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Ecological momentary assessment versus standard assessment instruments for measuring mindfulness, depressed mood, and anxiety among older adults

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ABSTRACT

As mobile data capture tools for patient-reported outcomes proliferate in clinical research, a key dimension of measure performance is sensitivity to change. This study compared performance of patient-reported measures of mindfulness, depression, and anxiety symptoms using traditional paper-and-pencil forms versus real-time, ambulatory measurement of symptoms via ecological momentary assessment (EMA). Sixty-seven emotionally distressed older adults completed paper-and-pencil measures of mindfulness, depression, and anxiety along with two weeks of identical items reported during ambulatory monitoring via EMA before and after participation in a randomized trial of Mindfulness-Based Stress Reduction (MBSR) or a health education intervention. We calculated effect sizes for these measures across both measurement approaches and estimated the Number-Needed-to-Treat (NNT) in both measurement conditions. Study outcomes greatly differed depending on which measurement method was used. When EMA was used to measure clinical symptoms, older adults who participated in the MBSR intervention had significantly higher mindfulness and significantly lower depression and anxiety than participants in the health education intervention at post-treatment. However, these significant changes in symptoms were not found when outcomes were measured with paper-and-pencil measures. The NNT for mindfulness and depression measures administered through EMA were approximately 25–50% lower than NNTs derived from paper-and-pencil administration. Sensitivity to change in anxiety was similar across administration modes. In conclusion, EMA measures of depression and mindfulness substantially outperformed paper-and-pencil measures with the same items. The additional resources associated with EMA in clinical trials would seem to be offset by its greater sensitivity to detect change in key outcome variables.

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1. Introduction

Ecological momentary assessment (EMA) is a data capture technique that involves repeated sampling of thoughts, feelings, or behaviors as close in time to the experience as possible in the naturalistic environment (Shiffman et al., 2008). Among the purported advantages of EMA is the mitigation of biases inherent in retrospective self-reports, such as the concern that the participant's reporting of subjective experiences in the past may be influenced by their current state (Axelson et al., 2003; Ebner-Priemer and Trull, 2009; Granholm et al., 2008; Johnson et al., 2009; Moskowitz and Young, 2006; Shiffman et al., 2008; Trull and Ebner-Priemer, 2009). Among older adults, memory impairment and unfamiliarity with questionnaire formats may further limit the validity of assessment tools that require the participant to recall their experience over the past week or month (Lenze and Wetherell, 2009). Assessing symptoms such as depressed mood or anxiety, or psychological constructs such as mindfulness, with retrospective self-report measures is particularly problematic given their variability within and between days (Baer et al., 2009; Bishop et al., 2004; Lau et al.,

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2006; Orsillo, 2005; Starr and Davila, 2012). EMA queries about present moment experiences in *real time* multiple times throughout the day, which could create more stable estimates of phenomena that fluctuate over time compared to single time-point measurement. For some internal experiences, such as mindfulness, in-the-moment questions may better enable sampling of experiences without the retrospective judgments that are inherent in global self-reports.

With the emergence of smartphones, there is unprecedented capacity to obtain EMA data in naturalistic environments. Even with the 'digital divide' in older adults' comfort and experience with technology, on average, relative to younger adults, a number of studies support the feasibility and acceptability of EMA techniques assessing multiple patient-reported outcomes with older adults (Cain et al., 2009). However, although much cross-sectional data support the feasibility and construct validity of EMA relative to traditional paper-and-pencil patient-reported outcomes, little is known about the sensitivity of EMA-based measures to change in clinical trials. The great majority of prior studies employing EMA have been observational studies and have not employed EMA in the context of detecting the effect of interventions. A number of authors have suggested that EMA could provide a useful approach to gathering patient-reported outcome measures and better representing the patient's experience over time during treatment (Gwaltney et al., 2008). Measurement error known to be associated with traditional paper-and-pencil measures can result in low assay sensitivity and potentially smaller intervention effect sizes of clinical trials (Cain et al., 2009; Collins et al., 2003; Slater and Bick, 1994). However "head-to-head" comparisons addressing sensitivity to change with identical point-in-time paper-and-pencil measures have, to our knowledge, not been performed. There is non-trivial participant training, burden, and expense in implementing EMA, and so its use as an outcome measurement tool would need to be justified by evidence of increased reliability, validity, and sensitivity to change over traditional self-reports. The added challenges posed by EMA implementation may be more substantial in older adults, who may require more training and support in using EMA.

In this study, we examined the psychometric properties and sensitivity of EMA in contrast to paper-and-pencil measures among older adults who participated in a randomized controlled trial examining Mindfulness-Based Stress Reduction (MBSR) vs. a health education control group. Identical EMA and paper-and-pencil measures of depression, anxiety (derived from Patient Reported Outcome Management System [PROMIS] Short-Form), and mindfulness (derived from the CAMS-R; Feldman et al., 2007) were administered at baseline and post-treatment, affording us the opportunity to contrast the reliability, concordance, and ability to detect changes over the study period. This is the first study, to our knowledge, to examine sensitivity to change of EMA methods in contrast to paper-and-pencil measures, and among the first to measure sensitivity to change in mindfulness as assessed via EMA. Comparing these two assessment methods is important because ultimately mindfulness-based interventions needs to show efficacy for clinical outcomes if it is to be a treatment for late-life mental disorders; this requires reliable measurement of clinical outcomes (Bierman et al., 2005). We hypothesized that 1) EMA would be associated with greater internal consistency and item-total correlations than paper-and-pencil measures, 2) changes in EMA would be associated with larger effect sizes than paper-and-pencil measures.

2. Material and methods

2.1. Participants and design

This multisite study was conducted at Washington University in St. Louis and the University of California, San Diego, and was approved by both sites' institutional review boards. This study represents a secondary aim of a randomized clinical trial in which participants with anxiety or depressive disorders and subjective cognitive complaints were randomized to either participate in MBSR or health education. Therefore, the study was statistically powered to detect change in anxious and depressive symptoms and to compare these two assessment methods and cross-validate these data with the same outcome measures collected by in-person raters. The primary aim of the clinical trial was to assess change in memory and executive functions. Expanded details of the two treatment conditions and the primary aim outcomes are described in a separate paper (Wetherell et al., 2016, under revision). Details about the patient-reported measures or EMA protocol have not been previously published.

All participants volunteered and provided written, informed consent. One hundred and three adults aged 65 years or older with clinically significantly anxiety-related distress and self-reported cognitive dysfunction were enrolled in the trial (Washington University: $n = 52$; UCSD: $n = 51$). The EMA program was still under development at the start of the trial, and this led to us being unable to capture EMA data on the first 10 participants. Given the focus on sensitivity to change, 21 participants were dropped because they completed less than 10 EMA surveys at baseline and an additional 5 were dropped due to insufficient EMA data a follow-up, resulting in a total of 67 participants included in this study.

Participants were excluded for: screening score <22 on the Penn State Worry Questionnaire-Abbreviated (PSWQ-A; Hopko et al., 2003); no self-reported cognitive dysfunction on screening question: "Have you noticed that you have any trouble with your memory or concentration?"; diagnosis of dementia based on known diagnosis or meeting criteria during screening exam (Katzman et al., 1983); lifetime diagnosis of psychotic or bipolar disorder; alcohol or substance use disorder within past six months; corticoid steroid use; current participation in psychotherapy, mediation practice, or yoga; unstable medical condition (e.g., congestive heart failure); or any condition or impairment likely to interfere with the ability to participate in MBSR.

2.2. Measures

2.2.1. Demographic characteristics

These included age, sex, years of formal education, race/ethnicity, and marital status.

2.2.2. EMA and paper-and-pencil clinical assessments

For depressive and anxiety symptoms, we used the National Institutes of Health (NIH) Patient Reported Outcomes Measurement Information System (PROMIS) adult depression and anxiety short form instruments (Bjorner et al., 2013). PROMIS derives from large item banks to measure patient-reported outcomes, and the psychometric properties of these item repositories have been rigorously tested (Cella et al., 2007; Reeve et al., 2007). The PROMIS short-form anxiety items focus on anxious apprehension (i.e., worry) and hyperarousal (i.e., tension, nervousness, and anxiousness). For the paper-and-pencil administration, we used the 7-item PROMIS anxiety scale. The PROMIS short-form depression items focus on negative mood (e.g., depressed, hopeless) and negative views of self (i.e., worthlessness, helplessness). For the paper-and-pencil administration, we used the 8-item PROMIS depression