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Mindfulness-based stress reduction for mental health in youth: a cluster randomized controlled trial

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Background: Mental illness is among the most common causes of morbidity, mortality, and disability in childhood. Mindfulness-based stress reduction (MBSR) has shown significant benefit in mental health; however, evidence of its effectiveness in youth is limited. The objective of this study was to compare the efficacy of MBSR plus usual care versus usual care alone for reducing mental health symptoms in youth. **Methods:** A two-arm, mixed methods, randomized cluster-controlled trial of 12–18 year olds who were residents of CASA House, a voluntary residential treatment program for adolescents, between January 2011 and March 2013 (clinicaltrials.gov, NCT01307943). **Interventions:** Treatment terms were randomized to usual care, or MBSR plus usual care, which included eight MBSR sessions of 2 hr/week. **Outcomes:** The primary outcome was impact on emotions and behavior at the end of the program, using the Behavior Assessment System for Children, Second Edition (BASC-2). Secondary outcomes included perceived stress levels, mindfulness, and emotional regulation. **Results:** A total of 85 participants were randomized to either the MBSR arm (n = 45) or control arm (n = 40). Significant differences in favor of MBSR were found on Teacher ratings of the Internalizing Problems (p = .038) and Adaptive Skills subscales (p = .022) on the BASC-2. No significant differences were found on other outcomes. A post hoc analysis found that the MBSR arm had a significantly shorter time to discharge (p = .02). **Conclusion:** The results of this study indicate that MBSR is effective for improved coping with internalizing problems and adaptive emotional skills in our sample. Future studies should focus on larger, longer-term studies in youth.

Key Practitioner Message

- This is a rigorous randomized controlled trial that indicates the positive impacts of MBSR on mental health in youth.
- Mental health issues are common in youth and negatively impact all aspects of a child's development. Mindfulness-based stress reduction (MBSR) has shown significant benefit in mental health, however, evidence in youth is lacking.
- This study is a rigorous randomized controlled trial assessing the impacts of MBSR in youth with mental health issues. The study found that MBSR has positive impacts on coping and adaptive emotional skills.

Keywords: Mental health; mindfulness; adolescence

Introduction

Eighty percent of mental illnesses begin in childhood (Leitch, 2007) and approximately 15% of Canadian children and youth live with a mental health disorder (Kirby & Keon, 2004). Mental illness is one of the five most common causes of morbidity, mortality, and disability in childhood; recent projections suggest the prevalence will increase by 50% by the year 2020 (World Health Organization, 2001). Concerns about children's social-emotional or mental health functioning have been fueled by evidence that mental illnesses that emerge in childhood often persist and are resistant to change (Eron, 1990; Hanna, Edgecombe, Jackson, & Newman, 2002; Snyder, 2001). Childhood mental illnesses have been associated with and are predictive of increased risk for academic failure, school dropout, general health problems, problems with family and peer relationships, and engaging in delinquent activities (Hanna et al., 2002; Masten & Coatsworth, 1998). The consequences of inadequately treating mental health disorders have clear monetary

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repercussions and even greater social penalty. According to the World Health Organization, 5 of the 10 leading causes of disability are related to mental health disorders (World Health Organization, 2001). In a recent Canadian mental health survey of individuals aged 15 and older, nearly 5% reported symptoms that met diagnostic criteria for major depressive disorder and nearly 3% reported symptoms that met diagnostic criteria for a generalized anxiety disorder (Statistics Canada, 2003). The impact of poor mental health on the Canadian economy is estimated at $51 billion per year (Lim, Jacobs, Ohinmaa, Schopflocher, & Dewa, 2008).

Medication is often a treatment of choice for childhood mental health disorders. However, parents and providers alike are interested in identifying nonpharmacological approaches as adjunctive therapy, particularly as concerns increase about potential side effects of long-term pediatric use of psychoactive medications. The use of complementary therapies is popular for children and youth (Barnes, Bloom, & Nahin, 2008; Goldman, Rogovik, Lai, & Vohra, 2008). Mindfulness is a complementary therapy that is described as a 'conscious, moment-to-moment awareness, cultivated by systematically paying attention on purpose in a particular way'(Kabat-Zinn, 1990). Mindfulness based-stress reduction (MBSR) is a structured program of instruction designed to enhance an individual's mindfulness, or present-focused awareness (Kabat-Zinn, 1982). The MBSR program can consist of instruction in mindfulness meditation, mindful yoga, and discussion of barriers to mindfulness practice (Kabat-Zinn, 1982).

Research has shown that MBSR reduces pain, psychological distress, and mood disturbance among chronic pain patients. MBSR instruction has also been associated with improvement in anxiety and depression among heterogeneous clinical populations, (Carlson, Ursuliak, Goodey, Angen, & Speca, 2001; Hoge et al., 2013; Ramel, Goldin, Carmona, & McQuaid, 2004; Reibel, Greeson, Brainard, & Rosenzweig, 2001; Roth & Robbins, 2004; Sephton et al., 2007; Speca, Carlson, Goodey, & Angen, 2000) including those with anxiety and/or depression, as well as generalized anxiety disorder (Evans et al., 2008; Jain et al., 2007). Furthermore, research suggests that the beneficial effect of MBSR on depression is mediated by a reduction in rumination (Grossman, Niemann, Schmidt, & Walach, 2004; Ramel et al., 2004). Meta-analyses of controlled MBSR studies found a significant medium strength effect size in both physical and mental health variables (Baer, 2003; Grossman et al., 2004).

Despite decades of research on MBSR for adults, there are few published studies in younger populations (Sibinga, Webb, Ghazarian, & Ellen, 2016; Sibinga et al., 2011). The current literature suggests that youth are able to engage meaningfully with mind-body techniques, including MBSR, and suggests that MBSR is worthy of further investigation in youth. If MBSR programs are also capable of providing psychological benefit, they would be a worthwhile nonpharmacological addition to the current tools for supporting pediatric mental health. Our approach will be to evaluate MBSR as an adjunct to high-risk youth referred to a residential treatment facility.

The primary objective of this study was to compare the efficacy of MBSR plus usual care versus usual care alone for reducing mental health symptoms and increasing coping/resiliency in adolescent patients referred for residential mental health treatment.

Methods

Ethical considerations

This study has the approval of the Health Research Ethics Board at the University of Alberta. Informed consent was obtained from the parent/legal guardian of participants <18 years of age. Assent was also obtained from those participants who were 12 years of age and over. This trial was registered at clinical trials.gov with the identifier NCT01307943 (https://clinicaltrials.gov/ct2/show/NCT01307943).

Design

A two-arm, mixed methods, cluster-controlled trial was carried out in Edmonton, Canada. This work was conducted collaboratively with other researchers who posed different research questions of the same study population (Singhal et al., 2012; Van Vliet et al., 2017). In this study, we assess the impacts of MBSR from a quantitative clinical outcomes perspective.

Participant eligibility

Residents of CASA House in Sherwood Park, Alberta, who are able to communicate in and comprehend the English language, were eligible to participate in this study. CASA House is a voluntary treatment program for adolescents (12–18 years old) who have a history of not responding to previous mental health interventions and require a high degree of intensive treatment. Participants were excluded if they had a diagnosis of psychosis, as it was felt to be a contraindication to meditation instruction (Arias, Steinberg, Banga, & Trestman, 2006).

Intervention and comparator

Regular care. The control group included youth receiving therapies and programs already used at CASA House. In addition to a structured day and evening schedule, standard treatment at CASA House includes: (a) daily group therapy; (b) medications; (c) schooling by Edmonton Public School Board teachers; (d) physical education and recreation; and (e) weekly multiple family therapy sessions.

MBSR in addition to regular care. Eight MBSR sessions of 2 hr/week were held during regular class time plus one 3-hr retreat at the completion of the eight sessions to review and consolidate experience with the various mindfulness practices. Methods and materials used in previously successful MBSR studies in youth were adapted for use in this local population (Sibinga et al., 2011). The MBSR concepts and techniques used emphasized portability and included didactic and experiential components. Participants were encouraged to find moments throughout their day in which to practice the techniques. Mindfulness concepts were linked with tag phrases like 'breathing break', 'autopilot', and 'choice points'. Homework emphasized experiential, concrete tasks ('notice five new things today'; 'eat one meal mindfully this week'). A workbook intended to facilitate instruction was adapted from that developed by our collaborator, Dr. Erica Sibinga et al. (2011). The intervention was administered by a local psychiatrist who is also a qualified MBSR instructor.

Allocation procedure

CASA House runs two terms per year, with the study running for a total for four terms. We ran the MBSR plus usual care group during one term per year, and just usual care during the other term. The order of treatment group administration was ABBA, in order to account for seasonal variation. A computer-generated randomization sequence was used to determine whether group A or group B received MBSR.

Blinding and control of bias

Since the nature of intervention precludes blinding, extra methodological precautions were taken in order to minimize potential bias: (a) careful documentation of participant characteristics in order to control for differences between groups, (b) use of randomization to determine which term MBSR will take place in; and (c) blinded analysis.

Outcomes

The primary outcome was the effect of MBSR on emotions and behavior at the end of the program (i.e., at 10 weeks). This was measured using the Behavior Assessment System for Children, Second Edition (BASC-2), which is a multi-method, multidimensional system used to evaluate the behavior and self-perceptions of children and young adults aged 2 through 25 (Reynolds & Kamphaus, 2004). The BASC-2 assesses a variety of problem behaviors, school problems, relations with peers and, adaptive skills. Internal consistency reliability ranges from 0.80 to 0.90 and test–retest reliabilities were found to be in the 0.70–0.90 range (Reynolds & Kamphaus, 2004). The BASC-2 was administered to the children/youth, parents, and teachers and consisted of the Self-Report of Personality (SRP), the Parent Rating Scales (PRS), and the Teacher Rating Scales (TRS) respectively.

Secondary outcomes assessed included: (a) Stress levels in children and youth, as measured by the Perceived Stress Scale (PSS), which is a 14-item instrument intended to measure the degree to which one's perception of stress (Cohen, Kamarck, & Mermelstein, 1983). Internal consistency reliability ranges from 0.84 to 0.86 and test–retest reliabilities are found to be 0.85 (Cohen et al., 1983); (b) Effect on mindfulness, as measured by the Child Acceptance and Mindfulness Measure (CAMM), which is a 10-item measure of mindfulness skills (Greco, Baer, & Smith, 2011). Internal consistency for this scale is 0.80 (Greco et al., 2011); and (c) Emotional regulation, as measured by the revised version of the Emotional Regulation Questionnaire (ERQ), which is a 10-item self-report scale designed to assess cognitive reappraisal and expressive suppression (Gross & John, 2003). Internal consistency ranges from 0.73 to 0.79, and test–retest reliability is 0.69 (Gross & John, 2003).

All questionnaires were administered three times: before and after each 10-week session, as well as at the end of the school term (i.e., 1–3 months postintervention).

Sample size

Sample size was calculated using a linear mixed model with various settings of intra-class correlation (ICC) and effect size. Based on previous data for the BASC-2, the intra-class correlation was approximately 0.5. Assuming ICC = 0.5, medium effect size $d = 0.5$, and $t = 3$ time points, a sample size of 84 individuals (i.e., 42 per intervention arm) achieves 80% power to detect a mean difference between the groups (Cohen, 1988; Diggle, Heagerty, Liang, & Zeger, 2002). SAS (Ver 9.4; SAS Institute Inc., Cary, NC) software and PASS 10 software were used for sample size calculations.

Statistical analysis

Numerical summaries (e.g., frequencies, means, and standard deviations) for all variables of the MBSR and control group are described separately. The primary analysis compared the MBSR and control group for change from baseline on the BASC-2 questionnaires. Secondary analyses examined the PSS, ERQ, and CAMM results.

Data were collected over multiple time points; therefore within-subject outcome variables may have been correlated. To deal with a correlated structure of outcomes, we used a linear mixed model, where compound symmetry (or exchangeable) was considered as correlated structure. All categorical variables in Table 1 were entered into the model as covariates and *program length of stay (days)* was entered into the model as a continuous covariate. After adjusting for the effect of covariates, we performed a linear mixed model to examine group differences, time effect interactions, and effects between group and time. Analysis of outcome data followed the intention-to-treat (ITT) principle, where all participants enrolled were included. Data missing from repeated measures were handled using the method of multiple imputation, when necessary. Residual diagnostics were used for model assessment. All statistical tests were two-sided, and analyses were carried out when all participants reached the end of the study.

Version 9.4 of the SAS System for Windows was used for analyses, and R program (R Foundation for Statistical Computing, Vienna, Austria) was used for all charts. All quantitative analyses were performed by a biostatistician within the Biostatistics Consulting Group at the University of Alberta.

Table 1. Participant characteristics

Variable	Group		Total
	Control ($N = 39$)	MBSR ($N = 42$)	($N = 81$)
Gender			
Male	25 (64.1)	23 (54.8)	48 (59.3)
Female	14 (35.9)	19 (45.2)	33 (40.7)
Grade			
Non-High school	23 (59.0)	29 (69.0)	52 (64.2)
High school	16 (41.0)	13 (31.0)	29 (35.8)
Primary diagnosis			
Attention deficit/ hyperactivity disorder	24 (61.5)	22 (52.4)	46 (56.8)
Mood disorder	9 (23.1)	13 (31.0)	22 (27.2)
Other	6 (15.4)	7 (16.7)	13 (16.0)
Ethnicity			
White/Caucasian	29 (74.4)	30 (71.4)	59 (72.8)
Other	10 (25.6)	12 (28.6)	22 (27.2)
Residence location			
Local	28 (71.8)	32 (76.2)	60 (74.1)
Distant	11 (28.2)	10 (23.8)	21 (25.9)
Household Income			
<$50K	11 (33.3)	8 (22.2)	19 (27.5)
$50-$74K	9 (27.3)	9 (25.0)	18 (26.1)
>$75K	13 (39.4)	19 (52.8)	32 (46.4)
Education			
Primary or Secondary	13 (34.2)	15 (39.5)	28 (36.8)
Post-secondary	25 (65.8)	23 (60.5)	48 (63.2)
Household structure			
Dual parent	14 (37.8)	16 (40.0)	30 (39.0)
Single parent	18 (48.6)	17 (42.5)	35 (45.5)
Other[a]	5 (13.5)	7 (17.5)	12 (15.6)
Age at enrollment (years)	14.4 (1.4)	14.0 (1.4)	14.2 (1.4)
Days b/*n* admission and enrollment	46.3 (35.6)	38.3 (34.8)	44.6 (19.0)
Program length of stay	150.6 (37.2)	132.8 (30.4)	141.4 (34.8)
Time in study	104.3 (46.3)	101.0 (43.6)	102.6 (44.6)

[a]Other' indicates child does not live with parent(s).

Results

Study participants

A total of 88 individuals were assessed for eligibility, of which 85 met the criteria. The study ran for a total of 2 years, and 4 terms (each year containing 2 terms) between January 2011 and March 2013. The first term of each year was randomized to receive MBSR plus usual care (a) or just usual care (b), and the second term received the other intervention. The final order of randomization over the four terms was ABBA. A total of 45 participants received MBSR plus usual care, and 40

participants received just usual care. Five participants dropped out during the study (four from the MBSR group and one from the control group), most often because they were discharged/transferred from residential care during the study; one individual preferred not to participate in the study. A total of 81 participants were included in the analysis. The flow of participants through the trial is shown in Figure 1. Baseline demographics for participant in each group are provided in Table 1. Attendance at MBSR sessions across all terms was 87.8%.

Efficacy of treatment

For the primary outcome, at 10 weeks, significant between-group differences in favor of the MBSR group were found on the TRS-Internalizing Problems subscale of the BASC-2 ($p = .038$) and the TRS-Adaptive Skills subscale of the BASC-2 ($p = .022$). No other statistically significant differences were seen. Descriptive statistics and the results of the linear mixed model analysis for the primary outcome are presented in Table 2, which shows the mean difference of outcomes by group over time.

There were no significant between-group differences on any of the secondary outcomes at either of the time points; however, trend findings were noted. Both treatment groups trended toward improvement (i.e., lower scores) on the PSS scale at 10 weeks and at the three-month mark, the MBSR group-maintained improvement, while the control group tended to regress toward baseline scores. Moreover, the scores on the ERQ-Cognitive reappraisal subscale trended toward improvement (i.e., higher scores) in the MBSR group at 10-weeks and this trend was maintained at 3 months, while the control group scores decreased at the 3-month mark. For both the MBSR and control groups, scores on the ERQ-Expressive suppression subscale trended downwards (favorable) from baseline to the 3-month mark. Both groups showed a decrease in CAMM scores (unfavorable) at both the 10-week and 3-month marks. Descriptive statistics and the results of the linear mixed model analysis for the secondary outcomes are presented in Table 3, which shows the mean difference of outcomes by group over time.

A surprising finding identified during a post hoc analysis was the considerably shorter admission time for participants enrolled in the MBSR arm (150.6 vs. 132.8 days) from admission to discharge ($p = .02$).

Risk of harm

No adverse events were reported throughout the duration of the trial.

Discussion

The results of this study indicate that in our sample of children and youth in residential psychiatric care, MBSR was effective based on teacher-ratings of internalizing problems (i.e., anxiety, depression, and somatization) and adaptive skills. For other outcomes at 10-weeks, although there was a trend toward improvement, MBSR did not significantly impact behavioral problems, perceived stress levels, mindfulness, and emotional regulation among children and youth at the CASA house. Moreover, while not significant, these trends lasted throughout the 3-month follow-up period, while the control arm improvements diminished over time. Interestingly, those participating in the MBSR arm had a significant decrease in their length of stay in the

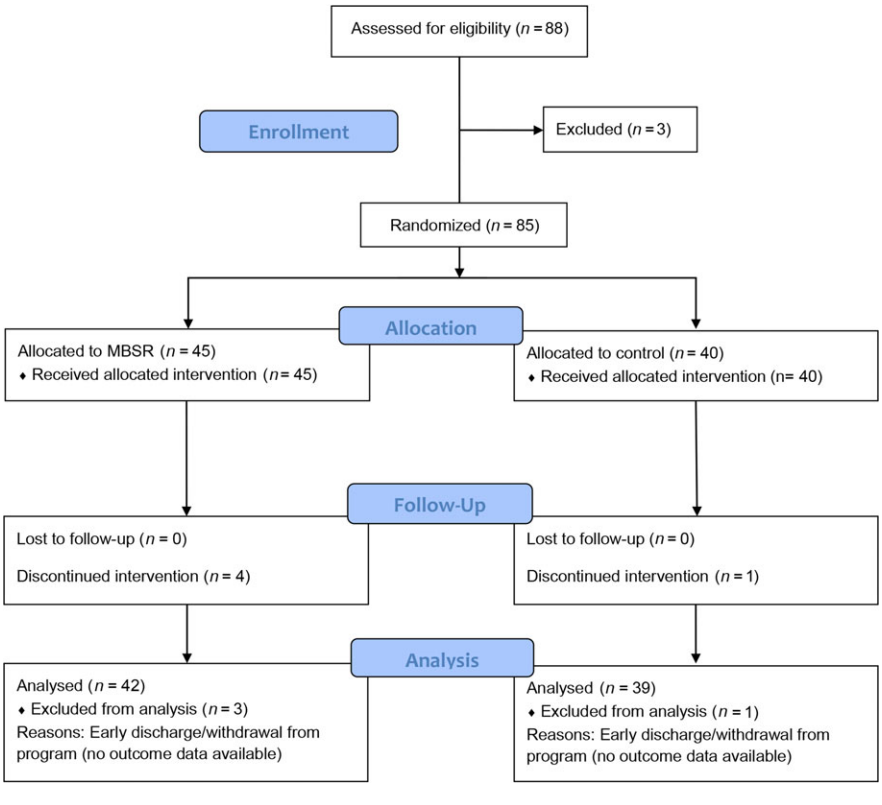

Figure 1. Participant flow through trial [Colour figure can be viewed at wileyonlinelibrary.com]

Table 2. Between-group comparisons on the BASC-2

		Time			Linear mixed model	
Scale	Group	Baseline Mean (*SD*)	10 weeks Mean (*SD*)	3 months Mean (*SD*)	β (*SE*)	*p*-value
SRP						
School problems	MBSR	58.95 (12.6)	54.88 (10.4)	52.11 (9.0)	−0.19 (2.55)	.136
	Control	53.87 (14.4)	51.67 (12.6)	56.36 (12.2)		
Internalizing problems	MBSR	59.72 (15.0)	55.50 (15.7)	53.74 (13.2)	−3.20 (2.84)	.169
	Control	54.83 (11.6)	54.83 (11.6)	55.50 (7.9)		
Emotional symptoms index	MBSR	57.69 (13.5)	54.15 (14.1)	52.63 (12.1)	−4.91 (2.91)	.151
	Control	58.39 (14.9)	52.60 (10.8)	55.86 (9.0)		
Personal adjustment	MBSR	44.74 (12.6)	46.24 (12.4)	43.89 (12.0)	5.09 (2.65)	.164
	Control	41.82 (12.9)	45.83 (10.3)	38.93 (8.8)		
TRS						
Externalizing problems	MBSR	51.44 (8.9)	52.21 (9.9)	–	2.12 (2.88)	.469
	Control	55.00 (10.4)	56.71 (10.6)	–		
Internalizing problems	MBSR	53.03 (13.7)	51.05 (13.5)	–	11.77 (5.32)	.038*
	Control	56.19 (9.9)	62.57 (18.7)	–		
School problems	MBSR	54.59 (8.5)	54.00 (7.0)	–	−0.92 (2.01)	.651
	Control	57.78 (9.6)	57.50 (9.3)	–		
Behavioral symptoms index	MBSR	52.03 (8.2)	52.16 (8.5)	–	3.95 (3.07)	.212
	Control	56.44 (8.6)	57.36 (10.4)	–		
Adaptive skills	MBSR	44.66 (6.1)	45.47 (6.5)	–	−5.87 (2.37)	.022*
	Control	44.41 (8.0)	44.64 (7.4)	–		
PRS						
Externalizing problems	MBSR	79.54 (15.4)	71.28 (14.2)	72.39 (13.9)	1.90 (2.95)	.785
	Control	73.79 (14.6)	67.96 (13.8)	73.00 (11.7)		
Internalizing problems	MBSR	72.03 (15.0)	61.66 (13.3)	61.67 (9.3)	2.92 (2.86)	.596
	Control	70.74 (13.8)	67.25 (11.0)	63.71 (4.9)		
Behavioral symptoms index	MBSR	77.54 (9.9)	69.34 (12.3)	68.78 (8.9)	0.56 (2.70)	.977
	Control	77.76 (12.4)	72.32 (11.8)	72.43 (6.5)		
Adaptive skills	MBSR	31.77 (6.9)	35.62 (8.3)	35.78 (8.7)	−0.91 (1.49)	.807
	Control	31.50 (6.8)	32.96 (6.9)	32.57 (5.0)		

Values are presented as means (*SD*s).
PRS, Parent Rating Scales; SRP, Self-report of personality; TRS, Teacher Rating Scales.
*$p < .05$

Table 3. Between-group comparisons of secondary outcomes

		Time			Linear mixed model	
Scale	Group	Baseline Mean (*SD*)	10 weeks Mean (*SD*)	3 months Mean (*SD*)	β (*SE*)	*p*-value
PSS	MBSR	20.18 (8.4)	16.85 (7.5)	17.05 (7.6)	0.48 (1.79)	.870
	Control	20.18 (6.8)	17.73 (7.2)	19.50 (6.7)		
ERQ-cognitive reappraisal	MBSR	17.88 (5.4)	19.03 (3.9)	18.40 (4.7)	0.90 (1.26)	.330
	Control	20.48 (4.3)	20.48 (4.3)	17.93 (4.5)		
ERQ-expressive suppression	MBSR	10.63 (3.7)	10.50 (3.3)	10.05 (3.5)	−1.21 (0.99)	.473
	Control	11.38 (3.6)	10.90 (3.9)	10.79 (3.0)		
CAMM	MBSR	17.58 (8.0)	16.62 (7.4)	11.63 (7.5)	−1.09 (1.83)	.097
	Control	17.67 (8.3)	17.41 (9.1)	14.21 (7.0)		

Values are presented as means (*SD*s).
CAMM, Child Acceptance and Mindfulness Measure, ERQ, Emotional Regulation Questionnaire; PSS, Perceived Stress Scale; *SE*, Standard error, *SD*, standard deviation.

in-patient program by 17.8 days, compared to those participating in the control arm.

Evidence on MBSR for children and youth has begun to emerge over the last few years. A recent RCT of 300 children and youth representing low-income, urban, minority populations compared MBSR with an active control (i.e., health information seminars; Sibinga et al., 2016). Consistent with our study, study authors have previously found that MBSR significantly improved symptoms of depression, anxiety, and somatization, and failed to show any differences on mindfulness skills, and levels of perceived stress between the two arms. Unlike our findings, this study found that MBSR significantly improved coping amongst participants (Sibinga et al., 2016). Another RCT compared 8 weeks of MBSR to usual care (psychotherapy and/or psychotropic medication treatment) in a group of 104 adolescents aged 14–18 years from an outpatient psychiatric facility (Biegel,

Brown, Shapiro, & Schubert, 2009). The investigators reported improvements favoring MBSR ($p < .05$) across a range of outcomes including state and trait anxiety, perceived stress, self-esteem, sleep quality, somatization symptoms, obsessive-compulsivity, interpersonal sensitivity, and depression. One possible explanation for the lack of consistency between our findings and the Biegel et al. study was the differences in the MBSR intervention used.

Although we designed a rigorous randomized controlled trial, the setting chosen to administer the MBSR was one where parents and children do not live together, and as a result, our findings may not be as informative or reliable as it relates to the parent-ratings. Moreover, given the nature of the intervention, the participants, teachers, and parents were not blinded to the study intervention, lending the study vulnerable to performance and detection bias. The study did not account for any MBSR exposure or practice outside of the sessions. In addition, the use of a relatively brief follow-up period (i.e., 3 months) may have been too short to detect the potential longer-term impacts of the intervention. Moreover, the demographic make-up of this study was limited to those enrolled in the treatment facility program, and was made-up of primarily Caucasian males, thus limiting the generalizability of the findings. Despite these drawbacks, this study represents a real-world, pragmatic trial, which included adapting a curriculum developed for adolescents for this local population. Moreover, since the intervention was being administered as part of a residential treatment facility program, attendance and adherence to the MBSR curriculum was high.

The findings from this small study are encouraging and fit well with other emerging data around the effects of MBSR on adolescents. Since all children and youth are at risk for developing mental health issues (not just those in residential treatment programs), future research should involve larger samples from more generalizable, community-based settings (e.g., schools) in order to promote resiliency and prevention. Future research should also evaluate the acceptability of MBSR amongst children and adolescents (which in turn impacts uptake), as well as investigate the maintenance of MBSR effects over time.

Conclusion

This trial provides some evidence toward the potential positive impacts of MBSR for children and adolescents in a residential treatment facility. While this study overcame many limitations of the current literature including use of an established MBSR curriculum, future efforts should focus on larger, longer-term studies of school-aged children and youth.

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Ethical information

This study has the approval of the Health Research Ethics Board at the University of Alberta. Informed consent was obtained from the parent/legal guardian of participants <18 years of age. Assent was also obtained from those participants who were 12 years of age and over.

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Supporting information

Additional Supporting Information may be found online in the Supporting Information section at the end of the article:

Appendix S1. CONSORT checklist

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