


BMJ Open Cluster randomised controlled trial to determine the impact of an activity enabling uniform on primary school student's fitness and physical activity: study protocol for the Active WeAR Everyday (AWARE) study

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Introduction Multicomponent school-based physical activity (PA) interventions can improve students' cardiorespiratory fitness (CRF) and PA. Due to the complex nature of such interventions when delivered at scale their effect sizes markedly reduce. Modifying student school uniforms, so that they are more PA enabling, may be a simple intervention that could enhance student health. The primary aim of this trial is to assess the effectiveness of an activity enabling uniform intervention (shorts, polo shirt and sports shoes) in improving children's CRF.

Methods and analysis A cluster randomised controlled trial will be conducted in 24 primary schools in New South Wales (NSW), Australia. Schools will be randomly allocated to either intervention or usual practice following baseline data collection. Active WeAR Everyday intervention schools will allow students in grades 4–6 (aged approx. 9–12 years) to wear their existing sports uniform (shorts, polo shirt and sports shoes) every day. To avoid any financial cost to students they will be provided with two additional sports shirts and one pair of shorts. Study outcomes will be assessed at baseline and 9 months postbaseline. The primary outcome is students' CRF measured using the 20 m multistage fitness test. Secondary outcomes include students': mean daily steps and steps/minute measured via accelerometer, quality of life, mental well-being and perceived PA self-efficacy. The acceptability, feasibility and cost of the intervention will be assessed. Analyses will be performed using an intention-to-treat framework. Linear mixed effects regression models will be used to assess intervention effects on the primary outcome at follow-up. Planned exploratory analyses will examine effects by subgroups (eg, gender). **Ethics and dissemination** This study has received approval from Hunter New England Local Health District Human Ethics Committee (2020/ETH02602) the University of Newcastle, Human Research Ethics Committee (H-2021-0013), NSW Department of Education (SERAP: 2020387) and Catholic School Offices. **Trial registration number** ACTRN12621000201875.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study uses a rigorous design and validated outcome measures to detect between group differences in primary and secondary outcomes.
- ⇒ Focus on the factors influencing implementation and intervention fidelity are additional study strengths.
- ⇒ Students' physical activity (steps and steps/minute) are only measured during school hours, any benefits or displacement to out of school physical activity will be unknown.

BACKGROUND

The World Heart Federation and the American Heart Association identify physical inactivity and cardiorespiratory fitness (CRF) as important modifiable risk factors for cardiovascular disease (CVD).¹ These risks manifest in childhood and track over time.^{2–3} Further, systematic reviews of longitudinal studies demonstrate that measures of physical activity and CRF in childhood are associated with CVD risks in adulthood.^{1–4} Moreover, both physical activity and CRF have been found to improve young people's mental health and well-being.^{5–8} The WHO global action plans for the prevention of chronic disease,⁹ recommends the promotion of physical activity and enhanced fitness through school-based interventions for the prevention of CVD.¹⁰

Meta-analyses of school-based interventions demonstrate their efficacy in improving physical activity and CRF.¹¹ However, reviews of efforts to 'scale-up' evidence-based



interventions in schools suggest they have little impact on such outcomes.¹² A primary impediment to the successful implementation of school-based physical activity interventions at scale is the poor alignment between interventions that have been tested and local school contexts.^{13 14} Specifically, most physical activity interventions are trialled under optimal research conditions, are complex, intensive, delivered by experts, and require knowledge, skills and resources that are not routinely available in schools.¹² Such intervention characteristics present considerable implementation challenges. Indeed, poor implementation has been responsible, in part, for the equivocal effects of government funded scale-up of physical activity interventions in education settings globally.^{15–19} In order to improve the cardiovascular health of the community, effective interventions that are easily implemented at scale with minimal ongoing cost are urgently needed.^{13 20 21}

Internationally many countries, including Australia, UK, Japan as well as parts of Canada, New Zealand, North and South America and south-east Asia, require students in some or all schools to wear a uniform to school.^{22–25} While the formality of these uniforms may differ between countries they can often require girls to wear a dress or tunic, skirt and blouse (or in some countries trousers with blouse), with socks or stockings and black leather shoes; and boys to wear pants or shorts with button-up or polo shirts, sometimes a tie and black leather shoes. The impracticality of such uniforms is a well-documented impediment to physical activity, particularly for girls.^{21 26–29} Qualitative research suggests that traditional school uniforms restrict movement, hold students back from playing sport and raise concerns regarding body image.^{26 27} Quantitative studies have reported positive associations between objective measures of physical activity and activity-supporting uniforms.²¹

While this research suggests that changing to activity-supporting school uniforms (ie, attire conducive to physical activity) may be effective in improving student fitness and physical activity,²¹ there has only been one randomised trial internationally that has tested the effects of this scalable intervention.³⁰ This study, conducted by the author team, undertook an initial randomised controlled trial (RCT) that compared accelerometer-assessed physical activity of students from schools randomised to wear their sports uniform (ie, polo shirt, shorts and sports shoes) in place of their traditional uniform on a randomly selected day; to student's from schools randomised to wear their traditional uniform on a randomly selected day. While non-significant, the results were promising, with improvements in students' accelerometer counts per minute (36.54; 95% CI –0.28 to 73.37; $p=0.12$) which were slightly higher for girls (36.97; 95% CI –13.90 to 87.85) than boys (35.33; 95% CI –18.04 to 88.71). There were also improvements in girls' light intensity physical activity (1.47 min, 95% CI – 0.06 to 3.00, $p=0.059$) and sedentary activity (– 2.23 min; 95% CI – 4.49 to 0.02, $p=0.052$).³¹ As the intervention occurred over a single school week, the impact of the intervention on measures of CRF outcomes,

which would take longer to accrue, were not assessed in the pilot. Furthermore, the study was not able to investigate the impact that such an intervention may have on children beyond their physical health such as mental health and well-being. While findings from the pilot study are promising, an adequately powered randomised trial undertaken in more naturalistic contexts and with longer-term follow-up and a broader range of outcomes is required.

This study aims to assess the effectiveness of an activity enabling uniform intervention in improving the CRF of children aged 9–12 years. The secondary aims are to assess the impact on students' mean daily step count, steps/minute, well-being, quality of life scores and self-efficacy for physical activity. The acceptability, feasibility and cost of the intervention will also be assessed.

METHODS

The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621000201875). The study will follow the Consolidated Standards of Reporting Trials reporting guidelines for cluster RCTs. This protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials.

Design and setting

This study will employ a cluster RCT. Twenty-four primary schools from New South Wales (NSW) Australia will be randomised to either the 'activity enabling school uniform' intervention group or usual care control group. NSW has a population of approximately 700 000 children aged 5–12 years attending more than 2100 primary schools, of which approximately 70% are government, 18% are Catholic and 12% are independent.³² The trial outcome measures will be assessed in the same cohort of children within both groups at baseline and follow-up.

Participants and recruitment

Schools

A purposive sample of NSW government, catholic and independent primary schools (catering for children aged 5–12 years) that do not currently have an activity-enabling uniform that children wear everyday will be identified by school websites and project officer records. Schools will be excluded if they: currently have an activity-enabling uniform available to wear each day (eg, not simply on a sport day), are participating in another physical activity intervention, or cater exclusively for children with special needs. School principals will be provided with a study information package (online supplemental file 1) and asked to provide written informed consent. At the principal's request, an in-person or virtual meeting may be held with school staff or parent representative groups to answer any specific questions regarding the trial. As schools allocated to the intervention arm will be required to wear their activity-enabling uniform everyday principals

will gain teacher and parent approval prior to consenting into the trial.

Students

Once the school has consented into the trial all children in the relevant school years will participate in the intervention that is, wear their activity-enabling uniform every day. Parents/carers and students from grades 4, 5 or 6 at baseline (aged approx. 9–12 years) will then be asked to provide active consent to take part in data collection. A study information package will be sent to parents of students in participating schools. The study information pack will be sent from the school to parents either electronically via email or in hard copy (sent home with their child) (online supplemental file 1). The information pack will encourage parents to discuss the study procedures with their child and to invite study participation. Parents and students will have 2 weeks to consider participation and are asked to provide active consent by returning the signed permission form to the school or by scanning the QR code on the form and completing consent online. Students will also be asked to consent to all data collection activities on the day which will include: the beep test to measure CRF, wearing an accelerometer for one school week to measure physical activity and completing a 15 min paper survey (online supplemental file 1) to measure quality of life, well-being, physical activity self-efficacy and perceived acceptability of the intervention (intervention students at follow-up only).

Parents

Parents/carers of students in grades 4, 5 or 6 who consent to their child's participation in data collection will be invited to complete an online survey at baseline and follow-up which takes approximately 10 min to complete (online supplemental file 1). Consenting parents will be asked to include their email address on the consent form and then will be emailed a link to complete the survey via REDCap. If the parent does not have an email address they can request a paper survey which will be sent to them. Parents will have 2 weeks to complete the survey which will ask about their child's quality of life, costs of uniforms and the perceived acceptability of the intervention (intervention group at follow-up only).

Principals and teachers

Principals of participating schools will be invited to complete a 5 min survey regarding their acceptability of the intervention (online supplemental file 1). Following their consent they will be emailed a link to a REDCap survey which they will have 2 weeks to complete. Principals can request a paper copy of the survey if they prefer. Teachers of students in Grades 5 and 6 will be invited to complete a 5 min paper survey at follow-up regarding their perceived acceptability of the intervention. These will be distributed to teachers during student's follow-up data collection. Teachers will be asked to return the survey to a sealed box in their school's staff room. Return

of a completed survey will be taken as implied consent to participate.

Randomisation and blinding

A statistician, independent of school recruitment and intervention delivery, will use permuted block randomisation to allocate schools to either intervention or control, following baseline data collection. Randomisation will be stratified by school type, that is, government or non-government (Catholic and Independent schools), and will use a 1:1 allocation ratio. Due to the nature of the intervention this trial will be conducted as an open trial. Schools and parents will be notified of their allocation following baseline data collection. All efforts will be made to keep data collectors blinded to group allocation however, they may become aware of group allocation during attendance at the school for follow-up data collection. Analysts will be blinded to group allocation

Active WeAR everyday intervention

Studies undertaken in primary and secondary schools have found that children believe their school sports uniform, consisting of shorts, polo shirt and sports shoes, facilitates their physical activity at school.^{21 28 29} Students at intervention schools will, at the beginning of the study period, be provided free school sports uniforms (2 × polo shirts and 1 × shorts) from their school uniform shop, paid for by the research trial. Students at intervention schools will then wear their sport uniform each school day (ie, 5 days) for approximately a 9-month period for all schools (up to 18 months for a sub group of schools recruited in 2021). The provision of extra uniforms, in addition to their own existing sports uniforms (which they already wear 1 day per week), will supply children with sufficient sports uniforms to last the school week. This was important to avoid parents/carers having to regularly wash their child's uniforms to wear each day and to ensure that there was no economic repercussions on families as a result of this intervention. There is currently department of education support for such a policy in NSW government schools.³³ Research staff will work with schools to support the transition to the activity-enabling uniform.

Control group and contamination

Control schools will continue with their usual school uniform policies. To identify any potential sources of contamination, we will assess whether principals report a change in their school uniform policy.

Data collection and measures

Schools will be progressively recruited from April 2021 to February 2022, with baseline data collected May 2021–February 2022, 9 months postbaseline (February–November 2022) and 18 months postbaseline (November 2022—for a sub group of schools recruited in 2021) (online supplemental file 2). All data will be collected on one school day (with accelerometers worn for the school week), the details of which are described in the measures below.

Primary trial outcome: children's CRF

Children's CRF will be assessed using the validated 20 m multistage fitness test (shuttle run test).^{34–36} This is an accepted pragmatic field-based measure of CRF, for use in public health,³⁷ with demonstrated validity^{38 39} and reliability.^{40 41} Further, shuttle run scores are associated with a range of indicators of cardiometabolic health.³⁷ A 20 m course will be set within school grounds on flat surfaces, for example, asphalt courts or grassed areas. Students will be instructed to run between two sets of lines, keeping pace with a prerecorded cadence (indicated by a single beep) with reduced time intervals passing each minute (indicated by three beeps). Students continue to run until they fail to complete a shuttle (ie, one 20 m lap) before the beep sounds, on two consecutive shuttles. The Beep Test Pro App will be used to record the number of 20 m shuttles ('laps') that each student completes. The total number of laps will be used to estimate maximal aerobic capacity, that is, VO_2 peak using the equation by Léger *et al.*⁴² The shuttle run test will be conducted at baseline and at follow-up time points by a trained team of research assistants experienced in physical education and implementation of school-based physical activity programmes or administering such tests. The shuttle run test will be conducted in small, gender-specific groups to ensure students are as comfortable as possible, and research assistants will facilitate an appropriate warm-up and cool-down with students before and after conducting the shuttle run test (which takes about 45 min to administer). All students will have the option of deciding on the day as to whether they complete the shuttle run test or not.

Secondary outcomes

Student's school day physical

Student's mean daily step count and steps per minute will be measured via accelerometer. Students will be asked to wear an ActiGraph GT9X wrist-worn accelerometer (ActiGraph Corporation, Pensacola, Florida, USA) on their non-dominant wrist for one school week that is, Monday through Friday, for the whole school day (ie, 9:00–15:00 hours) except for during water-based activities. Research assistants will visit eligible classes in participating schools and demonstrate to students and teachers how to fit the accelerometer. Teachers will distribute and collect the respective accelerometers to children each day. This method of data collection has been used successfully by the research team in previous trials.^{43 44}

Student's quality of life

Students will complete, via a paper survey, the Child Health Utility 9D (CHU9D) questionnaire—a valid and reliable instrument for assessing the preference-based health-related quality of life in young people.⁴⁵ The nine-item tool, asks children to report, on a five-point scale (1=not at all to 5=very), how they feel 'today' in respect to:

worried, sad, pain, tired and annoyed. The tool also asks students to report, on a five-point scale (1=no problem to 5=can't do), if they have any problems with: school work, sleep daily routines or joining in activities. This tool will enable utility weights to be generated, which will then be used to calculate quality-adjusted life-years (QALYs). As per CHU9D scoring and licensing utility weights will be calculated. A parent proxy measure of children's quality of life will also be collected via paper survey of consenting students using the validated 27-item parent KidScreen questionnaire.

Student's mental well-being

Student's mental well-being will be measured using the WHO Five Well-Being Index,⁴⁶ which has demonstrated validity for use in children aged over 9 years. Children will complete this five item tool via a paper survey which asks them to rate, on a six point scale (0=at no time to 5=all of the time) how much in the past 2 weeks they have felt: cheerful, calm and relaxed, active and vigorous, fresh and rested and interested in life. Scores are then tallied (range from 0 to 25) and multiplied by 4 to give a score out of 100, with 0 representing the worst imaginable well-being and 100 the best imaginable well-being.

Physical Activity Self-Efficacy Scale

Physical Activity Self-Efficacy Scale is a self-report, six-item measure which asks children to report, on a five-point Likert scale (1=strongly agree to 5=strongly disagree) their perceived ability to be physically active during free time: on most days, on most days instead of watching television or playing video games, when it is hot or cold out, when they have to stay home, when they are busy, and if they have the skills to be active in free time.⁴⁷ A mean overall score will be calculated.

Intervention cost, cost-effectiveness and QALY

Parents will be asked to report on average how many sports and traditional uniforms they currently have for their child as well as how much they spend on school shoes and sports shoes per year. At a follow-up, parents of children in both groups will be asked to report if they had to purchase any new uniforms or shoes for their child in the last 12 months. The inclusion of the CHU-9D enables the calculation of QALY. QALYs are a standard health economic outcome that allows for the assessment of disease burden. Inclusion enables a more thorough economic evaluation alongside the potential benefits of the intervention. Subject to assessment of effectiveness, a trial-based cost-effectiveness analysis will be conducted from multiple stakeholder perspectives. The reportable outcomes will be average cost and incremental cost-effectiveness ratios.

School, student and parent characteristics

Data regarding school type (government, Catholic, independent) number of students and the postcode of the locality of the school will be collected during a survey of school principals and classroom teachers, or collected from publicly available records. Items will be sourced from previous surveys conducted by the research team^{48–50} which have achieved participation rates of between 70% and 96%.^{48 50} Students' sex, age and residential postcode will be collected from student consent forms. Parents are asked to include their sex, date of birth and post-code (used to determine children's sociodemographic and geographic location). The baseline characteristics of student's who complete primary outcome data will be compared with any students who drop out from the study in order to investigate differences between them.

Acceptability and feasibility

Principals, teachers, parents and students will be asked via their respective surveys to report, on a 5-point Likert scale (1—strongly disagree to 5—strongly agree), the extent they agree that since children have been wearing their sports uniform everyday the extent they agree that:

- ▶ Principals and teachers: they prefer students wearing this uniform, students are more active, they (the teachers) are more active, it reflects poorly on the school, students are more disruptive.
- ▶ Parents: they prefer their child to wear this uniform, it makes their child more active at school, it makes their child more active outside of school, it has made it easier for their child to get ready for school, it reflects poorly on the school image, it has caused financial burden to their family.
- ▶ Students: they have enjoyed wearing their sports uniform, are more active at school, are more active after school, have found it easier to get ready for school in the morning, it makes the school look untidy and their teacher delivers more physical activity.

Principals will also be asked (yes/no/don't know) if they would consider implementing the uniform policy school-wide and if they have received any positive or negative feedback from the school community about the intervention (yes/no) and if yes to describe what the feedback was.

Adherence to uniform changes

In order to determine students' fidelity to the intervention parents and students will be asked at follow-up, via their respective paper or online survey, to report what uniform students wore each day over the last week.

Data management

All data management protocols, developed and approved by the project's advisory group, will be executed accordingly. Data will only be accessible to primary researchers and statisticians. Confidential participant data will be

stored securely. Data will be stored securely as per the requirements of the Hunter New England Human Research Ethics Committee and The University of Newcastle Human Research Ethics Committee.

Control group and contamination

Control schools will not make any modifications to their school uniform policy during the study period. Nonetheless, data regarding schools' uniform practices (and government/school department uniform policies) will be assessed at follow-up time points.

Statistical analysis

Between-group differences in trial outcomes at follow-up will be assessed using linear mixed models for continuous outcomes and generalised linear mixed models for dichotomous or categorical outcomes using appropriate distribution and link functions. All models will include a random intercept for school and class nested within school to account for the clustered design of the trial, and fixed effects for group and the baseline value of the outcome and variables prognostic of the outcome (eg, school sector) and the socioeconomic (higher socioeconomic or lower socioeconomic) or geographic (rural or urban) location of the child's primary home address based on their postcode. The primary analyses will be conducted under an intention-to-treat framework, with all available valid data analysed in the group originally allocated. Multiple imputation will be used to address missing data at follow-up using the fully conditional method and estimates combined using Rubin's rule. Per-protocol analyses will also be conducted to explore differences between students who reported that they wore an active uniform everyday in the week before to those who did not. An alpha level of 5% will be used to determine statistically significant differences. Planned exploratory analyses will examine effects by subgroups (eg, student sex, school sector, existing uniform policy), which will be assessed by including the variable for the relevant sub-group along with a relevant subgroup by group interaction term in the models. Descriptive statistics will be used to describe the sample and process data. To avoid biased interpretation of any research findings where possible process data will be analysed before trial outcomes are known.⁵¹

Sample size

Based on the pilot study³¹ using a conservative 50% response rate and 20% lost to follow-up, a sample of 24 schools (12 per arm) will provide a sample of 576 students (288 per group) at 9-month follow-up. An intra-class correlation of 0.03 (to account for clustering at the school level) will allow a standardised effect size of at least 0.37 on measures of CRF (ie, a detectable difference of approx. 4 laps) to be detected with 90% power.

Patient and public involvement

The opinion of children, parents, teachers and principals to changing school uniforms and barriers to doing so were collected by the team and used to inform this study



and to guide the outcome measures.^{24 29} Parent groups and representatives of the school education departments helped design the intervention, particularly regarding the burden of wearing sports uniforms each day and the acceptable number of additional uniforms that would need to be provided. Study findings will be delivered to school education departments and parent representative groups via written reports and presentations, for example, regional principal meetings. A KT consultant will also support broader dissemination to the public, for example, via social media.

DISCUSSION

To support children and adolescents to improve their physical activity, fitness and overall well-being, the WHO recommends the implementation of school-based physical activity programmes. However, findings of systematic reviews have found that, when implemented at scale, these programmes have minimal impact on students, and in particular on girls. Unless effective physical activity and fitness interventions can be delivered at scale, they cannot reduce CVD risks at a population level. This research tests an intervention that has been purposefully selected on the basis that it is amenable to rapid spread (highly scalable). If found to be effective, the intervention is simple and scalable thus it will have the potential to be implemented across any jurisdiction internationally which requires students' wearing of school uniforms.

Ethics and dissemination

The study is approved by the Hunter New England Local Health District Human Ethics Committee (2020/ETHO2602) the University of Newcastle, Human Research Ethics Committee (H-2021-0013) and the NSW Department of Education (SERAP: 2020387) human research ethics committees as well as relevant Catholic School Offices (Diocese of Maitland-Newcastle). 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 New England 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. All identifying information will be kept for the required 7 years, with electronic files deleted and all paper files shredded using approved shredding services employed by Hunter New England Health. Data collected as part of the study will be disseminated in peer-reviewed publications and conference presentations and will form part of PhD student theses. Group summaries will be provided to each school at the conclusion of the trial. Schools will then be

encouraged to share this deidentified summary data with the parent community.

Research trial governance

An advisory group consisting of researchers, policy makers, practitioners and experts within the school and health setting will oversee all aspects of the planning, implementation and evaluation of the project. 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.

Adverse events, trial discontinuation or modification

Given students will be wearing their usual sports uniform it is not expected that participants will be at any greater risk of adverse events than they would be when participating in normal school activities that would warrant discontinuation of the trial. However, any adverse events or unintended effects will be recorded and reported to the Chair of the ethics committee and 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. At the time of submitting this manuscript for publication an amendment was made to a secondary outcome (with trial registration updated accordingly). We originally intended to report student Moderate-Vigorous Physical Activity (MVPA) as a secondary outcome, however, given the potential for erroneous estimates of activity using cut points for wrist worn accelerometers it was decided to use an absolute measure of physical activity that is, mean daily steps.

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Contributors NN, NM and LW conceived the intervention concept. LW secured funding for the study. NN, NM, RS and LW guided the design and piloting of the intervention. NN, NM, AH and LW designed the intervention and research methodology. AH conducted the power calculation and guided the statistical analysis plan. PR guided the planning of the cost analysis. NN, AH, NM and LW are responsible for project management and data quality monitoring. NM, RJ, AS and CL will recruit schools and oversee intervention delivery and data collection. JB and BD will support school recruitment and advise on school policies and practices relevant to the intervention. NN, NM, AH, RS, LW, DG, JB and BD are all members of the Advisory Group that oversee the program and monitor data. NN and LW led the manuscript development. All authors provided critical review and endorsed the final version of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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