



Protocol Title:
**Training Church Leaders in Mental Health
First Aid**

Protocol Number:
7224

First Approval:
12/28/2015

Expiration Date:
12/27/2018

Contact Principal Investigator:
Sidney Hankerson , MD
Email: hankerss@nyspi.columbia.edu
Telephone: **646-774-6429**

Version Date:
06/29/2018

Research Chief:
Myrna Weissman, PHD

Cover Sheet

Choose **ONE** option from the following that is applicable to your study
If you are creating a new protocol, select "I am submitting a new protocol." As 5 Year Renewals are no longer required, this option remains for historical purposes. I am proposing an amendment only to an existing protocol

Division & Personnel

Division

What Division/Department does the PI belong to?

Psychiatry

Within the division/department, what Center or group are you affiliated with, if any? Epidemiology

Unaffiliated Personnel

List investigators, if any, who will be participating in this protocol but are not affiliated with New York State Psychiatric Institute or Columbia University. Provide: Full Name, Degrees and Affiliation.

Chih Hsu, B.S.N., Outreach and Wellness Nurse; Columbia Doctors/ Zuckerman Institute Nohemy Aguirre, B.S., Outreach and Wellness Officer; Columbia Doctors/Zuckerman Institute



Amendment

Describe the change(s) being made

1. The telephone script used for participant recruitment has been updated and made more comprehensive.
2. A RSVP confirmation script has been incorporated to the PSF and will be used to make confirmation calls to participants that have RSVP'd for the Mental Health First Aid training.
3. The thank you email and the email script for mental health referrals have been modified.
4. The post-training surveys (M3 and Z3) have been updated and the order of the questions have been reversed. The first set of questions ask participants about their health and second set of questions presents participants with a vignette.
5. The 3-month follow-up email script has been updated and made more comprehensive.
6. The telephone script and the questions for the post-training follow up interviews have been attached to this PSF.
7. The language on the consent form has been changed from "Church leaders" to "Community Members".

Provide the rationale for the change(s)

These changes are being made in order to make email and telephone scripts for participants more comprehensive. Contact information and signatures have been updated to reflect research personnel changes. A RSVP confirmation script has been incorporated to the PSF and will be used to make reminder calls to participants that have RSVP'd to the Mental Health First Aid training.

The post training surveys have been updated and the order of the questions have been reversed. We believe that reversing the order of the questions will reduce survey fatigue and increase survey completion rates.

The questions for the post-training follow up interviews have been attached to this PSF for IRB review.

The language on the consent form has been revised to reflect the expansion of the subject population from Church Leaders to community members.

Comment on the extent to which the proposed change(s) alter or affect risks/benefits to subjects These proposed changes do not alter or affect risks/benefits to subjects.

Comment on if the proposed change(s) require a modification to the Consent Form (CF)



The language in the consent form has been changed from "Church Leaders" to "Community Members" to reflect the populations that is being trained in Mental Health First Aid.

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures

- Quality Improvement/Program Evaluation Only
- Audio or Videotaping

Population

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

- Adults
- Adults over 50

Research Support/Funding

Will an existing internal account be used to support the project?

Yes

Describe internal account

1849

Is the project externally funded or is external funding planned?

Yes

Select the number of external sources of funding that will be applicable to this study

Funding Source #1

Is the PI of the grant/contract the same as the PI of the IRB protocol?

Yes

Select one of the following

The grant/contract is currently funded

Source of Funding

Federal

Institute/Agency

NIMH

Grant Name

Patient Oriented Career Development Award (K23)

Grant Number



K23 MH102540

Select one of the following

Single Site

Business Office

RFMH

Does the grant/contract involve a subcontract?

No

Study Location

Indicate if the research is/will be conducted at any of the following

NYSPI

This protocol describes research conducted by the PI at other facilities/locations

Yes

Community Sources

Community Sources

Type in location(s)

First Corinthian Baptist Church

1912 Adam Clayton Powell Jr Blvd

New York, NY 10026

(212) 864-5976

Church of St. Charles Borromeo

211 West 141st Street

New York, NY 10030

(212) 281-2100

Columbia Zuckerman Community Wellness Center

610 West 130th Street

New York, NY 10027

The Dream Center (<http://www.dreamcenterharlem.org/>) is a community center affiliated and owned by the First Corinthian Baptist Church. It is located at 205 West 119th Street New York, NY 10026



Lay Summary of Proposed Research

Lay Summary of Proposed Research

The overall goal of this study is to test the feasibility and acceptability of training Church Leaders in Mental Health First Aid. This study leverages the trusted role of churches in the African American community. Mental Health First Aid (MHFA) is a groundbreaking public education program which introduces participants to risk factors and warning signs of mental health problems, builds understanding of their impact, and overviews common treatments. MHFA is an 8-hour course, which uses role-playing and simulations to demonstrate how to assess a mental health crisis; select interventions and provide initial help; as well as connect persons to professional, peer, social, and self-help care. The program also teaches about the risk factors and warning signs of specific illnesses like anxiety, depression, schizophrenia, bipolar disorder, eating disorders, and addictions.

Background, Significance and Rationale

Background, Significance and Rationale

African American adults are less likely to seek mental health treatment than their white adult counterparts. Various factors contribute to racial disparity including, high attrition rates, distrust of providers, and stigma. Church-Based Health Promotion (CBHP) has potential to address non-financial barriers to mental health care among African Americans given churches' position as trusted, frequently attended institutions in the black community.

My prior qualitative research (IRB Protocol #6368 and #6909) identified a desire by African American church leaders to receive training in the signs / symptoms of common mental disorders, how to intervene in a mental health crisis, and how to encourage people to seek mental health care. Unfortunately, limited research examines such strategies in faith-based settings. This study is designed to utilize a train community-based participatory approach to train Church Leaders in Mental Health First Aid (MHFA).

Mental Health First Aid is a public education program that introduces participants to the risk factors and warning signs of mental health problems, builds an understanding of the importance of early intervention, and overviews common supports. This 8-hour course uses role-playing and simulations to demonstrate how to offer initial help in a mental health or substance use crisis through a 5-step action plan, with the ultimate goal to connect persons to appropriate professional, peer, social, and self-help care. The program also teaches the common risk factors and warning signs of specific types of illnesses like anxiety, depression, substance use, bipolar disorder, eating disorders, and schizophrenia. Participants are introduced to local



mental health resources, national organizations, support groups, and online tools for mental health and addictions treatment and support.

Mental Health First Aid USA is listed in the Substance Abuse and Mental Health Services Administration's National Registry of Evidence-based Programs and Practices. Originating in Australia in 2001, Mental Health First Aid has since expanded to more than 20 countries. The National Council for Behavioral Health, in partnership with Missouri and Maryland state departments of mental health, introduced Mental Health First Aid in the United States in 2008. To date, more than 160 thousand individuals have been certified as Mental Health First Aiders.

The MHFA curriculum uses role-playing and simulations to demonstrate how to assess a mental health crisis; select interventions and provide initial help; and connect persons to professional, peer and social supports as well as self-help resources.

Specific Aims and Hypotheses

Specific Aims and Hypotheses

Specific Aims and Hypotheses

Aim 1: To evaluate the feasibility and acceptability of a CPPR informed model to train Church Leaders in Mental Health First Aid (MHFA).

Hypothesis 1: Feasibility and acceptability will be demonstrated by Church Leaders attending MHFA training sessions, completion of pre- and post- measures to assess mental health literacy, and a posttraining evaluation.

Description of Subject Population

Sample #1

Specify subject population

Community Members

Number of completers required to accomplish study aims

400

Projected number of subjects who will be enrolled to obtain required number of completers

430



Age range of subject population
21 years and older

Gender, Racial and Ethnic Breakdown

Community Members (N = 400)

Male - 80

Female - 320

Hispanic - 12

American Indian/Alaska Native - 0 Asian - 0

Black or African American - 380

Native Hawaiian or Other Pacific Islander - 0

White - 8

Description of subject population

We've consolidated to one subject population called "Community Members". This includes participants who we previously referred to as Church Goers. These participants will be recruited from First Corinthian Baptist Church, which has approximately 10,000 members (80% African American). The church is located in Central Harlem, in the borough of Manhattan. African Americans comprise 87% of the population in Central Harlem, making it the largest African American population in New York City by percentage.

Community members will also include church leaders and lay participants from all listed study sites. This will include any adult who meets study eligibility criteria and consents to take the MHFA training at one of our approved study sites. Examples of community study sites are NYSPI and the Columbia University Wellness Center.

Recruitment Procedures

Describe settings where recruitment will occur

First Corinthian Baptist Church has a congregational size of roughly 10,000 members (80% African American).

1912 Adam Clayton Powell Jr Blvd
New York, NY 10026
(212) 864-5976

St. Charles Borromeo has a congregational size of roughly 800 members (90% African American).
Church of St. Charles Borromeo



211 West 141st Street
New York, NY 10030
(212) 281-2100

How and by whom will subjects be approached and/or recruited?

We will recruit a purposive sample of community members to be trained in MHFA. The PI and Research Personnel will contact community members via phone, email, and in-person correspondence to recruit them for training in MHFA. A standardized script will be used. We will also utilize the flyer titled "Mental Health First Aid USA" as recruitment materials to describe the study to prospective participants.

Participants that RSVP for the training will be contacted via phone two days before the training to confirm their availability. A standardized script will be used for these calls.

We will also use a snowball sampling strategy as follows. Within two weeks of each training, we will send these fully consented participants a thank you note expressing our gratitude for their participation. We will also ask them to share a Google Link about future training to anyone whom they think might have an interest in becoming trained in Mental Health First Aid.

During community recruitment efforts we have received feedback that a large portion of community members are monolingual Spanish speakers. While this research protocol does not provide Spanish speaking Mental Health First Aid training, our English information sheet has been translated to Spanish to provide community resources for this population. The translated information sheet provides Spanish-speakers with information about Mental Health First Aid and the contact information for the Spanish-speaking Project Coordinator. Spanish-speakers will be referred to the Department of Health and Mental Hygiene where they will be connected to linguistically appropriate Mental Health First Aid trainings.

How will the study be advertised/publicized?

There will be no public advertising for training Church Leaders in MHFA. The PI and Research Personnel contact church leaders via phone, email, and in-person correspondence to recruit them for training in MHFA. We have included telephone and email scripts.

Do you have ads/recruitment material requiring review at this time? Yes

Does this study involve a clinical trial?

No

Concurrent Research Studies

Will subjects in this study participate in or be recruited from other studies?

Yes

Describe concurrent research involvement

Participants who were previously involved in either IRB Protocol #6909 (Needs Assessment for Church-Based Mental Health Services) or #6975 (Community Partnered Approach to Implement EBPs for



Depression) will be eligible to participate in this study. A ward-off letter will be sent to potential subjects prior to approaching them for recruitment of this study.

Community members who were *not* involved in my prior studies will also be eligible to participate in this study and receive training in Mental Health First Aid.

Inclusion/Exclusion Criteria

Name the subject group/sub sample

Community Members

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

Inclusion

Must be 21 years or older

Must be English Speaking

Able to give informed consent

Method of Ascertainment

Self Reported

Self Reported

Signed Consent Form

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

Exclusion

Any significant medical condition
compromising

Inability to give informed consent

Method of Ascertainment

Clinician Judgement noted ability to
participate

Clinician Judgement noted ability to
participate

Waiver of Consent/Authorization

Indicate if you are requesting any of the following consent waivers

Waiver of consent for use of records that include protected health information (a HIPAA waiver of
Authorization)

No

Waiver or alteration of consent

No

Waiver of documentation of consent

No

Waiver of parental consent

No

Consent Procedures

Is eligibility screening for this study conducted under a different IRB protocol?



No

Describe procedures used to obtain consent during the screening process

The PI or designated research personnel will contact community members by e-mail, phone, or in-person meetings to review the study design and rationale. Research personnel will answer any questions potential subjects have, and then ask if they are interested in volunteering to participate in MHFA training.

Describe Study Consent Procedures

Research personnel will meet community members at a mutually agreed upon location, either the church or NYSPI. Research personnel will review the consent form with each community member. Interested community members will then sign informed consent, in a confidential, private location, and complete the demographic sheet. Once all community members have signed consent, they will meet collectively to take the MHFA training course as a group.

Indicate which of the following are employed as a part of screening or main study consent procedures

- Consent Form
- Information Sheet

Persons designated to discuss and document consent

Select the names of persons designated to obtain consent/assent ahmad-llewellyn, Jaylaan

Hankerson , Sidney, MD

Harris, Ivyonne

Lewis-Fernandez, Roberto, MD

Miller-Sethi, Faith

Mitchell, Lorena

Morris, La'Shay S., MPH

Murphy, Eleanor, PHD

Ntoso, Amma

Ojeda, Jesse

Payne, Jennifer

Pienkowski, Stefan rule,

alana, BA Santiago,

Emely

Svob, Connie

Williams, Maya

Type in the name(s) not found in the above list

Chih Hsu, B.S.N., Outreach and Wellness Center Nurse; Columbia Doctors and Zuckerman Institute

Nohemy Aguirre, B.S., Outreach and Wellness Officer; Columbia Doctors and Zuckerman Institute



Tatiana Mercedes

Study Procedures

Describe the procedures required for this study

Mental Health First Aid (MHFA) is an evidence-based, 8-hour, public educational program that has been found to improve people's recognition of emotional and mental health challenges and to increase people's confidence in providing help to others. MHFA training can take place during either a one-day, 8-hour training session or as a two-day, 4-hour training session program. Trainings will also be conducted by IRB-approved study personnel. Trainings will also be delivered by Steve Alexander, a certified MHFA instructor. The content of the training is the same regardless of whether the one-day or two-day format is used. The dates of delivering the training modules will be determined collaboratively by Church Leaders and academicians.

The trainings will take place at one of the IRB-approved study sites (First Corinthian Baptist Church, St. Charles Borromeo, Columbia University Wellness Center or the Dream Center).

After signing informed consent, participants will complete a pre-test on mental health literacy.

In the Mental Health First Aid course, participants will learn risk factors and warning signs for mental health and addiction concerns, strategies for how to help someone in both crisis and non-crisis situations, and where to turn for help. Participants will also learn a 5-step action plan ALGEE, for individuals to provide help to someone who may be in crisis.

Mavis Flowers will be authorized to facilitate the MHFA course. She has completed CITI training. She will not obtain consent.

- Assess for risk of suicide or harm
- Listen non-judgmentally
- Give reassurance and information
- Encourage appropriate professional help
- Encourage self-help and other support strategies

After the course, participants will take a post-test on mental health literacy and training course evaluation. Participants will use a new training course evaluation form that is in a bubble format so that data collected during the Mental Health First Aid training can be read by a computer.



Within two weeks of each training, we will send these fully consented participants a thank you note expressing our gratitude for their participation. We will ask them to share a Google Link about future training to anyone whom they think might have an interest in becoming trained in Mental Health First Aid.

In 1-14 days after the training, participants will be randomly selected for a follow-up interview. The purpose of the interview will be to assess participants' views on the MHFA training, how it could be improved, and topics for additional training. We will ask participants the convenient way for us to contact them (phone, email, mailing address, etc.) for the interview and 3-month follow-up evaluation.

At 3 months, participants will be contacted by the RA to take a follow-up evaluation. Participants will be able to take the 3-month evaluation by one of three methods: 1) email; 2) in-person at the church; and 3) over the telephone.

For participants who take the evaluation via email, Participants will be sent an email with a unique research identifier, that provides them the link to the Qualtrics evaluation survey. The email we send to each research participant will thank them again for their participation in the training and request their completion of the follow-up survey. Participants will also be reminded that we will send them a \$25 gift card as a token of our appreciation for their time upon our receipt of their completed survey.

For participants who take the evaluation in-person at the church, Research Staff will schedule a time to meet the person at the church. Research Staff will escort the participant to a private room in the church to facilitate privacy. The participant will then complete the assessment and Research Staff will assist with any questions that participants have.

For participants who take the evaluation over the telephone, Research Staff will contact the participant to schedule a time that is convenient for them. Research Staff will then contact the participant and ask the questions over the telephone and record the participants' responses.

You can upload charts or diagrams if any

Assessment Instruments

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

- 1) Pre-Course Questionnaire (Depression and Schizophrenia vignettes)
- 2) Post-Course Questionnaire (Depression and Schizophrenia vignettes)
- 3) Official MHFA Course Evaluation Form
- 4) 3-Month Follow-up Questionnaire
- 5) Participant Interview Question Guide



Please attach copies, unless standard instruments are used

Depression (M3)_FOLLOW UP Questionnaire_ MHFA Training 6.27.2018.pdf

Schizophrenia (Z3 FOLLOW-UP Questionnaire 6.27.18.pdf

INTERVIEW QUESTIONS Post-Course_Training MHFA 6.27.18.pdf

Research Related Delay to Treatment

Will research procedures result in a delay to treatment?

No

Treatment to be provided at the end of the study

No treatment to be provided at the end of the study

No treatment is provided as part of the MHFA training. However, referrals for mental health professionals will be provided if participants express a desire to seek care.

Dr. Hankerson will meet with participants who express a desire for a referral to mental health treatment. **He and his staff, Emely Santiago, MSW, and Dr. Faith Miller-Sethi will share the uniform-email response referring individuals to NYC WELL, Suicide Lifeline, the First Corinthian Baptist Church HOPE Center, and the online Psychology Today clinician finder. All participants will receive a copy of the New York Presbyterian Community Mental Health directory.** Dr. Hankerson will also utilize several online resources – www.bpgny.org and www.hitesite.org – to provide information for referrals based on low-cost clinic availability and the patient's insurance status.

Dr. Hankerson will also provide his professional contact information so participants can follow-up him in 1 week following the training to see if they were connected and / or are still interested in receiving care.

Risks/Discomforts/Inconveniences

Risks that could be encountered during the study period

Participation in this study has minimal anticipated risks. The 8-hour training MHFA training sessions and assessments are somewhat time consuming; participants may become tired.

During MHFA training sessions, we will schedule regular breaks and snacks for participants. If any of the material in the MHFA training is upsetting, we will have mental health treatment referrals available.

Describe procedures for minimizing risks

Participants reserve the right not to answer certain questions or to suspend their participation in the study. At the completion of the training all participants will be directed to discuss any concerns with Dr. Hankerson or a member of his research staff before they leave the church.



Participants are provided times for breaks as well as lunch breaks, with free food provided.

Methods to Protect Confidentiality

Describe methods to protect confidentiality

Participants' confidentiality will be protected in the MHFA Training Group sessions by the following methods:

- 1) Prior to MHFA training, the MHFA Instructor will inform participants that any personal information shared by other participants should be kept confidential.
- 2) The MHFA Instructor will inform participants that if they have any private / confidential issues they would like to discuss, Dr. Hankerson will be available to discuss with them privately.
- 3) Dr. Hankerson will provide all participants with his professional email (hankerss@nyspi.columbia.edu) and his professional telephone number (646-774-6429). He will inform participants that they can contact him if they would like to discuss anything that they would not like to discuss in front of other participants.
- 4) Participants identification will be protected in the Qualtrics evaluation survey because each participant will have a unique identification number.
- 5) Participants' phone numbers and addresses will be stored on a password protected desk computer. Participants's names will be replaced with unique study identifier to further protect their identity.

In addition, participant confidentiality to the extent permitted by law will be ensured by the following means:

*Each study participant will receive a code number through which all study data will be linked. The code will only be known by the Principal Investigator (Sidney Hankerson, MD) and the research team.

*Participant names, code numbers, and study data will be kept in a single locked file, accessible only to key personnel working on the study.

*Information stored on the computer will be coded numerically.

*All study data will be reported in tabular/group format while no individual data will be reported.

*Records will only be available to research staff, and State and Institutional regulatory personnel, who may review records as part of routine audits.

*Legal advocacy organizations that have the authority under state law can access confidential subject records, but cannot re-disclose this information without participant consent.



Will the study be conducted under a certificate of confidentiality?

No

Direct Benefits to Subjects

Direct Benefits to Subjects

Participants may benefit from this study by discussing the results of the interviews with the researcher. This research may help participants learn how to deal with stress and how the church can be utilized to provide mental health training for its members.

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?

Yes

Please describe and indicate total amount and schedule of payment(s).

Include justification for compensation amounts and indicate if there are bonus payments.

Research participants will receive a \$25 Gift card at two separate time points. The first Gift Card will be distributed immediately after completing the MHFA course. The second Gift Card will be distributed 3-months after the course upon completion of either the follow-up survey or the telephone interview.

Participants will also be provided a catered breakfast and lunch for free.

References

References

1. Kitchener BA, Jorm AF. Mental health first aid training for the public: evaluation of effects on knowledge, attitudes and helping behavior. *BMC Psychiatry*. 2002 Oct 1;2:10.
2. Kitchener BA, Jorm AF. Mental health first aid training in a workplace setting: a randomized controlled trial. *BMC Psychiatry*. 2004 Aug 15;4:23.
3. Reavley NJ, McCann TV, Cvetkovski S, Jorm AF. A multifaceted intervention to improve mental health literacy in students of a multicampus university: a cluster randomised trial. *Soc Psychiatry Psychiatr Epidemiol*. 2014 Oct;49(10):1655-66.
4. Hankerson SH, Fenton MC, Geier TJ, Keyes KM, Weissman MM, Hasin DS. Racial differences in symptoms, comorbidity, and treatment for major depressive disorder among black and white adults. *J Natl Med Assoc*. Jul 2011;103(7):576-584.
5. Gonzalez HM, Vega WA, Williams DR, Tarraf W, West BT, Neighbors HW. Depression care in the United States: too little for too few. *Arch Gen Psychiatry*. Jan 2010;67(1):37-46.



6. Williams DR, Gonzalez HM, Neighbors H, et al. Prevalence and distribution of major depressive disorder in African Americans, Caribbean blacks, and non-Hispanic whites: results from the National Survey of American Life. *Arch Gen Psychiatry*. Mar 2007;64(3):305-315.
7. Warden D, Rush AJ, Wisniewski SR, et al. Income and attrition in the treatment of depression: aSTAR*D report. *Depress Anxiety*. 2009 2009;26(7):622-633.
8. Nicolaïdis C, Timmons V, Thomas MJ, et al. "You don't go tell White people nothing": African American women's perspectives on the influence of violence and race on depression and depression care. *Am J Public Health*. Aug 2010;100(8):1470-1476.
9. Menke R, Flynn H. Relationships between stigma, depression, and treatment in white and AfricanAmerican primary care patients. *J Nerv Ment Dis*. 2009 2009;197(6):407-411.
10. DeHaven MJ, Hunter IB, Wilder L, Walton JW, Berry J. Health programs in faith-based organizations: are they effective? *Am J Public Health*. Jun 2004;94(6):1030-1036.

Uploads

Upload the entire grant application(s)

Upload copy(ies) of unbolded Consent Form(s)

CONSENT FORM #7224 UNBOLDED_6_27_18.pdf

Upload copy(ies) of bolded Consent Form(s)

CONSENT FORM #7224 BOLDED_6_27_18.pdf

Upload copy(ies) of unbolded Information Sheet(s)

Upload copy(ies) of bolded Information Sheet(s)

Upload copy(ies) of recruitment materials/ads to be reviewed

Telephone Script for MHFA recruitment 6.27.18.pdf

RSVP Confirmation Script 6.27.18.pdf

Thank you message for SNOWBALL SAMPLING 6.27.2018.pdf

Upload copy(ies) of the HIPAA form

Upload any additional documents that may be related to this study

Email script for 3 MONTH FOLLOW-UP SURVEY V. 6.27.18 (2).pdf

Email Script for Mental Health REFERRALS 6.27.2018.pdf

SCRIPT for Post-Training Interview Questions 6.27.2018.pdf