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Participant-level characteristics differ by recruitment setting when evaluating a behavioral intervention targeting adolescents with asthma

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ABSTRACT

Objective: The recruitment setting plays a key role in the evaluation of behavioral interventions. We evaluated a behavioral intervention for urban adolescents with asthma in three randomized trials conducted separately in three different settings over the course of 8 years. We hypothesized that characteristics of trial participants recruited from the ED and clinic settings would be significantly different from that of youth participating in the school-based trials. The intervention evaluated was Puff City, a web-based program that uses tailoring to improve asthma management behaviors.

Methods: The present analysis includes youth aged 13–19 years who reported a physician diagnosis of asthma and symptoms at trial baseline. In the three trials, all participants were randomized post-baseline to a web-based, tailored intervention (treatment) or generic web-based asthma education (control).

Results: Compared to school-based trial participants, ED participants had significantly more acute-care visits for asthma ($p < 0.001$) and more caregiver depression ($p < 0.001$). Clinic-based participants were more likely to have computer/ internet access than participants from the school-based trial ($p < 0.001$). Both ED and clinic participants were more likely to report controller medication (p 's < 0.001) and higher teen emotional support (p 's < 0.01) when compared to the schools, but were less likely to report Medicaid (p 's < 0.014) and exposure to environmental tobacco smoke ($p < 0.001$).

Conclusion: Compared to participants in the school-based trials, participants recruited from ED and clinic settings differed significantly in terms of healthcare use, as well as psychosocial and sociodemographic factors. These factors can inform intervention content, and may impact external validity of behavioral interventions for asthma.

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Introduction

Asthma continues to be a major public health challenge for the US and remains among the top chronic diseases causing missed school or work (1). Interventions designed to motivate patients to adapt behaviors and management strategies that can improve asthma control are best evaluated using a randomized controlled trial (RCT) (2–4). RCTs are often criticized because external validity (or the ability to generalize results to other populations) can be questionable (5,6). Particularly for asthma, when evaluating behavioral interventions, generalizability of

results may depend on the recruitment setting (5). The literature shows that p participant characteristics shown to be related to asthma management are strongly associated with the context in which youth and their families live (7–9). For example, researchers have found that asthma for some families is treated predominantly in the emergency department, so that participants recruited from the ED could be very different from those recruited from community or primary care clinic settings (10–12). In addition, patients recruited from the ED may be less likely to have health insurance, and/or a regular physician, or have a

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history of specialty care than patients recruited from a physician's office (12,13). It has also been reported that adolescents presenting to the ED for asthma may have asthma that is more severe, or mild/moderate asthma that is uncontrolled, or asthma that is co-morbid with other conditions (13–16). Recruiting from schools, however, where health insurance and health care access do not necessarily factor into the probability of being asked to participate in a trial, may result in a study sample more representative of the surrounding community (17). Together, these reports suggest that the recruitment setting should guide intervention content and delivery (13–15). Differences in recruitment settings have not been the topic of many asthma publications (18). In systematic reviews of asthma interventions, authors give considerable attention to where the intervention is delivered, but seldom make comparisons between recruitment settings (4,15). Nonetheless, early decisions facing investigators conducting behavioral trials in asthma include the selection of the setting for participant recruitment, and this decision may play a key role in the external validity of results (12).

We have had the opportunity of conducting three separate RCTs for one asthma intervention in three different time periods, using three different recruitment settings. The intervention was Puff City, a tailored, online asthma management tool for urban teens which was evaluated over the course of 8 years in public high schools, emergency departments, and primary care clinics (2,3,19). To our knowledge, we are unaware of studies within the last 10 years evaluating such a comparison (4,15). This paper describes the observed differences in participant self-reported demographics, healthcare utilization, asthma management behaviors, and psychosocial factors for the three settings. We hypothesized that patient-level characteristics of youth diagnosed with asthma and recruited from the emergency department or from primary care clinics to participate in an RCT of an asthma intervention, would be significantly different from that of patients recruited from high schools.

Methods

All study methods were approved by the Henry Ford Health System (HFHS) Institutional Review Board (IRB) and the IRBs of partner healthcare systems and institutions. Detailed recruitment methods for all three trials are described in previous publications (2,3,19). Briefly, for the school-based trial, parents of Detroit high school students attending one of six participating schools were notified of a health questionnaire to be

administered during a scheduled English class (19). Parents or students could opt out at any time. The questionnaire contained standardized and validated questions on asthma and asthma symptoms (19). Youth were eligible to participate if they had current asthma defined as report of ever having a physician or health care provider diagnosis of asthma accompanied by day or nighttime symptoms, use of medication for asthma symptoms in the past 30 days, medical care use for asthma in the past year, and ≥ 1 refill of beta agonists in the past year (16,20). These criteria were used to develop an algorithm that could then be applied to the questionnaires by a school contractor managing data for the district.

In the ED-based trial, five HFHS pediatric clinics located throughout the metropolitan Detroit were included (2,13). Two recruitment methods were used. The setting included First, age-eligible patients presenting to the ED with acute asthma exacerbations were recruited, consented, and enrolled in the ED by research staff. A second method used the electronic medical record (EMR) to generate listings of age-eligible patients making recent ED visits for asthma (3). Patients were contacted via mail and telephone and invited to participate (3).

The clinic-based trial included five HFHS pediatric clinics located throughout the metropolitan Detroit (2,13). The EMR was used to create a master list of patients meeting Healthcare Effectiveness Data and Information Set (HEDIS) criteria for persistent asthma (21). This master list was linked to the appointment scheduling system and monitored daily by research staff to identify potential participants with upcoming or same-day appointments (2). When patients were identified, the clinic was notified, and research staff were deployed to the clinic to recruit and enroll (22).

All three trials began with a baseline survey completed by the teen. With the exception of the clinic-based trial, caregivers of participants were also asked to complete a caregiver baseline survey. For all three trials, participants were randomized to receive four of the 20–30-min sessions of the Web-based program (Puff City) or an equal number of sessions of existing online asthma education (control) (2,3,19). Primary outcomes were measured at 12 months, and included indication of improved asthma control as determined by symptom-days (school-based trial), reduction in ED visits (ED-based trial), and improved Asthma Control Test (ACT) score (clinic-based trial).

Definitions

The following are definitions of standardized and validated tools used in the three trials. The Asthma

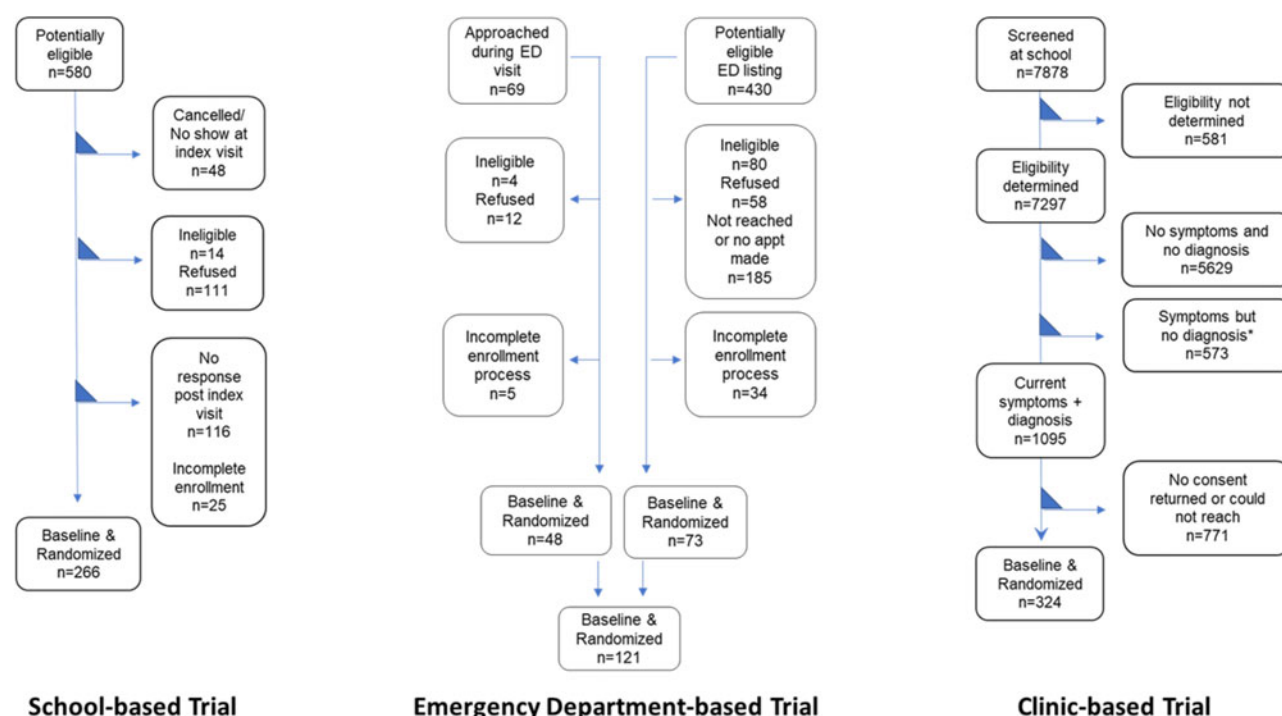


Figure 1. Consort charts for trials conducted in three different settings. *Only physician-diagnosed asthma included in this analysis.

Control TestTM or ACT, is a 5-question, patient-based tool designed to help physicians identify patients with poorly controlled asthma, assess frequency of asthma symptoms, use of rescue medications, and impact of asthma on daily functioning over the course of the previous 4 weeks (22). Definitions for the psychosocial variables are detailed in previous publications (2,3,19,23). Briefly, the Asthma Self-Regulation Instrument (ASRI), theorizes that self-regulation of asthma follows a sequential path and is influenced by fundamental beliefs about the condition, perceptions of vulnerability, and the perceived ability to manage the condition (24). The tool categorizes participants into one of four sequential phases (1–4) with lower phases representing less self-regulation. Mean ASRI for each sample is presented. Teen perceived emotional support was determined using questions adapted from the Multidimensional Scale of Perceived Social Support using a Likert scale of 1 = low support and 5 = high support, in response to “How much support do you feel you have when it comes to controlling your asthma?” (25). Caregiver perceived social support was determined by 12 questions from the Medical Outcomes Study Social Support Survey (26), including questions on emotional, informational, and tangible support, each on a Likert scale from 1 = none of the time to 5 = all of the time. Overall support is calculated as the mean of the 12 questions. Caregiver depression was defined as a response of ≥ 8 days’

duration to ≥ 4 of the questions on the Patient Health Questionnaire-9 completed by the caregiver (27). It is based on the nine diagnostic criteria for depression as per the DSM-IV and queries the caregivers about depressive symptoms in the prior 2 weeks (27).

Statistical methods

The study settings were compared using the chi-square test for categorical variables and 2-sample t-tests for normally distributed numerical variables. For comparisons involving non-normally distributed numerical variables, the Wilcoxon rank sum test was used. The analysis was performed using SAS version 9.4. A p values < 0.05 was used to determine statistical significance.

Results

A consort chart for each trial is presented as Figure 1. Table 1 shows recruitment results and baseline participant characteristics. Targeted enrollment was attained for the ED and clinic populations, with the clinic having 47% of those eligible going on to consent and randomization. Refusals for ED and clinic participants were also similar (16.9% vs. 19.6%, $p = 0.28$).

We were able to compare participants to non-participants when evaluating the intervention in each setting. In the school study, participants did not differ from non-participants, with the exception of sex, in

Table 1. Study and participant characteristics by study setting.

	A (reference) Schools		B EDs		C Clinics			
Recruitment end date	June 2010		Nov 2015		May 2016			
Recruitment Method(s)	School survey		ED visit/listing		Clinic visit			
Pool of potential participants	<i>n</i> = 1095		<i>n</i> = 499		<i>n</i> = 580			
Eligible and report diagnosis, <i>n</i> (%)	1095	(100)	415	(83.2)	566	(97.6)		
Refused, ^a <i>n</i> (%)	See note ^a		ED Visit	(18.4)	111	(19.6)		
			ED listing	(16.5)				
Not enrolled, ^b <i>n</i> (%)	771	(80.6)	224	(54.0)	189	(33.4)		
Randomized, <i>n</i> (%)	324	(29.6)	121	(29.2)	266	(47.0)		
Enrolled, target (% reached)	450 ^c	(72.0)	120	(100)	250	(100)		
							<i>p</i> value	
Demographics							B vs A	C vs A
Age, mean (sd)	15.9	(1.2)	15.4	(1.7)	14.8	(1.6)	<0.001	<0.001 ^d
African American, <i>n</i> (%)	296	(91.4)	107	(88.4)	186	(69.9)	0.347	<0.001
Female, <i>n</i> (%)	183	(56.5)	67	(55.4)	127	(47.7)	0.834	0.035
Mom education ≤ High School, <i>n</i> (%)	143	(49.3)	38	(31.4)	Not available		<0.001	–
Medicaid, <i>n</i> (%)	197	(74.3)	75	(60.3)	10	(3.7)	0.014	<0.001
Computer + Internet access, <i>n</i> (%)	232	(75.3)	86	(71.1)	249	(93.6)	0.366	<0.001
Utilization and morbidity								
≥1 Hospitalization/12 months, <i>n</i> (%)	61	(18.8)	43	(35.5)	15	(5.6)	<0.001	<0.001
≥1 ED visit/12 months, <i>n</i> (%)	135	(42.1)	104	(85.9)	90	(33.8)	<0.001	0.041
≥2 School missed/30 days, <i>n</i> (%)	180	(56.8)	55	(49.1)	93	(35.2)	0.161	<0.001
Asthma management								
Controller medication, <i>n</i> (%)	126	(38.9)	69	(57.0)	141	(53.1)	<0.001	<0.001
Sharing medications, <i>n</i> (%)	84	(27.0)	26	(21.5)	54	(20.3)	0.237	0.060
Report regular asthma doctor, <i>n</i> (%)	161	(56.1)	67	(55.4)	163	(61.3)	0.893	0.217
ASRI, ^e mean (sd)	2.62	(1.17)	2.79	(1.04)	2.45	(1.24)	0.292 ^f	0.127 ^f
Home ETS, ^g <i>n</i> (%)	218	(67.9)	48	(39.6)	82	(30.8)	<0.001	<0.001
Teen smoker, <i>n</i> (%)	25	(7.8)	9	(7.6)	8	(3.0)	0.962	0.013
Psychosocial								
Teen emotional support, mean (sd)	3.84	(0.80)	4.08	(0.71)	4.15	(0.68)	0.004 ^f	<0.001 ^f
CG social support, mean (sd)	4.11	(0.93)	3.95	(1.05)	Not available		0.341 ^f	–
CG depression symptoms, <i>n</i> (%)	34	(12.3)	38	(38.8)	Not available		<0.001	–

Note. All *p* values are based on Chi-Square analysis, unless otherwise noted.

^aYouth were screened using a self-administered questionnaire. Based on questionnaire results, students were invited by mail to participate. Of an estimated 9125 students present in English class, 7878 were screened, 1233 were not screened, and 14 refused screening.

^bNot reached or enrollment appointment not kept.

^cTargeted enrollment was 500 students, of which 90% (*n* = 450) were to be diagnosed. The denominator of 450 is used as only students reporting a physician diagnosis are included in this analysis.

^dTwo-Sample T-Test.

^eAsthma Self-Regulation Instrument with phases 1–4 with phase 1 being less asthma self-regulation.

^fWilcoxon Rank Sum Test.

^gEnvironmental tobacco smoke.

which more participants were female ($p = 0.004$) (19). In the ED-based RCT, participants were significantly more likely to have Medicaid ($p < 0.001$) than non-participants (3,13). In the clinic-based RCT, participants did not differ from refusals in terms of sex ($p = 0.41$), mean age ($p = 0.72$), race ($p = 0.23$), ethnicity ($p = 0.91$), and gaps in health insurance in the last month ($p = 0.56$) (2).

Description of the school-based trial participants

The mean age of participants in the school-based trial was 15.9 (sd = 1.2) and 91.4% of participants were African American (Table 1). Slightly over half of the participants were female (56.5%), and 49.3% had mothers with no more than a high school education. Most of the participants (74.3%) were on Medicaid, and 75.3% had internet access at home. Forty-two percent of youth reported an ED visit in the last

12 months, and 56.8% had missed 2 or more school days in the last month. Only 38.9% reported a controller medication, and home exposure to environmental tobacco smoke was high at 67.9%. We compared the ED and clinic-based participants to the school-based trial participants (Table 1).

ED-based trial participants

Compared to school participants, ED participants were slightly younger, (15.4 vs. 15.9, $p < 0.001$ for ED and school, respectively), but were similar in terms of percentage African American and female. There were fewer mothers with less than a high school education (31.4% vs. 49.3%, $p < 0.001$), and fewer participants on Medicaid (60.3% vs. 74.3%, $p = 0.014$). Compared to the school-based participants, healthcare utilization was significantly higher for ED participants for

Table 2. Results summary for primary outcomes of three randomized trials to evaluate an asthma intervention conducted in three different settings.

Setting	Primary outcome	Intervention		Control		Estimate	(95%CI)	<i>p</i>
School-based trial ^a	Symptom-days/past 2 weeks, mean (sd)	3.9	(5.9)	5.2	(6.4)	aRR ^b = 0.80	(0.60–1.00)	0.019
ED-based trial ^c	ED/hospital visit/past 12 months, <i>n</i> (%)	22	(33.8)	26	(46.4)	OR ^d = 0.53	(0.24–0.15)	0.150
Clinic-based trial ^e	Asthma Control Test (ACT) (median, Q1, Q3 ^f)	22	(20,24)	21	(19,24)	–	–	0.416

^aH: Symptom days and days of uncontrolled asthma would be lower for students randomized to the intervention group compared to the control group).

^bAdjusted relative risk.

^cH: Patients randomized to the intervention group will have fewer ED visits than patients randomized to the control group (*a priori* significance $p < 0.20$).

^dOdds ratio.

^eH: Improvement in baseline ACT scores for patients randomized to the intervention group compared to the controls.

^fQ1 = first quartile; Q3 = third quartile.

asthma-related hospitalizations (35.5% vs. 18.8%, $p < 0.001$ for ED and school, respectively) and for ED visits (85.9% vs. 42.1%, $p < 0.001$). ED participants were also more likely to report a controller medication, (57.0% vs. 38.9%, $p < 0.001$), and caregivers were more likely to meet study criteria for depression (38.8% vs. 12.3%, $p < 0.001$) compared to school participants.

Clinic-based participants

Compared to participants in the school-based trial, clinic-based participants had fewer African Americans (69.9 vs. 91.4, $p < 0.001$), fewer females (47.7% vs. 56.5%, $p = 0.035$), and fewer persons on Medicaid (3.7 vs. 74.3, $p < 0.001$). Fewer clinic participants reported asthma-related hospitalizations (5.6% vs. 18.8%, $p < 0.001$) and ED visits (33.8 vs. 42.1, $p = 0.041$) in the last year, and fewer missed ≥ 2 school days in the past 30 days (35.2% vs. 56.8%, $p < 0.001$), compared to the school-based trial. Clinic patients were more likely to report a controller medication (53.1% vs. 38.9%, $p < 0.001$), and were less likely to be exposed to environmental tobacco smoke (30.8% vs. 67.9%, $p < 0.001$) or report that they were smokers themselves (3.0% vs. 7.8%, $p = 0.013$) when compared to those recruited from schools. Teen emotional support was also higher in this group than in the school group (mean = 4.15 vs. 3.8, $p = 0.001$).

Summary results of each trial

In the school-based trial, results were positive in that the treatment group reported significantly better asthma control (as indicated by fewer symptom-days and other indicators of uncontrolled asthma) than the control group (Table 2) (19). For the ED-based pilot study, a p values of $p \leq 0.20$ was decided a prior to indicate significantly fewer ED visits in the treatment group compared to the control group. Results showed that ED visits were 50% lower for treatment participants compared to controls with $p = 0.15$ (i.e. less than

the *a priori* target of ≤ 0.20) (3,13). For the clinic-based program, improved ACT scores for the treatment versus control group were not observed. Other findings from the clinic-based trial included improved ACT scores from baseline, and a significant reduction in sharing medications observed for the treatment group (28).

Discussion

Differences in participant characteristics varied by recruitment setting for an asthma intervention and may have impacted intervention effectiveness and the representativeness of study results. Puff City was originally designed specifically for African-American adolescents and Detroit public high schools were initially targeted for program evaluation. Health insurance and healthcare access were not factors used in determining eligibility for the school-based trial, and participants were characterized by indicators often used to determine low socioeconomic status (e.g. low maternal education, high Medicaid enrollment). In fact, across the participating schools, approximately 64% of students reported eligibility for free school lunch (17). Therefore, it might be expected that school-based participants were more similar to patients recruited from an ED setting, where, according to the literature, patients seeking asthma care are often lower income and have less health care access. Differences noted between the school and the ED participants may indicate a subgroup of patients from the target population that has had more interaction with the healthcare system, perhaps because of uncontrolled or severe asthma combined with the access that Medicaid enrollment confers. These patients were more likely to have asthma-related healthcare utilization as well as a report of controller medication. We observed that ED trial participants were characterized by uncontrolled asthma, high utilization of health care, and high prevalence of depression symptoms reported among the caregivers when compared to schools. This is also supported by existing literature.

Beck found that socioeconomic status and hardships explained over half of the racial disparity in pediatric asthma re-admissions to Cincinnati's Children's Hospital Medical Center (7,8). Franklin reported that smoking in the home, mental illness, and low education were predictors of ED use for asthma among children 6–17 years in Atlanta, Georgia (10). Caregiver depression, also higher among caregivers in the ED trial compared to the school trial, may exacerbate asthma management difficulties, or reflect the teen/family difficulty in achieving asthma control (29,30). Fagnano reported that depressed mothers felt less efficacious in communicating with physicians about their child's asthma and were more likely to leave the visit feeling that their needs were unmet (31). We expected higher reports of caregiver smoking in the ED study, given the literature and the known association between smoking and depression (31–33). For example, the prevalence of smoking among depressed mothers in one study was 52% vs. 25% for mothers without symptoms of depression, and another study found that maternal depression was associated with reduced likelihood of achieving smoking cessation (31,33). Our results could reflect under-reporting of smoking among caregivers reporting to the ED with a child in the midst of an asthma exacerbation (34,35).

Reports of sharing asthma medication was not significantly different for ED participants when compared to those from the school-based trial. This phenomenon has rarely appeared in the literature, but has been reported in a study of Medicaid patients with asthma, for which results showed that the behavior was not associated with asthma-related morbidity (36). The Puff City intervention directly addresses sharing asthma medication in the first of four asthma management modules and results of the clinic-based trial demonstrated significant reductions in medication sharing for the treatment group versus the control group (28).

There are limitations to this report. Caregiver baseline were only conducted in the school- and ED-based trials and therefore could not be included in the clinic comparisons. The 8-year span in recruitment end-date for the three trials is a limitation. Had these trials been conducted at the same time, our observations may have differed as trends change or new trends arise (37,38). Perhaps a good example of this might be internet access. In a 2015 Pew Report, Hispanic and African-American youth had less access to desktops compared to white teens, however, access to smartphones has continued to grow for African-American youth (39,40). According to a 2018 Pew

report, 95% of teens have access to a smartphone, which is the dominate method for online connectivity (40). Finally, we note that our comparisons are subject to a selection bias inherent in the recruitment rates of 30–47% across the three trials (2,3,19). While participants were similar to participants in each trial, with the exception of more females in the school study and more Medicaid enrollees in the ED trial, we cannot account for potential differences between the study samples (e.g. distribution of asthma severity) that could result from other variables we did not measure, and biases we did not detect.

Despite limitations, the differences observed suggest contextual variation in the lives of participants and could inform researchers designing asthma programs or interventions (41). Certainly, investigators seeking to improve outcomes in low-resource communities might select to recruit from schools or the ED. Interventions would need to differentiate asthma that is inherently severe from asthma that may be less severe, but is not controlled (42). ETS exposure and healthcare utilization for asthma were higher in these settings as well, perhaps a reflection of greater poverty and stress accompanied by caregiver depression. In previous publications we demonstrated that teen depression was associated with caregiver depression and influenced intervention impact on adherence and other outcomes (43,44).

In summary, participant characteristics varied significantly as the recruitment setting changed. These characteristics may be associated with healthcare utilization, asthma severity, and family context may in turn, influence health behaviors and ultimately, response to the intervention (45). An awareness of these differences can aid in selection of study samples, inform intervention content, provide insight into generalizability of results, and may help to explain variation in outcomes for trials conducted in multiple settings.

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Declaration of interest

The authors declare no conflicts of interest.

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