UNMUTE/NYU Culturally Affirming Racial Equity (CARE) Study

Research Informed Consent Form — PATIENT

PID _____

Title of Study:	Unmute's Culturally Affirming Racial Equity (CARE) framework: A Novel Approach to Strengthen the Therapeutic Alliance and Reduce Treatment Disparities with Racial/Ethnic Minority Patients Study #: IRB-FY2024-9189
Trials registration number	ClinicalTrials.gov Identifier: NCT06625502
Principal Investigators:	Dr. Doris F. Chang NYU Silver School of Social Work 1 Washington Square North Rm 206 New York, NY 10003 Colleen Leung Unmute Enterprises, Inc. 65 Breakwater Drive Chelsea, MA 02150
Emergency Contact:	Dr. Doris F. Chang (212) 998-5889 dfchang@nyu.edu
Funder	National Institutes of Mental Health

1. SUMMARY OF THE RESEARCH STUDY

You are invited to participate in a research study to learn more about how to improve mental health services for treatment-seeking Asian Americans. The Principal Investigators are Doris F. Chang, PhD (New York University) and Colleen Leung (Unmute). Dr. Chang is also a co-founder, equity holder, and the Chief Clinical Officer of Unmute. As part of the study, you are eligible to receive up to 15 sessions of teletherapy covered by your insurance or paid out of pocket. Your therapy will be guided by the Culturally Affirming Racial Equity (CARE) framework, which emphasizes therapist-patient collaboration and culturally-informed assessment to center the patient's experience. The goal is to improve the cultural fit of

treatment for diverse populations, even when the therapist may not share the same cultural background as the patient.

This study is focusing on English-speaking Asian Americans residing in New York State who are seeking short-term (up to 15 sessions) psychotherapy. Because of the short-term nature of the treatment, it may not be suitable for individuals who are struggling with more severe conditions that may be more effectively treated through longer-term or in-person modalities.

If you agree to be in this study and pursue treatment with one of our clinicians, you will be asked to do the following:

1. Attend a maximum of 15 sessions of individual teletherapy, typically on a weekly basis.
2. Complete online surveys about your experiences of working with your therapist and any changes in your presenting concerns. These surveys consist of 6 longer surveys (~10 min) administered at 4 week intervals and shorter surveys (2-3 min) after each session.
3. You give consent for your video recordings to be used for supervision and quality assurance purposes. At no time will your name be associated with these recordings. You may consent to allow your session videos to be retained for future research. Otherwise, we will delete the recordings at the end of treatment.
4. After treatment is complete, you will be given the option to engage in a semi-structured interview conducted online to share feedback about your experiences of treatment to improve the approach.

The risks associated with this study are comparable to the risks associated with psychotherapy in general. For example, it may be difficult or uncomfortable to talk about the things that bring you to therapy. It is also possible that you may not find the treatment or therapist to be helpful**,** in which case you may end your involvement in the study without penalty. There is a potential risk of loss of confidentiality; however, we have procedures in place to protect your confidentiality, as we will explain below.

The benefits which may reasonably be expected to result from this study are that you may experience improvement in your problem or symptoms as a result of the treatment and relationship with your therapist. Your participation also may inform the development of more culturally-responsive services for Asian Americans and other racial and ethnic minority groups.

Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. Your decision whether or not to participate in this study will not affect your eligibility to see a different therapist within your insurance network. Please read the rest of this consent form for more information about the study.

2. PURPOSE OF THE STUDY

The purpose of the Unmute CARE study is to test an approach to improving the cultural fit of treatment for diverse patients, even when the therapist does not share the same cultural background as the patient. The study examines how patients respond to the treatment approach and whether it improves the patient's experience and the effectiveness of short-term psychotherapy.

3. ELIGIBILITY TO PARTICIPATE

We are seeking prospective patients who meet the following criteria:

- 18+ years of age
- Identify as Asian or Asian American, comfortable receiving therapy in English
- Physically residing in New York and willing to meet therapist over video platform
- Interested in receiving brief (15-sessions) of treatment
- Has health insurance and willing to use it for mental health services OR is willing to pay out of pocket
- Willing to complete periodic brief assessments
- Consent to having their treatment videorecorded for clinician supervision and quality assurance purposes

Patients who have severe mental health symptoms requiring a higher level of care may not be eligible to participate in this study.

4. DESCRIPTION OF STUDY PROCEDURES

If you agree to participate in this study, you will be asked to complete the following activities. Any information that you provide will be kept confidential. Please note that the data that you provide through these various activities (surveys, group supervision, debriefing interviews, etc.) will be linked to each other, on the individual level, using your unique participant ID number. We will create a code number for you that will help us keep track of your participation in the different parts of the study. Your participation is voluntary. Your personal choices and decisions will be respected in every part of the project.

A. Baseline survey

We will ask you to complete a baseline survey. This will take 5-10 minutes to complete. In the survey, we will ask you for basic information such as your name, date of birth, address, contact information, race, ethnicity, gender, language, health insurance, education, and employment. We will also ask you questions about the reasons you are seeking therapy and the treatment goals that you have, your prior history of treatment, current symptoms such as depression and anxiety, how you are functioning in your daily life (e.g., work/school, relationships), and any health-related concerns.

B. Attend up to 15 sessions of teletherapy with a provider trained in evidence-based treatment approaches (such as cognitive-behavioral therapy) and our Culturally Affirming Racial Equity (CARE) framework and assessment protocol.

The treatment you will receive emphasizes therapist-patient collaboration and culturally-informed assessment to center *your* needs and experiences. After an initial assessment phase, when you will discuss your presenting concerns and other aspects of your life, you will work with your therapist to develop a customized treatment approach that takes into account your unique context and culture. You will continue to meet with your therapist (typically once/week) until you have completed the 15-week treatment. All sessions will take place over Zoom, a videoconferencing platform, and we will record these sessions for quality assurance and supervision purposes.

C. Post-Session Questionnaires

After each session, you will be sent a link to complete a very short (2-3 minute) survey about the session you just had. You will be asked to rate the session on several characteristics and identify any issues or challenges that arose in your work with the therapist. The information you provide will be confidential and not shared with your therapist.

D. Other Assessments

About every 4 sessions, you will be sent a link to another online survey (less than 10 min), similar to the baseline survey, so that we can track changes in your symptoms and presenting concerns, and treatment progress over time. At the end of the treatment, we will share with you a summary of changes in these measures over time for you to keep. You will be sent a final survey 3 months after treatment ends.

At the end of treatment, you will be invited to participate in an optional interview. This is an opportunity to meet with a study staff member (over Zoom) to reflect on your treatment experience and share any feedback you have. We will ask if we can audiorecord this interview. However this is optional, and you can do the interview even if you do not want it recorded.

5. RISKS OR DISCOMFORTS

The risks associated with this study are comparable to the risks associated with psychotherapy in general. For example, it can be hard or uncomfortable to talk about the things that bring you to therapy. You do not have to answer any questions or engage in any activity at any time for any reason. It is also possible that you may not find the treatment or therapist to be helpful**,** in which case you may end your involvement in the study at any time. All answers you give will be kept confidential.

Another possible risk is loss of confidentiality. The study will do everything possible to protect your confidentiality. Confidentiality of your research records will be strictly maintained by the

research team. Every participant will receive a patient identification number (PID). The PID will be used instead of your name on all surveys, videorecordings, and materials. Activities will take place through a secure online survey platform or over Zoom, a web-based video conferencing and web conferencing service that employs industry-grade encryption and other measures to ensure data confidentiality.

The study may involve other risks that are unknown at this time.

6. BENEFITS

You may experience personal benefits from participating in the study. You may experience improvement in your problem or symptoms as a result of the treatment and relationship with your therapist.

The following results from this study may be relevant to you: changes in your self-reported mental health symptoms and treatment progress. You will receive a summary report describing changes in your scores at the end of treatment. You may enjoy the process of monitoring changes in your symptoms, and receiving a summary of data collected over the course of treatment.

There may be benefits to others as well. This study may help us learn how to improve the quality of mental health services for Asian Americans, by exploring how therapists can effectively collaborate with patients on a course of treatment tailored to their needs and cultural contexts, and to address any issues that may arise due to cultural differences. Results from this study may also help us develop better services for other racial and ethnic minority groups as well.

But, you may or may not get any direct benefit from being in the study.

7. COMPENSATION

You will be eligible to receive a total of $210 in incentives in the form of e-gift cards, disbursed through the Tango gift card platform (https://www.tangocard.com/) and redeemable at 100+ popular retailers. Your compensation will be disbursed according to the following timeline:

- You will be compensated $5 for each brief post-session questionnaire (PSQ) you complete after each therapy session throughout your 15-week treatment period. Payment will be provided in a lump sum amount upon completing your final session (maximum of $75).
- You will also be compensated $20 after completing a longer questionnaire once/month (following sessions 4, 8, 12, 15 and 3 months after treatment completion, for a maximum of $100). Payment will be provided within two business days of completing each of these monthly assessments.
- At the end of your treatment, you will be invited to complete a 30-minute interview with the patient coordinator for a user interview to debrief your experience and share feedback. You will be compensated $35 for your time within two business days of completing this interview.

8. VOLUNTARY PARTICIPATION

You are free to choose not to participate in the study without any loss of services or benefits to which you may otherwise be entitled. Your decision whether or not to participate in this study will not affect your eligibility to see a different therapist within your insurance network if you choose.

The study ends after you have completed the 15 sessions of treatment and completed the 3-month follow-up survey. If you agree to participate, you are free to quit at any time. You may refuse to answer any question or engage in any activity.

You may be withdrawn from the study if your therapist determines that your therapeutic needs exceed what they are able to provide in a short-term telehealth format. In that case, they will discuss various options with you and refer you to a more suitable treatment approach, such as more intensive in-person treatment.

If you leave the study or you are withdrawn from the study, you may still be eligible to complete some of the surveys and optional interview. You will only be compensated for the activities you engage in.

9. PRIVACY AND DATA CONFIDENTIALITY

NYU and Unmute are committed to protecting the privacy and confidentiality of the information you provide to us.

Confidentiality of your data, including survey data and video/audio recordings, will be strictly maintained, and shared only with your provider and supervision team, and research staff to ensure quality of care. As mentioned, your patient identification number (PID) will be used instead of your name on all surveys, videorecordings, and materials to protect your identity. Activities will take place through a secure online survey platform or over Zoom. Data will be stored on password-protected computers and a cloud-based back-up system. In written reports, data will only be reported in the aggregate.

The information you provide to us will be used by the research team and others involved in the study to conduct and oversee the study. Video recordings will be used for therapist supervision purposes to ensure that the intervention is being delivered as designed. Some sessions may be transcribed for training purposes with all personal information (e.g., names, places) removed from the transcript to protect your identity. At the end of treatment, you will have an opportunity to consent to allow your video and/or audiorecordings to be retained for research and/or training purposes. Recordings will be retained only if the therapist also provides consent. Otherwise, the recordings will be destroyed six months after the completion of the study.

Survey data, video and audio files, and transcripts (if applicable) will be kept on a computer that is password protected and also backed up to a password-protected cloud-based storage system. Only study personnel will have access to the files. Please note that information not containing

identifiers may be used in future research, shared with other researchers, or placed in a data repository without your additional consent.

If there is anything about the study or your participation that is unclear or that you do not understand, if you have questions or wish to report a research-related problem, you may contact Dr. Doris F. Chang at (212) 998-5889, dfchang@nyu.edu, 1 Washington Square North, Room 206, New York, NY 10003.

For questions about your rights as a research participant, you may contact the University Committee on Activities Involving Human Subjects (UCAIHS), New York University, 665 Broadway, Suite 804, New York, New York, 10012, at ask.humansubjects@nyu.edu or (212) 998-4808. Please reference the study IRB-FY2024-9189 when contacting the IRB (UCAIHS).

10. Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena.

Exceptions include:

- A federal, state, or local law requires disclosure, such as information about suspicion of child abuse or neglect or suspicion of harm to yourself or others.
- Your explicit approval for the researchers to release your name and/or personally identifiable information.

11. Clinicaltrials.gov

A description of this clinical trial will be available on https://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

You will receive a copy of this consent document to keep.

Do you agree to participate in this research study?

Name of Participant (Print)	Signature of Participant	Date
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

I agree to have my sessions videorecorded for supervision and quality assurance purposes.

_____ Yes _____ No

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I agree to allow my session video and/or audiorecordings to be retained for future research and training. (You can say no and continue in the study)

Video _____ Yes _____ No Audio only _____ Yes _____ No

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I agree to be contacted for future research. (You can say no and continue in the study)

_____ Yes _____ No

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