

BRIEF REPORT

Youth-focused group mindfulness-based intervention in individuals with early psychosis: A randomized pilot feasibility study

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Aim: To assess the feasibility of a randomized pilot trial that evaluated the acceptability and potential clinical utility of the Mindfulness Ambassador Program (MAP), a unique, standardized 12-session facilitated group mindfulness-based intervention (MBI) for youth experiencing early psychosis.

Methods: Twenty-one patients of an early psychosis intervention program were randomized to receive MAP ($n = 11$) or treatment as usual ($n = 10$). Acceptability was measured by group attendance rate and client satisfaction; feasibility of the study design was measured by the recruitment and retention rate. The means, standard deviations, and 95% confidence intervals were described for outcomes of interest.

Results: MAP is associated with a high degree of acceptability and has beneficial effects for depression and fatigue. The randomized trial design is feasible.

Conclusions: This study provides important pilot data supporting a larger randomized trial of effectiveness for MAP as a group MBI for early psychosis. Details of MAP and study limitations are discussed.

KEYWORDS

affective symptoms, early medical intervention, mindfulness, psychosis, schizophrenia

1 | INTRODUCTION

There is increasing interest in using mindfulness-based interventions (MBIs) in psychosis. Mindfulness, a meditative practice, focuses awareness on the present moment whereas acknowledging and accepting current sensations without judgement, including voices, sounds, or thoughts (Strauss, Thomas, & Hayward, 2015). MBIs could be valuable in treating early psychosis by helping individuals “accept” their illness, disengage from illness experiences, reduce distress and dysfunction, and address feelings of social rejection and interpersonal stress (Chadwick, 2014); thereby improving self-

esteem and general well-being, and possibly reducing psychotic symptoms.

An increasing number of studies demonstrate evidence for MBIs' acceptability, feasibility, and effect on clinical outcomes for patients with psychotic disorders, including reducing negative and mood/anxiety symptoms and improving quality of life and functioning, with less robust effects on positive symptoms. Most extant research is focused on older, chronic psychosis populations (Chadwick et al., 2016; Chien & Thompson, 2014; Cramer, Lauche, Haller, Langhorst, & Dobos, 2016; Khoury, Lecomte, Gaudiano, & Paquin, 2013; Louise, Fitzpatrick, Strauss, Rossell, & Thomas, in press). Relatively less is

known about the utility of MBIs for younger adults in earlier stages of recovery.

In a qualitative study by Ashcroft, Barrow, Lee, and MacKinnon (2012), early psychosis intervention (EPI) clients who underwent a MBI reported improved control of emotional reactions, better understanding of others, and better self-understanding/acceptance. There have been four subsequent pre-post (Khoury, Lecomte, Comtois, & Nicole, 2015; Samson & Mallindine, 2014; Tong et al., 2016) and non-randomized studies (van der Valk, van de Waerdt, Meijer, van den Hout, & de Haan, 2013) in EPI samples undergoing MBIs. Three have reported significant reductions in depression and/or anxiety (Khoury et al., 2015; Tong et al., 2016; van der Valk et al., 2013), but one did not (Samson & Mallindine, 2014), and there have been mixed results with respect to indices of general psychopathology (cf. Khoury et al., 2015; Tong et al., 2016; van der Valk et al., 2013). Three studies including assessments of mindfulness skills (Khoury et al., 2015; Samson & Mallindine, 2014; van der Valk et al., 2013) did not find evidence of effects, whereas Tong et al. (2016) reported pre-to-post improvements in skills related to observing and acting with awareness. There is a need for randomized controlled studies of the impact of mindfulness in EPI clients (Khoury et al., 2015; Langer et al., 2017; Tong et al., 2016; van der Valk et al., 2013). Because early psychosis is a period of intense distress, stigma and social isolation (Brunet, Birchwood, Upthegrove, Michail, & Ross, 2012; Lolic & Leiderman, 2008), learning emotion regulation strategies might prove useful in diminishing the distress associated with psychotic experience in this population (Khoury et al., 2015).

Recently, a standardized mindfulness program known as the Mindfulness Ambassador Program (MAP) (formerly known as the Mindfulness Ambassador Council) has been shown to be feasible, acceptable and a promising tool for stress and anxiety reduction, strengthening relationships, and promoting inner well-being and social-emotional learning in youth (Smith-Carrier & Gallinaro, 2013). In contrast to the MBI utilized by Ashcroft et al. (2012), MAP is a youth-focused curriculum that emphasizes building integral social and emotional competencies related to recovery through the aforementioned core mindfulness skills and practices. MAP therefore differs from more traditional MBIs such as Mindfulness Based Stress Reduction (MBSR; Kabat-Zinn, 2003) and Mindfulness Based Cognitive Therapy (MBCT; Segal, Williams, & Teasdale, 2002) which focus primarily on the individual and their symptoms.

This randomized pilot feasibility study evaluated this standardized, youth-focused MAP in the early psychosis intervention context to help inform future trials of effectiveness. The objectives of this study were to provide indices for (a) the acceptability of MAP for young people experiencing early psychosis and (b) the feasibility of the pilot's RCT design. Given MAP's emphasis on both mindfulness skills and social-emotional competencies, ancillary analyses were conducted on the following outcomes of interest: mindfulness skills, emotional state, self-esteem, social functioning, and positive and negative symptoms of EPI clients.

2 | METHODS

2.1 | Design

This pilot study followed a randomized single-blind design. An external researcher used a random number generator to randomize participants ($n = 21$) to one of two groups: group EPI-MAP received typical EPI treatment plus the MBI ($n = 11$) or Group EPI-TAU (treatment as usual) ($n = 10$). All participants were notified of their group allocation by their EPI clinic case manager. The EPI-MAP group completed post-intervention evaluations on the acceptability of the intervention. Both groups were assessed pre- and post-intervention on all other outcome measures by a trained research assistant who was blinded to group allocation. This study was pre-registered with the National Institute of Health (ID NCT02342210) and adheres to the CONSORT reporting guidelines for pilot studies (Eldridge, Chan, Campbell, Bond, Hopewell, Thabane et al., 2016).

2.2 | Participants

Outpatients (18-35 years) of the prevention and early intervention program for psychoses (PEPP), an EPI program in London, Ontario, Canada were recruited via poster advertisements and/or referrals from their clinic providers. Eligible participants were receiving treatment at PEPP for <3 years for a DSM-V diagnosis of a primary psychotic disorder. See Table 1 for baseline demographic and clinical characteristics. Participants were approached by a research assistant who explained the study, and they were given the opportunity to ask questions. Participants provided informed consent. Study protocol was approved by the Western University Health Sciences Research Ethics Board (ID 108941).

2.3 | Intervention

The usual treatment at PEPP includes assertive case management, pharmacotherapy, and psychosocial interventions for clients and families (see Norman & Manchanda, 2016). The novel intervention was a group-MBI, the "Mindfulness Ambassador Program" (MAP). Developed by Mindfulness Without Borders (MWB; www.mindfulnesswithoutborders.org), MAP is a standardized group program with 12 weekly 1-hour sessions, each having a specific focus (eg, practicing gratitude, open-mindedness, handling conflict skillfully), facilitated group learning and discussion, in-session mindfulness skills practice (eg, mindful breathing, mindful listening, body scan), and take-away assignments designed to reinforce learned skills. MAP's curriculum emphasizes building social and emotional competencies through core mindfulness skills, making it particularly promising for young people recovering from early psychosis.

2.4 | Outcomes

2.4.1 | Primary outcome

The primary outcome focused on the acceptability of MAP for youth experiencing early psychosis. Participant attendance was recorded and participant satisfaction was measured using the Client Satisfaction Questionnaire (CSQ-8; Larsen, Attkisson, Hargreaves, & Nguyen, 1979), in which respondents indicate their satisfaction with MAP, the

TABLE 1 Baseline demographic and clinical characteristics

Characteristic		N	Mean
Age		17	23.71
		N	%
Gender	Male	13	76.5
	Female	4	23.5
Ethnicity	Caucasian	10	58.8
	Black/African Canadian	2	11.8
	Hispanic/Latino	2	11.8
	Indigenous/First Nations/Metis	2	11.8
	Asian/Pacific Islander	1	5.9
Marital status	Single	16	94.1
	Married/Domestic Partnership	1	5.9
Highest education level completed	Elementary School	5	29.4
	Secondary School/GED	11	64.7
	College/University	1	5.9
Living arrangement	Live alone	8	47.1
	Live with partner	1	5.9
	Live with family	7	41.1
	Inpatient	1	5.9
Primary diagnosis	Schizophrenia	8	47.1
	Schizophreniform Disorder	1	5.9
	Schizoaffective Disorder	1	5.9
	Psychosis NOS	3	17.6
	Delusional Parasitosis	1	5.9
	Substance Induced Psychotic Disorder	1	5.9
	Psychotic Disorder due to a medical condition	1	5.9
	Unknown/Other	1	5.9

extent to which MAP met their needs, and whether they would recommend MAP to others.

2.4.2 | Secondary outcome

The secondary outcome focused on the feasibility of the RCT design of this pilot study. To this end, recruitment and retention rates were calculated, and the reasons for study drop outs described.

2.5 | Ancillary outcomes

In accordance with the CONSORT guidelines extended for pilot studies (Eldridge et al., 2016), ancillary measures are reported to inform whether or not a future, larger trial of effectiveness is justified. Specifically, outcomes of interest including psychotic symptoms, specific mindfulness skills, and measures reflecting general well-being (Chadwick, 2014) such as self-esteem, emotional state, and social functioning are described.

Psychotic symptoms were assessed with the Scale for the Assessment of Positive Symptoms (SAPS; Andreasen, 1984) and the Scale for the Assessment of Negative Symptoms (SANS; Andreasen, 1983). Trained interviewers conducted the assessments with reference to the previous month. Total scores of global items were calculated.

Mindfulness skills were assessed using the Kentucky inventory of mindfulness skills (KIMS), a self-report measure with good reliability

that yields scores related to observing, describing, acting with awareness, and accepting without judgement (Baer, Smith, & Allen, 2004).

Self-esteem was assessed using the Rosenberg Self-Esteem Scale (RSES; Rosenberg, 1965), a widely used index of self-esteem that has been used successfully in past research with psychosis patients (eg, Barrowclough et al., 2003; Norman, Windell, Lynch, & Manchanda, 2012).

Emotional state was assessed by the Profile of Mood States (POMS) short form (Curran, Andrykowski, & Studts, 1995). Respondents rated the extent to which they experienced various feelings/moods during the previous 2 weeks. The POMS has been widely used to assess mood in clinical populations including EPI (Keilp et al., 2010; Norman et al., 2012) and yields scores for depression, tension, anger, fatigue, confusion and vigour.

The Social Functioning Scale (SFS; Birchwood, Smith, Cochrane, Wetton, & Copestake, 1990) assesses dimensions of social functioning for people with psychotic disorders, including social engagement/withdrawal, interpersonal behaviours, pro-social activities, recreation/hobbies, competence in and performance of independent living skills, and employment/occupation. Total score was used as the index of social functioning.

2.6 | Analysis

For the primary outcome of acceptability, the criteria were compliance (attendance at MAP group sessions) and reported satisfaction with the intervention. For the secondary outcome of feasibility, the ratio of actual to planned recruitment ($n = 24$) was calculated. Participant retention was computed by dividing the number participants at follow-up ($n = 17$) by the total number of participants enrolled in the study ($n = 21$) (see Figure 1). The ancillary outcomes were reported descriptively using means, standard deviations, and 95% confidence intervals, the latter of which was computed around the mean for each outcome and separated by randomized group (see Table 2). We compared the confidence interval for each group for overlap. As a general rule of thumb, when comparing two parameter estimates, if the confidence intervals do not overlap then the statistics will be statistically significantly different (Knezevic, 2008).

3 | RESULTS

3.1 | Acceptability

Attendance records showed that in the EPI-MAP group ($n = 9$) five participants attended at least six MAP sessions, two attended all 12 sessions, and two attended four sessions. The mean CSQ-8 score (30.2, $SD = 1.6$) is suggestive of a high degree of client satisfaction with MAP.

3.2 | Feasibility

Twenty-one outpatients entered the study and completed pre-intervention assessments (Figure 1) consistent with a ratio of actual to planned recruitment rate of 87.5%. Four participants withdrew (two from each group) for reasons unrelated to the study (eg, moving away) and were not assessed post-intervention. The retention rate from baseline to follow-up was 81%.

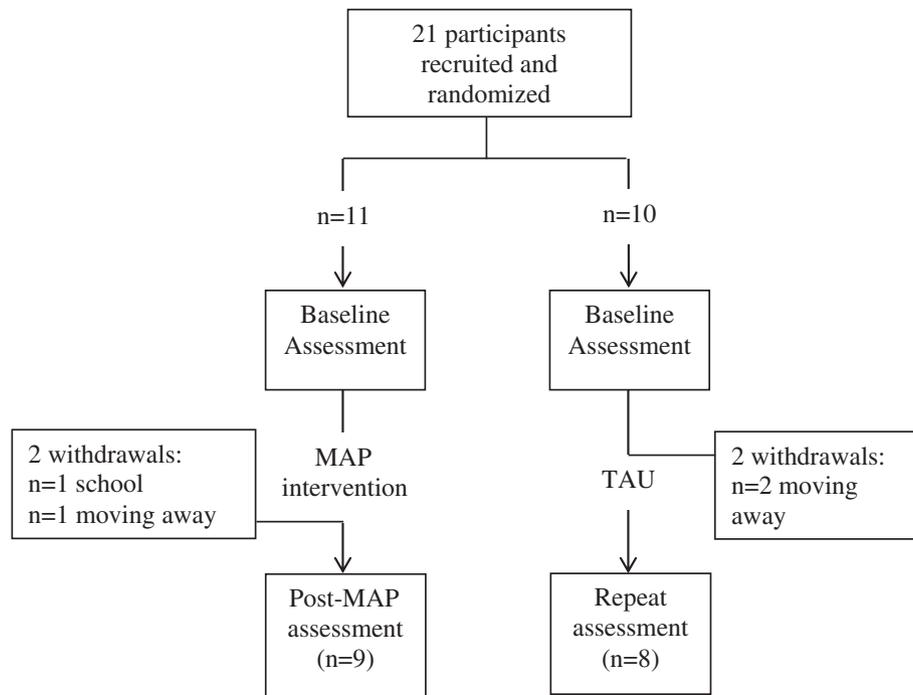


FIGURE 1 Participant flow diagram

TABLE 2 Means, SDs and 95% confidence intervals for ancillary outcomes at time 2

Outcome	Scale	Group EPI-MAP		Group EPI-TAU	
		Mean (SD)	95% confidence interval	Mean (SD)	95% confidence interval
Positive symptoms	SAPS global score	2.6 (2.35)	[1.0, 4.1]	2.1 (2.03)	[0.7, 3.5]
Negative symptoms	SANS global score	5.9 (3.18)	[3.8, 7.9]	7.0 (3.42)	[4.6, 9.4]
Mindfulness skills	KIMS observing	37.1 (11.09)	[29.9, 44.4]	35.9 (10.26)	[28.7, 42.9]
	KIMS acting with awareness	32.8 (6.74)	[28.4, 37.2]	26.6 (7.23)	[21.6, 31.6]
	KIMS accepting without judgement	32.2 (7.61)	[27.2, 37.2]	26.5 (11.61)	[18.5, 34.5]
	KIMS describing	27.9 (5.21)	[24.5, 31.3]	27.9 (6.49)	[23.4, 32.4]
Affect	POMS—tension	6.0 (4.21)	[3.2, 8.8]	9.4 (5.01)	[5.9, 12.9]
	POMS—anger	3.3 (2.50)	[1.7, 4.9]	8.1 (6.03)	[3.9, 12.3]
	POMS—confusion	5.2 (4.12)	[2.5, 7.9]	6.9 (5.14)	[3.3, 10.4]
	POMS—fatigue	3.7 (2.35)	[2.1, 5.2]	9.8 (3.77)	[7.1, 12.4]
	POMS—vigour	11.1 (5.49)	[7.5, 14.7]	11.1 (5.38)	[7.4, 14.9]
	POMS—depression	3.4 (3.64)	[1.1, 5.8]	12.5 (8.38)	[6.7, 18.3]
Self-esteem	RSES total score	24.4 (4.64)	[21.4, 27.5]	17.6 (6.97)	[12.8, 22.5]
Social functioning	SFS social withdrawal	101.0 (8.72)	[95.4, 106.7]	96.3 (9.73)	[89.5, 103.0]
	SFS interpersonal communication	120.0 (21.72)	[105.8, 134.2]	116.8 (15.56)	[105.9, 127.5]
	SFS prosocial behaviour	118.5 (8.25)	[113.1, 123.9]	112.1 (16.54)	[106.4, 117.7]
	SFS recreational activities	111.4 (14.43)	[102.0, 120.9]	110.6(19.29)	[97.4, 124.1]
	SFS Independence competence	114.2 (10.18)	[107.6, 120.9]	113.1 (4.63)	[104.6, 122.8]
	SFS Independence performance	112.9 (10.97)	[105.8, 120.1]	113.6 (12.64)	[104.9, 122.4]
	SFS employment	103.1 (12.53)	[94.92111.3]	102.3 (7.42)	[97.1, 107.4]

Abbreviations: KIMS, Kentucky Inventory of Mindfulness Skills; POMS, Profile of Mood States; RSES, Rosenberg Self-Esteem Scale; SANS, Scale for the Assessment of Negative Symptoms; SAPS, Scale for the Assessment of Positive Symptoms; SFS, Social Functioning Scale. EPI-MAP, Early Psychosis Intervention - Mindfulness Ambassador Program; EPI-TAU, Early Psychosis Intervention - Treatment As Usual.

3.3 | Ancillary analyses

The data from the participants who withdrew were not included in the ancillary analyses. See Table 2 for descriptive statistics for each of the outcome measures, stratified by randomized group. The

confidence intervals for the Fatigue and Depression subscales of the POMS did not overlap, which is suggestive of a statistically significant difference between the groups at follow-up. These data suggest that participants in the EPI-MAP group reported significantly lower

depressed mood and lower fatigue compared to the EPI-TAU control group at follow-up. The confidence intervals of the remaining ancillary outcomes did overlap to varying degrees.

4 | DISCUSSION

This pilot is the first of its kind to introduce the Mindfulness Ambassador Program to an EPI sample. The recruitment rate, retention rate and drop outs suggest that the study design was feasible among youth receiving care at an early intervention for psychosis program. The study provides evidence that the intervention was acceptable and the data suggest that MAP may be beneficial with respect to certain negative emotional states (depression, fatigue) in young adults with early psychosis. These findings regarding mood are consistent with past literature (eg, Khoury et al., 2015).

Although the confidence intervals of the remaining ancillary outcomes did overlap to varying degrees, Sedgwick (2014) states that it is a common misinterpretation that overlapping 95% confidence intervals for two treatment groups implies that there is no significant difference between the groups in outcome at the 5% level. If two 95% confidence intervals for a population mean overlap, it is not possible to make any inference about the statistical significance at the 5% level—either present or absent, of the difference between the treatment groups in outcome. The EPI-MAP group had descriptively higher scores on the RSES than the EPI-TAU groups warranting further analysis of this outcome as part of a larger trial of effectiveness. Beneficial effects of MBIs on self-esteem have been reported in other clinical populations (eg, Biegel, Brown, Shapiro, & Schubert, 2009; Tan & Martin, 2013), but there has been little past prior investigation of such impacts for those with psychotic disorders.

The early stages of psychotic disorders are frequently associated with dysphoria (Birchwood et al., 2007) and such reactions can increase vulnerability to symptoms of psychosis (Birchwood, 2003; Lecomte, Leclerc, & Wykes, in press; Palmier-Claus, Dunn, Drake, & Lewis, 2011). Improving mood through mindfulness could, therefore, be expected to reduce symptoms of psychosis, but there was only the suggestion of such an impact in the current study. Previous trials of MBIs in psychosis yield stronger effects for composite indices of symptoms or mood than for specific positive or negative symptoms (Louise et al., in press) and some advocates for the use of such interventions have argued that primary outcomes should focus on general well-being rather than specific symptoms of psychosis (Chadwick, 2014). Nevertheless, if mindfulness does reduce vulnerability to psychosis, perhaps an index reflecting future likelihood of relapse would be more appropriate.

In their meta-analysis, Khoury et al. (2013) found evidence that MBIs demonstrated pre-to-post improvements in functioning, but these effects were not significant in comparison to control conditions (see also Louise et al., in press). In the current study, with the exception of independent performance of life skills, post-intervention levels of social functioning were generally higher for the mindfulness condition, but larger samples are needed to confirm whether these differences are statistically significant. We also acknowledge that the SFS used in the current study may be more attuned to variation in

functioning in more chronic patients, and a measure more attuned to first episode patients (eg, Lecomte et al., 2014) may be more appropriate for future evaluations.

Our findings suggest that further investigation of the use of MBIs in early psychosis is warranted. Specifically, the descriptive results suggest it would be justified to conduct a larger trial of effectiveness. In addition to the provisos mentioned above with respect to choice of outcome measures, two limitations of the current study which should be addressed in future work are the use of larger sample sizes and longer term follow-up. The current sample size was considered sufficient for the purposes of a pilot trial to evaluate acceptability (Leon, Davis, & Kraemer, 2011). However, a larger sample is needed to formally test between-group differences, especially given the need to correct for multiple testing given the large number of outcome measures. We are currently conducting an adequately powered multi-site RCT that includes a 3-month follow-up time point (ID NCT03143907).

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