Four-year Behavioural, Health Related Quality of Life and BMI Outcomes From a Cluster Randomized Whole of Systems Trial of Prevention Strategies for Childhood Obesity (Whostops Childhood Obesity)

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Abstract

**Objectives:** To test the effectiveness of the Whole of Systems Trial of Prevention Strategies for Childhood Obesity (WHOSTOPS) for behavioural, health related quality of life and Body Mass Index (BMI) outcomes.

**Design:** Cluster randomized trial of ten communities randomly allocated (1:1) to start intervention in 2015 (step one) or in 2019 (after 4-years).

**Setting:** Community based trial in South West Victoria, Australia, including all major health and local council agencies.

**Participants:** Data were collected from 59 participating primary schools April-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).

**Interventions:** Local leaders, organisations and community members developed obesity prevention interventions and implementation measures using a five phase process to change existing conditions that lead to childhood obesity.

**Main outcome measures:** Measured height and weight (Grades two, four and six), self-reported behavioural, and health-related quality of life (Grade four and six).

**Results:** There was an intervention by time interaction in both age and sex standardized BMI (BMIZ) (p=0.031) and obesity/overweight prevalence (p=0.006). The control communities remained unchanged whereas BMIZ and overweight/obesity prevalence decreased between 2015 and 2017 and increased between 2017 and 2019 in intervention communities. The intervention reduced take away food consumption (p=0.006) and improved physical (p=0.036) and global (p=0.036) health related quality of life. Water consumption increased among girls (p=0.019) as did energy-dense and nutrient poor snack consumption (p=0.015) and take-away food consumption among boys (p= 0.012). BMIZ of the grade two cohort steadily increased.

**Conclusions:** WHOSTOPS had a positive impact on takeaway food intake and health-related quality of life.

**Trial registration:** Australian New Zealand Clinical Trials Registry (ANZCTR): 12616000980437. Registered 26 July 2016 - Retrospectively registered

https://www.anzctr.org.au/Trial/Registration/

Introduction

Childhood obesity is a precursor to adult obesity, and is a major determinant of multiple diseases including type 2 diabetes, ischaemic heart disease, and several cancers. The World Health Organization Commission for Ending Childhood Obesity made childhood obesity a priority in the Global 2013–2020 Action Plan for the prevention and control of non-communicable diseases. The size and scope of the disease, cost burden and inequitable distribution of prevalence, make a compelling case for childhood obesity prevention. With the high prevalence of obesity and its attendant diseases projected to rise treatment costs are likely to continue to grow. Funding and innovation for preventive action is vital, especially in childhood where excess adiposity and associated behaviours track across the lifespan.

Meta-analysis of obesity prevention studies in children showed promising overall benefits of community-based interventions among children. Australian community-based interventions were among the first to demonstrate a reduction in the prevalence of obesity. These include studies of children under age five, primary school age and adolescents. We discovered from these trials that improving broader system determinants (e.g. community capacity for healthy change), strongly predicted the degree of reduction in childhood obesity and sustainability, with the prevalence of obesity continuing to reduce among intervention communities after three years. The broader systems approach also stimulated action and impact in the surrounding communities, highlighting diffusion of prevention action.

The 2015 Lancet Obesity Series identified sustainability and scalability as challenges for community-based childhood obesity prevention initiatives. The 2019 Lancet Commission and other scholars have 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 (Healthy Together Victoria), New Zealand (Healthy Families New Zealand) and England (Whole Systems Approach to Obesity). 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 to better promote health and prevent obesity. Our experiences in Victoria, Australia, have shown that building community capacity to understand and act to strengthen these systems is critical.

The Whole of Systems Trial of Prevention Strategies for Childhood Obesity (WHOSTOPS 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. 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 BMIZ and overweight and obesity prevalence collected via an opt-out monitoring system. Secondary outcomes were obesity-related behaviours and perceived health-related quality of life. Here we report the results from the WHOSTOPS trial for the following research questions:

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 behaviours and health-related quality of life (secondary outcomes) among children attending primary schools in the intervention communities, compared with children in control communities?

Methods

Design

The trial design is described in more detail elsewhere.[24] We planned to implement a two step cluster-randomised stepped-wedge design in 10 communities. The unit of randomisation and intervention was community (rather than individual children) allocated using a random number generator by the researchers. Communities were chosen based on their geographical closeness to each other, and their interest in implementing new approaches to improve the health of children. Following the baseline measurement of all participating children in the 10 communities in April-June 2015, five communities were randomised to begin the intervention phase in late 2015.

Under the original design, the remaining five communities were intended to begin the intervention in 2017, two years after baseline. Delays occurred in community engagement resulting from natural disasters (e.g. bushfire), staff turnover (in partner organisations) and shifting priorities of partners [Victorian Royal Comissions into Family Violence (2015–2016)[26] and Victoria’s Mental Health System (2018 to present)].[27] As a result the step two communities were not engaged in 2017 but entered into the trial in 2019, therefore they are referred as to “control communities”. The original step-one communities were engaged as intended and maintained the intervention from the initial time period across the four-year reporting period and are referred as to “intervention communities”. This paper reports the comparison of intervention versus control communities over four years (2015 to 2019). Primary and secondary measurements were collected as originally planned in April– June 2015, 2017 and 2019.

School and participant recruitment

All primary schools (Government, Independent, and Catholic) within the 10 communities, covering the six local government areas in South West Victoria, Australia, were invited to participate.

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, four and six available on the day of data collection at their school who had not opted out were eligible. Data were collected in Term 2 (April-June) of 2015, 2017 and 2019. All data were recorded on an electronic tablet (Samsung Galaxy) using a specifically designed application.

WHOSTOPS intervention description

The intervention comprised a process for building community-led collective action creating multiple changes across communities, from individual behaviours to policy and systemic change.[24] A standard process resulted in different intervention strategies tailored to each community. Through five phases, local leaders/key leaders, organisations and community members engaged with complexity at the local level and developed obesity prevention interventions and means to measure implementation and change in the system over time.

The first phase involved the collection and sharing of monitoring data, providing a baseline assessment of obesogenic risk factors and measured height and weight of children in the study areas. The information was used 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) with shared agendas for childhood health, obesity prevention, healthy eating or physical activity and other community leaders who had influence over children’s food and/or physical activity environments were identified.

The second intervention phase involved identifying and working with community members and supporters who have authority to initiate action and who outline the context for intervention and set the boundaries. These leaders built a systems map of the causes of childhood obesity in their community,[26] called a causal loop diagram (e.g. Figure one), using techniques from community based system dynamics[29] and a software called Systems Thinking in Community Knowledge Exchange (STICKE).[30] The resultant map captured drivers of childhood obesity in the community and community leaders to advocating for the trial and provide 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 includes remit and capacity to influence children’s food and activity environments and choices; including retailers, health organisations, 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 can carry out across the community, which are inspired by the systems map.

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 move through the intervention at their own pace.

Demographic characteristics

Demographic data that were collected as a part of the self-reported questionnaire included gender, date-of-birth, country of birth, Aboriginal and/or Torres Strait Islander background, and language spoken at home, which was dichotomised as English or Other. Socioeconomic position was examined at the school-level through the ICSEA (Index of Community Socio-Educational Advantage).[31]
Anthropometry measures

Students' height and weight were measured by trained health professionals in private booths; the children wore light clothing, no shoes, and any items were removed from pockets. A portable stadiometer (Charter HM-200P Portstad, Charter 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; A&D Medical, San Jose, CA) was used to measure weight to the nearest 0.1 kg. Two measurements were taken for both height and weight and a third measurement taken if a discrepancy of > 0.5 cm for height or > 0.1 kg was recorded between the two initial measures. An average height and weight was calculated for each child across these measures and used to generate age and sex-specific body mass index (BMI) z-scores and overweight/obese categories using the WHO's growth reference.\(^{[22]}\)

Physical activity and sedentary behaviour

Self-reported time spent in moderate-to-vigorous physical activity (MVPA) and screen-time for recreation (sedentary behaviour) over the 7 days previous to completing the survey were collected using a hybrid of two questionnaires that have previously been psychometrically tested among the target population.\(^{[33]}\) Participants were asked to indicate the time they spent in MVPA (none, < 15 minutes, 15–29 minutes, 30–59 minutes, 1–2 hours, ≥2 hours) or screen-time for recreation outside of school (none, < 1 hour, 1–2 hours, 2–5 hours and ≥5 hours) using these response options for each of the 7-days prior to the survey. These data were used to determine adherence to Australia's physical activity and sedentary behaviour guidelines of ≥60 minutes/day of MVPA and ≤2hrs/day of screen-time (e.g. electronic media) for entertainment for ≥5 out of 7 days.\(^{[35]}\) Participants reported mode of transport they usually took to and from school in the 7-days prior to the survey (car, school bus, public bus, train or tram, cycling, other active and other inactive). Transport was classified as active if modes of transport involved physical activity to and/or from school.

Diet quality: questionnaire

A modified version of the psychometrically tested Simple Dietary Questionnaire\(^{[37]}\) was used to collect self-reported ‘usual’ intake of core-foods and beverages (e.g. fruit, vegetables, water, unsweetened dairy products) and non-core foods and beverages (e.g. takeaway foods, packaged snacks, sugar sweetened beverages). These data were used to determine adherence to the Australian Dietary Guidelines which recommend daily consumption of two serves of fruit for children aged 9–18 years and 5 serves of vegetables for girls aged 9–18 and boys 9–11 years and 5.5 serves of vegetables for older boys (12–18 years).\(^{[39]}\) Water serves were measured in number of cups (one cup approximately 250 ml) per day. Water data were dichotomised into < 5 and ≥5 cups per day, based on the adequate intake level recommended for children 9–13 years old.\(^{[40]}\) Cut points of ≤1 SSB per day and consumption of one take-away food meal per week were used.

Health-related quality of life

Version four of the 23-item Paediatric Quality of Life Inventory 4.0 (PedsQL™) generic core scale\(^{[41]}\) was used to measure children's perceived health-related quality of life (HRQoL). It consists of four domains including 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 0-100. We report on the physical sub score, psychosocial sub score and global which combines emotional, social and school functioning scores. The minimal clinically important difference (MCID) of the PedsQL summary score is 4.5 points.\(^{[42]}\)

Statistical analyses

Sample Size: For ten clusters and three data collection points with an average of 300 children in each cluster, and the minimum detectable difference between groups will be 0.13 in BMIz with 80% power. BMIz standard deviation (1.2) and intra-cluster correlation (0.027) were estimated in a previous study of > 2500 Victorian school children (2014–2015).

Because of the disruptions and shifts in community priorities outlined in the design section, the communities allocated to shift to intervention at Step two were not able to start the intervention until 2019. Thus, the trial was analysed as a parallel design. All statistical analyses were conducted on an intention-to-treat basis, i.e. communities were analysed by the original arm assignment regardless of whether intervention communities had completed all the intervention phases or whether the control communities had implemented other strategies to improve healthy behaviours or prevent obesity.

The effect of the WHOSTOPS 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. The effect of the intervention on binary variables was estimated using generalized estimating equations (GEE, logit link and binomial distribution, compound symmetry correlation). The models included group (intervention, control), wave (2015, 2017, 2019), the interaction group × wave, the schools' ICSEA tertile and type of intervention on binary variables was estimated using generalized estimating equations (GEE, logit link and binomial distribution, compound symmetry correlation). 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. We report for each outcome two pre-specified contrasts: mean difference (BMIz) or prevalence difference (binary outcomes) between study arms in a) change between 2017 and baseline, and b) change between 2019 and baseline. We did not adjust for multiplicity of outcomes. All analyses were performed using SAS (version 9.4).

Patient and Public Involvement

The public were involved in the conception of the research project, the design and delivery of the interventions and in supporting collection of outcome measures. The research questions arose directly from local health and other key organisations priority areas and the public were involved in agreeing the study design and the choice of measures. Key local agencies including health services, education departments and primary care partnerships contributed recruitment of participants to the study via the school system. Through the study management committee and local implementation committee, community members have been involved in planning dissemination, including this paper, and including several as authors.
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. The number of schools increased in 2017 and 2019 due to 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).

<table>
<thead>
<tr>
<th>School</th>
<th>Student</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2015</strong></td>
<td><strong>2017</strong></td>
</tr>
<tr>
<td>INV</td>
<td>CONS</td>
</tr>
<tr>
<td>Intervention</td>
<td>34</td>
</tr>
<tr>
<td>Control</td>
<td>21</td>
</tr>
<tr>
<td>Total</td>
<td>55</td>
</tr>
</tbody>
</table>

INV = Invited; CONS = Consent; RR = Response Rate. NB: This table includes values for all government, catholic and independent schools (excluding Catholic schools in 2015)

**BMiz**

Overall: A significant interaction trial arm by study wave on BMiz was observed (p = 0.031), although no significant difference was observed between intervention and control groups in change in BMiz between 2015 to 2017 or 2015 to 2019. Significant reduction in BMiz within the intervention group was 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).

| Table 2 Demographic, anthropometric, and behavioural outcomes by wave, and trial arm |
|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| **Variables** | **Intervention communities** | **Control communities** | **Difference in change from 2015 to 2017** | **Difference in change from 2015 to 2019** |
| | | | | |
| Demographic data | | | | |
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By gender: Within intervention group, girls’ BMIz initially reduced from 2015 to 2017 followed by an increase whereas control girls experienced a steady increase from 2017 to 2019. A similar pattern was observed within boys in the intervention group where BMIz initially reduced from 0.59 in 2015 to 0.54 in 2017 and a significant increase 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. Among intervention communities grade four BMIz was significantly lower in the 2017 grade four intervention cohort compared to 2015 (p = 0.01 for grade 4) increasing again in 2019, while intervention BMIz among grade fours remained stable over the same period (Table 4).
Proportion overweight and obese 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; -1.24), p = 0.005) between 2015 and 2017 and a significant increase between 2015 to 2019 [(+ 4.9 (95%CI: 1.8; 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 initial reduction in prevalence of overweight and obesity in intervention communities followed by an increase in prevalence within the control communities the prevalence of overweight or obese 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%,-3.8%, p = 0.003) among grade four between 2015 and 2017 and −4.2% (95%CI: -12.6%, 4.1%, p = 0.322) among grade 6 over the same time period. Over the four year period, prevalence increased by + 9.7% (95%CI: 0.9%, 18.6%) in grade two intervention communities (Table 4). Among control communities, prevalence within year levels between measurement periods remained relatively stable. No interaction effects were observed for wave and trial arm within any year level.
Overall: Within intervention communities, 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. However the interaction group by time was not significant (Table 2). An intervention effect (p = 0.038) was observed for fruit consumption favouring intervention (+4.2%) between 2015 and 2017 and favouring control (-3.3%) across 2015 to 2019. In intervention communities, fruit consumption increased between 2015 and 2017 and decreased again in 2019, while in control communities fruit consumption gradually increased between 2017 and 2019.

Intake of takeaway food showed a significant intervention * time interaction (p = 0.006) with a significant intervention effect in 2019 relative to 2015 favouring intervention children detected: 6.0% (95% CI: 0.5, 11.6) (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, while among control communities, this percentage significantly decreased between 2015 and 2019 (-5.1%; 95%CI: -9.1%, -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 group by time (p = 0.001) for prevalence of meeting fruit guidelines, with an increased prevalence in 2017 in the intervention communities but a stable prevalence in the control communities (Table 2). There was also a clear intervention effect on water consumption (interaction, p = 0.019) with increased percentage of girls consuming more than 5 glasses of water/day in intervention communities in between 2015 and 2017 (18.1% increase) and 2015 to 2019 (11.8% increase) compared to control communities (Table 3).

Among boys, there was a significant intervention effect on takeaway (interaction, p = 0.012) and package snack consumption (interaction, p = 0.015) (Table 3). Prevalence of takeaway less than once a week (i.e., the lowest intake category) was significantly higher in intervention than control 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 higher in the intervention group in 2017 (11.4%) and 2019 (12.2%) relative to the control group (Table three).

By year level: Among grade fours, interactions were observed for behavioural changes favouring intervention (p = 0.001) for low takeaway food consumption (8.4%; p = 0.006) and low packaged snack consumption (10.1%; p = 0.050) between 2015 and 2019. Among grade sixes, the proportion of students reporting low SSB consumption increased in the control communities whereas intervention community SSB consumption remained relatively stable.

**Health-related quality of life outcomes**

Overall: Significant intervention effects were observed for physical and global HRQoL scores (p = 0.036 for both). The intervention significantly improved the psychosocial score in 2019 relative to 2015 (5.1%; 95%CI: 1.1%, 9.1%, p = 0.013) indicating that takeaway food consumption increased for children in control communities.

By gender: Among girls there was a significant intervention effect on takeaway (interaction, p = 0.012) and package snack consumption (interaction, p = 0.015) (Table 3). Prevalence of takeaway less than once a week (i.e., the lowest intake category) did not change across the study period, while among control communities, this percentage significantly decreased between 2015 and 2019 and 2015 (5.1%; 95%CI: 1.1%, 9.1%, p = 0.013) indicating that takeaway food consumption increased for children in control communities.

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**Table 4** Demographic, anthropometric, and outcomes by year-level, wave, and trial arm

<table>
<thead>
<tr>
<th>Wave 2015</th>
<th>Wave 2017</th>
<th>Wave 2019</th>
<th>Change</th>
<th>Significance</th>
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<tr>
<td>Behavioural outcomes</td>
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<tr>
<td>N</td>
<td>Intervention</td>
<td>N</td>
<td>Control</td>
<td>N</td>
</tr>
<tr>
<td>Physical activity</td>
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<td></td>
</tr>
<tr>
<td>Increased</td>
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<td>Global HRQoL</td>
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<td></td>
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<tr>
<td>Improved</td>
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<td>2.87 points</td>
<td>3.11 points</td>
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<tr>
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<tr>
<td>Global HRQoL</td>
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<tr>
<td>Improved</td>
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Discussion

Statement of principal findings

No intervention effect for the primary outcome BMIz or overweight or obesity was observed for intervention communities compared to control communities over the four years of the trial. While we observed a statistically significant (4%) reduction in the prevalence of overweight and obesity in intervention communities in the first two years (2015 to 2017), this was followed by a large increase in the final two-year period against a backdrop of no change in control communities. We positive interventions effects were observed among girls for water consumption while among boys, positive effects were observed for takeaway food and packaged snack consumption. 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[43] of contemporary studies (2013–2017) 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 RCT with two years follow up and the remainder were quasi-experimental.[43] The RCT[44] targeted children aged 5–8 years recruited via recreation centres in San Diego USA. Unlike our study, no intervention effects on BMIz or behaviours were identified after two years, although significant intervention effects for reduction in BMIZ were observed for girls.

A systematic review[7] of community-based interventions identified eight trials between 1990 and 2011 with seven of the eight having a positive impact on weight status. Their meta-analysis aligns with the first two years of WHOSTOPS trial where BMIZ was reduced by 0.12 among girls and 0.04 among boys. For WHOSTOPS these improvements were reversed in the following two years whereas control communities’ BMIZ remained unchanged. The longest intervention period reported in the Wolfenden review was three years.[45] Tarro et al., observed lower BMIZ and obesity prevalence among intervention children (5 to 7 years old at baseline) compared to control children 2-years post-intervention from their healthy lifestyle education program.[46] Economos et al., observed a significant reduction in BMIZ 1-year post-intervention for Shape up Somerville, a reduction that persisted after 20 months before dissipating as intervention intensity dropped.[47]

The initial reductions followed by increase in prevalence and BMIZ in WHOSTOPS may be related to intervention length. A systematic review[48] of 26 prevention studies in the same age group as WHOSTOPS found interventions of 12 months or less most effective in preventing obesity. They conclude duration was critical for intervention outcomes and mean BMI reduction or interventions of 12 months or less was almost twice higher than those lasting >1 year. Our results are consistent with this observation and suggest that initial positive changes in BMIZ and obesity prevalence are difficult to sustain.

The drop and subsequent increase in intervention communities remains a question for further investigation but our initial explanations are as follows; Firstly, at the two-year time point the research team reduced their implementation support to step one communities to begin recruiting step two communities. Whilst this was planned, the impact of bushfires and other natural disasters, resulted in the control communities delaying uptake of intervention for a further two years, and the resources allocated to supporting the first set of intervention communities was reduced by a factor of at least half of what was planned for the second two-year period. 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 ‘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[49-50] and in this trial, building on experience in community intervention, we set out to build capacity within communities to apply techniques from systems science to the design and implementation of interventions. This clearly was successful over the first two years but, as actions continued to be rolled out, a peak in capacity and or engagement may have been reached. Improvements in behaviours 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 behaviours 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. These broad secular changes may have impacted on the intervention communities’ ability to maintain healthy environments for children and lower obesity prevalence.

The Chirpy Dragon study, is a cluster RCT[51] of primary school based obesity prevention efforts similar to WHOSTOPS. Chirpy Dragon targeted physical activity and dietary behaviours using the UK Medical Research Council Complex intervention framework[52]. The trial was of a similar size to WHOSTOPS (1,641 children) and resulted in actions across home, family and school. A mean difference in BMIZ between intervention an control was observed (0.13) and positive intervention effects were observed for fruit and vegetables, SSBs, snacking, screen time behaviour and physical activity. We do not know if these changes persisted however as the trial was conducted over a 12-month period.

The intervention design are comparable to capacity building trials evaluated using quasi-experimental designs such as Economos[47] and Malakellis et al.[54] Both these trials delivered multi component interventions in multiple settings and reported significantly lower BMIZ scores.

Strengths and weaknesses of the study

Our study represents the longest follow-up (four years) of any contemporary community-based intervention. Until now, the longest was three years with one to two years being most common.[49] The trial utilised a cluster randomized design and electronic tablets for data collection saving time compared to paper-based surveys[55]. Local, high quality data was recognised by community partners as to a key aspect of the community engagement and ongoing intervention.
adaptation.\textsuperscript{[53]} Student participation rates were higher than 80\% using an opt-out approach which compares favourably to other active (opt-in) school-based data collection where participation rates ranged between 30–60\%.\textsuperscript{[56]} Participation bias has been observed in regard to differing student response rates and resulting estimates of BMIz and overweight/obesity prevalence.\textsuperscript{[57]}

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 there was no single ‘start date’ for each community meaning the intervention period varied. This variation in intervention period likely impacted our primary outcome. One community had completed all phases as described in the WHOSTOPS intervention description section by 2017, while the other four communities had completed the second phase, where leaders come together to build a systems model. Four of the five had completed all phases by 2019 and the remainder were preparing to begin phase three, engaging the broader community. Intention-to-treat analysis is likely to overlook the nuance of early or late adoption.

This trial was designed to engage community leaders in understanding the systemic drivers of childhood obesity and to identify and commit to making changes that were feasible, realistic and, therefore, more likely to be sustained. Thus interventions differ by community and vary depending on community resources, priorities and capacity to engage. This responds directly to the Lancet Commission on Obesity\textsuperscript{[16]} call for a step change in engaging communities in prevention.\textsuperscript{[58]} Levels of community action varied and showed some promise; one community recorded 400 intervention actions\textsuperscript{[59]} involving by > 20 community leaders and > 150 community members.

WHOSTOPS has intentionally focussed on fidelity of process\textsuperscript{[60]} while the package of interventions were adaptable to the needs, abilities and resources available to the community. In practice this means intervention dose was impacted by changes in context, priorities baseline and community capacity.

Our study did not achieve the proposed sample size of 1500 in each trial arm at each wave\textsuperscript{[24]} 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 as to detect a significant change in a percentage variable (e.g. \% PA guide) require large changes.

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

WHOSTOPS reduced obesity prevalence over two-years, and over four-years helped a majority of children keep their takeaway food intake low, and sustained health-related quality of life in a context where this was declining. Results varied with gender and age group indicating that single behaviour, single setting interventions are unlikely to generate the level of change required to improve child health or prevent obesity across the spectrum of childhood. Instead, 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 were already in place to address childhood obesity.

While the first two years of this intervention reduced obesity prevalence, the initial effect appears to have been reversed in the subsequent two years. The reasons for this are to likely relate to context, capacity and timing and possibly the length of the WHOSTOPS trial. It appears one to two years is a meaningful intervention period after which the efficacy of prevention efforts may wane.

Childhood obesity is demonstrably preventable and community-based interventions are effective, feasible, and acceptable to government, industry and the public\textsuperscript{[61]}. These interventions should plan to mitigate unforeseen social and economic shocks that may distract community efforts. The adaptive design of this trial meant the actions were able to be adapted to existing capacity, resources and priorities. The trial itself may have suffered as community priorities shifted. For WHOSTOPS bushfire brought this issue into stark relief though any community effort at significant scale is bound to be beset by unexpected challenges. Long term (e.g. >1 year) trials need regular short term revisions to narrowly focused change efforts. New adaptive trial methodologies provide one direction.\textsuperscript{[61]}

A second interpretation of these results may be the need to ring fence resources to the obesity prevention regardless of other priorities. The better sustained community efforts in WHOSTOPS were supported by larger auspice organisation and regional leadership over longer periods of time. Similarly the Kiel Obesity Prevention Study found obesity prevention was more likely to be sustained when embedded in existing social education systems.\textsuperscript{[62]}

Conclusion

Work is underway\textsuperscript{[23 62 63]} to undertake more detailed cause and effect\textsuperscript{[24 64]} and economic analysis\textsuperscript{[65]} to determine how underlying systemic conditions shift in these types of community-led interventions.

Declarations


Consent for publication: Not applicable
Availability of data and material: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: All authors affirm that they have no conflicts of interest and the funding agencies had no input to the design, conduct or analysis of the study.

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

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Figures
Figure 1

Example of a community causal loop diagram of causes of childhood obesity

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CONSORTExtensionforClusterTrials2012Checklist.docx
- TIDieRChecklistWord.docx