Protocol for Mindfulness-based Mobile Application to Reduce Rumination in Adolescents

PI: Lori M. Hilt, PhD., Lawrence University
NCTNCT03900416
01/01/2019
Background

Adolescence is a vulnerable period for the development of psychopathology, with adolescents experiencing increases in symptoms of depression, certain types of anxiety, and self-injurious behavior. For example, in one epidemiological study, the lifetime prevalence of Major Depressive Disorder (MDD) was 1% up to age 11, but rose to 21% up to age 18 (Hankin et al., 1998). In another epidemiological study, rates of MDD and several anxiety disorders rose steadily over the teen years (Merikangas et al., 2010). Many more adolescents experience high levels of internalizing symptoms without meeting diagnostic criteria for a disorder, and these symptoms may develop into more severe mental health problems in adulthood (Kessler, Avenevoli, & Merikangas, 2001; Leadbeater, Thompson, & Gruppuso, 2012), underscoring the importance of prevention. Self-injurious behavior, in the form of nonsuicidal self-injury, is a prevalent phenomenon among adolescents (Muehlenkamp, Claes, Havertape, & Plener, 2012), and though less common, suicide is the second leading cause of death among adolescents (CDC, 2014). Thus, it is imperative to develop preventive interventions that address these mental health problems faced by adolescents. One way to approach these problems from a public health perspective is to target a transdiagnostic risk factor.

Rumination has been identified as a transdiagnostic risk factor involved in the development of several forms of psychopathology including depression, anxiety and self-injurious behavior (for reviews see Aldao, Nolen-Hoeksema, & Schweizer, 2010; Nolen-Hoeksema & Watkins, 2011; Nolen-Hoeksema, Wisco, & Lyubomirsky, 2008). Rumination involves repetitively focusing on one’s negative emotions and brooding about their meaning and consequences (Nolen-Hoeksema, 1991). A meta-analysis showed that rumination is associated with depressive symptoms, concurrently and prospectively among adolescents (Rood, Roelofs, Bogels, Nolen-Hoeksema, & Schouten, 2009), and rumination also prospectively predicts depression diagnosis among adolescents (Abela & Hankin, 2011). Studies have also found that rumination concurrently and prospectively predicts anxiety symptoms in adolescents (e.g., McLaughlin & Nolen-Hoeksema, 2011; Muris, Roelofs, Meesters, & Boomsma, 2004). Finally, rumination has emerged as an important risk factor for both nonsuicidal self-injury (e.g., Hilt, Cha, & Nolen-Hoeksema, 2008; Barrocas, Gilleta, Hankin, Prinstein, & Abela, 2015) and suicidal ideation (e.g., Miranda & Nolen-Hoeksema, 2007; Smith, Alloy, & Abramson, 2006). Given the involvement of rumination in the development of internalizing symptoms and self-injurious behavior, it is an important target for preventive interventions.

Mindfulness meditation is an intervention strategy that has shown promise in targeting rumination. It involves focusing attention on the present moment without judgement (Kabat-Zinn, 2003). Rumination typically involves a perseverative focus on past events (Nolen-Hoeksema et al., 2008), and mindfulness may help alleviate rumination through its focus on the present and emphasis on detaching from mental events, rather than becoming caught up in them as one does while ruminating (Ma & Teasdale, 2004). Trait (i.e., habitual) levels of mindfulness are negatively associated with trait levels of uncontrollable rumination (Raes & Williams, 2010), suggesting these strategies may be antithetical. Indeed, mindfulness meditation interventions have resulted in decreases in distress and negative affect, and decreased rumination appears to be a mediator of these effects (Chiesa & Serretti, 2009).

Mindfulness interventions that show decreases in trait rumination typically involve instruction and home practice over the course of several weeks. For example, an 8-week Mindfulness Based Stress Reduction (MBSR; Kabat-Zinn, 1982) course that involves meeting for two hours once per week along with daily home practice resulted in decreased trait rumination in multiple studies with adult participants (e.g., Deyo, Wison, Ong, & Koopman, 2009; Shapiro, Brown, & Biegel, 2007). Similarly, a month-long mindfulness intervention with distressed college students showed decreases in trait rumination that were not seen in the active control condition (Jain et al., 2007). Although promising, these intensive interventions have not been examined for their effects on rumination with
adolescents. Furthermore, it is unclear how much practice is required to produce reductions in trait rumination.

Recent work by the PI has shown that a brief mindfulness intervention can reduce state (i.e., momentary) rumination. In two laboratory studies, one with college students (Villa & Hilt, 2014) and one with younger adolescents (Hilt & Pollak, 2012), the PI and her colleagues showed that an 8-minute guided mindfulness exercise reduced state rumination relative to active control conditions. These studies highlight the benefit of even brief mindfulness interventions for adolescents, but they do not show whether occasional or regular use of brief mindfulness exercises would impact trait rumination and subsequent psychopathology.

Because state rumination is positively associated with trait rumination (Moberly & Watkins, 2008), we expect that regular use of brief mindfulness exercises will allow adolescents to repeatedly make state adjustments that will reinforce a behavioral cycle leading to reductions in trait rumination and psychopathology.

Overview

The primary objective of this study is to examine whether the mindfulness mobile application engages adolescents and reduces rumination and subsequent psychopathology. We hypothesized that adolescents in the mindfulness intervention condition would experience a reduction in symptoms of depression, anxiety, and self-injury relative to those in the control group and that this would be accounted for by a reduction in the tendency to ruminate. We test this by using a randomized, controlled design, comparing the intervention group to a control group that uses the same mobile application for EMA but does not receive the mindfulness exercises.

Aims of the study and significance

1. To determine whether this intervention may be acceptable and engaging to adolescents.

   Participants will report on their satisfaction with the app as well as be offered the opportunity to continue using it during a follow up period beyond the initial intervention period. Their use will be tracked electronically during the 12-week, follow-up period as an indicator of engagement. If the app engages adolescents, it has the potential to be utilized with a large public health impact.

2. To examine whether the intervention reduces state and/or trait rumination and whether this reduction accounts for a reduction in symptoms of psychopathology.

   Testing this putative mechanism is an important advancement that has yet to be examined. By comparing the intervention to a control condition, the proposed study will offer a more rigorous test of this research question than the previously completed small pilot studies. Additionally, we will use multiple informants of psychopathology symptoms at pre, post, and follow-up time points, strengthening our outcome measurement. We will also use multilevel modeling to test the effects of state changes in the proposed mechanism and outcomes on trait levels. If the app shows efficacy, it can be tested in a larger trial to determine whether it may be indicated as a wide-scale preventive intervention. If the app reduces rumination, a transdiagnostic risk factor, as hypothesized, it has the potential to prevent many deleterious mental health outcomes.

Mobile applications are needed to address the mental health needs of adolescents. The majority of youth who need treatment for mental health disorders such as depression do not receive it, due to barriers including perceived stigma and inclination toward self-reliance (Gulliver, Griffiths, & Christensen, 2010). Furthermore, the cost of mental health care and lack of available quality care, especially for racial and ethnic-minority individuals, make the
need for new and readily available modes of service, such as mobile mental health care
interventions, of tantamount importance (Kazdin & Blase, 2011). Although many mindfulness
mobile applications have been developed, almost none have been subject to rigorous
empirical investigation (Mani, Kavanaugh, Hider, & Stoyanov, 2015). One randomized,
controlled study using a self-selected group of adults showed promise, with those using a
mindfulness application 10 minutes per day for 10 days showing a modest reduction in
depressive symptoms (Howells, Ivtzan, & Eiroa-Orosa, 2016). The proposed study has the
potential to serve as a proof of concept that could help inform intervention researchers,
clinicians, parents, and educators about the effectiveness of mobile mindfulness exercises
for adolescents. This study also has the potential to inform the broader field of mobile mental
health. Many mobile mental health applications collect ecological momentary assessment
(EMA) data and subsequently recommend customized interventions. However, it is unclear
whether the effects are due to the specific mental health intervention, the EMA process or
both. By comparing the intervention to a control condition that receives EMA only, I will be
able to parse these effects while offering a strong test of Aim 1 (efficacy of the intervention).

In sum, the proposed study addresses the important need of transdiagnostic
preventive interventions. Risk for developing psychopathology increases during
adolescence, and successful preventive measures can reduce the lifetime burden of
psychopathology. For example, preventing a first episode of depression is of great import,
given the findings that a first episode results in scars that make future episodes more likely
(Rohde, Lewinsohn, & Seeley, 1994; Kendler, Thornton, & Gardner, 2000). The proposed
study targets rumination, a transdiagnostic risk factor, using a mindfulness intervention that
will be delivered in a format that has the potential for a large public health impact.
Furthermore, undergraduate students will be involved in all aspects of the research (i.e.,
recruitment, scheduling, data collection, analysis, interpretation and presentation), thereby
enhancing research training opportunities at the PI’s undergraduate-only institution.

Sample
We will recruit 150 adolescent girls and boys, ages 12-15. This age range was
chosen to capture the developmental period directly preceding increased rates of depression
(Hankin et al., 1998), providing an opportune window for prevention. Participants will be
recruited through a recruitment letter mailed to students enrolled in grades 7-10 at a large,
local, public school district with over 5000 students in our target age range. In order to
maximize the potential of targeting the proposed mechanism, we will only enroll adolescents
who report at least moderate baseline levels of trait rumination. This will be accomplished
through a 2-question phone screen. Once parents verbally consent and the child has
verbally assented, we will ask them to respond to two questions from the Children’s
Response Style Questionnaire (CRSQ; Abela, Brozina, & Haigh, 2002) that assess
brooding, a particularly maladaptive aspect of rumination (Treynor, Gozalez, & Nolen-
Hoeksema, 2003). The aggregate of these two questions are highly correlated with the full
rumination subscale from the CRSQ (r = .79, p < .01) and have been associated with
depressive symptoms and NSSI in previous work by the PI (Hilt et al., 2008). Adolescents
who meet the screening criteria (age 12-15, score of 2 or higher on the brooding questions,
and physically and cognitively able to use a mobile application) will be invited to participate
in the study. Once they provide written consent and assent, they will be randomly assigned
to a condition: EMA only or EMA + Mindfulness at a 1:1 ratio (i.e., ~ 75 participants per
condition).

Procedure
Participants and a parent or guardian will come to the laboratory to provide written
assent and consent, complete baseline questionnaires, and get the mobile application and
instructions. The lab visit will last approximately 40 minutes. We will put the application on
participants’ own mobile devices (android or iOS platform) if they have them and loan mobile
devices (android phones without calling services) to participants who do not have their own.
The active intervention period will last three weeks, during which time participants will be
asked to use the application at least three times per day. Undergraduate research assistants (RAs) masked to condition will monitor daily use via the database where responses are logged. Midway through each week of the active intervention period, RAs will send reminder messages for motivation and encouragement. A small bonus ($5 per week) will be offered to participants for protocol compliance (i.e., using the app 21 times that week). The weekly emails will let participants know whether they were on track to receive the bonus or encourage them to use the app more regularly. At the end of three weeks (i.e., post), participants will be notified to complete questionnaires online. At this time, participants still have the opportunity to use the mobile application, but they will not be reminded to use it so that we can monitor self-motivated use. All use will be monitored electronically through a database that tracks responses with time stamps. After six weeks, participants will again be notified to complete questionnaires online (follow-up 1). Finally, after an additional six weeks (approximately 3 months after post), participants will be notified to complete questionnaires online (follow-up 2) and return borrowed phones if applicable (via drop-off, pick up or mail). The total time that participants’ use is monitored will be 15 weeks (i.e., 3 weeks for the active intervention period and 12 weeks of follow up). See Figure 1 for depiction of timeline.

Figure 1. Overview of participant activities and compensation.

Questionnaires

At each time point (baseline, post, follow-up 1, follow-up 2), internalizing symptoms will be assessed using multiple informants (adolescent and parent). Additionally, adolescents will self-report on their self-injurious thoughts and behaviors, trait rumination, and trait mindfulness. Finally, parent-reported demographics will be obtained at baseline, and adolescent satisfaction with the application will be obtained at post. Questionnaires will take adolescents approximately 30 minutes to complete and less than 10 minutes for parents. Questionnaires will be completed online using Qualtrics (a survey software platform with secure data storage) except for the demographics form which will be completed on paper to avoid storing any identifying data on the server.

Internalizing symptoms. Depression will be assessed using the gold-standard, self-report Children’s Depression Inventory (CDI; Kovacs, 1992). This 27-item questionnaire assesses behavioral, cognitive, and physical symptoms of depression and has high reliability and validity (α=.88). Anxiety will be assessed using the Multidimensional Anxiety Scale for Children (MASC; March, Parker, Sullivan, Stallings, & Connors, 1997), a 39-item reliable and valid index of anxiety in youth (α=.88). It yields a total score along with subscales for physical symptoms of anxiety, harm avoidance, social anxiety, and separation anxiety. Parent-reported internalizing symptoms will be assessed using the 5-item, internalizing subscale from the Pediatric Symptom Checklist (PSC; Jellinek & Murphy, 1988), a widely-used 35-item measure of psychopathology in youth with sound psychometric properties. All of these questionnaires have shown change in response to interventions in previous research.
Self-injury. Thoughts and behaviors related to suicide and NSSI will be assessed with the self-report form of the Self-injurious Thoughts and Behavior Interview (SITBI; Nock, Homberg, Photos, & Michel, 2007), a highly reliable and valid assessment tool used with adolescents.

Rumination. Trait rumination will be assessed with the rumination subscale from the CRSQ (Abela, Brozina, & Haigh, 2002). This 13-item subscale has demonstrated good reliability and validity (α=.88).

Mindfulness. Trait mindfulness will be assessed with the modified Five Facet Mindfulness Questionnaire (FFMQ; Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006). This 39-item, self-report questionnaire measures five facets of mindfulness including: observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience. The factor structure and construct validity have been demonstrated, and it has high internal consistency (α=.80).

Demographics. Parents will report on child birth date, sex, race, ethnicity, family socioeconomic status (SES; i.e., occupation, income, family size), and living situation. Adolescents will also report on gender, race, and ethnicity.

Satisfaction. Adolescents will answer several questions about the mobile application regarding ease of use and acceptability.

Mobile Application and EMA
There are two versions of the mobile application, depending on the condition: EMA or EMA + Mindfulness. Participants will be randomized using a true randomization procedure (i.e., rolling die with even or odd number determining their condition). The first time they use the mobile application (i.e., during the lab visit), participants enter a unique identification number. Thus, all responses will be logged electronically based on the identification number. Participants are also prompted to enter their wake time and bed time. The application uses this information to time the three daily notifications. Adolescents will be told to respond as soon as possible after receiving a notification, but instructed not to use the phone if they were in a situation where it is not permitted. When accessing the application, adolescents will respond to 10 EMA questions assessing the following:

Time and place. Participants are asked whether they are thinking about the past, present, future; whether they are alone or with others and where they are located (e.g., school, home, other). These questions were adapted from a large EMA study (Killingsworth & Gilbert, 2010).

State rumination. Participants will respond to two questions regarding focus on emotions and focus on problems using a sliding scale from 0 to 100 for each. These questions were adapted from a previous EMA study on rumination (Moberly & Watkins, 2008) and have been used to assess state rumination in other work (e.g., Hilt & Pollak, 2012; Hilt, Sladek, Doane, & Stroud, 2017).

State mood. Using sliding scales ranging from 0 to 100, participants indicate how happy, sad, calm, and anxious they currently feel.

State mindfulness. Participants rate their degree of focusing on bodily sensation using a 0 to 100 scale.

Mindfulness Intervention
In the EMA + Mindfulness condition, participants have a 67% chance of receiving a mindfulness exercise, unless their sad or anxious mood rating is 90 or above, in which case their chance is 85%. This graded strategy was chosen so that participants would not be able to easily figure out the mood rating that results in an exercise and so that participants would have a greater chance of receiving an exercise when they most needed it.

If an exercise is assigned, participants are prompted to enter how much time they have to engage in an activity (from 0-15 minutes). There are three 1-minute exercises (written instructions for focusing on the breath, sounds, or physical sensations); six 3-5 minute exercises (guided audio focusing on breathing, sounds, or body scan); and five 10-12 minute exercises (guided audio focusing on breath, body scan, or mountain metaphor).
Participants who indicate having less than 5 minutes receive one of the 1-minute exercises, those who indicate having at least 5 minutes receive either a 1-minute or a 3-5 minute exercise, and those who indicate having at least 12 minutes receive any exercise. Exercises are randomly assigned based on these parameters. The guided audio exercises were chosen based on those freely available that represent the type of mindfulness exercises typically found in MBSR courses, appeared accessible for adolescents, featured a variety of voices, and performed well in pilot testing. Following each mindfulness exercise, participants were prompted with the same EMA questions plus an additional question asking how helpful the activity was, rated on a 0-100 sliding scale.

**Data Handling and Record Keeping**

All data (EMA, questionnaire) will be stored electronically and password protected using only an ID number (i.e., without identifying information). The PI will maintain a password protected document linking ID numbers to participant names. A paper copy of information that includes identifying information will be stored in a locked file cabinet in a locked room in a folder labeled with an ID number.

The PI will put several actions in place to assure quality of data collected in the study. The PI will oversee recruitment and enrollment and assure that enrollment targets are met. The PI will be in close contact with the research associate who managed recruitment and enrollment and updates will be monitored weekly. The PI will also oversee data collection and management to insure its validity and integrity. Only key project personnel will have access to the data. Any personnel doing data analysis will work with a copy of the data to avoid any changes being made to original data files. The PI will assure that the dissemination plan is followed. Finally, all project staff, including the PI will complete a Good Clinical Practice training course (e.g., https://gcp.nidatraining.org/).

**Assessment of Safety**

Questionnaires assessing self-injury (including suicidal thoughts and behaviors) will be collected from adolescents at four time points (baseline, post-intervention, and three follow-up periods). Participants who indicate suicidal ideation (by responding to an item on the Children’s Depression Inventory indicating that they want to kill themselves, i.e., scoring a 3 on item 9) or serious self-injurious behavior (by responding affirmatively to questions on the Self-Injurious Thoughts and Behaviors inventory indicating having a suicide plan or attempt in the past year/week/since the last assessment) will be contacted by the PI, a licensed clinical psychologist with extensive experience doing research and treatment for self-injury. The PI will assess risk by talking with the participant and determine whether contact with a mental health professional is warranted. If necessary, the PI will talk with the adolescent's parent to determine whether the participant is currently in treatment, and if so, will advise the parent and adolescent to make contact with their mental health professional. If a participant requests confidentiality regarding serious self-injurious behavior, we will remind them that this is one of the exceptions to confidentiality because we are seriously concerned for their safety. Every effort will be made to allow the adolescent some control in how the information is presented to the parent (i.e., the adolescent tells the parent or the PI tells the parent), but serious concerns will be communicated with parents, regardless, for safety. For participants not currently under the care of a mental health professional, we will provide a list of local mental health resources and help the family with the referral. We will re-contact families to monitor the participants and determine whether contact with a mental health professional has been made. For participants deemed in imminent risk of suicide, we will inform the parent and advise them to transport the subject to an emergency room or call 911 for assistance with transportation.

Participants will report on their daily mood during the active intervention period (three weeks) and during the optional follow up periods (6 months). In order to monitor and address any potential distress or dissatisfaction during the active intervention period, we will invite participants to contact us with concerns. During our twice-weekly emails to motivate
participants, we will tell them that they should contact us if they are having any difficulties or feeling upset so that we can talk with them by phone and intervene as needed (e.g., conduct a suicide safety assessment as described above).

In all cases, we will document conversations and interactions with subjects and any health professionals they ask us to contact on their behalf. We will also report any adverse events or unanticipated problems to the appropriate party (e.g., IRB). Because of the low risk involved in the proposed study, the PI will be responsible for carrying out this data and safety monitoring plan.

Adverse Event

We do not anticipate any risks, as no serious adverse events have been reported in the literature with respect to brief mindfulness interventions. Potential serious adverse events would include hospitalization and suicide attempt. To protect participants against foreseeable risks, participants who indicate serious suicidal concerns will be excluded from or withdrawn from the study until these concerns are resolved. Potential adverse events may include increases in suicidal thoughts or behaviors, breach of confidentiality, upsetting experiences, distress or dissatisfaction as the result of assessment or use of the app. We will ask both participants and their parents about any adverse events that may have occurred during the active intervention period (e.g., upsetting experiences, distress or dissatisfaction as the result of assessment or use of the app). Adverse and serious adverse events will be reported to the appropriate individuals (see section below).

Written informed consent and assent will be obtained by trained research assistants (RAs) during the laboratory visit to Lawrence University at the beginning of the study. The RA will bring the parent and adolescent into a private room and read the assent form to the adolescent. The RA will ask the parent and adolescent separately if they have any questions about the study and answer them. If the parent signs the written consent form, then the RA will say to the adolescent, “Would you like to be in the study and complete the activities? If you say yes, this means you have read this paper or had it read to you and want to be in the study. If you say no, that means you do not want to be in the study. You can say yes or no. Being in the study is your choice. No one will be mad or upset if you do not say yes, sign this paper, or even change your mind later.” If the adolescent indicates a definite “yes”, the RA will obtain their signature and certify the assent procedure was followed.

To project against a potential breach of confidentiality, the EMA data are stored on a secure, password protected website, without any identifying information. The questionnaire data are also stored on a secure, password protected website, without any identifying information. Data collected during the first lab visit are obtained in separate, private rooms for each parent and child. Family background and contact information (i.e., identifying information) will be collected on paper and stored in a locked file cabinet in a locked room only accessible to study staff. No information collected from the adolescent participants will be shared with parents unless there are serious concerns about the child’s safety (i.e., suicide concerns or child abuse). Participants and project staff will communicate via phone, email, and text regarding scheduling and completing study materials, but no data or sensitive information will be shared.

The trial will be stopped should findings suggest that the intervention is resulting in mean suicide and/or self-injury levels to increase to a level of clinical concern (e.g., ideation with a plan, attempts, or completions).

Statistical Analysis Plan

General Analytic Strategies. The number of participants recruited and retained will be documented, and comparisons will be made on all study variables between those who complete and those who drop out of the study in order to inform external validity. Compliance and intervention dose will be assessed with time-stamped electronic records generated through the app. All data will be inspected for normality and transformations will
be applied as needed. Missing questionnaire data will handled using multiple imputation if data are missing completely at random (Enders, 2013).

**Specific Aim 1.** There are multiple ways to assess participants’ engagement to determine the acceptability of the intervention. The first two involve examining how much adolescents use the mobile application. We will examine compliance during the 3-week intervention period by comparing the amount of application use (as recorded electronically) in the intervention group to the control group. We will also examine use during the follow-up periods (12 weeks), when it is optional. Both of these usage questions can be answered with t-tests comparing use between groups.

The other two ways of measuring acceptability are more direct. Participants will complete a satisfaction questionnaire during the post-assessment, and we will compare scores on these questions between groups using t-tests. Finally, participants in the intervention condition will answer a question after each mindfulness exercise regarding how helpful it was using a 0-100 scale ranging from not at all helpful to extremely helpful. Scores on this question can be averaged and examined separately for each type of mindfulness exercise to see if they fall above the benchmark of 50, indicating that adolescents find them helpful in the moment. With all statistical analyses, we will use best current practices regarding correction for multiple tests.

**Specific Aim 2.** Testing of the hypothesis that the intervention will reduce symptoms through the mediating effect of reduced rumination will be accomplished by capitalizing on both trait-level questionnaire data and state-level EMA data. Using trait-level data, an indirect effect model will be tested to examine the effect of condition (EMA-only vs. EMA + Mindfulness) on each outcome (depressive symptoms, anxiety symptoms, parent-reported internalizing symptoms, and self-injury) through the indirect effect of rumination (see Figure 2). These analyses will be accomplished using the PROCESS macro (Hayes, 2013) for SPSS (IBM Corp.) which relies on bootstrapping to generate bias corrected confidence intervals. This approach is particularly well-suited for testing mediation models with relatively small sample sizes. It also allows for the addition of covariates and/or moderators if inclusion of them are warranted. For example, if there are sex differences in rumination and/or symptoms, as is likely based on previous research (e.g., Hilt, McLaughlin, & Nolen-Hoeksema, 2010), sex can be covaried or tested as a moderator of effects (Exploratory Aim) using methods described by Preacher, Rucker, and Hayes (2007). Dose can also be examined as a covariate, to test whether variability in use of the mobile application affects outcomes. These indirect effects models will be tested at each time period (post, follow-up 1, and follow-up 2). If the hypothesis is supported for

![Figure 2. Conceptual indirect effect model. Note that moderators (e.g., sex) may also be included.](image)

the post-intervention time period, it will be helpful to see if effects are maintained at 6 and 12 weeks. If the hypothesis is not supported at the post-intervention period, it will be possible to examine delayed effects at the follow-up time points. For example, the intervention could reduce rumination first and have a delayed effect on symptoms.
The primary hypothesis can also be examined on a finer-grain time scale using state-level EMA data to test whether a mindfulness exercise results in reduced negative mood immediately or at subsequent time points relative to each person’s average level of mood. Relatedly, we can examine whether mindfulness exercises reduce state rumination compared to one’s average level of state rumination and if so, test mediation. Similar to the trait-level models, covariates (i.e., between-person factors such as sex, SES, and race/ethnicity) may be included if warranted. These multilevel models will be estimated in Mplus (Muthén & Muthén, 1998-2015) using maximum likelihood estimation with robust standard errors to account for the nested nature of the data. This approach will allow for the examination of between- and within-person variation in outcomes and is consistent with current recommendations for handling missing data (Baraldi & Enders, 2010).

Although rumination is the proposed mediator, we can also test an alternative mechanism, i.e., changes in mindfulness (Exploratory Aim). Another mindfulness intervention found that changes in state mindfulness predicted changes in trait mindfulness (Kiken, Garland, Bluth, Palsson, & Gaylord, 2015). Furthermore, there appears to be an inverse relationship between trait mindfulness and depressive symptoms (e.g., Way, Creswell, Eisenberger, & Liberman, 2010). Thus, it is possible that the intervention will improve symptoms by increasing mindfulness, reducing rumination, or both. Both trait- and state-level mindfulness can be included as mediators in the above-mentioned models (Preacher & Hayes, 2008).

References


Mani M, Kavanagh DJ, Hides L, Stoyanov SR. Review and evaluation of mindfulness-based iPhone apps. JMIR Mhealth Uhealth 2015;3(3):e82 https://doi.org/10.2196/mhealth.4328


hypotheses: Theory, methods, and prescriptions. *Multivariate behavioral research*, 42(1), 185-227. [https://doi.org/10.1080/00273170701341316](https://doi.org/10.1080/00273170701341316)


