Original Article
PEDIATRIC OBESITY

Obesity

Four-Year Behavioral, Health-Related Quality of Life, and BMI Outcomes from a Cluster Randomized Whole of Systems Trial of Prevention Strategies for Childhood Obesity

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Objective: This study aimed to test the effectiveness of the Whole of Systems Trial of Prevention Strategies for Childhood Obesity (WHO STOPS Childhood Obesity) for behavioral, health-related quality of life (HRQoL), and BMI outcomes.

Methods: This was a cluster randomized trial of 10 communities randomly allocated (1:1) to start intervention in 2015 (step 1) or in 2019 (after 4 years) in South West Victoria, Australia. Data were collected from participating primary schools in April to June of 2015 (73% school participation rate), 2017 (69%), and 2019 (63%). Student participation rates were 80% in 2015 (1,792/2,516 invited), 81% in 2017 (2,411/2,963), and 79% in 2019 (2,177/2,720). Repeat cross-sectional analyses of measured height and weight (grades two, four, and six [aged approximately 7 to 12 years]), self-reported behavior, and HRQoL (grades four and six) were conducted.

Results: There was an intervention by time interaction in BMI *z* scores ($P = 0.031$) and obesity/overweight prevalence ($P = 0.006$). BMI *z* score and overweight/obesity prevalence decreased between 2015 and 2017 and increased between 2017 and 2019 in intervention communities. The intervention significantly reduced takeaway food consumption ($P = 0.034$) and improved physical ($P = 0.019$), psychosocial ($P = 0.026$), and global ($P = 0.012$) HRQoL. Water consumption increased among girls ($P = 0.033$) in the intervention communities, as did energy-dense, nutrient-poor snack consumption among boys ($P = 0.006$).

Conclusions: WHO STOPS had a positive impact on takeaway food intake and HRQoL.

Obesity (2021) **29**, 1022-1035.

Study Importance

What is already known?

- Community-based interventions are seen as promising approaches to childhood obesity prevention.
- New trials are needed that engage with the complex nature of community trials.
- Long-term sustainability (>2 years) of shorter-term trial effects are as yet unstudied.

What does this study add?

- This is a longer trial (4 years) than any previously of its type.
- WHO STOPS initially reduced overweight/obesity in the intervention group in the first 2 years followed by increases in subsequent years.
- Over 4 years, WHO STOPS helped intervention children keep their takeaway food intake low and sustain HRQoL compared with control children.

How might these results change the direction of research or the focus of clinical practice?

- Prevention efforts need to be embedded in all aspects of community health, including education settings and clinical practice, to be sustainable and effective.

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Received: 10 September 2020; **Accepted:** 16 December 2020; **Published online 5 May 2021. doi:10.1002/oby.23130**

Introduction

Childhood obesity is a precursor to adult obesity, a major determinant of multiple diseases (1), and prevention of childhood obesity is a global priority (2,3). The high prevalence of obesity, attendant diseases, and treatment costs are projected to rise (4). Childhood obesity (5) and associated behaviors track across the life-span (6), making a compelling case for childhood obesity prevention.

- Sustained improvements in behaviors and HRQoL can be achieved if efforts are supported across multiple community systems.
- Adaptive trial methodologies that allow for unforeseen impacts on trial design are needed for the next phase of childhood obesity prevention.

Meta-analyses of obesity prevention studies in children showed promising overall benefits of community-based interventions among children (7,8). Australian community-based interventions among children under age 5 (9), primary school age (10), and adolescents (11) were among the first to demonstrate a reduction in the prevalence of obesity. These trials show that improving broader system determinants (e.g., community capacity for healthy change) strongly predicted the degree of reduction in childhood obesity (12) and encouraged diffusion of prevention action (13).

Several Lancet Commissions on obesity identified sustainability and scalability as challenges for community-based childhood obesity prevention initiatives (14). The 2019 Lancet Commission (15) pointed to systems thinking as a way to enhance the reach, impact, and sustainability of such initiatives. Early examples of systems thinking being applied to obesity prevention include efforts in Australia (16), New Zealand (17), and England (18). These interventions fostered a shared understanding of the broader systemic determinants of obesity and engaged communities in asking how existing systems can be strengthened or new systems created (19). Building community capacity to understand and act to strengthen these systems is critical (12,20).

Whole of Systems Trial of Prevention Strategies for Childhood Obesity (WHO STOPS Childhood Obesity) was a stepped wedge, cluster randomized trial of a whole of community systems-based approach to preventing childhood obesity in the Great South Coast region of Victoria, Australia (21). The intervention helped community leaders and members identify and take actions to prevent childhood obesity in children aged 5 to 12 years (primary school age). The primary outcome was measured child BMI *z* score (BMIz) and overweight and obesity prevalence collected via an opt-out monitoring system (22). Secondary outcomes were obesity-related behaviors and perceived health-related quality of life (HRQoL). Here, we answer the following questions for the WHO STOPS trial:

- What were the 4-year changes in BMIz and overweight and obesity prevalence (primary outcomes) among children attending primary schools in the intervention communities, compared with children in control communities?
- What were the 4-year changes in obesity-related behaviors and HRQoL (secondary outcomes) among children attending primary schools in the intervention communities, compared with children in control communities?

Methods

Design

Following the baseline measurement of behaviors and height and weight in ten communities (April to June 2015), five communities were randomized to begin the intervention phase in late 2015. Under the original design (21), the remaining five communities were intended to begin the intervention in 2017. Delays occurred resulting from natural disasters (e.g., bushfire), staff turnover (in partner organizations), and shifting priorities of partners. As a result, the step 2 communities are treated here as "control communities." The original step 1 communities were engaged as intended and maintained the intervention across the 4 years, and they are referred to as "intervention communities." This paper reports the comparison of intervention versus control communities over 4 years (2015 to 2019). Full ethics clearances have been received from: Deakin University's Human Research Ethics Committee (DU-HREC) 2014-279, DU-HREC 2013-095, Deakin University's Human Ethics Advisory Group-Health (HEAG-H) 194_2014, HEAG-H 17 2015, HEAG-H 155_2014, the Victorian Department of Education and Training 2015_002622, 2013_002013, and the Catholic Archdiocese of Melbourne, Sale, Sandhurst, and Ballarat.

School and participant recruitment

All primary schools (government, independent, and Catholic) across 10 communities in six local government areas in South West Victoria, Australia, were invited. An opt-out approach was used, whereby students were enrolled in data collection unless either the child or a parent or guardian actively declined participation. All children in grades two (mean age 7.8 years), four (mean age 9.8 years), and six (mean age 11.9 years) available on the day of data collection at their school who had not opted out were eligible. Repeat cross-sectional measurement of these age groups provided a good representation across the school cohort without having to collect data from all children. Data were collected in Term 2 (April to June) of 2015, 2017 and 2019 on an electronic tablet (Samsung Galaxy; Samsung Group, Seoul, South Korea) using a specifically designed application.

WHO STOPS intervention description

The intervention comprised a multistage process (21).

The first phase involved the collection and sharing of baseline monitoring data to raise awareness of childhood obesity and to engage and recruit community leaders. Leaders included representatives of agencies (e.g., Departments of Health and Education, health services, business) and other community leaders with shared agendas or influence on childhood health, obesity prevention, healthy eating, or physical activity.

The second intervention phase involved identifying and working with community members and supporters who had authority to initiate action and who outlined the context for intervention and set the boundaries. This group included chief executive officers of health services and local council, business leaders, executives from the local water board, leaders of the local chamber of commerce, school principals, others in executive roles, and other informal and respected local community leaders. These leaders built a causal loop

diagram of the causes of childhood obesity in their community (23) (e.g., Figure 1) using STICKE (Systems Thinking in Community Knowledge Exchange) version 1.7.1(Institute for Intelligent Systems Research and Innovation, Deakin University, Geelong, Australia) (24). The resultant diagram (known as a system map) captured drivers of childhood obesity in the community. Community leaders committed to advocating for the trial and providing resources (e.g., personnel) to support intervention implementation.

The third phase involved engaging a larger group of community representatives from organizations whose activities and agenda included remit and capacity to influence children's food and activity environments and choices, including retailers, schools, health organizations, leading community groups, and others.

The fourth phase involved this large group of engaged community representatives working together to design actions to prevent childhood obesity that they could carry out across the community, which were inspired by the systems map and informed by a prepared evidence brief on obesity prevention, including case studies from previous successful interventions.

Levels of community action implemented varied by the community. Action registers were recorded throughout the duration of the project. One community recorded 250 actions over 4 years, whereas another community recorded 11 actions in 2 years. Some key examples of actions were (1) a rural health service changing its beverage provision and cafe to be "green only," in line with government healthy choices guidelines (25); (2) a local government area constructing a new footpath to allow schoolchildren to engage in active transport more easily to and from school; (3) implementing a junior sporting-association-wide water-only policy; (4) a local primary school constructing signs encouraging children to be dropped off at set points away from the school gate to allow them to walk to school; and (5) implementing a healthy beverage policy at family day care.

The fifth and final phase involved ongoing data collection and updates of the systems map to enhance implementation and diffusion of the selected actions and stimulate new ideas in a constructive, capacity-building cycle. The intervention design was deliberately adaptive so that communities moved through the intervention at their own pace.

At the 2017 data monitoring time point, step 1 communities were in the intervention phase (one had completed all five phases; the rest had completed phase two and were planning for phase three). At the 2019 data monitoring point, all step 1 communities in this analysis were ongoing in the fifth phase.

Demographic characteristics

A detailed description of the data collection procedures, psychometric properties of instruments used, and data management techniques has previously been published (22). Demographic data collected included gender, date of birth, country of birth, Aboriginal and/or Torres Strait Islander background, and language spoken at home, which was dichotomized as English or Other. Socioeconomic position was examined at the school level through the Index of Community Socio-Educational Advantage (26).

Anthropometry measures

For all students, height and weight were measured by trained health professionals in private booths; the children wore light clothing and removed their shoes. A portable stadiometer (Charder HM-200P Portstad, Charder Electronic Co. Ltd., Taichung City, Taiwan) was used to measure height to the nearest 0.1 cm, and an electronic weight scale (A&D Precision Scale UC-321, A7D Medical, San Jose, California) was used to measure weight to the nearest 0.1 kg. Two measurements were taken for both height and weight, and a third measurement was taken if a discrepancy of >0.5 cm for height or >0.1 kg for weight was recorded between the two initial measures. Average height and weight were calculated for each child across these measures and used to generate age- and sex-specific BMIz and overweight/obesity categories using the World Health Organization's growth reference (27).

Physical activity and sedentary behavior

Grade-four and -six students self-reported time spent in moderate-to-vigorous physical activity (MVPA) and screen time for recreation (sedentary behavior) over the previous 7 days. Using the Core Indicators and Measures of Youth Health-Physical Activity & Sedentary Behavior Module questionnaire (28), participants were asked to indicate the time they spent in MVPA (none, 1 to 14 minutes, 15 to 29 minutes, 30 to 59 minutes, 1 to 2 hours, or >2 hours) or screen time for recreation outside of school (none, <1 hour, 1 to 2 hours, 2 to 5 hours, and ≥5 hours) using these response options for each of the previous 7 days. These data were used to determine adherence to the physical activity (≥60 min/d of MVPA) and sedentary behavior (≤2 h/d of electronic media for entertainment) components of Australia's 24-hour movement and screen time guidelines (29). Contextual information was also collected (but not reported here) relating to physical activity and sedentary behaviors (e.g., having a TV in the bedroom, participation in active transportation to and from school) and perceived psychosocial influences on physical activity participation (e.g., social support, parental modeling) using the School Health Action, Planning and Evaluation System (SHAPES) questionnaire (30). Participants also reported the mode of transport they usually took to get to and from school in the past 7 days using response options (car, school bus, public bus, train or tram, cycling, other active, and other inactive) using the Core Indicators questionnaire (28). Students were classified as using active transport if they used one of these modes of transport to and/or from school.

Diet quality

For grade-four and -six students, a modified version of the psychometrically tested Simple Dietary Questionnaire (31) was used to collect self-reported "usual" intake of core foods and beverages (e.g., fruit, vegetables, water, unsweetened dairy products) and noncore foods and beverages (e.g., takeaway foods, packaged snacks, sugar-sweetened beverages [SSBs]).

These data were used to determine adherence to the Australian Dietary Guidelines, which recommend daily consumption of 2 servings of fruit for children aged 9 to 18 years, 5 servings of vegetables for girls aged 9 to 18 years and boys aged 9 to 11 years, and 5.5 servings of vegetables for older boys (12 to 18 years) (32). Water servings were measured in cups (1 cup to approximately 250 mL), and students reported how many cups they consumed each day. Water data were dichotomized into <5 and ≥5 cups per day, based on the adequate intake level recommended for children 9 to 13 years old (33). There is no recommendation for SSB consumption in Australian children. An arbitrary cut point of ≤1 SSB per day was used. Takeaway food consumption was dichotomized as ≤2 times per week or above.

HRQoL

For grade-four and -six students, version four of the 23-item Pediatric Quality of Life Inventory 4.0 generic core scale (34) was used to measure children's perceived HRQoL. It consists of four domains: physical, emotional, social, and school functioning. Questions were reverse scored, and domain scores were summed to provide an overall HRQoL score with potential ranges of 0 to 100. We report on the physical subscore, psychosocial subscore, and global, which combines emotional, social, and school functioning scores. The minimal clinically important difference of the Pediatric Quality of Life Inventory summary score is 4.5 points (35).

Statistical analyses

The sample size calculation was conducted under the original stepped wedge design (10 clusters, three steps, three measurement points, average of 300 children per cluster at each measurement time, α=0.05), assuming BMIz standard deviation (1.2) and intracluster correlation (0.027) estimated from a previous study of >2,500 Victorian schoolchildren (2013 to 2014) (36). Under these assumptions the study had 80% power to detect a difference of 0.13 BMIz score between groups. Because the second step of the stepped wedge design did not occur (see "Design" subsection) the study was analyzed as a parallel cluster randomized trial. When considering a cluster randomized trial with a baseline measure, the proposed sample size (10 clusters, average of 300 children per cluster at each measurement time) had 80% power to detect a 0.17 BMIz difference between arms (37).

The trial was analyzed as a parallel design with all statistical analyses conducted on an intention-to-treat basis.

The effect of the WHO STOPS intervention on BMIz was estimated using linear mixed models with school as a random effect to adjust for clustering. Community was not incorporated as a clustering factor because its contribution to variance was negligible after school was considered. Further, additional sensitivity analyses are reported in the online Supporting Information. The effect of the intervention on binary variables was estimated using generalized estimating equations (logit link and binomial distribution, compound symmetry correlation). The models included group (intervention, control), wave (2015, 2017, 2019), the interaction group × wave, the schools' Index of Community Socio-Educational Advantage tertile, and type of school (government, independent, Catholic). These last two factors were incorporated to adjust for potential imbalances in the type/socioeconomic level of schools participating at different waves. The same models were fitted for gender and grade level separately. For completeness, we report two prespecified contrasts for each outcome: mean difference (BMIz) and prevalence difference (binary outcomes) between study arms in (1) change between 2017 and baseline and (2) change between 2019 and baseline. We did not adjust for multiplicity of outcomes. All analyses were performed using SAS (version 9.4; SAS Institute, Cary, North Carolina).

Results

Of the primary schools invited in each study year, 40/55 (73%) participated in 2015, 48/70 (69%) participated in 2017, and 44/70 (63%) participated in 2019 (Table 1). The number of schools increased in 2017 and 2019 because of the inclusion of Catholic schools. Student participation rates were 80% in 2015 (1,792/2,251), 81% (2,411/2,963) in 2017, and 79% (2,137/2,720) in 2019. The average age of children ranged between 9.6 years and 9.9 years over the study waves, and between 93% and 96% reported speaking English at home.

TABLE 1 School and student participation rate for 2015, 2017, and 2019

	School								Student							
	2015			2017			2019		2015			2017			2019	
	INV	CONS	RR	INV	CONS	RR	INV	CONS	RR	INV	CONS	RR	INV	CONS	RR	INV	CONS	RR
Intervention	34	25	73.5	41	25	61.0	41	23	56.1	1,202	972	80.9	1,260	1,041	82.6	1,127	878	77.9
Control	21	15	71.4	29	23	79.3	29	21	72.4	1,049	820	78.2	1,703	1,370	80.4	1,593	1,259	79.0
Total	55	40	72.7	70	48	68.6	70	44	62.9	2,251	1,792	79.6	2,963	2,411	81.4	2,720	2,137	78.6

This table includes values for all government, Catholic, and independent schools (excluding Catholic schools in 2015).
CONS, consent; INV, invited; RR, response rate.

TABLE 2 Demographic, anthropometric, and behavioral outcomes by wave and trial arm

	Intervention communities						Control communities						Difference in change (Int. vs. Control)		Difference in change (Int. vs. Control)		Wave × group interaction
	2015		2017		2019		2015		2017		2019		2017 vs. 2015		2019 vs. 2015		
	N	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	Estimate (95% CI)	*P*	Estimate (95% CI)	*P*	*P*
Demographic data																	
Age, y (mean)	970	9.6 (9.5 to 9.8)	1,030	9.9 (9.7 to 10.0)	878	9.8 (9.7 to 10.0)	820	9.8 (9.6 to 9.9)	1,370	9.9 (9.7 to 10.0)	1,259	9.8 (9.7 to 10.0)	0.15 (−0.06to 0.37)	0.169	0.13 (−0.09to 0.36)	0.236	0.345
English language at home (%)	568	93.4 (89.9 to 96.9)	696	93.8 (91.5 to 96.1)	583	96.3 (94.8 to 97.7)	541	94.6 (93.1 to 96.0)	928	92.5 (90.6 to 94.3)	830	93.9 (92.2-95.6)	2.5 (−1.4 to 6.5)	0.207	3.5 (−0.2 to 7.3)	0.065	0.178
Student SEIFA score (grade 4 & grade 6) (mean)	588	972 (962 to 983)	1,026	972 (962 to 983)	872	973 (962 to 983)	540	984 (972 to 995)	1,363	982 (970 to 994)	1,249	982 (971-994)	1.7 (−1.6 to 5.0)	0.319	1.4 (−2.1 to 4.6)	0.471	0.607
Anthropometric outcomes																	
BMIz (WHO)	966	0.64 (0.52 to 0.76)	993	0.55 (0.44 to 0.67)	868	0.74 (0.62 to 0.86)	815	0.60 (0.46 to 0.73)	1,329	0.60 (0.48 to 0.73)	1,228	0.60 (0.48-0.72)	−0.09 (−0.24 to 0.06)	0.217	0.10 (−0.06 to 0.25)	0.219	**0.031**
Overweight and obesity (%)	966	35.5 (31.6 to 39.4)	993	**31.5 (27.4 to 35.6)**[b]	868	**40.4 (35.8 to 45.0)**[b]	815	34.3 (29.5 to 39.2)	1,329	32.9 (29.0 to 36.7)	1,228	34.7 (30.8-38.7)	−2.5 (−7.2 to 2.2)	0.297	4.5 (−0.5 to 9.4)	0.079	**0.006**
Behavioral outcomes																	
Met PA guideline, 5 days (%)	594	32.1 (24.8 to 39.4)	700	36.7 (30.2 to 43.3)	587	**40.3 (32.2 to 48.4)**[a]	544	33.4 (25.3 to 41.6)	930	33.7 (26.3 to 41.1)	831	37.0 (30.1-43.9)	4.4 (−5.7 to 14.4)	0.396	4.6 (−5.5 to 14.8)	0.371	0.632
Met sedentary guideline, 5 days (%)	564	82.9 (77.5 to 88.4)	661	81.4 (76.9 to 85.9)	584	79.7 (74.7 to 84.6)	539	83.1 (77.6 to 88.6)	893	82.9 (78.6 to 87.2)	829	78.4 (73.6 to 83.2)	−1.3 (−8.2 to 5.5)	0.701	1.4 (−6.5 to 9.4)	0.722	0.658
Active transport to or from school (%)	593	25.3 (17.0 to 33.5)	699	27.9 (22.9 to 32.8)	587	23.0 (17.3 to 28.7)	544	28.1 (19.2 to 37.0)	931	30.3 (21.5 to 39.1)	831	25.8 (18.4 to 33.3)	0.4 (−6.5 to 7.4)	0.903	0.0 (−9.0 to 9.0)	0.999	0.987
Met vegetable guideline (%)	588	19.2 (15.2- 23.2)	695	18.9 (15.8 to 22.1)	585	17.4 (14.4 to 20.4)	541	19.8 (15.3 to 24.4)	921	18.6 (14.1 to 23.2)	824	18.9 (15.1 to 22.7)	0.9 (−5.1 to 7.0)	0.764	−1.0 (−6.4 to 4.5)	0.730	0.733
Met fruit guideline (%)	580	72.9 (68.8 to 77.0)	675	**77.5 (74.3 to 80.8)**[a]	588	73.2 (69.0 to 77.4)	538	76.4 (71.3 to 81.5)	909	76.9 (72.4 to 81.4)	831	80.0 (76.2 to 83.9)	4.2 (−3.5 to 11.9)	0.290	−3.3 (−11.3 to 4.7)	0.415	**0.038**
Takeaway (less than once a week) (%)	593	87.9 (84.1 to 91.7)	696	87.6 (84.7 to 90.5)	588	88.8 (85.9 to 91.8)	545	91.1 (87.5 to 94.6)	930	91.0 (88.0 to 94.0)	830	**86.0 (82.6 to 89.4)**[a]	−0.2 (−5.2 to 4.8)	0.942	**6.0 (0.5 to 11.6)**	**0.034**	**0.006**
Packaged snacks (≤1 times/d) (%)	582	69.9 (65.5 to 74.3)	655	73.2 (69.9 to 76.6)	588	74.1 (70.1 to 78.1)	530	76.2 (71.3 to 81.1)	861	75.1 (70.0 to 80.2)	831	73.6 (69.4 to 77.9)	4.4 (−3.7 to 12.5)	0.290	6.7 (−0.9 to 14.4)	0.085	0.227
Water ≥ 5 glasses/d (%)	538	56.6 (50.6 to 62.6)	625	61.7 (56.2 to 67.2)	590	55.7 (50.4 to 61.0)	486	60.6 (53.9 to 67.3)	803	56.8 (50.1 to 63.4)	831	53.7 (48.2 to 59.1)	8.9 (−0.1 to 18.0)	0.054	6.1 (−3.3 to 15.4)	0.204	0.140
SSB ≤ 1/d (%)	593	82.8 (78.8 to 86.8)	693	86.2 (81.9 to 90.6)	588	84.2 (79.9 to 88.6)	542	83.7 (78.7 to 88.6)	927	85.6 (81.2 to 90.1)	829	88.6 (84.6 to 92.6)	1.4 (−4.3 to 7.1)	0.619	−3.5 (−10.5 to 3.4)	0.318	0.189
HRQoL																	
HRQoL psychosocial score	565	75.6 (73.4 to 77.9)	677	74.7 (72.7 to 76.7)	578	73.8 (71.7 to 76.0)	530	78.4 (76.0 to 80.8)	903	**75.4 (73.2 to 77.6)**[b]	821	**73.6 (71.5 to 75.8)**[c]	2.0 (−0.53 to 4.53)	0.122	**2.9 (0.4 to 5.5)**	**0.026**	0.079
HRQoL physical score	576	83.0 (81.0 to 84.9)	687	84.0 (82.3 to 85.8)	586	82.6 (80.7 to 84.5)	537	86.2 (84.1 to 88.4)	913	**84.4 (82.5 to 86.3)**[b]	830	**82.7 (80.8 to 84.6)**[c]	**2.87 (0.34 to 5.39)**	**0.026**	**3.1 (0.5 to 5.7)**	**0.019**	**0.036**

TABLE 2 (continued).

	Intervention communities						Control communities						Difference in change (Int. vs. Control)		Difference in change (Int. vs. Control)		Wave × group interaction
	2015		2017		2019		2015		2017		2019		2017 vs. 2015		2019 vs. 2015		
	N	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	Estimate (95% CI)	*P*	Estimate (95% CI)	*P*	*P*
HRQoL global score	564	78.3 (76.4 to 80.3)	673	78.0 (76.2 to 79.8)	576	76.9 (75.0 to 78.8)	530	81.3 (79.1 to 83.4)	901	**78.7 (76.7 to 80.6)**[b]	821	**76.9 (74.9 to 78.8)**[c]	**2.28 (0.00 to 4.57)**	**0.050**	**3.0 (0.6 to 5.3)**	**0.012**	**0.036**

[a] $P < 0.05$.
[b] $P < 0.01$.
[c] $P < 0.001$.
Boldface indicates significant difference within trial group between 2015 and 2017 or 2015 and 2019. Estimates are based on generalized mixed models (logit link, binary distribution, compound symmetry covariance matrix) or linear mixed models with school as a random effect. All models included time, group, and their interaction. Models for outcomes additionally included school type and Index of Community Socio-Educational Advantage tertile. Behavioral and HRQoL outcomes only collected in grade-four and grade-six children.
HRQoL, Health-Related Quality of Life; Int., intervention; PA, physical activity; SEIFA, Socio-Economic Indexes For Areas; SSB, sugar-sweetened beverage; WHO, World Health Organization.

BMIz

Overall. A significant trial arm by study wave interaction effect on BMIz was observed ($P = 0.031$), although no significant difference was observed between intervention and control groups in change in BMIz between 2015 and 2017 or between 2015 and 2019. Reductions in BMIz within the intervention group were observed from 2015 to 2017 followed by an increase to 2019. Conversely, BMIz remained stable within the control group across the study period (Table 2).

By gender. No significant changes were observed in girls' BMIz within groups or between groups. However, in the intervention group, girls' BMIz initially reduced from 2015 to 2017 followed by an increase to 2019, whereas control girls experienced a steady increase from 2015 to 2019. A similar pattern was observed within boys in the intervention group in which BMIz initially reduced (but not significantly) from 0.59 in 2015 to 0.54 in 2017 but significantly increased between 2015 and 2019 to 0.77 ($P = 0.047$). Among control group boys, BMIz was stable from 2015 to 2019 (Table 3).

By year level. Over the study period, BMIz of the grade-two cohort increased with each wave, although nonsignificantly. Among intervention communities, BMIz was significantly lower in the 2017 grade-four intervention cohort compared with 2015 ($P = 0.01$ for grade four), although this was not sustained at 2019, whereas BMIz in the grade-four control group remained stable over the same period, with a significant interaction effect ($P = 0.033$) (Table 4).

Proportion with overweight and obesity in 2015, 2017, and 2019

Overall. There was a significant interaction effect between trial group and time ($P = 0.006$) (Table 2). Within intervention communities, the prevalence of combined overweight and obesity was 35.5% in 2015, 31.5% in 2017, and 40.4% in 2019. This represented a significant reduction in prevalence of −4.0% (95% CI: −6.77% to −1.24%, $P = 0.005$) between 2015 and 2017 and a significant increase between 2015 and 2019 (+4.9% [95% CI: 1.8% to 8.0%, $P = 0.002$]). Prevalence within the control group remained stable at 34.3% in 2015 and 34.7% in 2019.

By gender. For both girls and boys (Table 3), a similar pattern of nonsignificant initial reduction in prevalence of overweight and obesity in intervention communities followed by an increase in prevalence was observed, whereas in the control communities the prevalence remained stable. A significant interaction effect was observed among boys ($P = 0.045$).

By year level. Differential effects were observed within grade levels. The prevalence of overweight and obesity within intervention communities changed −11.4% (95% CI: −18.9% to −3.8%, $P = 0.003$) among grade-four students between 2015 and 2017 (significant group by wave, $P = 0.038$). Over the 4-year period, prevalence significantly increased by + 9.7% (95% CI: 0.9% to 18.6%) in grade-two intervention communities (Table 4). Among control communities, prevalence within year levels remained relatively stable. No interaction effects were observed for wave and trial arm within grade-two and grade-six levels.

Behavioral outcomes

Overall. The number of children reporting meeting the physical activity guidelines increased by 8.2% (95% CI: 0.7%-15.7%, $P = 0.032$) between 2015 and 2019 within intervention communities but not in

TABLE 3 Demographic, anthropometric, and outcomes by gender, wave, and trial arm

	Intervention communities						Control communities						Difference in change (Int. vs. Control		Difference in change (Int. vs. Control)		
	2015		2017		2019		2015		2017		2019		2017 vs. 2015		2019 vs. 2015		Wave × group interaction
	N	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	Estimate (95% CI)	*P*	Estimate (95% CI)	*P*	*P*
Girls																	
Demographic data																	
Age, y (mean)	470	9.6 (9.4 to 9.8)	493	**9.8 (9.6 to 10.0)**[a]	421	9.8 (9.6 to 10.0)	409	9.9 (9.7 to 10.1)	680	9.9 (9.7 to 10.1)	579	9.8 (9.7 to 10.0)	0.20 (−0.11 to 0.51)	0.206	0.23 (−0.08 to 0.55)	0.149	0.305
English language at home (%)	279	93.5 (90.3 to 96.8)	332	93.3 (90.3 to 96.4)	277	**97.7 (95.9 to 99.5)**[a]	288	95.6 (93.9 to 97.3)	463	**93.3 (90.8 to 95.8)**[a]	388	96.5 (95.2 to 97.9)	2.1 (−2.3 to 6.5)	0.351	3.3 (−1.1 to 7.6)	0.142	0.339
Student ICSEA score (grade four and grade six) (mean)	288	974 (963 to 984)	487	974 (963 to 984)	420	973 (963 to 984)	285	986 (974 to 998)	674	983 (971 to 995)	575	984 (972 to 996)	2.4 (−2.2 to 7.0)	0.299	1.8 (−3.0 to 6.5)	0.467	0.582
Anthropometric outcomes																	
BMIz (WHO)	470	0.69 (0.54 to 0.84)	477	0.57 (0.43 to 0.71)	416	0.72 (0.58 to 0.86)	405	0.59 (0.43 to 0.75)	660	0.64 (0.50 to 0.78)	571	0.63 (0.49 to 0.78)	−0.16 (−0.36 to 0.04)	0.118	−0.01 (−0.22 to 0.20)	0.930	0.190
Overweight and obesity (%)	470	39.2 (34.5 to 43.8)	477	35.3 (30.1 to 40.4)	416	41.7 (36.5 to 47.0)	405	37.7 (31.9 to 43.5)	660	37.0 (33.0 to 41.1)	571	37.9 (32.5 to 43.3)	−3.2 (−11.3 to 4.8)	0.432	2.4 (−6.1 to 10.8)	0.582	0.420
Behavioral outcomes																	
Met PA guideline, 5 days (%)	291	23.7 (14.1 to 33.2)	335	31.7 (24.3 to 39.2)	279	31.5 (21.8 to 41.1)	287	23.2 (14.2 to 32.2)	464	29.5 (19.9 to 39.0)	388	31.0 (22.9 to 39.2)	1.8 (−12.8 to 16.4)	0.809	−0.1 (−13.1 to 13.0)	0.993	0.953
Met sedentary guideline, 5 days (%)	282	86.5 (82.1 to 90.8)	320	86.4 (82.2 to 90.6)	277	82.2 (77.6 to 86.9)	285	87.0 (82.3 to 91.7)	439	87.9 (83.7 to 92.0)	388	83.2 (78.7 to 87.7)	−0.9 (−8.5 to 6.8)	0.824	−0.4 (−8.5 to 7.7)	0.922	0.973
Active transport to or from school (%)	292	24.8 (14.8 to 34.8)	335	27.8 (21.5 to 34.1)	279	20.5 (16.0 to 25.0)	288	32.4 (22.3 to 42.5)	464	37.0 (27.6 to 46.4)	388	28.0 (19.2 to 36.8)	−1.6 (−10.7 to 7.6)	0.739	0.1 (−10.3 to 10.5)	0.983	0.872
Met vegetable guideline (%)	291	23.1 (17.9 to 28.4)	334	20.1 (15.5 to 24.6)	279	19.9 (15.6 to 24.2)	287	20.4 (14.0 to 26.8)	463	19.3 (13.3 to 25.2)	388	18.8 (13.8 to 23.8)	−2.0 (−9.4 to 5.4)	0.601	−1.6 (−10 to 6.7)	0.701	0.870
Met fruit guideline (%)	287	77.8 (72.0 to 83.5)	323	**85.9 (81.1 to 90.8)**[a]	279	76.6 (71.8 to 81.5)	284	82.4 (75.2 to 89.7)	453	82.1 (76.6 to 87.5)	388	84.0 (79.2 to 88.8)	8.6 (−2.4 to 19.6)	0.127	−2.7 (−12.7 to 7.4)	0.600	**0.001**
Takeaway (less than once a week) (%)	292	90.7 (86.7 to 94.6)	333	91.1 (87.8 to 94.3)	279	91.7 (87.7 to 95.6)	288	93.6 (89.4 to 97.7)	463	93.9 (90.5 to 97.2)	388	90.5 (86.8 to 94.3)	0.1 (−5.4 to 5.5)	0.978	4.1 (−2.7 to 10.8)	0.238	0.311
Packaged snacks (≤1 times/d) (%)	288	71.9 (67.0 to 76.9)	313	74.3 (69.0 to 79.7)	279	75.1 (69.7 to 80.4)	283	75.8 (69.0 to 82.5)	429	80.8 (74.7 to 86.9)	388	78.7 (73.2 to 84.2)	−2.6 (−12.5 to 7.2)	0.603	0.2 (−9.7 to 10.0)	0.975	0.820
Water ≥5 glasses/d (%)	269	52.9 (45.5 to 60.3)	299	**67.4 (60.4 to 74.4)**[a]	281	59.1 (52.7 to 65.4)	255	60.7 (51.3 to 70.1)	391	57.1 (47.4 to 66.9)	388	55.0 (48.8 to 61.3)	**18.1 (4.3 to 31.8)**	**0.010**	**11.8 (1.0 to 22.7)**	**0.033**	**0.019**
SSB ≤1/d (%)	291	83.1 (77.6 to 88.5)	331	**87.9 (83.8 to 92.0)**[a]	279	86.0 (81.1 to 90.9)	285	87.7 (82.3 to 93.1)	463	89.9 (85.8 to 94.1)	386	90.5 (86.4 to 94.7)	2.7 (−3.5 to 8.8)	0.394	0.1 (−8.6 to 8.8)	0.980	0.561
HRQoL																	
HRQoL psychosocial score	275	77.4 (74.7 to 80.1)	329	77.2 (74.7 to 79.6)	274	75.0 (72.4 to 77.6)	285	80.9 (78.0 to 83.7)	454	**77.3 (74.7 to 79.9)**[b]	383	**75.8 (73.2 to 78.4)**[c]	3.4 (−0.1 to 6.8)	0.055	2.6 (−0.9 to 6.2)	0.148	0.144
HRQoL physical score	281	85.5 (83.0 to 88.0)	333	85.8 (83.5 to 88.1)	279	83.1 (80.7 to 85.5)	288	88.0 (85.3 to 90.6)	457	85.8 (83.4 to 88.2)	388	**83.6 (81.2 to 86.0)**[c]	2.5 (−0.9 to 5.8)	0.154	2.0 (−1.5 to 5.4)	0.272	0.340
HRQoL global score	274	80.3 (77.9 to 82.7)	329	80.3 (78.1 to 82.4)	272	**77.9 (75.6 to 80.2)**[a]	285	83.5 (81.0 to 86.0)	453	**80.3 (78.0 to 82.6)**[b]	383	**78.6 (76.3 to 80.9)**[c]	**3.1 (0.0 to 6.2)**	**0.049**	2.4 (−0.8 to 5.7)	0.136	0.129
Boys																	
Demographic data																	
Age, y (mean)	499	9.7 (9.5 to 9.8)	540	**9.9 (9.8 to 10.1)**[a]	454	9.9 (9.7 to 10.0)	411	9.7 (9.5 to 9.9)	690	9.9 (9.7 to 10.0)	673	9.9 (9.7 to 10.0)	0.09 (−0.21 to 0.38)	0.565	0.05 (−0.25 to 0.35)	0.738	0.848

TABLE 3 (continued).

	Intervention communities						Control communities						Difference in change (Int. vs. Control		Difference in change (Int. vs. Control)		Wave × group interaction
	2015		2017		2019		2015		2017		2019		2017 vs. 2015		2019 vs. 2015		
	N	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	Estimate (95% CI)	*P*	Estimate (95% CI)	*P*	*P*
English language at home (%)	289	93.3 (88.6 to 98.1)	364	94.3 (91.8 to 96.8)	303	95.5 (93.7 to 97.3)	253	93.4 (90.9 to 95.9)	465	91.6 (88.4 to 94.9)	435	91.3 (88.0 to 94.7)	2.8 (–3.0 to 8.6)	0.344	4.3 (–1.5 to 10.1)	0.148	0.350
Student SEIFA score (grade four and grade six) (mean)	300	972 (961 to 982)	542	972 (961 to 982)	449	972 (962 to 983)	255	981 (969 to 994)	689	981 (969 to 993)	667	982 (970 to 994)	0.5 (–4.2 to 5.3)	0.831	0.1 (–4.7 to 5.0)	0.959	0.970
Anthropometric outcomes																	
BMIz (WHO)	496	0.59 (0.42 to 0.77)	516	0.54 (0.38 to 0.70)	452	**0.77 (0.60 to 0.94)**[a]	410	0.60 (0.40 to 0.79)	669	0.58 (0.40 to 0.75)	657	0.58 (0.40 to 0.75)	–0.03 (–0.25 to 0.19)	0.782	0.2 (–0.02 to 0.42)	0.077	0.062
Overweight and obesity (%)	496	32.7 (27.4 to 38.0)	516	28.9 (23.7 to 34.2)	452	**40.1 (33.8 to 46.4)**[b]	410	31.1 (24.9 to 37.3)	669	29.2 (24.1 to 34.3)	657	32.1 (27.1 to 37.1)	–1.9 (–8.1 to 4.3)	0.546	6.4 (–0.9 to 13.7)	0.088	**0.045**
Behavioral outcomes																	
Met PA guideline, 5 days (%)	303	41.1 (32.9 to 49.3)	365	41.6 (33.7 to 49.6)	305	**49.2 (41.1 to 57.3)**[a]	257	45.7 (33.9 to 57.5)	466	38.7 (29 to 48.4)	436	42.8 (34.5 to 51.2)	7.5 (–6.0 to 20.9)	0.276	10.9 (–3.6 to 25.4)	0.142	0.340
Met sedentary guideline, 5 days (%)	282	79.0 (70.7 to 87.2)	341	77.0 (70.3 to 83.7)	304	76.9 (70.5 to 83.4)	254	78.0 (69.7 to 86.3)	454	78.4 (72 to 84.8)	435	74.5 (67.6 to 81.4)	–2.4 (–11.4 to 6.7)	0.607	1.4 (–9.2 to 12.1)	0.793	0.637
Active transport to or from school (%)	301	26.7 (18.2 to 35.1)	364	28.0 (21.7 to 34.3)	305	26.2 (18.2 to 34.1)	256	25.2 (14.3 to 36.1)	467	26.4 (15.9 to 36.8)	436	25.0 (16.8 to 33.2)	0.2 (–9.1 to 9.5)	0.972	–0.3 (–10.0 to 9.4)	0.953	0.996
Met vegetable guideline (%)	297	16.5 (11.7 to 21.3)	361	18.1 (13.7 to 22.5)	303	15.5 (12.0 to 19.0)	254	21.2 (17.6 to 24.8)	458	20.0 (15.5 to 24.5)	429	21.4 (17.6 to 25.2)	2.8 (–4.7 to 10.4)	0.464	–1.2 (–7.0 to 4.6)	0.677	0.503
Met fruit guideline (%)	293	69.6 (64.1 to 75.0)	352	70.0 (66.3 to 73.7)	306	70.1 (63.4 to 76.8)	254	71.5 (65.5 to 77.5)	456	74.1 (69.5 to 78.8)	436	**78.8 (73.8 to 83.8)**[a]	–2.2 (–10.7 to 6.4)	0.617	–6.8 (–18.8 to 5.2)	0.264	0.503
Takeaway (less than once a week) (%)	301	85.0 (79.8 to 90.2)	363	85.1 (82.0 to 88.1)	306	87.3 (83.8 to 90.7)	257	88.8 (84.3 to 93.3)	467	88.7 (85.8 to 91.5)	435	**82.7 (78.8 to 86.6)**[a]	0.2 (–6.2 to 6.6)	0.951	**8.4 (0.1 to 16.7)**	**0.047**	**0.012**
Packaged snacks (≤1 times/d) (%)	294	67.9 (61.4 to 74.3)	342	**72.6 (67.9 to 77.2)**[a]	306	**73.1 (67.7 to 78.4)**[b]	247	76.4 (71.5 to 81.4)	432	**69.7 (64.2 to 75.3)**[a]	436	**69.4 (64.2 to 74.7)**[a]	**11.4 (1.3 to 21.5)**	**0.027**	**12.2 (3.5 to 20.9)**	**0.006**	**0.015**
Water ≥5 glasses/d (%)	269	60.1 (52.2 to 68.0)	326	56.3 (49.6 to 63.0)	306	52.1 (45.4 to 58.8)	231	60.3 (52.0 to 68.5)	412	56.2 (50.2 to 62.3)	436	52.4 (45.3 to 59.5)	0.2 (–10.3 to 10.8)	0.966	–0.1 (–13.8 to 13.6)	0.987	0.997
SSB ≤1/d (%)	302	82.5 (77.3 to 87.7)	362	85.2 (79.1 to 91.3)	306	82.5 (77.6 to 87.3)	257	79.5 (72.4 to 86.6)	464	81.7 (76.4 to 87.0)	436	**87.2 (82.4 to 92)**[a]	0.5 (–8.7 to 9.7)	0.915	–7.7 (–17.0 to 1.6)	0.105	0.087
HRQoL																	
HRQoL psychosocial score	290	74.2 (71.4 to 77.0)	348	72.8 (70.3 to 75.3)	301	73.2 (70.6 to 75.9)	245	76.5 (73.3 to 79.7)	449	74.1 (71.3 to 76.8)	431	**72.4 (69.6 to 75.1)**[a]	1.0 (–2.6 to 4.6)	0.587	3.1 (–0.6 to 6.8)	0.096	0.214
HRQoL physical score	295	80.8 (78.0 to 83.6)	354	82.6 (80.1 to 85.2)	304	82.4 (79.7 to 85.1)	249	84.6 (81.5 to 87.8)	456	83.2 (80.4 to 85.9)	435	**82.0 (79.2 to 84.7)**[a]	3.3 (–0.5 to 7.0)	0.085	**4.3 (0.4 to 8.1)**	**0.029**	0.080
HRQoL global score	290	76.7 (74.0 to 79.3)	344	76.3 (73.9 to 78.6)	301	76.4 (73.9 to 78.9)	245	79.4 (76.5 to 82.4)	448	77.4 (74.8 to 80.0)	431	**75.7 (73.1 to 78.3)**[a]	1.7 (–1.6 to 5.0)	0.319	**3.5 (0.2 to 6.9)**	**0.040**	0.117

[a]$P < 0.05$.
[b]$P < 0.01$.
[c]$P < 0.001$.
Boldface indicates significant difference within trial group between 2015 and 2017 or 2015 and 2019. Estimates are based on generalized mixed models (logit link, binary distribution, compound symmetry covariance matrix) or linear mixed models with school as a random effect. All models included time, group, and their interaction. Models for outcomes additionally included school type and Index of Community Socio-Educational Advantage tertile. Behavioral and HRQoL outcomes only collected in grade-four and grade-six children.
HRQoL, Health-Related Quality of Life; Int., intervention; PA, physical activity; SEIFA, Socio-Economic Indexes For Areas; SSB, Sugar Sweetened Beverages; WHO, World Health Organization.

TABLE 4 Demographic, anthropometric, and outcomes by year level, wave, and trial arm

	Intervention communities						Control communities						Difference in change (Int. vs. Control)		Difference in change (Int. vs. Control)		Wave × group interacton
	2015		2017		2019		2015		2017		2019		2017 vs. 2015		2019 vs. 2015		
	N	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	Estimate (95% CI)	*P*	Estimate (95% CI)	*P*	*P*
YEAR 2																	
Demographic data																	
Age, y (mean)	374	7.8 (7.8 to 7.9)	327	7.8 (7.8 to 7.9)	281	7.8 (7.8 to 7.9)	275	7.9 (7.9 to 8.0)	436	7.9 (7.8 to 7.9)	421	7.9 (7.8 to 7.9)	**0.09 (0.01 to 0.17)**	**0.036**	0.04 (−0.05 to 0.12)	0.409	0.102
Anthropometric outcomes																	
BMIz (WHO)	373	0.63 (0.47 to 0.80)	325	0.66 (0.50 to 0.82)	280	0.8 (0.64 to 0.96)	275	0.57 (0.39 to 0.76)	431	0.61 (0.45 to 0.78)	420	0.69 (0.53 to 0.86)	−0.01 (−0.25 to 0.22)	0.908	0.04 (−0.2 to 0.28)	0.722	0.879
Overweight and obesity (%)	373	30.8 (24.4 to 37.1)	325	32 (26.2 to 37.7)	280	**40.5 (33.6 to 47.4)**[a]	275	32.0 (25.7 to 38.3)	431	30.0 (25.3 to 34.6)	420	36.1 (30.8 to 41.4)	3.2 (−8.4 to 14.9)	0.586	5.7 (−6.1 to 17.4)	0.346	0.641
Grade four																	
Demographic data																	
Age, y (mean)	316	9.8 (9.8 to 9.9)	364	9.9 (9.8 to 9.9)	303	9.8 (9.8 to 9.9)	306	9.9 (9.9 to 10.0)	477	9.9 (9.9 to 9.9)	437	9.9 (9.9 to 10.0)	0.08 (−0.01 to 0.16)	0.073	0.03 (−0.06 to 0.12)	0.530	0.179
English language at home (%)	297	92.8 (88.7 to 97)	361	94.1 (91.3 to 97.0)	295	96.4 (94.3 to 98.6)	302	92.3 (89.8 to 94.9)	473	94.2 (91.8 to 96.5)	431	93 (90.9 to 95)	−0.5 (−5.9 to 4.9)	0.858	3.0 (−2.3 to 8.3)	0.266	0.216
Student SEIFA score (grade four and grade six) (mean)	309	973 (962 to 984)	359	973 (963 to 984)	300	973 (962 to 984)	303	983 (971 to 995)	476	981 (969 to 993)	434	982 (970 to 995)	2.5 (−2.4 to 7.3)	0.320	0.7 (−4.3 to 5.7)	0.788	0.569
Anthropometric outcomes																	
BMIz (WHO)	315	0.76 (0.59 to 0.94)	350	**0.52 (0.36 to 0.69)**[a]	300	0.83 (0.66 to 1.00)	306	0.69 (0.50 to 0.88)	460	0.66 (0.49 to 0.84)	418	0.66 (0.49 to 0.83)	−0.22 (−0.47 to 0.04)	0.092	0.10 (−0.16 to 0.35)	0.466	**0.033**
Overweight and obesity (%)	315	41.7 (35.3 to 48.1)	350	**30.3 (24.2 to 36.5)**[b]	300	42.9 (36.6 to 49.2)	306	38.6 (32.0 to 45.1)	460	36.4 (31.8 to 41.1)	418	37.9 (32.2 to 43.6)	−9.3 (−18.7 to 0.1)	0.053	1.9 (−8.2 to 12.0)	0.715	**0.038**
Behavioral outcomes																	
Met PA guideline, 5 days (%)	314	26.7 (18.3 to 35.0)	362	30.3 (23.5 to 37.1)	297	33.5 (23.8 to 43.1)	305	30.6 (21.7 to 39.5)	475	25.4 (17.2 to 33.6)	431	28.0 (20.0 to 35.9)	8.8 (−3.3 to 21.0)	0.154	9.5 (−4.9 to 23.8)	0.195	0.328
Met sedentary guideline, 5 days (%)	289	78.7 (73.0 to 84.4)	334	82.6 (77.3 to 87.8)	296	81.9 (77.3 to 86.5)	303	81.2 (74.8 to 87.6)	451	81.1 (76.6 to 85.7)	430	79.4 (74.9 to 83.9)	4.0 (−5.6 to 13.6)	0.419	5.0 (−4.8 to 14.8)	0.319	0.592
Active transport to or from school (%)	313	20.7 (13.1 to 28.3)	362	20.2 (15.2 to 25.1)	297	16.0 (10.1 to 21.8)	305	23.0 (13.0 to 33.0)	476	24.2 (15.5 to 32.9)	431	23.9 (15.9 to 31.8)	−1.7 (−10.2 to 6.8)	0.695	−5.6 (−15.7 to 4.6)	0.284	0.555
Met vegetable guideline (%)	311	18.6 (13.8 to 23.4)	361	21.8 (18.4 to 25.1)	297	19.4 (15.7 to 23.1)	305	21.9 (16.0 to 27.8)	473	17.2 (12.3 to 22.0)	431	21.0 (17.0 to 25.1)	8.0 (−0.4 to 16.3)	0.061	1.7 (−5.5 to 8.9)	0.644	0.081
Met fruit guideline (%)	304	71.1 (65.7 to 76.5)	351	75.1 (70.7 to 79.5)	297	74.1 (68.2 to 80.0)	301	74.4 (68.0 to 80.7)	462	75.4 (70.7 to 80.1)	431	**82.9 (77.9 to 88)**[a]	3.0 (−5.8 to 11.8)	0.499	−5.5 (−15.7 to 4.6)	0.286	0.092
Takeaway (less than once a week) (%)	312	85.4 (80.3 to 90.4)	361	83.6 (79.8 to 87.3)	297	87.7 (83.7 to 91.7)	306	87.6 (83.2 to 91.9)	476	87.3 (84.3 to 90.4)	430	**81.5 (77.2 to 85.8)**[a]	−1.5 (−8.5 to 5.4)	0.667	**8.4 (0.3 to 16.5)**	**0.041**	**0.006**
Packaged snacks (≤1 times/d) (%)	304	66.2 (60.5 to 72.0)	339	72.9 (67.2 to 78.7)	297	71.8 (66.6 to 77.0)	295	77.5 (72.6 to 82.5)	442	74.0 (68.2 to 79.7)	431	73.0 (67.3 to 78.7)	10.3 (−0.2 to 20.8)	0.054	**10.1 (0.3 to 20.0)**	**0.044**	**0.050**
Water ≥5 glasses/d (%)	286	56.5 (52.4 to 60.5)	327	**64.7 (59.2 to 70.2)**[b]	298	55.7 (49.8 to 61.6)	279	63.1 (57.1 to 69.2)	419	59.8 (53.3 to 66.3)	431	57.0 (52.5 to 61.5)	**11.6 (1.9 to 21.3)**	**0.019**	5.4 (−4.5 to 15.2)	0.288	0.061
SSB ≤1/d (%)	312	81.3 (75.8 to 86.9)	358	86.2 (82.5 to 89.9)	297	83.4 (78.0 to 88.9)	304	86.2 (80.6 to 91.7)	473	83.7 (78.9 to 88.5)	430	86.7 (82.1 to 91.4)	7.3 (−0.3 to 14.9)	0.060	1.5 (−7.5 to 10.6)	0.738	0.054

TABLE 4 (continued).

YEAR 2	Intervention communities						Control communities						Difference in change (Int. vs. Control)		Difference in change (Int. vs. Control)		Wave × group interacton
	2015		2017		2019		2015		2017		2019		2017 vs. 2015		2019 vs. 2015		
	N	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	Estimate (95% CI)	*P*	Estimate (95% CI)	*P*	*P*
HRQoL																	
HRQoL psychosocial score	292	73.5 (71.2 to 75.8)	343	73.8 (71.7 to 75.8)	291	73.2 (71.0 to 75.3)	297	76.6 (74.2 to 79.0)	455	75.1 (73.1 to 77.2)	425	**71.9 (69.9 to 74.0)**[c]	1.8 (−1.7 to 5.2)	0.313	**4.3 (0.8 to 7.9)**	**0.016**	**0.050**
HRQoL physical score	300	80.8 (78.4 to 83.2)	353	83.0 (80.8 to 85.2)	295	81.1 (78.8 to 83.4)	301	85.0 (82.4 to 87.5)	462	82.9 (80.8 to 85.1)	430	**80.8 (78.6 to 83.0)**[b]	**4.2 (0.6 to 7.9)**	**0.023**	**4.5 (0.7 to 8.2)**	**0.019**	**0.032**
HRQoL global score	291	76.3 (74.2 to 78.5)	341	77.1 (75.2 to 79.0)	289	76.0 (74.1 to 78.0)	297	79.8 (77.6 to 82.0)	453	78.1 (76.2 to 80.0)	425	**75.2 (73.4 to 77.1)**[c]	2.4(−0.7 to 5.6)	0.128	**4.39 (1.1 to 7.5)**	**0.009**	**0.034**
Grade six																	
Demographic data																	
Age, y (mean)	280	11.9 (11.8 to 11.9)	344	11.9 (11.8 to 11.9)	294	11.9 (11.8 to 11.9)	239	11.9 (11.8 to 11.9)	457	11.9 (11.8 to 11.9)	401	11.9 (11.9 to 11.9)	−0.01 (−0.10 to 0.08)	0.769	−0.05 (−0.14 to 0.04)	0.306	0.546
English language at home (%)	270	94.3 (90.7 to 98.0)	340	93.5 (90.8 to 96.3)	288	96.4 (94.5 to 98.4)	239	97.5 (96.0 to 99.0)	455	90.9 (88.4 to 93.4)	399	95.2 (92.4 to 98.0)	**5.8 (1.0 to 10.6)**	**0.018**	4.4 (−0.3 to 9.1)	0.067	**0.041**
Student SEIFA score (grade four and grade six) (mean)	278	974 (963 to 984)	339	972 (961 to 982)	292	973 (962 to 983)	237	985 (973 to 997)	454	985 (973 to 997)	397	985 (973 to 997)	−1.9 (−7.5 to 3.6)	0.500	−1.0 (−6.7 to 4.7)	0.734	0.793
Anthropometric outcomes																	
BMIz (WHO)	278	0.56 (0.37 to 0.75)	323	0.48 (0.32 to 0.65)	288	0.61 (0.44 to 0.79)	234	0.52 (0.31 to 0.73)	438	0.56 (0.39 to 0.74)	390	0.46 (0.28 to 0.63)	−0.11 (−0.39 to 0.16)	0.416	0.12 (−0.16 to 0.40)	0.400	0.189
Overweight and obesity (%)	278	35.5 (28.4 to 42.7)	323	31.3 (24.9 to 37.7)	288	38.2 (30.1 to 46.3)	234	32.1 (25.1 to 39.2)	438	32.1 (26.9 to 37.3)	390	29.6 (24.1 to 35.1)	−4.2 (−14.0 to 5.5)	0.398	5.3 (−5.8 to 16.3)	0.350	0.163
Behavioral outcomes																	
Met PA guideline, 5 days (%)	279	37.9 (31.4 to 44.3)	343	43.7 (37.2 to 50.2)	290	**47.5 (40.3 to 54.7)**[b]	239	38.3 (29.0 to 47.5)	455	44.0 (36.8 to 51.2)	400	48.3 (39.8 to 56.8)	0.1 (−9.7 to 9.8)	0.991	−0.5 (−12.8 to 11.9)	0.942	0.996
Met sedentary guideline, 5 days (%)	274	87.5 (80.4 to 94.7)	332	**80.5 (73.9 to 87.2)**[a]	288	**77.6 (70.6 to 84.5)**[b]	236	85.6 (78.3 to 92.8)	442	84.8 (77.4 to 92.1)	399	**77.5 (70.8 to 84.2)**[a]	−6.2 (−14.0 to 1.7)	0.123	−1.9 (−11.6 to 7.9)	0.706	0.287
Active transport to or from school (%)	279	30.2 (18.8 to 41.5)	342	36.2 (29.7 to 42.8)	290	31.6 (24.6 to 38.7)	239	35.0 (24.1 to 45.9)	455	38.5 (27.2 to 49.7)	400	29.3 (19.2 to 39.3)	2.6 (−6.8 to 12.1)	0.583	7.2 (−4.0 to 18.5)	0.209	0.374
Met vegetable guideline (%)	276	21.9 (16.3 to 27.6)	339	17.1 (12.7 to 21.5)	288	16.6 (12.9 to 20.4)	236	19.5 (12.4 to 26.6)	448	22.7 (16.3 to 29.1)	393	18.7 (13.7 to 23.7)	−8.0 (−18.6 to 2.5)	0.136	−4.5 (−13.1 to 4.0)	0.300	0.327
Met fruit guideline (%)	275	75.6 (70.7 to 80.5)	329	80.3 (77.1 to 83.4)	291	72.0 (66.5 to 77.5)	237	80.4 (70.8 to 90.0)	447	80.0 (74.4 to 85.6)	400	78.1 (73.7 to 82.6)	5.1 (−7.9 to 18.0)	0.445	−1.3 (−13.6 to 10.9)	0.830	0.333
Takeaway (less than once a week) (%)	280	90.8 (87.1 to 94.4)	340	92.0 (89.6 to 94.5)	291	90.1 (87.1 to 93.1)	239	95.6 (92.7 to 98.5)	454	95.2 (92.2 to 98.2)	400	**91 (87.4 to 94.6)**[a]	1.6 (−2.7 to 6.0)	0.463	3.9 (−1.8 to 9.5)	0.179	0.404
Packaged snacks (≤1 times/d) (%)	277	73.7 (67.5 to 80.0)	320	72.9 (66.3 to 79.5)	291	75.8 (71.3 to 80.3)	235	74.1 (67.6 to 80.6)	419	76.0 (70.1 to 81.8)	400	73.9 (67.6 to 80.2)	−2.7 (−13.9 to 8.5)	0.638	2.2 (−7.9 to 12.4)	0.666	0.687
Water ≥5 glasses/d (%)	251	57.3 (47.6 to 67.0)	303	58.6 (51.0 to 66.2)	292	56.2 (48.7 to 63.8)	207	59.7 (48.0 to 71.3)	384	55.3 (46.6 to 63.9)	400	51.3 (43.4 to 59.1)	5.7 (−8.4 to 19.8)	0.427	7.3 (−6.6 to 21.3)	0.302	0.564
SSB ≤1/d (%)	280	84.3 (80.5 to 88.1)	340	87.1 (82.0 to 92.2)	291	85.2 (81.1 to 89.4)	238	81.3 (76.6 to 86.0)	454	**88.3 (84.1 to 92.5)**[a]	399	**90.9 (86.9 to 94.9)**[b]	−4.2 (−11.0 to 2.7)	0.232	**−8.7 (−15.9 to −1.4)**	**0.019**	0.062
HRQoL																	
HRQoL psychosocial score	272	77.3 (74.2 to 80.4)	339	75.4 (72.6 to 78.1)	287	**73.8 (70.9 to 76.7)**[b]	233	81.0 (77.6 to 84.5)	448	**75.6 (72.5 to 78.7)**[c]	396	**75.6 (72.6 to 78.7)**[c]	**3.6 (0.2 to 7.0)**	**0.045**	1.9 (−1.6 to 5.5)	0.283	0.133

TABLE 4 (continued).

	Intervention communities						Control communities						Difference in change (Int. vs. Control)		Difference in change (Int. vs. Control)		Wave × group interacton
	2015		2017		2019		2015		2017		2019		2017 vs. 2015		2019 vs. 2015		
YEAR 2	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	*N*	Estimate (95% CI)	Estimate (95% CI)	*P*	Estimate (95% CI)	*P*	*P*
HRQoL physical score	275	84.6 (81.9 to 87.4)	339	84.5 (82.1 to 86.9)	291	83.5 (80.9 to 86.1)	236	87.3 (84.3 to 90.4)	451	85.5 (82.8 to 88.2)	400	**84.5 (81.8 to 87.2)**[a]	1.7 (−1.6 to 4.9)	0.312	1.7 (−1.6 to 5.0)	0.320	0.533
HRQoL global score	272	79.8 (77.0 to 82.5)	337	78.6 (76.1 to 81.1)	287	**77.1 (74.5 to 79.7)**[a]	233	83.3 (80.2 to 86.4)	448	**79 (76.3 to 81.8)**[c]	396	**78.7 (75.9 to 81.4)**[c]	**3.1 (0.0 to 6.2)**	**0.048**	1.95 (−1.2 to 5.1)	0.226	0.140

[a]$P < 0.05$.
[b]$P < 0.01$.
[c]$P < 0.001$.
Boldface indicates significant difference within trial group between 2015 and 2017 or 2015 and 2019. Estimates are based on generalized mixed models (logit link, binary distribution, compound symmetry covariance matrix) or linear mixed models with school as a random effect. All models included time, group, and their interaction. Models for outcomes additionally included school type and Index of Community Socio-Educational Advantage tertile. Behavioral and HRQoL outcomes only collected in grade-four and grade-six children.
HRQoL, Health-Related Quality of Life; Int., intervention; PA, physical activity; SEIFA, Socio-Economic Indexes For Areas; SSB, Sugar Sweetened Beverages; WHO, World Health Organization.

control communities. However, control communities. However, the group by time interaction was not significant (Table 2). An interaction effect ($P = 0.038$) was observed for fruit consumption. In intervention communities, fruit consumption increased between 2015 and 2017 (+4.2%) and decreased again in 2019, whereas in control communities, fruit consumption gradually increased between 2017 and 2019.

Intake of takeaway food significantly improved in the intervention communities by 2019 relative to 2015 compared with control (6.0%; 95% CI: 0.5% to 11.6%, interaction, $P = 0.006$) (Table 2). Among intervention communities, the proportion of children consuming takeaway food less than once a week (i.e., the lowest intake category) did not change across the study period, whereas among control communities, this percentage significantly decreased between 2015 and 2019 (−5.1%; 95% CI: −9.1% to −1.1%, $P = 0.013$), indicating that takeaway food consumption increased for children in control communities.

By gender. Among girls, there was a significant interaction of group by time ($P = 0.001$) for prevalence of meeting fruit guidelines, with an increased prevalence in 2017 in the intervention communities, and a decrease by 2019, but a stable prevalence in the control communities (Table 3). There was a significant intervention effect on water consumption (interaction, $P = 0.019$) with an increased percentage of girls consuming more than five glasses of water per day in intervention communities between 2015 and 2017 (18.1% increase) and 2015 to 2019 (11.8% increase) compared with control communities (Table 3).

Among boys, there was a significant intervention effect on takeaway food (interaction, $P = 0.012$) and packaged snack consumption (interaction, $P = 0.015$) (Table 3). Prevalence of takeaway food less than once a week (i.e., the lowest intake category) was significantly higher in intervention than control communities in 2019 relative to 2015 (8.4%) (Table 3). Prevalence of boys reporting consumption of packaged snacks less than once a day relative to 2015 was significantly higher in the intervention group in 2017 (11.4%) and 2019 (12.2%) relative to the control group (Table 3).

By year level. Among grade-four students, there were significant behavioral changes favoring intervention for low takeaway food consumption (8.4%; interaction, $P = 0.006$) and low packaged snack consumption (10.1%; interaction, $P = 0.050$) between 2015 and 2019 (Table 4). Among grade-six students, the proportion of students reporting low SSB consumption significantly increased in the control communities, whereas in the intervention communities, SSB consumption remained relatively stable.

HRQoL

Overall. Significant intervention effects were observed for the physical and global HRQoL scores (interaction, $P = 0.036$ for both). Compared with control, and relative to 2015, the intervention significantly improved the psychosocial score in 2019 (2.9 points), the physical score in 2017 and 2019 (2.9 and 3.1 points, respectively), and the global score in both 2017 and 2019 (2.3 and 3.0 points, respectively) (Table 2).

By gender. Significant intervention effects favoring intervention communities for physical HRQoL (+4.3; $P = 0.029$) and global health (+3.5; $P = 0.040$) were observed over the 4-year intervention period among boys; for girls, there was an intervention effect for the global HRQoL score between 2015 and 2017 (Table 3).

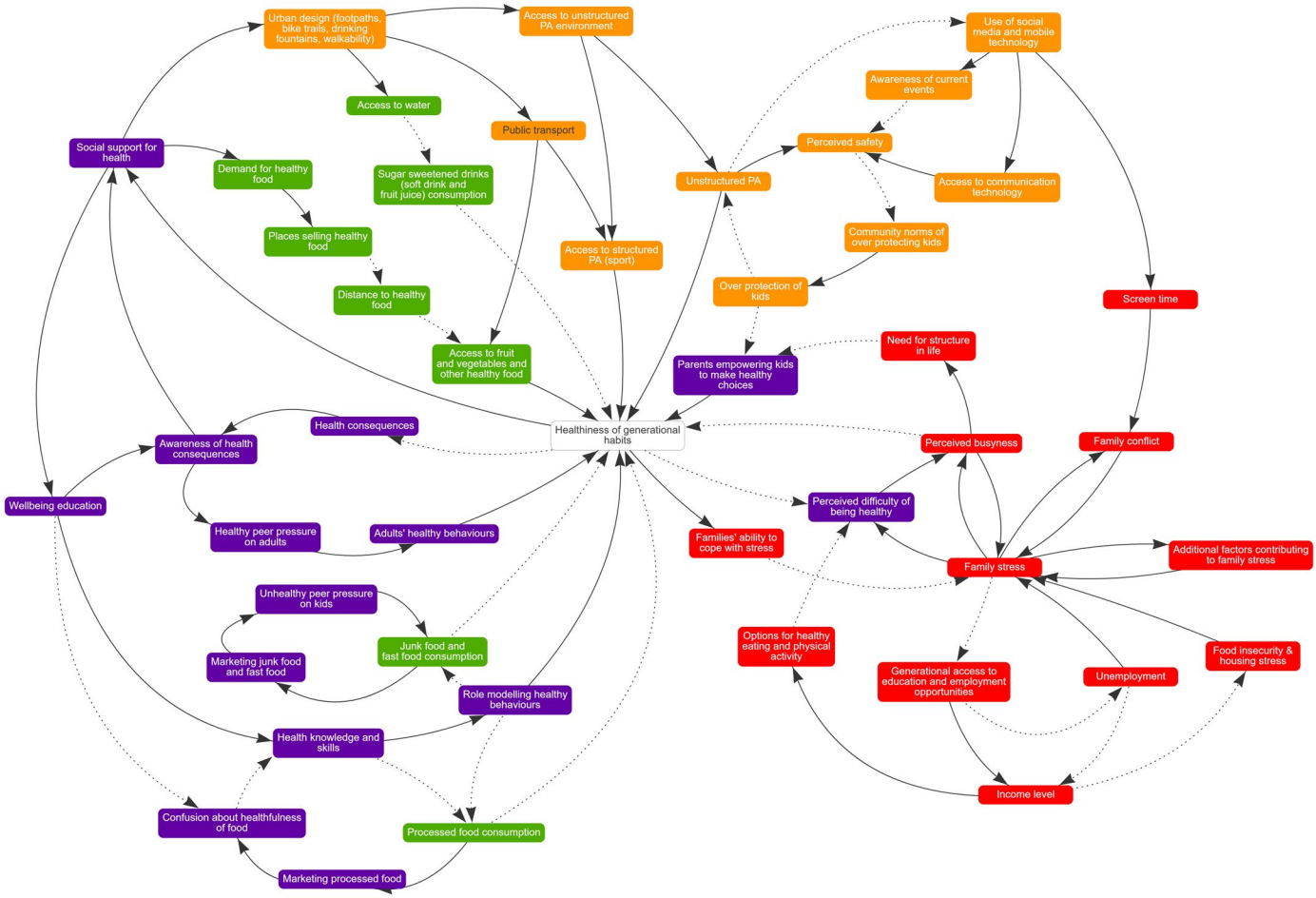

Figure 1 Community causal loop diagram of causes of obesity. PA, physical activity. [Color figure can be viewed at wileyonlinelibrary.com]

Discussion

Statement of principal findings

No intervention effect for the primary outcome BMIz or overweight or obesity was observed for intervention communities compared with control communities over the 4 years of the trial. Although we observed a statistically significant (4%) reduction in the prevalence of overweight and obesity in intervention communities in the first 2 years (2015 to 2017), this was followed by a large increase in the final 2-year period against a backdrop of no change in control communities. Positive effects of the intervention were observed for takeaway consumption, water consumption among girls, and packaged snacks among boys. Positive intervention effects were reported for physical, psychosocial, and global HRQoL scores driven by reductions in all HRQoL outcomes among control communities relative to stable levels among intervention children.

Comparison with other studies

High-quality community-based obesity prevention studies are limited; a recent review (32) of contemporary studies (2013 to 2017) identified only seven studies that presented a quality design with a minimum follow-up duration of 12 months and measured anthropometric outcomes. Of these studies, one was a randomized controlled trial (RCT) with 2 years' follow-up, and the remainder were quasi-experimental (32). The RCT (33) targeted children aged 5 to 8 years recruited via recreation centers in San Diego, California. Unlike our study, no intervention effects on BMIz or behaviors were identified after 2 years, although significant intervention effects for reduction in BMIz were observed for girls.

A meta-analysis (7) of eight community-based interventions (1990 to 2011) found that seven had a positive impact on weight status in which BMIz was reduced by 0.16 among girls and 0.03 among boys, in line with the first 2 years of the WHO STOPS trial. For WHO STOPS, these improvements were reversed in the following 2 years, whereas control communities' BMIz remained unchanged. The longest intervention period reported in this review was 3 years (38). Tarro et al. observed lower BMIz and obesity prevalence among intervention children (5 to 7 years old at baseline) compared with control children 2 years after intervention from their healthy lifestyle education program (39). Economos et al. observed a significant reduction in BMIz 1 year after intervention for Shape Up Somerville, a reduction that persisted after 20 months before dissipating as intervention intensity dropped (40).

The initial reductions followed by increase in prevalence and BMIz in WHO STOPS may be related to intervention length. A systematic

review (41) of 26 prevention studies in the same age group as WHO STOPS found that interventions of 12 months or less were the most effective in preventing obesity.

The drop and subsequent increase in intervention communities remains a question for further investigation but our initial explanations are as follows: Firstly, at the 2-year time point, the research team reduced their implementation support to step 1 communities to begin recruiting step 2 communities. Although this was planned, the impact of bushfires and other natural disasters resulted in the control communities delaying uptake of intervention for a further 2 years, and resources were reduced to what was planned for the second 2-year period. These disasters were not uniformly distributed across the study region, and subsequent subanalyses should examine whether there may have been some impact on children's health and behavior. Secondly, the data collection methods meant that monitoring data were available and presented back to communities in close to real time. One possible unintended consequence of the early signs of positive change in the intervention communities may have led to some complacency or shifting of priorities as the initial reduction suggested that "the job was done" and reductions in obesity were being observed. Thirdly, it is possible that as actions accumulated over time, they overwhelmed implementation capacity. It is generally agreed that multicomponent interventions targeting both physical activity and nutrition are most likely to be effective (42). In this trial, this was successful over the first 2 years, but as actions continued to be rolled out, a peak in capacity and or engagement may have been reached. Improvements in behaviors in the intervention communities between 2015 and 2017 (e.g., fruit guideline [all], SSB [girls]) that diminished thereafter, and the absence of change in targeted behaviors are consistent with this explanation. Finally, changes in the control communities suggest that, in the absence of intervention, regional Victorian environments were becoming more obesogenic for children (e.g., increased takeaway [all], reduced water [all], increased SSB [boys], increased packaged snacks [boys]) and negatively impacting HRQoL.

The Chirpy Dragon cluster RCT (43) of primary-school-based obesity prevention efforts was similar to WHO STOPS. Chirpy Dragon targeted physical activity and dietary behaviors using a complex intervention framework (44). A mean difference in BMIz between intervention and control was observed (−0.13), and positive intervention effects were observed for fruit and vegetables, SSBs, snacking, screen time behavior, and physical activity. We do not know whether these changes persisted, however, as the trial was conducted over a 12-month period.

This intervention design is comparable to capacity-building trials, such as those by Economos (40) and Sanigorski et al. (10), which have reported significantly lower BMIz. The similarities between these and the current trial was the focus on building the capacity of communities to design and implement prevention activities tailored to their local context.

Strengths

Our study represents the longest follow-up (4 years) of any contemporary community-based intervention. Until now, the longest was 3 years, with 1 to 2 years being most common (45). The trial used a cluster randomized design and electronic tablets for data collection saving time compared with paper-based surveys. Local, high-quality data were recognized by community partners as a key aspect of the community engagement and ongoing intervention adaptation. Student participation rates were higher than 80% using an opt-out approach, which compares favorably to other active (opt-in) school-based data collection in which participation rates typically range between 30% and 60%. Participation bias has been observed in regard to differing student response rates and resulting estimates of BMIz and overweight/obesity prevalence (36).

Weaknesses

Communities were considered to be "active" once they had completed the third phase of the five-phase intervention design process. This gave a clear "start point" adapted to community readiness but meant, for each community, the intervention period varied. This variation in intervention period likely impacted our primary outcome. One community had completed all phases as described in the WHO STOPS intervention description section by 2017, whereas the other four communities had completed the second phase. All communities in this analysis had completed all phases by 2019. Intention-to-treat analysis is likely to overlook the nuance of early or late adoption.

This trial was designed to engage community leaders in making changes that were feasible, realistic, and more likely to be sustained. Thus, interventions differ by community and vary depending on community resources, priorities, and capacity to engage. Levels of community action varied and showed some promise; one community recorded 400 intervention actions involving >20 community leaders and >150 community members.

Our study did not achieve the proposed sample size of 1,500 in each trial arm at each wave (21), so our analyses are underpowered for detection of BMIz change of an estimated −0.13. The observed changes that were shown to be significant and the intervention effects in secondary outcomes are therefore highly relevant because to detect a significant change in a percentage variable (e.g., percentage physical activity guide) requires large changes.

Meaning of the study: possible mechanisms and implications for clinicians or policy makers

WHO STOPS reduced obesity prevalence over 2 years and over 4 years helped a majority of children keep their takeaway intake low and sustained HRQoL in a context in which this was declining. Results varied with gender and age group, indicating that single-behavior, single-setting interventions are unlikely to generate the level of change required to improve child health or prevent obesity across the spectrum of childhood. Rather, interventions need to adapt to children's needs considering age, gender, and the capacity or limitations of the surrounding systems. These were not "greenfield" communities (with no previous or existing prevention efforts), and any interpretation of overall study effect needs to consider that a range of efforts was already in place to address childhood obesity.

Childhood obesity is demonstrably preventable, and community-based interventions are effective, feasible, and acceptable to government, industry, and the public (8). These interventions should plan to mitigate unforeseen social and economic shocks that may distract community efforts. For WHO STOPS, bushfire brought this issue into stark relief. To be more effective community interventions should be supported by larger auspice organizations, such as health services or local government, and they should be considered a priority across community leadership (39).O

Acknowledgments

Because of ethical constraints on data sharing (e.g., participants did not consent for data to be shared with third parties), there are no data that can be shared.

Funding agencies: This study was supported by an Australian National Health and Medical Research Council Partnership Project titled "Whole of Systems Trial of Prevention Strategies for childhood obesity: WHO STOPS Childhood Obesity" (APP1114118). During this time, SA was partly supported by funding from an Australian National Health and Medical Research Council/Australian National Heart Foundation Career Development Fellowship (GNT1045836). SA, NC, KAB, PF, ADB, HL, MM, BS, CB, and CS were researchers within a National Health and Medical Research Council Centre for Research Excellence in Obesity Policy and Food Systems (GNT1041020/APP1041020) at the time the study was conducted. Community partners also providing support to the research include Portland District Health, Western Alliance, Southern Grampians and Glenelg Primary Care Partnership, Colac Area Health, Southwest Primary Care Partnership, Portland Hamilton Principal Network of Schools, Colac Corangamite Network of Schools, The Glenelg Shire Council, Southern Grampians Shire Council, Warrnambool and District Network of Schools, Western District Health Service, and Victorian Department of Health and Human Services. The opinion and analysis in this article are those of the authors and are not those of the Department of Health and Human Services, the Victorian Government, the Secretary of the Department of Health and Human Services, or the Victorian Minister for Health.

Disclosure: The authors declared no conflict of interest.

Author contributions: SA, CS, KdLH, JL, LM, MM, BS, and CB conceived the trial design and data collection for the whole trial. LO, CS, NC, PF, and HL monitored data collection for the whole trial, wrote the statistical analysis plan, and cleaned and analyzed the data. SA, NC, KAB, PF, ADB, JL, and CS supported communities to implement the trial. SA, NC, KAB, KdLH, LM, MM, BS, CB, and CS designed data collection tools. All authors contributed to interpretation of results and drafting and revision of the paper.

Clinical trial registration: Australian New Zealand Clinical Trials Registry (ANZCTR.org.au) identifier 12616000980437.

Supporting information: Additional Supporting Information may be found in the online version of this article.

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