identifiers. Should any of the information gathered from you be used for scientific publications or presentations, you will be protected through the use of a system of codes that will not reveal the identity of individuals. Any report based on this study will only be used as grouped information without mention or description of the individual participants.

The NYSPI Remote Communications Guidance will be followed to ensure protection of confidentiality. This discussion and documentation of consent is carried out in a HIPAA – compliant teleconference as well as the psychotherapy sessions. Instruments to be completed will be completed via REDCap, a HIPAAA-compliant platform to ensure confidentiality. Our research assistants will assist you in using those platforms.

In case of Injury
Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research-related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator Dr. Ronit Kishon at 646-724-4171 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute will provide short-term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances.

New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Questions

Dr. Kishon will answer to the best of her ability any questions that the participant may have now or in the future about the research procedures, or about the subject's response to the procedures. She can be

reached during the day, and outside of regular business hours at 646-724-4171. Dr. Kishon can be called outside of regular business hours for important issues that should not wait until the next business day. In the case of an EMERGENCY go to your nearest emergency room and call Dr. Kishon.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main Office at (646)774-7155 during regular office hours.

You will be given a copy of the signed Consent Form.

Documentation of Consent

I voluntarily agree to participate in the research study described above.

Name:_____ (print)

Signed _____Study Participant

Date: _____

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

Name:_____(print)

Signed:_____ Person Designated to Obtain Consent

Date:_____

08/20/2021

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- **Voluntary**

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- **Alternative Treatments/Alternatives to Participation**

Medications, interpersonal psychotherapy (IPT), dialectic behavior therapy (DBT), group therapy.

- **Procedures**

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- **Benefits**

Although some benefit is possible such as reduction of depressive symptoms, you may not have any benefit if the treatment is not effective.

- **Questions**

You may contact the study principal investigator, Ronit Kishon, at 646 724 4171 with any question

08/20/2021

CONSENT FORM Study # 6806R
Cognitive Behavior Therapy for Depression

Purpose and Overview

The purpose of the study is to compare two forms of therapy for depression since we still can't predict which one will be more helpful for a particular person. Previous studies suggested that *Cognitive Behavior Therapy (CBT)* is an effective treatment for depression in nearly half of the individuals who do it, however there are others who do not benefit from it. *Nonspecific supportive treatment* focuses on meeting with a therapist, receiving support, having one's hope restored, and overcoming demoralization. In each of the treatments you will receive12 virtual sessions. You will be randomly assigned to one or the other. The purpose of this study is to explore whether your concepts about yourself and others are related to the effectiveness of each of the treatments. Also, you will be asked to consent to participate in Dr. Kayser's study (#6559) for the purpose of behavioral and electrophysiological tests at two time points that will contribute to our study. The aim is to learn more about brain function in people who are depressed and receive different types of talk therapy.

Voluntary

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Alternative Treatments/ Alternatives to Participation

You do not have to participate in this study to receive treatment for your depression. CBT and nonspecific supportive therapy can be obtained outside of study participation. There are medications that have been shown to be effective for depression and can be prescribed by your regular physician. There are also other non-medication treatments for depression beside CBT such as interpersonal psychotherapy, or group therapy.

Procedures

Precautionary measures will be taken to prevent the transmission of COVID-19 in experimental processes. All your visits in this protocol will be conducted remotely using the telephone or HIPAA-compliant video teleconferencing. In this study most of the evaluation process and all psychotherapy sessions will be done virtually. We will discuss with you the technology HIPAA-compliant platforms to be used and any concerns you may have, such as access to a private space in which to take calls, or accessibility—access at home to adequate devices, cell signal, or Wi-Fi. In the CBT treatment, you will receive 12 weekly remote psychotherapy sessions that last about 50 minutes each. The treatment involves being asked questions about your thoughts and feelings, as well as learning skills to manage

them. In nonspecific supportive therapy you will also receive 12 sessions that last 50 minutes each. In the sessions you will receive support and understanding for your problems, so to have your hope restored and to overcome demoralization.

Study measures:
You will be interviewed remotely and you will fill some self-report measures online for a total of an hour and 15 minutes before treatment, in week 6, and after 12 weeks when the treatment is completed. We will also ask you before each session to fill a self-report measure that takes 5 minutes so we can monitor your symptoms. Every 3 weeks we will interview you for 15 minutes, again with the intention of monitoring your level of symptoms. The brain tests will be administered in Dr. Kayser's study(#6559).

Medications during the study:
You can participate in the study if you did not take prescribed antidepressant, or over the counter antidepressant medications, in the past month (three months for fluoxetine). You will be able to continue receiving psychotherapy sessions in the study if your clinical condition will initiate your outside physician to prescribe psychotropic medications.

The study doctors will end your study participation if they determine it is no longer in your best interest. In addition, you may stop participating in this study at any time for any reason. If you stop participating in the study before 12 weeks end**,** the study principal investigator, Dr. Kishon, will continue to see you for sessions until an appropriate referral will be made. Completion of the study is not required for you to receive these sessions by Dr. Kishon.

Cognitive Behavior Therapy and Nonspecific Supportive Therapy – Audiotaping:
You will be audiotaped during your treatment visits. The audio recording will be used for education, research or training purposes only. Any audio recording will not include your full name, and will be reviewed by Dr. Kishon who will evaluate the treatment provided by therapists in this study. The audio recordings are kept for no more than 10 years after which they will be destroyed. If you withdraw your consent, audio recordings can be destroyed during or after the interview or procedure.

Treatment After the End of the Study:
After the study is over, the Principal Investigator, Dr. Kishon, will meet with you, and answer any questions you may have. If after completion of the study you have not improved, you will receive referrals for continuation of psychotherapy and/or medications. You will be able to see Dr. Kishon for weekly sessions until the referral is in place.

Investigator Initiated Discontinuation of Study:
There may be times when the investigator carrying out this study decides to stop the study even though you may wish to continue to participate. Examples include missing 4 number of sessions or not responding to repeated attempts to contact you.

Risks and Inconveniences
The primary risk of participating in this study is that the treatment may not help your symptoms. If you do not improve it may be up to 12 weeks from the time you enter the study until you would be provided with another type of treatment. Therefore, if you do not improve, participating in this study will delay your receiving treatment for up to 12 weeks with medications and other psychotherapies known to be helpful. The risks of psychotherapy treatment include the possibility of increased anxiety or sadness, and the therapists will try to help you with that if it occurs. We anticipate that the risks of study participation are

no greater than those encountered in routine clinical treatment. However, you may be withdrawn from the study and offered other treatment.

Benefits:

A direct benefit to you is the possibility that the treatments will help your symptoms of depression. In addition, your participation may help researchers learn more about how to treat depression. There may be no benefit to you if the treatment is not effective.

The knowledge gained from this study may contribute to a better understanding of psychiatric disorders, and it may contribute to the development of objective measures for diagnosis and treatment selection.

Confidentiality

All records will be stored in locked files and will be kept confidential to the extent permitted by law. Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits).

Your name and other personal identifying information will be stored in an electronically secure database at New York State Psychiatric Institute. Research data that is entered into the computer will be stored according to study ID. A master list linking the patient name to the assigned ID is kept in a separate file. In order to access, the computer and appropriate data files, the staff member must know have knowledge of the password and be given rights to access the data by the data manager.
All data that is transmitted via computer is encoded and identifying information is removed.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your private information could be used for future research studies or distributed to another investigator for future research studies, with or without identifiers. Should any of the information gathered from you be used for scientific publications or presentations, you will be protected through the use of a system of codes that will not reveal the identity of individuals. Any report based on this study will only be used as grouped information without mention or description of the individual participants.

The NYSPI Remote Communications Guidance will be followed to ensure protection of confidentiality. This discussion and documentation of consent is carried out in a HIPAA – compliant teleconference as well as the psychotherapy sessions. Instruments to be completed will be completed via REDCap, a HIPAAA-compliant platform to ensure confidentiality. Our research assistants will assist you in using those platforms.

In case of Injury

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research-related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator Dr. Ronit Kishon at 646-724-4171 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute will provide short-term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's

doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances.

New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Questions

Dr. Kishon will answer to the best of her ability any questions that the participant may have now or in the future about the research procedures, or about the subject's response to the procedures. She can be

reached during the day, and outside of regular business hours at 646-724-4171. Dr. Kishon can be called outside of regular business hours for important issues that should not wait until the next business day. In the case of an EMERGENCY go to your nearest emergency room and call Dr. Kishon.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main Office at (646)774-7155 during regular office hours.

You will be given a copy of the signed Consent Form.

Documentation of Consent

I voluntarily agree to participate in the research study described above.

Name:_____ (print)

Signed _____Study Participant

Date: _____

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

Name:_____(print)

Signed:_____ Person Designated to Obtain Consent

Date:_____

08/20/2021

Consent Summary Page

- **Overview**

Below is a summary of the study that you are asked to participate in. This outline is meant to be a guide for you to use while considering the study and reading the consent form. It is not meant to replace the consent form, which you will have to sign if you decide to participate in the study. The consent form contains detailed information about the study and about the risks which you will need to consider before making your decision. Read the consent form carefully and discuss it with others before deciding to take part. And remember that, even if you agree to participate, you can change your mind at any time.
The purpose of the study is to compare two forms of therapy for depression *Cognitive Behavior Therapy (CBT)* and *Nonspecific supportive treatment*, and examine whether their effectiveness relates to concepts about self and others. In each therapy you will receive 12 individual sessions. You will not be able to choose which therapy you will receive but both are considered effective for treating depression. Precautionary measures will be taken to prevent the transmission of COVID-19 in experimental processes. Most of your visits will be conducted remotely using the telephone or HIPAA-compliant video teleconferencing.

- **Voluntary**

As with all research, this is a voluntary study, and you do not have to participate if you do not want to. Also, you may stop participating at any time.

- **Alternative Treatments/Alternatives to Participation**

Medications, interpersonal psychotherapy (IPT), dialectic behavior therapy (DBT), group therapy.

- **Procedures**

1. Evaluation for Major Depression Disorder (remote session).
2. Self-report study measures (beginning, midpoint, end) done online**.**
3. EEG and cognitive tests (beginning and end) done in the lab at NYSPI.
4. 12 weekly sessions of Cognitive Behavior Therapy for Depression or 12 weekly sessions of Supportive Therapy for Depression(remote sessions).
5. Participants cannot be on psychotropic medications during the study. Medicating for depression will not be part of this study.
6. Participants will be interviewed about symptoms of depression every 3 weeks, and will fill a self-report measure on their symptoms every week (remote sessions, and measures done online).

- **Risks and Inconveniences**

This study includes some risks and discomforts (please refer to the consent form for further details and explanations of these risks). These include no change of your depressive symptoms. Sometimes psychotherapy might increase sadness and anxiety.
You should exercise caution when traveling in public and follow public health guidelines, such as wearing masks in public and avoiding crowds. It is important for you to stay informed about public health recommendations and guidelines regarding COVID-19, such as those issued by the Centers for Disease Control (CDC.gov) and local government guidelines and directives. If you have questions about how you will travel for appointments, or do not feel safe traveling, please let us know, and be advised that you can call to reschedule visits

- **Benefits**

Although some benefit is possible such as reduction of depressive symptoms, you may not have any benefit if the treatment is not effective.

- **Questions**

You may contact the study principal investigator, Ronit Kishon, at 646 724 4171 with any question

CONSENT FORM Study # 6806R
Cognitive Behavior Therapy for Depression

Purpose and Overview

The purpose of the study is to compare two forms of therapy for depression since we still can't predict which one will be more helpful for a particular person. Previous studies suggested that *Cognitive Behavior Therapy (CBT)* is an effective treatment for depression in nearly half of the individuals who do it, however there are others who do not benefit from it. *Nonspecific supportive treatment* focuses on meeting with a therapist, receiving support, having one's hope restored, and overcoming demoralization. In each of the treatments you will receive12 virtual sessions. You will be randomly assigned to one or the other. The purpose of this study is to explore whether your concepts about yourself and others are related to the effectiveness of each of the treatments. Also, you must enroll in Dr. Kayser's study (#6559) for the purpose of behavioral and electrophysiological tests at two time points that will contribute to our study. The aim is to learn more about brain function in people who are depressed and receive different types of talk therapy.

Voluntary

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate or withdraw your participation will not affect your current or future treatment at the New York State Psychiatric Institute or Columbia University Medical Center. If you are determined to be eligible for the study and later stop your participation for any reason, the study principal investigator, Dr. Kishon will treat you until the appropriate referral will be in place. You will be notified of significant new findings that may relate to your willingness to continue to participate in the study.

Alternative Treatments/ Alternatives to Participation

You do not have to participate in this study to receive treatment for your depression. CBT and nonspecific supportive therapy can be obtained outside of study participation. There are medications that have been shown to be effective for depression and can be prescribed by your regular physician. There are also other non-medication treatments for depression beside CBT such as interpersonal psychotherapy, or group therapy.

Procedures

Precautionary measures will be taken to prevent the transmission of COVID-19 in experimental processes. All your visits in this protocol will be conducted remotely using the telephone or HIPAA-compliant video teleconferencing. In this study most of the evaluation process and all psychotherapy sessions will be done virtually. We will discuss with you the technology HIPAA-compliant platforms to be used and any concerns you may have, such as access to a private space in which to take calls, or accessibility—access at home to adequate devices, cell signal, or Wi-Fi. In the CBT treatment, you will receive 12 weekly remote psychotherapy sessions that last about 50 minutes each. The treatment involves being asked questions about your thoughts and feelings, as well as learning skills to manage

them. In nonspecific supportive therapy you will also receive 12 sessions that last 50 minutes each. In the sessions you will receive support and understanding for your problems, so to have your hope restored and to overcome demoralization.

Study measures:
You will be interviewed remotely and you will fill some self-report measures online for a total of an hour and 15 minutes before treatment, in week 6, and after 12 weeks when the treatment is completed. We will also ask you before each session to fill a self-report measure that takes 5 minutes so we can monitor your symptoms. Every 3 weeks we will interview you for 15 minutes, again with the intention of monitoring your level of symptoms. The brain tests will be administered in Dr. Kayser's study(#6559).

Medications during the study:
You can participate in the study if you did not take prescribed antidepressant, or over the counter antidepressant medications, in the past month (three months for fluoxetine). You will be able to continue receiving psychotherapy sessions in the study if your clinical condition will initiate your outside physician to prescribe psychotropic medications.

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Cognitive Behavior Therapy and Nonspecific Supportive Therapy – Audiotaping:
You will be audiotaped during your treatment visits. The audiotaping is optional. The audio recording will be used for education, research or training purposes only. Any audio recording will not include your full name, and will be reviewed by Dr. Kishon who will evaluate the treatment provided by therapists in this study. The audio recordings are kept for no more than 10 years after which they will be destroyed. If you withdraw your consent, audio recordings can be destroyed during or after the interview or procedure.

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After the study is over, the Principal Investigator, Dr. Kishon, will meet with you, and answer any questions you may have. If after completion of the study you have not improved, you will receive referrals for continuation of psychotherapy and/or medications. You will be able to see Dr. Kishon for weekly sessions until the referral is in place.

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There may be times when the investigator carrying out this study decides to stop the study even though you may wish to continue to participate. Examples include missing 4 number of sessions or not responding to repeated attempts to contact you.

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The primary risk of participating in this study is that the treatment may not help your symptoms. If you do not improve it may be up to 12 weeks from the time you enter the study until you would be provided with another type of treatment. Therefore, if you do not improve, participating in this study will delay your receiving treatment for up to 12 weeks with medications and other psychotherapies known to be helpful. The risks of psychotherapy treatment include the possibility of increased anxiety or sadness, and the therapists will try to help you with that if it occurs. We anticipate that the risks of study participation are

no greater than those encountered in routine clinical treatment. However, you may be withdrawn from the study and offered other treatment.

Benefits:

A direct benefit to you is the possibility that the treatments will help your symptoms of depression. In addition, your participation may help researchers learn more about how to treat depression. There may be no benefit to you if the treatment is not effective.

The knowledge gained from this study may contribute to a better understanding of psychiatric disorders, and it may contribute to the development of objective measures for diagnosis and treatment selection.

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All data that is transmitted via computer is encoded and identifying information is removed.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your private information could be used for future research studies or distributed to another investigator for future research studies, with or without identifiers. Should any of the information gathered from you be used for scientific publications or presentations, you will be protected through the use of a system of codes that will not reveal the identity of individuals. Any report based on this study will only be used as grouped information without mention or description of the individual participants.

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In case of injury, New York State Psychiatric Institute will provide short-term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances.

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reached during the day, and outside of regular business hours at 646-724-4171. Dr. Kishon can be called outside of regular business hours for important issues that should not wait until the next business day. In the case of an EMERGENCY go to your nearest emergency room and call Dr. Kishon.

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You will be given a copy of the signed Consent Form.

Documentation of Consent

I voluntarily agree to participate in the research study described above.

Name:_____ (print)

Signed _____Study Participant

Date: _____

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

Name:_____(print)

Signed:_____ Person Designated to Obtain Consent

Date:_____

New York State Psychiatric Institute (NYSPI)
Authorization to Use or Disclose Health Information during a Research Study

Protocol Number: #6806 **Principal Investigator:** Ronit Kishon Ph.D.

Name of Study: Cognitive Behavior Therapy for Depression

Before researchers can use or share any identifiable health information ("Health Information") about you as part of the above study (the "Research"), the New York State Psychiatric Institute (NYSPI) is required to obtain your authorization. You agree to allow the following individuals and entities to use and disclose Health Information about you as described below:

- New York State Psychiatric Institute (NYSPI), your doctors and other health care providers, if any, and
- The Principal Investigator and his/her staff (together "Researchers"). Researchers may include staff of NYSPI, the New York State Office of Mental Health (OMH), Research Foundation for Mental Hygiene, Inc. (RFMH), and Columbia University (CU), provided such staff is a part of the study, and
- Providers of services for the Research at CU, NYSPI and/or RFMH, such as MRI or PET, or Central Reference Laboratories (NKI), if indicated in the consent form**.**

1. The Health Information that may be used and/or disclosed for this Research includes:

☑ All information collected during the Research as told to you in the Informed Consent Form.
☐ Health Information in your clinical research record which includes the results of physical exams, medical and psychiatric history, laboratory or diagnostic tests, or Health Information relating to a particular condition that is related to the Research.
☐ Additional information may include:

2. **The Health Information listed above may be disclosed to:**

☑ Researchers and their staff at the following organizations involved with this Research:
Nathan Kline Institute (where laboratory specimens are analyzed)

☐ The Sponsor of the Research,

and its agents and contractors (together, "Sponsor"); and
☑ Representatives of regulatory and government agencies, institutional review boards, representatives of the Researchers and their institutions to the level needed to carry out their responsibilities related to the conduct of the research.
☐ Private laboratories and other persons and organizations that analyze your health information in connection with this study

☐ Other (family members or significant others, study buddies, outside agencies etc.) Specify:

3. By giving permission to release your Health Information as described above, you understand that your Health Information may be disclosed to individuals or entities which are not required to comply with the federal and state privacy laws which govern the use and disclosure of personal Health Information by NYSPI. This means that once your Health

Information has been disclosed to a third party which does not have to follow these laws (e.g., a drug company or the Sponsor of the Research), it may no longer be protected under the HIPAA or NYS Mental Hygiene Law requirements but is subject to the terms of the consent form and may be subject to other state or federal privacy laws or regulations.

4. Please note that:

- You do not have to sign this Authorization form, but if you do not, you may not be able to participate in the study or receive study related care. You may change your mind at any time and for any reason. If you do so, you may no longer be allowed to participate in the study. If you withdraw this Authorization the research staff and the Sponsor, if this is sponsored research, may still use or disclose Health Information containing identifying information they already have collected about you as needed to maintain the reliability of the research. Any request to withdraw this Authorization must be made in writing to (enter name and contact information below):

  Ronit Kishon Ph.D.
  1051 Riverside Drive
  New York, NY 10032

- While the Research is going on, you may not be allowed to review the Health Information in your clinical research record that has been created or collected by NYSPI. When this research has been completed you may be allowed to see this information. If it is needed for your care, your Health Information will be given to you or your Doctor.

5. This Authorization does not have an end date.

6. You will be given a copy of this form after you have signed it.

I agree to the use and disclosure of Health Information about me as described above:

_____ _____

Signature of Participant/ Legal Representative Date

_____

Printed Name of Participant

_____

Relationship of Legal Representative to Participant (if applicable)

We also ask you or your legal representative to initial the statements below:

☐ **I have received a copy of the NYSPI/OMH Notice of Privacy Practices.**