K23 Aim 2 Study Protocol

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1. SPECIFIC AIMS (5-year project; Aim 2 highlighted)

In 2017, gay, bisexual, and other men who have sex with men (MSM) made up 70% of new HIV infections in the U.S., and young adult MSM (age 18-34; YMSM) account for the majority of HIV cases. YMSM also experience prevalent, often co-occurring mental health issues, including depression, anxiety, and substance use, creating a "syndemic" condition surrounding HIV risk and suboptimal HIV testing.

A key driver of such disparities experienced by YMSM is minority stress. Experiences of identity-based discrimination lead to internalized stigma and maladaptive coping (e.g., emotion dysregulation, avoidant coping, impulsivity) The "downstream" effects of minority stress are poor mental health (depression and anxiety), increased sexual risk, and lack of engagement in key health services such as HIV testing due to anxiety related to identity disclosure to providers and anticipation of stigmatizing encounters. Recent evidence also suggests discrimination exposure is linked to heightened physiological stress response (cortisol level) that represents depletion of coping resources and increased risk for development of stress-linked psychological disorders (depression, anxiety). Therefore, **reducing minority stress represents a promising transdiagnostic approach to reduce the burden of HIV and mental health issues experienced by YMSM**.

Our research suggests that MBIs target mechanisms relevant to minority stress, including self-acceptance, emotional dysregulation, and avoidant coping. Therefore, as an individual-level intervention, MBIs may serve as an innovative HIV prevention intervention by lowering the syndemic risk among YMSM through reducing psychological symptoms, improving coping, and enhancing HIV-related behavioral health. However, no evidence-based MBIs have been tested for HIV prevention, and clinical and research evidence suggests further adaptation is warranted to improve its relevance and optimize engagement for YMSM.

This K23 aims to develop an internet-delivered MBI to address minority stress and its negative HIV-related health consequences experienced by YMSM. Specifically, we propose to adapt, refine, and pilot-test an evidence-based MBI, Mindfulness-based Stress Reduction (MBSR), to promote mental and sexual health and HIV testing engagement among distressed, high-risk YMSM. Aims 1-3 will support the subsequent production and evaluation of the adapted intervention. To maximize reach, scalability, and availability to a population that experience challenges seeking in-person counseling and health services, the intervention will also be adapted for internet-based delivery.

Aim 1. Adapt MBSR for distressed, high-risk YMSM using internet delivery, guided by the ADAPT-ITT model. We will conduct iterative phases of formative research including online-based focus groups with YMSM, solicitation of feedback from stakeholders, and revision of intervention protocols. This process will result in the first-draft of an internet-delivered, mindfulness-based intervention protocol for use with YMSM.

Aim 2. Refine intervention protocol by administering adapted materials to distressed, high-risk YMSM (*n*=18) through internet-based open pilot and gather feedback. Following integration of feedback, this process will result in a finalized protocol of an internet-delivered, mindfulness-based intervention protocol for YMSM.

Aim 3. Examine the feasibility and acceptability of an internet-delivered mindfulness-based intervention (iMBI) for HIV prevention. A sample of 40 distressed, high-risk YMSM will be randomized into the adapted iMBI or a waitlist control condition. Primary outcomes are HIV testing and self-reported sexual risk behaviors. Secondary outcomes are stress biomarker (hair cortisol), psychological health, minority stress and coping. The study will examine recruitment and retention, number of sessions attended, self-reported at-home practice of mindfulness, completion of assessment, and acceptability of the intervention.

2. Inclusion and Exclusion Criteria (updated Spring 2022):

The following is the most updated inclusion/exclusion criteria, and inclusion of STI testing (beyond HIV self-testing, we are also including STI self-testing, including Chlamydia and Gonorrhea):

- Inclusion criteria:
  (1) assigned male at birth,
  (2) being 18 to 34 of age,
  (3) identify as a cisgender man,
  (4) reside in the United States,
  (5) can read and speak English,
  (6) engaged in condomless anal sex with another man in past 6 months,
  (7) endorse distress, measured by the PHQ-9 and GAD-7,
  (8) possess a devise (phone, tablet, computer) that allows for online conferencing.
  (9) HIV-negative or status unknown
- About HIV status: In Aim 2, HIV status will be assessed by self-report only (due to budget and non-intervention activity for these Aims). We will provide rapid oral HIV testing in Aim 3.
- Exclusion criteria: YMSM will be excluded from the study if they are determined to have symptoms that would prevent them from giving meaningful consent or participate in study activities including any of the following criteria:
  (1) Significant cognitive impairment
  (2) Psychosis
  (3) Imminent suicidal risk
  (4) Substance abuse
- YMSM will be excluded from the study if they are determined to have symptoms preventing them from giving meaningful consent or study activities including (1) significant cognitive impairment, (2) psychosis, (3) imminent suicidal risk, and (4) substance abuse.

3. Steps in Recruitment, Screening, and Assessment:

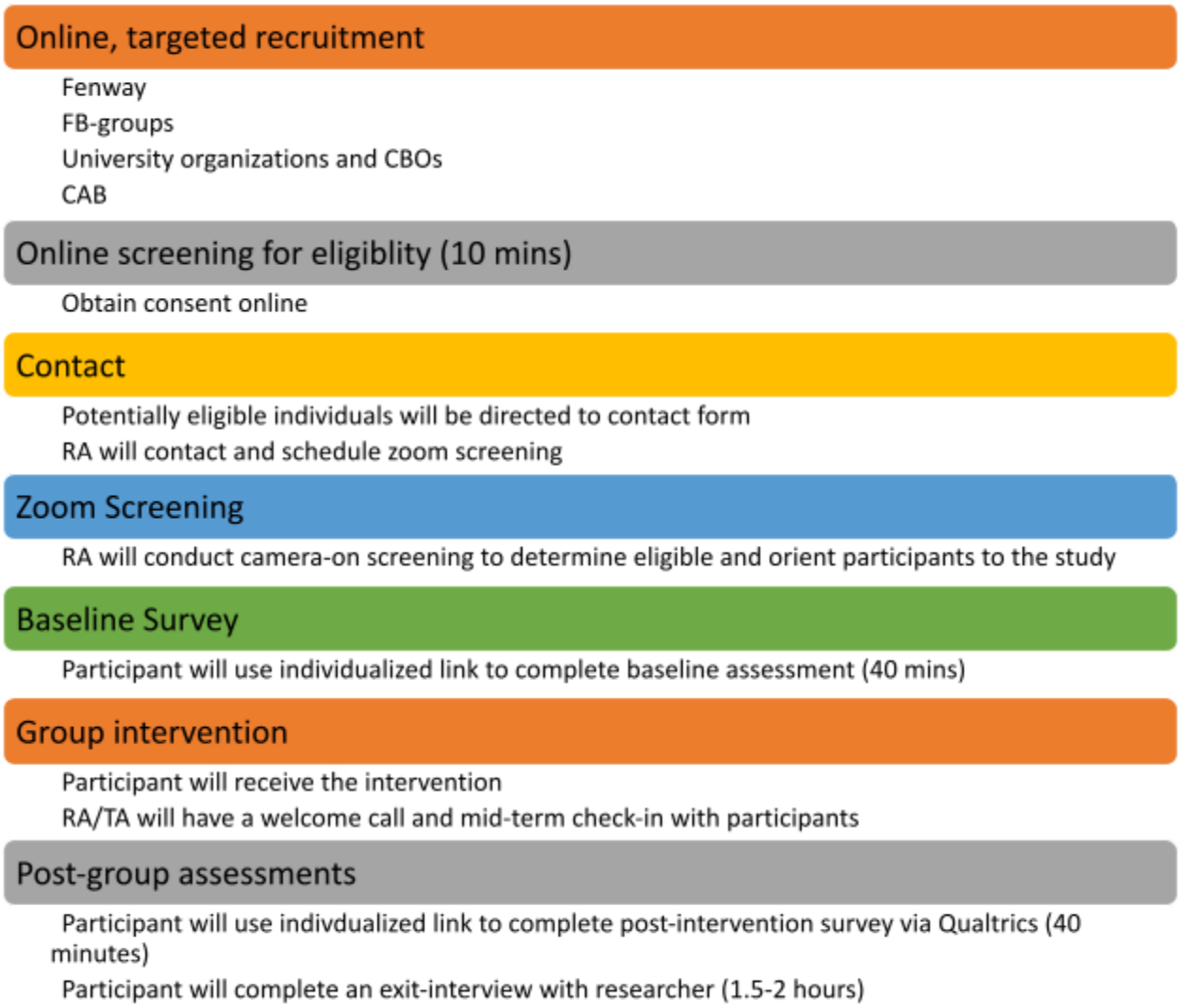
Recruitment and Screening Procedures

1) Timeline for recruitment:
   a. All prep efforts to be ready 6-8 weeks prior to the open pilot group
   b. Recruitment efforts to take place a month prior to the open pilot group
2) Recruitment will be conducted through 6 methods:
   a. Fenway Institute- Bob to make connection
   b. Arryn to ask LA LGBTQ Center & Howard Brown
   c. Facebook-based community groups for gay and bisexual men
      i. Lab recruitment team: Ty, Matt, Jane, Miguel
   d. Campus and CBO-based recruitment strategy
      i. Organize previous contacts into excel spreadsheet to be used via MailChimp or Qualtrics
      ii. Contact Stephanie for Qualtrics-based group emails
   e. Advertise through CAB members
   f. Today@Brown

    g. Recruit via Mindfulness Center
3) TBD: CAB members as participant-observer?
4) Team will determine best way to recruit participants who can gather around same time for group:
    a. Options include: (1) pre-determine group time; (2) recruit and then determine a time that works for most people and teachers?
5) Participants will complete an internet-based screening form via Qualtrics to determine their initial eligibility.
    a. Once screened eligible, participants will be directed to a contact form.
6) Zoom screening: Study RA will contact potentially eligible participants to schedule a Zoom-based screening and information session.
    a. RA will screen participants via Zoom, determine participants' eligibility, and provide study information/orientation (e.g., via ppt).
    b. At the end of Zoom session, if participants is deemed as eligible and a good fit, RA will invite the participant to complete baseline survey via Qualtrics.
    c. If excluded, RA will record reason for exclusion.
7) The following data from recruitment, screening, and enrollment will be maintained by RA:
    a. # screened
    b. # eligible for zoom interview
    c. # excluded – including reasons for exclusion (e.g., HIV-positive, not residing in the U.S., age, etc.)
    d. # completed baseline survey
    e. # enrolled
8) Participants will complete baseline survey via Qualtrics.
    a. Following baseline survey completion (and attending of orientation session), participants are considered as "enrolled".
9) Assign participant ID
    a. Generate PID through Qualtrics at screening.
    b. PID will be consistent across all time points of the study.
    c. This PID will be used at baseline and post-intervention survey--- Participants will receive a personalized link to complete their survey (generated by Qualtrics). The personalized link will ensure that every assessment completed by a participant (baseline and post-pilot survey) will have the same PID.
10) Data storage and tracking
    a. Participants data will be stored on a secure server (SunLab SPH folder or stronghold folder)
    b. During recruitment, study enrollment, and post-intervention assessment, RA will check daily on Qualtrics regarding:
        i. Number of people screened, potentially eligible participants, who to email, etc.
        ii. Data flow, any issues to be reported in order to revise recruitment strategy
        iii. Data quality (e.g., any fraud activities)

11) Participant contacts during the study:
    a. Retention: **Retention** information includes multiple contact details for participant as well as contact information from a trusted friend or relative to serve as an alternative contact. Study RA will use additional recruitment techniques in Aims 2-3 given their longitudinal design. This includes phone reminders, updating of contact information, and calling their alternative contact as needed.

An abbreviated study flowchart is presented.



4. Intervention protocol

1) Participants will receive 10-week group-based intervention, including 1 week of orientation and 9 weeks of classes (including a week of retreat)

2) Participants will also receive two check-ins from the Teaching Assistant, including 1-2 weeks since the start of the class (the welcome call), and mid-term check-in (after session 5). TA will use motivational interviewing skills to learn about participants' intention for participation, goals and expectations, experiences in the group so far, potential challenges/barriers, etc.
    As suggested by CAB, TA will also function as a channel of communication if participant experience adverse events/reactions during the course of intervention.
3) Teachers will receive ongoing weekly supervision to support their work.
4) Once the group intervention ends, TA will contact participants about next steps re:
    a) Complete post-group survey
    b) After survey, we will schedule zoom interview with a study team member

5. Baseline and Post-Pilot (2.5 months FU) Qualtrics Assessment:

1) At baseline, participants will fill out assessments related to:
    a. demographics
    b. primary outcomes (sexual risk behavior only, no testing)
    c. secondary outcomes
    d. exploratory outcomes
2) During the intervention, participants will complete weekly report on:
    a. monitoring of sexual risk (condomless sex)
    b. monitoring of depression (PHQ-9) and anxiety symptoms (GAD-7)
    c. log on weekly/daily practice (via Qualtrics- individualized links)
    d. report on attendance (from zoom sessions)
3) At post-intervention (2.5 months FU), participants will complete assessments related to:
    a. Via Qualtrics:
        i. Primary outcomes
        ii. Secondary outcomes
        iii. Exploratory outcomes
        iv. Acceptability measures
            1. note that this includes description on two methods of cortisol collection (hair or nail) and ask participants to rate their willingness
    b. Via Zoom-based interview
        i. Interview will be conducted after completion of all other study activities

Table 1. Measures of Feasibility, Acceptability, and Outcomes		Baseline	During Intervention	Post-Intervention
Demographics	Socio-demographics	X		
Primary outcomes	Sexual risk behaviors	X	X	X
Secondary Outcomes	Depression: PHQ-9 (also monitored weekly)	X	X	X
	Anxiety: GAD-7 (also monitored weekly)	X	X	X

	Internalized Homophobia Scale	X		X
	Difficulties of Emotion Regulation (DERS)	X		X
	Sexual Compulsivity Scale (SCS)	X		X
	Safe Sex Self-Efficacy Scale	X		X
Exploratory Outcomes	PTSD: PCL-5	X		X
	Resilience	X		X
	UCLA Loneliness Scale	X		X
	HIV knowledge	X		X
	PrEP willingness	X		X
Feasibility	Recruitment	X		X
	Attendance & attrition		X	
	Weekly report of home practice - log		X	
	Missing data in assessment	X		X
Acceptability	Session Evaluation Form			X
	Client Satisfaction Survey (CSQ-8)			X
	Questions related to cortisol collection			X
	Exit-interview (Qualitative)			X

7. Post-Pilot (2.5 months FU) Exit-Interview

1) RA will schedule exit-interview after participant completes all other study activities
2) Exit-interview will focus on participant's experience in the study, feasibility and acceptability of the intervention, areas for further adaptation, etc.
3) One-on-one, Zoom-based interview will be conducted by a study team member or PI. Interview will be recorded. The recording will be stored on a secure server.
4) Team will transcribe and analyze qualitative data.