RESEARCH
ADVANTAGE

HEALTH PROFESSIONALS RESEARCH EDUCATION PROGRAM –

Session 3:

IMPLEMENTATION TRIALS

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

NSW GOVERNMENT Health Hunter New England Local Health District

NSW GOVERNMENT Health Central Coast Local Health District

12.30 – 2.00pm Thursday 29 August 2019
HOST: John Hunter Hospital – Small Lecture Theatre [6067]
Alternative site: Gosford Hospital – Conference Centre
Zoom – Meeting ID 186 958 204

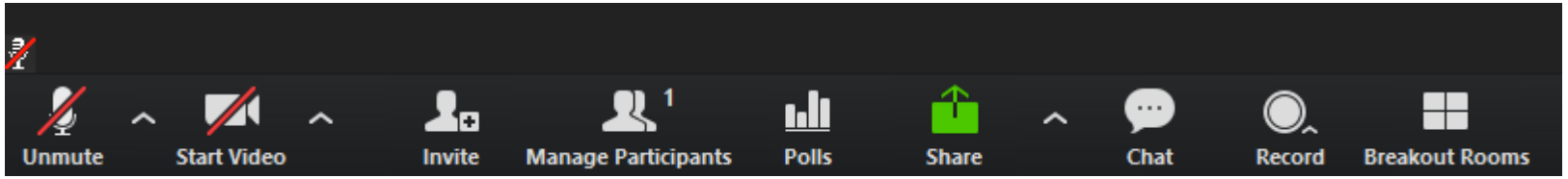
RESEARCH ADVANTAGE
connecting and empowering

ZOOM ETIQUETTE

- This Education session is being **recorded**

- If you are joining us from a remote location – **WELCOME**

- May I ask you to complete login – then **MUTE YOUR MICROPHONE & turn off your video**



RESEARCH ADVANTAGE
connecting and empowering

ACKNOWLEDGEMENT OF COUNTRY

We acknowledge and pay respect to the Awabakal People, traditional custodians of the land on which the John Hunter Hospital is situated
and
also pay respect to the Darkinjung People, traditional custodians of the land on which Gosford Hospital is situated.

We further acknowledge and respect all other Aboriginal and Torres Strait Islander nations joining us today

PROFESSOR JOHN WIGGERS

Director, Clinical Research and Translation, HNELHD

SCENE SETTING

NSW GOVERNMENT Health Hunter New England Local Health District

RESEARCH ADVANTAGE connecting and empowering

NSW GOVERNMENT Health Central Coast Local Health District

SCENE SETTING

- Increased policy focus on ensuring/accelerating ‘translation’ (ie. implementation) of proven interventions into routine clinical practice
- Evidence that this is not occurring, or occurring too slowly
- Evidence that traditional strategies of practice change/quality improvement (eg. guidelines, training):
  - have limited/no effect on clinician implementation of proven interventions into clinical care
  - fail to adequately address barriers to changing clinician care delivery behaviours

SCENE SETTING

- *Implementation Science* '…. the [scientific] study of [behavioural] methods and strategies to promote [clinician] uptake and integration of interventions that have proven effectiveness, into routine clinical practice…'

- 2018 HPREP
  - Duff and Wolfenden: 'Implementation Science'

  - Implementation Science is a diverse area of scientific endeavour

Objective	Description	Example methods
Describe/ Explore	Describe/ explore an idea or phenomenon to make hypotheses or improve understanding.	Qualitative Methods; Surveys; Network Analysis; Mixed Methods.
Develop	Create a ‘knowledge tool’ that synthesises best evidence into a usable product.	Design Methods (Design Thinking); Delphi; Co-design Methods; Quality Improvement
Act	Implement best available evidence using local practice knowledge.	Action Research; Knowledge Translation; Quality Improvement .
Test	Test whether an intervention produces an expected practice change outcome.	Experimental (C-RCT, Stepped Wedge); and Quasi Experimental (ITS, Before-and-After).
Explain	Develop a theory to explain the relationship between concepts and/or events.	Qualitative Methods; Realist Evaluation; Experimental (SMART RCT); Hybrid Trials.

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Explain	Develop a theory to explain the relationship between concepts and/or events.	Qualitative Methods; Realist Evaluation; Experimental (SMART RCT); Hybrid Trials.

SCENE SETTING

- *Implementation Trials*
  - Provide evidence of the effect of intervention strategies on clinician uptake of evidence-based practice, and quality of health care
  - Increasing researcher and funder interest given increasing focus on insufficient translation of evidence into clinical practice

SCENE SETTING

- *Implementation Trials*
  - Differ in a number of design/methods respects relative to ‘therapeutic’ trials
  - Have been criticised due to inconsistent/lack of scientific rigour in designs, methods, outcomes, inconsistent terminology, poor reporting, limited use of theory
  - Rapid development of theories, methods, measures and reporting standards
  - Lack of awareness/understanding of relevant methods by researchers

SCENE SETTING

- Purpose of this presentation
  - ‘How to…’ conduct an implementation trail

ASSOCIATE PROFESSOR LUKE WOLFENDEN

NHMRC Fellow (Career Development Fellow II) and Brawn Career Development Fellow, School of Medicine and Public Health, Faculty of Health and Medicine, University of Newcastle and Program Manager, Hunter New England Clinical Research Fellow, HNE Population Health

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How to conduct an implementation trial

Associate Professor Luke Wolfenden
Luke.wolfenden@hnehealth.nsw.gov.au

Terminology

Terms	Definitions
Implementation science	is commonly defined as the study of methods and strategies to promote the uptake and integration of interventions that have proven effective into routine practice or policy, with the aim of improving health.
Implementation strategies	Methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice
Implementation outcomes	The effects of deliberate and purposive actions to *implement* new treatments, practices, and services.
Implementation trial	Tests the effects of implementation strategies on implementation outcomes

How do implementation trials differ from conventional clinical trials?

CONVENTIONAL CLINICAL TRIALS

Efficacy of the intervention is not known

Assesses impact of intervention e.g.,

- A therapy, surgical procedure, medication, public health program

Outcomes e.g.,

- Patient measures
- Disease measures
- etc

IMPLEMENTATION TRIALS

Efficacy of the intervention is known

Effectiveness of implementation strategy is not known

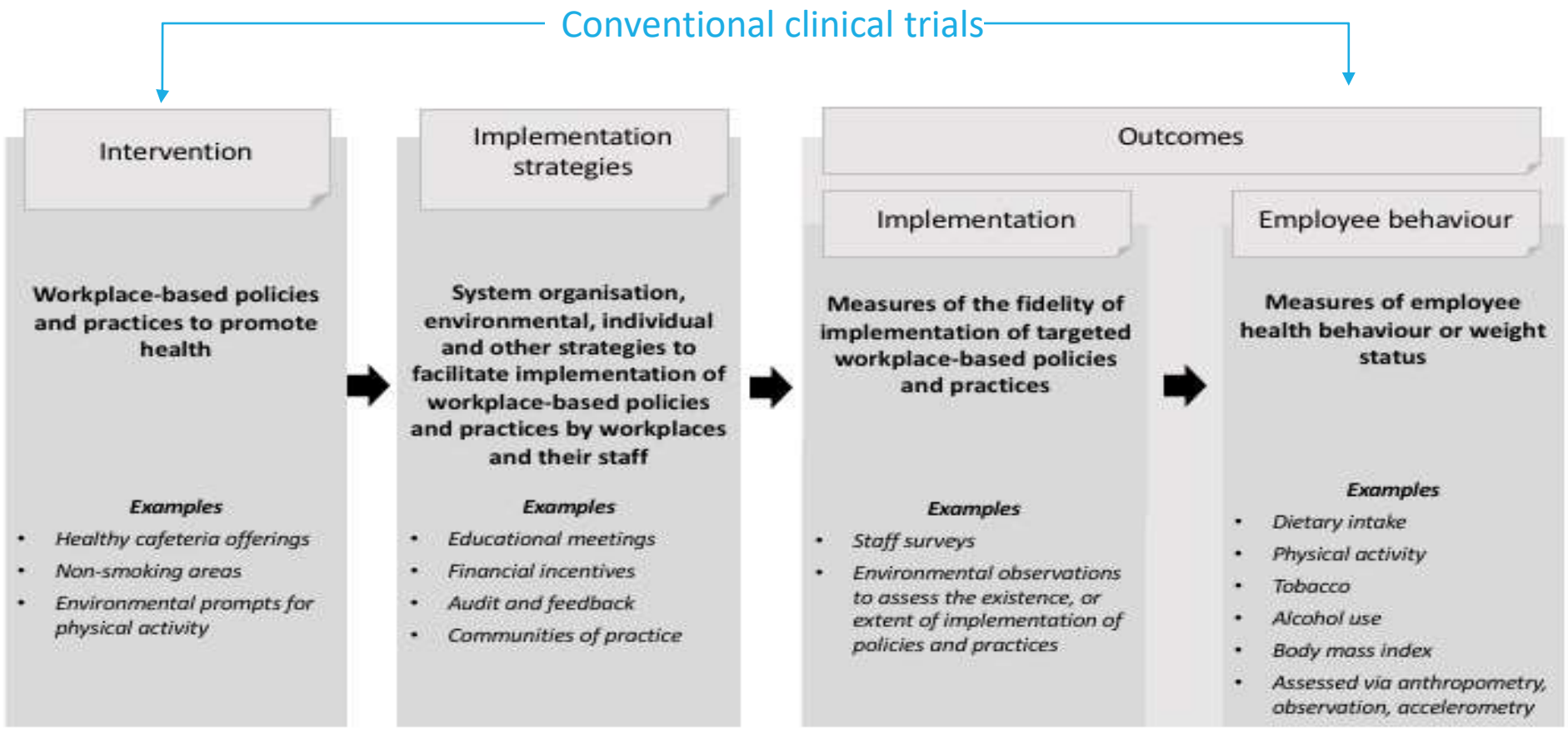
Assesses impact of implementation strategies e.g

- audit and feedback, training, reminders

Outcomes e.g.,

- Quality of health care
- Use of clinical practice guidelines
- etc

How do implementation trials differ from conventional clinical trials?



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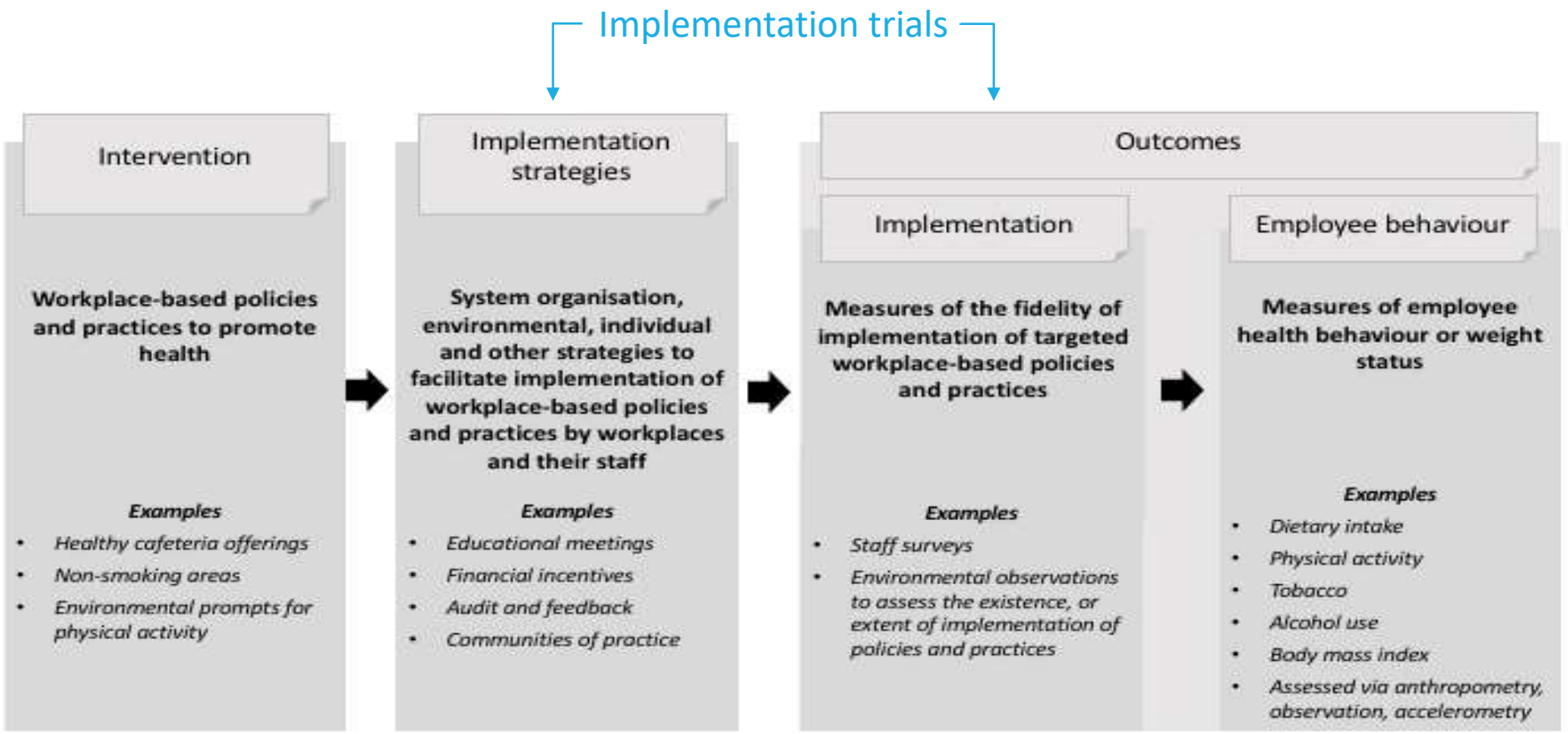

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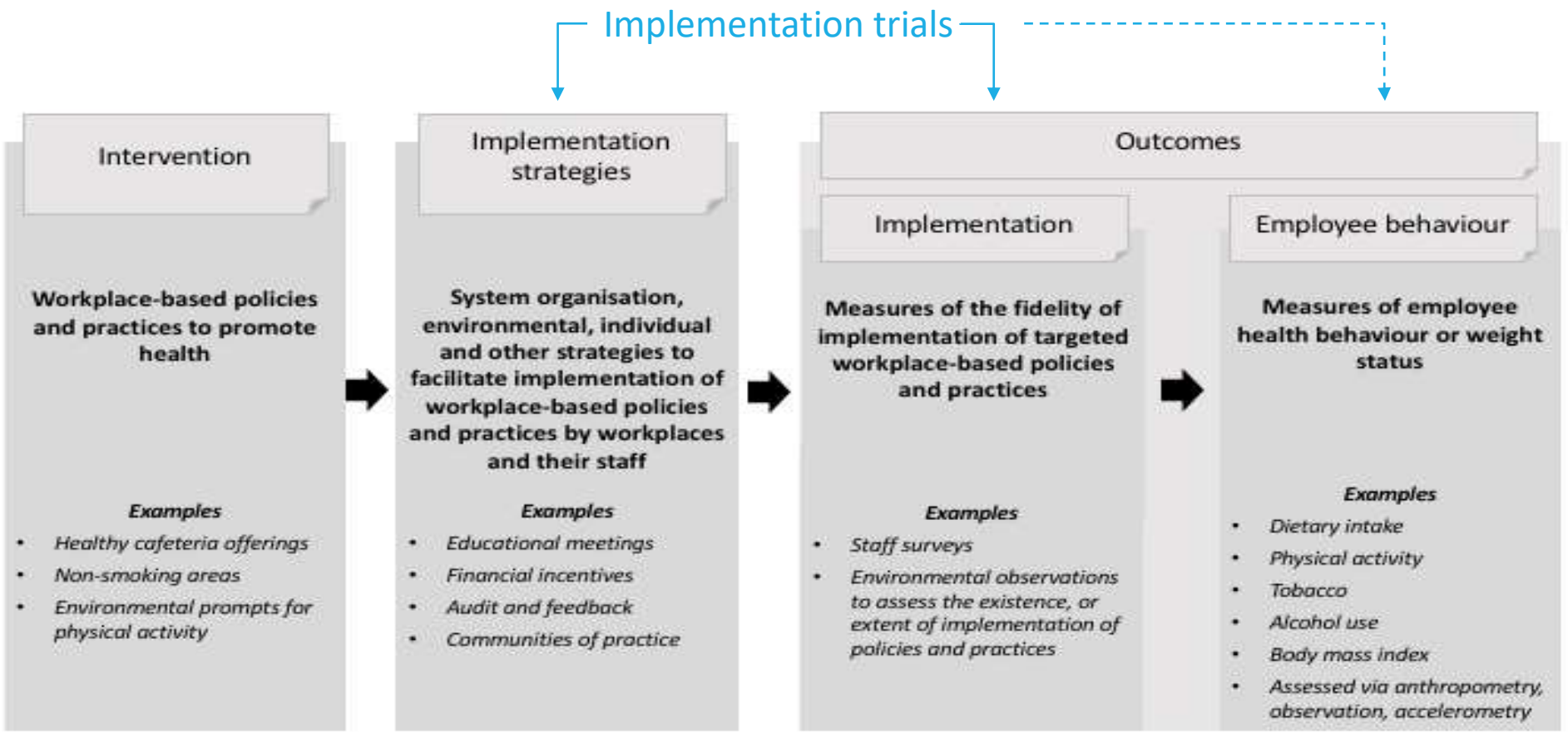
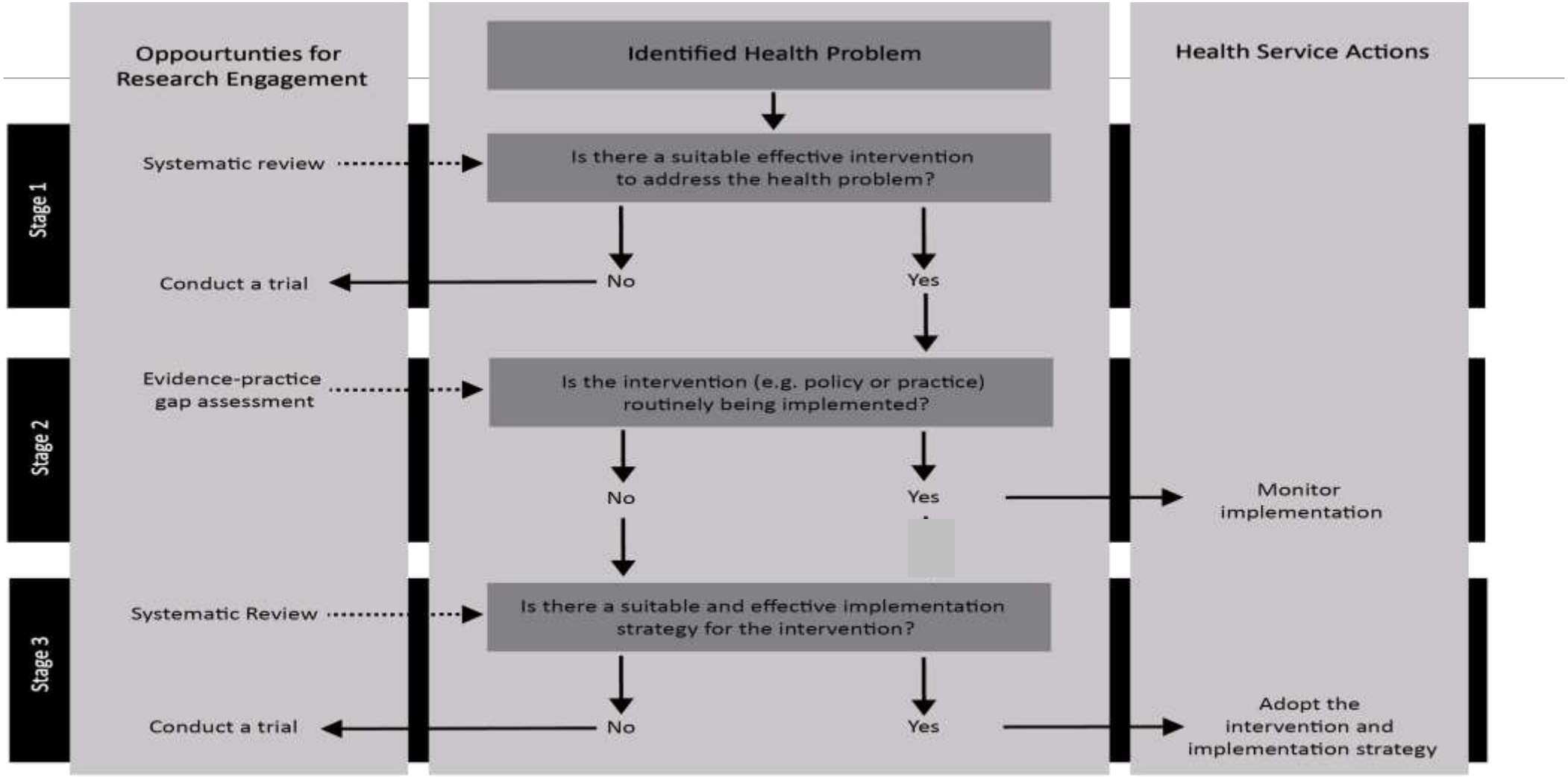


When is an implementation trial warranted?



Recommendations for conducting a implementation RCT

An international group of experts in implementation science was assembled from the UK, Canada, the US and Australia

Synthesis of seminal methods and implementation texts

Guide to be applicable to diverse disciplines including medicine, allied health, mental health and public health

Focus on issues most relevant (unique) to implementation trials – assumes knowledge of existing recommendations for rigorous RCTs

Follows paper chronologically

Nathan et al. BMC Public Health (2019) 19:170
https://doi.org/10.1186/s12889-019-6492-z

BMC Public Health

STUDY PROTOCOL Open Access

A cluster randomised controlled trial of an intervention to increase the implementation of school physical activity policies and guidelines: study protocol for the physically active children in education (PACE) study

Nicole Nathan[1,4*], John Wiggers[1,4], Adrian E. Bauman[5,6], Chris Rissel[7,8], Andrew Searles[4], Penny Reeves[2,4], Christopher Oldmeadow[4], Patti-Jean Naylor[9], Angie L. Cradock[10], Rachel Sutherland[1,4], Karen Gillham[1,4], Bernadette Duggan[11], Sally Chad[12], Nicole McCarthy[1,4], Matthew Pettett[1,4], Rebecca Jackson[1,4], Kathryn Reilly[1,4], Vanessa Herrmann[1], Kirsty Hope[2,3], Adam Shoesmith[2,3] and Luke Wolfenden[1,4]

Abstract

Background: In an attempt to improve children's physical activity levels governments have introduced policies specifying the minimum time schools are to schedule physical activity each week. Despite this, the majority of schools in many jurisdictions fail to implement these policies. This study will assess the effectiveness of a multi-component implementation strategy on increasing the minutes of planned physical activity scheduled by primary school teachers each week.

Methods: A cluster randomised controlled trial will be conducted in 62 primary schools in the Hunter New England region of New South Wales, Australia. Schools will be randomly allocated to receive either a multi-component implementation strategy that includes; obtaining executive support, training in-school champions, provision of tools and resources, implementation prompts, reminders and feedback; or usual practice. The study will employ an effectiveness-implementation hybrid design, assessing both policy implementation and individual (student) behavioural outcomes. The primary trial outcome of mean minutes of physical activity scheduled by classroom teachers across the school week will be

Ethics

Multi-level, naturalistic nature of implementation trials can complicate ethical considerations.

Is a trial necessary

- *Equipoise* (genuine uncertainty regarding therapeutic benefits of the trial arms

Who is consent required from

- Patient?
- Provider / clinician?
- Health administrators / managers (gate keepers)?

The Ottawa Statement on the ethical design and conduct of cluster randomised trials addresses many of the issues often encountered by implementation trials

Weijer, et al. (2012). The Ottawa statement on the ethical design and conduct of cluster randomized trials. *PLoS medicine*, *9*(11), e1001346.

Statement of trial aim

Primary aim:

- Seek to assess the effects of an implementation strategy on the implementation outcome of greatest importance

Secondary aims:

- Seek to assess the effects of other implementation strategies considered important

Hypotheses should be:

- Testable research questions specifying magnitude of effect of implementation strategy on each primary trial outcome
- Superiority trial vs equivalence trial vs non inferiority trial

Statement of trial aim

Aims - a precise statement of which includes information about the population, implementation strategy, comparison and outcome under investigation

Standards for reporting implementation studies (STaRI) guidelines recommend distinguishing clearly between the aims of the implementation strategy and the therapeutic intent of the intervention that is being implemented

For example “The aim of the study was to assess the effectiveness of audit and feedback (implementation strategy), relative to usual care (*comparison*) in improving clinician provision of nicotine replacement therapy (implementation *outcome*) to inpatients of a cardiac ward (*population)*.

Effectiveness-Implementation hybrid designs

Have a dual focus on:

- The clinical effectiveness of the intervention
- The effect of the implementation strategy on an implementation outcomes.

Represent a way of

- Confirming trial effects on patient level outcomes
- Harvesting information to support implementation across trials at various translation stages

For example “The aim of the study was to assess the effectiveness of audit and feedback (implementation strategy), relative to usual care (*comparison*) in improving clinician provision of nicotine replacement therapy (implementation *outcome*) to inpatients of a cardiac ward (*population*) to support smoking cessation (*therapeutic intent of the intervention*).

Nathan, 2019: “The aim of the trial was to assess the effectiveness of a multi-strategic intervention to increase implementation of a state-wide healthy canteen policy. The impact of the intervention on the energy, total fat, and sodium of children’s canteen purchases and on schools’ canteen revenue was also assessed.”

Effectiveness-implementation hybrid designs: characteristics

	Type 1	Type 2	Type 3
Research aims	**Primary**: To assess the effectiveness of a clinical or public health intervention on individual patient or population health outcomes **Secondary**: To describe characteristics of the intervention, implementation strategy or broader implementation context to inform future implementation efforts	Co-Primary : i) To assess the effectiveness of a clinical or public health interventions on individual patient or population health outcomes; and, ii) to assess the effects of a strategy to implement a clinical or public health intervention on implementation outcomes.	**Primary**: to assess the effects of a strategy to implement a clinical or public health intervention on implementation outcomes. **Secondary**: To describe individual or population health outcomes associated with implementation of an intervention.
Sample	**Primary**: individual patients or community members **Secondary**: clinicians, policy makers or service providers responsible for implementation or delivery of the intervention; and/or patients or community members that have been exposed to the intervention.	Both individual patients or community members; and clinicians, policy makers or service providers responsible for implementation	**Primary**: clinicians, policy makers or service providers responsible for implementation or delivery of the intervention **Secondary**: individual patients or community members

Effectiveness-implementation hybrid designs: characteristics

	Type 1	Type 2	Type 3
Research aims	**Primary**: To assess the effectiveness of a clinical or public health intervention on individual patient or population health outcomes – **NOT AN IMPLEMENTATION TRIAL** **Secondary**: To describe characteristics of the intervention, implementation strategy or broader implementation context to inform future implementation efforts	Co-Primary : i) To assess the effectiveness of a clinical or public health interventions on individual patient or population health outcomes; and, ii) to assess the effects of a strategy to implement a clinical or public health intervention on implementation outcomes.	**Primary**: to assess the effects of a strategy to implement a clinical or public health intervention on implementation outcomes. **Secondary**: To describe individual or population health outcomes associated with implementation of an intervention.
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Background

Physical inactivity is the fourth leading cause of death worldwide [1] and is estimated to be responsible for approximately 6–10% of all non-communicable deaths or 5·7 million deaths globally [1]. International physical activity guidelines recommend that children aged 5–17 years accumulate at least 60 min of moderate to vigorous physical activity (MVPA) each day [2]. However, data from the United States (U.S.), United Kingdom (U.K.) and Australia suggest only a third of primary school aged children meet these guidelines [3–5]. As child physical activity patterns track into adulthood [4, 6], ensuring children are sufficiently physically active has been identified as a public health priority [7].

Schools are a key setting for the promotion of physical activity in children [6] as they provide convenient access to the majority of young people and possess the necessary facilities, personnel and ethos to engage children in activity [6]. Furthermore systematic reviews have found that interventions that increase opportunities to be physically active during the school day through regular quality physical education (PE), sport or physical activity in the classroom are effective in increasing children's MVPA [8]. For example, reviews of school sport [9] and other structured activities in class such as energisers [10] have been shown to provide students with potentially 30mins of activity per day. As such, many governments have released guidelines or policy mandating minimum accumulated periods each week that primary schools are to schedule structured activity for children [11–14].

Despite the benefits of implementing such policies, research suggests that internationally most schools fail to implement physical activity policies at scale. For example, the 2014 physical activity report card for Ireland found that, based upon an audit of timetabled weekly PE of 419 schools, only 17% were providing the compulsory 2 h of PE per week [13]. Similarly, a 2011 U.S. study that undertook observations of 154 PE lessons found that only 5% of schools were compliant with mandated state policies that require 100 min of PE be taught each week [15]. A 2011 study found that only 43% of Canadian primary school teachers reported implementing the mandatory daily 30-min physical activity policy [14]. Furthermore a 2013 study, using 64 independent observers placed within Australian primary school classes for 9 weeks found only 13% of classes routinely engaged in physical activity during class time [16].

A recently published systematic review [17] of 17 qualitative and quantitative studies identified that primary schools face a number of barriers to the implementation of planned physical activities which relate to 'environmental context and resources' (e.g., availability of equipment, time or staff), 'goals' (e.g., the perceived priority of the policy in the school), 'social influences' (e.g., support from school boards), and 'skills' (e.g., teachers' ability to implement the policy). Without the provision of implementation support to schools to overcome these barriers, the potential benefits of school-based physical activity policies on children's health will not be realised [18]. However, there is little evidence regarding the most effective strategies to overcome these barriers and enhance implementation of physical activity policies in schools. A recent Cochrane review of the impact of implementation interventions in schools identified only one controlled trial in primary schools of a strategy to support the implementation of school physical activity policies [19]. The randomised trial undertaken in seven U.S. schools in 1994 aimed to enhance the quantity and quality of PE lessons by comparing the training of classroom teachers (whom received on-site training, intensive on-going technical assistance, modelling, audit and feedback, resources and coalition building support) to specialist PE teachers to control to improve teaching practices in PE lessons. Based on observational data of PE lessons, the study reported a significant improvement in implementation compared to control during the 3-year intervention period, however this was not sustained once the intensive support was removed.

The lack of evidence of effective strategies and their relative cost to support the implementation of physical activity policies represents a significant impediment to translation. Therefore, the primary aim of this trial is to assess the effectiveness and cost-effectiveness of a multi-component implementation strategy in increasing the minutes of planned weekly physical activity scheduled by classroom teachers consistent with the New South Wales (NSW) Government School Sport and Physical Activity Policy. As a secondary outcome of the trial, the study will assess the effectiveness of scheduled physical activity on children's activity levels.

Methods

The study methods will be reported in accordance with the CONSORT statement for cluster randomised controlled trials [20] and the Standards for Reporting Implementation Studies (StaRI) statement [21].

Context

In 2015 the NSW Department of Education (DoE) amended its Sport and Physical Activity Policy (here after "policy") [11], requiring students from Kindergarten to Year 10 to participate in a minimum of 150 min (increased from 120 min) of planned moderate with some vigorous physical activity across the school week. Planned physical activity includes time spent in PE, sport and other structured activities that is inclusive of all

Sampling, recruitment and retention strategies

Strategies to improve trial participation or reduce participant attrition

Implementation trials often require participation at multiple levels

- Participating organisation
- Staff (e.g., clinicians or school teachers)
- Patients

Samples should be naturalistic, emphasise external validity.

Motivations and capacity are different for

- Managers of these organisations vs patients

Engage potential trial organisational ‘sites’ through co-production processes

Selecting research design

Considerations of RCTs for assessing the effects of implementation interventions

Description	Strengths	Limitations	Considerations
Trials using random assignment			
RCT **Units (e.g. hospitals or patients) are randomly assigned to receive a treatment (implementation strategy) or an alternative condition (e.g. usual practice or control).** **Measurement of outcomes is undertaken on the same unit that is randomised**	• An efficient trial design • Protects against most threats to internal validity: ambiguous temporal precedence, selection, history, maturation, testing, instrumentation, regression to the mean." (Mercer et al., 2007) • Decreases selection bias and minimises confounding due to unequal distribution in a chosen population	• May have low external validity. (Mercer et al., 2007) (Mazzucca et al., 2018) • Time consuming and expensive (Eccles et al., 2003) • Risk of contamination between individuals randomized to one condition to the comparison condition when randomised from the same group (Crespi, 2016). • Acceptability and ethical issues that can arise when individuals in the same group are treated differently (Crespi, 2016).	• Most appropriate when there is low risk of contamination of implementation strategies or their effects on the comparison group and where external, random allocation is ethically justifiable and acceptable to stakeholders (Brown et al., 2017)

Considerations of RCTs for assessing the effects of implementation interventions

Description	Strengths	Limitations	Considerations
Trials using random assignment			
Cluster RCT **Units (e.g. hospitals) representing groups (e.g. patients) are randomly assigned to receive a treatment (implementation strategy) or an alternative condition (e.g. usual practice or control). Measurement of outcomes is undertaken on group members (e.g. patients)**	• Can reduce the risk of implementation strategy contamination. • With large number of clusters the design provides a robust assessment of intervention effects • Can be some logistical and cost efficiencies of undertaking the trial at a group level (Crespi, 2016)	• With small numbers of clusters there is an increased probability of non-equivalence of groups which may confound effect estimates • Logistically challenging, time consuming and expensive (Eccles et al., 2003) • Not as statistically efficient as an individual RCT. Sample sizes for cluster RCTs need to be inflated to adjust for clustering." (Grimshaw Chapter) • As individuals are consented after randomization in cluster RCTs, there is the potential for selection bias.	• Most appropriate when contamination is likely from individual allocation, and when there is sufficient number of clusters (e.g hospitals) for allocation – as a rule of thumb 10 units per arm.

Considerations of RCTs for assessing the effects of implementation interventions

Description	Strengths	Limitations	Considerations
Trials using random assignment			
Stepped wedge RCT **Following a baseline period (comparison phase), an implementation strategy is sequentially provided to clusters. The order in which the different cluster are assigned to receive the implementation strategy is randomised. Over time all units will have received implementation support (Brown & Lilford, 2006). Measurement of outcomes is undertaken on the same unit that is randomised**	• Can reduce the risk of implementation strategy contamination. • Each cluster serves as its own control (within-cluster) and can be compared with the performance of other sites (between-cluster). (Landsverk et al., 2017) • Is consistent with processes of rolling out new innovations in health service which may improve feasibility and acceptability of the design to stakeholders (Shah et al., 2015).	• Is likely to require substantially longer trial duration than RCT or CRCT designs as implementation strategy is delivered sequentially (Brown & Lilford, 2006). • Logistically challenging, time consuming and expensive (Shah et al., 2015) • Repeated measurement of outcomes at each interval can be prohibitive unless routinely collected data is available. • Methodological complexities to power calculations and analyses. (Shah et al., 2015) (Hussey & Hughes, 2007) • May not be suitable for testing implementation strategies where effects are not expected for some time (until more than one time interval after the intervention is introduced) (Hussey & Hughes, 2007)	• Most appropriate for evaluating strategies to implement a proven evidence based intervention, (i.e., in cases where there is a lack of true collective equipoise about the merits of the intervention) (Hussey & Hughes, 2007), where it may be unethical withhold intervention, where there is a limited number of clusters, where routinely collected data is available for outcome assessment, and where staged delivery of implementation support is preferable.

"The study employed a randomised trial design. Primary schools (those catering for children aged 5–12 years) in the Hunter region of NSW, Australia, with a canteen were randomised to receive a 12–14-month, multi-strategic implementation intervention or to a no intervention control group."

children and is part of their regular programming and planning. To support primary school teachers meet the policy requirements, the research team will target increases in planned physical activity across the three areas identified by the policy, that is; i) ***PE***- teachers will be supported to programme PE throughout the school week by developing a scope and sequence for each school stage (K-2; 3–4; 5–6) and deliver active, effective and enjoyable PE. ii) ***Sport***- teachers will be supported to programme sufficient time for sport and maximise student activity via strategies to improve student participation and enjoyment. iii) ***Other structured activities***- teachers will be supported to integrate short-bouts of activity into class routines e.g. energisers [10] or active lessons [22]. Energisers are short classroom-based physical activities that break-up sitting time by getting students to engage in short bursts i.e. 3–5 min of MVPA involving no equipment. Active lessons integrate physical activity into another subject area by making the traditional lesson more active, for example, getting students to skip as they recite their times tables.

Design and setting

This study will employ a cluster randomised controlled trial (RCT). Sixty-two primary schools, in the Hunter New England (HNE) region, of NSW will be randomised to receive either a multi-component implementation strategy to support policy implementation or 'usual practice'. The trial will assess between-group differences in the mean minutes of scheduled weekly physical activity with data collected at baseline (Oct 2017- Feb 2018), and immediately following the delivery of the implementation strategy (Oct-Dec 2018). To determine the longer-term sustainability data will be collected approximately 6-months following completion of the implementation strategy (April–June 2019) (see Fig. 1).

Participants and recruitment

Schools

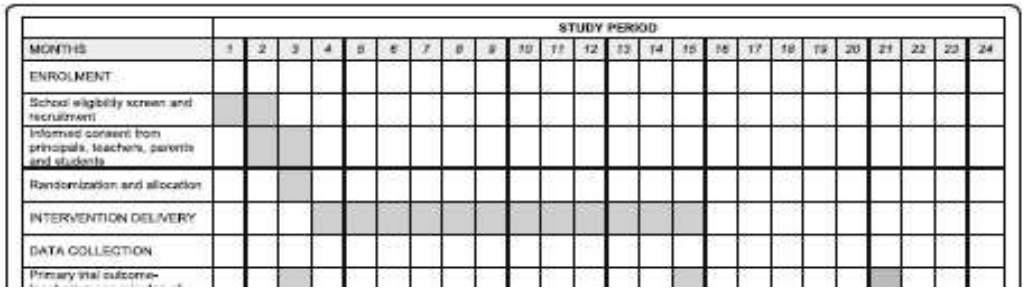
All government and Catholic schools in the study region (approximately 90% of all schools) will serve as the sampling frame. Schools participating in another physical activity intervention, schools with both primary and secondary students (i.e. central schools) and schools catering exclusively for children with special needs will be excluded. School principals will be provided with a study information package and asked to provide written informed consent. Recruitment will continue until the sample of schools have consented.

Teachers

Following principal consent, a member of the research team will attend a school staff meeting to provide teachers with a brief overview of the purpose of the study and to answer any questions teachers may have. Consenting teachers will be invited to complete a paper survey during the week of their school's scheduled data collection visit which will include a log-book of their class scheduled physical activity.

Students

As the effect of scheduling physical activity on children's physical activity has been established in a previous pilot of this study [23] for pragmatic reasons only a subset of school students i.e. those in grades 2 and 3 will be invited to take part in the accelerometer data collection



	STUDY PERIOD																							
MONTHS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
ENROLMENT																								
School eligibility screen and recruitment																								
Informed consent from principals, teachers, parents and students																								
Randomization and allocation																								
INTERVENTION DELIVERY																								
DATA COLLECTION																								
Primary trial outcome-																								

Selecting theories & frameworks

Using theory and frameworks

Implementation trials should include an explicit programme theory that details the rationale and assumptions about the mechanisms linking implementation strategy (and intervention), processes and inputs to trial outcomes.

- Informal theory - understandings of the problem and its determinants through experience/ tacit knowledge.
- Formal behavioural or implementation theories or frameworks

Program theory is the skeleton for trial evaluation

component of the trial. An information package will be sent to parents of students in participating schools encouraging them to discuss the study procedures with their child and to invite study participation. Two weeks following distribution of the information packages, parents who have not returned a consent form will be telephoned by staff employed through the school and asked if they would like to consent to child participation.

Parents

Parents of students in grades 2 and 3 who consent to have their child participate in data collection will be invited to complete a telephone survey regarding the physical activity and wellbeing of their children. Parents who are interested in completing the survey will be asked to include their telephone number on their child's consent form.

Randomisation and blinding

Following baseline data collection, an independent statistician will set-up block randomisation using a computerised random number function to randomise schools in a 1:1 ratio to either an intervention or control group. Block randomisation will ensure group allocation is approximately equal. Allocation will be stratified by the geographic (rural vs urban) location of the school given the association with implementation of school physical activity policies or practices [24]. Allocation will follow baseline data collection. Due to the nature of the intervention school staff will be aware of school group allocation. Whilst all efforts will be made to keep data collectors blinded to group allocation, due to the provision of some resources to schools (e.g. manuals) they may become aware of group allocation during attendance at the school for follow-up data collection. Data entry staff will be blinded.

Intervention group: implementation strategy

Development and theoretical framework

The implementation strategy has been developed using both the Behaviour Change Wheel (BCW) and Theoretical Domains Framework (TDF) [25], which together ensure; a comprehensive assessment of factors (i.e. capabilities, opportunities and motivation) impacting on an individual's behaviour are considered, and that modifiable factors and potential behaviour change techniques that may be utilised to influence the desired behaviour of an individual are identified. Following extensive formative research which included i) literature reviews; ii) interviews using an adapted form of the validated TDF barriers to the BCW and TDF. Potential behaviour change techniques and implementation strategies were then identified. Following consultation with an advisory group consisting of, implementation and health behaviour scientists, physical activity experts, teachers, principals and senior government policy makers (who will oversee delivery of the study) the proposed implementation strategies were presented and discussed. To be included, implementation strategies were also assessed against the APEASE criteria [25], a systematic approach for considering contextual factors during the selection of implementation strategies, which includes; Affordability (can be delivered on budget), Practicality (is feasible to deliver), Effectiveness and cost-effectiveness (it works), Acceptability (to the school community), Side-effects/safety (no negative consequences), Equity (no groups disadvantaged in particular Aboriginal or Torres Strait Islander communities). The selected implementation strategies have previously been utilised by members of the research team to successfully change the health promoting policies and practices of schools [27, 28] and other organisations [29–33]. Table 1 describes each of the implementation strategies using the Expert Recommendations for Implementing Change (ERIC) taxonomy [34] and shows how these were mapped against the BCW and TDF to address barriers to practice change.

Data collection and measures

Primary trial outcome- mean minutes of planned weekly physical activity scheduled by classroom teachers

The primary trial outcome is the mean minutes of physical activity scheduled during a 1-week data collection periods at baseline, 12 and 18 months following baseline. Scheduled physical activity includes time spent in PE, sport and other structured physical activities - as required to be compliant with the DoE Sport and Physical Activity Policy. Time scheduled for physical activity for each class will be assessed via class teacher completion of a daily activity log-book, which has been previously utilised by the project team [23]. At the end of each day of the week of data collection, each teacher responsible for the class that day will complete a written log of the day's teaching including the time and occasions of physical activity for PE, sport or other structured activities i.e. energisers or active lessons. The use of teacher log-books is frequently used in classroom-based obesity prevention interventions [35, 36] with high response rates (i.e. >80%) [35] and established reliability and validity [37].

Secondary outcomes

Theory / framework type	Description	Application
Classic theories (e.g theory of planned behaviour, Social cognitive theory, situated change theory	Originate from related disciplines (e.g psychology) and help understand or explain individual, group or organisational behaviour.	Classic and implementation theories describe precise mechanisms of behaviour change. One or more of these theories can be used to developed targeted implementation strategies and describe how change in the behaviour of those involved in an implementation process is anticipated to occur. Classical theories may be useful when an appropriate and empirically supported implementation theory, appropriate to the implementation problem and context is not available
Implementation theories (e.g Implementation Climate, Normalization Process Theory).	Theories developed (or adapted classical theories) specifically to understand, explain and inform implementation. They describe provide precise mechanisms of change for one or more aspect of implementation.	
Determinants frameworks (e.g Consolidated Framework for Implementation Research, Theoretical Domains Framework)	Often developed through the consolidation of a range or theories, they aim to understand and explain factors that may influence (facilitate or impede) implementation	Do not describe mechanisms for change. However, determinants frameworks can help identify factors thought to be associated with implementation, and implementation strategies that can be employed to address these, for which programme theory can be developed.

Case study using the TDF

Theoretical domain	Definition [21]
Knowledge	An awareness of the existence of something
Skills	An ability or proficiency acquired through practice
Social/professional role and identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting
Beliefs about capabilities	Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use
Optimism	The confidence that things will happen for the best or that desired goals will be attained
Beliefs about consequences	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation
Reinforcement	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus
Intentions	A conscious decision to perform a behaviour or a resolve to act in a certain way
Goals	Mental representations of outcomes or end states that an individual wants to achieve
Memory, attention and decision processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives
Environmental context and resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour
Social influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours
Emotion	A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event
Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions

Application of formal theory

Suggested steps for the development of a theory-informed implementation strategy (French et al, 2012)

- 1. Identify who (e.g individual/s or professional group/s) needs to do what differently in order for implementation to be improved.
- 2. Using informal and formal theory and frameworks, identify barriers and enablers that need to be addressed articulate a pathway of change for the targeted behaviour change to occur. A variety of research methods, including literature reviews and local qualitative and quantitative data collection should be used to support the development of the change pathway (programme theory).
- 3. Select implementation strategies (behaviour change techniques, modes of delivery) that may be effective, locally relevant, acceptable and feasible to overcome identified barriers and enhance facilitators to change. Selection of strategies could be based on matrices recommended by determinant frameworks, empirical evidence, and engagement with end-users.
- 4. Decide how change in implementation can be robustly and feasible measured, including factors on the hypothesised casual pathway (mediators) and appropriate implementation outcomes.

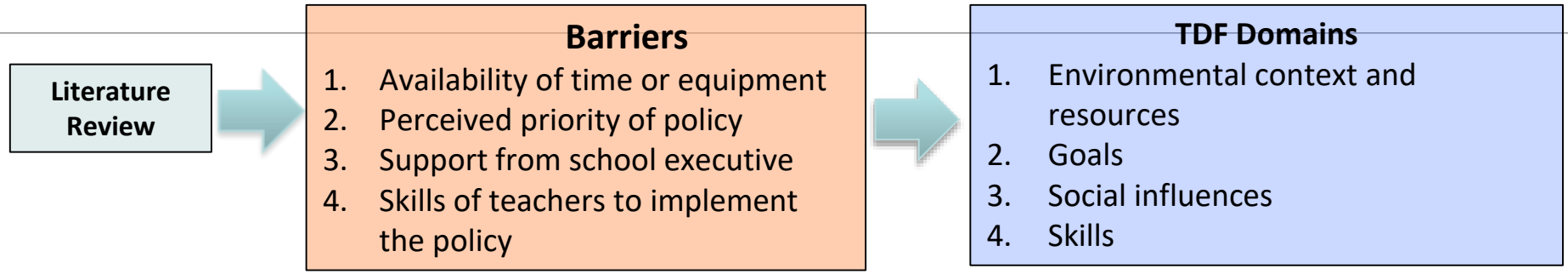
Designing the PACE (pilot) intervention

Step 1

- **Who needs to do what, differently?**
- Using a theoretical framework, which barriers and enablers need to be addressed?
- Which intervention components could overcome the modifiable barriers and enhance the enablers
- How can behaviour change be measured and understood?

Step 2

- Using a theoretical framework, which barriers and enablers need to be addressed?



Step 2

- Using a theoretical framework, which barriers and enablers need to be addressed?

Literature Review

Barriers

1. Availability of time or equipment
2. Perceived priority of policy
3. Support from school executive
4. Skills of teachers to implement the policy

TDF Domains

1. Environmental context and resources
2. Goals
3. Social influences
4. Skills

Interviews and observation

Additional barriers

4. Knowledge of policy
5. Personal attitude to policy
6. Concerns regarding other subjects
7. Remembering to do

Additional TDF domains

4. Knowledge
5. Goals
6. Beliefs about consequences/ Social/professional role and identity
7. Memory attention

Designing the PACE Pilot Trial intervention

- Who needs to do what, differently?

Step 2

- Using a theoretical framework, which barriers and enablers need to be addressed?

Step 3

- **Which implementation strategies could overcome the modifiable barriers and enhance the enablers**

- How can behaviour change be measured and understood?

Step 3

- Which implementation strategies could overcome the modifiable barriers and enhance the enablers

Techniques judged to be effective in changing each construct domain

1 Social/Professional role and identity
2 Knowledge
3 Skills
4 Beliefs about capabilities
5 Beliefs about consequences
6 Motivation and goals
7 Memory, attention, decision processes
8 Environmental context and resources
9 Social influences
10 Emotion
11 Action planning

KEY[a]:

	Agreed use
	Uncertain
	Disagreement
	Agreed non-use

Technique for behaviour change	Techniques judged to be effective in changing each construct domain										
	1	2	3	4	5	6	7	8	9	10	11
Goal/target specified: behaviour or outcome											
Monitoring											
Self-monitoring											
Contract											
Rewards; incentives (inc. self-evaluation)											
Graded task, starting with easy tasks											
Increasing skills: problem-solving, decision-making, goal-setting											
Stress management											
Coping skills											
Rehearsal of relevant skills											
Role-play											
Planning, implementation											
Prompts, triggers, cues											
Environmental changes (e.g. objects to facilitate behaviour)											
Social processes of encouragement, pressure, support											
Persuasive communication											
Information regarding behaviour, outcome											
Personalised message											
Modelling/demonstration of behaviour by others											
Homework											
Personal experiments, data collection (other than self-monitoring of behaviour)											
Experiential: tasks to gain experiences to change motivation											
Feedback											
Self talk											
Use of imagery											
Perform behaviour in different settings											
Shaping of behaviour											
Motivational interviewing											
Relapse prevention											
Cognitive restructuring											
Relaxation											
Desensitisation											
Problem-solving											
Time management											
Identify/prepare for difficult situation/problems											

Measures

Trial outcomes measures

Should be directly linked to the trials primary and secondary aims

Hybrid trial measures need to be included to assess implementation outcomes and clinical level health outcomes

Trial outcomes should:

- Have evidence of validity
- Be sufficiently sensitive for use in an RCT

school rings. Teachers will be responsible for distributing and collecting the accelerometers on a daily basis. Students will be asked to wear the accelerometers for the whole school day except for water-based activities. Student data will be analysed if accelerometers are worn for ≥80% of the school day on ≥3 days. Accelerometer non-wear time will be calculated by summing the number of consecutive zero counts accumulated in strings ≥20 min. Wear time will be estimated by subtracting non-wear time from the total monitoring time for the school day. For each valid school day, counts per minute (cpm) will be calculated by dividing the total accelerometer counts by the minutes of wear time. Accelerometer counts will be classified as sedentary, light-intensity PA, and MVPA using the vertical axis wrist cut-points developed by Chandler et al. [38]

Student physical activity outside of school hours whilst the purpose of the policy is to increase physical activity during school hours, to identify any compensatory physical activity behaviour occurring out of school hours [39] parents will be asked to report via the telephone survey, at baseline and follow-up, on their child's physical activity outside of school hours and on weekends. Measures will be taken from the 2011–2012 NSW child population health survey [40].

Student well-being previous research indicates quality of life is associated with increased physical activity among children [2]. To further assess the impact of the intervention, the differences between groups at follow-up in Pediatric Quality of Life Inventory as reported by parents via the telephone survey will be assessed as a secondary outcome of the trial.

Student on-task behaviour breaking up long periods of sitting time with physical activity is associated with increased attention and focus of children [10]. At baseline and follow-up teachers will, as part of their paper survey, be asked to complete selected items from the Teaching and Learning International Survey (TALIS) (OECD 2010), which will provide a class-based measure of student's on-task behaviour.

Implementation outcomes

To characterise implementation the measures recommended by Proctor et al. [41] of implementation outcomes will also be assessed. This includes;

- Acceptability- defined as *the perception among*

via paper based survey, the Acceptability of Intervention Measure (AIM) [42], developed by Weiner et al., a four-item valid and reliable scale.

- Adoption- defined as *the intention, initial decision, or action to try or employ an innovation or evidence-based practice*. Based upon a previously developed tool from the research team [43] at baseline and follow-up all intervention and control principals will be asked to report, via paper based survey, their stage of adoption for implementing the physical activity policy.
- Appropriateness- defined as *the perceived fit, relevance, or compatibility of the innovation or evidence based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem*. At follow-up intervention principals and teachers will be asked to complete, via paper based survey, the Intervention Appropriateness Measure (IAM), a four-item valid and reliable scale.
- Feasibility- defined as *the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting*. At follow-up intervention principals and teachers will be asked to complete, via paper based survey, the Feasibility of Intervention Measure (FIM), a four-item valid and reliable scale.
- Fidelity- defined as *the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the programme developers*. Project records as well as post-intervention questionnaires completed by intervention principals, school champions and teachers will be used to determine the proportion of schools that received and attended to each of the implementation strategies.
- Implementation cost- defined as *the cost impact of an implementation effort;* see cost and cost-effectiveness measure below.
- Penetration- defined as *the integration of a practice within a service setting and its subsystems* will be measured as per the primary trial outcome to assess the proportion of teachers scheduling the required minutes as per the DoE Sport and Physical Activity Policy. Penetration will then be calculated by the number of teachers who meet the policy requirements, divided by the total number of teachers expected to implement the policy.

Common measures in implementation trials

Terms	Proctor et al.'s 8 implementation measures
Acceptability	is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory.
Adoption	is defined as the intention, initial decision, or action to try or employ an innovation or evidence-based practice
Appropriateness	is the perceived fit, relevance, or compatibility of the innovation or evidence based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem
Costs	is defined as the cost impact of an implementation effort. Implementation costs vary according to three components.
Feasibility	is defined as the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting
Fidelity	is defined as the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers
Penetration	is defined as the integration of a practice within a service setting and its subsystems
Sustainability	is defined as the extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing, stable operations

Proctor et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Administration and Policy in Mental Health and Mental Health Services Research. 2011 Mar 1;38(2):65-76.

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Abbreviated Acceptability Rating Profile (AARP)

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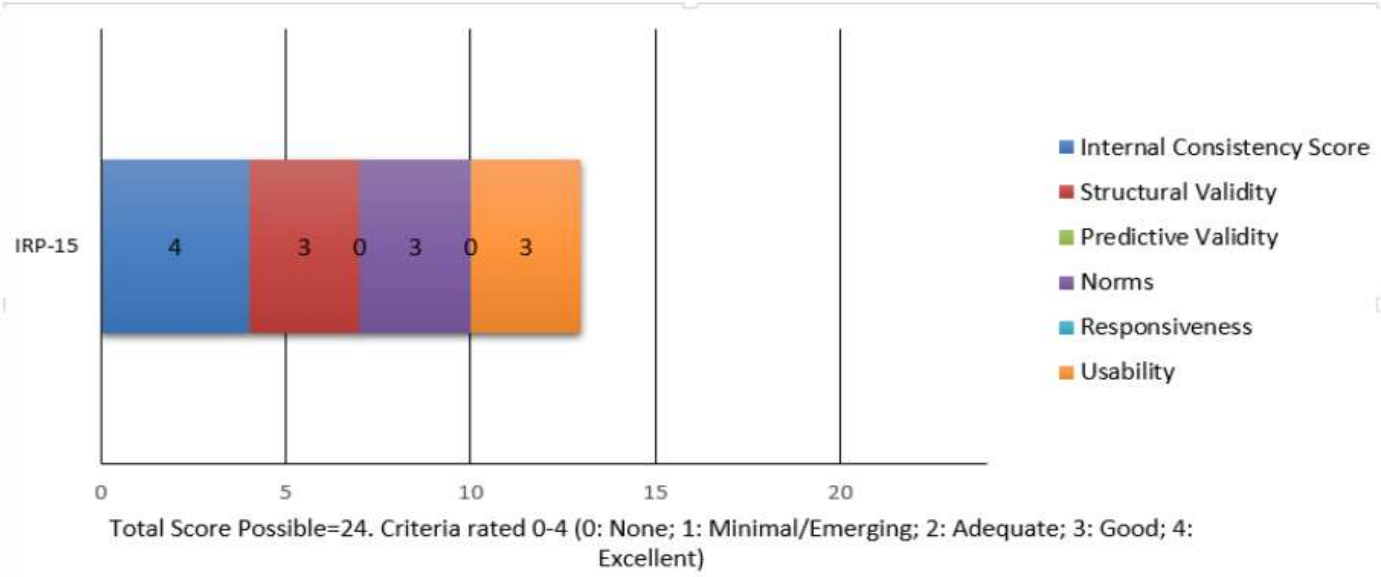
The Abbreviated Acceptability Rating Profile is an 8-item instrument used to

Evidence-Based Assessment Rating Profile



Total Score Possible=24. Criteria rated 0-4 (0: None; 1: Minimal/Emerging; 2: Adequate; 3: Good; 4: Excellent)

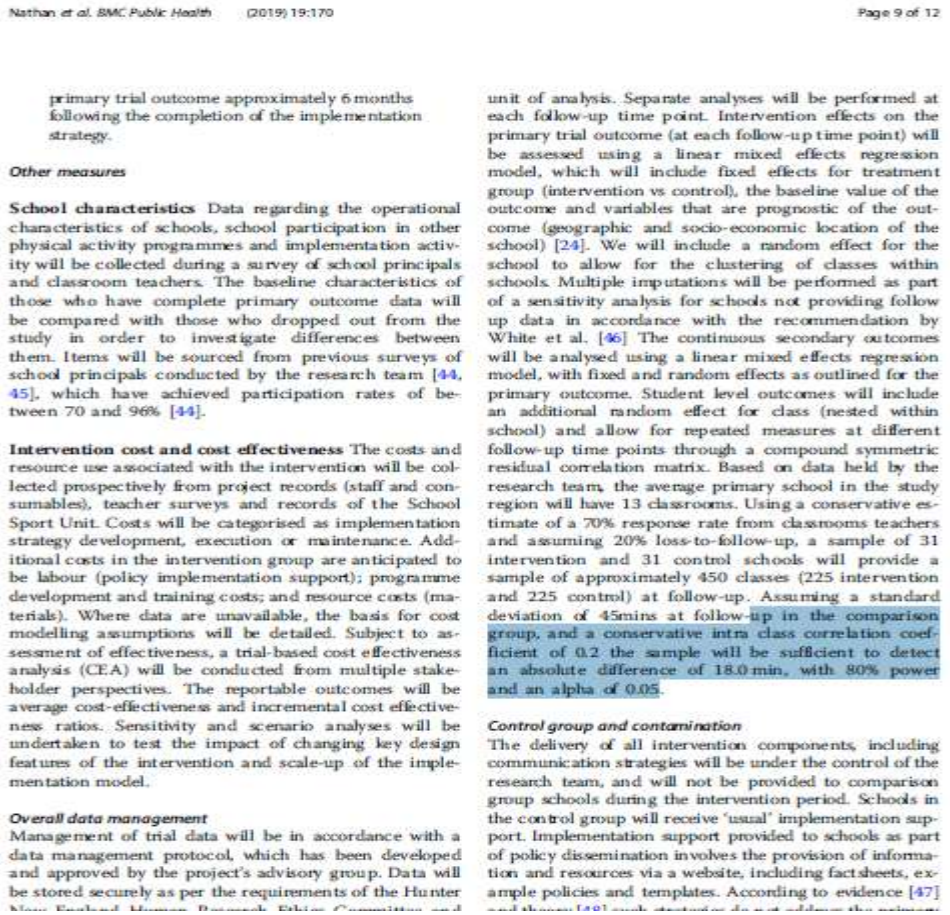
Sample size calculation

Conducted prior to enrolment as part of study planning process

Sample size estimates are important to enrol the required number of participants to detect significant important effects

Sample size calculations should be performed on the primary implementation outcomes

- Potentially other health outcomes for hybrid trials
- Effect size for implementation outcome needs to be considered from a health system perspective (rather than biological individual participant level)



primary trial outcome approximately 6 months following the completion of the implementation strategy.

Other measures

School characteristics Data regarding the operational characteristics of schools, school participation in other physical activity programmes and implementation activity will be collected during a survey of school principals and classroom teachers. The baseline characteristics of those who have complete primary outcome data will be compared with those who dropped out from the study in order to investigate differences between them. Items will be sourced from previous surveys of school principals conducted by the research team [44, 45], which have achieved participation rates of between 70 and 96% [44].

Intervention cost and cost effectiveness The costs and resource use associated with the intervention will be collected prospectively from project records (staff and consumables), teacher surveys and records of the School Sport Unit. Costs will be categorised as implementation strategy development, execution or maintenance. Additional costs in the intervention group are anticipated to be labour (policy implementation support); programme development and training costs; and resource costs (materials). Where data are unavailable, the basis for cost modelling assumptions will be detailed. Subject to assessment of effectiveness, a trial-based cost effectiveness analysis (CEA) will be conducted from multiple stakeholder perspectives. The reportable outcomes will be average cost-effectiveness and incremental cost effectiveness ratios. Sensitivity and scenario analyses will be undertaken to test the impact of changing key design features of the intervention and scale-up of the implementation model.

Overall data management

Management of trial data will be in accordance with a data management protocol, which has been developed and approved by the project's advisory group. Data will be stored securely as per the requirements of the Hunter

unit of analysis. Separate analyses will be performed at each follow-up time point. Intervention effects on the primary trial outcome (at each follow-up time point) will be assessed using a linear mixed effects regression model, which will include fixed effects for treatment group (intervention vs control), the baseline value of the outcome and variables that are prognostic of the outcome (geographic and socio-economic location of the school) [24]. We will include a random effect for the school to allow for the clustering of classes within schools. Multiple imputations will be performed as part of a sensitivity analysis for schools not providing follow up data in accordance with the recommendation by White et al. [46] The continuous secondary outcomes will be analysed using a linear mixed effects regression model, with fixed and random effects as outlined for the primary outcome. Student level outcomes will include an additional random effect for class (nested within school) and allow for repeated measures at different follow-up time points through a compound symmetric residual correlation matrix. Based on data held by the research team, the average primary school in the study region will have 13 classrooms. Using a conservative estimate of a 70% response rate from classrooms teachers and assuming 20% loss-to-follow-up, a sample of 31 intervention and 31 control schools will provide a sample of approximately 450 classes (225 intervention and 225 control) at follow-up. Assuming a standard deviation of 45mins at follow-up in the comparison group, and a conservative intra class correlation coefficient of 0.2 the sample will be sufficient to detect an absolute difference of 18.0 min, with 80% power and an alpha of 0.05.

Control group and contamination

The delivery of all intervention components, including communication strategies will be under the control of the research team, and will not be provided to comparison group schools during the intervention period. Schools in the control group will receive 'usual' implementation support. Implementation support provided to schools as part of policy dissemination involves the provision of information and resources via a website, including factsheets, example policies and templates. According to evidence [47]

Reporting guidelines

Standards for reporting implementation studies (STaRI) guidelines

CONSORT reporting guideline (and extension) specific to the RCT type

The Enhancing the Quality and Transparency of Health Research Network (Equator) houses a range of reporting guidelines

Table 1| **Standards for Reporting Implementation Studies: the StaRI Checklist of items to be reported**

Checklist item		Implementation strategy	Intervention†
Title	1	Identification as an implementation study, and description of the methodology in the title and/or keywords	
Abstract	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes	
Introduction	3	Description of the problem, challenge, or deficiency in healthcare or public health that the intervention being implemented aims to address	
	4	The scientific background and rationale for the implementation strategy (including any underpinning theory, framework, or model, how it is expected to achieve its effects, and any pilot work)	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects)
Aims and objectives	5	The aims of the study, differentiating between implementation objectives and any intervention objectives	
Methods: description	6	The design and key features of the evaluation (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons	
	7	The context in which the intervention was implemented (consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere)	
	8	The characteristics of the targeted "site(s)" (locations, personnel, resources, etc) for implementation and any eligibility criteria	The population targeted by the intervention and any eligibility criteria
	9	A description of the implementation strategy	A description of the intervention
	10	Any subgroups recruited for additional research tasks, and/or nested studies are described	
Methods: evaluation	11	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets

End of presentation

QUESTIONS

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RESEARCH ADVANTAGE
connecting and empowering

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Central Coast
Local Health District

WHAT'S NEXT

Health Professionals Research Education Program: ***Session 4:***
TBC 11.00am – 5.00pm Aboriginal Research ***Friday 15 November 2019***
Host: John Hunter Hospital – 6067 Lecture Theatre
Alternative location: Gosford Hospital – Conference Centre and via Zoom

http://www.newcastle.edu.au/research-and-innovation/resources/research-advantage