One Method for Objective Adherence Measurement in Mind–Body Medicine

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Abstract

Objectives: Home practice is frequently prescribed as part of mind–body medicine interventions, although rarely objectively measured. This brief methods report describes one method for objectively measuring home practice adherence using a custom monitoring software program.

Design: Methods for objectively measuring adherence were developed as part of a randomized controlled trial on the mechanisms of mindfulness meditation.

Settings/location: The study was conducted at Oregon Health & Science University, Portland, Oregon.

Subjects: The subjects comprised 11 combat veterans with post-traumatic stress disorder.

Interventions: The method used was mindfulness meditation.

Outcome measures: There were subjective and objective adherence measurements of mindfulness meditation home practice.

Results: The first iteration of objective adherence monitoring used an iPod device and had limitations in participant usage and correctly capturing data. In the second iteration, objective data were easily collected, uploaded, and viewed using the custom software application, iMINDr. Participants reported that iMINDr was straightforward to use, and they returned the monitoring units as directed.

Conclusions: The iMINDr is an example of a simple objective adherence measurement system that may help mind–body researchers examine how home practice adherence may affect outcomes in future clinical trials.

Introduction

ADHERENCE ASSESSMENT IS GAINING attention reflected in the recent release of Request for Information (NOT-OD-10-078) by the National Institutes of Health, which calls for information to assess the critical gaps in the science of adherence at the level of basic mechanisms, measurement, methodology, and/or intervention. Adherence data are important because they elucidate the extent to which adhering to an intervention influences the outcomes of interest. Drug trials regularly use Medication Event Monitoring System and pill counts as objective adherence measures. No such standards exist in mind–body medicine research.

In mind–body medicine, there are two intervention aspects that can be measured for adherence: class/instruction and home practice. Instruction adherence can be easily collected through attendance records; however, these are rarely reported. For example, a recent meta-analysis examined the relationship between the number of class hours and effect size for physiologic distress measures.¹ The researchers could only include assigned class hours rather than actual

participant attendance due to lack of attendance reporting in the studies assessed.

Home practice refers to the time the participant spends doing the intervention at home in a self-directed manner. Adherence to home practice is usually assessed through self-report. Although this is an improvement from not measuring home practice adherence at all, it has limitations. First, the self-report adherence data are rarely reported.^{2–4} Second, self-report diaries are easily altered by the patient as is well known in medication trials.⁵ Results based on self-report home practice logs must be interpreted with caution because there are no objective measures validating their accuracy.^{1,4,6,7} Not assessing objective adherence is an important problem because any results from an intervention that includes home practice will have an element of uncertainty due to the unknown parameter of how much the subjects practiced at home.

To date, no reported mind–body clinical trial has used objective methods to measure home practice adherence. The next step in mind–body medicine research is to explore various methods to objectively assess adherence. The goal of

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this brief report is to describe one such method being used in a mind-body clinical trial and may be replicated elsewhere.

Materials and Methods

An objective adherence measurement program was developed for a randomized control trial examining the mechanisms of mindfulness in combat veterans with post-traumatic stress disorder. Participants were randomized to one of four groups: mindfulness meditation, slow breathing, mindfulness meditation and slow breathing, and a book on tape. Participants had one in-lab training visit per week for 6 weeks and were asked to practice at home for 20 minutes per day. The meditation groups were asked to practice their meditation, either a mindful body scan meditation or a mindful slow breathing meditation that was guided by listening to an audio recording. This report will focus on the objective adherence collection method developed for the home practice of the two meditation groups.

As a first iteration, an iPod Nano (iPod) (Apple Inc., Cupertino, CA) music listening device was used to collect home practice adherence data. The iPod had seven copies of the same meditation track on the unit, one for each day of the week. Participants were given verbal instructions and a graphical written brochure that guided them to choose the track named for the weekday they were practicing. At each visit, play count, last played date, and last played time were collected when the device was connected to the lab computer. Each participant practiced using the iPod in the lab before leaving to ensure they knew how to use it. Participants were asked to use the device any time they practiced their meditation. Seven (7) participants had their home practice tracked with the iPod system. Limitations were encountered with this method: (1) after ensuring proper usage in the lab, the participants were still unable to play the appropriate track each day; (2) the iPod only recorded the beginning time the track was last played (i.e., if they played each track more than once, the data were lost); and (3) sometimes the participant would

not turn off the iPod after use and it would continue playing the track repeatedly, resulting in excessive play counts. Our observations with the iPod highlight the need to ensure that the objective measurement system is actually tracking what the investigators have intended.

Due to these limitations, iMINDr, a custom software application, was developed for use with an iPod Touch (iTouch) (Apple, Inc.) to more accurately track home practice adherence. Again, participants were asked to use the device any time they practiced their meditation. Before each participant started their training visits, the research assistant set up the iTouch with a study ID and participant ID. Participants were trained on the device in person with verbal and graphical instruction. An iMINDr icon appeared when the device was turned on. After the icon was pressed, a window opened where the participant could adjust the volume, press "play" to initiate the 20-minute track, and press "pause" if needed. The iMINDr application solved many of the issues seen in the iPod by collecting all actions performed (date, time, action [start, stop, pause, volume change]). At each training visit, the data were uploaded to a server. The server stored the data and exported it to a Microsoft Excel file that contained raw data, daily summary statistics, and study summary statistics for each participant.

Conclusions

Four (4) participants have used the iTouch iMINDr application to date (Fig. 1). Participants reported ease of use and returned the units as directed. Objective data were collected, uploaded, and viewed through the application with no difficulty. Mean home practice time objectively reported was 528 ± 165 minutes out of 720 total possible over 6 weeks. Home practice time subjectively reported was 615 ± 93 minutes. Due to the small number of participants having yet completed their training on the iTouch, valid statistical tests were not possible. In conclusion, the iMINDr is an example of a simple objective adherence measurement system that may help mind-body researchers examine how home practice adherence may affect outcomes in future clinical trials.

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Disclosure Statement

No competing financial interests exist.

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FIG. 1. Subjective and objective adherence reporting. Mean home practice time objectively reported was 528 ± 165 minutes of 720 total possible over 6 weeks as collected with the iMINDr custom software application. Participants were given a Daily Practice Log each week upon which to record their practice date, time, and amount. Home practice time subjectively reported on these forms was 615 ± 93 minutes.

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