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Original Research

Three-year behavioural, health-related quality of life, and body mass index outcomes from the RESPOND randomized trial

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ABSTRACT

Objectives: Evaluate RESPOND, a community-based systems intervention to prevent childhood obesity and non-communicable diseases (NCD).
Study design: Cluster randomized trial of building community capacity to use systems science for child obesity and NCD prevention in 10 local government areas in northeast Victoria, Australia. Four-year stepped wedge trial, adapted due to COVID-19 restrictions
Methods: Cluster randomized trial of building community capacity to use systems science for child obesity and NCD prevention in 10 local government areas in northeast Victoria, Australia. Four-year stepped wedge trial, adapted due to COVID-19 restrictions. Data from 31 primary schools participating at both March to June 2019 (60 % school participation rate), and March to August 2022 (30 %) analysed using linear mixed models. Primary outcome was age-sex-adjusted body mass index z-scores (BMIz) calculated from measured height and weight (children in grades 2, 4 and 6 [aged 7–12 years]). Secondary outcomes were health-related quality of life (HRQoL) and self-reported health behaviours (grades 4 and 6).
Results: Non-significant intervention effects were observed for BMIz (−0.10; 95 % CI: 0.30, 0.11), and percentage with overweight or obesity (−5.4 %; 95 % CI: 13.6 %, 2.7 %). HRQoL deteriorated between 2019 and 2022, except where intervention effects for HRQoL were observed in boys' psychosocial health summary score (7.4; 95% CI: 3.5, 11.2) and total scale score (9.9; 95% CI: 5.5, 14.2). There was an intervention effect for the proportion of boys consuming ≥5 glasses of water per day (15.2 %; 95% CI: 0.9–29.6).
Conclusion: RESPOND protected overall and psychosocial health and had positive effects on BMIz.

Introduction

Childhood obesity is a serious and intractable global public health challenge[1] which persists into adulthood,[2] and is associated with a variety of non-communicable diseases, reinforcing the need for prevention early in life and throughout the life-course.[1] Resistance to intervention may result from the complex and multiple nature of child obesity risk factors.[3] Children's food consumption, for example, has multiple influences, including exposure to a variety of foods early in life,[4] food availability at home[5] and within the community,[6,7] and socioeconomic

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status,.[4] The need to address such complexity was emphasised in a meta-analysis that found small significant reductions in child weight gain at the community-level where interventions applied multiple strategies across multiple levels.[8]

The intersection of obesity causes and actions to prevent obesity represent a complex problem, requiring multiple actors operating over different time scales and with differing goals.[9–11] System science and systems thinking accommodate active engagement with the interactions of component factors driving complex systems[12] providing promising and innovative approaches to prevent child obesity. Examples include *Shape Up Sommerville* in the United States (2002–2005),[13,14] *Romp & Chomp* in Geelong, Australia (2004–2008),[15,16] and *B'More Healthy Communities for Kids* in Baltimore, United States (2013–2016).[17] More recent examples seeking to explicitly apply systems thinking within community-based interventions include *ACT It's Your Move* (2014 - ongoing) in the Australian Capital Territory,[18] *Shape Up Under 5* (2015–2017) in the United States,[19] the *Whole Systems Approach to Obesity* in England (2019 - ongoing),[20] and the *Whole of Systems Trial of Prevention Strategies* (WHOSTOPS) for childhood obesity (2015–2021) in Victoria, Australia.[21]

These interventions are characterised by co-creation with community leaders built on the assumption that engaging those living within communities in intervention design provides insight into the complexity and behaviours of local systems that will increase the effectiveness of subsequent solutions.[22] This approach aligns with Public Health England's definition of whole of system interventions which deliberately 'engage stakeholders across the wider system, to develop a shared vision and actions that tackle the upstream drivers of obesity outside the realms of public health. The approach should be agreed collectively by local stakeholders to reflect the local context.'[20]

Overall, these interventions report reductions in BMI z-scores (BMIz) up to −0.10 (*Shape Up Sommerville*[13]). Improvements in obesity-related behaviours (more healthy eating, less screen time) and health-related quality of life (HRQoL).[21]

Although these trials have demonstrated effectiveness, they are generally heavily reliant on researchers delivering interventions. The WHOSTOPS cluster randomized trial[21,23,24] of a community-based systems dynamics (CBSD)[25] intervention, for example, showed reductions in BMI and overweight and obesity prevalence among intervention communities in the first two years (although non-significant compared to controls).[21] WHOSTOPS relied on external researchers facilitating workshops within communities. When external support was reduced in years 3 and 4, improvements in BMIz and overweight obesity reversed. The researchers hypothesized that the reduced amount of researcher support for the intervention coming from outside of the communities was a factor in the reversal of the initial improvements in children's weight status.[21] If these types of interventions are to have ongoing effects, capacity building may be necessary to support communities in assuming leadership of these health promotion efforts.

Our experience has been that candidates with allied health qualifications typically fill community health positions. Many have limited training or experience with community health promotion, presenting a significant opportunity for capacity building to improve child health outcomes. The Reflexive Evidence and Systems interventions to Prevent Obesity and Non-communicable Disease (RESPOND) trial set out to test whether building capacity of key community health staff at-scale could create a sustainable model to deliver systems-based interventions for childhood obesity prevention. In this paper, we address the following research aim:

To evaluate the impact of RESPOND, a community-led systems intervention to address childhood weight status, quality of life and related behaviours.

Methods

Design and changes in design due to the COVID-19 pandemic

RESPOND was planned as a 4-year stepped-wedge cluster-randomized childhood obesity prevention trial. Ten local government areas (LGAs) in regional northeast Victoria, Australia were randomized to commence the intervention in July 2019 (step one – five LGAs) or July 2021 (step two – five LGAs). Baseline child-level data were collected from March to June 2019, with follow-up data collection planned for 2021 (Year 2) and 2023 (Year 4).

As a result of the COVID-19 pandemic, the 10 study LGAs were subject to State Government-imposed lockdowns consisting of stay-at-home orders, school closures and remote learning, and travel restrictions, with settings frequently adjusted to limit movement and time spent in public (supplementary file 3). These conditions restricted the movement of people, like researchers and health promotion staff, both within and from outside communities. Among the communities where the RESPOND trial was conducted, in 2020 and 2021, nine of these communities experienced 134 days locked down under varying settings, and one (control) community had 186 days in lockdown (see Appendix A).

Pandemic-related public health measures meant the intervention was paused, with only step one LGAs reaching a stage where actions were being implemented in communities. The lockdowns also resulted in the suspension of research in schools[26] meaning the 2021 data collection was delayed to between March and August 2022.

The step one communities partially implemented intervention actions and, in this paper, are referred to as *intervention communities*. The step two communities did not start the intervention due to COVID-19 and, therefore, were treated as *control communities*. This paper reports the comparison of intervention versus control communities over three years (2019–2022).

Ethics approval for the trial was received from university (Deakin University Human Research Ethics Committee, 2018-381) and relevant education bodies (Victorian Government Department of Education and Training, 2019_003943; Catholic Archdiocese of Melbourne, Catholic Education Melbourne, 2019-0872; and Diocese of Sandhurst, May 24, 2019). The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12618001986268). A detailed trial protocol is published elsewhere.[27]

Recruitment

All 112 primary schools (government, independent, and Catholic) in the 10 LGAs were invited to participate and 67 (60 %) of these schools participated in the study in 2019. Children were eligible to participate in the trial if they were in grades 2, 4, or 6 of participating schools, were present at school on the day of data collection and had not opted out. There were no exclusion criteria.

In 2022, all 112 primary schools were invited to participate again, with 36 schools consenting (32 %) of which 34 were included (2 of the initial 36 were impacted by COVID and student opt out leading to no student participation despite school assent), 33 schools that had already participated in 2019 and 3 new schools. Schools' non-participation reasons included: limited capacity (n = 29), school board policy restricting external contact due to COVID-19 (n = 10), other priorities (n = 3), and rejection of weight measurement (n = 2). The 31 schools which had students participating at both time points were included in the final analysis.

RESPOND intervention

The RESPOND intervention comprised a multistage process where community members (leaders and staff of health and community service organizations) were supported to use CBSD[25] to design and implement

community-led, locally tailored actions for childhood obesity prevention. Specifically, capacity in system dynamics was built locally to implement group model building (GMB) workshops, which were used with each LGA to create causal loop diagrams and identify factors that contribute to childhood obesity within their local community and map the relationships between these factors.

In the initial stage (catalyse and set up) partner agencies identified organizations and key people with a shared agenda for childhood obesity prevention. Example of partners in this project were Deakin University (research lead), State Departments of Education and Health, local health services, health-related non-government organizations, and local councils. The governance structure comprised state level advisory oversight, a partnership group (all partner agencies), a regional implementation network (agency leads at regional and community levels) and working groups within each community (local health leadership, key agency staff, community members, and research group project staff).

Stakeholders in the health, education, local government, and community sectors were trained in system dynamics and in facilitation methods for GMB workshops. The training involved two-day intensive workshops and a series of 10 shorter online and in-person sessions. In each community/LGA, partner agencies recruited 10 to 20 cross-sector community leaders to participate in three GMB workshops. The third GMB workshop was a community forum, with no limit on participants set by the university but rather determined by local leadership. Using GMB in these workshops, participants identified factors that they perceived contributed to childhood obesity and the causal connections between these factors. In the third workshop, participants also discussed and prioritised local actions to address childhood obesity. The GMB and intervention development process have been described in detail elsewhere.[28–31] An online and in person community of practice was formed to support the implementation of local actions and provide peer mentoring and capacity building.

Across the intervention communities a range of different actions at multiple levels led by multiple agencies were designed and implemented. Examples include very specific actions in one community to increase access to healthy food via changing the school curriculum to increase healthy food access and literacy, new food markets to bring local produce to the local communities, social events constructed around healthy food and changing activity environments to signpost and direct active travel. Other examples include communities working at a more strategic level – one community, for example, provided training to increase the advocacy skills of community leaders, engaging experts in sleep health, physical activity, and child development to support local government planning and greater alignment of routine outcomes measures with local council plans.

Measures and data collection

School-based monitoring of child outcomes was conducted at baseline and 36 months. Trained staff took anthropometric measurements of children in grade 2, 4, and 6 and distributed and supervised the self-report questionnaire, which was completed by children in grades 4 and 6 using electronic tablets. Data collection from children typically took place for one 50-min class, with each class having up to 30 students.

Demographic characteristics

Date of birth (used to calculate exact age), gender, town/city of residence, postcode of residence, country of birth, Aboriginal and/or Torres Strait Islander background, and language spoken at home were self-reported. Socioeconomic status was measured at the school level using the Index of Community Socio-Educational Advantage (ICSEA),[32] which incorporates school (geographic location, proportion of indigenous students) and student factors (parents' occupations, parents' education), with higher values indicative of greater educational advantage. A binary ICSEA variable (low <1000; high ≥ 1000) was created based on the average ICSEA value.

Anthropometric measurements

Height was measured with a portable stadiometer (Charder HM-200P Portstad, Charder Electronic, Taichung City, Taiwan) and weight using digital scales (A&D Precision Scale UC-321; A7D Medical, San Jose, CA). Children wore light clothing and no shoes. Height and weight were measured to the nearest 0.1 cm and 0.1 kg, respectively. Two measurements were taken and, when the first two observed measurements differed by 0.5 cm for height and 0.1 kg for weight, a third measurement was taken. The average of all measurements was used for data analysis.

The World Health Organization sex-specific BMI-for-age child growth references[33] were used to generate z scores for BMI (BMIz). These scores were dichotomized to define child's weight status as 'normal weight or thinness' ($<$1SD) and 'overweight or obesity' ($\geq$1SD). The primary outcomes were weight status (binary) and BMIz (continuous).

Health-related quality of life (HRQoL)

HRQoL was measured using the Paediatric Quality of Life Inventory™ Version 4.0 (PedsQL™ 4.0) Generic Core Scale.[34] The PedsQL child self-report (ages 8 to 12) has 23 items that assess four domains: physical functioning (eight items), emotional functioning (five items), school functioning (five items), and social functioning (five items). A 5-point scale is used, anchored with *never a problem* (0) and *almost always a problem* (4). Responses for each of the items are reverse-scored and linearly transformed to a 100-point scale, whereby higher scores indicate better quality of life. The total scale score and the sub-scale summary scores (physical health and psychosocial health) were calculated as the sum of the scores for each of the items divided by the number of items completed overall for each sub-scale.

Physical activity, sedentary screen time, and sleep

Three items from the physical activity and sedentary behaviour module of the Core Indicators and Measures of Youth Health[35] were used for self-report of moderate-to-vigorous physical activity duration (response options: none, 1–14 min, 15–29 min, 30–59 min, 1–2 h, or >2 h) and sedentary screen time duration (response options: none, <1 h a day, 1–2 h, >2 to <5 h, or ≥ 5 h) for each of the past 7 days, as well as usual mode of transport to school and from school (e.g., car, school bus, walking, cycling) during the past 7 days. Based on previous research,[36] sleep duration was derived using the times children reported they usually went to bed on school nights and woke up on school mornings.

Responses were dichotomized as meeting or not meeting the Australia's 24-h Movement Guidelines: $\geq$60 min per day of moderate-to-vigorous physical activity (MVPA) for children and young people aged 5–17 years, $\leq$2 h day of sedentary recreational screen time for those aged 5–17 years, and sleep duration of 9–11 h per night for children aged 5–13 years.[37]

Diet intake

Children's diets were assessed using self-reported items from several instruments. Consumption (serves/day) of fruit and vegetables was reported using two items modified from the Child Nutrition Questionnaire (CNQ).[38] Consumption of non-core food (e.g., chocolate, lollies, cake, and biscuits), sugar-sweetened beverages (SSB; e.g., fruit juice, cordial, soda, and flavoured milk), and takeaway food was reported using 14 items from the Food, Health, and Choices questionnaire (FHC-Q).[39]

Responses for fruit and vegetable consumption were dichotomized according to whether they met or did not meet the Australian Dietary Guidelines of $\geq$5 serves of vegetables per day for girls aged 9–13 years and boys aged 9–11 years, $\geq$5.5 serves of vegetables per day for boys aged 12–13 years, or 2 serves of fruit per day for girls and boys aged 9–13 years.[40] In the absence of recommendations, we created cut-points for healthy intake of takeaway food ($\leq$1 instance per fortnight), non-core snacks ($<$1 instance per day), and SSBs ($<$1 per day).

Statistical analysis

The sample size calculation was conducted for the original stepped wedge design (10 clusters, three steps, three measurement points, average of 300 children per cluster at each measurement time, $\alpha = 0.05$), with BMIz standard deviation (1.2) and intra-cluster correlation (0.027) estimated from a previous study of >2500 Victorian school children (2013–2014).[23] Under these assumptions, the study had 80 % power to detect a difference of 0.13 BMIz score between intervention and control communities.

Due to the impact of public health measures implemented during the COVID-19 pandemic and the challenges in recruiting schools for the second study wave (2022), the study was analysed as a cluster parallel randomized trial and only schools participating in both waves were included in the main analysis (31 schools, n = 2129 children) to avoid bias due to self-selection of schools into the study. The results include data from all participating schools (n = 70) - including 31 participating in both waves (n = 2129 children), 36 only in 2019 (n = 1655 children), and 3 only in 2022 (n = 139) – are reported in supplementary files.

All statistical analyses were conducted on an intention-to-treat basis. The effect of the RESPOND intervention was estimated using linear mixed models for continuous outcomes (BMIz and HRQoL scores) and mixed logistic regression for binary outcomes (overweight/obesity and behavioural outcomes) with school as a random effect and exchangeable covariance matrix. All models included year (categorical), intervention group and intervention × year interaction, and adjusted for child gender and grade at school, and school ICSEA (>1000, ≤1000) and rurality (major cities/inner regional, outer regional). LGA was not incorporated as a clustering factor because its contribution to variance was negligible after school was considered. The same models were fitted for each gender. For each outcome we report the estimated change between 2019 and 2022 within study condition, and the difference in change between study condition. We did not adjust for multiplicity of outcomes. All analyses were performed using Stata 17.[41]

Results

Of the primary schools invited in each data collection wave, 60 % (67/112) participated in 2019 and 30 % (34/112) took part in 2022. Baseline student and school characteristics for all 67 schools are provided in Supplementary Table 1. Of these schools, 31 participated in both waves (2019 and 2022). Student participation rates across all schools were 79 % (2865/3605) in 2019 and 59 % (1058/1790) in 2022. For schools in both waves, student participation rates were 80 % (1210/1509) in 2019 and 61 % (919/1518) in 2022. No significant differences between intervention and control communities were observed at baseline for student and school characteristics (Table 1).

A comparison of children baseline measures in 2019 for schools in both waves and those in the 2019 wave is presented in Supplementary Table 2. Children from schools participating in both waves consumed takeaway foods and snacks less frequently, and had a higher HRQoL physical health summary score, than those from schools that participated in the 2019 wave only.

BMIz and proportion with overweight or obesity

Within intervention communities, across time (2019–2022), non-significant decreases in BMIz (−0.02; 95 % CI: 0.16, 0.13) and percentage with overweight or obesity (−1.8 %; 95 % CI: 7.5 %, 3.9 %) were observed (Table 2). For control communities, across time, there were non-significant increases in BMIz (0.08; 95 % CI: 0.07, 0.23) and percentage with overweight or obesity (3.7 %; 95 % CI: 2.2 %, 9.5 %). No significant intervention effects (condition by wave interactions) were observed for BMIz (−0.10; 95 % CI: 0.30, 0.11) and percentage with overweight and obesity (−5.4 %; 95 % CI: 13.6 %, 2.7 %) but the effects were in the expected direction.

Table 1
Baseline (2019) student and school characteristics for schools participating in both waves.

	Intervention (N = 589)			Control (N = 621)			
	N	n	%	N	n	%	*p*
Student characteristics							
Gender	589			620			
Male		303	51.4		318	51.3	0.9999
Female		286	48.6		302	48.7	
Don't wish to say		0	0.0		0	0	
Age (years) (N, mean, SD)	589	9.8	1.6	621	9.9	1.6	0.3072
Grade							
2	589	182	30.9	621	186	30	0.3725
4		223	37.9		218	35.1	
6		184	31.2		217	34.9	
Aboriginal and/or Torres Strait Islander	322	23	7.1	361	36	10	0.2199
Speak LOTE at home	402	32	8	427	29	6.8	0.5949
	Intervention (N=14)[b]			**Control (N=17)[b]**			
	N	n	%	N	n	%	*p*[a]
School characteristics							
SES (School ICSEA score) (N, mean, sd)	14	1009.8	53.7	17	985.3	42.9	0.1683
SES (School ICSEA above or below 1000)	14			17			
Below		6	42.9		10	58.8	0.4795
Above		8	57.1		7	41.2	
School type	14			17			
Government		12	85.7		17	100	0.1070
Catholic/ Independent		2	14.3		0	0	
ASGS School Remoteness Areas	14			17			
Major cities/ Inner regional		11	78.6		12	70.6	0.6980
Outer regional		3	21.4		5	29.4	

LOTE = language other than English, SES = socio-economic status, ICSEA = Index of Community Socio-Educational Advantage, N = number, SD = standard deviation, ASGS = Australian Statistical Geography Standard.

[a] T-test for continuous variables and Fisher's exact test for categorical variables.

[b] 33 schools participated in both waves, but 31 schools had children who were present and who had not opted out on the day of data collection at both time points.

For both girls (Table 3) and boys (Table 4), the intervention effects for BMIz and percentage of overweight and obesity were non-significant and favoured children in the intervention communities.

Behavioural outcomes

For intervention communities, across time, there were significant decreases in physical activity (≥1 h/day MVPA, 5 days/week) (−10.4 %; 95 % CI: 17.4 %, −3.5 %), recreational screen time (≤2 h/day, 7 days/week) (−9.0 %; 95 % CI: 16.3 %, −1.6 %), and infrequent takeaway consumption (≤1/fortnight) (−7.8 %; 95 % CI: 15.0 %, −0.7 %). Within control communities, across time, there were decreases in physical activity (≥1 h/day MVPA, 5 days/week) (−8.0 %; 95 % CI: 15.3 %, −0.7 %) recreational screen time of ≤2 h/day on 5 days/week (−9.4 %; 95 % CI: 16.0 %, −2.8 %) and on 7 days/week (−11.3 %; 95 % CI: 18.8, −3.8), and infrequent consumption of takeaway food (≤1/fortnight) (−14.8 %; 95 % CI: 22.1 %, −7.5 %), snacks (≤1/day) (−7.6 %; 95 % CI: 15.2 %, 0.0 %), and sweetened drinks (≤1/day) (−7.6 %; 95 % CI: 14.9 %, −0.3 %). No significant intervention effects (condition by wave interactions) were found for any of the behavioural outcomes.

Table 2
Changes in children's BMI, weight status, health behaviours, and health-related quality of life for schools participating in both waves.

	Intervention												Control												Difference in Change			
	2019 (N = 589)				2022 (N = 477)				Change: 2022–2019				2019 (N = 621)				2022 (N = 442)				Change: 2022–2019				Intervention - Control			
	N	%	95 % CI		N	%	95 % CI		Diff	95 % CI		*p*	N	%	95 % CI		N	%	95 % CI		Diff	95 % CI		*p*	Diff	95 % CI		*p*
Overweight/obese (WHO)[a]	575	32.1	27.0	37.1	455	30.3	24.9	35.7	−1.8	−7.5	3.9	0.5416	601	31.4	26.5	36.4	425	35.1	29.5	40.6	3.7	−2.2	9.5	0.2179	−5.4	−13.6	2.7	0.1899
Meeting guidelines:																												
MVPA (≥1 h/day, 5 days/wk)	404	46.4	40.3	52.5	314	36.0	29.5	42.4	**−10.4**	**−17.4**	**−3.5**	**0.0034**	430	46.8	40.6	53.1	286	38.8	32.1	45.6	**−8.0**	**−15.3**	**−0.7**	**0.0315**	−2.4	−12.5	7.6	0.6366
MVPA (≥1 h/day, 7 days/wk)	404	23.1	18.2	28.1	314	17.6	12.8	22.3	−5.6	−11.3	0.1	0.0536	430	27.2	21.9	32.5	286	20.9	15.6	26.3	−6.3	−12.7	0.2	0.0557	0.7	−7.9	9.2	0.8797
Recreational screen time (≤2 h/day, 5 days/wk)	403	77.5	71.9	83.0	314	71.3	64.5	78.0	−6.2	−12.7	0.3	0.0604	428	76.5	71.1	81.8	287	67.1	60.2	73.9	**−9.4**	**−16.0**	**−2.8**	**0.0053**	3.2	−6.0	12.4	0.4979
Recreational screen time (≤2 h/day, 7 days/wk)	403	57.4	51.6	63.1	314	48.4	41.9	54.9	**−9.0**	**−16.3**	**−1.6**	**0.0167**	428	57.1	51.6	62.5	287	45.8	39.4	52.1	**−11.3**	**−18.8**	**−3.8**	**0.0032**	2.3	−8.1	12.8	0.6618
Active transport (to and/or from school)	404	29.0	19.5	38.5	314	30.5	20.5	40.6	1.56	−4.6	7.7	0.6178	430	35.0	25.2	44.9	287	30.8	21.2	40.4	−4.2	−10.5	2.0	0.1853	5.8	−2.9	14.5	0.1939
Sleep (9–11 h/day)	372	72.6	67.8	77.5	294	72.2	66.7	77.8	−0.4	−7.3	6.5	0.9084	389	74.7	69.9	79.4	264	71.6	65.8	77.4	−3.1	−10.1	3.9	0.3879	2.7	−7.1	12.4	0.5910
Vegies (≥5 serves/day, ≥5.5 for boys 12+)	404	14.0	10.6	17.4	313	16.0	11.8	20.2	2.1	−3.2	7.3	0.4445	430	18.3	14.5	22.2	287	18.2	13.7	22.8	−0.2	−6.2	5.8	0.9489	2.3	−5.7	10.2	0.5784
Fruit (≥2 serves/day)	404	77.5	73	82.1	314	77.1	71.8	82.4	−0.4	−6.6	5.7	0.8961	429	74.4	69.5	79.3	287	78.8	73.6	83.9	4.3	−1.9	10.6	0.1749	−4.7	−13.5	4.0	0.2871
Takeaway (≤1/fortnight)	404	67.1	62.4	71.7	313	59.2	53.6	64.8	**−7.8**	**−15.0**	**−0.7**	**0.0321**	430	65.7	61.1	70.3	287	50.9	45.1	56.7	**−14.8**	**−22.1**	**−7.5**	**0.0001**	7.0	−3.3	17.2	0.1819
Snacks (<1/day)	403	45.2	38.5	52.0	314	37.3	30.3	44.4	−7.9	−15.0	−0.8	0.0295	430	46.7	39.9	53.5	287	39.1	31.7	46.5	**−7.6**	**−15.2**	**0.0**	**0.0494**	−0.3	−10.7	10.1	0.9524
Sweetened drinks (<1/day)	404	62.5	56.6	68.3	314	62.5	55.9	69.1	0.0	−7.0	7.1	0.9926	430	62.3	56.5	68.0	286	54.7	48.0	61.3	**−7.6**	**−14.9**	**−0.3**	**0.0410**	7.6	−2.5	17.8	0.1389
Water (≥5 glasses/day)	404	53.1	48.1	58.1	313	56.7	51.0	62.5	3.7	−3.7	11.0	0.3315	430	56.4	51.2	61.5	287	51.2	45.3	57.1	−5.2	−12.8	2.4	0.1820	8.8	−1.7	19.4	0.1016
	N	**mean**	**95 % CI**		**N**	**mean**	**95 % CI**						**N**	**mean**	**95 % CI**		**N**	**mean**	**95 % CI**									
zBMI (WHO)[a]	575	0.57	0.45	0.69	455	0.55	0.42	0.68	−0.02	−0.16	0.13	0.7968	601	0.50	0.38	0.62	425	0.58	0.45	0.71	0.08	−0.07	0.23	0.2887	−0.10	−0.30	0.11	0.3465
HRQoL:																												
Total scale score	402	74.5	72.5	76.5	312	72.3	70.1	74.4	**−2.2**	**−4.3**	**−0.1**	**0.0359**	426	77.3	75.3	79.2	285	71.1	69.0	73.3	**−6.2**	**−8.3**	**−4.0**	**<0.0001**	**3.9**	**1.0**	**6.9**	**0.0092**
Physical health	401	82.6	80.7	84.5	312	79.3	77.2	81.4	**−3.3**	**−5.5**	**−1.2**	**0.0027**	424	83.1	81.2	84.9	285	78.3	76.2	80.4	**−4.8**	**−7.0**	**−2.6**	**<0.0001**	1.5	−1.6	4.5	0.3556
Psychosocial health	402	70.2	67.9	72.4	311	68.6	66.1	71.0	−1.6	−3.9	0.7	0.1787	426	74.3	72.0	76.5	285	67.3	64.9	69.8	**−6.9**	**−9.3**	**−4.5**	**<0.0001**	**5.3**	**2.0**	**8.7**	**0.0017**

Estimates and p-values from mixed logistic (binary outcomes) and linear (continuous outcomes) models with school as random effect (exchangeable correlation), including year, intervention, intervention[a]year interaction and adjusting for gender, grade, binary ICSEA (>1000, ≤1000) and school rurality (major/inner regional city, outer regional)

HRQoL = Health Related Quality of Life, ICSEA = Index of Community Socio-Educational Advantage, MVPA = Moderate-to-Vigorous Physical Activity, WHO = World Health Organization.

[a] Includes Grades 2, 4 and 6 (all other outcomes Grades 4 and 6 only).

Table 3
Changes in girls' BMI, health behaviours, and health-related quality of life for schools participating in both waves.

	Intervention												Control												Difference in Change			
	2019 (N = 286)				2022 (N = 231)				Change: 2022–2019				2019 (N = 302)				2022 (N = 206)				Change: 2022–2019				Intervention - Control			
	N	%	95 % CI		N	%	95 % CI		diff	95 % CI		*p*	N	%	95 % CI		N	%	95 % CI		diff	95 % CI		*p*	diff	95 % CI		*p*
Overweight/obese (WHO)[a]	279	33.7	28.1	39.4	223	30.0	23.8	36.2	−3.7	−11.9	4.6	0.3828	292	29.3	24.0	34.6	198	34.1	27.6	40.6	4.8	−3.5	13.2	0.2566	−8.5	−20	3.2	0.1542
Meeting guidelines:																												
MVPA (≥1 h/day, 5 days/wk)	192	38.6	30.4	46.8	137	27.8	19.3	36.3	**−10.8**	**−20.8**	**−0.8**	**0.0351**	220	38.7	29.7	47.7	129	30.9	20.9	40.9	−7.8	−18.4	2.7	0.1458	−3.0	−17.5	11.6	0.6893
MVPA (≥1 h/day, 7 days/wk)	192	17.9	12.6	23.3	137	11.7	6.4	17.0	−6.3	−13.7	1.2	0.0986	220	20.1	14.6	25.6	129	17.6	10.9	24.3	−2.5	−11.0	6.1	0.5743	−3.8	−15.1	7.5	0.5121
Recreational screen time (≤2 h/day, 5 days/wk)	191	82.4	76.8	88.0	137	71.7	63.7	79.7	−10.6	−20.2	−1.0	0.0301	219	81.3	76.3	86.3	130	71.4	63.7	79.0	**−9.9**	**−19.0**	**−0.9**	**0.0320**	−0.7	−13.9	12.5	0.9182
Recreational screen time (≤2 h/day, 7 days/wk)	191	61.1	54.1	68.1	137	53.7	45.2	62.3	−7.4	−18.2	3.5	0.1813	219	60.9	54.4	67.5	130	48.6	40.0	57.1	**−12.4**	**−23.1**	**−1.6**	**0.0238**	5.0	−10.2	20.2	0.5207
Active transport (to and/or from school)	192	31.3	21.9	40.7	137	31.0	20.6	41.3	−0.3	−10.0	9.4	0.9476	220	34.4	24.8	44.0	130	31.3	20.8	41.8	−3.2	−12.7	6.4	0.5187	2.8	−10.8	16.4	0.6829
Sleep (9–11 h/day)	180	69.9	63.2	76.6	134	72.1	64.4	79.8	2.2	−7.9	12.3	0.6682	201	75.9	69.9	81.9	121	67.0	58.7	75.3	−8.9	−19.1	1.3	0.0863	11.1	−3.2	25.4	0.1267
Vegies (≥5 serves/day, ≥5.5 for boys 12+)	192	15.0	9.9	20.1	137	16.6	10.2	23.0	1.6	−6.4	9.6	0.6926	220	17.0	11.8	22.3	130	18.5	11.8	25.3	1.5	−7.0	10.0	0.7300	0.1	−11.5	11.7	0.9830
Fruit (≥2 serves/day)	192	80.4	74.2	86.6	137	74.8	66.8	82.8	−5.6	−14.7	3.5	0.2286	220	78.6	72.2	85.0	130	80.9	73.7	88.1	2.3	−6.3	10.9	0.5995	−7.9	−20.3	4.5	0.2127
Takeaway (≤1/fortnight)	192	71.9	65.4	78.4	137	58.0	49.4	66.5	**−14.0**	**−24.5**	**−3.5**	**0.0092**	220	72.2	66.3	78.1	130	54.0	45.5	62.5	**−18.2**	**−28.5**	**−7.9**	**0.0005**	4.2	−10.4	18.9	0.5709
Snacks (<1/day)	192	42.6	34.6	50.6	137	35.3	26.4	44.2	−7.3	−17.6	3.1	0.1707	220	51.6	43.3	59.9	130	37.0	27.3	46.8	**−14.6**	**−25.4**	**−3.8**	**0.0081**	7.3	−7.6	22.2	0.3362
Sweetened drinks (<1/day)	192	66.2	57.7	74.7	137	69.2	59.9	78.5	3.0	−7.0	13.0	0.5543	220	69.5	62.0	76.9	130	60.7	51.1	70.3	−8.8	−19.0	1.5	0.0933	11.8	−2.5	26.1	0.1057
Water (≥5 glasses/day)	192	53.4	46.3	60.5	136	48.6	40.0	57.2	−4.8	−15.8	6.1	0.3873	220	55.7	48.9	62.6	130	50.6	42.0	59.2	−5.2	−16.1	5.8	0.3561	0.3	−15.1	15.7	0.9688
	N	**mean**	**95 % CI**		**N**	**mean**	**95 % CI**						**N**	**mean**	**95 % CI**		**N**	**mean**	**95 % CI**									
zBMI (WHO)[a]	279	0.56	0.42	0.69	223	0.52	0.37	0.67	−0.04	−0.23	0.16	0.7248	292	0.42	0.29	0.56	198	0.58	0.42	0.74	0.15	−0.05	0.36	0.1423	−0.19	−0.48	0.10	0.1913
HRQoL:																												
Total scale score	190	76.5	74.4	78.6	135	70.6	68.0	73.1	**−5.9**	**−9.1**	**−2.7**	**0.0003**	219	75.2	73.2	77.2	129	68.9	66.4	71.4	**−6.3**	**−9.5**	**−3.1**	**0.0001**	0.4	−4.1	4.9	0.8628
Physical health	189	83.8	81.7	85.8	135	78.9	76.4	81.4	**−4.9**	**−8.1**	**−1.7**	**0.0030**	218	80.5	78.5	82.5	129	75.3	72.8	77.8	**−5.2**	**−8.4**	**−2.0**	**0.0014**	0.4	−4.2	4.9	0.8789
Psychosocial health	190	72.6	69.9	75.2	135	66.1	63.0	69.2	**−6.4**	**−10.0**	**−2.9**	**0.0004**	219	72.4	69.9	75.0	129	65.6	62.5	68.7	**−6.8**	**−10.4**	**−3.3**	**0.0002**	0.4	−4.6	5.4	0.8786

Estimates and p-values from mixed logistic (binary outcomes) and linear (continuous outcomes) models with school as random effect (exchangeable correlation), including year, intervention, intervention[a]year interaction and adjusting for grade, binary ICSEA (>1000, ≤1000) and school rurality (major/inner regional city, outer regional)

HRQoL = Health Related Quality of Life, ICSEA = Index of Community Socio-Educational Advantage, MVPA = Moderate-to-Vigorous Physical Activity, WHO = World Health Organization.

[a] Includes Grades 2, 4 and 6 (all other outcomes Grades 4 and 6 only).

Table 4
Changes in boys' BMI, health behaviours, and health-related quality of life for schools participating in both waves.

	Intervention												Control												Difference in Change			
	2019 (N = 303)				2022 (N = 239)				Change: 2022–2019				2019 (N = 318)				2022 (N = 232)				Change: 2022–2019				Intervention - Control			
	N	%	95 % CI		N	%	95 % CI		diff	95 % CI		*p*	N	%	95 % CI		N	%	95 % CI		diff	95 % CI		*p*	diff	95 % CI		*p*
Overweight/obese (WHO)[a]	296	30.8	23.9	37.7	232	31.2	23.6	38.8	0.36	−7.7	8.38	0.9294	309	32.7	25.7	39.6	227	35.6	28	43.2	2.97	−5	10.9	0.4648	−2.6	−14	8.7	0.6504
Meeting guidelines:																												
MVPA (≥1 h/day, 5 days/wk)	212	54.2	47.4	61.0	170	44.1	36.6	51.6	**−10.1**	**−19.9**	**−0.2**	**0.0447**	210	54.3	47.2	61.5	154	46.0	38.1	54.0	−8.3	−18.6	1.9	0.1120	−1.7	−15.9	12.5	0.8103
MVPA (≥1 h/day, 7 days/wk)	212	28.4	21.4	35.5	170	23.0	16.0	30.0	−5.4	−14.0	3.1	0.2100	210	32.9	25.5	40.3	154	23.7	16.4	31.0	−9.2	−18.5	0.1	0.0531	3.7	−8.8	16.3	0.5595
Recreational screen time (≤2 h/day, 5 days/wk)	212	71.3	63.0	79.5	170	68.7	59.5	77.9	−2.5	−11.7	6.6	0.5856	209	73.3	65.6	81.1	154	63.4	53.9	72.8	**−10.0**	**−19.2**	**−0.7**	**0.0343**	7.4	−5.5	20.4	0.2610
Recreational screen time (≤2 h/day, 7 days/wk)	212	53.2	45.5	60.9	170	43.2	34.7	51.8	−9.9	−19.9	0.0	0.0506	209	53.7	46.0	61.4	154	42.9	34.3	51.5	−10.8	−21.2	−0.4	0.0410	0.9	−13.5	15.2	0.9060
Active transport (to and/or from school)	212	29.1	18.7	39.5	170	33.4	21.9	44.9	4.3	−4.6	13.1	0.3423	210	40.6	28.8	52.3	154	34.5	23.2	45.9	−6.0	−15.3	3.2	0.2015	10.3	−2.5	23.1	0.1140
Sleep (9–11 h/day)	192	75.4	69.2	81.5	155	72.5	65.3	79.7	−2.9	−12.2	6.5	0.5477	188	73.1	66.7	79.6	140	75.3	68.2	82.3	2.1	−7.4	11.6	0.6599	−5.0	−18.3	8.3	0.4613
Vegies (≥5 serves/day, ≥5.5 for boys 12+)	212	13.1	8.6	17.6	169	15.6	10.2	21.1	2.5	−4.5	9.5	0.4813	210	19.7	14.0	25.4	154	18.1	11.9	24.3	−1.7	−10.1	6.6	0.6836	4.2	−6.6	15.1	0.4439
Fruit (≥2 serves/day)	212	74.3	68.0	80.6	170	78.1	71.0	85.1	3.8	−4.9	12.4	0.3930	209	70.6	64.1	77.1	154	76.7	70.0	83.4	6.1	−2.9	15.1	0.1857	−2.3	−14.8	10.1	0.7146
Takeaway (≤1/fortnight)	212	62.6	56.0	69.2	169	59.5	52.0	67.0	−3.1	−12.9	6.8	0.5408	210	59.5	52.8	66.3	154	48.0	40.1	55.9	**−11.6**	**−21.9**	**−1.2**	**0.0281**	8.5	−5.8	22.7	0.2436
Snacks (<1/day)	211	44.8	37.2	52.4	170	36.3	28.3	44.2	−8.5	−18.0	1.0	0.0799	210	39.3	31.9	46.8	154	37.8	29.6	46.0	−1.5	−11.7	8.6	0.7692	−7.0	−20.9	6.9	0.3250
Sweetened drinks (<1/day)	212	58.6	51.8	65.3	170	54.9	47.0	62.8	−3.7	−13.6	6.3	0.4676	210	55.8	48.9	62.7	153	49.5	41.6	57.4	−6.3	−16.5	3.9	0.2280	2.6	−11.6	16.8	0.7180
Water (≥5 glasses/day)	212	52.7	45.1	60.4	170	63.3	55.2	71.4	**10.6**	**0.7**	**20.5**	**0.0355**	210	55.6	47.3	63.8	154	50.9	41.9	59.8	−4.7	−15.1	5.8	0.3823	**15.2**	**0.9**	**29.6**	**0.0377**
	N	**mean**	**95 % CI**		**N**	**mean**	**95 % CI**						**N**	**mean**	**95 % CI**		**N**	**mean**	**95 % CI**									
zBMI (WHO)[a]	296	0.58	0.41	0.75	232	0.59	0.40	0.78	0.01	−0.19	0.22	0.8998	309	0.56	0.39	0.73	227	0.60	0.41	0.78	0.04	−0.17	0.24	0.7362	−0.02	−0.32	0.27	0.8809
HRQoL:																												
Total scale score	212	72.5	69.7	75.2	170	73.4	70.5	76.3	1.0	−1.7	3.6	0.4879	207	79.1	76.4	81.9	153	72.7	69.8	75.6	**−6.4**	**−9.2**	**−3.6**	**<0.0001**	**7.4**	**3.5**	**11.2**	**0.0002**
Physical health	212	81.3	78.4	84.1	170	79.3	76.3	82.3	−2.0	−4.9	0.9	0.1818	206	85.7	82.8	88.5	153	80.9	77.9	83.9	**−4.8**	**−7.8**	**−1.8**	**0.0017**	2.8	−1.3	7.0	0.1806
Psychosocial health	212	67.9	65.0	70.8	169	70.5	67.4	73.6	2.6	−0.4	5.6	0.0944	207	75.7	72.8	78.6	153	68.4	65.3	71.5	**−7.3**	**−10.4**	**−4.1**	**<0.0001**	**9.9**	**5.5**	**14.2**	**<0.0001**

Estimates and p-values from mixed logistic (binary outcomes) and linear (continuous outcomes) models with school as random effect (exchangeable correlation), including year, intervention, intervention[a]year interaction and adjusting for grade, binary ICSEA (>1000, ≤1000) and school rurality (major/inner regional city, outer regional)

HRQoL = Health Related Quality of Life, ICSEA = Index of Community Socio-Educational Advantage, MVPA = Moderate-to-Vigorous Physical Activity, WHO = World Health Organization.

[a] Includes Grades 2, 4 and 6 (all other outcomes Grades 4 and 6 only).

For boys, however, there was a significant intervention effect for water consumption (≥5 glasses/day) favouring intervention communities (Table 4). No significant intervention effects were observed for girls.

Health-related quality of life

Within intervention communities, significant decreases in the physical health summary score (−3.3; 95 % CI: 5.5, −1.2) and total scale score (−2.2; 95 % CI: 4.3, −0.1) were observed. For control communities, significant decreases in the physical health summary score (−4.8; 95 % CI: 7.0, −2.6), psychosocial health summary score (−6.9; 95 % CI: 9.3, −4.5), and total scale score (−6.2; 95 % CI: 8.3, −4.0) were found. Significant intervention effects (condition by wave interactions) in favour of intervention communities were found for the psychosocial health summary score (5.3; 95 % CI: 2.0, 8.7), and total scale score (3.9; 95 % CI: 1.0, 6.9).

For boys, significant intervention effects (condition by wave interactions) in favour of intervention communities were found for the psychosocial health summary score (9.9; 95 % CI: 5.5, 14.2), and total scale score (7.4; 95 % CI: 3.5, 11.2). No significant intervention effects were found for girls.

Discussion

Main findings

RESPOND had positive effects on HRQoL (psychosocial health and total scale score for boys) and water consumption (for boys). There were significant declines in several key obesity-related behaviours (MVPA, recreational screen time, takeaway food consumption), for children in both intervention and control communities across this period, which coincided with the COVID-19 pandemic. Although not significant, shifts in BMIz, the prevalence of overweight and obesity, and several behavioural outcomes (active transport to and from school, sleep, and consumption of takeaway food and sweetened drinks) were in the direction anticipated if the intervention were to succeed.

Comparison with the literature

The findings from RESPOND reinforce systematic review evidence that whole of systems approaches can be effective for tackling obesity.[9] Like other whole of systems approaches, the changes in BMIz, overweight and obesity, and several obesity-related behavioural outcomes were in in line with a positive intervention effect in favour of the intervention communities, although nonsignificant likely because the COVID-19 pandemic interrupted the implementation of the intervention and the study was underpowered. Due to pandemic-related public health measures, the original stepped wedge design (2 steps, 3 measurement times [2029, 2021, 2023]) was changed to a cluster randomised design with two measurement points (2019, 2022). The pandemic also affected school recruitment rate (60 % in 2019, 30 % in 2022) and children recruitment rates (80 % in 2019, 61 % in 2022).

Findings from RESPOND showed a decline in the psychosocial health of children throughout the period in which COVID-19 public health measures (e.g., prolonged lockdowns including school closures) were in place. The decline in psychosocial health observed in RESPOND aligns with other research showing that the mental health of Victorian children worsened during COVID-19 outbreaks and strict lockdowns.[42] These data present evidence that RESPOND was protective against the effects of COVID-19 lock-down measures on the psychosocial health of children.

The positive effects of RESPOND on HRQoL are like those of the WHOSTOPS intervention.[21] WHOSTOPS significantly increased HRQoL total scale score and physical health summary score. RESPOND had beneficial effects on the HRQoL total scale score and psychosocial health summary score. In both cases, these effects were observed in the context of quality of life decreasing overall.

COVID lockdowns, were associated with reduced physical activity, more screen time, altered sleep patterns, and changes in food consumption.[43,44] In addition, the study communities were also heavily impacted by bushfires in 2019 and 2020.[45] It is likely that the combined impact of these far-reaching external shocks resulted in changes in organizational priorities, loss of momentum for implementation, redeployment of human resources, fatigue, and exhaustion. Other studies have demonstrated similar organizational responses to the pandemic.[46] Our findings suggest RESPOND may have protected children from overweight/obesity and worsening HRQoL and we observed the health workforce adapt to new conditions supported by 'soft infrastructure', like strong relationships between organizations, community trust in institutions, and community empowerment.[47]

Strengths and limitations

This trial had several strengths. First, the implementation and control communities were geographically dispersed, which reduced the likelihood of actions in intervention communities 'spilling over' and having effects on children in control communities. The COVID pandemic placed immense strain on school and community resources, further reducing the likelihood of any additional actions happening outside usual practice in control communities. Randomisation further reduced the likelihood of unexpected or unique actions happening in the control arm without similar actions happening in intervention arms. In addition, project funded staff members living within communities were tracking actions in control communities and there were no relevant new actions observed. Second, this study is one of the few trials of whole-of-community approaches to childhood obesity prevention with an RCT design. Third, the opt-out recruitment approach meant student participation rates of 79 % for 2019 and 59 % for 2022 were achieved, which compare favourably with the usual 30–60 % participation.[48] We observed absentee rates of 17 % in the second wave of data collection due to COVID-19 outbreaks and related restrictions (9 % in 2019).

This trial had limitations. First, the sample sizes and change in study design compromised statistical power. Despite opt-out recruitment, school participation in 2022 was lower than expected. COVID-19 increased absenteeism during the data collection period and student non-response increased. Non-participation rates (or opt-out) increased in 2022 to 24 % (from 11 % in 2019) and we hypothesise this change was due public health surveillance fatigue (e.g., vaccination mandates, travel restrictions). Therefore, the observed changes may be due to differences in the populations measured. Second, the schools that formed this data corpus differed by socio-educational advantage, rurality, and type (government versus Catholic/independent). Third, COVID-19 was spreading rapidly in schools and between students from April–June 2022, due to the increased interaction of people after lockdowns ceased and schools had returned to face-to-face teaching at the start of the school year in February 2022. Fourth, there was no formal evaluation of the effectiveness of the CBSD training, meaning the extent to which stakeholders' knowledge and skills were developed is unclear.

Implications for practice

Appraising RESPOND based solely on the statistical significance of the primary outcome would lead to erroneous conclusions about the potential of the intervention to protect child health. Challenges recruiting sufficiently large samples to achieve adequate statistical power mean that RCTs can produce inconclusive findings, which sway public health decision makers away from recommending the interventions.[49,50] RESPOND employed systems thinking to identify and target risks for childhood obesity. Macro and local understandings of these drivers, generated during interventions, such as RESPOND, need to be considered when assessing the merit of this intervention.

Although the change in overweight/obesity prevalence was not statistically significant, the 95 % confidence interval was between −14 % and +3 % when comparing intervention and control communities. Empowering communities to use systems thinking in obesity prevention appears to have a positive impact even in times of great upheaval, such as pandemic-related restrictions, bushfires,[45] and other severe events. Given the dearth of effective interventions for addressing childhood obesity, building capacity within communities to deliver systems-based interventions seems to be a promising path forward. The findings from RESPOND warrant further study of the case for investment in broader training of community health workers in systems thinking, and creating a learning system so lessons learned are learned and shared quickly.

Conclusions

The observed protective impact of RESPOND on HRQoL, and particularly psychosocial health, merits further study. One hypothesis is that the collaboration and engagement from the broader community created by RESPOND, created a protective environment for children despite the impact of pandemic on shifting staff roles and health priorities. Differences in effect were observed for boys compared to girls and these interactions also merit further investigation.

Despite pandemic-related public health measures adversely affecting children's health, RESPOND had a protective effect on the psychosocial health of children. In addition, the non-significant effects of RESPOND on overweight and obesity, as well as several behaviours (active transport, sleep, and consumption of takeaway food and sweetened drinks), indicated changes in the direction that favoured the intervention communities, reflecting the impact of training community health workers in systems thinking for preventing childhood obesity.

Author statements

Ethical approval

Ethics approval for the trial was received from university (Deakin University Human Research Ethics Committee, 2018-381) and relevant education bodies (Victorian Government Department of Education and Training, 2019_003943; Catholic Archdiocese of Melbourne, Catholic Education Melbourne, 2019-0872; and Diocese of Sandhurst, 24th May 2019). The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12618001986268). A detailed trial protocol is published elsewhere.32 16

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Competing interests

None declared.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2024.10.015.

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