



Telephone-Delivered Mindfulness Training to Promote Medication Adherence and Reduce Sexual Risk Behavior Among Persons Living with HIV: An Exploratory Clinical Trial

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Abstract

This study explored whether telephone-delivered mindfulness training (MT) to promote medication adherence and reduce sexual risk behavior was feasible for and acceptable to people living with HIV. Participants ($N=42$; 50% female; M age = 47.5 years) were randomized to MT or health coaching (HC). Pre- and post-intervention, and at 3-month follow-up, we assessed adherence to ART, sexual risk behavior, and hypothesized mediators; we also conducted individual interviews to obtain qualitative data. Results showed that 55% of patients assigned to MT completed $\geq 50\%$ of the training calls compared with 86% of HC patients ($p < .05$). Most patients reported satisfaction with their intervention (MT = 88%, HC = 87%). Patients in MT and HC reported improvements in medication adherence, mindfulness, and sexual risk reduction as well as reductions in anxiety, depressive symptoms, perceived stress, and impulsivity over time; however, no between-groups differences were observed.

Keywords Mindfulness · HIV · Clinical trial · Adherence · Sexual risk behavior · Stress

Resumen

Este estudio exploró si el entrenamiento de atención plena (MT) impartido por teléfono para promover la adherencia a los medicamentos y reducir el comportamiento de riesgo sexual era factible y aceptable para las personas que viven con el VIH (PVVS). Los participantes ($N=42$; 50% mujeres; edad $M=47.5$ años) fueron asignados al azar a MT o entrenamiento de salud (HC). Antes y después de la intervención, y a los 3 meses de seguimiento, evaluamos la adherencia a medicación antirretroviral, el comportamiento de riesgo sexual y los mediadores hipotetizados; También realizamos entrevistas individuales para obtener datos cualitativos. Los resultados mostraron que el 55% de los pacientes asignados a MT completaron $\geq 50\%$ de las llamadas de entrenamiento en comparación con el 86% de los pacientes con HC ($p < .05$). La mayoría de los pacientes reportaron satisfacción con su intervención (MT = 88%, HC = 87%). Los pacientes en MT y HC reportaron mejoramiento en la adherencia a la medicación, la atención plena y la reducción del riesgo sexual, y también reducciones en la ansiedad, los síntomas depresivos, el estrés percibido y la impulsividad al transcurso del tiempo; sin embargo, no se observaron diferencias entre grupos.

Palabras clave Mindfulness · VIH · Ensayo clínico · Adherencia · Comportamiento de riesgo sexual · Estrés

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Introduction

Antiretroviral therapy (ART) improves viral suppression, reduces infectiousness and HIV-related morbidities, and increases survival for people living with HIV (PLWH) [1–3]. Despite the benefits of ART, medication adherence can be challenging [4, 5]. One of the strongest predictors of non-adherence is life stress [6–8]. Living with HIV can be stressful for many reasons including its uncertain course, the need for lifelong care, and the cost of HIV care. Additional stress can result from disease-related stigma [9]. Moreover, because HIV in the U.S. is most prevalent among racial, ethnic, and sexual minorities, PLWH often experience minority stress and discrimination [10] and are more likely to be economically disadvantaged [11, 12]. Collectively, these life stressors can increase impulsivity [13] and depression [14] as well as alcohol and other substance use [15, 16], factors that can undermine medication adherence.

Psychosocial stress also affects other health behaviors, such as sleep, physical activity, and safer sexual practices. Safer sexual practices, including condom use, are especially important for PLWH because protective behaviors lower the risk of transmitting HIV to an uninfected partner as well as the risk of acquiring other sexually transmitted infections (STIs). However, some PLWH often report condomless sex at their last sexual encounter [17, 18]. One way to improve health behaviors, including medication adherence and safer sexual behaviors, is to help PLWH cope with psychosocial stress.

Among extant stress management practices, mindfulness training (MT) has received widespread attention. Indeed, scientific publications and news media articles on mindfulness and meditation have grown exponentially over the past two decades [19, 20]. Although the term “mindfulness” has been used to refer to a large number of practices, herein we use it to refer to interventions that seek to cultivate a particular way of paying attention to the present moment’s experience (“on purpose and non-judgmentally”) [22]. Previously, we presented a conceptual model by which MT may help PLWH achieve better adherence to ART [21]. In our model, we suggested that MT could help PLWH to improve appraisal and coping processes; these benefits, in turn, could then help to reduce distress and make it easier to follow medical recommendations, including adherence to ART and safer sex behavior [21].

Empirical evidence provides preliminary support for the value of MT. Meta-analyses show that MT can reduce anxiety, distress, and symptoms of depression among patients with chronic illnesses, including HIV [22]. Several studies have examined the effects of MT on immune functioning

among PLWH [23–25] and preliminary results are encouraging [26]. However, to our knowledge, no study has investigated MT as a way to enhance medication adherence. In addition, many published studies of MT for PLWH have several methodological limitations (e.g., failure to use rigorous control or comparison conditions, to match homework and daily practice, and to match expertise and confidence of the instructors) [27]. Research that targets medication adherence specifically while addressing the methodological limitations of prior research is needed.

In addition, as a practical matter, traditional approaches to MT (i.e., in person workshops) are limited by the need to attend extensive sessions. Because many PLWH report unstable housing, lack of access to reliable transportation, poor access to internet resources, and family and work responsibilities that can prevent them from attending in-person interventions, a delivery mode of MT that has fewer barriers would be more practical for PLWH.

Telephone-delivery can help to reduce barriers associated with face-to-face interventions. Telephone-delivery also allows more individualized training compared to traditional, group-based MT. The feasibility of telephone delivery was suggested by pilot data that indicated that nearly all PLWH, even those with severe financial hardship, had access to mobile telephones [28]. We were also encouraged by the demonstrated feasibility and acceptability of telephone-delivered MT with other patient populations [29, 30].

The primary purpose of this exploratory trial was to determine the feasibility and acceptability of telephone-delivered MT for PLWH. We set quantitative benchmarks for feasibility and acceptability consistent with guidelines from the National Center for Complementary and Integrative Health (NCCIH), which recommends that such benchmarks be relevant to the specific treatment conditions and population under study. For the current study, we proposed that $\geq 70\%$ of patients attending $\geq 50\%$ of the intervention sessions provide evidence that MT was feasible. We also expected high levels of acceptability; thus, we set a benchmark of $\geq 80\%$ of patients reporting positive satisfaction with MT.

A secondary purpose of the study was to collect evidence regarding the effect of MT for medication adherence and sexual risk reduction. We expected that, compared to a time- and attention-matched control intervention, MT would improve ART adherence and reduce sexual risk behaviors. In addition, we sought to gauge the effects of MT on possible mediators of MT; (i.e., mindfulness, anxious and depressive symptoms, perceived stress, impulsivity). We expected that MT would improve mindfulness and reduce negative affect, perceived stress, and impulsivity.

Methods

Design

Details on the study design have been published elsewhere [31]. Briefly, we used a parallel-group, randomized clinical trial design. After completing the baseline assessments, patients were randomized to receive either telephone-delivered MT or telephone-delivered health coaching (HC), which served as a time- and attention-matched control condition. We reassessed patients at post-intervention and at a three-month follow-up.

Participants

The sample was recruited at a hospital-based HIV clinic in the northeastern United States.

Inclusion criteria were: (a) ≥ 18 years of age; (b) infected with HIV; (c) sub-optimally adherent to ART based on self-reported medication lapses and/or chart recorded viral load of > 20 copies/mL; (d) sexually active (past 3 months); (e) self-reported psychological distress; and (f) access to a landline telephone or mobile phone.

Exclusion criteria were (a) cognitive impairment or other contraindication to enrollment in a research study according to their clinic provider; (b) non-English speaking; (c) lower literacy (i.e., reported they often or always needing someone to read instructions or other written materials from a doctor or pharmacy to them); (d) enrolled in another behavioral research study; (e) prior MT or practice of mindfulness or related mind–body techniques; (f) hearing impairment that would interfere with telephone delivery; (g) suicidal ideation; and (h) planning to move out of the geographic area within the study period.

Measures

All behaviors and constructs were assessed using measures validated in previous research. Assessments were conducted at baseline, post-intervention, and 3 months post-intervention.

Participant Characteristics

At baseline, we assessed *demographic characteristics* (i.e., age, gender, income, educational level, employment status), *perceived social support* (MSPSS) [32], *alcohol misuse* (AUDIT) [33], *drug use* (DAST) [34], and *medical history* (i.e., date of HIV diagnosis, length of time since initiating ART, VL and CD4 counts, adherence to medical

appointments, number of HIV-related hospitalizations, medical and psychiatric comorbidities, and current medications).

Primary Outcomes

The primary outcomes were feasibility and acceptability.

Feasibility Metrics of feasibility included recruitment, retention, and session attendance. Participants were also asked a series of questions during a qualitative interview (e.g., “Were the telephone calls and the schedule acceptable? Did you miss any sessions and, if so, why?”).

Acceptability To assess the acceptability of the interventions, patients completed a validated survey [35] on which they rated the quality of and satisfaction with the MT or HC, whether it improved their health, if they would recommend to a friend, if they received the intervention they wanted, and their overall level of satisfaction. In addition, patients were asked a series of questions during the qualitative interviews (e.g., “What was most helpful/least helpful about the sessions?” “Did you notice any benefits or problems?”).

Secondary Outcomes

The secondary outcomes were medication adherence and sexual risk behaviors.

Medication adherence Consistent with recommendations [36], adherence was assessed using a multi-modal approach (self-report, an objective measure, and a biomarker).

Self-reported adherence was obtained using a validated measure developed through extensive cognitive testing [37]. Patients were asked to respond to the item that had been shown to be the least likely to produce a ceiling effect in the validation study, namely: “In the last 30 days, on how many days did you miss at least one dose of any of your HIV medicines?” Patients provided a numerical response that could range from 0 to 30.

The *objective measure of adherence* was obtained during unannounced telephone-based pill counts, which have been shown to be reliable and valid [38–40]. Consistent with validated protocols [39], calls were conducted for 2 months prior to the intervention to establish a stable baseline. Thereafter, calls continued monthly on an unannounced basis for the remainder of the study. Calls were conducted by trained assessors working in the laboratory of the originator of this assessment protocol.

The *biomarker* was HIV viral load (HIV-1 RNA copies/mL). Because there is no universally accepted threshold for viral suppression (i.e., investigators have used values ranging from 50 to 1000 copies/mL) [41], we chose to operationalize viral suppression with a middle value of < 500 copies/mL level. Blood samples were collected at baseline, post-intervention, and follow-up via phlebotomy and processed using standard procedures.

Sexual risk behaviors. Information was collected using both self-reported and objective assessments. Participants were asked to report their sexual behavior for the past 3 months. For each partner, they reported the partner's gender, relationship type (regular, other), types of sex (anal, vaginal, and oral), number of times for each type of sex, and number of times a condom was used for each type of sex. Their responses allowed us to calculate the total number of condomless events. We provided definitions of all terms and used items that we and many others have used in sexual risk reduction research [42].

As an indirect but *objective* measure of risk behavior we tested for (a) *Neisseria gonorrhoea* (NG), *Chlamydia trachomatis* (CT), and *Trichomonas vaginalis* (women) using nucleic acid amplification testing (NAAT) of urine specimens, (b) pharyngeal and rectal NG and CT using NAAT from swabs at these sites, and (c) *syphilis serologies* using blood specimens. Because point-prevalence testing does not capture STIs that have been treated between visits, we also abstracted information about STI incidence from the medical record.

Tertiary Outcomes

We assessed five hypothesized mediators [21] using brief measures that had been used in prior studies with PLWH.

Anxiety was measured with the 7-item Generalized Anxiety Disorder (GAD) scale [43]. A sample item is “Over the last 2 weeks, how often have you been bothered by feeling nervous, anxious, or on edge?” Response options ranged from 0 = not at all to 3 = nearly every day, with total scores ranging from 0 to 21.

Depression was assessed using the 9-item Patient Health Questionnaire (PHQ) [44]. A sample item is “Over the last 2 weeks, how often have you been bothered by feeling down, depressed or hopeless?” Response options ranged from 0 = not at all to 3 = nearly every day, with total scores ranging from 0 to 27.

Perceived stress was measured with the 4-item Perceived Stress Scale (PSS) [45]. A sample item is “In the last 30 days, how often have you felt difficulties were piling up so high that you could not overcome them?” Response options ranged from 0 = never to 4 = very often, with total scores ranging from 0 to 16.

Mindfulness was assessed using the 15-item Five Facets of Mindfulness Questionnaire (FFMQ) [46]. A sample item is “I pay attention to sensations, such as the wind in my hair or sun on my face.” Response options ranged from 1 = never to 5 = very often or always true, with total scores ranging from 15 to 75.

Impulsivity was measured using the 8-item version of the Barratt Impulsiveness Scale (BIS) [47]. A sample item

is “I do things without thinking.” Response options ranged from 1 = never to 4 = almost always, with total scores ranging from 8 to 32.

All measures have been psychometrically-evaluated and shown to be reliable and valid in prior research. They were administered using published instructions and response options. For all measures, we summed across items as recommended to obtain a total score. Items were reverse scored when indicated such that higher scores indicate more of the construct being measured.

Procedures

All procedures were approved by the Institutional Review Board of the hospital.

Screening

We first conducted a preliminary review of the clinic medical records to identify patients who (a) had a detectable HIV-1 plasma viral load (VL) within the past 12 months, (b) were ≥ 18 years of age, and (c) had a clinic visit planned within the next 3 months. We also distributed flyers to clinic providers asking them to refer potentially eligible patients. We did not screen patients if their physician indicated that they were cognitively impaired and unable to participate meaningfully in the research.

Potentially eligible patients were approached in person by the project director (PD) or a research assistant (RA) at a clinic visit. The PD or RA obtained verbal consent to conduct a brief screening interview to determine eligibility. A script and survey were used to standardize screening. During the screening, we assessed ART adherence (eligible if $< 100\%$ adherent during the past 6 months), psychological distress (eligible if scoring ≥ 2 on the PHQ-4), sexual risk behavior (eligible if reporting any condomless sex and/or > 1 sexual partner in the past 6 months), and telephone access (eligible if they had access). We also screened for, and excluded, patients who reported prior training in mindfulness, meditation, or related mind–body techniques (past year), hearing impairment, suicidal thoughts, plans, or attempts during the past month [48], low literacy (unable to read at a $\geq 6^{\text{th}}$ grade level) [49].

Recruitment and Consent

Eligible patients were informed about the study purpose, procedures, risks, and benefits and if interested, they were asked to provide written informed consent. Participants were compensated for their time by receiving a modest stipend.

Baseline Visit

The baseline visit involved four components: (1) completing a survey on a laptop computer in a private exam room, (2) providing a bio-specimen later tested for VL and STIs, (3) receiving instruction regarding the telephone-based, unannounced pill count assessment, and (4) providing contact information.

Randomization

Participants were randomly assigned (1:1 ratio) to either MT or the HC condition using a permuted block randomization procedure with small, random-sized blocks generated by the study biostatistician.

Blinding

MT instructors and HC coaches were blinded to the study hypotheses. Adherence assessors were blinded to treatment allocation and study hypotheses.

Interventions

The intervention began 2 months after the baseline visit (i.e., after the completion of 2 months of unannounced pill counts). Participants in both conditions were told that they would receive a scheduled telephone call each week for 8 weeks lasting 30 min. Patients were encouraged but not required to accept the intervention telephone call in a quiet place, such as in their home.

To avoid contamination, different individuals delivered the MT and HC intervention. MT instructors were two female graduates of the teachers' training program at the University of Massachusetts Center for Mindfulness with ≥ 5 years teaching experience. Health coaches were two clinical psychology residents (one male and one female) with 5 years of clinical training. Both the MT instructors and the health coaches received 3 h of study-specific training that involved reading and reviewing the intervention protocols as well as discussing telephone-delivery, record keeping, and communicating with participants.

To ensure that interventions were delivered with fidelity, interventionists followed a written protocol for each session; however, they were allowed to use specific phrases and examples that were consistent with their style and experience. The interventionists received supervision from the investigators weekly during the first month of the study, biweekly during the second month, and monthly thereafter. For both conditions, we assessed treatment fidelity following the Treatment Fidelity Workgroup guidelines [50]. Thus, instructors audio-recorded each session (instructor's voice only) and the investigators audited 10% of all recordings

using a checklist of intervention components. Features unique to each intervention are described next.

Mindfulness training (MT) This intervention maintained the basic components of Mindfulness-based Stress Reduction (MBSR [51]) but was streamlined to distill the active ingredients for telephone delivery [31]. The intervention included three basic components: (1) the body scan, a technique based on the cultivation of attention to bodily sensations; (2) awareness of breath, in which participants are taught to focus their attention on the sensations of breathing; (3) open awareness, in which they were instructed to just notice which event (e.g., physical sensation, sound, visual object, and/or thought) their attention was spontaneously drawn to from moment to moment. In addition, participants were trained to direct their attention to activities of daily life (e.g., eating, drinking, driving), sounds, visual objects, thoughts, and emotions and to recognize when their attention was no longer focused on that specific object of attention. Patients did not receive materials usually provided to MBSR trainees in the form of poetry or other readings. Likewise, they did not practice hatha yoga exercises due to the impossibility to monitor the correctness of the yoga postures over the telephone, which could expose them to risk of muscular strains and skeletal injuries. In addition to the weekly training session, patients were instructed to practice mindfulness techniques for 15 min daily using an audio recording that guided them through the techniques learned with their instructor [29]. The recording was provided in a format (e.g., CD, MP3 file) that the participant preferred. These and other minor adaptations were made based on input from focus groups conducted with HIV patients, providers, and community advocates [28].

Health coaching (HC) The HC condition consisted of educational modules designed to control for the contact time and attention received in the MT condition. The topics (i.e., nutrition, sun safety, physical activity, sleep, home and travel safety) were chosen based on input from focus groups conducted with HIV patients, providers, and community advocates [28]. Educational content was adapted from published, empirically-based recommendations (e.g., the American Heart Association [52]). Importantly, HC did not address ART adherence or safer sexual behavior or their possible determinants (i.e., anxiety, depression, impulsivity, perceived stress, mindfulness).

To match the time MT patients spent doing mindfulness exercises at home, HC patients were assigned a 15-minute daily activity that aligned with the coaching topics (e.g., keeping a sleep diary, trying healthy foods).

Post-intervention Assessment

The post-intervention assessment occurred within 2 weeks of the last scheduled intervention call. Participants returned

to the clinic to complete the survey, provide biospecimens for testing, and take part in a brief, semi-structured qualitative interview. The qualitative assessment addressed the following topics: study procedures, most/least helpful intervention content, use of home practice materials (i.e., mindfulness recordings or health coaching workbook), and ability to complete study, including the acceptability of the telephone delivery of the study content.

Follow-up Assessment

The follow-up assessment occurred 3 months (± 2 weeks) after the last scheduled intervention call. Participants returned to the clinic to complete the survey, provide biospecimens for testing, and take part in a brief, semi-structured qualitative interview. The qualitative assessment addressed changes since completing the study, thoughts regarding study compensation, and continued use of mindfulness or health coaching skills.

Data Analyses

Preliminary analyses examined equivalence of 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 (i.e., categorical or continuous) and the distribution (i.e., normal or skewed) of the variables. We examined the distributional properties of continuous variables to determine if normalizing transformations should be applied before conducting analyses.

Primary Outcomes

We calculated the percentage of individuals who were eligible; consented; accepted randomization; and returned for the post-intervention and 3-month follow-up assessments. We calculated session attendance for both conditions and the percentage of individuals who completed at least half of the training sessions. To determine the acceptability of the interventions, we calculated means for the satisfaction surveys.

Secondary and Tertiary Outcomes

This was an exploratory study; therefore, it was not powered to detect treatment effects or to formally test mediation. Therefore, we examined both within- and between-group effects on ART adherence and sexual risk behavior as well as on each of the posited mediators.

Qualitative Analyses

Recordings of the interviews were reviewed and recorded in a standardized written debrief and summary form and

included direct quotations of relevant passages. Thematic and comparative analyses were conducted using NVivo [53]. Qualitative data were sorted and reviewed both in aggregate and also based on call completion rates, to identify themes specifically related to the acceptability of the telephone-delivered intervention format. Throughout the coding and analysis process, categories and subcategories were compared and revised as new information was considered and as we came to new understandings of the data.

Results

Baseline Characteristics

Table 1 displays the participants' characteristics (overall and by condition) at baseline. The final study sample ($N = 42$) was 50% female and ranged in age from 24 to 68 years ($M = 47.5$; $SD = 11.3$); 24 patients (57%) identified as racial/ethnic minorities and 18 (43%) identified as White. Overall, randomization produced similar groups. There were no differences in sex, gender identity, age, race, ethnicity, educational level, current finances, social support (MPSS), alcohol misuse (AUDIT), or drug use (DAST). The only significant between-groups difference was employment status, with those in the MT group more likely to be unemployed or retired.

Feasibility

As shown in Fig. 1 (consort diagram), after reviewing the medical records of 297 patients, we screened 128 PLWH. Of these, 69 (54%) were eligible and 50 (72%) enrolled. However, six patients were lost prior to randomization and two patients were randomized but never started the intervention leaving a final analytic sample of 42 patients.

As displayed in Fig. 1, 17/20 (85%) patients in the MT condition and 22/22 (100%) of those in the HC returned for the post-intervention assessment. Attendance at the follow-up assessment was 100% for both conditions.

As shown in Table 2, 55% (11/20) of the patients in the MT condition and 86% (19/22) of those in the HC condition attended $\geq 50\%$ of the planned calls. Neither the mean of sessions attended ($MT = 4.55$, $HC = 5.64$) nor the proportion of weeks with rescheduled calls ($MT = .52$, $HC = .51$) differed between conditions ($ps > .10$).

Regarding individual home practice, MT patients reported they practiced (both with and without the audio files we provided) on 3.4 days/week, with an average of 12 min per home practice session. HC patients reported engaging in practice on 4.5 days/week, with an average of 12 min/day.

Qualitative data Patient reports about the MT were mixed. Some patients reported that the telephone-delivered

Table 1 Participant characteristics for entire sample and by group at baseline

	Entire sample <i>N</i> = 42	Health coaching <i>n</i> = 22	Mindfulness training <i>n</i> = 20	χ^2/t	<i>p</i>
Sex (assigned at birth)				0.00	1.00
Male	21 (50%)	11 (50%)	10 (50%)		
Female	21 (50%)	11 (50%)	10 (50%)		
Gender identity				0.11	.746
Male	22 (52%)	11 (50%)	11 (55%)		
Female	20 (48%)	11 (50%)	9 (45%)		
Age	47.5 (11.2)	48.5 (11.0)	46.4 (11.7)	0.60	.551
Race				1.96	.744
White	18 (43%)	8 (36%)	10 (50%)		
Black	11 (26%)	7 (32%)	4 (20%)		
Native Hawaiian/Pacific Islander	1 (2%)	0	1 (5%)		
American Indian/Alaska Native	4 (10%)	2 (9%)	2 (10%)		
Other	8 (19%)	5 (23%)	3 (15%)		
Ethnicity				0.04	.845
Hispanic/Latino	11 (26%)	6 (27%)	5 (25%)		
Education				4.03	.776
< High school	15 (36%)	7 (32%)	8 (40%)		
High school graduate or GED	14 (33%)	6 (27%)	8 (40%)		
Vocational school	1 (2%)	1 (5%)	0		
College (some)	12 (29%)	8 (36%)	4 (20%)		
Employment				9.16	.027
Not working	24 (57%)	8 (36%)	16 (80%)		
Retired	1 (2%)	1 (5%)	0		
Employed	14 (33%)	10 (46%)	4 (20%)		
Self-employed	3 (7%)	3 (14%)	0		
Finances				5.44	.142
Comfortable, room for extras	3 (7%)	1 (5%)	2 (10%)		
No room for extras but enough	21 (50%)	8 (36%)	13 (65%)		
Have had to cut back	6 (14%)	5 (23%)	1 (5%)		
Not enough	12 (29%)	8 (36%)	4 (20%)		
Social support (MPSS; 1–5)					
Family	3.28 (1.34)	3.35 (1.40)	3.20 (1.31)	0.36	.719
Friend	3.32 (1.49)	3.24 (1.55)	3.40 (1.46)	−0.35	.731
Significant other	3.63 (1.14)	3.59 (1.43)	3.66 (1.41)	−0.16	.871
Total	3.41 (1.03)	3.39 (1.14)	3.42 (.93)	−0.08	.934
Drug abuse (DAST; 0–10)	1.31 (2.72)	1.00 (2.27)	1.65 (3.17)	−0.77	.446
	Median 0.0	Median 0.0	Median 0.0		
Alcohol abuse ^a (AUDIT; 1–28)	6.32 (7.01)	6.07 (6.23)	6.64 (8.21)	−0.20	.846
	Median 3.0	Median 5.0	Median 3.0		

N (%) for categorical variables. Mean (SD) for continuous variables

^a*n* = 25

MT was convenient and flexible, whereas others were not able to fully participate in calls or do their home practice due to life stress. Others noted that it was not always convenient to be in a quiet place (e.g., at home) to receive the calls. Among the nine patients who completed fewer than 50% of MT sessions, four stated the study was helpful and four reported continued use of the mindfulness audio files at

follow-up despite minimal completion of intervention calls. Specific reasons for missing calls included life stress (*n* = 4), dislike of mindfulness training (*n* = 1), dislike of the study in general (*n* = 1), scheduling problems (*n* = 1), and a preference for in-person training (*n* = 1).

Reports about HC were more consistently positive. Most patients reported that the telephone delivery was flexible

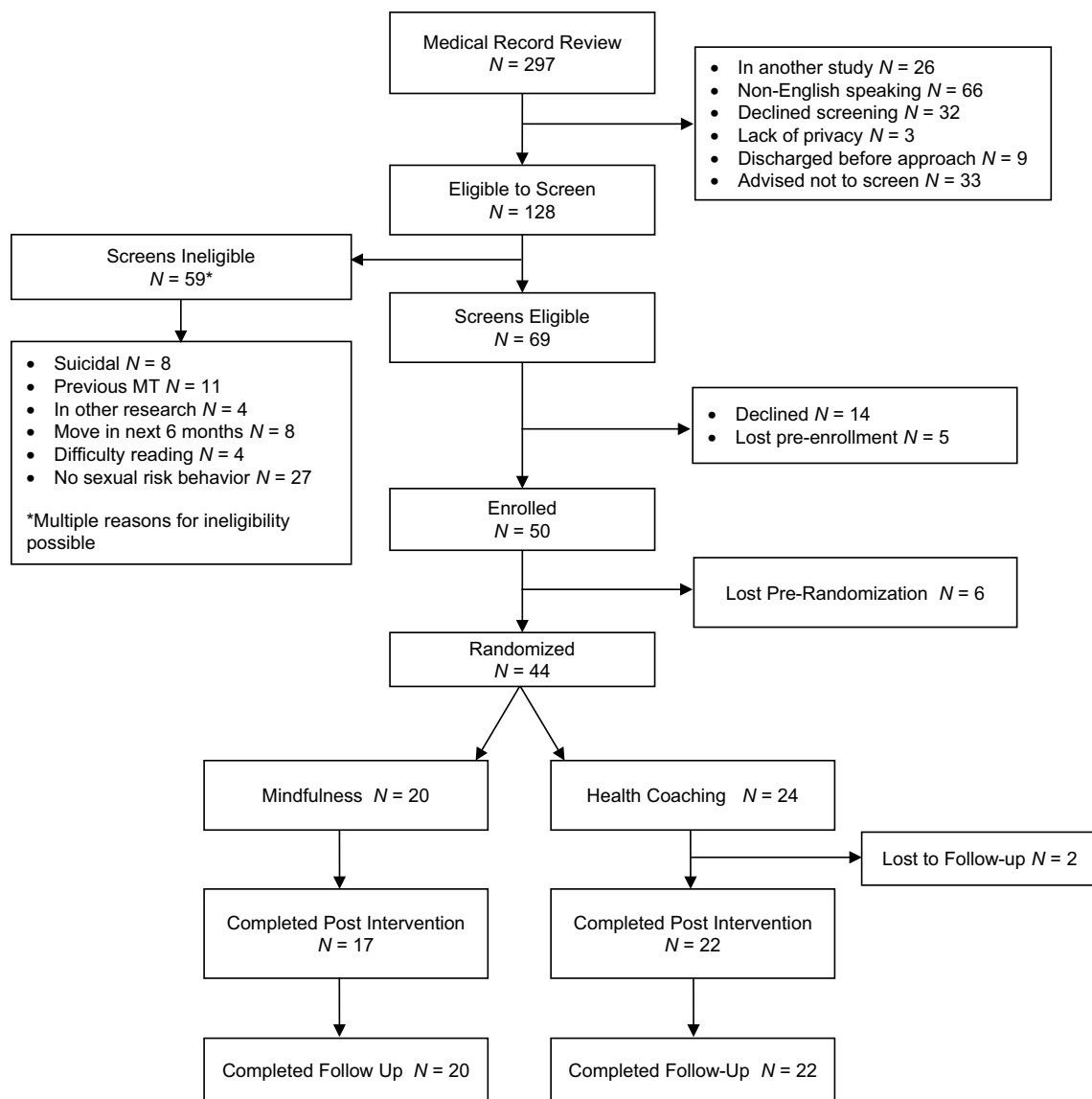


Fig. 1 Consort diagram

and rescheduling occurred “seamlessly.” Patients reported that the health-related information was helpful, while others reported that the intervention was “lengthy” and would have preferred a shorter program.

Some patients reported concerns related to confidentiality and privacy. One patient reported difficulties engaging in the study calls due to fears about inadvertent disclosure of his HIV status. Another patient noted that pill counts were challenging because the patient removed labels from pill bottles to prevent others from identifying the medications. Some patients also thought that the pill count calls were part of the study intervention.

Acceptability

As seen in Table 3, ratings for both interventions exceeded the a priori standard for acceptability (i.e., $\geq 80\%$ of patients reporting positive satisfaction ratings). Thus, we concluded that both interventions were acceptable to patients.

However, greater satisfaction was reported by patients who received HC. Relative to patients who received MT, patients who received HC were more likely to rate the quality of their experience as excellent (HC = 86%, MT = 53%; $p < .05$). Though not statistically significant, HC patients were more likely to report they would definitely recommend the intervention to a friend (HC = 77%, MT = 59%), and to report being very satisfied with the amount of coaching

Table 2 Feasibility

	Health coaching <i>n</i> = 22	Mindfulness train- ing <i>n</i> = 20	χ^2/t	<i>p</i>
Number of sessions attended (count)			11.43	.178
0	1 (5%)	0 (0%)		
1	1 (5%)	5 (25%)		
2	0 (0%)	1 (5%)		
3	1 (5%)	3 (15%)		
4	2 (9%)	1 (5%)		
5	5 (23%)	0 (0%)		
6	2 (9%)	2 (10%)		
7	5 (23%)	5 (25%)		
8	5 (23%)	3 (15%)		
Number of sessions attended (mean)	5.65	4.55	1.39	.174
Proportion completing $\geq 50\%$ of sessions	86%	55%	5.05	.025
Number of sessions rescheduled (count)			10.00	.189
0	2 (9%)	2 (10%)		
1	0 (0%)	1 (5%)		
2	2 (9%)	4 (20%)		
3	2 (9%)	6 (30%)		
4	6 (27%)	2 (10%)		
5	2 (9%)	4 (20%)		
6	5 (23%)	1 (5%)		
7	1 (5%)	0 (0%)		
8	0 (0%)	0 (0%)		
Number of sessions rescheduled (mean)	4.05	3.05	1.74	.090
Proportion of sessions rescheduled	51%	52%	-0.19	.885

received (HC = 82%, MT = 53%) and their assigned intervention overall (HC = 64%, MT = 47%).

Qualitative data Patients found our recruitment methods (i.e., in-person, by telephone and mail outreach) acceptable; their experiences with MT were varied. Although some patients reported initial hesitation regarding MT, many found themselves coming to enjoy it and to engage in daily practice; for example, one patient stated: “this is something I didn’t expect in the beginning but I am so glad I was able to take part in this study [and learn mindfulness] because it has helped me on so many levels.” Participants reported positive experiences with mindfulness and their instructors, reporting “I am more relaxed, more focused, I find myself going back to [name of instructor]...I find myself going back in and doing the things that [instructor] taught me to do... the sitting still, paying attention to your body, just sitting still and listening.” In contrast, one patient reported discomfort sitting in silence and focusing attention.

Reports about HC were more consistently positive. Several patients described the program as “pretty amazing” and appreciated the positive interactions with health coaches. One participant noted “I loved it. I think it helped me tremendously to take care, better care of myself. I would recommend it, and I would enjoy to continue to have it. Definitely

a good experience.” Patients thought the study was about overall health related to living with HIV. For example, a HC participant described the study as “helping us to keep it together. I mean, because a lot of the time we don’t think about those things because we are stuck on ‘when am I going to die?’ And you can’t do that, you have to think about life!”

Adherence

Self-report Patients reported modest declines in the number of “missed days” from baseline through follow-up (Table 4). The number of days in which patients missed at least one medication dose decreased in the MT group (baseline = 4.2, post-intervention = 3.4, follow-up = 2.7) and in the HC group [Means (*Ms*) = 1.9, 1.6, 1.5]. We did not observe a time-by-condition interaction for self-reported medication adherence, $F(2, 80) = 0.21, p = .809$.

Unannounced pill counts Unadjusted average adherence scores at each measurement point are presented in Table 4. To ease interpretation, we averaged data from the two intervention phase intervals to create a single adherence measure during intervention; similarly, we averaged data from the follow-up intervals. The unadjusted average adherence composite scores at baseline, during

Table 3 Acceptability

	Health coaching <i>n</i> = 22	Mindfulness training <i>n</i> = 20	χ^2	<i>p</i>
Quality of intervention			5.35	.069
Fair	1 (5%)	2 (12%)		
Good	2 (9%)	6 (35%)		
Excellent	19 (86%)	9 (53%)		
Received kind of coaching wanted			1.54	.464
No, not really	1 (5%)	0 (0%)		
Yes, generally	7 (32%)	8 (47%)		
Yes, definitely	14 (64%)	9 (53%)		
Recommend coaching to a friend			3.04	.218
No, definitely not	1 (5%)	0 (0%)		
Yes, I think so	4 (18%)	7 (41%)		
Yes, definitely	17 (77%)	10 (59%)		
Satisfaction with amount of coaching			5.73	.057
Very dissatisfied	1 (5%)	0 (0%)		
Mostly satisfied	3 (14%)	8 (47%)		
Very satisfied	18 (82%)	9 (53%)		
Coaching received helped improve health			1.54	.464
Yes, helped a great deal	14 (64%)	9 (53%)		
Yes, helped a little	7 (32%)	8 (47%)		
No, didn't help	1 (5%)	0 (0%)		
Satisfaction overall			2.37	.500
Very satisfied	14 (64%)	8 (47%)		
Mostly satisfied	5 (23%)	7 (41%)		
Indifferent or mildly dissatisfied	1 (5%)	0 (0%)		
Quite dissatisfied	2 (9%)	2 (12%)		

intervention, and during follow-up are presented by group in Fig. 2. Average adherence for the HC group ranged from 81% at baseline to 76% during the intervention and 80% at follow-up; for the MT group, adherence ranged from 85% at baseline to 74% during the intervention and 82% post-intervention. Mixed effects models indicated that the two groups did not differ on adherence during either the intervention ($b = -.05$, $SE = .07$, $p = .49$) or follow-up ($b = -.03$, $SE = .05$, $p = .57$).

Viral load Patients in both the MT and HC groups showed improvements in viral load data. With viral suppression operationalized as < 500 copies/mL, there was a time-by-condition trend from baseline to post-intervention, $F(1, 35) = 4.07$, $p = .051$, such that the proportion of MT patients who were suppressed increased (from 67% to 77%) while it decreased in the HC group (from 91% to 81%). This trend was not sustained, as proportions suppressed at 3-month follow-up (MT = 70%, HC = 95%) regressed toward baseline levels for both conditions.

Sexual Risk Behavior

Patients in the MT condition reported a higher proportion of *condom protected events* ($M_s = 57%$, 100%, and 71%) relative to patients in the HC condition ($M_s = 32%$, 49%, and 43%). Assumption of sphericity was violated ($p = .015$) and the group-by-time interaction was non-significant, Greenhouse–Geisser $F(2, 22) = 0.89$, $p = .387$.

The occurrence of *new STIs* was rare; therefore, we combined STIs identified with laboratory testing with STIs reported in the medical chart. Overall, the proportion of STIs at follow-up was 9.1% in HC, and 5% in MT ($p = .607$).

Hypothesized Mediators

We observed a consistent pattern of improvement in both conditions over time. Reductions were observed in *anxiety* (HC = 7.5, 5.0, 4.5; MT = 9.3, 7.9, 7.2), *depression* (HC = 8.6, 5.7, 5.2; MT = 9.8, 8.8, 6.9), *perceived stress* (HC = 5.9, 5.6, 5.7; MT = 6.9, 6.1, 5.8), and *impulsivity* (HC = 17.5, 15.6, 16.5; MT = 18.2, 17.8, 16.1). While group-by-time interactions were not significant, there was a significant within-subjects effect of time for anxiety, $F(2,$

Table 4 Unadjusted outcome measures by condition over time

	Health coaching <i>n</i> = 22	Mindfulness training <i>n</i> = 20	Condi- tion × time interaction	
			<i>F</i>	<i>p</i>
<i>Medication adherence</i>				
Pill counts (% adherent)			0.09	.963
Baseline	81% (27%)	80% (19%)		
During Intervention 1	79% (30%)	76% (31%)		
During Intervention 2	79% (21%)	68% (32%)		
Follow-up 1	76% (26%)	74% (31%)		
Follow-up 2	82% (21%)	85% (19%)		
Follow-up 3	84% (22%)	85% (19%)		
Self-report (number of days missed dose of ART)			0.21	.809
Baseline	1.95 (3.15)	4.20 (7.02)		
Post-intervention	1.64 (3.30)	3.41 (6.57)		
Follow-up	1.45 (1.99)	2.70 (3.53)		
Virally suppressed (< 500 copies/mL)			2.87	.063
Baseline	20 (91%)	12 (67%)		
Post-intervention	17 (81%)	13 (77%)		
Follow-up	19 (95%)	14 (70%)		
<i>Sexual risk behavior</i>				
Sexual events, count ^a (SD)			0.23	.762
Baseline	13.40 (18.88)	20.45 (30.87)		
Post-intervention	11.17 (16.80)	21.25 (21.12)		
Follow-up	10.83 (20.50)	29.00 (35.60)		
Sexual events, % protected			0.89	.387
Baseline	32% (44%)	57% (44%)		
Post-intervention	49% (71%)	100% (236%)		
Follow-up	43% (48%)	71% (49%)		
<i>Medical data</i>				
Sexually transmitted infections, number			0.21	.648
Baseline	3 (14%)	0 (0%)		
Follow-up	3 (14%)	1 (5%)		
New infections (incidence)	2 (9.1%)	1 (5%)		
<i>Mediators</i>				
Anxiety (GAD) (0–21)	7.50 (6.20)	9.25 (5.87)	0.29	.753
Baseline				
Post-intervention	5.00 (4.58)	7.88 (6.15)		
Follow-up	4.45 (4.22)	7.20 (5.33)		
Depression (PHQ9) (0–27)			0.27	.767
Baseline	8.55 (5.54)	9.80 (6.58)		
Post-intervention	5.68 (4.82)	8.82 (6.66)		
Follow-up	5.18 (3.72)	6.90 (5.23)		
Perceived stress (PSS) (0–16)			0.42	.661
Baseline	5.86 (3.01)	6.90 (4.09)		
Post-intervention	5.64 (2.75)	6.06 (3.58)		
Follow-up	5.73 (3.28)	5.80 (3.71)		
Mindfulness (FFMQ) (15–75)			1.19	.312
Baseline	49.09 (8.09)	47.70 (7.09)		
Post-intervention	52.73 (8.98)	53.06 (10.32)		
Follow-up	52.18 (7.84)	53.05 (7.49)		

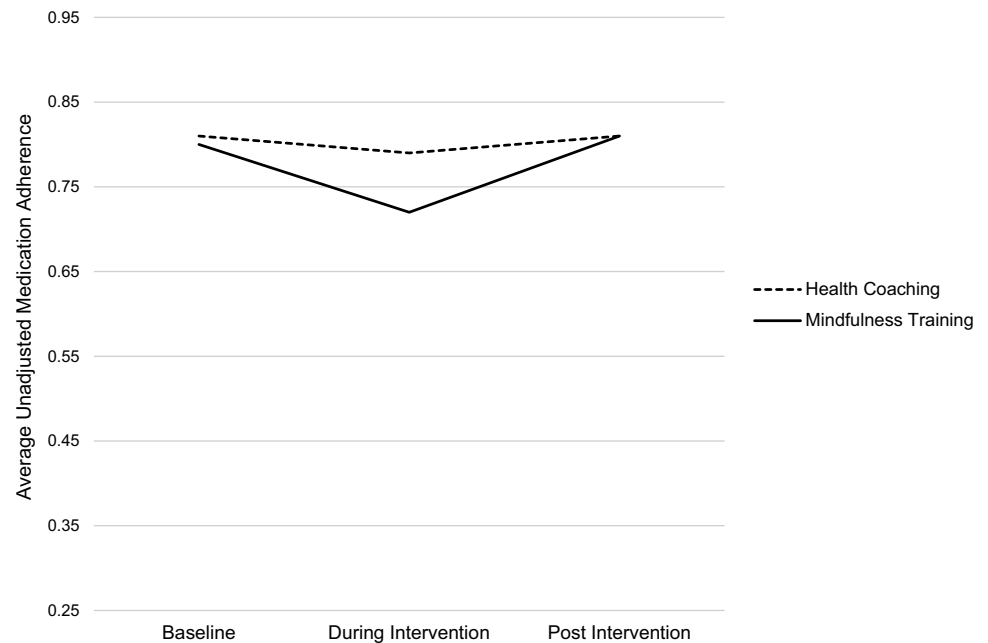
Table 4 (continued)

	Health coaching <i>n</i> = 22	Mindfulness training <i>n</i> = 20	Condi- tion × time interaction	
			<i>F</i>	<i>p</i>
Impulsivity (BIS) (8–32)			2.45	.093
Baseline	17.50 (4.36)	18.15 (3.76)		
Post-intervention	15.68 (3.40)	17.76 (4.31)		
Follow-up	16.50 (4.42)	16.05 (4.07)		

n (%) for categorical variables, Mean (SD) for continuous variables. For outcomes for which the unit is %, standard deviations are also %. Confidence intervals in these cases can surpass 100%, however, this is a function of the formula for standard deviation and should be viewed as inclusive of 100%

^aSexual events were operationalized to include all penetrative sexual acts (i.e., oral, anal and vaginal sex)

Fig. 2 Medication adherence by group at baseline, during the intervention, and during the post-intervention interval



74) = 4.59, *p* = .021, depression, *F* (2, 74) = 6.13, *p* = .003, and impulsivity *F* (2, 74) = 4.90, *p* = .010. Mindfulness scores improved in both conditions over time (HC = 49.1, 52.7, and 52.2; MT = 47.7, 53.1, and 53.1). Similarly, while the group-by-time interaction was non-significant, a significant within-subjects effect for time was observed, *F* (2, 74) = 11.06, *p* < .001.

Qualitative data The data obtained during interviews corroborated quantitative changes. Patients in both groups reported improvements in medication adherence. Patients correctly inferred that a purpose of the study was to improve adherence. As an example, when asked what the study was about, one patient responded: “I think it was to help get me on track with my HIV meds.” A second patient responded: “This study was about how ... to be able to continue to take my medication, not to lose a time or to lose a date. The study

was about if I continue to take my medication I would be healthy enough.”

Several patients also thought that the unannounced pill count calls were a part of the intervention and credited the calls with helping to improve adherence. “[The pill counts] influenced me because, first of all, I was feeling sickly, or whatever. I just wasn’t, I wasn’t feeling right. So, when she used to call me, she used to do the pill count [and] I wasn’t taking them. Like some bottles had more [pills] than others, I was like, ‘this didn’t add up’ or whatever. So I started putting it in my weekly pill box, and that reminded me to take them every day!... I put them in a spot where I could see them every day, so when she called [instead of] ‘oh my God, I can’t find them;’ they would be right there. And I see the pills, so I, that made me take them. Yeah, she really, that really helped.”

A second patient offered: “[The pill count caller] helped too, with trying to keep me on track with those pills.” And a third stated: “I found [the pill count calls] very much helpful. It’s actually helped me stay on track with taking my medication every day. So that to me was awesome.”

With respect to the psychological effects of the interventions, patients described changes associated with MT: “As time went on and we had more appointments, and we went over it again, there were things that I was doing that I didn’t realize I was doing. You know. I was controlling my breathing. I was moving a lot of my feeling and my sensations from my nose down to my fingertips and down to my toes and back up to my chest. And breathing in calmly and doing things I never, you know, took the time to pay attention to before.”

Participants in MT also noted positive changes in their daily life, such as: “I am more mindful of everything that’s happening. I pay more attention to what’s going on I guess. I didn’t think I didn’t pay that much attention, but before I talked to [mindfulness instructor] to what I do now is like two different animals!”

Participants in the HC also reported making changes in their life, such as, “I am trying to take care of myself better, because this whole study gave me insight. On my pills, my doctors, and my eating habits. I’m not completely excellent at it, but I’m making progress.”

Discussion

To our knowledge, this study is the first to explore telephone-delivery of MT to improve medication adherence and reduce sexual risk behavior among PLWH. The results document a complex pattern regarding the feasibility and acceptability of telephone-delivered MT for PLWH. With respect to feasibility, 55% of those assigned to MT group completed at least half of their scheduled sessions. This completion rate was lower than expected, based on what has been observed during in-person MT with PLWH (e.g., 75% in prior studies [25, 54]), and lower than the rate we observed for the health coaching condition (i.e., 86%). Most commonly, patients missed sessions due to life stress, similar to findings from a study that was conducted in a resource-constrained environment [24]. Most patients reported that they liked telephone-delivery but one patient voiced a preference for face-to-face training; importantly, no patient reported concerns about their instructor or any adverse experience.

To fully benefit from MT, trainees need to invest a considerable amount of time and personal effort [22]. They also need a quiet space for formal mindfulness practice. Several patients described busy schedules and chaotic home environments that did not permit them to take telephone calls or practice mindfulness regularly. Patients with the most

stressful life circumstances—those who might have the most to gain from MT—also find it most difficult to create the conditions needed for receiving telephone calls and engaging in regular practice. It is common for people learning to practice mindfulness to initially report they sometimes find the practice challenging or difficult to fit into busy schedules [55]. These “start-up” challenges can undermine a person’s willingness and ability to persevere with the practice, especially in the early stages of training. It is likely that such challenges are even greater given the background life circumstances of many PLWH.

Given the challenges that some participants described, research might consider ways to further adapt MT to the life circumstances of PLWH. One possibility might be to employ a hybrid approach that blends in-person training with telephone sessions. For example, it might be useful to schedule one or more initial in person sessions to establish a therapeutic relationship in person, correct potential misunderstandings, provide tailored instructions, address patient concerns, and plan for home-based practice. The concepts and skills associated with MT can seem foreign and certainly novel, and more time and orientation to key concepts may be necessary. Once a patient is comfortable with their instructor and more familiar with the concepts and practice of mindfulness, subsequent sessions could be completed by telephone to minimize transportation and other external barriers. Previous research provides a useful precedent [24]. In that study, the lack of private space (in an impoverished, endemic HIV setting) led to a key adaptation of the intervention, namely, a greater focus on informal practice and mindfulness of daily life activities.

Despite these implementation challenges, patients reported liking and benefiting from MT. (Only one patient mentioned a dislike of MT; this participant found the silence uncomfortable). Indeed, as displayed in Table 3, most patients rated the intervention and the instructors positively, found MT helpful, and continued to use the study recordings. Interestingly, when interviewed at follow-up, even those patients who attended fewer than 50% of the sessions reported that they continued to use the MT recordings.

Overall, the feasibility and acceptability data suggest that attending MT sessions, even by telephone, and practicing mindfulness was challenging for some patients but that most of them generally liked the experience and found it acceptable. For those PLWH who can create the conditions needed for practice and tolerate start-up challenges, MT offers a promising self-care and stress management approach.

A secondary goal of this exploratory study was to explore the effects of MT on medication adherence and sexual risk behaviors. With respect to medication adherence, patients in both conditions reported fewer missed days of medication taking from baseline through the follow-up period. These self-reports were partially corroborated by the unannounced

pill count assessments and improvements in viral suppression. Plotted data from the unannounced pill count calls (Fig. 2) showed a U-shaped curve reflective of reduced medication adherence during the intervention phase of the study for both groups. Viral suppression also declined during the intervention phase for the HC group. Both groups showed improvement from the intervention phase to the follow-up phase. We have no compelling explanation for the decline in adherence during the intervention phase and hypothesize that this result is likely spurious. Additional research is needed with larger samples to further investigate the effects of MT on medication adherence.

With respect to sexual risk behavior, patients who received MT increased the proportion of times they used condoms relative to patients in the HC condition (71% vs. 43%) but the observed effects were not statistically significant. The incidence of new infections was also lower in the MT group (5.0%) compared to the HC group (9.1%). We hasten to add that the groups did not differ significantly (likely due to the small sample size) but note that the sexual risk reduction results were in the expected direction.

A tertiary goal of this study was to assess the effects of MT on the hypothesized psychological antecedents (mediators) of behavioral change. The effects of MT were consistently in the predicted direction. Thus, patients in the MT group reported fewer symptoms of depression and anxiety as well as lower perceived stress and impulsivity. Mindfulness levels also increased post-intervention. That said, there were no between-group differences in these effects. These results are consistent with those of a recent trial of mindfulness-based stress reduction for PLWH that showed no differences between MBSR and a self-management skills control condition on depression, perceived stress, and mindfulness; [54] significant effects were seen only for positive affect. Similar findings were reported in a meta-analysis showing low or insufficient evidence that meditation programs are more effective than active comparison conditions (e.g., exercise, progressive muscle relaxation, cognitive-behavioral therapy, and others) [24]. In regard to the lack of group differences in self-reported mindfulness, which increased in both conditions, prior research has shown no between-group effects on self-reported mindfulness for randomized controlled trials using an active control condition [56]. Such results are often explained by concerns about the validity and usefulness of extant mindfulness questionnaires; these concerns point to the need for more valid and objective assessments of mindfulness skills [57].

Comparisons of the MT and the HC groups are clearly preliminary given the early stage of this research and the small sample size recruited for this study. With respect to future research, we note that the use of a potent comparison condition can make finding an effect more difficult. We used health coaching as a time- and attention-matched control

group. Health coaching is an increasingly popular intervention approach [58, 59] with mounting empirical support. We identified topics for HC from our formative research [28], developed a training manual, and delivered the intervention with fidelity using highly trained clinical psychology trainees. Even though the health coaching protocol prohibited discussion of mental health issues (including mindfulness), and fidelity checks and supervision confirmed that the health coaches followed the protocols, it is possible that the psychology trainees who served as health coaches enacted health coaching differently than a less well-trained health coach might have. It is also possible that discussion of health topics did, indirectly, improve mindfulness.

Overall, health coaching performed well with respect to its feasibility and acceptability. Patients in the HC condition responded well to the telephone-delivered intervention. This was not surprising, as the content for the coaching was developed using focus groups of PLWH to ensure that this condition would be meaningful for patients. Patients in HC described the program as helpful and reported continued use of the coaching tips, including healthy eating and sun safety behavior. A potential explanation for the greater call completion and favorability of HC is that the health behavior topics are more relatable and immediately useful to PLWH, and the sessions and practice required less “work” compared to learning a new skill (as required with the MT). Future research on health coaching as an active intervention is warranted.

There are several alternative explanations for the muted effects observed in this exploratory study. First, with respect to between-groups effects, we used a small sample of PLWH with limited statistical power. Second, the dose and duration of the MT may have been inadequate. Third, finding an effect in a research study can be challenging due to “assessment reactivity.” Consistent with this possibility, some patients stated during follow-up interviews that the unannounced pill counts helped them to remain adherent; these patients thought the pill count calls were part of the intervention. Assessment reactivity can make it difficult to isolate the effects of an intervention from efforts to measure those effects.

The current study used telephone-delivery to mitigate the potential barriers of attending in-person interventions (e.g., unstable housing, lack of access to reliable transportation, inflexible family and work responsibilities). Prior studies have demonstrated feasibility of this intervention modality with other chronic health populations (e.g., cardiac patients [30]). The results of this study corroborate prior work and confirm our expectation that this modality would be feasible and acceptable. Although one patient expressed a preference for in-person MT sessions, most patients appreciated the convenience of attending by telephone. Several patients expressed an interest in meeting their instructor or coach, as

they had developed appreciation for and attachment to their interventionist.

The results of this study should be interpreted with its strengths and limitations in mind. Strengths of the study include preliminary formative research with the patient population; use of a controlled design; the structural equivalence of the comparison condition; use of written assessment and intervention protocols; blinding of assessors and interventionists to the study hypotheses; delivery of the theoretically-guided interventions with fidelity by skilled and experienced interventionists; use of a comprehensive, reliable, and valid evaluation system (with self-report, objective, and biological outcomes); and use of mixed methods including qualitative as well as quantitative assessments.

Several limitations should also be acknowledged. First, this was an exploratory study with a small sample size; thus, the study was not powered to detect group differences or examine mediation effects. A larger, randomized controlled trial examining efficacy of telephone-delivered MT is needed. Second, the findings are limited in generalizability by the study inclusion criteria and use of a single recruitment site. Third, with respect to medication non-adherence, we allowed patients with relatively mild levels of non-adherence (i.e., viral load of > 20 copies/mL) to participate in the trial. This decision likely made it more difficult to observe improvement on this outcome (i.e., a “floor” effect). Fourth, some of the outcomes and all of the mediators relied upon self-report. Such measures can be influenced by both social demand (e.g., the desire to please the assessor and investigators) and cognitive limitations (e.g., memory constraints). To minimize these potential biases, we used computerized assessments, assessors who were blinded to study hypotheses, assessments of shorter intervals, and multimodal assessments (i.e., supplementing self-report with objective measures and biomarkers); nonetheless, the limitations of self-report must be acknowledged.

In summary, this study shows that telephone-based mindfulness training is feasible and acceptable to many PLWH. For some PLWH, MT may require adaptation to optimize its acceptability. Providers in HIV healthcare settings should take this into consideration when recommending mindfulness training to patients. Future research might examine patient characteristics associated with acceptability of MT for PLWH so that interventions can be targeted appropriately and adapted as needed. The study results also suggest that telephone-delivered health coaching is feasible and acceptable as an alternative intervention. For both MT and health coaching, telephone delivery can overcome some of the barriers to participating in psychosocial interventions and should be explored further for PLWH.

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Compliance with Ethical Standards

Conflict of interest All the authors declare that they have no conflict of interest.

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