Document Coversheet

Study Title: Increasing Treatment Efficacy Using SMART Methods for Personalizing Care

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	1/10/2025
NCT Number:	NCT04642898
IRB Number	59307
Coversheet created:	5/8/2025

IMPORTANT NOTE:

If you accidentally select the wrong IRB type or "Protocol Process Type" while your Initial Review (IR) application is in draft form (unsubmitted), you may change your selections. Please contact the Office of Research Integrity (ORI) at 859-257-9428, IRBsubmission@uky.edu, or request a consult to resolve any questions regarding your selections *prior* to submitting your Initial Review application.

If your **submitted IR application has been returned to you for requested revisions or additional information,** to streamline the review process **do not make changes** to your selections here **unless instructed to do so by the ORI/IRB.**

Changes to this section cannot be made after initial approval has been issued (the option is not available for MR or CR).

For guidance, see:

- Which IRB?
- Which Protocol Process Type?
- "Getting Started"

Which IRB

- ○ Medical ◉ NonMedical

Protocol Process Type

- ○ Exemption
- ○ Expedited (Must be risk level 1)
- ◉ Full

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the Exemption Categories Tool.

CONTINUATION REVIEW/FINAL REVIEW

0 unresolved comment(s)

In accordance with federal regulations and/or local policies, the IRB conducts periodic review of all currently approved projects. If you need your IRB approval to continue and you do not complete and submit the required materials in a timely manner, IRB approval will expire at the end of your current approval period.

If you have any questions, please contact the Office of Research Integrity at 859-257-9428 or email IRBsubmission@uky.edu.

To initiate your continuation review (CR)/annual administrative review (AAR), or properly close your study, complete this section and update/correct all other sections of your IRB application as applicable.
*****IMPORTANT*** Before leaving this page to update other sections of your application, be sure to SAVE this section first.**

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1. Status of the Research

Check the statement(s) that best describe(s) the current status of your research:

- ☐ No subjects have enrolled to date.
- ☐ Recruitment and/or enrollment of new subjects or review of records/specimens continue.
- ☐ Study is closed to enrollment, but subjects still receive research-related interventions (e.g., treatment, blood draws).
- ☐ Study enrollment is permanently closed; subjects have completed all research-related interventions; and the study remains active only for long-term follow-up of subjects (see Tool Tip above for info on long-term follow-up of subjects).*
- ☑ Research has progressed to the point that it involves 1) Data analysis, including analysis of identifiable private information or identifiable biospecimens; and/or 2) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.*
- ☐ The remaining research activities are limited only to data analysis. There is access to records or specimens either directly or through codes or links to the data.*
- ☐ The remaining research activities are limited only to data analysis. There is no subject/record/specimen identifying codes or links to the data; the researcher or research team cannot readily ascertain the subject's identity.*
- ☐ All study activities are complete. IRB approval can be inactivated.

*Possibility that review will move from Full to Expedited.

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2. If subjects have been enrolled within the last year, and the IRB approved a consent/assent form for your study:

Please attach a complete, signed copy for the last two subjects enrolled with **each** consent/assent form/HIPAA form since the last annual review.
(Example: If 3 different approved consent forms were used since the last annual review, please provide the two most recent signed copies of each version for a total of six.)

Attachments

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3. Informed Consent

If the study is **open to subject enrollment, please go to the Informed Consent section of the E-IRB Application and verify attachment(s) include:**

- One clean copy in PDF (without the IRB Approval stamp) of the currently approved consent/assent document(s), or,
- If requesting changes to the consent/assent document(s), submit one copy with the changes highlighted (and designate Document Type as "Highlighted"), and one clean copy in PDF (without the changes highlighted).

If the study is **open to subject enrollment and the IRB has waived the requirement to document informed consent, please go to the Informed Consent section of the E-IRB Application and verify attachment(s) include:**

- One clean copy in PDF of the currently approved document used for the informed consent process (e.g., cover letter, phone script), or,
- If requesting changes to the consent/assent document(s), submit one copy with the changes highlighted (and designate Document Type as "Highlighted"), and one clean copy in PDF (without the changes highlighted).

If the study is **closed to subject enrollment, please go to the Informed Consent section of the E-IRB Application and remove Informed Consent Documents designated to get an IRB approval stamp to avoid having them appear valid for enrollment.**

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4. Unanticipated Problems Involving Risk to Subjects or Others/Adverse Events Summary & Assessment

Did any **problems/adverse events** occur during the last 12 months?

○ Yes ◉ No

In the space below, provide a written summary of both unanticipated problems* and available information regarding adverse events since the last review (e.g., initial review or annual/continuing review). The amount of detail provided in such a summary will vary depending on the type of research being conducted; in many cases, such a summary could be a brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and investigator's brochure (if applicable). **The summary must include the PI's assessment whether the problems/adverse events warrant changes to the protocol, consent process, or risk/benefit ratio.**

Note: It is the IRB's expectation that all unanticipated problems involving risk to subjects or others or related deaths requiring prompt reporting are submitted in the appropriate time frame (See Policy [PDF]). Your response to this Annual/Continuing Review is considered assurance that all prompt reportable problems/adverse events have been submitted for IRB review.

*For multisite studies, the written summary should describe external events determined to be unanticipated problems involving risk to subjects or others.

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5. Subject Info To-Date

Our records for the previously approved IRB application indicate the **IRB approved estimate** of subjects to be enrolled (or records/specimens reviewed) is:

80

Enter the number of enrolled subjects (or records/specimens reviewed) that **have not been previously reported** to the IRB

0

Our records for the previously approved IRB application indicate the previous total # of subjects enrolled (or records/specimens reviewed) since activation of the study is:

50

The new total number of subjects enrolled (or records/specimens reviewed) since activation of the study:

50

Please review the Project Info section for the IRB approved estimate of subjects to be enrolled (or records/specimens reviewed). If this new total exceeds your approved estimate of subjects to be enrolled (or records/specimens reviewed), please update the number in the field for Number of Human Subjects in the Project Info section.

6. Data and Safety Monitoring Board (DSMB)/Plan (DSMP)

If your study is monitored by a DSMB or under a DSMP, attach all documentation (i.e. summary report; meeting minutes) representing Data and Safety Monitoring activities that have not been previously reported to the IRB.

Attachments

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7. Since the most recent IRB Initial/Continuation Review Approval:

Have there been any **participant complaints** regarding the research?

○ Yes ◉ No

If yes, in the field below, provide a summary describing the complaints.

Have any **subjects withdrawn** from the research voluntarily or by you as the PI for reasons related to safety, welfare, or problems related to the conduct of the research? If a participant does not meet the screening criteria for a study even if they signed a screening consent it is NOT considered a withdrawal.

○ Yes ◉ No

If yes, in the field below, provide a detailed explanation to the withdrawal(s) including if participants were lost to contact.

Has any **new and relevant literature** been published since the last IRB review, especially literature relating to risks associated with the research?

○ Yes ◉ No

If yes, attach a copy of the literature as well as a brief summary of the literature including, if pertinent, the impact of the findings on the protection of human subjects.

Attachments

Have there been any **interim findings?**

○ Yes ◉ No

If yes, attach a copy of **Interim Findings.**

Attachments

Have **subjects experienced any benefits?**

○ Yes ◉ No

If yes, in the field below, provide a description of benefits subjects have experienced.

Have there been any **inspections/audits/quality improvement reviews** of your research protocol resulting in the need for corrective action in order to protect the safety and welfare of subjects?

○ Yes ◉ No

If yes, please attach documentation evidencing the outcome(s) and any corrective action(s) taken as a result.

Attachments

Was an FDA 483 issued as a result of any inspections/audits?

○ Yes ◉ No

If yes, submit documentation using attachment button above.

8. Risk Level:

Our records for the previously approved IRB application show your research is:

Risk Level: 1

Has something during the course of your research changed the level of risk?

○ Yes ◉ No

If yes, go to the Risk Level section, mark the appropriate risk level, and in the field below, describe why the risk level has changed:

9. Funding/Support:

Our records for the **previously approved** IRB application indicate your research is being submitted to, supported by, or conducted in cooperation with the following external or internal agency(ies) or funding program(s):

☑ Grant application pending
☑ (HHS) Dept. of Health & Human Services

- [x] (NIH) National Institutes of Health
- [ ] (CDC) Centers for Disease Control & Prevention
- [ ] (HRSA) Health Resources and Services Administration
- [ ] (SAMHSA) Substance Abuse and Mental Health Services Administration
- [ ] (DoJ) Department of Justice or Bureau of Prisons
- [ ] (DoE) Department of Energy
- [ ] (EPA) Environmental Protection Agency
- [ ] Federal Agencies Other Than Those Listed Here
- [ ] Industry (Other than Pharmaceutical Companies)
- [ ] Internal Grant Program w/ proposal
- [ ] Internal Grant Program w/o proposal
- [ ] National Science Foundation
- [ ] Other Institutions of Higher Education
- [ ] Pharmaceutical Company
- [ ] Private Foundation/Association
- [ ] U.S. Department of Education
- [ ] State

Other:

Please **update the Funding/Support section of your IRB application** if needed, including the following attachments if they contain changes not previously reported to the IRB:

- A current copy of your **protocol if you are conducting industry/pharmaceutical research;**
- A current **Investigator Brochure** (submit a copy with all changes underlined).
- A **new or revised grant application** for this project.

Did your project receive extramural funding?

(•) Yes ( ) No

If yes, please review and correct if necessary, the OSPA Account # information under the **Funding/Support section** of your IRB application.

If the project is externally funded, has the sponsor offered any of the research team enrollment incentives or other personal benefit bonuses? (e.g., cash/check, travel reimbursements, gift checks, etc.)

( ) Yes (•) No ( ) N/A

Note: It is University of Kentucky policy that personal benefit bonuses are not allowed. If these conditions change during the course of the study, please notify the IRB.

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10. Project Information

Our records for the previously approved IRB application indicate your estimated project end date is:

08/01/2026

If you have a new estimated project end date, please go to the Project Info section and change the date in the field for Anticipated Ending Date of Research Project.

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11. Study Personnel

Our records for the previously approved IRB application indicate the following individuals are study personnel on this project (if applicable):

Last Name	First Name
Cecil	Sarah
Hines	Alexandra
Kushner	Madeline
Maynard	Caden

Last Name	First Name
Southward	Matthew
Stumpp	Nicole
Terrill	Douglas

Please review the individuals listed above and update your records as needed in the Study Personnel section of the E-IRB application, being sure that each individual listed has completed or is up-to-date on the mandatory human research protection training [see the policy on Mandatory Human Subject Protection Training FAQs (required every three years)].

12. Progress of the Research

To meet federal requirements the IRB is relying on your RESEARCH DESCRIPTION as a protocol summary and their expectation is that it is up-to-date. If the currently approved protocol (or research description) in your E-IRB application is outdated, please make applicable changes, and describe in the field below any substantive changes and explain why they are essential. If none, insert "N/A" in the text field below. If you are closing your study, you may use the space below to summarize the final status of the research.

NA

Note: No changes in the research procedures should have occurred without previous IRB review. Approval from the IRB must be obtained before implementing any changes.

Provide a brief **summary** of any **modifications that affect subject safety and/or welfare** approved by the IRB since the last initial or continuation review (If none, insert "N/A" in the text field below.):

NA

Attach one copy of the most recent progress report sent to the FDA, if available. All PI-sponsored IND/IDE studies are required to submit a copy of the FDA progress report.

Attachments

13. Confidentiality/Security

Review your Research Description section and update the Confidentiality portion, if necessary, to describe measures for security of electronic and physical research records (e.g., informed consent document(s), HIPAA Authorization forms, sensitive or private data).

14. Subject Demographics

Our records for the previously approved IRB application indicate the following categories of subjects and controls are included in your research:

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking
- ☐ International Citizens
- ☑ Normal Volunteers

- ☐ Military Personnel and/or DoD Civilian Employees
- ☑ Patients
- ☐ Appalachian Population

Please review the Subject Demographics section of your IRB application for accuracy, and note the following:

If during the course of your research 1) any prisoners have been enrolled, OR 2) subjects have been enrolled that became involuntarily confined/detained in a penal institution that have not been previously reported to the IRB, go to Subject Demographic section in your E-IRB application and mark "prisoners" in the categories of subjects to be included in the study, if it is not already marked.

Note: If either 1 or 2 above apply, and you have received funding from the Department of Health and Human Services (HHS), a Certification Letter should have been submitted to the Office for Human Research Protections (OHRP); prisoners and individuals who have become involuntarily confined/detained in a penal institution cannot continue participation in the research until OHRP issues approval. If the Certification has not been submitted, contact the Office of Research Integrity.

Based on the **total # of subjects** who have enrolled, complete the subject demographic section below:

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native	0	0		
Asian	0	1		
Black or African American	2	0		
Latinx	0	1		
Native Hawaiian or Other Pacific Islander	0	0		
White	11	33		
American Arab/Middle Eastern/North African	0	0		
Indigenous People Around the World	0	0		
More than One Race	0	1		
Unknown or Not Reported				1

If unknown, please explain why:

2 people were lost to contact before filling out the demographic survey

15. Research Sites

Our records for the previously approved IRB application indicate that you are conducting research at the following sites:

UK Sites

- [x] UK Classroom(s)/Lab(s)
- [x] UK Clinics in Lexington
- [ ] UK Clinics outside of Lexington
- [ ] UK Healthcare Good Samaritan Hospital
- [ ] UK Hospital

Schools/Education Institutions Schools/Education Institutions

- [ ] Fayette Co. School Systems *
- [ ] Other State/Regional School Systems
- [ ] Institutions of Higher Education (other than UK)

Other Medical Facilities

- [ ] Bluegrass Regional Mental Health Retardation Board
- [ ] Cardinal Hill Hospital
- [ ] Eastern State Hospital
- [ ] Nursing Homes
- [ ] Shriner's Children's Hospital
- [ ] Other Hospitals and Med. Centers

- [ ] Correctional Facilities
- [ ] Home Health Agencies
- [ ] International Sites

Other:

Suffolk University

If the above listed sites are not accurate, go to the Research Sites section of the E-IRB application to update the facilities at which research procedures have been or will be conducted.

If you are adding a new off-site facility, you may also need to update your E-IRB application Research Description, Research Sites, Informed Consent, and other affected sections as well as any documents which will list the off-site facility. Documents needing updating may include, but not limited to:

- Consent forms (attachment under Informed Consent section)
- Brochures (attachment under Additional Info section)
- Advertisements (attachment under Research Description section) ;
- Letter of support (attachment under Research Sites section)).

Please revise applicable sections and attachments as necessary.

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16. Disclosure of Significant Financial Interest

Disclosure of Significant Financial Interest:

Our records for the previously approved IRB application indicate that you, your investigators, and/or key personnel (KP) have a significant financial interest (SFI) related to your/their responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2):

○ Yes ◉ No

If you need to update your records, please go to the PI Contact Information section and/or Details for individuals listed in the Study Personnel section to change your response to the applicable question(s).

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17. Supplementals

To ensure the IRB has the most accurate information for your protocol you are expected to re-visit the E-IRB application sections and make corrections or updates as needed. At a minimum you are being asked to review the following sections for accuracy:

STUDY DRUG INFORMATION—Please review for accuracy.
STUDY DEVICE INFORMATION—Please review for accuracy.
RESEARCH ATTRIBUTES—Please review for accuracy.
OTHER REVIEW COMMITTEES -- Please review for accuracy.

PROJECT INFORMATION

0 unresolved comment(s)

Title of Project: (Use the exact title listed in the grant/contract application, if applicable).
If your research investigates any aspect of COVID-19, please include "COVID19" at the beginning of your Project Title and Short Title

Increasing Treatment Efficiency Using SMART Methods for Personalizing Care

Short Title Description
Please use a few key words to easily identify your study - this text will be displayed in the Dashboard listing for your study.

UK Psychiatry Personalization Study

Anticipated Ending Date of Research Project: 8/1/2026

Maximum number of human subjects (or records/specimens to be reviewed) 80

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? ○ Yes ◉ No

Are you requesting that the UK IRB serve as the lead IRB for a multi-site study, **OR** that the UK IRB defer review to another IRB? [Click here for "IRB Reliance" help]
◉ Yes ○ No
If "Yes," before completing your IRB application, fill out the Reliance Request Form and submit it to irbreliance@uky.edu.

PI CONTACT INFORMATION

0 unresolved comment(s)

Principal Investigator (PI) role for E-IRB access
The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*).

If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be listed as PI here.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to myUK and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a 'Name Change Form' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the HR Benefits Office for additional information.

The Principal Investigator's (PI) contact information is filled in automatically based on who logged in to create the application.

If you are not the Principal Investigator, do NOT add yourself as study personnel.
To change the PI contact information on an application in Researcher edit status:

- click "Change Principal Investigator";
- search for the PI's name using the search feature;
- click "Select" by the name of the Principal Investigator, then "Save Contact Information".

You will automatically be added as study personnel with editing permissions to continue editing the application.

Change Principal Investigator:

First Name:	Shannon	Room# & Bldg:	115 Kastle Hall
Last Name:	Sauer-Zavala	Speed Sort#:	40508
Middle Name	E		
Department:	Psychology - 8E120	Dept Code:	8E120
PI's Employee/Student ID#:	10000325	Rank:	
PI's Telephone #:	8594571117	Degree:	
PI's e-mail address:	ssz@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	2/3/2023
		RCR Trained:	Yes

Do you, the PI, have a significant financial interest related to your responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2)?

○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

- (•) (Risk Level 1) Not greater than minimal risk
- ( ) (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- ( ) (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ( ) (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Refer to UK's guidance document on assessing the research risk for additional information.

SUBJECT DEMOGRAPHICS **0 unresolved comment(s)**

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc.) 18 to 65

Study Population:

Describe the characteristics of the subject population, including age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- Justification for the inclusion of vulnerable groups such as children, prisoners, adults with impaired consent capacity, or others who may be vulnerable to coercion or undue influence.

Please consider these resources:
NIH Diversity Policy
FDA Diversity Guidance

Patient Participants:

Inclusion Criteria: We aim to recruit individuals diagnosed with at least one emotional disorder will be eligible to participate. Specifically, emotional disorders include DSM-5 anxiety disorders, obsessive-compulsive disorders, and trauma- and stressor-related disorders. These individuals will be 18 years of age or older and fluent in English. Patients on psychotropic medications will be included if they are willing to maintain a stable dosage throughout the study period; this procedure allows for a broader range of participants and avoids having outcomes assessment confounded by the initiation of medication during treatment. Finally, patients must be willing to refrain from additional treatment for the duration of the study. Medication stability and exclusion of individuals in concurrent therapy are long-standing inclusion criteria in clinical trials conducted by the PI (see Barlow et al., 2017)

Exclusion Criteria:
We will exclude individuals diagnosed with psychological conditions that may be better addressed by alternative treatments; these conditions include psychotic disorders, bipolar disorder, imminent risk of suicide (i.e., intent/plan), and substance use disorders.

In order to have 60 individuals complete study procedures, we anticipate having to screen a higher number of potential participants.

These inclusion/exclusion criteria were designed to provide the UP modules to individuals with the presenting problems that have been proven to be addressed with this treatment. With regard to racial/ethnic characteristics, we expect that our patient population will reflect the demographics of greater Lexington. Given that women are more likely to seek therapy, we expect a higher ratio of women in this study. Inclusion of women (and men) along all races/ethnicities ensures greater generalizability of our findings. See "Subject Demographics" section for a breakdown of our expected ethnic/racial composition. We plan to begin enrollment in January 2021 and end enrollment by January 2023.

Clinician Participants
Clinicians will be eligible to participate if they (a) have completed their terminal degree, (b) are independently licensed to practice in Kentucky, (c) are employed at least half time at UK Psychiatry (to ensure adequate schedule availability/flexibility to take on study patients), and (d) are able to engage in training activities (i.e., workshop attendance, consultation calls). To maximize generalizability by soliciting acceptability data from a range of individuals, we seek to recruit at least 6 clinicians.

Attachments

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Census Regional Analyst Edition, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported at Continuation Review time for Pre-2019 FDA-regulated Expedited review and Full review applications):

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:	0	0		
Asian:	0	0		
Black/African American:	5	1		
Latinx:	3	3		
Native Hawaiian/Pacific Islander:	0	0		
White:	21	43		
American Arab/Middle Eastern/North African:	0	0		
Indigenous				

People Around the World:	0	0		
More than One Race:	1	3		
Unknown or Not Reported:	0	0		

If unknown, please explain why:

Other category = more than one race.

Note = Planned enrollment reflects a total n of 80 patient completers and 6 clinician completers. Race/ethnicity categories above are not mutually exclusive.

Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depending on the subject categories which apply to your research. If the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check populations which the research does not specifically target. For example: a large record review of a diverse population may incidentally include a prisoner or an international citizen, but you should not check those categories if the focus of the study has nothing to do with that status.

Check All That Apply (at least one item must be selected)

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking (translated long or short form)
- ☐ International Citizens
- ☑ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☑ Patients
- ☐ Appalachian Population

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults
- Economically or Educationally Disadvantaged Persons

Other Resources:

- UKMC Residents or House Officers [see requirement of GME]
- Non-English Speaking [see also the E-IRB Research Description section on this same topic]
- International Citizens [DoD SOP may apply]
- Military Personnel and/or DoD Civilian Employees

Assessment of the potential recruitment of subjects with impaired consent capacity (or likelihood):

☐ Check this box if your study does NOT involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

Does this study focus on adult subjects with any conditions that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

○ Yes ◉ No

If Yes and you are not filing for exemption certification, go to "Form T", complete the form, and attach it using the button below.

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

For creating your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and edit to match your research project.

Additional Resources:

- Informed Consent/Assent Website
- Waiver of Consent vs. Waiver of Signatures
- Sample Repository/Registry/Bank Consent Template

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- If another site is serving as the IRB for the project, attach the form as a "Reliance Consent Form" so the document will not receive a UK IRB approval stamp; the reviewing IRB will need to stamp the consent forms.
- Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
- It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.
- Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.
  Document Types that do NOT get an IRB approval stamp are:
  - "Highlighted Changes",
  - "Phone Script", and
  - "Reliance Consent Form",
  - "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must:

   a) provide a response in the text box below describing how investigators will obtain consent/assent, and
   b) check the box for at least one of the consent items and/or check mark one of the waivers

2. If applicable attach each corresponding document(s) **as a read-only PDF.**
3. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

Check All That Apply

- ☐ Informed Consent Form (and/or Parental Permission Form and/or translated short form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script
- ☐ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Reliance Consent Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- ☑ Stamped Consent Doc(s) Not Needed

Attachments

Informed Consent Process:

Using active voice, in the text box below, describe how investigators will obtain consent/assent. Include:

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)

- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

Will electronic consent form/process be utilized on-site or remotely for this study?

◉ Yes ○ No

If yes, in addition to addressing the above bullet points, describe the e-consent method and platform, including any hyperlinks, videos, or enhancements used to convey information, if applicable. Attach a representation of the e-consent with signature fields. For guidance, see the ORI E-Consent web page.

Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Special considerations may include:

- Obtaining consent/assent for special populations such as children, prisoners, or people with impaired decisional capacity
- *Research Involving Emancipated Individuals*
  If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **prior to submitting this application to the IRB**. Include research legal counsel's recommendations in the "Additional Information" section as a separate document.
- *Research Involving Non-English Speaking Subjects*
  For information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.
- *Research Repositories*
  If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template.

Patients who, after the phone screening, are interested in participating will be scheduled for an in-person meeting at UK Psychiatry or a virtual meeting via phone or HIPAA-compliant UK HealthCare Zoom. At this time, study staff (i.e., doctoral students in clinical psychology/post-doctoral scholars) will explain study procedures. Participants who attend this meeting virtually will be sent a copy of the informed consent form ahead of time to review. The participant will be given a chance to read the informed consent document and ask any questions. The description of the treatment-length randomization procedure will be fully explained. The description of module-ordering randomization procedures in the consent form will be purposefully vague (i.e., "You'll be assigned by chance to one of three methods for ordering treatment modules") instead of explaining that we are randomizing people to receive modules according the UP's standard order, prioritization of strengths, or prioritization of weaknesses. We believe that a vague explanation is necessary because explaining the randomization in detail could influence patients' expectations about the study and their subsequent behavior. The study staff member will explain that that the participant may withdraw their consent at any time and choose not to complete any study procedures that cause distress. No study procedures will be completed until participants provide their informed consent. Participants attending this meeting virtually will provide their informed consent via a REDCap consent form. This consent form (see Informed Consent section documents) will be structured identically to the hard copy form and will allow for participants to electronically initial and sign their name, where required, using a mouse-drawn signature to document consent. These forms will be stored in REDCap separately from participants' data. Participants will be provided with a copy of the signed consent form for their records, regardless of whether they sign a hard copy or electronic copy of the form. Only UK study staff will obtain consent (not Suffolk staff). UK study staff will write their name on the consent form (physically or electronically) to indicate that they witnessed the consent process.

With regard to clinician participants, those that express interest in participating following receipt of the email invitation will be scheduled for individual informed consent visits at UK psychiatry. Study staff (i.e., doctoral students in clinical psychology/post-doctoral scholars) will explain study procedures. The clinician participants will be given a chance to read the informed consent document and ask any questions. Similarly, these informed consent documents may be hard copies or electronic copies stored in REDCap. Electronic copies with participants' electronic initials and signatures will be stored separately from participants' data. Patients will be encouraged to discuss any issues that arise with their study assessor (not their therapist, who is not study staff). However, if they do not feel comfortable expressing concerns with this person, they are encouraged to reach out the PI via the contact information on the consent form. The PI will make every effort to address these concerns, if necessary, following up with appropriate study staff (without identifying the particular patient) and implementing procedural changes. We will also provide ORI's contact information for participants in the event that they would have complaints or concerns. Clinicians participants will be encouraged to reach out to the PI directly with concerns and will also be provided ORI's contact information.

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, complete, Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to

single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting a waiver of the requirement for the informed consent process.

☐ I am requesting an alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered and/or omitted, and justify the alteration.

SECTION 2.

Explain how each condition applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

e) If the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

- Private information/specimens are “identifiable” if the investigator may ascertain the identity of the subject or if identifiers are associated with the information (e.g., medical records). This could be any of the 18 HIPAA identifiers including dates of service.
- If not using identifiable private information or identifiable biospecimens, insert N/A below.

☑ Request for Waiver of Signatures

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (e.g., a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk to the subject, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study.

If the IRB approves a waiver of signatures, participants must still be provided oral or written information about the study. To ensure you include required elements in your consent document, use the ***Cover Letter Template*** *as a guide. There is an English and a Spanish version.*

○ **Option 1**

Describe how your study meets these criteria:

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

◉ **Option 2**

Describe how your study meets these criteria:

a) The research presents no more than minimal risk to the participant:

We are requesting a waiver of the documentation of informed consent process for the phone screen portion of this study. Our phone screen presents no more than minimal risk to participants because it is designed to a) briefly gather basic contact information about participants and b) ask enough questions about their recent emotional difficulties to indicate that they likely meet diagnostic criteria for at least one emotional disorder. We have included language to confirm that participants are in an area in which they would feel comfortable answering these questions to further reduce the risk of participants sharing personal information. Information will be collected by research assistants over the phone and documentation of participants' answers to the phone screen questions will either be kept in a locked cabinet in a locked office in the TIPS Lab space or on the password-protected server space at UK dedicated to the PI's research lab.

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

Given that written consent is not normally required outside of the research context for a phone script, we are requesting a waiver of the documentation of informed consent for the phone screen portion of this study only.

○ **Option 3**

Describe how your study meets these criteria:

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

STUDY PERSONNEL **0 unresolved comment(s)**

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must click the 'Save Study Personnel Information' button.

◉ Yes ○ No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is required for a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed below. ***Residents and students who are PI's are encouraged to designate the faculty advisor or at least one other individual as a contact with an editor role (DP).***
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR/FR, MR) or 'Other Review", and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature:

- Search for personnel;
- Click "select" by the listing for the person you want to add;
- For each person, specify responsibility in the project, whether authorized to obtain informed consent, AND denote who should receive E-IRB notifications (contact status).

NOTE: Study personnel must complete human subject protection (HSP) and Responsible Conduct of Research (RCR) training before implementing any research procedures. For information about training requirements for study personnel, visit UK's HSP FAQ page, the RCR Getting Started page, or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (HSPTrainingSupport@uky.edu) for credit.

Study personnel assisting in research project:

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Cecil	Sarah	Project Assistance/Support	SP	Y	N	B.A.	N	Y	03/03/3000		N	05/14/2024	N	Y
Hines	Alexandra	Study Coordinator	DP	Y	Y		P	Y	07/23/2024	Y	N	09/25/2023	N	Y
Kushner	Madeline	Data Collection	SP	Y	N		S	Y	06/15/2022	Y	N	06/12/2022	N	Y
Maynard	Caden	Project Assistance/Support	SP	Y	N	B.A.	N	Y	03/03/3000		N	05/14/2024	N	Y
Southward	Matthew	Co-Investigator	DP	Y	Y	PhD	P	Y	08/01/2022	N	N	11/24/2020	N	Y
Stumpp	Nicole	Co-Investigator	DP	Y	N	B.A.	P	Y	09/26/2022	Y	N	04/26/2020	N	Y
Terrill	Douglas	Data Analysis/Processing	SP	Y	N	B.A.	S	Y	05/21/2024	Y	N	06/10/2021	N	Y
Allison-Brown	Morgan	Data Collection	SP	Y	N		N	Y	03/03/3000		Y	12/11/2024	N	Y
Birtwell	Madelyn	Project Assistance/Support	SP	Y	N		N	Y	03/03/3000		Y	12/11/2024	N	Y
Bugher	Christian	Project Assistance/Support	SP	Y	N		P	N	07/23/2020		Y	01/03/2024	N	N
Coon	Jorden	Project Assistance/Support	SP	Y	N		S	N	02/20/2019		Y	02/23/2022	N	N
Cravens	Elaina	Project Assistance/Support	SP	Y	N			N	04/03/2021		Y	12/11/2024	N	N
Cravens	Lauren	Project Assistance/Support	SP	Y	N		S	N	09/15/2019		Y	09/22/2022	N	N
Escobar	Katherine	Data Collection	SP	Y	N		N	Y	03/03/3000		Y	12/11/2024	N	Y
Feddock	Riley	Recruitment	SP	Y	N		S	Y	09/01/2024	N	Y	12/11/2024	N	Y
Garlock	Anna	Data Collection	DP	Y	N		P	N	01/28/2019		Y	02/23/2022	N	Y
Holcomb	Juliana	Data Collection	SP	Y	N		N	Y	03/03/3000		Y	12/11/2024	N	Y
Jasinski	Lindsey	Consultant/Advisor	SP	N	N	PhD	P	Y	08/01/2023	Y	Y	01/03/2024	N	Y
Langer	David	Co-Investigator	DP	Y	N	Ph.D.	N				Y	12/12/2024	N	Y
Linker	Valerie	Project Assistance/Support	SP	Y	N		S	Y	09/10/2023	N	Y	02/23/2022	N	N
MacLean	Destiney	Data Collection	DP	Y	N		P	Y	09/03/2024	Y	Y	02/23/2022	N	Y
Miller	Lauren	Study Coordinator	SP	Y	N		P	N	09/15/2021		Y	09/22/2022	N	N
Mitcheson	Morgan	Data Collection	SP	Y	N		N	Y	03/03/3000		Y	10/02/2023	N	Y
Patel	Shivani	Project Assistance/Support	SP	Y	N		N	Y	03/03/3000		Y	12/11/2024	N	Y
Rahman	Abrar	Recruitment	SP	Y	N		S	Y	09/07/2022	N	Y	12/11/2024	N	N
Schild	Jennifer	Data Collection	SP	Y	N		N	Y	03/03/3000		Y	12/11/2024	N	Y

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Semcho	Stephen	Co-Investigator	DP	Y	N	MA	P	Y	06/13/2022	Y	Y	12/11/2024	N	Y
Shroyer	Sara	Project Assistance/Support	SP	Y	N		S	Y	10/04/2022		Y	12/11/2024	N	Y
Vijayakumar	Kaviya	Project Assistance/Support	SP	Y	N		N	Y	03/03/3000		Y	12/11/2024	N	Y
Woodie	Heather	Project Assistance/Support	SP	Y	N		P	N	08/19/2020		Y	01/03/2024	N	N
Wright	Kathleen	Project Assistance/Support	SP	Y	N		P	N	08/20/2020	N	Y	01/03/2024	N	N

RESEARCH DESCRIPTION

0 unresolved comment(s)

You may attach a sponsor's protocol pages in the "Additional Information" section and refer to them where necessary in the Research Description. However, each prompt that applies to your study should contain at least a summary paragraph.

Pro Tips:

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section or under the Additional Information section to include supplemental information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background

Include a brief review of existing literature in the area of your research. You should identify gaps in knowledge that should be addressed and explain how your research will address those gaps or contribute to existing knowledge in this area. For interventional research, search PubMed and ClinicalTrials.gov for duplicative ongoing and completed trials with same condition and intervention(s).

This protocol reflects similar procedures to previously approved protocol #53545; however, instead of being conducted in the PI's lab space, this study will take place at in UK Psychiatry's Adult Outpatient clinic. The primary purpose of this study is to explore whether the efficiency of treatment for anxiety and depressive disorders can be increased using two discrete strategies: personalized skill ordering and 2) treatment discontinuation based on proximal indicators of improvements. The present study will specifically use treatment components drawn from an evidence-based psychological intervention, the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders (UP; Barlow et al 2011; 2018). This intervention has strong empirical support for patients presenting with anxiety, depressive, and related disorders (see: Barlow et al., 2017) and contains therapeutic skills that are common in psychological interventions (e.g., psychoeducation, mindfulness training, cognitive restructuring, countering emotional avoidance, increasing interoceptive tolerance). Skill modules in the UP are typically delivered in a standard order. Recent research conducted by the PI has shown that each UP module, when presented in isolation, leads to change in its associated skill (e.g., the mindfulness module leads to increased mindfulness), as well as improved symptoms (Sauer-Zavala et al., 2017). Given this evidence that each skill is self-contained, the PI recently conducted a pilot study personalizing the sequencing of UP modules (Sauer-Zavala et al., 2019). Specifically, a small sample (n=12) was randomly assigned to received UP skills in an order that prioritized relative strengths vs. relative weaknesses. Results suggest that it is feasible to order modules in this manner, that patients were satisfied with their personalized order, and that, by the final session, patients in both conditions demonstrated similar levels of symptom improvement (comparable to effects for the standard presentation of the UP). There was also preliminary evidence to suggest that capitalizing on patient strengths is associated with steeper trajectories of change (i.e., faster symptom improvement) compared to compensating for deficits.

The majority of research evaluating the UP has provided participants with a relatively standard number of sessions (usually 12-16 sessions; Barlow et al., 2017; Farchione et al., 2012). However, given that patients in the community only attend five sessions of psychotherapy on average (Gibbons et al., 2011), that personalizing psychotherapy based on patient strengths may lead to more rapid symptom improvements (Sauer-Zavala et al., 2019), and that the rise of value-based care means healthcare providers will be reimbursed based on the quality, not quantity, of treatment services provided, there is a need to empirically test briefer forms of treatment. While briefer treatments may not be indicated for all patients, it is important to understand whether certain baseline characteristics of patients or variation in certain treatment-engaging behaviors predicts success in briefer models. This information could then be used by providers to help match patients to their most efficacious and cost-effective treatment.

Objectives

List your research objectives. Please include a summary of intended research objectives in the box below.

The present study aims to 1) explore whether ordering modules based on patient strengths or weaknesses leads to more efficient skill acquisition and/or symptom improvement, compared to a standard order, in the context of treatment for psychological disorders. We further aim to identify 2) whether certain putative mechanisms of action in the UP change in briefer treatment and are associated with post-treatment symptom change. Finally, we aim to explore 3) whether community clinicians find these adaptations to treatment (variable order, early treatment termination) acceptable and feasible. The information gathered in this study is key to further refining the delivery of the UP and tailoring it to the needs of each unique patient.

Study Design

Describe and explain the study design (e.g., observational, secondary analysis, single/double blind, parallel, crossover, deception, etc.).

- *Clinical Research*: Indicate whether subjects will be randomized and whether subjects will receive any placebo.
- *Community-Based Participatory Research*: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.
- *Qualitative research*: Indicate ranges where flexibility is needed, if a fixed interview transcript is not available, describe interview topics including the most sensitive potential questions.

- *Research Repositories*: If the purpose of this submission is to establish a Research Repository (bank, registry) and the material you plan to collect is already available from a commercial supplier, clinical lab, or established IRB approved research repository, provide scientific justification for establishing an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance or the UK Research Registry Guidance.

In this 3 x 2 design, patient participants (N = 150) will be randomly assigned to receive treatment modules sequenced according to the following three module-ordering conditions: 1) Standard: In accordance with the standard, published UP manual; 2) Capitalization: organized to prioritize skills that capitalize on patient strengths; 3) Compensation: organized to prioritize skills that compensate for patient weakness. All participants will also be randomized to two treatment-duration conditions: 1) Brief: 7 sessions; or 2) Full; 13 sessions. Deception will not be used – patients will be fully informed about the possibility of being assigned to the Brief or Full treatment length condition. However, during the consent process, we have elected to limit the information provided about each ordering scheme. Instead, participants will be told that we may use their self-report questionnaire data to determine the order of their skills. This omission of information is justified for the following reasons: 1) knowing their condition may bias results and, given that the conditions are face valid, patients may be able to guess their assignment if they are provided detailed information about the possibilities, and; 2) although research provision of manualized interventions (like the UP) are typically delivered in a standard order, it is common in routine practice for therapists to make decisions about how to order treatment skills without providing patients with reasoning. Following the final assessment, patients will be provided with information about the three module-ordering conditions and the condition to which they had been assigned will be revealed.

Clinician participants will not be randomized - all clinicians will be asked to attend a training workshop in the Unified Protocol and participate in weekly consultation calls with Dr. Sauer-Zavala or Southward. They will provide care in each patient condition (standard, capitalization, compensation; brief, full). Clinicians will be asked to complete surveys and interviews about their impressions participating in this study/providing care based patient strengths/weaknesses.

Attachments

Subject Recruitment Methods & Advertising

Describe how the study team will identify and recruit subjects. Please consider the following items and provide additional information as needed so that the IRB can follow each step of the recruitment process.

- How will the study team identify potential participants?
- Who will first contact the potential subjects, and how?
- Will you use advertisements? If so, how will you distribute those?
- How and where will the research team meet with potential participants?
- If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations.
- How you will minimize undue influence in recruitment?
- Attach copies of all recruiting and advertising materials (emails, verbal scripts, flyers, posts, messages, etc.).

For additional information on recruiting and advertising:

- IRB Application Instructions - Advertisements
- PI Guide to Identification and Recruitment of Human Subjects for Research

As of December 21, 2020, no participants have been enrolled, recruited, or completed any study procedures.

Patient participants will be recruited from the pool of individuals seeking treatment at UK Psychiatry's Outpatient Clinic. During their intake appointment for non-research services at UK Psychiatry, participants will be asked to provide their consent to be contacted by research teams to learn more about ongoing research studies. A member of our study team will attend weekly staffing meetings at UK Psychiatry, where intakes from the previous week are discussed. Study staff may overhear PHI for people not involved in the study in the course of these meetings. We will work to mitigate these occurrences by having study staff only attend portions of these meetings when new potential patients are being introduced. Even so, study staff still may overhear PHI regarding potential participants who do not ultimately meet study criteria. This process will be designed to minimize the amount of non-study-related PHI study staff may overhear. Study staff will obtain observer privileges from UK Healthcare in order to attend these meetings. Patients that likely meet study criteria (who gave their consent to be contacted by ongoing research studies) will be contacted by our study team to conduct a phone screen (see attached). Residents will provide study staff with the names, phone number(s), and email address(es) of potential participants so study staff do not have to access participants' and potential participants' medical records.

With regard to clinician participants, UK Psychiatry currently employs 10 clinicians who meet study inclusion criteria. Leadership at UK Psychiatry (i.e., Department Chair, VP of Research, Director of Outpatient Services) are invested in successful completion of this study and have assessed clinician interest in being a part of this effort (see attached letter of support). To recruit clinician participants, we will ask the Director of Outpatient Services at UK Psychiatry to send an informational email about the study to UK psychiatry clinicians; those with interest in participating will be asked to contact study staff directly (see attached email template).
We will recruit directly from the patient/clinician pool at UK Psychiatry. In line with current standard practice, residents and supervisors within the UK Psychiatry department will ask patients and potential patients if they are interested in being contacted to participate in research studies. No further advertising will be conducted.

Attachments

Research Procedures

Describe how the research will be conducted.

- What experience will study participants have?
- What will study participants be expected to do?
- How long will the study last?
- Outline the schedule and timing of study procedures.
- Provide visit-by-visit listing of all procedures that will take place.
- Identify all procedures that will be carried out with each group of participants.
- Describe deception and debrief procedures if deception is involved.

Upon referral to the study via the recruitment methods described above, patient participants will complete a brief telephone screening (see attached). The screen will predominantly be conducted by trained undergraduate/post-baccalaureate research assistants, however the PI or a supervised graduate students/post-doctoral scholars may also conduct the phone screens. Screening forms for individuals who are deemed to be ineligible for the study will be shredded.

Likely eligible participants, determined by the phone screen, will be invited to attend an in-person session at UK Psychiatry or a virtual session using either UKHealthCare HIPAA-compliant Zoom or phone (Assessment Visit 1). As described above (see "Informed Consent" section), a study assessor (i.e., doctoral students in clinical psychology/post-doctoral scholar) will review study procedures with potential participants and ask them to provide their informed consent. After informed consent is provided, an interview-based diagnostic assessment will be administered in order to confirm clinical inclusion/exclusion criteria, as well as to provide a baseline level of clinical severity. This assessment visit will be audio-recorded provided participants give their consent for this. Next, patients will be asked to complete a battery of self-report questionnaires, which will assess symptoms of anxiety/depression, level of functioning (i.e., clinical interference, quality of life), and proficiency in the skills taught during treatment with the UP. Those that are deemed ineligible after this assessment will be withdrawn, whereas we will work with eligible participants to schedule their next study session (Treatment Session 1). After Assessment Visit 1, study staff (i.e., research assistant) will randomly assign them to one of three module-ordering conditions: Standard (modules order according to the published manual), Capitalization (modules ordered to prioritize patient strengths) and Compensation (modules ordered to prioritize patient weaknesses). The completed self-report battery from Assessment Visit 1 will be used to order modules for those assigned to the Capitalization and Compensation conditions. Study therapists (i.e., clinicians at UK psychiatry), study assessors (i.e., doctoral students in clinical psychology/post-doctoral scholar), and participants will be blind to module-ordering condition.

Following Assessment Visit 1, all participants will begin completing weekly treatment sessions in person, via phone, or via HIPAA-compliant video conferencing service (i.e., Zoom via the UK HealthCare portal); the order of treatment skills will be determined based on their assignment to module-ordering condition. Before the start of Treatment Session 5, clinician participants will alert study staff (i.e., research assistant) to request a randomization to a Treatment Length Condition: Brief (6 sessions) or Full (12 sessions). Treatment Length Randomization will occur at this stage to limit expectancy effects on therapists' and participants' behaviors, while also allowing therapists and participants to plan their final 2 sessions together with this randomization in mind. Participants randomized to the Brief treatment condition be reminded during Treatment Session 6 how they can use the skills learned in the previous sessions in the upcoming weeks to prevent relapse. In the event that participants are at an imminent risk of harm to themselves or others at this session, the therapist will work with the PI to develop a safety plan with the participant which may include referrals to other psychotherapy resources or hospitalization.

We will use a treatment window during which the assigned number of sessions will be completed; specifically, patients randomized to the Brief condition will complete 7 sessions during an 10-week window and patients randomized to the Full condition will complete 13 sessions during a 20-week window. This will allow us to account for scheduling challenges (e.g., patient/therapist illness, vacation). The first session for all participants will be an "orientation to treatment" session in which presenting concerns will be reviewed and an overview of the treatment model will be provided. As noted previously, the skills delivered during the remaining sessions in this study will be drawn from the UP. Four of the five UP modules will be implemented 2 sessions: Understanding Emotions, Mindful Emotion Awareness, Cognitive Flexibility, and Increasing Interoceptive Tolerance. The 5th UP module, Countering Emotional Behaviors, is designed to be implemented in 4 sessions. All sessions will last for 60 minutes in duration. Thus, depending on treatment length and module order, each participant will receive 2 to 5 UP modules during this study. It is important to note that the therapeutic strategies involved in all modules are all common, evidence-based cognitive-behavioral strategies and are not, themselves, under study; instead, we are interested in whether personalized sequencing leads to faster improvements (not whether patients improve at all - we expect that most will improve). Every module involves reading from a published manual (the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders; Barlow et al., 2018) and completing homework assignments outside of the treatment session (this intervention has previously been reviewed by UK's non-medical IRB). These treatment sessions will be audio-recorded provided participants give their consent for this; this will allow study staff to rate sessions for fidelity to the protocol.

Regardless of randomization, all participants will be scheduled for Assessment Visit 2 to occur between treatment sessions 5 and 6. Participants will complete an interview-based diagnostic assessment with a study assessor that will focus on the diagnoses assigned at Assessment Visit 1. This assessment may take place in person at UK psychiatry, over the phone, or via HIPAA-compliant Zoom. This assessment visit will be audio-recorded. Participants will also complete the same battery of self-report questionnaires at this visit as at Assessment Visit 1. All participants will also complete Assessment Visit 3, which will take place between weeks 13-16 (corresponding to the end of the treatment window for the Full length condition). This assessment visit will also be audio-recorded and may take place in person at UK Psychiatry, over the phone, or via HIPAA-compliant Zoom. Finally, Assessment Visit 4 will take place (in person at UK Psychiatry, over the phone, or via HIPAA-compliant Zoom) between 46 and 50 weeks after Assessment 1 and will include the same questionnaires.

Following the last treatment session (Treatment Session 13 for participants in the Full treatment condition; Treatment Session 7 for participants in the Brief treatment condition), participants will be asked to provide satisfaction ratings and written qualitative feedback on their experience with the treatment they received. Additionally, all participants will be asked to complete a weekly self-report battery assessing symptoms, skill proficiency, and skill knowledge for 20 weeks (again corresponding to the treatment window for the Full length condition); patients in the Brief condition will continue to complete these questionnaires after discontinuing treatment. These questionnaires will be emailed to participants and we will ask that they are completed within two days of receipt.

All self-report questionnaires will be completed online via REDCap. This survey platform is designed specifically for collection of research data, and therefore meets the privacy standards imposed on health care records by the Health Insurance Portability and Accountability Act (HIPAA). For Assessment Visits (1-4) that take place at UK psychiatry, self-report batteries will be completed on-site using a study iPad. The battery administered weekly between treatment sessions, along with the Assessment visits that take place remotely, will be emailed to participants to be completed on their own devices. Finally, although we anticipate that most patients will prefer to complete these measure electronically, we can provide paper and pencil versions of the questionnaires if requested.

There may be circumstances in which study patients are referred for additional care (i.e., they finish all study procedures and request a referral, they are withdrawn due to deterioration and given referrals to immediate treatment). No written information from the official study record (i.e., self-report questionnaire scores, assessor ratings) would be shared with UKHealthcare, or any other outside provider, upon referral after study. However, to streamline care, we will instruct the patient to ask their new provider to serve the study with a medical release of information (signed by the new provider and the patient) that allows their study clinician to speak with their new provider and provide clinical impressions. The release of information is a standard form for medical practitioners in routine care; since this is a not a study document, we have not attached it here.

Clinician Participants will be asked to attend a one-day training workshop on the Unified Protocol. The PI, Dr. Sauer-Zavala, was the founding director of the Unified Protocol Institute in her previous academic position at Boston University; in this role, she routinely provided this training, which will consist of didactic lecture and role plays. After the workshop, clinicians will be asked to begin implementing the UP with patients on their caseload that have consented to participate in this study. Clinicians will also attend weekly consultation calls with the PI who will provide additional guidance on the delivery of the study intervention; clinicians will be asked to participate in these calls for the duration of time they have study patients on their caseload. Clinicians will be asked to audio-record their work delivering the UP with their study patients; these tapes will be rated for adherence and competence with the protocol (see attached adherence checklists that study staff will use to rate tapes). Study staff will provide clinicians these audio-recorders for the duration of the study; study staff will stop by clinicians' offices to pull recordings off the audio recorder and upload them directly to the UK provided, password-protected TIPS lab server space. Finally, clinicians will be asked to fill out questionnaires at several time points during the study: 1) directly following provision of their informed consent, 2) following completion of the didactic workshop, and 3) after all patient treatment has been completed. Following their provision of informed consent, all questionnaires will be collected via an email with a link to an online REDCap survey.

To assess clinician and patient perspectives on the study design and treatment provided, trained study staff will conduct semi-structured individual qualitative interviews and small focus groups with clinicians (at the conclusion of their final study treatment case) and patients (at week 20). These qualitative interviews will be conducted by study staff members at Suffolk University who have been added as study personnel. These staff members have obtained guest LinkBlue IDs that allow them to access HIPAA-compliant UK resources to conduct research procedures involved in this study. The Suffolk University site will oversee the qualitative component of this protocol (see Reliance Agreement, submitted with this modification request). UK IRB-approved Suffolk University-based study staff will conduct the qualitative interviews remotely (by phone calls or Zoom via the UK HealthCare portal), transcribe the interview recordings, and code the transcriptions. All recordings, transcriptions, and coding files will be saved on the approved UK server. Suffolk University-based study staff have created guest LinkBlue IDs and have submitted the necessary paperwork through UK's IT department to be granted access by the PI to this server. Suffolk University-based study staff will also have access to UK HealthCare's HIPAA-compliant Zoom portal to ensure the confidentiality of communications with participants.

Post-treatment qualitative interviews, lasting 30 min, will be conducted with participants. Qualitative interviewers will use an interview guide designed to gather information on participant experience and perceived acceptability of the study and the personalized treatment more broadly at first, narrowing to a focus on specific questions of interest (e.g., experience with second stage randomization, patient treatment values and preferences, desire for more collaborative approaches to treatment planning, patient-identified points of confusion understanding capitalization vs compensation approaches). The outlines of the clinician and patient interview guides, with the primary topic areas and questions, are included in the Data Collection section. These guides will be refined as interviews continue, in response to participant feedback (e.g., clarifying questions participants find confusing, including questions to collect more information on topics that previous participants have raised). The process of iteratively refining interview questions in response to participant feedback is a common and necessary practice in qualitative research, as participants provide researchers with new insights they had not previously considered. Modifications to the interview guide (e.g., including questions about a completely new topic) will be submitted to the UK IRB for review. Interviews, averaging 30 minutes, will use established procedures described in detail by Gilchrist (1992), and will be audio-recorded and transcribed. At the conclusion of the study, two focus groups, lasting 1 hour each, with clinicians (4-6 clinicians each) and two focus groups with patients (4-6 patients each) will be used as a form of “member checking” to both validate through triangulation the researchers’ interpretations of the information obtained from the semi-structured interviews and to identify through expansion any additional information or insights as to clinician and patient perspectives on the study and treatment. Predetermined probes will be used to keep the discussion on track, following a funnel structure beginning with broader researcher-driven issues and narrowing to more participant-driven illustrations of the issues (Morgan, 1988).

Attachments

Attach Type	File Name
ResearchProcedures	Clinician Participant Recruitment Email Template.docx

ResearchProcedures	Gevedon LOS.pdf
ResearchProcedures	UP Adherence Rating Forms (1).doc
ResearchProcedures	Phone Screen Script.docx
ResearchProcedures	Phone Screen_4_30_20.docx

Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.
- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

Data collection will be accomplished via phone screening questions, diagnostic interview, and self-report questionnaires attached below. Through these measures we will collect data regarding participants' experiences with psychological symptoms, life functioning, and interpersonal interactions throughout the study.

The measures will be administered to patients according to the following schedule:
Assessment Visits:
DIAMOND
Demographic form (A1 only)
OASIS
ODSIS
UCLA Loneliness-3
DASS
WSAS-CR
Q-LES-Q
MEAQ
PANAS
BES
SMQ
ASI
PAI-BOR
NEO-FFI
EPQR-S
IIP-BPD
NEO-PI-R-N
CBTSQ-BA
Hope Scale
Medication list (Assessment Visit 1 only)
Concurrent Treatment Form (Assessment Visits 2, 3, and 4 only)
Feedback Form (post-Assessment Visit 3 only)
URICA (Assessment Visit 1 only)
Decision-making self-efficacy scale (Assessment Visit 1 only)
Initial Treatment Preferences Questionnaire (Assessment Visit 1 only)
C-SSRS - Full measure
HAM-A
HAM-D
CSQ-8 (Assessment Visit 3 only)
Patient Post-Treatment Feedback Form (Assessment Visit 3 only)

Pre-Session (Weekly):
OASIS
ODSIS
UCLA Loneliness-3
MEAQ
PANAS
BES
SMQ
CBTSQ-BA
MEAQ-BA
ASI
Self-perception of Skill Use
C-SSRS items 1-6
UP-CSQ

Post-Session (Weekly):

WAI-SR
CEQ (post-1st session only)

The following measures will be administered to clinicians according to the following schedule:

During initial visit (after informed consent):
EBPAS
Motivation to Learn Scale
Therapist Demographics

After the didactic workshop:
Post workshop provider feedback
Therapist Knowledge Acquisition quiz

After each patient has completed treatment:
CGI

After all study patients on the clinician's caseload completes their last session:
Provider feedback form

Qualitative Interviews for:
Patient Participants
Clinician Participants

Because focus groups for Patient Participants and Clinician Participants will occur 9-12 months after the conclusion of treatment, and because the questions involved in these focus groups will be based, in part, on the information gleaned from the post-study qualitative interviews, focus group questions are not available at this time. This is standard practice in qualitative research, and before beginning any focus group activities, we will submit the proposed questions to the IRB for approval via a Modification Request to ensure these questions respect participant safety and privacy. Given that these focus groups will include multiple Clinician Participants, we will include language clearly specifying that participants should not discuss information about patients that would constitute PHI.

Attachments

Attach Type	File Name
DataCollection	Semi-structured qualitative interview guide 9.24.21 patient.docx
DataCollection	Semi-structured qualitative interview guide 9.24.21 clinician.docx
DataCollection	ColumbiaForPsychiatryStudy.docx
DataCollection	CBTSQ-BA.docx
DataCollection	CEQ.docx
DataCollection	DASS-21 - Depression Anxiety Stress Scale - 21 item.docx
DataCollection	Evidence-based Practice Attitude Scale (EBPAS).docx
DataCollection	Hope Scale.docx
DataCollection	MEAQ- Multidimensional Experiental Avoidance Questionnaire.docx
DataCollection	PAI-BOR.docx
DataCollection	UCLA Loneliness-3.docx
DataCollection	WAI-SR Client Version.docx
DataCollection	DecisionSelfEfficacy_Personali.pdf
DataCollection	URICA_PersonalizationAtUKPsych (1).pdf
DataCollection	InitialTreatmentPreferencesQue.pdf
DataCollection	HAM-A.doc
DataCollection	CSQ8_PersonalizationAtUKPsychi.pdf
DataCollection	CGI.pdf
DataCollection	UP-CSQ.pdf
DataCollection	PatientPostTxFeedbackForm_Pers (1).pdf
DataCollection	HAM-D.doc
DataCollection	Post-Treatment Therapist Feedback Form_Tracked.docx
DataCollection	Post-Treatment Therapist Feedback Form_Clean.docx
DataCollection	A1 Medication list.docx
DataCollection	3 Concurrent Treatment Form.docx
DataCollection	ASI.pdf
DataCollection	EPQR-S- Eysenck Personality Questionnaire Revised- Short-Form.pdf
DataCollection	IIP-BPD.pdf
DataCollection	NEO-FFI.pdf
DataCollection	NEO-PI-R-N - Neuroticism and facets.pdf
DataCollection	OASIS-Overall Anxiety Severity and Impairment Scale.pdf
DataCollection	ODSIS- Overall Depression Severity and Impairment Scale.pdf
DataCollection	PANAS - Positive and Negative Affect Schedule.pdf

DataCollection	Q-LES-Q - Quality of Life and Enjoyment and Satisfaction Questionnaire.pdf
DataCollection	SMQ - Southampton Mindfulness Questionnaire.pdf
DataCollection	TIPS DIAMOND.pdf
DataCollection	WSAS-CR.pdf
DataCollection	BES - Beliefs about Emotions Scale.pdf
DataCollection	Post-workshop provider feedback.docx
DataCollection	Therapist Demographics Form.docx
DataCollection	Motivation to Learn Scale-2.doc
DataCollection	Therapist Knowledge Acquisition.docx
DataCollection	Self-perceptions of skills use.pdf
DataCollection	Demographics_TreatmentPersonal.pdf

Resources

Describe the availability of the resources and adequacy of the facilities that you will use to perform the research. Such resources may include:

- Staffing and personnel, in terms of availability, number, expertise, and experience;
- Computer or other technological resources, mobile or otherwise, required or created during the conduct of the research;
- Psychological, social, or medical services, including equipment needed to protect subjects, medical monitoring, ancillary care, or counseling or social support services that may be required because of research participation;
- Resources for communication with subjects, such as language translation/interpretation services.

Personnel: The PI is a licensed clinical psychologist with 15 years of clinical experience providing evidence-based care to individuals with anxiety, depressive, and related disorders. The PI is also a co-developer of treatment provided in this study and has ample experience training others in its provision. The PI's team currently includes one post-doctoral scholar with a PhD in clinical psychology and 6 years of experience providing evidence-based therapy and several doctoral students in clinical psychology. These individuals will, under the PI's supervision, conduct assessments and support the clinician participants who will be receiving training in the study intervention. The team also includes several undergraduate research assistants to conduct phone screens (under supervision) and complete day-to-day study management tasks. The Co-PI, located at Suffolk University, is a licensed clinical psychologist with over 10 years of experience conducting qualitative interviews with participants providing and/or receiving psychotherapy treatment. The Co-PI will assume a leading role in administering the qualitative interviews and focus groups. The Co-PI's team currently includes two doctoral students in clinical psychology at Suffolk University. These students will, under the PI and Co-PI's supervision, conduct qualitative interviews and focus groups with clinician and patient participants after receiving training from the Co-PI in the administration of qualitative interviewing techniques.

Facilities: This study will take place through UK Psychiatry. As noted in the letter of support from Dr. Gevedon, the medical director of the Adult Outpatient Service, our team will be provided with space and/or UK HealthCare Zoom access, to facilitate the conduct of this project. The PI also has dedicated technology resources (computers, study iPad) to facilitate the use of our online data management service, licensed by UK (REDCap). Additionally, the PI has several audio-recording devices to tape therapy sessions.

Potential Risks & Benefits

Risks

- Describe any potential risks – including physical, psychological, social, legal, ability to re-identify subjects, or other risks. Assess the seriousness and likelihood of each risk.
- Which risks may affect a subject's willingness to participate in the study?
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

Benefits

- Describe potential direct benefits to study participants – including diagnostic or therapeutic, physical, psychological or emotional, learning benefits. This cannot include incentives or payments.
- State if there are no direct benefits.
- Describe potential benefits to society and/or general knowledge to be gained.

Describe why potential benefits are reasonable in relation to potential risks. If applicable, justify why risks to vulnerable subjects are reasonable to potential benefits.

The primary risk in the current study is termination of treatment before symptom remission is achieved for those in the Brief condition. Participants will be informed about this risk on the phone screen and at Assessment Visit 1. It is important to note, however, that the average number of sessions community patients typically attend is 5, which suggests that this risk may be no greater than what is experienced in usual care. Additionally, a large proportion of symptom improvement occurs within the first 5 sessions of treatment (Fennell & Teasdale, 1987; Lutz, Stulz, & Köck, 2009), further mitigating this risk. Finally, in the event that participants in the Brief treatment are at an imminent risk of harm to themselves or others at their final session, they will be brought to the attention of the PI to

develop a safety plan with the participant which may include referrals to other psychotherapy resources or hospitalization.

Participants may experience some interference with daily activities due to scheduling of sessions. Additionally, some patients may find answering the questionnaires uncomfortable because of the sensitive nature of some of the questions (e.g., asking about symptoms of anxiety). In any of the modules the primary risk is the evocation of uncomfortable levels of anxiety or other emotions during the sessions. Some patients may find sessions stressful and react to them with anxiety. However, it is not expected that anxiety will be higher than would be experienced in real life situations or in the course of usual and customary clinical treatment. Participants will be informed about these risks and told that they may withdraw from the study at any time and may refuse to complete any procedures they find too uncomfortable.

There is also risk of a breach of confidentiality. Every precaution will be taken to protect participant's confidentiality. Paper data will be stored in locked cabinets and electronic data will be stored in password protected files. Additionally, each participant will be assigned a unique study ID number and this number will appear on all of his or her assessments. Information linking the study ID to the participant will be housed separately from the data. Participants who choose to engage in remote sessions will use secure electronic communications (e.g., phone calls or Zoom via the UK HealthCare portal). Despite all of these precautions, a breach of confidentiality remains a risk inherent in the research. Participants will be informed of this risk, as well as the measures in place to avoid such a breach, in the informed consent form.

The primary risk for clinician participants is the the time burden associated with the study (i.e., filling out questionnaires, attending consultation calls and the training workshop). Every effort has been made to minimize the number of questionnaires that clinicians are asked to complete. Although the training workshop and consultation calls are time-consuming, clinicians may benefit/enjoy these educational experiences.
Study participants may directly benefit from the skills that they learn from treatment. These skills (i.e. mindfulness, psycho-education, cognitive restructuring, and countering emotion-drive behaviors) have been shown to help reduce the symptoms of anxiety disorders. Therefore, it is possible that patients who take part in this study will obtain some relief from symptoms of anxiety and associated distress during the duration of this study. The risk of loss of confidentiality and mild emotional distress from filling out questionnaires and engaging in treatment are no more than patients would experience during routine care for emotional disorders. Additionally, this study will allow us to increase our knowledge of how to increase treatment efficiency by systematically exploring different methods of treatment-delivery based on a patient's presentation (i.e., focusing on strengths or weaknesses). Clinician participants may benefit from training in cutting edge advances in the provision of cognitive behavioral therapy that may enhance their practices.

Available Alternative Opportunities/Treatments

Describe alternative treatments or opportunities that might be available to those who choose not to participate in the study, and which offer the subject equal or greater advantages. If applicable, this should include a discussion of the current standard of care treatment(s).

The treatment provided in our research study is very similar to the standard of care. If potential participants choose not to provide their informed consent, or if participants withdraw, they can continue to pursue care at UK Psychiatry.

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Records, Privacy, and Confidentiality

Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Specify who will have access to the data/specimens and why they need access.

Describe how data will be managed after the study is complete:

- If data/specimens will be maintained, specify whether identifiers will be removed from the maintained information/material.
- If identifiers will not be removed, provide justification for retaining them and describe how you will protect confidentiality.
- If the data/specimens will be destroyed, verify that this will not violate retention policies and will adhere to applicable facility requirements.

If this study will use de-identified data from another source, describe what measures will be taken to ensure that subject identifiers are not given to the investigator.

If applicable, describe procedures for sharing data/specimens with collaborators not affiliated with UK.

For additional considerations:
Return of Research Results or Incidental Research Findings
HIPAA policies
FERPA policies
Procedures for Transfer agreements
Information regarding multi-site studies
NIH Genomic Data Sharing (GDS) Policy
Digital Data

Data includes participants' self-reported questionnaire responses, clinician-rated interview responses, and audio tapes from sessions, assessments, qualitative interviews, and focus groups. This information is necessary to answer the proposed research questions and ensure fidelity to the treatment being delivered. Session recordings will be collected via HIPAA-compliant UK HealthCare's Zoom

software and stored directly on UK HealthCare's HIPAA-compliant cloud servers.

Please note: (1) no member of the study team (none of whom are part of the covered entity) would access study subjects' medical records through UK HealthCare, (2) no information obtained from patient subjects during the course of the research project would go back into their UK HealthCare medical records, and (3) no information from the interview or focus group activities conducted by Suffolk staff would go back into patient subjects' UK HealthCare medical records.
Physical data will be stored in locked cabinets and electronic data will be stored in password-protected databases online (via REDCap and downloaded onto local computers connected to and protected by the University of Kentucky network). All data will be de-identified and assigned a unique participant ID number. This number will appear on all study forms. The information linking this number to any identifying information will be stored in a separate file on a local computer hard-drive. Only study staff and UK institutional oversight (i.e., IRB personnel) will have access to identifying information or the information linking the ID number to the participant. Following completion of the study, the key linking participants identities to their data will be destroyed. Final online data will be downloaded from the REDCap server and saved to password-protected local computer hard drives; remaining data on the REDCap server will be deleted. De-identified (i.e., labeled with participant code) paper and electronic data will be maintained for at least six years after the study's closure or at least seven years after the last patient is seen (whichever comes first) through the National Institute of Mental Health Data Archive. Any publications based on this data will not include identifying information. Patients will be made aware of this information in the consent form.

Suffolk University-based study staff will access electronic data via remote access to the authorized UK servers. Suffolk staff have received LinkBlue IDs and been authorized by UK, UK IT, and the PI to access this information for the purposes of this study. These study staff members will complete all interviews remotely via the UK HealthCare Zoom portal and save the recordings of these interviews directly onto the authorized UK server using their LinkBlue access.

Focus groups present and inherent limitation to confidentiality in that we cannot control what participants say about the focus groups after the fact. Study staff will clearly state this at the start of the focus group and remind participants during the group. We have also included language about this limitation in the informed consent form that all participants will review before engaging in any study procedures.
The following procedures will be used to minimize risks for participants:

1. Study exclusion criteria precludes any patients who are currently experiencing imminent suicidal risk. In addition, the study will also exclude individuals who might require more immediate and/ or intensive treatment for more severe clinical difficulties.

2. Although unlikely, risk issues may arise over the course of study participation. The PI (a licensed clinical psychologist with nearly 15 years working with high risk patients) will conduct regular, weekly meetings with research staff and clinician participants. At these meetings, any concerns regarding patient safety will be fully discussed, and the PI will intervene as clinically indicated.

3. Moreover, any patient showing significant deterioration or developing active suicidal potential as judged clinically by the clinician, the PI, and the director of outpatient services at UK Psychiatry will be removed from the study and will be referred for immediate and intensive clinical intervention. The PI will review any adverse events that occur during the course of the study.

4. The clinician participants in this study, who will be providing care to the study patients, are licensed mental health professionals. The study assessors (graduate students and post-docs) and well-trained and experienced, and will be working under the direct supervision of the PI.

5. For participants engaged in remote sessions, they will only be contacted via secure electronic means (e.g., telephone or Zoom via the UK HealthCare portal).

6. Post-treatment qualitative interviews will be conducted through the UK HealthCare HIPAA-compliant Zoom portal. This is to ensure recordings of interviews can be saved directly to UK-controlled servers with password protection.

7. During post-treatment focus groups with patient participants, we will remind them of the limits of confidentiality in that we cannot control whether other participants share information from the focus groups. We will also ask that all participants respect the privacy and confidentiality of focus group members. We will make it clear that, because we are not accessing patients' medical records, no information obtained through the interview or focus group activities will be entered into patients' UK HealthCare medical records.

8. During post-treatment focus groups with clinician participants, we will specifically ask them not to share patient PHI so as to protect the privacy and confidentiality of patient participants. We will remind clinician participants about this request throughout the focus groups.

9. As in any clinical research program, participant (patients and clinicians) confidentiality will be carefully guarded and respected. All data with identifying information will be stored in locked files and all other data will be identified with subject identification codes (see Confidentiality section below for full procedures).

10. Finally, all participants (patients & clinicians) will be clearly informed of their right to withdraw from the study at any point.

☑ **UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Check this item to confirm that you will retain all IRB-related records for a minimum of 6 years after study closure.**

Payment

Describe the incentives (monetary or other) being offered to subjects for their participation. If monetary compensation is offered, indicate the amount and describe the terms and schedule of payment. Please review this guidance for more information on payments to subjects, including restrictions and expectations.

Patient participants will be compensated $25 for completing Assessment Visits 2, 3, and 4. They will also receive their therapy sessions at no cost.

Clinician participants will have a percentage of their effort covered by study funds in order to ensure they have adequate time to complete study procedures.

Costs to Subjects

Describe any research costs which participants may be responsible for if they participate in the study (e.g., urine, HIV test).

There are no costs to participating in this research.

Data and Safety Monitoring

The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research or NIH-funded/FDA-regulated clinical investigations.

- If you are conducting greater than minimal risk research, or your clinical investigation is NIH-funded, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.
- If this is a non-sponsored investigator-initiated protocol considered greater than minimal risk research, and if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

Data will be collected and entered continuously throughout the project. There are no plans for independent data and safety monitoring. The PI will be responsible for managing unanticipated problems, adverse events, and data quality. All cases seen in this study will be supervised by the PI, which will allow for continuous monitoring of adverse events or clinical worsening.

No PHI will be shared with NIH. NIH's Data Archive system will read, but not store, the following PHI: patients' first name, middle name, last name, their birthdate, and birth city. NIH will assign a unique code to this combination of values for each patient but will not store patients' data to ensure the data is de-identified. After the completion of the study, study staff will remove this information from locally-stored files.

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Future Use and Sharing of Material (e.g., Data/Specimens/Information)

If the material collected for this study will be used by members of the research team or shared with other researchers for future studies, please address the following:

- list the biological specimens and/or information that will be kept
- briefly describe the types, categories and/or purposes of the future research
- describe any risks of the additional use
- describe privacy/confidentiality protections that will be put into place
- describe the period of time specimens/information may be used
- describe procedures for sharing specimens/information with secondary researchers
- describe the process for, and limitations to, withdrawal of specimens/data

We will remove identifying information from all datasets upon the close of this study. Selected self-report data is currently being shared in a de-identified format with NIMH through their Data Archive system on a regular basis in accordance with the funding mandate of this project. Future researchers may examine questions using the self-report data in this study and, after consultation with the primary investigators, will have access to a de-identified dataset as needed. Audio/video recordings of participants will continue to be stored and maintained only on UK servers and access will be limited to researchers approved by the IRB. The self-report and audio/video data may be accessible for 6 years or more. The biggest risk of additional use is breaches of confidentiality, although we believe the procedures we have laid out will mitigate this risk as much as is reasonable.

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short form use for incidentally encountered non-English subjects)

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.
When recruiting Non-English-speaking subjects, provide a consent document in the subject's primary language. After saving this section, attach both the English and translated consent documents in the "Informed Consent" section.

Cultural and Language Consultants:

The PI is required to identify someone who is willing to serve as the cultural consultant to the IRB.

- This person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted.
- The consultant should not be involved with the study or have any interest in its IRB approval.
- Please include the name, address, telephone number, and email of the person who agrees to be the cultural consultant for your study.
- ORI staff will facilitate the review process with your consultant. Please do not ask them to review your protocol separately.

For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

Local Requirements:

If you will conduct research at an international location, identify and describe:

- relevant local regulations
- data privacy regulations
- applicable laws
- ethics review requirements for human subject protection

Please provide links or sources where possible. If the project has been or will be reviewed by a local ethics review board, attach a copy in the "Additional Information/Materials" section. You may also consult the current edition of the International Compilation of Human Research Standards

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?

○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [PDF], and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the investigator assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [PDF], IDE regulatory requirements for SR device trials [PDF], and abbreviated regulatory requirements for NSR device trials [PDF]. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe the experience/knowledge/training (if any) of the investigator serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if any sponsor obligations have been transferred to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?

○ Yes ○ No

If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.

Attachments

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ◉ Yes ○ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

I have attached a HIPAA Waiver of Authorization. ○ Yes ◉ No

Attachments

STUDY DRUG INFORMATION

0 unresolved comment(s)

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?

○ Yes ◉ No

If yes, complete the questions below. Additional study drug guidance.

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize Investigational Drug Service (IDS) pharmacies (Oncology or Non-Oncology). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ○ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐	Held By:		
Investigator: ☐	Held By:		
Other: ☐	Held By:		

☐ Checkmark if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND) or if this is an Individual Patient Expanded Access IND (FDA Form 3926).

FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs, and attach the following:

- FDA Form 3926;
- FDA expanded access approval or correspondence;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Expanded Access SOP.

Complete and attach the required Study Drug Form picking "Study Drug Form" for the document type. Any

applicable drug documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.) should be attached using "Other Drug Documentation" for the document type.

Attachments

STUDY DEVICE INFORMATION

0 unresolved comment(s)

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

○ Yes ◉ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer "no" above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE) or Compassionate Use?

○ Yes ○ No

If Yes, complete the following:
IDE or HDE #(s)

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment IDE or Compassionate Use under the Food and Drug Administration (FDA) Expanded Access program.

For Individual or Small Group Expanded Access, see FDA's Early Expanded Access Program Information, and attach the following:

- FDA expanded access approval or sponsor's authorization;
- An independent assessment from an uninvolved physician, if available;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Medical Device SOP.

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition of Significant Risk (SR) device?

- Yes. Device(s) being tested in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- No. All devices being tested in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Complete and attach the required Study Device Form, picking the "Study Device Form" for the document type. Any applicable device documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.) should be attached using "Other Device Documentation" for the document type.

Attachments

RESEARCH SITES

0 unresolved comment(s)

To complete this section, ensure the responses are accurate then click "SAVE".

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☑ UK Classroom(s)/Lab(s)
- ☑ UK Clinics in Lexington
- ☐ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☐ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky (UK) or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page), including:

- A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.
- Supportive documentation, including letters of support, can be attached below.
- NOTE: If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK sites.

- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

List all other non-UK owned/operated locations where the research will be conducted:

Suffolk University

Describe the role of any non-UK site(s) or non-UK personnel who will be participating in your research.

Please describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites:

Attachments

Attach Type	File Name
-IRB Authorization Agreement	59307 Sauer-Zavala UK - IRB auth agreement with Suffolk as secondary _fully executed.pdf
-IRB Authorization Agreement	UK Communications Plan Form UK reviews.docx
-IRB Authorization Agreement	UK Relying Site Form when UK Reviews.pdf

B) If your research involves collaboration with any sites and/or personnel outside the University of Kentucky, then it is considered multisite research and IRB reliance issues will need to be addressed. This may include national multi-center trials as well local studies involving sites/personnel external to UK. If you would like to request that the University of Kentucky IRB (UK IRB) serve as the lead IRB for your study, or if you would like the UK IRB to defer review to another IRB, please contact the IRBReliance@uky.edu.

RESEARCH ATTRIBUTES

0 unresolved comment(s)

Instructions: For various reasons, it is necessary to determine whether your research activities meet the definition of clinical research and/or a clinical trial. Your responses to the next series of questions will make that determination. For more details on the definitions, go to ORI's clinical research vs. clinical trial web page or visit NIH's decision tree for the NIH Clinical Trial definition.

My research activities include one or more of the following:

Patient-oriented research regarding mechanisms of human disease, therapeutic interventions, clinical studies, or development of new technologies
◉ Yes ○ No

Material of human origin (such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects
◉ Yes ○ No

Epidemiologic or Behavioral Studies
◉ Yes ○ No

Outcomes Research or Health Services Research
◉ Yes ○ No

Does your research involve one or more human subjects prospectively assigned into one or more health-related biomedical or behavioral interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes?
◉ Yes ○ No

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

☐ Academic Degree/Required Research
☐ Alcohol/Drug/Substance Abuse Research
☐ Biological Specimen Bank Creation (for sharing)
☐ Cancer Research
☑ CCTS-Center for Clinical & Translational Science
☐ Certificate of Confidentiality
☐ Collection of Biological Specimens for banking and use
☐ Community-Based Participatory Research
☐ Deception
☐ Educational/Student Records (e.g., GPA, test scores)
☐ Emergency Use (Single Patient)
☐ Gene Transfer
☐ Genetic Research
☐ NIH Genomic Data Sharing (GDS) (databases such as GWAS, dbGaP, GenBank)
☐ Treatment with Human Cells, Tissues, and Cellular and Tissue Based Products
☐ Individual Expanded Access or Compassionate Use
☐ International Research
☐ Planned Emergency Research Involving Exception from

For additional requirements and information:

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality (look up "Confidentiality/Privacy...")
- CCTS (Center for Clinical and Translational Science)
- Clinical Research (look up "What is the definition of....)
- Clinical Trial
- Collection of Biological Specimens for Banking (look up "Specimen/Tissue Collection...")
- Collection of Biological Specimens (look up "Specimen/Tissue Collection...")
- Community-Based Participatory Research (look up "Community-Engaged...")
- Data & Safety Monitoring Board (DSMB)

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

  *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
- Genetic Research (look up "Specimen/Tissue

Informed Consent

- ☐ Recombinant DNA
- ☐ Registry or data repository creation
- ☐ Stem Cell Research
- ☐ Suicide Ideation or Behavior Research
- ☑ Survey Research
- ☐ Transplants
- ☐ Use, storage and disposal of radioactive material and radiation producing devices
- ☐ Vaccine Trials

Collection...")

- Gene Transfer
- HIV/AIDS Research (look up "Reportable Diseases/Conditions")
- Screening for Reportable Diseases [E2.0000] (PDF)
- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Waiver of Informed Consent*

*For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Use, storage and disposal of radioactive material and radiation producing devices

FUNDING/SUPPORT

0 unresolved comment(s)

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☐ Not applicable

Check All That Apply

- ☑ Grant application pending
- ☑ (HHS) Dept. of Health & Human Services
  - ☑ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Click applicable listing(s) for additional requirements and information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info]
- National Science Foundation
- (DoEd) U.S. Department of Education
- (DoJ) Department of Justice or Bureau of Prisons
- (DoE) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist
- (EPA) Environmental Protection Agency

Other:

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

Received Just in Time notification from NIMH

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.
If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP and DoD Summary for details)

○ Yes ◉ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

Assurance/Certification Attachments

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

○ Yes ◉ No

Additional Information

- ☐ Institutional Biosafety Committee
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- Institutional Biosafety Committee (IBC) - Attach required IBC materials
- Radiation Safety Committee (RSC) - For applicability, see instructions and attach form
- Radioactive Drug Research Committee (RDRC)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)** - Attach MCC PRMC materials, if any, per instructions.
- Office of Medical Education (OME)
- Graduate Medical Education Committee (GME)

Attachments

**** If your study involves cancer research, be sure to select "Cancer Research" in the "Research Attributes" section.** ORI will send your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRMC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

Do you want specific information inserted into your approval letter? ○ Yes ◉ No

Approval Letter Details:

If you wish to have specific language included in your approval letter (e.g., serial #, internal tracking identifier, etc…), type that language in the box below exactly as it should appear in the letter. The text you enter will automatically appear at the top of all approval letters, identical to how you typed it, until you update it. Don't include instructions or questions to ORI staff as those will appear in your approval letter. **If these details need to be changed for any reason, you are responsible for updating the content of this field.**

Additional Materials:

If you have other materials you would like to include for the IRB's consideration, check all that apply and attach the corresponding documents using the Attachments button below.

- ☐ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☑ Other Documents

Protocol/Other Attachments

Attach Type	File Name
Other	PHI for NIH Data Archive.docx

NOTE: [Instructions for Dept. of Health & Human Services (DHHS)-approved protocol]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

To view the materials currently attached to your application, click “All Attachments” on the left menu bar.

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

Introduction

All IRB applications require additional assurances by a Department Chairperson or equivalent (DA), and when applicable, a Faculty Advisor or equivalent (FA). This signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. The person assigned as DA *should not* also be listed in the Study Personnel section, and the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, refer to "What does the Department Chairperson's Assurance Statement on the IRB application mean?"

For a detailed illustration of how to complete this section, please review the short online video tutorial "Signatures (Assurance) Section - How to Complete." Otherwise, follow the steps below.

Required Signatures:

Individuals chosen as signees may remove the application from their Inbox without signing the Assurance Statement by clicking "Return to PI" with a comment about why it is being returned (e.g., specific edits are deemed necessary).

The PI, and personnel chosen as a contact, will receive an email notification that edits are needed, and can find the draft application in both the "Draft" folder and the "Signatures Needed" folder located in the menu in the left margin of the default Inbox page. The researcher does not have a 'reply' option to the signee's comments and must make the requested edits directly in the application, or communicate outside the E-IRB system as to why not. Once the response is finalized, the researcher must re-visit the "Assurances Required" section to click the "Return to Signee" button for their re-consideration; the signee will receive an email notification at that time.

Hover your mouse cursor here for additional instructions.

First Name	Last Name	Role	Department	Signee Return Comment	Date Signed	
Gregory	Smith	Department Authorization	Psychology		05/01/2020 09:10 AM	View/Sign
Shannon	Sauer-Zavala	Principal Investigator	Psychology		04/30/2020 11:37 PM	View/Sign

Department Authorization

☑ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator has been notified of the additional regulatory requirements of the sponsor and by signing the principal investigator Assurance Statement, confirms he/she can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

**IF APPLICABLE FOR RELIANCE: I attest that the principal investigator has been notified of the regulatory requirements of both the Reviewing and Relying IRBs, according to the information provided in the E-IRB application. The attached Reliance Assurance Statement, signed by the principal investigator, confirms that he/she can comply with both sets of IRB requirements.

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☑ Furthermore, by checking this box, I also attest that:

- I have appropriate facilities and resources for conducting the study;
- I am aware of and take full responsibility for the accuracy of all materials submitted to the IRB for review;
- If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the categories specified in the Protocol Type: Exemption Categories section.
- If applying for an Abbreviated Application (AA) to rely on an external IRB, I understand that certain items above (1, 3, 4, 7-8) may not apply, or may be altered due to external institutional/IRB policies. I document my agreement with the Principal Investigator Reliance Assurance Statement by digitally signing this application.

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Please notify the personnel required for signing your IRB application after sending for signatures. Once all signatures have been recorded, you will need to return to this section to submit your application to ORI.

SUBMISSION INFORMATION

0 unresolved comment(s)

***** If this Continuation Review entails a change in the scope of your activities to include COVID-19 related research, please insert "COVID19" at the start of your Project and Short Titles.*****

Each Section/Subsection in the menu on the left must have a checkmark beside it (except this Submission section) indicating the Section/Subsection has been completed. Otherwise your submission for IRB review and approval cannot be sent to the Office of Research Integrity/IRB.

If applicable, remember to update the Approval Letter Details text box under the Additional Information section

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and you will receive a message to notify you of the date.

If you are making a change to an attachment, you need to delete the attachment, upload a highlighted version that contains the changes (use Document Type of "Highlighted Changes"), and a version that contains the changes without any highlights (use the appropriate Document Type for the item(s)). Do **not** delete approved attachments that are still in use.

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects, and I attest to:

1. Having reviewed all the investigational data from this study, including a compilation of all internal and external unanticipated problems.
2. Having reviewed, if applicable, information from the sponsor including updated investigator brochures and data and safety monitoring board reports.

I also attest that I have reviewed pertinent materials concerning the research and concluded either:

A. The human subject risk/benefit relationship is NOT altered, and that it is not necessary to modify the protocol or the informed consent process,
OR,
B. The human subject risk/benefit relationship has been altered, and have previously submitted or am including with this continuation review submission, a modification of the research protocol and informed consent process.

☑ By checking this box, I am providing assurances for the applicable items listed above.

Your protocol has been submitted.

Statistical Design and Power

Statistical Design

Study Feasibility. Clinician and patient enrollment, a measure of feasibility of a large RCT, will be assessed by reporting percentages for the 6 clinician and 5 patient enrollment variables. Rates of treatment and assessment completion will also be reported. Clinician adherence will be evaluated by coding 20% of treatment sessions according to a UP adherence checklist and reporting adherence rates within each condition.

Study and Treatment Acceptability. Quantitative measures of study and treatment acceptability (e.g., the AFQ, Clinician and Patient Versions) will be assessed through the use of descriptive statistics. Qualitative analyses of clinician and patient perceptions of study and treatment protocols will be analyzed in conjunction with quantitative results (e.g., QUAL + QUAN[121, 122]). Qualitative analysts will review interview recordings and transcriptions, identifying and coding the primary issues raised by respondents using a grounded theory[123], embedded in Willms, et al.'s[124] guidelines for coding: reaching consensus on coding assignment, identifying concordance among codes, and using the process of constant comparisons to generate a taxonomy of themes and identify their relationships to one another. This will have analysts: 1) review all transcripts to develop a broad understanding of the content and document initial impressions of topics and themes, defining the boundaries of specific codes[125], 2) independently code empirical material to condense data into analyzable units and form a codebook, 3) discuss disagreements in code assignment/description (each test will be reviewed by at least two analysts), 4) compare reliability of assigning the same codes to identical text segments[126], and 5) use the computer program *NVivo* to examine the association between different a priori and emergent categories.

Pilot Test of Personalization Aims (ordering and discontinuation). In addition to our primary aim of establishing the feasibility/acceptability of our personalization strategies and study design, we seek to determine whether a preliminary signal exists to support the notion that personalized sequencing and target-informed discontinuation can enhance treatment efficiency. First, to explore whether personalized sequencing leads to more efficient improvements in the core process addressed by the UP, we will use hierarchical linear mixed modeling (HLMM) to compare the average rate of change in clinical outcomes among the three UP sequencing conditions (UPS, UPP-CA, and UPP-CO). The primary outcome measure for aim is the distress aversion subscale from the MEAQ (MEAQ-DA), which has previously been used to demonstrate target engagement with the UP (see Preliminary Studies). Additionally, to examine whether core process engagement can serve as an early indicator of treatment response, prompting discontinuation, we will assess variability in MEAQ-DA levels at the second stage randomization (S5 assessment), along with the degree to which any patients randomized to discontinue demonstrate additional symptom improvement (using HAM-A ratings) in the absence of treatment such that they are responders by the W20 assessment. We will also explore whether patterns exist between S5 MEAQ-DA scores and responder status for those that discontinued after session 6.

Power Analyses.

This proposal is designed as a pilot trial to, as noted in the RFA, collect relevant data to inform the design (and increase the likelihood of obtaining meaningful results) in a subsequent well-powered trial. To do this, we are measuring potential mechanisms of change and exploring preliminary effect sizes and the variability of treatment effects. This will allow us (and future reviewers) to determine whether further testing is warranted.

IRB Approval
4/9/2021
IRB # 59307
NMED

KEY INFORMATION FOR TRANSDIAGNOSTIC TREATMENT PERSONALIZATION:

We are asking you to choose whether or not to volunteer for a research study about whether personalized delivery of psychological treatment results in faster symptom improvement. We are asking you because you recently sought treatment at UK Psychiatry and indicated an interest in being contacted by research studies for which you may be eligible. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

In this study, we hope to learn whether teaching cognitive-behavioral skills in a personalized order (based on your responses to brief intake questionnaires) leads to faster improvements in emotional distress, compared to a standard order. Participating in this research will involve completing an Assessment (visit 1) today to determine if you are eligible for this study (this visit is not compensated), completing 6 or 12 weekly therapy sessions (50-60 min each), as well as two follow-up assessments (1 hr each) and a post-study qualitative interview (30 min). You will also have the opportunity to participate in a 1-hr focus group 9-12 months after today. We anticipate that your participation will last approximately 9-12 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The greatest benefit to participating in this research is that volunteers will receive high quality, evidence-based treatment at no cost. Additionally, volunteers will be compensated for completing follow-up assessments. For a complete description of benefits and/or rewards, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Participation in this study involves answering interview and self-report questions. Some people may be uncomfortable disclosing information about their emotional health or find these procedures time- consuming and boring. For a complete description of risks, refer to the Detailed Consent.

AUDIOTAPING

We would like to audiotape you during this study. If you are audiotaped, we will take several steps to protect your confidentiality. We will store electronic session recordings on a password-protected secure server maintained by UK so only approved study staff will be able to access the recordings. We will label these recordings with a code instead of your name. The key to the code connects your name to your recording. The researcher will keep the key to the code in a password-protected computer. Your therapist will refrain from identifying you by name on the audio-recording and we request that you also do not refer to yourself by name. All recordings will be stored for seven years after the completion of the study.

Do you agree to let us audiotape you during this study? _____YES _____NO _____INITIALS

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Shannon Sauer-Zavala, PhD of the University of Kentucky, Department of Psychology at ssz@uky.edu.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

We will conduct a detailed assessment at the start of this study to ensure that the treatment skills taught in this study are a good fit for your difficulties. Participation in this study requires that volunteers are currently diagnosed with an emotional disorder (e.g., panic disorder, social anxiety disorder, generalized anxiety disorder, obsessive-compulsive disorder, depressive disorder); if you do not have an emotional disorder, you will be excluded. Additionally, people with conditions (i.e., substance use disorders, recent mania) that are better addressed with a different treatment will be excluded. We will also exclude individuals who are under 18 years of age. People seeking talk therapy from other counselors outside of UK Psychiatry will also be excluded. Participants taking medication for emotional difficulties will be allowed to participate as long as they are willing to inform their therapist or a member of the research team of any medication changes over the course of the study.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

This study will take place in-person at UK Psychiatry, located at 245 Fountain Court, Lexington, Ky, and/or via remote meetings that take place over the phone or videoconference software. These remote meetings will primarily be with clinicians located at UK Psychiatry or study staff located on UK's main campus. However, two remote meetings (the qualitative interview at month 9-10 and the optional focus group at month 9-12) will be conducted by study staff located at Suffolk University. You will be asked to complete 10-16 study visits throughout your participation, either in-person or remotely. The first visit is today and will last approximately 2 hours; if you sign this consent form, we will conduct an assessment to determine if you are eligible to participate in this study. If you do not qualify, you will be withdrawn. If you are eligible, you will then be asked to complete either 6 or 12 weekly therapy sessions, each lasting 1 hour. Next, we will ask you to complete three more assessments: one after the 5th therapy session (1 hr), one approximately 4 months after your 1st therapy session (1.5 hrs), and one approximately 9-10 months following your first therapy session (1 hr). We will also ask you complete weekly online questionnaires (max. 30 minutes in duration) for the first 12 weeks of the study. Finally, you will be contacted to determine your interest in participating in an optional 1-hr focus group 9-12 months after your first therapy session. The total amount of time you will be asked to volunteer for this study is up to 24.5 hours over the next 9-12 months.

WHAT WILL YOU BE ASKED TO DO?

Assessment Visit 1

Assessment Visit 1 (today) will take about two hours to complete. During this meeting, we will first ask you to review and sign this consent form. Then we will conduct an interview-based assessment in order to determine if you qualify to participate; we will also ask you to fill out a number of self-report questionnaires on an iPad or via a link we can email to you. If you prefer, we can also provide paper and pencil versions of these questionnaires. The interview and questionnaires will ask you about anxiety, depression, how you are currently coping with these difficulties (e.g., avoiding situations that are upsetting), including the effects of these experiences on your physical health/well-being. Your answers to the self-report questionnaires may be used determine the order of the treatment modules you receive.

After Assessment Visit 1, we will assign you by chance (like a coin toss) to one of three methods for ordering treatment modules: a standard order or one of two personalized orders. Neither you nor the researcher can choose your study group. You will have an **equal chance** of being assigned to these study groups.

Treatment Sessions (up to 12 visits)

After Assessment Visit 1, we will ask you to complete weekly treatment sessions with a UK Psychiatry clinician, each of which will last 60 minutes. After session 5, you be randomized to **either** discontinue treatment after session 6 **or** continue treatment until session 12. Your therapist will alert you to which condition you will be in at the start of session 6.

Assessment Visits 2-4

Assessment Visit 2 will be scheduled to occur between treatment sessions 5 and 6. Assessment Visit 3 will be scheduled to occur about 3-4 months after your first treatment session. Assessment Visit 4 will be scheduled to occur about 9-10 months after your first treatment session. All of these assessments will include a briefer interview than Assessment Visit 1 and the completion of self-report questionnaires.

Weekly Questionnaires

We will also ask you to fill out online questionnaires related to anxiety, depression, and treatment skills, which will take up to 30 minutes, each week while you are in the study (12 times). While you are receiving treatment, we will ask that these questionnaires are completed prior to your scheduled session; if you are unable to fill out the online questionnaires prior to your scheduled session, your appointment will be rescheduled to a time after you have completed the questionnaires. Additionally, we will ask you to complete 1-2 questionnaires (< 5 minutes each week) after each session (6 or 12 times).

Post-Study Interview

Immediately after your last therapy session or your 12th week in the study, you will be contacted to participate in a 30 min qualitative interview over the phone or via video conference. This interview will be conducted by independent study staff from Suffolk University, an IRB-approved affiliate site for this study. The interview will involve questions about your perspective on and experiences with the treatment provided. The interview will be video recorded and saved on a password-protected server at UK.

Post-Study Focus Group

Nine to twelve months after beginning the study, you will be contacted by study staff to ask if you are interested in participating in a 1-hour focus group organized around the feasibility, acceptability, and experiences with the treatment and study design. These focus groups will include 4-6 participants each and will be facilitated by independent study staff from Suffolk University. These focus groups will be video recorded so the information provided may be analyzed at a later date. All recordings will be saved directly on a password-protected server maintained by UK.

TELEHEALTH

Telehealth service is the delivery of healthcare when the therapist and patient are not in the same physical location/site through the use of various technology. There may be circumstances (e.g., public health crises like COVID-19) when UK Psychiatry will shift services to remote platforms. Although we anticipate that therapy visits will take place in face-to-face meetings, we want to ensure continuity of care by obtaining your permission to conduct study visits remotely now.

Information provided via Telehealth may be used for diagnosis, therapy, follow-up and/or education, and may include any combination of the following: (1) live two-way audio and video (i.e., videoconferencing) or (2) interactive audio (phone calls). Electronic systems used will incorporate network and software security protocols to protect the confidentiality of participant identification and data and to ensure its integrity against intentional or unintentional corruption. It is important that you understand, acknowledge and agree to the following statements:

- I understand that I have undertaken to engage in a telehealth encounter for myself that will contain personal identifying information as well as protected health information, as well as audio and/or video recordings of sessions. I understand that the study therapist/assessor will be at a different location from me.
- I voluntarily consent to healthcare services provided which may include review of diagnostic assessments, therapy sessions, and consultation on recommendations considered necessary for treatment.
- I understand that I have the right to withhold or withdraw my consent to the use of telehealth services at any time in the course of my participation in this study.
- I understand and accept the potential risks associated with telehealth, such as failure of security protocols that may cause a breach of privacy of personal and/or medical information.
- I understand that the laws that protect privacy and the confidentiality of medical information also apply to telehealth, and that no information obtained in the use of telehealth which identifies me will be disclosed to other entities without my consent or as may be allowed by law.

Based on this information, are you willing to conduct study visits using Telehealth platforms?

_____YES _____NO _____INITIALS

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The primary risk is the possibility that you will not have attained full symptom relief at the end of treatment, whichever condition you are randomized to. You may feel emotional or upset when answering some of the questions included in the interviews/questionnaires. Tell the clinician at any time if you want to take a break or stop filling out the questionnaires. You may also be uncomfortable with some of the topics we will ask about. You do not have to answer any questions that make you feel uncomfortable.

The main risk of allowing us to use and store your information (i.e., responses to interview questions/questionnaires, session recordings, interview/focus group recordings) is a potential loss of privacy. We will protect your privacy by labeling your information with a code and keeping the key to the code in a password-protected computer, making it difficult to connect your responses with your identity.

Finally, because we cannot control what participants in a focus group say after the conclusion of the group, we cannot guarantee the confidentiality of information you share in the focus group. Although we will ask all participants to respect each other's privacy and confidentiality after the conclusion of the group, this remains a risk.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, each treatment skill provided in this study are supported by research in their own right; thus, it is possible that participating in this study may provide some relief from any emotional difficulties you are experiencing. Additionally, if you take part in this study, information learned may help others.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, you will still be able to receive regular clinical services at UK Psychiatry.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

Every effort will be made to keep your records confidential. We will keep the records of this study confidential by storing all physical (i.e., pencil and paper) data in locked cabinets. Any electronic questionnaire data will be collected through REDCap. REDCap is a secure, web- based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. Study recordings of sessions will be made using UK HealthCare's HIPAA-compliant Zoom portal. We cannot guarantee the security of data obtained by way of the Internet. Access to all data is restricted. However, any third-party applications (i.e., REDCap, Zoom) used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky. After data is collected, it will be stored on a UK server space dedicated to this study. UK server space access is regulated by the Researcher in combination with UK IT. Only the principal investigator (PI) and study staff will be able to access your data. Anyone who is not on the research team will thus not be able to access any of your data. Members of the research team will also be instructed not to confirm or deny your participation in the research if asked. As an additional security measure, your data will be labeled with an ID number, and the key linking your ID number to your name will be kept in separate locked file cabinets, and destroyed following study completion. Data will be stored for seven years following the conclusion of the study.

There are times, however, when federal or state law requires the disclosure of your records.

Reporting child/elder abuse: If, during your participation in this study, we have reasonable cause to believe that child/elder abuse is occurring, we must report this to authorities as required by law. The researcher will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court might demand the release of identifiable research information.

Reporting suicidal risk: If, during your participation of this study, we have reason to believe that you are at risk if attempting suicide or otherwise harming yourself, we are required to take the necessary actions. This may include notifying your doctor, or other individuals. If this were to occur, we would not able to assure confidentiality.

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

You should know that in some cases we may have to show your information to other people for purposes such as quality control or safety. For example, the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, if you report information about a child being abused; or if you pose a danger to yourself or someone else
- the Researcher and any member of her research team
- the Institutional Review Board at the University of Kentucky and Suffolk University. The Institutional Review Board is a group of people who review human research studies for safety and protection of people who take part in the studies.
- federal and state agencies that oversee or review research.

To ensure the study is conducted properly, officials of the University of Kentucky may look at or copy pertinent portions of records that identify you.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study that involves a cognitive behavior therapy intervention. It is important to let the investigator know if you are in another research study. You should discuss this with the investigator before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Shannon Sauer-Zavala at 859-218-4082 immediately. If you experience an emergency during participation in this study, please call 911 immediately.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm:

- will be your responsibility; ***or***
- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); ***or***
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You may receive up to $75 for taking part in this study. We will compensate you $25 for completing Study Assessment 2, $25 for completing Study Assessment 3, and $25 for completing Study Assessment 4.

With a few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

You may be given feedback about the results from your tests or surveys done for purposes of this research. Specifically, the research team will provide you with information about any clinical diagnoses you are assigned following Study Assessment 1.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to no more than 3 times per year.

Do you give your permission to be contacted in the future by Dr. Shannon Sauer-Zavala regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many National Institute of Mental Health (NIMH) studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about mental health and substance use more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about mental health and substance use and how to help others who have problems with mental health and substance use. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the

study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Your name
- Your birthdate
- Your phone number
- Your email address
- Any psychiatric diagnoses for which you meet criteria

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- National Institute of Health (NIH);
- Center for Clinical and Translational Science (CCTS); and
- IRB-Approved study personnel at the University of Kentucky
- IRB-approved study personnel at Suffolk University.

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information may still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans; or
- Eligibility for benefits.

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- Send a written letter to: Dr. Shannon Sauer-Zavala at 106A Kastle Hall, 171 Funkhouser Dr., Lexington, KY 40508 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

Signature of research subject *or, if applicable, *research subject's legal representative*	**Date**
Printed name of research subject	
Printed name of [authorized] person obtaining informed consent and HIPAA authorization	Date