

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [info.bmjopen@bmj.com](mailto:info.bmjopen@bmj.com)

# BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2023-078410
Article Type:	Protocol
Date Submitted by the Author:	01-Aug-2023
Complete List of Authors:	<p>Koorts, Harriet ; Deakin University Institute for Physical Activity and Nutrition  Timperio, Anna; Deakin University Institute for Physical Activity and Nutrition  Lonsdale, Chris; Australian Catholic University, Institute for Positive Psychology and Education  Ridgers, Nicola D.; Deakin University Institute for Physical Activity and Nutrition; University of South Australia  Lubans, David; The University of Newcastle, Centre for Active Living and Learning; The University of Newcastle Hunter Medical Research Institute  Della Gatta, Jacqui; Deakin University Institute for Physical Activity and Nutrition  Bauman, Adrian; The University of Sydney School of Public Health  Telford, Amanda; Australian Catholic University, National School of Education  Barnett, Lisa; Deakin University, School of Health &amp; Social Development  Lamb, Karen; The University of Melbourne - Parkville Campus, School of Population and Global Health  Lander, Natalie; Deakin University Institute for Physical Activity and Nutrition  Lai, Samuel K.; Deakin University Institute for Physical Activity and Nutrition  Sanders, Taren; Australian Catholic University, Institute for Positive Psychology and Education  Arundell, Lauren; Deakin University Institute for Physical Activity and Nutrition  Brown, Helen; Deakin University Institute for Physical Activity and Nutrition  Wilhite, Katrina; Australian Catholic University, Institute for Positive Psychology and Education,  Salmon, Jo; Deakin University Institute for Physical Activity and Nutrition</p>
Keywords:	Schools, PUBLIC HEALTH, Community child health < PAEDIATRICS

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



1  
2  
3 1 **Scaling up a school-based intervention to increase physical activity and reduce**  
4 **sedentary behaviour in children: Protocol of the *TransformUs* hybrid effectiveness-**  
5 **implementation trial**  
6  
7  
8

9  
10 4 Harriet Koorts<sup>1</sup>, Anna Timperio<sup>1</sup>, Chris Lonsdale<sup>2</sup>, Nicola D. Ridgers<sup>1,3</sup>, David Lubans<sup>4,5,6</sup>,  
11 5 Jacqueline Della Gatta<sup>1</sup>, Adrian Bauman<sup>7</sup>, Amanda Telford<sup>8</sup>, Lisa M. Barnett<sup>9</sup>, Karen E.  
12 6 Lamb<sup>10</sup>, Natalie Lander<sup>1</sup>, Samuel K. Lai<sup>1</sup>, Taren Sanders<sup>2</sup>, Lauren Arundell<sup>1</sup>, Helen Brown<sup>1</sup>,  
13 7 Katrina Wilhite<sup>2</sup>, Jo Salmon<sup>1</sup>  
14  
15  
16

17 8 **Journal:** BMJ Open  
18

19  
20 9 <sup>1</sup>Deakin University, Geelong, Institute for Physical Activity and Nutrition, School of Exercise  
21 and Nutrition Sciences, VIC 3216, Australia  
22

23  
24 11 <sup>2</sup>Institute for Positive Psychology and Education, Australian Catholic University, North  
25 Sydney, NSW 2060, Australia  
26  
27

28  
29 13 <sup>3</sup>Alliance for Research in Exercise, Nutrition and Activity (ARENA), Allied Health and  
30 Human Performance, University of South Australia, Adelaide, South Australia 5001,  
31 Australia  
32  
33

34 16 <sup>4</sup>Centre for Active Living and Learning, College of Human and Social Futures, University of  
35 Newcastle, Callaghan, New South Wales, Australia  
36  
37

38  
39 18 <sup>5</sup>Hunter Medical Research Institute, New Lambton Heights, NSW 2305, Australia  
40

41 19 <sup>6</sup>Faculty of Sport and Health Sciences, University of Jyväskylä, Jyväskylä, Finland.  
42

43  
44 20 <sup>7</sup>School of Public Health, University of Sydney, Sydney, NSW 2006, Australia  
45

46 21 <sup>8</sup>Australian Catholic University, National School of Education, VIC 3065, Australia  
47

48 22 <sup>9</sup>Deakin University, Geelong, Institute for Physical Activity and Nutrition, School of Health  
49 and Social Development, VIC 3125, Australia  
50

51  
52 24 <sup>10</sup>Melbourne School of Population and Global Health, University of Melbourne, VIC 3053,  
53 Australia  
54  
55

56 26 **Correspondence to:** Harriet Koorts, Deakin University, 221 Burwood Highway, Burwood,  
57 VIC 3125, Australia. Email: [h.koorts@deakin.edu.au](mailto:h.koorts@deakin.edu.au)  
58  
59  
60

## 28 **Abstract**

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

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

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

57 **Trial Registration:** Australian Clinical Trials Registration Number:  
58 ACTRN12617000204347

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

1  
2  
3 60 **Strengths and limitations of this study**  
4

- 5 61 • Strengths include the hybrid effectiveness-implementation trial design undertaken in a  
6  
7 62 real-world context, the inclusion of multiple levels of data collected at multiple time  
8  
9 63 points, and the use of robust frameworks to guide implementation and scale up.  
10  
11 64 Device-based measurement of children’s physical activity and sedentary time in the  
12  
13 65 effectiveness trial strengthens study findings.  
14  
15 66 • Testing the hypothesised mediating and/or moderating relationships, such as  
16  
17 67 organisational readiness for change, with implementation and effectiveness outcomes  
18  
19 68 will help understand primary barriers to, and facilitators of, implementation of school-  
20  
21 69 based interventions, such as *TransformUs*.  
22  
23 70 • Limitations include reliance on teacher self-reported implementation of the program.  
24  
25 71 However, additional implementation data will be captured using Google Analytics  
26  
27 72 (e.g., use of the *TransformUs* website, professional development completed by  
28  
29 73 teachers, and which program resources are downloaded).  
30  
31 74 • Facilitation of program dissemination activities via stakeholders and the research team  
32  
33 75 may not reflect true real-world promotion, but will highlight practices required for  
34  
35 76 sustainable scale up.  
36  
37 77 • Extended COVID-19 lockdowns and government restrictions in Australia meant on-  
38  
39 78 site data collection in schools was prohibited in Victoria between 2020 and April  
40  
41 79 2023, and in NSW during 2021. This resulted in a need to revise the study protocols.  
42  
43 80 Nevertheless, the conduct of both an implementation and effectiveness trial will  
44  
45 81 enable us to compare differences between schools to ascertain the level of  
46  
47 82 implementation, ‘real world’ program impact, and generalisability of results.  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## 84 Introduction

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

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

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

1  
2  
3 117 to reduce prolonged sitting both at school and home among children.<sup>24</sup> The initial  
4  
5 118 *TransformUs* program<sup>25</sup> was one of the earliest programs (developed in 2009) to incorporate  
6  
7 119 many of these elements with a particular focus on reducing and breaking up children's sitting  
8  
9 120 throughout the school day.

10  
11 121 The efficacy of the initial *TransformUs* program was demonstrated in a 4-arm two-by-two  
12  
13 122 factorial design cluster-randomised controlled trial (RCT) involving 20 primary (elementary)  
14  
15 123 schools, 226 teachers and over 1,600 children in Melbourne, Australia (2010-13).<sup>25</sup> The three  
16  
17 124 intervention arms targeted either increases in physical activity (PA-I), reductions in sedentary  
18  
19 125 behaviour (SB-I), or a combination of both (PA+SB I), compared to a usual practice control.  
20  
21 126 At 18-months (n=348), compared to usual practice, children who received the physical  
22  
23 127 activity intervention (groups PA-I and PA+SB I) had significantly less weekday sedentary  
24  
25 128 time (-27 mins/day). Children who received the sedentary behaviour intervention (SB-I and  
26  
27 129 PA+SB I) spent more time in daily physical activity (5.5 mins/day) at 18-months, and at 30-  
28  
29 130 months spent 33 mins less in daily sedentary time, and specifically, 63 mins less in sedentary  
30  
31 131 time on weekdays, compared to usual practice.<sup>25</sup> Thus strategies to promote both children's  
32  
33 132 physical activity and reduce sedentary behaviour were important. Results also showed  
34  
35 133 beneficial effects on children's adiposity markers (body mass index [BMI] and waist  
36  
37 134 circumference [n=564]). However, there were mixed effects on children's blood pressure  
38  
39 135 ([BP] positive effects on systolic BP and negative effects on diastolic BP [n=537]) and in a  
40  
41 136 sub-sample of children (n=206), on blood parameters (e.g., negative effects on some  
42  
43 137 inflammatory markers such as CRP, IL-6, IL-2 and TNF- $\alpha$ , beneficial effects on vitamin D,  
44  
45 138 BDNF, and PAI-1).<sup>26</sup>

46  
47 139 Teachers, parents and children reported that the program was positively received, and  
48  
49 140 teachers involved in the intervention arms also reported perceptions of better classroom  
50  
51 141 management and improved 'on-task' behaviour during lessons.<sup>27</sup> Although barriers to  
52  
53 142 implementation were experienced (including a lack of school leadership to support  
54  
55 143 implementation long-term, promotion and awareness raising, teacher time constraints, and  
56  
57 144 challenges with sustained integration into existing practices), overall, the program was  
58  
59 145 effectively integrated into the school curriculum.<sup>27</sup> Existing teaching practices, children's  
60  
146 enjoyment, and teacher awareness of program values and benefits were the main facilitators  
147  
148 of delivery and sustainability.<sup>27</sup> Following the success of *TransformUs*, and exploration of  
149  
149 adaptations for scaling (described in Methods section), the Victorian Department of  
Education (DoE) committed to partnering with the research team to support the dissemination



1  
2  
3 150 and implementation of the program to all primary (elementary) schools in Victoria, Australia.  
4  
5 151 Given the small number of school-based interventions that are studied at scale<sup>28</sup> and that use  
6  
7 152 implementation theories to guide this process;<sup>29, 30</sup> scaling up of *TransformUs* presented a  
8  
9 153 unique opportunity to investigate real-world implementation at scale. Assessment of  
10  
11 154 intervention implementation among school-based interventions is greatly needed in the  
12  
13 155 field.<sup>18</sup>

14 156 This paper describes the study protocol for a five-year trial (launched September 2018 - final  
15  
16 157 data collection December 2023), which aims to evaluate the real-world effectiveness and  
17  
18 158 implementation of *TransformUs* at scale. To note, the paper outlines the *intended* protocol for  
19  
20 159 the trial (including planned dates and timelines for data collection), but also describes where  
21  
22 160 and how this *changed* due to the impacts of the COVID-19 global pandemic. In line with the  
23  
24 161 RE-AIM framework criteria,<sup>31</sup> we will evaluate the following five aims: the program's **Aim**  
25  
26 162 **1: Reach** (proportion and representativeness of Principals and teachers, parents and children  
27  
28 163 participating in *TransformUs*); **Aim 2: Effectiveness** (change in children's daily physical  
29  
30 164 activity and sedentary time 12- and 24-months post-baseline); **Aim 3: Adoption** (proportion  
31  
32 165 and representativeness of schools choosing to implement *TransformUs*); **Aim 4:**  
33  
34 166 *Implementation* (dissemination by education and health partners, uptake of intervention  
35  
36 167 components, frequency, dose and adaptation to *TransformUs* delivery, and barriers and  
37  
38 168 enablers to implementation); and **Aim 5: Individual-level Maintenance** (change in children's  
39  
40 169 physical activity and sedentary time 24-months post baseline) and *Organisational-level*  
41  
42 170 *Maintenance* (institutionalisation and sustainability of the program within the education and  
43  
44 171 health systems, school settings and by teachers as part of routine practice).

42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## 173 **Methods and analysis**

### 174 **Overview of the *TransformUs* program**

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

1  
2  
3 182 Ecological Systems Theory.<sup>35</sup> The health lessons, active academic lessons and active breaks  
4 are all aligned with the Victorian<sup>36</sup> and Australian curriculum and standards.<sup>37</sup> All  
5 183  
6 184 *TransformUs* components are contained in the members' area of the website  
7  
8 185 (<https://transformus.com.au>). To access these resources, Victorian primary school teachers  
9  
10 186 need to register (at no cost) using their work email address. A detailed description of the  
11  
12 187 program strategies<sup>32</sup> and program logic model have been published elsewhere.<sup>27</sup> Adaptations  
13  
14 188 to the *TransformUs* program for scale up are described later in Methods section, and  
15  
16 189 Supplementary File 1 presents the evolution of *TransformUs* since the original RCT (2009) to  
17  
18 190 date.

191

## 192 **Study design**

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

197

## 198 **Implementation trial**

199 Every primary school in Victoria (government, independent and Catholic) will be offered  
200 *TransformUs*, and will be eligible for inclusion in the state-wide implementation trial. Our  
201 objective is for the program to be adopted by at least 715 primary schools (40% of a total of  
202 1,786 primary schools in Victoria<sup>40</sup>) by the end of the trial. The adoption estimates are based  
203 on school uptake of state-wide initiatives offered by the Victorian DoE and previous  
204 implementation trials in schools.<sup>41</sup> As *TransformUs* dissemination will be ongoing over 5-  
205 years, schools can register anytime between September 2018 and December 2022. Data are  
206 planned to be collected from schools and teachers who agree to participate in the evaluation  
207 at baseline (T1), 12-months (T2), 24-months (T3) and 36-months (T4) post registration;  
208 within the funding time period (September 2018 - December 2022). These data will  
209 contribute to assessing reach, adoption, implementation, and organisational-level  
210 maintenance (Aims 1, 3, 4 and 5).

211

## 212 **Effectiveness trial**

1  
2  
3 213 To determine short- and long-term changes in children's levels of physical activity and  
4 214 sedentary time under 'real world' conditions (based on adaptations from the original  
5 215 *TransformUs* program described below), an embedded effectiveness trial is planned with 20  
6 216 intervention schools in Victoria and 20 control schools in the state of New South Wales  
7 217 (NSW). A quasi-experimental pre-post non-equivalent group design<sup>42</sup> with follow-up will be  
8 218 adopted. As this is a real-world roll-out in Victoria, a non-randomised two-group parallel arm  
9 219 approach was adopted. Data collected at baseline (T1), 12-months (T2), and 24-months (T3)  
10 220 will contribute to assessing program effectiveness and maintenance at the student level (Aims  
11 221 2 and 5). Schools in NSW were considered suitable controls as NSW has a similar population  
12 222 size and geographic spread to Victoria compared to other states and territories, and the  
13 223 *TransformUs* program was not available in NSW.  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24

### 25 225 **Program adaptation and piloting**

26 226 The *TransformUs* RCT showed that strategies to promote children's physical activity and  
27 227 reduce sedentary behaviour were both important,<sup>26</sup> and therefore the combined (PA+SB I)  
28 228 approach was the focus for wider scale up. During the RCT, teacher Professional  
29 229 Development (PD) was delivered face-to-face by the research team, and schools received  
30 230 ongoing support from the team over the 2.5 years of the study. This approach was not  
31 231 considered feasible for scale up. To facilitate scale up, PD, support, and all program materials  
32 232 and resources were converted into an online format to maximise potential reach at a lower  
33 233 cost. Formative evaluation with partners responsible for implementing interventions at scale  
34 234 can also be useful to inform adaptations to the intended dissemination strategy and refine the  
35 235 program materials to enhance scalability.<sup>43</sup> Therefore, in close partnership with local councils  
36 236 (from Local Government Areas) and teachers, the *TransformUs* online materials were tested  
37 237 in two pilot dissemination trials and formative evaluation was conducted with key partner  
38 238 organisations involved in scale up, detailed in the following section.  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49

### 50 239 51 52 240 ***TransformUs* pilot dissemination trials (2015-17)**

53 241 Two 12-month pilot dissemination trials were conducted during July 2015-16 (pilot trial 1;  
54 242 n=4 schools, n=41 teachers) and 2017 (pilot trial 2; n=5 schools, 22 teachers), to assess the  
55 243 feasibility of *TransformUs* dissemination and the online teacher PD. In both pilots, the  
56 244 program was advertised to schools via two councils (representing two different Local  
57  
58  
59  
60

1  
2  
3 245 Government Areas) in Victoria. The costs of program equipment (e.g., standing easels, sports  
4 246 equipment) and installation of playground line markings (e.g., hopscotch) were subsidised by  
5 247 the councils to support uptake. Schools located in a lower income area were offered a greater  
6 248 subsidy than schools in a higher income area (determined using the Schools in a Socio-  
7 249 Economic Indexes for Areas [SEIFA]; methods consistent with the original RCT).<sup>44</sup> All  
8 250 teachers within participating pilot schools were asked to, preferably, complete the online PD  
9 251 (lasting 30-45 minutes) during a session on their school site that was facilitated by a  
10 252 representative from the relevant council. As this was to inform the real-world dissemination  
11 253 trial and to help understand the feasibility of online PD, schools could also send a nominated  
12 254 teacher and adopt a train-the-trainer approach.

13 255 Teachers completed online surveys pre- and post- the PD session, 2-months and 12-months  
14 256 post-baseline (max n=51 teachers; Pilot trial 1), and at 4-months post-baseline (n=22  
15 257 teachers; Pilot trial 2). Most teachers reported that they: (1) gained new knowledge of ways to  
16 258 increase children's physical activity (88%) and reduce sedentary behaviour (90%) at school;  
17 259 (2) learnt new teaching methods (78%); (3) perceived the online training to be an appropriate  
18 260 delivery method (82%); and (4) gained the required knowledge (90%) and confidence (80%)  
19 261 to implement the program. Teachers requested visual examples of program implementation  
20 262 (i.e., digital video clips), which they felt would strengthen teacher engagement and sustained  
21 263 delivery of the program. Although the RCT focused on children in Grades 3-5 (ages 8-11  
22 264 years), in both pilot trials, participating schools planned a whole-of-school approach to  
23 265 implementation across all school year levels, Foundation to Grade 6 (ages 5-12 years). For  
24 266 scale up, program materials were modified to accommodate delivery across all year levels,  
25 267 covering a range of learning areas (e.g., mathematics, English, science and humanities), and  
26 268 digital video clips were developed to demonstrate appropriate implementation.

27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49

### 270 ***Formative evaluation with key partner organisations (2016)***

50 271 Through an integrated research-practice partnership approach, collaboration began with one  
51 272 government (Victorian State government DoE) and six non-government organisations (the  
52 273 Victorian Health Promotion Foundation [VicHealth], the Victorian Principals Association,  
53 274 Independent Schools Victoria, the Australian Council for Health, Physical Education and  
54 275 Recreation Victoria [ACHPER], and Peak Phys Ed). These partners play various roles in the  
55 276 education and health systems including, for example, responsibility for delivery of education  
56 277 to children and young people in Victorian government and independent schools (e.g., DoE),

1  
2  
3 278 and coordinating and delivering teacher education professional development (e.g., ACHPER  
4 and Peak Phys Ed). In collaboration, these partners will provide ongoing input into the state-  
5 279 wide dissemination strategy, ensuring that the program aligns with other existing school-  
6 280 based health promotion initiatives in the state (e.g., the Victorian Achievement Program,  
7 281 which aims to create healthier early childhood services, schools and workplaces;  
8 282 <http://www.achievementprogram.health.vic.gov.au/>), and that all resources (e.g., health  
9 283 lessons) are linked to the Victorian Curriculum and each resource identifies the specific  
10 284 Strand, Sub-strand, Content Description and Achievement Standard. For example,  
11 285 *TransformUs* supports the development of student capabilities (e.g., Critical and Creative  
12 286 Thinking, Personal and Social capabilities), which are taught explicitly in and through the  
13 287 learning area resources. *TransformUs* also provides cross-curriculum opportunities for  
14 288 students to strengthen their literacy and numeracy general capabilities.  
15 289  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27

## 28 **291 Implementation and scale up of *TransformUs***

### 29 **30 Theoretical underpinnings**

31 293 Our approach to scale up is ‘horizontal’, defined as extending the reach of an intervention by  
32 294 replicating it in other localities, cities or states.<sup>45</sup> Our implementation approach is derived  
33 295 from evidence-based recommendations for the successful scalability of population-level  
34 296 health interventions,<sup>43, 46, 47</sup> and concepts within the translation, support and delivery systems  
35 297 of the Interactive Systems Framework.<sup>48</sup> We draw on ways to improve implementation and  
36 298 sustainability as outlined in the Quality Implementation Framework,<sup>49</sup> PRACTIS Guide,<sup>43</sup>  
37 299 and from literature on ways to increase public health program sustainability.<sup>50</sup> To identify  
38 300 underlying barriers and facilitators to individual-level implementation, qualitative data  
39 301 collection will be informed by the Theoretical Domains Framework,<sup>51</sup> which is a systematic  
40 302 and theoretically based approach to behaviour change that identifies barriers to practice  
41 303 change and potential strategies to intervene. The RE-AIM framework<sup>31</sup> informs the  
42 304 overarching evaluation outcomes following implementation and scale up.  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54

### 55 **306 Implementation and scale up strategies**

56 307 In addition to findings from the *TransformUs* pilot adaptation studies described above, scale  
57 308 up strategies were also guided by literature on strategies for effective implementation and  
58 309 scale up planning<sup>43, 45</sup> and attributes of successful scale up (i.e., compatibility of the program  
59  
60

1  
2  
3 310 with the values and facilities of intended users, and perceived need for the innovation within  
4 311 the organisation).<sup>52</sup> Supplementary File 2 presents the 14 *TransformUs* implementation and  
5 312 scale up strategies, reported in line with recommendations and definitions for specifying  
6 313 implementation strategies.<sup>53</sup>

7  
8  
9  
10 314 Our focus is on implementation *quality* as opposed to controlling rigorous program fidelity  
11 315 that is essential in efficacy trials. In school-based intervention implementation, ‘quality’ can  
12 316 include: (i) sufficient exposure (dose); (ii) fidelity to the program protocol; (iii)  
13 317 implementation (engaging students through active participation); (iv) adaptation (modifying  
14 318 the intervention to meet developmental and cultural needs); and (v) teachers' attitudes,  
15 319 understanding of the concepts/issues and prior experience.<sup>54</sup> In *TransformUs*, schools were  
16 320 encouraged to choose contextually relevant strategies for implementation at their school,  
17 321 rather than a prescriptive program, to enhance quality and ensure program adoption occurs in  
18 322 the most contextually relevant way to achieve health benefits. This approach is associated  
19 323 with increased effectiveness of real-world interventions and those more likely to produce  
20 324 sustainable results.<sup>49</sup>

21 325 In the context of *TransformUs*, we will be creating an implementation infrastructure for  
22 326 schools via DoE endorsement, provision of sustainability resources (i.e., template policy  
23 327 statements for schools to embed the program), and active engagement with State education  
24 328 decision-makers and other non-government partner organisations. Implementation resources  
25 329 will also be provided to support and encourage school level leadership to implement the  
26 330 program, and provide recommendations to promote integration and sustainability (i.e.,  
27 331 *TransformUs* champion roles and responsibilities, a template policy document).

28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43 332

### 44 333 ***TransformUs* program for scale up**

45 334 Figure 1 presents the *TransformUs* program components for scale up. Based on outcomes  
46 335 from the two pilot trials and formative work with our partner organisations and to maximise  
47 336 program reach, all supporting program materials, implementation and training resources are  
48 337 available online via a program website. The website (<https://transformus.com.au/>) is managed  
49 338 by the research team at Deakin University. Teachers are required to complete the mandatory  
50 339 online PD via the *TransformUs* website. The PD provides strategies to integrate and sustain  
51 340 implementation of the program in schools, and thus is essential to ensure minimum standards  
52 341 and knowledge are established prior to program delivery. Based on evidence for the

1  
2  
3 342 determinants of effective implementation by adopting individuals (users, i.e., teachers),<sup>55, 56</sup>  
4  
5 343 the content of the PD program has been designed to address the following seven key areas: (i)  
6  
7 344 *support for implementation* (teacher and school level); (ii) *skills required for implementation*;  
8  
9 345 (iii) *knowledge required for implementation*; (iv) *self-efficacy to implement*; (v) *fit of the*  
10  
11 346 *program into existing practices*; (vi) *relative advantage of the intervention over existing*  
12  
13 347 *practices*; and (vii) *perceived ownership of the program* (allowing for adaptation). For  
14  
15 348 example, the PD includes ways of embedding the program in practice, such as development  
16  
17 349 of a tailored implementation plan (i.e., a checklist of activities teachers wish to undertake and  
18  
19 350 how they plan to sustain delivery), and knowledge reflection (quizzes) to test learning.

20  
21 351 Multiple dissemination routes will be used to maximise program uptake and sustainability  
22  
23 352 (e.g., via our partners, through sharing the web link, email lists, social media, teacher  
24  
25 353 professional learning networks, and teacher professional development conferences and  
26  
27 354 workshops). Interactions with stakeholders will include face-to-face or online meetings (e.g.,  
28  
29 355 approximately two group meetings per year in addition to regular one-on-one meetings), and  
30  
31 356 the provision of dissemination materials and communication packs to stakeholders, to enable  
32  
33 357 them to promote *TransformUs* via their existing social media platforms and newsletters.

34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

359 **Figure 1.** *TransformUs* program components for scale up

360 >> INSERT FIGURE 1 HERE<<

361

## 362 **Recruitment**

### 363 ***Implementation trial: Partners (state level)***

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

371

1  
2  
3 372 ***Implementation Trial: Principals (school level) and teachers***  
4

5  
6 373 Schools and teachers will be made aware of *TransformUs* via multiple dissemination routes  
7  
8 374 (as described in section ‘***TransformUs program for scale up***’). All schools and teachers who  
9  
10 375 wish to adopt *TransformUs* register free of charge via the *TransformUs* website, and teachers  
11  
12 376 can register to access the *TransformUs* program regardless of whether their school (i.e.,  
13  
14 377 principal) has registered. This is to allow for both top-down and bottom-up program  
15  
16 378 adoption. To access the PD, registration is mandatory. Upon registration, a unique login  
17  
18 379 username for each teacher/school will be generated, which they can use to revisit the website  
19  
20 380 and access the PD and online resources. During registration, schools/teachers will be invited  
21  
22 381 to participate in the survey component of the Implementation Trial, where they will receive a  
23  
24 382 plain language statement and online consent form.

25  
26 383 The registration process collects information about where they heard about the program,  
27  
28 384 general physical activity policy and practice information for their school (e.g., information on  
29  
30 385 participation in additional physical activity programs will also be collected), and which  
31  
32 386 elements of the *TransformUs* program their school plans to implement. There are no costs to  
33  
34 387 access the online resources. Implementation schools wishing to install new playground line  
35  
36 388 markings or purchase physical activity equipment will not receive funding from the research  
37  
38 389 project to do so. To help minimise the financial investment required, information on how to  
39  
40 390 best utilise existing playground line markings and physical activity equipment is provided  
41  
42 391 online.

43  
44 392 We plan to reach 714 schools (based on an estimate of 40% of the total number of schools in  
45  
46 393 Victoria<sup>40</sup>; n =1,786). As part of the Implementation Trial, we aim to recruit ~15 school  
47  
48 394 leaders who registered for the survey evaluation component of *TransformUs* to participate in  
49  
50 395 a qualitative interview about their experiences of adopting and implementing the program.  
51  
52 396 This sample size provides sufficient ‘information power’.<sup>58</sup> Whilst schools/teachers will  
53  
54 397 provide online consent to participate in the survey component of the implementation trial at  
55  
56 398 the point of *TransformUs* registration, the sub sample of participants invited to complete and  
57  
58 399 interview will be required to provide additional consent prior to the interview commencing.

59 400

56 401 ***Effectiveness trial: Schools and teachers***

58  
59 402 Twenty schools in Victoria will be recruited using stratified non-random sampling to  
60  
403 maximise area-level socioeconomic position and geographic location. Targeted recruitment



1  
2  
3 404 of twenty control schools in NSW will be matched as much as possible (based on school size,  
4 405 type [e.g., Government, Catholic and Independent), SEIFA index (a measure of socio-  
5 406 economic advantage and disadvantage by area in Australia), geographical area [e.g., rural,  
6 407 remote], single sex/mixed students), with schools enrolled in the effectiveness trial in  
7 408 Victoria. Schools will represent different socioeconomic urban and rural areas, including  
8 409 different types, based on a minimum of two Grade 3 classes or four composite classes (i.e.,  
9 410 Grade 3 and 4 classes combined).

11  
12  
13  
14  
15  
16 411

17  
18 412 ***Effectiveness trial: Children and parents***

19  
20 413 Grades 3 and 4 children attending schools enrolled in the effectiveness schools (and their  
21 414 parents) will be invited to help assess the effectiveness of the program. Children will be in  
22 415 Grades 3 or 4 at baseline with a planned follow up at 12-months and 24-months. Parents will  
23 416 receive information about the study via the schools' regular methods of communication (e.g.,  
24 417 school intranet system, email, text) and an information brochure sent home with the students.  
25 418 There will be a plain language statement and consent form for parents to provide consent for  
26 419 themselves and/or their child to participate in the assessments (e.g., parent online survey,  
27 420 child MVPA, body mass index and waist circumference). As part of the consent process,  
28 421 parents/guardians will provide contact details (email and mobile telephone), which will be  
29 422 used to email a unique link to an online parent survey at each time point and to communicate  
30 423 with parents about the wearing and return of data collection devices from their child. Three  
31 424 emails or texts will be sent over six weeks to remind parents to complete the survey.

32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42 425

43  
44 426 Figures 2 and 3 present flow diagrams of participant recruitment into the Effectiveness and  
45 427 Implementation trials, respectively.

46  
47  
48  
49 428

50 429 **Figure 2.** Effectiveness trial participant flow diagram

51 430 >> INSERT FIGURE 2 HERE<<

52  
53  
54 431

55  
56 432 **Figure 3.** Implementation trial participant flow diagram

57  
58 433 >> INSERT FIGURE 3 HERE <<

434

**435 Sample size and power**

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

457

**458 Inclusion and exclusion criteria: Implementation trial**

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

464

**465 Inclusion and exclusion criteria: Effectiveness trial**

1  
2  
3 466 Schools that participated in the 2010-2013 *TransformUs* RCT and 2015-2017 pilot trials will  
4  
5 467 be excluded from the sample frame for the effectiveness trial. Special schools for children  
6  
7 468 with a disability (defined by the school) and schools with less than 30 students across both  
8  
9 469 Grades 3 and 4 will also be excluded to ensure that there is sufficient power to test the  
10  
11 470 effectiveness of the program among students (n=20 schools, 550 students from VIC versus  
12  
13 471 n=20 schools and 550 students from NSW) and parents. A matrix containing the names and  
14  
15 472 types of all Victorian primary schools will be used for sampling, to ensure a range of  
16  
17 473 government, independent and Catholic schools from inner city, outer suburban and regional  
18  
19 474 areas are approached for recruitment. To be eligible as a control school in NSW, the school  
20  
21 475 should not be implementing a similar health or physical activity-related program at baseline  
22  
23 476 data collection. Any uptake of similar programs was monitored at each time point. For  
24  
25 477 pragmatic and cost-related reasons, schools need to be located within a 4-hour drive from  
26  
27 478 Deakin University (Burwood, Victoria) or Australian Catholic University (North Sydney,  
28  
29 479 NSW).

480

### 481 **Program dissemination and implementation timeline**

31 482 Supplementary File 3 shows the timing of the implementation activities over five years and  
32  
33 483 how data collection maps to the RE-AIM framework. Program refinement and online training  
34  
35 484 took place in the first six months (2017). Program dissemination and implementation began  
36  
37 485 in September 2018 and is ongoing. It will be monitored until December 2023. Final data  
38  
39 486 collection (interviews with partners) will occur in December 2023.

487

### 488 **Patient and Public Involvement**

45 489 *At what stage in the research process were patients/the public first involved in the research*  
46  
47 490 *and how?*

49 491 Six organisations were formal partners prior to the project being funded. This included a state  
50  
51 492 government department of education and independent schools' peak body, teacher  
52  
53 493 professional development organisations, a principals' association, and a health promotion  
54  
55 494 foundation. As this is an implementation/effectiveness trial designed to scale up a previously  
56  
57 495 efficacious school-based intervention, we engaged closely with these partners in the  
58  
59 496 adaptation of the program for scale up. After funding was secured, these partnerships will  
60  
497 continue to be integral to the dissemination and evaluation of this project.

1  
2  
3 498 *How were the research question(s) and outcome measures developed and informed by their*  
4  
5 499 *priorities, experience, and preferences?*  
6  
7

8 500 The research question related to the effectiveness of implementing and scaling up an  
9  
10 501 evidence-based school intervention on children's physical activity and sedentary behaviour,  
11  
12 502 is directly aligned with the policy priorities of the Victorian DoE. The DoE has *Education*  
13  
14 503 *State* targets which aim to increase the percentage of children in Victoria meeting physical  
15  
16 504 activity guidelines by 20% by 2025. This alignment was critical in securing partnership with  
17  
18 505 the DoE in Victoria.

19 506 *How were patients/the public involved in the design of this study?*  
20  
21

22 507 As previously noted, from study inception and through the adaptation process for scale up,  
23  
24 508 we have had input from teachers, teacher Professional Development organisations (e.g.,  
25  
26 509 ACHPER and Peak Phys Ed), as well as key stakeholders such as Local Councils.

27  
28 510 *How were they involved in the recruitment to and conduct of the study?*  
29  
30

31 511 Stakeholder partners have actively disseminated the program and assisted with the  
32  
33 512 recruitment of schools and teachers for this study, and some partners have also assisted with  
34  
35 513 implementation of the intervention.

36  
37  
38 514 *Were they asked to assess the burden of the intervention and time required to participate in*  
39  
40 515 *the research?*  
41

42 516 An economic evaluation was conducted in the previous RCT which assessed the burden and  
43  
44 517 time required for teachers to implement the program. Interviews with teachers during a pilot  
45  
46 518 phase prior to the RCT, also informed the number of standing lessons and active breaks per  
47  
48 519 day were feasible for teachers to implement in terms of time requirements. We also pilot  
49  
50 520 tested the feasibility of the program in terms of fitting it into the curriculum with teachers.  
51  
52 521 This evidence was critical for informing the design and adaptations for the current project.  
53  
54 522 Formal partners on the trial were also asked to consider the time required for their  
55  
56 523 involvement in the trial (including any potential burden), as part of the in-kind contributions  
57  
58 524 they provided as a partner organisation.  
59  
60

1  
2  
3 525 *How were (or will) they be involved in your plans to disseminate the study results the*  
4 526 *participants and relevant wider patient communities (e.g., by choosing what*  
5 527 *information/results to share, when, and in what format)?*  
6  
7  
8

9 528 All stakeholder partners will play a role in dissemination of findings to teachers, schools, and  
10 529 broader audience (e.g., health promotion officers, sport and recreation industry, etc) via a  
11 530 range of communication platforms (e.g., social media, websites, newsletters, email  
12 531 distribution lists) and teacher education professional learning events and opportunities (e.g.,  
13 532 seminars, professional learning sessions and conference presentations, keynote addresses,  
14 533 etc).  
15  
16  
17  
18  
19

20 534  
21  
22

### 23 535 **Data Collection**

24  
25 536 Table 1 presents the mixed method data to be collected at the partner (state), principal  
26 537 (school), teacher, parent, and child levels, in accordance with the RE-AIM framework.  
27 538 Recruitment and baseline data collection from schools in the effectiveness trial commenced  
28 539 in 2018.  
29  
30  
31  
32

33 540  
34

### 35 541 **Measures**

#### 36 542 **Reach**

37  
38  
39 543 Estimation of reach (Table 1) consists of all teachers and children in registered schools (based  
40 544 on Victorian DoE records) who will be classified as potentially exposed to the program. The  
41 545 total number of program recipients (teachers and children) compared to the total number  
42 546 eligible will represent one measure of potential reach. However, teachers could register and  
43 547 complete PD without a school being registered or be included within a participating school  
44 548 but chose not to complete PD. Therefore, we will also compare the number of teachers  
45 549 completing PD (actual PD recipients) versus the total number of teachers in Victorian schools  
46 550 (potentially eligible for PD) as an additional measure of program reach. The *TransformUs*  
47 551 website will be used to capture the number of teachers registered and if teachers complete the  
48 552 PD. Unique tracking codes (Google Analytics) associated with different promotional  
49 553 campaigns will contribute to assessing *TransformUs* dissemination.  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59

60 554

## 555 **Effectiveness and individual-level maintenance**

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

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

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

1  
2  
3 586 Additional exploratory outcomes will include children's awareness of the program, and self-  
4 587 reported quality of life,<sup>65</sup> assessed via an online survey at T1 (baseline), T2 (12-months) and  
5 588 T3 (24-months). The EQ-5D-Y-3L questionnaire<sup>66</sup> for children and adolescents aged 8-16  
6 589 years is an internationally validated English-Australian version of the EQ-5D questionnaire  
7 590 developed by the EuroQol Research Foundation. The Health-Related Quality of Life  
8 591 (HRQoL) section contains five items that capture (on a three-point scale) mobility,  
9 592 independence, usual activity, pain and feelings, and a sixth item that captures the child's  
10 593 perceived overall health rating (sliding scale 0-100) on the day of survey completion.  
11 594 Following EQ-5D-Y-3L scoring protocols, an overall HRQoL score will be created.  
12  
13 595 Parents will provide via an online survey a proxy-report of their child's physical activity  
14 596 using a validated single item measure assessing compliance with Australian physical activity  
15 597 guidelines.<sup>67</sup>  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26

### 27 599 ***Adaptations to data collection due to COVID-19 restrictions***

28  
29 600 The COVID-19 pandemic had a significant impact on data collection resulting in a need to  
30 601 change our protocol (Supplementary File 3). Due to extended COVID-19 lockdowns and  
31 602 government restrictions in Australia, on site data collection in schools was prohibited in  
32 603 Victoria during 2020 and 2021, and in NSW during 2021. During periods when children were  
33 604 able to attend school over that time, accelerometers were sent directly to families, or directly  
34 605 to schools for distributing to students (NSW only), and the child and parent surveys were  
35 606 completed online. Height, weight, and waist circumference data were not collected. Teacher  
36 607 and principal data (survey and interview) were also not collected to reduce burden on school  
37 608 staff during the challenges of teaching remotely. These adaptations impacted six schools at  
38 609 T2, and 20 schools at T3 in Victoria and two schools at T3 in NSW. Due to differences in  
39 610 lockdown restrictions between the states in 2020, the timing of data collection in NSW was  
40 611 adjusted to match Victoria. As a result, principal/teachers interviews were only conducted at  
41 612 12-months.  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51

52 613 As primary schools in Victoria were unable to operate as normal and ran learning from home  
53 614 for a total of 267 days across 2020 and 2021, additional teacher support was provided so they  
54 615 could apply the pedagogical elements of *TransformUs* to online teaching and learning. This  
55 616 included a remote learning sample pack with active English and Maths lesson ideas that could  
56  
57  
58  
59  
60

1  
2  
3 617 be delivered online. An online family pack was also provided for parents to help support their  
4  
5 618 child's physical activity at home.

6  
7 619

## 8 9 620 **Adoption**

10  
11 621 All schools in Victoria are eligible to participate in *TransformUs* and therefore the total  
12  
13 622 number of schools in the state (potentially eligible) and the total number who register (actual  
14  
15 623 schools who adopt *TransformUs*) will be used to estimate the adoption rate (Table 1). The  
16  
17 624 *TransformUs* website will be used to capture the number of schools registered and if the  
18  
19 625 teacher completes the PD. Partner interviews were due to occur at 12-months, 24-months and  
20  
21 626 36-months post baseline, however, due to COVID-19 restrictions outlined previously,  
22  
23 627 interviews were conducted at 12-months (September – October 2019) and a final interview  
24  
25 628 will occur at 5 years post baseline (2023).

26  
27 629

## 28 29 630 **Implementation**

30  
31 631 To capture implementation at the school-level (Table 1), survey and interview data will  
32  
33 632 capture organisational infrastructure and resource availability, organisational readiness, and  
34  
35 633 capacity to implement *TransformUs*, planned implementation, strategies for implementation  
36  
37 634 and perceived impact of the program on children's physical activity, sedentary behaviour and  
38  
39 635 classroom behaviour outcomes, and outcomes at the school level (e.g., change in teaching  
40  
41 636 behaviours). Existing survey measures will be sourced from previous studies of children's  
42  
43 637 physical activity<sup>32, 68, 69</sup> and school-based implementation<sup>70</sup>. Organisational readiness will be  
44  
45 638 assessed using the Organisational Readiness for Implementation Change (ORIC) scale,<sup>71</sup>  
46  
47 639 adapted for the *TransformUs* context.

48  
49 640

50  
51 641 Interviews with partners (12-months and 5 years post baseline) and principals/teachers (12-  
52  
53 642 months) will be based on the 14 domains of the Theoretical Domains Framework<sup>51</sup> to  
54  
55 643 identify barriers and targeted strategies to enhance teacher and school implementation of the  
56  
57 644 program. In addition, we will use Google Analytics to capture how schools and teachers use  
58  
59 645 the *TransformUs* website, which program components are downloaded, and which aspects of  
60  
61 646 the website are most and least accessed. For parents and children, survey data will capture  
62  
63 647 dose received and perceptions of the program.



1  
2  
3 648  
45 649 **Organisational-level maintenance**

6  
7 650 For the implementation trial, organisational-level maintenance is defined as continued  
8  
9 651 activities by implementers (e.g., adaptation over time, changes in implementation dose,  
10  
11 652 institutionalisation within the school setting and change to policies and practices) and  
12  
13 653 continued capacity within the community (e.g., stakeholder engagement and support for the  
14  
15 654 intervention, and activities over time). Organisational-level maintenance will be assessed via  
16  
17 655 partner self-report and interviews, principal and teacher online surveys/interviews, and  
18  
19 656 parent/child survey data on dose received and perceptions of the program (Table 1). Google  
20  
21 657 Analytics data will inform on continued use of the *TransformUs* website.

22 658

23  
24 659  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

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

RE-AIM Dimension	Assessment criteria			
	Partners/State	School (Principal)/Teachers	Parents*	Children*
<b>Implementation and Effectiveness trial</b>				
<b>Reach</b>	<ul style="list-style-type: none"> <li>No. partners; organisational characteristics (type)<sup>a</sup></li> <li>No., frequency and audience for promotional &amp; dissemination activities<sup>a,f,g</sup></li> <li>Perceived reach of dissemination strategy<sup>f</sup></li> </ul>	<u><b>Teacher-level</b></u> <ul style="list-style-type: none"> <li>No. teachers registered and no. completed training<sup>d</sup>, and total no. eligible teachers in Victorian schools</li> <li>Descriptive characteristics teachers; reasons for uptake; program awareness<sup>b</sup></li> </ul>	<ul style="list-style-type: none"> <li>No. parents participating in trial<sup>c</sup></li> <li>Descriptive characteristics; program awareness<sup>c</sup></li> </ul>	<ul style="list-style-type: none"> <li>No. students at participating schools<sup>h</sup> and no. Victorian students eligible</li> </ul>
<b>*Effectiveness</b>	/	/	<ul style="list-style-type: none"> <li>Proxy report of child's PA and sedentary time<sup>c</sup></li> </ul>	<ul style="list-style-type: none"> <li>Device-assessed PA and sedentary time<sup>e</sup></li> </ul>
<b>Adoption</b>	<ul style="list-style-type: none"> <li>Perceived barriers/facilitators/ reasons for school adoption<sup>f</sup></li> </ul>	<u><b>School-level</b></u> <ul style="list-style-type: none"> <li>No. schools registered and no. completed training<sup>d</sup> and total no. eligible schools in Victoria<sup>i</sup></li> <li>Descriptive characteristics schools; reasons for adoption; program awareness<sup>b</sup></li> </ul>	/	/
<b>Implementation</b>	<ul style="list-style-type: none"> <li>Partner role in implementation<sup>f</sup></li> <li>Perceived implementation barriers/facilitators<sup>f</sup></li> </ul>	<u><b>School-level</b></u> <ul style="list-style-type: none"> <li>No. and type of <i>TransformUs</i> website visits, program component downloads<sup>d,g</sup></li> <li>Organisational infrastructure and resource availability to support implementation<sup>b</sup></li> <li>Organisational readiness and capacity to implement <i>TransformUs</i> (adapted ORIC scale)<sup>71</sup>; implementation climate<sup>72</sup> (6qu)<sup>b</sup></li> </ul>	<ul style="list-style-type: none"> <li>Dose received (no. newsletters, use newsletters)<sup>c</sup></li> </ul>	<ul style="list-style-type: none"> <li>Dose received (active lessons, active breaks, homework, health lessons, line markings)<sup>j</sup></li> <li>Perceptions of program<sup>i</sup></li> </ul>

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

		<ul style="list-style-type: none"> <li>• Implementation strategies; appropriateness, acceptability, barriers, and facilitators to implementation<sup>b</sup></li> <li>• Perceived impact on school culture (norms, values and beliefs); impact on child<sup>b</sup></li> </ul> <p><b><i>Teacher-level</i></b></p> <ul style="list-style-type: none"> <li>• No. and type of <i>TransformUs</i> website visits, no. program component downloads<sup>d</sup></li> <li>• No., frequency, duration of components (dose delivered), adherence and adaptation (fidelity), feasibility, appropriateness, self-efficacy to implement; satisfaction; barriers/facilitators<sup>b</sup>.</li> <li>• Implementation climate<sup>72</sup> (2qu)<sup>b</sup></li> <li>• Perceived impact on child behavioural outcomes (time on task, academic outcomes, concentration)<sup>b</sup></li> </ul>		
<b><i>*Individual-level Maintenance</i></b>	/	/	<ul style="list-style-type: none"> <li>• Proxy report of child’s PA and sitting time<sup>c</sup></li> <li>• Proxy report of impact of active homework (concentration and completion)<sup>c</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Device-assessed PA and sedentary time<sup>e</sup></li> <li>• Self-reported PA and sedentary time<sup>j</sup></li> </ul>
<b><i>Organisational-level Maintenance</i></b>	<ul style="list-style-type: none"> <li>• No. partners; organisational characteristics (type)<sup>a</sup></li> <li>• No., frequency and audience for promotional and dissemination activities<sup>a,f,g</sup></li> <li>• Perceived reach of dissemination strategy<sup>f</sup></li> <li>• Perceived barriers/facilitators to program maintenance in</li> </ul>	<p><b><i>School-level</i></b></p> <ul style="list-style-type: none"> <li>• Intention to continue<sup>b</sup></li> <li>• No. and type of <i>TransformUs</i> website visits, program component downloads<sup>g</sup></li> <li>• Organisational infrastructure and resource availability to support implementation<sup>b</sup></li> <li>• Organisational readiness and capacity to implement <i>TransformUs</i> (adapted ORIC scale)<sup>71</sup>; implementation climate<sup>72</sup> (6qu)<sup>b</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Program awareness; continued support<sup>c</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Dose received (active lessons, active breaks, homework, health lessons, line markings)<sup>j</sup></li> <li>• Perceptions of program<sup>j</sup></li> </ul>

	schools; continued program support <sup>f</sup>	<ul style="list-style-type: none"> <li>• Implementation strategies; appropriateness, acceptability, barriers and facilitators to implementation<sup>b</sup></li> </ul> <p><b><u>Teacher-level</u></b></p> <ul style="list-style-type: none"> <li>• Intention to continue<sup>b</sup></li> <li>• No. and type of <i>TransformUs</i> website visits, no. program component downloads<sup>g</sup></li> <li>• No., frequency, duration of components (dose delivered), adherence and adaptation (fidelity), feasibility, appropriateness, self-efficacy to implement, satisfaction; barriers/facilitators<sup>b</sup></li> <li>• Implementation climate<sup>72(2qu)</sup><sup>b</sup></li> </ul>		
--	---	--	--	--

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

## 663 **Data Analysis**

### 664 **Qualitative data**

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

671

### 672 **Quantitative data**

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

680

#### 681 *Quantitative data: Effectiveness Trial*

682 The effectiveness component of the study will compare primary, secondary and exploratory  
683 outcomes among children, between intervention and control schools. Linear mixed models  
684 will be fitted to compare mean average daily sedentary time and MVPA at T1 (baseline), T2  
685 (12-mths) and T3 (24-mths) (primary outcomes), average sedentary time and MVPA on  
686 weekdays and during school hours, zBMI, waist circumference (secondary outcomes) and  
687 quality of life (exploratory outcomes) at 12-months and 24-months between children in  
688 intervention and control schools. Linear mixed models will include fixed effects for group  
689 (intervention/control), time (months since baseline [time 1]) and a group by time interaction,  
690 and random effects for clustering of time nested within children, class and school. In the  
691 absence of random assignment, propensity scores will be developed to determine the  
692 probability of a child receiving the intervention based on observed baseline covariates (e.g.,  
693 age, sex, area-level socioeconomic status of residence). Inverse probability of treatment  
694 weighting (IPTW) using the propensity score will be adopted to assist in obtaining unbiased  
695 estimates of average treatment effects, although it is acknowledged that this will not control

1  
2  
3 696 for the difference in location (Victoria or NSW) between intervention and control schools.<sup>75</sup>  
4  
5 697 Due to the impact of COVID interruptions on this study, sensitivity analysis will consider  
6  
7 698 only children who participated in baseline and 12-month follow-up in intervention and  
8  
9 699 control schools to examine the effectiveness prior to home schooling and other COVID  
10  
11 700 impacts.

12 701  
13 702 Descriptive statistics will be calculated for the additional exploratory outcomes: children's  
14  
15 703 perceptions and awareness of the program, at 12-months and 24-months for children in the  
16  
17 704 intervention group, and parent proxy report of their child's physical activity at baseline, 12-  
18  
19 705 months and 24-months in both the control and intervention group. All statistical analyses will  
20  
21 706 be performed using Stata SE v17.

22 707

### 23 24 708 **Ethics and Dissemination**

25  
26 709 The trial was approved by the Deakin University human research ethics committee (HEAG-H  
27  
28 710 28\_2017), Victorian Department of Education and Training, the NSW Department of  
29  
30 711 Education, Australian Catholic University (2017-145R) and the relevant Catholic Education  
31  
32 712 Offices. Findings from this trial will be disseminated via peer review publications, scientific  
33  
34 713 conferences, summary reports to schools and our partner organisations. This trial builds on  
35  
36 714 the successful cluster RCT of *TransformUs*.<sup>25</sup> Completion of the *TransformUs* RCT was  
37  
38 715 timely, as in 2016, the Victorian DoE released the Education State policy, with a 10-year  
39  
40 716 target to increase the number of children meeting physical activity guidelines on weekdays by  
41  
42 717 20%.<sup>76</sup> *TransformUs* directly aligns with the policy priorities of DoE, and this alignment was  
43  
44 718 critical in securing partnership with DoE in Victoria. Establishing how best to scale up this  
45  
46 719 efficacious program will generate important learnings that will inform future research studies  
47  
48 720 in terms of implementation assessment and monitoring of policy uptake, and provide key  
49  
50 721 information for relevant stakeholders wishing to expand similar initiatives.

51 722

### 52 723 **References**

- 53  
54  
55 724 1. Tambalis, K.D. and L.S. Sidossis, *Physical Activity and Cardiometabolic Health*  
56  
57 725 *Benefits in Children*, in *Cardiorespiratory Fitness in Cardiometabolic Diseases:*  
58  
59 726 *Prevention and Management in Clinical Practice*, P. Kokkinos and P. Narayan,  
60 727 Editors. 2019, Springer International Publishing: Cham. p. 405-423.

- 1  
2  
3 728 2. Biddle, S.J.H., et al., *Physical activity and mental health in children and adolescents:*  
4 729 *An updated review of reviews and an analysis of causality.* Psychology of Sport and  
5 730 Exercise, 2019. **42**: p. 146-155.
- 6  
7  
8 731 3. Singh, A.S., et al., *Effects of physical activity interventions on cognitive and academic*  
9 732 *performance in children and adolescents: a novel combination of a systematic review*  
10 733 *and recommendations from an expert panel.* Br J Sports Med, 2019. **53**(10): p. 640-  
11 734 647.
- 12  
13  
14 735 4. Watson, A., et al., *Effect of classroom-based physical activity interventions on*  
15 736 *academic and physical activity outcomes: A systematic review and meta-analysis.*  
16 737 International Journal of Behavioral Nutrition and Physical Activity, 2017. **14**(1).
- 17  
18  
19 738 5. Schmidt, M., V. Benzing, and M. Kamer, *Classroom-Based Physical Activity Breaks*  
20 739 *and Children's Attention: Cognitive Engagement Works!* Front Psychol, 2016. **7**: p.  
21 740 1474.
- 22  
23  
24 741 6. Minges, K.E., et al., *Classroom Standing Desks and Sedentary Behavior: A*  
25 742 *Systematic Review.* Pediatrics, 2016. **137**(2): p. 1-18.
- 26  
27  
28 743 7. Tremblay, M.S., et al., *Sedentary Behavior Research Network (SBRN) – Terminology*  
29 744 *Consensus Project process and outcome.* International Journal of Behavioral Nutrition  
30 745 and Physical Activity, 2017. **14**(1): p. 75.
- 31  
32  
33 746 8. Chaput, J.P., et al., *2020 WHO guidelines on physical activity and sedentary*  
34 747 *behaviour for children and adolescents aged 5–17 years: summary of the evidence.*  
35 748 International Journal of Behavioral Nutrition and Physical Activity, 2020. **17**(1): p.  
36 749 141.
- 37  
38  
39 750 9. Dornhecker, M., et al., *The Effect of Stand-biased Desks on Academic Engagement:*  
40 751 *An Exploratory Study.* Int J Health Promot Educ, 2015. **53**(5): p. 271-280.
- 41  
42  
43 752 10. Welfare., A.I.o.H.a., *Australia's health 2022.* 2022, Canberra: AIHW.
- 44  
45  
46 753 11. Health., D.o., *Physical activity and exercise guidelines for all Australians.* 2021:  
47 754 Canberra: Australia.
- 48  
49  
50 755 12. Ridgers, N.D., et al., *Agreement between activPAL and ActiGraph for assessing*  
51 756 *children's sedentary time.* Int J Behav Nutr Phys Act, 2012. **9**: p. 15.
- 52  
53  
54 757 13. Ridgers, N.D., et al., *Five-year changes in school recess and lunchtime and the*  
55 758 *contribution to children's daily physical activity.* Br J Sports Med, 2012. **46**(10): p.  
56 759 741-6.
- 57  
58  
59  
60

- 1  
2  
3 760 14.  
4  
5 761 <https://www.education.vic.gov.au/school/teachers/teachingresources/disciplin>  
6 [e/physed/Pages/activeschoolstoolkit.aspx](https://www.education.vic.gov.au/school/teachers/teachingresources/disciplin). [cited 2022 11 August].  
7 762  
8 763 15. Prevention, C.f.D.C.a., *Comprehensive School Physical Activity Programs: A Guide*  
9 *for Schools*. Retrieved from Atlanta, GA: . 2013, Department of Health and Human  
10 764 Services: Atlanta, GA: U.S.  
11 765  
12 766 16. Lai, S.K., et al., *Do school-based interventions focusing on physical activity, fitness,*  
13 *or fundamental movement skill competency produce a sustained impact in these*  
14 *outcomes in children and adolescents? A systematic review of follow-up studies.*  
15 767  
16 768 *Sports Med*, 2014. **44**(1): p. 67-79.  
17 769  
18 770 17. Hegarty, L.M., et al., *School-based Interventions to Reduce Sedentary Behaviour in*  
19 *Children: A Systematic Review*. *AIMS Public Health*, 2016. **3**(3): p. 520-541.  
20 771  
21 772 18. Love, R., J. Adams, and E.M.F. van Sluijs, *Are school-based physical activity*  
22 *interventions effective and equitable? A meta-analysis of cluster randomized*  
23 *controlled trials with accelerometer-assessed activity.* *Obesity Reviews*, 2019. **20**(6):  
24 773  
25 774 p. 859-870.  
26 775  
27 776 19. Koorts, H., et al., *Is level of implementation linked with intervention outcomes?*  
28 *Process evaluation of the TransformUs intervention to increase children's physical*  
29 *activity and reduce sedentary behaviour.* *Int J Behav Nutr Phys Act*, 2022. **19**(1): p.  
30 777  
31 778 122.  
32 779  
33 780 20. Lonsdale, C., et al., *A systematic review and meta-analysis of interventions designed*  
34 *to increase moderate-to-vigorous physical activity in school physical education*  
35 *lessons.* *Prev Med*, 2013. **56**(2): p. 152-61.  
36 781  
37 782  
38 783 21. Parrish, A.M., et al., *Interventions to Change School Recess Activity Levels in*  
39 *Children and Adolescents: A Systematic Review and Meta-Analysis.* *Sports Med*,  
40 784  
41 785 2020. **50**(12): p. 2145-2173.  
42 786  
43 786 22. Escalante, Y., et al., *Playground designs to increase physical activity levels during*  
44 *school recess: a systematic review.* *Health Educ Behav*, 2014. **41**(2): p. 138-44.  
45 787  
46 788 23. Santos, F., et al., *School-Based Family-Oriented Health Interventions to Promote*  
47 *Physical Activity in Children and Adolescents: A Systematic Review.* *Am J Health*  
48 789  
49 790 Promot, 2023. **37**(2): p. 243-262.  
50 791  
51 792 24. Hinckson, E., et al., *Standing Classrooms: Research and Lessons Learned from*  
52 *Around the World.* *Sports Med*, 2016. **46**(7): p. 977-87.  
53  
54  
55  
56  
57  
58  
59  
60



- 1  
2  
3 793 25. Salmon, J., et al., *Transform-Us! cluster RCT: 18-month and 30-month effects on*  
4 794 *children's physical activity, sedentary time and cardiometabolic risk markers*. British  
5 795 *Journal of Sports Medicine*, 2023. **57**(5): p. 311-319.
- 6  
7  
8 796 26. Salmon, J., et al., *The Transform-Us! cluster RCT: 18- and 30-month effects on*  
9 797 *children's physical activity, sedentary time and cardiometabolic risk markers*. Under  
10 798 *Review*, 2022.
- 11  
12  
13 799 27. Koorts, H., et al., *Is implementation linked with outcomes? Process evaluation of the*  
14 800 *Transform-Us! intervention to increase children's physical activity and reduce*  
15 801 *sedentary behaviour* IJBNPA, 2022.
- 16  
17  
18 802 28. Lonsdale, C., et al., *Scaling-up an efficacious school-based physical activity*  
19 803 *intervention: Study protocol for the 'Internet-based Professional Learning to help*  
20 804 *teachers support Activity in Youth' (iPLAY) cluster randomized controlled trial and*  
21 805 *scale-up implementation evaluation*. BMC Public Health, 2016. **16**(1): p. 873.
- 22  
23  
24 806 29. Cassar, S., et al., *Adoption, implementation and sustainability of school-based*  
25 807 *physical activity and sedentary behaviour interventions in real-world settings: a*  
26 808 *systematic review*. International Journal of Behavioral Nutrition and Physical  
27 809 *Activity*, 2019. **16**(1): p. 120.
- 28  
29  
30 810 30. Koorts, H., et al., *Tensions and Paradoxes of Scaling Up: A Critical Reflection on*  
31 811 *Physical Activity Promotion*. International Journal of Environmental Research and  
32 812 *Public Health*, 2022. **19**(21): p. 14284.
- 33  
34  
35 813 31. Glasgow, R., T. Vogt, and S. Boles, *Evaluating the public health impact of health*  
36 814 *promotion interventions: the RE-AIM framework*. Am J Public Health, 1999. **89**(9): p.  
37 815 1322-7.
- 38  
39  
40 816 32. Salmon, J., et al., *A cluster-randomized controlled trial to reduce sedentary behavior*  
41 817 *and promote physical activity and health of 8-9 year olds: The Transform-Us! Study*.  
42 818 *BMC Public Health*, 2011. **11**(1): p. 759.
- 43  
44  
45 819 33. Bandura, A., *Social foundations of thought and action: A Social Cognitive Theory*.  
46 820 1986, Englewood Cliffs, NJ: Prentice Hall.
- 47  
48  
49 821 34. Rachlin, H., *Judgement, decision, and choice: A cognitive/behavioral synthesis*. 1989,  
50 822 *New York: WH Freeman*.
- 51  
52  
53 823 35. Bronfenbrenner, U., *Ecological Systems Theory*, in *Six theories of child development:*  
54 824 *revised formulations and current issues*, R. Vasta, Editor. 1992, Jessica Kingsley  
55 825 *Publishers: London*. p. 187-249.
- 56  
57  
58 826 36. <https://victoriancurriculum.vcaa.vic.edu.au/>. 10/06/2018].

- 1  
2  
3 827 37. <https://www.australiancurriculum.edu.au/>. 18/05/2018].
- 4  
5 828 38. Curran, G.M., et al., *Effectiveness-implementation hybrid designs: combining*  
6  
7 829 *elements of clinical effectiveness and implementation research to enhance public*  
8  
9 830 *health impact*. Med Care, 2012. **50**(3): p. 217-26.
- 10 831 39. Peters, D.H., N.T. Tran, and T. Adam, *Implementation research in health: a practical*  
11  
12 832 *guide*. 2013.
- 13 833 40. [www.education.vic.gov.au/Documents/about/department/brochureJuly.docx](http://www.education.vic.gov.au/Documents/about/department/brochureJuly.docx),. [cited  
14  
15 834 2016 10/08/2016].
- 16  
17 835 41. Dunton, G., et al., *State-wide dissemination of a school-based nutrition education*  
18  
19 836 *programme: a RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance)*  
20  
21 837 *analysis*. Public Health Nutr, 2012. **17**(2): p. 422-30.
- 22 838 42. Shadish, W.R., T.D. Cook, and D.T. Campbell, *Experimental and quasi-experimental*  
23  
24 839 *designs for generalized causal inference*. 2002, Boston: Houghton Miffler Company.
- 25 840 43. Koorts, H., et al., *Implementation and scale up of population physical activity*  
26  
27 841 *interventions for clinical and community settings: the PRACTIS guide*. International  
28  
29 842 *Journal of Behavioral Nutrition and Physical Activity*, 2018. **15**(1): p. 51.
- 30 843 44. Australian Bureau of Statistics, *Information Paper: An Introduction to Socio-*  
31  
32 844 *Economic Indexes for Areas (SEIFA) 2006*. 2006: Canberra.
- 33 845 45. World Health Organization, *Practical guidance for scaling up health service*  
34  
35 846 *innovations*. 2009, World Health Organization: Geneva, Switzerland.
- 36 847 46. Milat, A.J., R. Newson, and L. King, *Increasing the scale of population health*  
37  
38 848 *interventions: A Guide*. 2014, Centre for Epidemiology and Evidence: Sydney: NSW  
39  
40 849 *Ministry of Health*.
- 41 850 47. O'Hara, B.J., et al., *'Translational formative evaluation': critical in up-scaling public*  
42  
43 851 *health programmes*. Health Promot Int, 2013. **29**(1): p. 38-46.
- 44  
45 852 48. Wandersman, A., et al., *Bridging the gap between prevention research and practice:*  
46  
47 853 *the interactive systems framework for dissemination and implementation*. Am J  
48  
49 854 *Community Psychol*, 2008. **41**(3-4): p. 171-81.
- 50 855 49. Meyers, D.C., J.A. Durlak, and A. Wandersman, *The quality implementation*  
51  
52 856 *framework: a synthesis of critical steps in the implementation process*. Am J  
53  
54 857 *Community Psychol*, 2012. **50**(3-4): p. 462-80.
- 55 858 50. Wiltsey Stirman, S., et al., *The sustainability of new programs and innovations: a*  
56  
57 859 *review of the empirical literature and recommendations for future research*.  
58  
59 860 *Implement Sci*, 2012. **7**: p. 17.

- 1  
2  
3 861 51. Michie, S., et al., *From Theory to Intervention: Mapping Theoretically Derived*  
4 862 *Behavioural Determinants to Behaviour Change Techniques*. Applied Psychology,  
5 863 2008. **57**(4): p. 660-680.  
6  
7  
8 864 52. Simmons, R. and J. Shiffman, *Scaling up health service innovations: a framework for*  
9 865 *action*, in *Scaling up health service delivery*, F.P. Simmons R, Ghiron L,, Editor.  
10 866 2007, World Health Organization: Geneva. p. 1-30.  
11  
12  
13 867 53. Proctor, E.K., B.J. Powell, and J.C. McMillen, *Implementation strategies:*  
14 868 *recommendations for specifying and reporting*. Implementation Science, 2013. **8**(1):  
15 869 p. 139.  
16  
17  
18 870 54. Dusenbury, L., et al., *Quality of implementation: developing measures crucial to*  
19 871 *understanding the diffusion of preventive interventions*. Health Education Research,  
20 872 2004. **20**(3): p. 308-313.  
21  
22  
23 873 55. Fleuren, M., K. Wiefferink, and T. Paulussen, *Determinants of innovation within*  
24 874 *health care organizations: literature review and Delphi study*. Int J Qual Health Care,  
25 875 2004. **16**(2): p. 107-23.  
26  
27  
28 876 56. Chaudoir, S., A. Dugan, and C. Barr, *Measuring factors affecting implementation of*  
29 877 *health innovations: a systematic review of structural, organizational, provider,*  
30 878 *patient, and innovation level measures*. Implement Sci, 2013. **8**.  
31  
32  
33 879 57. Clarke, V. and V. Braun, *To saturate or not to saturate? Questioning data saturation*  
34 880 *as a useful concept for thematic analysis and sample-size rationales*. Qualitative  
35 881 Research in Sport, Exercise and Health, 2020.  
36  
37  
38 882 58. Malterud, K., V.D. Siersma, and A.D. Guassora, *Sample Size in Qualitative Interview*  
39 883 *Studies: Guided by Information Power*. Qual Health Res, 2016. **26**(13): p. 1753-1760.  
40  
41  
42 884 59. Rutterford, C., A. Copas, and S. Eldridge, *Methods for sample size determination in*  
43 885 *cluster randomized trials*. Int J Epidemiol, 2015. **44**(3): p. 1051-67.  
44  
45  
46 886 60. Evenson, K.R., et al., *Calibration of two objective measures of physical activity for*  
47 887 *children*. J Sports Sci, 2008. **26**(14): p. 1557-65.  
48  
49  
50 888 61. Gabel, L., et al., *Associations of sedentary time patterns and TV viewing time with*  
51 889 *inflammatory and endothelial function biomarkers in children*. Pediatric Obesity,  
52 890 2016. **11**(3): p. 194-201.  
53  
54  
55 891 62. Ridgers, N.D., et al., *Five-year changes in school recess and lunchtime and the*  
56 892 *contribution to children's daily physical activity*. British Journal of Sports Medicine,  
57 893 2012. **46**(10): p. 741-746.  
58  
59  
60

- 1  
2  
3 894 63. Arundell, L., et al., *5-Year Changes in Afterschool Physical Activity and Sedentary*  
4 *Behavior*. American Journal of Preventive Medicine, 2013. **44**(6): p. 605-611.  
5 895  
6 896 64. Kuczmarski, R.J., C.L. Ogdon, and S.S. Guo, *2000 CDC growth charts for the United*  
7 *States: Methods and development*. In: , in *Vital Health Statistics*, N.C.f.H. Statistics,  
8 897  
9 898 Editor. 2002: Washington.  
10  
11 899 65. Wille, N., et al., *Development of the EQ-5D-Y: a child-friendly version of the EQ-5D*.  
12  
13 Quality of life research : an international journal of quality of life aspects of  
14 900  
15 901 treatment, care and rehabilitation, 2010. **19**(6): p. 875-886.  
16  
17 902 66. Dalziel, K., et al., *Feasibility, Validity and Differences in Adolescent and Adult EQ-*  
18 *5D-Y Health State Valuation in Australia and Spain: An Application of Best–Worst*  
19 903  
20 904 *Scaling*. PharmacoEconomics, 2020. **38**(5): p. 499-513.  
21  
22 905 67. Ridgers, N.D., et al., *Validity of a brief self-report instrument for assessing*  
23 *compliance with physical activity guidelines amongst adolescents*. J Sci Med Sport,  
24 906  
25 907 2012. **15**(2): p. 136-41.  
26  
27 908 68. Telford, A., et al., *Reliability and Validity of Physical Activity Questionnaires for*  
28 *Children: The Children’s Leisure Activities Study Survey (CLASS)*. 2004. **16**(1): p. 64.  
29 909  
30 910 69. Salmon, J., et al., *Association of Family Environment with Children's Television*  
31 *Viewing and with Low Level of Physical Activity*. Obesity Research, 2005. **13**(11): p.  
32 911  
33 912 1939-1951.  
34  
35 913 70. Naylor, P., et al., *Action Schools! BC: a socioecological approach to modifying*  
36 *chronic disease risk factors in elementary school children*. Prev Chronic Dis, 2006.  
37 914  
38 915 **3**(2): p. A60.  
39  
40 916 71. Shea, C.M., et al., *Organizational readiness for implementing change: a psychometric*  
41 *assessment of a new measure*. Implementation Science, 2014. **9**(1): p. 1-15.  
42 917  
43 918 72. Jacobs, S.R., B.J. Weiner, and A.C. Bunger, *Context matters: measuring*  
44 *implementation climate among individuals and groups*. Implement Sci, 2014. **9**: p. 46.  
45 919  
46 920 73. Holtrop, J.S., B.A. Rabin, and R.E. Glasgow, *Qualitative approaches to use of the*  
47 *RE-AIM framework: rationale and methods*. BMC Health Services Research, 2018.  
48 921  
49 922 **18**(1): p. 177.  
50  
51 923 74. Joffe, H. and L. Yardley, *Content and Thematic Analysis*, in *Research Methods for*  
52 *Clinical and Health Psychology*, D. Marks and L. Yardley, Editors. 2004, Sage  
53 924  
54 925 Publications. p. 56-66.  
55  
56 926 75. Wasserstein, R.L., A.L. Schirm, and N.A. Lazar, *Moving to a World Beyond*  
57 *“p < 0.05”*. The American Statistician, 2019. **73**(sup1): p. 1-19.  
58 927  
59  
60

1  
2  
3 928 76. Department of Education and Training, *The Education State: Schools*. Published by  
4 the State of Victoria, Department of Education and Training.  
5 929  
6  
7 930  
8  
9

10 931 **Authors' contributions**

11  
12 932 **JS, HK, AT, CL, NDR, DL, JDG, AB, AT, LMB, KEL, LA, & HB** contributed to the  
13 study design. **HK** led writing of manuscript with **JS**, and **KEL** led development of the  
14 933 analysis plan for the effectiveness component. All authors revised the manuscript for  
15 934 intellectual content and read and approved the final draft.  
16  
17 935  
18  
19  
20 936

21  
22 937 **Funding**

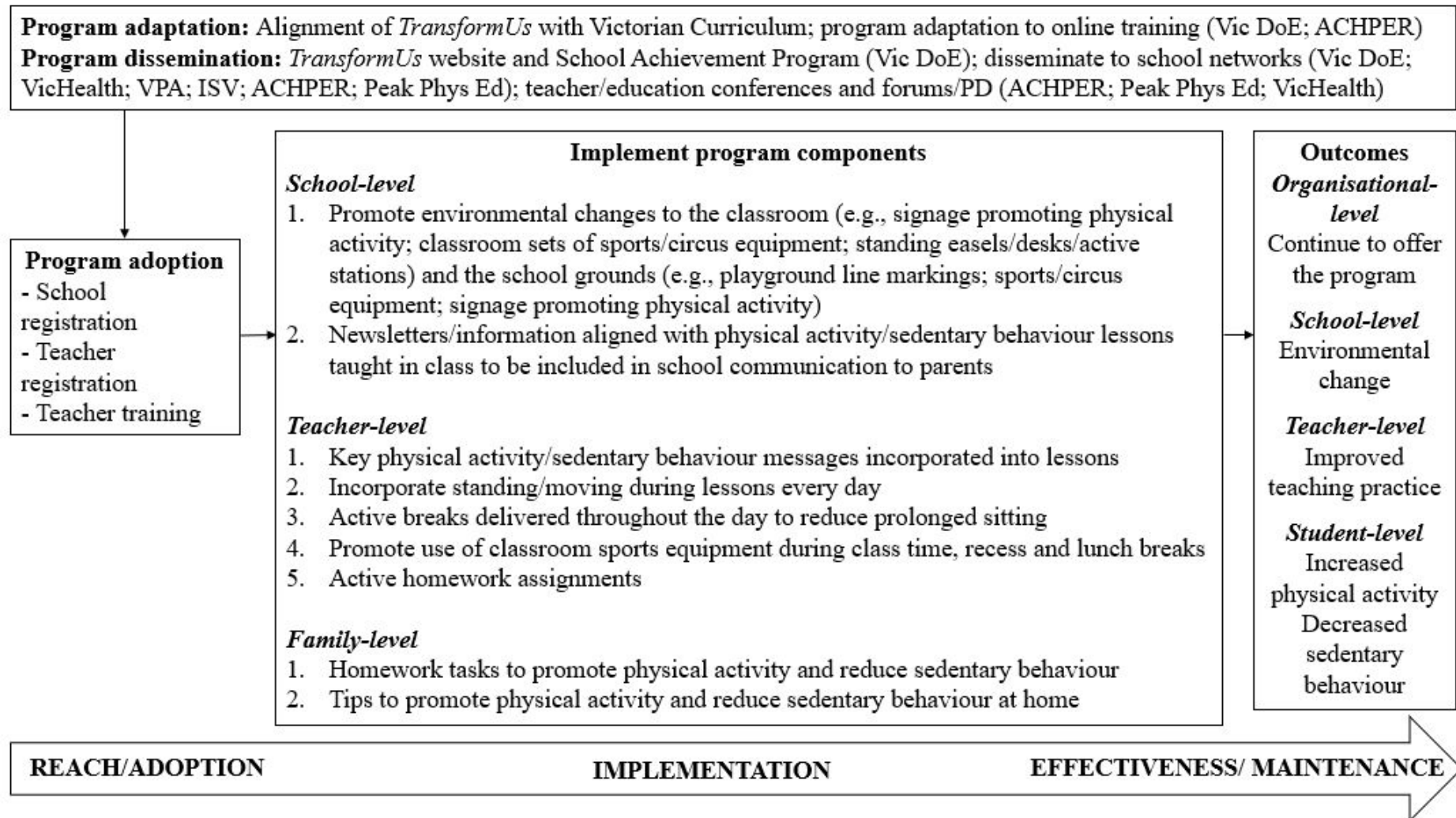
23  
24 938 This work is funded by an Australian National Health and Medical Research Council  
25 939 (NHMRC) Partnership Grant (APP1115708) and VicHealth. **JS** is supported by a NHMRC  
26 940 Leadership Level 2 Fellowship (APP1176885). **DRL** is supported by an NHMRC Senior  
27 941 Research Fellowship (APP1154507). **NDR** was supported by a Future Leader Fellowship  
28 942 from the National Heart Foundation of Australia (ID 101895). **LA** is supported by an  
29 943 Australian Research Council Discovery Early Career Researcher Award (DE220100847).  
30  
31  
32  
33  
34  
35  
36 944

37  
38 945 **Competing interests**

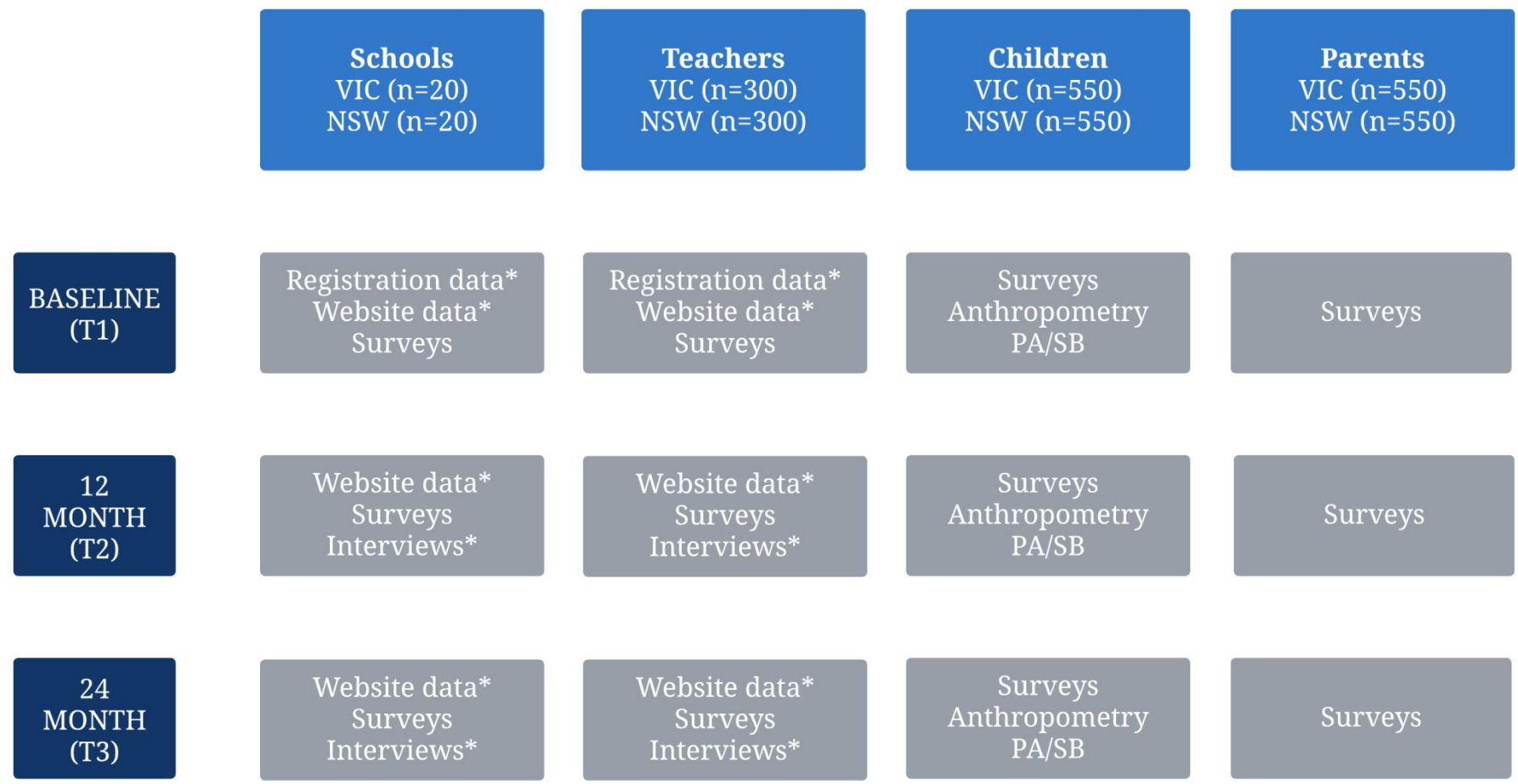
39  
40 946 All authors have completed the ICMJE uniform disclosure form at  
41 947 [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) and declare: no support from any organisation for the  
42 948 submitted work; no financial relationships with any organisations that might have an interest  
43 949 in the submitted work in the previous three years [or describe if any]. However, this research  
44 950 does not fund schools to implement the program (which is made available at no cost), and no  
45 951 product endorsements are made to schools by the research team for implementation of any  
46 952 aspect of the program. All remaining authors declare no other relationships or activities that  
47 953 could appear to have influenced the submitted work.  
48  
49  
50  
51  
52  
53  
54  
55 954

56  
57 955 **Word Count: 6995**  
58  
59  
60

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

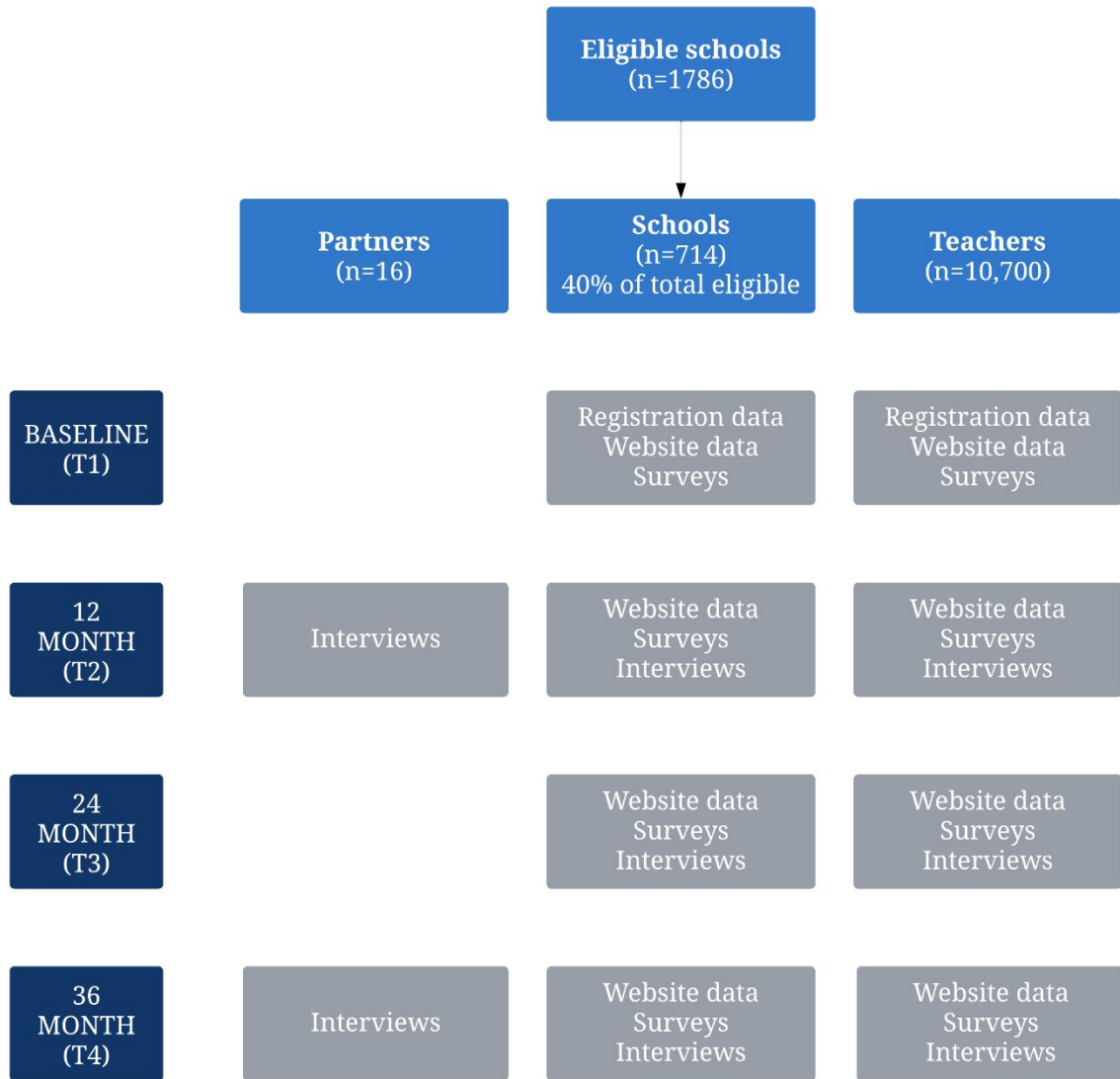
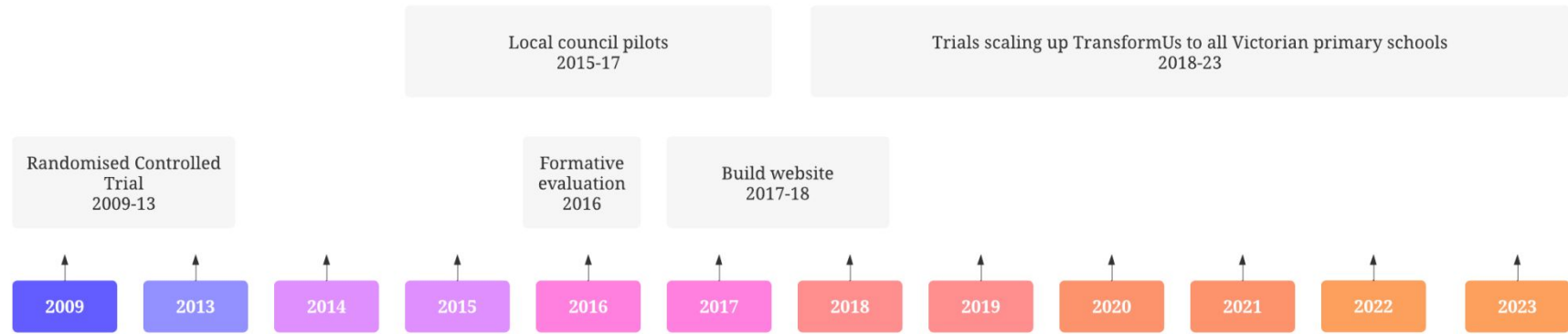


Figure 3. Implementation Trial Participant Flow Diagram





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



ew only

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	<b>Formative work with stakeholders</b>	Research-practice partnership to identify strategies, barriers/facilitators to program dissemination, implementation and sustainability at scale	<i>TransformUs</i> 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 <sup>1</sup> , and organisational implementation capacities and structures are considered <sup>2</sup>
2	<b>Creation of coalitions and networks for program/policy advocacy</b>	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 <sup>2</sup> . 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	<b>Utilise multiple dissemination routes/channels</b>	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	<i>TransformUs</i> school principals and teachers (delivery system)	Program reach and adoption	Ongoing over 5 years	Multiple dissemination routes can widen scale up reach <sup>2</sup>
4	<b>Online program training to build implementation capacity</b>	Teachers required to complete online training prior to gaining access to program materials, implementation resources	<i>TransformUs</i> school principals and teachers (delivery system)	Completion of online training provides a unique log-in for access to online resources	<i>TransformUs</i> 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 <sup>3</sup> , skills, knowledge, self-efficacy, perceived fit with existing practices, relative advantage, and ownership of program <sup>4-6</sup>

#	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	<b>Online platform for program materials and training</b>	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	<i>TransformUs</i> research team with State-level partner organisations (support system)	Website hosted and maintained by <i>TransformUs</i> research team, link disseminated by all partner organisations.	School principals and teachers (delivery system)  Parents of children at <i>TransformUs</i> schools	Reach, adoption	Ongoing over 5 years	Maximises potential program dissemination/ implementation <sup>7</sup> . Enables more efficient data collection, refinements to materials and resource updates over time
6	<b>Enable implementation flexibility and contextual adaptation</b>	Non-prescriptive approach to implementation. Schools and teachers encouraged via training and in resources to adapt program	<i>TransformUs</i> 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 <sup>8</sup> . <i>TransformUs</i> 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 <sup>9</sup>
7	<b>Enable both ‘top-down’ and ‘bottom-up’ program adoption</b>	School-level adoption not required for teacher-level implementation. Schools and teachers can register to deliver the program independently	<i>TransformUs</i> 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	<i>TransformUs</i> school principals, teachers (delivery system)  Parents of children at <i>TransformUs</i> schools	Reach and adoption	Ongoing over 5 years	Capturing both individual and organisational innovation-decision processes, can elucidate influences on adoption and implementation <sup>10</sup>
8	<b>Utilise existing resources in the delivery system</b>	Program strategies can use existing school resources, equipment and	<i>TransformUs</i> research team with State-level partner	Program training and resources include ways of using/adapting existing school	<i>TransformUs</i> school principals, teachers (delivery system)	Adoption, implementation, sustainability	Ongoing over 5 years	Using existing resources can promote sustainability <sup>2</sup> , 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	<b>Development of recognition and incentive system</b>	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	<i>TransformUs</i> 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 <sup>1</sup> . Formative work identified CPD as an incentive for training completion
10	<b>Alignment with existing state-</b>	Program aligned with the	<i>TransformUs</i> research team	<i>TransformUs</i> included as part	<i>TransformUs</i> school	Reach, adoption, implementation	Program aligned with	Interventions which align with

#	Strategy	Definition	Actors <i>(those who deliver imp strategy)</i>	Action <i>(specific action or process)</i>	Action target <i>(who its meant to affect)</i>	Implementation outcome(s) affected	Temporality and dose	Justification
	<b>level initiatives and guidelines</b>	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 <sup>2</sup>
11	<b>Promote use of program champions</b>	Schools identify champion(s) who advocate for are a point of contact for staff, students and families regarding <i>TransformUs</i> implementation	<i>TransformUs</i> 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	<i>TransformUs</i> 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 <sup>11</sup>  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	<b>Online implementation support network</b>	Schools can access an online discussion forum to share implementation strategies and ways of overcoming barriers.	<i>TransformUs</i> champion/teachers (delivery system)	Online discussion forum hosted on the program website, accessible only to registered teachers/schools	<i>TransformUs</i> 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 <sup>11</sup>
13	<b>Provision of resources to support implementation processes and sustainability</b>	Providing schools resources and suggested strategies to enhance implementation and sustainability in their setting	<i>TransformUs</i> 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)	<i>TransformUs</i> school principals and teachers (delivery system)	Implementation (e.g. skills, knowledge and capacity to implement program) and effectiveness. Institutionalisation within the school	Post registration, available online over 5 years	Increasing general and intervention-specific capacity within support system can enhance implementation <sup>7</sup> and sustainability <sup>12</sup> . Implementation plan can increase accountability <sup>8</sup>
14	<b>Monitoring and evaluation to adjust scaling strategy,</b>	Multilevel data (system, organisational, implementer and	<i>TransformUs</i> 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 <i>(those who deliver imp strategy)</i>	Action <i>(specific action or process)</i>	Action target <i>(who its meant to affect)</i>	Implementation outcome(s) affected	Temporality and dose	Justification
	<b>feedback to support schools</b>	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 <i>TransformUs</i> 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 <sup>2</sup> . Feedback can increase teacher implementation performance.

**References**

1. Koorts, H., et al., *Implementation and scale up of population physical activity interventions for clinical and community settings: the PRACTIS guide*. International Journal of Behavioral Nutrition and Physical Activity, 2018. **15**(1): p. 51.
2. World Health Organization, *Practical guidance for scaling up health service innovations*. 2009, World Health Organization: Geneva, Switzerland.
3. Leeman, J., et al., *What strategies are used to build practitioners' capacity to implement community-based interventions and are they effective?: a systematic review*. Implement Sci, 2015. **10**(1): p. 80.
4. Fleuren, M., K. Wiefferink, and T. Paulussen, *Determinants of innovation within health care organizations: literature review and Delphi study*. Int J Qual Health Care, 2004. **16**(2): p. 107-23.
5. Chaudoir, S., A. Dugan, and C. Barr, *Measuring factors affecting implementation of health innovations: a systematic review of structural, organizational, provider, patient, and innovation level measures*. Implement Sci, 2013. **8**.

- 1
- 2
- 3
- 4 6. Michie, S., et al., *From Theory to Intervention: Mapping Theoretically Derived Behavioural Determinants to Behaviour Change Techniques*. Applied Psychology, 2008. **57**(4): p. 660-680.
- 5
- 6 7. Wandersman, A., et al., *Bridging the gap between prevention research and practice: the interactive systems framework for dissemination and implementation*. Am J Community Psychol, 2008. **41**(3-4): p. 171-81.
- 7
- 8 8. Meyers, D.C., J.A. Durlak, and A. Wandersman, *The quality implementation framework: a synthesis of critical steps in the implementation process*. Am J Community Psychol, 2012. **50**(3-4): p. 462-80.
- 9
- 10 9. Koorts, H., et al., *Is level of implementation linked with intervention outcomes? Process evaluation of the TransformUs intervention to increase children's physical activity and reduce sedentary behaviour*. Int J Behav Nutr Phys Act, 2022. **19**(1): p. 122.
- 11
- 12 10. Rogers, E.M., *Diffusion of Innovations*. 3rd ed. 1983, New York: The Free Press.
- 13
- 14 11. Rogers, E.M., *Diffusion of preventive innovations*. Addictive Behaviors, 2002. **27**(6): p. 989-993.
- 15
- 16 12. Wiltsey Stirman, S., et al., *The sustainability of new programs and innovations: a review of the empirical literature and recommendations for future research*. Implement Sci, 2012. **7**: p. 17.
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31
- 32
- 33
- 34
- 35
- 36
- 37
- 38
- 39
- 40
- 41
- 42
- 43
- 44
- 45
- 46

Supplementary File 3. Project timeline

Year	2017				2018				2019				2020				2021				2022				2023							
Term	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
<i>Preparation activities</i>																																
Resource development original <i>TransformIt</i> website																																
Build original <i>TransformIt</i> website																																
Launch original <i>TransformIt</i> website																																
Build updated <i>TransformIt</i> website																																
Relaunch of <i>TransformIt</i> website																																
Management of <i>TransformIt</i> website																																
Build databases for both trials																																
Program dissemination via partner organisations (a)																																
Expressions of interest in <i>TransformIt</i> (Effectiveness Trial only)																																
Schools/teachers register via <i>TransformIt</i> website																																
Teachers complete mandatory online training (a)																																
<i>Effectiveness Trial activities</i>																																
<b>CHILD/PARENT data collection</b>																																
Recruit schools VIC (n=20) NSW (n=20) (a)																																
BL measures VIC & NSW (a, b)																																
T2 (12 month) measures VIC & NSW (b, e)																																
T3 (24 month) measures VIC & NSW (b, e)																																
<b>TEACHER/SCHOOL data collection</b>																																
BL surveys teachers/schools VIC & NSW (a, c)																																
T2 (12 month) surveys and interviews teachers/schools VIC & NSW (b, d, e)																																
T3 (24 month) surveys and interviews teachers/schools VIC & NSW (b, d, e)																																
<i>Implementation Trial activities</i>																																
BL surveys teachers/schools (a, b, c, d)																																
T2 (12 month) surveys teachers/schools (b, d, e)																																
T3 (24 month) surveys teachers/schools (b, d, e)																																
T4 (36 month) surveys teachers/schools (b, d, e)																																
T2 (12 month) interviews teachers/principals (a, b, c, d, e)																																
T3 (24 month) interviews teachers/principals (a, b, c, d, e)																																
T4 (36 month) interviews teachers/principals (a, b, c, d, e)																																
T2 (12 month) interviews partner organisations (a, b, c, d, e)																																
T3 (24 month) interviews partner organisations (a, b, c, d, e)																																
T4 (36 month) interviews partner organisations (a, b, c, d, e)																																
Website data on online visits/downloads (a, e)																																
<i>Other activities</i>																																
Partner data on program dissemination/promotion (a, c, d, e)																																

(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

# BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2023-078410.R1
Article Type:	Protocol
Date Submitted by the Author:	02-Oct-2023
Complete List of Authors:	Koorts, Harriet ; Deakin University Institute for Physical Activity and Nutrition Timperio, Anna; Deakin University Institute for Physical Activity and Nutrition Lonsdale, Chris; Australian Catholic University, Institute for Positive Psychology and Education Ridgers, Nicola D.; Deakin University Institute for Physical Activity and Nutrition; University of South Australia Lubans, David; The University of Newcastle, Centre for Active Living and Learning; The University of Newcastle Hunter Medical Research Institute Della Gatta, Jacqui; Deakin University Institute for Physical Activity and Nutrition Bauman, Adrian; The University of Sydney School of Public Health Telford, Amanda; Australian Catholic University, National School of Education Barnett, Lisa; Deakin University, School of Health & Social Development Lamb, Karen; The University of Melbourne - Parkville Campus, School of Population and Global Health Lander, Natalie; Deakin University Institute for Physical Activity and Nutrition Lai, Samuel K.; Deakin University Institute for Physical Activity and Nutrition Sanders, Taren; Australian Catholic University, Institute for Positive Psychology and Education Arundell, Lauren; Deakin University Institute for Physical Activity and Nutrition Brown, Helen; Deakin University Institute for Physical Activity and Nutrition Wilhite, Katrina; Australian Catholic University, Institute for Positive Psychology and Education, Salmon, Jo; Deakin University Institute for Physical Activity and Nutrition
<b>Primary Subject Heading</b>:	Public health
Secondary Subject Heading:	Public health, Research methods
Keywords:	PUBLIC HEALTH, Community child health < PAEDIATRICS, Schools

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



SCHOLARONE™  
Manuscripts

1  
2  
3 1 **Scaling up a school-based intervention to increase physical activity and reduce**  
4 **sedentary behaviour in children: protocol for the *TransformUs* hybrid effectiveness-**  
5 **implementation trial**  
6  
7  
8

9  
10 4 Harriet Koorts<sup>1</sup>, Anna Timperio<sup>1</sup>, Chris Lonsdale<sup>2</sup>, Nicola D. Ridgers<sup>1,3</sup>, David Lubans<sup>4,5,6</sup>,  
11 5 Jacqueline Della Gatta<sup>1</sup>, Adrian Bauman<sup>7</sup>, Amanda Telford<sup>8</sup>, Lisa M. Barnett<sup>9</sup>, Karen E.  
12 6 Lamb<sup>10</sup>, Natalie Lander<sup>1</sup>, Samuel K. Lai<sup>1</sup>, Taren Sanders<sup>2</sup>, Lauren Arundell<sup>1</sup>, Helen Brown<sup>1</sup>,  
13 7 Katrina Wilhite<sup>2</sup>, Jo Salmon<sup>1</sup>

14  
15  
16  
17 8 <sup>1</sup>Deakin University, Geelong, Institute for Physical Activity and Nutrition, School of Exercise  
18 9 and Nutrition Sciences, VIC 3216, Australia

19  
20  
21 10 <sup>2</sup>Institute for Positive Psychology and Education, Australian Catholic University, North  
22 11 Sydney, NSW 2060, Australia

23  
24  
25 12 <sup>3</sup>Alliance for Research in Exercise, Nutrition and Activity (ARENA), Allied Health and  
26 13 Human Performance, University of South Australia, Adelaide, South Australia 5001,  
27 14 Australia

28  
29  
30  
31 15 <sup>4</sup>Centre for Active Living and Learning, College of Human and Social Futures, University of  
32 16 Newcastle, Callaghan, New South Wales, Australia

33  
34  
35 17 <sup>5</sup>Hunter Medical Research Institute, New Lambton Heights, NSW 2305, Australia

36  
37 18 <sup>6</sup>Faculty of Sport and Health Sciences, University of Jyväskylä, Jyväskylä, Finland.

38  
39  
40 19 <sup>7</sup>School of Public Health, University of Sydney, Sydney, NSW 2006, Australia

41  
42 20 <sup>8</sup>Australian Catholic University, National School of Education, VIC 3065, Australia

43  
44  
45 21 <sup>9</sup>Deakin University, Geelong, Institute for Physical Activity and Nutrition, School of Health  
46 22 and Social Development, VIC 3125, Australia

47  
48  
49 23 <sup>10</sup>Melbourne School of Population and Global Health, University of Melbourne, VIC 3053,  
50 24 Australia

51  
52  
53 25 **Correspondence to:** Harriet Koorts, Deakin University, 221 Burwood Highway, Burwood,  
54 26 VIC 3125, Australia. Email: [h.koorts@deakin.edu.au](mailto:h.koorts@deakin.edu.au)

55  
56  
57  
58 28 **Word count:** 6995  
59  
60

29

**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

1  
2  
3 61 sustainable ways to promote physical activity and reduce sedentary behaviours population-  
4  
5 62 wide.

6  
7 63 **Trial registration:** Australian New Zealand Clinical Trials Registry,  
8  
9 64 ACTRN12617000204347.

10  
11 65  
12  
13 66 **Keywords:** Scale up, scalability, dissemination, school, implementation science, population

14  
15  
16 67  
17  
18 68 **Strengths and limitations of this study**

- 19  
20 69 • Strengths include the hybrid effectiveness-implementation trial design undertaken in a  
21  
22 70 real-world context, the inclusion of multiple levels of data collected at multiple time  
23  
24 71 points, the use of robust frameworks to guide implementation and scale up, and  
25  
26 72 device-based measurement of children's physical activity and sedentary time in the  
27  
28 73 effectiveness trial.
- 29 74 • Testing the hypothesised mediating and/or moderating relationships, such as  
30  
31 75 organisational readiness for change, with implementation and effectiveness outcomes  
32  
33 76 will help understand primary barriers to, and facilitators of, implementation of school-  
34  
35 77 based interventions, such as *TransformUs*.
- 36 78 • Limitations include reliance on teacher self-reported implementation of the program,  
37  
38 79 although, additional implementation data will be captured using Google Analytics  
39  
40 80 (e.g., use of the *TransformUs* website, professional development completed by  
41  
42 81 teachers, and which program resources are downloaded).
- 43 82 • Facilitation of program dissemination activities via stakeholders and the research team  
44  
45 83 may not reflect true real-world promotion, but will highlight practices required for  
46  
47 84 sustainable scale up.
- 48 85 • Extended COVID-19 lockdowns and government restrictions in Australia meant on-  
49  
50 86 site data collection in schools was prohibited in Victoria between 2020 and April  
51  
52 87 2023, and in NSW during 2021; nevertheless, the conduct of both an implementation  
53  
54 88 and effectiveness trial will enable us to compare differences between schools to  
55  
56 89 ascertain the level of implementation, 'real world' program impact, and  
57  
58 90 generalisability of results.
- 59  
60 91



## 92 Introduction

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

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

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

1  
2  
3 125 active equipment during recess, and incorporate playground markings can also successfully  
4  
5 126 increase children's physical activity.(22, 23) A systematic review has also shown that school  
6  
7 127 interventions with a family element can be more effective at increasing physical activity than  
8  
9 128 just focusing on the school setting alone,(24) however, few studies have determined the  
10  
11 129 efficacy of strategies to reduce prolonged sitting both at school and home among  
12  
13 130 children.(25) The initial *TransformUs* program(26) was one of the earliest programs  
14  
15 131 (developed in 2009) to incorporate many of these elements with a particular focus on  
16  
17 132 reducing and breaking up children's sitting throughout the school day.

18 133 The efficacy of the initial *TransformUs* program was demonstrated in a 4-arm two-by-two  
19  
20 134 factorial design cluster-randomised controlled trial (RCT) involving 20 primary (elementary)  
21  
22 135 schools, 226 teachers and over 1,600 children in Melbourne, Australia (2010-13).(26) The  
23  
24 136 three intervention arms targeted either increases in physical activity (PA-I), reductions in  
25  
26 137 sedentary behaviour (SB-I), or a combination of both (PA+SB I), compared to a usual  
27  
28 138 practice control. The results of this RCT are described and interpreted in detail  
29  
30 139 elsewhere.(26) However, in brief, at 18-months (n=348), compared to usual practice, children  
31  
32 140 who received the physical activity intervention (groups PA-I and PA+SB I) had significantly  
33  
34 141 less weekday sedentary time (-27 mins/day). Compared to usual practice, children who  
35  
36 142 received the sedentary behaviour intervention (SB-I and PA+SB I) spent more time in daily  
37  
38 143 physical activity (5.5 mins/day) at 18-months, and at 30-months spent 33 mins less in daily  
39  
40 144 sedentary time, and specifically, 63 mins less in sedentary time on weekdays, with no  
41  
42 145 differences in physical activity at 30-months.(26) Thus strategies to promote both children's  
43  
44 146 physical activity and reduce sedentary behaviour were important. Results also showed  
45  
46 147 beneficial effects on children's adiposity markers (body mass index [BMI] and waist  
47  
48 148 circumference [n=564]). However, there were mixed effects on children's blood pressure  
49  
50 149 ([BP] positive effects on systolic BP and negative effects on diastolic BP [n=537]) and in a  
51  
52 150 sub-sample of children (n=206), on blood parameters (e.g., negative effects on some  
53  
54 151 inflammatory markers such as CRP, IL-6, IL-2 and TNF- $\alpha$ , beneficial effects on vitamin D,  
55  
56 152 BDNF, and PAI-1).(26)

53 153 Teachers, parents and children reported that the program was positively received, and  
54  
55 154 teachers involved in the intervention arms also reported perceptions of better classroom  
56  
57 155 management and improved 'on-task' behaviour during lessons.(27) Although barriers to  
58  
59 156 implementation were experienced (including a lack of school leadership to support  
60  
157 157 implementation long-term, promotion and awareness raising, teacher time constraints, and

1  
2  
3 158 challenges with sustained integration into existing practices), overall, the program was  
4  
5 159 effectively integrated into the school curriculum.(27) Existing teaching practices, children's  
6  
7 160 enjoyment, and teacher awareness of program values and benefits were the main facilitators  
8  
9 161 of delivery and sustainability.(27) Following the success of *TransformUs*, and exploration of  
10  
11 162 adaptations for scaling (described in Methods section), the Victorian Department of  
12  
13 163 Education committed to partnering with the research team to support the dissemination and  
14  
15 164 implementation of the program to all primary (elementary) schools in Victoria, Australia.  
16  
17 165 Given the small number of school-based interventions that are studied at scale(28) and that  
18  
19 166 use implementation theories to guide this process;(29, 30) scaling up of *TransformUs*  
20  
21 167 presented a unique opportunity to investigate real-world implementation at scale. Assessment  
22  
23 168 of intervention implementation among school-based interventions is greatly needed in the  
24  
25 169 field.(19)

26  
27 170 This paper describes the study protocol for a five-year trial (launched September 2018 - final  
28  
29 171 data collection December 2023), which aims to evaluate the real-world effectiveness and  
30  
31 172 implementation of *TransformUs* at scale. To note, the paper outlines the *intended* protocol for  
32  
33 173 the trial (including planned dates and timelines for data collection), but also describes where  
34  
35 174 and how this *changed* due to the impacts of the COVID-19 global pandemic. In line with the  
36  
37 175 RE-AIM framework criteria,(31) we will evaluate the following five aims: the program's  
38  
39 176 **Aim 1: Reach** (proportion and representativeness of Principals and teachers, parents and  
40  
41 177 children participating in *TransformUs*); **Aim 2: Effectiveness** (change in children's daily  
42  
43 178 physical activity and sedentary time 12- and 24-months post-baseline); **Aim 3: Adoption**  
44  
45 179 (proportion and representativeness of schools choosing to implement *TransformUs*); **Aim 4:**  
46  
47 180 **Implementation** (dissemination by education and health partners, uptake of intervention  
48  
49 181 components, frequency, dose and adaptation to *TransformUs* delivery, and barriers and  
50  
51 182 enablers to implementation); and **Aim 5: Individual-level Maintenance** (change in children's  
52  
53 183 physical activity and sedentary time 24-months post baseline) and **Organisational-level**  
54  
55 184 **Maintenance** (institutionalisation and sustainability of the program within the education and  
56  
57 185 health systems, school settings and by teachers as part of routine practice).

58

## 187 **Methods and analysis**

### 188 **Overview of the *TransformUs* program**

1  
2  
3 189 *TransformUs* is a behavioural and environmental intervention delivered in the classroom,  
4  
5 190 broader school environment and family setting to increase children's physical activity levels  
6  
7 191 and reduce sedentary behaviour.(32) The program includes: (i) health lessons incorporating  
8  
9 192 key physical activity/sedentary behaviour messages; (ii) active academic lessons; (iii) active  
10  
11 193 breaks; (iv) changes to the school environment; (v) active homework, and (vi) parent  
12  
13 194 newsletters promoting physical activity/reducing sitting time (for more detail see Figure 1).  
14  
15 195 The program was based on the Social Cognitive Theory,(33) Behavioural Choice Theory(34)  
16  
17 196 and Ecological Systems Theory.(35) The health lessons, active academic lessons and active  
18  
19 197 breaks are all aligned with the Victorian(36) and Australian curriculum and standards.(37)  
20  
21 198 All *TransformUs* components are contained in the members' area of the website  
22  
23 199 (<https://transformus.com.au>). To access these resources, Victorian primary school teachers  
24  
25 200 need to register (at no cost) using their work email address. A detailed description of the  
26  
27 201 program strategies(32) and program logic model have been published elsewhere.(27)  
28  
29 202 Adaptations to the *TransformUs* program for scale up are described later in Methods section,  
30  
31 203 and Supplementary File 1 presents the evolution of *TransformUs* since the original RCT  
32  
33 204 (2009) to date.  
34  
35 205

### 206 ***Study design***

36 207 This study uses a type II hybrid effectiveness-implementation trial design,(38, 39) to  
37  
38 208 concurrently examine both effectiveness outcomes and implementation and scale-up  
39  
40 209 processes. Mixed method data will be collected at the systems- (State government, partner  
41  
42 210 organisations), organisational- (school) and individual- (teacher, parent and child) levels.  
43  
44 211 Supplementary File 2 contains the Standard Protocol Items: Recommendations for  
45  
46 212 Interventional Trials (SPIRIT) checklist, relevant to this manuscript.  
47  
48 213

### 49 214 ***Implementation trial***

50  
51 215 Every primary school in Victoria (government, independent and Catholic) will be offered  
52  
53 216 *TransformUs*, and will be eligible for inclusion in the state-wide implementation trial. Our  
54  
55 217 objective is for the program to be adopted by at least 715 primary schools (40% of a total of  
56  
57 218 1,786 primary schools in Victoria(40)) by the end of the trial. The adoption estimates are  
58  
59 219 based on school uptake of state-wide initiatives offered by the Victorian Department of  
60  
220 Education and previous implementation trials in schools.(41) As *TransformUs* dissemination

1  
2  
3 221 will be ongoing over 5-years, schools can register anytime between September 2018 and  
4 222 December 2022. Data are planned to be collected from schools and teachers who agree to  
5 223 participate in the evaluation at baseline (T1), 12-months (T2), 24-months (T3) and 36-months  
6 224 (T4) post registration; within the funding time period (September 2018 - December 2022).  
7 225 These data will contribute to assessing reach, adoption, implementation, and organisational-  
8 226 level maintenance (Aims 1, 3, 4 and 5).  
9  
10  
11  
12  
13  
14  
15  
16  
17

### 18 227 19 228 ***Effectiveness trial***

20 229 To determine short- and long-term changes in children's levels of physical activity and  
21 230 sedentary time under 'real world' conditions (based on adaptations from the original  
22 231 *TransformUs* program described below), an embedded effectiveness trial is planned with 20  
23 232 intervention schools in Victoria and 20 control schools in the state of New South Wales  
24 233 (NSW). A quasi-experimental pre-post non-equivalent group design(42) with follow-up will  
25 234 be adopted. As this is a real-world roll-out in Victoria, a non-randomised two-group parallel  
26 235 arm approach was adopted. Data collected at baseline (T1), 12-months (T2), and 24-months  
27 236 (T3) will contribute to assessing program effectiveness and maintenance at the student level  
28 237 (Aims 2 and 5). Schools in NSW were considered suitable controls as NSW has a similar  
29 238 population size and geographic spread to Victoria compared to other states and territories,  
30 239 and the *TransformUs* program was not available in NSW.  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40

### 41 241 ***Program adaptation and piloting***

42 242 The *TransformUs* RCT showed that strategies to promote children's physical activity and  
43 243 reduce sedentary behaviour were both important,(43) and therefore the combined (PA+SB I)  
44 244 approach was the focus for wider scale up. During the RCT, teacher professional  
45 245 development was delivered face-to-face by the research team, and schools received ongoing  
46 246 support from the team over the 2.5 years of the study. This approach was not considered  
47 247 feasible for scale up. To facilitate scale up; professional development, support, and all  
48 248 program materials and resources were converted into an online format to maximise potential  
49 249 reach at a lower cost. Formative evaluation with partners responsible for implementing  
50 250 interventions at scale can also be useful to inform adaptations to the intended dissemination  
51 251 strategy and refine the program materials to enhance scalability.(44) Therefore, in close  
52 252 partnership with local councils (from Local Government Areas) and teachers, the  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 253 *TransformUs* online materials were tested in two pilot dissemination trials and formative  
4  
5 254 evaluation was conducted with key partner organisations involved in scale up, detailed in the  
6  
7 255 following section.  
8

9 256

10  
11 257 ***TransformUs pilot dissemination trials (2015-17)***

12  
13 258 Two 12-month pilot dissemination trials were conducted during July 2015-16 (pilot trial 1;  
14  
15 259 n=4 schools, n=41 teachers) and 2017 (pilot trial 2; n=5 schools, 22 teachers), to assess the  
16  
17 260 feasibility of *TransformUs* dissemination and the online teacher professional development. In  
18  
19 261 both pilots, the program was advertised to schools via two councils (representing two  
20  
21 262 different Local Government Areas) in Victoria. The costs of program equipment (e.g.,  
22  
23 263 standing easels, sports equipment) and installation of playground line markings (e.g.,  
24  
25 264 hopscotch) were subsidised by the councils to support uptake. Schools located in a lower  
26  
27 265 income area were offered a greater subsidy than schools in a higher income area (determined  
28  
29 266 using the Schools in a Socio-Economic Indexes for Areas [SEIFA]; methods consistent with  
30  
31 267 the original RCT).(45) All teachers within participating pilot schools were asked to,  
32  
33 268 preferably, complete the online professional development (lasting 30-45 minutes) during a  
34  
35 269 session on their school site that was facilitated by a representative from the relevant council.  
36  
37 270 As this was to inform the real-world dissemination trial and to help understand the feasibility  
38  
39 271 of online professional development, schools could also send a nominated teacher and adopt a  
40  
41 272 train-the-trainer approach.

42  
43 273 Teachers completed online surveys pre- and post- the professional development session, 2-  
44  
45 274 months and 12-months post-baseline (max n=51 teachers; Pilot trial 1), and at 4-months post-  
46  
47 275 baseline (n=22 teachers; Pilot trial 2). Most teachers reported that they: (1) gained new  
48  
49 276 knowledge of ways to increase children's physical activity (88%) and reduce sedentary  
50  
51 277 behaviour (90%) at school; (2) learnt new teaching methods (78%); (3) perceived the online  
52  
53 278 training to be an appropriate delivery method (82%); and (4) gained the required knowledge  
54  
55 279 (90%) and confidence (80%) to implement the program. Teachers requested visual examples  
56  
57 280 of program implementation (i.e., digital video clips), which they felt would strengthen teacher  
58  
59 281 engagement and sustained delivery of the program. Although the RCT focused on children in  
60  
282 Grades 3-5 (ages 8-11 years), in both pilot trials, participating schools planned a whole-of-  
283 school approach to implementation across all school year levels, Foundation to Grade 6 (ages  
284 5-12 years). For scale up, program materials were modified to accommodate delivery across  
285 all year levels, covering a range of learning areas (e.g., mathematics, English, science and

1  
2  
3 286 humanities), and digital video clips were developed to demonstrate appropriate  
4  
5 287 implementation.  
6  
7 288

9  
10 289 ***Formative evaluation with key partner organisations (2016)***

11 290 Through an integrated research-practice partnership approach, collaboration began with one  
12  
13 291 government (Victorian State government Department of Education) and six non-government  
14  
15 292 organisations (the Victorian Health Promotion Foundation [VicHealth], the Victorian  
16  
17 293 Principals Association, Independent Schools Victoria, the Australian Council for Health,  
18  
19 294 Physical Education and Recreation Victoria [ACHPER], and Peak Phys Ed). These partners  
20  
21 295 play various roles in the education and health systems including, for example, responsibility  
22  
23 296 for delivery of education to children and young people in Victorian government and  
24  
25 297 independent schools (e.g., Department of Education), and coordinating and delivering teacher  
26  
27 298 education professional development (e.g., ACHPER and Peak Phys Ed). In collaboration,  
28  
29 300 that the program aligns with other existing school-based health promotion initiatives in the  
30  
31 301 state (e.g., the Victorian Achievement Program, which aims to create healthier early  
32  
33 302 childhood services, schools and workplaces;  
34 303 <http://www.achievementprogram.health.vic.gov.au/>), and that all resources (e.g., health  
35  
36 304 lessons) are linked to the Victorian Curriculum and each resource identifies the specific  
37  
38 305 Strand, Sub-strand, Content Description and Achievement Standard. For example,  
39 306 *TransformUs* supports the development of student capabilities (e.g., Critical and Creative  
40  
41 307 Thinking, Personal and Social capabilities), which are taught explicitly in and through the  
42  
43 308 learning area resources. *TransformUs* also provides cross-curriculum opportunities for  
44  
45 309 students to strengthen their literacy and numeracy general capabilities.  
46  
47 310

48  
49 311 **Implementation and scale up of *TransformUs***

50  
51 312 ***Theoretical underpinnings***

52  
53 313 Our approach to scale up is ‘horizontal’, defined as extending the reach of an intervention by  
54  
55 314 replicating it in other localities, cities or states.(46) Our implementation approach is derived  
56  
57 315 from evidence-based recommendations for the successful scalability of population-level  
58  
59 316 health interventions,(44, 47, 48) and concepts within the translation, support and delivery  
60  
317 systems of the Interactive Systems Framework.(49) We draw on ways to improve

1  
2  
3 318 implementation and sustainability as outlined in the Quality Implementation Framework,(50)  
4  
5 319 PRACTIS Guide,(44) and from literature on ways to increase public health program  
6  
7 320 sustainability.(51) To identify underlying barriers and facilitators to individual-level  
8  
9 321 implementation, qualitative data collection will be informed by the Theoretical Domains  
10  
11 322 Framework,(52) which is a systematic and theoretically based approach to behaviour change  
12  
13 323 that identifies barriers to practice change and potential strategies to intervene. The RE-AIM  
14  
15 324 framework(31) informs the overarching evaluation outcomes following implementation and  
16  
17 325 scale up.

18 326

### 20 327 ***Implementation and scale up strategies***

21  
22 328 In addition to findings from the *TransformUs* pilot adaptation studies described above, scale  
23  
24 329 up strategies were also guided by literature on strategies for effective implementation and  
25  
26 330 scale up planning(44, 46) and attributes of successful scale up (i.e., compatibility of the  
27  
28 331 program with the values and facilities of intended users, and perceived need for the  
29  
30 332 innovation within the organisation).(53) Supplementary File 3 presents the 14 *TransformUs*  
31  
32 333 implementation and scale up strategies, reported in line with recommendations and  
33  
34 334 definitions for specifying implementation strategies.(54)

35 335 Our focus is on implementation *quality* as opposed to controlling rigorous program fidelity  
36  
37 336 that is essential in efficacy trials. In school-based intervention implementation, ‘quality’ can  
38  
39 337 include: (i) sufficient exposure (dose); (ii) fidelity to the program protocol; (iii)  
40  
41 338 implementation (engaging students through active participation); (iv) adaptation (modifying  
42  
43 339 the intervention to meet developmental and cultural needs); and (v) teachers' attitudes,  
44  
45 340 understanding of the concepts/issues and prior experience.(55) In *TransformUs*, schools were  
46  
47 341 encouraged to choose contextually relevant strategies for implementation at their school,  
48  
49 342 rather than a prescriptive program, to enhance quality and ensure program adoption occurs in  
50  
51 343 the most contextually relevant way to achieve health benefits. This approach is associated  
52  
53 344 with increased effectiveness of real-world interventions and those more likely to produce  
54  
55 345 sustainable results.(50)

56 346 In the context of *TransformUs*, we will be creating an implementation infrastructure for  
57  
58 347 schools via Department of Education endorsement, provision of sustainability resources (i.e.,  
59  
60 348 template policy statements for schools to embed the program), and active engagement with  
349 State education decision-makers and other non-government partner organisations.



1  
2  
3 350 Implementation resources will also be provided to support and encourage school level  
4  
5 351 leadership to implement the program, and provide recommendations to promote integration  
6  
7 352 and sustainability (i.e., *TransformUs* champion roles and responsibilities, a template policy  
8  
9 353 document).

10  
11 354

### 12 13 355 ***TransformUs* program for scale up**

14  
15 356 Figure 1 presents the *TransformUs* program components for scale up. Based on outcomes  
16  
17 357 from the two pilot trials and formative work with our partner organisations and to maximise  
18  
19 358 program reach, all supporting program materials, implementation and training resources are  
20  
21 359 available online via a program website. The website (<https://transformus.com.au/>) is managed  
22  
23 360 by the research team at Deakin University. Teachers are required to complete the mandatory  
24  
25 361 online professional development via the *TransformUs* website. The professional development  
26  
27 362 provides strategies to integrate and sustain implementation of the program in schools, and  
28  
29 363 thus is essential to ensure minimum standards and knowledge are established prior to  
30  
31 364 program delivery. Based on evidence for the determinants of effective implementation by  
32  
33 365 adopting individuals (users, i.e., teachers),(56, 57) the content of the professional  
34  
35 366 development program has been designed to address the following seven key areas: (i) *support*  
36  
37 367 *for implementation* (teacher and school level); (ii) *skills required for implementation*; (iii)  
38  
39 368 *knowledge required for implementation*; (iv) *self-efficacy to implement*; (v) *fit of the program*  
40  
41 369 *into existing practices*; (vi) *relative advantage of the intervention over existing practices*; and  
42  
43 370 (vii) *perceived ownership of the program* (allowing for adaptation). For example, the  
44  
45 371 professional development includes ways of embedding the program in practice, such as  
46  
47 372 development of a tailored implementation plan (i.e., a checklist of activities teachers wish to  
48  
49 373 undertake and how they plan to sustain delivery), and knowledge reflection (quizzes) to test  
50  
51 374 learning.

52  
53 375 Multiple dissemination routes will be used to maximise program uptake and sustainability  
54  
55 376 (e.g., via our partners, through sharing the web link, email lists, social media, teacher  
56  
57 377 professional learning networks, and teacher professional development conferences and  
58  
59 378 workshops). Interactions with stakeholders will include face-to-face or online meetings (e.g.,  
60  
379 approximately two group meetings per year in addition to regular one-on-one meetings), and  
380 the provision of dissemination materials and communication packs to stakeholders, to enable  
381 them to promote *TransformUs* via their existing social media platforms and newsletters.

1  
2  
3 3824  
5 383 **Recruitment**6  
7  
8 384 ***Implementation trial: Partners (state level)***

9  
10 385 One representative from each of our partner organisations (six organisations were formal  
11 386 partners prior to the project being funded) who has experience in disseminating and/or  
12 387 supporting the *TransformUs* roll-out will be invited to participate in interviews to capture  
13 388 system-level impact (e.g., organisational-level maintenance, which relates to Aim 5 of the  
14 389 study). We expect to recruit one representative from each of our partner organisations. As  
15 390 depth of qualitative data is more important than sample size,(58) we aim to recruit a  
16 391 purposeful sample of representatives from our partner organisations. Recruited participants  
17 392 will be asked to provide signed consent prior to taking part.

18  
19  
20  
21  
22  
23  
24  
25 39326  
27 394 ***Implementation Trial: Principals (school level) and teachers***

28  
29 395 Schools and teachers will be made aware of *TransformUs* via multiple dissemination routes  
30 396 (as described in section ‘*TransformUs* program for scale up’). All schools and teachers who  
31 397 wish to adopt *TransformUs* register free of charge via the *TransformUs* website, and teachers  
32 398 can register to access the *TransformUs* program regardless of whether their school (i.e.,  
33 399 principal) has registered. This is to allow for both top-down and bottom-up program  
34 400 adoption. To access the professional development, registration is mandatory. Upon  
35 401 registration, a unique login username for each teacher/school will be generated, which they  
36 402 can use to revisit the website and access the professional development and online resources.  
37 403 During registration, schools/teachers will be invited to participate in the survey component of  
38 404 the Implementation Trial, where they will receive a plain language statement and online  
39 405 consent form.

40  
41 406 The registration process collects information about where they heard about the program,  
42 407 general physical activity policy and practice information for their school (e.g., information on  
43 408 participation in additional physical activity programs will also be collected), and which  
44 409 elements of the *TransformUs* program their school plans to implement. There are no costs to  
45 410 access the online resources. Implementation schools wishing to install new playground line  
46 411 markings or purchase physical activity equipment will not receive funding from the research  
47 412 project to do so. To help minimise the financial investment required, information on how to

1  
2  
3 413 best utilise existing playground line markings and physical activity equipment is provided  
4  
5 414 online.

6  
7 415 We plan to reach 714 schools (based on an estimate of 40% of the total number of schools in  
8  
9 416 Victoria(40); n =1,786). As part of the Implementation Trial, we aim to recruit ~15 school  
10  
11 417 leaders who registered for the survey evaluation component of *TransformUs* to participate in  
12  
13 418 a qualitative interview about their experiences of adopting and implementing the program.  
14  
15 419 This sample size provides sufficient ‘information power’.(59) Whilst schools/teachers will  
16  
17 420 provide online consent to participate in the survey component of the implementation trial at  
18  
19 421 the point of *TransformUs* registration, the sub sample of participants invited to complete an  
20  
21 422 interview will be required to provide additional consent prior to the interview commencing.

22 423

#### 23 24 424 ***Effectiveness trial: Schools and teachers***

25  
26 425 Twenty schools in Victoria will be recruited using stratified non-random sampling to  
27  
28 426 maximise area-level socioeconomic position and geographic location. Targeted recruitment  
29  
30 427 of twenty control schools in NSW will be matched as much as possible (based on school size,  
31  
32 428 type [e.g., Government, Catholic and Independent), SEIFA index (a measure of socio-  
33  
34 429 economic advantage and disadvantage by area in Australia), geographical area [e.g., rural,  
35  
36 430 remote], single sex/mixed students), with schools enrolled in the effectiveness trial in  
37  
38 431 Victoria. Schools will represent different socioeconomic urban and rural areas, including  
39  
40 432 different types, based on a minimum of two Grade 3 classes or four composite classes (i.e.,  
41  
42 433 Grade 3 and 4 classes combined).

43 434

#### 44 45 435 ***Effectiveness trial: Children and parents***

46  
47 436 Grades 3 and 4 children attending schools enrolled in the effectiveness schools (and their  
48  
49 437 parents) will be invited to help assess the effectiveness of the program. Children will be in  
50  
51 438 Grades 3 or 4 at baseline to enable a planned follow up at 12-months and 24-months, and is  
52  
53 439 consistent with the target age group evaluated in the original TransformUs RCT.(32) Parents  
54  
55 440 will receive information about the study via the schools’ regular methods of communication  
56  
57 441 (e.g., school intranet system, email, text) and an information brochure sent home with the  
58  
59 442 students. There will be a plain language statement and consent form for parents to provide  
60  
443 consent for themselves and/or their child to participate in the assessments (e.g., parent online

1  
2  
3 444 survey, child MVPA, body mass index and waist circumference). As part of the consent  
4  
5 445 process, parents/guardians will provide contact details (email and mobile telephone), which  
6  
7 446 will be used to email a unique link to an online parent survey at each time point and to  
8  
9 447 communicate with parents about the wearing and return of data collection devices from their  
10  
11 448 child. Three emails or texts will be sent over six weeks to remind parents to complete the  
12  
13 449 survey.

14 450 Figure 2 and Figure 3 present flow diagrams of participant recruitment into the Effectiveness  
15  
16 451 and Implementation trials, respectively.

17  
18 452

### 19 20 453 ***Sample size and power***

21  
22 454 Twenty Victorian schools will be recruited to ensure we have a diverse sample from a range  
23  
24 455 of school types (Government, Catholic and Independent), Socio Economic Status (SES)  
25  
26 456 tertiles (based on SEIFA data), and geographical areas. The target recruitment of children for  
27  
28 457 the effectiveness study is based on statistical power calculations of the minimum number of  
29  
30 458 participants required to detect differences in mean average daily sedentary behaviour  
31  
32 459 (primary outcome) at 12 months (primary time point) between children in control and  
33  
34 460 intervention schools. In the efficacy trial, average daily sedentary time was 347 minutes  
35  
36 461 (SD=60) for the PA+SB intervention group and 371 minutes (SD=80) for the control group at  
37  
38 462 Time 3 (18-month post baseline). Sample size calculations were conducted assuming a pre-  
39  
40 463 post design, adjusting for baseline, in accordance with a published formula.<sup>(60)</sup> Based on  
41  
42 464 estimates from the original cluster-RCT, to account for the design effect, an ICC of 0.03 for  
43  
44 465 children within school clusters was used, with a conservative correlation of 0.015 assumed  
45  
46 466 between two different pupils within a cluster at different time points and a correlation of 0.22  
47  
48 467 between the same pupils at different time points. Assuming  $\alpha=0.05$ , 80% power will be  
49  
50 468 available to detect a 16-minute difference in sedentary time (two-thirds of that observed in  
51  
52 469 the efficacy trial as effects may diminish at scale)<sup>(61)</sup> at 12-months between intervention and  
53  
54 470 control with recruitment of 1,094 children (547 from intervention and control schools,  
55  
56 471 assuming approximately 28 students/school sampled). This number is sufficient to detect as  
57  
58 472 small an effect as a 6-minute difference in physical activity between the control and  
59  
60 473 intervention schools, based on estimated standard deviations of 9-minutes for the PA + SB  
474  
475 group and 7-minutes for the control group from the cluster-RCT.

1  
2  
3 475***Inclusion and exclusion criteria: Implementation trial***

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

482

***Inclusion and exclusion criteria: Effectiveness trial***

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

498

***Program dissemination and implementation timeline***

499  
500 Supplementary File 4 shows the timing of the implementation activities over five years and  
501 how data collection maps to the RE-AIM framework. Program refinement and online training  
502 took place in the first six months (2017). Program dissemination and implementation began  
503 in September 2018 and is ongoing. It will be monitored until December 2023. Final data  
504 collection (interviews with partners) will occur in December 2023.

505  
58  
59  
60

1  
2  
3 506 ***Patient and public involvement***

4  
5 507 *At what stage in the research process were patients/the public first involved in the research*  
6  
7 508 *and how?*

8  
9  
10 509 Six organisations were formal partners prior to the project being funded. This included a state  
11 510 government department of education and independent schools' peak body, teacher  
12  
13 511 professional development organisations, a principals' association, and a health promotion  
14  
15 512 foundation. As this is an implementation/effectiveness trial designed to scale up a previously  
16 513 efficacious school-based intervention, we engaged closely with these partners in the  
17  
18 514 adaptation of the program for scale up. After funding was secured, these partnerships will  
19  
20 515 continue to be integral to the dissemination and evaluation of this project.

21  
22  
23 516 *How were the research question(s) and outcome measures developed and informed by their*  
24  
25 517 *priorities, experience, and preferences?*

26  
27 518 The research question related to the effectiveness of implementing and scaling up an  
28  
29 519 evidence-based school intervention on children's physical activity and sedentary behaviour,  
30  
31 520 is directly aligned with the policy priorities of the Victorian Department of Education. The  
32  
33 521 Department of Education has *Education State* targets which aim to increase the percentage of  
34  
35 522 children in Victoria meeting physical activity guidelines by 20% by 2025. This alignment  
36  
37 523 was critical in securing partnership with the Department of Education in Victoria.

38  
39 524 *How were patients/the public involved in the design of this study?*

40  
41  
42 525 As previously noted, from study inception and through the adaptation process for scale up,  
43  
44 526 we have had input from teachers, teacher professional development organisations (e.g.,  
45  
46 527 ACHPER and Peak Phys Ed), as well as key stakeholders such as Local Councils.

47  
48 528 *How were they involved in the recruitment to and conduct of the study?*

49  
50  
51 529 Stakeholder partners have actively disseminated the program and assisted with the  
52  
53 530 recruitment of schools and teachers for this study, and some partners have also assisted with  
54  
55 531 implementation of the intervention.

56  
57 532 *Were they asked to assess the burden of the intervention and time required to participate in*  
58  
59 533 *the research?*

1  
2  
3 534 An economic evaluation was conducted in the previous RCT which assessed the burden and  
4  
5 535 time required for teachers to implement the program. Interviews with teachers during a pilot  
6  
7 536 phase prior to the RCT, also informed the number of standing lessons and active breaks per  
8  
9 537 day were feasible for teachers to implement in terms of time requirements. We also pilot  
10  
11 538 tested the feasibility of the program in terms of fitting it into the curriculum with teachers.  
12  
13 539 This evidence was critical for informing the design and adaptations for the current project.  
14  
15 540 Formal partners on the trial were also asked to consider the time required for their  
16  
17 541 involvement in the trial (including any potential burden), as part of the in-kind contributions  
18  
19 542 they provided as a partner organisation.

20 543 *How were (or will) they be involved in your plans to disseminate the study results the*  
21  
22 544 *participants and relevant wider patient communities (e.g., by choosing what*  
23  
24 545 *information/results to share, when, and in what format)?*

25  
26 546 All stakeholder partners will play a role in dissemination of findings to teachers, schools, and  
27  
28 547 broader audience (e.g., health promotion officers, sport and recreation industry, etc) via a  
29  
30 548 range of communication platforms (e.g., social media, websites, newsletters, email  
31  
32 549 distribution lists) and teacher education professional learning events and opportunities (e.g.,  
33  
34 550 seminars, professional learning sessions and conference presentations, keynote addresses,  
35  
36 551 etc).

37 552

### 39 553 **Data collection**

41  
42 554 Supplementary File 4 presents the mixed method data to be collected at the partner (state),  
43  
44 555 principal (school), teacher, parent, and child levels, in accordance with the RE-AIM  
45  
46 556 framework. Recruitment and baseline data collection from schools in the effectiveness trial  
47  
48 557 commenced in 2018.

49 558

### 51 559 **Measures**

#### 53 560 ***Reach***

54  
55  
56  
57 561 Estimation of reach (Supplementary File 4) consists of all teachers and children in registered  
58  
59 562 schools (based on Victorian Department of Education records) who will be classified as  
60  
563 potentially exposed to the program. The total number of program recipients (teachers and

1  
2  
3 564 children) compared to the total number eligible will represent one measure of potential reach.  
4  
5 565 However, teachers could register and complete the professional development without a  
6  
7 566 school being registered or be included within a participating school but chose not to complete  
8  
9 567 the professional development. Therefore, we will also compare the number of teachers  
10  
11 568 completing the professional development (actual recipients) versus the total number of  
12  
13 569 teachers in Victorian schools (potentially eligible for the professional development) as an  
14  
15 570 additional measure of program reach. The *TransformUs* website will be used to capture the  
16  
17 571 number of teachers registered and if teachers complete the professional development. Unique  
18  
19 572 tracking codes (Google Analytics) associated with different promotional campaigns will  
20  
21 573 contribute to assessing *TransformUs* dissemination.  
22

23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

### 575 ***Effectiveness and individual-level maintenance***

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

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



1  
2  
3 595 Children's height (cm) and waist circumference (cm), and weight (kg) will be assessed twice  
4 596 (to the nearest 0.1cm and 0.1kg respectively) in school at each timepoint by trained research  
5 597 assistants. If the difference between the two measurements is greater than the following  
6 598 thresholds (Height=0.5cm; Waist=1cm; Weight=0.2kg) a third measurement will be taken.  
7 599 An average of the two closest measurements will then be calculated for analyses. Height will  
8 600 be assessed using a portable stadiometer (SECA 220, Los Angeles, California, USA). Weight  
9 601 will be assessed using digital scales (Wedderburn Tanita, Melbourne, Victoria, Australia),  
10 602 and a flexible steel tape will assess waist circumference at the narrowest point between the  
11 603 bottom rib and the iliac crest, in the midaxillary plane. BMI (kg/m<sup>2</sup>) z-scores will be  
12 604 calculated by subtracting the sex-age population median BMI scores from children's raw  
13 605 BMI scores.(66)

14 606 Additional exploratory outcomes will include children's awareness of the program, and self-  
15 607 reported quality of life,(67) assessed via an online survey at T1 (baseline), T2 (12-months)  
16 608 and T3 (24-months). The EQ-5D-Y-3L questionnaire(68) for children and adolescents aged  
17 609 8-16 years is an internationally validated English-Australian version of the EQ-5D  
18 610 questionnaire developed by the EuroQol Research Foundation. The Health-Related Quality of  
19 611 Life (HRQoL) section contains five items that capture (on a three-point scale) mobility,  
20 612 independence, usual activity, pain and feelings, and a sixth item that captures the child's  
21 613 perceived overall health rating (sliding scale 0-100) on the day of survey completion.  
22 614 Following EQ-5D-Y-3L scoring protocols, an overall HRQoL score will be created.

23 615 Parents will provide via an online survey a proxy-report of their child's physical activity  
24 616 using a validated single item measure assessing compliance with Australian physical activity  
25 617 guidelines.(69)

26 618

### 27 619 ***Adaptations to data collection due to COVID-19 restrictions***

28 620 The COVID-19 pandemic had a significant impact on data collection resulting in a need to  
29 621 change our protocol (Supplementary File 4). Due to extended COVID-19 lockdowns and  
30 622 government restrictions in Australia, on site data collection in schools was prohibited in  
31 623 Victoria during 2020 and 2021, and in NSW during 2021. During periods when children were  
32 624 able to attend school over that time, accelerometers were sent directly to families, or directly  
33 625 to schools for distributing to students (NSW only), and the child and parent surveys were  
34 626 completed online. Height, weight, and waist circumference data were not collected. Teacher

1  
2  
3 627 and principal data (survey and interview) were also not collected to reduce burden on school  
4  
5 628 staff during the challenges of teaching remotely. These adaptations impacted six schools at  
6  
7 629 T2, and 20 schools at T3 in Victoria and two schools at T3 in NSW. Due to differences in  
8  
9 630 lockdown restrictions between the states in 2020, the timing of data collection in NSW was  
10  
11 631 adjusted to match Victoria. As a result, principal/teachers interviews were only conducted at  
12  
13 632 12-months.

14 633 As primary schools in Victoria were unable to operate as normal and ran learning from home  
15  
16 634 for a total of 267 days across 2020 and 2021, additional teacher support was provided so they  
17  
18 635 could apply the pedagogical elements of *TransformUs* to online teaching and learning. This  
19  
20 636 included a remote learning sample pack with active English and Maths lesson ideas that could  
21  
22 637 be delivered online. An online family pack was also provided for parents to help support their  
23  
24 638 child's physical activity at home.

25 639

#### 27 640 ***Adoption***

29  
30 641 All schools in Victoria are eligible to participate in *TransformUs* and therefore the total  
31  
32 642 number of schools in the state (potentially eligible) and the total number who register (actual  
33  
34 643 schools who adopt *TransformUs*) will be used to estimate the adoption rate (Supplementary  
35  
36 644 File 4). The *TransformUs* website will be used to capture the number of schools registered  
37  
38 645 and if the teacher completes the professional development. Partner interviews were due to  
39  
40 646 occur at 12-months, 24-months and 36-months post baseline, however, due to COVID-19  
41  
42 647 restrictions outlined previously, interviews were conducted at 12-months (September –  
43  
44 648 October 2019) and a final interview will occur at 5 years post baseline (2023).

45 649

#### 47 650 ***Implementation***

48  
49 651 To capture implementation at the school-level (Supplementary File 4), survey and interview  
50  
51 652 data will capture organisational infrastructure and resource availability, organisational  
52  
53 653 readiness, and capacity to implement *TransformUs*, planned implementation, strategies for  
54  
55 654 implementation and perceived impact of the program on children's physical activity,  
56  
57 655 sedentary behaviour and classroom behaviour outcomes, and outcomes at the school level  
58  
59 656 (e.g., change in teaching behaviours). Existing survey measures will be sourced from  
60  
61 657 previous studies of children's physical activity(32, 70, 71) and school-based implementation

1  
2  
3 658 (72). Organisational readiness will be assessed using the Organisational Readiness for  
4 Implementation Change (ORIC) scale,(73) adapted for the *TransformUs* context.  
5  
6  
7 660

8 661 Interviews with partners (12-months and 5 years post baseline) and principals/teachers (12-  
9 months) will be based on the 14 domains of the Theoretical Domains Framework(52) to  
10 662 identify barriers and targeted strategies to enhance teacher and school implementation of the  
11 663 program. In addition, we will use Google Analytics to capture how schools and teachers use  
12 664 the *TransformUs* website, which program components are downloaded, and which aspects of  
13 665 the website are most and least accessed. For parents and children, survey data will capture  
14 666 dose received and perceptions of the program.  
15  
16  
17  
18  
19  
20  
21 668

### 22 669 ***Organisational-level maintenance***

23  
24 670 For the implementation trial, organisational-level maintenance is defined as continued  
25 671 activities by implementers (e.g., adaptation over time, changes in implementation dose,  
26 672 institutionalisation within the school setting and change to policies and practices) and  
27 673 continued capacity within the community (e.g., stakeholder engagement and support for the  
28 674 intervention, and activities over time). Organisational-level maintenance will be assessed via  
29 675 partner self-report and interviews, principal and teacher online surveys/interviews, and  
30 676 parent/child survey data on dose received and perceptions of the program (Supplementary  
31 677 File 4). Google Analytics data will inform on continued use of the *TransformUs* website.  
32  
33  
34  
35  
36  
37  
38  
39 678  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 6794  
5 680 **Data analysis**6  
7 681 *Qualitative data*

8  
9 682 Qualitative data in this study contributes to assessing all five dimensions of the RE-AIM  
10 683 framework. Qualitative interview data will be transcribed and analysed thematically via  
11 684 NVivo12. Coding and theme development will be firstly deductive, guided by the study aims  
12 685 and RE-AIM domains(74) followed by an inductive approach that will be directed by content  
13 686 of the data.(75) Themes will be grouped against the 14 domains of the TDF.(52) Data will be  
14 687 coded by two independent researchers.

15  
16 68817  
18 689 *Quantitative data*

19 690 Survey data for program Reach, Adoption, Implementation, and Organisational-level  
20 691 Maintenance will be reported descriptively. Methods for calculating level of implementation  
21 692 will be based on a previous implementation evaluation of the *TransformUs* efficacy trial (27).  
22 693 In brief, teachers will be grouped by level of implementation based on the proportion of the  
23 694 entire intervention delivered (dose delivered and fidelity). Implementation levels will  
24 695 correspond to: (i) 'low' (<33% of the entire intervention delivered); (ii) 'moderate' (33-67%  
25 696 delivered); and (iii) 'high' (>67% delivered).(27)

26  
27 69728  
29 698 *Quantitative data: Effectiveness Trial*

30 699 The effectiveness component of the study will compare primary, secondary and exploratory  
31 700 outcomes among children, between intervention and control schools. Linear mixed models  
32 701 will be fitted to compare mean average daily sedentary time and MVPA at T1 (baseline), T2  
33 702 (12-mths) and T3 (24-mths) (primary outcomes), average sedentary time and MVPA on  
34 703 weekdays and during school hours, zBMI, waist circumference (secondary outcomes) and  
35 704 quality of life (exploratory outcomes) at 12-months and 24-months between children in  
36 705 intervention and control schools. Linear mixed models will include fixed effects for group  
37 706 (intervention/control), time (months since baseline [time 1]) and a group by time interaction,  
38 707 and random effects for clustering of time nested within children, class and school. In the  
39 708 absence of random assignment, propensity scores will be developed to determine the  
40 709 probability of a child receiving the intervention based on observed baseline covariates (e.g.,  
41 710 age, sex, area-level socioeconomic status of residence). Inverse probability of treatment  
42 711 weighting (IPTW) using the propensity score will be adopted to assist in obtaining unbiased

1  
2  
3 712 estimates of average treatment effects, although it is acknowledged that this will not control  
4 713 for the difference in location (Victoria or NSW) between intervention and control  
5 714 schools.<sup>(76)</sup> Due to the impact of COVID interruptions on this study, sensitivity analysis will  
6 715 consider only children who participated in baseline and 12-month follow-up in intervention  
7 716 and control schools to examine the effectiveness prior to home schooling and other COVID  
8 717 impacts.

718

15 719 Descriptive statistics will be calculated for the additional exploratory outcomes: children's  
16 720 perceptions and awareness of the program, at 12-months and 24-months for children in the  
17 721 intervention group, and parent proxy report of their child's physical activity at baseline, 12-  
18 722 months and 24-months in both the control and intervention group. All statistical analyses will  
19 723 be performed using Stata SE v17.

724

### 725 **Ethics and dissemination**

28 726 The trial was approved by the Deakin University human research ethics committee (HEAG-H  
29 727 28\_2017), Victorian Department of Education and Training, the NSW Department of  
30 728 Education, Australian Catholic University (2017-145R) and the relevant Catholic Education  
31 729 Offices. Partners, schools/teachers, and parents will provide informed signed consent prior to  
32 730 taking part in surveys or interviews. Parents will provide consent for their child to participate  
33 731 in assessments as part of the effectiveness trial.

39 732 Findings from this trial will be disseminated via peer review publications, scientific  
40 733 conferences, summary reports to schools and our partner organisations. This trial builds on  
41 734 the successful cluster RCT of *TransformUs*.<sup>(26)</sup> Completion of the *TransformUs* RCT was  
42 735 timely, as in 2016, the Victorian Department of Education released the Education State  
43 736 policy, with a 10-year target to increase the number of children meeting physical activity  
44 737 guidelines on weekdays by 20%.<sup>(77)</sup> *TransformUs* directly aligns with the policy priorities of  
45 738 Department of Education, and this alignment was critical in securing partnership with  
46 739 Department of Education in Victoria. Establishing how best to scale up this efficacious  
47 740 program will generate important learnings that will inform future research studies in terms of  
48 741 implementation assessment and monitoring of policy uptake, and provide key information for  
49 742 relevant stakeholders wishing to expand similar initiatives.

743

1  
2  
3 744 **Contributors**  
4

5 745 JS, HK, AT, CL, NDR, DL, JDG, AB, AT, LMB, KEL, LA, & HB contributed to the study  
6  
7 746 design. HK led writing of manuscript with JS, and KEL led development of the analysis plan  
8  
9 747 for the effectiveness component. JS, HK, AT, CL, NDR, DL, JDG, AB, AT, LMB, KEL, LA,  
10  
11 748 NL, SL, TS, HB & KW revised the manuscript for intellectual content and read and approved  
12  
13 749 the final draft.  
14

15 750

16  
17 751 **Funding**  
18

19  
20 752 This work is funded by an Australian National Health and Medical Research Council  
21  
22 753 (NHMRC) Partnership Grant (APP1115708) and VicHealth. JS is supported by a NHMRC  
23  
24 754 Leadership Level 2 Fellowship (APP1176885). DRL is supported by an NHMRC Senior  
25  
26 755 Research Fellowship (APP1154507). NDR was supported by a Future Leader Fellowship  
27  
28 756 from the National Heart Foundation of Australia (ID 101895). LA is supported by an  
29  
30 757 Australian Research Council Discovery Early Career Researcher Award (DE220100847).  
31

32 758

33 759 **Competing interests**  
34

35 760 All authors have completed the ICMJE uniform disclosure form at  
36  
37 761 [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) and declare: no support from any organisation for the  
38  
39 762 submitted work; no financial relationships with any organisations that might have an interest  
40  
41 763 in the submitted work in the previous three years. This research does not fund schools to  
42  
43 764 implement the program (which is made available at no cost), and no product endorsements  
44  
45 765 are made to schools by the research team for implementation of any aspect of the program.  
46  
47 766 All authors declare no other relationships or activities that could appear to have influenced  
48  
49 767 the submitted work.  
50

51 768

52  
53 769 **References**  
54

55 770 1. Tambalis KD, Sidossis LS. Physical Activity and Cardiometabolic Health Benefits in  
56  
57 771 Children. In: Kokkinos P, Narayan P, editors. Cardiorespiratory Fitness in Cardiometabolic  
58  
59 772 Diseases: Prevention and Management in Clinical Practice. Cham: Springer International  
60  
773 Publishing; 2019. p. 405-23.

- 1  
2  
3 774 2. Biddle SJH, Ciaccioni S, Thomas G, Vergeer I. Physical activity and mental health in  
4 775 children and adolescents: An updated review of reviews and an analysis of causality.  
5  
6 776 *Psychology of Sport and Exercise*. 2019;42:146-55.
- 7  
8 777 3. Singh AS, Saliassi E, Van Den Berg V, Uijtdewilligen L, De Groot RH, Jolles J, et al.  
9 778 Effects of physical activity interventions on cognitive and academic performance in children  
10 779 and adolescents: a novel combination of a systematic review and recommendations from an  
11  
12 780 expert panel. *Br J Sports Med*. 2019;53(10):640-7.
- 13  
14 781 4. Watson A, Timperio A, Brown H, Best K, Hesketh KD. Effect of classroom-based  
15 782 physical activity interventions on academic and physical activity outcomes: A systematic  
16  
17 783 review and meta-analysis. *International Journal of Behavioral Nutrition and Physical*  
18  
19 784 *Activity*. 2017;14(1).
- 20  
21 785 5. Schmidt M, Benzing V, Kamer M. Classroom-Based Physical Activity Breaks and  
22 786 Children's Attention: Cognitive Engagement Works! *Front Psychol*. 2016;7:1474.
- 23  
24 787 6. Minges KE, Chao AM, Irwin ML, Owen N, Park C, Whittemore R, et al. Classroom  
25 788 Standing Desks and Sedentary Behavior: A Systematic Review. *Pediatrics*. 2016;137(2):1-18.
- 26  
27 789 7. Tremblay MS, Aubert S, Barnes JD, Saunders TJ, Carson V, Latimer-Cheung AE, et  
28 790 al. Sedentary Behavior Research Network (SBRN) – Terminology Consensus Project process  
29 791 and outcome. *International Journal of Behavioral Nutrition and Physical Activity*.  
30  
31 792 2017;14(1):75.
- 32  
33 793 8. Chaput JP, Willumsen J, Bull F, Chou R, Ekelund U, Firth J, et al. 2020 WHO  
34 794 guidelines on physical activity and sedentary behaviour for children and adolescents aged 5–  
35 795 17 years: summary of the evidence. *International Journal of Behavioral Nutrition and*  
36 796 *Physical Activity*. 2020;17(1):141.
- 37  
38 797 9. Dornhecker M, Blake J, Benden M, Zhao H, Wendel M. The Effect of Stand-biased  
39 798 Desks on Academic Engagement: An Exploratory Study. *Int J Health Promot Educ*.  
40 799 2015;53(5):271-80.
- 41  
42 800 10. Australian Institute of Health and Welfare. Australia's health 2022. Canberra: AIHW;  
43 801 2022.
- 44  
45 802 11. Department of Health. Physical activity and exercise guidelines for all Australians.  
46 803 Canberra: Australia2021.
- 47  
48 804 12. Ridgers ND, Salmon J, Ridley K, O'Connell E, Arundell L, Timperio A. Agreement  
49 805 between activPAL and ActiGraph for assessing children's sedentary time. *The international*  
50 806 *journal of behavioral nutrition and physical activity*. 2012;9:15.

- 1  
2  
3 807 13. Ridgers ND, Timperio A, Crawford D, Salmon J. Five-year changes in school recess  
4 808 and lunchtime and the contribution to children's daily physical activity. *Br J Sports Med.*  
5 809 2012;46(10):741-6.  
6  
7  
8 810 14.  
9  
10 811 <https://www.education.vic.gov.au/school/teachers/teachingresources/discipline/physe>  
11 [d/Pages/activeschoolstoolkit.aspx](https://www.education.vic.gov.au/school/teachers/teachingresources/discipline/physe/d/Pages/activeschoolstoolkit.aspx) Victoria: Australia: Department of Education and Training.  
12 812  
13 813 15. Centers for Disease Control and Prevention. Comprehensive School Physical Activity  
14 814 Programs: A Guide for Schools. Atlanta, GA: U.S: Department of Health and Human  
15 815 Services; 2013.  
16  
17 816 16. World Health Organization. Global Action Plan on Physical Activity 2018-2030:  
18 817 more active people for a healthier world. Geneva; 2018. Contract No.: Licence: CC BY-NC-  
19 818 SA 3.0 IGO.  
20  
21 819 17. Lai SK, Costigan SA, Morgan PJ, Lubans DR, Stodden DF, Salmon J, et al. Do  
22 820 school-based interventions focusing on physical activity, fitness, or fundamental movement  
23 821 skill competency produce a sustained impact in these outcomes in children and adolescents?  
24 822 A systematic review of follow-up studies. *Sports Med.* 2014;44(1):67-79.  
25  
26 823 18. Hegarty LM, Mair JL, Kirby K, Murtagh E, Murphy MH. School-based Interventions  
27 824 to Reduce Sedentary Behaviour in Children: A Systematic Review. *AIMS Public Health.*  
28 825 2016;3(3):520-41.  
29  
30 826 19. Love R, Adams J, van Sluijs EMF. Are school-based physical activity interventions  
31 827 effective and equitable? A meta-analysis of cluster randomized controlled trials with  
32 828 accelerometer-assessed activity. *Obesity Reviews.* 2019;20(6):859-70.  
33  
34 829 20. Koorts H, Timperio A, Abbott G, Arundell L, Ridgers ND, Cerin E, et al. Is level of  
35 830 implementation linked with intervention outcomes? Process evaluation of the TransformUs  
36 831 intervention to increase children's physical activity and reduce sedentary behaviour. *The*  
37 832 *international journal of behavioral nutrition and physical activity.* 2022;19(1):122.  
38  
39 833 21. Lonsdale C, Rosenkranz RR, Peralta LR, Bennie A, Fahey P, Lubans DR. A  
40 834 systematic review and meta-analysis of interventions designed to increase moderate-to-  
41 835 vigorous physical activity in school physical education lessons. *Prev Med.* 2013;56(2):152-  
42 836 61.  
43  
44 837 22. Parrish AM, Chong KH, Moriarty AL, Batterham M, Ridgers ND. Interventions to  
45 838 Change School Recess Activity Levels in Children and Adolescents: A Systematic Review  
46 839 and Meta-Analysis. *Sports Med.* 2020;50(12):2145-73.  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



- 1  
2  
3 840 23. Escalante Y, García-Hermoso A, Backx K, Saavedra JM. Playground designs to  
4 841 increase physical activity levels during school recess: a systematic review. *Health education*  
5 842 & behavior : the official publication of the Society for Public Health Education.  
6  
7 843 2014;41(2):138-44.  
8  
9 844 24. Santos F, Sousa H, Gouveia É R, Lopes H, Peralta M, Martins J, et al. School-Based  
10 845 Family-Oriented Health Interventions to Promote Physical Activity in Children and  
11  
12 846 Adolescents: A Systematic Review. *Am J Health Promot.* 2023;37(2):243-62.  
13  
14 847 25. Hinckson E, Salmon J, Benden M, Clemes SA, Sudholz B, Barber SE, et al. Standing  
15 848 Classrooms: Research and Lessons Learned from Around the World. *Sports Med.*  
16 849 2016;46(7):977-87.  
17  
18 850 26. Salmon J, Arundell L, Cerin E, Ridgers ND, Hesketh KD, Daly RM, et al. Transform-  
19 851 Us! cluster RCT: 18-month and 30-month effects on children's physical activity, sedentary  
20 852 time and cardiometabolic risk markers. *British Journal of Sports Medicine.* 2023;57(5):311-9.  
21  
22 853 27. Koorts H, Timperio A, Abbott G, Arundell L, Ridgers ND, Cerin E, et al. Is  
23 854 implementation linked with outcomes? Process evaluation of the Transform-Us! intervention  
24 855 to increase children's physical activity and reduce sedentary behaviour IJBNPA. 2022.  
25  
26 856 28. Lonsdale C, Sanders T, Cohen KE, Parker P, Noetel M, Hartwig T, et al. Scaling-up  
27 857 an efficacious school-based physical activity intervention: Study protocol for the 'Internet-  
28 858 based Professional Learning to help teachers support Activity in Youth' (iPLAY) cluster  
29 859 randomized controlled trial and scale-up implementation evaluation. *BMC Public Health.*  
30 860 2016;16(1):873.  
31  
32 861 29. Cassar S, Salmon J, Timperio A, Naylor PJ, van Nassau F, Contardo Ayala AM, et al.  
33 862 Adoption, implementation and sustainability of school-based physical activity and sedentary  
34 863 behaviour interventions in real-world settings: a systematic review. *International Journal of*  
35 864 *Behavioral Nutrition and Physical Activity.* 2019;16(1):120.  
36  
37 865 30. Koorts H, Bauman A, Edwards N, Bellew W, Brown WJ, Duncan MJ, et al. Tensions  
38 866 and Paradoxes of Scaling Up: A Critical Reflection on Physical Activity Promotion.  
39 867 *International Journal of Environmental Research and Public Health.* 2022;19(21):14284.  
40  
41 868 31. Glasgow R, Vogt T, Boles S. Evaluating the public health impact of health promotion  
42 869 interventions: the RE-AIM framework. *Am J Public Health.* 1999;89(9):1322-7.  
43  
44 870 32. Salmon J, Arundell L, Hume C, Brown H, Hesketh K, Dunstan DW, et al. A cluster-  
45 871 randomized controlled trial to reduce sedentary behavior and promote physical activity and  
46 872 health of 8-9 year olds: The Transform-Us! Study. *BMC Public Health.* 2011;11(1):759.  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 873 33. Bandura A. Social foundations of thought and action: A Social Cognitive Theory.  
4 874 Englewood Cliffs, NJ: Prentice Hall; 1986.
- 5  
6 875 34. Rachlin H. Judgement, decision, and choice: A cognitive/behavioral synthesis. New  
7 876 York: WH Freeman; 1989.
- 8  
9 877 35. Bronfenbrenner U. Ecological Systems Theory. In: Vasta R, editor. Six theories of  
10 878 child development: revised formulations and current issues. London: Jessica Kingsley  
11 879 Publishers; 1992. p. 187-249.
- 12  
13 880 36. <https://victoriancurriculum.vcaa.vic.edu.au/>
- 14  
15 881 37. <https://www.australiancurriculum.edu.au/>
- 16  
17 882 38. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation  
18 883 hybrid designs: combining elements of clinical effectiveness and implementation research to  
19 884 enhance public health impact. *Med Care*. 2012;50(3):217-26.
- 20  
21 885 39. Peters DH, Tran NT, Adam T. Implementation research in health: a practical guide.  
22 886 2013.
- 23  
24 887 40. [www.education.vic.gov.au/Documents/about/department/brochureJuly.docx](http://www.education.vic.gov.au/Documents/about/department/brochureJuly.docx)
- 25  
26 888 41. Dunton G, Liao Y, Grana R, Lagloire R, Riggs N, Chou CP, et al. State-wide  
27 889 dissemination of a school-based nutrition education programme: a RE-AIM (Reach, Efficacy,  
28 890 Adoption, Implementation, Maintenance) analysis. *Public health nutrition*. 2012;17(2):422-  
29 891 30.
- 30  
31 892 42. Shadish WR, Cook TD, Campbell DT. Experimental and quasi-experimental designs  
32 893 for generalized causal inference. Boston: Houghton Miffler Company; 2002.
- 33  
34 894 43. Salmon J, Arundell L, Cerin E, Ridgers ND, Hesketh KD, Daly RM, et al. The  
35 895 Transform-Us! cluster RCT: 18- and 30-month effects on children's physical activity,  
36 896 sedentary time and cardiometabolic risk markers. Under Review. 2022.
- 37  
38 897 44. Koorts H, Eakin E, Estabrooks P, Timperio A, Salmon J, Bauman A. Implementation  
39 898 and scale up of population physical activity interventions for clinical and community settings:  
40 899 the PRACTIS guide. *International Journal of Behavioral Nutrition and Physical Activity*.  
41 900 2018;15(1):51.
- 42  
43 901 45. Australian Bureau of Statistics. Information Paper: An Introduction to Socio-  
44 902 Economic Indexes for Areas (SEIFA) 2006. Canberra; 2006. Report No.: 2039.0.
- 45  
46 903 46. World Health Organization. Practical guidance for scaling up health service  
47 904 innovations. Geneva, Switzerland: World Health Organization; 2009.
- 48  
49 905 47. Milat AJ, Newson R, King L. Increasing the scale of population health interventions:  
50 906 A Guide. Sydney: NSW Ministry of Health: Centre for Epidemiology and Evidence; 2014.

- 1  
2  
3 907 48. O'Hara BJ, Phongsavan P, King L, Develin E, Milat AJ, Eggins D, et al. 'Translational  
4 908 formative evaluation': critical in up-scaling public health programmes. *Health Promot Int.*  
5 909 2013;29(1):38-46.  
6  
7  
8 910 49. Wandersman A, Duffy J, Flaspohler P, Noonan R, Lubell K, Stillman L, et al.  
9 911 Bridging the gap between prevention research and practice: the interactive systems  
10 912 framework for dissemination and implementation. *American journal of community*  
11 913 *psychology.* 2008;41(3-4):171-81.  
12  
13 914 50. Meyers DC, Durlak JA, Wandersman A. The quality implementation framework: a  
14 915 synthesis of critical steps in the implementation process. *American journal of community*  
15 916 *psychology.* 2012;50(3-4):462-80.  
16  
17 917 51. Wiltsey Stirman S, Kimberly J, Cook N, Calloway A, Castro F, Charns M. The  
18 918 sustainability of new programs and innovations: a review of the empirical literature and  
19 919 recommendations for future research. *Implement Sci.* 2012;7:17.  
20  
21 920 52. Michie S, Johnston M, Francis J, Hardeman W, Eccles M. From Theory to  
22 921 Intervention: Mapping Theoretically Derived Behavioural Determinants to Behaviour Change  
23 922 Techniques. *Applied Psychology.* 2008;57(4):660-80.  
24  
25 923 53. Simmons R, Shiffman J. Scaling up health service innovations: a framework for  
26 924 action. In: Simmons R FP, Ghiron L., editor. *Scaling up health service delivery.* Geneva:  
27 925 World Health Organization; 2007. p. 1-30.  
28  
29 926 54. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations  
30 927 for specifying and reporting. *Implementation Science.* 2013;8(1):139.  
31  
32 928 55. Dusenbury L, Brannigan R, Hansen WB, Walsh J, Falco M. Quality of  
33 929 implementation: developing measures crucial to understanding the diffusion of preventive  
34 930 interventions. *Health Education Research.* 2004;20(3):308-13.  
35  
36 931 56. Fleuren M, Wiefferink K, Paulussen T. Determinants of innovation within health care  
37 932 organizations: literature review and Delphi study. *Int J Qual Health Care.* 2004;16(2):107-23.  
38  
39 933 57. Chaudoir S, Dugan A, Barr C. Measuring factors affecting implementation of health  
40 934 innovations: a systematic review of structural, organizational, provider, patient, and  
41 935 innovation level measures. *Implement Sci.* 2013;8.  
42  
43 936 58. Clarke V, Braun V. To saturate or not to saturate? Questioning data saturation as a  
44 937 useful concept for thematic analysis and sample-size rationales. *Qualitative Research in*  
45 938 *Sport, Exercise and Health.* 2020.  
46  
47 939 59. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview  
48 940 Studies: Guided by Information Power. *Qual Health Res.* 2016;26(13):1753-60.

- 1  
2  
3 941 60. Rutterford C, Copas A, Eldridge S. Methods for sample size determination in cluster  
4 942 randomized trials. *Int J Epidemiol.* 2015;44(3):1051-67.
- 5  
6 943 61. Nettlefold L, Naylor PJ, Macdonald HM, McKay HA. Scaling up Action Schools!  
7 944 BC: How Does Voltage Drop at Scale Affect Student Level Outcomes? A Cluster  
8 945 Randomized Controlled Trial. *Int J Environ Res Public Health.* 2021;18(10).
- 9  
10 946 62. Evenson KR, Catellier DJ, Gill K, Ondrak KS, McMurray RG. Calibration of two  
11 947 objective measures of physical activity for children. *J Sports Sci.* 2008;26(14):1557-65.
- 12  
13 948 63. Gabel L, Ridgers ND, Della Gatta PA, Arundell L, Cerin E, Robinson S, et al.  
14 949 Associations of sedentary time patterns and TV viewing time with inflammatory and  
15 950 endothelial function biomarkers in children. *Pediatric obesity.* 2016;11(3):194-201.
- 16  
17 951 64. Ridgers ND, Timperio A, Crawford D, Salmon J. Five-year changes in school recess  
18 952 and lunchtime and the contribution to children's daily physical activity. *British Journal of*  
19 953 *Sports Medicine.* 2012;46(10):741-6.
- 20  
21 954 65. Arundell L, Ridgers ND, Veitch J, Salmon J, Hinkley T, Timperio A. 5-Year Changes  
22 955 in Afterschool Physical Activity and Sedentary Behavior. *American journal of preventive*  
23 956 *medicine.* 2013;44(6):605-11.
- 24  
25 957 66. Kuczmarski RJ, Ogdon CL, Guo SS. 2000 CDC growth charts for the United States:  
26 958 Methods and development. In: Statistics NCH, editor. *Vital Health Statistics.* 11.  
27 959 Washington, 2002.
- 28  
29 960 67. Wille N, Badia X, Bonsel G, Burström K, Cavrini G, Devlin N, et al. Development of  
30 961 the EQ-5D-Y: a child-friendly version of the EQ-5D. *Quality of life research : an*  
31 962 *international journal of quality of life aspects of treatment, care and rehabilitation.*  
32 963 2010;19(6):875-86.
- 33  
34 964 68. Dalziel K, Catchpool M, García-Lorenzo B, Gorostiza I, Norman R, Rivero-Arias O.  
35 965 Feasibility, Validity and Differences in Adolescent and Adult EQ-5D-Y Health State  
36 966 Valuation in Australia and Spain: An Application of Best–Worst Scaling.  
37 967 *PharmacoEconomics.* 2020;38(5):499-513.
- 38  
39 968 69. Ridgers ND, Timperio A, Crawford D, Salmon J. Validity of a brief self-report  
40 969 instrument for assessing compliance with physical activity guidelines amongst adolescents. *J*  
41 970 *Sci Med Sport.* 2012;15(2):136-41.
- 42  
43 971 70. Telford A, Salmon J, Jolley D, Crawford D. Reliability and Validity of Physical  
44 972 Activity Questionnaires for Children: The Children's Leisure Activities Study Survey  
45 973 (CLASS). 2004;16(1):64.
- 46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 974 71. Salmon J, Timperio A, Telford A, Carver A, Crawford D. Association of Family  
4 975 Environment with Children's Television Viewing and with Low Level of Physical Activity.  
5 976 Obesity Research. 2005;13(11):1939-51.
- 6  
7  
8 977 72. Naylor P, Macdonald H, Reed K, McKay H. Action Schools! BC: a socioecological  
9 978 approach to modifying chronic disease risk factors in elementary school children. Prev  
10 979 Chronic Dis. 2006;3(2):A60.
- 11  
12  
13 980 73. Shea CM, Jacobs SR, Esserman DA, Bruce K, Weiner BJ. Organizational readiness  
14 981 for implementing change: a psychometric assessment of a new measure. Implementation  
15 982 Science. 2014;9(1):1-15.
- 16  
17  
18 983 74. Holtrop JS, Rabin BA, Glasgow RE. Qualitative approaches to use of the RE-AIM  
19 984 framework: rationale and methods. BMC Health Services Research. 2018;18(1):177.
- 20  
21  
22 985 75. Joffe H, Yardley L. Content and Thematic Analysis. In: Marks D, Yardley L, editors.  
23 986 Research Methods for Clinical and Health Psychology: Sage Publications; 2004. p. 56-66.
- 24  
25  
26 987 76. Wasserstein RL, Schirm AL, Lazar NA. Moving to a World Beyond “ $p < 0.05$ ”. The  
27 988 American Statistician. 2019;73(sup1):1-19.
- 28  
29 989 77. Department of Education and Training. The Education State: Schools. Published by  
30 990 the State of Victoria, Department of Education and Training.

991

**992 FIGURE TITLES****993 Figure 1.** *TransformUs* program components for scale up

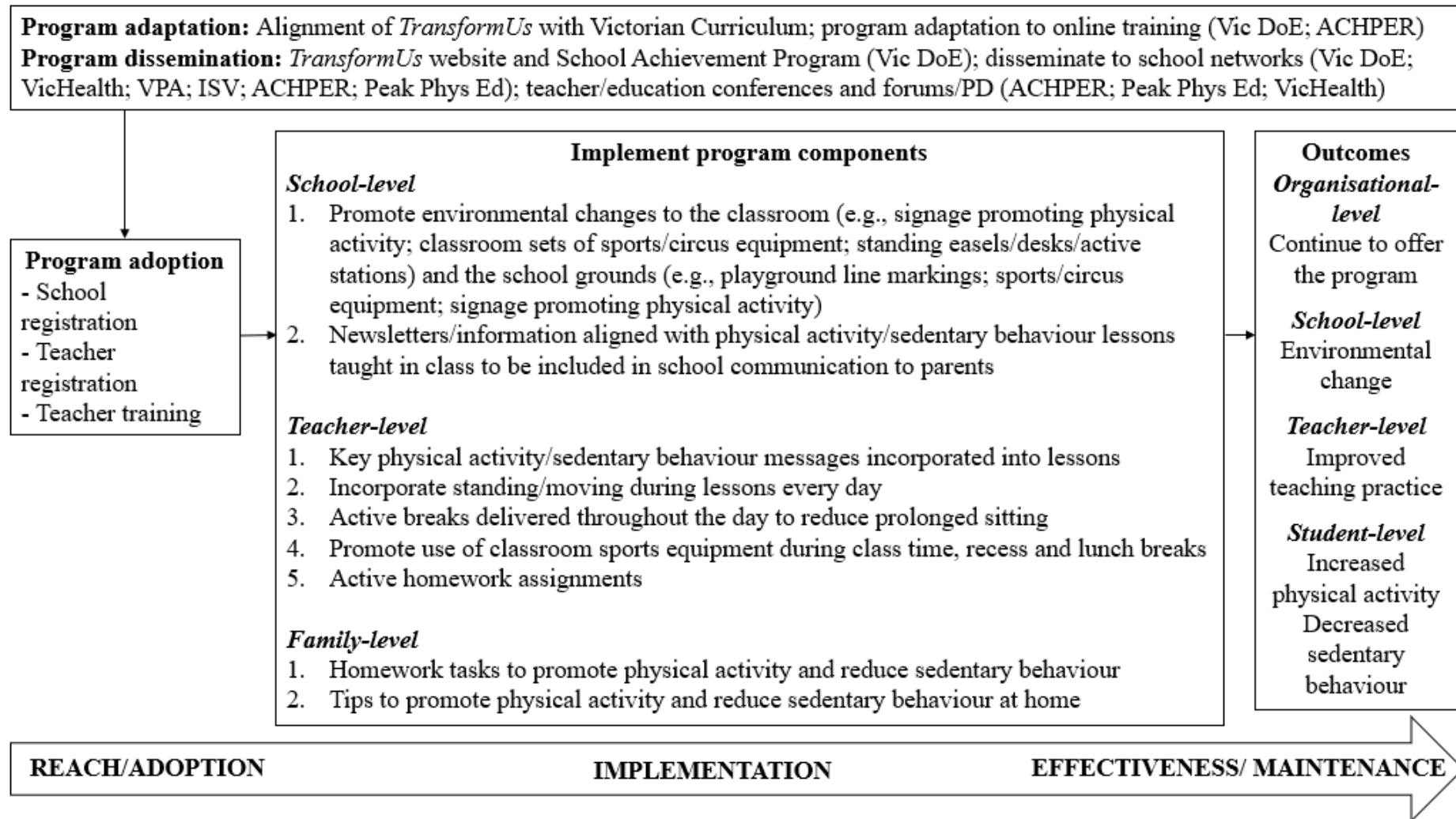
994

**995 Figure 2.** Effectiveness trial participant flow diagram

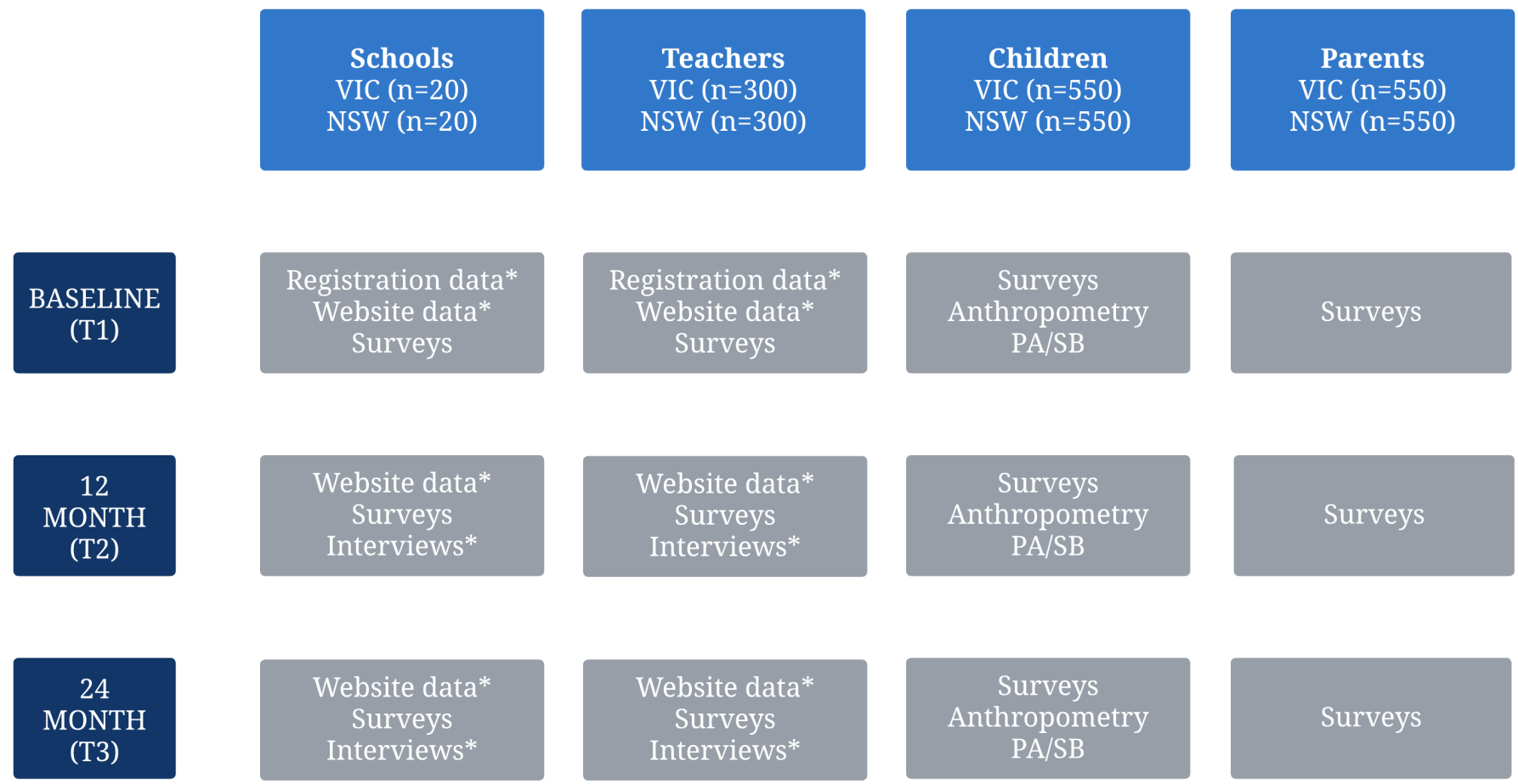
996

**997 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

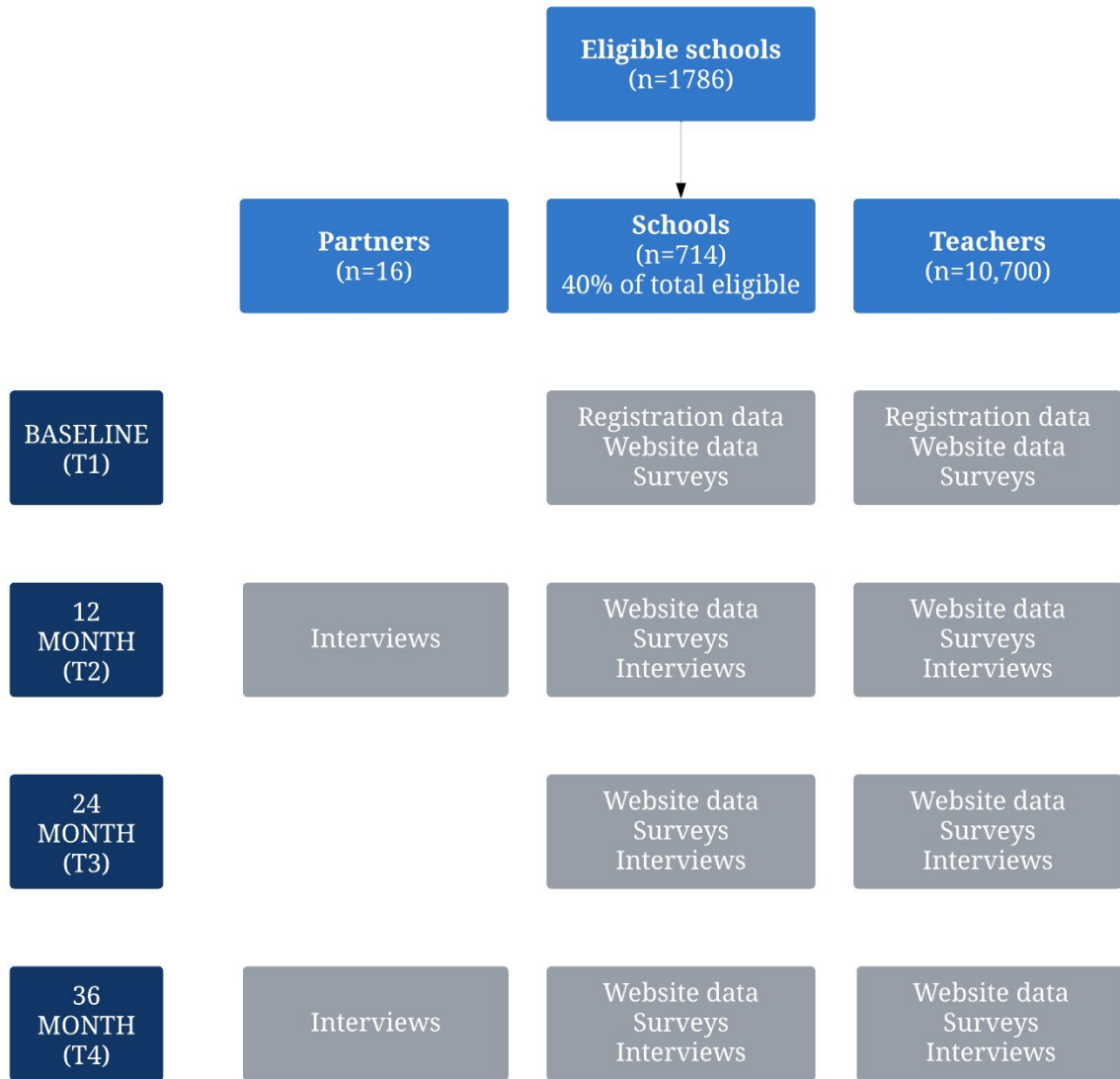
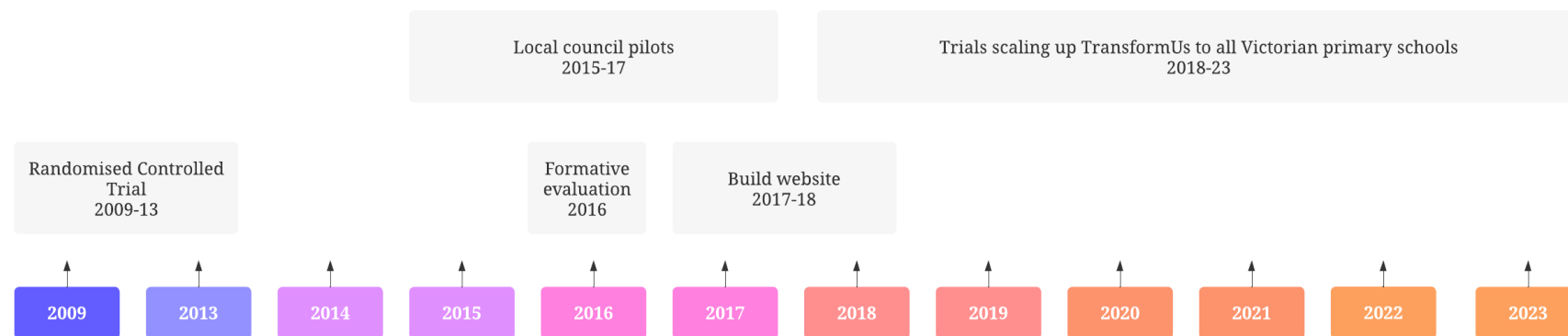


Figure 3. Implementation Trial Participant Flow Diagram





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



ew only



STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

## 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
<b>Administrative information</b>			
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
<b>Introduction</b>			
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
<b>Methods: Participants, interventions, and outcomes</b>			
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

1	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
2	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	13 - 15
3	<b>Methods: Assignment of interventions (for controlled trials)</b>			
4	Allocation:			
5	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
6	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
7	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
8	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
9		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
10	<b>Methods: Data collection, management, and analysis</b>			
11	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
<b>Methods: Monitoring</b>			
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
<b>Ethics and dissemination</b>			

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
<b>Appendices</b>			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A

1 2 3 4 5 6	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
----------------------------	----------------------	----	--	-----

7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

\*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

For peer review only

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	<b>Formative work with stakeholders</b>	Research-practice partnership to identify strategies, barriers/facilitators to program dissemination, implementation and sustainability at scale	<i>TransformUs</i> 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 <sup>1</sup> , and organisational implementation capacities and structures are considered <sup>2</sup>
2	<b>Creation of coalitions and networks for program/policy advocacy</b>	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 <sup>2</sup> . 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	<b>Utilise multiple dissemination routes/channels</b>	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	<i>TransformUs</i> school principals and teachers (delivery system)	Program reach and adoption	Ongoing over 5 years	Multiple dissemination routes can widen scale up reach <sup>2</sup>
4	<b>Online program training to build implementation capacity</b>	Teachers required to complete online training prior to gaining access to program materials, implementation resources	<i>TransformUs</i> school principals and teachers (delivery system)	Completion of online training provides a unique log-in for access to online resources	<i>TransformUs</i> 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 <sup>3</sup> , skills, knowledge, self-efficacy, perceived fit with existing practices, relative advantage, and ownership of program <sup>4-6</sup>

#	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	<b>Online platform for program materials and training</b>	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	<i>TransformUs</i> research team with State-level partner organisations (support system)	Website hosted and maintained by <i>TransformUs</i> research team, link disseminated by all partner organisations.	School principals and teachers (delivery system)  Parents of children at <i>TransformUs</i> schools	Reach, adoption	Ongoing over 5 years	Maximises potential program dissemination/ implementation <sup>7</sup> . Enables more efficient data collection, refinements to materials and resource updates over time
6	<b>Enable implementation flexibility and contextual adaptation</b>	Non-prescriptive approach to implementation. Schools and teachers encouraged via training and in resources to adapt program	<i>TransformUs</i> 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 <sup>8</sup> . <i>TransformUs</i> 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 <sup>9</sup>
7	<b>Enable both 'top-down' and 'bottom-up' program adoption</b>	School-level adoption not required for teacher-level implementation. Schools and teachers can register to deliver the program independently	<i>TransformUs</i> 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	<i>TransformUs</i> school principals, teachers (delivery system)  Parents of children at <i>TransformUs</i> schools	Reach and adoption	Ongoing over 5 years	Capturing both individual and organisational innovation-decision processes, can elucidate influences on adoption and implementation <sup>10</sup>
8	<b>Utilise existing resources in the delivery system</b>	Program strategies can use existing school resources, equipment and	<i>TransformUs</i> research team with State-level partner	Program training and resources include ways of using/adapting existing school	<i>TransformUs</i> school principals, teachers (delivery system)	Adoption, implementation, sustainability	Ongoing over 5 years	Using existing resources can promote sustainability <sup>2</sup> , 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	<b>Development of recognition and incentive system</b>	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	<i>TransformUs</i> 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 <sup>1</sup> . Formative work identified CPD as an incentive for training completion
10	<b>Alignment with existing state-</b>	Program aligned with the	<i>TransformUs</i> research team	<i>TransformUs</i> included as part	<i>TransformUs</i> 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
	<b>level initiatives and guidelines</b>	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 <sup>2</sup>
11	<b>Promote use of program champions</b>	Schools identify champion(s) who advocate for are a point of contact for staff, students and families regarding <i>TransformUs</i> implementation	<i>TransformUs</i> 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	<i>TransformUs</i> 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 <sup>11</sup>  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	<b>Online implementation support network</b>	Schools can access an online discussion forum to share implementation strategies and ways of overcoming barriers.	<i>TransformUs</i> champion/teachers (delivery system)	Online discussion forum hosted on the program website, accessible only to registered teachers/schools	<i>TransformUs</i> 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 <sup>11</sup>
13	<b>Provision of resources to support implementation processes and sustainability</b>	Providing schools resources and suggested strategies to enhance implementation and sustainability in their setting	<i>TransformUs</i> 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)	<i>TransformUs</i> school principals and teachers (delivery system)	Implementation (e.g. skills, knowledge and capacity to implement program) and effectiveness. Institutionalisation within the school	Post registration, available online over 5 years	Increasing general and intervention-specific capacity within support system can enhance implementation <sup>7</sup> and sustainability <sup>12</sup> . Implementation plan can increase accountability <sup>8</sup>
14	<b>Monitoring and evaluation to adjust scaling strategy,</b>	Multilevel data (system, organisational, implementer and	<i>TransformUs</i> 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
	<b>feedback to support schools</b>	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 <sup>2</sup> . Feedback can increase teacher implementation performance.

**References**

1. Koorts, H., et al., *Implementation and scale up of population physical activity interventions for clinical and community settings: the PRACTIS guide*. International Journal of Behavioral Nutrition and Physical Activity, 2018. **15**(1): p. 51.
2. World Health Organization, *Practical guidance for scaling up health service innovations*. 2009, World Health Organization: Geneva, Switzerland.
3. Leeman, J., et al., *What strategies are used to build practitioners' capacity to implement community-based interventions and are they effective?: a systematic review*. Implement Sci, 2015. **10**(1): p. 80.
4. Fleuren, M., K. Wiefferink, and T. Paulussen, *Determinants of innovation within health care organizations: literature review and Delphi study*. Int J Qual Health Care, 2004. **16**(2): p. 107-23.
5. Chaudoir, S., A. Dugan, and C. Barr, *Measuring factors affecting implementation of health innovations: a systematic review of structural, organizational, provider, patient, and innovation level measures*. Implement Sci, 2013. **8**.

- 1
- 2
- 3
- 4 6. Michie, S., et al., *From Theory to Intervention: Mapping Theoretically Derived Behavioural Determinants to Behaviour Change Techniques*. Applied Psychology, 2008. **57**(4): p. 660-680.
- 5
- 6 7. Wandersman, A., et al., *Bridging the gap between prevention research and practice: the interactive systems framework for dissemination and implementation*. Am J Community Psychol, 2008. **41**(3-4): p. 171-81.
- 7
- 8 8. Meyers, D.C., J.A. Durlak, and A. Wandersman, *The quality implementation framework: a synthesis of critical steps in the implementation process*. Am J Community Psychol, 2012. **50**(3-4): p. 462-80.
- 9
- 10 9. Koorts, H., et al., *Is level of implementation linked with intervention outcomes? Process evaluation of the TransformUs intervention to increase children's physical activity and reduce sedentary behaviour*. Int J Behav Nutr Phys Act, 2022. **19**(1): p. 122.
- 11
- 12 10. Rogers, E.M., *Diffusion of Innovations*. 3rd ed. 1983, New York: The Free Press.
- 13
- 14 11. Rogers, E.M., *Diffusion of preventive innovations*. Addictive Behaviors, 2002. **27**(6): p. 989-993.
- 15
- 16 12. Wiltsey Stirman, S., et al., *The sustainability of new programs and innovations: a review of the empirical literature and recommendations for future research*. Implement Sci, 2012. **7**: p. 17.
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31
- 32
- 33
- 34
- 35
- 36
- 37
- 38
- 39
- 40
- 41
- 42
- 43
- 44
- 45
- 46



Supplementary File 4. Project timeline

Year	2017				2018				2019				2020				2021				2022				2023			
Term	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
<b>Preparation activities</b>																												
Resource development original <i>TransformUs</i> website																												
Build original <i>TransformUs</i> website																												
Launch original <i>TransformUs</i> website																												
Build updated <i>TransformUs</i> website																												
Relaunch of <i>TransformUs</i> website																												
Management of <i>TransformUs</i> website																												
Build databases for both trials																												
Program dissemination via partner organisations (a)																												
Expressions of interest in <i>TransformUs</i> (Effectiveness Trial only)																												
Schools/teachers register via <i>TransformUs</i> website																												
Teachers complete mandatory online training (a)																												
<b>Effectiveness Trial activities</b>																												
<b>CHILD/PARENT data collection</b>																												
Recruit schools VIC (n=20) NSW (n=20) (a)																												
BL measures VIC & NSW (a, b)																												
T2 (12 month) measures VIC & NSW (b, e)																												
T3 (24 month) measures VIC & NSW (b, e)																												
<b>TEACHER/SCHOOL data collection</b>																												
BL surveys teachers/schools VIC & NSW (a, c)																												
T2 (12 month) surveys and interviews teachers/schools VIC & NSW (b, d, e)																												
T3 (24 month) surveys and interviews teachers/schools VIC & NSW (b, d, e)																												
<b>Implementation Trial activities</b>																												
BL surveys teachers/schools (a, b, c, d)																												
T2 (12 month) surveys teachers/schools (b, d, e)																												
T3 (24 month) surveys teachers/schools (b, d, e)																												
T4 (36 month) surveys teachers/schools (b, d, e)																												
T2 (12 month) interviews teachers/principals (a, b, c, d, e)																												
T3 (24 month) interviews teachers/principals (a, b, c, d, e)																												
T4 (36 month) interviews teachers/principals (a, b, c, d, e)																												
T2 (12 month) interviews partner organisations (a, b, c, d, e)																												
T3 (24 month) interviews partner organisations (a, b, c, d, e)																												
T4 (36 month) interviews partner organisations (a, b, c, d, e)																												
Website data on online visits/downloads (a, e)																												
<b>Other activities</b>																												
Partner data on program dissemination/promotion (a, c, d, e)																												

(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*
<b>Implementation and Effectiveness trial</b>				
<b>Reach</b>	<ul style="list-style-type: none"> <li>No. partners; organisational characteristics (type)<sup>a</sup></li> <li>No., frequency and audience for promotional &amp; dissemination activities<sup>a,f,g</sup></li> <li>Perceived reach of dissemination strategy<sup>f</sup></li> </ul>	<u><b>Teacher-level</b></u> <ul style="list-style-type: none"> <li>No. teachers registered and no. completed training<sup>d</sup>, and total no. eligible teachers in Victorian schools</li> <li>Descriptive characteristics teachers; reasons for uptake; program awareness<sup>b</sup></li> </ul>	<ul style="list-style-type: none"> <li>No. parents participating in trial<sup>c</sup></li> <li>Descriptive characteristics; program awareness<sup>c</sup></li> </ul>	<ul style="list-style-type: none"> <li>No. students at participating schools<sup>h</sup> and no. Victorian students eligible</li> </ul>
<b>*Effectiveness</b>	/	/	<ul style="list-style-type: none"> <li>Proxy report of child's PA and sedentary time<sup>c</sup></li> </ul>	<ul style="list-style-type: none"> <li>Device-assessed PA and sedentary time<sup>e</sup></li> </ul>
<b>Adoption</b>	<ul style="list-style-type: none"> <li>Perceived barriers/facilitators/ reasons for school adoption<sup>f</sup></li> </ul>	<u><b>School-level</b></u> <ul style="list-style-type: none"> <li>No. schools registered and no. completed training<sup>d</sup> and total no. eligible schools in Victoria<sup>i</sup></li> <li>Descriptive characteristics schools; reasons for adoption; program awareness<sup>b</sup></li> </ul>	/	/
<b>Implementation</b>	<ul style="list-style-type: none"> <li>Partner role in implementation<sup>f</sup></li> <li>Perceived implementation barriers/facilitators<sup>f</sup></li> </ul>	<u><b>School-level</b></u> <ul style="list-style-type: none"> <li>No. and type of <i>TransformUs</i> website visits, program component downloads<sup>d,g</sup></li> <li>Organisational infrastructure and resource availability to support implementation<sup>b</sup></li> <li>Organisational readiness and capacity to implement <i>TransformUs</i> (adapted ORIC scale)<sup>73</sup>; implementation climate<sup>74</sup> (6qu)<sup>b</sup></li> </ul>	<ul style="list-style-type: none"> <li>Dose received (no. newsletters, use newsletters)<sup>c</sup></li> </ul>	<ul style="list-style-type: none"> <li>Dose received (active lessons, active breaks, homework, health lessons, line markings)<sup>j</sup></li> <li>Perceptions of program<sup>j</sup></li> </ul>

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

		<ul style="list-style-type: none"> <li>• Implementation strategies; appropriateness, acceptability, barriers, and facilitators to implementation<sup>b</sup></li> <li>• Perceived impact on school culture (norms, values and beliefs); impact on child<sup>b</sup></li> </ul> <p><b><u>Teacher-level</u></b></p> <ul style="list-style-type: none"> <li>• No. and type of <i>TransformUs</i> website visits, no. program component downloads<sup>d</sup></li> <li>• No., frequency, duration of components (dose delivered), adherence and adaptation (fidelity), feasibility, appropriateness, self-efficacy to implement; satisfaction; barriers/facilitators<sup>b</sup>.</li> <li>• Implementation climate<sup>74</sup> (2qu)<sup>b</sup></li> <li>• Perceived impact on child behavioural outcomes (time on task, academic outcomes, concentration)<sup>b</sup></li> </ul>		
<b><i>*Individual-level Maintenance</i></b>	/	/	<ul style="list-style-type: none"> <li>• Proxy report of child’s PA and sitting time<sup>c</sup></li> <li>• Proxy report of impact of active homework (concentration and completion)<sup>c</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Device-assessed PA and sedentary time<sup>e</sup></li> <li>• Self-reported PA and sedentary time<sup>j</sup></li> </ul>
<b><i>Organisational-level Maintenance</i></b>	<ul style="list-style-type: none"> <li>• No. partners; organisational characteristics (type)<sup>a</sup></li> <li>• No., frequency and audience for promotional and dissemination activities<sup>a,f,g</sup></li> <li>• Perceived reach of dissemination strategy<sup>f</sup></li> <li>• Perceived barriers/facilitators to program maintenance in</li> </ul>	<p><b><u>School-level</u></b></p> <ul style="list-style-type: none"> <li>• Intention to continue<sup>b</sup></li> <li>• No. and type of <i>TransformUs</i> website visits, program component downloads<sup>g</sup></li> <li>• Organisational infrastructure and resource availability to support implementation<sup>b</sup></li> <li>• Organisational readiness and capacity to implement <i>TransformUs</i> (adapted ORIC scale)<sup>73</sup>; implementation climate<sup>74</sup> (6qu)<sup>b</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Program awareness; continued support<sup>c</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Dose received (active lessons, active breaks, homework, health lessons, line markings)<sup>j</sup></li> <li>• Perceptions of program<sup>j</sup></li> </ul>

	schools' continued program support <sup>f</sup>	<ul style="list-style-type: none"> <li>• Implementation strategies; appropriateness, acceptability, barriers and facilitators to implementation<sup>b</sup></li> </ul> <p><b><u>Teacher-level</u></b></p> <ul style="list-style-type: none"> <li>• Intention to continue<sup>b</sup></li> <li>• No. and type of <i>TransformUs</i> website visits, no. program component downloads<sup>g</sup></li> <li>• No., frequency, duration of components (dose delivered), adherence and adaptation (fidelity), feasibility, appropriateness, self-efficacy to implement, satisfaction; barriers/facilitators<sup>b</sup></li> <li>• Implementation climate<sup>74(2qu)</sup><sup>b</sup></li> </ul>		
--	---	--	--	--

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