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Scaling up a school-based intervention to increase physical activity and reduce sedentary behaviour in children: Protocol of the *TransformUs* hybrid effectiveness-implementation trial

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Abstract

Introduction: Efficacious programs require implementation at scale to maximise their public health impact. *TransformUs* is an efficacious behavioural and environmental intervention for increasing primary (elementary) school children's (5-12 years) physical activity and reducing their sedentary behaviour within school and home settings. This paper describes the study protocol of a five-year effectiveness-implementation trial to assess the scalability and effectiveness of the *TransformUs* program.

Methods and analysis: A type II hybrid implementation-effectiveness trial. *TransformUs* is being disseminated to all primary schools in the state of Victoria, Australia (n=1,786). Data are being collected using mixed methods at the system- (State government, partner organisations), organisation- (school), and individual- (teacher, parent, and child) levels. Evaluation is based on program Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM framework). RE-AIM domains are being measured using a quasi-experimental, pre-post, non-equivalent group design, at baseline, 12- and 24-months. Effectiveness will be determined in a subsample of 20 intervention (in Victoria) and 20 control schools (in New South Wales [NSW], Australia), at baseline 12- and 24-months. Primary outcomes include *TransformUs* Reach, Adoption, Implementation and organisational Maintenance (Implementation trial), and children's physical activity and sedentary time assessed using accelerometers (Effectiveness trial). Secondary outcomes include average sedentary time and MVPA on weekdays and during school hours, body mass index z-scores (zBMI) and waist circumference (Effectiveness trial). Linear mixed effects models will be fitted to compare outcomes between intervention and control participants accounting for clustering of children within schools, confounding, and random effects.

Ethics and dissemination: The trial was approved by the Deakin University human research ethics committee (HEAG-H 28_2017), Victorian Department of Education, the NSW Department of Education, Australian Catholic University (2017-145R), Melbourne Archdiocese Catholic Schools and Catholic Schools NSW. Findings will inform education policy and practice on effective and sustainable ways to promote physical activity and reduce sedentary behaviours population-wide.

Trial Registration: Australian Clinical Trials Registration Number: ACTRN12617000204347

Keywords: Scale up, scalability, dissemination, school, implementation science, population

Strengths and limitations of this study

- Strengths include the hybrid effectiveness-implementation trial design undertaken in a real-world context, the inclusion of multiple levels of data collected at multiple time points, and the use of robust frameworks to guide implementation and scale up. Device-based measurement of children's physical activity and sedentary time in the effectiveness trial strengthens study findings.
- Testing the hypothesised mediating and/or moderating relationships, such as organisational readiness for change, with implementation and effectiveness outcomes will help understand primary barriers to, and facilitators of, implementation of school-based interventions, such as *TransformUs*.
- Limitations include reliance on teacher self-reported implementation of the program. However, additional implementation data will be captured using Google Analytics (e.g., use of the *TransformUs* website, professional development completed by teachers, and which program resources are downloaded).
- Facilitation of program dissemination activities via stakeholders and the research team may not reflect true real-world promotion, but will highlight practices required for sustainable scale up.
- Extended COVID-19 lockdowns and government restrictions in Australia meant on-site data collection in schools was prohibited in Victoria between 2020 and April 2023, and in NSW during 2021. This resulted in a need to revise the study protocols. Nevertheless, the conduct of both an implementation and effectiveness trial will enable us to compare differences between schools to ascertain the level of implementation, 'real world' program impact, and generalisability of results.

Introduction

Regular physical activity is beneficial for children's cardiometabolic health (including lipids, adiposity and blood pressure),[1] and mental health.[2] Physical activity has also been positively associated with academic results, including cognitive skills (e.g., executive functioning, attention, memory, comprehension), attitude (e.g., motivation, self-concept, satisfaction and enjoyment), academic behaviour (e.g. organisation), engagement in learning (e.g., on-task time), and academic achievement (e.g., standardised test scores).[3-5] Few studies have examined the impact of prolonged sitting on children's health, with the evidence still primarily observational and indeterminate.[6] Whilst there is currently insufficient evidence for a dose-response relationship between sedentary behaviour (defined as any waking behaviour characterized by an energy expenditure ≤1.5 metabolic equivalents while in a sitting, reclining or lying posture)[7] and health outcomes in children and adolescents (aged 5-17 years), greater time spent sedentary has been linked to poorer health outcomes such as lower fitness, and poorer cardiometabolic and mental health in this population.[8] There is some evidence that breaking up sedentary time may improve cognitive outcomes in children.[9]

In Australia, only 26% of children aged 5-12 years meet the government recommendation of at least one hour of moderate- to vigorous-intensity physical activity (MVPA) every day.[10] As part of the Australian 24-hour movement guidelines for children and young people (5-17 years) which integrate physical activity, sedentary behaviour and sleep, it is recommended that children reduce and break up prolonged sitting throughout the day.[11] More than 60% of children's class time is spent sitting[12] and only 25-30% of morning recess and lunch breaks at school are spent in MVPA.[13] Comprehensive school physical activity programs that use whole-of-school approaches to promoting activity, and adopt active school environments (i.e., active classrooms, active environments, quality physical education and sport) have been recommended to address low levels of physical activity among children.[14, 15]

There are some examples of efficacious school-based approaches to promoting children's physical activity[16] and reducing sedentary behaviour[17], although the association between implementation fidelity and intervention outcomes is unclear.[18, 19] Most interventions target organised sport and physical education,[20] yet interventions which provide sports and active equipment during recess, and incorporate playground markings can also successfully increase children's physical activity.[21, 22] A systematic review has also shown that school interventions with a family element can be more effective at increasing physical activity than just focusing on the school setting alone,[23] however, few studies have determined the efficacy of strategies

to reduce prolonged sitting both at school and home among children.[24] The initial *TransformUs* program[25] was one of the earliest programs (developed in 2009) to incorporate many of these elements with a particular focus on reducing and breaking up children's sitting throughout the school day.

The efficacy of the initial *TransformUs* program was demonstrated in a 4-arm two-by-two factorial design cluster-randomised controlled trial (RCT) involving 20 primary (elementary) schools, 226 teachers and over 1,600 children in Melbourne, Australia (2010-13).[25] The three intervention arms targeted either increases in physical activity (PA-I), reductions in sedentary behaviour (SB-I), or a combination of both (PA+SB I), compared to a usual practice control. At 18-months (n=348), compared to usual practice, children who received the physical activity intervention (groups PA-I and PA+SB I) had significantly less weekday sedentary time (-27 mins/day). Children who received the sedentary behaviour intervention (SB-I and PA+SB I) spent more time in daily physical activity (5.5 mins/day) at 18-months, and at 30-months spent 33 mins less in daily sedentary time, and specifically, 63 mins less in sedentary time on weekdays, compared to usual practice.[25] Thus strategies to promote both children's physical activity and reduce sedentary behaviour were important. Results also showed beneficial effects on children's adiposity markers (body mass index [BMI] and waist circumference [n=564]). However, there were mixed effects on children's blood pressure ([BP] positive effects on systolic BP and negative effects on diastolic BP [n=537]) and in a sub-sample of children (n=206), on blood parameters (e.g., negative effects on some inflammatory markers such as CRP, IL-6, IL-2 and TNF-α, beneficial effects on vitamin D, BDNF, and PAI-1).[26]

Teachers, parents and children reported that the program was positively received, and teachers involved in the intervention arms also reported perceptions of better classroom management and improved 'on-task' behaviour during lessons.[27] Although barriers to implementation were experienced (including a lack of school leadership to support implementation long-term, promotion and awareness raising, teacher time constraints, and challenges with sustained integration into existing practices), overall, the program was effectively integrated into the school curriculum.[27] Existing teaching practices, children's enjoyment, and teacher awareness of program values and benefits were the main facilitators of delivery and sustainability.[27] Following the success of *TransformUs*, and exploration of adaptations for scaling (described in Methods section), the Victorian Department of Education (DoE) committed to partnering with the research team to support the dissemination

and implementation of the program to all primary (elementary) schools in Victoria, Australia. Given the small number of school-based interventions that are studied at scale[28] and that use implementation theories to guide this process;[29, 30] scaling up of *TransformUs* presented a unique opportunity to investigate real-world implementation at scale. Assessment of intervention implementation among school-based interventions is greatly needed in the field.[18]

This paper describes the study protocol for a five-year trial (launched September 2018 - final data collection December 2023), which aims to evaluate the real-world effectiveness and implementation of *TransformUs* at scale. To note, the paper outlines the *intended* protocol for the trial (including planned dates and timelines for data collection), but also describes where and how this *changed* due to the impacts of the COVID-19 global pandemic. In line with the RE-AIM framework criteria,[31] we will evaluate the following five aims: the program's **Aim 1**: *Reach* (proportion and representativeness of Principals and teachers, parents and children participating in *TransformUs*); **Aim 2**: *Effectiveness* (change in children's daily physical activity and sedentary time 12- and 24-months post-baseline); **Aim 3**: *Adoption* (proportion and representativeness of schools choosing to implement *TransformUs*); **Aim 4**: *Implementation* (dissemination by education and health partners, uptake of intervention components, frequency, dose and adaptation to *TransformUs* delivery, and barriers and enablers to implementation); and **Aim 5**: *Individual-level Maintenance* (change in children's physical activity and sedentary time 24-months post baseline) and *Organisational-level Maintenance* (institutionalisation and sustainability of the program within the education and health systems, school settings and by teachers as part of routine practice).

Methods and analysis

Overview of the *TransformUs* program

TransformUs is a behavioural and environmental intervention delivered in the classroom, broader school environment and family setting to increase children's physical activity levels and reduce sedentary behaviour.[32] The program includes: (i) health lessons incorporating key physical activity/sedentary behaviour messages; (ii) active academic lessons; (iii) active breaks; (iv) changes to the school environment; (v) active homework, and (vi) parent newsletters promoting physical activity/reducing sitting time (for more detail see Figure 1). The program was based on the Social Cognitive Theory,[33] Behavioural Choice Theory[34] and

Ecological Systems Theory.[35] The health lessons, active academic lessons and active breaks are all aligned with the Victorian[36] and Australian curriculum and standards.[37] All *TransformUs* components are contained in the members' area of the website (https://transformus.com.au). To access these resources, Victorian primary school teachers need to register (at no cost) using their work email address. A detailed description of the program strategies[32] and program logic model have been published elsewhere.[27] Adaptations to the *TransformUs* program for scale up are described later in Methods section, and Supplementary File 1 presents the evolution of *TransformUs* since the original RCT (2009) to date.

Study design

This study uses a type II hybrid effectiveness-implementation trial design,[38, 39] to concurrently examine both effectiveness outcomes and implementation and scale-up processes. Mixed method data will be collected at the systems- (State government, partner organisations), organisational- (school) and individual- (teacher, parent and child) levels.

Implementation trial

Every primary school in Victoria (government, independent and Catholic) will be offered *TransformUs,* and will be eligible for inclusion in the state-wide implementation trial. Our objective is for the program to be adopted by at least 715 primary schools (40% of a total of 1,786 primary schools in Victoria[40]) by the end of the trial. The adoption estimates are based on school uptake of state-wide initiatives offered by the Victorian DoE and previous implementation trials in schools.[41] As *TransformUs* dissemination will be ongoing over 5-years, schools can register anytime between September 2018 and December 2022. Data are planned to be collected from schools and teachers who agree to participate in the evaluation at baseline (T1), 12-months (T2), 24-months (T3) and 36-months (T4) post registration; within the funding time period (September 2018 - December 2022). These data will contribute to assessing reach, adoption, implementation, and organisational-level maintenance (Aims 1, 3, 4 and 5).

Effectiveness trial

To determine short- and long-term changes in children's levels of physical activity and sedentary time under 'real world' conditions (based on adaptations from the original *TransformUs* program described below), an embedded effectiveness trial is planned with 20 intervention schools in Victoria and 20 control schools in the state of New South Wales (NSW). A quasi-experimental pre-post non-equivalent group design[42] with follow-up will be adopted. As this is a real-world roll-out in Victoria, a non-randomised two-group parallel arm approach was adopted. Data collected at baseline (T1), 12-months (T2), and 24-months (T3) will contribute to assessing program effectiveness and maintenance at the student level (Aims 2 and 5). Schools in NSW were considered suitable controls as NSW has a similar population size and geographic spread to Victoria compared to other states and territories, and the *TransformUs* program was not available in NSW.

Program adaptation and piloting

The *TransformUs* RCT showed that strategies to promote children's physical activity and reduce sedentary behaviour were both important,[26] and therefore the combined (PA+SB I) approach was the focus for wider scale up. During the RCT, teacher Professional Development (PD) was delivered face-to-face by the research team, and schools received ongoing support from the team over the 2.5 years of the study. This approach was not considered feasible for scale up. To facilitate scale up, PD, support, and all program materials and resources were converted into an online format to maximise potential reach at a lower cost. Formative evaluation with partners responsible for implementing interventions at scale can also be useful to inform adaptations to the intended dissemination strategy and refine the program materials to enhance scalability.[43] Therefore, in close partnership with local councils (from Local Government Areas) and teachers, the *TransformUs* online materials were tested in two pilot dissemination trials and formative evaluation was conducted with key partner organisations involved in scale up, detailed in the following section.

TransformUs pilot dissemination trials (2015-17)

Two 12-month pilot dissemination trials were conducted during July 2015-16 (pilot trial 1; n=4 schools, n=41 teachers) and 2017 (pilot trial 2; n=5 schools, 22 teachers), to assess the feasibility of *TransformUs* dissemination and the online teacher PD. In both pilots, the program was advertised to schools via two councils (representing two different Local

Government Areas) in Victoria. The costs of program equipment (e.g., standing easels, sports equipment) and installation of playground line markings (e.g., hopscotch) were subsidised by the councils to support uptake. Schools located in a lower income area were offered a greater subsidy than schools in a higher income area (determined using the Schools in a Socio-Economic Indexes for Areas [SEIFA]; methods consistent with the original RCT).[44] All teachers within participating pilot schools were asked to, preferably, complete the online PD (lasting 30-45 minutes) during a session on their school site that was facilitated by a representative from the relevant council. As this was to inform the real-world dissemination trial and to help understand the feasibility of online PD, schools could also send a nominated teacher and adopt a train-the-trainer approach.

Teachers completed online surveys pre- and post- the PD session, 2-months and 12-months post-baseline (max n=51 teachers; Pilot trial 1), and at 4-months post-baseline (n=22 teachers; Pilot trial 2). Most teachers reported that they: (1) gained new knowledge of ways to increase children's physical activity (88%) and reduce sedentary behaviour (90%) at school; (2) learnt new teaching methods (78%); (3) perceived the online training to be an appropriate delivery method (82%); and (4) gained the required knowledge (90%) and confidence (80%) to implement the program. Teachers requested visual examples of program implementation (i.e., digital video clips), which they felt would strengthen teacher engagement and sustained delivery of the program. Although the RCT focused on children in Grades 3-5 (ages 8-11 years), in both pilot trials, participating schools planned a whole-of-school approach to implementation across all school year levels, Foundation to Grade 6 (ages 5-12 years). For scale up, program materials were modified to accommodate delivery across all year levels, covering a range of learning areas (e.g., mathematics, English, science and humanities), and digital video clips were developed to demonstrate appropriate implementation.

Formative evaluation with key partner organisations (2016)

Through an integrated research-practice partnership approach, collaboration began with one government (Victorian State government DoE) and six non-government organisations (the Victorian Health Promotion Foundation [VicHealth], the Victorian Principals Association, Independent Schools Victoria, the Australian Council for Health, Physical Education and Recreation Victoria [ACHPER], and Peak Phys Ed). These partners play various roles in the education and health systems including, for example, responsibility for delivery of education to children and young people in Victorian government and independent schools (e.g., DoE),

and coordinating and delivering teacher education professional development (e.g., ACHPER and Peak Phys Ed). In collaboration, these partners will provide ongoing input into the state-wide dissemination strategy, ensuring that the program aligns with other existing school-based health promotion initiatives in the state (e.g., the Victorian Achievement Program, which aims to create healthier early childhood services, schools and workplaces; http://www.achievementprogram.health.vic.gov.au/), and that all resources (e.g., health lessons) are linked to the Victorian Curriculum and each resource identifies the specific Strand, Sub-strand, Content Description and Achievement Standard. For example, *TransformUs* supports the development of student capabilities (e.g., Critical and Creative Thinking, Personal and Social capabilities), which are taught explicitly in and through the learning area resources. *TransformUs* also provides cross-curriculum opportunities for students to strengthen their literacy and numeracy general capabilities.

Implementation and scale up of *TransformUs*

Theoretical underpinnings

Our approach to scale up is 'horizontal', defined as extending the reach of an intervention by replicating it in other localities, cities or states.[45] Our implementation approach is derived from evidence-based recommendations for the successful scalability of population-level health interventions,[43, 46, 47] and concepts within the translation, support and delivery systems of the Interactive Systems Framework.[48] We draw on ways to improve implementation and sustainability as outlined in the Quality Implementation Framework,[49] PRACTIS Guide,[43] and from literature on ways to increase public health program sustainability.[50] To identify underlying barriers and facilitators to individual-level implementation, qualitative data collection will be informed by the Theoretical Domains Framework,[51] which is a systematic and theoretically based approach to behaviour change that identifies barriers to practice change and potential strategies to intervene. The RE-AIM framework[31] informs the overarching evaluation outcomes following implementation and scale up.

Implementation and scale up strategies

In addition to findings from the *TransformUs* pilot adaptation studies described above, scale up strategies were also guided by literature on strategies for effective implementation and scale up planning[43, 45] and attributes of successful scale up (i.e., compatibility of the program

with the values and facilities of intended users, and perceived need for the innovation within the organisation).[52] Supplementary File 2 presents the 14 *TransformUs* implementation and scale up strategies, reported in line with recommendations and definitions for specifying implementation strategies.[53]

Our focus is on implementation *quality* as opposed to controlling rigorous program fidelity that is essential in efficacy trials. In school-based intervention implementation, 'quality' can include: (i) sufficient exposure (dose); (ii) fidelity to the program protocol; (iii) implementation (engaging students through active participation); (iv) adaptation (modifying the intervention to meet developmental and cultural needs); and (v) teachers' attitudes, understanding of the concepts/issues and prior experience.[54] In *TransformUs*, schools were encouraged to choose contextually relevant strategies for implementation at their school, rather than a prescriptive program, to enhance quality and ensure program adoption occurs in the most contextually relevant way to achieve health benefits. This approach is associated with increased effectiveness of real-world interventions and those more likely to produce sustainable results.[49]

In the context of *TransformUs,* we will be creating an implementation infrastructure for schools via DoE endorsement, provision of sustainability resources (i.e., template policy statements for schools to embed the program), and active engagement with State education decision-makers and other non-government partner organisations. Implementation resources will also be provided to support and encourage school level leadership to implement the program, and provide recommendations to promote integration and sustainability (i.e., *TransformUs* champion roles and responsibilities, a template policy document).

***TransformUs* program for scale up**

Figure 1 presents the *TransformUs* program components for scale up. Based on outcomes from the two pilot trials and formative work with our partner organisations and to maximise program reach, all supporting program materials, implementation and training resources are available online via a program website. The website (https://transformus.com.au/) is managed by the research team at Deakin University. Teachers are required to complete the mandatory online PD via the *TransformUs* website. The PD provides strategies to integrate and sustain implementation of the program in schools, and thus is essential to ensure minimum standards and knowledge are established prior to program delivery. Based on evidence for the

determinants of effective implementation by adopting individuals (users, i.e., teachers),[55, 56] the content of the PD program has been designed to address the following seven key areas: (i) *support for implementation* (teacher and school level); (ii) *skills required for implementation;* (iii) *knowledge required for implementation;* (iv) *self-efficacy to implement*; (v) *fit of the program into existing practices;* (vi) *relative advantage of the intervention over existing practices*; and (vii) *perceived ownership of the program* (allowing for adaptation). For example, the PD includes ways of embedding the program in practice, such as development of a tailored implementation plan (i.e., a checklist of activities teachers wish to undertake and how they plan to sustain delivery), and knowledge reflection (quizzes) to test learning.

Multiple dissemination routes will be used to maximise program uptake and sustainability (e.g., via our partners, through sharing the web link, email lists, social media, teacher professional learning networks, and teacher professional development conferences and workshops). Interactions with stakeholders will include face-to-face or online meetings (e.g., approximately two group meetings per year in addition to regular one-on-one meetings), and the provision of dissemination materials and communication packs to stakeholders, to enable them to promote *TransformUs* via their existing social media platforms and newsletters.

Figure 1. *TransformUs* program components for scale up

>> INSERT FIGURE 1 HERE<<

Recruitment

Implementation trial: Partners (state level)

One representative from each of our partner organisations who has experience in disseminating and/or supporting the *TransformUs* roll-out will be invited to participate in interviews to capture system-level impact (e.g., organisational-level maintenance, which relates to Aim 5 of the study). As depth of qualitative data is more important than sample size,[57] we aim to recruit a purposeful sample of representatives from our partner organisations. Recruited participants will be asked to provide signed consent prior to taking part.

Implementation Trial: Principals (school level) and teachers

Schools and teachers will be made aware of *TransformUs* via multiple dissemination routes (as described in section '***TransformUs* program for scale up'**). All schools and teachers who wish to adopt *TransformUs* register free of charge via the *TransformUs* website, and teachers can register to access the *TransformUs* program regardless of whether their school (i.e., principal) has registered. This is to allow for both top-down and bottom-up program adoption. To access the PD, registration is mandatory. Upon registration, a unique login username for each teacher/school will be generated, which they can use to revisit the website and access the PD and online resources. During registration, schools/teachers will be invited to participate in the survey component of the Implementation Trial, where they will receive a plain language statement and online consent form.

The registration process collects information about where they heard about the program, general physical activity policy and practice information for their school (e.g., information on participation in additional physical activity programs will also be collected), and which elements of the *TransformUs* program their school plans to implement. There are no costs to access the online resources. Implementation schools wishing to install new playground line markings or purchase physical activity equipment will not receive funding from the research project to do so. To help minimise the financial investment required, information on how to best utilise existing playground line markings and physical activity equipment is provided online.

We plan to reach 714 schools (based on an estimate of 40% of the total number of schools in Victoria[40]; n =1,786). As part of the Implementation Trial, we aim to recruit ~15 school leaders who registered for the survey evaluation component of *TransformUs* to participate in a qualitative interview about their experiences of adopting and implementing the program. This sample size provides sufficient 'information power'.[58] Whilst schools/teachers will provide online consent to participate in the survey component of the implementation trial at the point of *TransformUs* registration, the sub sample of participants invited to complete and interview will be required to provide additional consent prior to the interview commencing.

Effectiveness trial: Schools and teachers

Twenty schools in Victoria will be recruited using stratified non-random sampling to maximise area-level socioeconomic position and geographic location. Targeted recruitment

of twenty control schools in NSW will be matched as much as possible (based on school size, type [e.g., Government, Catholic and Independent), SEIFA index (a measure of socio-economic advantage and disadvantage by area in Australia), geographical area [e.g., rural, remote], single sex/mixed students), with schools enrolled in the effectiveness trial in Victoria. Schools will represent different socioeconomic urban and rural areas, including different types, based on a minimum of two Grade 3 classes or four composite classes (i.e., Grade 3 and 4 classes combined).

Effectiveness trial: Children and parents

Grades 3 and 4 children attending schools enrolled in the effectiveness schools (and their parents) will be invited to help assess the effectiveness of the program. Children will be in Grades 3 or 4 at baseline with a planned follow up at 12-months and 24-months. Parents will receive information about the study via the schools' regular methods of communication (e.g., school intranet system, email, text) and an information brochure sent home with the students. There will be a plain language statement and consent form for parents to provide consent for themselves and/or their child to participate in the assessments (e.g., parent online survey, child MVPA, body mass index and waist circumference). As part of the consent process, parents/guardians will provide contact details (email and mobile telephone), which will be used to email a unique link to an online parent survey at each time point and to communicate with parents about the wearing and return of data collection devices from their child. Three emails or texts will be sent over six weeks to remind parents to complete the survey.

Figures 2 and 3 present flow diagrams of participant recruitment into the Effectiveness and Implementation trials, respectively.

Figure 2. Effectiveness trial participant flow diagram

>> INSERT FIGURE 2 HERE<<

Figure 3. Implementation trial participant flow diagram

>> INSERT FIGURE 3 HERE <<

Sample size and power

Twenty Victorian schools will be recruited to ensure we have a diverse sample from a range of school types (Government, Catholic and Independent), Socio Economic Status (SES) tertiles (based on SEIFA data), and geographical areas. The target recruitment of children for the effectiveness study is based on statistical power calculations of the minimum number of participants required to detect differences in mean average daily sedentary behaviour (primary outcome) at 12 months (primary time point) between children in control and intervention schools. In the efficacy trial, average daily sedentary time was 347 minutes (SD=60) for the PA+SB intervention group and 371 minutes (SD=80) for the control group at Time 3 (18-month post baseline). Sample size calculations were conducted assuming a pre-post design, adjusting for baseline, in accordance with a published formula.[59] Based on estimates from the original cluster-RCT, to account for the design effect, an ICC of 0.03 for children within school clusters was used, with a conservative correlation of 0.015 assumed between two different pupils within a cluster at different time points and a correlation of 0.22 between the same pupils at different time points. Assuming alpha=0.05, 80% power will be available to detect a 16-minute difference in sedentary time (two-thirds of that observed in the efficacy trial as effects may diminish at scale) at 12-months between intervention and control with recruitment of 1,094 children (547 from intervention and control schools, assuming approximately 28 students/school sampled). This number is sufficient to detect as small an effect as a 6-minute difference in physical activity between the control and intervention schools, based on estimated standard deviations of 9-minutes for the PA + SB group and 7-minutes for the control group from the cluster-RCT.

Inclusion and exclusion criteria: Implementation trial

All Government, Independent, and Catholic primary schools in Victoria (n=1,786)[40] will be eligible to adopt the program and thus participate in this research. In the Implementation trial, registered schools can include those previously involved in the original RCT and adaptation pilot trials. Schools or teachers located outside of Victoria are not able to register for the program or gain access to the PD and online resources.

Inclusion and exclusion criteria: Effectiveness trial

Schools that participated in the 2010-2013 *TransformUs* RCT and 2015-2017 pilot trials will be excluded from the sample frame for the effectiveness trial. Special schools for children with a disability (defined by the school) and schools with less than 30 students across both Grades 3 and 4 will also be excluded to ensure that there is sufficient power to test the effectiveness of the program among students (n=20 schools, 550 students from VIC versus n=20 schools and 550 students from NSW) and parents. A matrix containing the names and types of all Victorian primary schools will be used for sampling, to ensure a range of government, independent and Catholic schools from inner city, outer suburban and regional areas are approached for recruitment. To be eligible as a control school in NSW, the school should not be implementing a similar health or physical activity-related program at baseline data collection. Any uptake of similar programs was monitored at each time point. For pragmatic and cost-related reasons, schools need to be located within a 4-hour drive from Deakin University (Burwood, Victoria) or Australian Catholic University (North Sydney, NSW).

Program dissemination and implementation timeline

Supplementary File 3 shows the timing of the implementation activities over five years and how data collection maps to the RE-AIM framework. Program refinement and online training took place in the first six months (2017). Program dissemination and implementation began in September 2018 and is ongoing. It will be monitored until December 2023. Final data collection (interviews with partners) will occur in December 2023.

Patient and Public Involvement

At what stage in the research process were patients/the public first involved in the research and how?

Six organisations were formal partners prior to the project being funded. This included a state government department of education and independent schools' peak body, teacher professional development organisations, a principals' association, and a health promotion foundation. As this is an implementation/effectiveness trial designed to scale up a previously efficacious school-based intervention, we engaged closely with these partners in the adaptation of the program for scale up. After funding was secured, these partnerships will continue to be integral to the dissemination and evaluation of this project.

How were the research question(s) and outcome measures developed and informed by their priorities, experience, and preferences?

The research question related to the effectiveness of implementing and scaling up an evidence-based school intervention on children's physical activity and sedentary behaviour, is directly aligned with the policy priorities of the Victorian DoE. The DoE has *Education State* targets which aim to increase the percentage of children in Victoria meeting physical activity guidelines by 20% by 2025. This alignment was critical in securing partnership with the DoE in Victoria.

How were patients/the public involved in the design of this study?

As previously noted, from study inception and through the adaptation process for scale up, we have had input from teachers, teacher Professional Development organisations (e.g., ACHPER and Peak Phys Ed), as well as key stakeholders such as Local Councils.

How were they involved in the recruitment to and conduct of the study?

Stakeholder partners have actively disseminated the program and assisted with the recruitment of schools and teachers for this study, and some partners have also assisted with implementation of the intervention.

Were they asked to assess the burden of the intervention and time required to participate in the research?

An economic evaluation was conducted in the previous RCT which assessed the burden and time required for teachers to implement the program. Interviews with teachers during a pilot phase prior to the RCT, also informed the number of standing lessons and active breaks per day were feasible for teachers to implement in terms of time requirements. We also pilot tested the feasibility of the program in terms of fitting it into the curriculum with teachers. This evidence was critical for informing the design and adaptations for the current project. Formal partners on the trial were also asked to consider the time required for their involvement in the trial (including any potential burden), as part of the in-kind contributions they provided as a partner organisation.

How were (or will) they be involved in your plans to disseminate the study results the participants and relevant wider patient communities (e.g., by choosing what information/results to share, when, and in what format)?

All stakeholder partners will play a role in dissemination of findings to teachers, schools, and broader audience (e.g., health promotion officers, sport and recreation industry, etc) via a range of communication platforms (e.g., social media, websites, newsletters, email distribution lists) and teacher education professional learning events and opportunities (e.g., seminars, professional learning sessions and conference presentations, keynote addresses, etc).

Data Collection

Table 1 presents the mixed method data to be collected at the partner (state), principal (school), teacher, parent, and child levels, in accordance with the RE-AIM framework. Recruitment and baseline data collection from schools in the effectiveness trial commenced in 2018.

Measures

Reach

Estimation of reach (Table 1) consists of all teachers and children in registered schools (based on Victorian DoE records) who will be classified as potentially exposed to the program. The total number of program recipients (teachers and children) compared to the total number eligible will represent one measure of potential reach. However, teachers could register and complete PD without a school being registered or be included within a participating school but chose not to complete PD. Therefore, we will also compare the number of teachers completing PD (actual PD recipients) versus the total number of teachers in Victorian schools (potentially eligible for PD) as an additional measure of program reach. The *TransformUs* website will be used to capture the number of teachers registered and if teachers complete the PD. Unique tracking codes (Google Analytics) associated with different promotional campaigns will contribute to assessing *TransformUs* dissemination.

Effectiveness and individual-level maintenance

The effectiveness trial outcome variables will be assessed at T1 (baseline) and T2 (12-mths) using accelerometers (Table 1). Primary outcomes include children's average minutes/day of MVPA and sedentary time. Secondary outcomes include children's average weekday MVPA and sedentary time (minutes/day), average minutes/day of MVPA and sedentary during school hours, body mass index z-scores (z-BMI), and waist circumference. Individual-level maintenance will be assessed at T3 (24-mths). Individual-level maintenance is defined as continued benefits among recipients (i.e., sustained increases in MVPA or decreases in sedentary time).

Grades 3 and 4 children's MVPA and sedentary time will be assessed using hip-mounted ActiGraph GT3X+ accelerometers (Pensacola, FL, USA) during waking hours for eight consecutive days (excluding water-based activities). To capture the sporadic nature of children's PA, data will be collected in 5-second epochs, and will be processed using Evenson cut points.[60] Non-wear time is defined as ≥20 minutes of consecutive zeros[61] and a cut-point of 100 counts per minute will be used to indicate sedentary time in children. Primary and secondary outcomes will be computed using only data from days on which a minimum of 8 hours of wear time on weekdays and 7 hours of wear time on weekend days were recorded (valid days). A minimum of 4 valid days (either weekday or weekend) will be required for inclusion in analysis. Inclusion criteria for school days will be accelerometer data for at least 50% of school hours.[62, 63]

Children's height (cm) and waist circumference (cm), and weight (kg) will be assessed twice (to the nearest 0.1cm and 0.1kg respectively) in school at each timepoint by trained research assistants. If the difference between the two measurements is greater than the following thresholds (Height=0.5cm; Waist=1cm; Weight=0.2kg) a third measurement will be taken. An average of the two closest measurements will then be calculated for analyses. Height will be assessed using a portable stadiometer (SECA 220, Los Angeles, California, USA). Weight will be assessed using digital scales (Wedderburn Tanita, Melbourne, Victoria, Australia), and a flexible steel tape will assess waist circumference at the narrowest point between the bottom rib and the iliac crest, in the midaxillary plane. BMI (kg/m^2) z-scores will be calculated by subtracting the sex-age population median BMI scores from children's raw BMI scores.[64]

Additional exploratory outcomes will include children's awareness of the program, and self-reported quality of life,[65] assessed via an online survey at T1 (baseline), T2 (12-months) and T3 (24-months). The EQ-5D-Y-3L questionnaire[66] for children and adolescents aged 8-16 years is an internationally validated English-Australian version of the EQ-5D questionnaire developed by the EuroQol Research Foundation. The Health-Related Quality of Life (HRQoL) section contains five items that capture (on a three-point scale) mobility, independence, usual activity, pain and feelings, and a sixth item that captures the child's perceived overall health rating (sliding scale 0-100) on the day of survey completion. Following EQ-5D-Y-3L scoring protocols, an overall HRQoL score will be created.

Parents will provide via an online survey a proxy-report of their child's physical activity using a validated single item measure assessing compliance with Australian physical activity guidelines.[67]

Adaptations to data collection due to COVID-19 restrictions

The COVID-19 pandemic had a significant impact on data collection resulting in a need to change our protocol (Supplementary File 3). Due to extended COVID-19 lockdowns and government restrictions in Australia, on site data collection in schools was prohibited in Victoria during 2020 and 2021, and in NSW during 2021. During periods when children were able to attend school over that time, accelerometers were sent directly to families, or directly to schools for distributing to students (NSW only), and the child and parent surveys were completed online. Height, weight, and waist circumference data were not collected. Teacher and principal data (survey and interview) were also not collected to reduce burden on school staff during the challenges of teaching remotely. These adaptations impacted six schools at T2, and 20 schools at T3 in Victoria and two schools at T3 in NSW. Due to differences in lockdown restrictions between the states in 2020, the timing of data collection in NSW was adjusted to match Victoria. As a result, principal/teachers interviews were only conducted at 12-months.

As primary schools in Victoria were unable to operate as normal and ran learning from home for a total of 267 days across 2020 and 2021, additional teacher support was provided so they could apply the pedagogical elements of *TransformUs* to online teaching and learning. This included a remote learning sample pack with active English and Maths lesson ideas that could

be delivered online. An online family pack was also provided for parents to help support their child's physical activity at home.

Adoption

All schools in Victoria are eligible to participate in *TransformUs* and therefore the total number of schools in the state (potentially eligible) and the total number who register (actual schools who adopt *TransformUs*) will be used to estimate the adoption rate (Table 1). The *TransformUs* website will be used to capture the number of schools registered and if the teacher completes the PD. Partner interviews were due to occur at 12-months, 24-months and 36-months post baseline, however, due to COVID-19 restrictions outlined previously, interviews were conducted at 12-months (September – October 2019) and a final interview will occur at 5 years post baseline (2023).

Implementation

To capture implementation at the school-level (Table 1), survey and interview data will capture organisational infrastructure and resource availability, organisational readiness, and capacity to implement *TransformUs*, planned implementation, strategies for implementation and perceived impact of the program on children's physical activity, sedentary behaviour and classroom behaviour outcomes, and outcomes at the school level (e.g., change in teaching behaviours). Existing survey measures will be sourced from previous studies of children's physical activity[32, 68, 69] and school-based implementation [70]. Organisational readiness will be assessed using the Organisational Readiness for Implementation Change (ORIC) scale,[71] adapted for the *TransformUs* context.

Interviews with partners (12-months and 5 years post baseline) and principals/teachers (12-months) will be based on the 14 domains of the Theoretical Domains Framework[51] to identify barriers and targeted strategies to enhance teacher and school implementation of the program. In addition, we will use Google Analytics to capture how schools and teachers use the *TransformUs* website, which program components are downloaded, and which aspects of the website are most and least accessed. For parents and children, survey data will capture dose received and perceptions of the program.

Organisational-level maintenance

For the implementation trial, organisational-level maintenance is defined as continued activities by implementers (e.g., adaptation over time, changes in implementation dose, institutionalisation within the school setting and change to policies and practices) and continued capacity within the community (e.g., stakeholder engagement and support for the intervention, and activities over time). Organisational-level maintenance will be assessed via partner self-report and interviews, principal and teacher online surveys/interviews, and parent/child survey data on dose received and perceptions of the program (Table 1). Google Analytics data will inform on continued use of the *TransformUs* website.

Table 1. RE-AIM evaluation of the *TransformUs* program at scale

RE-AIM Dimension	Assessment criteria			
	Partners/State	**School (Principal)/Teachers**	**Parents***	**Children***
Implementation and Effectiveness trial				
Reach	• No. partners; organisational characteristics (type)[a] • No., frequency and audience for promotional & dissemination activities[a,f,g] • Perceived reach of dissemination strategy[f]	***Teacher-level*** • No. teachers registered and no. completed training[d], and total no. eligible teachers in Victorian schools • Descriptive characteristics teachers; reasons for uptake; program awareness[b]	• No. parents participating in trial[c] • Descriptive characteristics; program awareness[c]	• No. students at participating schools[h] and no. Victorian students eligible
****Effectiveness***	/	/	• Proxy report of child's PA and sedentary time[c]	• Device-assessed PA and sedentary time[e]
Adoption	• Perceived barriers/ facilitators/ reasons for school adoption[f]	***School-level*** • No. schools registered and no. completed training[d] and total no. eligible schools in Victoria[i] • Descriptive characteristics schools; reasons for adoption; program awareness[b]	/	/
Implementation	• Partner role in implementation[f] • Perceived implementation barriers/facilitators[f]	***School-level*** • No. and type of *TransformUs* website visits, program component downloads[d,g] • Organisational infrastructure and resource availability to support implementation[b] • Organisational readiness and capacity to implement *TransformUs* (adapted ORIC scale)[71]; implementation climate[72] (6qu)[b]	• Dose received (no. newsletters, use newsletters)[c]	• Dose received (active lessons, active breaks, homework, health lessons, line markings)[j] • Perceptions of program[j]

		• Implementation strategies; appropriateness, acceptability, barriers, and facilitators to implementation[b] • Perceived impact on school culture (norms, values and beliefs); impact on child[b] ***Teacher-level*** • No. and type of *TransformUs* website visits, no. program component downloads[d] • No., frequency, duration of components (dose delivered), adherence and adaptation (fidelity), feasibility, appropriateness, self-efficacy to implement; satisfaction; barriers/facilitators[b]. • Implementation climate[72] (2qu)[b] • Perceived impact on child behavioural outcomes (time on task, academic outcomes, concentration)[b]		
***Individual-level Maintenance**	/	/	• Proxy report of child's PA and sitting time[c] • Proxy report of impact of active homework (concentration and completion)[c]	• Device-assessed PA and sedentary time[e] • Self-reported PA and sedentary time[j]
Organisational-level Maintenance	• No. partners; organisational characteristics (type)[a] • No., frequency and audience for promotional and dissemination activities[a,f,g] • Perceived reach of dissemination strategy[f] • Perceived barriers/facilitators to program maintenance in	***School-level*** • Intention to continue[b] • No. and type of *TransformUs* website visits, program component downloads[g] • Organisational infrastructure and resource availability to support implementation[b] • Organisational readiness and capacity to implement *TransformUs* (adapted ORIC scale)[71]; implementation climate[72] (6qu)[b]	• Program awareness; continued support[c]	• Dose received (active lessons, active breaks, homework, health lessons, line markings)[j] • Perceptions of program[j]

	schools; continued program support[f]	• Implementation strategies; appropriateness, acceptability, barriers and facilitators to implementation[b] ***Teacher-level*** • Intention to continue[b] • No. and type of *TransformUs* website visits, no. program component downloads[g] • No., frequency, duration of components (dose delivered), adherence and adaptation (fidelity), feasibility, appropriateness, self-efficacy to implement, satisfaction; barriers/facilitators[b] • Implementation climate[72](2qu)[b]		

No. = number; [a]Partner self-report; [b]School/teacher survey/interview; [c]Parent survey; [d]*TransformUs* website [e]ActiGraph accelerometers; [f]Partner interviews; [g]Google Analytics; [h]Australian Bureau of Statistics data; [i]My Schools data (https://www.myschool.edu.au/); [j]Child survey. PA: physical activity. *Asterisk indicates Effectiveness trial only.

Data Analysis

Qualitative data

Qualitative data in this study contributes to assessing all five dimensions of the RE-AIM framework. Qualitative interview data will be transcribed and analysed thematically via NVivo12. Coding and theme development will be firstly deductive, guided by the study aims and RE-AIM domains[73] followed by an inductive approach that will be directed by content of the data.[74] Themes will be grouped against the 14 domains of the TDF.[51] Data will be coded by two independent researchers.

Quantitative data

Survey data for program Reach, Adoption, Implementation, and Organisational-level Maintenance will be reported descriptively. Methods for calculating level of implementation will be based on a previous implementation evaluation of the *TransformUs* efficacy trial [27]. In brief, teachers will be grouped by level of implementation based on the proportion of the entire intervention delivered (dose delivered and fidelity). Implementation levels will correspond to: (i) 'low' (<33% of the entire intervention delivered); (ii) 'moderate' (33-67% delivered); and (iii) 'high' (>67% delivered).[27]

Quantitative data: Effectiveness Trial

The effectiveness component of the study will compare primary, secondary and exploratory outcomes among children, between intervention and control schools. Linear mixed models will be fitted to compare mean average daily sedentary time and MVPA at T1 (baseline), T2 (12-mths) and T3 (24-mths) (primary outcomes), average sedentary time and MVPA on weekdays and during school hours, zBMI, waist circumference (secondary outcomes) and quality of life (exploratory outcomes) at 12-months and 24-months between children in intervention and control schools. Linear mixed models will include fixed effects for group (intervention/control), time (months since baseline [time 1]) and a group by time interaction, and random effects for clustering of time nested within children, class and school. In the absence of random assignment, propensity scores will be developed to determine the probability of a child receiving the intervention based on observed baseline covariates (e.g., age, sex, area-level socioeconomic status of residence). Inverse probability of treatment weighting (IPTW) using the propensity score will be adopted to assist in obtaining unbiased estimates of average treatment effects, although it is acknowledged that this will not control

for the difference in location (Victoria or NSW) between intervention and control schools.[75] Due to the impact of COVID interruptions on this study, sensitivity analysis will consider only children who participated in baseline and 12-month follow-up in intervention and control schools to examine the effectiveness prior to home schooling and other COVID impacts.

Descriptive statistics will be calculated for the additional exploratory outcomes: children's perceptions and awareness of the program, at 12-months and 24-months for children in the intervention group, and parent proxy report of their child's physical activity at baseline, 12-months and 24-months in both the control and intervention group. All statistical analyses will be performed using Stata SE v17.

Ethics and Dissemination

The trial was approved by the Deakin University human research ethics committee (HEAG-H 28_2017), Victorian Department of Education and Training, the NSW Department of Education, Australian Catholic University (2017-145R) and the relevant Catholic Education Offices. Findings from this trial will be disseminated via peer review publications, scientific conferences, summary reports to schools and our partner organisations. This trial builds on the successful cluster RCT of *TransformUs*.[25] Completion of the *TransformUs* RCT was timely, as in 2016, the Victorian DoE released the Education State policy, with a 10-year target to increase the number of children meeting physical activity guidelines on weekdays by 20%.[76] *TransformUs* directly aligns with the policy priorities of DoE, and this alignment was critical in securing partnership with DoE in Victoria. Establishing how best to scale up this efficacious program will generate important learnings that will inform future research studies in terms of implementation assessment and monitoring of policy uptake, and provide key information for relevant stakeholders wishing to expand similar initiatives.

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Authors' contributions

JS, HK, AT, CL, NDR, DL, JDG, AB, AT, LMB, KEL, LA, & HB contributed to the study design. **HK** led writing of manuscript with **JS,** and **KEL** led development of the analysis plan for the effectiveness component. All authors revised the manuscript for intellectual content and read and approved the final draft.

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Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years [or describe if any]. However, this research does not fund schools to implement the program (which is made available at no cost), and no product endorsements are made to schools by the research team for implementation of any aspect of the program. All remaining authors declare no other relationships or activities that could appear to have influenced the submitted work.

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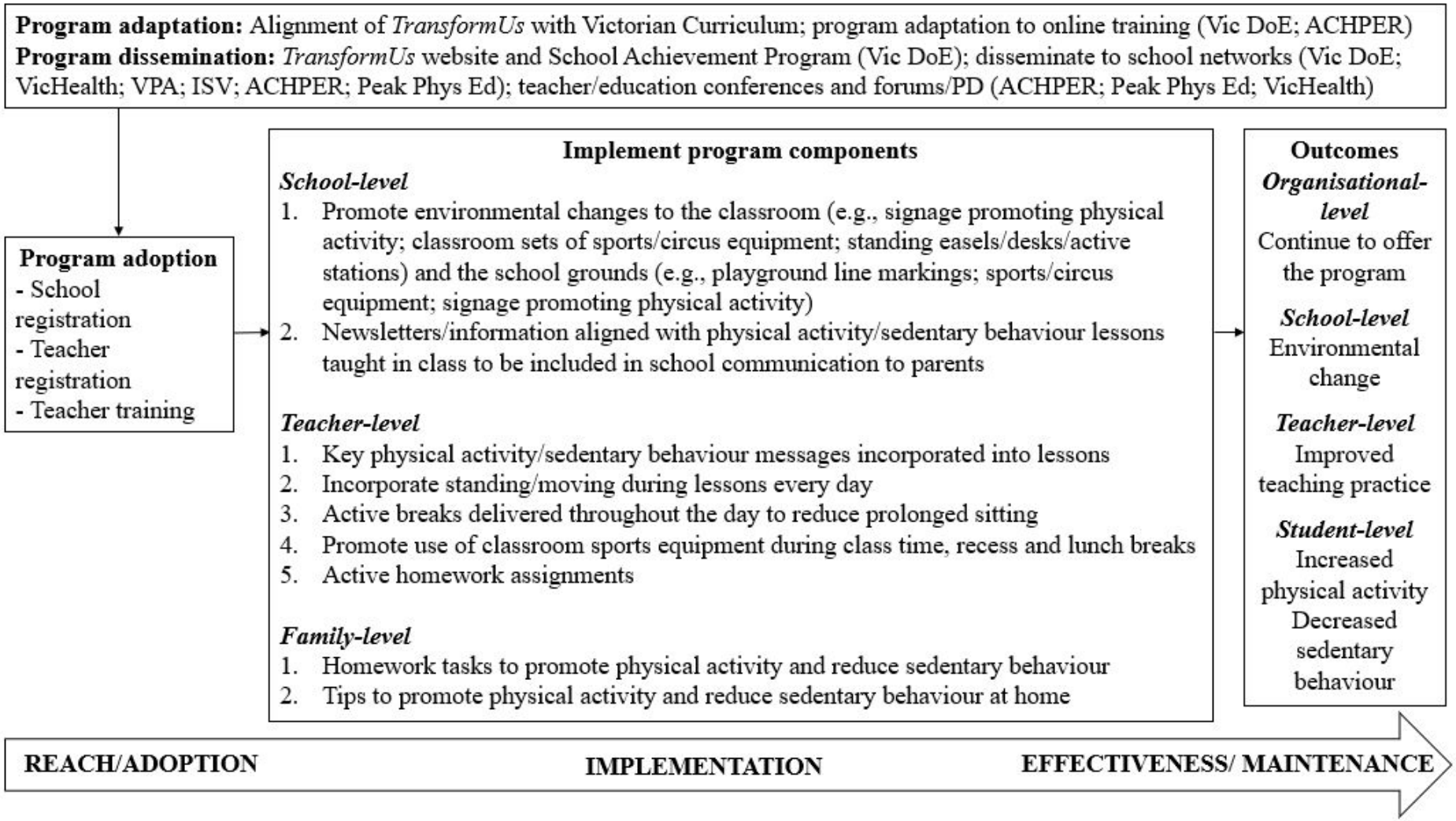
Figure 1. *TransformUs* program components for scale up



Vic DoE = Victorian Department of Education; ACHPER = Australian Council for Health, Physical Education and Recreation; VPA = Victorian Principals Association; ISV = Independent Schools Victoria; PD = Professional Development.

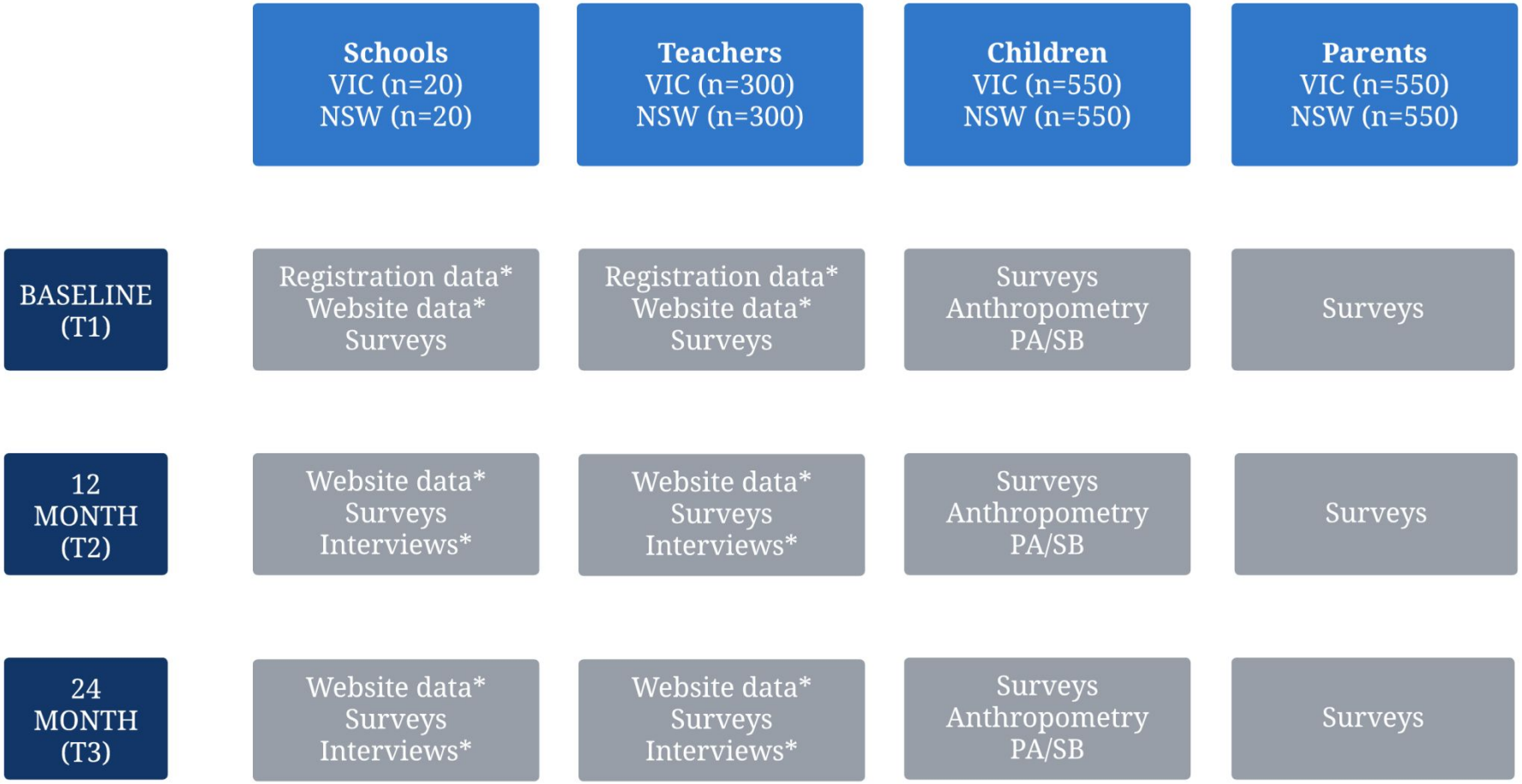


Figure 2. Effectiveness Trial Participant Flow Diagram

*VIC only

VIC= Victoria; NSW = New South Wales; PA = physical activity; SB = sedentary behaviour

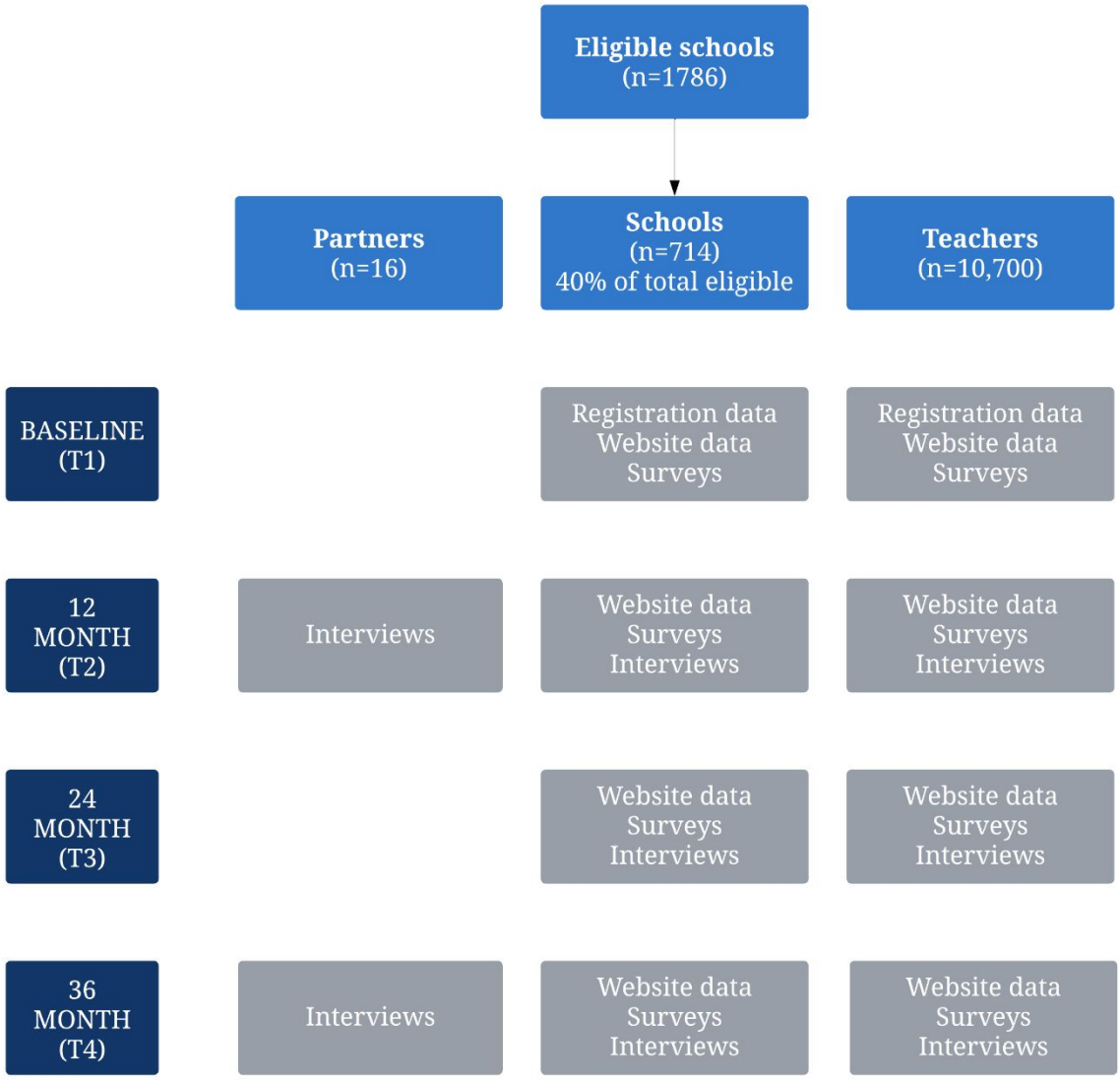
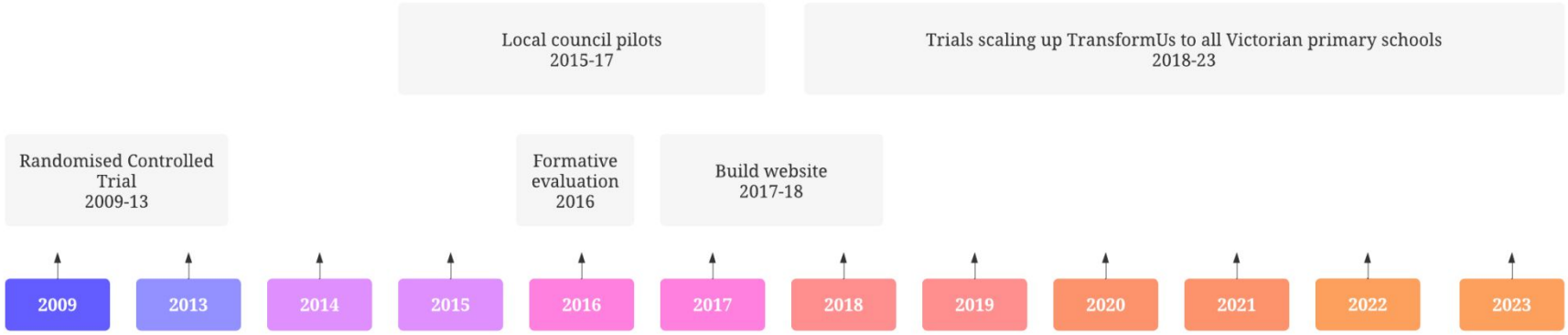


Figure 3. Implementation Trial Participant Flow Diagram

Supplementary File 1. Evolution of *TransformUs* (2009-2023)



Supplementary File 2. *TransformUs* implementation and scale up strategies

#	**Strategy**	**Definition**	**Actors** *(those who deliver imp strategy)*	**Action** *(specific action or process)*	**Action target** *(who its meant to affect)*	**Implementation outcome(s) affected**	**Temporality and dose**	**Justification**
1	**Formative work with stakeholders**	Research-practice partnership to identify strategies, barriers/ facilitators to program dissemination, implementation and sustainability at scale	*TransformUs* research team with State-level partner organisations (support system)	Multiple stakeholder workshops to explore aspects of the support system and delivery context Co-develop resources and strategies for implementation and scale up	State-level partner organisations (system level) School principals and teachers (organisational/ implementer level)	Program reach and adoption, degree of implementation and sustainability	Over 6 months prior to state-wide implementation and scale up	Can enhance implementation by ensuring system level goals and objectives are established and priorities aligned[1], and organisational implementation capacities and structures are considered[2]
2	**Creation of coalitions and networks for program/policy advocacy**	Active engagement with State education decision-makers, engaging opinion leaders (in government and non-government) to support and endorse implementation	State-level partner organisations (support system)	Consultation with key state-level stakeholders and decision makers to align program with state-level targets (e.g. Vic Education State target)	State-level partner organisations (system level) School principals and teachers (delivery system)	State-level program and implementation sustainability Organisational level reach/ adoption	Formal annual/ bi-annual stakeholder meetings Informal pursuit of opportunities over 5 years	Use of existing networks provides ongoing opportunities for training/ program promotion[2]. Formative work suggests promotes legitimacy, and implementation

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
								infrastructure for schools
3	**Utilise multiple dissemination routes/channels**	Program dissemination and promotion will occur via multiple channels known to have high reach among relevant decision-makers	State-level partner organisations (support system) School principals and teachers (delivery system)	Program launch with media involvement. Dissemination via web links, email listservs, newsletters, teacher prof. learning networks, conferences and workshops	*TransformUs* school principals and teachers (delivery system)	Program reach and adoption	Ongoing over 5 years	Multiple dissemination routes can widen scale up reach[2]
4	**Online program training to build implementation capacity**	Teachers required to complete online training prior to gaining access to program materials, implementation resources	*TransformUs* school principals and teachers (delivery system)	Completion of online training provides a unique log-in for access to online resources	*TransformUs* school principals and teachers (delivery system)	Online to maximise reach and adoption Training to enhance implementation (e.g. implementer skills, knowledge, self-efficacy to implement, perceived	~30minutes after registration and prior to accessing program materials. On completed, unlimited access over 5 years	To increase implementation capacity[3], skills, knowledge, self-efficacy, perceived fit with existing practices, relative advantage, and ownership of program[4-6]

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
						relative advantage, fit, ownership and sustainability of delivery)		
5	**Online platform for program materials and training**	All program materials, training, resources and data collection housed within an online platform aimed at schools, teachers and families. Schools and teachers must register to access training and materials	*TransformUs* research team with State-level partner organisations (support system)	Website hosted and maintained by *TransformUs* research team, link disseminated by all partner organisations.	School principals and teachers (delivery system) Parents of children at *TransformUs* schools	Reach, adoption	Ongoing over 5 years	Maximises potential program dissemination/ implementation[7]. Enables more efficient data collection, refinements to materials and resource updates over time
6	**Enable implementation flexibility and contextual adaptation**	Non-prescriptive approach to implementation. Schools and teachers encouraged via training and in resources to adapt program	*TransformUs* research team with State-level partner organisations (support system)	Resources include modifiable lesson plans and 'example' ways of delivering strategies (e.g. active breaks). Training videos	School principals and teachers (delivery system)	Adoption, implementation (e.g. perceived appropriateness, acceptability, feasibility) and sustainability (e.g. org-level	Ongoing over 5 years	Adaptability associated with increased effectiveness/ sustainability of real-world interventions[8]. *TransformUs* RCT showed

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
		strategies for setting relevance		illustrate ways of adapting program to different contexts		program embeddedness)		differences in implementation unrelated to efficacy[9]
7	**Enable both 'top-down' and 'bottom-up' program adoption**	School-level adoption not required for teacher-level implementation. Schools and teachers can register to deliver the program independently	*TransformUs* research team with State-level partner organisations (support system)	Schools and teachers register via the program website. At registration schools encouraged to invite all teachers, and teachers encouraged to advocate for senior leadership support. Parents can advocate for school adoption. Template email invites provided	*TransformUs* school principals, teachers (delivery system) Parents of children at *TransformUs* schools	Reach and adoption	Ongoing over 5 years	Capturing both individual and organisational innovation-decision processes, can elucidate influences on adoption and implementation[10]
8	**Utilise existing resources in the delivery system**	Program strategies can use existing school resources, equipment and	*TransformUs* research team with State-level partner	Program training and resources include ways of using/adapting existing school	*TransformUs* school principals, teachers (delivery system)	Adoption, implementation, sustainability	Ongoing over 5 years	Using existing resources can promote sustainability[2], reducing

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
		facilities where appropriate	organisations (support system)	resources and delivering program within existing schools infrastructure to achieve effective implementation				potential costs for schools to deliver may enhance program uptake (esp. in lower resourced schools)
9	**Development of recognition and incentive system**	Online training mapped against current teaching standards, to contribute towards teachers' annual continuing professional development (CPD) requirements. Schools encouraged to recognise Champion role during staff appraisals	School principals and teachers (delivery system)	Certificate of completion provided after training to evidence CPD hours. Importance/role of champion promoted via online training, downloadable template position description provided for schools	*TransformUs* school principals, teachers (delivery system)	All RE-AIM dimensions	Certificate provided on completion of online training. Champion recruitment determined by school, ongoing over 5 years	Positive incentives may be necessary for widespread adoption and delivery[1]. Formative work identified CPD as an incentive for training completion
10	**Alignment with existing state-**	Program aligned with the	*TransformUs* research team	*TransformUs* included as part	*TransformUs* school	Reach, adoption, implementation	Program aligned with	Interventions which align with

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
	level initiatives and guidelines	Victorian Achievement Program to count towards program physical activity benchmarks for schools. Program materials (e.g. health lessons) aligned with the Victorian Curriculum	with State-level partner organisations (support system)	of Achievement Program materials and promotion. Alignment with Victorian Curriculum promoted via website and in training	principals, teachers (delivery system)		Achievement Program for 3 years as part of planned promotion phase. Alignment to Curriculum guidelines updated as necessary over 5 years	state or national priorities/goals are more likely to gain political/ administrative support required for scale up[2]
11	**Promote use of program champions**	Schools identify champion(s) who advocate for are a point of contact for staff, students and families regarding *TransformUs* implementation	*TransformUs* champion/ teachers (delivery system) State-level partner organisations (support system)	Template champion position description provided to schools after registration. Online training encourages teachers to self-nominate	*TransformUs* school principals, champion/ teachers (delivery system)	Adoption, implementation and sustainability	Promoted to principals and teachers during online training and on website. Ongoing promotion via partner organisations during teacher prof. learning networks, conferences and workshops over 5 years	Champions can encourage the adoption of preventive interventions[11] Formal 'position description' identified in formative work as a strategy to increase legitimacy of role in schools

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
12	**Online implementation support network**	Schools can access an online discussion forum to share implementation strategies and ways of overcoming barriers.	*TransformUs* champion/ teachers (delivery system)	Online discussion forum hosted on the program website, accessible only to registered teachers/schools	*TransformUs* champion/teachers (delivery system)	Adoption, implementation	Ongoing for 5 years	Pilot trials suggested knowledge sharing can increase implementation capacity. Peer networks can increase rates of adoption[11]
13	**Provision of resources to support implementation processes and sustainability**	Providing schools resources and suggested strategies to enhance implementation and sustainability in their setting	*TransformUs* school principals and teachers (delivery system)	Online video clips showing implementation, downloadable resources (e.g. active break strategies) and tools to support embedment (e.g. template school PA policy doc and implementation plan)	*TransformUs* school principals and teachers (delivery system)	Implementation (e.g. skills, knowledge and capacity to implement program) and effectiveness. Institutionalisa-tion within the school	Post registration, available online over 5 years	Increasing general and intervention-specific capacity within support system can enhance implementation[7] and sustainability[12]. Implementation plan can increase accountability[8]
14	**Monitoring and evaluation to adjust scaling strategy,**	Multilevel data (system, organisational, implementer and	*TransformUs* research team and state-level partner	6 monthly monitoring of partner organisations	State-level partner organisations (support system)	State-level sustainability of program promotion	6-monthly monitoring over 5 years	Monitoring and evaluation key to identifying obstacles and

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
	feedback to support schools	recipient level), on partner organisations. dissemination activities (type, freq. and dose) and setting-level implementation	organisations (support system) School principals and teachers (delivery system)	dissemination activities Recruitment for interviews and surveys embedded within program website Schools submit implementation case studies via website; shared in quarterly newsletters	School principals and teachers (delivery system) Parents of children at *TransformUs* schools	School-level reach, adoption, implementation and organisational level maintenance	Baseline (pre and post online training) and annually thereafter for 5 years Requests for case studies 4 times/year	opportunities to adjust scaling approach[2]. Feedback can increase teacher implementation performance.

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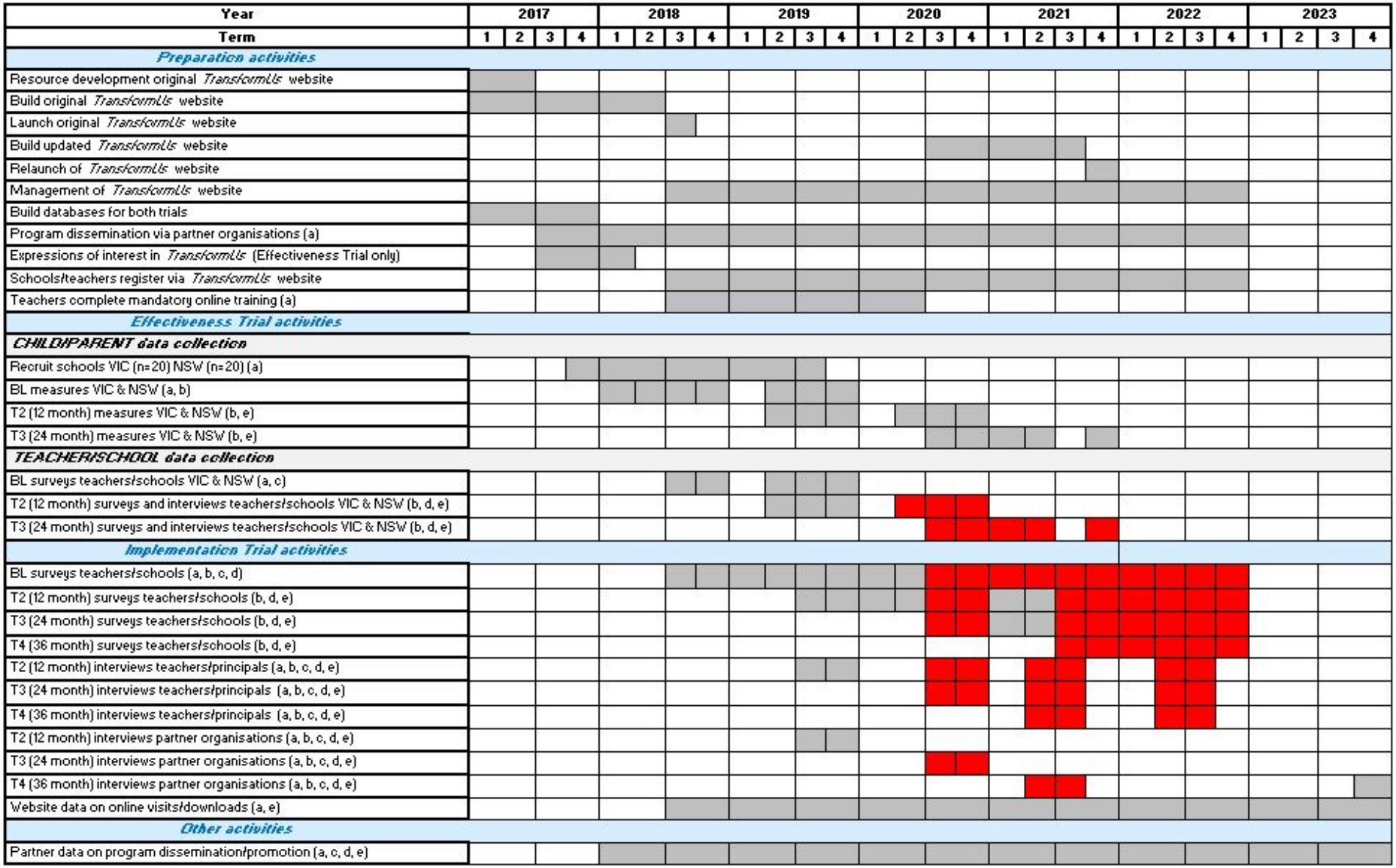
Supplementary File 3. Project timeline



(a) Reach; (b) Effectiveness; (c) Adoption; (d) Implementation; (e) Maintenance; BL=Baseline, T2=12 month follow up; T3=24 month follow up; T4=36 month follow up; NSW=New South Wales; VIC=Victoria; Red highlight indicates data could not be collected due to COVID-19 restrictions

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Scaling up a school-based intervention to increase physical activity and reduce sedentary behaviour in children: protocol for the TransformUs hybrid effectiveness-implementation trial

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Scaling up a school-based intervention to increase physical activity and reduce sedentary behaviour in children: protocol for the *TransformUs* hybrid effectiveness-implementation trial

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Abstract

Introduction: Efficacious programs require implementation at scale to maximise their public health impact. *TransformUs* is an efficacious behavioural and environmental intervention for increasing primary (elementary) school children's (5-12 years) physical activity and reducing their sedentary behaviour within school and home settings. This paper describes the study protocol of a five-year effectiveness-implementation trial to assess the scalability and effectiveness of the *TransformUs* program.

Methods and analysis: A type II hybrid implementation-effectiveness trial. *TransformUs* is being disseminated to all primary schools in the state of Victoria, Australia (n=1,786). Data are being collected using mixed methods at the system- (State government, partner organisations), organisation- (school), and individual- (teacher, parent, and child) levels. Evaluation is based on program Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM framework). RE-AIM domains are being measured using a quasi-experimental, pre-post, non-equivalent group design, at baseline, 12- and 24-months. Effectiveness will be determined in a subsample of 20 intervention schools (in Victoria) and 20 control schools (in New South Wales [NSW], Australia), at baseline 12- and 24-months. Primary outcomes include *TransformUs* Reach, Adoption, Implementation and organisational Maintenance (Implementation trial), and children's physical activity and sedentary time assessed using accelerometers (Effectiveness trial). Secondary outcomes include average sedentary time and MVPA on weekdays and during school hours, body mass index z-scores (zBMI) and waist circumference (Effectiveness trial). Linear mixed effects models will be fitted to compare outcomes between intervention and control participants accounting for clustering of children within schools, confounding, and random effects.

Ethics and dissemination: The trial was approved by the Deakin University human research ethics committee (HEAG-H 28_2017), Victorian Department of Education, the NSW Department of Education, Australian Catholic University (2017-145R), Melbourne Archdiocese Catholic Schools and Catholic Schools NSW. Partners, schools/teachers, and parents will provide informed signed consent prior to participating. Parents will provide consent for their child to participate in the effectiveness trial. Findings will be disseminated via peer review publications, scientific conferences, summary reports to schools and our partner organisations, and will inform education policy and practice on effective and

sustainable ways to promote physical activity and reduce sedentary behaviours population-wide.

Trial registration: Australian New Zealand Clinical Trials Registry, ACTRN12617000204347.

Keywords: Scale up, scalability, dissemination, school, implementation science, population

Strengths and limitations of this study

- Strengths include the hybrid effectiveness-implementation trial design undertaken in a real-world context, the inclusion of multiple levels of data collected at multiple time points, the use of robust frameworks to guide implementation and scale up, and device-based measurement of children's physical activity and sedentary time in the effectiveness trial.
- Testing the hypothesised mediating and/or moderating relationships, such as organisational readiness for change, with implementation and effectiveness outcomes will help understand primary barriers to, and facilitators of, implementation of school-based interventions, such as *TransformUs*.
- Limitations include reliance on teacher self-reported implementation of the program, although, additional implementation data will be captured using Google Analytics (e.g., use of the *TransformUs* website, professional development completed by teachers, and which program resources are downloaded).
- Facilitation of program dissemination activities via stakeholders and the research team may not reflect true real-world promotion, but will highlight practices required for sustainable scale up.
- Extended COVID-19 lockdowns and government restrictions in Australia meant on-site data collection in schools was prohibited in Victoria between 2020 and April 2023, and in NSW during 2021; nevertheless, the conduct of both an implementation and effectiveness trial will enable us to compare differences between schools to ascertain the level of implementation, 'real world' program impact, and generalisability of results.

Introduction

Regular physical activity is beneficial for children's cardiometabolic health (including lipids, adiposity and blood pressure),(1) and mental health.(2) Physical activity has also been positively associated with academic results, including cognitive skills (e.g., executive functioning, attention, memory, comprehension), attitude (e.g., motivation, self-concept, satisfaction and enjoyment), academic behaviour (e.g. organisation), engagement in learning (e.g., on-task time), and academic achievement (e.g., standardised test scores).(3-5) Few studies have examined the impact of prolonged sitting on children's health, with the evidence still primarily observational and indeterminate.(6) Whilst there is currently insufficient evidence for a dose-response relationship between sedentary behaviour (defined as any waking behaviour characterized by an energy expenditure ≤1.5 metabolic equivalents while in a sitting, reclining or lying posture)(7) and health outcomes in children and adolescents (aged 5-17 years), greater time spent sedentary has been linked to poorer health outcomes such as lower fitness, and poorer cardiometabolic and mental health in this population.(8) There is some evidence that breaking up sedentary time may improve cognitive outcomes in children.(9)

In Australia, only 26% of children aged 5-12 years meet the government recommendation of at least one hour of moderate- to vigorous-intensity physical activity (MVPA) every day.(10) As part of the Australian 24-hour movement guidelines for children and young people (5-17 years) which integrate physical activity, sedentary behaviour and sleep, it is recommended that children reduce and break up prolonged sitting throughout the day.(11) More than 60% of children's class time is spent sitting(12) and only 25-30% of morning recess and lunch breaks at school are spent in MVPA.(13) Comprehensive school physical activity programs that use whole-of-school approaches to promoting activity, and adopt active school environments (i.e., active classrooms, active environments, quality physical education and sport) have been recommended to address low levels of physical activity among children.(14, 15) Whole-of-school approaches are also recommended within the World Health Organization Global Action Plan for Physical Activity, as a way to promote enjoyment and participation in physical activity among youth.(16)

There are some examples of efficacious school-based approaches to promoting children's physical activity(17) and reducing sedentary behaviour(18), although the association between implementation fidelity and intervention outcomes is unclear.(19, 20) Most interventions target organised sport and physical education,(21) yet interventions which provide sports and

active equipment during recess, and incorporate playground markings can also successfully increase children's physical activity.(22, 23) A systematic review has also shown that school interventions with a family element can be more effective at increasing physical activity than just focusing on the school setting alone,(24) however, few studies have determined the efficacy of strategies to reduce prolonged sitting both at school and home among children.(25) The initial *TransformUs* program(26) was one of the earliest programs (developed in 2009) to incorporate many of these elements with a particular focus on reducing and breaking up children's sitting throughout the school day.

The efficacy of the initial *TransformUs* program was demonstrated in a 4-arm two-by-two factorial design cluster-randomised controlled trial (RCT) involving 20 primary (elementary) schools, 226 teachers and over 1,600 children in Melbourne, Australia (2010-13).(26) The three intervention arms targeted either increases in physical activity (PA-I), reductions in sedentary behaviour (SB-I), or a combination of both (PA+SB I), compared to a usual practice control. The results of this RCT are described and interpreted in detail elsewhere.(26) However, in brief, at 18-months (n=348), compared to usual practice, children who received the physical activity intervention (groups PA-I and PA+SB I) had significantly less weekday sedentary time (-27 mins/day). Compared to usual practice, children who received the sedentary behaviour intervention (SB-I and PA+SB I) spent more time in daily physical activity (5.5 mins/day) at 18-months, and at 30-months spent 33 mins less in daily sedentary time, and specifically, 63 mins less in sedentary time on weekdays, with no differences in physical activity at 30-months.(26) Thus strategies to promote both children's physical activity and reduce sedentary behaviour were important. Results also showed beneficial effects on children's adiposity markers (body mass index [BMI] and waist circumference [n=564]). However, there were mixed effects on children's blood pressure ([BP] positive effects on systolic BP and negative effects on diastolic BP [n=537]) and in a sub-sample of children (n=206), on blood parameters (e.g., negative effects on some inflammatory markers such as CRP, IL-6, IL-2 and TNF-α, beneficial effects on vitamin D, BDNF, and PAI-1).(26)

Teachers, parents and children reported that the program was positively received, and teachers involved in the intervention arms also reported perceptions of better classroom management and improved 'on-task' behaviour during lessons.(27) Although barriers to implementation were experienced (including a lack of school leadership to support implementation long-term, promotion and awareness raising, teacher time constraints, and

challenges with sustained integration into existing practices), overall, the program was effectively integrated into the school curriculum.(27) Existing teaching practices, children's enjoyment, and teacher awareness of program values and benefits were the main facilitators of delivery and sustainability.(27) Following the success of *TransformUs*, and exploration of adaptations for scaling (described in Methods section), the Victorian Department of Education committed to partnering with the research team to support the dissemination and implementation of the program to all primary (elementary) schools in Victoria, Australia. Given the small number of school-based interventions that are studied at scale(28) and that use implementation theories to guide this process;(29, 30) scaling up of *TransformUs* presented a unique opportunity to investigate real-world implementation at scale. Assessment of intervention implementation among school-based interventions is greatly needed in the field.(19)

This paper describes the study protocol for a five-year trial (launched September 2018 - final data collection December 2023), which aims to evaluate the real-world effectiveness and implementation of *TransformUs* at scale. To note, the paper outlines the *intended* protocol for the trial (including planned dates and timelines for data collection), but also describes where and how this *changed* due to the impacts of the COVID-19 global pandemic. In line with the RE-AIM framework criteria,(31) we will evaluate the following five aims: the program's **Aim 1**: *Reach* (proportion and representativeness of Principals and teachers, parents and children participating in *TransformUs*); **Aim 2**: *Effectiveness* (change in children's daily physical activity and sedentary time 12- and 24-months post-baseline); **Aim 3**: *Adoption* (proportion and representativeness of schools choosing to implement *TransformUs*); **Aim 4**: *Implementation* (dissemination by education and health partners, uptake of intervention components, frequency, dose and adaptation to *TransformUs* delivery, and barriers and enablers to implementation); and **Aim 5**: *Individual-level Maintenance* (change in children's physical activity and sedentary time 24-months post baseline) and *Organisational-level Maintenance* (institutionalisation and sustainability of the program within the education and health systems, school settings and by teachers as part of routine practice).

Methods and analysis

Overview of the *TransformUs* program

TransformUs is a behavioural and environmental intervention delivered in the classroom, broader school environment and family setting to increase children's physical activity levels and reduce sedentary behaviour.(32) The program includes: (i) health lessons incorporating key physical activity/sedentary behaviour messages; (ii) active academic lessons; (iii) active breaks; (iv) changes to the school environment; (v) active homework, and (vi) parent newsletters promoting physical activity/reducing sitting time (for more detail see Figure 1). The program was based on the Social Cognitive Theory,(33) Behavioural Choice Theory(34) and Ecological Systems Theory.(35) The health lessons, active academic lessons and active breaks are all aligned with the Victorian(36) and Australian curriculum and standards.(37) All *TransformUs* components are contained in the members' area of the website (https://transformus.com.au). To access these resources, Victorian primary school teachers need to register (at no cost) using their work email address. A detailed description of the program strategies(32) and program logic model have been published elsewhere.(27) Adaptations to the *TransformUs* program for scale up are described later in Methods section, and Supplementary File 1 presents the evolution of *TransformUs* since the original RCT (2009) to date.

Study design

This study uses a type II hybrid effectiveness-implementation trial design,(38, 39) to concurrently examine both effectiveness outcomes and implementation and scale-up processes. Mixed method data will be collected at the systems- (State government, partner organisations), organisational- (school) and individual- (teacher, parent and child) levels. Supplementary File 2 contains the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist, relevant to this manuscript.

Implementation trial

Every primary school in Victoria (government, independent and Catholic) will be offered *TransformUs,* and will be eligible for inclusion in the state-wide implementation trial. Our objective is for the program to be adopted by at least 715 primary schools (40% of a total of 1,786 primary schools in Victoria(40)) by the end of the trial. The adoption estimates are based on school uptake of state-wide initiatives offered by the Victorian Department of Education and previous implementation trials in schools.(41) As *TransformUs* dissemination

will be ongoing over 5-years, schools can register anytime between September 2018 and December 2022. Data are planned to be collected from schools and teachers who agree to participate in the evaluation at baseline (T1), 12-months (T2), 24-months (T3) and 36-months (T4) post registration; within the funding time period (September 2018 - December 2022). These data will contribute to assessing reach, adoption, implementation, and organisational-level maintenance (Aims 1, 3, 4 and 5).

Effectiveness trial

To determine short- and long-term changes in children's levels of physical activity and sedentary time under 'real world' conditions (based on adaptations from the original *TransformUs* program described below), an embedded effectiveness trial is planned with 20 intervention schools in Victoria and 20 control schools in the state of New South Wales (NSW). A quasi-experimental pre-post non-equivalent group design(42) with follow-up will be adopted. As this is a real-world roll-out in Victoria, a non-randomised two-group parallel arm approach was adopted. Data collected at baseline (T1), 12-months (T2), and 24-months (T3) will contribute to assessing program effectiveness and maintenance at the student level (Aims 2 and 5). Schools in NSW were considered suitable controls as NSW has a similar population size and geographic spread to Victoria compared to other states and territories, and the *TransformUs* program was not available in NSW.

Program adaptation and piloting

The *TransformUs* RCT showed that strategies to promote children's physical activity and reduce sedentary behaviour were both important,(43) and therefore the combined (PA+SB I) approach was the focus for wider scale up. During the RCT, teacher professional development was delivered face-to-face by the research team, and schools received ongoing support from the team over the 2.5 years of the study. This approach was not considered feasible for scale up. To facilitate scale up; professional development, support, and all program materials and resources were converted into an online format to maximise potential reach at a lower cost. Formative evaluation with partners responsible for implementing interventions at scale can also be useful to inform adaptations to the intended dissemination strategy and refine the program materials to enhance scalability.(44) Therefore, in close partnership with local councils (from Local Government Areas) and teachers, the

TransformUs online materials were tested in two pilot dissemination trials and formative evaluation was conducted with key partner organisations involved in scale up, detailed in the following section.

TransformUs pilot dissemination trials (2015-17)

Two 12-month pilot dissemination trials were conducted during July 2015-16 (pilot trial 1; n=4 schools, n=41 teachers) and 2017 (pilot trial 2; n=5 schools, 22 teachers), to assess the feasibility of *TransformUs* dissemination and the online teacher professional development. In both pilots, the program was advertised to schools via two councils (representing two different Local Government Areas) in Victoria. The costs of program equipment (e.g., standing easels, sports equipment) and installation of playground line markings (e.g., hopscotch) were subsidised by the councils to support uptake. Schools located in a lower income area were offered a greater subsidy than schools in a higher income area (determined using the Schools in a Socio-Economic Indexes for Areas [SEIFA]; methods consistent with the original RCT).(45) All teachers within participating pilot schools were asked to, preferably, complete the online professional development (lasting 30-45 minutes) during a session on their school site that was facilitated by a representative from the relevant council. As this was to inform the real-world dissemination trial and to help understand the feasibility of online professional development, schools could also send a nominated teacher and adopt a train-the-trainer approach.

Teachers completed online surveys pre- and post- the professional development session, 2-months and 12-months post-baseline (max n=51 teachers; Pilot trial 1), and at 4-months post-baseline (n=22 teachers; Pilot trial 2). Most teachers reported that they: (1) gained new knowledge of ways to increase children's physical activity (88%) and reduce sedentary behaviour (90%) at school; (2) learnt new teaching methods (78%); (3) perceived the online training to be an appropriate delivery method (82%); and (4) gained the required knowledge (90%) and confidence (80%) to implement the program. Teachers requested visual examples of program implementation (i.e., digital video clips), which they felt would strengthen teacher engagement and sustained delivery of the program. Although the RCT focused on children in Grades 3-5 (ages 8-11 years), in both pilot trials, participating schools planned a whole-of-school approach to implementation across all school year levels, Foundation to Grade 6 (ages 5-12 years). For scale up, program materials were modified to accommodate delivery across all year levels, covering a range of learning areas (e.g., mathematics, English, science and

humanities), and digital video clips were developed to demonstrate appropriate implementation.

Formative evaluation with key partner organisations (2016)

Through an integrated research-practice partnership approach, collaboration began with one government (Victorian State government Department of Education) and six non-government organisations (the Victorian Health Promotion Foundation [VicHealth], the Victorian Principals Association, Independent Schools Victoria, the Australian Council for Health, Physical Education and Recreation Victoria [ACHPER], and Peak Phys Ed). These partners play various roles in the education and health systems including, for example, responsibility for delivery of education to children and young people in Victorian government and independent schools (e.g., Department of Education), and coordinating and delivering teacher education professional development (e.g., ACHPER and Peak Phys Ed). In collaboration, these partners will provide ongoing input into the state-wide dissemination strategy, ensuring that the program aligns with other existing school-based health promotion initiatives in the state (e.g., the Victorian Achievement Program, which aims to create healthier early childhood services, schools and workplaces; http://www.achievementprogram.health.vic.gov.au/), and that all resources (e.g., health lessons) are linked to the Victorian Curriculum and each resource identifies the specific Strand, Sub-strand, Content Description and Achievement Standard. For example, *TransformUs* supports the development of student capabilities (e.g., Critical and Creative Thinking, Personal and Social capabilities), which are taught explicitly in and through the learning area resources. *TransformUs* also provides cross-curriculum opportunities for students to strengthen their literacy and numeracy general capabilities.

Implementation and scale up of *TransformUs*

Theoretical underpinnings

Our approach to scale up is 'horizontal', defined as extending the reach of an intervention by replicating it in other localities, cities or states.(46) Our implementation approach is derived from evidence-based recommendations for the successful scalability of population-level health interventions,(44, 47, 48) and concepts within the translation, support and delivery systems of the Interactive Systems Framework.(49) We draw on ways to improve

implementation and sustainability as outlined in the Quality Implementation Framework,(50) PRACTIS Guide,(44) and from literature on ways to increase public health program sustainability.(51) To identify underlying barriers and facilitators to individual-level implementation, qualitative data collection will be informed by the Theoretical Domains Framework,(52) which is a systematic and theoretically based approach to behaviour change that identifies barriers to practice change and potential strategies to intervene. The RE-AIM framework(31) informs the overarching evaluation outcomes following implementation and scale up.

Implementation and scale up strategies

In addition to findings from the *TransformUs* pilot adaptation studies described above, scale up strategies were also guided by literature on strategies for effective implementation and scale up planning(44, 46) and attributes of successful scale up (i.e., compatibility of the program with the values and facilities of intended users, and perceived need for the innovation within the organisation).(53) Supplementary File 3 presents the 14 *TransformUs* implementation and scale up strategies, reported in line with recommendations and definitions for specifying implementation strategies.(54)

Our focus is on implementation *quality* as opposed to controlling rigorous program fidelity that is essential in efficacy trials. In school-based intervention implementation, 'quality' can include: (i) sufficient exposure (dose); (ii) fidelity to the program protocol; (iii) implementation (engaging students through active participation); (iv) adaptation (modifying the intervention to meet developmental and cultural needs); and (v) teachers' attitudes, understanding of the concepts/issues and prior experience.(55) In *TransformUs*, schools were encouraged to choose contextually relevant strategies for implementation at their school, rather than a prescriptive program, to enhance quality and ensure program adoption occurs in the most contextually relevant way to achieve health benefits. This approach is associated with increased effectiveness of real-world interventions and those more likely to produce sustainable results.(50)

In the context of *TransformUs,* we will be creating an implementation infrastructure for schools via Department of Education endorsement, provision of sustainability resources (i.e., template policy statements for schools to embed the program), and active engagement with State education decision-makers and other non-government partner organisations.

Implementation resources will also be provided to support and encourage school level leadership to implement the program, and provide recommendations to promote integration and sustainability (i.e., *TransformUs* champion roles and responsibilities, a template policy document).

TransformUs program for scale up

Figure 1 presents the *TransformUs* program components for scale up. Based on outcomes from the two pilot trials and formative work with our partner organisations and to maximise program reach, all supporting program materials, implementation and training resources are available online via a program website. The website (https://transformus.com.au/) is managed by the research team at Deakin University. Teachers are required to complete the mandatory online professional development via the *TransformUs* website. The professional development provides strategies to integrate and sustain implementation of the program in schools, and thus is essential to ensure minimum standards and knowledge are established prior to program delivery. Based on evidence for the determinants of effective implementation by adopting individuals (users, i.e., teachers),(56, 57) the content of the professional development program has been designed to address the following seven key areas: (i) *support for implementation* (teacher and school level); (ii) *skills required for implementation;* (iii) *knowledge required for implementation;* (iv) *self-efficacy to implement*; (v) *fit of the program into existing practices;* (vi) *relative advantage of the intervention over existing practices*; and (vii) *perceived ownership of the program* (allowing for adaptation). For example, the professional development includes ways of embedding the program in practice, such as development of a tailored implementation plan (i.e., a checklist of activities teachers wish to undertake and how they plan to sustain delivery), and knowledge reflection (quizzes) to test learning.

Multiple dissemination routes will be used to maximise program uptake and sustainability (e.g., via our partners, through sharing the web link, email lists, social media, teacher professional learning networks, and teacher professional development conferences and workshops). Interactions with stakeholders will include face-to-face or online meetings (e.g., approximately two group meetings per year in addition to regular one-on-one meetings), and the provision of dissemination materials and communication packs to stakeholders, to enable them to promote *TransformUs* via their existing social media platforms and newsletters.

Recruitment

Implementation trial: Partners (state level)

One representative from each of our partner organisations (six organisations were formal partners prior to the project being funded) who has experience in disseminating and/or supporting the *TransformUs* roll-out will be invited to participate in interviews to capture system-level impact (e.g., organisational-level maintenance, which relates to Aim 5 of the study). We expect to recruit one representative from each of our partner organisations. As depth of qualitative data is more important than sample size,(58) we aim to recruit a purposeful sample of representatives from our partner organisations. Recruited participants will be asked to provide signed consent prior to taking part.

Implementation Trial: Principals (school level) and teachers

Schools and teachers will be made aware of *TransformUs* via multiple dissemination routes (as described in section '*TransformUs* program for scale up'). All schools and teachers who wish to adopt *TransformUs* register free of charge via the *TransformUs* website, and teachers can register to access the *TransformUs* program regardless of whether their school (i.e., principal) has registered. This is to allow for both top-down and bottom-up program adoption. To access the professional development, registration is mandatory. Upon registration, a unique login username for each teacher/school will be generated, which they can use to revisit the website and access the professional development and online resources. During registration, schools/teachers will be invited to participate in the survey component of the Implementation Trial, where they will receive a plain language statement and online consent form.

The registration process collects information about where they heard about the program, general physical activity policy and practice information for their school (e.g., information on participation in additional physical activity programs will also be collected), and which elements of the *TransformUs* program their school plans to implement. There are no costs to access the online resources. Implementation schools wishing to install new playground line markings or purchase physical activity equipment will not receive funding from the research project to do so. To help minimise the financial investment required, information on how to

best utilise existing playground line markings and physical activity equipment is provided online.

We plan to reach 714 schools (based on an estimate of 40% of the total number of schools in Victoria(40); n =1,786). As part of the Implementation Trial, we aim to recruit ~15 school leaders who registered for the survey evaluation component of *TransformUs* to participate in a qualitative interview about their experiences of adopting and implementing the program. This sample size provides sufficient 'information power'.(59) Whilst schools/teachers will provide online consent to participate in the survey component of the implementation trial at the point of *TransformUs* registration, the sub sample of participants invited to complete an interview will be required to provide additional consent prior to the interview commencing.

Effectiveness trial: Schools and teachers

Twenty schools in Victoria will be recruited using stratified non-random sampling to maximise area-level socioeconomic position and geographic location. Targeted recruitment of twenty control schools in NSW will be matched as much as possible (based on school size, type [e.g., Government, Catholic and Independent), SEIFA index (a measure of socio-economic advantage and disadvantage by area in Australia), geographical area [e.g., rural, remote], single sex/mixed students), with schools enrolled in the effectiveness trial in Victoria. Schools will represent different socioeconomic urban and rural areas, including different types, based on a minimum of two Grade 3 classes or four composite classes (i.e., Grade 3 and 4 classes combined).

Effectiveness trial: Children and parents

Grades 3 and 4 children attending schools enrolled in the effectiveness schools (and their parents) will be invited to help assess the effectiveness of the program. Children will be in Grades 3 or 4 at baseline to enable a planned follow up at 12-months and 24-months, and is consistent with the target age group evaluated in the original TransformUs RCT.(32) Parents will receive information about the study via the schools' regular methods of communication (e.g., school intranet system, email, text) and an information brochure sent home with the students. There will be a plain language statement and consent form for parents to provide consent for themselves and/or their child to participate in the assessments (e.g., parent online

survey, child MVPA, body mass index and waist circumference). As part of the consent process, parents/guardians will provide contact details (email and mobile telephone), which will be used to email a unique link to an online parent survey at each time point and to communicate with parents about the wearing and return of data collection devices from their child. Three emails or texts will be sent over six weeks to remind parents to complete the survey.

Figure 2 and Figure 3 present flow diagrams of participant recruitment into the Effectiveness and Implementation trials, respectively.

Sample size and power

Twenty Victorian schools will be recruited to ensure we have a diverse sample from a range of school types (Government, Catholic and Independent), Socio Economic Status (SES) tertiles (based on SEIFA data), and geographical areas. The target recruitment of children for the effectiveness study is based on statistical power calculations of the minimum number of participants required to detect differences in mean average daily sedentary behaviour (primary outcome) at 12 months (primary time point) between children in control and intervention schools. In the efficacy trial, average daily sedentary time was 347 minutes (SD=60) for the PA+SB intervention group and 371 minutes (SD=80) for the control group at Time 3 (18-month post baseline). Sample size calculations were conducted assuming a pre-post design, adjusting for baseline, in accordance with a published formula.(60) Based on estimates from the original cluster-RCT, to account for the design effect, an ICC of 0.03 for children within school clusters was used, with a conservative correlation of 0.015 assumed between two different pupils within a cluster at different time points and a correlation of 0.22 between the same pupils at different time points. Assuming alpha=0.05, 80% power will be available to detect a 16-minute difference in sedentary time (two-thirds of that observed in the efficacy trial as effects may diminish at scale)(61) at 12-months between intervention and control with recruitment of 1,094 children (547 from intervention and control schools, assuming approximately 28 students/school sampled). This number is sufficient to detect as small an effect as a 6-minute difference in physical activity between the control and intervention schools, based on estimated standard deviations of 9-minutes for the PA + SB group and 7-minutes for the control group from the cluster-RCT.

Inclusion and exclusion criteria: Implementation trial

All Government, Independent, and Catholic primary schools in Victoria (n=1,786)(40) will be eligible to adopt the program and thus participate in this research. In the Implementation trial, registered schools can include those previously involved in the original RCT and adaptation pilot trials. Schools or teachers located outside of Victoria are not able to register for the program or gain access to the professional development and online resources.

Inclusion and exclusion criteria: Effectiveness trial

Schools that participated in the 2010-2013 *TransformUs* RCT and 2015-2017 pilot trials will be excluded from the sample frame for the effectiveness trial. Special schools for children with a disability (defined by the school) and schools with less than 30 students across both Grades 3 and 4 will also be excluded to ensure that there is sufficient power to test the effectiveness of the program among students (n=20 schools, 550 students from VIC versus n=20 schools and 550 students from NSW) and parents. A matrix containing the names and types of all Victorian primary schools will be used for sampling, to ensure a range of government, independent and Catholic schools from inner city, outer suburban and regional areas are approached for recruitment. To be eligible as a control school in NSW, the school should not be implementing a similar health or physical activity-related program at baseline data collection. Any uptake of similar programs was monitored at each time point. For pragmatic and cost-related reasons, schools need to be located within a 4-hour drive from Deakin University (Burwood, Victoria) or Australian Catholic University (North Sydney, NSW).

Program dissemination and implementation timeline

Supplementary File 4 shows the timing of the implementation activities over five years and how data collection maps to the RE-AIM framework. Program refinement and online training took place in the first six months (2017). Program dissemination and implementation began in September 2018 and is ongoing. It will be monitored until December 2023. Final data collection (interviews with partners) will occur in December 2023.

Patient and public involvement

At what stage in the research process were patients/the public first involved in the research and how?

Six organisations were formal partners prior to the project being funded. This included a state government department of education and independent schools' peak body, teacher professional development organisations, a principals' association, and a health promotion foundation. As this is an implementation/effectiveness trial designed to scale up a previously efficacious school-based intervention, we engaged closely with these partners in the adaptation of the program for scale up. After funding was secured, these partnerships will continue to be integral to the dissemination and evaluation of this project.

How were the research question(s) and outcome measures developed and informed by their priorities, experience, and preferences?

The research question related to the effectiveness of implementing and scaling up an evidence-based school intervention on children's physical activity and sedentary behaviour, is directly aligned with the policy priorities of the Victorian Department of Education. The Department of Education has *Education State* targets which aim to increase the percentage of children in Victoria meeting physical activity guidelines by 20% by 2025. This alignment was critical in securing partnership with the Department of Education in Victoria.

How were patients/the public involved in the design of this study?

As previously noted, from study inception and through the adaptation process for scale up, we have had input from teachers, teacher professional development organisations (e.g., ACHPER and Peak Phys Ed), as well as key stakeholders such as Local Councils.

How were they involved in the recruitment to and conduct of the study?

Stakeholder partners have actively disseminated the program and assisted with the recruitment of schools and teachers for this study, and some partners have also assisted with implementation of the intervention.

Were they asked to assess the burden of the intervention and time required to participate in the research?

An economic evaluation was conducted in the previous RCT which assessed the burden and time required for teachers to implement the program. Interviews with teachers during a pilot phase prior to the RCT, also informed the number of standing lessons and active breaks per day were feasible for teachers to implement in terms of time requirements. We also pilot tested the feasibility of the program in terms of fitting it into the curriculum with teachers. This evidence was critical for informing the design and adaptations for the current project. Formal partners on the trial were also asked to consider the time required for their involvement in the trial (including any potential burden), as part of the in-kind contributions they provided as a partner organisation.

How were (or will) they be involved in your plans to disseminate the study results the participants and relevant wider patient communities (e.g., by choosing what information/results to share, when, and in what format)?

All stakeholder partners will play a role in dissemination of findings to teachers, schools, and broader audience (e.g., health promotion officers, sport and recreation industry, etc) via a range of communication platforms (e.g., social media, websites, newsletters, email distribution lists) and teacher education professional learning events and opportunities (e.g., seminars, professional learning sessions and conference presentations, keynote addresses, etc).

Data collection

Supplementary File 4 presents the mixed method data to be collected at the partner (state), principal (school), teacher, parent, and child levels, in accordance with the RE-AIM framework. Recruitment and baseline data collection from schools in the effectiveness trial commenced in 2018.

Measures

Reach

Estimation of reach (Supplementary File 4) consists of all teachers and children in registered schools (based on Victorian Department of Education records) who will be classified as potentially exposed to the program. The total number of program recipients (teachers and

children) compared to the total number eligible will represent one measure of potential reach. However, teachers could register and complete the professional development without a school being registered or be included within a participating school but chose not to complete the professional development. Therefore, we will also compare the number of teachers completing the professional development (actual recipients) versus the total number of teachers in Victorian schools (potentially eligible for the professional development) as an additional measure of program reach. The *TransformUs* website will be used to capture the number of teachers registered and if teachers complete the professional development. Unique tracking codes (Google Analytics) associated with different promotional campaigns will contribute to assessing *TransformUs* dissemination.

Effectiveness and individual-level maintenance

The effectiveness trial outcome variables will be assessed at T1 (baseline) and T2 (12-mths) using accelerometers (Supplementary File 4). Primary outcomes include children's average minutes/day of MVPA and sedentary time. Secondary outcomes include children's average weekday MVPA and sedentary time (minutes/day), average minutes/day of MVPA and sedentary during school hours, body mass index z-scores (z-BMI), and waist circumference. Individual-level maintenance will be assessed at T3 (24-mths). Individual-level maintenance is defined as continued benefits among recipients (i.e., sustained increases in MVPA or decreases in sedentary time).

Grades 3 and 4 children's MVPA and sedentary time will be assessed using hip-mounted ActiGraph GT3X+ accelerometers (Pensacola, FL, USA) during waking hours for eight consecutive days (excluding water-based activities). To capture the sporadic nature of children's PA, data will be collected in 5-second epochs, and will be processed using Evenson cut points.(62) Non-wear time is defined as ≥20 minutes of consecutive zeros(63) and a cut-point of 100 counts per minute will be used to indicate sedentary time in children. Primary and secondary outcomes will be computed using only data from days on which a minimum of 8 hours of wear time on weekdays and 7 hours of wear time on weekend days were recorded (valid days). A minimum of 4 valid days (either weekday or weekend) will be required for inclusion in analysis. Inclusion criteria for school days will be accelerometer data for at least 50% of school hours.(64, 65)

Children's height (cm) and waist circumference (cm), and weight (kg) will be assessed twice (to the nearest 0.1cm and 0.1kg respectively) in school at each timepoint by trained research assistants. If the difference between the two measurements is greater than the following thresholds (Height=0.5cm; Waist=1cm; Weight=0.2kg) a third measurement will be taken. An average of the two closest measurements will then be calculated for analyses. Height will be assessed using a portable stadiometer (SECA 220, Los Angeles, California, USA). Weight will be assessed using digital scales (Wedderburn Tanita, Melbourne, Victoria, Australia), and a flexible steel tape will assess waist circumference at the narrowest point between the bottom rib and the iliac crest, in the midaxillary plane. BMI (kg/m^2) z-scores will be calculated by subtracting the sex-age population median BMI scores from children's raw BMI scores.(66)

Additional exploratory outcomes will include children's awareness of the program, and self-reported quality of life,(67) assessed via an online survey at T1 (baseline), T2 (12-months) and T3 (24-months). The EQ-5D-Y-3L questionnaire(68) for children and adolescents aged 8-16 years is an internationally validated English-Australian version of the EQ-5D questionnaire developed by the EuroQol Research Foundation. The Health-Related Quality of Life (HRQoL) section contains five items that capture (on a three-point scale) mobility, independence, usual activity, pain and feelings, and a sixth item that captures the child's perceived overall health rating (sliding scale 0-100) on the day of survey completion. Following EQ-5D-Y-3L scoring protocols, an overall HRQoL score will be created.

Parents will provide via an online survey a proxy-report of their child's physical activity using a validated single item measure assessing compliance with Australian physical activity guidelines.(69)

Adaptations to data collection due to COVID-19 restrictions

The COVID-19 pandemic had a significant impact on data collection resulting in a need to change our protocol (Supplementary File 4). Due to extended COVID-19 lockdowns and government restrictions in Australia, on site data collection in schools was prohibited in Victoria during 2020 and 2021, and in NSW during 2021. During periods when children were able to attend school over that time, accelerometers were sent directly to families, or directly to schools for distributing to students (NSW only), and the child and parent surveys were completed online. Height, weight, and waist circumference data were not collected. Teacher

and principal data (survey and interview) were also not collected to reduce burden on school staff during the challenges of teaching remotely. These adaptations impacted six schools at T2, and 20 schools at T3 in Victoria and two schools at T3 in NSW. Due to differences in lockdown restrictions between the states in 2020, the timing of data collection in NSW was adjusted to match Victoria. As a result, principal/teachers interviews were only conducted at 12-months.

As primary schools in Victoria were unable to operate as normal and ran learning from home for a total of 267 days across 2020 and 2021, additional teacher support was provided so they could apply the pedagogical elements of *TransformUs* to online teaching and learning. This included a remote learning sample pack with active English and Maths lesson ideas that could be delivered online. An online family pack was also provided for parents to help support their child's physical activity at home.

Adoption

All schools in Victoria are eligible to participate in *TransformUs* and therefore the total number of schools in the state (potentially eligible) and the total number who register (actual schools who adopt *TransformUs*) will be used to estimate the adoption rate (Supplementary File 4). The *TransformUs* website will be used to capture the number of schools registered and if the teacher completes the professional development. Partner interviews were due to occur at 12-months, 24-months and 36-months post baseline, however, due to COVID-19 restrictions outlined previously, interviews were conducted at 12-months (September – October 2019) and a final interview will occur at 5 years post baseline (2023).

Implementation

To capture implementation at the school-level (Supplementary File 4), survey and interview data will capture organisational infrastructure and resource availability, organisational readiness, and capacity to implement *TransformUs*, planned implementation, strategies for implementation and perceived impact of the program on children's physical activity, sedentary behaviour and classroom behaviour outcomes, and outcomes at the school level (e.g., change in teaching behaviours). Existing survey measures will be sourced from previous studies of children's physical activity(32, 70, 71) and school-based implementation

(72). Organisational readiness will be assessed using the Organisational Readiness for Implementation Change (ORIC) scale,(73) adapted for the *TransformUs* context.

Interviews with partners (12-months and 5 years post baseline) and principals/teachers (12-months) will be based on the 14 domains of the Theoretical Domains Framework(52) to identify barriers and targeted strategies to enhance teacher and school implementation of the program. In addition, we will use Google Analytics to capture how schools and teachers use the *TransformUs* website, which program components are downloaded, and which aspects of the website are most and least accessed. For parents and children, survey data will capture dose received and perceptions of the program.

Organisational-level maintenance

For the implementation trial, organisational-level maintenance is defined as continued activities by implementers (e.g., adaptation over time, changes in implementation dose, institutionalisation within the school setting and change to policies and practices) and continued capacity within the community (e.g., stakeholder engagement and support for the intervention, and activities over time). Organisational-level maintenance will be assessed via partner self-report and interviews, principal and teacher online surveys/interviews, and parent/child survey data on dose received and perceptions of the program (Supplementary File 4). Google Analytics data will inform on continued use of the *TransformUs* website.

Data analysis

Qualitative data

Qualitative data in this study contributes to assessing all five dimensions of the RE-AIM framework. Qualitative interview data will be transcribed and analysed thematically via NVivo12. Coding and theme development will be firstly deductive, guided by the study aims and RE-AIM domains(74) followed by an inductive approach that will be directed by content of the data.(75) Themes will be grouped against the 14 domains of the TDF.(52) Data will be coded by two independent researchers.

Quantitative data

Survey data for program Reach, Adoption, Implementation, and Organisational-level Maintenance will be reported descriptively. Methods for calculating level of implementation will be based on a previous implementation evaluation of the *TransformUs* efficacy trial (27). In brief, teachers will be grouped by level of implementation based on the proportion of the entire intervention delivered (dose delivered and fidelity). Implementation levels will correspond to: (i) 'low' (<33% of the entire intervention delivered); (ii) 'moderate' (33-67% delivered); and (iii) 'high' (>67% delivered).(27)

Quantitative data: Effectiveness Trial

The effectiveness component of the study will compare primary, secondary and exploratory outcomes among children, between intervention and control schools. Linear mixed models will be fitted to compare mean average daily sedentary time and MVPA at T1 (baseline), T2 (12-mths) and T3 (24-mths) (primary outcomes), average sedentary time and MVPA on weekdays and during school hours, zBMI, waist circumference (secondary outcomes) and quality of life (exploratory outcomes) at 12-months and 24-months between children in intervention and control schools. Linear mixed models will include fixed effects for group (intervention/control), time (months since baseline [time 1]) and a group by time interaction, and random effects for clustering of time nested within children, class and school. In the absence of random assignment, propensity scores will be developed to determine the probability of a child receiving the intervention based on observed baseline covariates (e.g., age, sex, area-level socioeconomic status of residence). Inverse probability of treatment weighting (IPTW) using the propensity score will be adopted to assist in obtaining unbiased

estimates of average treatment effects, although it is acknowledged that this will not control for the difference in location (Victoria or NSW) between intervention and control schools.(76) Due to the impact of COVID interruptions on this study, sensitivity analysis will consider only children who participated in baseline and 12-month follow-up in intervention and control schools to examine the effectiveness prior to home schooling and other COVID impacts.

Descriptive statistics will be calculated for the additional exploratory outcomes: children's perceptions and awareness of the program, at 12-months and 24-months for children in the intervention group, and parent proxy report of their child's physical activity at baseline, 12-months and 24-months in both the control and intervention group. All statistical analyses will be performed using Stata SE v17.

Ethics and dissemination

The trial was approved by the Deakin University human research ethics committee (HEAG-H 28_2017), Victorian Department of Education and Training, the NSW Department of Education, Australian Catholic University (2017-145R) and the relevant Catholic Education Offices. Partners, schools/teachers, and parents will provide informed signed consent prior to taking part in surveys or interviews. Parents will provide consent for their child to participate in assessments as part of the effectiveness trial.

Findings from this trial will be disseminated via peer review publications, scientific conferences, summary reports to schools and our partner organisations. This trial builds on the successful cluster RCT of *TransformUs*.(26) Completion of the *TransformUs* RCT was timely, as in 2016, the Victorian Department of Education released the Education State policy, with a 10-year target to increase the number of children meeting physical activity guidelines on weekdays by 20%.(77) *TransformUs* directly aligns with the policy priorities of Department of Education, and this alignment was critical in securing partnership with Department of Education in Victoria. Establishing how best to scale up this efficacious program will generate important learnings that will inform future research studies in terms of implementation assessment and monitoring of policy uptake, and provide key information for relevant stakeholders wishing to expand similar initiatives.

Contributors

JS, HK, AT, CL, NDR, DL, JDG, AB, AT, LMB, KEL, LA, & HB contributed to the study design. HK led writing of manuscript with JS, and KEL led development of the analysis plan for the effectiveness component. JS, HK, AT, CL, NDR, DL, JDG, AB, AT, LMB, KEL, LA, NL, SL, TS, HB & KW revised the manuscript for intellectual content and read and approved the final draft.

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Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years. This research does not fund schools to implement the program (which is made available at no cost), and no product endorsements are made to schools by the research team for implementation of any aspect of the program. All authors declare no other relationships or activities that could appear to have influenced the submitted work.

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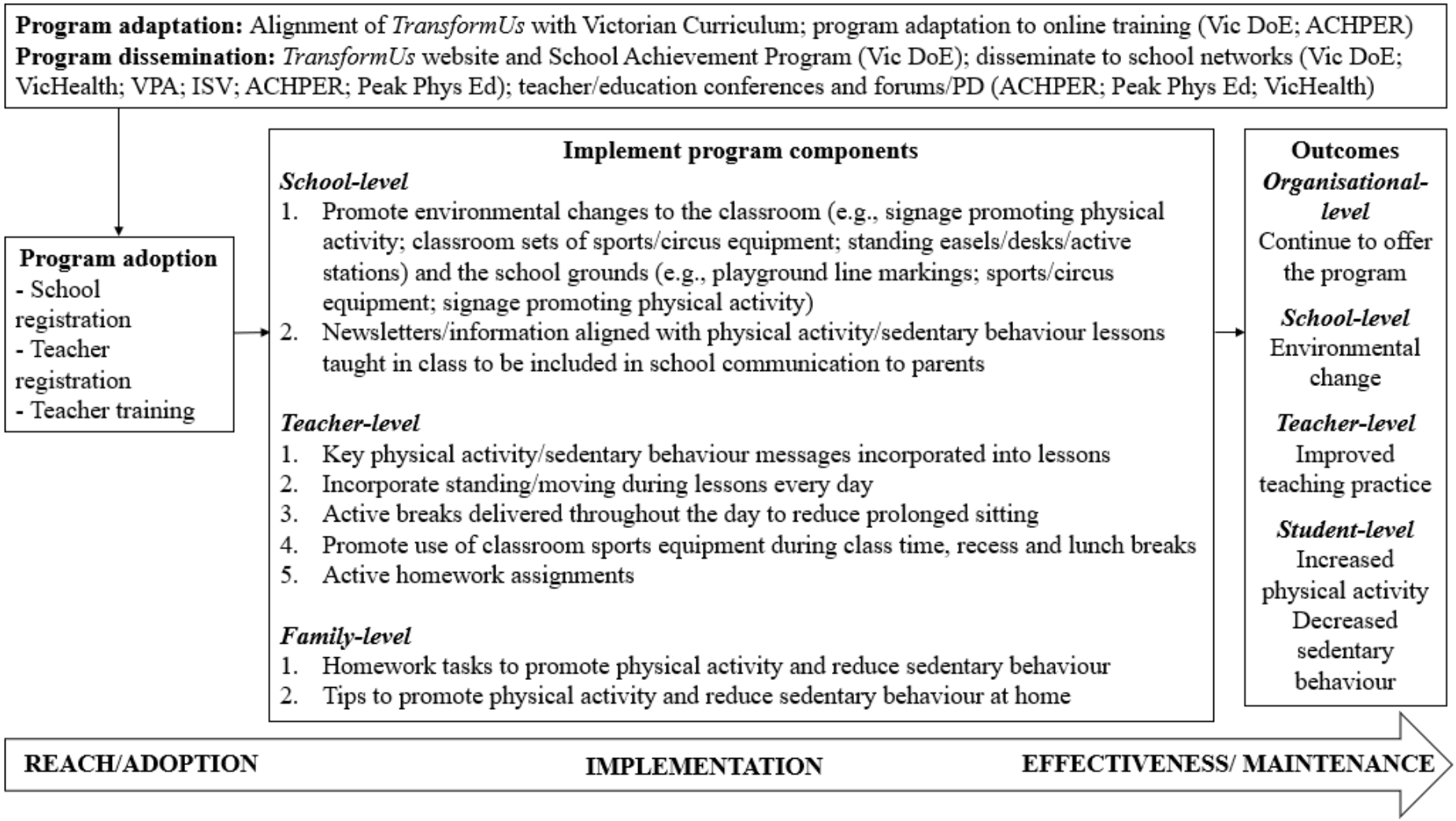
FIGURE TITLES

Figure 1. *TransformUs* program components for scale up

Figure 2. Effectiveness trial participant flow diagram

Figure 3. Implementation trial participant flow diagram

Figure 1. *TransformUs* program components for scale up



Vic DoE = Victorian Department of Education; ACHPER = Australian Council for Health, Physical Education and Recreation; VPA = Victorian Principals Association; ISV = Independent Schools Victoria; PD = Professional Development.

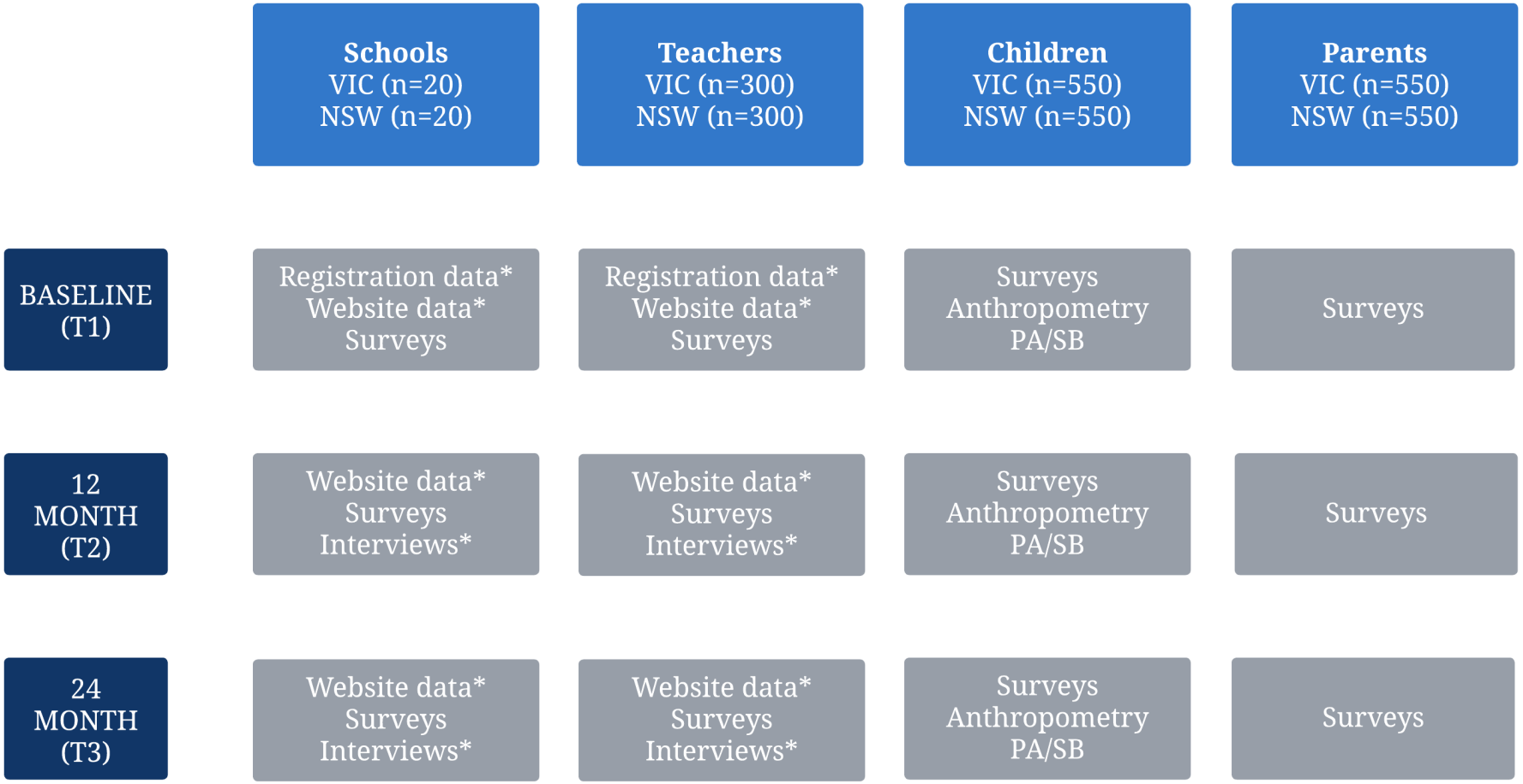


Figure 2. Effectiveness Trial Participant Flow Diagram

*VIC only

VIC= Victoria; NSW = New South Wales; PA = physical activity; SB = sedentary behaviour

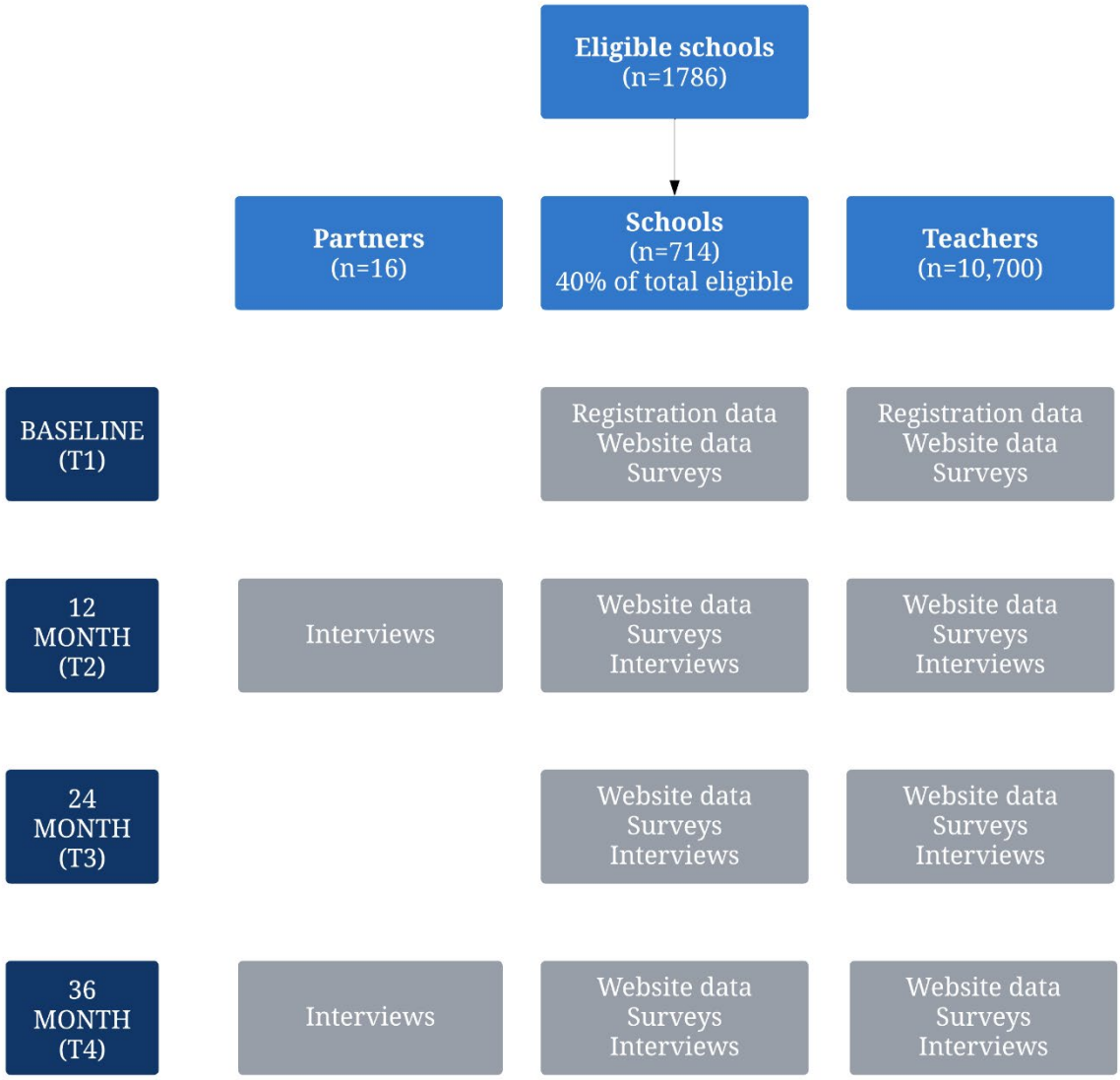
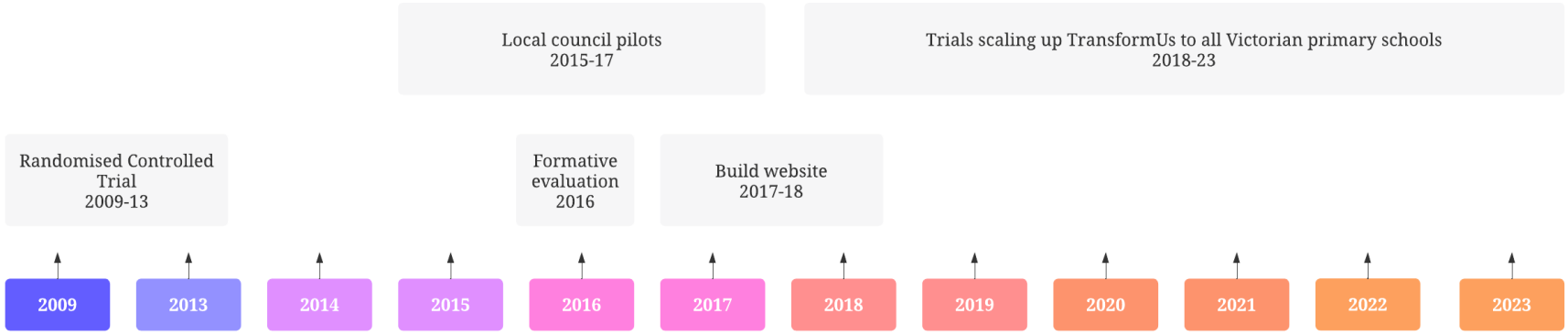


Figure 3. Implementation Trial Participant Flow Diagram

Supplementary File 1. Evolution of *TransformUs* (2009-2023)



Supplementary File 2: *SPIRIT Checklist TransformUs Implementation-Effectiveness Trial*

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Location in manuscript
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	34
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	34
	5b	Name and contact information for the trial sponsor	34
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	34
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4 - 6
	6b	Explanation for choice of comparators	7 - 8

Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	16
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	12
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	13 - 15
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	19 – 25 See Table 1
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figures 2 and 3, Supplementary File 4

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	13 - 15
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	18

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	18
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	26
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	26
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	26
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2 and 27
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	2, 13, 14 and 27
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	26
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	35
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	2 and 27
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Supplementary File 3. *TransformUs* implementation and scale up strategies

#	**Strategy**	**Definition**	**Actors** *(those who deliver imp strategy)*	**Action** *(specific action or process)*	**Action target** *(who its meant to affect)*	**Implementation outcome(s) affected**	**Temporality and dose**	**Justification**
1	**Formative work with stakeholders**	Research-practice partnership to identify strategies, barriers/ facilitators to program dissemination, implementation and sustainability at scale	*TransformUs* research team with State-level partner organisations (support system)	Multiple stakeholder workshops to explore aspects of the support system and delivery context Co-develop resources and strategies for implementation and scale up	State-level partner organisations (system level) School principals and teachers (organisational/ implementer level)	Program reach and adoption, degree of implementation and sustainability	Over 6 months prior to state-wide implementation and scale up	Can enhance implementation by ensuring system level goals and objectives are established and priorities aligned[1], and organisational implementation capacities and structures are considered[2]
2	**Creation of coalitions and networks for program/policy advocacy**	Active engagement with State education decision-makers, engaging opinion leaders (in government and non-government) to support and endorse implementation	State-level partner organisations (support system)	Consultation with key state-level stakeholders and decision makers to align program with state-level targets (e.g. Vic Education State target)	State-level partner organisations (system level) School principals and teachers (delivery system)	State-level program and implementation sustainability Organisational level reach/ adoption	Formal annual/ bi-annual stakeholder meetings Informal pursuit of opportunities over 5 years	Use of existing networks provides ongoing opportunities for training/ program promotion[2]. Formative work suggests promotes legitimacy, and implementation

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
								infrastructure for schools
3	**Utilise multiple dissemination routes/channels**	Program dissemination and promotion will occur via multiple channels known to have high reach among relevant decision-makers	State-level partner organisations (support system) School principals and teachers (delivery system)	Program launch with media involvement. Dissemination via web links, email listservs, newsletters, teacher prof. learning networks, conferences and workshops	*TransformUs* school principals and teachers (delivery system)	Program reach and adoption	Ongoing over 5 years	Multiple dissemination routes can widen scale up reach[2]
4	**Online program training to build implementation capacity**	Teachers required to complete online training prior to gaining access to program materials, implementation resources	*TransformUs* school principals and teachers (delivery system)	Completion of online training provides a unique log-in for access to online resources	*TransformUs* school principals and teachers (delivery system)	Online to maximise reach and adoption Training to enhance implementation (e.g. implementer skills, knowledge, self-efficacy to implement, perceived	~30minutes after registration and prior to accessing program materials. On completed, unlimited access over 5 years	To increase implementation capacity[3], skills, knowledge, self-efficacy, perceived fit with existing practices, relative advantage, and ownership of program[4-6]

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
						relative advantage, fit, ownership and sustainability of delivery)		
5	**Online platform for program materials and training**	All program materials, training, resources and data collection housed within an online platform aimed at schools, teachers and families. Schools and teachers must register to access training and materials	*TransformUs* research team with State-level partner organisations (support system)	Website hosted and maintained by *TransformUs* research team, link disseminated by all partner organisations.	School principals and teachers (delivery system) Parents of children at *TransformUs* schools	Reach, adoption	Ongoing over 5 years	Maximises potential program dissemination/ implementation[7]. Enables more efficient data collection, refinements to materials and resource updates over time
6	**Enable implementation flexibility and contextual adaptation**	Non-prescriptive approach to implementation. Schools and teachers encouraged via training and in resources to adapt program	*TransformUs* research team with State-level partner organisations (support system)	Resources include modifiable lesson plans and 'example' ways of delivering strategies (e.g. active breaks). Training videos	School principals and teachers (delivery system)	Adoption, implementation (e.g. perceived appropriateness, acceptability, feasibility) and sustainability (e.g. org-level	Ongoing over 5 years	Adaptability associated with increased effectiveness/ sustainability of real-world interventions[8]. *TransformUs* RCT showed

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
		strategies for setting relevance		illustrate ways of adapting program to different contexts		program embeddedness)		differences in implementation unrelated to efficacy[9]
7	**Enable both 'top-down' and 'bottom-up' program adoption**	School-level adoption not required for teacher-level implementation. Schools and teachers can register to deliver the program independently	*TransformUs* research team with State-level partner organisations (support system)	Schools and teachers register via the program website. At registration schools encouraged to invite all teachers, and teachers encouraged to advocate for senior leadership support. Parents can advocate for school adoption. Template email invites provided	*TransformUs* school principals, teachers (delivery system) Parents of children at *TransformUs* schools	Reach and adoption	Ongoing over 5 years	Capturing both individual and organisational innovation-decision processes, can elucidate influences on adoption and implementation[10]
8	**Utilise existing resources in the delivery system**	Program strategies can use existing school resources, equipment and	*TransformUs* research team with State-level partner	Program training and resources include ways of using/adapting existing school	*TransformUs* school principals, teachers (delivery system)	Adoption, implementation, sustainability	Ongoing over 5 years	Using existing resources can promote sustainability[2], reducing

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
		facilities where appropriate	organisations (support system)	resources and delivering program within existing schools infrastructure to achieve effective implementation				potential costs for schools to deliver may enhance program uptake (esp. in lower resourced schools)
9	**Development of recognition and incentive system**	Online training mapped against current teaching standards, to contribute towards teachers' annual continuing professional development (CPD) requirements. Schools encouraged to recognise Champion role during staff appraisals	School principals and teachers (delivery system)	Certificate of completion provided after training to evidence CPD hours. Importance/role of champion promoted via online training, downloadable template position description provided for schools	*TransformUs* school principals, teachers (delivery system)	All RE-AIM dimensions	Certificate provided on completion of online training. Champion recruitment determined by school, ongoing over 5 years	Positive incentives may be necessary for widespread adoption and delivery[1]. Formative work identified CPD as an incentive for training completion
10	**Alignment with existing state-**	Program aligned with the	*TransformUs* research team	*TransformUs* included as part	*TransformUs* school	Reach, adoption, implementation	Program aligned with	Interventions which align with

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
	level initiatives and guidelines	Victorian Achievement Program to count towards program physical activity benchmarks for schools. Program materials (e.g. health lessons) aligned with the Victorian Curriculum	with State-level partner organisations (support system)	of Achievement Program materials and promotion. Alignment with Victorian Curriculum promoted via website and in training	principals, teachers (delivery system)		Achievement Program for 3 years as part of planned promotion phase. Alignment to Curriculum guidelines updated as necessary over 5 years	state or national priorities/goals are more likely to gain political/ administrative support required for scale up[2]
11	**Promote use of program champions**	Schools identify champion(s) who advocate for are a point of contact for staff, students and families regarding *TransformUs* implementation	*TransformUs* champion/ teachers (delivery system) State-level partner organisations (support system)	Template champion position description provided to schools after registration. Online training encourages teachers to self-nominate	*TransformUs* school principals, champion/ teachers (delivery system)	Adoption, implementation and sustainability	Promoted to principals and teachers during online training and on website. Ongoing promotion via partner organisations during teacher prof. learning networks, conferences and workshops over 5 years	Champions can encourage the adoption of preventive interventions[11] Formal 'position description' identified in formative work as a strategy to increase legitimacy of role in schools

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
12	**Online implementation support network**	Schools can access an online discussion forum to share implementation strategies and ways of overcoming barriers.	*TransformUs* champion/ teachers (delivery system)	Online discussion forum hosted on the program website, accessible only to registered teachers/schools	*TransformUs* champion/teachers (delivery system)	Adoption, implementation	Ongoing for 5 years	Pilot trials suggested knowledge sharing can increase implementation capacity. Peer networks can increase rates of adoption[11]
13	**Provision of resources to support implementation processes and sustainability**	Providing schools resources and suggested strategies to enhance implementation and sustainability in their setting	*TransformUs* school principals and teachers (delivery system)	Online video clips showing implementation, downloadable resources (e.g. active break strategies) and tools to support embedment (e.g. template school PA policy doc and implementation plan)	*TransformUs* school principals and teachers (delivery system)	Implementation (e.g. skills, knowledge and capacity to implement program) and effectiveness. Institutionalisa-tion within the school	Post registration, available online over 5 years	Increasing general and intervention-specific capacity within support system can enhance implementation[7] and sustainability[12]. Implementation plan can increase accountability[8]
14	**Monitoring and evaluation to adjust scaling strategy,**	Multilevel data (system, organisational, implementer and	*TransformUs* research team and state-level partner	6 monthly monitoring of partner organisations	State-level partner organisations (support system)	State-level sustainability of program promotion	6-monthly monitoring over 5 years	Monitoring and evaluation key to identifying obstacles and

#	Strategy	Definition	Actors *(those who deliver imp strategy)*	Action *(specific action or process)*	Action target *(who its meant to affect)*	Implementation outcome(s) affected	Temporality and dose	Justification
	feedback to support schools	recipient level), on partner organisations. dissemination activities (type, freq. and dose) and setting-level implementation	organisations (support system) School principals and teachers (delivery system)	dissemination activities Recruitment for interviews and surveys embedded within program website Schools submit implementation case studies via website; shared in quarterly newsletters	School principals and teachers (delivery system) Parents of children at *TransformUs* schools	School-level reach, adoption, implementation and organisational level maintenance	Baseline (pre and post online training) and annually thereafter for 5 years Requests for case studies 4 times/year	opportunities to adjust scaling approach[2]. Feedback can increase teacher implementation performance.

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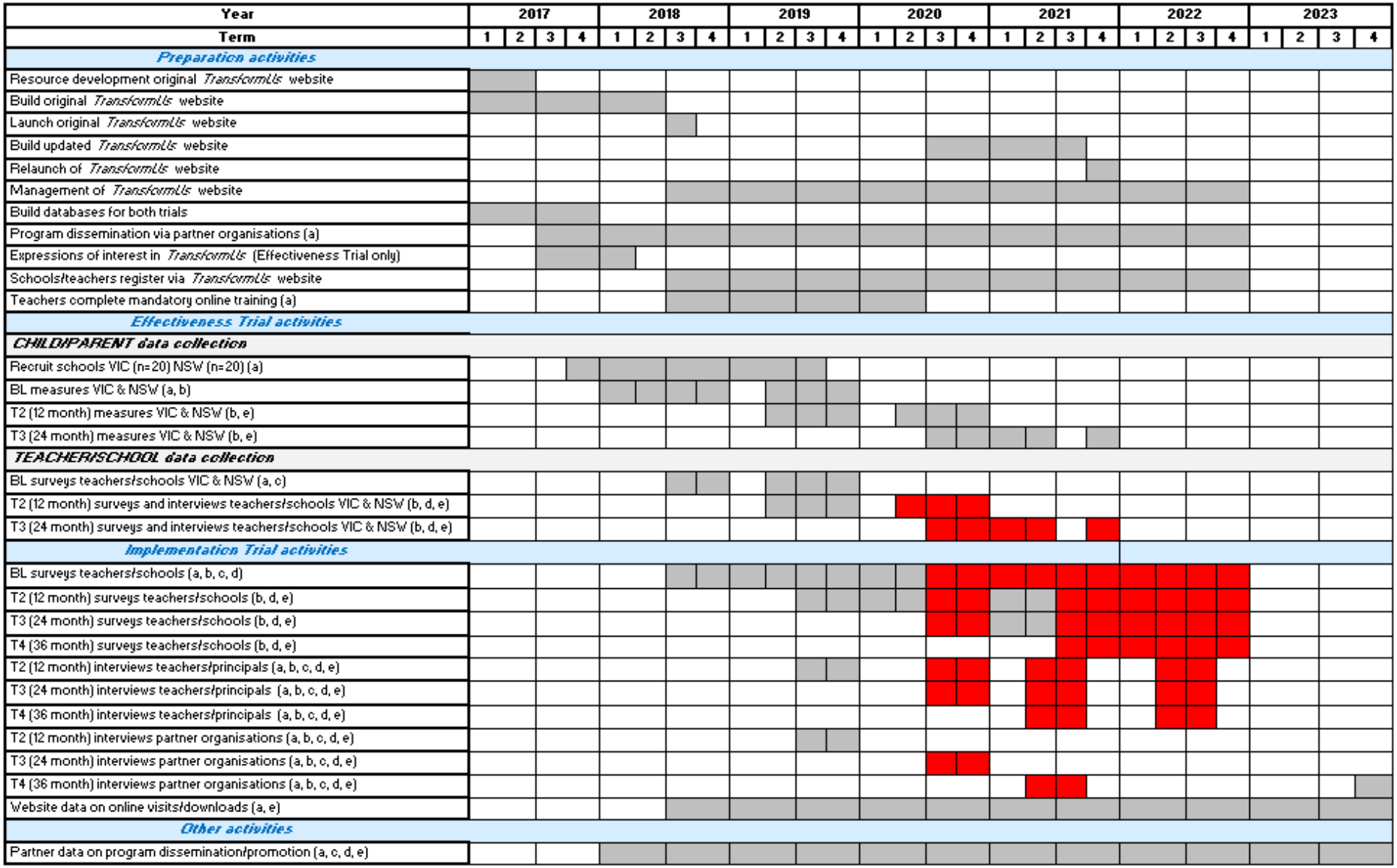
Supplementary File 4. *Project timeline*



(a) Reach; (b) Effectiveness; (c) Adoption; (d) Implementation; (e) Maintenance; BL=Baseline, T2=12 month follow up; T3=24 month follow up; T4=36 month follow up; NSW=New South Wales; VIC=Victoria; Red highlight indicates data could not be collected due to COVID-19 restrictions

Supplementary File 4. RE-AIM evaluation of the *TransformUs* program at scale

RE-AIM Dimension	Assessment criteria			
	Partners/State	**School (Principal)/Teachers**	**Parents***	**Children***
Implementation and Effectiveness trial				
Reach	• No. partners; organisational characteristics (type)[a] • No., frequency and audience for promotional & dissemination activities[a,f,g] • Perceived reach of dissemination strategy[f]	***Teacher-level*** • No. teachers registered and no. completed training[d], and total no. eligible teachers in Victorian schools • Descriptive characteristics teachers; reasons for uptake; program awareness[b]	• No. parents participating in trial[c] • Descriptive characteristics; program awareness[c]	• No. students at participating schools[h] and no. Victorian students eligible
****Effectiveness***	/	/	• Proxy report of child's PA and sedentary time[c]	• Device-assessed PA and sedentary time[e]
Adoption	• Perceived barriers/ facilitators/ reasons for school adoption[f]	***School-level*** • No. schools registered and no. completed training[d] and total no. eligible schools in Victoria[i] • Descriptive characteristics schools; reasons for adoption; program awareness[b]	/	/
Implementation	• Partner role in implementation[f] • Perceived implementation barriers/facilitators[f]	***School-level*** • No. and type of *TransformUs* website visits, program component downloads[d,g] • Organisational infrastructure and resource availability to support implementation[b] • Organisational readiness and capacity to implement *TransformUs* (adapted ORIC scale)[73]; implementation climate[74] (6qu)[b]	• Dose received (no. newsletters, use newsletters)[c]	• Dose received (active lessons, active breaks, homework, health lessons, line markings)[j] • Perceptions of program[j]

		• Implementation strategies; appropriateness, acceptability, barriers, and facilitators to implementation[b] • Perceived impact on school culture (norms, values and beliefs); impact on child[b] ***Teacher-level*** • No. and type of *TransformUs* website visits, no. program component downloads[d] • No., frequency, duration of components (dose delivered), adherence and adaptation (fidelity), feasibility, appropriateness, self-efficacy to implement; satisfaction; barriers/facilitators[b]. • Implementation climate[74] (2qu)[b] • Perceived impact on child behavioural outcomes (time on task, academic outcomes, concentration)[b]		
****Individual-level Maintenance***	/	/	• Proxy report of child's PA and sitting time[c] • Proxy report of impact of active homework (concentration and completion)[c]	• Device-assessed PA and sedentary time[e] • Self-reported PA and sedentary time[j]
Organisational-level Maintenance	• No. partners; organisational characteristics (type)[a] • No., frequency and audience for promotional and dissemination activities[a,f,g] • Perceived reach of dissemination strategy[f] • Perceived barriers/facilitators to program maintenance in	***School-level*** • Intention to continue[b] • No. and type of *TransformUs* website visits, program component downloads[g] • Organisational infrastructure and resource availability to support implementation[b] • Organisational readiness and capacity to implement *TransformUs* (adapted ORIC scale)[73]; implementation climate[74] (6qu)[b]	• Program awareness; continued support[c]	• Dose received (active lessons, active breaks, homework, health lessons, line markings)[j] • Perceptions of program[j]

	schools; continued program support[f]	• Implementation strategies; appropriateness, acceptability, barriers and facilitators to implementation[b] ***Teacher-level*** • Intention to continue[b] • No. and type of *TransformUs* website visits, no. program component downloads[g] • No., frequency, duration of components (dose delivered), adherence and adaptation (fidelity), feasibility, appropriateness, self-efficacy to implement, satisfaction; barriers/facilitators[b] • Implementation climate[74](2qu)[b]		

No. = number; [a]Partner self-report; [b]School/teacher survey/interview; [c]Parent survey; [d]TransformUs website [e]ActiGraph accelerometers; [f]Partner interviews; [g]Google Analytics; [h]Australian Bureau of Statistics data; [i]My Schools data (https://www.myschool.edu.au/); [j]Child survey. PA: physical activity. *****Asterisk indicates Effectiveness trial only and data are collected at baseline, 12-months and 24-months follow up.