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Examining local smoke-free coalitions in Armenia and Georgia: context and outcomes of a matched-pairs community-randomised controlled trial

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ABSTRACT

Introduction Local coalitions can advance public health initiatives such as smoke-free air but have not been widely used or well-studied in low-income and middle-income countries.

Methods We conducted a matched-pairs community-randomised controlled trial in 28 communities in Armenia and Georgia (N=14/country) in which we helped establish local coalitions in 2019 and provided training and technical assistance for coalition activity promoting smoke-free policy development and enforcement (2019–2021). Surveys of ~1450 households (Fall 2018, May–June 2022) were conducted to evaluate coalition impact on smoke-free policy support, smoke-free home adoption, secondhand smoke exposure (SHSe), and coalition awareness and activity exposure, using multivariable mixed modelling.

Results Bivariate analyses indicated that, at follow-up versus baseline, both conditions reported greater smoke-free home rates (53.6% vs 38.5%) and fewer days of SHSe on average (~11 vs ~12 days), and that intervention versus control condition communities reported greater coalition awareness (24.3% vs 12.2%) and activity exposure (71.2% vs 64.5%). Multivariable modelling indicated that intervention (vs control) communities reported greater rates of complete smoke-free homes (adjusted Odds Ratio [aOR] 1.55, 95% confiedence interval [CI] 1.11 to 2.18, p=0.011) and coalition awareness (aOR 2.89, 95% CI 1.44 to 8.05, p=0.043) at follow-up. However, there were no intervention effects on policy support, SHSe or community-based activity exposure.

Conclusions Findings must be considered alongside several sociopolitical factors during the study, including national smoke-free policies implementation (Georgia, 2018; Armenia, 2022), these countries' participation in an international tobacco legislation initiative, the COVID-19 pandemic and regional/local war). The intervention effect on smoke-free homes is critical, as smoke-free policy

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Multisectoral local coalitions are effective in shifting social norms, creating community readiness for policy change and changing policy, and have shown particular application and success for tobacco control initiatives.

⇒ However, local coalitions have not been widely leveraged or studied in low-income and middle-income countries.

WHAT THIS STUDY ADDS

⇒ This study examined the impact of local coalitions in promoting smoke-free policy adoption and enforcement over a 3-year period (2019–2022) using an experimental design (ie, matched-pairs community-randomised controlled trial) in 28 communities in Armenia and Georgia.

⇒ Intervention (vs control) communities showed greater rates of complete smoke-free homes at follow-up—but no intervention effects on policy support or secondhand smoke exposure.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Study findings indicate the promise of local coalitions in enhancing the impact of smoke-free legislation, particularly for promoting smoke-free home adoption, even in the face of several sociopolitical factors (national smoke-free policy implementation, COVID-19, military conflict).

⇒ Given the specific intervention effects on smoke-free homes, future research should examine strategies to promote smoke-free policies in private settings (eg, homes, vehicles), as well as other settings not covered by the public policy, in the wake of national legislation by leveraging local coalitions.

implementation provides opportunities to accelerate smoke-free home adoption via local coalitions.

Trial registration number NCT03447912.

INTRODUCTION

Multisectoral local coalitions are effective in engaging local communities,[1 2] shifting social norms,[3 4] creating community readiness for policy change[3 4] and changing policy.[5–10] The World Health Organization's (WHO's) Healthy Cities initiative, which began in 1986 in cities in high-income countries (ie, Canada, USA, Australia, many European nations), is among the largest, best-known examples of such approaches.[11] This model highlights municipalities as critical drivers in 'establishing the conditions for health', encouraging community participation and ownership, and promoting intersectoral partnerships.[11] However, globally, community coalitions driving public health initiatives have not been optimally leveraged.[12 13]

Some of the greatest successes of local coalitions have been in tobacco control,[3 4 7 8 10] particularly public smoke-free legislation.[14] Such legislation reduces secondhand smoke exposure (SHSe), youth tobacco use initiation, overall use prevalence and tobacco-related morbidity and mortality.[15] Accordingly, state/local coalitions are among the US Centers for Disease Control's (CDC's) 'Best Practices for Comprehensive Tobacco Control Programmes'.[3] The WHO Framework Convention on Tobacco Control (FCTC) mandates ratifying nations to implement specific evidence-based policies[14]; further, FCTC implementation guidelines suggest the importance of engaging civil society to raise awareness and promote social change.[16 17] However, the processes guiding the activities or organisation of civil society are not well specified. Furthermore, in many countries, tobacco control efforts involving coalitions are often at the national level, missing opportunities for local efforts to strengthen smoke-free policy support and compliance (a common gap[18 19]) and potentially accelerate spillover effects to smoke-free homes.[20 21]

One theory that can guide civil society mobilisation is the Community Coalition Action Theory (CCAT),[22] which has been used to synthesise coalition-building processes and outcomes across various topics.[23–28] CCAT posits that, in response to an opportunity or threat (eg, tobacco-related health risks), a convening organisation can form a coalition representing diverse stakeholders who pool resources, implement evidence-based or promising interventions, and ultimately change policies, systems, environments and programmes to drive population-based outcomes.[22] However, coalition formation and effectiveness can be inhibited by insufficient resources,[29 30] a particular concern for low-income and middle-income countries (LMICs) where catalysing public health initiatives may be most needed.[31 32] Unfortunately, the literature is limited with regard to the processes and effects of local coalitions in LMICs.[10 13]

Another limitation to the literature and theories related to coalitions is that studies have been largely observational or evaluations, with few using experimental designs.[33] A 2020 review of public health coalitions from 2000 to 2018 reported only 18 studies with over 10 communities, only 4 of which were randomised in experimental studies.[33] This underscores the need for research using rigorous randomised experimental trials to enhance the evidence base and theory related to coalition processes and effects.[33] However, in many contexts, using uncontaminated control conditions in experimental designs is not possible because of the widespread use of local community-based partnerships to advance public health initiatives.

Tobacco-related diseases and deaths, including those attributed to SHSe,[31] are among the public health problems disproportionately impacting LMICs. Armenia and Georgia represent two LMICs where tobacco use and SHSe are prominent. Smoking rates among men are among the top ten highest globally (56.1% and 49.5%, respectively); rates among women are lower (2.6% and 8.5%).[34 35] Moreover, 74.2% of people (79.5% in Armenia, 68.9% in Georgia) experience past-month SHSe, with 24.4% experiencing daily SHSe.[36] SHSe rates are high even where smoking is prohibited.[36 37] Armenia and Georgia ratified the FCTC in 2004 and 2006, respectively; yet, tobacco control progress has lagged until recently.[38 39] Notably, the use of community mobilisation efforts, such as coalitions, to promote public health initiatives has been limited, given the sociopolitical histories in these former Soviet Union countries.

Given the promise of coalitions[3] but the limited research regarding their application in LMICs or using randomised experimental designs,[33] this study aimed to advance the literature by examining coalition effectiveness in Armenia and Georgia using an experimental design. These countries are ideal settings for such research, given their high smoking and SHSe rates and limited history of smoke-free policies and community mobilisation to promote public health initiatives, providing a relatively unique opportunity for this experimental study. We used a matched-pairs community-randomised controlled trial (CRCT) to test the effects of local coalitions to promote smoke-free policy adoption and enforcement in Armenia and Georgia from 2018 to 2022. Primary outcomes included smoke-free policy support, smoke-free home adoption and SHSe. Findings from this experimental study can advance theory and the literature regarding coalition processes and effects and expand our understanding of their utility in LMICs.[13]

METHODS

Study overview

Georgia and Armenia Teams for Healthy Environments and Research is a Fogarty-funded study was a collaboration between Georgia's National Center for Disease Control and Public Health, Armenia's National Institute

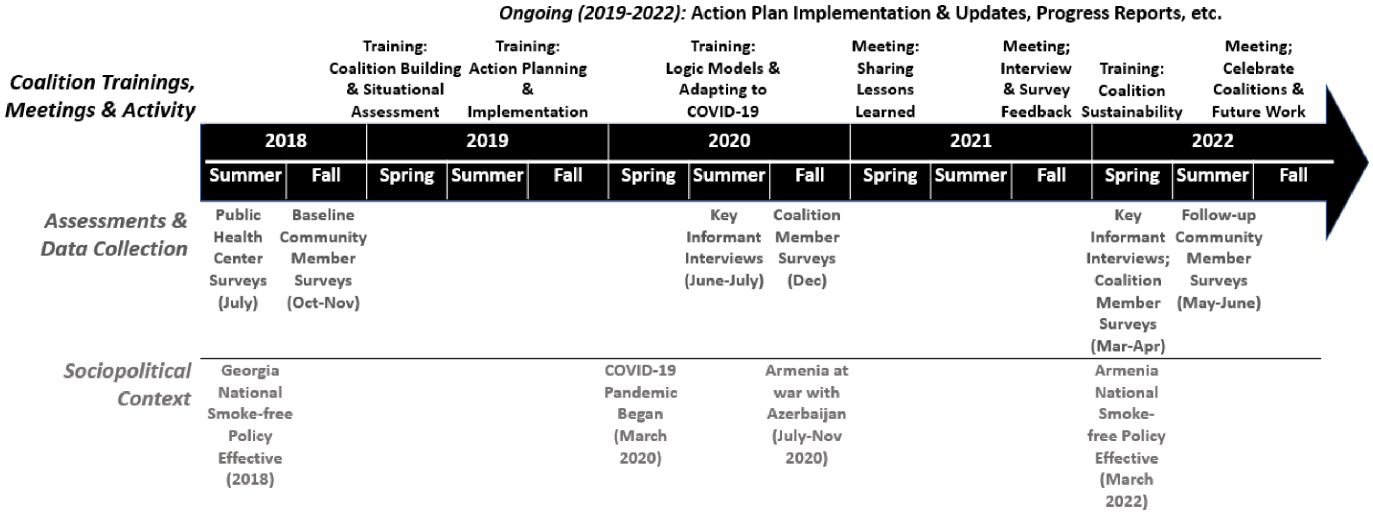

Figure 1 Study timeline.

of Health and National Center for Disease Control, American University of Armenia, George Washington University and Emory University.[40 41] This CRCT examining local coalition effects on smoke-free policy support, smoke-free home adoption and SHSe was launched in Fall 2018 and culminated in Summer 2022 (figure 1). This study complied with Consolidated Standards of Reporting Trials (CONSORT) guidelines (online supplemental appendix 1).

Community selection and randomisation

Power calculations to determine the minimum number of communities[42] assumed a 10% intraclass correlation, 50 participants per community,[43] and a small-to-medium effect size (d=0.35) for the outcome of days of SHSe,[44] indicating that 28 communities provided adequate power. In each country, 14 communities (defined as a distinct municipality) were purposively selected. Eligible communities were those with small-to-medium populations (ie, 5000–60 000), given that coalitions serving small-to-medium communities are most effective.[45] Based on population size, there were ~37 eligible communities in Armenia and ~34 in Georgia. Communities were paired in each country based on population size and administrative region (10 in Armenia, 9 in Georgia), thus limiting the number of possible pairings of communities with roughly equal population sizes in the same region. The final sample of matched pairs (overall: M=24 114, SD=11 735; Armenia: M=19 835, SD=10 873; Georgia: M=28 392, SD=11 330) were randomly assigned to intervention or assessment-only control (14 communities/condition).

Intervention versus control conditions

In intervention communities, local public health centres or regional offices served as lead agencies and received grant funding of ~US$17 500 over the 3-year study period (2019–2022) to execute coalition activities. The trainings and technical assistance provided to the local coalitions were based on CCAT (eg, coalition formation/representation, pooling resources/expertise, selecting evidence-based strategies).[22] Specifically, in January–February 2019, the research team trained key members of the lead agencies in forming coalitions and conducting situational assessments. The lead agencies then formed coalitions by recruiting partner organisations from various sectors (eg, healthcare, education and municipal administration) and executed situational assessments of smoke-free policy needs and opportunities in their communities. In June 2019, the coalitions were trained to develop and implement action plans to promote smoke-free policy adoption and enforcement. Throughout the 3-year period, the coalitions submitted action plans and progress reports quarterly to biannually, and the research team and grantee communities met annually to share activities, progress and lessons learnt.

Our published process evaluation further describes the coalition processes,[46] drawing directly from CCAT[22]; current analyses focus on population-level outcomes (ie, SHSe, policy support and smoke-free home adoption). Briefly, the process evaluation indicated that, on average, coalitions had seven members, most commonly representing education (30.5%), healthcare (17.1%), public health (17.1%) and local municipal administration (12.2%).[46] During the study period, half of the coalitions created at least one smoke-free policy in specific settings (eg, factories, parks), all 14 promoted compliance with existing policies via no-smoking signage/stickers, and the majority executed awareness-raising events in school, healthcare and community settings.[46]

Context

Community-based research often faces challenges in terms of unexpected events that impact implementation and findings. In the current study, several contextual factors warrant consideration, as suggested by our process evaluation[46] (figure 1). First, despite lagging tobacco control progress historically,[38 39] both countries made significant strides during the study period.

Armenia's smoke-free policy enacted in 2004 only applied to certain public places (eg, educational, healthcare, cultural), but in February 2020, Armenia adopted legislation extending smoke-free policies to all public places (eg, workplaces, indoor/outdoor dining facilities) and all tobacco products (eg, e-cigarettes), effective in March 2022. In 2018, Georgia implemented smoke-free policies in a broad range of indoor and outdoor public places and all tobacco products. These policy differences and changes over time likely impacted local community capacity, social norms and SHSe,[40] and introduced potential ceiling effects (ie, reductions in SHSe regardless of coalitions). Further, Georgia began participating in the FCTC 2030 initiative in 2018 and Armenia began in 2020; this initiative involved monitoring smoke-free policy implementation and enforcement,[47] which introduced potential community-based activity exposure among participants in all communities (including control).

Second, COVID-19 was declared a global pandemic 11 March 2020, about a year after the coalitions launched their activities. Pandemic-related study implications included: (1) constraints (and differences in constraints across communities) on public health resources for tobacco control versus COVID-19-related initiatives; (2) relevance of public smoke-free policies during stay-at-home and/or self-imposed restrictions; (3) ability to execute coalition activities and maintain coalition member engagement during the pandemic (eg, competing priorities like childcare) and (4) impact of related stressors (eg, financial, seclusion) on tobacco use.

A third set of factors pertains to military conflicts. In July 2020, Armenia and Azerbaijan engaged in a 5-day battle in the Tavush region of Armenia. Ongoing tension led to a full-scale 44-day war between Azerbaijan and Nagorno-Karabakh (east of Armenia), which began September 2020. In November 2020, a Russian-brokered agreement ceded parts of Nagorno-Karabakh to Azerbaijan, but periodic violations escalated into Azerbaijan's invasion of several locations inside Armenia in September 2022. Together, these conflicts resulted in tens of thousands of evacuations and displacements and thousands of deaths in Armenia. Additionally, both countries have been impacted by Russia's invasion of Ukraine, which began in February 2022, resulting in displacement of >25 000 refugees into Armenia and Georgia alone.

In addition to these important contextual factors underscored by our process evaluation,[46] other factors may have impacted study execution and findings, such as existing institutional infrastructure and interorganisational relationships, among others, some of which were assessed at baseline to ensure there were no differences between communities randomised to intervention versus control.[40]

Community member survey data collection

Community member surveys were conducted in October–November 2018 (pre coalition launch in intervention communities) and May–June 2022 (postcoalition activity). Sampling strategies were different across countries because of availability of household data in Armenia (but not Georgia) and the utility of 'clusters' (ie, geographically defined areas of 150 households) in Georgia (but not Armenia). In both countries, we obtained census data for households within the municipality limits, then interviewed one eligible participant (ie, ages 18–64) per household to reach target recruitment (n=50/city).[40 43] For households with more than one eligible person, we used the Kish method to select the participant; this method entails listing eligible household members by oldest to youngest age within each sex and then using a selection table to randomly choose the participant.[48]

In Armenia, addresses in each city were randomly ordered; assessments began at the beginning of the list and continued to reach recruitment targets. In 2018, 1128 households were visited, of which 27.4% (n=309) were ineligible (ie, unable to contact a household member ≥18); of the 819 eligible, 705 (86.1%) participated.[41] In 2022, 1140 households were visited; of the 890 (78.1%) eligible, 756 (86.1%) participated.

In Georgia, 5 clusters per city were identified, then 15 households per cluster were selected using a random walking method.[41] In 2018, 958 households were visited, 5.0% (n=48) were ineligible. Of the 910 eligible, 751 (82.5%) participated.[41] In 2022, 916 households were visited; of the 839 (91.6%) eligible, 705 (84.0%) participated.

Measures

We analysed the following variables, assessed in 2018 and 2022.

Primary outcomes

To assess smoke-free policy support, we asked, 'To what extent do you support or oppose a complete cigarette smoking ban in the following settings: in restaurants, cafes and cafeterias; on the outdoor terrace of restaurants, cafes and cafeterias; in bars, pubs, or nightclubs; on the outdoor terrace of bars, pubs, or nightclubs; indoor common areas of apartment or condominium complexes like hallways, lobbies and stairwells; outdoor common areas of apartment or condominium complexes (playgrounds, park benches, etc); within individual apartment or condo units within a complex; private vehicles when children under age 18 are present; parks and beaches; and other public outdoor areas, such as open stadiums'. Response options ranged from 1=strongly oppose to 4=strongly support.[41 49 50] As done in prior research,[41 51] we calculated the average of the responses across the 10 items to serve as an index score summarising overall policy support (Cronbach's alpha=0.93).

To assess smoke-free home status, we asked, 'Which of the following statements best describes the smoking rules in your home: smoking in your home is allowed, smoking in your home is generally not allowed with certain exceptions, smoking in your home is never allowed, or there

are no rules about smoking in your home?'[49 50] 'Never allowed' was coded as complete smoke-free home restrictions.

We assessed SHSe by asking, 'In the past 30 days, on how many days did you breathe the smoke from someone else's smoking?' To assess SHSe in distinct settings for descriptive purposes, we asked, 'In the past 30 days, on how many days did you breathe the smoke from someone smoking tobacco products in: your home? your car? the indoor area where you work? an indoor public place (eg, school buildings, stores, restaurants, sports arenas? an outdoor public place (eg, school grounds, parking lots, stadiums, parks)?'.[49 50]

Secondary outcomes

In 2022, we assessed coalition awareness among participants in both conditions by asking, 'Have you heard of a coalition—or group of people—who have been working together on issues related to smoking, reducing SHSe and promoting smoke-free air in your community?' Exposure to community-based tobacco control activity was assessed by asking, 'In the past 2 years, have you seen any of the following in your community: school-based events, for example, educating youth about dangers of tobacco use and SHSe; signage/stickers promoting smoke-free environments in public places; community member surveys regarding smoke-free policy support; groups of people cleaning up cigarette butts in parks/stadiums; events/activities in healthcare settings, for example, circulating education about dangers of SHSe; other activities; or none of the above.'

Covariates

We assessed sociodemographics (age, sex, education level, employment status, relationship/marital status, children under age 18 in the home) and current (past 30-day) cigarette use.

Data analysis

Descriptive and bivariate analyses characterised the samples across: (1) baseline and follow-up by intervention versus control; (2) intervention and control by time point and (3) baseline and follow-up by country (using SPSS V.27). Then, mixed-modelling (PROC MIXED for continuous outcomes, PROC GLIMMIX for dichotomous in SAS V.9.4) examined intervention effects through an interaction effect between condition and time on primary outcomes (policy support, smoke-free home status, SHSe), that is, $Outcome_{ij} = \gamma_{00} + \gamma_{10} \times Group + \gamma_{20} \times Time + \gamma_{30} \times Group \times Time + \gamma_{40} \times Gender + \gamma_{50} \times Country + u_{oj} + r_{ij}$, when γ_{30} is the intervention effect estimate, controlling for gender and country with fixed effects and for community through the random effect $u_0 j$. Multivariable logistic regression models assessed for intervention effects on secondary outcomes (coalition awareness and activity exposure, assessed only at follow-up). In exploratory analyses, mixed-models assessed coalition activity exposure in relation to primary outcomes, controlling for gender and nesting. Significance level was set at alpha=0.05.

Patient and public involvement

This study involved public health staff and multisectorial community stakeholders (eg, education, healthcare and private sectors[46]) who were involved as members of the coalitions and/or key community-based collaborators, who led or contributed to planning and executing coalition activities, met semiannually via conference calls and in-person meetings to share their work and lessons learnt, and participated in the coalition process evaluation (ie, surveys and interviews).[46] Study team members (ie, coinvestigators) at the national and local public health agencies provided input regarding relevant, timely tobacco-related measures to include in the community member surveys. At the culmination of the study, the study team (representing all partner organisations) presented the findings to the local coalition leaders, and the national and local research partners were actively involved in research dissemination.

RESULTS

Sample characteristics

As shown in table 1, bivariate analyses indicated that, in both intervention and control, greater proportions of participants at follow-up (vs baseline) were male, employed and not married/cohabitating; in the intervention condition, there was a larger proportion of those who smoked at follow-up (vs baseline). Online supplemental table 1 shows differences by intervention versus control at baseline and follow-up. Notable differences include younger age in intervention (vs control) at baseline and follow-up, and more people reporting complete smoke-free homes in intervention (vs control) at baseline and follow-up. Online supplemental table 2 shows differences by country at baseline and follow-up. At both time points, the Georgian (vs Armenian) samples had greater proportions of men and those who smoked, greater proportions of smoke-free homes, and fewer days of SHSe. Additionally, there was greater policy support in Armenia at baseline but greater policy support in Georgia at follow-up.

Effects of intervention versus control condition on primary outcomes

Bivariate analyses (table 1) indicated that, at follow-up versus baseline, there were greater proportions reporting smoke-free homes and fewer days of SHSe on average (except for specific measures for SHSe in household vehicles and outdoor public settings, which showed the opposite).

Multivariable results (table 2) indicated a significant intervention effect for complete smoke-free home status, with intervention participants reporting greater odds of smoke-free homes at follow-up (adjusted odds ration [aOR] 1.55, 95% confidence interval [CI] 1.11 to 2.18, p=0.011), even accounting for general increases in smoke-free homes across communities over time (aOR

Table 1 Participant characteristics and results regarding changes in smoke-free (SF) policy support, complete SF home status, secondhand smoke exposure (SHSe), coalition awareness and exposure to community-based activities among participants at baseline and follow-up by condition

Variables	Intervention			Control		
	Baseline N=732	Follow-up N=749		Baseline N=724	Follow-up N=719	
	M (SD) r N (%)	M (SD) r N (%)	P value	M (SD) r N (%)	M (SD) r N (%)	P value
Sociodemographics						
Armenia, N (%)	351 (48.0)	384 (51.3)	0.212	354 (48.9)	379 (52.7)	0.839
Age, M (SD)	42.52 (13.71)	41.84 (13.63)	0.337	44.19 (13.22)	44.05 (13.37)	0.155
Male, N (%)	303 (41.4)	375 (50.1)	<0.001	272 (37.6)	338 (47.0)	<0.001
College or more, N (%)	236 (32.2)	298 (39.8)	0.003	232 (32.2)	263 (36.6)	0.076
Employed, N (%)	359 (49.0)	467 (62.3)	<0.001	354 (48.9)	433 (60.2)	<0.001
Married/living with partner, N (%)	528 (72.1)	488 (65.2)	0.004	533 (73.6)	489 (68.0)	0.021
Children <18 years old in the home, N (%)	378 (52.9)	383 (51.1)	0.532	353 (49.2)	341 (47.4)	0.527
Current smoking, N (%)	187 (25.5)	243 (32.4)	0.004	195 (26.9)	221 (30.7)	0.117
Policy support index, M (SD)*	3.03 (0.68)	3.03 (0.84)	0.985	3.03 (0.80)	2.97 (0.81)	0.195
Complete smoke-free home status, N (%)†	298 (40.7)	418 (55.8)	<0.001	263 (36.3)	369 (51.3)	<0.001
Past-month SHSe, no of days, M (SD)‡	11.70 (12.14)	10.86 (11.77)	0.184	12.08 (12.35)	10.51 (11.92)	0.017
SHSe in distinct settings:						
In the home	6.83 (11.48)	4.88 (9.83)	<0.001	7.18 (11.53)	4.72 (9.83)	<0.001
In household vehicles	3.87 (8.15)	4.43 (8.27)	<0.001	3.93 (8.36)	4.74 (9.27)	<0.001
In indoor workplace	4.16 (8.66)	2.91 (7.70)	<0.001	4.44 (8.85)	3.06 (7.68)	<0.001
In indoor public setting	1.74 (4.71)	1.66 (5.21)	0.773	2.00 (5.17)	1.15 (3.89)	<0.001
In outdoor public setting	5.34 (8.86)	6.78 (9.68)	0.003	4.83 (8.79)	6.49 (9.02)	<0.001
Coalition awareness and exposure§						
Coalition awareness, N (%)	--	174 (24.3)	--	--	85 (12.2)	<0.001
Exposure to community-based activity (≥1), N (%)	--	533 (71.2)	--	--	464 (64.5)	0.004
By setting/activity:						
School-based events	--	96 (12.8)	--	--	58 (8.1)	0.002
Signage and/or stickers promoting SF air	--	446 (59.5)	--	--	364 (50.6)	<0.001
Community member surveys regarding SF policies	--	130 (17.4)	--	--	88 (12.2)	0.004
People picking up cigarette butts or promoting SF air	--	82 (10.9)	--	--	102 (14.2)	0.036
Events/activities in healthcare settings	--	106 (14.2)	--	--	62 (8.6)	0.001
Other community-based activities	--	29 (3.9)	--	--	16 (2.2)	0.046
No of activities exposed, M (SD)	--	1.19 (1.09)	--	--	0.96 (0.96)	<0.001

All other p values from t-tests and χ^2 tests examining differences between baseline and follow-up among intervention and control, respectively.
*Average score of 10 items assessing support in different settings (1=strongly oppose to 4=strongly support).
†Complete smoke-free home operationalised as 'never allowed'.
‡Response to 'in the past 30 days, on how many days did you breathe the smoke from someone else's smoking?'
§P values from χ^2 tests comparing intervention and control at follow-up.
M, mean; SD, standard deviation; SF, smoke-free; SHSe, secondhand smoke exposure.

4.07, 95% CI 3.21 to 5.16, p<0.001). However, no intervention effects were found for policy support or SHSe.

Regarding other findings, a significant time effect indicated fewer days of SHSe at follow-up versus baseline across intervention and control communities (β=−0.26, standard error [SE]=0.59, p<0.001). Females (vs males) reported greater policy support and smoke-free homes, as well as fewer days of SHSe at follow-up (p<0.01). Participants in Georgia (vs Armenia) reported fewer days of SHSe at follow-up, but also lower rates of smoke-free homes, controlling for baseline smoke-free home rates (p<0.001).

Table 2 Intervention versus control condition as a predictor of smoke-free (SF) policy support, complete SF home status, secondhand smoke exposure (SHSe) and coalition awareness and community-based activity exposure

Policy support index*	Beta	SE	P value
Intercept	2.52	0.06	<0.001
Intervention effect	0.04	0.05	0.463
Intervention (vs control) at baseline‡	0.03	0.07	0.618
Time effect	0.002	0.04	0.961
Female (vs male)	0.77	0.03	<0.001
Georgia (vs Armenia)	0.10	0.06	0.09
Complete smoke-free home status	OR	95% CI	P value
Intervention effect	1.55	1.11 to 2.18	0.011
Intervention (vs control) at baseline‡	0.77	0.52 to 1.13	0.175
Time effect	4.07	3.21 to 5.16	<0.001
Female (vs male)	1.27	1.07 to 1.50	0.006
Georgia (vs Armenia)	0.54	0.39 to 0.75	<0.001
Past-month SHSe, no of days	Beta	SE	P value
Intercept	19.76	12.43	<0.001
Intervention effect	0.95	0.82	0.249
Intervention (vs control) at baseline‡	−0.81	1.37	0.552
Time effect	−0.26	0.59	<0.001
Female (vs male)	−7.39	0.42	<0.001
Georgia (vs Armenia)	−5.59	1.01	<0.001
Coalition awareness†	OR	95% CI	P value
Intervention effect	2.89	1.04 to 8.05	0.043
Female (vs male)	1.62	1.19 to 2.21	0.002
Georgia (vs Armenia)	0.41	0.15 to 1.13	0.085
Community-based activity exposure (≥1)†	aOR	95% CI	P value
Intervention effect	1.37	0.66 to 2.81	0.397
Female (vs male)	1.38	1.09 to 1.76	0.008
Georgia (vs Armenia)	0.49	0.24 to 1.01	0.052

*Reached significance among those who reported no current smoking in Georgia.
†At follow-up only.
‡Variable indicating differences in baseline reports of outcome in intervention versus control communities.
aOR, adjusted odds ratio; CI, confidence interval; SE, standard error; SF, smoke-free; SHSe, secondhand smoke exposure.

Effects of intervention versus control on secondary outcomes

At follow-up, greater proportions of intervention (vs control) participants reported coalition awareness (24.3% vs 12.2%, p<0.001) and exposure to at least one community-based activity (71.2% vs 64.5%, p=0.004; number of activities exposed, mean [M]=1.19, standard deviation [SD]=1.09 vs 0.96, SD=0.96, p<0.001; table 1). Online supplemental table 3 shows coalition awareness and community-based activity exposure by country, showing similar findings in Armenia (ie, awareness: 24.6% vs 5.3%, p<0.001; any exposure: 69.8% vs 51.2%, p<0.001; number of activities, M=1.33, SD=1.20 vs M=0.77, SD=0.93, p<0.001). However, in Georgia, there were no differences in coalition awareness between intervention and control (24.1% vs 19.8%, p=0.101), and a greater proportion of control versus intervention participants reported any activity exposure (79.4% vs 72.6%, p=0.021).

Multivariable analyses (table 2) indicated an intervention effect for coalition awareness (aOR 2.89, 95% CI 1.04 to 8.05, p=0.043) but not activity exposure. Regarding other findings, females (vs males) reported greater coalition awareness and community-based activity exposure (p<0.01).

Given the reported levels of community-based activity exposure among participants in intervention and control communities, we explored activity exposure as a predictor of primary outcomes among both intervention and control participants. Findings indicated no effect (although signalling an effect on smoke-free

homes at alpha=0.1: aOR 1.28, 95% CI 0.99 to 1.66, p=0.064).

DISCUSSION

Current findings from this CRCT testing the CCAT-informed[22] coalition intervention add to the literature indicating the promise of local coalitions for public health in LMICs,[13] specifically in relation to smoke-free policies[14] in Armenia and Georgia.[34 35] Findings indicated effects on complete smoke-free homes, even beyond increasing rates over time in both intervention and control communities (53.6% at follow-up vs 38.5% at baseline), as well as effects on coalition awareness. These effects were detected despite significant sociopolitical events during the study, including national smoke-free policy implementation (Georgia, 2018; Armenia, 2022), these countries' participation in the FCTC 2030 initiative,[47] the COVID-19 pandemic, and military conflict in Armenia and regionally. Our process evaluation analysis documented diverse representation within the coalitions and their effective use of the funding, training and technical assistance to execute various community-based activities and effect policy change.[46] Given FCTC's emphasis on engaging civil society and diverse community sectors in raising awareness, understanding and support for legislation addressing SHSe,[16 17] these findings provide valuable insights regarding coalitions and effective coalition processes that might harness the potential of these crucial stakeholders.[19]

Despite these promising findings, there was no intervention effect for smoke-free policy support or SHSe. The null effect on policy support may be related to a ceiling effect, as support was already high (average of 3 on a 4-point scale). The literature indicates generally high levels of public support for smoke-free policies but mixed results in their actual implementation and impact in LMICs.[19] From this perspective, better indicators of coalition impact may be smoke-free home and SHSe outcomes. The null intervention effect on SHSe may be due to the significant time effect on SHSe, which may have diminished our ability to detect an intervention effect. In addition, exploratory subgroup analyses indicated that those who smoked in intervention and control at baseline and follow-up reported ~18–19 days of SHSe, while days of SHSe among non-smokers in both conditions decreased from ~10 days to ~7 days. Thus, findings were likely impacted by little change in SHSe among those reporting smoking and limited power to conduct subgroup analyses among non-smokers.

The intervention effect for smoke-free homes is important, as establishing smoke-free homes represents intentional, volitional behaviour. Smoke-free legislation can increase rates of smoke-free home adoption,[15] but little research has examined the utility of community-based interventions, such as coalitions, in enhancing their adoption in the wake of public policy implementation.[20 21] Current findings suggest a critical window for continued promotion of smoke-free home restrictions in Armenia and Georgia. In one analysis of 2022 data, one-fourth of households without complete restrictions in Armenia and Georgia had partial restrictions, had no smokers in the home and/or had recently attempted to establish restrictions; furthermore, 35.5% intended to establish restrictions.[52]

Regarding other findings, females (vs males) reported greater policy support, smoke-free homes, coalition awareness and community-based activity exposure, as well as fewer days of SHSe at follow-up, aligning with literature indicating that females are more receptive to tobacco control policies and related efforts.[41 53] Moreover, there were differences across countries. For example, in Georgia versus Armenia, there were lower rates of smoke-free homes, controlling for baseline smoke-free home rates; however, over half of Georgian participants reported smoke-free homes at both baseline and follow-up, while the proportion of Armenian participants reporting smoke-free homes increased from ~25% to 39%. Country-based differences likely relate to earlier implementation of smoke-free—and other tobacco control—legislation in Georgia (vs Armenia), as well as Georgia's earlier participation in the FCTC 2030 initiative.[47]

Study strengths and limitations

This study used a matched-pairs randomised experimental design (ie, CRCT) with population-level baseline and follow-up assessments to test an evidence-based strategy for tobacco control (ie, local coalitions)[3 14] and was guided by a well-supported conceptual model (CCAT).[22] However, the relatively small sample size per community limited power to conduct subgroup analyses, which is especially relevant given the differences in tobacco control legislation and related activity over time and the male smoking prevalence in these countries.[34 35] Additionally, societal complexities, including COVID-19 and military conflicts, likely impacted study findings.

CONCLUSIONS

Results of this experimental study indicate the promise of local coalitions in enhancing the impact of smoke-free legislation. Specifically, local coalitions may catalyse smoke-free home adoption in the wake of such legislation. However, we found no intervention effects for smoke-free policy support or SHSe, likely due to ceiling effects for support and the significant time effect for SHSe undermining our ability to detect effects. Future research should examine strategies to further bolster smoke-free legislation impact on volitional behaviours, such as implementing smoke-free policies in private settings (eg, homes, vehicles) and other settings not covered by the public policy.

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Ethics approval This study involves human participants and the Institutional Review Boards of Emory University (#IRB00097093), the National Academy of Sciences of the Republic of Armenia (#IRB00004079), the American University of Armenia (#AUA-2017-013) and the National Center for Disease Control and Public Health of Georgia (#IRB00002150) approved this study. Participants gave informed consent to participate in the study before taking part.

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Supplementary Table 1. Participant characteristics and results regarding changes in smoke-free policy support, complete smoke-free home status, and SHSe among participants at baseline and follow-up by condition

	Baseline			Follow-up		
	Intervention N=732	Control N=724		Intervention N=749	Control N=719	
Variables	**M (SD) or N (%)**	**M (SD) or N (%)**	**p**	**M (SD) or N (%)**	**M (SD) or N (%)**	**p**
Sociodemographics						
Armenia, N (%)	351 (48.0)	354 (48.9)	.719	384 (51.3)	379 (52.7)	.580
Age, M (SD)	42.52 (13.71)	44.19 (13.22)	**.018**	41.84 (13.63)	44.05 (13.37)	**.002**
Male, N (%)	303 (41.4)	272 (37.6)	.136	375 (50.1)	338 (47.0)	.241
College or more, N (%)	236 (32.2)	232 (32.2)	.995	298 (39.8)	263 (36.6)	.217
Employed, N (%)	359 (49.0)	354 (48.9)	.955	467 (62.3)	433 (60.2)	.403
Married/living with partner, N (%)	528 (72.1)	533 (73.6)	.523	488 (65.2)	489 (68.0)	.246
Children <18 years old in the home, N (%)	378 (52.9)	353 (49.2)	.161	383 (51.1)	341 (47.4)	.155
Current smoker, N (%)	187 (25.5)	195 (26.9)	.547	243 (32.4)	221 (30.7)	.482
Policy support index, M (SD) [a]	3.03 (0.68)	3.03 (0.80)	.949	3.03 (0.84)	2.97 (0.81)	.217
Complete smoke-free home status, N (%) [b]	298 (40.7)	263 (36.3)	**.048**	418 (55.8)	369 (51.3)	**.047**
Past-month SHSe, number of days, M (SD) [c]	11.70 (12.14)	12.08 (12.35)	.572	10.86 (11.77)	10.51 (11.92)	.572
SHSe in distinct settings:						
In the home	6.83 (11.48)	7.18 (11.53)	.565	4.88 (9.83)	4.72 (9.83)	.751
In household vehicles	3.87 (8.15)	3.93 (8.36)	.905	4.43 (8.27)	4.74 (9.27)	.607
In indoor workplace	4.16 (8.66)	4.44 (8.85)	.700	2.91 (7.70)	3.06 (7.68)	.804
In indoor public setting	1.74 (4.71)	2.00 (5.17)	.312	1.66 (5.21)	1.15 (3.89)	**.037**
In outdoor public setting	5.34 (8.86)	4.83 (8.79)	.295	6.78 (9.68)	6.49 (9.02)	.556

Notes: [a] Average score of 10 items assessing support in different settings (1=strongly oppose to 4=strongly support). [b] Complete smoke-free home operationalized as "Never allowed". [C] Response to "In the past 30 days, on how many days did you breathe the smoke from someone else's smoking?"

Supplementary Table 2. Participant characteristics and results regarding changes in smoke-free policy support, complete smoke-free home status, and SHSe among participants at baseline and follow-up by country

	Baseline			Follow-up		
	Armenia N=705	Georgia N=751		Armenia N=763	Georgia N=705	
Variables	**M (SD) or N (%)**	**M (SD) or N (%)**	**p**	**M (SD) or N (%)**	**M (SD) or N (%)**	**p**
Sociodemographics						
Age, M (SD)	42.56 (13.41)	44.08 (13.53)	**.032**	42.10 (12.91)	43.82 (14.16)	**.015**
Male, N (%)	210 (29.8)	365 (48.6)	**<.001**	338 (44.3)	375 (53.2)	**<.001**
College or more, N (%)	226 (32.1)	242 (32.2)	.955	297 (38.9)	264 (37.4)	.591
Employed, N (%)	311 (44.1)	402 (53.5)	**<.001**	450 (59.0)	450 (63.8)	.061
Married/living with partner, N (%)	534 (75.7)	527 (70.2)	**.018**	533 (69.9)	444 (63.0)	**.006**
Children <18 years old in the home, N (%)	386 (56.6)	345 (45.9)	**<.001**	422 (55.3)	302 (42.8)	**<.001**
Current smoker, N (%)	137 (19.4)	245 (32.6)	**<.001**	217 (28.4)	247 (35.0)	**.007**
Policy support index, M (SD) [a]	3.10 (0.71)	2.96 (0.77)	**.001**	2.94 (0.89)	3.06 (0.74)	**.004**
Complete smoke-free home status, N (%) [b]	168 (23.8)	393 (52.3)	**<.001**	299 (39.2)	488 (53.6)	**<.001**
Past-month SHSe, number of days, M (SD) [c]	15.10 (12.70)	8.77 (10.92)	**<.001**	12.08 (12.12)	9.19 (11.36)	**<.001**
SHSe in distinct settings:						
In the home	11.00 (13.25)	3.24 (7.90)	**<.001**	6.61 (11.13)	2.87 (7.76)	**<.001**
In household vehicles	4.80 (9.58)	3.04 (6.63)	**.002**	4.16 (8.23)	5.20 (9.48)	.094
In indoor workplace	5.86 (9.95)	3.02 (7.41	**<.001**	3.30 (7.87)	2.60 (7.45)	.253
In indoor public setting	3.49 (6.30)	0.44 (2.57)	**<.001**	2.00 (5.56)	0.77 (3.18)	**<.001**
In outdoor public setting	8.32 (10.50)	2.27 (5.73)	**<.001**	6.75 (9.15)	6.52 (9.58)	.638

Notes: [a] Average score of 10 items assessing support in different settings (1=strongly oppose to 4=strongly support). [b] Complete smoke-free home operationalized as "Never allowed". [C] Response to "In the past 30 days, on how many days did you breathe the smoke from someone else's smoking?"

Supplementary Table 3. Coalition awareness and exposure to community-based activity among participants by condition and by country

	Armenia			Georgia		
	Intervention N=384	**Control N=379**		**Intervention N=365**	**Control N=340**	
Variables	**M (SD) or N (%)**	**M (SD) or N (%)**	**p**	**M (SD) or N (%)**	**M (SD) or N (%)**	**p**
Coalition awareness, N (%)	89 (24.6)	19 (5.3)	**<.001**	85 (24.1)	66 (19.8)	.101
Exposure to community-based activity (≥1), N (%)	268 (69.8)	194 (51.2)	**<.001**	265 (72.6)	270 (79.4)	**.021**
By setting/activity:						
School-based events	64 (16.7)	35 (9.2)	**.002**	32 (8.8)	23 (6.8)	.198
Signage and/or stickers promoting SF air	222 (57.8)	120 (31.7)	**<.001**	224 (61.4)	244 (71.8)	**.002**
Community member surveys regarding SF policies	92 (24.0)	44 (11.6)	**<.001**	38 (10.4)	44 (12.9)	.176
People picking up cigarette butts or promoting SF air	46 (12.0)	63 (16.6)	**.042**	36 (9.9)	39 (11.5)	.284
Events/activities in health care settings	65 (16.9)	17 (4.5)	**<.001**	41 (11.2)	45 (13.2)	.243
Other community-based activities	23 (6.0)	13 (3.4)	.067	6 (1.6)	3 (0.9)	.289
Number of activities exposed, M (SD)	1.33 (1.20)	0.77 (0.93)	**<.001**	1.03 (0.94)	1.17 (0.96)	.055

Author Reflexivity Statement: The research team has: 1) engaged constructively with the reflexivity statement (engagement); 2) co-developed the research study, which addresses priority research questions for the LMIC partners (co-development); 3) honored the LMIC partners as co-authors (albeit not first or last, as the MPIs on the study serve as first and last on this trial outcomes paper; several other publications have LMIC partner first and/or last authors) and incorporated LMIC early career researchers as authors (i.e., Torosyan, Dekanosidze, Grigoryan, Sargsyan, Hayrumyan); and 4) shared the data with LMIC partners to address research needs and will ensure open access funding to improve publication dissemination (dissemination).

Supplementary Appendix 1. CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Location
Title and abstract			
	1a	Identification as a randomised trial in the title	Title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Abstract
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Introduction
	2b	Specific objectives or hypotheses	Introduction, last paragraph
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Methods
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Methods
Participants	4a	Eligibility criteria for participants	Methods (Community Member Survey Data Collection)
	4b	Settings and locations where the data were collected	Methods (Community Selection & Randomization; Community Member Survey Data Collection)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Methods (Intervention vs. Control Conditions)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Methods (Measures)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	Methods (Community Selection & Randomization)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			Methods (Community Selection & Randomization; Community Member Survey Data Collection)
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Methods (Community Selection & Randomization; Community Member Survey Data Collection)
Allocation concealment	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Methods (Community Selection & Randomization;

mechanism			Community Member Survey Data Collection)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Methods (Community Selection & Randomization; Community Member Survey Data Collection)
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Methods (Community Selection & Randomization; Community Member Survey Data Collection)
	11b	If relevant, description of the similarity of interventions	Methods (Intervention vs. Control Conditions)
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods (Data Analysis)
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Methods (Data Analysis)
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Methods (Community Member Survey Data Collection); Results (Sample Characteristics)
	13b	For each group, losses and exclusions after randomisation, together with reasons	n/a
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Methods
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Results, Tables
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results, Tables
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Results, Tables
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Results, Tables
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Discussion (Limitations)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Methods (Context); Discussion (Limitations)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Discussion
Other information			Clinicaltrials.gov (NCT03447912)

Registration	23	Registration number and name of trial registry	Clinicaltrials.gov (NCT03447912)
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	US NIH/Fogarty International Center (R01TW010664)

Citation: Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Medicine. 2010;8:18.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.