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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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 postive 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 >1600 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 literacy 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, randomized 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.

2.7.1. 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 min 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 ≥2 years teaching experience. Instructors will receive 3 h of training with respect to phone delivery protocol, fidelity checks, and reporting.

2.7.2. 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...
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