Protocol Title:
One-session Intervention to Reduce Fear

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7293

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05/24/2016

Clinic:
Anxiety Disorders Clinic

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05/01/2019

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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

Division & Personnel

Division

What Division/Department does the PI belong to?
Clinical Therapeutics
Within the division/department, what Center or group are you affiliated with, if any?
ADC

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.

na

Application for Continuation of Research

Status

Current Status of Study:
All research interventions were completed. Only data analysis 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.
To date, we have enrolled 7 subjects with SAD and 1 subject with OCD.
Study procedures have been generally well tolerated. There have not been any study findings, recent literature, or untoward events occurring here or at other sites in the past year which might affect the analysis of the safety, risks or benefits of study participation.

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
40
Total number of participants enrolled to date
8
Number of participants who have completed the study to date
6
Have there been any significant deviations from the anticipated study recruitment, retention or completion estimates?
Yes
Describe actions taken or planned to address these problems.
Recruitment was less than expected, so data is being analyzed for the small sample actually collected.
Comments / additional information

Sample Demographics

Specify population
SAD
Total number of participants enrolled from this population to date
7
Specify population #2
OCD
Total number of participants enrolled from this population to date
1
Gender, Racial and Ethnic Breakdown

Gender:
Female: 5
Male: 3

Race:
Other: N=2
Caucasian: N=2
African American: N= 3
Asian: N= 1

Ethnicity:
Hispanic: 1
Non-Hispanic: 7

Summary of Current Year's Enrollment and Drop-out

Number of participants who signed consent in the past year
2

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
✓ Medication Trial
✓ Use of Placebo or Sham Treatment
✓ Off-label Use of Drug or Device

Population

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

✓ Adults
✓ Adults over 50

Research Support/Funding

Will an existing internal account be used to support the project?
Yes
Describe internal account
The study will use an RFMH account
Is the project externally funded or is external funding planned?
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
Proven obsessive-compulsive disorder (OCD) and social anxiety disorder (SAD) treatments include medications called serotonin reuptake inhibitors (SRIs) and cognitive-behavioral therapy (CBT). However, up to half of OCD and SAD patients do not achieve wellness from these treatments. Thus, new treatments are needed.
This study will examine the efficacy of disrupting fear reconsolidation with propranolol hydrochloride (HCI), a method recently found effective in adults with spider fears but not yet tested in OCD or SAD, in 2 pilot randomized controlled trials (one in OCD, one in SAD).
A total of 20 adults with OCD, and 20 adults with SAD, between the ages of 18 and 60 years will participate in the study.

Background, Significance and Rationale

Background, Significance and Rationale
The two first-line treatments for OCD and SAD are a class of medications called serotonin re-uptake inhibitors (SRIs) and disorder-specific cognitive behavioral therapy. However, up to half of patients with OCD or SAD do not achieve wellness from these treatments.
Recent research suggests that pharmacologically modulating the process of fear memory reconsolidation may be a promising therapeutic avenue in the treatment of fear-related disorders such as OCD and SAD. For example, in a spider phobic sample, Soeter and Kindt (2016) administered 40mg of propranolol HCI after reactivating spider fear (by presenting a tarantula for 2 minutes) to disrupt reconsolidation of the fear memory. Participants who received propanolol HCI had reduced fear at two-week follow up compared to participants who received placebo. One year later, the benefits were maintained.

We propose two small pilot randomized placebo-controlled trial to test whether disrupting fear reconsolidation using propranolol HCI in adult OCD and SAD patients leads to a significant reduction in OCD and SAD symptoms and a significant improvement in a standardized behavioral avoidance test (BAT). We will study the subgroup of SAD patients with performance only fears related to public speaking, because these circumscribed fears may be most responsive to the treatment tested here. The intent is to collect pilot data on the feasibility, acceptability, and preliminary efficacy of this approach in OCD and SAD patients to support grant application for a future randomized controlled trial with a longer follow-up.

Specific Aims and Hypotheses

Specific Aims and Hypotheses
The goal of these pilot studies is to investigate whether disrupting fear reconsolidation with propranolol HCI in adult OCD and SAD patients is feasible and leads to a reduction in OCD and SAD symptoms and an improvement in a Behavioral Avoidance Task (BAT).

Description of Subject Population

Sample #1

Specify subject population
Adult individuals with OCD
Number of completers required to accomplish study aims
20
Projected number of subjects who will be enrolled to obtain required number of completers
25
Age range of subject population
18-60

Sample #2

Specify subject population
Adult individuals with public speaking fears and SAD, performance only type
Number of completers required to accomplish study aims
20
Projected number of subjects who will be enrolled to obtain required number of completers
25
Age range of subject population
18-60

Gender, Racial and Ethnic Breakdown
Based on the community from which we will be drawing patients and proportions to those encountered during previous clinical trials at this site, we expect the sample to be approximately 5% Hispanic and 95% Non-Hispanic; racially there will be 89% White, 9% Black, 2% Asian. Based upon the prevalence of OCD, it is expected that the sample will be approximately 1:1 =male:female.
Description of subject population
Females and male adults with a diagnosis of OCD or SAD (performance only type) and clinically significant symptoms of OCD or fear of public speaking.
All ethno-racial groups will be recruited.

Recruitment Procedures

Describe settings where recruitment will occur

Recruitment will draw from the broadest possible population with respect to gender and ethnic origin. Participants will be enrolled through the Anxiety Disorders Clinic, located on the third floor of the New York State Psychiatric Institute.

How and by whom will subjects be approached and/or recruited?
OCD and SAD patients will be recruited by physician or mental health practitioner referrals, or patient or

family referrals following advertisement of our work.
How will the study be advertised/publicized?
Depending on rates of response, IRB-approved advertisements and flyers will be posted both online and in the local community (e.g., in and around the CUMC campus). Online advertisements may be posted on websites dedicated to obsessive compulsive disorder or psychiatry research [e.g., our own clinic website (www.columbia-ocd.org), www.ocfoundation.org, Columbia clinical trials website] and on such community websites as Craigslist.org, Myspace.com, Facebook.com, Friendster.com, Livedeal.com, Citynews.com, Adwords.google.com, ResearchMatch.org, Topix.net **and Columbia RecruitMe**. For web-based forums or discussion groups that are open only to patient members, permission to recruit will be obtained from group leaders prior to posting.
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
NCT02790710; NCT02790736

Concurrent Research Studies

Will subjects in this study participate in or be recruited from other studies?
Yes
Describe concurrent research involvement

All participants in the current study will be screened under “IRB #6112R - Anxiety Disorders Clinic and Hispanic Treatment Program Screening and evaluation Process."

Eligible subjects who have finished other studies in the Anxiety Disorders Clinic will be offered participation. These protocols will include:
IRB#6628. Attaining and maintaining wellness in OCD.
IRB#7000. Control and Reward Circuits in OCD.
IRB#7127. Toward Precision Medicine for OCD.
IRB#7059 Pilot study of personalized-computerized inhibitory control training for OCD.
IRB# 6837 Internet Based Treatment for OCD (iCBT.)
Participants will be allowed to participate in other studies at our center at the same time if these studies do not involve treatment (e.g. IRB#7127 Toward Precision Medicine for OCD or IRB#711. Stress Reactivity in Patients with Anxiety).
After finishing the study, participants will be allowed to participate in other treatment and non-treatment studies at our center if they meet the eligibility criteria for those studies.
Participants will be re-screened if there is a delay of more than 4 weeks between screening and participation.

Inclusion/Exclusion Criteria

Name the subject group/sub sample
Adult OCD participants
Create or insert table to describe the inclusion criteria and methods to ascertain them

CRITERION	METHOD OF ASCERTAINMENT
1) Patient must be 18-60 years of age at the time of consent	Clinical Interview
2) Patient must be physically healthy and, if female, must be non-pregnant and not nursing.	Clinical interview and physical examination (including blood pressure, heart rate, and EKG for all participants plus urine pregnancy test for females) by M.D, and as part of screening.
3) Patients must fulfill DSM-5 criteria for OCD, OCD being the principal disorder (i.e., currently the most severe and needing of treatment) **and have clearly identified fears of specific stimuli that can be utilized during a BAT.**	Clinical Interview by M.D. or Ph.D. and results of MINI
4) Patients with a Y-BOCS score of greater than or equal to 16 prior to entering trial and avoidance of OCD triggers.	Clinical interview and assessment by trained rater
5) Patient is either off all psychotropic drugs or if taking a serotonin reuptake inhibitor (SRI) the dose has been stable for at least 8 weeks and remains stable during this study.	Clinical interview
6) Each patient must have a level of understanding sufficient to provide written informed consent to all required study tests and procedures.	Clinical interview

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

Exclusion criteria	
1) Presence of psychotic symptoms or lifetime history of schizophrenia, bipolar disorder, substance-induced psychotic disorder, or history of violence; **or current major depressive disorder.**	Psychiatric evaluation/MINI
2) Presence of developmental disorder or intellectual disability.	Clinical interview
3) Moderately/severely depressed patients with HDRS-17 (17-item Hamilton Depression Rating Scale) >20 or judged clinically to be at risk of	Clinical Interview/MINI and HDRS-17

suicide.	
4) OCD patients with primary symptoms of hoarding or for whom no clear fear/anxiety triggers can be detected.	MINI/Y-BOCS check-list
5) Female patients who are either pregnant or nursing.	Clinical interview, medical exam, and Urine pregnancy test
6) Patients planning to commence EX/PR during the period of the study or currently in EX/RP treatment.	Clinical interview
7) Current substance use disorders (meeting criteria within the past 3 months, with the exception of nicotine).	Clinical interview
8) History of any significant medical condition that might increase the risk of participation due to the effects of propranolol (e.g., seizure disorder, respiratory disorders [e.g., bronchial asthma], cardiovascular disease [e.g., congestive heart failure, heart arrhythmias, **sinus bradycardia and greater than first degree block**], low blood pressure [< 90/60], diabetes, liver or kidney disorders) or current use of medications that may negatively interact with a one time dose of 40 mg of propranolol (e.g., ACE inhibitors; **catecholamine depleting drugs, such as reserpine; calcium channel blockers; digitalis glycosides; haloperidol; chlorpromazine; aluminum hydroxide gel; phenytoin; phenobarbitone; rifampin; antipyrine; lidocaine; cimetidine; theophylline)**	Clinical interview and medical history, and medical examination including blood pressure, heart rate, and EKG.

Inclusion/Exclusion Criteria #2

Name the subject group/sub sample
Adult SAD participants
Create or insert table to describe the inclusion criteria and methods to ascertain them

Inclusion criteria	
CRITERION	METHOD OF ASCERTAINMENT
1) Patient must be 18-60 years of age at the time of consent	Clinical Interview

2) Patient must be physically healthy and, if female, must be non-pregnant and not nursing.	Clinical interview and physical examination (including blood pressure, heart rate, and EKG for all participants plus urine pregnancy test for females) by M.D, and as part of screening.
3) Patients must fulfill DSM-5 criteria for SAD, performance only type (**public speaking**), SAD being the principal disorder (i.e., currently the most severe and needing of treatment).	Clinical Interview by M.D. or Ph.D. and results of MINI
4) Patients with clinically significant fear of public speaking.	Clinical interview and assessment by trained rater
5) Patient is off all psychotropic drugs for at least 4 weeks.	Clinical interview
6) Each patient must have a level of understanding sufficient to provide written informed consent to all required study tests and procedures.	Clinical interview

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

Exclusion criteria	
1) Presence of psychotic symptoms or lifetime history of schizophrenia, bipolar disorder, substance-induced psychotic disorder, or history of violence; or current major depressive disorder.	Psychiatric evaluation/MINI
2) Presence of developmental disorder or intellectual disability.	Clinical interview
3) Moderately/severely depressed patients with HDRS-17 (17-item Hamilton Depression Rating Scale) >20 or judged clinically to be at risk of suicide.	Clinical Interview/MINI and HDRS-17
4) SAD patients with SAD not of the performance only type.	MINI, Liebowitz Social Anxiety Scale score >60
5) Female patients who are either pregnant or nursing.	Clinical interview, medical exam, and Urine pregnancy test
6) Patients planning to commence CBT during the period of the study or currently in CBT treatment.	Clinical interview
7) Current substance use disorders (meeting criteria within the past 3 months, with the	Clinical interview

exception of nicotine).	
8) History of any significant medical condition that might increase the risk of participation due to the effects of propranolol (e.g., seizure disorder, respiratory disorders [e.g., bronchial asthma], cardiovascular disease [e.g., congestive heart failure, heart arrhythmias, **sinus bradycardia and greater than first degree block],** low blood pressure [< 90/60], diabetes, liver or kidney disorders) or current use of medications that may negatively interact with a one time dose of 40 mg of propranolol (e.g., ACE inhibitors; catecholamine depleting drugs, such as reserpine; calcium channel blockers; digitalis glycosides; haloperidol; chlorpromazine; aluminum hydroxide gel; phenytoin; phenobarbitone; rifampin; antipyrine;lidocaine; cimetidine; theophylline)	Clinical interview and medical history, and medical examination including blood pressure, heart rate, and EKG.

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 #
6112R
Describe Study Consent Procedures
After determining eligibility under 6112R the subjects will go over the consent for this study and have

questions answered by the consenter. If the subject agrees the consent form will be signed and the study begun.
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
2
Campeas, Raphael, MD
Sanchez-Lacay, jose, MD
Schneier, Franklin, MD
Type in the name(s) not found in the above list

Study Procedures

Describe the procedures required for this study

VISIT 1. Screening/evaluation for eligibility (conducted under IRB #6112R - Anxiety Disorders Clinic and Hispanic Treatment Program Screening and evaluation Process**) and study consent followed by BAT.**

Patients deemed eligible following phone screening will undergo with their written consent: 1) a clinical interview by a senior clinician (M.D. or Ph.D.) that will include a MINI for DSM-5; 2) a physical examination (i.e., history, physical, EKG test, and urine pregnancy test [for females]) by an MD; ; and 3a) for OCD patients a Y-BOCS for OCD severity; 3b) for SAD patients LSAS and PRCS for SAD and public speaking fear severity; 4) **and** HDRS to assess depression severity.~~**; and 5) a personalized Behavioral Avoidance Task (BAT) by a trained rater.**~~ **Those who meet entry criteria will provide written informed consent for this study and then complete a personalized Behavioral Avoidance Task (BAT) by a trained rater.** The BAT for OCD patients will assess degree of fear (using a subjective 0-100 scale) and overt approach behavior while being exposed to an OCD trigger (e.g. a toilet in patients with contamination fears). For SAD patients it will assess fear during a brief speech task.**Following this procedure, participants will be dismissed for the day and they will be re-contacted to schedule visit 2 once their EKG and blood results come back and it is confirmed that they are eligible to complete the study**.

~~Those who meet entry criteria will provide written informed consent for this study and then enter the baseline assessment and intervention.~~

VISIT 2. ~~**Consent**,~~ Baseline assessment (independent evaluator) and intervention

~~Consent and~~ Baseline Assessment: ~~After participants have signed consent,~~ An independent evaluator will assess global psychopathology (CGI); depressive symptoms (HDRS); and anxiety symptoms (DASS). OCD patients will also be assessed for OCD symptoms (YBOCS), and

SAD patients will also be assessed for SAD (LSAS) and fear of public speaking (PRCS). Then participants within each disorder will be randomized to one of two groups. Randomized assignments will be generated using a random number generator in SPSS using a block design.

Intervention:

OCD participants will receive a short exposure (2') to an OCD phobic stimulus trigger (e.g. a toilet). SAD participants will be asked to prepare and give a short (2 minute) speech before an audience of several staff members. These exposures will be conducted by either a psychologist or psychiatrist on the study team.

After that, half of the OCD participants and half of the SAD participants will receive a single oral dose of propranolol HCI 40 mg. The other half of participants (within each diagnostic group) will receive a placebo. Following the administration of the propanolol or placebo participants will be asked to wait in the Anxiety Disorders Clinic for 90'. The participant's blood pressure, heart rate, and possible side effects will be assessed (using a side-effects checklist) at three time points: before the short exposure, after the administration of the propranolol/placebo, and after the 90' waiting period. Participants will be told that the intervention they have received may help them overcome their fears during the following 2 weeks. They will be asked to keep a daily record of their avoidance/approach behaviors (for OCD patients, using the avoidance item from the self-report YBOCS). OCD participants will be also asked to assess daily their OC symptoms using two visual separate visual analogue scales (VAS), one for obsessions and one for compulsions. SAD participants will assess their public speaking fears daily using a VAS for anxiety and a VAS for avoidance.

Follow-up (independent evaluator)

After 1 week, participants will be contacted on the phone by the independent evaluator to assess depressive, and anxiety symptoms during the past week (using the HDRS-17, DASS, and CGI). OCD patients will also complete the YBOCS, and SAD patients will complete the LSAS and PRCS.

VISIT 3. Final assessment (independent evaluator)

After 14 days, participants will be assessed in our clinic by the independent evaluator with the same instruments (i.e., YBOCS, LSAS, PRCS, HDRS-17, DASS, and CGI) used in the baseline. In addition, the BAT conducted at screening will be repeated to measure any change in avoidance. The daily records of OC avoidance/approach behaviors as well as their VAS will then be collected.

You can upload charts or diagrams if any

Criteria for Early Discontinuation

Criteria for Early Discontinuation

Participants are free to withdraw from the study at any time for any reason. **Participants who discontinue will be given referrals, exactly as is done for study completers**. Study doctors are to discontinue patients from the study if patients:

- **Are determined to be ineligible to proceed after review of EKG and lab results**
- Request early discontinuation or withdrawal of consent.
- Experience a serious or intolerable adverse event that prevents the patient from continuing.
- In the Investigator's opinion, are experiencing a clinically significant deterioration. For example, if a patient became suicidal or their symptoms of depression increased such that the depressive symptoms were much or very much worse relative to baseline and the HDRS-17 is no longer <20 (1 week follow-up evaluation), they would be discontinued from the study.
- Commit a protocol violation, including lack of compliance.
- Are "lost to follow-up."
- Encounter other conditions (such as administrative issues or pregnancy).

If a patient discontinues from the study at any time at their own request or at the study doctor's discretion, the reason(s) for discontinuation are to be recorded by the study. Patients withdrawing from the study for reasons related to the study medication (usually adverse events) will be followed until the event(s) have resolved or no further action is required.

Blood and other Biological Samples

Please create or insert a table describing the proposed collection of blood or other biological specimens
NA

Assessment Instruments

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

- MINI- International Neuropsychiatric Interview (MINI, 1 hour). The MINI is a semi-structured clinician rated instrument that assesses the major adult Axis I disorders in DSM-5.
- Yale-Brown Obsessive Compulsive Scale (Y-BOCS, 45 minutes) This is a semi-structured clinician rated instrument used to measure obsessions and compulsions separately over five separate dimensions (time consumed, distress, interference, degree of resistance, control).This is the gold-standard measure or OCD symptoms.

- Liebowitz Social Anxiety Scale (LSAS, 10 minutes). Clinician rated instrument assessing fear and avoidance of 24 situations.

- Personal Report of Confidence as a Speaker (PCRS, short form, 10 minutes) 30-item self-rating about public speaking fears.

- Clinical Global impression (CGI, 1 minute). This is a clinician rated instrument for rating global psychopathological severity.

- 17-Item Hamilton Depression Rating Scale (HDRS-17, 5 minutes). This is a clinician rated instrument for rating depression.

- Depression Anxiety Stress Scale (DASS, 5 minutes). A self-report of anxiety and depressive symptoms.

- Behavioral Avoidance Test for Obsessive-Compulsive Disorder (BAT-OCD, 15 minutes). This is a structured instrument, which has been previously used (Steketee et al., 1996) to assess changes in OCD symptoms and approach behaviors.

- Subject unit of distress scale (1 min) will be used during the SAD BAT to rate intensity of anxiety on a 100 point scale.

- Side Effect Checklist (SECL, 3 minutes): Side Effect Assessment: possible side effects will be rated on a scale from 0 (none) to 3 (severe).

- Visual analogue scales for obsessions and compulsions (VAS-OCD, 1 minute)

- Visual analogue scales for public speaking anxiety and avoidance (VAS-SAD, 1 minute)

- Self-report of OCD-related avoidance (avoidance item of self-report YBOCS, 1 minute)

Please attach copies, unless standard instruments are used

Off label and investigational use of drugs/devices

Choose from the following that will be applicable to your study
✓ Drug
Select the number of drugs used in this study
1

Drug #1

Name of the drug
Propanolol
Manufacturer and other information

It is available generically from several manufacturers.
Approval Status
No IND is required
Choose one of the following options
FDA conditions are met (see 'Rules')
Explain
The investigation is not intended to be reported to the FDA in support of a new indication or any significant change in labeling. The drug is marketed. The investigation is not intended to support a change in advertising. It uses a standard route of administration and dosage in a low risk patient population.

Research Related Delay to Treatment

Will research procedures result in a delay to treatment?
Yes
Maximum duration of delay to any treatment
Two weeks
Maximum duration of delay to standard care or treatment of known efficacy

This study is two weeks long and during this period the participant is asked not to seek additional treatment. Some OCD patients may be on a stable dose of an SRI. For these individuals, they will already be receiving a treatment of known efficacy for OCD.

Other OCD and all SAD patients will not be on any medications, so the delay to treatment would be the two weeks of the study. Participants will be informed of this delay and offered referrals for treatment at the time of screening if they want immediate treatment.

Treatment to be provided at the end of the study

None as part of this protocol. However, we will make referrals to appropriate accessible treatment settings for participants who desire treatment, and we will follow up to confirm that they have connected with a referral. During the final phone call (one month after the intervention), participants will be assessed on the phone with the YBOCS (OCD participants) or LSAS (SAD participants). If the original referrals have not worked out, we will provide additional referrals and check if they have worked out.

Clinical Treatment Alternatives

Clinical treatment alternatives

Subjects do not have to participate in this study to receive treatment for OCD of SAD. There are two evidence-based first-line treatments for OCD and SAD. The first is a class of medications called *Serotonin*

Reuptake Inhibitors (SRIs). The second is CBT. Subjects will have these treatment options explained to them by the study doctor, and they will be offered the option to receive outside referrals for one or both of these treatments rather than participating in the study.

Risks/Discomforts/Inconveniences

Risks that could be encountered during the study period

Risks associated with propranolol HCI

(Source: Physician Desk Report)

Propranolol hydrochloride is a synthetic beta-adrenergic receptor blocking agent. It is commonly used to treat the following conditions: hypertension, atrial fibrillation, myocardial infarction, migraine, essential tremor, hypertrophic subaortic stenosis, pheochromocytoma, and arrhythmias. Adult dosage for these conditions can be up to 640mg/day.

Propranolol is contraindicated in 1) cardiogenic shock; 2) sinus bradycardia and greater than first degree block; 3) bronchial asthma; and 4) in patients with known hypersensitivity to propranolol hydrochloride. All these conditions are part of the exclusion criteria.

The known side effects of a chronic/prolonged administration of propranolol include bradycardia, CHF, hypotension, lightheadedness, mental depression, N/V, agranulocytosis, and respiratory distress.

A number of drug interactions with propranolol HCI have been described. These include CYP450 substrates, inducers, and inhibitors; CYP2D6 substrates/inhibitors; hepatic enzyme inducers; etc (see http://www.pdr.net/drug-summary/Propranolol-Hydrochloride-Tablets-propranolol-hydrochloride-1400 for a complete list). Participants taking any of these drugs will be not eligible for the current study.

Propranolol HCI has been also used as a treatment for anxiety disorders (n>200, only including randomized controlled trials) using daily doses of up to 320 mg/day for up to 6 weeks (Steenen et al., 2016). No side effects were reported in a double-blind placebo controlled study using a single dose of propranolol HCI (80 or 120 mg) in dental phobia (n=23) (Liu et al., 1991).

In this protocol participants are being given just one 40 mg dose of propranolol and therefore no significant side effects are expected.

Propranolol has been used to disrupt fear reconsolidation in several human experimental studies involving hundreds of healthy participants (e.g. Kindt et al., 2009: Soeter & Kindt, 2010, 2011a, 2011b, 2012a, 2012b) and more than 70 patients with anxiety disorders (Brunet et al., 2008, 2011; Soeter & Kindt, 2015) (see Giustino et al., 2016 for a review) and no significant risks/side effects have been reported. Human research has shown that the declarative components of memory remain intact following propranolol-induced

reconsolidation blockade and that disruption of reconsolidation by noradrenergic receptor antagonism is memory specific and does not eliminate associated or non-reactivated memories (Otis et al., 2015)

Risks associated with delay in treatment initiation:

Dr. Simpson and her clinical research team will be in contact with the OCD and SAD patients every week throughout this two week protocol. If a patient suddenly meets any exclusion criteria (e.g., active suicidal ideation) or no longer met the inclusion criterion of being "able to tolerate a treatment-free period," the patient would be removed from the study and referred for treatment. Patients may refuse to participate at any point and seek outside treatment.

Risks associated with assessment:

Patients are assessed in person by experienced clinicians for discomfort or frustration associated with psychiatric interviewing or filling out questionnaires. Study clinicians are skilled at dealing with these events and will make efforts to help clients to feel as comfortable as possible (e.g., by giving breaks during an evaluation, offering encouragement).

Describe procedures for minimizing risks

1. Patients will be monitored frequently both during and immediately after the administration of propranolol HCI.

2. Patients with medical and psychiatric co-morbidity (e.g., psychosis) that makes participation unsafe will not be eligible.

3. Patients with any adverse events associated with the administration of propranolol HCI will be hospitalized, if needed.

Methods to Protect Confidentiality

Describe methods to protect confidentiality

In the informed consent form, subjects will be told that the information they provide and all findings will be kept strictly confidential, with access limited to the research staff, with two exceptions: state or federal regulatory personnel and legal advocacy organizations authorized by law will have access to review records, and state law mandates that study doctors must follow (i.e., cases of suspected child or elder abuse or neglect be reported to state officials). Data collected with identifying information will be stored in locked cabinets or in password-protected computer files.
Subject identity will not be revealed in the presentation or publication of any results. All staff working on the project will be educated about the importance of strictly respecting patient

confidentiality. When the results of the study are published, data which might reveal the identity of any particular subject will be disguised.

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

Direct Benefits to Subjects

Direct Benefits to Subjects

~~It is not clear whether this study will be of direct benefit to subjects. This is the point of this pilot study. pasting~~ **This study was not designed to directly benefit participants.**

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?
Yes
Please describe and indicate total amount and schedule of payment(s).
Include justification for compensation amounts and indicate if there are bonus payments.

Subjects will be paid $25 for completion of the daily records of symptoms and $25 for the final assessments in the study (total possible compensation = $50).

References

References

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Uploads

Upload copy(ies) of unbolded Consent Form(s)
Consent form SAD unstamped_Clean 4.27.18.pdf
OCD Unstamped Consent Form_Clean 4.27.18.pdf
Upload copy(ies) of bolded Consent Form(s)
Upload copy(ies) of recruitment materials/ads to be reviewed
proposed PS pull-tab ad.pdf
Seeking Subjects for Study on Public Speaking Fears.pdf
Upload copy(ies) of the HIPAA form

HIPAA_form-1.pdf
Upload any additional documents that may be related to this study

Brief Intervention for Public Speaking Fears

Are you between the ages of 18 – 60?

Do you have bothersome fears of speaking in front of groups?

Do presentations at work or school give you anxiety?

Are you interested in trying a novel intervention?

This research study tests whether a brief intervention using a medication called propranolol is effective at reducing public speaking fears. This approach has recently been shown to help adults with other types of fears.

For more information or to schedule a confidential phone screening, please contact the study coordinator: Abby Crete at 646-774-8113

Anxiety Disorders Clinic
New York State Psychiatric Institute/RFMH

Columbia University Medical Center
NYSPI
New York State Psychiatric Institute

Public Speaking Study
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Seeking Subjects for Study on Public Speaking Fears (Inwood / Wash Hts)

RESEARCH STUDY:
Brief Intervention for Public Speaking Fears (IRB#7293).

- Are you between the ages of 18 - 60?
- Do you have bothersome fears of public speaking?
- Are you interested in trying a novel intervention?

This research study tests whether a brief intervention using a medication called propranolol is effective at reducing public speaking fears. This approach has recently been shown to help adults with other types of fears.

COMPENSATION FOR PARTICIPATION:
Total of $50, paid after 3 visits.

For more information or to schedule a confidential phone screening, please contact the study coordinator: Abby Crete at 646-774-8113

Brief intervention to reduce public speaking fears
Informed Consent

PURPOSE AND OVERVIEW: You are being asked to take part in a research study because you have fear of public speaking that meets criteria for social anxiety disorder (SAD). The purpose of this research study is to test a one-session intervention, which targets your fear/anxiety using a medication called propranolol. Propranolol is FDA-approved for the treatment of high blood pressure, angina, certain heart rhythm abnormalities, heart attacks, arterial narrowing, catecholamine-secreting tumors, migraine headaches, and tremors. It is not FDA-approved for treatment of public speaking anxiety.

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.

ALTERNATIVE TREATMENTS/ALTERNATIVES TO PARTICIPATION: Instead of participating in this study, you can seek outside treatment that could include cognitive-behavior therapy and/or medications for SAD. Serotonin reuptake inhibitors (SRIs) are the standard approved medications for SAD. These include fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft), citalopram (Celexa), and escitalopram (Lexapro).

PROCEDURES: All study procedures will take place at the New York State Psychiatric Institute (NYSPI) in New York, NY. Twenty patients with SAD will participate in the study. The study consists of several steps, which will take place in this order:

VISIT 1. Screening for eligibility: As part of the screening done in the Anxiety Disorders Clinic (IRB#6112R), you have already met with staff of the Anxiety Disorders Clinic to review your medical and psychiatric history; undergone a physical exam and measurement of your heart rate, blood pressure, EKG, and urine pregnancy test (if you are female), and filled out symptom ratings You have confirmed that you are not taking any psychiatric medications, and you have been informed that if you start any new non-study medication you should notify study personnel and may be removed from study participation. You are being given this consent form because you may be eligible to participate in this study. If you consent for the study, you will complete a task assessing your public speaking anxiety symptoms, and you will be dismissed for the day. We will re-contact you after your EKG and blood test results come back. If the results confirm that you are eligible to complete the study, we will schedule your visit 2. If the results show that you are not eligible to continue, we will offer you a referral for clinical non-study treatment.

VISIT 2. Baseline assessment, and intervention: If you are eligible to continue in the study, you will return to the Anxiety Disorders Clinic. At this visit, you will have your heart rate and blood pressure measured, fill out some questionnaires and prepare a short speech that you may be asked to present to an audience of several evaluators. Then you will receive "randomly" a single dose of propranolol or a single dose of placebo (a pill with no medication in it). “Randomly” means that you will be placed into one of the two groups (propranolol or placebo) by chance (like the flip of a coin). You and the study person evaluating your symptoms will not know which group you are in. Ninety minutes after taking the medication, you will again have your heart rate and blood pressure measured and asked to fill out some questionnaires. (Time commitment: approximately 2.5 hours).

Follow-up: You will be asked to keep a daily record of some symptoms and behaviors related to your public speaking fears during 2 weeks after the one-session intervention. Half-way through this follow-up (1 week) you will be contacted over the phone by the study team for an evaluation of your mood and

anxiety symptoms. (Time commitment: approximately 3 minutes/day plus 30 minutes for the phone evaluation, for which you will be compensated $25).

VISIT 3. Final assessment. At the end of the two weeks, you will come back to the clinic for a post-treatment evaluation of your public speaking fears, including questionnaires and preparing a short speech that you may be asked to present to an audience of several evaluators (Time commitment: 2 hours, for which you will be compensated $25).

You may be asked to videotape your public speaking. If you are asked, this will be explained in a separate consent form. You do not need to consent to videotaping in order to participate in this study.

Upon completion of or withdrawal from the study, if you desire, you will meet with one clinician from our team to provide you an overview of treatment options and to discuss a possible referral to appropriate accessible treatment settings.

RISKS AND INCONVENIENCES:
Medication (propranolol). Propranolol is approved by the Food and Drug Administration as a treatment for several medical conditions, including hypertension (high blood pressure). For these medical conditions, propranolol is usually used for weeks/months/years (this is called "chronic or prolonged use"). Potential side effects of propranolol in cases of chronic or prolonged use are: bradycardia (slow heart rate), hypotension, lightheadedness, mental depression, nausea or vomiting, agranulocytosis (lowered white blood cells), and respiratory problems. Thus, if you have any of these medical problems, you should not participate in the study. If we have any concerns about your participation, we may ask to speak with your medical doctor.

You will receive a single dose of propranolol. A single dose of propranolol has been tested in hundreds of healthy adults and in patients with anxiety disorders (performance anxiety, post-traumatic stress disorder and phobias). A single dose is usually well tolerated and previous studies have not reported significant side effects. Given the safety profile of propanolol and the fact that you will receive only one dose, few side effects are anticipated. As with any drug, however, there may be associated risks and side effects, which cannot be predicted. Thus, we will carefully monitor you, including measuring your heart rate and blood pressure.

Delay in Treatment Initiation. Participating in this study could result in a delay of 2 weeks to start alternative (and approved) treatments for SAD.

Assessment: It is possible that the clinical assessments and interviews, including assessments of public speaking, may make you anxious, tired, or upset because they ask you about personal things, such as your thoughts and feelings, and because you have had fear of public speaking. If at any time the assessments make you uncomfortable or tired, you can choose not to answer specific questions or ask to take a break or stop at any time.

BENEFITS: This study was not designed to directly benefit participants. Your participation in this study, however, may help us understand more about the treatment of SAD, and it is possible that others might benefit in the future from your contribution.

CONFIDENTIALITY: If you consent to participate in this study, we will do everything possible to prevent others from knowing about your participation. No identifying information will be shared with any researchers outside of NYSPI. All data will be kept in locked file cabinets and password-protected computer files, accessible only to the research staff. Your name and other personal identifying information will be stored in an electronically secure database at New York Psychiatric Institute. All

research information obtained will not be identified with your name; research staff will use only a coded number and/or your initials. We do keep identifying information (e.g., the coding key, email addresses) but that these data reside in a different database section with password-protected access by only select research staff/investigators. Records will only be available to research staff, and Federal, State, and Institutional regulatory personnel who may review the records as part of routine audits. 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. Any publications resulting from this study will not identify you.

STUDY COMPENSATION: You will be compensated $25 in cash for completion of the daily records of symptoms and $25 in cash after the final assessment ($50 in total).

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. 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: The researchers will answer any questions you might have about the procedures described above, or about the results of the study. You will be informed of any significant new findings that may relate to your willingness to continue to participate in the study. If you have any questions, you may call Dr. Franklin Schneier at (646) 774-8041. 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 human subjects in research studies). You may call the IRB Main Office at (646) 774-7155 during regular office hours.

DOCUMENTATION OF CONSENT:

I voluntarily agree to participate in the research study described above. If I am a female, I understand I should not participate if there is any chance that I am pregnant.

Print name: _____

Signed: _____ 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.

Print name: _____
Person Designated to Obtain Consent

Signed: _____ Date: _____

04/27/18

IRB #7293

VIDEOTAPE CONSENT

You have been asked as part of the study of "Brief Intervention for Public Speaking Fears" to be videotaped during public speaking.

The purpose of videotaping is for the videotapes to be reviewed by study staff to rate your public speaking behavior. Your name and identifying information will not be used. Only clinic personnel will have access to the recordings.

You may continue to participate in this study even if you do not agree to be videotaped. Also, refusing to be videotaped will not affect you treatment in the Anxiety Disorders Clinic.

All video recordings will be labeled using ID numbers of the participants and will be stored in a locked cabinet accessible only to authorized clinic personnel. All recordings will be destroyed within five years to allow sufficient time to review the recordings before all study analyses are concluded.

You have the right to withdraw consent for videotaping at any time without affecting your participation. You may also request that these videos be erased at any time during or after the videotaping.

You have been given a copy of this consent form to keep.

I agree to be videotaped. I reserve the right to withdraw this consent at any time.

Name:

Signature:

Date:

I have discussed the proposed videotaping procedures with this participant and in my opinion this participant understands the benefits, risks, alternatives (including nonparticipation) and is freely capable of consenting to participate in the videotaping component of this study.

Name:

Signature:

Date:

Consent Form Summary Page

Brief Intervention for OCD Fears

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.

Participation is 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

Alternatives

Instead of participating in this study, you can seek outside treatment that could include cognitive-behavior therapy, and/or serotonin reuptake inhibitor medications (e.g. Prozac) that are FDA-approved for OCD. You could also choose not to seek any treatment.

Procedures

- Screening assessment (30 minutes): You will be asked to complete an exercise that asks you to confront a situation you fear in order to assess the degree of your symptoms
- Baseline Assessment and Intervention (2.5 hours): Questionnaires, measurement of blood pressure and heart rate, task assessing OCD symptoms when you may be exposed to a feared situation, and taking a single dose of propranolol or placebo (inactive "sugar" pill).
- Follow-Up Assessment (30 min phone session and 3min/day record-keeping): Daily recording of symptoms, phone evaluation of mood and symptoms.
- Final assessment (2 hours): Questionnaires, measurement of blood pressure and heart rate, task assessing OCD symptoms when you may be exposed to a feared situation.

Risks

This study includes some risks and discomforts (please refer to the consent form for further details and explanations of these risks). These include possible anxiety or distress when completing questionnaires or being exposed to a feared situation and possible side effects, such as lightheadedness, from a single dose of the medication propranolol.

Benefits

This research study is not meant to benefit you directly.

You may contact the study doctor, Franklin Schneier, M.D at 646 774-8041 with any questions.

Brief intervention for OCD fears
Informed Consent

PURPOSE AND OVERVIEW: You are being asked to take part in a research study because you have symptoms of Obsessive-Compulsive Disorder (OCD). The purpose of this research study is to test a one-session intervention, which targets your fear/anxiety using a medication called propranolol. Propranolol is FDA-approved for the treatment of high blood pressure, angina, certain heart rhythm abnormalities, heart attacks, arterial narrowing, catecholamine-secreting tumors, migraine headaches, and tremors. It is not FDA-approved for the treatment of OCD.

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.

ALTERNATIVE TREATMENTS/ALTERNATIVES TO PARTICIPATION: Instead of participating in this study, you can seek outside treatment that could include cognitive-behavior therapy consisting of exposure and response prevention (EX/RP), and/or medications for OCD. Serotonin reuptake inhibitors (SRIs) are the standard medications for OCD. These include clomipramine (Anafranil), fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft), citalopram (Celexa), and escitalopram (Lexapro). The addition of risperidone (Risperdal) and of EX/RP to SRI medication are standard methods for attempting to improve upon SRI response in OCD.

PROCEDURES: All study procedures will take place at the New York State Psychiatric Institute (NYSPI) in New York, NY. Twenty patients with OCD will participate in the study. The study consists of several steps, which will take place in this order:

VISIT 1. Screening for eligibility: As part of the screening done in the Anxiety Disorders Clinic (IRB#6112R), you have already met with staff of the Anxiety Disorders Clinic to review your medical and psychiatric history; undergone a physical exam and measurement of your heart rate, blood pressure, EKG, and urine pregnancy test (if you are female); and filled out symptom ratings. You have confirmed that you are not taking any psychiatric medications (except stable dose of an SSRI medication, e.g. sertraline (brand name Zoloft), fluoxetine (Prozac), paroxetine (Paxil), fluvoxamine (Luvox), citalopram (Celexa) or escitalopram (Lexapro)), and you have been informed that if you start any new non study medication or change the dose of existing SSRI medication during the study, you should notify study personnel and may be removed from study participation. You are being given this consent form because you may be eligible to participate in this study. If you consent for the study, you will complete a task assessing your OCD symptoms and you will be dismissed for the day. We will re-contact you after your EKG and blood results come back. If the results confirm that you can complete the study we will schedule you for visit 2. If the results show that you are not eligible to continue, we will offer you a referral for clinical treatment.

VISIT 2. Baseline assessment and intervention: If you qualify, you will return to the Anxiety Disorders Clinic. At this visit, you will have your heart rate and blood pressure measured, fill out some questionnaires and complete a short (2 minute) task related to your OCD fears. Then you will receive "randomly" a single dose of propranolol or a single dose of placebo (a pill with no medication in it). "Randomly" means that you will be placed into one of the two groups (propranolol or placebo) by chance (like the flip of a coin). You and the study person evaluating your symptoms will not know which group you are in. Ninety minutes after taking the medication, you will again have your heart rate and blood pressure measured and asked to fill out some questionnaires. (Time commitment: approximately 2.5 hours).

Follow-Up: You will be asked to keep a daily record of some symptoms and behaviors related to your OCD during 2 weeks after the one-session intervention. Half-way through this follow-up (1 week) you will be contacted over the phone by the study team for an evaluation of your OCD, mood, and anxiety symptoms. (Time commitment: approximately 3 minutes/day plus 30 minutes for the phone evaluation, for which you will be compensated $25).

VISIT 3. Final assessment. At the end of the two weeks, you will come back to the clinic for a post- treatment evaluation of your OCD symptoms. You will again fill out symptom ratings and participate in a task assessing your OCD symptoms (Time commitment: 2 hours, for which you will be compensated $25). Upon completion of or withdrawal from the study, if you desire, you will meet with one clinician from our team to provide you an overview of treatment options and to discuss a possible referral to appropriate accessible treatment settings.

RISKS AND INCONVENIENCES:

Medication (propranolol). Propranolol is approved by the Food and Drug Administration as a treatment for several medical conditions, including hypertension (high blood pressure). For these medical conditions, propanolol is usually used for weeks/months/years (this is called "chronic or prolonged use"). The most common side effects of propranolol in cases of chronic or prolonged use are: bradycardia (slow heart rate), hypotension, lightheadedness, mental depression, nausea or vomiting, agranulocytosis (lowered white blood cells), and respiratory problems. Thus, if you have any of these medical problems, you should not participate in the study. If we have any concerns about your participation, we may ask to speak with your medical doctor.

You will receive a single dose of propranolol. A single dose of propranolol has been tested in hundreds of healthy adults and in patients with anxiety disorders (performance anxiety, post-traumatic stress disorder and phobias). A single dose is usually well tolerated and previous studies have not reported significant side effects. Given the safety profile of propanolol and the fact that you will receive only one dose, few side effects are anticipated. As with any drug, however, there may be associated risks and side effects, which cannot be predicted. Thus, we will carefully monitor you, including measuring your heart rate and blood pressure.

Delay in Treatment Initiation. Participating in this study could result in a delay of 2 weeks to start alternative (and approved) treatments for OCD.

Assessments. It is possible that the clinical assessments and interviews, including assessments that include possible exposure to a situation you fear, may make you anxious, tired, or upset because they ask you about personal things, such as your thoughts and feelings, and because you have had fear of particular situations. If at any time the assessments make you uncomfortable or tired, you can choose not to answer· specific questions or ask to take a break or stop at any time.

BENEFITS: This study was not designed to directly benefit participants. However, your participation in this study may help us understand more about the treatment of OCD, and it is possible that others might benefit in the future from your contribution.

CONFIDENTIALITY: If you consent to participate in this study, we will do everything possible to prevent others from knowing about your participation. No identifying information will be shared with any researchers outside of NYSPI. All data will be kept in locked file cabinets and password-protected computer files, accessible only to the research staff. Your name and other personal identifying information will be stored in an electronically secure database at New York Psychiatric Institute. All research information obtained will not be identified with your name; research staff will use only a coded number and/or your initials. We do keep identifying information (e.g., the coding key, email addresses) but that these data reside in a different database section with password-protected access by only select research staff/investigators. Records will only be

available to research staff, and Federal, State, and Institutional regulatory personnel who may review the records as part of routine audits. 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. Any publications resulting from this study will not identify you.

STUDY COMPENSATION: You will be compensated $25 in cash for completion of the daily records of symptoms and $25 in cash after the final assessment ($50 in total).

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. 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: The researchers will answer any questions you might have about the procedures described above, or about the results of the study. You will be informed of any significant new findings that may relate to your willingness to continue to participate in the study. If you have any questions, you may call Dr. Franklin Schneier at (646) 774-8041. 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 human subjects in research studies). You may call the IRB Main Office at (646) 774-7155 during regular office hours.

DOCUMENTATION OF CONSENT:

I voluntarily agree to participate in the research study described above. If I am a female, I understand I should not participate if there is any chance that I am pregnant.

Print name: _____

Signed: _____ 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.

Print name: _____
Person Designated to Obtain Consent

Signed: _____ Date: _____

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

Protocol Number: 7293 **Principal Investigator:** Franklin Schneier

Name of Study: One session intervention to reduce fear

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:
NYSPI

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):

     Franklin Schneier, MD, 1051 Riverside Drive, Unit 69, 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.**