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Phone-delivered mindfulness training to promote medication adherence and reduce sexual risk behavior among persons living with HIV: design and methods

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Abstract

Introduction—Two-thirds of people living with HIV (PLWH) show sub-optimal adherence to antiretroviral therapy (ART) and one-third engages in risky sex. Both non-adherence and risky sex have been associated with emotional distress and impulsivity. To allay distress and lessen impulsivity, mindfulness training (MT) can be helpful. In this trial, we will investigate the utility of phone-delivered MT for PLWH. The primary outcomes comprise feasibility and acceptability of phone-delivery; secondary outcomes are estimates of efficacy of MT on adherence to ART and safer sexual practices as well as on their hypothesized antecedents.

Methods/Design—Fifty participants will be enrolled in this parallel-group randomized clinical trial (RCT). Outpatients recruited from an HIV treatment clinic will be randomized (1:1 ratio) to either MT or to an attention-control intervention; both interventions will be administered during 8 weekly phone calls. ART adherence (self-reported measure and unannounced phone pill counts), sexual behavior (self-reports and biomarkers), mindfulness, depression, stress, and impulsivity will be measured at baseline, post-intervention, and 3 months post-intervention.

Conclusions—MT has great potential to help PLWH to manage stress, depressive symptoms, and impulsivity. Positive changes in these antecedents are expected to improve safer sex practices and ART adherence. If results from this exploratory trial support our hypotheses, we will conduct

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Conflicts of Interest
None.

a large RCT to test (a) the efficacy of MT on ART adherence and safer sex practices and (b) the hypothesis that improved ART adherence and safer sex will reduce viral load, and decrease the incidence of sexually transmitted infections, respectively.

Keywords

Mindfulness; HIV; clinical trial; adherence; sexual risk behavior; stress

1. INTRODUCTION

More than 1 million Americans are living with HIV and 50,000 are newly infected each year. (1) To protect the health of people living with HIV (PLWH) and to reduce HIV incidence, the Centers for Disease Control and Prevention recommend strict adherence to antiretroviral therapy (ART) and the adoption of safer sex practices. ART adherence improves viral suppression, reduces infectiousness and HIV-related morbidities, and increases survival. (2–4) Safer sex practices decrease the risk of acquiring other sexually transmitted infections (STIs) and of HIV super-infection, and lower the risk of transmitting HIV to an uninfected partner. Only 30% of PLWH, however, adhere to ART to the point of achieving viral suppression and about one-third of HIV-infected men who have sex with men report recent condomless intercourse. (5–8)

Life stress, depression, and impulsivity conspire to make adherence to the CDC recommendations difficult. (9–15) Because PLWH are more likely to be ethnic and sexual minorities and to be socioeconomically disadvantaged, they are more likely to experience discrimination and psychosocial stress. (16–19) Given their stressful life circumstances, it is not surprising that PLWH report elevated levels of depression. (20, 21) Both stress and depression have been associated with poor ART adherence (10, 11, 22–25) and with risky sexual behavior. (26–28) Particularly in the absence of strong coping skills, stress and depression can also enhance impulsivity in vulnerable persons, (29) who may then cope maladaptively by engaging in risky sex and/or using alcohol and other drugs. (30, 31)

Previous research has shown that mindfulness training (MT), a behavioral approach aimed at the cultivation of a particular way of paying attention to the present moment's experience ("on purpose, and non-judgmentally"), (32) reduces distress and symptoms of depression among patients with chronic illnesses. (33–35) Despite this promising evidence, MT has received limited attention with PLWH. A possible reason is that MT (which is traditionally delivered in a class-based format) presents several barriers to delivery and implementation among PLWH (i.e., transportation, need for child care). However, phone-delivery has the potential to overcome some of these barriers and also has the advantage of allowing more individualized training. Preliminary work has demonstrated that MT can be delivered by phone with strong patient participation and positive effects on psychological distress (36, 37).

This will be the first study to evaluate the feasibility and acceptability of phone-delivered MT for PLWH. We will conclude that the study is feasible if at least 80% of participants complete the final follow-up visit and if participants attend at least 75% of the sessions planned for each condition. We expect, and will consider evidence of acceptability, 80% of

participants to report positive satisfaction ratings with both conditions. As a secondary outcome, we will obtain estimates (i.e., effect sizes) of MT's effects on ART adherence and risky sex behaviors as well as on four hypothesized mediators (i.e., mindfulness, depression, perceived stress, impulsivity). We expect that, compared to an attention control, MT will improve ART adherence, reduce risky sexual behaviors, and enhance posited mediators.

2. MATERIALS AND METHODS

2.1. Design

The study will be a phase 2 randomized clinical trial. Participants ($n = 50$; 25 per condition) will be randomized to either the MT or to a Health Coaching (HC) intervention. Both interventions will be delivered during 8 weekly telephone calls. Assessments will be conducted at baseline, post-intervention, and 3 months post-intervention.

2.2. Setting and Participants

Participants will be recruited from patients receiving outpatient care at an academically affiliated and hospital-based HIV clinic in the northeastern United States. The clinic provides comprehensive care for more than 1,600 HIV-infected patients. The demographic profile of HIV-infected patients at the clinic (30% female; 30% African American, and 25% Hispanic) is diverse, ensuring an adequate representation of minorities and women for this study. To be included, patients will need to be (a) 18 years old; (b) infected with HIV; (c) sub-optimally adherent to ART (less than "always" taking ART medication and/or VL > 20 copies/mL); (d) psychologically distressed; (e) report risky sexual behavior (i.e., any condomless sex or > 1 sexual partner) in the past 6 months; and (f) able to access a telephone or cell phone. Patients will be ineligible if they (a) are unwilling or unable to provide informed consent; (b) have cognitive impairment; (c) are non-English speaking; (d) report that they "often" or "always" need someone to read instructions, pamphlets, or other written material from a doctor or pharmacy to them (an indication that their literary skills will interfere with completing self-report surveys); (e) are enrolled in another behavioral research study; (f) have received prior formal mindfulness training or have practiced of mindfulness or related mind-body techniques in the previous year; (g) have a severe hearing impairment not allowing phone delivery; (h) report suicidal ideation; and (i) are planning to move out of the area within the study period. Patients will also be excluded if (j) their clinic provider advises the research team that the patient should not be approached for the study.

2.3. Recruitment

Two approaches will be used to identify possible participants. First, the clinic database will be queried to identify patients who (a) have a laboratory-confirmed, detectable HIV-1 plasma viral load (VL) within the past 12 months, (b) are 18 years of age or older, and (c) have a clinic visit planned within the next 3 months. Second, flyers containing eligibility criteria and other study information will be distributed to clinic providers, who will be asked to refer potentially eligible patients. The project director (PD) or a research assistant (RA) will approach patients at their next scheduled clinic visit to complete screening.

2.4. Screening, Consenting, and Baseline Procedures

If patient is interested in the study, verbal consent will be obtained to conduct a brief screen to determine whether the patient is eligible. Once eligibility is confirmed, patients will receive information about the study risks and benefits and they will be asked to provide written informed consent. Once consent procedures are completed, participants will complete the baseline measures, provide bio-specimens, and receive pill count training (a measure of ART adherence).

2.5. Randomization

After all baseline assessments have been completed, the PD will randomly assign participants (1:1 ratio) to either MT or the HC condition using a randomization schedule generated by the study biostatistician using a permuted block randomization procedure with small, random-sized blocks.

2.6. Retention Plan

We will maintain an electronic tracking system to identify patients due for an assessment. We will maintain continuous contact through email, mail, and phone reminders. In addition, participants will receive monetary compensation for completing all study assessments.

2.7. Interventions

Participants assigned to the MT condition will receive a phone-delivered 30-minute mindfulness training once a week for 8 weeks. Participants assigned to the HC condition will receive a phone-delivered 30-minute health coaching once a week for 8 weeks. To ensure consistency of delivery in both conditions each patient will be trained by the same instructor throughout the intervention; however, to avoid contamination, different instructors will deliver the MT and HC interventions.

Mindfulness Training (MT)—This intervention maintains the basic components of Mindfulness-Based Stress Reduction (MBSR) (32) but has been streamlined to distill the active ingredients for phone delivery (Table 1). In addition to the weekly training session, participants will be instructed to practice mindfulness techniques for 15 minutes daily using a standardized audio recording to guide them through the techniques learned with the instructor. The recording will be provided in a format (e.g., CD, MP3 file) that the participant prefers.

MT instructors will be graduates of the teachers' training program at the University of Massachusetts Center for Mindfulness with 5 years teaching experience. Instructors will receive 3 hours of training with respect to phone delivery protocol, fidelity checks, and reporting.

Health coaching (HC)—The HC condition will consist of educational modules designed to control for the contact time and attention received in the MT condition. Topics (i.e., nutrition, sun safety, physical activity, sleep, home and travel safety) were chosen based on feedback from focus groups conducted with clinic patients and HIV providers as well as community-based HIV advocates (Table 2). Specific content was identified and adapted

from health recommendations published on publicly available websites (i.e., the American Heart Association [<http://www.heart.org/>] and the National Sleep Foundation [<http://pa-foundation.org/wp-content/uploads/NSF-Sleep-Diary.pdf>]). Importantly, the HC will not directly address either ART adherence or safer sex, nor will it address the hypothesized determinants of ART adherence or safer sex such as depression, impulsivity, or stress. To match the time MT participants will spend doing mindfulness exercises at home, HC participants will be assigned a 15-minute daily activity that is aligned with the HC topics (e.g., keeping a sleep diary, trying healthy foods, and/or readings related to the HC topics).

Health coaches will be clinical psychology interns with 5 years of clinical training. They will undergo a 3-hour training in the delivery of the health coaching and fidelity checks. Supervision will be provided during regular conference calls scheduled weekly during the first month, biweekly during the second month, and monthly thereafter. Additional *ad hoc* calls will be scheduled if needed.

2.8. Blinding

Principal Investigators, Co-Investigators, and data analysis personnel will be blinded to group assignment. Other research staff will be blinded as practical regarding group assignment and study hypotheses.

2.9. Study Assessments

Assessments will be conducted at baseline, post-intervention (i.e., within two weeks of program completion) and follow-up (i.e., 3 months $\pm$ 2 weeks since program completion). A summary of the study-related assessments can be seen in Table 3.

2.10. Screening Measures

These assessments will determine if a clinic patient is eligible for the study. HIV infection status and VL will be determined from the medical record. ART adherence will be self-reported. Participants who report to be < 100% adherent during the past six months and/or have a VL > 20 copies/mL will be eligible. Psychological distress will be measured using the 4-item Patient Health Questionnaire (PHQ) (38); individuals scoring 2 on the PHQ will be eligible. Sexual risk behavior will be self-reported; patients reporting any condomless sex and/or > 1 sexual partner over the past six months will be eligible. Prior training in mindfulness, meditation, or related mind-body techniques will be self-reported; participants who received formal mindfulness training or have been practicing mindfulness or other mind-body techniques in the previous year will be excluded. Severe hearing impairment and telephone access will be self-reported. Cognitive impairment will be evaluated by the referring physician. Suicidal ideation will be measured using the Symptom-Driven Diagnostic System for Primary Care (SDDS-PC) (39) assessing suicidal thoughts, plans, and attempts during the past month. Individuals endorsing any items will be excluded from the study. Literacy will be assessed by the Single Item Literacy Screener (SILS). (40)

2.11. Primary Outcomes

Feasibility—Recruitment metrics will include the number of individuals who are consented and randomized as well as the percentage of eligible and ineligible individuals

(and reasons for ineligibility). Retention metrics will include the number of participants who withdraw from the study and the number who are lost to follow-up (reasons for both will be obtained). To assess feasibility of both interventions we will calculate the percentage of individuals who complete all 8 training sessions, and the number of missed and rescheduled sessions. Participants will be asked how many times (and for how long) they listened to the audio file or did their assigned activity and to report this information in a log to be submitted each week throughout the intervention.

Acceptability—Acceptability will be assessed both quantitatively and qualitatively in both conditions. All participants will complete a satisfaction survey (41) rating how informative, interesting, and helpful the MT or HC 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 improvement. Participants will also rate either intervention on a scale from 0 (“not satisfied”) to 4 (“very satisfied”). In addition, participants will participate in two semi-structured interviews to solicit information about their experiences in the study. During the interviews participants will be asked open-ended questions such as “What did you like (dislike) about the mindfulness (control) intervention? Did you notice any benefits/problems? Was the schedule acceptable (too many/few sessions)? Did you miss any sessions (why)? What did you like about your instructor? What made it hard (easier) for you to practice at home?” We will also ask for suggestions on best way to optimize the appeal of the study; strategies to increase retention and survey completion (e.g., stipends) for a future larger study; and burden and usefulness of study materials and forms.

2.12. Secondary Outcomes

ART adherence—Consistent with recommendations (42) we will employ a multi-modal assessment of adherence with self-report, an objective measure, and a biomarker. *Self-reported adherence* will be obtained using a validated 3-item measure. (43) Our *objective measure of adherence* will be unannounced phone-based pill counts, which have been shown to be reliable and valid. (44–46). (47) The use of a phone-based measure has the additional advantage of being consistent with the phone-based interventions. The *biomarker* will be VL, which correlates closely with adherence. (48) Blood samples will be collected via phlebotomy and processed using standard procedures.

Sexual risk behavior—Consistent with recommendations (49) we will also employ a multi-modal assessment of sexual risk behavior. Participants will *self-report* the number of male and female sexual partners; number of occasions of condom-protected and condomless oral, anal, and vaginal sex; and partner type and partner serostatus over previous 3 months. (50) As an indirect but *objective* measure of sexual risk behavior we will collect information about *STIs* from medical records. This information is helpful because laboratory testing does not capture STIs that have been treated between visits. Laboratory-diagnosed STIs will be used as a *biomarker* of sexual risk behavior. Although not a direct measure of sexual risk behavior, a STI diagnosis provides a proxy indicator of risk behavior and is an important health outcome in itself. We will collect blood, urine, rectal, and pharyngeal specimens using standard processing methods. We will test for (a) urethral (men) and cervical (women) gonococcus (Gc), Chlamydia trachomatis (CT), and Trichomonas vaginalis (women) using

urine specimens, (b) pharyngeal Gc and CT using pharyngeal swabs, (c) Syphilis RPR using blood specimens and (d) rectal swabs for Gc and CT for all MSM and for heterosexual men and women who report anal intercourse.

Mediators—We will also measure four hypothesized mediators through which the intervention is expected to produce an effect on the efficacy outcomes. Because of the pilot nature of this study and the small sample size will not allow formal mediation testing, all analyses involving these mediators will be exploratory and used to refine the conceptual model for a future larger RCT.

Mindfulness will be assessed will be assessed using the 15 item Five Facets of Mindfulness Questionnaire, an instrument derived from a factor analysis of instruments measuring mindfulness in daily life. Each item is rated on a Likert scale ranging from 1 (never or very rarely true) to 5 (very often or always true). (51)

Depression will be assessed using the Patient Health Questionnaire (PHQ), which scores nine DSM-IV diagnostic criteria for depression from “0” (not at all) to “3” (nearly every day). (52)

Perceived Stress will be measured with the 4-item Perceived Stress Scale (PSS), which assesses the degree to which participants perceive life circumstances as stressful. Higher scores indicate greater levels of perceived stress. (53)

Impulsivity will be measured using a brief version of the Barratt Impulsiveness Scale (BIS), a widely used and validated instrument with 5 factors (attention, motor, self-control, cognitive complexity, perseverance, and cognitive instability). (54)

2.13. Descriptors and Covariates

We will also measure demographic characteristics and other factors in order to describe the sample and/or because they have been linked with ART adherence and safer sex in prior research. All constructs will be assessed using standard questions/measures developed in previous research. *Perceived physical health* will be assessed with a single item from the Medical Outcomes Study General Health Survey. (55) *Medical history* will be culled from the patient’s medical records and include date of HIV diagnosis, likely mode of contracting HIV, length of time since initiating ART, VL and CD4 counts, adherence to medical appointments, AIDS diagnosis (yes/no, date), number of HIV-related hospitalizations, medical and psychiatric comorbidities and current medications. *Socia support* will be measured using the Multidimensional Scale of Perceived Social Support. (56) *Sleep quality* will be measured using the Pittsburgh Sleep Study Index, a self-report instrument designed to measure sleep quality and disturbance based on recall of sleep behaviors in the past month. (57) *Alcohol use* will be assessed with (a) the Alcohol Use Disorders Identification Test (58), and with (b) the PhenX Measures for Lifetime Use, 30-day Frequency, and maximum Drink in 24 Hours. (59) *Drug use* will be measured with the PhenX Substances-Lifetime Use, Substances-30 Day Frequency and DAST-10. (59, 60) *Smoking* will be measured using standard questions about lifetime and past 30 days smoking. *Nutrition* will be measured by asking questions about frequency of eating breakfast. *Food Security* will be

measured using the U. S. Household Food Security Survey, a 6-item index. (61) All measures have evidence of reliability and validity.

2.14. Data Collection

Data will be collected via in-person interviews at each visit. Electronic data capture technology (REDCap) (62) will be used for direct data entry during self-report and interviews; clinical data will be collected using abstraction forms and then entered into electronic forms.

2.15. Quality Control

Treatment fidelity—To ensure that interventions are delivered with fidelity, we have developed an intervention protocol and a script for each session. The script will not be used *verbatim* but instructors will be trained to follow the sequence indicated in the script. Regularly scheduled conference calls will be held to discuss issues that arise during the intervention. Assessments of treatment fidelity will follow Treatment Fidelity Workgroup guidelines. (63) Instructors will audio-record each session (instructor's voice only) and we will audit 10% of all recordings using an auditor checklist of essential intervention components for the MT and HC.

Data management—Data entry systems developed using REDCap include skip patterns and parameter limits to ensure that data are entered accurately. Other data quality steps will include automatic checks for values that are out-of-range or represent errors of logic. Electronic data will be stored in password protected data files accessible only to authorized project personnel. Data containing identifiers will be stored on password-protected secure servers separately from de-identified study data. For analyses, data will be exported from the REDCap system to create the official analysis files for the study.

2.16. Statistical Analyses

Preliminary analyses will examine equivalence of participants in the MT and HC groups at baseline on demographic and other characteristics using Fisher, *t*-tests or Mann-Whitney depending on the level of measurement of the specific variables (i.e., categorical or continuous) and the distribution (i.e., normal or skewed). We will examine the distributional properties of continuous variables to determine if normalizing transformations should be applied before conducting analyses. If group differences are found for any variables, we will control for them statistically in subsequent analyses.

Primary outcome: Feasibility—We will calculate the percentage of individuals who were eligible; consented; accepted randomization; and returned for the post-intervention and 3-month follow-up. We will calculate session attendance for both conditions. We will conclude that the study is feasible if at least 80% of participants complete the final follow-up visit and if participants attend at least 6 out of the 8 sessions (75%) planned for each condition.

Primary outcome: Acceptability—To determine the acceptability of the interventions, we will calculate means for the satisfaction surveys. The intervention will be considered

acceptable if 80% of participants (both conditions) respond that they are satisfied with the intervention. We will also collect session metrics (e.g., duration of calls, number of cancelled sessions) and construe the following as evidence of acceptability: (a) patients completing 7 sessions, with (b) call durations averaging 20 minutes per call, and (c) with 3 rescheduled sessions.

Secondary outcomes—Because this is a pilot study, analyses are not powered to detect treatment effects or to formally test mediation; thus, analyses will be exploratory and focus on estimates of effect rather than strict statistical hypothesis testing. We will examine within- and between-group effects on sexual risk and ART adherence as well as on the hypothesized mediators (i.e., mindfulness, perceived stress, depression, impulsivity). 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. Using a series of longitudinal mixed effects models, we will simultaneously regress outcomes (i.e., sex risk and ART adherence, and mediators) at end of intervention and follow-up, on condition (MT vs. HC), time, condition $\times$ 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 hypothesized mediators, as well as estimate the effect size with respect to between-group effects. We predict an intervention condition $\times$ time interaction such that, relative to HC recipients, MT recipients will increase mindfulness and ART 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 the follow-up interval is too brief an interval to expect changes (we are collecting these data to demonstrate feasibility and to finalize the protocol in advance of a larger trial).

Qualitative analyses—Audio recordings of the patients' interviews will be reviewed and summarized in a framework matrix. Thematic and comparative analysis will be conducted using NVivo software. 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.

Sample size—We chose to enroll a convenience sample of 50 participants taking into account funding and timeline limitations. Because efficacy estimates based on trial results using small samples have large standard deviations and wide confidence intervals, (64) we will use these pilot data only to gauge whether changes in ART and sexual risk are in the expected direction and to estimate effect sizes and confidence intervals.

3. DISCUSSION

Although mindfulness-based approaches are recognized as potentially helpful for PLWH, (65) MT has not been well-studied in this context. We found only nine published studies (66–74) and one unpublished study (75, 76) of mindfulness-based interventions with PLWH. Overall, the available evidence suggests that MT reduces distress and promotes more adaptive coping in PLWH. (35, 77) The only study assessing the effect of MT on ART adherence did not show improvements; however, only self-report measures of adherence were used, and suboptimal ART adherence was (apparently) not an inclusion criterion. (69) No study has investigated the effect of MT on sexual behavior outcomes. Furthermore, most studies have methodological limitations (e.g., small sample size, recruitment of low risk participants leading to possible ceiling effects on the outcomes). An important limitation is the low class attendance and high attrition reported in previous studies of group-based MT; these findings suggest that participants may not have received an adequate dose of MT. (68, 72)

Building upon the available empirical evidence in support of the efficacy of MT in reducing stress and depression (33–35, 77) and attenuating impulsivity (78, 79) as well as on theories of mindfulness, (80, 81) we propose the following conceptual model to guide our research. As shown in Figure 1, we expect that the MT intervention will reduce stress, depressive symptoms, and impulsivity, results that, in turn, are expected to improve safer sex practices and ART adherence.

If the findings from this exploratory clinical trial support our hypotheses, we anticipate conducting a large randomized clinical trial that will provide the statistical power needed to investigate two longer-term hypotheses, namely, that improved adherence to ART will ultimately improve CD4 counts and reduce VL, and that improved adherence to safer sex will ultimately reduce the incidence of STIs. Key to testing these hypotheses is that participants receive an adequate “dose” of the mindfulness intervention, which will be made possible because of the phone-delivery approach, which will ensure high attendance and retention.

Strengths

This is the first study to investigate the role of MT to promote safer sexual behaviors in PLWH and only the second study to evaluate the use of mindfulness training to improve adherence to ART. Another notable strength is the delivery of mindfulness training as a mobile-health, telephone-based intervention to PLWH. Compared to group- and class-based delivery, one-on-one telephone delivery reduces patient-related barriers (e.g., transportation, parking, need for child care, time off from work); it allows the instructor to give his/her undivided attention to the individual participant; and lastly, it reduces the burden for space and staffing on the outpatient clinic because instructors can deliver the intervention remotely. Clinic providers could simply refer patients to mindfulness instructors, who would schedule calls with patients at convenient times. The study is also strengthened by the use of a contact and attention-control comparison condition and by rigorous assessments of treatment fidelity; this approach will increase the validity of our findings and allow us to draw stronger inferences about the efficacy of the intervention.

Challenges

We considered the use of electronic medication monitoring devices (i.e., MEMS caps) as an alternative objective assessment of medication adherence. Although MEMS caps have some advantages, they interfere with the use of pill boxes, which many patients rely upon, and do not account for doses that participants may have taken without opening the pill cap (e.g., took out afternoon doses when opening the bottle in the morning).(82)

Because the both mindfulness training and health coaching are delivered by phone, another concern regards participants' telephone access. We note, however, that more than 90% of Americans own a cell phone, and that low-income patients (i.e., at or below 135% of the federal Poverty Guidelines or if participating in federal or state assistance programs) are eligible to receive a cell phone through the Lifeline Program for Low-Income Consumers (see <http://www.fcc.gov/lifeline>).

Conclusion

If the MT approach proposed in this pilot study is proven feasible and acceptable the next step will be to conduct a large RCT to evaluate the efficacy of MT in promoting ART adherence and safer sex in PLWH. Further, this larger RCT will be powered to test the longer-term hypotheses shown in Figure 1, namely, that improved adherence to ART and safer sex will reduce VL as well as the incidence of STIs, respectively. We will also conduct formal mediation analyses to test the hypotheses that improvement in ART adherence and safer sexual practices are mediated by positive changes in perceived stress, depressive symptoms, and impulsivity. Such findings would have great impact on individual and population health because better ART adherence and lower risky sexual behaviors reduce HIV-related premature morbidity and mortality as well as the incidence of new HIV infections.

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Figure 1.

Study conceptual framework

ART = Antiretroviral therapy

VL = Viral load

STI = Sexually transmitted infection

CD4 = cluster of differentiation 4, a glycoprotein found on the surface of immune cells

Table 1**Mindfulness Training (Experimental Condition)**

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	(10')
• Feedback from participant	(10')
• Participant encouraged to practice AOB exercise during the following week - 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')
• Exercise: direct the attention to the bodily sensations associated with breathing	(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 - track 1 once a day; confirm next meeting	
Session 3: AOB/Body Scan	
• Questions and answers related to practice in previous week	(10')
• Body scan exercise: participant is invited to sit in comfortable chair	(10')
Participant 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 - 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 instructed to practice attention to daily activities (i.e., drinking, eating, walking) throughout the day; practice Body Scan exercise during the following week - track 2 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')
• Feedback from participant	(10')
• Participant encouraged 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 encouraged 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 use study CD (either track) or practice 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 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. (15')
 - Feedback from participant (5')
 - Participant encouraged to practice attention to daily activities throughout the day and to bring this skill to all their experiences (pleasant and unpleasant ones). Thank participant.
-

Table 2**Health Coaching (Attention-Control Condition)**

Session 1: Eating Well to Feel Well	
• Questions related to material discussed in the last session	(5')
• Foods to Feel Better; Benefits of Fruits and Vegetables, Strategies to add fruits and vegetables	(10')
• Instructor asks participant for any comments or questions related to the material discussed	(10')
• Explanation of daily activity (trying new fruits/vegetables, readings); participant encouraged to complete daily activity; confirm next meeting	(5')
Session 2: Healthy Choices When Eating Out	
• Questions and answers related to material discussed in the last session	(5')
• Fast food choices; corner store choices; soup kitchen choices; restaurant choices	(10')
• Instructor asks participant for any comments or questions related to the material discussed	(10')
• Explanation of daily activity (readings, daily effort to make healthy choices when eating out); participant encouraged to complete daily activity; confirm next meeting	(5')
Session 3: Food Labels	
• Questions and answers related to material discussed in the last session	(5')
• Food labels; portion size; measurements	(10')
• Instructor asks participant for any comments or questions related to the material discussed	(10')
• Explanation of daily activity (reading labels at home and grocery store; making choices based on labels); participant encouraged to complete daily activity; confirm next meeting	(5')
Session 4: Smart Snacking	
• Questions and answers related to material discussed in the last session	(5')
• Assess snacking behaviors; healthy snacking; more filling food choices	(10')
• Instructor asks participant for any comments or questions related to the material discussed	(10')
• Explanation of daily activity (making healthier snack choices); participant encouraged to complete daily activity; confirm next meeting	(5')
Session 5: 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 related to the material discussed	(10')
• Explanation of daily practice (Reading); Participant encouraged to complete daily practice; confirm next meeting	(5')
Session 6: Physical Activity	
• Questions and answers related to material discussed in the last session	(5')
• Assess physical activity; benefits of physical activity; safe stretching; walking; posture	(10')
• Instructor asks participant for any comments or questions related to the material discussed	(10')
• Explanation of daily activity (readings; implementing physical activity); participant encouraged to complete daily activity; confirm next meeting	(5')
Session 7: Healthy Home	
• Questions and answers related to material discussed in the last session	(5')
• Tips for a healthy home: chemicals (including drugs); noise protection; carbon monoxide,	(10')

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- radon, lead, ozone
- Instructor asks participant for any comments or questions related to the material discussed (10')
- Explanation of daily activity (readings); participant encouraged to complete daily activity; confirm next meeting (5')

Session 8: 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 comments / questions related to the material discussed (10')
- Explanation of daily sleep diary; participant encouraged to complete diary activity; confirm next meeting (5')

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Table 3

Overview of Study Measures and Timing of Assessment

Measure	Screening	Baseline	Weekly (Weeks 1–8)	Post- intervention	Follow-up
Screening					
HIV infection status	X				
ART adherence	X				
Viral load (VL; medical record)	X				
Psychological distress	X				
Sexual risk behavior	X				
Prior mind-body training	X				
Hearing impairment	X				
Telephone access	X				
Cognitive impairment	X				
Suicidal ideation	X				
Literacy	X				
Primary Outcomes: Feasibility and Acceptability					
<i>n</i> of screened individuals	X				
<i>n</i> eligible	X				
<i>n</i> enrolled	X				
<i>n</i> refusing to participate	X				
Reasons for refusing participation	X				
<i>n</i> of dropouts and lost to follow-up			X	X	X
Reason(s) for dropping out			X	X	X
Sessions attendance			X		
Individual home practice			X	X	X
Satisfaction scale				X	X
Semi-structured Interview				X	X
Secondary Outcomes					
ART adherence		X		X	X
Self-reported measure					

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Measure	Screening	Baseline	Weekly (Weeks 1-8)	Post- intervention	Follow-up
Objective measure (pill count)		X*		X	X
Viral load (biomarker)		X		X	X
Sexual risk		X		X	X
Self-reported measure					
STI testing (biomarker)		X			X
Mindfulness		X		X	X
Depression		X		X	X
Perceived stress		X		X	X
Impulsivity		X		X	X
<i>Participants' descriptors/covariates</i>					
Sociodemographic characteristics		X			
Perceived physical health		X			
Medical history; medications		X			
Social support		X			
Sleep quality		X		X	X
Alcohol use		X		X	X
Drug use		X		X	X
Smoking		X		X	X
Nutrition/Eating		X		X	X
Food Insecurity		X			
<i>Quality Control</i>					
Audit of 10% of recordings (MT only)			X		
Instructor checklist			X		

* Scheduled within one week of the baseline. ART = antiretroviral therapy.