Study Name:	HEALTH IMPROVEMENT PROJECT – PROVIDENCE (HIP-P)
NCT Number:	NCT02886234
Grant Title:	MINDFULNESS TRAINING TO IMPROVE ART ADHERENCE AND REDUCE RISK BEHAVIOR AMONG PERSONS LIVING WITH HIV
Grant #:	R34AT008930
Date of Document:	March 27, 2017
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Study 4 Protocol

Exploratory Clinical Trial

CONTENTS

REVISION HISTORY

Version Number:	1.0
Version Date:	June 2, 2016
Summary of Revisions Made:	Original Draft
Version Number:	2.0
Version Date:	June 30, 2016
Summary of Revisions Made:	Addition of personnel
Version Number:	3.0
Version Date:	August 25, 2016
Summary of Revisions Made:	Addition of two personnel (Naomi Krieger and Cynthia Merly) and deletion of one (Gloria Mensah)
Version Number:	4.0
Version Date:	October 19, 2016
Summary of Revisions Made:	Addition of one personnel (Abbey Salvas) and deletion of one (Rebecca Eldridge); Modification to Appendix 4 Qualitative Interview Scripts
Version Number:	5.0
Version Date:	October 26, 2016
Summary of Revisions Made	Addition of one personnel (Erin Sharaf); Modification to the screening questionnaire; Modification to the baseline measures; Modification to the follow-up measures.
Version Number:	6.0
Version Date:	February 7, 2017
Summary of Revisions Made	Two recruitment strategies added; Consent modified to add time limits on completing baseline protocols and coaching sessions; Two week window for extenuating circumstances added to the time between completing baseline and starting coaching.
Version Number:	7.0
Version Date:	February 28, 2017
Summary of Revisions Made	Definition of Project Director (PD) added to list of abbreviations and defined on the first reference in the text; Clarification of intervention materials.
Version Number:	8.0
Version Date:	March 17, 2017
Summary of Revisions Made	Addition of one personnel (Dr. Philip Chan).
Version Number:	9.0
Version Date:	March 27, 2017
Summary of Revisions Made	Removal of one personnel (Dr. Aadia Rana).

RESEARCH TEAM

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1. LIST OF ABBREVIATIONS

AC	Attention Control
AE	Adverse Event
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
CBPM	Centers for Behavioral and Preventive Medicine
CDC	Centers for Disease Control and Prevention
CFAR	Center for AIDS Research
Co-I	Co-Investigator
CT	Chlamydia trachomatis
IMC	Data Safety Monitoring Committee
Gc	Gonorrhea
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
IRB	Institutional Review Board
MBSR	Mindfulness-Based Stress Reduction
MT	Mindfulness Training
NCCIH	National Center for Complementary and Integrative Health
NIH	National Institutes of Health
PCP	Primary Care Provider
PD	Project Director
PLWH	People living with HIV
PHI	Protected Health Information
PI	Principal Investigator
RCT	Randomized Clinical Trial
SAE	Serious Adverse Event
STI	Sexually Transmitted Infections
RA	Research Assistant
Trich	Trichomoniasis
TMH	The Miriam Hospital

2. BACKGROUND AND RATIONALE

2.1 Background

Based on estimates from the CDC, 1.2 million persons aged ≥ 13 years are living with HIV infection, while incidence rates of new infections reach 50,000 new cases per year.[1-4] In 2012, ~28,000 people were diagnosed with AIDS[5] and ~14,000 people with an AIDS diagnosis died in 2011.[5]

CDC recommendations for people living with HIV (PLWH) include the adoption of safer sex practices and strict adherence to antiretroviral therapy (ART) when prescribed.[6] Safer sex practices such as condom use with all partners and reduction in the number of partners, decrease the risk of contracting other sexually transmitted infections (STIs) and HIV super-infection, and reduce the likelihood of transmitting HIV to an uninfected partner. Adherence to ART improves viral suppression, reduces infectiousness and HIV-related morbidities, and increases longevity.[7-9] Together, safer sex practices and ART adherence improve the health of PLWH and reduce the incidence of new HIV infections.[10-17]

Despite CDC recommendations, a significant proportion of PLWH still engage in risky sexual practices and show sub-optimal ART adherence to ART. For example, 26% to 35% of HIV-infected men who have sex with men report recent unprotected anal intercourse.[18,19] Risky sexual behavior places the infected person at risk for other STIs and for HIV super-infection.[20] Unprotected sex also places partners at risk for HIV infection, fueling the epidemic. Likewise, only 30% of PLWH persons adhere to ART to the point of achieving viral suppression.[21,22] Sub-optimal adherence to ART compromises individual health, increases health care costs, and can lead to the development of ART-resistant strains of HIV.[9,23] Thus, poor adherence to CDC recommendations adversely affects both an individual's and the population's health.

Among the multiple barriers to adherence to CDC recommendations[24] patient-related factors such as stress, depression, and poor impulse control have been the most difficult to modify. PLWH are exposed to considerable stress due to poverty[25] and/or discrimination due to minority social status.[26-29] Further, HIV remains highly stigmatized, further exacerbating stress levels. It is not surprising, given this stressful context, that many PLWH report elevated levels of depression.[30-34] In the absence of strong coping skills, stress and depression can enhance impulsivity in vulnerable persons,[35] who then cope maladaptively (i.e., by using alcohol and other drugs, engaging in risky sex).[36-46] Depression and stress have also been associated with poor ART adherence[24,47-57] and risky sexual behavior.[58-62] Thus, stressful life circumstances, depression, and impulsivity conspire to undermine adherence to CDC recommendations.[24,48,63-73]

2.2 Study Rationale

Mindfulness training can reduce perceived stress, depression, and impulsivity. Mindfulness has been defined as the act of paying attention to the present moment's experience in an intentional and non-judgmental way.[36-38] While mindfulness is a fundamental ability of the mind, studies have shown that mindfulness levels increase with training, thus showing that mindfulness is also a teachable skill.[74] The best known program is Mindfulness Based Stress Reduction (MBSR),[75] which offers training in traditional mindfulness meditation adapted to a non-Buddhist, clinical context. The MBSR program has been shown to be effective in reducing anxiety, depression, and a variety of physical symptoms in many medical conditions[76-78] including cancer,[79-82] chronic pain,[83,84] rheumatoid arthritis,[85] and fibromyalgia.[86]

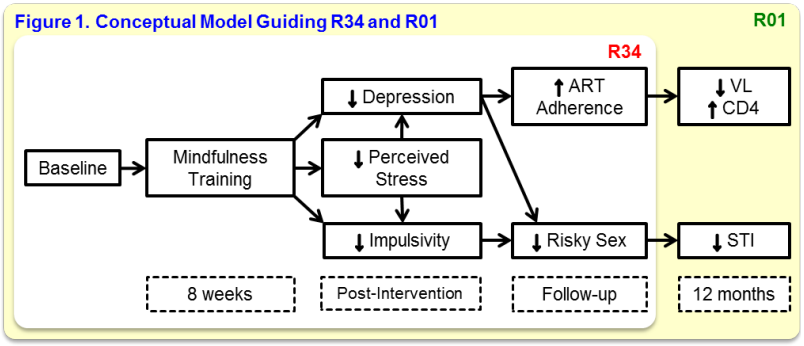
Current evidence suggests the efficacy of mindfulness training (MT) on the aforementioned barriers to adherence in the HIV context. First, MT improves depressive symptoms and perceived stress, with moderate to large effect sizes. Hofman et al.[87] reviewed 39 studies where

patients received MT for a range of psychiatric or medical conditions and reported that MT led to robust and sustained improvements in mood symptoms (Hedge's *g* = 0.95). The Campbell Collaboration[88] reviewed 31 RCTs, and found medium-sized post-intervention effects for depression (g=0.54) and for stress/distress (g=0.56). Goyal et al.[89] included 47 randomized clinical trials and found improvements in depression at 8 weeks that lasted up to 6 months. The most recent meta-analytic study[90] isolated results from 12 studies that included only participants diagnosed with a current episode of a depressive or anxiety disorder, and found significant benefits on depressive symptom severity for MT relative to controls.

Furthermore, by emphasizing the intentional and non-judgmental acceptance of any thought, feeling, or sensation arising in the field of consciousness, MT cultivates qualities that are the very opposite of impulsivity. Indeed, observational evidence suggests a possible effect of MT on impulsivity.[91] Dispositional mindfulness (i.e., the capacity that individuals have to be mindful prior to training)[92,93] has been associated with lower impulsivity and better self-control.[94] Higher dispositional mindfulness has been associated with reduced binge eating episodes and better sleep quality as well as with healthier dietary habits among students.[95,96]

Prior studies among PLWH. Although mindfulness-based approaches are increasing used by PLWH,[97-99] MT has not been well studied in the context of HIV. We found only 8 published studies[100-107] and one unpublished study[108-110] of mindfulness-based interventions with PLWH. Our review, as well as previous reviews,[111,112] suggests that MT reduces distress and promotes more adaptive coping in PLWH. The only study assessing the effect of MT on ART adherence did not show improvements; however, adherence was only a secondary outcome, only self-report measures of adherence were used, and low ART adherence was not an inclusion criterion.[104] No study has investigated the effect of MT on safer sex practices, and most studies suffer from methodological limitations (e.g., small samples, recruitment of low risk participants leading to possible ceiling effects on the outcomes). A particularly important limitation is that PLWH may have not received an adequate dose of MT due to low class attendance and high attrition in prior studies of group-based MT.[103,107]

Conceptual model. Stress, depression, and impulsivity are associated with poor adherence to ART and risky sex among PLWH. Previous research with patients having various chronic illnesses, including HIV, shows that MT reduces distress and symptoms of depression. There is also observational evidence that MT may improve impulsivity. Building upon this empirical evidence as well as theories of mindfulness,[113,114] we propose a model to guide the proposed R34 research and a future RCT. Figure 1 shows our expectation that a MT intervention will reduce stress, depressive symptoms, and impulsivity, which will improve safer sex practices and ART adherence. We will explore these relationships in the proposed R34 research. For the future RCT, we will also investigate the longer-term hypotheses, i.e., that improved adherence to ART and safer sex will improve CD4 counts, reduce viral load, and reduce incident STIs. Key to these hypotheses is confirmation that patients receive an adequate dose of the MT intervention.



Rationale for the proposed research. The proposed research is needed (1) to adapt a previously developed phone-delivered mindfulness intervention to assure that it will deliver an adequate dose of MT for PLWH; (2) to refine the evaluation protocol; (3) to develop a comparison condition that controls for the time and attention patients receive in the MT intervention; and (4) to pilot-test the interventions and assessment protocols for feasibility and

acceptability. After this R34, we envision a R01-supported RCT to evaluate the efficacy of MT on adherence and safer sex among PLWH. This large RCT will advance the field and will have the following strengths: intervention mapping based on a conceptual model; provision of an adequate dose of MT; implementation of MT by skilled instructors following a detailed manual; separate instructors to avoid contamination across conditions; confirmation of intervention fidelity; measurement of psychological (e.g., depression), behavioral (e.g., ART adherence, risky sex), and biomedical (e.g., VL, STIs) outcomes; testing of hypothesized mediators and moderators; use of computerized assessments to minimize demand. These strengths will greatly enhance the quality of the research and permit stronger inferences to be drawn about the key hypotheses, namely: (1) MT will reduce perceived stress, depressive symptoms, and impulsivity, which (2) will improve ART adherence and increase safer sexual practices, which will in turn (3) improve CD4 counts and reduce VL, and (4) reduce the incidence of STIs. If effective, these hypothesized changes can also reduce HIV-related premature morbidity.

3. AIMS

This protocol seeks to satisfy Aim 4 of our R34 grant, namely:

> **Pilot test both interventions as well as the evaluation protocol for feasibility and acceptability (Study 4).** PLWH (*n*=50) will be recruited and randomly assigned to MT (*n*=25) or to the control intervention (*n*=25), and assessed at baseline, post-intervention (3 months since baseline), and follow-up (5 months since baseline). The primary outcomes will be feasibility and acceptability. The secondary outcomes will include ART adherence and risky sex behaviors as well as possible mediators (i.e., depression, perceived stress, impulsivity) that will be included in full mediation analyses in the future RCT.

4. SAFETY ASSESSMENT

4.1. Overview

Overall, this is a low risk study. The attention control intervention and mindfulness training are low-risk, behavioral interventions. Thus, we anticipate that patients will incur minimal risks due to their participation in this study.

4.2. Protection Against Possible Risks

Possible risks during the study involve:

a. Emotional discomfort during mindfulness practice
b. Breach of confidentiality
c. Minor side effects from venipuncture for assessments of viral load
d. Depression and Suicidality

The level of risk for each of these events is minimal.

a. Emotional discomfort during mindfulness practice: Psychological distress during mindfulness practice is mild, of short duration, and rarely occurs in absence of ongoing serious psychiatric conditions; participants with suicidal ideation and ongoing psychosis will be excluded from participation in the study. In case a patient presents signs of severe psychological discomfort during or between sessions, he/she will be excused from participating in the mindfulness intervention. The mindfulness instructor will actively inquire at each phone session about psychological side effects that might occur during the session or during individual practice. Mindfulness instructors are experienced and trained on how to help individuals

presenting such issues. Participants will also be instructed to contact the Project Director (PD) should any discomfort arise during the training.

b. Breach of confidentiality: The likelihood of loss of privacy or confidentiality is rare and its impact on participants is likely to be minimal. Risks to privacy and confidentiality associated with this study will be described in the consent form along with our procedures to minimize this risk. Participant confidentiality will be maintained through a number of strategies. Each participant will be assigned a unique study identification number. The only individuals who will have access to participants' identifiers will be the PD, assessors, mindfulness instructors, and health educators. Mindfulness instructors and health educators must have access to participant identifiers in order to call the participants for their weekly sessions. Assessors will have access to participant identifiers in order to call the participants for their monthly pill counts. Assessors, mindfulness instructors, and health educators are all trained and experienced in following research protocols and participant confidentiality. Audio recordings of mindfulness and health education sessions will be reviewed promptly to ensure treatment fidelity and then destroyed. Checklists and paper records of the treatment fidelity review will not include identifying information but will be stored and handled using the same methods as with other paper data. Audio recordings of interviews will be summarized without participant identifiers and then destroyed following analysis.

Protection of study data will be assured by the use of locked files and password-protected computer databases with access available only to the study personnel. Biospecimens will be labeled only with the collection date and an anonymous numerical code; no identifiable patient information will be present on the samples. The PD will be responsible for collecting, handling and bringing the samples to the designated lab for analysis; no other personnel will have access to these samples.

c. Side effects from the venipuncture. Blood samples will be taken by venipuncture by IC phlebotomists. Venipuncture is a procedure commonly performed in general medical care which involves inserting a needle into a vein in the arm and withdrawing a sample of blood. Participants may experience mild discomfort associated with blood sample collection, including pain during blood drawing and subsequent bruising. In very rare circumstances participants may experience fainting or local infection. These risks will be minimized by having an experienced certified phlebotomist performing the venipuncture.

d. Depression and suicidality. Although participants with suicidality will be excluded from the study, depression is common among PLWH and suicidal ideation could emerge during the course of the study. The PD will calculate depression scores on the study questionnaire immediately after survey completion at each data collection point. If scores indicate that severe depressive symptoms are reported and/or if suicidal ideation is reported or if the PD has reason to be concerned about the welfare of the participant then the PD will follow the suicide protocol (Appendix 5). The PD, Carla Rich, a licensed mental health counselor; will either directly conduct an assessment of suicidality risk, or she will arrange for the PI, Dr. Carey, a licensed psychologist, to conduct an assessment of suicidality risk. If neither of these persons are available, a licensed clinical psychologist who works full-time at the Immunology Center will be contacted to conduct an assessment of suicidality risk. If the licensed psychologist is not available other providers in the Clinic are likely to be available. If none of these options were available, the participant can be escorted to The Miriam Hospital Emergency Room.

A protocol for the assessment and management of suicidality risk is included in Appendix 5 of this application.

4.3. Expected Benefits

The proposed research may result in direct benefits to participants and we expect that these benefits will outweigh the minor risk associated with participating in this research study. Individuals who complete the mindfulness training may experience reduced levels of distress, depression, and impulsivity; and an improved quality of life. Individuals who complete the general health intervention may improve their health behaviors. The magnitude of the benefits may be mild to moderate, and such benefits may last for the duration of the intervention and likely for the following months. Participants may also benefit from receiving additional medical assessments (e.g., sexually transmitted infection testing). By participating in the research, participants will also benefit from knowing they may ultimately be helping others to reduce their risk behavior, adhere better to their HIV treatments, and improve their health.

4.4. Data Safety and Monitoring Plan

Several different entities will safeguard the participants' safety and the integrity and quality of the data.

1. Institutional Review Board (IRB) at The Miriam Hospital: The study will be submitted for approval and meet all IRB requirements and directions.

2. PIs (Drs. Carey and Salmoirago-Blotcher) will closely supervise all study activities on a day-to-day basis. They will meet weekly with the Project Director, Carla Rich and other study personnel to monitor recruitment procedures, accrual and retention, side effects, and data integrity in order to take the necessary measures in a timely fashion.

3. Independent Monitoring Committee (IMC): Consistent with NIH guidelines for smaller studies (see: http://nccam.nih.gov/grants/policies/data-safety-monitoring) an IMC will be responsible for monitoring the safety of participants and the validity and integrity of the data. IMC members will include experts in HIV/AIDS, mindfulness, and statistics; members will be approved by the Program Officer of the NIH funding Institute (NCCIH). The IMC will meet yearly, either in person or via conference call. However, the IMC will convene on a more frequent (i.e., ad hoc) basis when immediate study concerns arise. At both scheduled and ad hoc meetings, they will review adverse events, re-evaluate measures for the protection of human subjects if needed, and re-assess the risk/benefit ratio of the study. A report will be compiled after each meeting and will include (a) a list of adverse and serious adverse events classified by severity and likelihood of being related to the study intervention; (b) whether adverse event rates are consistent with pre-study assumptions; (c) rates and reasons for study withdrawal; (d) whether all participants met entry criteria; (e) whether continuation of the study is justified. Summary reports of IMC meetings will be sent to the PI, the IRB and to the funding NIH agency and included in the annual NIH report (non-competing continuation grant) for the project.

Study safety and progress will be monitored according to the schedule outlined in the table below (and more frequently, if needed).

Table 1.	**Frequency of data collection**	**Frequency of data review**	
Data type	**PD**	**PIs**	**IMC**
Accrual, retention and attrition	Weekly	Every 2 weeks	Yearly
Adverse events *	Weekly	Weekly	Yearly
Participants' compliance to the intervention protocol	Weekly	Every 2 weeks	Yearly
Providers' compliance to intervention protocol	Weekly	Every 2 weeks	Yearly
Missing data/data integrity	Weekly	Every 2 weeks	Yearly

*** Please note: serious adverse events will be reported within 24 hours to the IMC, IRB,**

and to the sponsor (NIH) in accordance with their requirements.

4.5. Adverse Events and Serious Adverse Events

a. Definition. An adverse event (AE) is defined as any untoward medical occurrence in a participant temporally associated with participation in the clinical study. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.) or any combination of these. A Serious Adverse Event (SAE) is any adverse event that results in one or more of the following outcomes:
   - Death
   - A life-threatening event
   - Inpatient hospitalization or prolongation of existing hospitalization
   - A persistent or significant disability/incapacity
   - Important medical event based upon appropriate medical judgment

   Note: A birth defect is a highly unlikely event considering our study intervention. This outcome has been excluded.

b. Classification of AE Severity. AEs will be labeled according to severity, which is based on their impact on the patient. An AE will be termed 'mild' if it does not have a major impact on the patient, 'moderate' if it causes the patient some minor inconvenience and 'severe' if it causes a substantial disruption to the patient's wellbeing.

c. AE Attribution Scale. AEs will be categorized according to the likelihood that they are related to the study intervention. Specifically, they will be labeled either definitely, probably, possibly or unrelated to the study intervention. The determination of whether an AE is related to the study intervention will be made by the PD. If relatedness is unclear, the PD will seek the guidance of the PI.

Reportable and non-reportable events. The IRB at TMH requires reporting of all SAEs as well as of those AEs that are unanticipated and related to the study protocol or procedures (that is, they are "unlikely", "possibly", "probably" or "definitely" related). Unanticipated AEs are events, signs and symptoms that are not listed as risks on the consent form. Please note that AEs that are either anticipated or are "definitely not" related to the intervention procedures ***are not reportable to the IRB at TMH***.

4.6. AE Reporting Procedures and Follow-Up

All *reportable AEs* (see 4.5. for definition) will be reported by the PIs to the Institutional Review Board (IRB) at TMH. Serious adverse events (SAEs) are reported to the IRB within 24 hours as described below ("SAE reporting"). All other reportable adverse events will be reported during the routine annual continuation reports to the IRB. In addition, all AEs (reportable and non-reportable) will be provided to the Chair of the IMC prior to each IMC meeting and to the NCCIH program officer, annually.

All intervention visits (mindfulness and control sessions) and follow-up assessments will include proactive assessments of potential adverse events. The PD will record all AEs and SAEs in a secure database using the format in the example below:

Subject Identifier	AE Onset	AE End	AE Code	Severity	SAE? (y/n)	Relatedness	Action Taken	Outcome	Comments
Subj001	11/1/15			1		2	1	1	Subject felt anxious during MT; resolved within 15 minutes
Subj002									
Subj003	12/18/15			3		0	4	4	Subject fell while hiking; broke leg; withdrew from study

Severity of AE:	**Relatedness to intervention**:	**Action Taken**:	**Outcome**:
1 = Mild	0 = Definitely unrelated	0 = None	1 = Resolved
2 = Moderate	1 = Unlikely	1 = Intervention modification	2 = Recovered with minor sequelae
3 = Severe	2 = Possibly related	2 = Medical intervention (specify in comments)	3 = Recovered with major sequelae
4 = Life threatening or disabling	3 = Probably related	3 = Hospitalization	4 = Continuing treatment
	4 = Definitely related	4 = Intervention discontinued	5 = Condition worsening
		5 = Other (specify in comments)	6 = Subject death

Participants will be asked about all AEs at each intervention session and at each follow up assessment. AEs will be recorded on the AE log. The PD will report all AEs to the PIs as soon as possible. All AEs will be assessed to determine their classification and whether they meet criteria for an SAE. The PD will refer participants to their own physician for assistance with adverse symptoms. Each week the PIs will review AE reports from the previous week for events that were reported as new or continuing, and will follow all AEs to the point of a satisfactory resolution. The PIs will be available at all times to discuss other adverse symptoms with the PD and the study participants.

SAE Reporting. SAEs that are unanticipated, serious, and/or possibly related to the study intervention will be reported to the IMC, the IRB at TMH, and to the sponsor (NIH) in accordance with their requirements.

- Unexpected fatal or life-threatening AEs related to the intervention will be reported to the NCCIH Program Officer within 7 days. Other serious and unexpected AEs related to the intervention will be reported to the Program Official within 15 days.
- Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the Independent Monitor(s), IRB, GCRC/CTSA, NCCIH, and other oversight

organizations in accordance with their requirements. In the annual AE summary, the Independent Monitor(s) Report will state that they have reviewed all AE reports.

Stopping rules. Considering the low-risk of this study, stopping rules have not been established. However, the IMC will closely monitor the risk/benefit ratio and the progress of the study and should issues in accrual, retention, data quality or safety arise, will take prompt action including considering the interruption of the study. Given the low risk of this study, no interim analyses are proposed.

4.7. Monitoring of Study Progress (see also Table 1 in 4.4.)

Accrual, retention. Review of the number of screened and eligible participants/month, accrual rates, adherence to inclusion/exclusion criteria will occur weekly. This will help evaluate the adequacy of the eligibility criteria and of the recruitment procedures and to address concerns in a timely fashion.

Compliance with the intervention protocol. Protocol compliance will be assessed in an ongoing fashion. Participants' compliance will be monitored by the instructors and PD and will involve tracking of the number of session attended and of the total time of individual mindfulness practice. Instructors' compliance will be supervised by Dr. Salmoirago-Blotcher according to the Treatment Fidelity Workgroup guidelines. At the end of each intervention session the instructor will complete a checklist in which duration and delivery of the intervention as specified in the intervention script will be evaluated, as well as the patient's level of engagement during the session. In order to monitor the consistency of the delivery of the intervention, each session will be digitally recorded. Ten percent of all recorded sessions will be randomly reviewed.

Data accuracy.The PD and data manager , in collaboration with the data analyst, will be responsible for tracking participants to ensure that all data are collected in a timely and efficient fashion; for developing and generating monitoring reports; for providing timely and relevant feedback to project staff and leadership regarding the accuracy and precision of data. The following data verification procedures are planned:

Research Electronic Data capture (REDCap) technology will be used for direct data entry during the interviews. REDCap employs automatic checks for values that are out of range or represent errors of logic. Outliers will be corrected with verification from participants.

Calculations (i.e., from self-report measures, when necessary) will be independently performed by two different persons and any invalid score (i.e. scores that differ between the two people) will be recalculated.

5. ELIGIBILITY

5.1. Population

This study will enroll 50 *HIV*+ adult outpatients (25 per condition). The sample will be representative of the demography of the HIV epidemic and of the clinic outpatient population (*n* = 1614 outpatients with 70% male and 30% female; 60% White, 30% African American; 10% other/mixed; 25% Hispanic). We expect no difficulties recruiting 50 patients for this research.

5.2. Participant Source

Participants will be recruited from the Immunology Clinic (IC) at The Miriam Hospital (TMH) in Providence, RI. The Immunology Center is an urban HIV-clinic that provides comprehensive primary and specialty care for over 1,600 HIV-infected patients. It is the largest HIV clinic in Rhode Island with patients also referred from western Connecticut and southern Massachusetts. An average of 300-400 HIV-infected patients are seen in the clinic per month.

The Immunology Center is located at 1125 North Main St., Providence, RI. The clinic occupies the first floor. The second floor, designed to support clinical research, has exam and interview rooms dedicated to clinical research. Co-I Dr. Philip Chan, who is also a clinic treatment provider, will act as a liaison between the study and the clinic.

Vulnerable populations. This study will not recruit individuals from the traditionally vulnerable populations (i.e., adults unable to consent, infants, children, teenagers or pregnant women). However, the PIs and the research team recognize that HIV-infected persons are vulnerable because of their disease status and because the disease disproportionately affects individuals with a range of vulnerability characteristics—including racial/ethnic minorities, women, and/or injecting drug users—not necessarily specified in the current definition and categories. Therefore, we will uphold the highest standards to protect study participants.

An overriding concern in HIV research is confidentiality and privacy because breaches of confidentiality could have adverse consequences. Therefore, as described in this protocol (and in our research application and other study communications), we will establish procedures that ensure that our study guards and protects participants' confidentiality. We will adopt standard protections, including as the following: (a) where identifiers are not required, they will not to be recorded; (b) if identifiers are recorded, they will be separated, to the greatest extent possible, from data and securely stored, with linkage restored only if necessary to conduct the research; (c) potential participants will be given a fair and clear explanation of how information about them will be handled, including whether and how the information will be recorded in their medical records; (d) we will seek and obtain a Federal Certificate of Confidentiality so that we can resist attempts to force disclosure of participants' research records; and (e) information that is recorded (e.g., focus group discussions) will have all identifying information removed from transcripts, and the source materials will be destroyed once transcripts are prepared and checked for accuracy.

Assessments for Study 4 will be collected at baseline, at completion of intervention sessions (post-intervention), and approximately 3 months after completion of intervention sessions (3 month follow-up). In addition, we will conduct monthly telephone calls for the unannounced pill counts, to be used as a measure of medication adherence. The entire duration of the study is projected to be 2 years. Each individual will be involved for about 6 months from enrollment with the maximum individual involvement to be 7.5 months in cases where the participant's intervention start date is delayed due to extenuating circumstances (e.g., death in the family or hospitalization).

5.3. Inclusion Criteria

Participants must meet all of the following inclusion criteria to participate in this study:

1. Age ≥18 years
2. HIV infection
3. Sub-optimal adherence to ART (Less than "always" taking ART medication and/or VL >20 copies/mL);
4. Psychological distress (PHQ-4 score ≥ 2);
5. Access to a telephone or cell phone

5.4. Exclusion Criteria

Participants meeting any of the following criteria will be excluded from participating in this study:

1. Inability or unwillingness to give informed consent
2. Cognitive impairment
3. Non-English speaking

4. Enrollment in another ongoing behavioral research project
5. Prior formal training in MBSR or active practice of mindfulness, meditation, or related mind-body techniques in the past year
6. Severe hearing impairment not allowing phone delivery
7. Suicidal ideation
8. Psychosis (e.g., diagnosis of a severe and persistent mental disorder)
9. Planning to move out of the area within the study period
10. Health care provider (i.e. physician, nurse, or mental health professional) at the Immunology Clinic recommends patient should not be approached for the study

6. ENROLLMENT

6.1. Recruitment Processes

Participants will be recruited from patients receiving care at the Immunology Center at The Miriam Hospital. Dr. Philip Chan, a Co-Investigator on the project who is also a clinic treatment provider, will act as a liaison between the study and the clinic. The Immunology Center is an enthusiastic supporter of clinical research.

Study 4 will rely on four methods of recruitment: (1) patients from the clinic, using a patient database query and in person recruitment, (2) direct referral from clinic providers (e.g., research nurses, physicians, mental health professionals) at the Immunology Center followed up by in person recruitment, (3) recruitment letter, and (4) phone recruitment.

(1) **Direct appeal to patients in person**: The Immunology Center Database (ICDB) will be queried to identify all patients who have had a detectable HIV-1 Plasma viral load within the past 12 months, are 18 years of age or older, and have an upcoming appointment within the next 3 months. The PD will review the IC appointment list on a daily basis to assess which patients from the ICDB query are coming in for an appointment. The PD will review the eligibility with the participant's HIV provider. If considered eligible by the HIV provider, the PD will approach the patient at their scheduled appointment.

(2) **Physician referral**: The PD will share some eligibility criteria with clinic providers from the IC through the use of a flyer which can be emailed or hand delivered. The PD will ask for referrals from the clinic providers. The PD will check the IC appointment list to assess the patient's next clinic visit. The patient will be approached in person at their scheduled appointment.

(3) **Direct appeal to patients by Letter**: The Immunology Center Database (ICDB) will be queried to identify all patients who have had a detectable HIV-1 Plasma viral load within the past 12 months and are 18 years of age or older. The PD will review the eligibility with the participant's HIV provider. The PD will ask the HIV provider if contacting the participant via letter is appropriate. If the HIV provider provides permission the PD will mail the recruitment letter.

(4) **Direct appeal to patients by phone**: If no response is received within two week of mailing the letter (see #3), the PD will ask the HIV provider if contacting the participant via phone is appropriate. If the HIV provider provides permission for phone contact the PD will call the participant following the phone recruitment script.

If a participant is found ineligible or refuses to be screened and/or participate at any of above the four recruitment methods he or she will not be contacted again for the life of the study.

6.2. Screening and Consenting Procedures

For recruitment methods (1) and (2) the PD will meet individually with referred patients in a private room at the Immunology Center. For recruitment methods (3) and (4) the PD will screen the participant via telephone. The PD will summarize the study and its requirements and enquire whether the patient is still interested. If the patient is interested, the PD will explain the need to collect some preliminary information to determine whether he/she is eligible to participate. A screening script and screening instrument will be used to standardize this phase of screening. Patients meeting initial eligibility criteria will receive a thorough explanation of the study design, including what they will be expected to do if they join the study as well as detailed information regarding risks and benefits. All questions answered to the patient's satisfaction and understanding.

Once informed consent procedures are completed, the PD will complete screening assessments to confirm the participant's eligibility for the study (see 8.2 for a detailed description of screening assessments).

Participants who are eligible and agree to participate will proceed to the completion of all baseline measures, with the exception of baseline objective assessments of ART adherence.

Screen failures

Filemaker Pro will be used for tracking all participants for Study 4 who expressed interest in participating and were screened for eligibility. We will collect data from all individuals assessed for eligibility (i.e., individuals who consented but then resulted non-eligible at the completion of the screening process) so that we can provide a complete Consort diagram and description of the recruitment process both for publication purposes and as an indicator of future generalizability of the study. We estimate that 70% of screened participants will be eligible for this study.

Screening window

We will make every effort to minimize the time between the completion of all screening procedures and the beginning of the intervention in Study 4 (max, 8 weeks).

Randomization

After all baseline assessments have been completed, the PD will randomly assign participants (1:1 ratio) to the MT or AC condition using a randomization schedule generated by the study biostatistician, Dr. Dunsiger. The schedule will be generated using a permuted block randomization procedure with small, random-sized blocks. The allocation table will be password protected and saved to the CBPM secure drive. The unit of randomization will be the individual patient. We do not anticipate contamination between MT and AC, as patients will likely have no chance to exchange experiences about the interventions and instructors delivering the MT intervention will be different from those delivering the AC intervention.

Participants will be given the option to pick up intervention materials in person after randomization occurs or to have the materials mailed to them. Intervention materials for the MT condition consist of a compact disc with audio recordings of the mindfulness instructor's voice as well as a box of raisins to be used during mindfulness sessions and daily practice. Scripts of these recordings are located in Appendix 1 of this protocol. The compact disc doesn't contain the name of the study nor any identifying information about the study or the participant. Intervention materials for the AC condition consist of a packet of material pertaining to the session topics (i.e. nutrition, sleep) that is available to the public on the internet. These materials were chosen from websites such as the Centers for Disease Control and the

American Heart Association. Intervention materials for both MT and AC condition do not mention HIV or HIV status.

6.3. Retention Plan

Patients will be asked to provide two different telephone numbers (home and mobile phone number) and an email address. Participants will be asked to provide contact information for two locators to be used in the event that contact is lost with the participant. Locators will not be given information about the nature of the research study. The study tracking system will identify participants due for a visit. We will send mail/email reminders or phone messages to remind patients of their follow-up appointments. Participants who wish to drop out of the study will be queried as to their reasons for doing so and every attempt will be made to address their concerns. In addition, we will provide monetary compensation to patients for their time and expenses. Participants will receive $40 cash for the baseline assessment, $40 cash for the post-intervention assessment, $50 cash for the follow-up assessment and $10 cash each for the pill count telephone calls (seven total) for a total of $200.

If a participant does not complete all of the baseline procedures (including the two pill counts) within 60 days of enrollment, then he or she will be considered lost to follow-up.

If a participant does not complete two intervention weeks in a row he or she may be withdrawn from the intervention portion of the study per PD and PI discretion. These participants would still be contacted for pill count assessments and follow-up assessments.

7. DESIGN AND DRAFT PROCEDURES

This is a pilot, Phase 2, behavioral randomized controlled trial, which is primarily designed to determine the feasibility and patient acceptability of mindfulness training for improving adherence to ART and promoting safer sex practices among persons living with HIV (PLWH).

As a secondary purpose, we will obtain preliminary estimates of efficacy of MT on two clinically relevant outcomes (namely, actual adherence to ART and adoption of safer sexual practices) and the hypothesized mediators (i.e., mindfulness, depression, perceived stress, impulsivity).

7.1. Study Outcomes

Primary outcomes: feasibility and acceptability.

Feasibility: Key metrics will include the number of screened, eligible, consented and randomized participants; retention rates; session attendance; and individual mindfulness practice. We will consider either condition feasible under the following conditions:

1) If we achieve retention rates of 80% at the final follow-up visit
2) If patients attend at least 70% of the planned sessions
3) If patients report to have completed 70% of the assigned individual home practice exercises
4) Intervention session calls lasting approximately 20 minutes
5) Fewer than three rescheduled intervention calls

Acceptability: We will assess the following domains:

1) Participants' experience in the study (qualitative data collection)

2) Participants' ratings of the interventions on a satisfaction survey. The intervention will be considered acceptable if ≥80% of participants responds that they are at least somewhat satisfied with the intervention.

Secondary outcomes:
Preliminary estimates of effect size of mindfulness training vs. attention control on changes from baseline ART adherence, risky sex behaviors as well as on hypothesized mediators (i.e., mindfulness, depression, perceived stress, and impulsivity) will be assessed. We expect that the mindfulness training condition will achieve larger positive changes in ART adherence and risky sexual behaviors compared to the attention control condition.

7.2. Design Overview

Participants (*n* = 50; 25 per condition) will be assessed (i.e., baseline), randomized to intervention (i.e., 8 weekly phone-delivered sessions of mindfulness training or the attention control intervention), and reassessed at the end of the intervention (i.e., post-intervention), and at 3 month post-intervention follow-up.

7.3. Study Interventions

Intervention setting. Intervention sessions for both conditions will be individually delivered over the phone. Prior to the beginning of the intervention instructors will contact participants to set up the best time to deliver the intervention.

Session frequency. Participants in both conditions will receive a 30-minute phone call session once a week for 8 weeks.

Mindfulness training (MT). The intervention protocol is based on the MT protocol pilot-tested in our preliminary work[120] (see Appendix 1 for a script of each session). This intervention maintains the basic components of Mindfulness Based Stress Reduction (MBSR)[75] but has been streamlined to distill the active ingredients for phone delivery. The MT intervention involves training in the following practices: (1) Awareness of breath, a technique in which trainees learn to attend to the sensations associated with breathing; and (2) Body scan, a technique based on the cultivation of attention to bodily sensations that would normally go unnoticed. Later, participants are gradually trained to (3) direct their attention to simple activities of daily life and (4) to become aware of their own thoughts and emotions. Only at the final session they (5) practice "open awareness" – a technique by which the participant is invited to direct his/her attention to any event arising in their field of experience at a given moment, whatever it may be, e.g., a physical sensation, sound, emotion, or thought.

Individual home practice. In addition to the weekly training session, participants will practice mindfulness techniques for 15 minutes daily on their own with the guidance of a digitally recorded, standardized guided mindfulness practice containing the techniques learned with the instructor. The mindfulness practice digital recording will be provided in different formats (CD or MP3 file) depending on the participant's preference. (Please see Appendix 1 for a detailed script of the CD/MP3 recording).

MT instructors. MT instructors will be graduates from the teachers' training program at the University of Massachusetts Center for Mindfulness with ≥ 5 years teaching experience. To ensure consistency of delivery, each patient will be trained by the same instructor throughout the intervention. Instructors will receive 3-hour training session in the delivery of the MT intervention, self-recording and fidelity checks, protocols, and reporting. Supervision will be

provided during regular conference calls. These calls will be scheduled weekly during the first month, biweekly during the second month, and monthly thereafter. Additional ad hoc calls will be scheduled if needed. The calls will be led by Dr. Elena Salmoirago-Blotcher, and will involve discussion of issues that arise during MT sessions.

Attention control (AC) condition. The AC condition is an active, structurally equivalent, intervention to control for the time and attention received in the MT condition. The content of the AC intervention was developed using participants' feedback from the Study 1-3 focus groups and will include health topics suggested by the focus groups including: Sleep, Nutrition, Sun Safety, Physical Activity, and Home and Travel Safety (see Appendix 2 for a script of each session).

Individual home practice. Each health topic has an associated daily practice activity to control for the time patients in the MT intervention spend practicing mindfulness exercises on their own (15 minutes daily). (See Appendix 2 for an explanation of daily practice for the AC condition).

AC instructors. Instructors will be clinical psychology residents with ≥ 5 years of experience. To ensure consistency of delivery, each patient will be trained by the same instructor throughout the intervention. Instructors will receive undergo training in the delivery of the general health intervention. Supervision will be provided during regular conference calls. These calls will be scheduled weekly during the first month, biweekly during the second month, and monthly thereafter. Additional ad hoc calls will be scheduled if needed. The calls will be led by Carla Rich, and will involve discussion of issues that arise during AC sessions.

7.4. Concomitant Interventions

Allowed Interventions: Participants are allowed to continue ALL the medications and follow all behavioral recommendations prescribed by their care providers. We will monitor all medications used and control for these in data analyses.

Prohibited Interventions: Yoga, stress reduction, or other mind-body training.

7.5. Treatment Fidelity

To ensure that interventions are delivered with fidelity, we will have developed, a protocol, manual, and script of each session. The script will not be used verbatim but instructors will be trained to follow the sequence indicated in the Session Guides. As noted earlier, to avoid contamination, different instructors will deliver the MT and AC interventions. Assessments of treatment fidelity will be conducted following the guidelines developed by the Treatment Fidelity Workgroup.[121,122] We will create checklists of essential intervention components for the MT and AC. At the end of each session instructors will complete the auditor checklist corresponding to that session. Instructors will also digitally record each session. We will audit 10% of all recordings using the checklist to ensure that the interventions are being delivered as intended.

7.6. Blinding

This is a phase 2 pilot study testing the feasibility of a behavioral intervention; participants will not be blinded.

Blinded personnel:

- Principal Investigators and all Co-Investigators
- Data management and data analysis personnel
- MT and AC instructors will be blinded to the study outcomes.

Non-blinded personnel:

- Project Director. Blinding the PD would be impractical given that she will be randomizing the patients to either condition. The impact of un-blinding the PD will be minimal because study

surveys are completed electronically by participants and the PD will NOT be involved in data analysis.

8. STUDY ASSESSMENTS

Overview

Table 8.2 provides the schedule of study assessments for this pilot RCT. All assessments will be conducted in-person. The PD will be responsible for data collection; see section 7.6 for blinding consideration. Because not all participants can be reached for assessments on their due date, windows have been established to determine when to record a protocol violation or consider assessments missing (Table 8.1).

Table 8.1

Assessment	Window
Baseline	Within 60 days from screening visit
Post-Intervention	Within 2 weeks of final intervention session
Follow-up	12 weeks (+/- 2) after completing final intervention session

All visits will be conducted at the Immunology Center (described earlier).

Table 8.2 Schedule of Study Assessments

Assessment	S	BL	At each session	Post	FU
Screening					
HIV infection status	**X**				
ART adherence	**X**				
Viral load	**X**				
Psychological distress	**X**				
Sexual risk behavior (past 3 months)	**X**				
Prior mind-body training	**X**				
Hearing impairment	**X**				
Suicidal ideation	**X**				
Telephone Access	**X**				
Literacy	**X**				
Feasibility and Acceptability					
n of screened individuals		**X**			
n eligible		**X**			
n enrolled		**X**			
n refusing to participate		**X**			
Reasons for refusing participation		**X**			
n of dropouts and lost to follow-up			**X**	**X**	**X**
Reason(s) for dropping out			**X**	**X**	**X**
Sessions attendance (both conditions)			**X**		
Individual home practice (both conditions)			**X**	**X**	**X**
Acceptability Survey/ Satisfaction scale				**X**	**X**
Qualitative Interview				**X**	**X**
Efficacy					

ART adherence: self-reported measure		X		X	X
ART adherence: objective measure (unannounced pill count)		X*		X	X
Viral load (ART adherence biomarker)		X		X	X
Sexual risk: Self-report		X		X	X
STI (sexual risk biomarker)		X			X
Mediators					
Mindfulness		X		X	X
Depression		X		x	X
Anxiety		X		X	X
Perceived stress		X		x	X
Impulsivity		X		x	x
Moderators and Descriptors					
Demographic characteristics		X			
Perceived physical health		X		X	X
Medical history; medications		X			X
Social support		X			
Sleep		X		X	X
Alcohol use		X		X	X
Other Drug Use		X		X	X
Smoking		X		X	X
Nutrition/Eating		X		X	X
Food Security		X		X	X

S = screening; BL = baseline; post = post-intervention; FU = follow-up. * Scheduled within one week of the baseline.

8.2. Screening Assessments

These evaluations occur to determine if the Immunology Center patient is eligible for the study.

- HIV infection status will be obtained from the medical record.
- ART Adherence will be assessed using self-report and viral load: participants who are less than 100% adherent during the past six months and/or those with a viral load (obtained from the medical record) > 20 copies/mL will be eligible.
- Psychologically distress will be measured using the PHQ-4[115]; only individuals scoring ≥ 2 on the PHQ-4 will be included in the study.
- Recent sexual risk behavior assessed with self-report.
- Prior training in mindfulness, meditation, or related mind-body techniques will be assessed using self-report.
- Severe hearing impairment not allowing phone delivery will be self-reported and corroborated by the PD.
- Telephone access will be assessed by self-report.
- Literacy will be assessed by the SILS.
- Suicidal ideation will be assessed by questions on recent suicidal thoughts and plans. Individuals endorsing 1 or more of these items will be assessed further by use of the suicide protocol (Appendix 5).
- Additional foil questions about other health factors (e.g., smoking, alcohol use) will be included to decrease the likelihood of potential participants figuring out eligibility criteria.

8.3. Baseline Assessments

FEASIBILITY

To assess feasibility the following will be recorded: number of screened, eligible, consented and randomized participants; number of patients who refuse participation and reasons for refusal.

EFFICACY OUTCOMES

1. Medication Adherence

Consistent with NIH (e.g., PA-14-335)[124] and expert recommendations,[125-128] we will employ a multi-modal assessment of medication adherence: self-reported ART adherence, objectively reported ART adherence, and a biological health-related indicator (viral load).

- *Self-report*: we will use the Wilson 3 item Self-Report Adherence measure, a recently developed and validated 3-item measure.[130]

- *Objective*: phone-based unannounced pill counts.[131-133] Unannounced phone-based pill counts are reliable and valid.[132-136] Field studies show high concordance between phone-based and home-based number of pills counted (Spearman's rho = .995, $p < .001$) and percentage of pills taken ($r = .997$, $p < .001$).[132] Concordance between participants defined as 90% adherent to their medications by the phone count and home count was 95%, Kappa coefficient = .995. Adherence determined by unannounced cell phone-based pill counts also corresponds with VLs at a similar magnitude observed between unannounced home-based pill counts and VL.[131] Use of a phone-based method has the additional advantage of being consistent with the phone-based MT intervention we are evaluating. A detailed protocol for the phone-based unannounced pill count protocol can be found in Appendix 3. This protocol has been provided by Dr. Kalichman, our consultant.

- *Biological indicator: Viral load*: Although not a direct measure of adherence, VL is closely aligned with adherence.[137-139] Participants will provide blood specimens for performing VL lab work. Samples will be collected using standard phlebotomy and processed at Lifespan laboratories.

2. Sexual Risk Behavior

Also consistent with the NIH Consensus Panel and recommendations from HIV prevention experts, we will employ a multi-modal assessment of sexual risk behavior with self-report, medical chart review, and laboratory testing.

- *Self-report*: This information will be collected using a self-reported survey developed according to standard strategies.[140-143] We will collect information using items that we have used in previous studies,[144-147] namely, number of male and female sexual partners; number of occasions of protected and unprotected oral, anal, and vaginal sex; partner type and partner serostatus over previous 3 months.

- *Medical chart review for clinical diagnosis of STI:* This information will be collected from medical, consistent with current guidelines[148] and prior work.[145,149] This information is necessary to capture STIs that have been treated between visits[150] because successfully treated bacterial infections will not be detected with laboratory testing.

- *Laboratory-diagnosed STI*: this data will be collected as a proxy of risk sexual behavior. We will collect blood, urine, rectal, and pharyngeal specimens, and test these using at Lifespan laboratories using standard processing methods. STI testing will be supervised by Co-I Chan, an infectious disease physician. Detailed procedures about specimen collection and

lab testing will be included in the Manual of Procedures. We will collect:

- Urine specimens for urethral (men) and cervical (women) Gc, CT, and Trichomoniasis
- Pharyngeal swabs for Gc.
- Rectal swabs for Gc and CT.

Laboratory results will be reviewed by the Dr. Chan and the PD. If there is a positive test the participant and his or her Immunology Center provider will be notified. The Immunology Center provider will advise the participant on treatment options (if applicable). If the STI is reportable, it will be reported to the Health Department as required by law.

MODERATORS AND PARTICIPANT DESCRIPTORS

Research suggests a number of person factors that may be associated with adherence to ART and safer sex. We will seek to balance comprehensiveness of the data set with participant burden. We will look for precise measures of constructs with the fewest items that yield reliable and valid estimates of the constructs.

- *Demographic characteristics* (e.g., sex assigned at birth, gender identity, age, race/ethnicity, relationship and employment status, income, educational attainment) will be assessed using standard questions developed in previous research with this population.
- *Perceived physical health* will be assessed with a single item from the Medical Outcomes Study General Health Survey.[154,155]
- *Medical history* will be obtained from patient's medical record, and will include: date of initial HIV diagnosis, likely mode of contracting HIV, length of time since initiating ART, VL and CD4 counts, adherence to medical appointments (# of missed appointments, if any), AIDS diagnosis (yes/no, date), number of HIV-related hospitalizations, medical and psychiatric comorbidities and current medications. Our hospital system now maintains an electronic medical record, and data will be corroborated as appropriate.
- *Social support* will be measured using 12 items from the Medical Outcomes Study Social Support Survey, a 19 item survey used to measure how perceive social support (i.e., family, friends, and significant other).
- *Sleep* will be measured using the Pittsburgh Sleep Quality Index, a 7 item measure.
- *Alcohol use* will be assessed with the Alcohol Use Disorders Identification Test (AUDIT),[163] widely used in healthcare settings; scores of ≥8 indicate hazardous drinking, and scores ≥16 suggest alcohol use disorder; and PhenX Measures for Lifetime Use, 30-Day Frequency, and Maximum Drink in 24 Hours.
- *Other drug use* will be measured with the PhenX Substances-Lifetime Use, Substances-30 Day Frequency and DAST-10.
- *Smoking* will be measured with questions about lifetime smoking and past 30 days.
- *Food Security* will be measured using the U.S. Household Food Security Survey, a 6 item index.

MEDIATORS

- *Mindfulness* will be assessed with the FFMQ-15, a measure of trait (dispositional) mindfulness comprised of 15 items.
- *Depression* will be assessed using the PHQ-9.

- *Anxiety* will be assessed using the GAD-7.

- *Perceived Stress* will be measured with the 4-item Perceived Stress Scale (PSS),[117,175] which assesses the degree to which participants perceive circumstances as stressful in the last month. Higher scores indicate greater levels of perceived stress.

- *Impulsivity*. The Barratt Impulsiveness Scale (BIS-11)[176,177] has 5 factors (attention, motor, self-control, cognitive complexity, perseverance, and cognitive instability impulsiveness) and is widely used.

8.4. Post-Intervention and Follow-up Assessments

Two additional assessments will take place (a) post-intervention (within two weeks of finishing the program) and (b) at 3 months post-intervention (within 12 weeks (+/- 2 weeks) after finishing the program):

- Feasibility
    - Retention rates; drop-out counts and reason for dropping out will be maintained by the RA.
    - Adherence to Mindfulness Training and Health Coaching
        - Session attendance will be recorded at each session by the instructor using an attendance log.
        - Individual practice at home will be self-reported during each session.
- Acceptability
    - Satisfaction Survey[178] reporting how informative, interesting, and helpful the MT was; how likely they are to continue practicing after the training; whether they would recommend it to other PLWH; and whether they have suggestions for how we might improve it. Participants will rate the interventions on a scale from 0 to 6.

- Qualitative data collection
    - At each assessment, participants will be asked to participate in an interview to solicit information about their experiences. They will be asked open-ended questions about their experiences. The semi-structured qualitative interview guide can be found in Appendix 4.

- Efficacy (measures described at Baseline)
    - Adherence to ART
        - Self-reported adherence
        - Unannounced pill counts
        - Viral Load
    - Sexual Risk
        - Self-report of risk behavior
        - STI (chart diagnosis)
        - STI (lab-diagnosed)
- Moderators (measures described at Baseline)
    - Perceived health
    - Sleep
    - Alcohol Use
    - Substance Use
    - Smoking
- Mediators (measures described at Baseline)
    - Mindfulness

- Depression
- Perceived stress
- Impulsivity
- Anxiety

9. DATA COLLECTION

9.1. Data Sources

With participant consent, information about concurrent medical conditions and history as well as current medications will be collected from electronic medical records.

9.2. Data Safety

Electronic data will be stored in password protected data files accessible only to authorized project personnel including the PIs, Data Systems Analyst, Statistician and the PD. All data files will be automatically backed up daily. Paper data will be stored in locked file cabinets. Data containing identifiers (e.g., name, address, phone number of participants) will be stored on password-protected secure servers separately from de-identified study data (e.g., surveys, screeners).

9.3. Data Collection

The PD will collect data via in-person interviews at each assessment. Electronic data capture technology will be used for direct data entry during the interviews; clinical data will be entered by the PD from the abstraction forms into electronic version of the abstraction forms. Any ambiguity in the response to a question will be brought to the attention of the Data Systems Analyst for clarification. If the Data Systems Analyst is unsure how to code the response, the matter will be brought to the attention of the PI.

9.4. Qualitative Data Collection

Data from qualitative interviews will be collected using audiotapes and observer/interviewer notes. Audio recordings will be analyzed using a framework matrix and will be reviewed by study staff. At the conclusion of the study recordings will be destroyed.

10. DATA MANAGEMENT

10.1. Tracking Systems

Prior to beginning participant recruitment; the Data Systems Analyst will develop a tracking system using Filemaker software. The tracking system will help the PD in ensuring that all procedures are followed, interventions are adhered to, and assessments administered in a timely fashion. The tracking system will include all steps included within the Recruitment, Treatment and Follow up phases of participant participation in the trial.

10.2. Data Entry and Storage

Our major data management and analysis needs for the proposed project can be met by using a Pentium-based microcomputer. The data systems analyst will conduct data management under the supervision of the study biostatistician and the PIs. De-identified data will be exported directly into study datasets. Depending upon the analytic question, either STATA 14 (Stata

Corporation) or SAS statistical software will be used for analyses, as determined by the study biostatistician, Dr. Dunsiger.

Electronic data will be stored in password protected data files accessible only to authorized project personnel including the PIs, Data Systems Analyst, Statisticians and PD. All data files will be automatically backed up daily. Paper data will be stored in locked file cabinets. Data containing identifiers (e.g., name, address, phone number of participants from ACCESS files) will be stored on password-protected secure servers separately from de-identified study data (e.g., surveys, screeners).

The Data Systems Analyst will work with project statistician Dr. Dunsiger and the PIs to ensure that data are cleaned prior to analysis. When ready for analysis, he will provide a STATA database of collected data to the statistician.

11. QUALITY CONTROL AND QUALITY ASSURANCE

11.1. Treatment Fidelity

Procedures are described in section 7.5.

11.2. Training

All staff involved in data collection will be trained and certified regarding their competence. This includes training on administration and scoring of all questionnaires as well as on reviewing assessment instruments immediately for omissions. When information is missing or incomplete, the PD will contact participants to obtain the necessary information. *A manual of operations* will be developed during the study start-up period that explicitly describes the specific procedures related to data collection and quality assurance. At study beginning, the first 10 participants will have their data audited to make sure there are not any systematic problems with regards to entry. This preliminary audit process will reveal any possible problems at the onset as opposed to the end of the study, which would result in more work cleaning the data.

Staff will receive extensive training in maintaining patient confidentiality, supervised by Dr. Carey, a licensed clinical psychologist with 30 years of research and clinical experience in sexual health, HIV, substance use, and related socially sensitive topics. Training will focus on procedures for making sure data are not accessed by individuals outside of the research team, keeping identifying information separate from data, and not disclosing participant information or participant names to individuals outside of the research team. Staff will be assigned readings about confidentiality and research ethics; readings will be discussed with Dr. Carey. All staff will complete on-line NIH- and Hospital-based ethics training. Staff will also receive extensive confidentiality training, which will involve reading, online videos and other training materials, and discussing scenarios in which confidentiality could be breached. Staff will be required to sign an agreement to keep all patient information confidential. In addition, staff will receive training in duty to warn and duty to report child abuse. They will be told to immediately contact one of the investigators if a participant threatens to hurt him/herself or someone else, or if a participant reports child abuse.

Staff will also receive training in study policies and procedures, the need for clinical sensitivity in working with patients, gender and developmental sensitivity, and cultural and sexual orientation competence. Staff will role play recruitment and assessment sessions with the investigators, to demonstrate competence with the study protocol. When hiring project staff, we will recruit individuals with previous research experience who demonstrate a good understanding of the importance of participant confidentiality and research ethics, and evince personal integrity. We,

and the Miriam Hospital Human Resources Department, will check personal and professional references to be sure that all research staff have high personal standards regarding confidentiality and clinical sensitivity, as well as an ability to maintain the scientific responsibilities entrusted to them.

11.3. Data Monitoring

With supervision from the PIs and the Study Biostatistician (Dr. Dunsiger), the Data Systems Analysts (Chris Breault) will ensure that entered data accurately represent data collected. He will conduct error-checking procedures quarterly on all data to ensure their accuracy. Data entry systems developed using Access will include appropriate skip patterns and parameter limits to ensure that data are entered accurately (e.g., item response formats from 1-5 will not permit entry of other numbers). Data entry systems will be tested to ensure that these constraints are working correctly prior to entering real data. Microsoft ACCESS employs automatic checks for values that are out of range or represent errors of logic. Outliers will be corrected if possible with verification from participants.

Quantitative data will be cleaned prior to analysis and then made available to the study statisticians for analysis. Dr. Dunsiger will be primarily responsible for the final outcome analyses and will assist in the preparation of manuscripts and reports.

11.4. Metrics

Direct entry of study data into electronic forms by the study participant and automatic parameter limits and error-checking procedures embedded into the Access system eliminate the need for re-entry of data and cross-referencing with paper copies, as well as auditing procedures. See Section 11.3 for data monitoring procedures.

11.5. Protocol Deviations

A *minor protocol deviation* is defined as an accidental and unintentional change, or non-compliance with the IRB approved research protocol that does not increase risk or decrease benefit or does not have a significant effect on the participant's rights, safety or welfare; and/or on the integrity of the data; for example, the need to reschedule a visit because the participant is traveling, or a follow up visit that occurred outside the protocol required time frame because of the participant's schedule. A *major protocol violation* is a divergence from the protocol that materially (a) reduces the quality or completeness of the data, (b) makes the Informed Consent Form inaccurate, or (c) impacts a participant's safety, rights, or welfare. Examples include: inadequate or delinquent informed consent; enrollment of non-eligible individuals; unreported or misreported serious adverse events; breaking of the blind; use of prohibited interventions; incorrectly collected or missing tests; multiple visits missed or visits outside permissible windows; intentional deviation from protocol, Good Clinical Practice, or regulations by study personnel.

Capture, documentation, and review. All protocol deviations will be captured using a protocol deviations tracking log as they occur. The PI will sign each form after it has been completed or immediately prior to a monitoring visit. If it has been signed with fewer than five deviations entered into it, the next identified deviation will be reported on a new page to ensure that all deviations have been reviewed by the PI. Pages will be numbered and stored in reverse chronological order in the study Regulatory Binder. At the conclusion of the study, the final page of the log will be identified by checking the box in the footer. ALL protocol deviations will be reviewed by the PI at weekly study staff meetings; SAE reporting procedures will be followed (see 4.5 and 4.6) if a protocol deviation results in a SAE.

Reporting. Minor protocol deviations will be included in IMC reports and in the TMH IRB continuing review application. Major protocol violations will be reported to the TMH IRB and to the NCCIH Program Officer.

Please note that retention, attendance are feasibility outcomes; consequently dropouts, missing session, and missing self-reported practice will not be considered protocol deviations. This information will be collected and monitored (as aggregate data and without breaking the PI blind status)*.*

Protocol amendments. Please also not that given the pilot nature of this study, we may need to amend the original protocol in response to feasibility issues (e.g., if we realize that our eligibility criteria are too strict, unnecessary and negatively affect recruitment). If needed, we will submit an amended protocol to NCCIH for approval in the following cases: any change that may affect patient safety (e.g., change in eligibility criteria; change in risk, regardless of whether risk is increased or decreased); any change that changes scientific intent or study design, or affects human subject protection; addition/deletion of a site; addition/deletion of key study personnel; change of institution for key study personnel; change in enrollment targets. Amendments will also be submitted to the IRB in accordance with IRB policies at TMH.

12. STATISTICAL CONSIDERATIONS

12.1. Preliminary Analyses

Expertise. Co-Investigator Dr. Shira Dunsiger, Ph.D., is a biostatistician who has extensive research experience in the context of behavioral medicine research, including research. She is familiar with the challenges associated with the analyses of count data, missing data, longitudinal data, and has used SAS, Stata, and other statistical packages for more than a decade. She will be responsible for the analysis of all quantitative data.

Preliminary analyses will examine comparability of participants in the MT and AC groups at baseline on demographic and other characteristics using Fisher or t-tests depending on the specific variable characteristics (categorical or continuous). We will examine the distributional properties of continuous variables to determine if normalizing transformations should be applied before conducting further analyses. If group differences are found for any variables, we will evaluate them and statistically control them in outcome analyses (e.g., employing them as covariates in analyses to control for their effects on the outcomes).

12.2. Primary Outcomes: Feasibility and Acceptability

Because this is a pilot study, analyses are not powered to detect treatment effects nor to formally test mediation or moderation**.** Any formal statistical testing will be only exploratory.

Feasibility. To determine feasibility of conducting a RCT, we will calculate the percentage of individuals who were: eligible; consented; accepted randomization; and returned for the post-intervention and 3-month follow-up. Based on our recent trials (R01-MH068171), we expect ≥80% of all patients to return for the 3-month follow-up and will conclude the intervention is feasible if the follow-up rate is at least 80%. To determine feasibility of the MT and AC interventions, we will calculate the percentage of individuals who attended their intervention sessions. Based on previous research, we predict that ≥ 70% of those assigned to a MT will complete all intervention sessions.

Acceptability. To determine the acceptability of the interventions, we will calculate means for the satisfaction surveys, and inspect responses. The intervention will be considered acceptable if ≥80% of participants respond that they are satisfied with the intervention. We will also collect metrics (e.g., duration of calls, number of cancelled sessions). We will construe as evidence of acceptability, patients completing all ≥7 sessions, with call durations averaging 20 minutes per call, and with fewer than 3 rescheduled sessions.

12.3. Secondary Outcomes

Preliminary estimates of efficacy. We will examine the within- and between-group effects on both efficacy outcomes (i.e., sexual risk, ART adherence) and potential mediators (mindfulness, perceived stress, depression, impulsivity, alcohol use). We will use intent-to-treat analyses, as well as per-protocol analyses to fully understand the data we obtain from this exploratory clinical trial. We predict an intervention condition x time interaction such that, relative to AC recipients, MT recipients will increase mindfulness and adherence, and decrease perceived stress, depression, impulsivity, and sexual risk behavior over time. We do not expect to see changes in VL or STIs at the follow-up, because this is too brief an interval to expect changes. Using a series of longitudinal mixed effects models, we will simultaneously regress outcomes (efficacy measures and mediators) at end of intervention and follow-up, on condition (MT vs. AC), time, condition x time, baseline value of the outcome and potential confounders of the intervention effect (including variables not balanced by randomization). Models will include a subject-specific intercept to account for within-subject correlation in the outcome over time. Modeling will be done using a likelihood-based approach and thus will make use of all available data (on the intent-to-treat sample) to produce consistent estimates of the regression parameters. Models require specification of the distribution of the outcome and will be adapted for continuous, binary, and count variables. Models will allow us to estimate the average change over time within condition for efficacy outcomes and potential mediators, as well as estimate the effect size with respect to between group effects.

12.4. Qualitative Analyses

Audio recordings of the patients' interviews will be reviewed and summarized in a framework matrix. Dr. Rosen and a second rater will listen to and summarize the audios. NVivo software will be used to manage the framework matrix and the audio. Throughout the coding and analysis process, categories and subcategories will be compared and revised as new information is considered or as the team comes to new understandings of the data.

12.6. Sample Size

Because effect size estimates based on small samples have large SDs and wide confidence intervals (CIs),[184] we will use these pilot data only to gauge whether MT effects are encouraging, to examine distribution of the outcomes, and to inform future analytic approaches. The choice of the proposed sample size (n = 50 – 25 participants per condition) was based on practical considerations.

12.7. Missing Data

As noted earlier, the primary analysis will be performed according to the intention to treat approach. Withdrawals will be asked to complete follow-up assessments and home visits or phone interviews will be arranged if necessary. If we encounter substantial missing data, possible options will include using accepted statistical methods (e.g., use of complete data only, use of multiple imputation, use of modified weights and model-based procedures).

13. REGULATORY REQUIREMENTS

13.1 Institutional Review Board (IRB) Review

This protocol and any subsequent modifications will be reviewed and approved by the IRB at TMH responsible for oversight of the study.

13.2 Informed Consent and HIPAA

Consent will be obtained at the screening visit. Individuals will provide written consent using an IRB approved consent form. In addition to describing the study and the participant's involvement in detail, the consent form also emphasizes that participation is voluntary, that consent may be withdrawn at any time, and that participants may withdraw from the study verbally or in writing by contacting the study RA and/or the PIs. Participants are given ample opportunity to ask questions before providing consent. Contact information for the PIs as well as the IRB (for complaints) is provided in the consent form. Signed informed consent forms will be kept in locked filing cabinets separate from all data. Participants will receive a copy of the consent and HIPAA document for their records.

13.3 Participant Confidentiality

Protection of Participant Privacy: All phone contacts with the participants will take place in a private, locked office and will be conducted by the PD who has been trained and certified in the protection of human subjects in research trials and HIPAA requirements according to TMH policies. Individuals who are interested in the study will provide Contact Information (e.g., name, address, phone, email) and will be scheduled for a screening visit (screening visit 1) to learn more about the study requirements and procedures, and to sign written informed consent as approved by TMH Institutional Review Board (IRB).

In addition, because of the potentially sensitive nature of the data we are collecting, we will apply for a **Certificate of Confidentiality** for this study to ensure that participants' data cannot be subpoenaed with a court order. We have successfully obtained Certificates of Confidentiality for other, similar research projects.

Because some of the qualitative assessments involve participation in focus groups with multiple participants, it is impossible to guarantee privacy of information that is shared in a group format. However, at the beginning of each focus group, a statement will be read to participants regarding maintaining the privacy of information shared in the group. In addition, participants will be reminded of these instructions and to respect each other's privacy and not repeat information shared with the group outside of the study setting at the start of each focus group.

Data Safety

- Participants will be identified with a randomly generated identification code unique to the participant and all personal identifiers will be removed from the study questionnaires and from datasets. Electronic communication with outside collaborators will involve only unidentifiable information. AE reports and annual summaries will not include participant-identifiable material.
- Data collected for screening (i.e. reasons for ineligibility and refusal) and tracking reasons (Filemaker data base) that contain identifiers will be stored into a password-protected server separate from other study data and will be destroyed at study completion. This Filemaker database is password accessible only to the PD, the data systems analyst, and the PI.

- Signed consent forms will be stored in locked filing cabinets separate from all other study data.
- Audio files from qualitative data collection will have no identifiers and will be destroyed following approval of the summarization.
- Patients will be informed in the consent form that the instructors' voice during mindfulness sessions will be digitally recorded for assessments of treatment fidelity and digital recordings will be treated as explained above for focus groups recordings.
- All copies of de-identified study questionnaires (paper and/or electronic) will be destroyed at the earlier of two dates: 1) seven years after the end of the study; 2) after the manuscript based on the work is published.

13.4. Study Discontinuation

The study may be discontinued by the IRB, the NCCIH, the OHRP, the FDA, or other government agencies as part of their duties to ensure that research participants are protected.

13.5. Unanticipated Problems

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research (in the guidance document, 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
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

An incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in order to protect the safety, welfare, or rights of participants or others.

Procedures for handling the reporting of adverse events and serious adverse events to the Institutional Review Board at The Miriam Hospital, NCCIH and the Data Safety and Monitoring Committee are detailed in the DSM plan and in section 4.4 of this protocol.

APPENDICES

DESCRIPTION

1 Protocol for Mindfulness Training

2 Protocol for Health Coaching

3 Protocol for Telephone-Based Pill Count

4 Qualitative Interview Guide

5 Suicide Protocol

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Appendix 1
Study 4
Mindfulness Training Materials

Sources:

Salmoirago-Blotcher E, Crawford SL, Carmody J, et al. Phone-delivered mindfulness training for patients with implantable cardioverter defibrillators: results of a pilot randomized controlled trial. Ann Behav Med. 2013; 46: 243-250. PMID: 23605175; PMCID: PMC3758416.

Salmoirago-Blotcher E, Carmody J, Yeh G, Crawford S, Rosenthal L, Ockene I. Design and methods for a pilot study of a phone-delivered, mindfulness-based intervention in patients with implantable cardioverter defibrillators. Evid Based Complement Alternat Med. 2012; 2012: 972106. PMID: 22536294; PMCID: PMC3320061.

CONTENTS

MINDFULNESS INTERVENTION OVERVIEW

	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Session 7	Session 8
Awareness of breath	X	X	X	X	X	X	X	X
Body scan			X	X	X	X	X	X
Attention to daily experience exercise		X		X				
Awareness of sounds exercise					X			X
Awareness of emotions exercise						X		X
Awareness of thoughts exercise							X	X
Open awareness exercise								X

MINDFULNESS INTERVENTION OUTLINE (MT condition)

Source: Salmoirago-Blotcher E, Crawford SL, Carmody J, et al. *Ann Behav Med.* 2013.
Schedule: 1 session once a week for 8 weeks; duration of each session: 30 minutes

Session 1: Awareness of Breath (AOB)

- Introduction to intervention (and what we will be doing over next 8 weeks) (10')
- Exercise: direct the attention to the bodily sensations associated with breathing (AOB) (10')
- Feedback from participant (10')
- Participant encouraged to practice AOB exercise during the following week with aid of study CD - track 1 once a day; confirm next meeting

Session 2: AOB/Attention to Daily Experience

- Questions and answers related to practice in previous week (10')
  Ask family member to get small raisin box (provided)
- Exercise: direct the attention to the bodily sensations associated with breathing (AOB) (10')
- Attention to daily experience: exercise of paying attention to everyday activity (eating a raisin) (5')
- Feedback from participant (5')
- Participant encouraged to practice AOB exercise during the following week with aid of study CD - track 1 once a day; confirm next meeting

Session 3: AOB/BodyScan

- Questions and answers related to practice in previous week (10')
- Body scan exercise: participant is invited to sit in comfortable chair. (10')
  Participant is instructed to move his/her awareness to different parts of the body in a systematic way, beginning with the toes and progressing to the top of the head, noticing whatever sensations happen to be present in that part of the body at that moment. End with short AOB exercise.
- Feedback from participant (10')
- Participant encouraged to practice Body Scan exercise during the following week with aid of study CD - track 2 once a day; confirm next meeting

Session 4: AOB/Body Scan/Attention to Daily Experience

- Questions and answers related to practice in previous week (10')
  Ask relative to get a glass of water or other non-alcoholic drink that participant likes
- Short AOB exercise, followed by Body Scan exercise (10')
- Attention to daily experience: drinking exercise. (5')
- Feedback from participant (5')

- Participant is instructed to practice attention to daily activities (i.e., drinking, eating, walking), throughout the day; practice Body Scan exercise during the following week with aid of study CD - track 2 at least once a day; confirm next meeting

Session 5: AOB/Body Scan/Sounds

- Questions and answers related to practice in previous week (10')
- Short AOB, short body scan, followed by awareness of sounds exercise (10')
  (e*xplain what observing means: the sound, the reactions to the sound, memories, associations with the sound).*
- Feedback from participant (10')
- Participant is instructed to practice attention to daily activities throughout the day and particularly to sounds. Participant is encouraged to practice AOB exercise OR Body Scan during the following week with aid of study CD - tracks 1 or 2 once a day; confirm next meeting

Session 6: AOB/Body Scan/Emotions

- Questions and answers related to practice in previous week (10')
- Short AOB, short Body Scan followed by awareness of emotions exercise (10')
- Feedback from participant (10')
- Participant is instructed to practice attention to daily activities throughout the day and particularly to emotions. Participant instructed to practice using study CD once a day (either track). Confirm next meeting.

Session 7: AOB/Body Scan/Thoughts

- Questions and answers related to practice in previous week (10')
- Short AOB, short body scan followed by awareness of emotions exercise (10')
- Feedback from participant (10')
- Participant is instructed to practice attention to daily activities throughout the day and particularly to thoughts (pleasant and unpleasant ones). Participant instructed to practice using study CD once a day (either track) or without CD once a day. Confirm next meeting.

Session 8: **AOB/Body Scan/ Sounds/Emotions/Thoughts/Open Awareness**

- Questions and answers related to practice in previous week (10')
- Awareness of breathing exercise, body scan, sounds, emotions, thoughts (15')
  and open awareness.(During open awareness exercise, participant is instructed to just notice where the attention goes when it is not directed on a specific object.
- Feedback from participant (5')
- Participant is encouraged to practice attention to daily activities throughout the day and to bring this skill to all their experiences (pleasant and unpleasant ones). Instruct participant to keep practicing with or without CD for at least 15' a day. Thank participant.

BODY SCAN CD SCRIPT– ~15 Minutes

In this recording you are beginning the practice of the body scan. This practice is to develop and increase your ability to pay deliberate, careful attention. So remember that each time you take the few minutes to practice this you are taking a powerful and active role in improving your health and well-being.

Do the body scan either lying or your bed or sitting in an easy chair. Dress in loose, comfortable clothes and try to arrange not to be interrupted by friends, family, or phone calls. It's most helpful to see this as a time for self care - a time to give yourself unconditional attention. Try to stay awake and alert - If you find yourself repeatedly falling asleep, experiment with changing your position to one in which you can remain awake.

We will be bringing awareness to areas of the body in a systematic way. As we go along use the instructions for guidance, simply doing what it says to do. There is no right or wrong way to feel while you do this exercise. Just allow yourself to be exactly as you are, accepting whatever you notice is happening in yourself.

And now bringing your attention to the breath - becoming aware of the flow of the breath into and out of the body. You may feel it at the chest or the abdomen, or the flow of air at the nostrils. Not trying to change it in any way - just letting your attention rest lightly upon the sensations of your breathing. [**PAUSE 5 SECONDS]** And now bringing your awareness to the abdomen and following the movement of your abdomen with the in-breath and the out-breath [**PAUSE 5 SECONDS]** On the in-breath the belly expands as the diaphragm muscle presses down, creating more space for the air and lungs. Noticing the flow of this movement with the breath – the belly expanding and then lowering with the out-breath **[PAUSE 15 SECONDS]**

Now letting the breath fade into the background as you take your attention and direct it through other areas of the body. So for now, take your attention to both feet and narrowing your focus to sense all of the toes, perhaps being aware of the skin of the toes - perhaps aware of the pads of the toes - perhaps aware of the spaces between the toes **[PAUSE 7 SECONDS]**.

Moving attention now from the toes to the rest of the feet - aware of any sensations here **[PAUSE 2 SECONDS]**. The soles and the tops of the feet, the heels - using your attention to explore deeply, noticing what's there for you right now. Perhaps there is a sensation of temperature - coolness or warmth - or lightness, or heaviness, moisture. Exploring the skin perhaps, or maybe exploring very deeply into the feet, aware of the bones, the muscles. Whatever sensations happen to be present in the feet. If you have no sensation there, being simply aware of that fact **[PAUSE 12 SECONDS]**.

Bringing attention now up to the ankles and the lower legs - to the bones and tendons passing through the ankles. Aware of the large calf muscles and the shinbones - exploring the density or thickness of the lower legs, and whatever sensations are present in the knees **[PAUSE 12 SECONDS]**.

Moving now to the thighs and the hamstrings and the hips - perhaps noticing the large muscles of this area - feeling the support on which you're lying, feeling the contact that the thighs and hamstrings are making here - perhaps aware of the touch of clothing, pulsation of circulation. Perhaps sensing no feeling at all, and just aware of that **[PAUSE 10 SECONDS]**.

Now, bringing attention to the buttocks and the pelvis. Perhaps aware of the muscles here - the contact with the supporting surface. Perhaps sensing any feelings in the intestines, the lower abdomen. Then bringing the attention to the upper abdomen and stomach area - aware of any sensations in that area including no sensations if that is the case **[PAUSE 10 SECONDS]**.

Now bringing your attention around to the lower back. Many of us hold tension in the lower back, so allowing this area to ease with deep attention. Noticing the muscles, the contact that the back makes with the surface you're lying or sitting on - noticing being held by that support **[PAUSE 2 SECONDS]**. Then bringing attention to the upper back - aware of the spine - aware of the all of the nerves encased in the spine and branching out to all parts of the body **[PAUSE 2 SECONDS]**. Aware of the muscles of the back - muscles which hold us upright **[PAUSE 5 SECONDS]**.

Aware now of the very bottom of the rib cage and in back, the ribs attaching to the spinal column and moving awareness into the area of the chest - deeply exploring here, bringing a very gentle attention **[PAUSE 2 SECONDS]**. You may be aware of the diaphragm gently moving with the in- and out-breath - feeling the movement of the back with each in-breath and each out-breath. Aware of the muscles of the chest region and the skin - sensing the movement of the ribcage opening to the volume of fresh air being brought into the body,

and what is no longer needed flowing out on the out breath **[PAUSE 2 SECONDS]**. Aware of the area of the heart and the lungs - the lungs filling with fresh oxygen with each in breath, delivering vitality to the blood - perhaps feeling the beating of the heart as it delivers fresh blood around the body **[PAUSE 5 SECONDS]**.

Remember, if any sensation or area is too uncomfortable at any time, you can always override the instructions and come back to the sensations of the abdomen moving with the breath. Simply paying attention to the breathing until the mind settles again **[PAUSE 10 SECONDS]**.

Now bringing the attention down both arms to the hands and fingers - aware of any sensations here - perhaps noticing moisture, or coolness, or warmth - aware of the skin of the palms, the back of the hands **[PAUSE 10 SECONDS]**.

And moving attention now to the wrists and forearms - the delicate skin on the underside of the wrist, and the bones and muscles in the lower arms, the elbows **[PAUSE 5 SECONDS]**. Exploring the upper arms, perhaps aware of the triceps and biceps muscles, aware of the bones inside the arms - the arm bones resting in the shoulder sockets - the arm pits. Aware of any sensations at all in this area, including no sensation if that is the case **[PAUSE 5 SECONDS]**.

And now coming to the shoulders and the tops of the shoulders. Here is another area that many of us hold tensions - exploring in detail all parts of the shoulders. Allowing our attention to be like a light fingertip massage, releasing any tightness as it moves. Breathing deeply in, and on the out-breath letting any tightness and congestion simply flow away **[PAUSE 10 SECONDS]**.

Aware now of the neck and the throat - aware of the ability to speak and to swallow, perhaps feeling the breath moving in the trachea. Noticing the muscles of the neck, the strong muscles that hold up the head, and the place where the spinal column meets the skull bones **[PAUSE 8 SECONDS]**.

And moving your attention up to the head, aware of the skull, or any sensations of the head being supported [**PAUSE 2 SECONDS]** And bringing attention now to the forehead - aware of any sensations in this area - moving attention from one temple across the forehead to the other, allowing the forehead to smooth with your attention **[PAUSE 10 SECONDS]**.

Aware of the eyelids and the eyeballs resting in their sockets **[PAUSE 5 SECONDS]** - the area of the nose. Perhaps feeling the coolness of the incoming breath in the nostrils, and noticing slight warmth on the outgoing breath **[PAUSE 10 SECONDS]**. Bringing your attention now to the cheeks and the muscles of the face that give expression to our many emotions. Aware of the jaw and the muscles of the jaw **[PAUSE 5 SECONDS] -** allowing the jaw to be completely slack and at ease **[PAUSE 5 SECONDS]**. Aware of the ears - the ability to hear at this moment **[PAUSE 5 SECONDS]**. Aware now of the mouth and the lips, the inside of the mouth, the tongue **[PAUSE 5 SECONDS]**. Breathing deeply, bringing the freshness of this breath to all parts of the head - and breathing out, releasing any tightness, any tensions - letting go of all congestion **[PAUSE 10 SECONDS]**.

Now bringing the attention back to the sensations of the breath and allowing the breath to bring fresh energy through every part of the body, right down to the feet. Feeling the freshness in lower legs, the upper legs, the torso, the hands, arms, shoulders and head - and releasing any tension or congestion on the out-breath **[PAUSE 15 SECONDS]**.

And now gently beginning to move the toes and fingers, the hands and feet - beginning to move and stretch. Moving in any way that feels comfortable for you right now - giving yourself plenty of time to do this. Knowing that by allowing yourself to be as you are you are inviting a sense of openness and presence to whatever is happening in your daily life and in this way you are supporting your health and wellbeing.

AWARENESS OF BREATH EXERCISE CD SCRIPT ~15 Minutes

In this exercise we will be building your attentional skills. We will be learning to use attention to bring increased awareness to everyday experiences - experiences that may have become so familiar we are perhaps no longer aware of them. So sitting in a comfortable chair just allow the body to become still - feeling the support of the floor and the chair and settling in to this stable seat. The back is straight without being stiff - the posture is relaxed yet awake and dignified.

And now just becoming aware of your breathing - aware of the movement of the breath as it flows in and out of the body. Not controlling it in any way. Just allowing it to be as it is. Simply aware of the sensations - how it feels. You may notice the sensations at the belly - sensing the belly expanding as you breathe in and

flattening as you breathe out - just allowing your attention to ride gently on the sensations of each breath. This is not thinking about breathing, but feeling it directly - the best you can. [**PAUSE 15 SECONDS]**

Just allowing the breath to breathe itself – giving it your full care and attention. Being there for the entire cycle of the breath - noticing the very beginning of the in-breath and following that breath as it enters the body, filling the lungs and expanding the abdomen, then as it comes to a tiny moment of stillness before it turns around and makes its journey out of the body. Just noticing this process - letting your attention rest lightly on the sensations. [**PAUSE 25 SECONDS]**

You may notice that from time to time that the attention will wander off – perhaps to memories, fantasies, judgments, worries or regrets. Or it may move to anticipation of the future - planning, wishing or concerns. As soon as you become aware that the attention has moved off to other things gently bring it back to the sensations of the breath - escorting it with a gentle firmness. No need to give yourself a hard time about it, it's the habit of the mind to wander. This is simply about bringing your attention back to the breath each time you notice it has wandered - once again aligning the attention with "this" breath in "this" moment. One breath following the next - noticing the movement in your body with each breath [**PAUSE 25 SECONDS]**

Bringing your attention to the breath in this way can be a powerful anchor to this present moment. This is a place you can return to whenever you become distracted, preoccupied or anxious – simply returning your awareness to the breath in this way and returning to this state of awake stillness [**PAUSE 25 SECONDS**].

You may find as you observe the breath that other sensations in your body come into your field of awareness - perhaps discomfort or perhaps restlessness or distress. These sensations may be more focused and intense from time to time. Just be aware of the body sitting - being present to whatever sensations or feelings may emerge, perhaps lingering, changing in intensity and passing away. Simply being here as you are in this moment - aware of the flow of the breath and whatever feelings happen to present themselves [**PAUSE 25 SECONDS]**.

Now for the next couple of minutes, experimenting with expanding the field of your attention to include any sound that may be present. Not stretching to reach out for the sounds but just allowing them to reach the ear - aware also of the silence between the sounds. Notice any tendency to judge the sounds - to like them or dislike them - just noticing this if it is present without trying to change it, and returning to simply being with hearing - embracing sounds as they occur moment to moment. You might notice the difference between the sound sensation reaching the ear, and the mind's naming and identifying the sound [**PAUSE 10 SECONDS]** If the attention wanders off, simply coming back to whatever sounds are occurring now - alert, alive, receiving sounds in stillness. [**PAUSE 25 SECONDS**]

At times, strong emotions may dominate the attention making it more difficult to focus. If a strong emotion emerges you may choose to investigate it, noticing its exact qualities. What are its qualities? Perhaps it is throbbing or pulsing? Not trying to change it or struggle with it, just noticing it with gentleness, kindness and patience. As these emotions subside, returning the attention again to the breath moving in and out of the body [**PAUSE 25 SECONDS**]

And now for the next few minutes we will be focusing attention on becoming aware of any thoughts that may be present in the mind. There may be big attention-getting thoughts, or quite subtle barely noticeable thoughts. Or there may be anxious thoughts – thoughts of memories, pressures, concerns or obligations. Or there may be fantasy thoughts - desires, likes, dislikes, plans. Just allowing whatever thoughts happen to be present without trying to change them. Just noticing them as thoughts, without engaging with whatever it is they are about. Allowing the thoughts to be like clouds, drifting through a vast, spacious sky – you are just being witness to the thoughts **[PAUSE 20 SECONDS]**

You may be finding your mind is quite busy and there are many thoughts, or perhaps it happens to be relatively quiet and there are few thoughts. It doesn't matter - just let it be as it is. It doesn't have to be a problem if it is busy – that's just the way it happens to be right now - just notice that it is busy **[PAUSE 20 SECONDS]**

If you find yourself carried away by a stream of thoughts or if the thoughts are too distressing or unsettling - there is no need to struggle with the thoughts. As soon as you recognize if they are too unsettling you can re-anchor your attention in the awareness of the breath - coming now to "this" breath. When you feel steady again, if you choose to you can return to witnessing the thoughts arising in the mind or simply stay with the breath [**PAUSE 30 SECONDS**].

And now for the time remaining, letting go of any particular focus of attention and allowing yourself to simply be here, fully present. Aware of the breath moving - sensations in the body - sounds - thoughts and emotions coming and going - allowing it all to be as it is. Just be witnessing it all as it unfolds. Complete, as you are right now. **PAUSE 25 SECONDS**.

And now as the recording comes to an end, once again narrowing your attention to the breath - this breath - your attention riding on the flow of the breath - fully present with each in-breath and with each out-breath. Nothing you need to do - just being fully present with the breath flowing into and out of the body [**PAUSE 15 SECONDS**]

You might now want to congratulate yourself for taking the time and the energy to do this and form an intention to make the time to do this on a regular basis. Deepening your ability to be fully present and allowing the benefits of this practice to flow into the experience of your daily life.

Appendix 2
Study 4
Health Coaching
Training Materials

CONTENTS

HEALTH COACHING OVERVIEW

	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Session 7	Session 8
Sleep	X							
Nutrition		X	x	x	x			
Sun Safety						X		
Physical Activity							X	
Home and Travel Safety								X

HEALTH COACHING OUTLINE (HC condition)

Source:
Schedule: 1 session once a week for 8 weeks; duration of each session: 30 minutes

Session 1: Tips for a Good Night's Sleep

- Questions and answers related to material discussed in the last session (5')
- Assess participant's current sleep habits; Tips for sound sleep; Assess barriers to implementing healthy sleep tips (10')
- Instructor asks participant for any comments or questions they may have related to the material discussed (10')
- Explanation of daily practice (Sleep Diary); Participant encouraged to complete daily practice; confirm next meeting (5')

Session 2: Eating to Feel Well

- Questions and answers related to material discussed in the last session (5')
- Foods to Feel Better; Benefits of Fruits and Vegetables, Strategies to add more fruits and vegetables to diet (10')
- Instructor asks participant for any comments or questions they may have related to the material discussed (10')
- Explanation of daily practice (Trying new fruits/vegetables, Reading); Participant encouraged to complete daily practice; confirm next meeting (5')

Session 3: Healthy Choices When Eating Out

- Questions and answers related to material discussed in the last session (5')
- Fast food choices; Bodega choices; Soup kitchen choices; Restaurant choices (10')
- Instructor asks participant for any comments or questions they may have related to the material discussed (10')
- Explanation of daily practice (Reading, Daily Effort to make healthy choices when eating out); Participant encouraged to complete daily practice; confirm next meeting (5')

Session 4: Reading Food Labels

- Questions and answers related to material discussed in the last session (5')
- Nutrition Facts; Serving Size; % Daily Value; Measurements (10')
- Instructor asks participant for any comments or questions they may have related to the material discussed (10')

- Explanation of daily practice (Reading labels at home and grocery story; making grocery choices based on labels); Participant encouraged to complete daily practice; confirm next meeting (5')

Session 5: Smart Snacking

- Questions and answers related to material discussed in the last session (5')
- Assess participant's current snacking behaviors; Healthy snacking options; More filing food choices (10')
- Instructor asks participant for any comments or questions they may have related to the material discussed (10')
- Explanation of daily practice (Daily effort to making healthier snack choices); Participant encouraged to complete daily practice; confirm next meeting (5')

Session 6: Sun safety

- Questions and answers related to material discussed in the last session (5')
- Importance of sun exposure; vitamin D; type of UV light; safe sun practices; importance of maintaining adequate hydration (10')
- Instructor asks participant for any comments or questions they may have related to the material discussed (10')
- Explanation of daily practice (Reading); Participant encouraged to complete daily practice; confirm next meeting (5')

Session 7: Physical Activity

- Questions and answers related to material discussed in the last session (5')
- Assess current level of physical activity; Benefits of physical activity; Safe stretching; Walking; Importance of Posture (10')
- Instructor asks participant for any comments or questions they may have related to the material discussed (10')
- Explanation of daily practice (Reading on physical activity; Implementing physical activity); Participant encouraged to complete daily practice; confirm next meeting (5')

Session 8: Healthy homes & Safety While Traveling

- Questions and answers related to material discussed in the last session (5')
- Tips for a healthy home: chemicals (including drugs); noise protection; carbon monoxide, radon, lead, ozone;

drinking water and hand hygiene. Tip for safety while traveling: Seatbelts, airbags, children in car. Bus safety, safety while waiting for the bus, crosswalks,
(10')

- Instructor asks participant for any comments or questions they may have related to the material discussed (10')

- Explanation of daily practice (Reading); Participant encouraged to complete daily practice; confirm next meeting (5')

Appendix 3

Study 4

Unannounced Telephone-based Pill Count Protocol

Sources:

Fredericksen R, Feldman BJ, Brown T, et al. Unannounced telephone-based pill counts: a valid and feasible method for monitoring adherence. AIDS Behav. 2014; 18: 2265-2273. PMID: 25331265.

Kalichman SC, Amaral CM, Stearns H, et al. Adherence to antiretroviral therapy assessed by unannounced pill counts conducted by telephone. J Gen Intern Med. 2007; 22: 1003-1006. PMID: 17390095; PMCID: PMC2219717.

Kalichman SC, Amaral CM, Cherry C, et al. Monitoring medication adherence by unannounced pill counts conducted by telephone: reliability and criterion-related validity. HIV Clin Trials. 2008; 9: 298-308. PMID: 18977718; PMCID: PMC2937191.

Kalichman SC, Amaral C, Swetsze C, et al. Monthly unannounced pill counts for monitoring HIV treatment adherence: tests for self-monitoring and reactivity effects. HIV Clin Trials. 2010; 11: 325-331. PMID: 21239360.

Phone Assessment Training

Prior to coming in for the pill count training, the participant is instructed to bring all of their pill form medications-ARV and Non-ARV. If the participant is currently out of medications and has not refilled the prescriptions, ask the participant to bring in the empty bottles in order that the prescription information may be gathered. If the participant has forgotten the medication, they are asked to go home and get their medications prior to beginning the pill count training.

The purpose of the in person pill count training is to introduce the pill counting procedure; but it is also a valuable opportunity for the pill counter to gain some information before the phone 0 interview. This needs to be individualized, and the pill counter needs to work to sensitively find out how much of this information each patient will be able to give.

During the pill count training the participant will meet the Interviewer and will be walked through the assessment protocol. All of the steps of the phone assessment will be part of this initial meeting. The outline for the assessment training sessions is as follows:

The Pill Counter meets and greets the participant.

Explain the phone pill counts and why we are doing them:

“A pill counter will call you several times during the study to talk to you for the study. The call will be done on the phone while you are home. On the phone calls, the pill counter will ask you to count your medications and tell her how many you have received and what you have left. It is very important we receive accurate information.”

Prior to beginning the practice pill count, review the sample pharmacy label with the patient. With the Consultant’s assistance, the TMH pill counter will highlight the pertinent information that will be used each month.

Run through a practice pill count using the pills that have been brought in for the baseline assessment.

BE SURE TO EMPHASIZE THE IMPORTANCE OF HAVING ALL MEDICATIONS OUT FOR THE PHONE CALL.

The Pill Counter will run through 3 sample question to demonstrate each type of response. Mention that the caller will also ask some questions about how the participant has been feeling and related issues.

Phone Assessment Training

1. Review the reason for the medication assessment: to learn how people are using their medications so that we can development better health programs.

2. Provide Health and Assessment Kit.

   Contents:
   - The Pill Tray
   - Pill Knife
   - Hand Wipes

3. Explain the pill count protocol. Use the Pill Counting Demo Kit to demonstrate how to count pills.

4. Practice a pill count with the Interviewer present. Pour the pills onto the pill tray. Instruct the participant to count their pills out loud by using the pill knife and sliding the pills into the valley of the pill tray. After all of the pills are counted have the participant put the pills back in the medication bottle and count the pills a second time. If the participant does not have medications to count, use the candy (Skittle, Tic Tacs, etc.).

5. Review protocol – answer questions – trouble shoot – problem solve

The Intake Interview is completed….participant given…

Copy of consent form
Take Home Kit
Incentive Payment

Phone Assessments and Pill Count

Time 0 Phone Assessment

Ideally participants are called within 3 days of Initial Intake for their Time 0 phone call.

Materials Needed for Phone Assessments

Previous Call Information Sheet

Assessment Form

Phone Tracking Sheet-(log of participants contacted with their participant ID)

Timing of interviews

Each month, the participant receives an unannounced call that includes a pill count and interview. Ideally, participants should be called within 3 days of the Initial Intake.

Calls should occur in 28-day intervals, +/- 7 days; in other words, participants should be called 21-35 days from their last phone call.

While interviews are ideally conducted every 21-35 days, they can be conducted 14-42 days from the date of last call if necessary.

Beyond this time span, the visit is considered a missed call and should be entered as a dummy record in the database.

If you do get off schedule with a participant's calls (for example, you couldn't call them until the end of the previous window), you should aim to get them back on schedule during the next month.

You should always try to maintain the 28-day (+/- 7 days) interval between calls.

The Tracking system will generate weekly schedules for phone interviews. Weekly schedules will include all participants due for visits within the 14 day window with the target date for the call.

Phone Interviews should *not* be scheduled with the participant. It is helpful to know the best times to call a participant and when he or she is likely to be out.

- If the interviewer calls the participant, but they are not able to take the call (they're too busy, etc.), then tell them that it's not a problem and you will call back later.

If participants call and ask to schedule a call because they need the money or will not be available, then we reiterate the fact that all calls are unannounced.

It can feel uncomfortable at times when the participant asks when you are calling and you cannot tell them. Simply explain that the way the project was designed was to have these types of calls and it actually makes it easier on everyone because then nobody's daily routine is disturbed by waiting around. If they say they would feel bad if you call when they are not around, you could say, "It's no problem if you're not home. People often aren't home when I call them, but I'm not wasting time because I can just call someone else and try again later or another day."

During the Interview

Before starting the interview it is good to review your notes from the last call and Intake Interview Survey. The Tracking Sheet and Phone Assessment Booklets have all of the necessary data you will need to collect during the call. While the tracking sheet and assessment booklet has all the information you will need, here are some key points to keep in mind:

- ***It is crucial to be sure that all of the participant's pill bottles are in front of the participant on the phone and that they get an accurate pill count.*** Sometimes a participant will not immediately have all of their pill bottles. Ask them if they have any other bottles, or pills in other containers, anywhere in their home. Use the information in the Intake Survey to help with this. Check the Rx dates of the bottles to the Rx dates recorded in the booklet to make sure that all bottles are accounted for.
- *To instruct participants in the phone assessment you should include the following:*
    1. Find a comfortable place with a flat surface where you can spread out your pill bottles in front of you.
    2. Get all of the bottles together and group them so that all of the medications are separate. Guide the grouping from the medication list in the Intake Interview Survey. Example, have all Combivir grouped in one area, then all of your Kaletra in another area…etc.
    3. Use an alcohol wipe to clean your pill tray and pill knife before starting.
    4. Select one drug to count first. Be sure that all of the medications are present for the count.

        a. Select one bottle to count.

        b. Collect Label information from the bottle.

        c. Pour mediations from a bottle into the Medications Cup.

        d. Pour medications from the cup on to the pill tray – this is especially for large pills. Small pills or small numbers of pills may be poured directly onto the tray.

        f. Have participant count the pills out loud and replace in the bottle.

        g. Tell interviewer the count.

        h. REPEAT STEPS c thru g for second confirming count – bottle by bottle.
- It is important to document all the bottles that are present during a call. The bottle information table is a tool for interviewers to keep track of bottles they have counted. Note the distinction between "Pills per Bottle" and "Refill Amount." For example, a participant might have received a refill of 240 RIT, which are

given to him in 2 bottles with 120 pills in each; in this case, “pills per bottle” is 120 and “refill amount” is 240—this is so that later you will recognize that the participant has 2 new bottles for RIT.

- It is very important to figure out whether or not the participant got a refill and, if so, how many since the last phone assessment. Look at the Rx info from the previous assessment booklet to see if the Rx label is the same or not. Also, remember that a participant may have received more than one refill between calls.
- Always have the participant count pills twice to verify that they have the correct number. Make sure to write the date of the bottle above each column in the pill count table.
- Do a quick check of the pill count, prior pill count and dispensed to see if it makes sense – that way if it does not make sense you have participant look for other bottles or get more information while you still have the participant on the phone.
- If the participant has changed regimens, you should have them count all old and new meds and find out from the participant what date (and dose) the old meds were stopped and the new ones were started.
- Tell participant they will be paid at the next in person visit. If the participant would like to be paid sooner arrange for an in person payment.
- Verify participant locator information.
- Provide reminder for next study activity and remind them of any upcoming intervention sessions or office assessments.

Pill Boxes/Medisets/Blister Packs

BE VERY CAREFUL WHEN COUNTING PILL BOXES AND MEDISETS

Some of our participants will be using Medisets dispensed by pharmacies or agencies. You need to handle these pill counts differently to obtain accurate data. Please refer to the “Medisets method” document. Medisets filled by the participant can be treated like any other pill count. Have the participant open each compartment and count by the pill. Go by color or shape or size. Count twice.

Blister packs are dispensed for the entire month.

Ask

-if all of the medications are dispensed in blister packs

-Do they have a.m. and p.m. doses

-What medications are in each pack

-Do they have pills from the blister pack that they do not take anymore

Change in Regimen Between Calls

Sometimes a participant will start a new regimen between visits. Often you will be able to determine the exact date and dose (am/pm) that the old pills were stopped and the new pills were started. These dates can be entered into the “start date” and “stop date” fields of the database, allowing the database to correctly arrive at an adherence calculation. In this situation, the Pill Count Summary is “1. All Pill Counts obtained,” and the Regimen Summary is “2. Change of ARVs prescribed.” Note that the “stop date” for a med is the first day a

participant did not take the med, not the last day she did take it. If you are not able to determine the start/stop dates, the visit is coded as "6. New Baseline after missed visit/no pill count."

Special circumstances

If the participant is in jail, prison, or the hospital: If the participant will be out of jail or the hospital soon (before their 42-day maximum visit window has passed), it is usually best to wait until they return home to conduct the interview. This is so that you can get a pill count, since the participant almost never has their own meds with them in the institutional setting. In this case, conduct the pill count as usual but be sure to find out the exact dates they were in jail or the hospital. You can then figure out the number of doses of meds they had dispensed in the institutional setting and add this number to the dispensed column in the grid. You would code this visit as "1. All Pill Counts Obtained." However, we only do this if the participant has received meds in the institutional setting for fewer than 14 days, or less than half the time period between visits (whichever is smaller). Beyond that, we consider the participant as not responsible for his own meds for that visit period. In this case, dispensed is –9 and the visit code is "3. No Pill Count."

If you cannot wait until after the participant has returned home, you can often conduct the self-report portion of the visit while they are in the hospital or at jail. In this case, the visit code is "3. No Pill Count" and you should mark an X in the pill count column. If the participant has returned home by the time of the next visit, you can often compute a 2-month adherence percentage by changing the start date and adjusting dispensed to account for meds given while in the hospital or jail.

Do not follow a participant if they have not done their baseline. They are dropped from the study.

If a participant has been randomized/baselined they should remain in the study.

If a participant moves and has done their baseline, they may continue to participate in the study by doing the monthly pill counts.

Avoid Performing Any Intervention

Because our study aims to gain an accurate picture of participants' adherence, we are not allowed to intervene in ways that would affect how they take their medication. For example, you should not praise a participant for improved adherence, suggest that participants use a Medisets, pick up meds for a participant, etc. Participants develop close relationships with us, but we must remember that we are researchers and not nurses, caretakers, or social workers. You might feel uncomfortable with some participants' requests or expectations of you; you should always feel free to talk with Seth or other project managers about the situation.

In some situations, intervention is permissible and important.

For example:

1. At Intake the participant doesn't understand their regimen; their self-report of how many pills they are supposed to take might be different from what is instructed on the Rx label. In this case, we should ask if they are aware that their routine is different from what their prescription says. We should tell them about the discrepancy and recommend that they talk to their doctor.
2. If the Rx is written or filled incorrectly, then we should inform the participant and call the pharmacy. If a participant's Medisets has been filled incorrectly by an agency, we should tell them and talk to their nurse at the agency.
3. If the participant's life is in jeopardy (for example, in cases of domestic violence), we may intervene in some ways. These extreme cases should be discussed with the Project Management immediately.

4. If it is apparent that the participant is mis-dosing, get the participant to call their doctor to fix the problem. Call back within two days and check in with the participant to assure that they contacted their doctor.

Pill Count Notes:

A. Help the participant group their pills together and set up tray. There are instructions on how to do this on page 4 of the assessment. If this is not done correctly participant might not report all of the medication they have.
B. Large pills can be difficult for the participant to count. It is helpful to dump them all in tumbler cup initially and then dump a few at a time onto the pill tray. After those have been counted you should have them put back into the bottle and then have more from the tumbler dumped onto the tray.
C. It is very important for the participants to count each medication twice.
D. Participants should count their medications out loud and the pill counter should make sure they are counting accurately.
E. Do refrigerated drugs first and then have them put them back in the fridge.
F. Work on one prescription at a time – Obtain bottle information and then count the medication.
G. Participants often think that you are only interested in their open bottles. Make sure they have all sealed bottles and pill boxes or other containers in front of them.
H. If a participant was not taking prescriptions in the previous call make sure that you ask them if they have begun taking pills. If they were taking pills make sure you ask them if they have changed their regiment.
I. If participant is not taking pills they are only asked the questions on pages 1, 2, 11, 12, 13, 14, 15 and 16.
J. If they lose the pill tray? Call the Share Project, let them know that they will need a new one and have the participant pick it up. Ask Share Project to let you know when person has picked up their new assessment kit.
K. Participants who are not taking ARVs, but are taking non-ARVs they are not asked the questions on page 11.
L. If the participant asks to set up an appointment? We don't set up appointments because it would inconvenience you. "We don't want you sitting around waiting for me to call. I don't mind calling and if I call at a bad time, please tell me and I will call another time. I don't mind doing that."
M. Pill counters do not track ARV's that are in liquid form.

During the assessment you should have the following in front of you:

1. Tracker sheet – 1 page.
2. Intake Interview Form = Refer to pages 3, 4, 5 & 7.
3. Last Monthly Assessment Booklet = Refer to page 8 = previous pill count.
4. Blank Monthly Assessment Booklet for this call. – It saves some time if you fill in some of the answers ahead of time. That would be name of medication; pharmacy used, and set up the pill box form if they are using a pill box.

Telephone Pill Count Script

1. Insert Reminder Notes Here

2. Introduction – Hi, is _____there? Hi, this is _____ from HIP-Providence. I am calling to do your monthly assessment. Is this a good time for you to do an assessment?

3. What is your Date of Birth? _____/_____/_____
Month Day Year

4. Where were you born? or, What is your Mother's name?

5. Please get your Pills

6. While you wait:

DATE _____/_____/_____
Month Day Year

Call Start Time _____AM / PM

Interviewer Initials _____

Phone Contacted On (circle one): Home Personal Cell Other_____

6. **Many people with HIV have many pills to take at different times during the day. Some find it hard to always remember their pills, for example…**

- Some people get busy and forget to carry their pills with them.
- Some people find it hard to take their pills according to instructions, such as "with food", "on an empty stomach", "every 8 hrs.", or with plenty of liquids".
- Some people decide to skip pills to avoid side effects or simply just don't want to take their meds that particular day.

I just want to remind you that the reason why we do these home assessments is because we want to understand what people with HIV are really doing with their pills. Please tell us what you are actually doing. Don't worry about telling us that you missed or stopped your meds. We need to know what is really happening, not what you think we want to hear. If we don't know all of the good and bad aspects to taking meds, then we won't be able to help others in the future.

7. Verify where the participant keeps their medication.

See INTAKE SURVEY- BE SURE TO MAKE ANY CHANGES TO WHERE MEDS ARE KEPT DIRECTLY TO THE INTAKE SURVEY

8. Verify the current drug regimen by asking about the drugs taken at last home assessment. Write the current regimen below.

FOR EACH PRESCRIPTION FROM INTAKE SURVEY, ASK:

- **Are you still taking [MED]?** IF SO, ASK: How many doses per day? How many pills per dose? *(Compare with cover sheet. Record changes in Table)*

- **Have you stopped taking any HIV meds since our last call?**
  Yes / No *(Record stop date in Table)*

- **Have you been prescribed any new HIV meds since the last call?**
  Yes / No. *(Record new drugs and dosage information in Table)*

Current PRESCRIPTION DRUGS (Compare to Last Assessment)

	Medication	**Dose/Times**
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____

9. Additional Information about Current Medications.

Keeps meds in bottles	Yes	No
Uses a Pill Box / Mediset	Yes	No
Carries doses	Yes	No
Gets meds in blister packs	Yes	No

-If yes, Do you have all of these pills with you.

10. To instruct participants in the phone assessment you should include the following:

1. Find a comfortable place with a flat surface where you can spread out your pill bottles in front of you.
2. Lay out the pill try, tumbler, and pill knife.
3. Get all of the bottles together and group them so that all of the medications are separate. Guide the grouping from the medication list in the Intake Interview Survey. Example, have all Combivir grouped in one area, then all of your Kaletra in another area…etc.
4. Use an alcohol wipe to clean your pill tray and pill knife before starting.
5. Select one drug to count first. Be sure that all of the medications are present for the count.
    a. Select one bottle to count.
    b. Collect Label information from the bottle.
    c. Pour mediations from a bottle into the Medications Cup.
    d. Pour medications from the cup on to the pill tray – this is especially for large pills. Small pills or small numbers of pills may be poured directly onto the tray.
    f. Have participant count the pills and replace in the bottle. Ask the participant to count out loud.
    g. Repeat Pill Count
    h. REPEAT STEPS c thru g for second confirming count – bottle by bottle

References

1. Kalichman SC, Amaral CM, Stearns H, et al. Adherence to antiretroviral therapy assessed by unannounced pill counts conducted by telephone. J Gen Intern Med. 2007; 22: 1003-1006. PMID: 17390095; PMCID: PMC2219717.
2. Kalichman SC, Amaral CM, Cherry C, et al. Monitoring medication adherence by unannounced pill counts conducted by telephone: reliability and criterion-related validity. HIV Clin Trials. 2008; 9: 298-308. PMID: 18977718; PMCID: PMC2937191.
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4. Fredericksen R, Feldman BJ, Brown T, et al. Unannounced telephone-based pill counts: a valid and feasible method for monitoring adherence. AIDS Behav. 2014; 18: 2265-2273. PMID: 25331265.

Appendix 4

Study 4

Qualitative Interview Scripts

OBJECTIVES

1. To obtain patient feedback on the Mindfulness-based Instruction
2. To obtain patient feedback on the Health Promotion curriculum
3. To obtain patient feedback on the study protocols
4. To use this data to inform refinements for our R01

INTRODUCTION

This agenda is intended to guide interviewers through the key content areas of data collection for this project, ensuring that the same content is discussed in each interview. While the agenda is used to guide the discussion, it is not a rigid script that will be adhered to verbatim. This ensures that the facilitators gather data on the same topics in each interview, while also allowing them the flexibility to adapt and clarify questions to suit the needs and experiences of individual participants. Similarly, questions need not be asked in this particular order. Rather, the facilitators will adapt the conversation as needed according to the narrative within each interview, pursuing both the a priori *research topics as well as any emergent relevant themes that evolve from the conversation.*

Good afternoon and welcome to our session. My name is Name of Interviewer and I work at The Miriam Hospital.

Thank you for taking the time out of your busy schedules. We would like to get your feedback about the Health Improvement Project in which you are taking part. Your input will be very important to help us see if we can improve the program for future studies. There are no right or wrong answers, just differing points of view. We are very interested in hearing a range of views. Please feel free to share your point of view especially if it differs from what others have said.

Before we begin, let me suggest some things that will make our discussion more productive. We are tape recording the session because we don't want to miss any of your comments. Please speak up so tape recorder can hear you. Everything said here is **confidential**.

My role here is to ask questions and listen. Let's begin.

Mindfulness-Based Training -- Coach-led Sessions
Let's start by thinking about the mindfulness-based training sessions you had with the coach who called you once a week on the phone.
1. What was most helpful about the sessions on mindfulness-based training? Why?
2. What was least helpful about the sessions? Why? How would you recommend we improve the mindfulness-based training sessions?
3. What did you helpful or not helpful about the mindfulness instructor? Why? How might the instructor have improved?
4. Overall, how can we make the mindfulness-based training sessions more interesting for other patients?
5. Can you tell me how you felt about your instructor? Alt: do you have any feedback about your instructor?
There were many exercises you did during the mindfulness-based training sessions. These included exercises about the awareness of breath, the raisin exercise, sensations, body movement, sounds, emotions, thoughts, and open awareness.
6. Which of the exercises was the most helpful? Why?
7. Which of the exercises was the least helpful? Why? How would you recommend we improve these exercises?

Mindfulness-Based Training – Individual Practice At Home
Think about the digital or MP3 recordings you used to practice at home, on your own.
1. What was most helpful about practicing at home? Why?
2. What was least helpful? Why? How would you suggest we improve the at home practice for other patients?
Now consider the two separate tracks: tracks 1 and 2.
1. What was most helpful about track 1? What was not helpful about track 1? Why? How might we improve this track?
2. What was most helpful about track 2? What was not helpful about track 2? Why? How might we improve this track?
Mindfulness-Based Training Program Overall
Please consider the mindfulness-based training program overall.
1. Are there any other aspects of the program you found particularly helpful or not helpful?
2. What changes would you recommend we make to this program to make it more interesting for other patients?
3. Which mindfulness technique(s) do you use the most? Why?
Health Coaching Sessions
Please think about the 8 Health Coaching sessions you had.
1. What was the most helpful about the Health Promotion sessions? Which topics did you like the best? Why?
2. What was the least helpful about the sessions? How would you recommend we improve the lessons? Why? Are their topics that we did not include that you wish we had?
3. *Show the packet.* What was most helpful about the packet? Why? What would you suggest we change to make it more useful and interesting for patients?
4. Any other thoughts about the 8 Health Coaching sessions that will help us improve them?
Study Procedures
The last thing we would like to ask you about is your experience in participating in the study.
1. How might we improve the way you were recruited in the study?
2. How would you recommend we improve the way we asked you to consent to be in the study?
3. How could we improve the process for completing study assessments at the Immunology Center? This included completing the computerized survey and giving biological samples.
4. How could we improve the completion of the pill count interviews by phone?
5. What would you recommend be done differently to make it easier to participate in this study in the future?
6. Did you have any thoughts about the pill counting exercise? Was it clear? Did you learn anything from it—if so, what? Is there anything we can do to improve the pill counting?
For participants who did not complete the study
We'd like to understand why you chose not to finish the formal part of the research study participation. Knowing this can help us improve experiences for other participants.
1. Why did you not finish the study?
2. Is there anything we could have done to have kept you involved in the study?
Final Thoughts
Is there anything we did not discuss that you would like to share with us?
THANK YOU so much for taking the time to meet with us and share your experience with the study! We will use your feedback to see how we can improve the program for other patients in the future.

Question for participants at the 3-month follow-up
We have a few open ended questions to ask you about your experiences since the study ended.
1. Can you tell me what has changed in your life since you finished the research study?
2. For smokers: has there been any change in your smoking habits?
3. Can you tell me in your own words, what did you think the study was about?
Mindfulness-Based Training Participants
1. How are you using the mindfulness skills you learned in the study?
a. What practices are you using? b. When are you practicing? Daily? c. Are you using any of the audios? Which ones? d. Are you practicing on your own?
2. Now that you have participated in the study, what does mindfulness mean to you
Health Promotion Participants
1. Are you using any of the skills you learned in the study?
a. What skills are you using? b. Have you changed any specific behaviors? Which ones? Why?

Appendix 5

Study 4

Suicide Assessment Protocol

Assessment of Suicide Ideation and Vulnerability

If any patient, at any time,

- endorses items assessing suicidal thoughts and plans during the past two weeks, or
- reports significant depression on the screening or computer-assisted self-interview questions (score ≥ 15 on the PHQ-9), or
- appears severely distressed during any in-person session (i.e., screening, baseline, or follow-up; as determined by recruiter judgment), or
- reports suicidal thoughts at any time to PD or Instructor, initiate a "distress check" to assess suicidality. This check must be conducted in a sensitive and caring way. For example, you can say to the participant the following: *"I would like to check in with you about how this experience was for you. I asked a lot of questions, and want to check in to ask how are you doing?"*

If participant says he/she is okay and does not meet any of the above criteria for enacting the suicide safety protocol, no further intervention will be taken.

However, if participant says she/he is upset, then the PD or Instructor will say: "*It is not uncommon for people to feel upset or emotional after answering questions like this (or, talking about experiences like this). We do ask many personal questions. It is also not uncommon for people to have thoughts of hurting themselves. Have you had thoughts of actually hurting yourself?"*

If participant has not had any thoughts of hurting herself and does not meet any of the criteria above for enacting the suicide safety protocol, then we will remind patients of the resources available for counseling within the Immunology Center. We will also give everyone a list of local agencies that provide counseling services, and say: "*You may find it helpful to contact one of these agencies to set up an appointment to talk to someone about the feelings that were raised today. Also, if you are ever in crisis or need to talk to someone immediately, you can call the Immunology Center."*

If participant has had thoughts of hurting herself or meets any of the above criteria for enacting the suicide safety protocol, then we will start suicide safety protocol, described next.

Script to Screen for Suicidal Concerns

If suicidal thoughts or severe distress are reported at screening or during any intervention or assessment session, the PD or Instructor will start the suicide safety protocol.

The PD and Instructors will be trained to use the following script. If indicated (as outlined earlier), they will ask:

"*I'd like to ask you a few additional questions, because I am concerned for your well-being and safety.*

1. Have you ever attempted to harm yourself in the past? NO YES

2. Have you thought about how you might actually hurt yourself? NO YES → [How? ___]

3. There's an important difference between having a thought and acting on a thought. How likely do you think it is that you will act on these thoughts about hurting yourself for ending your life some time over the next month?

a. Not at all likely _____

b. Somewhat likely _____

c. Very likely _____

4. Is there anything that would prevent or keep you from harming yourself?

NO YES → [What? _____]

Scoring:

1. **Minimal Risk**: no shaded items
2. **Lower Risk**: item 1 or 2 (or both) is shaded; neither item 3 nor 4 is shaded
3. **Higher Risk**: item 3 or 4 (or both) is shaded

Safety Protocol

1. If the patient falls into the **minimal risk category**, no further action will be taken. The PD or Instructor can say something like this:

> *Thank you for being open with me. We provide everyone with this list of counseling centers. You may find it helpful to contact one of these agencies to set up an appointment to talk to someone about the feelings that were raised today. Also, if you are ever in crisis or need to talk to someone immediately, you can call The Immunology Center.*

2. If the patient falls into the **lower risk category**, the PD or Instructor will work on developing a safety plan with the patient (described below). The PD or instructor can say something like this:

> *Thank you for being open with me. We provide everyone with this list of counseling centers. You may find it helpful to contact one of these agencies to set up an appointment to talk to someone about the feelings that were raised today. Also, if you are ever in crisis or need to talk to someone immediately, you can call The Immunology Center. I'd also like to work with you to develop a plan to make sure you are safe.* [see Safety Plan]

Safety Plan (see: http://www.suicidesafetyplan.com/Training.html)

> *What can you do, on your own, if you become suicidal, to help yourself not to act on your thoughts or urges?*
>
> *Who or what social settings help you take your mind off your problems at least for a little while? Who helps you feel better when you socialize with them?*
>
> *Among your family or friends, who do you think you could contact for help during a crisis? Who is supportive of you and who do you feel that you can talk with when you're under stress?*
>
> *Who are the mental health professionals that we should identify to be on your safety plan?*
>
> *How will you know when this safety plan should be used? What do you experience when you start to think about suicide or feel extremely depressed?*

3. If the patient falls into the **higher risk category**, the PD or Instructor can say something like this:

> *Thank you for being open with me. I would like to help support you. Given your situation, it seems best to have someone with more experience than me* [supervisor, and/or the community mobile crisis team] *talk with you.*
>
> [If in person] *I need to make a quick call and then I will sit with you until they arrive.*
>
> [If on the telephone] *I am going to make a quick phone call from another line. I will stay on the line with you until we have someone arrive.*

Order of which supervisor to contact: 1) Contact Carla Rich (licensed mental health clinician), 2) Dr. Carey (clinical psychologist, PI), 3) a licensed clinical psychologist at the Immunology Center clinical psychologist, or 3) another clinic provider at the Immunology Clinic (in that order, depending on immediate availability). The supervisor contacted will work with Immunology Center staff to call community mobile crisis team and wait with patient until crisis team arrives.

During Phone-based Sessions

If suicidal thoughts or severe distress are reported during the intervention, the Instructor will follow the suicide safety protocol. If the patient falls into the **minimal risk** category, no further action will be taken. If the patient falls into the **lower risk** category, the Instructor will work on developing a safety plan with the patient. If the patient falls into the **higher risk** category, the Instructor will contact the crisis team and continue to talk to the patient on the phone.

References

1. Broadhead WE, Leon AC, Weissman MM, et al. Development and validation of the SDDS-PC screen for multiple mental disorders in primary care. Arch Fam Med. 1995; 4: 211-219. PMID: 7881602.
2. Olfson M, Weissman MM, Leon AC, Sheehan DV, Farber L. Suicidal ideation in primary care. J Gen Intern Med. 1996; 11: 447-453. PMID: 88