

STUDY PROTOCOL

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A cluster randomised controlled trial to assess the effectiveness of a multi-strategy sustainability intervention on teachers' sustained implementation of classroom physical activity breaks (energisers): study protocol

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Abstract

Background Governments internationally have invested hugely in the implementation and scale-up of school-based physical activity interventions, but have little evidence of how to best sustain these interventions once active implementation support ceases. This study will assess the effectiveness of a multi-strategy sustainability intervention on classroom teachers' sustainment of energisers (short 3–5 min physical activity breaks during class-time) scheduled across the school day from baseline to 12 and 24-month follow-up.

Methods A cluster randomised controlled trial will be conducted in 50 primary schools within the Hunter New England, Illawarra Shoalhaven, Murrumbidgee and Northern New South Wales (NSW) Local Health Districts of NSW Australia. Schools will be randomly allocated to receive either usual support or the multi-strategy sustainability intervention that includes: centralised technical assistance from a trained project officer; formal commitment and mandated change obtained from school principals; training in-school champions; reminders for teachers; educational materials provided to teachers; capturing and sharing local knowledge; and engagement of parents, carers and the wider school community. The primary trial outcome will be measured via a teacher logbook to determine the between-group difference in the change in mean minutes of energisers scheduled across the school day at 12 and 24-month follow-up compared to baseline. Analyses will be performed using an intention to treat framework. Linear mixed models will be used to assess intervention effects on the primary outcome at both follow-up periods.

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Discussion This study will be one of the first randomised controlled trials to examine the impact of a multi-strategy sustainability intervention to support schools' sustainment of a physical activity intervention. The proposed research will generate new evidence needed for the partnering organisations to protect their considerable investments to date in physical activity promotion in this setting and will provide seminal evidence for the field globally.

Trial registration ACTRN12620000372987 version 1 registered 17th March 2020. Version 3 (current version) updated 4th August 2023.

Keywords Sustainability, Sustainment, Implementation science, School policy, Physical activity, Energiser, Schools

Introduction

To support children to meet daily physical activity guidelines the World Health Organization (WHO) has recommended schools implement physical activity policies that promote and enable children's regular physical activity throughout the day [1, 2]. Accordingly, many countries have developed policies or guidelines mandating the minimum amount of physical activity schools are to provide students each week. For example, the United Kingdom [3] and parts of Canada [4] and the United States [5] require schools to schedule between 120–150 min per week weekly physical activity. In New South Wales (NSW), Australia, the Department of Education (DoE) requires schools to schedule at least 150 min of planned moderate, with some vigorous, physical activity across the school week for students in Kindergarten to Grade 10 [6]. This can include time scheduled for physical education (PE), sport or other structured activities including integrated lessons and “energisers” (i.e., short 3–5 min physical activity breaks during class-time) [6]. Despite the existence of these policies, international research suggests that only 30% of schools routinely implement them [7–13].

The application of implementation science methods has led to significant improvements in schools' implementation of physical activity interventions [14]. For example, a 2022 Cochrane review of six randomised controlled trials (RCTs) aimed at assessing the effectiveness of strategies to enhance the implementation of school physical activity policies and practices found significant improvements in intervention schools relative to control (standardised mean difference 1.53, 95% CI: 0.78 to 2.28, $I^2 = 85.6\%$) [14]. Among these, a model of implementation support, developed by our research team, has been found to be effective at increasing schools' implementation of the NSW school physical activity policy [6]. The multi-strategy implementation intervention (Physically Active Children in Education (PACE)) has demonstrated, across a series of RCTs, to increase teachers' scheduling of physical activity by 36–44 min per week [13, 15, 16]. Across all studies, teacher' scheduling of energisers was consistently found to be driving the intervention effect, with

increases of approximately 23 min of energisers scheduled each week and contributing to 52–70% of the increase in overall weekly physical activity scheduled [13, 15, 16].

Maximising the benefits and health impact of these school physical activity interventions requires their sustained implementation. Sustainability is defined as: “*after a defined period of time, a program, clinical intervention, and/or implementation strategies continue to be delivered and/or individual behaviour change (i.e., clinician, patient) is maintained; the program and individual behaviour change may evolve or adapt while continuing to produce benefits for individuals/systems*” [17]. Achieving sustainability is however a considerable challenge. A comprehensive review of 125 empirical studies of public health interventions reported less than 23% of programs were sustained at least two years following initial implementation [18]. Specifically within schools, a recent review of the sustainability of health behaviour interventions found that of the 18 included school-based interventions, none were sustained in their entirety following withdrawal of initial implementation support [19]. Of concern, reviews suggest that when programs are not sustained, prevalence typically reverts to pre-intervention levels (or below) [20] and can adversely impact stakeholder trust and willingness to engage in future initiatives [18, 21].

Schools face a number of barriers to sustaining health promoting interventions [19, 22, 23]. For example, a recent review of the determinants of schools' sustainment of chronic disease prevention interventions found that the most frequent barriers include: the availability of funding, equipment, resources and facilities, continued executive or leadership support, staff turnover and workforce shortages, competing priorities, perceived program effectiveness or benefit and adaptability of the intervention [23]. There is however, little evidence of the most effective strategies to support schools to overcome these barriers and sustain their implementation of health promoting interventions [24]. Systematic reviews in school and childcare settings conducted by the research team have failed to identify any interventions to achieve sustained program implementation

will be excluded if they are participating in another physical activity intervention or cater exclusively for children with special needs. Principals from eligible schools will be provided with a study information package and asked to provide online written informed consent.

Teachers: All classroom teachers from eligible and consenting schools will be randomised to receive the sustainability strategy and an invitation to participate in data collection. Strategies will be employed to ensure high recruitment rates are achieved, including delivering a series of two follow-up emails and a phone call reminder to schools [30]. To maximise principal and teacher survey participation rates, evidence-based strategies will be delivered, including sending two email reminders to teachers (one week apart) and one follow-up phone call reminder to In-school Champions (ISCs) to complete the survey, as well as distribution of a AUD\$30 online gift card from a national grocery store for each principal and teacher who completes a survey in gratitude for their time. To maximise the retention of schools over the study period, strategies will be enacted including the delivery of non-program resources (including a pen, post-it notepad, and stickers for each class), to each teacher during data collection, as well as a letter of appreciation from the project team outlining the broad positive impact of their participation [31–33]. Previous studies conducted by the research team utilising such strategies have yielded school and or teacher participation rates of >80% and attrition of <20% [13, 34, 35].

Randomisation and blinding

An independent statistician will use a computerised random number function to randomise schools in a 1:1 ratio to either an intervention or control group. Randomisation will occur following consent and baseline data collection to reduce the risk of selection bias. Block randomisation will ensure group allocation is approximately equal. Allocation will not be stratified by any school-level factor given a lack of clear prognostic factors for the sustainability of physical activity implemented in schools [36, 37]. However, schools will be stratified by time (school phase) and by LHD (jurisdiction) to ensure the allocation across each LHD is approximately equal. Due to the nature and delivery of the intervention, school staff and program delivery staff will become aware of school group allocation. Data analysts will be blinded.

Intervention group: Multi-strategy sustainability intervention

The 12-month multi-strategy sustainability intervention was co-developed with a trial Advisory Group consisting of health and education policy makers, health promotion practitioners, teachers, physical activity experts,

implementation and behavioural scientists, education and public health practitioners. The development process was guided by formative evaluation undertaken by the research team to identify determinants to sustaining school based physical activity interventions generally and energisers specifically. Specifically this involved: i) systematic review evidence of sustainability determinants within the school setting [23]; ii) quantitative surveys with 240 classroom teachers assessing factors associated with local sustainability of weekly physical activity implementation using the adapted Program Sustainability Assessment Tool [37, 38]; and iii) qualitative research from our previous implementation trials (school-based observations by program delivery personnel, and interviews, and surveys of school staff [13, 39]. Utilising this evidence, identified barriers were mapped to the Integrated Sustainability Framework [21]. This empirically informed sustainability-determinants framework was developed for application in the field of public health to identify and synthesise multi-level factors previously found to influence the sustainability of EBIs across a range of community settings, including schools [21]. Barriers were also mapped to the Behaviour Change Wheel (BCW) [40] and Theoretical Domains Framework (TDF) [41] to ensure: i) consideration of a comprehensive assessment of factors (i.e., capabilities, opportunities and motivation) impacting on an individual's behaviour; and ii) identification of modifiable factors and potential behaviour change techniques that may be utilised to influence or enact the desired behaviour of an individual to sustain practice change. Potential sustainability strategies and behaviour change techniques were then identified using the recommended process described by Michie et al. [40] and, in consultation with members of the Advisory Group, assessed against the APEASE criteria [42] for their Affordability, Practicality, Effectiveness and cost effectiveness, Acceptability, Side-effects/safety and Equity. Finally, strategies were aligned to the sustainment-explicit Expert Recommendations for Implementing Change (ERIC) glossary [43], to ensure consistency in nomenclature, definitions and use of strategies. Table 2 includes a detailed description of each of the sustainability strategies using the sustainment-explicit ERIC Glossary [43] and how the delivery of each strategy will be operationalised according to the Action, Actor, Context, Target, Time AACTT) framework [44]; and shows how strategies were mapped against the Integrated Sustainability Framework, BCW and TDF to address barriers and behaviours to sustaining teacher's daily scheduling of energisers.

Control group and contamination

The delivery of all intervention components will be under the control of the research team and will not be provided to control group schools during the intervention period.

Table 2 Description of sustainability strategies mapped to the relevant theories and taxonomies

Sustainability strategy according to Nathan et al. [43]	Proposed mechanism of action				Intervention content	Sustainability strategy detailed explanation (according to the AACTT) framework [44]
	Barriers addressed	Integrated Sustainability Framework domain	COM-B and (TDF)	Intervention functions		
Centralize technical assistance and provide ongoing consultation	<ul style="list-style-type: none"> Teachers knowledge, ability or competence Lack of time Perceived priority of the program in the schools 	<ul style="list-style-type: none"> Inner contextual factors Characteristics of the interventionist and population 	<ul style="list-style-type: none"> Psychological capability (beliefs about capabilities, knowledge) Social opportunity (environmental context and resources) Reflective motivation (goals) 	<ul style="list-style-type: none"> Enablement Persuasion 	<ul style="list-style-type: none"> Review behaviour goal(s) Review outcome goal(s) 	<p>Project officers (a PE teacher and health promotion practitioner) will provide technical assistance to schools throughout the study period to support the sustained scheduling of daily energisers. They will work directly with schools and ISC to overcome barriers and provide expertise support and resources</p> <p>Project officers will provide ongoing consultation to ISCs via telephone or email to support the delivery of sustainability strategies</p>
Obtain formal commitments	<ul style="list-style-type: none"> Lack of executive endorsement and leadership Changing priorities Lack of support from executive and other staff Limited school culture/identity 	<ul style="list-style-type: none"> Characteristics of the interventionist and population Inner contextual factors 	<ul style="list-style-type: none"> Reflective motivation (beliefs about capabilities) Physical opportunity (environmental context and resources) Social opportunity (social influences) Reinforcement 	<ul style="list-style-type: none"> Enablement Environmental restructuring 	<ul style="list-style-type: none"> Social support Reframing Professional / social role and identity 	<p>Signed executive commitment will be obtained by project officers during an in-person meeting with the principal at the start of the study period, pledging their support to staff in the scheduling of daily energisers. Principals will commit to support their staff to continue to schedule energisers by:</p> <ul style="list-style-type: none"> Encouraging teachers to schedule daily energisers by forwarding an email of support to all staff Sharing evidence that energisers are an easy and effective way to help meet the NSW 150-min physical activity policy Allocating a regular short agenda item in staff meetings to share ideas and discuss the delivery of energisers Displaying their school's 'Energiser School' fence sign, framed certificate and newsletter snippets Completing a whole school physical activity timetable that indicates > 80% of classes schedule energisers 5 days a week

Table 2 (continued)

Sustainability strategy according to Nathan et al. [43]		Proposed mechanism of action			Sustainability strategy detailed explanation (according to the AACTT) framework [44]	
	Barriers addressed	Integrated Sustainability Framework domain	COM-B and (TDF)	Intervention functions	Intervention content	
Mandate change	<ul style="list-style-type: none"> Limited belief in their ability to schedule in a crowded curriculum (when competing priorities arise) Limited dedicated time to and within schedule Changing priorities; external and school Lack of executive endorsement and leadership 	<ul style="list-style-type: none"> Characteristics of the interventionist and population Inner contextual factors Characteristics of the intervention 	<ul style="list-style-type: none"> Reflective motivation (beliefs about capabilities) Physical opportunity (environmental context and resources) Social opportunity (social influences) 	<ul style="list-style-type: none"> Enablement Environmental restructuring 	<ul style="list-style-type: none"> Social support Reframing Prompts and cues 	<p>Following obtaining signed formal commitment, schools will receive a physical 'Enigiser School' certificate and a fence sign to display reflecting to staff and the school community the school's commitment to scheduling daily energisers. Principals will also receive a modifiable email template from project officers that can be personalised and circulated to their staff further highlighting their support to schedule daily energisers by:</p> <ul style="list-style-type: none"> Scheduling energisers every day Contacting their ISC or project officer for support Sharing their ideas at staff meetings Accessing the PACE online portal for resources and ideas
Identify and prepare champions	<ul style="list-style-type: none"> Lack of time in the curriculum Teachers knowledge, ability or competence 	<ul style="list-style-type: none"> Inner contextual factors Characteristics of the interventionist and population 	<ul style="list-style-type: none"> Social opportunity (environmental context and resources) Psychological and physical capability (beliefs about capabilities) 	<ul style="list-style-type: none"> Modelling Education Training 	<ul style="list-style-type: none"> Identification of self as role model Social support (unspecified) Problem solving Instruction on how to perform a behaviour Demonstration of the behaviour 	<p>Each school will nominate up to three ISCs at the start of the study period (existing teachers at the school who were previously identified and supported the initial implementation of PACE) to facilitate delivery of the sustainability strategies within each school. ISCs have previously undergone training to prepare them for their role (i.e., 1-day [5-h] face-to-face workshop run by project officers) and received a program delivery manual outlining their role, how they can support their staff, and where to seek program support. Project officers will provide support to ISCs to overcome resistance that the program may provoke in the school, or navigate any barriers faced to sustaining the daily scheduling of energisers</p>

Table 2 (continued)

Sustainability strategy according to Nathan et al. [43]	Proposed mechanism of action			Intervention content	Sustainability strategy detailed explanation (according to the AACTT) framework [44]
	Barriers addressed	Integrated Sustainability Framework domain	COM-B and (TDF)		
Remind teachers	<ul style="list-style-type: none"> • Forgetting to schedule each day • Lack of variety/adaptability of energisers • Limited access to energiser resources 	<ul style="list-style-type: none"> • Characteristics of the interventionist and population 	<ul style="list-style-type: none"> • Psychological capability (memory, attention and decision processes) • Enablement 	<ul style="list-style-type: none"> • Prompts and cues • Social support • Credible source • Instruction on how to perform the behaviour 	<p>Project officers will send targeted email prompts to ISCs quarterly, at the beginning of each school term. Each email will:</p> <ul style="list-style-type: none"> • Prompt ISCs to remind classroom teachers to schedule daily energisers • Include a link for teachers to access the existing online resource repository • Act as a mechanism to identify turnover in ISCs, by asking them to confirm that they are still available and have capacity to act in this role • Include a link to video testimonials or information snippets to include in their school newsletter, with the purpose of endorsing the scheduling of daily energisers, highlighting benefits of energisers and how to navigate any emerging barriers or priorities faced

Table 2 (continued)

Proposed mechanism of action		Intervention content	
Sustainability strategy according to Nathan et al. [43]	Barriers addressed	Integrated Sustainability Framework domain	COM-B and (TDF)
		Intervention functions	BCT Behaviours
		Sustainability strategy detailed explanation (according to the AACTT) framework [44]	
Distribute educational materials	<ul style="list-style-type: none"> • Remembering to schedule each term • Knowing what are energisers and which ones to do • Belief in their ability to schedule in a crowded curriculum (when competing priorities arise) • School culture/identify as an energiser school • Boredom with resources and scheduling • Limited adaptability and variety of resources • Limited accessible resources • Feeling overwhelmed • Staff turnover • Lack of support from executive • Changing priorities 	<ul style="list-style-type: none"> • Inner contextual factors • Processes • Characteristics of the interventionist and population • Characteristics of the intervention 	<ul style="list-style-type: none"> • Psychological capability (memory, attention and decision processes) • Reflective motivation (beliefs about capabilities) • Reinforcement • Emotion • Physical opportunity (environmental context and resources) • Social opportunity (social influences)
		<ul style="list-style-type: none"> • Enablement • Environmental restructuring • Modelling • Persuasion • Professional / social role and identity • Incentivisation • Training 	<ul style="list-style-type: none"> • Adding objects to the environment • Social support • Prompts/cues • Reframing • Demonstration of the behaviour • Information about social and environmental consequences • Information about health consequences • Social comparison • Self-monitoring of behaviour
			<ul style="list-style-type: none"> • Project officers will develop training and educational materials to disseminate to classroom teachers in the form of an energiser resource pack following receipt of formal commitment obtained from the school principal. The resources will be designed to remind teachers to schedule energisers each day and will include: <ul style="list-style-type: none"> • A template classroom timetable highlighting where teachers could potentially schedule energisers throughout the school day • An erasable A3 whiteboard sign where teachers can record their daily energisers for the class to see • An infographic with a QR code to the online portal of resources • An infographic linking common barriers to sustaining the delivery of energisers with possible solutions • A lanyard displaying a range of energiser options including the names and 'how to' deliver each to their class • New ISCs will also be sent a number of resources that will help upskill them and become familiar with the program, their role and where to seek program support including: (i) a copy of the ISC manual (electronic and hard copy); and (ii) online access to the online portal training modules for ISCs. This will be sent whenever a new ISC is identified within the school

Table 2 (continued)

Sustainability strategy according to Nathan et al. [43]	Proposed mechanism of action				Intervention content	Sustainability strategy detailed explanation (according to the AACTT) framework [44]
	Barriers addressed	Integrated Sustainability Framework domain	COM-B and (TDF)	Intervention functions		
Involve parents consumers and family members	<ul style="list-style-type: none"> Limited belief in benefits – for teachers and students Lack of leadership support and endorsement Lack of parental support 	<ul style="list-style-type: none"> Characteristics of the interventionist and population Characteristics of the intervention 	<ul style="list-style-type: none"> Reflective motivation (beliefs about consequences) Social opportunity (social influences) 	<ul style="list-style-type: none"> Persuasion Environmental restructuring 	<ul style="list-style-type: none"> Information about health consequences Credible source Information about others approval Restructuring the social environment 	<p>A range of documents will be provided by project officers and used to communicate to parents and the wider school community the schools dedication to scheduling daily energisers, and to illustrate to parents and carers the health, social, and learning benefits of energisers. These documents will include:</p> <ul style="list-style-type: none"> Information snippets embedded in the existing email prompts sent each school term that schools can include in their newsletter, online webpage or communications channel; and An information leaflet for inclusion in the kindergarten orientation booklet during Term 3 of the school year
Capture and share local knowledge	<ul style="list-style-type: none"> Lack of belief in their ability to schedule in a crowded curriculum (when competing priorities arise) Limited belief in benefits – for teachers and students 	<ul style="list-style-type: none"> Characteristics of the interventionist and population Characteristics of the intervention 	<ul style="list-style-type: none"> Reflective motivation (beliefs about capabilities) Beliefs about consequences 	<ul style="list-style-type: none"> Enablement Modelling Persuasion 	<ul style="list-style-type: none"> Reframing Demonstration of the behaviour Information about social and environmental consequences Information about health consequences 	<p>Video testimonials of a classroom teacher and principal/executive who have previously taken part in PACE and continue to schedule energisers in their school will be available on the online portal and embedded in the existing email prompts (that will be sent each school term by project officers to ISCs for distribution to other teachers within their school). These testimonials will highlight the importance of delivering energisers, and showcase the range of benefits, adaptability/flexibility and solutions to overcome barriers faced within the school</p>

Schools in the control group will receive ‘usual’ (reactive) support which is provided to schools as part of existing service delivery within the respective LHD. This involves the provision of information and resources specific to the PACE program on the existing online portal and includes factsheets, example policies, and templates not related to sustainability. According to evidence and theory [45], such strategies do not address the primary obstacles to sustainability, thus any impact on the primary trial outcome is likely to be minimal. Nonetheless, data regarding schools’ exposure to potential sources of contamination (or co-intervention) will be assessed via items included in teacher and principal follow-up surveys – if evident, potential effects on outcomes will be explored via sensitivity analyses.

Data collection and management

Principal and teacher data will be obtained through self-report surveys. These will be administered as a pen-and-paper version or using the Hunter New England Population Health (HNEPH) instance of the online data capture tool Research Electronic Data Capture (REDCap) [46, 47], depending on their preference. Management of trial data will be in accordance with a data management protocol, which has been developed and approved by the Advisory Group. Data will be stored securely as per the requirements of the HNE Human Research Ethics Committee and The University of Newcastle Human Research Ethics Committee. Data will only be accessible to primary researchers and statisticians. Confidential participant data will be stored securely and not linked to survey responses.

Measures

All outcome measures will be collected at baseline, 12- and 24-months post-recruitment.

Primary trial outcome

Sustainment of mean minutes of daily energisers scheduled by classroom teachers over 12- and 24-months

Given the scheduling of energisers consistently possessed the greatest impact on teachers overall scheduling of weekly physical activity in our previous implementation trials [13, 16], and thus increased the likelihood of achieving adherence of the NSW policy [6]; the primary trial outcome will be the between-group difference in the change in mean minutes of energisers scheduled across the school day at 24 month follow-up compared to baseline [18]. Outcome data will also be collected at 12 months in order to describe attenuation patterns. Scheduled daily energisers for each class will be assessed via classroom teacher completion of a daily activity log-book for one full school

week (5-days). At the end of each school day during the week of data collection, each teacher will complete a log of the time and occasions they planned physical activity for: energisers, PE, Sport or other structured activities e.g., integrated lessons. The use of teacher logbooks is frequently used in classroom-based obesity prevention interventions, with high response rates (i.e. > 80%) [48, 49] and established reliability [50]. This outcome measure and data collection method has been used in our previous studies assessing teachers’ scheduling of classroom physical activity, with completion rates of ~ 88% [13, 16, 51], which is the premise for use in the current study.

Secondary trial outcomes

Sustainment of mean minutes of weekly physical activity (PE, sport and other structured activities) scheduled by classroom teachers over 12- and 24-months

The difference in the change in mean minutes of overall physical activity and the individual components that make up overall physical activity, including sport and PE, and other planned activities (e.g., active lessons and energisers) implemented by classroom teachers across the school week, assessed via logbooks completed by teachers at 12 and 24-month follow-up compared to baseline.

Difference in the change in proportion of school adherence to the 150 min physical activity policy from baseline to 12- and 24-month follow-up

The difference between groups in the change in proportion of schools, from baseline to 12- and 24-month follow-up adhering to the government policy of 150 min of scheduled classroom activity per week.

Sustainability determinants to teachers’ scheduling of daily energisers

To assist in understanding the determinants experienced and addressed in this trial we will assess the theoretical factors hypothesised to impact the sustainability of teacher implementation of energisers [21]. Specifically, principals and classroom teachers will complete newly developed measures theoretically informed by the Integrated Sustainability Framework [21] to assess the determinants of sustaining school-based public health interventions at baseline, 12- and 24-months. Each measure was designed to assess the factors perceived by respective stakeholders (executive-level e.g., principal or executive staff member and implementer-level e.g., classroom teacher) as influential to the sustainability of EBIs delivered in the school setting. Using a five-point scale (1 = not at all influential; 2 = slightly influential; 3 = moderately influential; 4 = extremely influential; and 5 = not applicable to me), principals and teachers will be asked

to indicate how much the listed factors influence the delivery of daily energisers at their school. The 28-item executive scale to be completed by principals covers four framework domains and focuses on higher organisational and structural-level factors e.g., socio-political context, external funding, external partnerships. Whereas the 42-item implementer scale to be completed by classroom teachers covers all five framework domains and examines factors more relevant to frontline intervention delivery e.g., motivation, capability, training, executive support, and available resources.

Implementation outcomes

To characterise sustainment, the measures recommended by Proctor et al. [52] of implementation outcomes will also be assessed. This includes;

- *Acceptability* – The perceived acceptability of each sustainability support strategy will be assessed via a paper or online-based survey completed by principals and classroom teachers of intervention schools at 12 and 24-month follow-up using items from the validated Acceptability of Intervention Measure developed by Weiner et al. [53].
- *Adoption* – Based upon a previously developed tool from the research team [13, 54], at 12- and 24-month follow-up all intervention and control principals will be asked to report, via paper or online based survey, their school's adoption for scheduling energisers each day (i.e., proportion of classes at each school scheduling energisers each day).
- *Appropriateness* – The perceived appropriateness of each sustainability support strategy will be assessed via a paper or online-based survey completed by principals and classroom teachers of intervention schools at 12- and 24-month follow-up using items from the validated Intervention Appropriateness Measure developed by Weiner et al. [53].
- *Feasibility* – The perceived feasibility of each sustainability support strategy will be assessed via a paper or online-based survey completed by principals and classroom teachers of intervention schools at 12- and 24-month follow-up using items from the validated Feasibility of Intervention Measure developed by Weiner et al. [53].
- *Fidelity* – Project records as well as post-intervention questionnaires completed by intervention principals, ISC, and teachers will be used to determine the proportion of schools that received and attended to each of the sustainability strategies.
- *Strategy implementation cost* – Defined as the cost impact of sustainability effort; see economic analysis section below.
- *Penetration* – This will be calculated, using scheduling data from the teacher survey at 12- and 24-month follow-up, as the number of teachers who schedule daily energisers per school, divided by the total number of teachers expected to schedule daily energisers [52].
- *Sustainability* – See primary outcome section above.

Other measures

Economic analysis

A prospective economic analysis measuring the incremental cost and outcomes of the sustainability strategies will be undertaken from adapted societal and health service perspectives. Resource use for the intervention and usual practice will be prospectively identified and measured from project records (staff and consumables). Direct costs associated with the intervention are anticipated to include labour (sustainability support), and program materials. Systems to prospectively log and document costs were developed for our previous trials [13, 14, 39, 51] and will be adapted to the proposed study. Incremental cost will be calculated as the difference between intervention and usual care cost. The primary outcome for the economic analysis will align to the trial outcome, which is the between-group difference in the change in mean minutes of energisers scheduled across the school day at 24 months follow-up compared to baseline. A 'within trial' economic analysis will assess program value by comparing incremental costs and benefits at the school level across the study arms. Uncertainty intervals will be calculated for the mean incremental cost result and incremental cost effectiveness ratio using non-parametric bootstrapping. Resource use measurement will occur prospectively and continuously over the duration of the trial.

School characteristics and process data

Data regarding the operational characteristics of schools will be collected using a combination of surveys of the school website as well as survey items completed by school principals and classroom teachers that we have used in previous studies [13, 16]. Project officer records and survey items will be used to record delivery of sustainability support strategies, and exposure of individual schools and teachers to such strategies. Data will be collected, stored, and managed on the HNEPH server using REDCap [46, 47].

Statistical analysis

All analyses will be undertaken under an intention-to-treat framework. Analyses of outcomes at 12-month follow-up will provide evidence of any immediate impact

of the intervention. The 24-month follow-up will provide evidence of sustainment of energiser implementation and will represent the primary end-point. Teachers will be the unit of analysis. Between-group differences in the mean change in the primary outcome will be assessed at each time-point using linear mixed models. Models will include fixed effects for treatment group (intervention vs control), time (baseline, 12-month, and 24-month follow-up), and a time-by-treatment group interaction term. A random level intercept for school will be included to account for the clustered design of the study. A random intercept for teacher nested within school will also be included to account for potential repeated measures by teachers. The linear mixed models will use all available data, assuming missing data is at random.

Sample size

We are aiming for a sample size of 40 schools (20 per arm). Assuming a comparator mean of 7.08 min of energisers scheduled daily, a standard deviation of 4.88, an average of five classes per school and an intraclass correlation coefficient (ICC) of 0.11, based on our previous trial [13], a sample of 40 schools is sufficient to detect (with 80% power, an alpha of 0.05) a mean difference of approximately 2.38 min of daily energisers.

Research trial governance

This study has employed a research co-production approach in its design [55]. An external multi-disciplinary Advisory Group, consisting of 16 members including education policy makers, health promotion practitioners, Aboriginal Health Officers, as well as researchers with expertise in physical activity, implementation science, behavioural science, education and public health will oversee all aspects of the planning, implementation and evaluation of the project. A project team consisting of research staff and practitioners will conduct the study according to study protocol. The Advisory Group will oversee the project dissemination plan including all publications and reports to stakeholders. Authorship will conform to the International Committee of Medical Journal Editors guidelines.

Trial discontinuation or modification

Our Advisory Group will convene once a quarter to ensure the study is abiding by the prescribed ethics and timeline. It is not anticipated that any events would occur that warrant discontinuing the trial. However, any unforeseen adverse events will be recorded and assessed by the trial Advisory Group and reported to the HNE Human

Research Ethics Committee (primary approval committee), with advice sought regarding required action. The trial registration record will be updated with any protocol modifications, and any deviations from original protocol will be reported in study outcome papers.

Discussion

Physical inactivity is a leading cause of death and disability in Australia and internationally [56, 57] and is identified as a priority health issue [1, 2]. Improving children's activity levels is key to reducing the development of both short and long-term health burdens [58, 59]. School-based physical activity policies effectively improve child physical activity levels [50, 60, 61]. However, sustaining their implementation remains a considerable challenge globally [18, 19]. In Australia alone, approaches to sustain the implementation of school-based policies that mandate minimum periods for structured physical activity have the potential to improve the health, well-being and chronic disease risk of two million students [62]. This study is one of the first RCTs to test the effectiveness and efficiency of theoretically and empirically informed strategies to improve the sustainability of an EBI targeting a chronic disease risk factor in schools. The proposed trial will be seminal for the field, translate into fundamental outcomes in the knowledge base of sustainability research, and provide a platform for future research examining the sustainability of effective EBIs in the school setting.

Abbreviations

AACCT	Action, Actor, Context, Target, Time
APEASE	Affordability, Practicality, Effectiveness and cost effectiveness, Acceptability, Side-effects/safety and Equity
BCW	Behaviour Change Wheel
CONSORT	Consolidated Standards of Reporting Trials
DoE	Department of Education
ERIC	Expert Recommendations for Implementing Change
EBI	Evidence-based intervention
HNE	Hunter New England
ICC	Intraclass correlation coefficient
ISC	In-school champion
MVPA	Moderate-to-vigorous physical activity
NHMRC	National Health and Medical Research Council
NSW	New South Wales
PACE	Physically Active Children in Education
PE	Physical Education
RCT	Randomised controlled trial
REDCap	Research Electronic Data Capture
StaRI	Standards for Reporting Implementation Studies
TDF	Theoretical Domains Framework

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12889-023-16810-5>.

Additional file 1. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents

Acknowledgements

The authors would like to thank all of the participating schools and teachers involved in the PACE program.

Authors' contributions

NN led the development of this manuscript. NN and LW conceived the intervention concept. NN, LW, JW, AB, PJJ, RS, KG, PR, DG, BD, CO, JB secured funding for the study. AS, AH, ERG, WP led intervention development. RJ, NM, EP, PB, CG, MP and MM contributed to the design of the intervention. AS and AH led the evaluation design of the study. PR contributed to the development of data collection methods specific to the cost and cost-effectiveness measures. AH, AS, CO, CRL developed the analysis plan. NN, AH, AS, AB, JW, PJJ, RS, KG, PR, CD, TC, DG, BD, JB, CO and LW are all members of the Advisory Group that will oversee the program. NN, AH, AS, AB, BP, BD, CG, CL, CD, CRL, CO, DG, ERG, EP, JB, JW, KG, MP, MM, NM, PJJ, PR, PB, RS, RJ, TC, WP, LW contributed to developing the protocols and reviewing, editing, and approving the final version of the paper.

Funding

The work was supported by funding from a NHMRC Centre for Research Excellence (APP1153479)—'the National Centre of Implementation Science'. The contents are the responsibility of the authors and do not reflect the views of the NHMRC. This project has undergone independent peer review and is funded by the NHMRC Partnership Project grant (APP1190373). The NHMRC has not had any role in the design of the study as outlined in this protocol and will not have a role in data collection, analysis of data, interpretation of data and dissemination of findings. As part of the NHMRC Partnership Grant funding arrangement Hunter New England LHD also contributed funding. Individuals in positions that are fully or partly funded by these partner organisations (as described in 'Competing Interests') will have a role in the study design, data collection, analysis of data, interpretation of data and dissemination of findings. The University of Newcastle will act as study sponsor make final decisions on each of these study aspects. NN is supported by a NHMRC Medical Research Future Fund (MRFF) Investigator Fellowship (APP1194785); LW is supported by a NHMRC Investigator Fellowship (APP1197022); RS is supported by a NHMRC MRFF Investigator Fellowship (APP1194768).

Availability of data and material

All study materials are available from the research team upon request to lead investigators.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the Hunter New England Human Research Ethics Committee (no. 2019/ETH12353), and the University of Newcastle Human Research Ethics Committee (no. H-2008-0343). The NSW Department of Education and the Maitland-Newcastle Catholic Schools Offices provided consent to conduct research in their schools. Informed consent will be provided by all schools, and teachers participating.

Consent for publication

Not applicable.

Competing interests

Authors NN, RS, KG, NM, RJ, CRL, TC, EP, DG, JW and LW, receive salary support from Hunter New England LHD, which contributes funding to the project outlined in this protocol. None of these agencies were involved in the peer review of this grant. All other authors declare that they have no competing interests.

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Received: 11 September 2023 Accepted: 21 September 2023

Published online: 07 October 2023

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