C-LEARN PART 3 – RAPID NEEDS ASSESSMENT COVID-19

RESEARCH PROTOCOL

MAY 25, 2020

NCT03977844

INTRODUCTION

The Community Resilience Learning Collaborative and Research Network (C-LEARN) is a community partnered research trial that aims to determine best practices and intervention approaches to build and support in disaster-prone communities in Louisiana – specifically, Orleans Parish. We conducted this trial in two phases. In Phase 1, we conducted key informant interviews with community stakeholders throughout Southeast Louisiana to identify emergent themes in community strengths, weaknesses, and priority areas as related to mental health and disaster. Results from Phase 1 informed activities in Phase 2. Phase 2 is a two-tiered, randomized trial of two interventions at each tier. In Tier 1, participating agencies, providers, and administrators were randomized to either a) Technical Assistance (TA) in support for finances, housing, and disaster response, or b) Community Engagement and Planning (CEP) for multi-sector coalition support + TA. In Tier 2: clients of agencies that participated in Tier 1 were randomized to receive one of two text-message based interventions: a) A Community Resources (CR) guide and b) CR + eCBT, a text message-administered Cognitive Behavioral Therapy-based mental health intervention.

The onset of the COVID-19 pandemic interrupted individual participant recruitment and shifted community needs and priorities. Following the primary aim of C-LEARN to build and support disaster-prone communities in Louisiana, the primary goal of C-LEARN Part 3 is to conduct a rapid qualitative assessment of community priorities, strengths, and needs as a result of the COVID-19 pandemic.

Processes and activities will be similar to those of Part 1. Part 1 activities were determined to be non-Human Subjects Research **February 20, 2019.** Part 2 activities were reviewed and approved for annual renewal **September 20, 2019**.

DESIGN

Trained and IRB-approved study staff will conduct **up to 75 semi-structured de-identified interviews** of community stakeholders. Stakeholders will participate in one of two interview types:

1) Part 3.1: COVID-19 Rapid Assessment interview for all invited interview participants
2) Part 3.2: A Post-CEP impact interview following a COVID-19 Rapid Assessment (Part 3.1) (only for individuals who participated in C-LEARN CEP sessions).

POPULATION

INTERVIEWEES

Eligible participants for individual interviews in Part 3.1 must be:

- English-speaking
- age 18 years old or older

- Be identified through snowball sampling as a community leader, or employed by a community-based organization

Eligible participants for individual interviews in Part 3.2 must be:

- English-speaking
- Age 18 years old or older
- Enrolled in C-LEARN as a provider or administrator and participated in C-LEARN CEP sessions

Study Procedures and activities

To identify participants for Part 3.1, we will a) contact interviewees who previously completed interviews in C-LEARN Part 1, or b) identify and contact potentially eligible community leaders not previously affiliated with C-LEARN through snowball sampling and contact lists provided by other interviewees and/or C-LEARN Leadership Council members. Participants will be invited to participate via email using the IRB-approved participant invitation letter, or by phone using the invitation letter text as a script. Participants will be provided with another key information sheet, both by email and verbally before beginning the interview. Interviews for Part 3.1 will be approximately 45-60 minutes long.

To identify participants for Part 3.2, we will contact currently enrolled agency, provider, and administrator participants who participated in C-LEARN CEP sessions. We will contact potential participants via email or phone to conduct post-CEP interviews with COVID-19 Rapid assessments. Participants will be provided with another key information sheet, both by email and verbally before beginning the interview. Interviews for Part 3.2 will be approximately 60-90 minutes long

All Interviews will be recorded on a digital audio recorder by the interviewer/study staff. Notes will also be taken during interviews.

Interviews

Interviews will be conducted either in person or over the phone, whichever the participant indicates is easiest for them. If interviews are conducted over the phone, an invitation to participate will be sent to them via a secure LSUHSC-NO email with the verbal consent form attached. If the interview nominee accepts, study staff will read through the consent form with them again at the time of the interview. The member of the study team leading the interview will then conduct the interview as outlined in the appropriate interview guide.

Transcribed and de-identified interview and focus group recordings will be coded using qualitative data analysis software such as Atlast.ti to identify themes.

Interview participants will not receive compensation.

Data Safety and Storage

Interview and Focus Group Data

Storage

Recordings will be uploaded by a wired transfer onto a password protected LSUHSC-NO computer. The computer data will be backed up using secure data transfer protocols approved by LSUHSC-NO Information Technology department, and accessible only to IRB-approved study staff. Recording data on original recording devices will be deleted following upload and secure data backup. Any personal identifiers will be redacted from interview transcriptions. Interviews will be transcribed by a secure transcription service. After transcription, audio recordings will be permanently deleted from all electronic storage (computers, audio recorders, servers, etc.). Data will only be analyzed by IRB-approved study staff.

Potential Risk

There is always a risk of data breach, but safety precautions above will minimize that risk. Questions in the interview guide do not ask about personal health information, or personal identifying information.

Potential Benefit

By participating in the study, participants may contribute to a rapid assessment to inform the understanding of community needs, resilience, and available assets to address COVID-19, now and after the pandemic.

Safety Precautions

There are no questions about a participant's legal history or personal health information. Participants will be instructed prior to beginning not to name themselves, provide personal identifiers during the audio recordings, or information about their so that any risk, however unlikely, of potential data breach will be minimized to the maximum extent possible. If a breach were to occur, it would not be possible to identify participants using the available stored data.

Precautions have also been taken in data storage and analysis, detailed in the section above.

Notes taken will not include identifiers and will be stored in a locked drawer in a secure office.

Alternatives

Alternatives to participation are not to participate.

Community Resilience Learning Collaborative and Research Network (C-LEARN)

Parts 1 and 2

Research Protocol

May 30, 2019

Version 4

Contents

1. Introduction

This protocol describes the planned design, aims, and methods for the C-LEARN study, a two-level (program and individual) randomized trial of alternative approaches to promote resilience in Southern Louisiana. The design was developed in full partnership with community stakeholders.

2. Study Design

2.1 Aims

C-LEARN has the overall aim of determining how best to improve resilience, particularly mental health-related quality of life for individual adult clients of diverse health and community-social service programs, through alternative strategies to build capacity of programs to provide services for depression, social risk factors and disaster-related concerns, as well as through alternative forms of individual client information technology support for addressing the same range of issues.

Specific aims are:

1) To engage communities in South Louisiana in a community learning initiative on how to best build capacity to enhance resilience to depression, adverse social determinants of health, and disaster exposure. This aim includes a qualitative assessment of local community resilience priorities and assets to inform study implementation.
2) To compare the effectiveness for improving mental health quality of life (MHRQL) (primary) and coping with stressors and other resilience outcomes (secondary), of two program-level interventions to build capacity for resilience programs: 1) Technical Assistance (TA) to individual programs vs 2) TA with Community Engagement and Planning (CEP) (TA+CEP) to support multi-sector coalitions.
    a. Hypothesis: CEP will be more effective at enhancing individual client (primary and secondary) outcomes. In addition, CEP will be more effective than TA in engaging programs and providers in trainings to improve services for depression, social risks and disaster concerns (primary), and in increasing the use of such services by programs and providers (secondary).
3) To compare the effectiveness for improving MHRQL and other resilience outcomes of two mobile apps: CR and CR+eCBT: 1) CR - An app providing only information on community resources, or 2) CR+eCBT - An app providing information on community resources and education on a cognitive behavioral therapy (eCBT) based approach to enhance individual resilience (i.e., coping with mood and stressors).
    a. Hypothesis: CR+eCBT mobile app will be more effective CR in improving the same primary and secondary client outcomes as for Aim 2.

To describe strategies CEP coalitions used to address depression, social determinants and disaster resilience, to inform interpretation and dissemination of findings.

2.2 Design

As shown in Figure 1, the design has an overall CPPR approach to implement a 2 by 2, randomized comparative effectiveness trial. Randomization occurs at the program level to either

TA or TA+CEP, where a program is a discrete services program with its own staff and clients; there may be multiple programs within a given administrative agency, including different geographic sites such as clinics. Further, programs may offer services in different content areas, such as physical health, mental health, social services, disaster services, faith-based, etc., referred to as different "sectors." In addition, individual participants will be randomized to one of two mobile apps for coping with stressors and disasters.

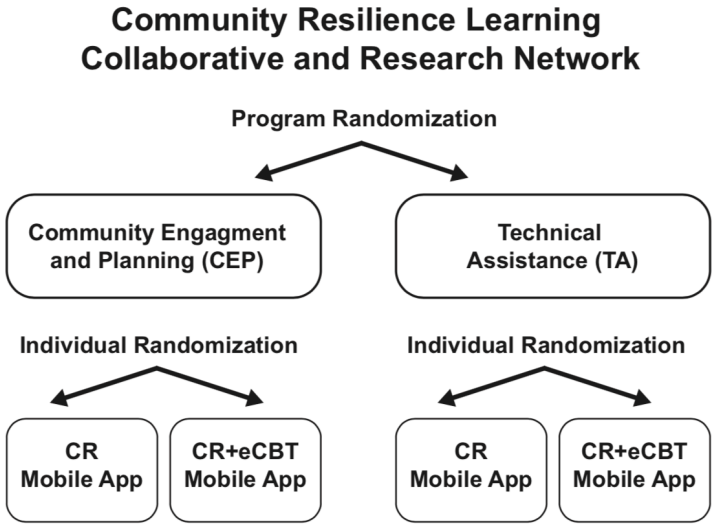

Figure 1: Community Resilience Learning Collaborative and Research Network Study Design.

The project and design phase has been led by a Leadership Council, including academic, community, and health system participants who have guided all aspects of the study, and operate under CPPR principles.[1] Initial leaders are academic and community partners from the Community and Patient Partnered Research Network (CPPRN) across South Louisiana and Los Angeles with additional stakeholder advisors from New Orleans, Baton Rouge and Coastal South Louisiana planned for as engagement of communities proceeds.[2] Through the assessment of stakeholder priorities (Aim 1), potential partners have been identified from different communities. As a CPPR initiative, the design has been refined with stakeholder input under a pre-specified, participatory process with initial design elements finalized prior to program recruitment and final design elements to be completed prior to client recruitment. The Council identified collaboration principles, leadership responsibilities, and issues such as data access, reviewing and sharing publications, and handling conflict. The Council reviews work group recommendations and facilitates larger community input and approval, including through larger community conferences.

2.3 Interventions

The main comparators are TA and TA+CEP TA. Healthcare and community-based programs that are assigned to CEP and TA will both receive training and support for implementation of an expanded model of evidence-based depression collaborative care that also addresses social determinants and disaster readiness. The depression toolkits to be used are from studies on

adults, including, racial/ethnic minority and low-income groups, with community health worker manuals from prior work in New Orleans, adapted for community-based programs in the Community Partners In Care (CPIC) study. [3–7] Toolkits use a team-based, stepped-care approach supporting assessment, referral and treatment, outcomes monitoring and care adjustment with specialty supervision and case managers for coordination and client education. While based on components of collaborative care for depression (clinical assessment and medication management for physicians; clinical assessment and CBT for licensed counselors; case management support for screening, education and patient activation, problem solving, care coordination and outreach; team management support), the interventions will also include resources to address main social determinants (e.g., poverty/financial planning, housing resources) and disaster preparedness/response, such as online resources developed after LACCDR. [8] Adaptations have been made with stakeholder input. The differences between CEP and TA are described in the following sections.

2.3.1 TA for Individual Programs

TA provides a series of webinars developed and delivered by content experts focused on team support for four community-identified emphasis areas to augment services offered by enrolled partner programs and agencies. TA uses experts to train program staff via webinars in a "train the trainer" approach with outside referral for intensive support. The four emphasis areas covered in webinar content includes resources and toolkits pertaining to: financial planning, disaster preparedness, housing, and mental health (including Cognitive Behavioral Therapy-based skills, Problem-Solving Therapy-based skills, and medication management). Experts include two psychiatrists, a CBT expert therapist, Licensed Social Worker, disaster preparedness and recovery specialist, program content lead of a local housing advocacy group, program content lead of a local financial assistance program, a case manager, support staff and two community leaders to engage service programs.

All TA content is adapted from publicly-available materials to best fit services available in and reviewed by content experts as well as the Leadership Council.

2.3.2 CEP for Coalitions (TA+CEP)

CEP uses a manualized intervention to create multi-sector networks to collaborate in evidence-based and community-prioritized toolkits or intervention materials. [9,10] The CEP manual used for C-LEARN was developed by adapting pre-existent and study-supported coalition-building intervention materials. [3–6,11–15] The intervention seeks to catalyze innovative cross-sector solutions devised by participating agencies. CEP supports a series of biweekly to monthly meetings over no more than three months to develop network and individual program capacity, prepare stakeholders as co-leads, and create a written training plan following CPPR principles. [1,7] CEP councils consider local context, i.e., cultural assets and stakeholder input. Disaster preparedness and public health sectors will be encouraged to offer education/resources on social determinants and disasters within CEP training plans. CEP may be supported by adjunctive resources such as a Learning Collaborative, pending participant interest. The end-goals of CEP are for coalition members a) establish relationships across sectors and b) among the coalition, to create and implement an innovative approach to improve community resilience and capacity.

Participating programs randomized to CEP will also receive the TA materials described in the previous section.

2.3.3 Individual-Level Mobile Apps

We compare two mobile apps created as part of this study (referred to as CR and CR+eCBT) that permit interactive text messaging, mobile web, or interactive voice response (IVR) interactions, using an information technology platform (Chorus) specifically designed for participatory development.[2] Each text-based intervention has been adapted through workgroups with stakeholders in order to tailor content to each community. The CR intervention will provide informational resources and referral information relevant to the local community in the form of a compiled resource guide available online to study participants. The CR materials were collected in partnership with Leadership Council and the Center Ethical Living and Social Justice Renewal, which produces a vetted, comprehensive list of health and services programs and agencies in New Orleans.

The CR+eCBT offers the CR guide described above supplemented with an interactive text-messaging-based CBT-informed intervention. This component was developed previously by our group using participatory methods with community partners and includes interactive support to enhance social support networks, support cognitive restructuring (framed through partnered input as "Catch it, Check it, Change it"), and encourage pleasant activities.[16] Participants will receive text message notifications (with frequency set by participants, up to several times per day) and can either reply back to messages to explore content or click a link in the message to access the interactive mobile app.

2.3.4 Driver Diagram

Building on the literature above and our prior work and stakeholder input, we formulated a logic model (Figure 2), specifying expected outcomes, main drivers and intermediate processes, and key intervention features. This logic model informs the measurement framework.

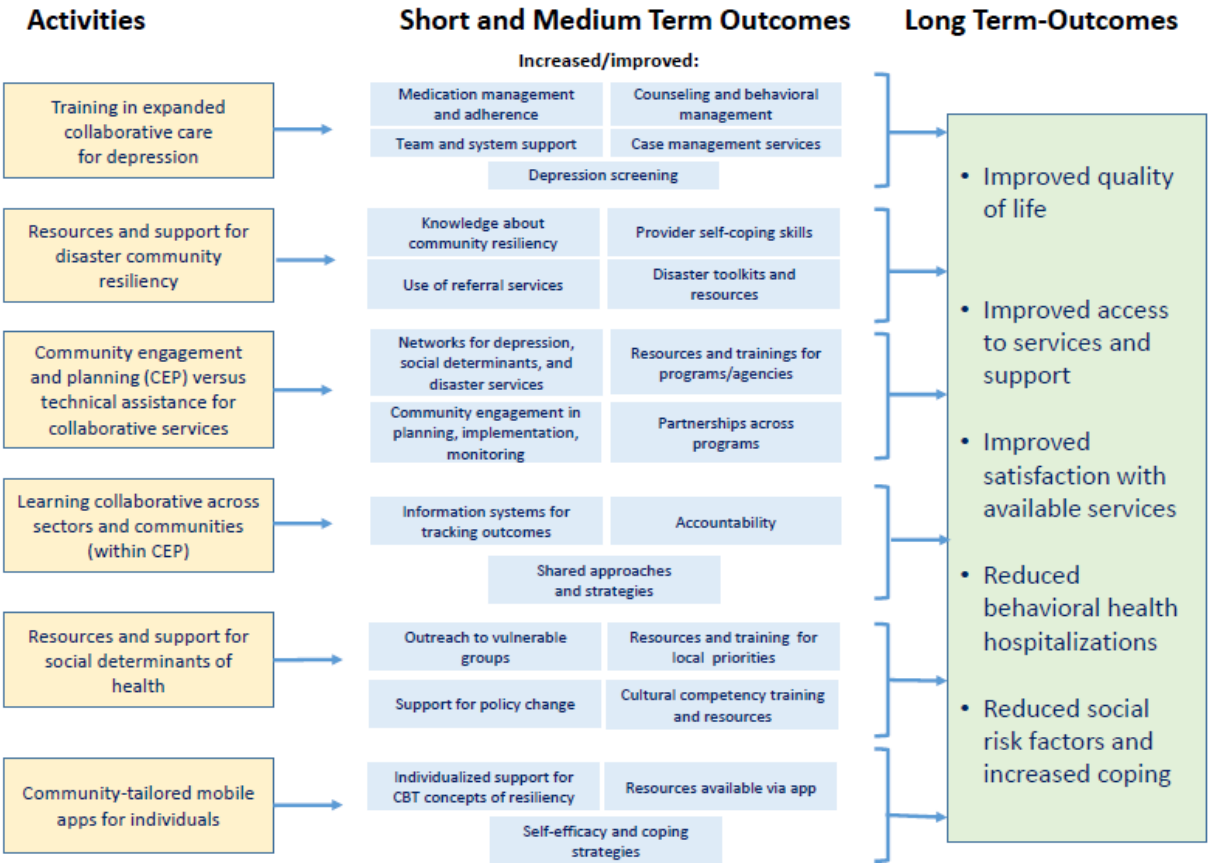

Figure 2. C-LEARN Logic Model

2.4 Measures

2.4.1 Measures for Client/Community Participants

We consider MHRQL (MCS-12) and depression (PHQ-8) as the primary outcomes. We include secondary outcomes as: individual resilience (BRS), physical health quality of life (PCS-12), mental health wellness, social determinants of health, behavioral health hospitalization, work loss days, and general anxiety disorder (GAD-2). Mediating factors are: self-efficacy in coping with depression, social contacts and use of health and social-community and disaster services for these concerns.[17,18] We will assess sociodemographic factors (age, gender, race/ethnicity, education, insurance coverage, family composition, family income, employment status) as moderators. We also assess exposure to social risk factors, disasters exposure and concern, post-traumatic stress disorder symptoms (PC-PTSD-5), presence of chronic medical conditions, and perceived community efficacy in dealing with disasters.[19,20] We also have the option of tailoring follow-up measures to specific events (e.g., floods, oil spill).[21,22] We will explore utilizing open-ended answers to "how are things going now?" to identify linguistic markers of resilience (e.g., emotional positivity).[23] Measures have been formulated with stakeholder and Leadership Council input.

Primary Outcomes

a) Mental Health Related Quality of Life (MCS-12); SF-12

Changes in mental health-related quality of life defined by a 12-item mental composite score (MCS-12). On a scale of 0-100, 40 is a standard cut-point for poor quality of life.

b) Depression (PHQ-8)

Depression severity defined by an 8-item Patient Health Questionnaire, scores 0-24. PHQ-8 score of 10 or greater indicates at least moderate depression.

Secondary Outcomes

c) Brief Resilience Scale (BRS)

Individual resilience is measured on a 1-5 point scale. Scores below 3 indicate low resilience; scores above 4.3 indicate high resilience.

d) Physical health quality of life (PCS-12); SF-12

Physical functioning using a standardized continuous 12-item physical composite score.

e) Mental Wellness Indicator

Self-reported indicator of mental wellness; a response of at least "sometimes in the prior 4 weeks" on feeling calm or peaceful, having energy, or being happy.

f) Social Determinants of Health

Self-reported social factors that potentially affect health outcomes (mental and physical), access to care, accuracy of care, quality of care. Determined by self-report in screening survey, baseline and follow-up measures.

g) Behavioral Health Hospitalization

Avoiding any behavioral health hospitalization, with a sensitivity analysis of avoiding having ≥ four hospital nights.

h) Work loss days

For those employed, number of work-loss days in the prior 30 days

i) General Anxiety Disorder (GAD-2)

General anxiety disorder is measured using a standardized questionnaire. Scores 3-6 indicate probable anxiety disorder.

j) Primary Care - Post Traumatic Stress Disorder Screen (PC-PTSD-5)

Standardized measure to screen for PTSD in a primary care setting. Score of 3 or more indicates possible PTSD.

k) Body Mass Index and risk factors

Self-report of weight, height, physical activity, cigarette smoking

l) Community Resilience

Measure of perceived community capacity for resilience with focus on disaster

m) Self-efficacy

Self-efficacy in coping with depression social risk factors and disaster threats. Measured on a 10-point scale, 10 being "extremely confident in one's ability."

n) Coping

Measure of individual coping skills and response to stressful situations.

o) Service use

Self-reported frequency of use and care satisfaction with health and social-community, housing, financial, and disaster services.

p) Life difficulties

Self-report of life difficulties in the previous 6 months. Includes exposure to disasters, violence, child custody changes, death, employment loss.

Pre-specified Outcomes

q) Medication for a mental health disorder

Self-reported use or prescription of any antidepressant, mood stabilizer, and any antipsychotic in the previous 6 months.

r) Barriers to care

Self-report of potential barriers to pursuing or receiving care, quality of care, or delayed service provision.

s) Alcohol Use Disorders Identification Test (AUDIT)

Standardized measure of identifying alcohol use disorder. Score of 8 or more indicator of harmful or hazardous drinking.

t) Drug Screening Questionnaire (DAST)

Standardized measure of identifying potential drug abuse/substance use disorder. Score of 3 or more indicates harmful use.

u) Social Support (MOS Social Support Survey)

Adapted from standardized measure of RAND social support instrument. Higher score indicates more support.

v) Chronic health conditions

Self-report of a series of chronic health conditions including but not limited to diabetes, hypertension, etc. Collected only at baseline.

2.4.2 Administrator/Provider Measures

Administrator measures for baseline and 6 months include organization partnerships for depression, social risk factors and disaster services. We will also assess program size, services offered, aspects of organizational structure, and at follow-up, participation in planning and trainings.[8,24,25] Provider or staff measures include time spent providing community services and intervention-relevant practices (e.g., problem-solving, screenings for depression, social risk factors, and disaster preparedness) (primary), and self and community efficacy to address stressors and disasters, and at baseline, training and job status.[8,10,26] These measures have received Leadership Council and community stakeholder input.

2.5 Randomization

2.5.1 Program-level (CEP vs TA)

Within each community, programs will be matched based on a) range of services offered, b) clientele base (i.e. people with serious mental illness, formerly incarcerated people, etc.), c) program size, and d) existing partnerships or affiliations. "Affiliation" refers to having a strong referral relationship and/or clients within and across programs. Programs that match on multiple categories or identify that they are part of an existing partnership or affiliation will be paired. Matched pairs will fall within four different types of grouping:

1) Unique Program: There is no similar program to match with. Will be randomized independently.
2) Paired Program: Two programs that are similar in the criteria described above are paired and do not have affiliations with other programs in the study. One program is randomly assigned to one of the interventions. The other program will be assigned to the other intervention.

3) Unique Cluster: Programs that are affiliated with more than one other program. All programs in the cluster will be treated and randomized as one unit.
4) Cluster Pair: Two sets of clustered programs that are reasonably similar as a whole to each other. One cluster will be randomized to one of the interventions. The other cluster will be assigned to the other intervention.

By pairing programs following this schema, we reduce the chance of intervention contamination; that is, an individual client may receive services from multiple programs enrolled in the study. Community Investigators in the C-LEARN Leadership Council will review matching to ensure that programs are appropriately paired.

After matching, we will then randomize programs or program clusters using a random seed to TA or TA+CEP. [24,27] All interventions are "encouragement" interventions. That is, participants are encouraged to consider interventions to which they are assigned, no one is forced to follow a given protocol. This is more of a public health rather than a clinical approach to intervention implementation.

2.5.2 Individual-level

Clients will be randomized at the individual level to receive one of the two mobile apps (CR or CR+eCBT), at the time of enrollment, using a random number generator method. A random number generator will be programmed in the CHORUS survey software.

2.6 Sampling

2.6.1 Communities

With stakeholder input, we will recruit services programs from New Orleans and Coastal South Louisiana. Racial and ethnic compositions of involved Louisiana communities are primarily African-American and Caucasian, with smaller populations of Latinos and also Vietnamese-Americans in coastal areas. The stakeholder Council has recommended specific communities with history of disaster exposure and diverse populations.

2.6.2 Programs

We will select eligible programs by combining program lists with community nominations, classifying programs as mental health, substance abuse, primary care/FQHCs/public health (health) or social services, community centers, parks and recreation community centers, businesses, salons, gyms, faith-based, and disaster preparedness/response programs (community). [28] We will invite programs through letters, phone calls and visits to recruit as many as 30 per community, expecting as many as 60 total programs.

2.6.3 Administrators and Providers/Staff

Each program will be asked to identify an administrator who will be invited to enroll and complete web-based surveys describing programs and partners at baseline and 6 month follow-up. Administrators will identify potentially eligible staff (full time, licensed or nonlicensed, but having direct client/community member contact) to be invited to enroll through meetings and

notices, anticipating 2-3 service providers or staff members per program to consent for surveys (N= up to 120 or more). Eligible staff may participate in trainings, tracked by sign-in logs, whether or not they participate in the survey subsamples.

2.6.4 Clients/ Community Members

Within enrolled programs we will invite adults ages 18 or older seeking services to complete self-or interviewer-administered eligibility screeners. Individuals will be eligible if they have access to a mobile device that receives short message service (SMS), screening positive in the last 6 months for exposure to social-risk factors (e.g., homelessness, below federal poverty level), disaster exposure or concern about future disasters; or depression by 8-item Patient Health Questionnaire (PHQ-8) score great than or equal to 10. We will exclude persons who: 1) do not provide contact information or do not have access to a phone with SMS-capability; 2) are severely cognitively impaired or intoxicated by survey-staff judgment; 3) are non-English speakers; 4) do not expect to live in South Louisiana over the following 12 months.

2.6.5 Data Collection

We will ask participants to complete baseline and 6-month surveys online or by telephone interview. In addition, we will make available brief (10 minute) surveys monthly via web, text-message or interactive voice on the primary and select secondary outcomes.

2.6.6 Human Subjects Protection

All procedures will have prior review and approval from the LSU Health Sciences Center-New Orleans (LSUHSC-NO) Institutional Review Board (IRB), and partnering research institutions will enter into reliance agreements with LSUHSC-NO.

2.6.7 Power calculations

The power calculations were based on expecting a percentage point difference between groups ranging from 8 to 10. With enrolling 600 to 720 individuals per group (1200 to 1440 in total), 80% power was projected to detect the difference between groups ranging from 9.3% to 10.7% with alpha level of 0.05 (two-sided) and ICC=.01, allowed a retention rate of 65-75% at 6 months follow-up.[27] For outcome measures assessed monthly during the 6-month period, the proposed sample size with 60% retention is adequate for a between group difference of 7.3-7.9%.

2.7 Proposed Analysis

2.7.1 General Issues

a) Modeling. We will use an intent-to-treat (ITT) framework and hierarchical approach with information on programs, service providers/staff, and clients. We will conduct bivariate analyses to identify potential covariates for multiple regressions and compare unadjusted and adjusted intervention coefficients to assess confounding. We will explore transformations and two-part models for skewed counts with smearing estimates for retransformation. b) Missing data. For missing data (item or survey non-response) we will use logical imputation for items as

appropriate and hot-deck multiple imputation using a predictive mean-matching method for item non-response.[29,30] c) Weights. We will create enrollment weights to represent intended populations.[31,32] d) Multiple Comparisons. We will consider methods that incorporate bounds on probability of false findings of significance, e.g., false discovery rate.[33] e) Multilevel Data**:** We will apply multi-level (i.e., hierarchical or random coefficient) models to account for clients within programs and three-levels for longitudinal data having repeated measures within clients.[27]

2.7.2 Aim 2 Analysis (TA vs TA+CEP)

The main analysis is of client outcomes. Using client/community member baseline and 6-month follow-up, we will evaluate CEP versus TA effects on primary (MHRQL, PHQ-8) and secondary/exploratory outcomes (e.g. mental wellness, homelessness risk factors, behavioral health hospitalizations; physical activity, productivity, self and community efficacy for coping, use of service for depression, social determinants and disaster preparedness and response, others as identified). For secondary analysis of programs, outcomes are training participation and partnerships with other service programs for depression, social determinants and disaster threat/exposure, examining intervention effects controlling for type of service sector for programs, and for community, reporting chi-square statistics. For staff/providers, also considered secondary, main outcomes are participation in training, providing community services and using problem-solving and other strategies for depression, social risk factors and disaster threat/exposure based on data from 12 month follow-up and logs at training events. In two-level hierarchical models, we will compare intervention effects on hours in training using two-part models for skewed distributions.[10,34]

2.7.3 Aim 3 Analysis: (CR app vs CR+eCBT app)

In regression models above (6-month endpoint or longitudinal), we will include as intervention indicators, CEP vs TA, CR app vs. CR+eCBT app, and their interaction. From estimated models, we will contrast a linear combination of coefficients to estimate CR vs CR+eCBT effects within each CEP or TA group and average effects across these interventions; and conduct stratified analyses by client baseline measures.

2.7.4 Qualitative Analysis

We will use several qualitative data collection methods.[35] We will use recorded interviews to assess stakeholder priorities (Aim 1), coalition strategies and strengths, and trends in services and disaster response (Aim 4). We will conduct case studies of CEP coalitions to describe coalition development, toolkit modification and training implementation using meeting notes, written plans, interviews, and group discussions at proposed learning collaboratives.[36–38]

2.7.5 Linguistic Predictors

We will explore the feasibility of identifying linguistic predictors of resiliency to inform future research. For this purpose, we will use longitudinally collected, open-ended responses on the monthly brief surveys and use automated text transcription algorithms to extract lexical and vocal acoustic features, associated with hope and stressor response.[23,39–43][23,37–40] We will use

supervised learning models (i.e., support vector machine) to explore linguistic features as resilience predictors, i.e., mental wellness and MHRQL.

2.7.6 Mixed-Methods Analyses

For thematic analyses we will enter data into MaxQda software. Academic and community members identify themes coding 5-10 percent together and resolving discrepancies by consensus.[44,45] We will code data deductively based on study goals, e.g., training plans, and inductively based on emergent themes, e.g., new priorities.[43] We will conduct comparative analyses to identify themes across coalitions and triangulate results to describe context, strategies to address resilience, implementation strategies and outcomes. All analyses will be partnered with stakeholders.[44]

2.7.7 Partnered Synthesis

We will use all sources of data in community conferences to support academic and community partners in generating research, community improvement and policy recommendations, following the model of CPPR that we have applied in Louisiana and Los Angeles.[12,24,45]

3. Data Safety Plan

3.1 Responsibility for Data Safeguarding

The principal investigator, Benjamin Springgate, MD, MPH has the ultimate responsibility for data safeguarding.

All project staff will have completed the CITI IRB training and LSUHSC-NO KDL training (LSUHSC-NO personnel) or other HIPAA and institutional-specific training (non-LSUHSC-NO personnel), and will abide by applicable compliance documents in accord with university policies and procedures to protect the privacy of the research data for their entire tenure on this project.

3.2 Data Storage

Data used as part of this study will be stored primarily on a server located at the Center for Health Services and Society at UCLA. The server is located in a locked server room and cabinet. The Center IT administrators will perform regular and encrypted backups of the data. The server is protected using standard security practices including being located behind the UCLA firewall, accessible only by designated users from our staff located at UCLA or connected through the UCLA Mednet VPN from an offsite location. Data transferred using devices (such as USB drives and laptops) will be encrypted following UCLA Health device encryption policies. Storage and access procedures are in full compliance with UCLA Health data security policies.

3.3 Participant Compensation Information

LSUHSC policy requires the collection of participant social security numbers (SSN) in order to receive payment for study participation. At the time of consent, New Orleans recruitment staff

will enter participant SSN, first and last name, address, date of screening, and payment dollar amount into the ClinCard system using study-specific iPads connected to the internet using a Wifi hotspot. ClinCards are a secure, LSUHSC-NO approved method of compensating study participants that function as loadable debit cards. In the event the Wifi hotspot isn't working, a tracking sheet will be filled out by IRB-approved study staff to record ClinCard token numbers, amounts, the participant's full name, SSN, and mailing address. These will only be recorded on paper and will be destroyed immediately after input into the ClinCard system. The participant's information will be used only for payment purposes, and never for research. All research and payment information will be stored separately.

3.4 Data Transmittal

The default mechanism for transferring files electronically includes encrypting files (256-bit AES approved using software that supports .zip format, e.g. WinZip) into a single archive, in compliance with UCLA Health data security policies. That archive may be delivered electronically (e.g. an e-mail attachment) or on removable media. In addition, direct connections between computers using encrypted communication protocols such as SSH and SFTP may also be employed.

3.5 Online Screening and Consent

The electronic screening and consent will be delivered via a website created using the Chorus platform. In the event electronic screening and consent are technologically infeasible temporarily, hard copy paper screening and consent will be substituted. Paper copies' data will be then entered as soon as feasible into the online system and paper copies will be shredded. Chorus is a web application that allows individuals to create websites and mobile apps to collect and display data similar to sites such as SurveyGizmo. Chorus was created at the Center for Health Services and Society at UCLA and is hosted by a server at that center. It has been approved by the UCLA Office of Information Security for use in research projects as well as patient care including protected health information. All communication to and from the server is encrypted using SSL certificates. It is also used by multiple IRB-approved studies at UCLA. Study staff will be able to export data in comma-separated format (CSV) and will import that to the study server for analysis.

3.6 Audit and Monitoring Plans
We have no specific auditing or monitoring plans.

3.7 Data Safeguarding Procedures
Our standard data safeguarding procedures include the following:

Additional electronic files used by study staff will be stored on secured, password protected computers accessible only to study staff members. At UCLA, the network is set up as a Windows domain and all files will be stored on a secured Window file server with folder-level password protection to ensure that only study staff have access to study files.

All study staff will also abide by basic procedures for protecting identifiable private and proprietary data that have been adopted by the project as a whole. For each stage of the research process, the following procedures will be implemented:
Training staff on data sensitivity and data safeguards being employed.
Processing sensitive data in a centralized location with established access control procedures.

- Storing sensitive hardcopy in locked files when not in use.
- Restricting access to shared disk files through appropriate use of file permissions.
- Printing sensitive material only when absolutely necessary. When it is necessary, project staff will ensure that an authorized person is at the printer when the sensitive material appears.
- Using Certified mail, return receipt requested, for sensitive data and Registered mail for very sensitive data when transferring materials by mail. (No transfer by mail is planned, but this procedure would be followed if applicable.)
- Re-training staff and reviewing sensitive data inventory and data safeguards annually.
- Reporting all serious violations of the Data Safeguarding Plan in writing to the Principal Investigator, with a copy to the Office of Research Services.

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