



Application of a RE-AIM Evaluation Framework to Test Integration of a Mindfulness Based Parenting Intervention into a Drug Treatment Program

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Abstract

Background The RE-AIM framework was applied to the Mindfulness Based Parenting (MBP) intervention to evaluate the feasibility and effectiveness of this innovative trauma informed model in a drug treatment program. The MBP intervention is aimed at mitigating the stress experienced by women in treatment for substance use disorders, and thereby improving parenting and dyadic attachment between mother and child. **Methods** This was a single arm pre-test post-test design using repeated measure data collected between 2013 and 2016. The design also includes comprehensive process and impact evaluation data. Participants were 120 parenting women enrolled in an opioid treatment program between 2013 and 2016 in Philadelphia, PA. The MBP intervention included weekly 2-h MBP group sessions over 12 weeks, including three dyadic sessions with their child. The main outcomes of this study include the five facets of RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance. **Results** The MBP intervention was associated with improvements in parenting across participants. Data showed implementation and sustainability are contingent upon a strong multidisciplinary team and clinical staff support and “buy-in”. Iterative adaptations of interventions used in the general population may be necessary when working with a traumatized population burdened by low literacy levels, trauma history and co-occurring disorders. **Conclusions** MBP is a feasible and effective intervention for improving parenting and dyadic attachment between women with opioid use disorder and their children, and may be useful for other programs that serve parenting women with substance use disorders.

Keywords Opioid · Parenting · Substance use · Mindfulness

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Significance

What is already known on this subject?

Parenting is challenged in women who are in medication assisted treatment for opioid use disorder, with limited resources and interventions available to support a healthy relationship with their child.

What this study adds?

The RE-AIM evaluation of the trauma-adapted Mindfulness Based Parenting Intervention identifies the necessary supports and resources to implement the model in a clinical setting and recommends tailoring for specific programs. MBP is a novel effective approach to an attachment based parenting design and is needed given the increase in the number of parenting mothers in drug treatment.

Background

The U. S. Department of Health and Human Services labeled the current opioid epidemic a national public health issue (United States Department of Health and Human Services. Accessed May 2017). The five-fold rise in incidence of neonatal opioid withdrawal syndrome highlighted a significant population of mothers with Substance Use Disorders (SUD) (Tolia et al. 2015). This is significant, given previous research demonstrating a mother's drug use is a risk factor for poor parenting (Kandel 1990; Beckwith et al. 1999; Harmer et al. 1999; Bagner et al. 2009). Women with Opioid Use Disorder (OUD) and other SUDs tend to face challenges that may affect their parenting behaviors, including higher levels of parenting stress (Bagner et al. 2009), more depressive symptoms (Liles et al. 2012) and feelings of being a failure (Sheinkopf et al. 2006). Further influencing parenting behaviors of mothers in treatment for SUDs are the effects of drug withdrawal, stresses associated with abstinence, fear of losing custody of their children which can impact parenting self-efficacy, and the time/resources needed for treatment (Marsh and Smith 2011; Osterling and Austin 2008; Sarfi et al. 2011). Enhancing treatment with effective parenting interventions is necessary, although currently funding is targeted to prevention models (Spoth et al. 2013), overdose education (Walley et al. 2013), increased police presence (Johnson et al. 2014), and expanding access to medication assisted treatment (MAT) (Schwartz et al. 2013).

We tested a Mindfulness Based Parenting (MBP) intervention model among mothers in treatment for OUDs. The model was based on a relational approach developed from the principles of mindfulness calling for the full attention of parents when interacting with their children; highlighting aspects of non-judgment, compassion, self-regulation, and cultivating emotional awareness (Duncan et al. 2009). Mindfulness has been tested in populations with SUDs showing improvements in decreased addiction craving and increased acceptance and acting with awareness (Bowen et al. 2009; Marcus and Fine 2001; Marcus et al. 2003). MBP interventions (Dawe et al. 2003; Singh et al. 2006; Coatsworth et al. 2010) have been studied and found to have positive results, although to date none have included a group-based model based in a drug treatment program serving pregnant and parenting women with OUD. The inherent complexity of a group-based drug treatment model requires more than an outcomes-focused lens or optimal/controlled research conditions, but an examination of how to integrate research into real clinical practice in a meaningful and feasible manner.

Reeves et al. (2013) argue interventions that build parental capacity are needed to influence long-term

childhood outcomes, as well as interventions with a strong evaluative component (Reeves et al. 2013) for replicability elsewhere. Published outcomes of studies are widespread, but to increase an intervention's public health impact a comprehensive and systemized evaluation of the feasibility of the intervention are warranted. We used the RE-AIM framework (Glasgow et al. 1999) to evaluate the impact of implementing the MBP intervention within a clinical program. The RE-AIM framework uses five structured domains to evaluate interventions: (1) reach, (2) effectiveness, (3) adoption, (4) implementation, and (5) maintenance. To date, there are no published studies using the RE-AIM framework to evaluate the public health impact of either a parenting intervention or a mindfulness intervention, and a limited number of the published RE-AIM studies looked at populations with SUDs (RE-AIM 2017). These results may bridge the gap between research and practice, informing the research and clinical community of recommendations for similar interventions in opioid and substance use treatment programs.

Materials and Methods

Intervention Design

MBP, a trauma informed intervention based off the tenets of Mindfulness Based Stress Reduction (Duncan et al. 2009), was developed as part of a larger project, "Practicing Safety Project for Mothers in Drug Treatment". MBP included twelve 2-h sessions held weekly, three of which incorporated mother/child dyad time where participants were guided in mindful and intentional play and provided with real-time feedback on their parenting behaviors. The MBP intervention has been described in detail elsewhere (Gannon et al. 2017; Short et al. 2017).

To evaluate the MBP intervention, interviews with project and clinical staff were conducted by research personnel using a set of pre-determined questions as a guide. Notes from these interviews were coded and analyzed as well as data from weekly meeting project notes to inform the evaluation.

Study Sample

Participants were recruited from an urban, university hospital system-affiliated comprehensive SUD treatment program for women who are pregnant, parenting, or working towards regaining custody of their child(ren). The licensed program provides both methadone and buprenorphine maintenance as well as non-medication assisted treatment.

Inclusion criteria for MBP were: (1) enrollment in SUD treatment program, (2) between 28 weeks gestation and 36

months post-partum, (3) current custody of children and (4) English speaking. All study procedures and materials were approved by the Institutional Review Boards at Thomas Jefferson University and the Philadelphia Department of Public Health and are in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Prior to inclusion, all participants consented to the study.

Data Sources

Data for this study were collected between 2013 and 2016 from MBP project files, process notes, four focus groups, and interviews with MBP project and clinic staff.

Measures

RE-AIM Framework

RE-AIM Framework was used to evaluate the MBP intervention. RE-AIM was developed by Glasgow and others (Glasgow et al. 1999) to understand the strengths and weaknesses of an intervention, calling special attention to elements including external validity to study the sustainable adoption and implementation potential of an intervention thereby improving the quality, speed, and public health impact it may have. RE-AIM's utility includes: evaluation of interventions/programs through examination of internal/external validity and how to address dissemination, planning of interventions/programs, policy development, community-based multilevel interventions, and reducing health disparities (Glasgow et al. 1999). Table 1 includes the questions used for each domain, as well as the data sources and tools used to gather this data.

Table 1 RE-AIM implementation framework elements and guide for evaluation 2014–2016

Dimension	Questions	Data sources	Time period data collected	Tools
Reach	What percentage of participants approached agreed to participate in the MBP intervention? Are those exposed representative of your target population? Are the individuals most at risk among those who are reached? Are there any recommended changes in recruitment that you would suggest?	Recruitment rates Attrition/Completion rates Demographic data Staff input	Post cohort 16	Participant database Notes from project meetings including FC staff input
Effectiveness	What is the effect of the MBP intervention on quality of parenting behavior?	KIPS pre and post qualitative data Perceptions of project staff	During cohorts 1–16	KIPS tool Interviews with project staff
Adoption	What are the greatest barriers to adopting the MBP intervention? What supports will need to be in place for other clinics to adopt this intervention? How many settings could adopt this versus how many that did?	Perceptions of project staff and FC staff	Post cohort 16	Notes from project meetings Interviews with project staff
Implementation	What supports need to be in place to ensure the intervention is delivered consistently? What tools/resources are needed to deliver the intervention consistently?	Interviews with staff	Post cohort 16	Notes from project meetings Interviews with project staff
Maintenance	What resources will be needed to maintain the intervention over time? Does the initiative produce lasting effects? Are there sufficient staffing/human/financial resources to sustain the intervention?	Interviews with staff Process notes	Post cohort 16	Notes from project meetings Interviews with project staff

Keys to Interactive Parenting Scale (KIPS)

Quality of parenting behavior was assessed using KIPS, a validated tool sensitive to detecting changes in parenting quality among diverse families, including those with substance use (Comfort and Gordon 2010), in children 2 months to 5 years old. The tool is a structured 20-min observational assessment of the parent–child interaction where parents are asked to play as they normally would. All sessions use the same standard age appropriate toys. The KIPS assessment contains twelve items scored individually on a Likert scale from 1 to 5, with an additional score category of “not observed behavior”. Parenting quality is measured as low quality (mean score of 1.0–2.9), moderate quality (mean score of 3.0–3.9), and high quality (mean score of 4.0–5.0). Three subscales are scored, “building relationships”, “promoting learning”, and “supporting confidence” and a total score. Quantitative results including interrater reliability of the KIPS data are reported elsewhere (Gannon et al. 2017).

Statistical Analysis

Analyses were conducted using IBM SPSS version 23 (IBM., 2015) (IBM Corp 2015) and Atlas version 7 (Atlas, 1999) (Atlas ti 2013). Frequencies were used for Likert scale responses. Means, standard deviations, and percentages were used to calculate specific recruitment, attrition, and completion rates.

Thematic analysis was used to analyze the effectiveness of the intervention on parenting, as well as the evaluation of the intervention’s implementation. Open coding procedures and constant comparative method of grounded theory informed the coding process (Corbin and Strauss 2007). Data files were annotated and coded in the primary data material after creating the hermeneutic unit (the “idea container”). A deductive coding structure (codebook) was created to use as a reference and support the analyses. Initial codes were deducted from the KIPS tool. Emergent codes were created as the data was examined. From these codes, networks (graphical tools for constructing theoretical models) were created which then informed the emerging theory derived from the data. Triangulation was used (looking at how the quantitative component of the KIPS tool compares to the qualitative analyses) to build validity checks into the research design.

Methods used to ensure that the conclusions drawn from qualitative data analyses were valid included logging each step taken in the analytic plan and archiving models from early stages of data analysis. Additionally, memos that were taken with their respective dates acted to document changes and the evolution of the interpretation and development of ideas (Richards 2005). An analytic working group was convened to validate coding integrity. These qualitative data

methodologies are similar to established work in the field (Cabassa et al. 2013). Data was compiled from each dimension and written into a detailed summary of findings. This data was used to generate suggestions to enhance implementation efforts of this intervention at other sites.

Results

Reach

Reach refers to the number, proportion, and representativeness of the individuals willing to participate in this intervention. Participants were mainly Caucasian, unemployed, and single (Table 2). The representativeness of our sample to a random sample of the clinic population was also assessed (Table 2). A total of 283 participants were approached about the intervention by the caseworker, of which only 247 were eligible and 204 consented. Of this, 120 participant data were used for analyses as not all who consented participated in the MBP intervention due to selection into control group or attrition before the intervention began.

Effectiveness

Effectiveness examines the effect of the MBP intervention on the quality of parenting behaviors of participants. Quality of parenting behavior was the outcome studied to

Table 2 Baseline demographics of participants 2016

Characteristic	N = 120 Study partici- pants	N = 167 Clinic partici- pants	P
Parent age (years, SD)	30.68 (4.24)	30.50 (5.48)	0.99
Race			
African American (%)	6.7%	13.6%	0.06
Caucasian (%)	68.3%	68.0%	0.96
Multiracial (%)	5.8%	2.7%	0.19
Other	19.2%	15.7%	0.44
Ethnicity			
Hispanic (%)	10.0%	13.6%	0.36
Non-Hispanic (%)	90.0%	86.4%	0.05
Education			
8th grade or less (%)	5.0%	6.8%	0.53
Some high school (%)	22.5%	28.6%	0.25
High school (%)	27.5%	62.1%	P < 0.0001
Some college (%)	22.5%	1.4%	P < .00001
College (%)	4.2%	0.70%	P < 0.05
Number of children (SD)	2.78 (2.02)	1.85 (1.42)	1.00
Employment (SD)	9.2%	8.8%	0.92

SD standard deviation, % percentage

evaluate the effectiveness of the MBP intervention. Primary outcomes are reported elsewhere (Gannon et al. 2017; Short et al. 2017). In this article, we report on the qualitative data by KIPS subscale as previously reported quantitative results (Gannon et al. 2017) revealed clinically significant improvements in KIPS total and all subscale scores.

Building Relationships

As previously reported, a large clinically significant increase in the KIPS construct, Building Relationships was observed post-MBP ($P < 0.0001$, $d = 1.25$) suggesting mothers' ability to build relationships with their child improved from "low quality" at baseline to "moderate quality" at program completion (Gannon et al. 2017). Qualitative findings suggest a major shift in the relationship between the dyad was an increase in sensitivity to toddler cues. Participants appeared less frustrated and reactive at follow-up, and more able to read the cues of their toddlers. As a result, mothers were better able to support the child's emotions and become involved in the child's activities. There was an improvement observed in physical play between the dyad, notably in the mother matching her child's preference for physical rather than sedentary play, more movement across the room, physical holding and soothing of the child and less interacting with their child in a mechanical way.

Participants were also deferring to their child's preferences for toys/activities, rather than the preoccupation with self-interest in toys observed at baseline assessment. Mothers were able to sustain interest in an activity with their child for a longer period of time. More facial expressions and positive emotions (smiling, laughing) were evident at follow-up demonstrating improvement in appropriate modeling of emotions, as well as in the range of emotions and affect in the mother. At baseline, emotional affect was largely absent compared to follow-up, where there was apparent sharing in emotion between the dyad as well as more verbalization of emotions and lingual expressions of tenderness towards the child.

Promoting Learning

As previously reported (Gannon et al. 2017), a large clinically significant increase in KIPS construct Promoting Learning was observed post-MBP ($P < 0.0001$, $d = 1.29$) indicating mothers' ability to promote their child's learning improved from "low quality" to "moderate quality" at program completion. Observationally, while there was not a difference noted between baseline and follow-up in terms of language development (use of simple phrases, labeling of objects and colors, reading, singing), there was an improvement observed in participants pausing after posing questions to their child to await a response as well as attempts

at conversational dialogue. Reading was a very meaningful activity to the participants and often the first activity they directed their child to. At follow-up, there was an improvement in the way the mothers would try to relate pictures and objects in the books to their child's daily lives.

A need for education in child development was apparent at baseline and follow-up. Participants appeared challenged in knowing what activities and behaviors were appropriate for their child's age. This often was accompanied by frustration and lack of confidence in parenting, which would lead to decreased parental involvement and interest in play.

Mothers exhibited more ability to make adjustments in their play by reading their child's cues, as well as in how they set limits with their child by remaining calm, explaining why they were saying "no", re-directing play, and following through on consequences.

Supporting Confidence

As previously reported (Gannon et al. 2017), a highly clinically significant increase in the KIPS construct Supporting Confidence was observed post-MBP ($P < 0.0001$, $d = 1.39$), indicating mothers' ability to build confidence in their children improved from "low quality" at baseline to "moderate quality" at program completion. At baseline mothers exhibited intrusive and frequent directions to their child which ultimately discouraged the child from thinking on their own. At follow-up the directions (verbal and physical) were much more supportive and encouraging. This was evident in clapping, smiles, words, as well as sustained attention to the child during play. Lastly, there was less exertion of control restricting play and exploration at follow-up. This was seen in the mother allowing the child more time in between activities to play with or discover toys, allowing the play to happen without attempting to direct it.

Adoption

As previously reported (Gannon et al. 2017), participants in the program completed an average of 8 of 12 sessions. Adoption looked at the supports and barriers to adopting the MBP intervention at the clinical site. Several barriers to adoption on the setting level exist including scheduling conflicts between clinical groups and MBP which prevented some mothers from participating. Some individual level barriers also interfered with the participant's adoption of the intervention including: the participants' past history of trauma which often leads to a disconnection to the body, histories of negative self-judgment that is exacerbated by drug use, chaotic home lives, and their children's illness and inability/hesitation to leave their children at the child care center on site. As previously reported (Gannon et al. 2017), our

participants had an average of four adverse child exposures at baseline, denoting a significant trauma burden.

The fundamental support that existed to ensure the intervention was adopted was its multi-disciplinary research team including a pediatric physician, PhD researchers, social workers, mindfulness based stress reduction teachers, epidemiologist, addiction specialists, clinical supervisors from the treatment program and caseworkers. Additionally, a peer specialist was important in reviewing recruitment and intervention materials prior to roll out and their feedback strongly informed the final materials used. Another important support to adoption of the intervention was the integration of clinical staff from the treatment program into the research project, through MBP updates during weekly clinical meetings, using mindfulness language in treatment, and being a resource for a participant if they presented to MBP with a pressing clinical issue.

Implementation

Implementation was evaluated by looking at the supports, tools, and resources needed to deliver the MBP intervention consistently to ensure fidelity. The complexity of the systems the intervention operated within (two urban hospitals), as well as the complexity of the lives of the participants necessitated a significant amount of staff salary and personnel to be supported by the grant.

Supports to ensure the intervention was delivered consistently included training of project and clinic staff in mindfulness and trauma informed care. The number of staff trained in mindfulness increased from 12 to 77%. Other supports to ensure the intervention was delivered consistently were meticulous curriculum notes, weekly process meetings among MBP teachers, MBP session debriefs with project staff, and continuous reinforcement of the study objectives/goals outlined in the original grant proposal.

Weekly notes comprised of the MBP teacher's reflections on how the session was experienced, session content, attendance, highlights, and challenges and were circulated to a subset of the research team for feedback. While fidelity to the intervention was the focus, adaptations to the curriculum were required to tailor the intervention to the needs of this population, including those who may have trauma histories, shorter attention spans, and low literacy levels. Some examples of adaptations include: focusing the body scan away from areas of the body that are common targets of assault, shortening meditations from 25 to 45 to only 5–15 min, simplifying language, allowing for eyes open meditations, option of standing or sitting meditations, movement, eliminating jargon, and repeating key terminology. Mothers had many barriers to adopting home practice (shorter attention span, lack of child care, complicated personal and family issues), thus instructors stressed

the importance of informal practice to give the participants freedom in how they practice mindfulness. Participants were surveyed in four focus groups (total N = 35) to evaluate the usefulness of tools offered in MBP and found yoga, mother child time, the breath, and the body scan to be the most useful.

Maintenance

Project activities that were sustained include: diffusion of mindfulness resources throughout the clinic through email and in meetings, meditations at beginning of counseling sessions and staff meetings, and mindfulness, yoga, and MBP onsite. Additionally, participants who completed the MBP program twice were eligible for scholarship into a local nationally recognized Mindfulness Based Stress Reduction (MBSR) course.

Diffusion of the intervention into the participants' daily lives were evident through the participants' self-report of using mindfulness language at home with their children and in their relationships with their partners, allowing them to remain calm during disagreements and not engage in unproductive exchanges (Table 3).

Discussion

The RE-AIM evaluation revealed the MBP intervention to be feasible and effective. This is the first study to use the RE-AIM framework to evaluate a MBP intervention targeting parenting women in medically assisted treatment for opioid use disorder. RE-AIM of the MBP intervention highlights the importance of a strong collaboration between research and clinical staff as well as the importance of adapting mindfulness curricula to be trauma-informed.

Table 3 Survey of participants' perceptions of usefulness of MBP tools and resources 2016

Tools	Number participants found tool useful N (%)
Yoga	35 (100)
Mother/child time	35 (100)
Body scan	30 (86)
Breath	32 (91)
Glitter globe	27 (77)
Mid-week note	5 (14)
STOP	25 (71)
Handouts/binders	5 (14)

Reach

The complicated lives of mothers in drug treatment were evident when evaluating the Reach domain, such as a lack of child care, employment, and clinical issues with their recovery. Repeated crises are common in basic needs such as food, shelter, and working utilities. Additionally, participants withdrew from the MBP intervention due to changes in child custody, feeling overwhelmed with other commitments, or being discharged from the treatment center.

From the first cohort, several participants expressed interest in repeating the intervention. Allowing repeaters served the project well in two important respects: (1) validating the acceptability of the intervention, and (2) allowing these “repeaters” to serve as “peer models” to others in the group. Three participants to date have gone on to complete MBSR training, and there is interest in leading a peer group demonstrating the leadership MBP has given them.

Effectiveness

Kabat-Zinn’s definition of mindfulness (Kabat-Zinn 1994) posits that it arises from a clear intention for self-regulation, self-exploration, or self-liberation. The participants in the present study cited any combination of these intentions (especially self-regulation) when bringing their attention to observing the moment with acceptance, kindness, and compassion. Shapiro and others (Shapiro et al. 2006) have described the practice and cultivation of mindfulness as re-perceiving, which can lead to increased clarity, self-regulation, and cognitive and emotional flexibility. Considering the stress and challenges in the dyad relationship this increased emotional flexibility is paramount. Letting go of the self-critic and judgment allowed them to be with themselves in the present. The space created in the reduced pace of play allowed the mother to value her child’s interests, which supported their relationship and helped the child build confidence.

Adoption

The integration of clinical staff into the MBP sessions was critical to the success of the MBP intervention. This afforded the group some authority as well as a resource if a participant arrived to the group with a pressing clinical issue. Future iterations would benefit from utilizing the counselors in a larger capacity to reinforce goal setting.

Considering the adoption of the MBP intervention at other sites, it would be critical for sites to consider their own specific patient populations for site specific adaptations. Additionally, staff buy-in and integration of the project with clinical staff is essential. Other considerations for dissemination include careful attention to how the intervention is

rolled out; word of mouth from the first participants experiences sets the tone for how the intervention is perceived by other women who are in therapy in the clinic. A positive experience by participants created buy-in, and encouraged others to enroll.

Implementation

Implementation of the intervention was successful due to staff training in mindfulness and trauma informed care. A barrier to implementation was the need for additional support in parent education. While parent education and childhood development is not the central focus of MBP, integration of these topics would increase the effectiveness of MBP training as it enhanced mothers’ ability to develop appropriate expectations of basic childhood development milestones and behavior.

Maintenance

One of the foundations to maintaining the intervention over the long term is the continual adaptation to the culture of the population it serves, reflecting their histories of trauma and the complexities of living in poverty. Coordination with other pre-natal, post-natal, and parenting groups is key to integrated care. Another key to maintaining the intervention over time is the use of acronyms and tailored mindful phrases to aid the participant in their retention of the materials. An example of a common phrase used was “Caring, calm, consistent parents connect and help children cooperate”. Other phrases such as “What you feed grows” and “Catch them being good and comment on it” help the participant learn to reinforce good behavior. Another recommendation is to use group-created slogans and recovery language in class instruction.

As MBP participants had more college experience than the sample taken from the general population this may contribute to a selection bias into a research study which may infer this group of women were more receptive to the intervention. Self-report bias is another limitation, as several data sources in the study relied on self-report and recall bias. While this evaluation focused on clinical and staff perspectives, it would be beneficial to add more participant perspective to this framework. Regarding the KIPS assessment, there is potential that observed behavior is not indicative of regular interactions between the mother/child dyad. As this was largely a feasibility study, there was no control group which limits generalizability. Further, this was tested in an urban clinic which may also hinder generalizability to rural clinic populations. Lastly, long-term follow-up is needed to investigate the durability of the intervention over time.

In summary, data from the RE-AIM shows the effect the intervention has had on the participants’ home lives

and relationships. The RE-AIM evaluation also outlined a very thoughtful iterative process of continually adapting the MBP intervention to fit the needs of this population. Thus, while the MBP intervention showed improvement among the participants who experienced the intervention research is needed in a larger randomized sample and at other sites to examine its application impact on parenting, treatment and recovery. The RE-AIM model identifies the necessary supports and resources to implement the model and recommends tailoring for specific programs. MBP is a novel approach to an attachment based parenting design, enhancing the emotional capacity of the parent through attunement, reflection, and compassion to both oneself and to the mother/child relationship. As the population of parenting mothers in MAT for opioid use disorder grows, innovative, trauma-adapted model interventions as this are needed to mitigate the deficits in parenting.

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Compliance with Ethical Standards

Conflict of interest The authors report that they have no conflict of interest.

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