Testing Effectiveness of a Peer-Led Intervention to Enhance Community Integration

NCT02508480

Study Protocol

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THE RESEARCH PROPOSAL

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2. **Project Title:** Testing Effectiveness of a Peer-Led Intervention to Enhance Community Integration

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4. **Principal Investigator(s)**

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5. **Location(s)**

The study will take place at four of the clubhouses of Riverside Community Care - Neponset River Clubhouse in Norwood, MA; Eliot House in Needham, MA; Horizon House in Wakefield, MA; and Crossroads Clubhouse in Hopedale, MA. Dr. Russinova (PI) and Dr. Rogers have had multiple contacts with this entity for the purpose of conducting this study. The following person at Riverside Community Care is the coordinator for this study:

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Riverside Community Care
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Dedham, MA 02026
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The following are the clubhouse addresses:

Neponset River House
595 Pleasant St, Norwood, MA 02062
(781) 762-7075

Elliot House
255 Highland Avenue
Needham, MA 02494
(781) 449-1212

Horizon House
78 Water Street
Wakefield, MA 01880
(781) 245-4272

Crossroads Clubhouse
11 Williams St,
Hopedale, MA 01747
(508) 473-4715

In 2013, a pilot study entitled "Anti-Stigma Empowerment through Photovoice (ASEP)", CORRC # 2012-15, was completed at the Neponset River House in Norwood, MA. A total of 15 non-randomized subjects were enrolled with recruitment taking place in January 2013 and final follow up assessments completed in September of that year. This pilot study was designed to assess the feasibility of implementing the Photovoice program at Riverside. The Photovoice program and study protocol were well received by participants and we established a very strong partnership with the Clubhouse staff and had their support for the entire pilot study.

6. Subjects

The inclusion criteria for the study refer to individuals who are: 1)18 or older; 2) meet the State of MA definition of SMI based on an Axis I or II DSM-IV diagnosis and impairment in at least one major area of functioning for at least 12 months; 3) currently receiving services from Riverside; 4) willing to give written informed consent to participate in the study; and 5) conversant in English. Exclusion criteria include: 1) prior exposure to Photovoice; and 2) history or existing diagnosis of intellectual disability, based on chart records. We plan to recruit approximately 50% of the study sample among individuals with primary diagnosis of schizophrenia-spectrum (schizophrenia, schizoaffective, schizophreniform) disorder. We anticipate that most of the remaining study participants will have a primary diagnosis of a major mood disorder, and that a small proportion will have other disorders. This sample profile is reflective of the individuals served at Riverside clubhouses and by CBFS teams, since both programs are funded by the MA DMH and all recipients of services meet criteria for SMI as established by the MA DMH.

A total of 192 participants or 96 participants per group (Photovoice as the experimental condition and Services as Usual enhanced with a 60-minute peer-led group discussion as the control condition) will be recruited and randomized over a period of 36 months across the three clubhouses of Riverside Community Care where the intervention will take place. We plan to have randomization cohorts of 16 individuals per delivery of the Photovoice program at each of Riverside's three clubhouses (Needham, Norwood, and Wakefield). Given the projected sample size of 192 participants, we will have 12 randomization cohorts – 4 at each clubhouse implemented at 6-month intervals. Anticipating that not all individuals who sign the consent form complete the baseline interview and are therefore not randomized to a study group, we will enroll up to n=222 individuals in order to achieve our target sample size.

We have been implementing the study according to this plan and have had 4 waves of recruitment at Horizon House, 5 at Neponset River House, and 3 at Eliot House for a total of 12 waves of recruitment. However, recruitment has been slowing down and we are unable to enroll approximately16 individuals per wave as was planned. We had previously discussed a backup plan with Riverside leadership to extend the study to their clubhouse in Hopedale in the event that recruitment slowed down and we were not able to meet target recruitment. At this time, we would like to implement this plan. We have approval from the sponsor, NIMH, to proceed with this plan.The procedures at Hopedale will remain the same as they have been at the other clubhouses.

We worked with Riverside senior management to establish the non-overlapping number of clients with SMI served in the catchment areas for the three clubhouses where the Photovoice program will be offered. About 1,300 individuals with SMI are served on an annual basis in the three catchment areas (Norwood, Needham and Wakefield) where the study will be conducted; of them, approximately 900 individuals are served by the clubhouses and the CBFS teams, all of whom meet MA criteria for SMI, with approximately 50% diagnosed with a schizophrenia-spectrum disorder. Riverside treats approximately 200 new clients with SMI per year, with most being served at the clubhouses or by CBFS teams. Thus, there are an ample number of eligible participants for the study. Furthermore, in our pilot feasibility study at the Norwood clubhouse, 8 (53%) out of the 15 participants had a diagnosis of schizophrenia-spectrum disorder.

Potentially eligible consumers will be identified by informing staff and members of the three targeted clubhouses and the CBFS teams about the study and eligibility criteria for participating in it. Project staff will make presentations to Riverside clinicians and other staff as well as to clients served at the corresponding clubhouses and CBFS teams to inform them about the study. Referrals of potentially eligible participants to the study will be made by Riverside staff using a "Consent to Contact" form which will prevent project staff from having Protected Health Information prior to ascertaining the individuals' interest in study participation. Clients attending study presentations may also complete the Consent to Contact form at the end of the presentation. Along with the Consent to Contact form we will ask potential participants to sign the Riverside Release of Information form to obtain authorization for research staff to check chart diagnoses in order to confirm diagnostic eligibility.

When a referral using the Consent to Contact form is made to the project, the potential participant will be contacted by phone or in person by the Project Coordinator to further determine their understanding of the research and their interest in participation. Prior to the phone call the Project Coordinator will obtain information about the person's diagnoses, including history or diagnosis of intellectual disability. In case an interested individual has a diagnosis associated with intellectual disability, the Project Coordinator will contact this person and inform him/her that they don't meet the study eligibility criteria based on information in their chart record. The Project Coordinator will explain the following to interested individuals who meet diagnostic eligibility: the details of the study, random assignment to two conditions, the interventions, and the research interviews as well as provisions for maintaining privacy and confidentiality. The Project Coordinator will screen for inclusion and exclusion criteria during this initial contact. Thus, all screening will be completed prior to administration of informed consent without implications for participants' compensation; hence, no references to pre-consent screening are included in the ICF. If the person remains interested in the study, the Project Coordinator will set up an appointment for the informed consent. If a person has a legal guardian, the guardian will be involved in the consent process. For those individuals who do not have a guardian, the Project Coordinator will explain the study in person and ask a brief set of questions to determine whether the individual has understood the nature of the research project, including the assessments and treatment approaches. We will provide corrective information as needed if the individual is unable to answer the quiz questions during the consent process, followed by additional checking to assure a participant's full and knowing consent. Potential participants who continue to express interest in the study and are able to demonstrate their understanding of the study by correctly answering these questions will then be asked to sign the informed consent form. Individuals who meet the eligibility criteria and who are able to provide full and knowing consent will proceed to scheduling of the baseline assessment with the Clinical Interviewer. Upon completion of the baseline assessment, participants will be randomly assigned to either the experimental (Photovoice) or the enhanced Services as Usual (SAU) conditions. The Project Coordinator will contact each participant and explain their randomization condition. Participants randomized to participate in the Photovoice program will be informed about the date of their first Photovoice session and participants randomized to the control condition will be informed about the date of the 60-minute peer-led group discussion session about understanding and coping with prejudice and discrimination. The Clinical Interviewer will be blind to participants' randomization.

If an interested potential participant has a legal guardian, the guardian will be contacted by project staff and the consent process will take place with the guardian. This could occur by phone or in person. The guardian will be informed of the project details and will consent on behalf of the potential participant. We will proceed through an assent process with the participant where they are informed of the project details, informed of their guardian's involvement and consent and asked to agree to project participation and sign an assent form.

7. Research Methods and Procedures

We will conduct a randomized controlled trial (RCT) comparing the 10-week peer-led Photovoice program to services as usual (SAU) enhanced with a 60-minute peer-led group discussion session. The RCT will be conducted at a large publicly funded community mental health agency (Riverside Community Care, Inc.). The 10-session, peer-led Photovoice program, designed to empower individuals with SMI to confront public prejudice and discrimination and reduce personal stigma (self-stigma and perceived stigma), was developed and pilot tested at our Center, with primary contributions from staff with a lived experience of mental illness (see Photovoice Manuals and a Summary at Glance Table submitted as an attachment in this application.) The control SAU condition will be enhanced with a 60-minute peer-led manualized educational group session (Leaders' Guidelines and Handout for Participants are attached). The content of this session has been adapted from the Recovery Strategies module of the Illness Management and Recovery (IMR) program for the purposes of this project. It will provide participants with information about the nature of stigma and the laws in the U.S. that protect people with disabilities from discrimination. Participants will be engaged in a discussion about their use of different strategies for proactive coping with psychiatric stigma. This session will be co-led by the same peers who will be delivering the Photovoice program to the experimental group at relevant wave and study sites. An optional educational handout will be provided to participants who wish to have material in writing. In addition, participants randomized to the enhanced Services as Usual control condition will be invited to join a Photovoice group once they complete the final 6-month follow-up assessment.

A total of 192 individuals with SMI (50% with schizophrenia spectrum disorders) will be randomized to either the Photovoice program (plus usual services) or enhanced SAU. Participants will be assessed by the Clinical Interviewer at baseline, post-treatment, 3-month and 6-month follow-ups on a range of primary and secondary outcomes related to personal stigma, coping, and functioning. Primary analyses will test the hypotheses that the Photovoice program will lead to significantly greater reductions in self-stigma and perceived stigma, greater improvements in proactive coping with psychiatric prejudice and discrimination, and greater improvements in community functioning and integration than SAU. Secondary analyses will evaluate whether the Photovoice program leads to greater gains than SAU in psychological adjustment, including wellbeing, personal growth and recovery.

Outcome measures include demographics, diagnosis, symptoms, levels of self-stigma and perceived stigma, coping with stigma, psychosocial functioning, community integration, psychological wellbeing, and recovery. All assessment interviews will be conducted in individual, face-to-face meetings with study participants in private offices at the research sites. Psychiatric diagnoses will be determined at baseline with the MINI. Eligibility determination will be supplemented by chart review of psychiatric diagnoses and presence of intellectual disability. All other primary (personal stigma, community functioning and integration) and secondary (psychological wellbeing, personal growth and recovery) outcome measures will be evaluated at baseline, post-treatment, 3-

month and 6-month post-treatment follow-ups by the Clinical Interviewer who will be blind to the participant randomization status. The Clinical Interviewer will be trained in methods for eliciting self-report information, and standard interviewing procedures. In order to ensure high reliability and prevent rater drift of the Clinical Interviewer, we will audiotape all assessments and we will randomly select 10-15% for reliability checks. We will collect all relevant service utilization information from Riverside using their administrative databases after participants have completed the 6-month follow-up assessment. Eligible individuals who consent to participate at the study will complete a second Riverside Release of Information (ROI) form to authorize release of service utilization data since the first ROI will authorize only release of their chart diagnoses to determine eligibility.

We will be using the following measures to assess these outcomes:

Mini Neuropsychiatric Interview (MINI) - is a widely used 15-minute structured interview assessing the presence of 17 DSM-IV Axis I disorders with good concordance with the SCID and the CIDI and with acceptable test-retest reliability.

Brief Psychiatric Rating Scale - is a 24-item scale that rates severity of a variety of psychiatric psychotic symptoms, positive and negative symptoms on a 7-point scale of 1 (absent) to 7 (severe).

Approaches to Coping with Stigma - (Link et al., 1989) – is a 27-item, 4-point scale (strongly disagree to strongly agree) measuring strategies to cope with stigma: secrecy, withdrawal, distancing, educating others, and challenging others. The total score of the first three subscales will represent the index for Avoidant Coping and the total score of the last two subscales – the index for Proactive Coping with Stigma. Internal consistency for subscales range: .63-.84.

Internalized Stigma of Mental Illness Scale - a 29-item, 4-point scale (strongly disagree to strongly agree) assesses behaviors, thoughts and feelings that are self-stigmatizing and includes alienation, stereotype endorsement, discriminatory experiences, social withdrawal, and stigma resistance subscales. Internal consistency is .9 and test-retest reliability is .92.

The Stigma Scale (King et al, 2007) - is a 28 item, 5 point scale (strongly disagree to strongly agree) measuring experienced and anticipated stigma. Internal consistency ranges from .85-.87 and test-retest reliability from .4 to .7.

Heinrich's Quality of Life Scale-Client Version - Is a 21 item semi-structured interview based rating of individual's psycho-social functioning and satisfaction with various life domains.

Temple University Community Participation Scale - is a 26 item instrument measuring frequency of participation and importance of various community activities (e.g., movies, library). Test-retest reliability is .7 and internal consistency is .9.

Scales of Psychological Well-Being - is a 54-item measure rating wellbeing (from strongly disagree to strongly agree) including subscales of mastery, personal growth, purpose in life, self-acceptance, autonomy and positive relations with others. Internal consistency is .94. It has been successfully used with individuals with SMI.

Maryland Assessment of Recovery - is a 25-item scale that assesses a person's sense of recovery from mental illness across a variety of dimensions. Internal consistency is.95 and test-retest reliability is .89).

Personal Growth and Recovery Scale - (BU CPR, 2009) - is a 16-item, 4 point scale (strongly disagree to strongly agree) developed for previous Photovoice study. Items tap aspects of person's psychosocial functioning and recovery. Internal consistency is 0.94 and retest reliability is .79.

Photovoice Program Fidelity Scale - the Photovoice Fidelity Scale was developed and used in our pilot RCT study (Russinova et al., 2014). The scale includes content fidelity items specific to each of the 10 Photovoice sessions and 13 process fidelity items which are specific to the Photovoice program as a whole. All items are measured on a 4-point scale from 1, "strongly disagree" to 4, "strongly agree". All Photovoice sessions will be audiotaped and fidelity will be assessed based on review of all audio-recorded sessions.

We will use a **Demographic Questionnaire** developed by the Boston University Center for Psychiatric Rehabilitation and previously used in multiple research studies. Questions inquire about the person's demographic characteristics, such as age, race, gender, education, employment status, housing situation, and basic clinical characteristics, such as perceived physical health and use of different mental health services in the past 3 months. We are using an abbreviated version of this questionnaire at post-treatment and follow-up assessments to capture information only on time varying variables included in the questionnaire.

We will employ several strategies to retain participants in both the VEP sessions and in study assessments. First, we will use information from the Locator Form they will complete at baseline. We may also gather contact information from the participant's Riverside treatment team. Participants in the experimental arm will receive regular calls from the Photovoice peer leaders to encourage participation in classes. We have established a protocol for the peer leaders to call all participants the day before each Photovoice class. If they do not reach the participant, they leave a voice message. For participants who have expressed a preference for email reminders, peer leaders will send an email message the day before each class. If participants miss a class they will be to encouraged to continue their involvement. Calls from the Photovoice peer co-leaders will allow an opportunity to discuss with participants any barriers to participation, such as transportation issues and to take steps to remedy those barriers.

We will implement the following protocol for contacting participants in both the experimental and control condition about upcoming assessments. The Clinical

Interviewer will initiate a phone call with each study participant approximately two weeks before the due date of each assessment and will schedule an appointment to administer the assessment. If the participant is not available, the Clinical Interviewer will leave a message asking the participant to call back to schedule an assessment. If the participant does not respond within two days, the Clinical Interviewer will make another call using the same procedural approach. If the participant still does not respond within two days, the Clinical Interviewer will send an email if such is available and will follow up depending on the participant's response. At the same time, the Clinical Interviewer will contact Riverside staff involved in the study to inquire about the participant's whereabouts in case information about changes in the participant's programmatic status (i.e., hospitalization, expulsion, etc.) has not been already provided to the research staff. Participants agreement to have Riverside staff provide information about their thereabout will sought as part of the initial consenting for study participation. In addition, we will send a letter to the participant's known address with information about the relevant study assessment point. If the participant does not respond to the email and letter and there are no changes in their programmatic status, the Clinical Interviewer will call the contacts identified by the study participant on the Locator Form they completed at the baseline assessment and will ask about ways to contact the participant either directly via new phone number or email or indirectly with the help of the contact person. If all these efforts to reach the participant are not successful, they will be repeated for the next assessment point.

The data will be managed by project staff, using the same procedures we have used for longitudinal studies and randomized trials conducted by the Center. We will design systems for tracking specifically for this project using Microsoft Access.
We have used Microsoft Access for data management, to design data entry forms, to perform direct data entry, to monitor recruitment efforts and participant retention, and to track the timeliness of the scheduled assessments. We will develop and test these systems and will train the Clinical Interviewer in the use of the direct data entry procedures. The Clinical Interviewer will perform data entry in the field on a laptop using the data entry forms developed specifically for this study. The laptop used for data collection will not store any data in its hard drive. The data will be collected using a software application (REDCap) and stored on a secure network as described below.

Study data will be collected using the REDCap data collection system, a software tool developed at Vanderbilt University and made available through the Clinical and Translational Science Awards network (CTSAs). To help protect and secure the data stored in REDCap's database, the software application employs several methods to protect against malicious users who may attempt to identify and exploit any security vulnerabilities in the system. Access to the REDCap data entry website will be based on permissions granted by username and password which will be managed by the Boston University Medical Campus Office of Information Technology. Only authorized study members will be able to enter or view data. The login information (username) of the person submitting the information, the date and time submitted, and other navigational information will be automatically obtained and stored in the database.

Information posted on forms will be electronically encrypted using secure socket layering (SSL) encryption technology so that only the intended recipient can decode the data. Data will reside on a secure, password protected server at Boston University Medical Center (BUMC) to which only designated individuals have access, thus providing a secure environment for all project data. The database will be automatically backed up on a nightly basis. Files stored on BUMC servers will be protected by electronic 'firewalls' that restrict access to designated users. Restrictions and permissions to update the database will be controlled through the REDCap web application. Therefore, the data will not reside on the hard drive of the laptop used to access REDCap.

Once the data is downloaded onto the BU Network from the BUMC server it will reside in a server specific to the Center for Psychiatric Rehabilitation and within that in a project specific folder that only project staff have access to. This server while not HIPAA compliant has the layers of protection described above to restrict access. We have been storing research data on this server for several years and have not encountered any breaches in security of data. All project staff with access to the server have training in the protection of human subjects and specifically oriented to maintaining confidentiality of PHI. Access to the project specific folders is regularly monitored to ensure only current project staff have access to them.

In addition, a Microsoft Access relational database will be created to facilitate close monitoring of potentially interested participants, enrolled participants, recruitment efforts across sites, the status of completed and pending assessments, and adverse events (should they occur). Microsoft Access queries can be used to monitor the proportion and timeliness of completed assessments, provide "ticklers" for pending and upcoming assessments, and allow the PI to readily aggregate information about recruitment efforts by site. The data entered in REDCap will be downloaded as SAS datasets for analyses. A test of the procedures to export Access files and import them into SAS will occur when half the data have been entered.

Based on the NIMH reviewers' comments we will also consider conducting a small qualitative sub-study to examine the range of positive changes participants in the Photovoice program may experience beyond those measured with our quantitative scales. We have proposed to conduct 60-minute focus groups with interested Photovoice participants in each of the 12 waves of the study after the corresponding 6-month follow-up assessments have been completed. We will submit an amendment to this protocol and will develop a separate informed consent form for Photovoice participants invited to contribute to these groups at a later point when these plans are finalized.

Start Date and Duration of the Study*:* This study is slated to be completed in four years and the recruitment will take place in waves with 16 participants randomized at a time. Each participant will be in the study for about 34 weeks; this includes 10 weeks of the intervention period through the follow-up at six months.

8. Assessment of Risk to Subjects

We believe that there are minimal risks resulting from participation in this study. The study design does not require that the individual's current mental health services be disrupted or altered in any way. Furthermore, anecdotal information from piloting the photovoice program suggests that it is a meaningful and engaging intervention and one that resonates well with participants. We have had no indications of distress or concern on the part of participants who participated in the several pilot sessions of the Photovoice. However, should an individual become distressed during a session, there are several steps we will take to minimize and address problems. First, all sessions are being conducted by highly skilled and experienced peer specialists, including one co-leader who is a certified peer specialist. These individuals have been trained and supervised at the Boston University Center for Psychiatric Rehabilitation to deliver similar interventions so that they will be experienced in detecting signs of distress. Peer specialists from Riverside who will be trained as Photovoice co-leaders will receive additional training about detecting and addressing signs of distress during the delivery of the Photovoice sessions. All Photovoice peer co-leaders will receive ongoing supervision during the course of the proposed research as well to insure that they are handling any issues that arise during the study with skill and sensitivity. If a participant becomes distressed during a class, one of the co-leaders will attend to the person to determine if their distress can be alleviated within the class. If that is not possible, they will be brought out of the group setting and attended to privately. If the co-leader is unable to address the person's distress, clubhouse staff will be notified to intervene, and if necessary, the individual's clinician or case worker will be contacted for further assistance.

Similar procedures will be followed during the assessments. We have pilot tested several of the measures and have had no indications of distress during administration of these measures. However, should an individual become distressed during an assessment, the Clinical Interviewer will be instructed to attend to the person's distress by stopping the interview and inquiring about the source of the person's discomfort. The Clinical Interviewer will offer to have the individual take a break from the interview, discuss their concerns, and allay any concerns about the interview itself. We will also remind subjects during the interview that their participation is totally voluntary and that they can refuse to answer single questions, or to stop the interview if desired. Participants will be reminded that the information collected is confidential and will not be shared with Riverside staff. If the Clinical Interviewer is not successful in addressing the person's distress, he or she will contact Riverside staff using a written protocol we will establish with them in advance. That may include contacting the person's clinician or case worker depending on the procedures desired by Riverside senior administration. The Clinical Interviewer will receive training and supervision about how to identify and respond to distress among study participants and how to proceed using these guidelines. We have used such procedures in prior research studies with success.

We will take several steps to insure that staff follows procedures to maintain privacy and confidentiality. First, all new staff will be required to be oriented and trained in procedures to maintain confidentiality of information, including written and electronic materials. Staff is required to sign a Confidentiality Contract, which describes the serious nature of maintaining confidentiality and enumerates procedures for maintaining it. All project staff

will be required to take and pass the CITI training course on the protection of human subjects. In addition, project staff will be instructed about PHI, the need to identify individuals by arbitrary identification numbers, the need to file materials with names or key lists separate from research materials, electronic privacy, the need for non-identifiable correspondence materials from the Center, removing or blacking out participant names from any forms; sorting all data in locked file cabinets; securing all computers that store data; and destroying audiotapes used for interviewer reliability checks and fidelity ratings at the end of the project.

Study participants will be informed that information obtained through research interviews is confidential. Data will be identified by a unique identification number rather than by the participant's name or any other PHI. Research data will be stored in locked cabinets and are accessible only by research staff. Riverside staff will assist with study recruitment, but at no time will have research materials in their possession. All potentially sensitive materials will be in the possession of the project staff only. Computers that store research data are in secure offices at the Boston University Center for Psychiatric Rehabilitation. Computer files with sensitive data such as names are protected by passwords. The peer co-leaders of the Photovoice program are highly experienced and well trained in issues about sensitive information and the need to maintain the confidentiality of any discussions that arise during the Photovoice groups. Any distress that may be expressed during the Photovoice classes will be dealt with sensitively by the co-leaders. If appropriate, peer co-leaders may use any distressing experiences to further the understanding, knowledge and resources of other participants in the group to cope with stigma. In our experiences with the pilot studies of the Photovoice program, very minimal distress was experienced and it was generally related not to the intervention, but rather to participants' prior experiences of prejudice and discrimination.

Photovoice participants are also trained in the ethics of taking pictures - including obtaining permission prior to photographing individuals, and respecting the privacy and confidentiality of others. In addition, all photographs are screened by project staff for appropriateness prior to being shared with the rest of the class. With these measures in place we do not anticipate that pictures taken by participants would raise any safety/ mandatory reporting issues. Should such a situation arise we will work with Riverside clinical staff to report to appropriate authorities. Participants will be informed of the limits to confidentiality and the mandatory abuse reporting requirements for research staff through the informed consent form.

9. Procedures for Monitoring Subjects' Well-Being

The Clinical Interviewer who will be collecting data will be trained prior to data collection to identify potential signs of distress in the participants and how to address situations when a participant indicates any thoughts about ending his/her life and/or about hurting oneself. In the event that distress in a participant during an interview appears to present a risk of suicide, the interviewer will respond by following procedures we have developed and implemented in previous research studies at the Center for Psychiatric Rehabilitation. Statements made during interviews by participants about thoughts of death, hurting

oneself, or ending one's life will be followed up with the following questions by the interviewer to determine severity of suicide risk, based on item 4 of the Brief Psychiatric Rating Scale (BPRS):

"In the past two weeks, have you thought about harming or killing yourself?
•What about just feeling tired of life?
•Or that you'd be better off dead?
[if patient reports suicidal ideation, ask the following]:
•How often in the past two weeks have you thought about [use the patient's description]
•Did you (do you) have a specific plan?"

If the participant's score on this item is 2 or above, indicating mild or higher suicidal ideation, the interviewer will immediately contact designated Riverside clinical staff to provide appropriate care, without leaving the participant alone.

Photovoice peer leaders who encounter any similar reports of suicidal thoughts or intentions before, during, or after a Photovoice class will be taught how to follow up the statement by asking similar questions to those described above for the interviewer (in private, if the statement was made during a class), and will follow up by contacting immediately Riverside clinical staff using the same procedures described above for interviewers if significant suicide risk is identified in a participant. We will work with Riverside staff to establish a protocol of which clinical staff should be contacted to prevent any harm if significant suicide risk is identified in a participant. Study participants will be informed as part of the consenting process and at the beginning of each assessment that if they were to share any risk of harm to themselves or others, such information will not be kept confidential and clinical staff at the agency will be informed and will follow the procedures of the agency to ensure participants' safety.

10. Care and Treatment Statement

Participation in the study will not result in any change to the services outside of the study that participants are already receiving or plan to enroll in.

11. Informed Consent (See Part F)

Consent will be obtained in person in an individual meeting with the Project Coordinator. The details of the study contained in the informed consent form will be reviewed section by section. After each section of the consent, the Project Coordinator will ask if potential participants have any questions about that section of the consent form. Individuals will be requested to complete the quiz (see attached) to determine their capacity to consent before proceeding with obtaining their signature on the consent. The quiz responses will be reviewed discreetly to ensure that each individual gets 8 out of the 10 items correct. If an individual does not get the required number of answers correct, the Project Coordinator will review the incorrect answers with the individual and make an individual determination of the individuals' capacity to understand the details of the study and to give knowing consent. If the person is found to be capable of giving consent, the potential participant will be asked to sign the consent form. If the potential participant

does not appear to have the capacity to give consent, he or she will be advised that they cannot participate in the study. All participants will be provided with a copy of the consent for their records. In addition participants are informed that they are free to withdraw their consent at any time during the course of the study should they change their mind.

If a person has a legal guardian, the guardian will be involved in the consent process. The guardian will be contacted by the Project Coordinator and the consent process will take place with the guardian. This could occur by phone or in person. The guardian will be informed of the project details and will consent on behalf of the potential participant. We will proceed through an assent process with the participant where they are informed of the project details, informed of their guardian's involvement and consent and asked to agree to project participation and sign an assent form.

12. Benefits

Our pilot study of the Photovoice program has shown evidence of reduced self-stigma, increased ability to cope proactively with stigma, improvements in the level of personal recovery. We anticipate participants in this project may experience these benefits as well. The Photovoice program is a promising mental health intervention that could provide an engaging way of helping individuals with serious mental illnesses to deal with psychiatric stigma and increase their community integration and psychosocial functioning.

We consider that the potential benefits of this study greatly outweigh any minimal risks of discomfort.

13. Remuneration, Costs and Reimbursements

There will be no cost to participants for taking part in this study, the intervention including all the materials will be provided free of cost. Participants will be paid $50 for the baseline assessment, to account for the extra time necessary for the MINI, and for the 6-month assessment to encourage completion of the last evaluation. Payment for the post-treatment and 3-month follow-up assessment will be $40, as we anticipate that each assessment will last approximately two-and-a-half hours. Therefore, a participant who completes all four assessments will receive a total of $180 over the period of their participation in the study.

14. Explain why the research requires the participation of persons with mental illness.

This research requires the participation of persons with mental illness as it studies a new approach to addressing issues related to stigma among persons with mental illness and enhancing the ability of persons with mental illness to overcome the impact of stigma on their lives. The specific aim of this project is to evaluate the effectiveness of this approach that could improve quality of life of persons with mental illness.

15. Safeguards for Confidentiality

The Center for Psychiatric Rehabilitation has developed extensive procedures for the protection of privacy and confidentiality of all research data collected. First, we will use sequential numeric identifiers on all data collected and will not use the person's name or other sensitive data on the research data. Only Center for Psychiatric Rehabilitation research staff on this project will have access to the identifier and the name. All research materials will be stored at the Center for Psychiatric Rehabilitation in locked file cabinets and electronic data files. Documents containing data will be kept until all analyses are completed - likely until the end of 2019 – and will be shredded afterwards. Consent forms will be kept for seven years and shredded afterwards. No individual participating in this study will be identified by name in any report or description of study findings. The photographs taken by participants in the intervention will be the property of the participants and will not be disseminated without their permission to do so.

We will take several steps to insure that staff follows procedures to maintain privacy and confidentiality. First, all new staff will be required to be oriented and trained in procedures to maintain confidentiality of information, including written and electronic materials. Staff is required to sign a Confidentiality Contract, which describes the serious nature of maintaining confidentiality and enumerates procedures for maintaining it. All project staff will be required to take and pass the CITI training course on the protection of human subjects. In addition, project staff will be instructed about PHI, the need to identify individuals by arbitrary identification numbers, the need to file materials with names or key lists separate from research materials, electronic privacy, the need for non-identifiable correspondence materials from the Center, removing or blacking out participant names from any forms; sorting all data in locked file cabinets; securing all computers that store data; and destroying audiotapes used for interviewer reliability checks and fidelity ratings at the end of the project.

16. Final Product(s)

Final results will be reported in aggregate form only. Results may be prepared for publication in peer reviewed professional journals in mental health and rehabilitation, and used as preliminary data for future development of the intervention.

17. Financial Summary

The project is being funded by the National Institute of Mental Health - Grant Proposal MH102230-01A1.

18. Compensation for Injuries

We do not anticipate any injuries related to participation in the study and do not plan on any compensation for injury. There may be a minimal risk for physical injuries while individuals are taking pictures in the community. The Informed Consent Form informs participants that if this occurs, the cost of required medical services will have to be covered by their insurance or by them personally.

19. Insurance

There are no entitlements or insurance for the subject that will be purchased or invoked for this project. There is no other insurance purchased by Boston University for the subjects.

20. Use of DMH Resources

No DMH resources will be used for this study.

21. Other IRBs Involved

Boston University Charles River Campus (CRC) IRB.

22. Adverse Events

An adverse event for this study is consonant with the guidelines set forth by the MA DMH. Reporting guidelines will be followed in the event of an adverse event.

It is highly unlikely that we will experience a serious, unexpected adverse events related to study participation in the Photovoice intervention. Riverside staff will be asked to report any unexpected serious adverse event among study participants to the PI within 3 days of becoming aware of the occurrence of any such event. The Project Coordinator will be required to report such events to the PI within 24 hours of becoming aware of their occurrence. The PI will follow the requirements of the Data Safety and Monitoring Board and the MA DMH IRB (the IRB of record for the study): a) in case of a serious adverse event – verbal notification as soon as possible and in writing by the next business day following the event; and b) non-serious adverse event will be monitored, recorded, and reported to the IRB Chair every 4 months. The PI will notify NIMH within 7 days of becoming aware of the occurrence of a study-related serious adverse event and will report non-serious adverse events in the corresponding progress reports to NIMH.

Continuous and close monitoring of study participants' safety by the PI will occur in conjunction with the Dartmouth College Data Safety Monitoring Board (DSMB). The current research project is a Phase II trial, involves a low risk intervention, is not conducted with a vulnerable population, and is not blinded to participant or treatment provider. However, given that the research is being conducted in three locations within one agency, a Data Safety and Monitoring Board (DSMB) will be constituted to provide additional human subjects' oversight. Two Investigators on this project are faculty at Dartmouth Medical School: Drs. Mueser and Xie (statistician). Through this affiliation with Dartmouth, we plan to use their standing DSMB comprised of three psychiatrists and a psychologist (see attached bio sketches of the Dartmouth Medical School DSMB members). Dr. Mueser has used the Dartmouth DSMB for multiple prior RCTs, supported by NIMH, evaluating the impact of psychosocial interventions on persons with SMI. The DSMB will establish a risk level for the study, and based on that assessment

will determine the frequency of DSMB meetings and review of pertinent data. The DSMB Chair (Dr. Hegel) will be notified by the PI of serious adverse events that are study related using the protocol specified in the next paragraph. An ongoing record of all adverse events will be kept by the PI for use and review of the DSMB at the meetings. Minutes will be kept of DSMB meetings, including any discussion or decisions made about adverse events, and including those that could affect the conduct of the study. The DSMB will report back to the PI within one business day any implications for patient safety that arise from discussions during the scheduled DSMB meetings.

23. Required Attachments

Resume of the Principal Investigator
Certificate of Completion of the Human Subjects Training Course
Unaffiliated Investigator Agreement
Recruitment Flyer and
Consent to Contact Form
Informed Consent Form
Copies of the research instruments
Competency quiz

24. Attachments that are appropriate, when applicable:

(a) Approval Form(s) from other IRBs that have reviewed this project.
(b) Copies of non-standardized questionnaires, instruments, tests, etc.
(c) Copies of posters, flyers, letters, etc.
(d) Scripts of intended communications by telephone or interview.
(e) External research protocols (usually, only five (5) copies are required of the technical drug research protocols - check with the CORRC before submitting materials).