Study Protocol and Informed Consent Form
Official Study Title: Guided group telehealth to deliver evidence-based therapeutic care to Black college students
NCT Number:
Date of Document: 01/31/2025

PRAIRIE VIEW A&M UNIVERSITY
A Member of the Texas A&M University System

To: **Anne Lippert, Ph.D.,** Principal Investigator

From: **Dennis Daniels, Ph.D.**
IRB Chair

Date: January 31, 2025

Re: IRB Protocol #2024-044
Guided Group Telehealth to Deliver Evidence-Based Therapeutic Care to Black College Students

The amendment to your IRB Protocol submitted on January 16, 2025 has been approved. Please continue to only use the consent tools with the "PVAMU Approved" stamp.

Any future correspondence regarding this study should reference the Protocol Title and Number.

Dennis Daniels, Ph.D.
IRB Chair
Email: dedaniels@pvamu.edu

PLEASE NOTE: As the principal investigator of this study, you assume the following responsibilities:

- ***Record Retention:*** Records must be retained for at least 3 years after study completion.
- ***Amendments:*** Changes to research study activities may not be initiated without IRB approval.
- ***Unanticipated Problems/Adverse events:*** Any unanticipated problems/adverse events must be reported to the IRB immediately.
- ***Informed Consent/Assent:*** If applicable, all subjects must be given a copy of the consent/assent document approved by the IRB (see attached).
- ***Completion:*** Once the study is complete, you must complete the IRB-Completion-Report-Form.pdf (pvamu.edu) and submit it to the Office of Research Compliance at researchcompliance@pvamu.edu.

Office of Research, Innovation & Sponsored Programs
P.O. Box 519, Mail Stop 2800 Prairie View, Texas 77446
Phone (936) 261-1553 Fax (936) 261-3529

Received 1/16/2025

PRAIRIE VIEW A&M UNIVERSITY
A Member of the Texas A&M University System

January 16th, 2025

To: Institutional Review Board (IRB) Committee
From: Dr. Anne Lippert
Subject: Request for Amendment to Approved Study – Additional Question
Study Title: Guided group telehealth to deliver evidence-based therapeutic care to Black college students
IRB Protocol Number: 2024-044

Dear Members of the IRB Committee,

We are writing to request an amendment to our approved study protocol to add an additional question to assess suicidality. If students are suicidal, we want to eliminate them from the study, provide access to resources for them, and alert student counseling services. We have attached 1. Our approved IRB protocol with a revised procedure on pg 8 of the protocol itself, indicating the suicidal risk assessment question, and the suicide risk assessment question itself on the bottom of page 18. 2. The sections we changed as individual documents so you do not need to search for the changes in the IRB protocol itself. We appreciate your time and effort in reviewing this amendment and are happy to provide any additional information or clarification as needed.

Anne M. Lippert
Assistant Professor,
Department of Psychology
Prairie View A&M University

PROCEDURES

What will participants be asked to do? (Describe the study in detail from recruitment to completion)
If you need additional space, put "see attached" in the box below and attach complete description of procedures.

Participants will access the study via an online link provided by email or via word of mouth. They will first answer a question to assess their suicide risk. If they have not had suicidal thoughts in the previous three weeks, they will continue on to the study. If they indicate they have had such thoughts in the prior three weeks, they will be disqualified from the study and a screen will appear with contact information regarding mental health resources. Dr. Lippert will then reach out to Student Counseling Services and ask them to reach out to the students to follow-up and provide additional support. For those students who continue with the study, they will take the PHQ-9 and the GAD-7 to measure their depression and anxiety levels. If they score 5 or above on either test they will be invited to participate in the therapy part of the study. In this part of the study the participant will be assigned to either receive individual teletherapy or group teletherapy for 12 weeks. This therapy takes place via text. Participants may be asked to read psychoeducational materials and complete homework assignments. Participants assigned to the individual therapy, will receive support in the form of direct asynchronous communication with the therapist. Participants assigned to the group therapy will receive support in the form of direct asynchronous communication with the therapist and asynchronous communication with peers struggling with similar issues. Throughout the at week 4, 8 and12 of therapy, participants will take the GAD-7, PHQ-9, and self-report questionnaires to measure their engagement and experience.

Describe the location where research activities will take place:

The research will take place on participants personal electronic devices by logging on to the web-based TheraGroup platform.TheraGroup is aproprietary real-time virtual based platform that provides text based group therapy. It is is a cloud software that offers HIPAA compliant asynchronous text chat.

How long will the participants be engaged in research? (*length of time, i.e. 15 minutes on day 1, etc.*):

up to 12 weeks

During data collection, describe what steps will be taken to ensure participant privacy:

Due to the longitudinal design of this project, collecting identifiable data is necessary. Specifically, participants' names and contact information are needed to match participant information at different time points and to contact participants about distributing their gift card compensation. In order to preserve participant confidentiality and minimize the potential harm of participant information being identified, participants' will be prompted to create an identification number comprised of the first two letters of their last name combined with the last four digits of their phone number (e.g., Jane

Is the research anonymous or confidential? (***Cannot be both***)

- ☐ **Anonymous**: The identity of the participant cannot be readily determined by the investigator AND the identity of the participant is not connected to information gathered.
- ☑ **Confidential**: Research participants can be identified; however, information gathered will be protected.

Provisions for anonymity/confidentiality:

- ☑ Secure storage (**required**)
- ☐ Replies coded

What specific steps will be followed to ensure anonymity or confidentiality of participants' responses?

The participant ID and identifying information (name-code-index) as described above will be stored on a password protected spreadsheet. Only Dr. Lippert and her team will have the ability to de-identify participants. Disclosure of data via research dissemination methods such as presentations at conferences and in study related publications will not contain identifying information. In addition, for the group therapy, participants use a name they make up for the purpose of the group only to ensure they remain anonymous. The therapy contains no face to face modalities. It all occurs via text based communication.

Participants will access the study via an online link provided by email or via word of mouth. After providing basic demographic and their email address (to receive payment), they will then answer a question to assess their suicide risk. If they have not had suicidal thoughts in the previous three weeks, they will continue on to the study. If they indicate they have had such thoughts in the prior three weeks, they will be disqualified from the study and a screen will appear with contact information regarding mental health resources (see attached survey measures). Dr. Lippert will then explain the situation to Student Counseling Services and provide the student's contact information (email address) to them. Student Counseling Services will then make contact with the student and carry out protocols they have in place to help suicidal students. For those students who continue with the study, they will take the PHQ-9 and the GAD-7 to measure their depression and anxiety levels. If they score 5 or above on either test they will be invited to participate in the therapy part of the study. In this part of the study the participant will be assigned to either receive individual teletherapy or group teletherapy for 12 weeks. This therapy takes place via text. Participants may be asked to read psychoeducational materials and complete homework assignments. Participants assigned to the individual therapy, will receive support in the form of direct asynchronous communication with the therapist. Participants assigned to the group therapy will receive support in the form of direct asynchronous communication with the therapist and asynchronous communication with peers struggling with similar issues. Throughout the at week 4, 8 and12 of therapy, participants will take the GAD-7, PHQ-9, and self-report questionnaires to measure their engagement and experience.

5. It was boring to use the telehealth therapy services
6. I felt frustrated using the telehealth therapy services
7. I found the telehealth services confusing
8. I felt unmotivated to use the telehealth services

User Feedback Experience

1. What, if anything, did you enjoy about your experience in using the guided telehealth therapy?

2. What, if anything, could be improved about your experience in using the guided telehealth therapy?

3. Did you feel the psychoeducational content was culturally relevant to you as a Black individual? Please explain

Suicide Assessment

"In the past few weeks, have you been thinking about killing yourself?"

If participant answers "yes" show the following resources:

- **24/7 National Suicide Prevention Lifeline 1-800-273-TALK (8255) En Español: 1-888-628-9454**
- **24/7 Crisis Text Line: Text "HOME" to 741-741**
- **PVAMU Student Counseling Services: (936) 553-0990**
- **9-1-1**

PRAIRIE VIEW A&M UNIVERSITY
A Member of the Texas A&M University System

To: **Anne Lippert, Ph.D.,** Principal Investigator

From: **Dennis Daniels, Ph.D.**
IRB Chair

Date: October 28, 2024

Re: IRB Protocol #2024-044

The IRB protocol application submitted by you titled "Guided Group Telehealth to Deliver Evidence-Based Therapeutic Care to Black college students" has been deemed expedited and approved on October 28, 2024.

Any future correspondence regarding this study should reference the Protocol Title and Number. Please also make sure to use the consent forms with the "PVAMU Approved" Stamp.

Dennis Daniels, Ph.D.
IRB Chair
Office: 936-261-3070

PLEASE NOTE: As the principal investigator of this study, you assume the following responsibilities:

- ***Record Retention:*** Records must be retained for at least 3 years after study completion.
- ***Amendments:*** Changes to research study activities may not be initiated without IRB approval.
- ***Unanticipated Problems/Adverse events:*** Any unanticipated problems/adverse events must be reported to the IRB immediately.
- ***Informed Consent/Assent:*** If applicable, all subjects must be given a copy of the stamped consent/assent document approved by the IRB (see attached).
- ***Completion:*** Once the study is complete, you must complete the IRB-Completion-Report-Form.pdf (pvamu.edu) and submit it to the Office of Research Compliance at researchcompliance@pvamu.edu.

Office of Research, Innovation & Sponsored Programs
P.O. Box 519, Mail Stop 6000 Prairie View, Texas 77446
Phone (936) 261-1553 Fax (936) 261-3529

PRAIRIE VIEW A&M UNIVERSITY
A Member of the Texas A&M University System

IRB USE ONLY

Last Name Lippert
IRB# 2024-044

Prairie View A&M University

IRB Protocol Application

Received 7/8/2024

INSTRUCTIONS

1. Complete Training

PI, Co-Investigator and anyone interacting with potential participants must complete necessary training.
Refresher training must be completed every three years. More details can be found at: http://www.pvamu.edu/research/office-of-research-compliance/207-revision-v1/irb-training/

2. Complete Form

Form must be typed and free of typographical/grammatical errors.

3. Attach Documents to Application

- ☑ Recruitment materials as applicable: flyers, letters, scripts, e-mail, etc.
- ☑ Consent documentation as applicable: consent protocol, consent form or assent form
- ☑ Survey and/or Interview Questions
- ☑ Funding Proposals (as applicable)
- ☑ Any other documents referenced in this application as applicable

4. Submit Application

Submit the complete IRB protocol (application and required documentation) to the Office of Research and Compliance, Wilhelmina Delco Building, Room #163 in person or by email at research@pvamu.edu.
Review of proposal will not begin until the **complete protocol** is received.

Warning: The following is considered protocol non-compliance:

a.) personnel beginning research with human subjects before being added to the approved IRB protocol;
b.) proceeding with the protocol before obtaining final IRB approval;
c.) failing to follow the established criteria or procedures that were approved by the IRB;
d.) adding, removing or modifying a research instrument (or adding to an existing instrument) in a survey study without prior IRB approval unless the changes are within a range of anticipated potential changes specified as acceptable within the IRB approval; and
e.) implementing any change in the protocol without IRB approval is considered protocol non-compliance.

Non-compliance may result in a report being made to the funding agency listed on this protocol and/or the Office of Human Research Protections (OHRP). PVAMU's Federalwide Assurance (FWA) with OHRP is restricted to research funded by the Department of Health and Human Services. However, the same process for conducting investigations and taking actions by the IRB will apply to all research regardless of funding source. PVAMU reserves the right to voluntarily report any event that is not associated with federal funding to OHRP.

If you have any questions or need assistance completing this application, please call Crysta Mendes (936) 261-1553, or e-mail research@pvamu.edu

INVESTIGATOR INFORMATION

Principal Investigator Name: Anne Lippert

☑ Faculty ☐ Staff ☐ Graduate Student* ☐ Undergraduate Student*

Department: Psychology College: Arts and Sciences

Mailing Address (if not PVAMU):

Phone: (936) 261-5267 Fax: E-mail: amlippert@pvamu.edu

Co - Investigator Name:

☐ Faculty ☐ Staff ☐ Graduate Student* ☐ Undergraduate Student*

Department: College:

Mailing Address (if not PVAMU):

Phone: Fax: E-mail:

Please list additional investigators (if applicable):

***For Students: Answer the following and list your faculty advisor**

Is this study part of your Thesis or Dissertation? ☐ Yes ☐ No

If Yes, do you have approval from your Thesis/Dissertation Committee? ☐ Yes ☐ No

Graduate Committee Chair/Faculty Advisor Name:

Department: College:

Mailing Address (if not PVAMU):

Phone: Fax: E-mail:

Project Title: Guided group telehealth to deliver evidence-based therapeutic care to Black college students

Anticipated Start and End Dates: 8/2024-8/2028

Funding Status: ☐ Externally Funded* ☑ Grant Application* ☐ Internally Funded* ☐ Not Funded

☐ Other

Funding Agency (if applicable): NIH

Must include a draft of the grant application. Once grant is completed/submitted, a final draft must be submitted to the IRB.

Does this protocol require approval from multiple IRBs? ☐ Yes, please state below ☑ No, only from PVAMU IRB

PURPOSE OF STUDY

Provide a **brief** statement, in lay terminology, outlining the purposes of this study. The following issues must be addressed:

a. Why are you doing this research project and what do you propose to learn?
b. What is the justification for doing the study? Include, as appropriate, preliminary data and/or references to previous research, or gaps in our knowledge.

If you need more space, put "see attached" in the box and attach your complete purpose of study statement. Please title the attachment.

The current mental health crisis across college campuses particularly impacts students at Historically Black Colleges and Universities (HBCUs), who, compared to their Predominantly White Institution (PWI) counterparts, have fewer resources and less funding to support student psychological health [1]. While online therapy offers benefits, it does not solve the issue that the number of available therapists is insufficient to treat the number of students seeking help [2]. A promising solution is to increase opportunities for group therapy, which is equivalent to individual therapy in terms of outcomes [3]. As such, the purpose of our study is to assess the impact of an online, group text based therapy (one mental health counselor to many students) against a one-to-one (one mental health counselor to one student) therapy among HBCU students. Specifically, we will compare a HIPPA compliant, guided group telehealth (GGT) therapy (group therapy) called TheraGroup against a HIPPA compliant individual telehealth (IT) therapy (individual therapy) on measures of engagement, user experience, and mental health outcomes. If outcome measures in the GGT group are in line with outcome measures in the IT group, the feasibility study will serve as a precursor to testing the effects

RISKS AND BENEFITS

Describe any potential risks or discomforts to the participant (including physical, psychological and/or social):
Risks to subjects are rated as "Low", "Medium", "High". ***Do not say "none".***

participants may be at risk of psychological harm. As the survey measures and therapy intervention ask participants to explore their mental health, specifically difficulties they may be having and traumatic events they have previously experienced, this process may exacerbate pre-existing mental health

Describe any potential benefits to the research participant or society:

Participants in this study will benefit from receiving mental health treatment from qualified professionals. Identifying effective group telehealth therapies to increase the access to mental health interventions contributes not only to the expansion of scientific knowledge within the field of mental health, but also to practical applications. Based on the findings of this study, interventions, trainings, and supports can be developed to treat mental illness in Black college students. This has potential

Describe alternatives to participation/opportunity to withdraw:

Participants may withdraw at any time

SUBJECT RECRUITMENT

Number of participants (target population): 8000 Ages of Participants: 18 years or older

Gender of subjects: ☑ Male ☑ Female

Maximum anticipated sample size: 200

What are the selection criteria for participation (i.e. include target population and maximum anticipated sample size)?
For clarification on target population and maximum anticipated sample size, please refer to FAQ #35 on the PVAMU IRB website.

Participants must be Black college students attending Prairie View A&M University (PVAMU) who are at least 18 years of age, and who qualify for psychological clinical intervention based on their current levels of depression and anxiety.

Do the criteria for selection exclude individuals based on gender, culture, language, economic status or ethnicity?

☑ Yes ☑ No

If yes, please justify exclusion:

We are excluding non-Black individuals. The telehealth program we are testing is tailored for the Black population and thus we would like to test it on a matching sample.

Are there any special physical or psychological conditions of subjects? (If so, please describe.)

Participants who score a 5 or more on the GAD-7 (anxiety) or the PHQ-9 (depression) will qualify for the therapeutic intervention aspect of the study. These scores represent at least a minimal level of anxiety and depression.

Source of participants:

☑ PVAMU students (provide explanation below) ☐ Community (provide explanation below)

☐ Schools* (provide explanation below) ☐ Other (provide explanation below)

Participants will be Black college students attending PVAMU

For studies involving schools:
Does the study involve a school district? ☐ Yes ☑ No

If Yes, which school district(s)?: _____

Note: <u>If the study involves a school district</u>, approval must be obtained from the school district.

Vulnerable Populations:

☑ Not applicable

☐ Children

☐ Pregnant women

☐ Prisoners

☐ Adults who lack ability to consent

☐ Employees

☐ Other, describe: _____

If vulnerable populations will be used, please describe additional safeguards to protect their rights and welfare:

N/A

Recruitment Method **(all flyers, advertisements, etc. are subject to IRB review):**

- ☐ Telephone solicitation (attach script)
- ☐ Radio (attach script)
- ☐ Television (attach script)
- ☐ Newspaper advertising (attach ad copy)
- ☐ Posted notices (attach copy)
- ☐ Letter (attach copy)
- ☑ E-mail (attach copy of text to be sent for recruitment)
- ☑ Direct person-to-person contact, describe: We will inform the student counseling center about the study and provide referral information
- ☐ Other, describe: _____

How will initial contact be made with potential participants? (*be specific*)

Participants will initially be made aware via an email sent to all PVAMU students. For students attending the mental health services at PVAMU, a mental health professional may tell them about the study.

Other than as an Investigator, do you have any other relationship with participants? (*i.e. doctor-patient, teacher-student, counselor-student, etc.*) ☑ Yes ☐ No

If Yes, explain the relationship and describe how you will avoid any type of coercion:

It is possible the PI may be a professor of some of the participants. However, no direct contact regarding the study will be made in this relationship capacity and she will not be recruiting participants directly through her courses.

CONSENT

LOCATION

Describe the setting where the consent process will take place (*i.e. classroom, office, park, personal computer, etc.*):

If the consent is in person, this will take place in Dr. Lippert's office, rm 219 Don Clark Hall, where Dr. Lippert will provide a paper version of the consent form that students will sign with a pen. If the consent will take place online via an electronic device such as a phone or computer, participants will receive the consent form via docusign. Through docusign they can sign electronically to indicate their consent.

PERSONNEL

Name individuals or group of individuals who will be speaking directly to potential participants during the consent process:

Dr. Lippert will be available to participants to answer any questions as they read through the consent form. Her contact information is available on the consent form.

CONSENT TOOLS

Please check all that apply and attach to the application:

- ☐ Cover Letter
- ☑ Adult Consent Form
- ☐ Information Sheet
- ☐ Minor Assent Form
- ☐ Telephone Script
- ☐ Parental Consent Form

Location where consent forms will be filed:
(***Consent forms must be kept on file for 3 years after completion of the study and data analysis***)

All data and forms including consent forms will be kept on a password protected computer in Dr. Lipperts office in Don Clark Hall, rm 219

WAIVER

Request for waiver of informed consent or waiver of documentation of informed consent:

☐ Yes ☑ No

If Yes, explain below:

COMPENSATION / COURSE CREDIT

Will monetary compensation be given to the participant?

☑ Yes ☐ No

If Yes, explain below and attach a detailed compensation of payment including amount and schedule of payments to participant:

Participants will receive payment in the form of Amazon gift cards. Our study has 4 time points in which participants may be compensated for their time. These time points are listed below along with the amount participants receive for taking part in each time point.

Time Compensation
Time 1: before therapy started $5
Time 2: 4 weeks after therapy has started $50
Time 3: 8 weeks after therapy has started $100

Will course credit be given to the participant as compensation?

☐ Yes ☑ No

If Yes, provide details below and alternate assignment to obtain equal credit:

SUBJECT MATTER

Check the appropriate box(es) concerning the subject matter of the research:

- ☐ No sensitive matters
- ☐ Abortion
- ☐ AIDS/HIV
- ☐ Alcohol
- ☐ Body composition
- ☐ Criminal activity
- ☑ Depression
- ☐ Drugs
- ☐ Learning disability
- ☐ Physical disability
- ☐ Psychological inventory
- ☐ Review of criminal records
- ☐ Review of educational records
- ☐ Sexual Activity
- ☐ Suicide
- ☑ Other, specify: general mental health issues

DECEPTION OR COERCION

Will deception or coercion be used?

☐ Yes ☑ No

If Yes, **attach debriefing form** and briefly describe deception:

PROCEDURES

What will participants be asked to do? (Describe the study in detail from recruitment to completion)
If you need additional space, put "see attached" in the box below and attach complete description of procedures.

Participants will access the study via an online link provided by email or via word of mouth. Next, they will take the PHQ-9 and the GAD-7 to measure their depression and anxiety levels. If they score 5 or above on either test they will be invited to participate in the therapy part of the study. In this part of the study the participant will be assigned to either receive individual teletherapy or group teletherapy for 12 weeks. This therapy takes place via text. Participants may be asked to read psychoeducational materials and complete homework assignments. Participants assigned to the individual therapy, will receive support in the form of direct asynchronous communication with the therapist. Participants assigned to the group therapy will receive support in the form of direct asynchronous communication with the therapist and asynchronous communication with peers struggling with similar issues. Throughout the at week 4, 8 and12 of therapy, participants will take the GAD-7, PHQ-9, and self-report questionnaires to measure their engagement and experience.

Describe the location where research activities will take place:

The research will take place on participants personal electronic devices by logging on to the web-based TheraGroup platform.TheraGroup is aproprietary real-time virtual based platform that provides text based group therapy. It is is a cloud software that offers HIPAA compliant asynchronous text chat.

How long will the participants be engaged in research? (*length of time, i.e. 15 minutes on day 1, etc.*):

up to 12 weeks

During data collection, describe what steps will be taken to ensure participant privacy:

Due to the longitudinal design of this project, collecting identifiable data is necessary. Specifically, participants' names and contact information are needed to match participant information at different time points and to contact participants about distributing their gift card compensation. In order to preserve participant confidentiality and minimize the potential harm of participant information being identified, participants' will be prompted to create an identification number comprised of the first two letters of their last name combined with the last four digits of their phone number (e.g., Jane

Is the research anonymous or confidential? (***Cannot be both***)

- ☐ **Anonymous**: The identity of the participant cannot be readily determined by the investigator AND the identity of the participant is not connected to information gathered.
- ☑ **Confidential**: Research participants can be identified; however, information gathered will be protected.

Provisions for anonymity/confidentiality:

- ☑ Secure storage (**required**)
- ☐ Replies coded

What specific steps will be followed to ensure anonymity or confidentiality of participants' responses?

The participant ID and identifying information (name-code-index) as described above will be stored on a password protected spreadsheet. Only Dr. Lippert and her team will have the ability to de-identify participants. Disclosure of data via research dissemination methods such as presentations at conferences and in study related publications will not contain identifying information. In addition, for the group therapy, participants use a name they make up for the purpose of the group only to ensure they remain anonymous. The therapy contains no face to face modalities. It all occurs via text based communication.

DATA COLLECTION

Research Type:

- ☐ Qualitative
- ☐ Quantitative
- ☑ Both

Will any new data or documents be collected? (*i.e. public records, survey instruments, evaluation tools, etc.)*

☑ Yes ☐ No

If Yes, describe what data or documents will be used and how they will be obtained:

Data will include the following: 1. Behavioral data (events that occur in the system due to students interacting with the system; e.g., time spent logged on) 2. Self-report data (measures of engagement, user experience surveys, the PHQ and GAD7 scores). Participant data will be collected via the TheraGroup systems backend in the form of log data (Behavioral Data) or through Qualtrics (Depression and Anxiety scores, measures of engagement, user experience surveys).

Will recordings be made?

☐ Yes ☑ No

If Yes:

- ☐ Video Taping
- ☐ Audio Taping
- ☐ Mandatory Recording
- ☐ Voluntary Recording

Is the use of recordings detailed in the consent form?

☐ Yes ☐ No

Will recordings be retained?

☐ Yes ☐ No

If Yes, how long will records be retained before they are destroyed/erased?

Will any new specimens be collected? (*i.e. blood tissue, etc.)*

☐ Yes ☑ No

If Yes, describe what specimens will be used and how they will be obtained:

Does the experiment involve the use of human fluid, tissue and/or blood?

☐ Yes ☑ No

Will any invasive or sensitive procedures be done?

☐ Yes ☑ No

If Yes, check all that apply:

- ☐ Blood Samples
- ☐ Physical Measurements (electrodes, etc)
- ☐ rDNA
- ☐ Stress Exercise
- ☐ Urine Samples
- ☐ Other, specify:_____

DOCUMENT RETENTION

Federal regulations require that human research documents be retained for a minimum of three years AFTER the completion of the study AND data analysis. Some disciplines or granting agencies require longer retention times.

Length of time retained after completion of study and data analysis:

At least three years

Person responsible for data retention (*If you are a student, please list faculty mentor) & data storage location:*

All data will be kept on a password protected computer in Dr. Lippert's office in Rm 219 in Don Clark Hall.

OTHER COMPLIANCE ISSUES

If the study involves the use of **animals, infectious biohazards (e.g. blood), and/or recombinant DNA**, it is required that approval be granted for the use of such through the appropriate compliance committee.

SIGNATURE ASSURANCES

PRINCIPAL INVESTIGATOR

I understand Prairie View A&M University's procedures concerning research involving human subjects and **by initialing** below, I certify:

AL I have read The Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" and subscribe to the principles it contains.

AL I accept responsibility for the scientific and ethical conduct of this research study.

AL I will obtain prior approval from the Institutional Review Board (IRB) before amending or altering the research protocol or implementing changes in the approved consent form and/or information sheet.

AL I will immediately report to the IRB any unanticipated effects on subjects which may occur as a result of this study.

AL I will retain the consent forms and other research documents in a locked/secure manner for a minimum of three years. Students must turn over all documents to the primary faculty advisor upon completion of the study in most cases.

AL I will complete, on request by the IRB, the Continuation/Final Review forms.

AL I do not have a personal/financial conflict of interest and I have submitted my Financial Conflict of Interest Disclosure Statement in Maestro (if applicable).
(If you have a conflict of interest, you must specify - as an attachment - the conflict of interest and describe what safeguards are in place to ensure that the conflict of interest does not affect the experimental results.)

AL I have reviewed all forms and documents being submitted.

Principal Investigator Signature: _____

Typed Name: Anne Lippert Date: 6/26/2024

FACULTY / RESEARCH ADVISOR

I certify that I have read and agree with this proposal, that the Principal Investigator has received adequate training to perform this research, and will receive adequate supervision while performing this research:

_____ By initialing, I certify that I do not have a personal/financial conflict of interest and I have submitted my Financial Conflict of Interest Disclosure Statement in Maestro (if applicable).
(If you have a conflict of interest, you must specify - as an attachment - the conflict of interest and describe what safeguards are in place to ensure that the conflict of interest does not affect the experimental results.)

Faculty/Research Advisor Signature: _____

Typed Name: _____ Date: _____

CO-INVESTIGATOR or PERSONNEL

(If needed, print additional copies for studies with more than one Co-Investigator or Personnel)

I understand Prairie View A&M University's procedures concerning research involving human subjects and **by initialing** below, I certify:

_____I have read The Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" and subscribe to the principles it contains.

_____I accept responsibility for the scientific and ethical conduct of this research study.

_____I will obtain prior approval from the Institutional Review Board (IRB) before amending or altering the research protocol or implementing changes in the approved consent form and/or information sheet.

_____I will immediately report to the IRB any unanticipated effects on subjects which may occur as a result of this study.

_____I will retain the consent forms and other research documents in a locked/secure manner for a minimum of three years. Students must turn over all documents to the primary faculty advisor upon completion of the study in most cases.

_____I will complete, on request by the IRB, the Continuation/Final Review forms.

_____I do not have a personal/financial conflict of interest and I have submitted my Financial Conflict of Interest Disclosure Statement in Maestro (if applicable).
(If you have a conflict of interest, you must specify - as an attachment - the conflict of interest and describe what safeguards are in place to ensure that the conflict of interest does not affect the experimental results.)

_____I have reviewed all forms and documents being submitted.

Co-Investigator or Personnel Signature: _____

Typed Name: _____ Date: _____

FACULTY / RESEARCH ADVISOR

I certify that I have read and agree with this proposal, that the Principal Investigator has received adequate training to perform this research, and will receive adequate supervision while performing this research:

_____By initialing, I certify that I do not have a personal/financial conflict of interest and I have submitted my Financial Conflict of Interest Disclosure Statement in Maestro (if applicable).
(If you have a conflict of interest, you must specify - as an attachment - the conflict of interest and describe what safeguards are in place to ensure that the conflict of interest does not affect the experimental results.)

Faculty/Research Advisor Signature: _____

Typed Name: _____ Date: _____

TRAINING

(for office use only)

PRINCIPAL INVESTIGATOR

Lippert

IRB Member: ☐ YES ☒ NO Date: Expires: 10/28/2024

Social/Behavioral Research Course: ☒ YES ☐ NO Date:

IRB accepts Alternative Training: YES NO Date:

_____ ☐ YES ☐ NO Date: _____

CO-INVESTIGATOR or PERSONNEL *(if more than one Co-Investigator or Personnel, please write training completion dates on a separate page)*

IRB Member: ☐ YES ☐ NO Date: _____

Social/Behavioral Research Course: ☐ YES ☐ NO Date: _____

IRB accepts Alternative Training: ☐ YES ☐ NO Date: _____

_____ ☐ YES ☐ NO Date: _____

Training Reviewer: Synthea Horton Date: 7/9/2024

PROTOCOL APPROVAL

(for office use only)

☐ **EXEMPT**

Declared by: _____ Date: _____

☒ **EXPEDITED**

Approved - Reviewer 1: Dennis Daniels, Ph.D. Date: 10/28/2024

Approved - Reviewer 2: _____ Date: _____

☐ **FULL REVIEW**

Referred for Full Review: _____ Date: _____

Approved: _____ Date: _____

Date of Full Review (attach minutes): _____

TITLE OF STUDY: Guided group telehealth to deliver evidence-based therapeutic care to Black college students

PROTOCOL NUMBER:

DEAR STUDY PARTICIPANT:

You are invited to participate in a research study about the effectiveness of virtual group therapy in Black college students. You were selected as a possible participant because you are
We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by: Dr. Anne Lippert, Department of Psychology, Prairie View A&M University

Background Information

The purpose of this study is to investigate the impact of virtual group therapy on mental health in Black college students

Procedures:

If you agree to participate in this study, we will ask you to do the following things:
First you will access the study via an online link. Next, you will complete two mental health assessments. At this point you may be asked to continue on in the study. If you decide to do so you will receive either individual teletherapy or group teletherapy for 12 weeks. This therapy may take place via video, audio or text. You may be asked to read psychoeducational materials and complete homework assignments as part of the therapy. Throughout the 12 weeks you will be asked to report on your experiences and take mental health assessments.

Risks and Benefits of participating in the Study

By participating in this study, you may be at risk of psychological harm. As the study asks you to explore your mental health, specifically difficulties you may be having and traumatic events you have previously experienced, this process may exacerbate pre-existing mental health issues. However, we believe these risks are low to medium and no greater than those encountered in everyday life. In addition, you are free to withdraw from the study at any time.

Participants in this study will benefit from receiving mental health treatment from qualified mental health professionals. In addition, based on the findings of this study, interventions, trainings,

and supports can be developed to treat mental illness in Black college students. This has potential benefits for stakeholders, including college campuses and the communities they serve, by increasing the psychological alternatives and improving the health and well-being of students.

Compensation:

You will receive payment in the form of Amazon gift cards. There are four time points in our study during which you may receive payment: Prior to therapy ($5.00), then four weeks after therapy has begun ($50.00), eight weeks after therapy has begun ($100.00), and 12 weeks after therapy has begun ($150.00). The amazon gift cards will be sent to the email address you provided no later than two weeks after the corresponding time period.

Confidentiality:

The records of this study will be kept private. In all reports resulting from this study, we will not include any information that will make it possible to identify you as a participant. Research records will be stored securely and only researchers will have access to the records.

Voluntary Nature of the Study:

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with Prairie View A&M University. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contacts and Questions:
The researchers conducting this study are: Dr. Anne Lippert.
You may ask any questions you have now. If you have questions later, **you are encouraged** to contact the Principal Investigator at 219 Don Clark Hall, 936.261.5267, amlippert@pvamu.edu.

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), **you are encouraged** to contact the Office of Research Compliance at (researchcompliance@pvamu.edu) in the Office for Research and Innovation, P.O. Box 519; MS 2800 Prairie View, Texas 77446 Phone 936.261.1553.

You will be given a copy of this information to keep for your records.

Statement of Consent:

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature:_____ Date: _____

Signature of Investigator:_____ Date: _____

Subject: Opportunity to Participate in a Research Project

Dear PVAMU students,

My name is Dr. Anne Lippert and I am an Assistant Professor in the Psychology Department at PV. I am emailing you to invite you to be part of a research project about virtual group mental health therapy for Black college students. The purpose of the research is to determine how group telehealth therapy compares to individual telehealth therapy.

If you participate in this project, you will be asked to first complete two mental health assessments. You may then be asked to continue the study and take part in a 12-week virtual therapy program. During this 12-week period you will be asked to complete activities related to the therapy, take mental health assessments, and provide feedback on your experience.

If you participate in this study, you may be eligible to earn up to $305.00 in the form of an Amazon gift card over approximately 12 weeks of your time. Participation is voluntary, but I hope you will choose to be part of this project. *To participate in the study you must be a Black PVAMU college student of 18 years or older.*

For more information, or to sign up, go to [enter study website here] or contact me at amlippert@pvamu.edu.

Thanks,

Anne Lippert, PhD

PHQ-9

Over the last 2 weeks, how often have you been bothered by any of the following problems?

Scale: 0 = not at all; 1 = several days; 2 = more than half the days; 3 = nearly every day

1.Little interest or pleasure in doing things
2. Feeling down, depressed, or hopeless
3. Trouble falling or staying asleep, or sleeping too much
4. Feeling tired or having little energy
5. Poor appetite or overeating
6. Feeling bad about yourself or that you are a failure or have let yourself or your family down
7. Trouble concentrating on things, such as reading the newspaper or watching television
8. Moving or speaking so slowly that other people could have noticed. Or the opposite being so fidgety or restless that you have been moving around a lot more than usual
9. Thoughts that you would be better off dead, or of hurting yourself

GAD-7

Over the last two weeks, how often have you been bothered by the following problems?
Scale: 0 = not at all; 1 = several days; 2 = more than half the days; 3 = nearly every day

1. Feeling nervous, anxious, or on edge
2. Not being able to stop or control worrying
3. Worrying too much about different things
4. Trouble relaxing
5. Being so restless that it is hard to sit still
6. Becoming easily annoyed or irritable
7. Feeling afraid, as if something awful might happen

Engagement

On a scale from 1 to 5 with 1 being not at all to 5 being completely, rate how much the following statement applies to your experience with the telehealth therapy program:

1. I was interested in the therapy
2. I was intrigued when i used the telehealth therapy services
3. I was focused when I used the telehealth therapy services
4. I enjoyed using the telehealth therapy services

5. It was boring to use the telehealth therapy services
6. I felt frustrated using the telehealth therapy services
7. I found the telehealth services confusing
8. I felt unmotivated to use the telehealth services

User Feedback Experience

1. What, if anything, did you enjoy about your experience in using the guided telehealth therapy?

2. What, if anything, could be improved about your experience in using the guided telehealth therapy?

3. Did you feel the psychoeducational content was culturally relevant to you as a Black individual? Please explain