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## Considerations in pediatric intervention research: Lessons learned from two pediatric pilot studies



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## ABSTRACT

**Background and purpose:** Pediatric populations represent a vulnerable research group. Careful thought must be given to many factors when designing and implementing pediatric intervention research studies. This article discusses methodological and implementation lessons learned from two pediatric intervention pilot studies and highlights facilitators and barriers encountered.

**Type of method:** Both studies used a pre/post with 6-week follow-up method and were adapted versions of an evidence-based program, Creating Opportunities for Personal Empowerment (COPE).

**Essential features:** COPE is a 7-session, cognitive behavioral skills building intervention. COPE for Asthma was implemented in schools with small groups for elementary-aged children with asthma and symptoms of anxiety. Mindstrong to Combat Bullying was implemented individually in the outpatient mental health setting for adolescents who had experienced bullying with concurrent symptoms of depression/anxiety.

**Methodological application:** Both intervention studies were successful in achieving their research aims, but more importantly the authors learned important lessons in how to successfully work with pediatric populations in research studies. Legal considerations, such as mandated reporting, suicide risk assessment and the inclusion of parents are reviewed. Other components, such as working with children vs. adolescents, integrating research into school-based settings vs. clinic-based settings, and completing intervention research in a group setting vs. individual setting are discussed.

**Conclusions:** The two pilot studies highlight important factors to consider when designing and implementing pediatric intervention studies. While challenges arise in working with this vulnerable population, research is ultimately needed to provide the best evidence-based care for our future generations.

**Clinical trial registration:** The COPE for Asthma study is registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) NCT03481673.

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### Background

Children and adolescents are considered vulnerable populations in research studies. They may lack the cognitive capacity to protect their own interests and therefore informed consent/assent can be a challenge. Additionally, important safeguards have been put into place to protect pediatric populations in research studies (Protection of Human Subjects, 45 C.F.R. §46; 2018). Though critical and well-meaning, these safeguards create additional considerations for researchers who strive to

conduct research with pediatric populations. This challenge is particularly notable in pediatric mental health, where calls for increased research and intervention studies due to the mental health crisis are abundant. Despite these calls and consequent increased research, pediatric mental health interventions do not always translate quickly and effectively into real-world clinical practices.

One reason for this research-to-practice gap could lie in the design and implementation of pediatric research studies. Particular attention must be paid to the ethics of involving pediatric populations in intervention research. For example, determining whether the study is less than minimal risk or involves a direct benefit to the child, is rooted in the *Additional Protections for Children Involved as Subjects in Research* 45 CFR 46 Subpart D (2018). Also, who will provide informed consent and

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assent? How and when will parents/caregivers (herein referred to as parents) participate in the research study? What are the developmental factors of each child and what are their interaction patterns with the parent providing informed consent? Other considerations include selecting a theoretical background in which to frame the research and considering whether the theoretical background applies to pediatric populations. Another consideration is the measurement tools and if they are they reliable and valid for pediatric populations (Melnik & Morrison-Beedy, 2018). A final major consideration in pediatric research is examining the setting in which the research will take place, such as schools, community settings, outpatient healthcare settings, and how to work with the staff in those settings. Therefore, extra time may need to be factored into the planning and implementation phases of pediatric intervention research.

The purpose of this methods article is to discuss the best practices and lessons learned in conducting intervention research with pediatric populations from two pediatric pilot studies, which both used an adapted version of the Creating Opportunities for Personal Empowerment (COPE) program. The aims of both studies were to examine the feasibility, acceptability, and preliminary efficacy of the adapted COPE program. Though the intervention program and aims were similar, the studies differed in their research setting (schools vs. outpatient mental health department), pediatric age group (child vs. adolescent), and intervention approach (group-based treatment vs. individual treatment). Both studies used a pre-experimental pre/post design with 6-week follow-up. Statistical procedures and main outcomes have been described elsewhere (Hutson & Melnyk, Under review; McGovern et al., 2019, 2020).

**Research methods and essential features**

*Creating opportunities for personal empowerment (COPE)*

Both intervention studies were based on the original COPE program. COPE is a cognitive behavioral skills building intervention that was developed by Bernadette Melnyk (Mazurek Melnyk et al., 2014). Based on cognitive-behavioral therapy, COPE is a 7-session manualized program that has been shown to reduce symptoms of depression, anxiety, stress and suicidal ideation, and improve healthy lifestyle behaviors and academic performance in children, adolescents, and college students. COPE has been delivered to children and adolescents in all 50 states, where teachers in schools, healthcare providers in primary care and private practices, and health professionals in community mental health settings are delivering COPE and receiving reimbursement for the program (Melnik, 2020). COPE has been rigorously studied in a variety of settings, including youth in schools who live in rural and inner-city settings and with youth who are overweight/obese and experiencing chronic recurrent headaches (Hickman et al., 2015; Hoying et al., 2016; Hoying & Melnyk, 2016; Kozlowski et al., 2015; Lusk & Melnyk, 2011b; Melnyk et al., 2013). Importantly, COPE also has been shown

to be feasible and cost-effective in the health care setting (Lusk & Melnyk, 2011a, 2011b; Melnyk, 2020). The general curriculum for the COPE program and both adaptations are described in Table 1.

*COPE for asthma*

COPE for Asthma was an intervention study for children with asthma and co-occurring symptoms of anxiety. IRB approval was obtained from The Ohio State University and Columbus City Schools. Children were recruited from one urban school district by sending an interest form home for parents to sign and return. The child participants completed screening tools asking about symptoms of depression (Pediatric PROMIS Short Form for Depression; (Assessment & Center, 2015)) and anxiety (Screen for Child Anxiety Related Disorders; (Birmaher et al., 1999)) during the consent/assent process. Asthma diagnosis was through school records and parental confirmation. Children with positive screens were invited for participation in the study. Full recruitment, the consent/assent process, full screening process, and main outcomes for the study have been described previously but are summarized here ((McGovern et al., 2019, 2020)).

COPE for Asthma was implemented in small groups of four - six children at three different elementary schools in one school district. The children were between 8 and 12 years of age, had a previous diagnosis of asthma and reported symptoms of anxiety or depression (initial screening described above). Groups met during the school day at lunch, once a week for approximately 30 min each time. The target sample size was thirty parent/child dyads but was expanded to 33 dyads due to interest. Parents completed surveys but did not participate in the intervention. The primary outcomes of the study were examining the feasibility and acceptability of the adapted intervention, but secondary aims included examining the effects of the intervention on anxiety/depressive symptoms, self-efficacy, and asthma symptoms and control.

*Mindstrong to combat bullying*

The second study evaluated an adapted COPE program for adolescents, ages 12–17, who had experienced bullying and had co-occurring symptoms of depression and/or anxiety. This study was approved by the Institutional Review Board of Nationwide Children's Hospital. Mindstrong to Combat Bullying was conducted in an outpatient mental health clinic, with the participants completing individual sessions with a member of the research team. Inclusion criteria for this study were: (1) 12–17 years of age; (2) a history of bullying victimization; (3) reporting at least one depressive or anxiety symptom; and (4) willingness of parent to attend two sessions. Sessions occurred weekly and lasted approximately 30–60 min. Participants were recruited from a large children's hospital's behavioral health department. When a parent called to schedule a behavioral health appointment for their child, they were asked, as had been previously determined by the intake department, if their child had experienced bullying in the school setting. If the parent said yes, and positively endorsed at least

**Table 1**  
COPE 7-session curriculum and adaptation.

Session #	Version – Original or Adapted/Added Content	COPE (Original)*	COPE for Asthma**	MINDSTRONG™ to Combat Bullying
1	Thinking, feeling, behaving: What's the connection?		Asthma triggers	Bullying Education
2	Positive thinking and forming healthy thinking habits		Asthma controller medication use and inhaler spacer technique	Self-esteem and positive self-talk during bullying situations
3	Stress and coping		Asthma symptom perception; stress and asthma	Stress and coping in bullying situations
4	Problem solving steps and goal setting		Daily asthma controller use	Problem solving around bullying situations
5	Handling emotions in healthy ways, positive thinking/effective communication		Diaphragmatic breathing	Emotion Regulation, Mental Imagery
6	Managing stressful situations		Asthma triggers	Managing emotions around bullying situations
7	Summary – bringing it all together		Benefits of exercise for those with asthma	No adaptation

\* Paraphrased from Melnyk et al., 2014.

\*\* COPE for Asthma included an introductory week since it was conducted in small groups.

one symptom of depression and/or anxiety, the parent was asked if they would like to be contacted by a member of the research team. From this, as well as online recruitment, Mindstrong to Combat Bullying enrolled 20 adolescents and their parents ( $N = 40$ ) with a retention rate of 75% ( $N = 30$ ). Similar to the COPE for Asthma program, the primary outcomes of this study were to examine the feasibility and acceptability of the adapted intervention and secondary aims were to examine the effects of the intervention on depression and anxiety symptoms, bullying victimization, self-concept, and somatic symptoms. Similarities and differences in design, sample setting, and intervention delivery format between COPE for Asthma and Mindstrong to Combat Bullying are discussed in Table 2.

#### Methodological application of pediatric intervention studies

During the development and implementation of each study important lessons were learned in working with pediatric populations. First, inherent to working with vulnerable populations, one must consider the ethical and legal issues that could arise. Next, how and when to involve parents is critical in working with pediatric populations. Lastly, for an intervention study, the appropriate treatment modality and setting, in our case small groups versus individual sessions and school-based versus clinic-based, must be considered. The methodological application section reviews the most salient points we learned during the development and implementation of each study.

#### Ethical and legal considerations

Inherent with any research study are protections for participants and, as a vulnerable population, children have extra required provisions in research (Protection of Human Subjects, 45 C.F.R. §46; 2018). Consent and assent processes, level of risk, and benefit to risk ratio are all priorities. Both pilot studies were identified as less than minimal risk, and measures were in place in the event a participant verbalized or demonstrated risk of self-harm or indicated concerns of abuse or neglect.

An example of protective procedures in place with the school-based COPE for Asthma pilot occurred during one of the sessions while reviewing diaphragmatic breathing. The student mentioned an episode of wanting to engage in self-harm during the prior week but had instead practiced the relaxation technique. The interventionist for COPE for Asthma addressed the student after the session ended, conducted a risk assessment, and followed the IRB approved school and study protocols, and referred the student to the school nurse and school social worker.

During the Mindstrong to Combat Bullying program, a participant disclosed abuse that had previously been unreported. The interventionist, also being a mandated reporter, followed hospital policy and the law in reporting the suspected abuse to the appropriate child protective services agency. Additionally, some situations arose where the participants in the Mindstrong to Combat Bullying study were passively suicidal, and

the interventionist followed safety protocols in place by the hospital and approved by the Institutional Review Board (IRB).

In both of the studies, the safety concerns were not necessarily surprising, given the high rates of suicidal ideation and behaviors among adolescents who have experienced bullying (Hinduja & Patchin, 2019) and children who have asthma (Goodwin, 2012). These occurrences underscore the importance of planning for safety concerns in pediatric research studies and having protocols in place that mirror the needs of the research setting location.

#### Parental Participation

In most cases, a legal guardian must be included to provide informed consent, but how much the parent should participate in the intervention research will vary. Some considerations include the outcomes being targeted and whether parents would be active participants with their child in the intervention or play a supportive/reinforcing role. Previous intervention research with pediatric and adolescent populations indicated that outcomes can be improved if parents are directly involved with the intervention (Carr, 2019; Grist et al., 2019). An assumption based on previous pediatric bullying intervention studies for Mindstrong to Combat Bullying was that parents participating in the sessions could help to reinforce session content throughout the week between sessions. However, parent engagement can be challenging due to family work schedules, sibling schedules, transportation and more (Weisenmuller & Hilton, 2021). Additionally, when parents and children participate together in psychotherapy-type interventions, there is a risk that the parent will “take over” the session and the child will not get an opportunity to learn or may not feel comfortable discussing their thoughts or feelings in front of their parent.

COPE for Asthma and Mindstrong to Combat Bullying used different approaches regarding parental participation. The Primary Investigator (PI) for COPE for Asthma was a veteran school nurse who had worked in a large, urban district and, based on her experience interacting with families and knowing the challenging daily demands on parents' time elected to *not* include parents in the intervention. Rationale for this decision was that previous research has indicated that children as young as 6 years old are responsible for administering their asthma medications (Bellin et al., 2017). Additionally, other studies have found that 20% of 7-year old children are managing their medications without parental assistance. By 11 years of age, 50% of children are independently managing their asthma medications (Orrell-Valente et al., 2008). With the above factors in mind, parents in COPE for Asthma did not participate in the intervention sessions, but they did complete the study questionnaires.

Conversely, Mindstrong to Combat Bullying did include parents in two of the intervention sessions, as past reviews have found parent training to be critical in the success of bullying prevention and intervention programs (Farrington & Ttofi, 2009; Hutson et al., 2018). Parent participation in bullying intervention programs have been theorized to be important as youth need to be able to go to an adult when they are dealing with bullying and importantly, the adult needs to be able to provide helpful advice. Specifically, the parents attended session three, which discussed the most bullying education material and session four, which discussed stress and coping with bullying situations. Additional rationale for including parents in the interventions for Mindstrong to Combat Bullying is that parent consent for treatment would need to be transported to the clinic by an adult, presumably a parent, thus parent would likely be at the intervention and participation would not be burdensome. Additionally, it is typically recommended that parents participate in outpatient psychotherapy with their child to some degree (Dowell & Ogles, 2010). Despite this careful planning parent participation was challenging. The rescheduling rate for appointments was 42% and often these were due to parent scheduling conflicts. The bottom line in parent participation in pediatric intervention research is that parents' schedules must be taken into consideration.

**Table 2**  
Similarities and differences in research methodology.

	COPE for Asthma	MINDSTRONG™ to Combat Bullying
<b>Similarities</b>		
Design	Pre/post design with 6-week follow-up	
Intervention	Adapted 7-session COPE Program lasting 30–60 min	
Aims	Feasibility and Acceptability of the adapted intervention and preliminary outcomes	
<b>Differences</b>		
Settings	Elementary School	Outpatient Mental Health Clinic
Population	Children (8–12 years old)	Adolescents (12–17 years old)
Comorbid Condition	Asthma and anxiety/depressive symptoms	Bullying Victimization and anxiety/depressive symptoms
Intervention Sessions	Group sessions	Individual sessions with parents participating in two sessions

with flexibility allowed. An unforeseen benefit of the COVID-19 pandemic is that it has expanded telehealth access, which should be implemented in intervention research as well to increase family participation.

#### *Intervention research with children in small group sessions*

Working with younger, school-aged children requires ongoing flexibility while also creating a routine within the sessions. Varying energy levels and dynamics between children in the groups can affect their ability to receive the intervention, particularly with elementary school students. The COPE for Asthma groups were separated by grades for their lunch times, so the 8–10 year-olds were in one group, while the 11–12 year-old children were in another. The age separation was advantageous, given the developmental differences between the age groups and differing levels of understanding of the intervention. The groups reported they enjoyed the small group activities, particularly during the lunch period. At the start-up of the COPE for Asthma intervention, although the interventionist needed to remind a few students of the day of the intervention session, they quickly caught on to the schedule and often would see who could arrive to the room first. Anecdotally, we also found that the children tended to be more settled, able to focus, and engage in sessions when they had recess prior to lunch.

Each COPE for Asthma session had a similar schedule. The approach was used to enhance fidelity of implementation and create a predictable routine for participants. Specifically, participants would arrive at the meeting room and start eating their lunch while the interventionist reviewed aspects of prior content and home practice (i.e., instead of framing it as “homework”). Then, objectives for the current session were reviewed and the content covered. Finally, the participants completed the comprehension questions, and the upcoming home practice sheet was reviewed, followed by dismissal to their scheduled classes. The above format allowed participants to settle into a routine and focus on the session content while enhancing efficiency with the limited time frame.

Over the course of the COPE for Asthma implementation, we discovered the need to modify a session because the children had difficulty understanding the content. We did not want to move on until we felt comfortable with their comprehension. Therefore, the session related to recognizing the difference between thoughts, feelings, and behaviors was split into two different sessions to assure the participants had a solid comprehension of the content.

Peer dynamics or previous interactions at school between children may create challenges within the group setting, particularly with the older children. During the introduction week, group guidelines were developed to help create a safe space for the participants. The PI did not encounter any situations/hurt feelings that could not be quickly resolved among participants. For example, two participants in one of the groups had been bantering about a situation prior to one the sessions; specifically, one participant “called out” the other about being dishonest. The interventionist was able to address the situation by encouraging the skills of respectful listening and taking responsibility for actions even when it is uncomfortable. Helping young people learn to navigate these circumstances is a powerful life-skill.

Lastly, some children were distressed when the COPE for Asthma sessions ended. A transition plan will be included in future studies and the intervention has been adapted to include social cognitive theory constructs to build social support in the groups that receive the intervention. On a positive note, participants in the groups were able to interact and develop relationships with children in other classes and grades that they would not have otherwise. Congruent with previous research (Stewart et al., 2011), the children reported appreciating the small groups and knowing “others like me.”

#### *Intervention research with adolescents in individual sessions*

Intervention research with adolescents involves its own set of considerations. The PI for Mindstrong to Combat Bullying had worked in

adolescent mental health for years and was well versed in the adolescent developmental period. The first adaption in the intervention process for adolescents was incorporating technology. Studies have found that over 95% of adolescents have a smartphone (Pew Research Center, 2018) and while many complain about adolescent smartphone overuse the researchers decided to harness the smartphones' power for this study. It was quickly recognized that adolescents struggled to remember to say their positive self-statements, which was their homework each week, so the research team discussed using their phone alarms to remind them or taking pictures of their written self-statements to help remember what they were. Rolling with resistance is key in working with adolescents.

Another consideration in working with adolescents in this study was whether to separate the parents and adolescents for their sessions or keep them together. It was initially decided to separate them for rapport building and engagement, however, it was discovered that many of the adolescents had difficulties opening up during the first session, so parents were brought in to facilitate this process. For example, at the end of the first session, the adolescent was asked to name things they liked about themselves. Due to the defeating nature of bullying, many adolescents struggled with self-esteem issues. We found that by having the parent sit in and name things they liked about their child brought joy to the adolescent and provided for an important bonding opportunity between the parent and child.

A final consideration for appointments with adolescents is to offer after-school appointments. This can be challenging with clinic hours often ending at 5:00 pm. Again, this is an area where telehealth could be used to offer increased flexibility in later appointments and parents and children being able to have the appointment at home.

#### *Intervention setting*

##### *School-based interventions*

The school setting can be an optimal place for interventions with children and youth since transportation is not an issue. In addition to addressing the ease of access, several other pre-implementation activities were critical to the success of the project. Specifically, stakeholder (e.g., Superintendent, Division/Area Directors in the district, Director of School health, building administrators, county public health division where applicable) education and buy-in at the district and school levels created a baseline of support essential when implementing school-based interventions. School staff (i.e., office staff, teachers, cafeteria workers) were educated regarding the goal of the project and importance of maximizing available time for group sessions. Teachers, school nurses, and secretaries were informed that a possible benefit for them could be less disruption of the school day if the children were less anxious and had well-controlled asthma.

To expedite the participants' getting to the session location at lunch time, children were given neon green tags labeled “fast passes” so they could go to the front of the lunch line, pick up their lunch, and promptly walk to the location where the group sessions were being held. School staff also helped remind students (e.g., participants) which day they had their “lunch bunch” group. Working in the school setting requires flexibility and ingenuity. A dedicated room for the sessions was not necessarily guaranteed each week and even with advanced scheduling, we discovered it was best when the interventionist arrived early to ensure availability.

Several challenges were encountered during recruitment and implementation of COPE for Asthma. School administrators and teachers assisted in planning the sessions around school assemblies and field trips, but communication with all school staff and flexibility was key. First, the school nurses initially thought they needed to assess children with asthma and evaluate whether they believed a child could have anxiety/depressive symptoms instead of sending the recruitment form home to all children with asthma. Although they were trying to be helpful, the interventionist needed to clarify that all children with asthma

were to be given the recruitment form to take home. Second, a teacher at one school intermittently wanted to withhold participation as a punishment for a child misbehaving during class time. This was remedied by talking to the teacher about alternative ways to manage the child's behavior. Third, disruptions such as emergency drills, weather-related school closures, and field trips could not always be anticipated.

#### *Mental health outpatient care-based interventions for adolescents*

While we initially considered conducting the research in the school setting, ultimately the confidentiality of the adolescent participants who had experienced bullying would have been difficult to maintain. Additionally, after conversations with school personnel and clinicians revealed that adolescents who had experienced more severe acts of bullying would be found in the mental health setting, we chose to conduct the intervention in an outpatient mental health clinic. This setting was optimal because other research had taken place there and the clinic staff was familiar with research procedures. A major consideration, which turned out to be a benefit for this research study was that the research staff were well known to the other clinicians in the clinic. These relationships were shown to be critical in that the other clinicians felt comfortable referring their patients to the research study.

Despite this, it was discovered that clinic staff would forget about recruiting research participants, so flyers were hung in the office, and announcements about the research project were made at staff meetings at regular intervals. It was also important to work with clinic staff to integrate the research protocol into the clinic procedures as much as possible. For example, the research screening questions were pulled directly from the clinic intake department, so that it would not create extra questions for the intake staff. The check-in process was also the same for research participants as clinic patients. One of the most important aspects to keeping the research momentum going was having the research staff have a physical presence at the clinic. This helped remind the providers about the study while they were seeing patients who were potentially eligible.

The most challenging issue for this project was the number of appointments that needed to be rescheduled, due to parent-related factors. Frequently, parents needed to reschedule for reasons outside of their control, such as other child illnesses, work conflicts, and their own health. This rescheduling ultimately made feasibility of delivering all sessions of the program challenging. Therefore, when designing an intervention study for pediatrics, the research team must carefully weigh the risks and benefits of parental involvement and consider more flexible appointments, such as with telehealth.

#### *Lessons learned highlights*

Small Group, School -Aged	Individual with Adolescents
<ul style="list-style-type: none"> <li>• Communicate with school staff about assemblies and fire/tornado drills already scheduled</li> <li>• Schedule a consistent time, day, and room as much as possible</li> <li>• Provide "fast passes" for children to expedite arrival to the sessions</li> <li>• Include a transition plan to build social support among participants</li> </ul>	<ul style="list-style-type: none"> <li>• Use technology!</li> <li>• Offer flexible, after-school scheduling</li> <li>• When in doubt, include parents in the session, but allow some individual time for adolescent to process on sensitive topics</li> <li>• Be aware of shortened attention spans and how to monitor engagement</li> </ul>
Both Approaches	
<ul style="list-style-type: none"> <li>• Stay in close communication with staff and clinicians related to the recruitment process.</li> <li>• Be flexible within the structure of protocols for unexpected disclosures during sessions.</li> <li>• Understand your rationale about whether to include parents in the receipt of the intervention.</li> </ul>	

#### **Conclusions**

The two pilot studies presented provide rich methodological information and lessons learned related to interventions in two different

settings and with different populations and different modes of intervention delivery. Both studies were adaptations of an evidence-based intervention that is manualized and theoretically driven and were ultimately well-received by their participants (Hutson & Melnyk, 2021; McGovern et al., 2019, 2020) even though each was delivered in different settings with and without parental involvement. Both formats, the individual and small groups, were successful for different reasons. While small groups were well-received by school-aged children, the older child and adolescent population may experience challenges related to social dynamics in the group setting and prefer the individual format. When conducting interventions in the group setting, children share information during the sessions that may be private. Maintaining confidentiality of the information shared must be continually emphasized among participants – respecting confidentiality can be difficult for children, depending on their age. Additionally, the individual setting may be more appropriate for situations where privacy and confidentiality are priorities or where the condition under study may be highly personal or stigmatizing, as was the case for bullying research.

Several key points were reinforced for each study methodology. For school-based implementation, flexibility and maximizing the available time is key. School assemblies, room changes, and weather are among factors that will affect implementation. Streamlining the participants arrival to the meeting space by reminding teachers and providing "fast passes" can save time. When working in the outpatient setting, maintaining a physical presence in the clinic is important to remind staff about recruiting for the study. As with the school-based population, flexibility is important for after-school appointments and telehealth should be considered for ongoing parent scheduling and transportation issues.

Ultimately, scalable interventions for children and adolescents experiencing mental health concerns are urgently needed. The pilot study methodologies discussed identified strategies for enhancing success in conducting pediatric intervention research in school-based and outpatient mental health settings highlighted several key potential barriers and our successful solutions to implementation. This information is critical in informing the design and implementation strategies for larger scale studies.

#### **Authorship**

Colleen McGovern conceptualized the manuscript, completed the initial draft of the manuscript and approved the final manuscript as submitted.

Dr. Elizabeth Hutson conceptualized the manuscript, contributed to text, writing and revising the manuscript, and approved the final manuscript as submitted.

Kimberly Arcoleo: Dr. Arcoleo conceptualized, supervised, and contributed to the text, revised the manuscript, and approved the final manuscript as submitted.

Bernadette Melnyk contributed to the text of the manuscript, and approved the final manuscript as submitted.

#### **Originality**

All writings are original except where other works are cited.

#### **Multiple publications**

No previous manuscripts have been published with the information from this paper.

#### **Ethical approval**

Approval from the appropriate Institutional Review Boards was obtained for this study.

### Declaration of competing interest

Bernadette Melnyk has a company, COPE2THRIVE that disseminates the COPE program. Colleen M. McGovern, Elizabeth Hutson, and Kimberly Arcoleo report no financial interests or potential conflicts of interest.

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