

Study title: Mindfulness and Diabetes Distress: Acceptability of Self-Led
Mindfulness-Based Intervention

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1. Study Protocol

Objectives

This study had two primary aims. First, to examine the associations of mindfulness and diabetes-related outcomes, and second, to examine the acceptability, feasibility, and potential utility of self-led mindfulness-based stress reduction (MBSR) intervention.

Participants

Participants for the present study included a sample of 25 adolescents (14 females; 56%), 14-18 years old ($M = 16.25$, $SD = 1.6$ years) from urban and rural areas of Nevada. Most participants identified as White ($n = 22$; 88%) and one participant as Asian, one participant as Native Hawaiian or Pacific Islander, and one participant as bi-racial. Participants reported a wide range of diagnosis length, ranging from less than a year to 16.15 years ($M = 5.3$, $SD = 4.1$). Nineteen participants reported using a continuous blood glucose monitor (76%) and 17 endorsed using an insulin pump (68%). Additionally, 10 participants reported that they qualify for free lunch at school (40%). Participants were asked to report on psychopathology and other medications that may impact attention for mindfulness activities. Inclusion criteria included being an adolescent (aged 13-19) with a type 1 diabetes diagnosis and currently attending school or being a recent high school graduate. Participants were excluded if they were a ward of the state, or had severe psychiatric disturbances (e.g., active psychosis) or severe developmental delay that hindered their ability to self-report. Participants were not excluded based on length of type 1 diabetes diagnosis. Trained undergraduate research staff screened participants for eligibility during the consent process.

Procedures

Procedures were approved by the Institutional Review Board at the University of Nevada, Reno. Electronic parental consent was obtained when the child was under the age of 18, in which case child assent was also obtained. Participants 18 and older provided electronic consent. Participants were recruited with flyers at a regional diabetes camp, flyers to community diabetes support groups, and direct recruitment by research staff in a local pediatric endocrinology clinic to obtain participants from both urban and rural areas of Nevada. Recruitment for this parallel pilot trial began in the fall of 2018 and completed in early spring 2020. All enrolled participants completed a baseline survey and were randomized to either begin the 10-week intervention period immediately or in 10-weeks. Based on prior studies of predictors of glycemic levels and treatment response, randomization was computerized and stratified based on gender, length since type 1 diabetes diagnosis (at or below 2 years versus more than 2 years) and most recent HbA1c (at or below 8.5% versus at or above 8.6%). After the baseline assessment and across the initial and waitlist intervention periods, participants also completed assessment questionnaires 10 weeks and 20 weeks after the study start date.

Research staff were trained by two graduate students on recruitment procedures and eligibility criteria. Sixty-four participants contacted our research staff indicating interest in participating in the study and provided permission to contact either online or in person (See Figure 1). During the study period, an interim study endpoint was reached where it was determined due to attrition and loss to follow-up as well as feedback from the enrolled participants ($n = 29$) that the intervention required revision to increase acceptability. Thus, enrollment was stopped prior to reaching the planned, per a priori power analyses, sixty participants. Of the 64 participants that indicated interested in the study, five participants

declined further screening and two participants were not eligible after screening. At the interim stop point, 29 participants had been consented and enrolled in the study. An additional 28 participants expressed interest in enrolling but did not complete the consent process before the interim study endpoint was reached. Among the 29 enrolled participants, 25 participants completed their baseline survey and were randomized to intervention now ($n=15$) or waitlist ($n=10$); groups were not balanced as enrollment was stopped early. Four of the 29 participants passively declined to complete the baseline survey and were not randomized. During the course of the study, two participants withdrew from the study after intake (reasons: busy with school, study participation was stressful), but nine were lost to follow-up at 10-weeks and another six were lost to follow-up at 20-weeks.

Intervention Program. The mindfulness-based intervention in the present study was delivered via a teen MBSR workbook and online communication across the 10-week intervention period. Participants were assigned weekly readings and activities from an MBSR workbook for teens (Biegel, 2017). Topics included understanding stress, introduction to mindfulness, mindful eating and other mindfulness-based principles and were recommended to be completed daily. Mindfulness-based exercises were either self-led per instructions provided in the workbook or to be completed using an audio recording directing participants' behaviors. Participants received emails twice per week with reminders about their assignments for the upcoming week and reminders to practice mindfulness daily. At the end of the week, participants received a reminder to complete a brief survey to obtain qualitative data regarding the acceptability of that week's content. Qualitative feedback regarding participants' acceptability of the workbook were used in analyses and included open-ended questions

regarding how helpful participants found each exercise and what hindered them from completing the exercises.

Participants could earn \$10 for each assessment questionnaire, \$10 for completing at least six of the ten weekly survey over the ten-week intervention period, and an additional \$10 for completing all 10 weekly surveys. Maximum earning for each participant was \$50. All measures were completed electronically through RedCap.

Measures

Mindful Attention Awareness Scale-Adolescent. The Mindful Attention Awareness Scale-Adolescent (MAAS-A; Brown et al., 2011), adapted from the MAAS for adults (Brown & Ryan, 2003), assesses dispositional mindfulness in adolescents. The MAAS-A has a single-factor structure with 14 items rated on a 6-point scale (1 = almost always, 6 = almost never). Higher scores indicate higher trait mindfulness. The MAAS-A has high internal consistency and test-retest reliability as well as both concurrent and incremental validity (Brown et al., 2011) with strong internal consistency in the study sample ($\alpha = .92$).

Self-Compassion Scale. The Self-Compassion Scale (SCS; Neff, 2003) is a 26-item measure that assesses different aspects of self-compassion in individuals 14 and older. Participants rate how often they engage in each self-compassionate behavior in specific situations (for example, “When I fail at something important to me, I try to keep things in perspective”). The SCS is rated on a 5-point scale (1 = almost never, 5 = almost always). Total score is calculated by computing the sum of all items. The SCS has been shown to have good internal consistency ($\alpha = 0.92$) and convergent validity with adolescents (Cunha, Xavier & Castilho, 2016) and had strong internal consistency in this sample ($\alpha = .95$).

Diabetes Distress. The Diabetes Stress Questionnaire (DSQ; Delamater et al., 2013) assesses different daily, diabetes-specific stressors. The measure consists of 65 items and includes eight subscales. Participants rate severity of stress across several diabetes-related scenarios on a 4-point scale (0 = not at all, 3 = very much). A total score is calculated by computing the mean of all items in addition to the mean score for each subscale. The DSQ has high internal consistency ($\alpha > 0.7$) and strong convergent validity ($0.46 < r < 0.77$; Kamody et al., 2014) and had strong internal consistency in this sample ($\alpha = .97$).

Health-related Quality of Life. The PedsQL 3.2 -Diabetes Module (PedsQL- DM; Varni et al., 2018) assesses diabetes-specific, health-related quality of life in children, adolescents, and young adults. Each item is rated on a 5-point scale (0 = never, 4 = almost always). Summary scores are calculated by computing the sum of all items divided by the total number of items answered. The PedsQL-DM has strong internal consistency and construct validity (Varni et al., 2018) and had strong internal consistency in this sample ($\alpha = .92$).

Perceived Stress. The Perceived Stress Scale-10 Item Version (PSS-10; Cohen, Kamarack, & Mermelstein, 1982) assesses the severity of broad, stressful situations. Participants rank how often each statement applies to their feelings of stress on a 5-point scale (0 = never, 4 = very often). Negative items are reversed and the sum of all 10 items is calculated. Higher scores indicate higher perceived stress. The PSS-10 has well-documented reliability and validity ($\alpha = 0.84$; Perera et al., 2017) and had strong internal consistency in this sample ($\alpha = .93$).

Psychosocial Impairment. The Pediatric Symptoms Checklist-17 (PSC-17; Gardner et al., 1999) assesses a child's psychosocial functioning. The present study uses the self-report PSC-17, consisting of three subscales. Participants rate how frequently each symptom occurs on a 3-

point scale (0 = never, 2 = often). Total scores range from 0-34 with higher scores indicating greater risk of psychosocial dysfunction. The PSC-17 has strong concurrent validity and high internal constancy ($\alpha = 0.89$; Murphy et al., 2016) and had sufficient internal consistency in this sample ($\alpha = .86$).

Diabetes Treatment Engagement. The Self Care Inventory (SCI), originally developed by La Greca et al. (1988), was modified to include eight additional items reflecting modern diabetes management behaviors (Helgeson et al., 2007). The SCI assesses to what degree individuals follow health care provider guidelines for diabetes-management behaviors. The investigators removed the item “how frequently do you come in for appointments” from the study as the measure was not used within a physician/ appointment context. After removing the item, the SCI consisted of 22 items and is rated on a 5-point scale (1 = never, 5 = always). A total score is calculated by computing the average of all of the items. The modified version of the SCI has high internal consistency ($\alpha = 0.78-0.82$) and is highly correlated with the original SCI (Helgeson et al., 2010) and had sufficient internal consistency in this sample ($\alpha = .88$).

Glycosylated hemoglobin percentage (HbA1c). At intake, participants self-reported their most recent HbA1c. Higher HbA1c percentages are associated with less optimal glycemic control in the past two to three months.

2. Statistical Analysis Plan

The aim of the present study was two-fold. First, to examine the association between mindfulness, diabetes distress, HbA1c, self-compassion, general perceived stress, diabetes treatment engagement, and diabetes-related quality of life, the investigators used baseline

assessment data from all randomized participants and conducted Pearson correlations.

Additionally, to inform what aspects of mindfulness are most connected with diabetes distress, the investigators explored the associations of each item on the MAAS-A scale with diabetes distress ratings. Second, to assess the feasibility, acceptability and utility of the self-led MBSR intervention for adolescents with type 1 diabetes the investigators examined attrition and the number of weekly surveys completed as well as feedback from the participants during the study.

To further consider the potential utility of the self-led MBSR intervention in this population, the investigators examined changes in the primary outcomes of mindfulness and diabetes related-stress at baseline and 10-week follow-up between the intervention and waitlist groups using independent sample t-tests and from pre-to post-intervention in high engagement participants (those who completed at least six of 10 weekly surveys) using paired sample t-tests. To limit bias from missing data at 10-week follow-up ($n = 11$) in independent sample t-tests an intent-to-treat approach was used, where the baseline level of mindfulness and diabetes-stress was used as the 10-week level for missing data rather than excluding those participants from analyses. The same intent to treat approach was used for the assessment of pre-to post-intervention changes in high engagement participants using paired sample t-tests.

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