Date: May 18, 2021

Title: Peer Online Motivational Interviewing and Affirmative Care for Sexual and Gender Minority Male Sexual Abuse Survivors: A Randomized Clinical Trial

ClinicalTrials.gov ID: NCT03794986

This work was supported through a Patient-Centered Outcomes Research Institute (PCORI) Project Program Award (AD-2018C1-110989). All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.

HRP-503E– Protocol for Social or Behavioral Science or Educational Research (2017-1)

Protocol Title: Peer Online Motivational Interviewing for Sexual and Gender Minority Male Survivors

Principal Investigator: Joan M. Cook, Ph.D.

Version Date: 11.20.2018 (Version 1)

(*If applicable***) Clinicaltrials.gov Registration #:** NCT03794986

INSTRUCTIONS

This template is intended to help investigators prepare a protocol that includes all of the necessary information needed by the IRB to determine whether a study meets approval criteria. **Read the following instructions before proceeding:**

1. Use this protocol template for a PI initiated study that includes direct interactions with research subjects. Additional templates for other types of research protocols are available in the system Library:
   - If the study involves genetic testing, blood draws, or MRIs, do not use this form. Use the biomedical protocol template.
   - If the study involves secondary analysis of data, use the Secondary Analysis of Data protocol.
   - For activities that may qualify as exempt research, use the Request for Exemption form (which includes a decision tree to determine whether or not your study qualifies as exempt).
2. If a section or question does not apply to your research study, type "Not Applicable" underneath.
3. Once completed, upload your protocol in the "Basic Information" screen in IRES IRB system.

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SECTION I: GENERAL INFORMATION

1. **Probable Duration of Project:** State the expected duration of the project, including all follow-up and data analysis activities.

The active phase of the study will take place over three years (i.e., no data collection past year 3). However, we anticipate data analysis will occur for two additional years making the entire duration of the study 5 years.

2. **Study location:** State where the study will take place and in what setting.

The study will include peer leaders from two non-profit organizations, MaleSurvivor and Men Healing, as well as emotionally distressed sexual and gender minority male survivors who have not recently engaged in mental health care. The study will largely take place in online discussion groups and via telephone/teleconferencing calls.

This is the second Patient-Centered Outcomes Research Institute (PCORI)-related grant that we have had in partnership with MaleSurvivor, a non-profit trauma survivor organization that provides resources to male abuse survivors and their loved ones worldwide. Their website currently sees hundreds of thousands of visits annually from persons all over the world, and their social media platforms reach millions every month with news and messages of hope, healing, and support. MaleSurvivor has over 5,250 followers on Facebook, and over 11,000 followers on Twitter. In addition, MaleSurvivor distributes their newsletter to over 12,000 unique, active email addresses. They also currently have 39 active online discussion forums that reach people worldwide.

If international, complete and submit **International checklist** (http://your.yale.edu/policies-procedures/forms/450-ch-1-international-research-checklist) Note: If your research involves interactions with any embargoed countries you should contact the Director of Corporate Contracts and Export Control Licensing (Donald.Deyo@yale.edu or call 203.785.3817) for guidance on how to proceed.

3. **Help us categorize your research**. Are you using any of the following?

☐ Class Project
☐ Participant Observation
☒ Interviews
☒ Surveys
☐ Focus groups (study is not anonymous)
☐ Research in K-12 schools (submit a School Agreement form for the study)
☐ Deception (submit a Debriefing sheet)
☒ Audiotaping, videotaping or photography of individuals (study is not anonymous)
☐ Public viewing of videotapes or photographs
☐ Yale Psychology Pool (study does not qualify for exemption)
☐ International research sites (attach the International Checklist)
☒ Online (web-based) activities
☒ Social networks

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SECTION IV: RESEARCH PLAN

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested.

This study builds on the findings from our Eugene Washington PCORI Engagement Award, entitled, "Facilitating Male Trauma Survivors' Meaningful Involvement in Health Research." Together with our non-profit community partner, MaleSurvivor, we tailored an evidence-based psychological treatment, motivational interviewing (MI; Miller & Rollnick, 2013) with trauma-informed, sexual and gender minority (SGM) affirmative care in order to encourage formal engagement in mental health treatment and reduce health disparities for SGM male sexual abuse survivors.

We then applied for and received a comparative effectiveness trial funded through PCORI (AD-2018C1-11098) entitled, "Peer Online Motivational Interviewing for Sexual and Gender Minority Male Survivors." The first specific aim is to train peer leaders to competently deliver MI in both its original and tailored versions. The second specific aim is to conduct a randomized controlled trial (n=356) to determine the comparative effectiveness of MI versus MI with trauma-informed SGM-affirmative care delivered by peers in online male survivor discussion groups. Our first hypothesis is that peer leaders will be able to effectively deliver both versions of MI. Our second hypothesis is that SGM male survivors who are randomized to tailored MI will significantly increase their engagement in formal mental health treatment, and reduce trauma-related symptoms as compared to SGM survivors who participate in traditional MI.

2. **Background:** Describe the background information that led to the plan for this project. **Provide references** to support the expectation of obtaining useful scientific data.

One in six men are sexually abused before their 18th birthday (Dube et al., 2005) and this number rises to one in four men who are sexually abused across their lifespan (Centers for Disease Control and Prevention, 2018). Survivors of sexual abuse and assault are at risk for a wide range of medical, psychological, behavioral, and sexual disorders (Maniglio, 2009). Indeed, sexual trauma is related to numerous psychiatric disorders, including PTSD, substance abuse and dependence, depression, anxiety, and suicidal behavior (Dube et al, 2005; Mohar, Buka, & Kessler, 2001). Men with histories of childhood and adult sexual victimization are more likely to report greater numbers of sexually transmitted infections, increased sexual risk for human immunodeficiency virus (HIV), higher sexual compulsivity, and greater gay-related stigma beliefs than men with no history of sexual assault (Hequembourg, Bimbi, & Parsons, 2011). In addition, men who have experienced sexual abuse report significantly greater educational, occupational and relationship difficulties than non-abused men (Lisak, & Luster, 1994). Sexual trauma is also linked to medical illnesses, increased health care utilization and poor quality of life (Kartha et al., 2008; Maniglio, 2009; Paras et al., 2009).

SGM male survivors of sexual trauma face significant health disparities. They are exposed to traumatic events, particularly sexual violence, at higher rates than the general population (Brown & Pantalone, 2011; Rothman et al., 2011). In addition, SGM male survivors exhibit significantly more negative psychological outcomes related to their sexual identities, including lower self-esteem (Smith, Cunningham, & Freyd, 2016), sexual identity formation disturbances, and difficulties forming healthy adult intimate relationships (Williams, Kisler, Glover, & Sciolla, 2011). The cumulative traumatic impact of sexual abuse, in conjunction with individuals' SGM status, also appears to result in higher rates of sexual re-victimization (Aosved, Long, & Voller, 2011), and anti-gay violence and discrimination (Badgett, 1995; Herek & Berrill, 1992; Human Rights Watch World Report, 2018; McLaughin, Hatzenbuehler, Xuan, & Conron, 2012; Safe Schools Coalition Annual Report, 2018).

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In addition to higher rates of sexual victimization, SGM males also experience significant minority stress, a term used to describe the sociopolitical stressors placed on individuals as a result of their minority status. Sexual orientation mental health disparities start relatively early in development. SGM individuals are disproportionately exposed to day-to-day discrimination, peer and parental rejection, unsupportive or hostile work or social environments, and unequal access to opportunities afforded to heterosexuals, including marriage, adoption and employment non-discrimination (Balsam, Rothblum, & Beauchine, 2005). Chronic expectations of rejection, internalized homophobia, alienation, and lack of integration with the community, can understandably lead to problems with self-acceptance (Hatzenbuehler, 2009; Meyer, 2003). As a result, SGM men may feel deficient, inferior or impaired. Further, they may view themselves as shameful, undesirable, underserving, or incapable of forming a loving relationship. Indeed, SGM individuals are significantly more likely than heterosexual males to report experiencing mental health problems, like depression and anxiety, as well as several behavioral health risks, such as alcohol use and risky sexual behavior (Hequembourg et al., 2011).

Preliminary studies suggest the acceptability, feasibility and potential ameliorative effects of peer-based online support for trauma survivors (Hundt, Robinson, Arney, Stanley, & Cully, 2015; Watson & Andrews, 2017) as well as SGM individuals (Westra, Aviram, & Doell, 2011).

Motivational Interviewing to Engage SGM Male Survivors in Mental Health Treatment

Increasing SGM male sexual abuse survivors' formal entry into mental health services may serve to address an important healthy disparity by alleviating psychiatric distress, increasing quality of life, and helping these men get the treatment they need and deserve. Motivational interviewing could help in assisting SGM men to enter mental health treatment. Motivational Interviewing is an evidence-based, patient-centered approach that explores and develops patients' motivation and commitment to change within a collaborative, highly empathic patient-clinician relationship (Miller & Rollnick, 2013; Miller & Rose, 2009). Clinicians blend a combination of fundamental patient-centered counseling techniques (e.g., reflective listening) with advanced strategic methods (e.g., develop discrepancies between important life goals and current behavior) to elicit patient statements that favor change, called "change talk" and diminish those that argue against change, called "sustain talk." The proficient use of MI methods has been shown to increase change talk and decrease sustain talk, which in turn has predicted behavior change (Apodaco et al., 2014).

Originally empirically validated for reducing substance use disorders, MI is now used to help individuals develop motivation to change a variety of other health-related problem behaviors (e.g., treatment non-adherence, poor weight management) and mental health issues highly comorbid with trauma, such as depression, anxiety, and eating disorders (Burke, Arkowitz, & Menchola, 2003; Rubak, Sandbaek, Lauritzen, & Christensen, 2005). MI has also been used as stand-alone or adjunct intervention to help people engage in more intensive mental health services (Seal et al., 2012). For example, in a sample of Iraq and Afghanistan veterans with mental health difficulties, four sessions of telephone-delivered MI increased intent to engage in mental health services and resulted in some improvements in mental health symptoms (Seal et al., 2012). In addition, among depressed and anxious college-age men, MI had a small to moderate effect on both professional and non-professional help-seeking behavior (Syzdek, Green, Lindgren, & Addis, 2016.

Though most often tested as an individually-delivered intervention, MI is also delivered in a group format (Westra et al., 2011), and a few randomized controlled trials have shown significant group MI treatment effects (Seal et al., 2012; Murphy & Rosen, 2006). Moreover, MI can be taught to a broad range of healthcare providers, including general practitioners (Soderlund, Madson, Rubak, & Nilsen, 2011), physician assistants (McLaughlin, Fasser, Spence, & Holcomb, 2010), and nurses (Lane, Johnson, Rollnick, Edwards, & Lyons, 2003). Thus, MI can be flexibly tailored and delivered to meet the needs of different populations and settings in which helping people become motivated for change is a core mission. In

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addition, a recent national initiative found that peer specialists can be successfully trained to deliver MI in the Department of Veterans Affairs health care system (Tsai et al., 2017). Thus, MI interventions can be taught to peers and can be easily integrated into usual care, facilitating dissemination and improving sustainability of the intervention.

The efficacy and effectiveness of MI has also been studied when delivered online. In fact, MI has also been adapted for online formats for weight loss (Webber, Tate, & Quintilliani, 2008; West et al., 2016), substance abuse, and eating disorders (Hotzel et al., 2014). In fact, some clients reported that, the web-based program felt less shameful, embarrassing, and uncomfortable than in-person treatments (Osilla, D'Amico, Diaz-Fuentes, Lara, & Watkins, 2012).

3. **Research Plan:** Summarize the study design and research procedures using non-technical language that can be readily understood by someone outside the discipline. If working with a Non-Government Organization (NGO) or other organization, be sure to highlight which are research-only activities and which activities would occur regardless of the research. If working with survey firms, please specify what research activities the research firm will be responsible for.

We will conduct a randomized comparative effectiveness trial of peer-facilitated, online, 6-week group MI vs. MI with a trauma-informed SGM affirmative care approach. Randomization will be counterbalanced by treatment status: treatment naive versus treatment-experienced (prior treatment not within the past 60 days). Randomization will be based on a list of computer-generated random numbers. We will randomize 356 SGM male trauma survivors to either condition. Assessments will occur at baseline, post-intervention, and at 60- and 120-day follow-ups, from the end of the intervention.

Comparators. Traditional MI will be compared to MI with trauma-informed SGM affirmative care (MI+). Groups will take place 1.5 hours once a week for 6-weeks and will be led by two peer specialists trained in MI or tailored MI. Groups will consist of approximately 8-10 members and be closed for the duration of the group. It is anticipated that new groups will begin every other month (allowing for a two week break between groups) to reduce burden on peer specialists and supervisors.

Traditional MI groups. Six traditional MI groups will take place for 1.5 hours online facilitated by two peer specialists.

Trauma-informed, SGM+ affirmative care MI groups. Six tailored MI groups will take place for 1.5 hours online facilitated by two peer specialists. Please see Appendix A for a detailed overview and outline of the major supplemental MI modules aimed at SGM minority stress, traditional masculinity, and male sexual abuse.

Through workshops and ongoing supervision/consultation, we will train peer leaders to competently deliver both versions of MI and conduct a randomized controlled trial comparing the two versions of MI to enhance treatment engagement in SGM male survivors with mental health problems. All SGM male survivors who meet inclusion criteria, including significant emotional distress, will complete pre-test measures and be randomized to 6-week traditional MI delivered by peers in online groups or 6-week MI with trauma-informed, SGM affirmative care delivered by peers in online groups. Randomization will be counterbalanced by treatment status: treatment naive versus treatment-experienced (prior treatment but not within the past 60 days). This same procedure of counterbalancing by treatment status was previously used in the randomized controlled trial of MI (Burke et al., 2003) to help Iraq and Afghanistan veterans with mental health difficulties engage in more mental health services. Participants will complete pre-intervention (baseline), end of the 6-week intervention, 60- and 120-days follow-up assessments via an online survey platform, to determine if there was an increase in formal mental health treatment engagement, and any significant changes in mental health symptomology (i.e., PTSD, depression, high-risk drinking, and

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illicit substance use). Peer leaders will co-facilitate groups throughout the study. It is anticipated that a peer leader will run between 1-3 groups throughout the study.

Parent Study Screening and Participant Eligibility Criteria.

Once recruitment advertisements are posted on the various websites (listed in detail below), those interested in finding out more information, will be directed to a website that contains the informed consent and Frequently Asked Questions about participation. Participants will then be asked to complete a short questionnaire including demographic questions with their contact information to be sent to a member of the research team to set up a screening appointment via telephone with the interested participant.

Screening

Demographics and SGM Identification. Participants will be asked about their age, gender at birth, current gender identification, race/ethnicity, sexual orientation, marital status, highest level of education, and employment status at screening. Participants will also be asked about their treatment status to ensure eligibility (not currently in mental health treatment and/or have not been in treatment for past 60 days). Across post-interventions and follow-ups, participants will be asked if there are any changes to their employment, education, or marital status.

Sexual Abuse Characteristics. Participants will be asked about the age of onset of sexual abuse; type of abuse (e.g., penetration, non-penetration); number of perpetrators; relationship to their perpetrator(s); and the frequency of the abuse. Participants will also be asked if someone had found out about the abuse while it was occurring, and if they received any kind of psychotherapy or counseling as a result.

Current Experiences of Distress will be measured using the ***Center for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977),*** a 20-item questionnaire that asks about experience and frequency of depressive symptoms over the past week. A score of 16 or higher identifies those individuals who are at risk for major depression. This score will be used as our cutoff for inclusion in the study.

Life Events Checklist (Blake et al., 1995) is a self-report measure that screens for 16 potentially traumatic events across individuals' lifetimes. Participants note whether the event happened to them personally, they witnessed it happen to someone else, they learned about it happening to someone close to them, or if it does not apply or does not fit.

MINI (Sheehan et al., 1998) is a structured interview that takes approximately 15-20 minutes to administer. The MINI is used extensively in research studies to make fairly quick and accurate diagnoses of psychiatric disorders and will be used here to assess, in part, for exclusion criteria.

The ***Telephone-Assessed Mental State (TAMS; Lanska et al., 1993)*** is a brief, easily administered, easily scored cognitive assessment tool which can be administered by telephone. The TAMS uses 4 items from the extensively used Mini-Mental State Examination (MMSE) to assess for orientation to time and place, attention, and memory. In the population sample of Alzheimer's disease patients, TAMS scores correlated strongly with those of instruments administered face to face, including the MMSE.

The Service Use and Resource Form (SURF; Rosenheck et al., 2016) is a questionnaire assessing current living situation, use of inpatient and outpatient mental health and alcohol or drug treatments, psychotropic medication use, and use of other support services. The SURF will be administered during

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screening, baseline, post-intervention and follow-up. This measure takes approximately 10-15 minutes to complete.

The ***Columbia-Suicide Severity Rating Scale (C-SSRS; Posner et al., 2011)*** is a widely used measure of suicidality that has been successfully implemented across many settings (e.g., military, primary care, etc.). It has demonstrated good convergent and divergent validity with other multi-informant suicidal ideation and behavior scales and has high sensitivity and specificity for suicidal behavior classifications. It is also sensitive to change over time. The C-SSRS is available in several versions free of charge, including a brief 6-item screener which can be used as a self-report or interview measure. The C-SSRS screener will be administered during the phone screening interview and at baseline, post-intervention and follow-up assessments. Any participants endorsing "high-risk" responses (i.e. those coded in red) will be flagged, and Drs. Cook, Ellis, or Simiola will conduct a follow-up phone assessment to determine their suicide risk and make a final eligibility determination.

Outcomes

Those participants who meet inclusion criteria will be provided a link to the online surveys for baseline assessment. Measures will include prior and current mental health treatment engagement, barriers and beliefs around seeking formal mental health treatment, as well as measures assessing symptomatology (e.g., substance use, depression, PTSD). At the completion of the 6-week group, participants will complete post-intervention assessments and 60- and 120-day follow-up assessments on the various outcome measures. A summary of the timing and purpose of assessments is shown in Table 1.

Baseline, Post-Intervention and Follow-up Outcomes

Primary Outcome: Mental Health Treatment Engagement. The primary outcome here will be the binary distinction between those who initiated mental health treatment/reinitiated mental health treatment versus those who did not. Mental health treatment engagement will be operationally defined as having ≥1 visit(s) or scheduled appointments to any mental health services within 120 days of the last online group.

Primary Outcome: Depression. Center for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977) is a 20-item questionnaire that asks about experience and frequency of depressive symptoms over the past week. A score of 16 or higher identifies those individuals who are at risk for major depression.

Secondary Outcome(s): will include PTSD, alcohol and drug abuse, quality of life, and service utilization.

PTSD Checklist for DSM-5 (PCL-5; Weathers et al., 2013) is a 20-item instrument that corresponds to the current psychiatric diagnostic criteria for PTSD.

Alcohol, Smoking and Substance Involvement Screening Test (ASSIST; WHO ASSIST Working Group, 2002; Humeniuk et al., 2008) is an 8-item measure of participants' use of alcohol, tobacco products, and other drugs across their lifetime and in the past three months.

Inventory of Psychosocial Functioning (IPF-B; Rodriguez, Holowka, & Marx, 2012) is a brief 7-item scale that assesses functional impairment or quality of life related to trauma and PTSD.

The Service Use and Resource Form (SURF; Rosenheck et al., 2016) is a questionnaire assessing current living situation, use of inpatient and outpatient mental health and alcohol or drug treatments, psychotropic medication use, and use of other support services. The SURF will be administered during screening, baseline, post-intervention and follow-up.

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The ***Columbia-Suicide Severity Rating Scale (C-SSRS; Posner et al., 2011)*** is a widely used measure of suicidality that has been successfully implemented across many settings (e.g., military, primary care, etc.). The C-SSRS is available in several versions free of charge, including a brief 6-item screener which can be used as a self-report or interview measure. The C-SSRS screener will be administered during the phone screening interview and at baseline, post-intervention and follow-up assessments. Any participants endorsing "high-risk" responses (i.e. those coded in red) will be flagged, and Drs. Cook, Ellis, or Simiola will conduct a follow-up phone assessment to determine their suicide risk and make a final eligibility determination.

The ***Brief Dissociative Experiences Scale (DES-B Modified; Dalenberg & Carlson, 2010)*** is a brief 8-item self-report measure that assesses the severity of dissociative experiences in individuals aged 18 and older. Higher scores indicate a greater severity of dissociative experiences. As the DES-B can track changes in the severity of brief dissociative experiences over time, participants will be asked to complete the measure at baseline, post-intervention, and follow-up assessments.

Potential Moderators:

Barriers to Help Seeking Scale (BHSS; Mansfield, Addis, & Courtenay, 2005) is a 31-item scale measures several barriers to help-seeking (e.g., need for control and self-reliance, minimizing problem and resignation, concrete barriers and distrust of caregivers, privacy, and emotional control).

Conformity to Masculine Norms Inventory (CMNI-46; Parent & Moradi, 2009) assesses conformity to the following masculine norms: winning, emotional control, primacy of work, risk-taking, violence, heterosexual self-presentation, sexual activity, self-reliance, and power over women.

Minority Stress Scale (MSS; Norcini Pala et al., 2017) is a 43-item questionnaire that assesses individuals' experiences of stigmatization, discrimination, and internalized homophobia due to their sexual orientation.

Working Alliance Inventory (WAI; Horvath & Greenberg, 1989), is a well-established measure of the therapeutic relationship. The measure contains three subscales (i.e., agreement on the goals of therapy, agreement on the tasks of therapy, and bond between client and therapist).

Adult Resilience Measure – Revised (ARM-R; Resilience Research Centre, 2018; Jefferies, McGarrigle, & Ungar, 2018) is a 17-item scale of social-ecological resilience designed to measure the resources (individual, relational, communal and cultural) available to individuals that may bolster their resilience.

Preferences Interview. A sample subset of the sample (N = 110) will be invited for a telephone interview where we will ask questions about treatment preferences (e.g., group versus individual, telehealth versus in person, etc.) to gain additional information from patients about their needs and wants for mental health treatment. Participants will be selected randomly from each intervention. Sampling will occur until 110 interviews are completed. Participants will be invited for the interview during the post-intervention assessment and all interviews will be completed within three months (to allow for scheduling) of the participant completing the intervention.

Peer Specialists

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Peer Training/Treatment Integrity. We will utilize the Independent Tape Rater Scale (ITRS; Martino, Canning-Ball, Caroll, & Rounsaville, 2011), a 39-item measure with items rated on a 7-point Likert scale, to monitor adherence to and competence in MI concepts. The ITRS will assess the degree to which peer leaders delivered both interventions with fidelity (i.e., with adherence and competence). The ITRS includes items that cover therapeutic strategies that are MI consistent (e.g., reflections) or inconsistent (e.g., unsolicited advice). For this trial, we will add 15 items that detail key aspects of trauma-informed, SGM affirmative care (e.g., avoiding gendered language, affirming healthy expressions of sexual orientation and identity, affirming and validating strengths of SGM males, and reframing help-seeking as a focus on regaining control over one's life). For each item, raters evaluate the peers for adherence (i.e., the extent of intervention delivery) and competence (i.e., the skill/quality of intervention delivery) along 7-point Likert scales. Namely, at least half the MI consistent items rated average or above for both adherence and competence. In addition, we will evaluate the degree to which peers addressed trauma-informed, SGM affirmative care during the session. Our investigative team has documented experience training ITRS raters to perform reliable ITRS session process ratings in randomized trials (Martino, Ball, Nich, Frankforter, & Carroll, 2008).

Fidelity monitoring will occur ad hoc by independent raters using audio-recordings of intervention sessions. At least 30% of the sessions (traditional MI and trauma-informed MI) will be coded (n =90). Three coders will rate each session. Dr. Steve Martino will host a training with the raters to familiarize them with the rating scales and interventions. The three raters will conduct the fidelity ratings over a six to eight month period (approximately) between June 2021 and February 2022. The three raters (Karen Hunkele, Tami Frankforter and Joanne Corvino) have previous experience conducting this task and will be supervised by Dr. Martino. Audio recordings of selected group sessions will be sent to the raters using Yale's secure file transfer (FileLocker).

Assessment Measures. Peer specialists will also be asked to complete a reflective journaling exercise (see attached) after each treatment cycle they co-facilitate. In addition, they will complete several assessments measures (see attached) prior to their attendance at the MI training then again after they attend the MI training. Peer specialists will be asked to answer approximately three open-ended questions at the end of the study.

Table 1: Assessment Schedule

Assessment Name		Screening	Baseline	Post-intervention	60-Day Follow-up	120-Day Follow-up
Peer Specialists	Independent Tape Rater Scale			x		
Male Survivors	Demographic and SGM identification	x	x	x	x	x
	Sexual abuse characteristics	x				
	Life Events Checklist	x				
	Mini International Neuropsychiatric Interview	x				
	Telephone-Assessed Mental State (TAMS)	x				
	Columbia-Suicide Severity Rating Scale (C-SSRS)	x	x	x	x	x

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	Brief Dissociative Experiences Scale (DES-B Modified for DSM-5)		x	x	x	x
	Center for Epidemiological Studies-Depression Scale	x	x	x	x	x
	PTSD Checklist for DSM-5		x	x	x	x
	Alcohol Smoking and Substance Involvement Screening Test (ASSIST)		x	x	x	x
	Inventory of Psychosocial Functioning		x	x	x	x
	Barriers to Help Seeking Scale		x	x	x	x
	Conformity to Masculine Norms Inventory		x	x	x	x
	Minority Stress Scale		x	x	x	x
	Working Alliance Inventory			x		
	Service Use and Resource Form (SURF)	x	x	x	x	x
	Adult Resilience Measure – Revised (ARM-R)		x	x	x	x

Participant Population: Provide a detailed description of the types of participants who will be recruited into this study.

The study will include peer leaders from MaleSurvivor and Men Healing as well as emotionally distressed SGM male survivors who have not recently engaged in mental health care and will largely take place in online discussion groups.

4. **Describe** how access to the population will be gained in the study.

As an organization, MaleSurvivor and Men Healing have been active in trying to dispel societal prejudice that keeps male survivors from engaging in research and participating more actively in health care decision-making. As such, we will establish a community-based research advisory board to facilitate the identification and enlistment of participants. In conducting focus groups with male survivors through our PCORI Engagement Award, we met a number of survivors who expressed an interest in working with us on future research studies. We will enlist and collaborate with them on how best to approach survivors. We will also work with these survivors to develop plans to share the study progress and results in formats most useful to the different communities involved, including SGM participants, other survivors and their families.

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5. **Participant classification:** Check off all classifications of participants that will be specifically recruited for enrollment in the research project. Will participants who may require additional safeguards or other considerations be enrolled in the study? If so, identify the population of participants requiring special safeguards and provide a justification for their involvement.

☐Children	☐ Healthy	☐Fetal material, placenta, or dead fetus
☐Non-English Speaking	☐ Prisoners	☐Economically disadvantaged persons
☐Decisionally Impaired	☐ Employees	☐Pregnant women and/or fetuses
☐Yale Students	☐ Females of childbearing potential	

X No special populations will be specifically recruited for enrollment.

NOTE: Is this research proposal designed to enroll children who are wards of the state as potential participants? ☐Yes ☒No

6. **Inclusion/Exclusion Criteria:** What are the criteria used to determine participant inclusion or exclusion?

Inclusion criteria will include 18+ age or older; English-speaking; men who have sex with men or individuals identifying as SGM males; individuals who report a history of sexual abuse; and individuals who self-report a minimum cut-off score of 16 or higher on depression, using a 20-item depression inventory. Similar to previous investigations with SGM males, we are using minimum distress scores to ensure that the sample adequately represents the population of SGM males who would be more inclined to seek intervention. A member of the research team will also administer the Mini International Neuropsychiatric Interview (MINI) to assist in determining participants' eligibility.

Exclusion criteria will include individuals who endorse active psychosis or cognitive impairment per the MINI and TAMS, respectively. We will also exclude SGM men who report that they are currently in formal mental health counseling. Participants who are actively suicidal will be excluded. The Columbia-Suicide Severity Rating Scale will be used to measure suicidal behavior and ideation. If a participant screens high risk a study psychologist will follow-up to assess imminent danger and provider resources as appropriate and noted in the protection of human subjects section.

SECTION V: RECRUITMENT/CONSENT AND ASSENT PROCEDURES

1. Recruitment Procedures:

a. Describe how potential participants will be identified and contacted, and by whom.

In addition to posting recruitment advertisements on the MaleSurvivor website and discussion boards, participants will also be recruited through social and informational networking websites and mobile applications, and affiliate websites. The following male sexual abuse survivor websites will be used for recruitment: MaleSurvivor; 1in6; and Ark of Freedom Alliance. The following SGM websites will be used for recruitment: GLBT National Help Center, and The Association for Lesbian, Gay, Bisexual & Transgender Issues in Counseling. A full list of potential recruitment sites/organizations provided as an Appendix A. Flyers were created that target different populations and organizations (Appendix B). The flyers will direct interested persons to our study website for additional information, contact information,

further eligibility requirements and procedures for enrollment. Flyers will be provided to organizations as a recruitment tool. Flyers will also be used in listserv distributions/mass e-mails through the organizations. We will also recruit on social media and sexual networking websites (e.g., Facebook, Twitter). A list of potential social media messages is included in Appendix C. These will be posted on the social media pages of sites/organizations included in Appendix A. We anticipate snowballing recruitment through social media (sharing of posts). Research suggests that strategies that involve photos related to the target population, and that modalities such as Facebook may be the most promising due to its ability to select criteria such as relationship interests (men interested in men), gender, and ethnicity in recruiting SGM males online. The flyers will be attached to social media posts. We will also utilize op-ed pieces written for the public as a recruitment strategy.

Study personnel including the investigators, research coordinator, research assistants will contact and consent participants. Consent will be obtained prior to screening patients.

Are you collecting any information about the individuals prior to their signing a consent form?
Yes ☐ No☒

If yes, indicate what information you will be collecting and how it will be gathered *(phone screen, paper questionnaire, etc.)* Click or tap here to enter text.

2. Indicate recruitment methods below. Attach copies of any recruitment materials that will be used.

☒Flyers	☒ Internet/web postings	☐ Radio
☐ Posters	☒ Mass email solicitation	☐ Telephone
☐ Letter	☐ Departmental/Center website	☐ Television
☐ Through local NGO or other local contact	☐ Departmental/Center research boards	☐ Newspaper
☐ Table set-up / in-person recruitment of public	☒ Snowball sampling	
☐ Classroom recruitment	☒ Social Media (Twitter/Facebook):	Facebook, Twitter, Instagram
☐ Other:		

3. Targeted Enrollment: Give the number of participants:

a. Targeted for enrollment at Yale for this protocol: 356 for the online groups.

b. If this is a multi-site study, give the total number of participants targeted across all sites.

4. How was this estimate derived?

Because this study examines repeated measures outcomes with the two treatment conditions, assigned at the individual level, power analysis makes several assumptions: continuous outcomes, a linear link function, random effects covariance structure, and homogeneous covariance structure (within treatment groups). These analyses also assume testing for HTE effects. Conservatively assuming an effect size of .35, with a power of .80 and an alpha of .05, 137 subjects per group would be required. This represents a total completed sample of 274. Assuming a dropout rate of 20% (rounded up to 70, for nearest multiple of 2), this requires a recruited sample of at least 344. In a meta-analysis of 72 clinical trials, the initial effect size, that is 1-month post-intervention, was quite high (d = .77). However, the strength of the effect decreased over time, with effect sizes of .39 at 1-3 months, and .31 at 6-12 months.

5. Process of Consent/Assent *(NOTE: When a study includes minors, parent provide permission [not consent] for the child's participation, and the child provides assent for participation)*

Informed consent is an ongoing process that is best suited by transparency and openness to participants. Thus, participants will give consent in the initial online screening contact form and verbally in the screening call. Participants will be provided with information about the nature of the study, as well as the expected time and energy commitment required to complete the assessments. It will also be explained to participants that they are consenting to be randomly assigned to one of two MI interventions (with brief explanation about content as well as frequency and length of sessions).

Participants will be asked to provide informed consent online, prior to completing in the screening questionnaires. Consent will be required in order to access the assessment measures. If a participant does not provide consent, they will not engage in the screening assessment or be enrolled in the study.

Peer specialists will also be asked to provide consent for participation in a research study (see attached form). They will also be asked to complete an attestation form (see attached) to ensure they agree to all requirements/commitments required to serve as a peer specialist (see attached). Information will be collected on peer specialists (e.g. demographic information such as age, race/ethnicity, education level, etc.). In addition, peer specialists will be asked to complete assessment measures (as documented above) and a reflective journaling exercise to capture their experiences leading the groups (see attached).

If a participant informs the study staff that they are no longer able to participate in the group intervention (e.g. participant was randomized and then unable to complete all six online group sessions) the study staff will contact that participant to confirm receipt of their message and also note their eligibility to complete ongoing assessment measures (see example of outreach language with submission). Similarly, if a participant stops attending group, without explicitly informing the study staff of their inability to complete the six sessions we will contact them informing them they are still eligible to complete the follow-up assessment measures. If a participant withdraws from the study entirely, we will not contact them to gather additional data.

Participants who engage in the online groups will be offered the opportunity to share their e-mail address with their fellow group participants and the two peer leaders for their group. Participants will be informed by the peer leaders during the 6th session that they will be provided a link to a consent form that will allow them to choose if they would like to share their e-mail address with fellow group members and/or peer leaders. They will be informed both during the 6th session (by the peer leaders) and in the online consent form (sent by the study staff) that sharing their information is completely voluntary. We will require that each participant provide written consent indicating 1) their preferred name to share, 2) their e-mail address, and 3) to whom they provide permission to share their information with (see attached form). If a participant does not provide signed consent, or complete the form in its entirety, their information will not be shared.

6. Evaluation of Participant(s) Capacity to Provide Informed Consent/Assent: Indicate how the personnel obtaining consent will assess the potential participant's ability and capacity to consent to the research being proposed, if applicable.

All potential participants will be administered the MINI during the screening process. The MINI is a structured interview that takes approximately 15-20 minutes to administer. The MINI is used extensively in research studies to make fairly quick and accurate diagnoses of psychiatric disorders and will be used here to assess, in part, for exclusion criteria and capacity evaluation.

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7. Documentation of Consent/Assent: Specify the documents or verbal scripts that will be used during the consent/assent process. Copies of all documents should be appended to the protocol, in the same format that they will be given or spoken to participants.

Please refer to the consent form included in this submission.

8. Non-English-Speaking Participants: Explain provisions in place to ensure comprehension for research involving non-English speaking participants. Translated copies of all consent materials must be submitted for approval prior to use. **Do you speak the local language? Will you require a translator? (If so, please elaborate on how the translators will be trained).**

Non-English speakers will be excluded from this study.

9. Are any of the study procedures likely to yield information subject to mandatory reporting requirements? (e.g. HIV testing – reporting of communicable diseases; parent interview -incidents of child abuse, elderly abuse, etc.). Please verify to whom such instances will need to be reported.
Not applicable. However, we have a data safety monitoring board in place:

General description of a monitoring plan: To ensure confidentiality, we have instituted a range of protocols. We will not include names and other protected health information in our publications, reports, or presentations. Wherever possible, we will refrain from using participants' names and other protected health information. We will use standard research procedures for coding data and referring to participants by their unique ID number. The document containing key decipher code will be destroyed immediately following the conclusion of the intervention.

We will also have a data and safety monitoring plan for the study. Dr. Ilan Harpaz-Rotem, an Associate Professor in the Department of Psychiatry at Yale, will serve as the internal monitor for our study to ensure that we are approaching the participants in ways that are not coercive. In addition, Dr. Harpaz-Rotem will serve as the psychological safety monitor and will detect patterns of possible adverse events and report these to the PI, who will notify the IRB in a timely fashion. Serious adverse events that are immediately reportable to the IRB would be death, a life-threatening experience (e.g., suicide attempt), and inpatient hospitalization. Dr. Ellis will oversee the data entry process to ensure that data is entered to maintain confidentiality and security. We do not anticipate a need for an interim analysis of the data.

Plans for ensuring necessary intervention in the event of adverse effects: Dr. Jeffrey Sonis, a primary care physician and Associate Professor from the University of North Carolina has agreed to serve as an external safety officer. Dr. Sonis will receive reports prepared by the PI's at 6-month intervals and review data on number of missing forms, number of potential participants excluded from participation, number of adverse events and serious adverse events, and number of terminations from the study. Dr. Sonis will prepare a report for the IRB every 6 months. The PI for this study, Dr. Cook, will be responsible for following established procedures for reporting adverse events to the Yale Human Investigations Committee, the funding source for this study, and other federal agencies as required by law.

10. Waiver of Consent/Documentation of Consent: In certain circumstances, the IRB may grant a waiver of documentation of consent, or a full waiver of consent, depending on the study. If you will request either a waiver of consent, or a waiver of signed consent for this study, complete the appropriate section below.

☐**Not Requesting any consent waivers**

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☐**Requesting a waiver of <u>signed</u> consent (e.g., verbal or online consent only):**

☐ **Recruitment/Screening only** *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☐ **Entire Study (**Note that an information sheet may be required.)

For a waiver of signed consent, address the following:

- Would the signed consent form be the only record linking the subject and the research? YES ☐ NO ☐
- Does a breach of confidentiality constitute the principal risk to subjects? YES ☐ NO ☐

OR

- Does the research pose greater than minimal risk? YES ☐ NO☐
- Does the research include any activities that would require signed consent in a non-research context? YES ☐ NO ☐

☐ **Requesting a waiver of consent (if you are not obtaining ANY consent):**

☐ **<u>Recruitment/Screening</u> only** *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☐ **<u>Entire Study</u>**

For a waiver of consent, please address all of the following:

- Does the research pose greater than minimal risk to subjects?
  ☐ Yes *<u>If you answered yes, stop. A waiver cannot be granted.</u>*
  ☐ No
- Will the waiver adversely affect subjects' rights and welfare? YES ☐ NO☐
- Why would the research be impracticable to conduct without the waiver?
  Click or tap here to enter text.
- Where appropriate, how will pertinent information be returned to, or shared with subjects at a later date? Click or tap here to enter text.

Request for waiver of HIPAA authorization: (When requesting a waiver of HIPAA Authorization for either the entire study, or for recruitment purposes only. Note: if you are collecting PHI as part of a phone or email screen, you must request a HIPAA waiver for recruitment purposes.)

Choose one:

☐ For entire study

☒ For recruitment/screening purposes only

☐ For inclusion of non-English speaking subject if short form is being used and there is no translated HIPAA research authorization form available on the University's HIPAA website at hipaa.yale.edu.

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i. Describe why it would be impracticable to obtain the subject's authorization for use/disclosure of this data:

ii. If requesting a waiver of signed authorization, describe why it would be impracticable to obtain the subject's signed authorization for use/disclosure of this data:

In order to contact participants to determine eligibility and obtain consent a waiver of HIPAA Authorization is needed. Due to the nature of the recruitment taking place online we will obtain participant's names, e-mail addresses and phone numbers prior to obtaining informed consent.

SECTION VI: PROTECTION OF RESEARCH PARTICIPANTS

1. Confidentiality & Security of Data: Describe the steps that will be taken to secure the data during storage, use and transmission as outlined in the below sections. NOTE: Data can include paper files, data on the internet or websites, computer files, audio/video files, photographs, etc. and should be considered in the responses to the below sections. Click or tap here to enter text.

We will take several steps to protect participant confidentiality as well as reduce burden. Methods of contact will involve telephone, web and computer-based measurement as well as online-based discussion groups at the participants' convenience. According to MaleSurvivor, peers who currently lead discussion groups, there have been no complaints of grievances or reports of emotional hardship. On the contrary, many have expressed appreciation for the opportunity to participate in the current peer-led support groups.

We will minimize risks to participants by thoroughly explaining to them that participation in the study is voluntary and that the decision not to participate will have no bearing on their connection to MaleSurvivor or Men Healing. Participants' first names or preferred nicknames/pseudonyms will only be used during the discussion groups to build rapport. In publications or presentations, we will report data in aggregate form and/or change names and disguise the identity of any persons we describe or quote for purposes of illustration or example. The audio-files will be labeled only by a non-identifying code and sent to the professional transcriptionist via a secure website. Pseudonyms will be used in all transcribed files, removing all subject names. A confidentiality agreement, BAA, and consultant agreement will be executed with the transcription company prior to transfer of any files. Interview recordings will be sent to the transcriptionist using a unique identifier and through Kaiser Permanente's Secure File Transfer system. Audio files will be sent using Kaiser Permanente's Secure File Transfer program which is powered by the Accellion platform and used by healthcare organizations to send protected health information safely. The Secure File Transfer program has SSL/TLS 1.2 encryption, secure client communication, secure data transfer between server nodes, secure transfer of large files, and a digital fingerprint to detect tampering. Files will also be returned by the transcriptionist using the Kaiser Permanente Secure File Transfer program. The transcriptionist will de-identify and names (including nicknames) recorded in the audio file with the pseudonym such as "Moderator" and "Participant" or "interviewer" and "interviewee". To delineate between the persons the transcriptionist will label each individual with a number e.g. "Participant 1" or "Participant 5". Audio files will be sent to a professional transcriptionist within one week of the completed recording. Audio files will be destroyed as soon as the transcribed files are received back from the professional transcriptionist and reviewed by the investigative team to ensure completeness. The review of the transcribed files will occur within one week of receiving the files from the transcriptionist.

Confidentiality of data files will be achieved by separating personally identifiable information from the web-based survey responses and transcribed interviews. All identifying information will be kept in secure locked files, accessible only to the study team and will be destroyed at the end of a five-year period. Responses to the web-based measurements will be stored on a Yale-approved secure server, behind the

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firewall. This information will be protected to the fullest extent possible using modern encryption technology, thus reducing the risk of unauthorized data interception.

A data use agreement will be fully executed between Yale University and Nova Southeastern University (Dr. Amy Ellis' primary institution) prior to any data transfer. Similarly, a data use agreement will be fully executed with Kaiser Permanente, Center for Health Research prior to any data transfer. Secure file transfer, approved by Yale University IT, will be the sole method for data transfer.

2. What participant information will you be collecting? Describe the identifiers that will be included or associated with the data and/or specimens (e.g., names, addresses, telephone/fax numbers, email addresses, dates (date of birth, admission/discharge dates, etc.), medical record numbers, social security numbers, health plan beneficiary numbers, etc.) Names, telephone number, e-mail address, date of birth, and postal address for those who request payment via postal mail.

Other potentially identifying information to be collected:

☒Audiotapes

☒Videotapes

☐Faces (focus groups, photographs or other way that an individual would be physically recognized)

☐Potential for identification from the bulk of the information, even if direct identifiers are not collected (deductive disclosure).

3. How will the research data be collected and recorded?

Training videos will be created. While we will do our best to only video record the trainer, it is possible that other persons in the room will be included in the video. Therefore, we will obtain consent to video record at the time of invitation to the training event to explicitly inform participants that by attending the training they are agreeing to be video recorded. Individuals who decline consent will not attend the training event. Similarly, to measure fidelity we will audio record a small subset of the intervention groups. Participants will be provided information about the audio recording prior to consenting to the study. Participants unwilling to be audio recorded will be excluded from participation.

4. If identifiers will be associated with the data and/or specimens, describe whether a record or list containing a code (i.e., code number, pseudonyms) will be used, where the list will be stored, who will have access to the list and when it will be destroyed.

Participants' first names or preferred nicknames/pseudonyms will only be used during the discussion groups to build rapport. In publications or presentations, we will report data in aggregate form and/or change names and disguise the identity of any persons we describe or quote for purposes of illustration or example. The audio-files will be labeled only by a non-identifying code and sent to the professional transcriptionist via a secure website. Confidentiality of data files will be achieved by separating personally identifiable information from the web-based survey responses and transcribed interviews.

5. Describe where, how and for how long the data (hardcopy (paper) and/or electronic data) and/or specimens will be stored.

All identifying information will be kept in secure locked files, accessible only to the study team and will be destroyed at the end of a five-year period. Responses to the web-based measurements will be stored on a Yale-approved secure server, behind the firewall. This information will be protected to the fullest extent possible using modern encryption technology, thus reducing the risk of unauthorized data interception. Drs.

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Cook, Ellis, and Simiola along with the project coordinator will have access to individually identifiable private information. Raw data will be stored in a double locked file cabinet located in data storage that only they will have access to. All electronic data will be password protected and stored on a secured, encrypted server which has limited access restricted to the research team. First names and any information volunteered during the course of the MI interventions will be known by peer specialists leading the groups as well as study personnel who will code the group sessions prior to sharing for fidelity analyses or any other data analyses.

Audio files will be sent to a professional transcriptionist within one week of the completed recording. Audio files will be destroyed as soon as the transcribed files are received back from the professional transcriptionist and reviewed by the investigative team to ensure completeness. The review of the transcribed files will occur within one week of receiving the files from the transcriptionist.

All portable devices must contain encryption software, per University Policy 5100. If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on URL http://its.yale.edu/egrc or email it.compliance@yale.edu

6. Identify who will have access to the data and/or specimens. *If the data and/or specimens will be transferred to and/or from outside collaborators, identify the collaborator to whom the data and/or specimens will be transferred and how the data and/or specimens will be transferred.*

   Drs. Cook, Simiola and Ellis along with the project coordinator will have access to individually identifiable private information.

7. What will be done with the data when the research is completed? Are there plans to destroy the identifiable data or the link to personal identifiers? If yes, describe how, by whom and when identifiers will be destroyed. If no, describe how the data and/or identifiers will be secured. Identifiable data will be destroyed at the earliest date based on federal and local regulations. Dr. Cook will work with Yale ITS to ensure that data is destroyed in an appropriate manner.

8. Will a Certificate of Confidentiality be needed? (*See also the NIH Certificate of Confidentiality Kiosk, http://grants.nih.gov/grants/policy/coc/index.htm)* We received a Certificate of Confidentiality from the NIH on April 25, 2019, and have submitted all appropriate documentation to the IRB.

SECTION VII: POTENTIAL RISKS AND BENEFITS

1. **Risks:** Describe the reasonably foreseeable risks, including risks to participant privacy, discomforts, or inconveniences associated with participants participating in the research. *Note: All studies have the potential for risk, if not physical, there may be psychological, reputational, or financial risks or risks to breach of confidentiality.*

There are no foreseeable physical or medical risks to participants in this study. There is extensive research showing that assessing study participants' trauma history or subsequent mental health difficulties does not unduly upset participants. The general findings across research studies in non-psychiatric samples are that distress responses are infrequent, mild, and transitory. Although, some studies have found that those with more severe trauma histories or those with PTSD symptoms had more distress reactions (Galea et al., 2003; Institute of Medicine, 2007). Interestingly, emotion or temporary distress in trauma studies is, at times, reported to correlate positively with perceived importance and general positive evaluation of the research (Griffin, Resick, Waldrop, & Mechanic, 2003). This underlines that research that involves

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disclosure of trauma, although difficult, can be beneficial. Indeed, disclosure of trauma has been associated with empirically measured physical as well as mental health benefits (Kluemper & Dalenberg, 2014; Lutgendorf & Antoni, 1999).

However small these risks may be, we will include in the consent form that, it is possible that some people will be upset by talking about some of their difficult past personal experiences. Further, we will make it clear that participants may stop the research process at any time and that any question can be skipped at any time. In the event that participants wish to talk further about any such difficult experiences, they will be given the telephone numbers of study staff, a local hotline, and information for mental health providers in their area. A breach of confidentiality is also possible, but not likely, and the data coding process will be used to help protect participant confidentiality.

2. **Minimizing Risks:** Describe the manner in which the above-mentioned risks will be minimized.

We will take several steps to protect participant confidentiality as well as reduce burden. Methods of contact will involve telephone, web and computer-based measurement as well as online-based discussion groups at the participants' convenience. According to MaleSurvivor, peers who currently lead discussion groups, there have been no complaints of grievances or reports of emotional hardship. On the contrary, many have expressed appreciation for the opportunity to participate in the current peer-led support groups.

We will minimize risks to participants by thoroughly explaining to them that participation in the study is voluntary and that the decision not to participate will have no bearing on their connection to MaleSurvivor or Men Healing. Participants' first names or preferred nicknames/pseudonyms will only be used during the discussion groups to build rapport. In publications or presentations, we will report data in aggregate form and/or change names and disguise the identity of any persons we describe or quote for purposes of illustration or example. The audio-files will be labeled only by a non-identifying code and sent to the professional transcriptionist via a secure website. Audio-files will be sent to a professional transcriptionist within one week of the completed recordings. Audio-files will be destroyed as soon as the transcribed files are received back from the professional transcriptionist and reviewed by the investigative team to ensure completeness. The review of the transcribed files will occur within one week of receiving the files from the transcriptionist. The video recording of the motivational interviewing training will be limited to the trainers as much as possible. Prior to distributing the training video to peer moderators unable to attend the training we will work with the video editor to ensure that all participant's identity is disguised (e.g. through blurring images or using black out techniques). The video file will be sent via e-mail to peer moderators. The video will require a password to access it. Raw footage from the training will be deleted within 6 months of the training or after the final edited version of the video is produced, whichever comes first.

Confidentiality of data files will be achieved by separating personally identifiable information from the web-based survey responses and transcribed interviews. All identifying information will be kept in secure locked files, accessible only to the study team and will be destroyed at the end of a five-year period. Responses to the web-based measurements will be stored on a Yale-approved secure web server. This information will be protected to the fullest extent possible using modern encryption technology, thus reducing the risk of unauthorized data interception.

A data use agreement will be fully executed between Yale University and Nova Southeastern University (Dr. Amy Ellis' primary institution) prior to any data transfer. Similarly, a data use agreement will be fully executed with Kaiser Permanente, Center for Health Research prior to any data transfer. Secure file transfer, approved by Yale University IT, will be the sole method for data transfer.

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A confidentiality agreement will be signed and executed with the professional transcription company and the videography company (CinemaSmith).

If, during the phone screening interview, any participant endorses a "high-risk" response on the C-SSRS screener (i.e., any response coded in red suggesting high risk of suicide), this will be flagged by the interviewer and brought to the attention of the Principal Investigator and investigative team. Drs. Cook, Ellis, or Simiola will then conduct a follow-up phone assessment to determine the participant's suicide risk. If the participant is actively suicidal (i.e., has imminent suicidal intent and plan), they will be advised to go to their local hospital emergency room and will be provided with tailored referrals to mental health services based on their location. If a participant reports significant emotional distress, passive or active suicidal ideation, or thoughts of hurting someone else during the study protocol, they will be provided with information for seeking additional help including being advised to go to their local hospital emergency room. (Please see attached resources sheet that provides the minimum information that will be posted: 1) during each intervention meeting (online) and reviewed at the start of the session and; 2) at the end of each online assessment (screening, baseline, post-intervention, 60-day follow-up, 120-day follow-up)).

Peer leaders will be trained during a 3-day in-person meeting specifically on identifying and managing emotional distress. They will also get ongoing training during weekly supervision where supervising psychologists will check in weekly with peer specialists about any distress observed or noted in their group(s). Peer leaders will be required to alert the study PI via phone and e-mail within 30 minutes of the conclusion of the session when the participant expressed, or the peer specialist identified, emotional distress. The PI will directly contact the participant via phone to assess current risk and needs. When appropriate, the PI will provide area specific resources to the participant based on their location. The PI will utilize databases such as the clinician directory of the American Psychological Association and the International Society for Traumatic Stress Studies to make a local referral for the patient. In addition, the PI will provide the patient with information to the nearest emergency room, based on the participants stated location.

3. **Data and Safety Monitoring Plan:** Include an appropriate Data and Safety Monitoring Plan (DSMP) based on the investigator's risk assessment stated below. (Note: the HSC will make the final determination of the risk to subjects.).

   a. What is your assessment of the overall risk level for subjects participating in this study?

   More than minimal risk.

   b. If children are involved, what is your assessment of the overall risk level for the children participating in this study? Not applicable.

   c. **Include an appropriate Data and Safety Monitoring Plan. Examples of DSMPs are available here http://your.yale.edu/policies-procedures/other/data-and-safety-monitoring-plan-template** for

      i. Minimal risk
      ii. Greater than minimal/moderate risk

1. Personnel responsible for the safety review and its frequency:

The PI will be responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews at the specified frequency, which must be conducted at a minimum of every 6 months (including when re-approval of the protocol is sought). During the review process, the PI (monitor) will evaluate whether the study should continue unchanged, require modification/amendment, or close to

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enrollment. Either the PI or the IRB have the authority to stop or suspend the study or require modifications.

2. The risks associated with the current study are deemed greater than minimal for the following reasons: (choose those that apply)

We do not view the risks associated with the online interventions as minimal risks. Although we have assessed the proposed study as one of greater than minimal risk, the potential exists for anticipated and/or unanticipated adverse events, serious or otherwise, to occur since it is not possible to predict with certainty the absolute risk in any given individual or in advance of first-hand experience with the proposed study methods. Therefore, we provide a plan for monitoring the data and safety of the proposed study as follows:

To ensure confidentiality, we have instituted a range of protocols. We will not include names and other protected health information in our publications, reports, or presentations. Wherever possible, we will refrain from using participants' names and other protected health information. We will use standard research procedures for coding data and referring to participants by their unique ID number. The document containing key decipher code will be destroyed immediately following the conclusion of the intervention.

We will also have a data and safety monitoring plan for the study. Dr. Ilan Harpaz-Rotem will serve as the internal monitor for our study to ensure that we are approaching the participants in ways that are not coercive. In addition, Dr. Harpaz-Rotem will serve as the psychological safety monitor and will detect patterns of possible adverse events and report these to the PI, who will notify the IRB in a timely fashion. Serious adverse events that are immediately reportable to the IRB would be death, a life-threatening experience (e.g., suicide attempt), and inpatient hospitalization. Dr. Cook will oversee the data entry process to ensure that data is entered to maintain confidentiality and security. We do not anticipate a need for an interim analysis of the data.

Plans for ensuring necessary intervention in the event of adverse effects: As mentioned above, Dr. Jeffrey Sonis has agreed to serve as an external safety officer. Dr. Sonis will receive reports prepared by the PI's at 6-month intervals and review data on number of missing forms, number of potential participants excluded from participation, number of adverse events and serious adverse events, and number of terminations from the study. Dr. Sonis will prepare a report for the IRB every 6 months. The PI for this study, Dr. Cook, will be responsible for following established procedures for reporting adverse events to the Yale Human Investigations Committee, the funding source for this study, and other federal agencies as required by law.

3. Attribution of Adverse Events:

Adverse events will be monitored for each subject participating in the study and attributed to the study procedures / design by the PI, Dr. Cook, according to the following categories:

a.) Definite: Adverse event is clearly related to the study.
b.) Probable: Adverse event is likely related to the study.
c.) Possible: Adverse event may be related to the study.
d.) Unlikely: Adverse event is likely not to be related to the study.
e.) Unrelated: Adverse event is clearly not related to the study.

4. Plan for Grading Adverse Events:

The following scale will be used in grading the severity of adverse events noted during the study:

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1. Mild adverse event
2. Moderate adverse event
3. Severe adverse event

5. Plan for Determining Seriousness of Adverse Events:

Serious Adverse Events:

In addition to grading the adverse event, the PI will determine whether the adverse event meets the criteria for a Serious Adverse Event (SAE). An adverse event is considered serious if it results in any of the following outcomes:

1. Death;
2. A life-threatening experience in-patient hospitalization or prolongation of existing hospitalization;
3. A persistent or significant disability or incapacity;
4. A congenital anomaly or birth defect; OR
5. Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

An adverse event may be graded as severe but still not meet the criteria for a SAE. Similarly, an adverse event may be graded as moderate but still meet the criteria for an SAE. It is important for the PI to consider the grade of the event as well as its "seriousness" when determining whether reporting to the IRB is necessary.

6. Plan for reporting UPIRSOs (including Adverse Events) to the IRB

The PI will report the following types of events to the IRB:

Any incident, experience or outcome that meets ALL 3 of the following criteria:

1. Is unexpected (in terms of nature, specificity, severity, or frequency) given (a) the research procedures described in the protocol-related documents, such as the IRB-approved protocol and informed consent document and (b) the characteristics of the subject population being studied; AND
2. Is related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); AND
3. Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, legal, or social harm) than was previously known or recognized.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) may be medical or non-medical in nature and include – but are not limited to – *serious, unexpected, and related adverse events* and *unanticipated adverse device effects*. ***Please note*** that adverse events are reportable to the IRB as UPIRSOs **only** if they meet all 3 criteria listed above.

These UPIRSOs/SAEs will be reported to the IRB in accordance with IRB Policy 710, using the appropriate forms found on the website. All related events involving risk but not meeting the *prompt* reporting requirements described in IRB Policy 710 should be reported to the IRB in summary form at the time of continuing review. If appropriate, such summary may be a simple brief statement that events have occurred at the expected frequency and level of severity as previously documented**.** In lieu of a summary of external

events, a current DSMB report can be submitted for research studies that are subject to oversight by a DSMB (or other monitoring entity that is monitoring the study on behalf of an industry sponsor).

7. Plan for reporting adverse events to co-investigators on the study, as appropriate the protocol's research monitor(s), e.g., DSMBs, study sponsors, funding and regulatory agencies, and regulatory and decision-making bodies.

For the current study, the following individuals, funding, and/or regulatory agencies will be notified (choose those that apply):

☒ All Co-Investigators listed on the protocol.
□ National Institutes of Health
□ National Science Foundation
☒ Study Sponsor
☒Other Data Safety Monitoring Board (DSMB) or Committee (DSMC)

The PI, Dr. Joan Cook, will conduct a review of all adverse events upon completion of every study subject. Dr. Cook will evaluate the frequency and severity of the adverse events and determine if modifications to the protocol or consent form are required.

d. For multi-site studies for which the Yale PI serves as the lead investigator:

i. How will adverse events and unanticipated problems involving risks to subjects or others be reported, reviewed and managed? Click or tap here to enter text.
ii. What provisions are in place for management of interim results? Click or tap here to enter text.
iii. What will the multi-site process be for protocol modifications? Click or tap here to enter text.

4. **Potential Benefits:** Identify any benefits that may be reasonably expected to result from the research, either to the participant(s) or to society at large. (*Payment of participants is not considered a benefit in this context of the risk benefit assessment.)*

In general, we believe that participants who take part in this research are contributing towards the care, treatment and well-being of countless numbers of people who have experienced sexual abuse or assault across their lifespan and have resulting emotional distress. In addition, participation contributes towards the advancement of science and may benefit those who experience sexual assault at some time in the future. Potential other benefits include taking an active role in one's own healthcare; exercising one's autonomy and helping to combat feelings of helplessness; having the possibility of trying a promising adapted evidence-based psychotherapy that is not yet widely available; and having the chance to potentially improve one's own mental health, psychological functioning, and quality of life. Some participants in this clinical research study may benefit from the extra attention from a dedicated team and community that is specifically focused on their health care and carefully monitoring any potential side effects.

SECTION VIII: RESEARCH ALTERNATIVES AND ECONOMIC CONSIDERATIONS

1. **Alternatives:** What other alternatives, if any, are available to the study participants outside of the research?

Other than declining participation, there are no alternatives to the proposed study of which we are aware.

2. **Payments for Participation (Economic Considerations):** Describe payments that will be made to participants, if any, the amount and timing of payments, and the conditions for receiving this compensation (if applicable). If you plan to hold a drawing, be sure to include the following on any consent or recruitment materials mentioning the lottery: 1) the value of the prize; 2) the sponsor of the prize (this cannot be a federal funding source); 3) the odds of winning; and 4) that there are no restrictions to winning.

Research subjects will be paid for their participation in assessment. For each completed assessment they will receive $20 for their participation.

Peer leaders will receive $180.00 for each group they co-facilitate. Specifically, they will receive $60.00 at the end of the third group session and another $60.00 at the end of the sixth group session they co-facilitate. Peer leaders will receive an additional $60.00 at the completion of the end of the 8th supervision session. This makes the total compensation for the peer leaders co-facilitating a group $180.00 per group. In addition, peer leaders will also be asked to participate in either an in-person or online (previously recorded) training for the intervention for which you they are co-leading. If attending in person travel expenses (e.g. train, airfare, ground transportation) will be covered by the research award to host them in New Haven, Connecticut. Lodging and per diem expenses will also be covered by the study for up to 3 days. In addition as a token of our appreciation you they will be compensated $100.00 per day (maximum 3 days) for their attendance in the training.

Participants will be given a choice regarding how they would like to receive payment: either by postal mail or via e-mail. Checks will be mailed to participants, if this is their preferred method. Electronic gift cards will be e-mailed to those who prefer an e-mail delivery.

3. **Costs for Participation (Economic Considerations):** Clearly describe the participant's costs associated with participation in the research, if any, and the interventions or procedures of the study that will be provided at no cost to participants.

Interventions will be at no cost to the participant. A travel stipend will be provided for peer specialists attending various trainings.

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Yale University

Research Study Summary:

We are asking you to join a research study. The purpose of this research study is to examine how different types of online peer support can help male survivors reduce their emotional struggles. In addition, we are interested in seeing if the interventions we are testing can be effectively delivered by peer moderators, such as yourself. Study activities will include co-leading at least two online discussion groups for male survivors of sexual assault, which occur for 6 weeks each for 1.5 hours per session. In addition, you will be asked to complete rating scales after each group session about whether or not you felt you covered each part of the treatment manual. We anticipate completion of the rating scales will take approximately 10 minutes of your time. We will also ask you to answer brief questions about your experience co-leading the groups, what you learned as a peer moderator, and other reflections you might have about your experience. As a peer moderator, you will also be asked to participate in one hour of weekly supervision per week with two psychologists. Your involvement will require approximately 20 hours over the course of each group cycle. There are no known or anticipated risks associated with this study. However, some questions or discussion online may make you uncomfortable. The study may have no benefits to you. By participating in this research study, you are contributing towards the advancement of knowledge on trauma treatment and may benefit those who experience sexual assault at some time in the future. Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with Yale University. If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Verbal/Online Informed Consent Script for Participation in a Research Study
HSC # 2000024842

Hi, my name is Dr. Joan Cook and I am a psychologist and an associate professor from Yale University. I am conducting a research study to examine how different types of online peer support can help male survivors cope with trauma-related emotional struggles and feel more comfortable seeking help for related issues. In addition, our study team is interested in seeing if the interventions we are testing can be effectively delivered by peer moderators, such as yourself.

Participation in this study will involve co-leading at least two online discussion groups for male survivors of sexual assault, which occur for 6 weeks each for 1.5 hours per session. In addition, you will be asked to complete rating scales after each group session about whether or not you felt you covered each part of the treatment manual. We anticipate completion of the rating scales will take approximately 10 minutes of your time. We will also ask you to keep answer brief questions about your experience co-leading the groups, what you learned as a peer moderator, and other reflections you might have about your experience. As a peer moderator, you will also be asked to participate in one hour of weekly supervision per week with two psychologists. Your involvement will require approximately 20 hours over the course of each group cycle. While we cannot compensate you on at an hourly rate you will receive $180.00 for each group you co-

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facilitate. Specifically, you will receive $60.00 at the end of the third group session and another $60.00 at the end of the sixth group session you co-facilitate. You will receive an additional $60.00 at the completion of the end of the 8th supervision session. This makes the total compensation for co-facilitating a group $180.00 per group. According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income. Payment for co-facilitating groups and your participation in supervision will be in the form of a check, mailed directly to you at the address you provide to the research staff. Alternatively, you may request your payment in the form of an electronic gift card, which will be e-mailed to you.

We hope to enroll 20 peer moderators into this study and 344 male survivor group participants. The study will run for 5 years, in total. However, we are asking for your participation in the first three years of the study only.

You will also be asked to participate in either an in-person or online (previously recorded) training for the intervention for which you will be co-leading. If attending in person your travel arrangements will be paid for and made by the research project, in compliance with Yale's travel policies and those of the funder, to host you in New Haven, CT. Lodging and per diem expenses will also be covered by the study for up to 3 days. In addition as a token of our appreciation you will be compensated $100.00 per day (maximum 3 days) for your attendance in the training.

Attendance at the in person training requires your agreement to be video recorded. The in-person training will be video recorded for distribution to those who are unable to attend in person. The video will focus primarily on the trainers, however it is possible that you will also appear in the video. A professional videographer from the company, CinemaSmith, will record the training and edit the footage to remove images of attendees other than the trainers (such as yourself) as best as possible. The videographer and video editor from CinemaSmith will complete a confidentiality agreement prior to the taping of the training. While we cannot guarantee that your image will not appear in the video, we will do everything we can to blur your face. The video recording will only be shared with other potential peer moderators, such as yourself, and will be password protected. Raw footage from the training will be deleted within 6 months of the training or after the final edited version of the video is produced, whichever comes first.

There are no known or anticipated risks associated with this study. However, some questions may make you uncomfortable and there is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. You may withdraw your consent for participation in this research study at any time by writing to the Principal Investigator:

Joan Cook, Ph.D.
Yale University
Department of Psychiatry
300 George Street, Suite 901
New Haven, CT 06511

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Yale University

By participating in this research project you are contributing towards the care, treatment and well-being of countless numbers of men (and women) who have experienced sexual abuse or assault across their lifespan. In addition, participation contributes towards the advancement of behavioral science and may benefit those who experience sexual assault at some time in the future.

Participation in this research study requires your permission to be audio-recorded. Your name or other identifiers will not be associated with the audio-file, which will be transcribed by a professional transcriptionist. Audio recordings will be used to measure adherence to the content of the group treatment. By signing this consent you are also agreeing to audio- recording of the group intervention sessions. The audio recordings will be sent outside of Yale for transcription. A confidentiality agreement will be executed with the transcription company prior to transfer of any files. The transcriptionist will de-identify and names (including nicknames) recorded in the audio file with the pseudonym "Moderator" and "Participant". To delineate between the persons the transcriptionist will label each individual with a number e.g. "Participant 1" or "Participant 5". Audio files will be sent to the professional transcriptionist within one week of the completed recordings. Audio files will be destroyed as soon as the transcribed files are received back from the professional transcriptionist and reviewed by the investigative team to ensure completeness. The review of the transcribed files will occur within one week of receiving the files from the transcriptionist.

All of your responses will be held in confidence. Only the researchers involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, and the Yale University Human Subjects Committee, and offices responsible for fiscal monitoring) will have access to any information that could identify that you provide. We will ask you to identify yourself in groups using a nickname or only your first name (not to include surname/last name). We will use a coding system to randomly assign a number associated with any information we get from you. Only the investigative team (Drs. Cook Amy Ellis, and Vanessa Simiola and their project coordinator) will have access to the key. This means that identifiable data such as your name, telephone number and e-mail address will be shared amongst the investigative staff. Drs. Ellis and Simiola are not affiliated with Yale University. They will conduct portions of this research study including the screening interview and post-intervention telephone interview from their respective organizations. Drs. Ellis and Simiola are associated Nova Southeastern University and Kaiser Permanente, Hawaii, respectively. Any exchange of protected health information (such as your name, telephone number, or e-mail address) or coded data will take place behind the Yale firewall using a secure file transfer program. Identifiable data (including the code key) will be destroyed as soon as permitted by law. All information will be stored on a password protected and encrypted computer.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The We are applying for a Certificate of Confidentiality from the National Institutes of Health. Once it is obtained, the researchers with this Certificate, may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to

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anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, elder abuse or neglect, or harm to self or others.

Please remember that while we (the researchers) will keep your information confidential and will remind all participants that what is said in the group should not be repeated outside of the group, we have no control over what happens outside of the group. You are reminded to not share anything you would not want repeated outside of this group. Also, as a peer moderator your are agreeing not to repeat anything you hear during the group outside of the group, with the following exceptions:

1. Study related supervision with designated supervisors
2. If a group participant reports significant emotional distress, passive or active suicidal ideation thoughts of hurting someone else during the study protocol you will alert the PI via phone and e-mail within 30 minutes of the conclusion of the session when the participant expressed or the peer specialist identified distress.

Participation in this study is completely voluntary. You are free to decline to participate, to end participation at any time for any reason, or to refuse to answer any individual question without penalty. Your decision whether or not to participate in this study will not affect your relationship with Yale University or MaleSurvivor.

If you have any questions about this study, you may contact the principal investigator, Joan Cook, Ph.D., Yale University, Department of Psychiatrym300 George Street Suite 901, New Haven, CT 06511 or via phone at (203) 856-2782.

If you would like to talk with someone other than the researchers to discuss problems or concerns, to discuss situations in the event that a member of the research team is not available, or to discuss your rights as a research participant, you may contact the Yale University Human Subjects Committee, 203-785-4688, human.subjects@yale.edu. Additional information is available at https://your.yale.edu/research-support/human-research/research-participants/rights-research-participant

By clicking “accept” below, you are agreeing to participate in this study.

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Adult Consent for Participation in a Research Project
200 FR 2 (2017-1)

Study Title: Peer Online Motivational Interviewing for Sexual and Gender Minority Male Survivors
Investigator: Joan M. Cook, Ph.D.
Funding Source: Patient Centered Outcomes Research Institute (PCORI)
HSC #: 2000024842

Research Study Summary:
We are asking you to join a research study. The purpose of this research study is to examine how different types of online peer support can help male survivors reduce their emotional struggles. Study activities will include a confidential phone interview with a member of the study team asking questions about your emotional well-being, completion of several online questionnaires, and participation in one of two online discussion groups, led by peer moderators (men who have had similar lived experiences as you). Your involvement will require 30-40 minutes for the phone interview, 30 minutes to complete the online questionnaires, and participation in the online groups will take 1.5 hours weekly for 6 consecutive weeks. There are no known or anticipated risks associated with this study. However, some questions or discussion online may make you uncomfortable.
The study may have no benefits to you. By participating in this research study, you are contributing towards the advancement of knowledge on trauma treatment and may benefit those who experience sexual assault at some time in the future. Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with Yale University. If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Please ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Purpose:
You are invited to participate in a research study designed to examine how different types of online peer support can help male survivors reduce their emotional struggles and feel more comfortable seeking help for issues related to their emotional health. You have been asked to take part because you are: a) 18 years of age or older; b) English-speaking; c) reporting a history of sexual abuse or assault at some point in your lifetime; d) identify as male; e) identify as at least one of the following: gay, bisexual, transgender, attracted to men, or have sex with men; f) experiencing emotional distress; and g) have not received any psychotherapy or formal mental health counseling in the past 60 days. We expect to enroll approximately 345 people in this research study, which will last approximately 3 years.

Procedures:
If you agree to take part in this study, your participation will involve a confidential phone interview with a member of the study team asking questions about your emotional well-being, and completion of several online questionnaires to determine eligibility for the study. Participation in the study will involve completion of a 6-week peer-led online group and follow-up questionnaires. The questionnaires and interview will ask you basic demographic questions about your age, ethnicity, gender identification, and sexual orientation identification. We will also ask you more personal questions about the nature of your sexual abuse and a few short questions asking symptoms of anxiety, depression, and posttraumatic stress. You'll also be asked to complete some questionnaires (all online) that ask about different emotional health symptoms you may be experiencing.

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After completion of the questionnaires, you will be randomly assigned to participate in either of two online discussion groups. Both groups will be led by peer moderators (men who have had similar lived experiences as you). The groups will last for 1.5 hours and meet weekly, online, for 6 consecutive weeks.

At the end of the 6-week group, and at two other times (two and four months post-group) we'll again ask you to complete online questionnaires about your emotional well-being. Finally, we will ask a small subset of participants (60 people) to complete a telephone interview following the completion of the treatment to get your feedback about the treatment as well as preferences for potential future mental health treatment.

We anticipate that your involvement in the entire study will require approximately 15-20 hours of your time spread across approximately 6 months. You will receive $20 dollars for each wave of questionnaires you complete (before the start of the treatment, immediately following the end of the 6-week treatment, at two months follow-up, and at four months follow-up) for a total possible amount of $80. If you participate in the final telephone interview you will receive an additional $30.

Participation in this research study requires your permission to be audio-recorded. Your name or other identifiers will not be associated with the audio file. Audio-recordings will be used to measure the peer moderators' adherence to the interventions well as to provide us more detailed data on the therapeutic process (e.g., what interventions have the most positive impact and which do not). By signing this consent you are also agreeing to audio-recording of the intervention sessions. The audio-recordings will be sent outside of Yale for transcription. A confidentiality agreement will be executed with the transcription company prior to transfer of any files. The transcriptionist will de-identify and names (including nicknames) recorded in the audio-file with the pseudonym "Moderator" and "Participant". To delineate between the persons the transcriptionist will label each individual with a number e.g. "Participant 1" or "Participant 5". Audio-files will be sent to the professional transcriptionist within one week of the completed recordings. Audio-files will be destroyed as soon as the transcribed files are received back from the professional transcriptionist and reviewed by the investigative team to ensure completeness. The review of the transcribed files will occur within one week of receiving the files from the transcriptionist.

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

Risks and Benefits:
There are no known or anticipated risks associated with this study. However, some questions may make you uncomfortable and it is possible that you may become upset or experience increased anxiety talking about some of these difficult past personal experiences. There is also the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. If you are deemed to be at high risk of suicide during the confidential phone interview with a member of the study team, one of the licensed clinical psychologists on the study team will follow up with you via a separate phone call to determine your risk and to provide you with tailored resources and referrals for immediate help. You may withdraw your consent for participation in this research study at any time by writing to the Principal Investigator:

Joan Cook, Ph.D.
Yale University
Department of Psychiatry
300 George Street, Suite 901

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New Haven, CT 06511
theconnectstudy@yale.edu

By participating in this research project you are contributing towards the care, treatment and well-being of countless numbers of men (and women) who have experienced sexual abuse or assault across their lifespan. In addition, participation contributes towards the advancement of behavioral science and may benefit those who experience sexual assault at some time in the future.

Confidentiality:
All of your responses will be held in confidence. Only the researchers involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, and the Yale University Human Subjects Committee, and offices responsible for fiscal monitoring) will have access to any information that could identify you. We will ask you to identify yourself in groups using a nickname or only your first name (not to include surname/last name). We will use a coding system to randomly assign a number associated with any information we get from you. Only the investigative team (Dr. Cook, Dr. Amy Ellis, Dr. Vanessa Simiola and the project coordinator) will have access to the key. This means that identifiable data such as your name, telephone number and e-mail address will be shared amongst the investigative staff. Drs. Ellis and Simiola are not affiliated with Yale University. They will conduct portions of this research study including the screening interview and post-intervention telephone interview from their respective organizations. Drs. Ellis and Simiola are associated with Nova Southeastern University and Kaiser Permanente, Hawaii, respectively. Any exchange of protected health information (such as your name, telephone number, or e-mail address) or coded data will take place behind the Yale firewall using a secure file transfer program. Identifiable data (including the code key) will be destroyed as soon as permitted by law. All information will be stored on a password protected and encrypted computer.

Please remember that while we (the researchers) will keep your information confidential and will remind all participants that what is said in the group should not be repeated outside of the group, we have no control over what happens outside of the intervention groups. You are reminded to not share anything you would not want repeated outside of this group. Although all participants in the group must agree to not disclose any of the information discussed within the group, ultimately, we cannot guarantee that all participants will maintain this confidentiality. You must be aware that there is the possibility that personal information may be discussed outside of the confines of the study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, elder abuse or neglect, or harm to self or others.

Note, however, that your records may be reviewed by those responsible for the proper conduct of research such as the Yale University Human Research Protection Program, Yale University Human Subjects Committee or representatives of the U.S. Department of Health and Human Services or the sponsor (Patient Centered

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Outcomes Research Institute). The information about your health that will be collected in this study includes: Name, date of birth, telephone number, and e-mail address. We will also collect information about your emotional health and well-being.

Information may be re-disclosed if the recipients are not required by law to protect the privacy of the information. At the conclusions of this study, any identifying information related to your research participation will be destroyed, rendering the data anonymous.

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

Voluntary Participation:
Your participation in this study is voluntary. You are free to decline to participate, to end your participation at any time for any reason, or to refuse to answer any individual question without penalty. Your decision whether to participate or not will have no effect on your relationship with Yale University or MaleSurvivor.

You may withdraw or take away your permission to use and disclose your health information at any time.

If you are assigned to a peer-led online group, you may **stop your participation in the group** at any time. You can do this by informing the study staff or by not attending groups. If you stop your participation in groups, you will be asked to complete the remaining study assessments, but again, this is voluntary, and you will not be penalized for declining.

You may also **withdraw** your permission to be in this study by telling the study staff. If you withdraw your permission, you will not be able to participate in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions:
If you have any questions about this study, you may contact the principal investigator, Joan Cook, Ph.D., Yale University, Department of Psychiatry, 300 George Street Suite 901, New Haven, CT 06511, via phone at (203) 856-2782 or email our study team at theconnectstudy@yale.edu.

If, after you have signed this form, you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919.

If you would like to talk with someone other than the researchers to discuss problems or concerns, to discuss situations in the event that a member of the research team is not available, or to discuss your rights as a research participant, you may contact the Yale University Human Subjects Committee, 203-785-4688, human.subjects@yale.edu. Additional information is available at http://your.yale.edu/research-support/human-research/research-participants

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Agreement to Participate:
I have read the above information, have had the opportunity to have any questions about this study answered and agree to participate in this study.

By signing below, you are agreeing to participate in this study.

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Analysis Plan

To assess the success of randomization, baseline demographic and clinical characteristics, the two randomized groups were compared using chi-square tests for categorical variables and t-tests or Mann-Whitney tests for continuous variables. Data analyses were conducted on the intent-to-treat sample. All variables were evaluated for their distributional properties and data processing errors. Robust estimators were used to address non-normal data.

Variables were assessed for amount and pattern of missing data. Full information maximum likelihood estimation was used in subsequent analyses to address missingness. Inclusion of informative variables were included as needed. Analyses were conducted in SPSS 28.0 (IBM, 2021). For outcome analyses, linear mixed models (LMM) of mental health symptoms were modeled as a repeated measures outcome variable, nested within participants. Baseline demographic, clinical variables, and sexual abuse experiences were included as time-invariant covariates (between participants), as was treatment group. Thus, for each outcome, the primary analysis included all observations nested in persons and cohorts, controlling for baseline clinical and demographic variables.

Before examining the potential role of any mediators, LMM was conducted to determine any main or interaction effects condition and/or time may have had on these mediators as outcomes. To assess heterogeneity of treatment effects, the potential moderating impact that participant demographic variables and significantly correlated covariates had on the relationship between condition and primary outcomes was examined by including a moderator x condition interaction term in models.

Inclusion of demographic and clinical variables in mixed models allowed for testing of heterogeneity of treatment effects (HTE), with adjusted *p*-values. Specifically, in addition to the primary analyses, subsequent supplementary analyses tested potential moderators by including a treatment group X demographic interaction (race, comorbidity, and education) as these are the most likely candidates for HTE effects. Potential moderating effects of baseline values of minority stress, conformity to masculine norms and barriers to help seeking were also examined using SPSS PROCESS, which provides estimates of conditional effects of focal predictor (treatment condition) at different values of the moderator.