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# Reflexive Evidence and Systems interventions to Prevention Obesity and Non-communicable Disease (RESPOND): protocol and baseline outcomes for a stepped-wedge cluster-randomised prevention trial

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## ABSTRACT

**Introduction** Systems science methodologies have been used in attempts to address the complex and dynamic causes of childhood obesity with varied results. This paper presents a protocol for the Reflexive Evidence and Systems interventions to Prevention Obesity and Non-communicable Disease (RESPOND) trial. RESPOND represents a significant advance on previous approaches by identifying and operationalising a clear systems methodology and building skills and knowledge in the design and implementation of this approach among community stakeholders.

**Methods and analysis** RESPOND is a 4-year cluster-randomised stepped-wedge trial in 10 local government areas in Victoria, Australia. The intervention comprises four stages: catalyse and set up, monitoring, community engagement and implementation. The trial will be evaluated for individuals, community settings and context, cost-effectiveness, and systems and implementation processes. Individual-level data including weight status, diet and activity behaviours will be collected every 2 years from school children in grades 2, 4 and 6 using an opt-out consent process. Community-level data will include knowledge and engagement, collaboration networks, economic costs and shifts in mental models aligned with systems training. Baseline prevalence data were collected between March and June 2019 among >3700 children from 91 primary schools.

**Ethics and dissemination** Ethics approval: Deakin University Human Research Ethics Committee (HREC 2018-381) or Deakin University's Faculty of Health Ethics Advisory Committee (HEAG-H_2019-1; HEAG-H 37_2019; HEAG-H 173_2018; HEAG-H 12_2019); Victorian Government Department of Education and Training (2019_003943); Catholic Archdiocese of Melbourne (Catholic Education Melbourne, 2019-0872) and Diocese of Sandhurst (24 May 2019). The results of RESPOND, including primary and secondary outcomes, and emerging studies developed throughout the intervention, will be published in the academic literature, presented at national and international conferences, community newsletters, newspapers, infographics and relevant social media.

**Trial registration number** ACTRN12618001986268p.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Reflexive Evidence and Systems interventions to Prevention Obesity and Non-communicable Disease (RESPOND) is designed as a stepped-wedge cluster randomised control trial that applies systems theories and community-based systems dynamics methodologies to inform all aspects of the intervention design, implementation and evaluation.

⇒ RESPOND's outcome evaluation is informed by the establishment of a high participatory childhood obesity and risk factor surveillance system, which seeks to reduce non-participation bias in outcome measurement evaluation.

⇒ As RESPOND is a community-based intervention, it is impossible to blind communities and intervention spill over may occur outside geographical boundaries.

## INTRODUCTION

Addressing overweight and obesity is a priority due to the high global prevalence, with 1.97 billion adults and 337 million children affected,[1] and due to the increased risk of various chronic diseases including type 2 diabetes, ischaemic heart disease and multiple cancers.[2] In Australia, approximately 63% of adults and 28% of children have overweight or obesity,[3] which is estimated to cost the economy as much as $21bn annually in direct and indirect healthcare costs.[4 5] The

WHO's Commission for Ending Childhood Obesity set a target to halt the rise in diabetes and obesity by 2020.[6] This target was not met and no country has reversed the epidemic and existing systemic and institutional drivers remain largely unchanged.[7]

Published evaluations of community-based interventions, such as Romp and Chomp,[8] Be Active, Eat Well,[9] It's Your Move[10] and Shape Up Somerville,[11] have demonstrated reductions in body mass index z-score (BMI-z) and/or health behaviours within 3 years of intervention in individual communities. These studies identified the importance of capacity building with communities and of the role of leadership. Some have identified diffusion into adjacent communities[12] and related populations,[13] although few studies have shown evidence of long-term impact.[14] Encouragingly, studies have shown that community interventions can prevent overweight and obesity in a cost-effective manner.[15]

While the success of trials in community interventions is promising, a sustained population impact requires the translation and scaling up of successful initiatives to achieve a broader reach across multiple levels of practice including regions, states, and countries. To date, larger scale, multicommunity interventions have produced mixed results.[16] Proposed reasons for this include insufficient training of staff in systems methods,[17 18] or actions arising from the systems workshops have not aligned well with the barriers and enablers previously identified by participants.[19]

Systems science methodologies are utilised to address a multitude of complex problems. Two examples include: the current climate change crisis where system methodologies are used to identify mitigation opportunities[20]; another example is the focus on creating support for children's mental health.[21] Likewise, systems methodologies have potential to build a common understanding of the underlying drivers of a complex problem and codesign potential solutions with stakeholders. These methods move beyond earlier approaches to prevention programmes in the specific identification of feedback loops, unintended consequences,[22] and actively engages with adaptation to context in the planning phase,[23] something that predefined programmatic responses are less likely to do.[24] While interest in systems approaches for obesity prevention is increasing,[25] the applied methodologies within studies are varied.[26] In a review of systems science in public health, half of the included papers call for the use of systems approaches but do not apply systems methodologies.[27] To date, systems methods are often reported as case studies due to the nature of inquiry[28] rather than reported as part of a large funded randomised controlled trial.

Healthy Towns (UK 2008–2011)[17] adopted a system-wide approach to obesity prevention. Stakeholders reported a theoretical understanding of a system-wide approach, but those responsible for the delivery reported that they lacked the skills to translate this system approach into action. This further highlights the need for capacity building in system approaches to include both the design and implementation of prevention activities.

A recent (2012–2016) large-scale intervention aiming to prevent obesity using an explicitly systems thinking informed approach was Healthy Together Victoria (HTV), in 12 local government areas (LGAs) of Victoria, Australia.[29] No studies have yet been published that report on anthropometric results from HTV. A qualitative study concluded that population-level reductions in chronic disease were unlikely due to inadequate system oversight and a lack of focus on intervention delivery.[30]

Our recent Whole of Systems Trial of Prevention Strategies (WHO STOPS 2016–2020)[31] relies on Hovmand's different levels of systems insights framework, which lays out how insights about a problem can range from 'There is a system' using system pictures down to 'Why do things happen' using formal simulation models. By engaging with communities for 5 years, the researchers aim to begin with systems pictures, and through a series of engagements, increase depth of understanding of the community through deepening rigour of system dynamics tools. In community-based system dynamics (CBSDs), through this capacity building process, communities build an understanding of how the feedback loops and accumulations that make up the structure internal to the community drive the problematic behaviour of interest (in this case, childhood obesity). As these insights deepen, the community will work together to take action to address the local structural elements driving childhood obesity (Hovmand, 2014 .49).[32] Within WHO STOPS, community workshops used system approaches led by academics. WHO STOPS provided some evidence for reductions in BMI-z in the first 2 years of intervention, and after 4 years improved health behaviours and quality of life but a rebound in BMI-z scores was observed.[33]

To advance the effectiveness of systems approaches it is recommended that a clear system theory be identified and applied, and relevant stakeholders receive training in this approach.[17 18 31] Previous approaches, including those with a focus on capacity building, have nevertheless still relied on the leadership of external experts to drive the application of systems approaches to prevent obesity in their communities. RESPOND (Reflexive Evidence and Systems interventions to Prevent Obesity and Non-communicable Disease) aims to address this gap by specifically training local stakeholders in CBSD and group model building (GMB), equipping them to lead local responses with a high degree of independence and autonomy. This advance has evolved from previous trials in a number of communities[31 34 35] that were researcher-led, to one that is community-led with skills and knowledge related to systems approaches actively embedded within communities.[31]

This protocol outlines how we will test the effectiveness and cost-effectiveness, at scale, of a community-led whole of systems approach to childhood obesity prevention: RESPOND will operate in ten regional LGAs in north-eastern Victoria, Australia. This protocol also

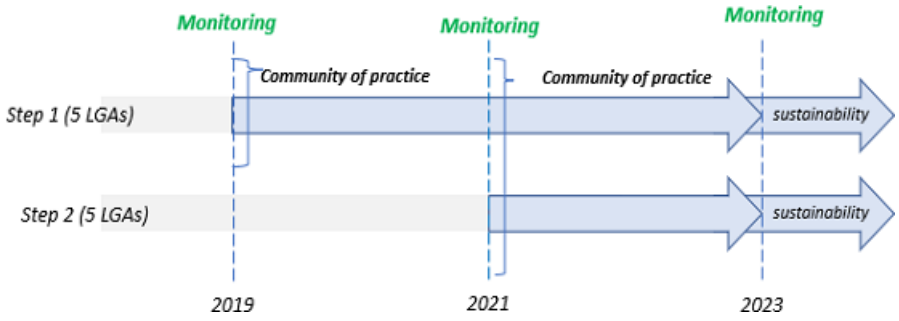


**Figure 1** RESPOND stepped-wedge intervention design 2019–2023. LGAs, local government areas; RESPOND, Reflexive Evidence and Systems interventions to Prevention Obesity and Non-communicable Disease.

presents baseline data regarding child behaviours and weight status. RESPOND aims to: (1) use systems science methods to guide planning and implementation and to accelerate uptake of efforts to prevent childhood obesity at regional scale and (2) evaluate the impact of a community-led systems intervention to address childhood weight status and related behaviours. It is hypothesised that RESPOND will reduce childhood obesity in regional Victorian communities.

## METHODS AND ANALYSIS

### Trial design

RESPOND is a 4-year cluster-randomised stepped-wedge trial in 10 LGAs in the Ovens Murray and Goulburn regions of Victoria, Australia, with five LGAs randomly allocated to start intervention immediately (step 1) and five communities to start after 2 years (step 2) (figure 1). All 10 LGAs have the option to divide their municipality into smaller intervention 'communities' to coordinate and support a localised systems approach to intervention planning and actions.

The unit of randomisation and intervention is the LGA. The main outcomes will be measured among children attending primary schools located within the LGAs. The stepped-wedge design was chosen for its suitability in situations where randomisation of individuals is not possible (ie, population level trials), where the intervention is expected to be of benefit and unlikely to do any harm, and where allocating groups to a control-only arm would be problematic, unethical or likely to result in groups refusing to participate.[36]

### Randomisation procedure

Randomisation was conducted by the study statistician (LO) who had no pre-existing relationships with, or particular knowledge of, the participating LGAs. The 10 LGAs were ranked in order of population size of children aged 0–12 years at the 2016 Australian Census[37] and organised into five blocks. One LGA in each block was randomly allocated to start the intervention at step 1 (July 2019) and the other to start intervention at step 2 (July 2021). No eligibility or exclusion criteria were involved in the selection of LGAs other than their geographic location in the Goulburn Valley or Ovens Murray region.

### Partnership approach

RESPOND is funded by Australia's National Health and Medical Research Council's (NHMRC's) Partnership Projects Research Grants scheme, (GNT1151572) with further funding and in-kind contributions from 12 partner organisations who were signatories to the grant. Partners to the RESPOND grant were Deakin University (lead agency), the Victorian Government Departments of Education and Training and of Health and Human Services, Beechworth Health Service, Yarrawonga Health, Gateway Health, Numurkah District Health, Lower Hume Primary Care Partnership, Central Hume Primary Care Partnership, Upper Hume Primary Care Partnership, Goulburn Valley Primary Care Partnership and VicHealth. Additional organisations who have joined the partnership since establishment include Greater Shepparton City Council, Murrindindi Shire Council and Nexus Primary Health.

### Setting

The whole of community intervention will focus on creating healthier environments for children aged 0–12 years in the region (n~30 000).[27] The study will evaluate the impact of the intervention in primary school aged children in grades 2, 4 and 6 (approximately n=8196 in the 2016 Australian Census)[27]) and on systems and environmental changes at the setting and LGA setting in the ten participating LGAs (figure 2). All primary schools in the region (government, independent or catholic) are eligible to participate, and all children within selected grades within participating schools will be invited to participate in the evaluation.

### Intervention

RESPOND will adopt CBSD methods[32] to design the intervention and catalyse systems change through community-led, locally tailored action. GMB, brings a group together to build a visual shared understanding of a complex problem, like obesity, represented in a diagram called a causal loop diagram (CLD). CLDs represent the variables participants perceive to be contributing to a problem and the causal connections between them.[32] Repeated modelling over time will move participants from drawing simple systems pictures that identify the potential parts of a system and their hypothesised

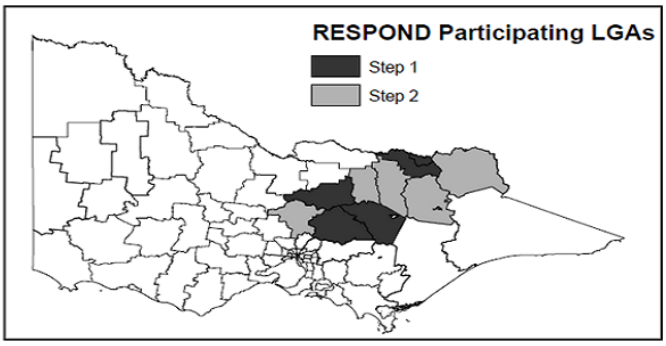


**Figure 2** Location of RESPOND Intervention LGAs within the state of Victoria, Australia. LGAs, local government areas; RESPOND, Reflexive Evidence and Systems interventions to Prevention Obesity and Non-communicable Disease.

interconnections to deeper understanding of the local structures causing childhood obesity to increase over time.[32] This shared understanding will support stakeholders in collaborating to address these local structures driving childhood obesity.

Researchers from Deakin University will work with local prevention experts to engage personnel in the health, education and local government and community sectors. These stakeholders will be trained in the concepts of CBSD and facilitation methods for GMB workshops, ensuring relevant CBSD expertise remains in the community. GMB was a method developed to engage stakeholders in the construction of system dynamics simulation models.[38] CBSD's approach to GMB emphasises empowering participants to play an increasingly more complex role in the model building process through repeated exposure to GMB and building a relationship with system dynamics experts. RESPOND will use the iteration of GMB described within CBSD to build stakeholders' understanding of the system structure driving obesity and develop increasingly effective actions to address the problem locally. This training is embodied within a standardised Community GMB Facilitation Manual which was developed by several coauthors in consultation with CBSD experts and follows well defined scripts based on Scriptapedia.[39] These stakeholders will act as facilitators to run local GMB workshops and community action planning processes. Participants in these workshops will develop a CLD of the perceived causal drivers of childhood obesity in their community. Local childhood obesity monitoring data collected shortly before the GMB workshops, will be presented back to the community to support the GMB process and to contextualise community conversations about local childhood obesity levels and response planning. The data may assist community stakeholders to engage with the problem at the local level with data that prior to this project would not exist. Intervention communities will be connected with each other in a community of practice, designed to support shared learning, diffusion of techniques and approaches to maintain community engagement, build local buy-in and support actions as they emerge in LGAs. Capacity to deliver the intervention action(s) is coalesced by the community stakeholders and partner organisations with Deakin University providing support on implementation science.

RESPOND comprises four stages as step out in table 1.

## Evaluation design and methodology

The trial will assess the effectiveness (and cost-effectiveness) of the intervention for individuals (primary school children), community settings and context, and systems and implementation processes.

### Individuals

The primary outcomes (BMI-z and overweight/obesity prevalence) and secondary outcomes (physical activity, sedentary behaviour, diet quality, sleep and well-being) will be collected in repeat cross-sectional surveys among primary school students and are described in detail in table 2. These outcomes will be measured among children in grade 2 (aged approx. 7–8 years), grade 4 (aged approx. 9–10 years) and grade 6 (aged approx. 11–12 years).

Across the 10 LGAs of RESPOND, a childhood obesity and risk factor monitoring system has been established to collect data across school terms 1 and 2 (January–June) in 2019, 2021 and 2023. All government, independent and catholic primary schools (n=112) will be invited to participate through a written invitation and follow-up phone call and/or in-person visit to each school principal. In participating schools, all students in grades 2, 4 and 6 will be invited to participate through an opt-out approach. Participating student will have height and weight measured, and older students (grades 4 and 6) will be invited to complete a self-report behavioural survey on an electronic tablet. A sub sample of approximately half of all grade 4 and grade 6 students will be invited to wear a wrist-worn ActiGraph wGT3X-BT accelerometer for 7 days to objectively measure physical activity, sedentary behaviour and sleep duration. At each participating school, all children in the first class approached for measurements in each year level (eg, 4A and 6C) will be invited to wear accelerometers at each participating school.

### *Public involvement*

This study has public involvement through three governance layers. The RESPOND partner group meets four times per year to assist with strategic decisions related to the overarching governance of the intervention. This group comprises representation from across each of the LGAs within the trial. The regional implementation network (RIN) meets six times per year to share experiences and learnings from their respective communities. At least one member of the research team is a member of the RIN. The RIN acts as a conduit from community to researchers and to overarching governance. The community action groups drive the community-led change in communities. These groups link to the RIN through local stakeholders.

**Table 1** Four stages of RESPOND

| Component | Who | What/responsibilities |
|---|---|---|
| 1. Catalyse and set up | ► Partner agencies identify relevant organisations with shared agenda for childhood obesity prevention | ► Establishment of effective and representative governance structure.<br>► Delivery of components 2 and 3 (below) directly or by identifying and supporting relevant organisations.<br>► Scheduling of regular, quarterly meetings of governance structure. |
| 2. Monitoring | ► Committed community agents and project partner capacity (local workforce)<br>► Deakin University | ► School-based monitoring of children's weight status, diet, exercise, sleep, quality of life @ baseline, 24, 48 months.<br>► Data used for community engagement (component 3) |
| 3. Community engagement | ► Partner agencies<br>► Identified relevant stakeholders<br>► Deakin University | ► Deakin University to lead the training in community based system dynamics, GMB, and community action planning.[28 29]<br>– Two-day intensive seminars<br>– Series of 10–12 online/in-person seminars<br>► Partner agencies recruit 10–20 cross-sector community leaders to participate in three GMB workshops, and a further up to 100 community members to attend the third GMB.<br>► GMB participants build a shared understanding of the local drivers of childhood obesity.<br>► In GMB 3, participants discuss and prioritise local actions to address childhood obesity. |
| 4. Implementation | ► Partner organisations<br>► Community stakeholders<br>► Deakin University | ► Facilitators from communities enrolled in step 1 of the five intervention communities form an online community of practice to engage with peer mentoring and additional capacity building as required.<br>► Relevant stakeholders from step 2 communities join the community of practice when step 2 commences. |

GMB, group model building; RESPOND, Reflexive Evidence and Systems interventions to Prevention Obesity and Non-communicable Disease.

### Community settings and context

Data will also be collected related to relevant settings and community contexts. Students spend a significant proportion of their week in school. Therefore, the extent to which the environment of the school enhances healthy choices may be associated with changes in health behaviours and BMIz. The community context, and characteristics of community leadership, engagement and resources are also crucial to effective implementation of a large-scale multi-setting prevention programme. We are measuring knowledge, engagement and social networks because we hypothesise that there will be common features of strong knowledge, engagement, collaborative leadership networks that are best placed to support and ultimately ensure the success of public health interventions in communities (table 3).

### Systems and implementation processes

Systems and implementation process evaluation will (1) explore the trained facilitators' experiences of being trained in GMB and running their first GMB workshops, (2) investigate changes in mental models of participants of GMB workshops (for example a shift from a focus on individual behaviour change strategies to environmental initiatives to support healthier behaviours) and (3) track intervention actions mapped to the community-generated CLDs over time. Evidence about the impact of GMB suggests that it changes people's mental models, the enduring ideas people hold about how the world works based on their knowledge and experiences.[40] Pretest and post-test, based on work by Scott *et al*, will ask participants to write down the causes and consequences of childhood obesity and three actions they would recommend to address the problem. Administering the same questions before and after the workshops will allow an analysis of the degree to which participants' top of mind ideas about childhood obesity changed in response to the workshops.[41]

Intervention action mapping will be undertaken using an action register (via an Excel template) for capturing current known actions, corresponding points of impact within the community-informed CLD, resources used or required, and geographical and population reach. Stakeholders will be encouraged to map actions onto their community CLDs through the use of the Systems

**Table 2** Overview of primary and secondary outcome(s) and measurement instrument

| Category | Outcome of interest | Measurement instrument | Procedure and instrument properties |
|---|---|---|---|
| Anthropometry | BMI-z score, overweight and obesity prevalence[54] | Height<br>Portable stadiometer<br>(Charder HM-200P Portstad, Charder Electronic, Taichung City, Taiwan)<br>Weight<br>Digital weight scales<br>(A&D Precision Scale UC-321; A7D Medical, San Jose, CA) | Year 2, Year 4 and Year 6: students invited to have their height and weight measured by trained staff, while wearing light clothing and without shoes. Two measurements each of height and weight taken and measured to the nearest 0.1 cm or 0.1 km. Where measurement differed by 0.5 cm for height and 0.1 kg for weight, a third measure is taken. The mean of all measurements was used. |
| Demographic characteristics | Age (date-of-birth), gender, country of birth, Aboriginal and/or Torres Strait Islander background, language spoken at home, socioeconomic position (postcode) | Health-Behaviours Questionnaire | All participating year 4 and year 6 students; behavioural questionnaire administered by trained staff on electronic tablets (Samsung Galaxy 4) Students encouraged but not required to answer all questions. Estimate questionnaire takes approximately 25–35 min to complete in class time. Students assisted in comprehension of the questions and standard prompts were given to clarify items such as serving sizes for fruit and vegetable consumption. |
| Physical Activity, Sedentary Behaviour and Sleep | Self-report<br>Adherence to Australia's 24-Hour Movement Guidelines for children (5–17 years)[55]<br>Proportion taking active transport to and/or from school | Two questionnaire items examining duration spent in MVPA and screen-time from the Core Indicators and Measures of Youth Health survey on each of the last 7 days.[56] One further question examining usual active transportation to and/or from school. A bespoke sleep question item based on Berentzen *et al*[57] in which students report the time they usually went to bed and woke up on school days. | Year 4 and year 6 students invited to complete the self-report behavioural questionnaire on an electronic tablet.<br>We examined the test–retest reliability and criterion validity of the Core Indicators and Measures of Youth Health survey[56] and the bespoke sleep item based on Berentzen *et al*[57] among a sample of 26 grade 4 and grade 6 (11.2±1.1 years) primary school children in Victoria, Australia in July–September 2014. Seven-day test–retest reliability was moderate for proportion meeting the physical activity component of the 24-hour movement guidelines (≥60 mins of MVPA/day) on all 7 days (percent agreement 88.5%; kappa 0.61) and fair for ≥5 days/week (percent agreement 73.1%; kappa 0.39). Test–retest reliability for adherence to the screen-time component of the 24-hour movement guideline (≤2 hrs/day for recreation) was moderate (percent agreement 69.2%; kappa 0.41) for all 7 days and fair (percent agreement 61.5%; kappa 0.23) for ≥5 days/wk. Test–retest reliability for duration spent sleeping ≥10 hours/night on school nights was substantial (per cent agreement 84.6%; kappa 0.68).<br>Criterion validity for self-report adherence to the MVPA component of the 24-hour movement guideline against accelerometry measured duration among 19 participants was slight (percent agreement 63.2%; kappa 0.24) for all 7 days. These findings also highlighted children typically under-reported MVPA. |
| | Objectively measured<br>Minutes per day spent in sleep, sedentary light, MVPA behaviour | wGT3X-BT ActiGraph wrist worn Accelerometer (ActiGraph, Pensacola, Florida, USA). Students instructed to wear the device for 7 days. | A subsample of year 4 and year 6 students invited to wear an accelerometer (eg, first class of year 6 and year 4 students) at each school. Participants instructed to wear the accelerometer on their non-dominant wrist for 7 days and only take the monitor off for water based and sparing activities and for contact sports (eg, martial arts, Australian Rules Football) as required. |

Continued

**Table 2** Continued

| Category | Outcome of interest | Measurement instrument | Procedure and instrument properties |
|---|---|---|---|
| Diet Quality | ► Typical/usual serves of fruit and vegetable daily<br>► Typical/usual serves and size of several non-core foods<br>► Typical/usual serves and size of sugar-sweetened beverages (SSBs)<br>► Typical/usual consumption of water<br>► Proportion of participants meeting the Australian Dietary guidelines for fruit and vegetable intakes[58] | Sixteen question items examined diet quality and were derived from the Child Nutrition Questionnaire (CNQ), the Food, Health, and Choices (FHC-Q)[59] and the Simple Dietary Questionnaire (SDQ) questionnaire.[60] Two modified question items examining fruit and vegetables serves each day were derived from the CNQ. Fourteen items from the FHC-Q were used to examine non-core food (eg, chips, lollies, chocolate, cakes, biscuits, pastries etc), SSB (eg, sodas, fruit juice/drink/cordial and flavoured milk) and takeaway consumption. One question item from the SDQ examined water consumption. | The CNQ[61] used to examine fruit and vegetable consumption and has psychometrically tested among 141 Australian children aged 10–12 years against a 7-day food diary. The reliability intraclass correlation coefficient (ICC) of fruit (ICC=0.66) and vegetables (ICC=0.66) was moderate, and validity for fruit (r=0.48) was moderate and weak for vegetables (r=0.36).<br>FHC-Q used to examine non-core, SSB and water consumption. This questionnaire was psychometrically tested among 221 children aged 9–12 years in New York, USA. The 14-day test-retest reliability of SSB (ICC=0.81), non-core foods (ICC=0.75), takeaway (ICC=0.75) was good to excellent. Validity against another questionnaire (relative validity) was moderate to strong for SSB (r=0.55), non-core foods (r=0.61) and takeaway (r=0.61) foods.<br>The SDQ examined reliability and validity properties (unpublished) among a sample of adolescents aged 13–18 years in Australia. Test–retest reliability for water was high (ICC=0.82) and validity against 24-hour diet recall was very weak (r=−0.436). |
| Well-being | Global summary score and subcomponents including psychological physical health summary score | The 23-item Paediatric Quality of Life Inventory 4.0 (PedsQL)[62] questionnaire was used to examine perceived health-related quality of life among participants. PedsQL[62] | The PedsQL examines self-rated physical, emotional, school and social health and has been widely used both in Australia[63–66] and internationally. It has undergone rigorous psychometric evaluation in a variety of languages[67] and has shown high internal consistency (α=0.90–0.91) among children aged 8–11 years in the USA with validity established in comparison with children with chronic health conditions (effect size d=0.63–0.72).[62] |

BMI, body mass index; MVPA, moderate-to-vigorous physical activity.

Table 3 Community settings and contexts data collection

| Category | Outcome of interest | Data collection instrument | Procedure |
|---|---|---|---|
| School environment audit | Schools' physical activity and healthy eating policies, practices and environments. | The survey comprises selected questions from the:<br>► Be Active Eat Well school environment audit[68] and<br>► International Study of Childhood Obesity, Lifestyle and the Environment school environment audit tool.[69] | The principal or nominee in each participating school will be invited to complete the survey.<br>The survey will be collected at three timepoints concurrent with the individual-level data collection in primary schools (as shown in table 2). |
| Knowledge and Engagement | Assessment of baseline and change over time in the knowledge and engagement of stakeholders | ► The Knowledge and Engagement sections of the Stakeholder-driven Community Diffusion Survey.[70] | The protocol for assessment of baseline and change over time in the knowledge and engagement of stakeholders has been published separately.[71]<br>The survey will be administered to all members of the governance structure via the Qualtrics online platform prior to intervention commencement, and at five time points during the intervention. |
| Social Network Analysis (SNA) | Key measures, at the LGA level, will be network characteristics including network size, density, reciprocity, centralisation, connectivity and clustering, for both the collaboration and advice networks. | ► The SNA survey questions will be drawn from the Stakeholder-driven Community Diffusion Survey[70] and will ask participants to indicate which other members of their community they have collaborated with, or sought advice from, on issues related to healthy eating and physical activity environments for children in their community, and the frequency of this collaborative work. | The SNA survey will be administered via the Qualtrics online platform.<br>Participants will include the RESPOND central leadership, trained facilitators from within each community, and community leaders and members who participate in each of the GMB workshops.<br>The survey will include, from the second time point forward, a question asking participants to indicate, on their own community CLD, where they are currently taking action, their perceived impact on that component of the system, and the ease or difficulty of influencing this area of the system. |

CLD, causal loop diagram; GMB, group model building; LGA, local government area; RESPOND, Reflexive Evidence and Systems interventions to Prevention Obesity and Non-communicable Disease.

Thinking in Community Knowledge Exchange Software V.3,[42] as shown in Maitland *et al*.[43]

### Sample size and power considerations

Calculations are based on detecting differences in the primary outcome, mean BMI-z score at the end of the study under the stepped wedge design (two steps, three measurement times, five clusters per step).[44] There are approximately 8200 children enrolled in grades 2, 4 or 6 in schools within the 10 participating LGAs. From our previous experience,[45] we anticipate that ≥60% of the schools in the region will participate. The approved opt-out procedure for recruitment of students can be anticipated to produce a participation rate above 80%.[45 46] Together, an 80% student participation rate in 60% of schools is expected to produce an overall participation rate of over 50% of children attending grades 2, 4 and 6 across the 10 LGAs in the RESPOND region. The within-LGA variability and intra-cluster correlation coefficients for BMI-z score (the primary outcome) were estimated from our previous study of Victorian children of the same ages, using a comparable methodology, by considering the upper limits of the corresponding 95% CIs.[29] Assuming 50% of children in grades 2, 4 and 6 within each LGA are measured at each wave gives a sample of 2600–3200 children measured per wave and given an ICC of 0.05 and SD of 1.25, provides a minimum detectable difference in BMI z-score of 0.15–0.16 units, with 80% power at $\alpha$=0.05 under the stepped-wedge design.

### Statistical analysis

Statistical analyses will be conducted on an intention-to-treat basis, that is, assuming that children were exposed to intervention during the full LGA intervention periods irrespective of when the actions resulting from the intervention effectively occurred. The effect of the intervention on the main outcome (BMI-z measured in primary school children) and on the continuous secondary outcome measures will be assessed using linear mixed models. Models will include time interval[1–3] and an indicator of whether the cluster (LGA) received the intervention during each period as fixed effects, and school

Table 4 School characteristics at baseline by trial group (N=67 schools)

| | | Step 1 (N=32) | | Step 2 (N=35) | | |
|---|---|---|---|---|---|---|
| | | Mean | SD | Mean | SD | P-value |
| ICSEA | | 1006.7 | 43.94 | 985.7 | 39.66 | 0.044 |
| | | n | % | n | % | P |
| School rurality | Major city | 0 | 0 | 1 | 2.9 | 0.153 |
| | Inner regional | 28 | 87.5 | 24 | 68.6 | |
| | Outer regional | 4 | 12.5 | 10 | 28.6 | |
| School type | Government | 27 | 84.4 | 34 | 97.1 | 0.135 |
| | Catholic | 3 | 9.4 | 0 | 0 | |
| | Other independent | 2 | 6.3 | 1 | 2.9 | |

ICSEA, Index of Community Socio-Educational Advantage.

as a random effect. Binary or categorical outcomes will be analysed using a generalised estimating equations approach with link and distribution selected according to the variable. The covariance matrix will account for clustering induced by LGAs, schools, and children contributing with repeated measures. We anticipate there will be limited number of missing data due to the selection criteria 'child present at school on the day of data collection'. Analyses will be adjusted for any clear imbalances in baseline characteristics between groups. Potential confounders to be considered include per capita funding of prevention workforce at the LGA level, socioeconomic status (Socio-Economic Index for Areas index at LGA level and Index of Community Socio-Educational Advantage (ICSEA) at the school level) and rurality. Because time to implementation of actions is likely to vary across LGAs, a sensitivity analysis will be conducted considering actual time the LGA has been actively implementing intervention actions.

## Cost-effectiveness

The economic evaluation will follow previously developed methods for evaluating the cost-effectiveness of a complex, systems-based obesity prevention intervention.[47] Given the complexity and research burden of collecting rigorous resource use data across all intervention communities, two intervention and two control communities will be selected for inclusion in the economic evaluation using predefined criteria.[47]

'Within-trial' (cost per BMI unit saved) and modelled cost-effectiveness analyses will be conducted from both a limited societal perspective, and from a local authority funder perspective. Intervention costs will account for attribution to the intervention and will be collected prospectively across all four intervention components: (1) monitoring; (2) catalyst, set up; (3) community engagement and (4) implementation and diffusion. An existing multistate life table Markov model (ie, the ACE-Obesity Policy model)[48] will estimate the health benefits (in health-adjusted life years (HALYs) saved) and healthcare cost savings of diseases averted as a result of the intervention.[49 50]

Results comparing the intervention vs the comparator (ie, control communities) will be analysed at the commencement of step 2 implementation (2020) and at 4 years (ie, 2 years post step 2 implementation (2022)). Analyses will be conducted as intention-to-treat and a discount rate of 5% will be applied to costs, cost-savings and health benefits.[51] Incremental cost-effectiveness ratios will compare the incremental cost of the intervention with the incremental benefits (compared with the 'no intervention' comparator). Cost-effectiveness will be determined using the commonly accepted $A50 000 per QALY/HALY gained threshold.[52]

Results comparing the intervention versus the comparator (ie, control communities) will be analysed at the commencement of step 2 implementation (2020) and at 4 years (ie, 2 years post step 2 implementation (2022)). Cost-effectiveness will be determined using the commonly accepted $A50 000 per QALY/HALY gained threshold.[52]

Cost-effectiveness results will also be presented alongside a qualitative summary of implementation considerations likely important to decision-makers, including considerations of intervention impact on equity, acceptability, feasibility and sustainability.[50]

## Ethical approval

All components of this study have received approval from Deakin University Human Research Ethics Committee (HREC 2018-381) or Deakin University's Faculty of Health Ethics Advisory Committee (HEAG-H_2019-1; HEAG-H 37_2019; HEAG-H 173_2018; HEAG-H 12_2019). School based data collection has been approved by the Victorian Government Department of Education and Training (2019_003943) and the Catholic Archdiocese of Melbourne (Catholic Education Melbourne, 2019-0872) and Diocese of Sandhurst (24 May 2019).

## Data monitoring

The data monitoring committee comprises the chief investigators on the grant and the RESPOND project

**Table 5** Sample characteristics at baseline

| | Step 1 | | | Step 2 | | | |
|---|---|---|---|---|---|---|---|
| **Girls** | **N** | | Mean (95% CI) | **N** | | Mean (95% CI) | **P-value** |
| Age (years) | 720 | | 9.8 (9.62 to 9.98) | 686 | | 9.75 (9.55 to 9.94) | 0.676 |
| Height (m) | 710 | | 1.4 (1.39 to 1.42) | 673 | | 1.4 (1.39 to 1.41) | 0.751 |
| Weight (kg) | 697 | | 37.2 (36.0 to 38.4) | 665 | | 36.9 (35.6 to 38.2) | 0.739 |
| BMIz (WHO) | 692 | | 0.6 (0.48 to 0.72) | 658 | | 0.58 (0.45 to 0.71) | 0.835 |
| Self-reported quality of life | | | | | | | |
| HRQoL psychosocial | 479 | | 71.2 (69.6 to 72.7) | 449 | | 72.4 (70.8 to 73.9) | 0.282 |
| HRQoL physical | 478 | | 81.2 (79.8 to 82.6) | 447 | | 80.7 (79.3 to 82.1) | 0.612 |
| HRQoL global | 479 | | 74.6 (73.3 to 75.9) | 450 | | 75.2 (73.8 to 76.5) | 0.567 |
| | **N** | **n** | % (95% CI) | **N** | **n** | % (95% CI) | **P** |
| English spoken at home | 478 | 457 | 95.6 (93.5 to 97.6) | 449 | 418 | 93.3 (90.7 to 96.0) | 0.183 |
| Overweight and obese (WHO) | 692 | 251 | 36.5 (32.1 to 41.0) | 658 | 218 | 33.2 (28.8 to 37.6) | 0.302 |
| Self-reported activity and diet | | | | | | | |
| Met PA guideline 5 days | 480 | 177 | 36.8 (29.8 to 43.7) | 453 | 164 | 43.2 (34.6 to 51.9) | 0.26 |
| Met sedentary guideline 5 days | 479 | 372 | 78.6 (73.4 to 83.7) | 452 | 353 | 79.7 (74.5 to 85.0) | 0.75 |
| Met sleep guideline | 453 | 324 | 71.5 (67.4 to 75.7) | 418 | 316 | 75.6 (71.5 to 79.7) | 0.174 |
| Active transport to OR from school | 481 | 153 | 33.1 (25.3 to 41.0) | 453 | 173 | 33.3 (24.9 to 41.8) | 0.975 |
| Met vegetable guideline | 481 | 81 | 16.5 (12.9 to 20.2) | 453 | 76 | 16.8 (13.1 to 20.4) | 0.927 |
| Met fruit guideline | 481 | 374 | 77.5 (73.3 to 81.8) | 453 | 349 | 77.6 (73.1 to 82.1) | 0.989 |
| Unhealthy snack (≤1/day) | 481 | 185 | 39.6 (33.6 to 45.7) | 453 | 175 | 42.5 (35.5 to 49.6) | 0.535 |
| Takeaway (≥2 times/week) | 481 | 319 | 66.4 (61.5 to 71.3) | 453 | 291 | 65 (59.8 to 70.2) | 0.701 |
| Water five glasses/day | 481 | 265 | 55.9 (50.4 to 61.5) | 453 | 231 | 51.9 (46.0 to 57.8) | 0.327 |
| SSB 1/day | 481 | 299 | 65.3 (59.2 to 71.4) | 453 | 296 | 66.6 (60.4 to 72.8) | 0.769 |
| | **N** | | Mean (95% CI) | **N** | | Mean (95% CI) | **P-value** |
| Objectively measured activity (subsample) | | | | | | | |
| Valid wear (days) | 278 | | 6.96 (6.63 to 7.30) | 250 | | 7.05 (6.70 to 7.40) | 0.726 |
| Daily wear-time (mins/day) | 278 | | 1143.7 (1126.4 to 1160.9) | 250 | | 1167.6 (1149.4 to 1185.8) | 0.061 |
| Daily sedentary time (mins/day) | 278 | | 861.5 (839.9 to 883.1) | 250 | | 888.5 (865.5 to 911.5) | 0.094 |
| Daily LPA (mins/day) | 278 | | 198.9 (194.8 to 203.0) | 250 | | 200.2 (195.8 to 204.6) | 0.669 |
| Daily MVPA (mins/day) | 278 | | 87.9 (80.6 to 95.1) | 250 | | 80.1 (72.7 to 87.6) | 0.144 |
| | **N** | **n** | % (95% CI) | **N** | **n** | % (95% CI) | **P** |
| Meeting MVPA guidelines (average day) | 278 | 256 | 90.4 (84.4 to 96.3) | 250 | 195 | 81.1 (72.0 to 90.2) | 0.083 |
| **Boys** | **N** | | Mean (95% CI) | **N** | | Mean (95% CI) | **P-value** |
| Age (years) | 752 | | 9.78 (9.63 to 9.93) | 705 | | 9.96 (9.80 to 10.12) | 0.115 |
| Height (m) | 747 | | 1.41 (1.39 to 1.42) | 694 | | 1.41 (1.40 to 1.42) | 0.718 |
| Weight (kg) | 727 | | 36.3 (35.2 to 37.4) | 687 | | 37.1 (35.9 to 38.3) | 0.333 |
| BMIz (WHO) | 727 | | 0.59 (0.45 to 0.72) | 684 | | 0.61 (0.47 to 0.75) | 0.806 |
| Self-reported quality of life | | | | | | | |
| HRQoL psychosocial | **497** | | 70.3 (68.1 to 72.5) | **477** | | 74 (71.8 to 76.3) | **0.02** |
| HRQoL physical | 495 | | 81.3 (79.4 to 83.2) | 475 | | 83.9 (81.9 to 85.9) | 0.07 |
| HRQoL global | **497** | | 74.1 (72.2 to 76.1) | **477** | | 77.5 (75.5 to 79.6) | **0.019** |
| | **N** | **n** | % (95% CI) | **N** | **n** | % (95% CI) | **P** |
| English spoken at home | 499 | 460 | 91.6 (88.4 to 94.8) | 479 | 434 | 92.3 (89.1 to 95.5) | 0.767 |
| Overweight and obese (WHO) | 727 | 230 | 31.7 (27.6 to 35.8) | 684 | 235 | 34.2 (29.8 to 38.6) | 0.428 |

Continued

**Table 5** Continued

| | Step 1 | | | Step 2 | | | |
|---|---|---|---|---|---|---|---|
| Self-reported activity and diet | | | | | | | |
| Met PA guideline 5 days | 499 | 241 | 49.8 (42.6 to 57.1) | 483 | 256 | 57.1 (49.5 to 64.7) | 0.174 |
| Met sedentary guideline 5 days | 497 | 323 | 66.6 (61.2 to 72.0) | 483 | 338 | 70.5 (65.2 to 75.8) | 0.312 |
| Met sleep guideline | 449 | 323 | 71.6 (66.6 to 76.6) | 432 | 323 | 73.9 (68.7 to 79.0) | 0.531 |
| Active transport to OR from school | 499 | 163 | 33 (25.0 to 40.9) | 484 | 192 | 36.3 (27.7 to 44.8) | 0.582 |
| Met vegetable guideline | 499 | 80 | 15.3 (11.2 to 19.4) | 483 | 76 | 14.3 (10.1 to 18.5) | 0.736 |
| Met fruit guideline | 498 | 347 | 69.6 (65.0 to 74.2) | 483 | 339 | 70.2 (65.5 to 74.9) | 0.863 |
| Unhealthy snack (≤1 /day) | 498 | 180 | 36.5 (30.4 to 42.6) | 483 | 169 | 36.3 (29.9 to 42.8) | 0.971 |
| Takeaway (≥2 times/week) | 499 | 284 | 57.5 (52.1 to 62.8) | 484 | 270 | 57.9 (52.1 to 63.8) | 0.906 |
| Water five glasses/day | 499 | 265 | 52.9 (47.7 to 58.1) | 484 | 288 | 59.3 (54.0 to 64.5) | 0.091 |
| SSB 1 /day | 499 | 267 | 56 (49.2 to 62.7) | 483 | 250 | 53.9 (46.8 to 60.9) | 0.671 |
| | **N** | | % (95% CI) | **N** | | % (95% CI) | **P-value** |
| Objectively measured activity (sub-sample) | | | | | | | |
| Valid wear (days) | 262 | | 6.89 (6.54 to 7.24) | 216 | | 6.51 (6.14 to 6.88) | 0.145 |
| Daily wear-time (mins/day) | 262 | | 1150.5 (1126.5 to 1174.6) | 216 | | 1130.6 (1104.2 to 1157.0) | 0.274 |
| Daily sedentary time (mins/day) | 262 | | 867.2 (838.7 to 895.7) | 216 | | 854.1 (823.6 to 884.7) | 0.54 |
| Daily LPA (mins/day) | 262 | | 196.1 (191.0 to 201.2) | 216 | | 195.4 (189.9 to 200.9) | 0.847 |
| Daily MVPA (mins/day) | 262 | | 88.5 (80.6 to 96.4) | 216 | | 82.2 (74.2 to 90.3) | 0.276 |
| | **N** | **n** | % (95% CI) | **N** | **n** | % (95% CI) | **P** |
| Meeting MVPA guidelines (average day) | 262 | 231 | 87.1 (80.8 to 93.4) | 216 | 163 | 78.8 (70.1 to 87.6) | 0.124 |

Model-based means and prevalences of baseline anthropometric and behavioural characteristics by gender and trial group (N=2863* children) and tests of difference between groups via mixed models with school as random effect; p1: tests of difference between steps 1 and 2 means conducted via mixed linear models, with school as random effect to account for within school clustering (bold if p<0.05); p2: tests of difference between steps 1 and 2 proportions conducted via mixed logistic models, with school as random effect to account for within school clustering (bold if p<0.05); *Two children have binary gender missing/ prefer not to say.
HRQoL, health-related quality of life; MVPA, moderate-to-vigorous physical activity; PA, physical activity.

management team. The chief investigators will hold annual meetings and the RESPOND project management team will meet fortnightly throughout the life of the project. All results will be aggregated to an appropriate level that will not allow reidentification, eg LGAs or higher. Only research staff approved on the ethics application will have access to the raw data. No adverse events are expected, however, the RESPOND project team will monitor the progress of the trial and report any adverse events to the Deakin University Human Research Ethics committee and act on advice received. Reports will be submitted annually to the ethics committee.

## Baseline results for individuals

Baseline data collection for the individual-level outcome evaluation was completed between April and June 2019. As per the design described above, 67/112 of schools agreed to participate in baseline monitoring, representing a school-level participation rate of 60%. In total 2738 grads 2, 4 and 6 students participated in data collection, out of 3461 total enrolments at the participating schools, yielding an individual-level participation rate of 79.1%.

### Sample characteristics

Data collected at baseline are presented in full in table 4 (school-level measures) and table 5 (child-level measures) and include tests of the differences between students recruited from step 1 LGAs and step 2 LGAs. Estimates and tests for child-level variables were obtained from mixed linear (for continuous variables) and logistic (for binary variables) models, with school included as a random variable to allow for within-school clustering. There was evidence of a school level socioeconomic difference between step 1 and step 2 schools at baseline, with step 1 schools having higher mean ICSEA scores than step 2 (p=0.044). At the child level, there were no significant baseline differences between the step 1 and step 2 cohorts in terms of BMI-for-age z-score, the prevalence of overweight and obesity, objectively measured physical activity or the meeting of any health or activity-related guidelines for either male or female students. Step 1 boys

had lower health-related quality of life (HRQoL) scores in both psychosocial (p=0.020) and global (p=0.019) domains. There was little evidence of a difference in baseline HRQoL across steps 1 and 2 in girls.

### Reporting and dissemination

The results of RESPOND, including primary and secondary outcomes, and emerging studies developed throughout the intervention, will be published in the academic literature, in conference presentations and in publications associated with postgraduate research projects. Relevant checklists such as TIDIER-PHP[53] will inform the writing of academic publications to ensure clear and consistent reporting of multi-component public health interventions. Publications will be developed in consultation with grant partners, as required under NHMRC Partnership Project requirements. Further reports will be developed following each round of individual-level outcome data in the primary school monitoring study and disseminated back to participating schools, to all grant partners and throughout the communities of practice. Further, these summary reports will be publicly available on the global obesity centre's website (https://globalobesity.com.au/project-reports/). Reports will serve to communicate the cross-sectional prevalence figures and frequencies for childhood obesity, various key behavioural outcomes, and well-being for children at the Ovens Murray and Goulburn regional level, as well as the individual LGA level.

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