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A school-based physical activity intervention for older adolescents: Rationale and study protocol for the Burn 2 Learn cluster randomised controlled trial

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Keywords: Physical fitness, Adolescents, Physical activity, Behaviour change, Resistance training, Cognition

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A school-based physical activity intervention for older adolescents: Rationale and study protocol for the Burn 2 Learn cluster randomised controlled trial

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Key words: Physical fitness; Adolescents; Physical activity; Behaviour change; Resistance Training; Mental health; Cognition

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ABSTRACT

Introduction: This trial aims to investigate the impact of a school-based physical activity program, involving high-intensity interval training (HIIT), on the physical and mental health of senior school students.

Methods and analysis: The B2L intervention will be evaluated using a two-arm parallel group cluster randomised controlled trial with allocation occurring at the school level (to treatment or wait-list control). Schools will be recruited in two cohorts from New South Wales, Australia. The trial will aim to recruit ~720 senior school students from 20 secondary schools (i.e., 10 schools per cohort). A range of implementation strategies will be provided to teachers (e.g., training, equipment, and support) to facilitate the delivery of HIIT sessions during scheduled classes. In Phase 1 and 2 (3-months each), teachers will facilitate the delivery of at least two HIIT sessions/week during lesson-time. In Phase 3 (6-months), students will be encouraged to complete sessions outside of lesson-time (teachers may continue to facilitate the delivery of B2L sessions during lesson-time). Study outcomes will be assessed at baseline, 6-months (primary endpoint) and 12-months. Cardiorespiratory fitness (shuttle run test) is the primary outcome. Secondary outcomes include: vigorous physical activity, muscular fitness, cognition, and mental health. Subgroup analyses will be performed on random subsamples assessing cortisol concentrations in hair, and multi-modal magnetic resonance imaging. A process evaluation will be conducted (i.e., recruitment, retention, attendance, and program satisfaction).

Ethics and dissemination: This study has received approval from the University of Newcastle (H-2016-0424) and the NSW Department of Education (SERAP: 2017116) human research ethics committees.

Trial registration: Australian New Zealand Clinical Trials Registry Number: ACTRN12618000293268.

Strengths and limitations of this study

 Strengths of this study include the cluster randomised controlled trial design and adequate power to detect changes in primary and secondary outcomes.

- The measurement and analysis of the potential mechanisms responsible for the effects of physical activity on cognitive and mental health are strengths of this study.
- Focus on the factors influencing implementation and intervention fidelity are additional study strengths.
- As the majority of assessments will take place in the schools, it is not possible to assess fitness parameters using gold standard measures.



INTRODUCTION

- 2 Physical inactivity has been described as a global pandemic, and global estimates suggest
- 3 that less than 20% of adolescents are sufficiently active.² Furthermore, physical activity
- 4 declines dramatically during the teenage years (~7% each year from age 11 to 19 years),³ and
- 5 Australian data indicate only 6% of older adolescents (15-17 years) are satisfying current
- 6 physical activity guidelines of 60 minutes of moderate-to-vigorous physical activity (MVPA)
- 7 per day. 4 Of additional concern, evidence suggests a decline in young people's
- 8 cardiorespiratory fitness (CRF), which is an important predictor of overall health status,⁵ has
- 9 occurred since the 1970s.⁶⁷ While previous studies have noted small-to-moderate

associations between physical activity and CRF in young people, the relationship is stronger

when activity of vigorous intensity is examined independently.

Adolescents who participate in physical activity of sufficient volume and intensity to improve their CRF will experience metabolic and cognitive benefits. For example, a recent longitudinal study involving a large sample of adolescents found that cardio-metabolic risk declined in a dose-response manner with increasing vigorous physical activity in adolescents (healthy adolescents participated in ≥7mins/day of vigorous activity), but not with increased volume of light or moderate physical activity. Both vigorous activity and CRF are also important for young people's mental ^{10 11} and cognitive health. Recent systematic reviews have concluded that participating in physical activity can improve young people's cognitive control and academic performance ^{13 14}, but the underlying neurobiological, psychosocial and behavioural mechanisms not well understood. 15

Schools are ideal settings for the delivery of physical activity programs because they have access to young people as well as the necessary facilities and equipment, and availability of qualified staff. School-based physical activity interventions targeting children (ages 5 to 11 years) and young adolescents (ages 12 to 15 years) have had mixed success. Figure 17 18 Efficacy studies usually produce positive findings, but the promising findings from small-scale studies are rarely seen in large-scale effectiveness trials. Focusing on organisational change (i.e., supportive school policies) and providing professional development for teachers can lead to improvements in physical activity and fitness in children and younger adolescents. However, it is relatively unknown if school-based interventions are effective with older adolescents (i.e., senior school students [16-18 years]) because few randomised controlled trials (RCTs) have been conducted with this population.

Conducting and evaluating health promotion interventions with older adolescents is challenging, in part, due to the pressures associated with standardised testing at the end of

secondary school and university entrance examinations. The focus on academic performance in the final years of secondary schooling and a lack of support from school administrators are major barriers to physical activity promotion in schools. ^{16 26 27} The success and sustainability of physical activity interventions is largely dependent upon 'buy in' from school principals and teachers, which may wane over time in the face of competing time demands. As enhancing students' academic performance is the core business of schools, providing evidence for the impact of vigorous physical activity on cognitive and academic outcomes may provide a novel 'hook' for schools to implement physical activity interventions.

Nevertheless, school-based physical activity interventions need to be time efficient because lack of time is the most commonly cited implementation barrier cited by teachers. ²⁶

High-intensity interval training (HIIT) is a time efficient strategy for improving metabolic health in adolescents and adults, ²⁸ ²⁹ and typically consists of short, yet intense bouts of vigorous activity interspersed with brief periods of rest or light activity. Previous studies have shown HIIT can improve CRF (unstandardised mean difference = 2.6 mL/kg/min, 95% CI = 1.8 to 3.3), reduce body mass index (-.6 kg/m², 95% CI = -.9 to -.4), and improve metabolic markers (i.e., insulin sensitivity and fasting plasma insulin) in adolescents. ²⁹ For most adolescents, the 'all out' maximal type of HIIT (i.e., 100% of heart rate max.) may not be palatable and such an approach has limited potential as a public health strategy. ³⁰ Alternatively, there is emerging evidence for the efficacy of less demanding HIIT protocols (e.g., 85% of heart rate max.), albeit that most experimental studies have been conducted in laboratory settings over short periods of time (~8 weeks). ³¹ Importantly, there is scope for developing novel HIIT protocols that retain the health-enhancing effects, but also satisfy adolescents' desire for enjoyment and variety. ³² ³³ ³⁴

We recently conducted the first 'teacher-facilitated' HIIT intervention for older adolescents, the Burn 2 Learn (B2L) pilot RCT.³⁵ School teachers were asked to provide at least two opportunities during the school week for students (N = 68) to complete HIIT sessions during class time. The program achieved high levels of recruitment (85%) and retention (90%) over the 14-week study period. Adherence to sessions was lower than prescribed (1.9 sessions/week during school) due to disruptions within the school (e.g., examinations). Overall program satisfaction was high among both students and teachers. Intervention effects were found for CRF, lower-body muscular power and psychological distress. Our pilot study demonstrated that teachers can successfully facilitate the delivery of HIIT during the school day to improve older adolescents' fitness and wellbeing. However, it is unclear whether these positive findings can be replicated on a larger scale.

Study objectives

71 The primary aim of this trial is to determine the effect of the B2L intervention on older

adolescents' CRF (primary outcome). Secondary outcomes of the trial include muscular

fitness, body composition, mental health and cognitive control. This study will also test a

range of potential neurobiological, psychosocial, and behavioural mechanisms responsible for

75 the effects of physical activity on cognitive and mental health. Finally, a detailed process

evaluation will be conducted to determine if the intervention was delivered as intended and

77 the factors influencing implementation.

METHODS

Study design

The trial is registered with the Australian New Zealand Clinical Trials Registry

82 (ACTRN12617000544370) and the design, conduct and reporting will adhere to CONSORT

83 ³⁶ and TIDier ³⁷ checklists. The B2L intervention will be evaluated using a two-arm parallel

group cluster RCT with an intervention group and wait-list control group. Assessments will

be conducted at baseline, 6-months (primary endpoint) and 12-months from baseline

86 (secondary endpoint). The RCT will include two cohorts, one starting in 2018 (10 schools; 5

intervention and 5 control), and the other starting in 2019 (10 schools; 5 intervention and 5

88 control) and finishing in 2020. Baseline data collection will occur in the school term

89 preceding the intervention delivery (i.e., Term 1 [February to April, 2018 and 2019]. The

90 intervention delivery will occur in Terms 2 and 3 [May to September, 2018, 2019]. Post-test

91 data collection (i.e., 6-month follow-up) will commence midway through Term 3 and

ontinue until the end of term (August to September, 2018 and 2019), with final follow-up

assessments (i.e., 12-month follow-up) being completed in Term 1 of the following year

94 (February to April, 2019 and 2020).

School recruitment and selection

97 New South Wales (NSW) government secondary schools that include senior school students

98 (i.e., Grades 11 and 12, students aged 16-18) will be eligible to participate in the study. In

99 Cohort 1, eligible secondary schools located within 90 minutes' drive from the University of

Newcastle, will be invited to participate. In Cohort 2, eligible secondary schools located

within 150 minutes' drive from the University of Newcastle, will be recruited. The selected

102 geographical regions (i.e., Hunter-Central Coast, Sydney, Northern Sydney, Western Sydney,

and New England) are broadly representative of urban and regional secondary schools in NSW.

Schools will be recruited via presentations at conferences and meetings (e.g., regional meetings of the NSW Principals' Association) and emails sent directly to eligible schools (i.e., school Principals and Grade 11 Coordinators). Once schools have expressed an interest in the study, our Project Manager will meet with the school representative(s) and explain the study requirements. At this time, schools will be asked to identify a minimum of two Grade 11 teachers willing to facilitate the delivery of scheduled B2L sessions during school hours. There are no restrictions regarding the teaching discipline (e.g., Mathematics, English, Health and Physical Education) of Grade 11 teachers eligible to participate in the study.

Participants

Two Grade 11 teachers per school (B2L school champions) who agree to facilitate the delivery of B2L during scheduled class time. Eligible participants will be Grade 11 students who are taught by one of the B2L school champions. Of note, students consenting to participate in the trial, are consenting to participate in the evaluation component (i.e., completion of study measures). Students with a health or medical condition that would preclude participation in vigorous physical activity will be excluded from the study, but will still participate in normal lessons adapted by the B2L school champion. We will aim to recruit ~36 students (i.e., 2 classes) per school.

Sample size calculation

Power calculations were based on the primary outcome of cardiorespiratory fitness (CRF), assessed using the Progressive Aerobic Cardiovascular Endurance Run (PACER) test 38 . Baseline post-test correlation (r =.90) and standard deviation (SD=29) values were obtained from our pilot trial, and conservative ICC values of .20 and .03 were used to account for clustering at the class- and school-levels, respectively. 39 To detect a clinically meaningful baseline-adjusted between-group difference of 6 laps 32 40 with 80% power at a 5% significance level will require 280 students per treatment group (i.e., 2 classes of 14 students from each of 10 schools). Inflating the sample size to 18 students per class, or 360 students per treatment arm (i.e., total sample of 720 students) allows for a potential drop-out rate of 20% at our primary study endpoint (i.e., 6-months).

Blinding and randomisation

Randomisation will occur once 10 schools (Cohort 1) have been recruited and completed baseline assessments. The same process will be repeated for Cohort 2. Pairs of schools will be matched based on the following characteristics: geographic location (i.e., region, rural/urban, coastal/inland), school area-level socio-economic status (i.e., using the Socio-Economic Indexes For Areas [SEIFA] Index of Relative Socio-Economic Disadvantage). 41 schools' student population educational advantage (i.e., using the Index of Community Socio-Educational Advantage [ICSEA]) and where possible, proposed class delivery (e.g., Mathematics, English, and Personal Development, Health and Physical Education). Schools will be randomised by an independent researcher using a computer-based random number generator, such that one school from each pair will be allocated to the intervention condition and the other to the control condition. Using this approach, each school will have an equal chance of being allocated to the intervention condition, whilst maintaining an appropriate balance of school characteristics across the two conditions. Schools randomised to the intervention condition will deliver the B2L program during the study period, whereas schools allocated to the control condition will continue with usual school practice (i.e., normal curricular lessons) for the duration of the study period (i.e., until completion of 12-month study assessments). Schools allocated to control group will then receive the intervention following final study assessments (i.e., the following year). The decision to use a wait-list control design, rather than an attention-matched placebo, was based on the following. First, the research team will have little contact with students, as the program will be delivered by teachers during their regularly scheduled lessons. Second, for our findings to have greater external validity, it is important that our control group reflects 'usual practice'. Finally, based on our previous studies, a wait-list control group is acceptable for schools and the majority of our school-based trials have achieved high levels of retention (80-90%). 23 42 43

Intervention delivery, components and implementation strategies

The B2L intervention will be delivered in three phases: Phase 1) *Getting started,* Phase 2) *Maintaining student interest,* and Phase 3) *Moving towards independence.* In Phases 1 and 2 (Term 2-Term 3; May-September, 2018 and 2019), school champions will be tasked with facilitating the delivery of at least two HIIT sessions/week during lesson time. During Phase 1, the focus will be on introducing students to HIIT and developing their competency. Phase 2 will involve a greater emphasis on student responsibility and control, and introduce additional intervention resources (i.e., new HIIT task cards) to maintain student interest. In Phase 3 (Term 4/Term 1; October-April 2018/2019 and 2019/2020), students will be

encouraged to complete sessions outside of lesson time (teachers may continue to facilitate the delivery of B2L sessions during lesson-time).

A common criticism of public health research is the development of interventions that are not 'scalable' and unlikely to be adopted and implemented in real world settings. 44 The B2L intervention has been designed in consultation with the NSW Department of Education and guided by the Consolidated Framework for Implementation Research 45 to maximise scalability and sustainability. A summary of the B2L intervention components are provided in Table 1. The multi-component intervention will target schools, principals, teachers, students and parents using: (i) an information seminar delivered by school champions, (ii) school-based physical activity sessions for two school terms, (iii) smartphone application and heart rate monitors and (iv) information for parents (i.e., print or e-newsletters). A range of implementation strategies were designed to support the delivery of the B2L program (Table 2) and include the following: (i) intervention characteristics, (ii) outer setting (i.e., educational authorities), (iii) inner setting (i.e., schools), (iv) characteristics of teachers, and (v) implementation process.

Theoretical framework for the intervention

Several theoretical frameworks have been used to guide intervention design. Firstly, Beets and colleagues' theory of expanded, extended, and enhanced opportunities ⁴⁶ suggests that the extension and enhancement of existing physical activity opportunities, as well as the creation of new opportunities (i.e., expansion) are needed to increase youth physical activity levels. For the current study, the provision of an entirely new opportunity for physical activity (i.e., expansion) was considered necessary, as the majority of secondary schools in NSW do not provide mandatory physical activity for senior students. During Phases 1 and 2 of the intervention, the HIIT sessions will be facilitated during scheduled class-time, therefore adopting a compulsory application of Theory of Expanded, Extended, and Enhanced Opportunities. In the third phase, students will be encouraged to complete two to three sessions per week within or beyond the school day. During this phase, students will be encouraged to self-monitor their participation in HIIT sessions using the B2L smartphone app.

With reference to self-determination theory, B2L HIIT sessions have been developed with a focus on enhancing students' autonomous motivation for vigorous physical activity within and beyond the school setting by satisfying their basic psychological needs for autonomy (feeling in control), competence (feeling capable) and relatedness (feeling

connected with others). Teachers will learn to facilitate the B2L sessions using the SAAFE (Supportive, Active, Autonomous, Fair and Enjoyable) physical activity delivery principles (see Table 3). Participants' need for autonomy will be satisfied by providing opportunities for choice within sessions (e.g., type of activity, music playing, and training partner) and explaining the rationale for the program in an information seminar. The introductory seminar will reinforce the importance of exercise for cognitive health and academic performance, which may be salient outcomes for students during this period of their schooling.

Competence will be satisfied using positive and specific feedback from teachers, an explicit focus on effort over performance (via heart rate feedback), and through the provision of resources designed to support the development of exercise skills. Teachers will be encouraged to adopt practices that support relatedness and group cohesion during HIIT sessions (i.e., encouraging supportive behaviour among students such as 'high fives' and partner work)⁴⁹.

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Measures and data collection

Apart from multi-modal magnetic resonance imaging, all assessments will be conducted at the study schools by trained research assistants, who will be blinded to group allocation at all time-points. Demographic information and self-report measures will be collected using electronic tablets under exam-like conditions. Anthropometric assessments will be conducted in a sensitive manner by same-sex research staff when possible. Cognitive testing will occur before fitness assessments. Participants will receive instructions and practice prior to performing each of the cognitive tasks. Research assistants will provide a brief verbal description and demonstration of each fitness test prior to commencement.

Primary outcome

Cardiovascular Endurance Run (PACER), using FITNESSGRAM® testing procedures. This test is the most widely accepted field-based measure of CRF, demonstrating high reliability and validity. ⁵⁰ A 20 m course will be set up on a hard surface with participants instructed to run back and forth between two sets of lines while keeping pace with a pre-recorded cadence (indicated by a single beep for each 20 m shuttle). The test begins at a slow pace (8.5 km/h), and increases by 0.5 km/h with each passing minute (as indicated by a triple beep). The test ends when participants fail to complete a shuttle (20 m lap) before the beep sounds, on two consecutive shuttles, or upon volitional failure. Verbal encouragement will be provided by

test administrators in order to maximise participant motivation. The last successful stage will
be recorded and converted into the number of 20 m laps completed, which will constitute the
primary outcome measure. The total number of laps will be used to estimate maximal aerobic
capacity (i.e., VO₂ max), using the following equation: 20.41012 + (PACER laps x
0.41304). Estimated VO₂ max will be used to classify participants into fitness zones
according to criterion-referenced age- and sex-specific cut-offs developed by the Cooper
Institute. Institute.

Secondary outcomes

Physical activity. Participants will be instructed to wear an ActiGraph GT9X Link accelerometer on their non-dominant wrist for 24 hours per day (even when bathing, swimming and sleeping) for a period of seven consecutive days. Weekday and weekend day (i.e., mean minutes per day) physical activity will be calculated separately, using existing thresholds for categorising physical activity into light, moderate and vigorous intensity. Muscular fitness. Upper body muscular endurance will be assessed using the 90-degree pushup test.³⁸ Using a cadence of 40 beats per minute, participants lower themselves in a controlled manner until a 90-degree angle is formed at the elbow before pushing back up. The test concludes when the participant either fails to lower themselves to the required depth on two non-consecutive repetitions (warning verbalised by assessor, repetitions counted), fails to maintain movement in time with the metronome, fails to maintain appropriate technique (back straight), or upon volitional failure of the test. Lower body muscular power will be assessed using the standing long jump test. 53 From a standing position behind a line marked at zero centimetres, participants perform a maximal long jump taking off and landing with two feet, simultaneously. The test will be performed twice, with the maximal distance jumped recorded as the participant's final score. Both measures of muscular fitness demonstrate high validity and reliability in adolescents. 54 55

Body composition. Body weight and height will be measured using a portable digital scale (A&D Medical UC-352-BLE Digital Scales) and a portable stadiometer (Seca 213 Portable Height Measuring Rod Stadiometer), respectively. Body mass index (BMI) will be calculated using the standard formula (weight[kg]/height[m]²). Age- and sex-specific BMI z-scores will be calculated and participants will be classified into weight categories according to International Obesity Task Force cut-offs. ⁵⁶

Cognitive control. Using a laptop, specialised software (PsychoPy) ⁵⁷ will be used to assess working memory and inhibition. A modified version of an Eriksen flanker task will be used to measure inhibition, which is a reliable and valid measure in youth.⁵⁸ In this task participants are required to respond (using specific keys) to the direction of the centrally presented arrow among either 'congruent' or 'incongruent' flanking arrows. Congruent trials consist of five horizontal arrows facing the same direction (i.e., <<<< or >>>>), while incongruent trials consist of the central arrow facing the opposite direction to the four flanking arrows (i.e., <<><< or >>>>). Participants are challenged with a random sequence of congruent and incongruent trials and instructed to identify the direction of the centrally presented, target arrow as quickly and accurately as possible. Following instructions, participants will be presented with a practice block consisting of 25 trials to familiarise themselves with the test. If participants achieve below satisfactory overall accuracy (<70%), they will complete another practice block of 25 trials, and the test administrator will confirm their understanding of the test. Participants then complete an experimental block consisting of 150 trials (with an equal distribution of congruent and incongruent). Stimuli are presented for 100 milliseconds (ms), with a randomly allocated inter-stimulus interval of 900, 1050, or 1200 ms separating each trial. Response time (i.e., the time in ms taken by the participant to press the key associated with the direction of the target arrow) and response accuracy (i.e., the percentage of trials for which the participant correctly indicated the direction of the target arrow) and will be recorded. An interference score (i.e., the difference in performance outcomes between congruent and incongruent trials) will also be calculated for both accuracy and response time. A lower interference score demonstrates higher inhibitory control.

Working memory will be assessed using a serial n-back task, which is a widely used and reliable measure. ^{59 60} Two task conditions (i.e., 1-back and 2-back) will be evaluated which differ in the degree of cognitive demand. In these tasks, participants are presented with a series of six basic shapes (i.e., square, star, circle, cross, crescent, triangle) and required to recall (using specific keys) whether the shape currently displayed (trial 'n') matches the shape immediately prior (1-back, 'n-1'), or two shapes prior (2-back, 'n-2'). For each trial (within each n-back condition) participants are required to indicate whether the shape is a match (i.e., target) or not a match (i.e., non-target). Shapes are presented for a duration of 250 ms following a fixed inter-stimulus interval of 2500 ms. Following task instructions, participants will complete a practice block consisting of 20 trials to ensure understanding. If overall accuracy is below 70%, participants will complete another practice block, and the test administrator will confirm their understanding of the test. Each task condition (i.e., 1-back, 2-

back) consists of two blocks of randomised target (n=24) and non-target (n=48) trials, and are presented in a counterbalanced order. Response time and accuracy will be recorded for both target shapes (i.e., correctly identifying a match) and non-target shapes (i.e., correctly identifying a non-match). Additionally, the relative proportion of 'hits' (correct target trials) to 'false alarms' (incorrect selection on target trial), otherwise known as the d-prime score, will be calculated for both task conditions. ⁶¹ A higher d-prime score reflects a greater capacity to differentiate target from non-target shapes when performing the n-back tasks, thereby indicating greater working memory.

Stress. Objectively measured stress will be determined by examining the build-up of cortisol within the hair shaft using a sample taken from the vertex at the rear of the head. As human hair grows at a rate of approximately 1 cm per month, each cm is considered to reflect life stressors experienced by the individual over the last month. 62 Cortisol concentrations will be determined from the 3-cm hair segment (maximum) most proximal to the scalp. This will represent the cumulative stress level in the past two to three months. Inter-individual variation in hair growth rate can be factored into analyses by measuring hair growth at the initial sampling site one month later. The intra-individual stability $(r = .68-.79)^{63}$ and validity of hair cortisol as a retrospective index of stress are supported in the literature in adults ^{64 65} and adolescents ⁶⁶. Perceived stress will be self-reported using the Perceived Stress Scale, which is designed to assess the degree to which situations in one's life are stressful ⁶⁷. Participants will be required to respond to the 10-item questionnaire in relation to the previous month (e.g., "In the last month, how often have you felt you were on top of things?"). Responses are scored on a 5-point scale ranging from 0 "Never" to 4 "Very often" and then summing across all scale items. Higher scores indicate a greater degree of subjective stress experienced by participants.

Psychological difficulties. The Strengths and Difficulties Questionnaire will be used to assess psychological distress. ⁶⁸ The questionnaire consists of 25 items, covering 2 subscales (i.e., strengths and difficulties). The strengths subscale consists of one domain (prosocial behaviour [e.g., "I try to be nice to other people. I care about their feelings."), and the difficulties subscale consists of four domains: emotional symptoms (e.g., "I worry a lot."), conduct problems (e.g., "I get very angry and often lose my temper."), hyperactivity (e.g., "I am restless, I cannot stay still for long."), and peer problems (e.g., "I would rather be alone than with people of my own age."). For each item, participants respond using a three-point

scale (i.e., "Not true" = 0, "Somewhat true" = 1, and "Certainly true" = 2). For each of the five domains the score can range from 0 to 10. A difficulties composite score will be obtained by adding the scores of all four difficulty domains, with a possible range from 0 to 40. Lower scores indicate fewer psychological difficulties. Autonomous motivation. Motivation for physical activity will be assessed using the 'Behavioural Regulations in Exercise Questionnaire'. 69 The identified (e.g., "I value the benefits of exercise"), and intrinsic (e.g., "I exercise because it's fun") regulation subscales will be used. Responses are scored on a 5-point scale ranging from 0 "Not true for me" to 4 "Very true for me". Basic psychological needs satisfaction. Friends' and teachers' support for exercise will be assessed via the 'Adolescent Psychological Need Support in Exercise Questionnaire'. 70 Items assess needs satisfaction during exercise across the three psychological needs identified within self-determination theory, namely autonomy support (e.g., "I feel that they understand why I choose to exercise"), relatedness support (e.g., "I feel they care about me"), and competence support (e.g., "They display confidence in my exercise ability"). Participants respond using a 7-point Likert scale ranging from 1 "Strongly disagree" to 7 "Strongly agree". Psychological well-being. Well-being is assessed using the validated Warwick-Edinburgh Mental Wellbeing Scale. The 14-item questionnaire requires participants to reflect on their experiences over the last two weeks. Items are scored on a 5-point scale ranging from 1 "None of the time" to 5 "All of the time", and summed across all to produce a well-being composite (possible range = 14 to 70). Perceived fitness. Perceived physical fitness will be self-reported using the International Fitness Scale. 72 Participants are required to report perceptions of their 'general fitness' and four specific sub-components of health-related fitness. The 5-item instrument is scored on a scale ranging from 1 "Very poor" to 5 "Very good". The validity and test-retest reliability of the IFIS has been found to be acceptable among a sample of 9-12 year old youth.⁷² HIIT self-efficacy. Self-efficacy for HIIT will be assessed using a 6-item scale developed for

the current study. The scale uses the common stem "If you really wanted to, how confident

are you that you can..." and participants respond as follows: 1 "Not at all confident" to 10 "Completely confident". Sample item- "maintain a high level of effort right through to the end of a HIIT session". The mean of the 6-items will be calculated.

Brain structure and function. To further elucidate exercise-induced neural changes, a target sub-sample of approximately 60 students (i.e., 15 students per school from 4 schools; 2 x intervention group, 2 x control group) identified as being in the bottom 50% of students from their school for CRF (using their baseline PACER test result) will undergo multi-modal magnetic resonance imaging. We have undertaken a systematic review of neuroimaging studies that have examined associations between physical activity, CRF or muscular fitness, and brain structure/function. Preliminary findings from this review informed our multi-modal magnetic resonance imaging protocol to explore changes in the following areas: (i) structural magnetic resonance imaging (T1 and T2-weighted imaging) to identify volumetric changes in white and grey matter of the hippocampus, 73-75 frontal regions/prefrontal cortex, 73 anterior cingulate cortex, ⁷⁶ and basal ganglia ⁷⁷; (ii) diffusion tensor imaging will be used to identify changes in white matter structural connectivity of the superior longitudinal fasciculus and corpus callosum. (iii) resting state functional magnetic resonance imaging will be used to assess changes in activation of the default mode network, cognitive control network, saliency network, 78 hippocampus, and prefrontal cortex 79 80; (iv) magnetic resonance spectroscopy will be used to identify changes in brain metabolite concentrations (i.e., gamma-aminobutyric acid, N-acetyl Aspartate, adenosine tri-phosphate, and glutamate/glutamine) in the hippocampus and frontal regions/prefrontal cortex.

Process evaluation

A detailed process evaluation will be conducted to determine intervention fidelity. Process measures will include: (i) students' mean heart rate from the HIIT sessions (measured using Bluetooth heart rate monitoring technology), (ii) teacher attendance and satisfaction with the professional learning workshop and curriculum materials (workshop evaluation questionnaires), (iii) students' satisfaction with all intervention components (student evaluation questionnaire), (iv) number of practical sessions delivered (school champion logs and session observations), (v) teachers' implementation questionnaire (adapted from an existing questionnaire) ⁸¹, (vi) student engagement (objective usage data) with the app, and (vii) practical session fidelity (3 observations per teacher) using the SAAFE observation checklist. ⁴⁸

Statistical analyses

Analyses of the primary and secondary outcomes will be conducted using linear mixed models in IBM SPSS Statistics for Windows, Version 20.0 (2010 SPSS Inc., IBM Company Armonk, NY), with alpha levels set at p < 0.05. The models will be used to assess the impact of treatment (B2L or control), time (treated as categorical with levels baseline, 6- and 12months) and the group-by-time interaction, using random effects to account for the clustered nature of the data. Although randomisation will occur at the school level, statistical analyses will be adjusted for the clustering of effects at the class level, as students from each school are nested in classes. Previous school-based studies have demonstrated that clustering at the school-level is negligible after adjusting for clustering at the class-level. 82 83 However, we will test this assumption and additionally adjust our analyses for school-level clustering if required ⁸⁴. Several potential moderators of intervention effects will be explored using interaction tests. Subgroup analyses will be conducted for the following variables if the significance of the group-by-moderator interaction is \leq .10. Socio-economic status (Low, Medium, High), sex (male, female), baseline weight status (not overweight, overweight/obese), baseline psychological distress (using established cut-offs from the Strengths and Difficulties Questionnaire), and baseline CRF (using FITNESSGRAM fitness standards). principle, assuming the data are missing at random 85. The validity of this assumption will be explored by assessing relationships between missingness and observed values of covariates

Compared

principle, assuming the data are missing at random ⁸⁵. The validity of this assumption will be explored by assessing relationships between missingness and observed values of covariates and previous outcomes. A range of sensitivity analyses will be conducted (e.g., multiple imputation and complete-case analysis). In addition to our primary analysis (i.e., intention-to-treat) and sensitivity analyses, we will also conduct two per-protocol analyses (i.e., at the class and student levels, respectively). After consideration of typical school disruptions (i.e., sporting events, school excursions, exams etc.), we estimate that a minimum of 28 exercise sessions offered over the duration of Phases 1 and 2 is achievable for schools, and sufficient to observe effects for our primary outcome at the primary end point (i.e., 6-months). Therefore, our class-level per-protocol analysis will include only students from classes in which at least 28 school-based sessions were offered. For our student-level per-protocol analysis, we will include only those students who achieved an average heart-rate of 80% of their age-predicted maximum across the intervention period (up until our primary endpoint), using heart-rate data drawn from the B2L smartphone app.

Patient and public involvement

The need for a time efficient physical activity intervention for older adolescents was identified through consultation with the NSW Department of Education School Sport Unit, who provided initial funding to evaluate the feasibility of the B2L intervention. The pilot study was conducted in two secondary schools in Newcastle (N = 68 students) and participants (i.e., students and teachers) were invited to provide feedback on the intervention and suggestions for further improvement. This feedback was then used to refine the B2L intervention components (e.g., B2L smartphone app) and implementation strategies (e.g., professional learning for teachers).

The findings of the RCT will be published in peer-reviewed journals and the NSW Department of Education and all participating schools will receive a report outlining the study findings at the conclusion of the trial. Burden of the intervention was not assessed prior to commencing the trial; teacher and student experiences in the intervention will be determined using a detailed process evaluation questionnaire at post-test.

DISCUSSION

Despite the importance of physical activity and fitness for adolescents' physical and mental health, increasing time demands and academic pressures in the final years of schooling often drive older adolescents to sacrifice time usually spent being active. Although schools are well equipped to promote physical activity to adolescents, secondary schools in NSW do not schedule mandatory physical activity opportunities (e.g., physical education, co-curricular school sport) for senior school students (i.e., Grades 11 and 12). Lack of physical activity may contribute to the high levels of stress, anxiety, and depression observed in older adolescents. The B2L intervention will be promoted to schools, teachers, students and parents as a strategy to improve older adolescents' cognitive control and academic performance (rather than focusing on the metabolic health benefits).

Beets and colleagues recently proposed the Theory of Expanded, Extended, and Enhanced Opportunities for physical activity promotion in youth. ⁴⁶ The authors suggest that the provision of new opportunities (i.e., expansion) to be physically active, (such as teacher-facilitated HIIT sessions) is needed to increase young people's activity levels. Phases 1 and 2 of the B2L intervention aim to provide Grade 11 students with additional physical activity opportunities embedded within the school day in order to increase fitness and physical activity levels. Phase 3 will provide an opportunity to explore fitness and behaviour change once the scheduled sessions are no longer facilitated by teachers. We hypothesize that

intervention group participants' fitness levels will decrease during this period, but remain higher than control group participants. Providing older adolescents with the knowledge, skills, and opportunities to engage in HIIT may compliment their participation in other types of leisure-time physical activity. It is therefore important to ensure that students are equipped with the necessary tools in order to engage in self-directed physical activity, outside of the school setting. Self-efficacy (i.e., a belief in one's capability or competence within a specific context) is consistently identified as a central determinant of human motivation, and exercise adherence. B2L has also been guided by self-determination theory and designed to satisfy students' basic psychological needs for autonomy (e.g., providing choice/allowing students to feel in control), competence (e.g., incorporating technique cards to develop correct exercise form), and relatedness (e.g., encouraging social connection and encouragement from others), ultimately impacting on students' autonomous motivation.

Poor implementation may explain why so many school-based physical activity interventions fail to reach their potential. Lack of time has been noted as the greatest barrier to implementation by teachers ⁹⁰ and providing robust evidence for the positive effects of vigorous physical activity on cognitive and mental health outcomes may provide the impetus for schools to make mandatory physical activity for older adolescents. While several studies have established that HIIT can be successfully delivered in schools, ⁹¹ previous studies have used research staff members or external providers to deliver HIIT sessions, which is neither 'scalable' nor 'sustainable'. Although we do not have funding to conduct an economic evaluation, incorporating short breaks into the school day appears to be a cost-effective way to increase young people's activity levels. ⁹²

ETHICS AND DISSEMINATION

Ethics approval for the RCT was obtained from the Human Research Ethics Committee of the University of Newcastle, Australia (H-2016-0424) and the NSW Department of Education and Communities (SERAP: 2017116). School Principals, teachers, parents and students all provided informed written consent prior to enrolment. It is not expected that participants will be at any greater risk of adverse events than they would be when participating in other types of school-based physical activity. However, the teacher handbook includes a section for teachers to report any injuries or adverse events that may occur. Any amendments to the study protocols will be publicly available via the Australian and New Zealand Clinical Trials Registry (Trial number: ACTRN12615000360516). Data management procedures will be

- 509 conducted by DRL and SK. All entered data will be de-identified using participant codes and 510 will be stored electronically in a password protected drive at the University of Newcastle.
- Quality checks of entered data will be completed by AL (i.e., range checks). Access to the
- 512 final trial dataset will comply with the conditions of the ethics committee approval and will
- be at the discretion of the lead investigator, DRL.

- 515 Contributors: DRL, CH, PJM, RCP, MN, CL, NE and JJS secured funding for the project.
- All authors contributed intellectually to the study design and research methodology, or will
- be directly involved in the collection and management of data. AL and DRL were responsible
- for drafting the manuscript. All authors provided critical review and endorsed the final
- version of the manuscript.

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Table 1: Intervention components and implementation evaluation

Level	Intervention component	Dose	Description	Implementation evaluation
TEACHER	Professional learning workshop	1 x 5 hour workshop	Professional development workshop for teachers responsible for facilitating the delivery of the B2L program in their school (hereafter referred to as school champions). The workshop will be delivered by members of the research team (i.e., the Principal Investigator and certain Chief Investigators), and will cover information and current evidence on the impact of vigorous physical activity and cardiorespiratory fitness on cognitive functioning and academic performance as well as adolescent mental health. Teachers will participate in practical exercise sessions, where they will be taught about high-intensity interval training (HIIT), and they will also be shown how to use the 'Burn 2 Learn' resources (i.e., HIIT task cards, smartphone application). A condensed online version of the workshop will be provided for school champions that could not attend the face-to-face workshop.	 Workshop evaluation questionnaire (following workshop completion by school champions) Post-program implementation questionnaire (school champions) developed for the current study based on an existing questionnaire ⁹³.
	2) Action plan	Once	At the completion of the B2L professional development workshop, teachers will be required to complete an action plan. This will include: timeline, necessary actions, potential barriers and solutions.	 Research team will sign-off once completed by school champions in the penultimate session of the workshop.
	3) Session observations	3 observations	The research team will conduct two B2L session observations using the SAAFE observation checklist and provide feedback to the school champions. The school champions will also be asked to observe one B2L session conducted by another school champion at their school.	 SAAFE observations⁴⁸ conducted by research team in Terms 2 and 3. SAAFE observation conducted by peer teacher in Term 2.

	4) Support from research team	On-going	The research team will create a Burn 2 Learn WhatsApp group and invite school champions to join. School champions will be encouraged to use the on-line messaging platform to share challenges and successful strategies.	 Post-program implementation questionnaire (school champions) Analysis of WhatsApp engagement
SCHOOL	5) Presentation to school staff	1 x 15 minutes	School champions will design a tailored presentation, scaffolded by pre-designed program resources (i.e., videos, presentation slides), to be delivered to school faculty during a regularly scheduled staff meeting. The purpose of the presentation is to inform staff of the objectives and details of the B2L program, and to promote a supportive school climate.	Research team will confirm staff presentation during meeting with school principal.
	6) Equipment	Once	Schools will be provided with a small equipment pack to assist in the delivery of the Burn 2 Learn program (~AUD\$2500) including: 1 x heart rate monitor/student, 1 x Bluetooth speaker for playing music during sessions and a selection of sports equipment (e.g., balls, cones).	Post-program implementation questionnaire (school champions)
	7) Technique and HIIT session cards	1 x set/school champion	B2L technique cards (i.e., describing key components to perform each exercise) and HIIT session cards (i.e., describing the various HIIT workouts).	Post-program implementation questionnaire (school champions)
STUDENT	8) Interactive seminar	1 x 2 hour seminar	Participating students will attend an interactive seminar delivered by the school champion, but supported by a member of the research team (present on the day of delivery). The interactive seminar will provide an overview of the Burn 2 Learn program and will address relevant information regarding physical activity, mental health and cognition, using a PowerPoint presentation and embedded videos designed specifically for this project. During this	Post-program evaluation questionnaire (students)- satisfaction

		introductory session, students will participate in a practical HIIT session using the Burn 2 Learn smartphone application.	
9) HIIT sessions	3/week	Sessions will be run at school during curricular time, supported by program resources and the B2L app. In Phases 1 and 2, teachers will be asked to facilitate the delivery of at least two exercise sessions/week across 2 school terms (i.e., 16 weeks) during regularly scheduled lessons. Each exercise session will last approximately 10-15 minutes in duration. In addition, students will be encouraged to complete additional sessions before or after school, during recess or lunch, and during free/study periods using the B2L app. In Phase 3, students will be encouraged to complete sessions outside of lesson time (teachers may continue to facilitate the delivery of B2L sessions during lesson-time). Students will also be encouraged to continue the exercise sessions during the school holiday breaks. The HIIT sessions will involve a combination of aerobic (e.g., shuttle runs, jumping jacks, boxing, dancing) and body weight muscle-strengthening exercises (e.g., push-ups, squat jumps and walking lunges), and have been designed to be fun and engaging as well as vigorous in nature. Students will be able to select from pre-designed HIIT workouts, which may be delivered for between 8-16 intervals (30 seconds work, 30 seconds rest; 1:1 work to rest ratio). A shorter option (i.e., 8 intervals; 20 seconds work, 10 seconds rest; 2:1 work to rest ratio; 4 minutes) will also be provided. Students will be provided with Bluetooth heart rate monitoring technology (Wahoo TICKR) which will connect with the B2L app to display concurrent heart rate data. Students will be encouraged to	 Students' attendance at the activity sessions will be tracked using the B2L app and via teacher recording. Average heart rate during sessions Post-program evaluation questionnaire- session preference, barriers to participation (students)

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		_	reach a target intensity of 85% of age-predicted heart rate max. HIIT sessions will include variety and choice of activities to enhance motivation, and will be student self-directed. School champions will facilitate the exercise sessions, but are not expected to guide/deliver the sessions themselves.	
	10) Smartphone app	On-going	A smartphone app has been developed to enable students to complete the B2L sessions at school and home. Android and iOS versions of the app are available. The app includes: (i) descriptions and depictions of exercise sessions, (ii) options for 'solo' or 'group' sessions (for up to 6 users per device), (iii) timer, audible prompts and display of heart rate using Bluetooth-synced commercial heart rate monitors (Wahoo brand) during HIIT sessions, (iv) personalised reports outlining heart rate (i.e., in bpm and % of maximum) achieved overall, and during each work interval across the session, (v) display of HIIT session log on app dashboard to aid self-monitoring and goal setting. A teacher version of the B2L app will also be developed to enable whole class heart rate monitoring for use during scheduled class sessions.	 Post-program evaluation questionnaire- satisfaction (students) Burn 2 Learn app usage and engagement- number of sessions completed, average heart rate
PARENT	11) e-newsletters for parents	2 x e-newsletters	Parents of intervention group students will receive two enewsletters containing information on the benefits of physical activity for academic performance and mental health and strategies to support their children's participation in physical activity during school holiday periods. The enewsletters will include video content, and will be emailed to parents, unless there is a preferred parental contact method provided by the school.	Post-program evaluation questionnaire (student)

Table 2: Strategies used to facilitate implementation in the Burn 2 Learn intervention

Domains Constructs Strategies		Strategies	
Intervention	Evidence strength and quality	B2L intervention resources and evidence from 2 pilot studies	
characteristics	Adaptability	Flexible intervention delivery model (i.e., during class-time, breaks, before or after school) requiring minimal access to facilities (i.e., can be done in the classroom) and equipment (i.e., body weight exercises).	
	Complexity	Time efficient, student-directed intervention requiring only two or three 10 minute sessions per week.	
	Design quality and packaging	Intervention resources developed by professional graphic designer.	
Outer setting	Partnerships and investment	Partnership with the NSW Department of Education.	
(Educational	External policy and incentives	Professional learning accreditation with NSW Educational Standards Authority.	
authorities)	Peer pressure	Media attention from the pilot study.	
Inner setting School culture Interactive seminar (20		Interactive seminar (20 minutes), B2L promotional posters for schools, short video for parents.	
(Schools)	Leadership engagement Meeting with School Principal to ensure commitment to the program.		
	Resources and facilities	Schools provided with B2L session cards, heart rate monitors and Bluetooth speaker (~\$2,000AUS). B2L sessions designed to be completed by students in a variety of settings (e.g., classroom, playground, sports hall).	
	Relative priority	Promoted to schools as strategy to improve cognitive function and mental health. Alignment with Stage 6 curricular material.	
	Organizational incentives	Teacher professional learning workshop accredited with New South Wales Education Standards Authority.	
Characteristics	Self-efficacy, knowledge and beliefs	Full day professional development workshop provided for teachers. Online version of workshop available.	
of individuals (Teachers)	Perceived barriers	Designed to be time efficient, and motivating for students, through the SAAFE teaching principles.	
Implementation	Planning for implementation	Teachers required to complete an action plan to support B2L implementation in their school.	
process	Champions	Recruitment of two school champions at each intervention school.	
	External change agents	Research team member allocated to each intervention school. Weekly SMS reminders to implement B2L sessions using messaging service (e.g., What's App).	
	Evaluation and feedback	B2L session observations and feedback provided by research team.	



784 Table 3: SAAFE principles and example strategies

Principle	Definition	Example strategies
Supportive	Sessions are designed to facilitate a	Provide constructive feedback
	supportive environment	 Praise effort and improvement
		 Encourage supportive behaviour among students
Active	Sessions involve a high level of	Commence sessions quickly
	movement	 Minimise talk and instruction time
		 Encourage students to exercise at high-intensity
Autonomous	Sessions involve elements of choice	 Provide students with opportunities of choice (e.g., music, partner, activity)
		 Minimise controlling language (e.g., ordering students around)
		Remind students about the benefits of high intensity activity
Fair	Sessions provided all students with an	Encourage self-comparison rather than peer-comparison
	opportunity to experience success	 Encourage students to modify exercises to personal fitness and ability level
		 Treat all students equally and fairly (i.e., high expectations for all)
Enjoyable	Sessions are designed to be enjoyable	 Play motivational music during exercise sessions
	and engaging for all students	 Provide students with a variety of HIIT workout options
		• Encourage students to reflect on their post exercise affect (i.e., how they are feeling)

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A school-based physical activity intervention for older adolescents: Rationale and study protocol for the Burn 2 Learn cluster randomised controlled trial

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ABSTRACT

Introduction: This trial aims to investigate the impact of a school-based physical activity program, involving high-intensity interval training (HIIT), on the physical and mental health of senior school students.

Methods and analysis: The Burn 2 Learn (B2L) intervention will be evaluated using a twoarm parallel group cluster randomised controlled trial with allocation occurring at the school level (to treatment or wait-list control). Schools will be recruited in two cohorts from New South Wales, Australia. The trial will aim to recruit ~720 senior school students (aged 16-18 years) from 20 secondary schools (i.e., 10 schools per cohort). A range of implementation strategies will be provided to teachers (e.g., training, equipment, and support) to facilitate the delivery of HIIT sessions during scheduled classes. In Phase 1 and 2 (3-months each), teachers will facilitate the delivery of at least two HIIT sessions/week during lesson-time. In Phase 3 (6-months), students will be encouraged to complete sessions outside of lesson-time (teachers may continue to facilitate the delivery of B2L sessions during lesson-time). Study outcomes will be assessed at baseline, 6-months (primary endpoint) and 12-months. Cardiorespiratory fitness (shuttle run test) is the primary outcome. Secondary outcomes include: vigorous physical activity, muscular fitness, cognition, and mental health. A subsample of students will (i) provide hair samples to determine their accumulated exposure to stressful events and (ii) undergo multi-modal magnetic resonance imaging to examine brain structure and function. A process evaluation will be conducted (i.e., recruitment, retention, attendance, and program satisfaction).

Ethics and dissemination: This study has received approval from the University of Newcastle (H-2016-0424) and the NSW Department of Education (SERAP: 2017116) human research ethics committees.

Trial registration: Australian New Zealand Clinical Trials Registry Number: ACTRN12618000293268.

Strengths and limitations of this study

- Strengths of this study include the cluster randomised controlled trial design and adequate power to detect changes in primary and secondary outcomes.
- The measurement and analysis of the potential mechanisms responsible for the effects of physical activity on cognitive and mental health are strengths of this study.
- Focus on the factors influencing implementation and intervention fidelity are additional study strengths.
- As the majority of assessments will take place in the schools, it is not possible to assess fitness parameters using gold standard measures.

INTRODUCTION

Physical inactivity has been described as a global pandemic, and global estimates suggest that less than 20% of adolescents are sufficiently active.² Furthermore, physical activity

declines dramatically during the teenage years (~7% each year from age 11 to 19 years),³ and

Australian data indicate only 6% of older adolescents (15-17 years) are satisfying current

physical activity guidelines of 60 minutes of moderate-to-vigorous physical activity (MVPA)

per day. 4 Recent data gathered from Australian secondary schools indicates that adolescent

girls were less likely to meet physical activity recommendations in comparison to boys. 5 Of

additional concern, evidence suggests a decline in young people's cardiorespiratory fitness

(CRF), which is an important predictor of overall health status, 6 has occurred since the

1970s.⁷⁸ While previous studies have noted small-to-moderate associations between physical

activity and CRF in young people, 9 the relationship is stronger when activity of vigorous

intensity is examined independently.

> Adolescents who participate in physical activity of sufficient volume and intensity to improve their CRF will experience metabolic and cognitive benefits. For example, a recent longitudinal study involving a large sample of adolescents found that cardio-metabolic risk declined in a dose-response manner with increasing vigorous physical activity in adolescents (healthy adolescents accumulated at least 7mins of vigorous activity each day), but not with increased volume of light or moderate physical activity. ¹⁰ Both vigorous activity and CRF are also important for young people's mental¹¹ and cognitive health. ¹³ ¹⁴ Recent systematic reviews have concluded that participating in physical activity can improve young people's cognitive control and academic performance, ^{14 15} but the underlying neurobiological, psychosocial and behavioural mechanisms not well understood. 16

> Schools are ideal settings for the delivery of physical activity programs because they have access to young people as well as the necessary facilities and equipment, and availability of qualified staff.¹⁷ School-based physical activity interventions targeting children (ages 5 to 11 years) and young adolescents (ages 12 to 15 years) have had mixed success. 18 19 Efficacy studies usually produce positive findings, but the promising findings from smallscale studies are rarely seen in large-scale effectiveness trials.²⁰ Focusing on organisational change (i.e., supportive school policies) and providing professional development for teachers can lead to improvements in physical activity and fitness in children²¹ ²² and younger adolescents.²³⁻²⁶ However, it is relatively unknown if school-based interventions are effective with older adolescents (i.e., senior school students [16-18 years]) because few randomised controlled trials (RCTs) have been conducted with this population.¹⁹

Conducting and evaluating health promotion interventions with older adolescents is challenging, in part, due to the pressures associated with standardised testing at the end of secondary school and university entrance examinations. The focus on academic performance in the final years of secondary schooling and a lack of support from school administrators are major barriers to physical activity promotion in schools. The success and sustainability of physical activity interventions is largely dependent upon 'buy in' from school principals and teachers, which may wane over time in the face of competing time demands. As enhancing students' academic performance is the core business of schools, providing evidence for the impact of vigorous physical activity on cognitive and academic outcomes may provide a novel 'hook' for schools to implement physical activity interventions.

Nevertheless, school-based physical activity interventions need to be time efficient because lack of time is the most commonly cited implementation barrier cited by teachers. The end of the end o

High-intensity interval training (HIIT) is a time efficient strategy for improving metabolic health in adolescents and adults, ^{29 30} and typically consists of short, yet intense bouts of vigorous activity interspersed with brief periods of rest or light activity. Previous studies have shown HIIT can improve CRF (unstandardised mean difference = 2.6 mL/kg/min, 95% CI = 1.8 to 3.3), reduce body mass index (-.6 kg/m², 95% CI = -.9 to -.4), and improve metabolic markers (i.e., insulin sensitivity and fasting plasma insulin) in adolescents. ³⁰ For most adolescents, the 'all out' maximal type of HIIT (i.e., 100% of heart rate max.) may not be palatable and such an approach has limited potential as a public health strategy. ³¹ Alternatively, there is emerging evidence for the efficacy of less demanding HIIT protocols (e.g., 85% of heart rate max.), albeit that most experimental studies have been conducted in laboratory settings over short periods of time (~8 weeks). ³² Importantly, there is scope for developing novel HIIT protocols that retain the health-enhancing effects, but also satisfy adolescents' desire for enjoyment and variety. ^{33 34 35}

We recently conducted the first 'teacher-facilitated' HIIT intervention for older adolescents, the Burn 2 Learn (B2L) pilot RCT.³⁶ School teachers were asked to provide at least two opportunities during the school week for students (N = 68) to complete HIIT sessions during class time. The program achieved high levels of recruitment (85%) and retention (90%) over the 14-week study period. Adherence to sessions was lower than prescribed (1.9 sessions/week during school) due to disruptions within the school (e.g., examinations). Overall program satisfaction was high among both students and teachers. Favourable intervention effects were found for CRF, lower-body muscular power (increases) and psychological distress (decrease) in the hypothesised directions. Our pilot study

demonstrated that teachers can successfully facilitate the delivery of HIIT during the school day to improve older adolescents' fitness and wellbeing. However, it is unclear whether these positive findings can be replicated on a larger scale.

Study objectives

The primary aim of this trial is to determine the effect of the B2L intervention on older adolescents' CRF (primary outcome). Secondary outcomes of the trial include muscular fitness, body composition, mental health and cognitive control. This study will also test a range of potential neurobiological, psychosocial, and behavioural mechanisms responsible for the effects of physical activity on cognitive and mental health. Finally, a detailed process evaluation will be conducted to determine if the intervention was delivered as intended and the factors influencing implementation.

METHODS

Study design

- The trial is registered with the Australian New Zealand Clinical Trials Registry
- 85 (ACTRN12617000544370) and the design, conduct and reporting will adhere to
- 86 CONSORT³⁷ and TIDier³⁸ checklists. The B2L intervention will be evaluated using a two-
- arm parallel group cluster RCT with an intervention group and wait-list control group.
- Assessments will be conducted at baseline, 6-months (primary endpoint) and 12-months from
- baseline (secondary endpoint). The RCT will include two cohorts, one starting in 2018 (10
- 90 schools; 5 intervention and 5 control), and the other starting in 2019 (10 schools; 5
- 91 intervention and 5 control) and finishing in 2020. Baseline data collection will occur in the
- school term preceding the intervention delivery (i.e., Term 1 [February to April, 2018 and
- 2019]. The intervention delivery will occur in Terms 2 and 3 [May to September, 2018,
- 94 2019]. Post-test data collection (i.e., 6-month follow-up) will commence midway through
- 95 Term 3 and continue until the end of term (August to September, 2018 and 2019), with final
- 96 follow-up assessments (i.e., 12-month follow-up) being completed in Term 1 of the
- 97 following year (February to April, 2019 and 2020).

School recruitment and selection

- New South Wales (NSW) government secondary schools that include senior school students
- 101 (i.e., Grades 11 and 12, students aged 16-18) will be eligible to participate in the study. In
- 102 Cohort 1, eligible secondary schools located within 90 minutes' drive from the University of

Newcastle, will be invited to participate. In Cohort 2, eligible secondary schools located within 150 minutes' drive from the University of Newcastle, will be recruited. The selected geographical regions (i.e., Hunter-Central Coast, Sydney, Northern Sydney, Western Sydney, and New England) are broadly representative of urban and regional secondary schools in NSW.

Schools will be recruited via presentations at conferences and meetings (e.g., regional meetings of the NSW Principals' Association) and emails sent directly to eligible schools (i.e., school Principals and Grade 11 Coordinators). Once schools have expressed an interest in the study, our Project Manager will meet with the school representative(s) and explain the study requirements. At this time, schools will be asked to identify a minimum of two Grade 11 teachers willing to facilitate the delivery of scheduled B2L sessions during school hours. There are no restrictions regarding the teaching discipline (e.g., Mathematics, English, Health and Physical Education) of Grade 11 teachers eligible to participate in the study.

Participants

Two Grade 11 teachers per school (B2L school champions) who agree to facilitate the delivery of B2L during scheduled class time. Eligible participants will be Grade 11 students who are taught by one of the B2L school champions. Of note, students consenting to participate in the trial, are consenting to participate in the evaluation component (i.e., completion of study measures). Students with a health or medical condition that would preclude participation in vigorous physical activity will be excluded from the study, but will still participate in normal lessons adapted by the B2L school champion. We will aim to recruit ~36 students (i.e., 2 classes) per school.

Sample size calculation

Power calculations were based on the primary outcome of cardiorespiratory fitness (CRF), assessed using the Progressive Aerobic Cardiovascular Endurance Run (PACER) test³⁹. Baseline post-test correlation (r =.90) and standard deviation (SD=29) values were obtained from our pilot trial, and conservative ICC values of .20 and .03 were used to account for clustering at the class- and school-levels, respectively.⁴⁰ To detect a clinically meaningful baseline-adjusted between-group difference of 6 laps^{33 41} with 80% power at a 5% significance level will require 280 students per treatment group (i.e., 2 classes of 14 students from each of 10 schools). Inflating the sample size to 18 students per class, or 360 students

per treatment arm (i.e., total sample of 720 students) allows for a potential drop-out rate of 20% at our primary study endpoint (i.e., 6-months).

Blinding and randomisation

Randomisation will occur once 10 schools (Cohort 1) have been recruited and completed baseline assessments. The same process will be repeated for Cohort 2. Pairs of schools will be matched based on the following characteristics: geographic location (i.e., region, rural/urban, coastal/inland), school area-level socio-economic status (i.e., using the Socio-Economic Indexes For Areas [SEIFA] Index of Relative Socio-Economic Disadvantage), 42 schools' student population educational advantage (i.e., using the Index of Community Socio-Educational Advantage [ICSEA]) and where possible, proposed class delivery (e.g., Mathematics, English, and Personal Development, Health and Physical Education). Schools will be randomised by an independent researcher using a computer-based random number generator, such that one school from each pair will be allocated to the intervention condition and the other to the control condition. Using this approach, each school will have an equal chance of being allocated to the intervention condition, whilst maintaining an appropriate balance of school characteristics across the two conditions. Schools randomised to the intervention condition will deliver the B2L program during the study period, whereas schools allocated to the control condition will continue with usual school practice (i.e., normal curricular lessons) for the duration of the study period (i.e., until completion of 12-month study assessments). Schools allocated to control group will then receive the intervention following final study assessments (i.e., the following year). The decision to use a wait-list control design, rather than an attention-matched placebo, was based on the following. First, the research team will have little contact with students, as the program will be delivered by teachers during their regularly scheduled lessons. Second, for our findings to have greater external validity, it is important that our control group reflects 'usual practice'. Finally, based on our previous studies, a wait-list control group is acceptable for schools and the majority of our school-based trials have achieved high levels of retention (80-90%). 24 43 44

Intervention delivery, components and implementation strategies

The B2L intervention will be delivered in three phases: Phase 1) *Getting started*, Phase 2) *Maintaining student interest*, and Phase 3) *Moving towards independence*. In Phases 1 and 2 (Term 2-Term 3; May-September, 2018 and 2019), school champions will be tasked with facilitating the delivery of at least two HIIT sessions/week during lesson time. During Phase

1, school champions will attend a one day professional learning workshop led by the research team. The workshop will focus on providing the school champions with the knowledge and skills needed to introduce students to HIIT and develop their competency. Phase 2 will involve a greater emphasis on student responsibility and control, and introduce additional intervention resources (i.e., new HIIT task cards) to maintain student interest. In Phase 3 (Term 4/Term 1; October-April 2018/2019 and 2019/2020), students will be encouraged to complete sessions outside of lesson time (teachers may continue to facilitate the delivery of B2L sessions during lesson-time).

The HIIT sessions will involve a combination of aerobic (e.g., shuttle runs, jumping jacks, boxing, dancing) and body weight muscle-strengthening exercises (e.g., push-ups, squat jumps and walking lunges), and have been designed to be fun and engaging as well as vigorous in nature. Participants will be able to select from a variety of pre-designed HIIT task cards which will be released across the phases of the program to promote variety and sustain participant interest. Phase 1) Getting started: (i) Gym HIIT - combination of aerobic (e.g., skipping) and strength exercises (e.g., squat jumps), (ii) Sport HIIT - utilising sports equipment (e.g., shuttle run while dribbling a basketball), (iii) Class HIIT - exercises that can be performed in a standard classroom (e.g., running on the spot, tricep dips), (iv) Quick HIIT - utilising Tabata protocol (e.g., 20s intense work, followed by 10s rest). Phase 2) Maintaining student interest: (i) Hip-Hop HIIT - high-intensity hip-hop dance movements, (ii) Combat HIIT - involves boxing/mixed martial arts movements (e.g., front kicks), (iii) Brain HIIT - activities that encourage thinking while participating in high-intensity activity, (iv) Rumble HIIT - high-intensity rough and tumble exercises (e.g., partner knee taps) combined with aerobic activity, (v) Custom HIIT - participants design their own HIIT workout. Phase 3) Moving towards independence: (i) Beach HIIT - utilising the natural coastal environment (e.g., sand shuttle runs and surfer style get-ups), (ii) Park HIIT - exercise sessions adapted for the park setting (e.g., triceps dips using park benches).

A common criticism of public health research is the development of interventions that are not 'scalable' and unlikely to be adopted and implemented in real world settings. The B2L intervention has been designed in consultation with the NSW Department of Education and guided by the Consolidated Framework for Implementation Research to maximise scalability and sustainability. A summary of the B2L intervention components are provided in Table 1. The multi-component intervention will target schools, principals, teachers, students and parents using: (i) an information seminar delivered by school champions, (ii) school-based physical activity sessions for two school terms, (iii) smartphone application and

heart rate monitors and (iv) information for parents (i.e., print or e-newsletters). A range of implementation strategies were designed to support the delivery of the B2L program (Table 2) and include the following: (i) intervention characteristics, (ii) outer setting (i.e., educational authorities), (iii) inner setting (i.e., schools), (iv) characteristics of teachers, and (v) implementation process.

Theoretical framework for the intervention

Several theoretical frameworks have been used to guide intervention design. Firstly, Beets and colleagues' theory of expanded, extended, and enhanced opportunities⁴⁷ suggests that the extension and enhancement of existing physical activity opportunities, as well as the creation of new opportunities (i.e., expansion) are needed to increase youth physical activity levels. For the current study, the provision of an entirely new opportunity for physical activity (i.e., expansion) was considered necessary, as the majority of secondary schools in NSW do not provide mandatory physical activity for senior students. During Phases 1 and 2 of the intervention, the HIIT sessions will be facilitated during scheduled class-time, therefore adopting a compulsory application of Theory of Expanded, Extended, and Enhanced Opportunities. In the third phase, students will be encouraged to complete two to three sessions per week within or beyond the school day. During this phase, students will be encouraged to self-monitor their participation in HIIT sessions using the B2L smartphone app.

With reference to self-determination theory, B2L HIIT sessions have been developed with a focus on enhancing students' autonomous motivation for vigorous physical activity within and beyond the school setting by satisfying their basic psychological needs for autonomy (feeling in control), competence (feeling capable) and relatedness (feeling connected with others). Teachers will learn to facilitate the B2L sessions using the SAAFE (Supportive, Active, Autonomous, Fair and Enjoyable) physical activity delivery principles (see Table 3). Participants' need for autonomy will be satisfied by providing opportunities for choice within sessions (e.g., type of activity, music playing, and training partner) and explaining the rationale for the program in an information seminar. The introductory seminar will reinforce the importance of exercise for cognitive health and academic performance, which may be salient outcomes for students during this period of their schooling.

Competence will be satisfied using positive and specific feedback from teachers, an explicit focus on effort over performance (via heart rate feedback), and through the provision of resources designed to support the development of exercise skills. Teachers will be

encouraged to adopt practices that support relatedness and group cohesion during HIIT sessions (i.e., encouraging supportive behaviour among students such as 'high fives' and partner work).⁵⁰

Measures and data collection

Apart from multi-modal magnetic resonance imaging, all assessments will be conducted at the study schools on the same day by trained research assistants, who will be blinded to group allocation at all time-points. Demographic information and self-report measures will be collected using electronic tablets under exam-like conditions. Cognitive testing will occur on University laptops and participants will receive instructions and practice prior to performing each of the cognitive tasks. Self-report and cognitive measures will occur prior to fitness assessments in a randomised order. Anthropometric assessments will be conducted in a sensitive manner by same-sex research staff when possible. Research assistants will provide a brief verbal description and demonstration of each fitness test prior to commencement. The timing for participants to complete all measures is approximately 90 minutes.

Primary outcome

Cardiorespiratory fitness. CRF will be assessed using the Progressive Aerobic Cardiovascular Endurance Run (PACER), using FITNESSGRAM® testing procedures. This test is the most widely accepted field-based measure of CRF, demonstrating high reliability and validity.⁵¹ A 20 m course will be set up on a hard surface with participants instructed to run back and forth between two sets of lines while keeping pace with a pre-recorded cadence (indicated by a single beep for each 20 m shuttle). The test begins at a slow pace (8.5 km/h), and increases by 0.5 km/h with each passing minute (as indicated by a triple beep). The test ends when participants fail to complete a shuttle (20 m lap) before the beep sounds, on two consecutive shuttles, or upon volitional failure. Verbal encouragement will be provided by test administrators in order to maximise participant motivation. The last successful stage will be recorded and converted into the number of 20 m laps completed, which will constitute the primary outcome measure. The total number of laps will be used to estimate maximal aerobic capacity (i.e., VO₂ max), using the following equation: 45.619 + (0.353*Pacer laps) – (1.121*Age).⁵² Estimated VO₂ max will be used to classify participants into fitness zones according to criterion-referenced age- and sex-specific cut-offs developed by the Cooper Institute.53

Secondary outcomes

Physical activity. Participants will be instructed to wear an ActiGraph GT9X Link accelerometer on their non-dominant wrist for 24 hours per day (even when bathing, swimming and sleeping) for a period of seven consecutive days. Weekday and weekend day (i.e., mean minutes per day) physical activity will be calculated separately, using existing thresholds for categorising physical activity into light, moderate and vigorous intensity.⁵⁴ Muscular fitness. Upper body muscular endurance will be assessed using the 90-degree pushup test.³⁹ Using a cadence of 40 beats per minute, participants lower themselves in a controlled manner until a 90-degree angle is formed at the elbow before pushing back up. The test concludes when the participant either fails to lower themselves to the required depth on two non-consecutive repetitions (warning verbalised by assessor, repetitions counted), fails to maintain movement in time with the metronome, fails to maintain appropriate technique (back straight), or upon volitional failure of the test. Lower body muscular power will be assessed using the standing long jump test.⁵⁵ From a standing position behind a line marked at zero centimetres, participants perform a maximal long jump taking off and landing with two feet, simultaneously. The test will be performed twice, with the maximal distance jumped recorded as the participant's final score. Both measures of muscular fitness demonstrate high validity and reliability in adolescents.⁵⁶ 57

Body composition. Body weight and height will be measured using a portable digital scale (A&D Medical UC-352-BLE Digital Scales) and a portable stadiometer (Seca 213 Portable Height Measuring Rod Stadiometer), respectively. Both weight and height will be measured twice to reduce the risk of measurement error. A third measurement will occur should there be a difference of >0.1 kg for weight, and >0.3 cm for height between the first and second measurement. Body mass index (BMI) will be calculated using the standard formula (weight[kg]/height[m]²). Age- and sex-specific BMI z-scores will be calculated and participants will be classified into weight categories according to International Obesity Task Force cut-offs.⁵⁸

Cognitive control. Using a laptop, specialised software (PsychoPy)⁵⁹ will be used to assess working memory and inhibition. A modified version of an Eriksen flanker task will be used to measure inhibition, which is a reliable and valid measure in youth.⁶⁰ In this task participants are required to respond (using specific keys) to the direction of the centrally presented arrow among either 'congruent' or 'incongruent' flanking arrows. Congruent trials

consist of five horizontal arrows facing the same direction (i.e., <<<< or >>>>), while incongruent trials consist of the central arrow facing the opposite direction to the four flanking arrows (i.e., <<>>< or >><>>). Participants are challenged with a random sequence of congruent and incongruent trials and instructed to identify the direction of the centrally presented, target arrow as quickly and accurately as possible. Following instructions, participants will be presented with a practice block consisting of 25 trials to familiarise themselves with the test. If participants achieve below satisfactory overall accuracy (<70%), they will complete another practice block of 25 trials, and the test administrator will confirm their understanding of the test. Participants then complete an experimental block consisting of 150 trials (with an equal distribution of congruent and incongruent). Stimuli are presented for 100 milliseconds (ms), with a randomly allocated inter-stimulus interval of 900, 1050, or 1200 ms separating each trial. Response time (i.e., the time in ms taken by the participant to press the key associated with the direction of the target arrow) and response accuracy (i.e., the percentage of trials for which the participant correctly indicated the direction of the target arrow) and will be recorded. An interference score (i.e., the difference in performance outcomes between congruent and incongruent trials) will also be calculated for both accuracy and response time. A lower interference score demonstrates higher inhibitory control.

Working memory will be assessed using a serial n-back task, which is a widely used and reliable measure. 61 62 Two task conditions (i.e., 1-back and 2-back) will be evaluated which differ in the degree of cognitive demand. In these tasks, participants are presented with a series of six basic shapes (i.e., square, star, circle, cross, crescent, triangle) and required to recall (using specific keys) whether the shape currently displayed (trial 'n') matches the shape immediately prior (1-back, 'n-1'), or two shapes prior (2-back, 'n-2'). For each trial (within each n-back condition) participants are required to indicate whether the shape is a match (i.e., target) or not a match (i.e., non-target). Shapes are presented for a duration of 250 ms following a fixed inter-stimulus interval of 2500 ms. Following task instructions, participants will complete a practice block consisting of 20 trials to ensure understanding. If overall accuracy is below 70%, participants will complete another practice block, and the test administrator will confirm their understanding of the test. Each task condition (i.e., 1-back, 2back) consists of two blocks of randomised target (n=24) and non-target (n=48) trials, and are presented in a counterbalanced order. Response time and accuracy will be recorded for both target shapes (i.e., correctly identifying a match) and non-target shapes (i.e., correctly identifying a non-match). Additionally, the relative proportion of 'hits' (correct target trials) to 'false alarms' (incorrect selection on target trial), otherwise known as the d-prime score,

will be calculated for both task conditions.⁶³ A higher d-prime score reflects a greater capacity to differentiate target from non-target shapes when performing the n-back tasks, thereby indicating greater working memory.

Stress. Objectively measured stress will be determined by examining the build-up of cortisol within the hair shaft using a sample taken from the vertex at the rear of the head. As human hair grows at a rate of approximately 1 cm per month, each cm is considered to reflect life stressors experienced by the individual over the last month.⁶⁴ Cortisol concentrations will be determined from the 3-cm hair segment (maximum) most proximal to the scalp. This will represent the cumulative stress level in the past two to three months. Inter-individual variation in hair growth rate can be factored into analyses by measuring hair growth at the initial sampling site one month later. The intra-individual stability $(r = .68 - .79)^{65}$ and validity of hair cortisol as a retrospective index of stress are supported in the literature in adults⁶⁶ 67 and adolescents. ⁶⁸ Perceived stress will be self-reported using the Perceived Stress Scale, which is designed to assess the degree to which situations in one's life are stressful.⁶⁹ Participants will be required to respond to the 10-item questionnaire in relation to the previous month (e.g., "In the last month, how often have you felt you were on top of things?"). Responses are scored on a 5-point scale ranging from 0 "Never" to 4 "Very often" and then summing across all scale items. Higher scores indicate a greater degree of subjective stress experienced by participants.

Psychological difficulties. The Strengths and Difficulties Questionnaire will be used to assess psychological distress. The questionnaire consists of 25 items, covering 2 subscales (i.e., strengths and difficulties). The strengths subscale consists of one domain (prosocial behaviour [e.g., "I try to be nice to other people. I care about their feelings."), and the difficulties subscale consists of four domains: emotional symptoms (e.g., "I worry a lot."), conduct problems (e.g., "I get very angry and often lose my temper."), hyperactivity (e.g., "I am restless, I cannot stay still for long."), and peer problems (e.g., "I would rather be alone than with people of my own age."). For each item, participants respond using a three-point scale (i.e., "Not true" = 0, "Somewhat true" = 1, and "Certainly true" = 2). For each of the five domains the score can range from 0 to 10. A difficulties composite score will be obtained by adding the scores of all four difficulty domains, with a possible range from 0 to 40. Lower scores indicate fewer psychological difficulties.

Autonomous motivation. Motivation for physical activity will be assessed using the 'Behavioural Regulations in Exercise Questionnaire'. The identified (e.g., "I value the benefits of exercise"), and intrinsic (e.g., "I exercise because it's fun") regulation subscales will be used. Responses are scored on a 5-point scale ranging from 0 "Not true for me" to 4 "Very true for me".

Basic psychological needs satisfaction. Friends' and teachers' support for exercise will be assessed via the 'Adolescent Psychological Need Support in Exercise Questionnaire'. The sassess needs satisfaction during exercise across the three psychological needs identified within self-determination theory, namely autonomy support (e.g., "I feel that they understand why I choose to exercise"), relatedness support (e.g., "I feel they care about me"), and competence support (e.g., "They display confidence in my exercise ability"). Participants respond using a 7-point Likert scale ranging from 1 "Strongly disagree" to 7 "Strongly agree".

Psychological well-being. Well-being is assessed using the validated Warwick-Edinburgh Mental Wellbeing Scale.⁷³ The 14-item questionnaire requires participants to reflect on their experiences over the last two weeks. Items are scored on a 5-point scale ranging from 1 "*None of the time*" to 5 "*All of the time*", and summed across all to produce a well-being composite (possible range = 14 to 70).

Perceived fitness. Perceived physical fitness will be self-reported using the International Fitness Scale.⁷⁴ Participants are required to report perceptions of their 'general fitness' and four specific sub-components of health-related fitness. The 5-item instrument is scored on a scale ranging from 1 "Very poor" to 5 "Very good". The validity and test-retest reliability of the IFIS has been found to be acceptable among a sample of 9-12 year old youth.⁷⁴

HIIT self-efficacy. Self-efficacy for HIIT will be assessed using a 6-item scale developed for the current study. The scale uses the common stem "If you really wanted to, how confident are you that you can..." and participants respond as follows: 1 "Not at all confident" to 10 "Completely confident". Sample item-"maintain a high level of effort right through to the end of a HIIT session". The mean of the 6-items will be calculated.

Brain structure and function. To further elucidate exercise-induced neural changes, a target sub-sample of approximately 60 students (i.e., 15 students per school from 4 schools; 2 x intervention group, 2 x control group) identified as being in the bottom 50% of students from their school for CRF (using their baseline PACER test result) will undergo multi-modal magnetic resonance imaging. We have undertaken a systematic review of neuroimaging studies that have examined associations between physical activity, CRF or muscular fitness, and brain structure/function. Preliminary findings from this review informed our multi-modal magnetic resonance imaging protocol to explore changes in the following areas: (i) structural magnetic resonance imaging (T1 and T2-weighted imaging) to identify volumetric changes in white and grey matter of the hippocampus, 75-77 frontal regions/prefrontal cortex, 75 anterior cingulate cortex, 78 and basal ganglia; 79 (ii) diffusion tensor imaging will be used to identify changes in white matter structural connectivity of the superior longitudinal fasciculus and corpus callosum. (iii) resting state functional magnetic resonance imaging will be used to assess changes in activation of the default mode network, cognitive control network, saliency network, 80 hippocampus, and prefrontal cortex; 81 82 (iv) magnetic resonance spectroscopy will be used to identify changes in brain metabolite concentrations (i.e., gamma-aminobutyric acid, N-acetyl Aspartate, adenosine tri-phosphate, and glutamate/glutamine) in the hippocampus and frontal regions/prefrontal cortex.

On-task behaviour

Cohort 2 schools will be invited to participate in a sub-study to determine the acute effect of the B2L intervention on students' behaviour in the classroom. Classroom observations will be conducted by trained research assistants at baseline and mid-intervention (week 5 to 8) using established methods. ^{83 84} During each 30 minute observation period (starting 5-mins after students enter the classroom), research assistants will assess the on- and off-task behaviour of six randomly selected students (5 min per student). For each lesson, two observers will randomly select 12 students (i.e., six boys and six girls) and the order in which they are observed (teachers and students will not know who is being observed). Observers will listen to an MP3 audio file via headphones, which will inform them when to observe and record (in 15-sec intervals). After each 10-sec interval, the observers will record the student's behaviour by circling an appropriate code (i.e., actively engaged, passively engaged, off-task motor, off-task verbal or off-task passive) using an observation sheet. After 15 seconds, the observer will then focus on the next student and repeat this process five times until the six students have been observed 20 times. On-task behaviour includes times when the child is actively

engaged in an academic activity (e.g., reading, writing, or performing the designated task) or passively engaged (i.e., sitting quietly and listening to the teacher). Off-task behaviour includes times when the student is not engaged in the designated task and can be classified as off-task motor (i.e., walking around the class), off-task verbal (i.e., talking) or off-task passive (i.e., passively not attending to the assigned academic activity). Time spent on- and off-task during the lesson will be expressed as a percentage of total lesson time. Two trained research assistants will be responsible for conducting all observations and inter-rater reliability scores will be established in the training phase.

Process evaluation

A detailed process evaluation will be conducted to determine intervention fidelity. Process measures will include: (i) students' mean heart rate from the HIIT sessions (measured using Bluetooth heart rate monitoring technology), (ii) teacher attendance and satisfaction with the professional learning workshop and curriculum materials (workshop evaluation questionnaires), (iii) students' satisfaction with all intervention components (student evaluation questionnaire), (iv) number of practical sessions delivered (school champion logs and session observations), (v) teachers' implementation questionnaire (adapted from an existing questionnaire), (iv) student engagement (objective usage data) with the app, and (vii) practical session fidelity (3 observations per teacher) using the SAAFE observation checklist. 49

Statistical analyses

Analyses of the primary and secondary outcomes will be conducted using linear mixed models in IBM SPSS Statistics for Windows, Version 20.0 (2010 SPSS Inc., IBM Company Armonk, NY), with alpha levels set at p<0.05. The models will be used to assess the impact of treatment (B2L or control), time (treated as categorical with levels baseline, 6- and 12-months) and the group-by-time interaction, using random effects to account for the clustered nature of the data. Although randomisation will occur at the school level, statistical analyses will be adjusted for the clustering of effects at the class level, as students from each school are nested in classes. Previous school-based studies have demonstrated that clustering at the school-level is negligible after adjusting for clustering at the class-level. 86 87 However, we will test this assumption and additionally adjust our analyses for school-level clustering if required. 88 Several potential moderators of intervention effects will be explored using interaction tests. 89 Subgroup analyses will be conducted for the following variables if the

significance of the group-by-moderator interaction is \leq .10: Socio-economic status (Low, Medium, High), sex (male, female), baseline weight status (not overweight, overweight/obese), baseline psychological distress (using established cut-offs from the Strengths and Difficulties Questionnaire), and baseline CRF (using FITNESSGRAM fitness standards).

Compared to complete case analyses, mixed models include available data for all participants in the analysis and are thus both more efficient and robust to bias. Mixed model analyses are consistent with the intention-to-treat principle, assuming the data are missing at random. 90 The validity of this assumption will be explored by assessing relationships between missingness and observed values of covariates and previous outcomes. A range of sensitivity analyses will be conducted (e.g., multiple imputation and complete-case analysis). In addition to our primary analysis (i.e., intention-to-treat) and sensitivity analyses, we will also conduct two per-protocol analyses (i.e., at the class and student levels, respectively). After consideration of typical school disruptions (i.e., sporting events, school excursions, exams etc.), we estimate that a minimum of 28 exercise sessions offered over the duration of Phases 1 and 2 is achievable for schools, and sufficient to observe effects for our primary outcome at the primary end point (i.e., 6-months). Therefore, our class-level per-protocol analysis will include only students from classes in which at least 28 school-based sessions were offered. For our student-level per-protocol analysis, we will include only those students who achieved an average heart-rate of 80% of their age-predicted maximum (220-age) across the intervention period (up until our primary endpoint), using heart-rate data drawn from the B2L smartphone app.

Patient and public involvement

The need for a time efficient physical activity intervention for older adolescents was identified through consultation with the NSW Department of Education School Sport Unit, who provided initial funding to evaluate the feasibility of the B2L intervention. The pilot study was conducted in two secondary schools in Newcastle (N = 68 students) and participants (i.e., students and teachers) were invited to provide feedback on the intervention and suggestions for further improvement. This feedback was then used to refine the B2L intervention components (e.g., B2L smartphone app) and implementation strategies (e.g., professional learning for teachers).

The findings of the RCT will be published in peer-reviewed journals and the NSW Department of Education and all participating schools will receive a report outlining the

study findings at the conclusion of the trial. Burden of the intervention was not assessed prior to commencing the trial; teacher and student experiences in the intervention will be determined using a detailed process evaluation questionnaire at post-test.

DISCUSSION

Despite the importance of physical activity and fitness for adolescents' physical and mental health, increasing time demands and academic pressures in the final years of schooling often drive older adolescents to sacrifice time usually spent being active. Although schools are well equipped to promote physical activity to adolescents, secondary schools in NSW do not schedule mandatory physical activity opportunities (e.g., physical education, co-curricular school sport) for senior school students (i.e., Grades 11 and 12). Lack of physical activity may contribute to the high levels of stress, anxiety, and depression observed in older adolescents. ⁹¹⁻⁹³ The B2L intervention will be promoted to schools, teachers, students and parents as a strategy to improve older adolescents' cognitive control and academic performance (rather than focusing on the metabolic health benefits).

Phases 1 and 2 of the B2L intervention aim to provide Grade 11 students with additional physical activity opportunities embedded within the school day in order to increase fitness and physical activity levels. Phase 3 will provide an opportunity to explore fitness and behaviour change once the scheduled sessions are no longer facilitated by teachers. We hypothesize that intervention group participants' fitness levels will decrease during this period, but remain higher than control group participants. Providing older adolescents with the knowledge, skills, and opportunities to engage in HIIT may compliment their participation in other types of leisure-time physical activity. It is therefore important to ensure that students are equipped with the necessary tools in order to engage in self-directed physical activity, outside of the school setting. Self-efficacy (i.e., a belief in one's capability or competence within a specific context) is consistently identified as a central determinant of human motivation, and exercise adherence. 94 B2L has also been guided by self-determination theory and designed to satisfy students' basic psychological needs for autonomy (e.g., providing choice/allowing students to feel in control), competence (e.g., incorporating technique cards to develop correct exercise form), and relatedness (e.g., encouraging social connection and encouragement from others), ultimately impacting on students' autonomous motivation.

Poor implementation may explain why so many school-based physical activity interventions fail to reach their potential. Lack of time has been noted as the greatest barrier

to implementation by teachers⁹⁵ and providing robust evidence for the positive effects of vigorous physical activity on cognitive and mental health outcomes may provide the impetus for schools to make mandatory physical activity for older adolescents. While several studies have established that HIIT can be successfully delivered in schools,⁹⁶ previous studies have used research staff members or external providers to deliver HIIT sessions, which is neither 'scalable' nor 'sustainable'. Although we do not have funding to conduct an economic evaluation, incorporating short breaks into the school day appears to be a cost-effective way to increase young people's activity levels.⁹⁷

ETHICS AND DISSEMINATION

Ethics approval for the RCT was obtained from the Human Research Ethics Committee of the University of Newcastle, Australia (H-2016-0424) and the NSW Department of Education and Communities (SERAP: 2017116). School Principals, teachers, parents and students all provided informed written consent prior to enrolment. It is not expected that participants will be at any greater risk of adverse events than they would be when participating in other types of school-based physical activity. However, the teacher handbook includes a section for teachers to report any injuries or adverse events that may occur. Any amendments to the study protocols will be publicly available via the Australian and New Zealand Clinical Trials Registry (Trial number: ACTRN12615000360516). Data management procedures will be conducted by DRL and SK. All entered data will be de-identified using participant codes and will be stored electronically in a password protected drive at the University of Newcastle. Quality checks of entered data will be completed by AL (i.e., range checks). Access to the final trial dataset will comply with the conditions of the ethics committee approval and will be at the discretion of the lead investigator, DRL.

Contributions: DRL, CH, PJM, RCP, MN, CL, NE and JJS secured funding for the project. DRL, CH, PJM, MN, NE, JJS, SAC, NH and SGK designed the intervention. CH, MN, SV and DRL designed the multimodal magnetic resonance imaging sub-study. CH, TTS and AL designed and contributed to the administration of the cognitive assessments. RW and PG designed the cortisol measurement protocol. EH conducted the power calculation and guided the statistical analysis. SY and SGK are responsible for project management, school recruitment and data collection. All authors contributed intellectually to the study design and research methodology, or will. AL and DRL were responsible for drafting the manuscript. All authors provided critical review and endorsed the final version of the manuscript.

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Level	Intervention component	Dose	Description	Implementation evaluation
TEACHER	Professional learning workshop	1 x 5 hour workshop	Professional development workshop for teachers responsible for facilitating the delivery of the Burn 2 Learn (B2L) program in their school (hereafter referred to as school champions). The workshop will be delivered by members of the research team (i.e., the Principal Investigator and certain Chief Investigators), and will cover information and current evidence on the impact of vigorous physical activity and cardiorespiratory fitness on cognitive functioning and academic performance as well as adolescent mental health. Teachers will participate in practical exercise sessions, where they will be taught about high-intensity interval training (HIIT), and they will also be shown how to use the 'Burn 2 Learn' resources (i.e., HIIT task cards, smartphone application). A condensed online version of the workshop will be provided for school champions that could not attend the face-to-face workshop.	 Workshop evaluation questionnaire (following workshop completion by school champions) Post-program implementation questionnaire (school champions) developed for the current study based on an existing questionnaire.⁹⁸
	2) Action plan	Once	At the completion of the B2L professional development workshop, teachers will be required to complete an action plan. This will include: timeline, necessary actions, potential barriers and solutions.	Research team will sign-off once completed by school champions in the penultimate session of the workshop.
	3) Session observations	3 observations	The research team will conduct two B2L session observations using the SAAFE observation checklist and provide feedback to the school champions. The school champions will also be asked to observe one B2L session conducted by another school champion at their school.	 SAAFE observations⁴⁹ conducted by research team in Terms 2 and 3. SAAFE observation conducted by peer teacher in Term 2.

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	4) Support from research team	On-going	The research team will create a B2L WhatsApp group and invite school champions to join. School champions will be encouraged to use the on-line messaging platform to share challenges and successful strategies.	 Post-program implementation questionnaire (school champions) Analysis of WhatsApp engagement
	5) Presentation to school staff	1 x 15 minutes	School champions will design a tailored presentation, using pre-designed program resources (i.e., videos, presentation slides), to be delivered to school faculty during a regularly scheduled staff meeting. The purpose of the presentation is to inform staff of the objectives and details of the B2L program, and to promote a supportive school climate.	Research team will confirm staff presentation during meeting with school principal.
SCHOOL	6) Equipment	Once	Schools will be provided with a small equipment pack to assist in the delivery of the B2L program (~AUD\$2500) including: 1 x heart rate monitor/student, 1 x Bluetooth speaker for playing music during sessions, 1 x WASP device (connect Ant+ to WiFi) and a selection of sports equipment (e.g., balls, cones).	Post-program implementation questionnaire (school champions)
	7) Technique and HIIT session cards	1 x set/school champion	B2L technique cards (i.e., describing key components to perform each exercise) and HIIT session cards (i.e., describing the various HIIT workouts).	Post-program implementation questionnaire (school champions)
STU DEN T	8) Interactive seminar	1 x 2 hour seminar	Participating students will attend an interactive seminar delivered by the school champion, but supported by a member of the research team (present on the day of delivery). The interactive seminar will provide an overview of the B2L program and will address relevant information regarding physical activity, mental health and cognition, using a PowerPoint presentation and embedded videos designed specifically for this project. During this	Post-program evaluation questionnaire (students)- satisfaction

9)) HIIT sessions	3/week	introductory session, students will participate in a practical HIIT session using the B2L smartphone application. Sessions will be run at school during curricular time, supported by program resources and the B2L app. In Phases 1 and 2, teachers will be asked to facilitate the delivery of at least two exercise sessions/week across 2 school terms (i.e., 16 weeks) during regularly scheduled lessons. Participants will be able to select from a variety of pre-designed HIIT workouts including: Gym HIIT, Sport HIIT, Class HIIT, Quick HIIT, Hip-hop HIIT, Combat HIIT, Brain HIIT, Rumble HIIT, and Custom HIIT. Each exercise session will last approximately 10-15 minutes in duration. In addition, students will be encouraged to complete additional sessions before or after school, during recess or lunch, and during free/study periods using the B2L app. In Phase 3, students will be encouraged to complete sessions outside of lesson time (teachers may continue to facilitate the delivery of B2L sessions during lesson-time). Students will also be encouraged to continue the exercise sessions during the school holiday breaks. Two additional HIIT workouts will be provided during this phase (Beach HIIT, Park HIIT) which utilise the natural environment. Students will be able to select from pre-designed HIIT workouts, which may be delivered for between 8-16 intervals (30 seconds work, 30 seconds rest; 1:1 work to rest ratio). A shorter option (i.e., 8 intervals; 20 seconds work, 10 seconds rest; 2:1 work to rest ratio; 4 minutes) will also be provided. Although recommendations will be provided, teachers and students will have the capacity to modify the work-to-rest ratios and number of intervals. Students will be provided with Bluetooth heart rate monitoring technology (Wahoo TICKR) which will connect with the B2L app to display concurrent heart rate data. Students will be encouraged to	 Students' attendance at the activity sessions will be tracked using the B2L app and via teacher recording. Average heart rate during sessions Post-program evaluation questionnaire- session preference, barriers to participation (students)
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			reach a target intensity of 85% of age-predicted heart rate max. HIIT sessions will include variety and choice of activities to enhance motivation, and will be student self-directed. School champions will facilitate the exercise sessions, but are not expected to guide/deliver the sessions themselves.	
	10) Smartphone app	On-going	A smartphone app has been developed to enable students to complete the B2L sessions at school and home. Android and iOS versions of the app are available. The app includes: (i) descriptions and depictions of exercise sessions, (ii) options for 'solo' or 'group' sessions (for up to 6 users per device), (iii) timer, audible prompts and display of heart rate using Bluetooth-synced commercial heart rate monitors (Wahoo brand) during HIIT sessions, (iv) personalised reports outlining heart rate (i.e., in bpm and % of maximum) achieved overall, and during each work interval across the session, (v) display of HIIT session log on app dashboard to aid self-monitoring and goal setting. A teacher version of the B2L app will also be developed to enable whole class heart rate monitoring for use during scheduled class sessions.	 Post-program evaluation questionnaire- satisfaction (students) B2L app usage and engagement-number of sessions completed, average heart rate
PARENT	11) e-newsletters for parents	2 x e-newsletters	Parents of intervention group students will receive two e- newsletters containing information on the benefits of physical activity for academic performance and mental health and strategies to support their children's participation in physical activity during school holiday periods. The e- newsletters will include video content, and will be emailed to parents, unless there is a preferred parental contact method provided by the school.	Post-program evaluation questionnaire (student)

Note. B2L = Burn 2 Learn, SAAFE = Supportive, Active, Autonomous, Fair, Enjoyable teaching principles



Table 2: Strategies used to facilitate implementation in the Burn 2 Learn intervention

Domains	Constructs	Strategies
Intervention	Evidence strength and quality	B2L intervention resources and evidence from 2 pilot studies
characteristics	Adaptability	Flexible intervention delivery model (i.e., during class-time, breaks, before or after school) requiring minimal access to facilities (i.e., can be done in the classroom) and equipment (i.e., body weight exercises).
	Complexity	Time efficient, student-directed intervention requiring only two or three 10 minute sessions per week.
	Design quality and packaging	Intervention resources developed by professional graphic designer.
Outer setting	Partnerships and investment	Partnership with the NSW Department of Education.
(Educational	External policy and incentives	Professional learning accreditation with NSW Educational Standards Authority.
authorities)	Peer pressure	Media attention from the pilot study.
Inner setting	School culture	Interactive seminar (20 minutes), B2L promotional posters for schools, short video for parents.
(Schools)	Leadership engagement	Meeting with School Principal to ensure commitment to the program.
	Resources and facilities	Schools provided with B2L session cards, heart rate monitors, WASP device (connect Ant+ to WiFi) and Bluetooth speaker (~\$2,500AUS). B2L sessions designed to be completed by students in a variety of settings.
	Relative priority	Promoted to schools as strategy to improve cognitive function and mental health. Alignment with Stage 6 curricular material.
	Organizational incentives	Teacher professional learning workshop accredited with New South Wales Education Standards Authority.
Characteristics	Self-efficacy, knowledge and beliefs	Full day professional development workshop provided for teachers. Online version of workshop available.
of individuals (Teachers)	Perceived barriers	Designed to be time efficient, and motivating for students, through the SAAFE teaching principles.
Implementation	Planning for implementation	Teachers required to complete an action plan to support B2L implementation in their school.
process	Champions	Recruitment of two school champions at each intervention school.
	External change agents	Research team member allocated to each intervention school. Weekly SMS reminders to implement B2L sessions using messaging service (e.g., What's App).
	Evaluation and feedback	B2L session observations and feedback provided by research team.

Note. B2L = Burn 2 Learn

Table 3: SAAFE principles and example strategies

Principle	Definition	Example strategies
Supportive	Sessions are designed to facilitate a	Provide constructive feedback
	supportive environment	 Praise effort and improvement
		 Encourage supportive behaviour among students
Active	Sessions involve a high level of	Commence sessions quickly
	movement	Minimise talk and instruction time
		 Encourage students to exercise at high-intensity
Autonomous	Sessions involve elements of choice	Provide students with opportunities of choice (e.g., music, partner, activity)
		 Minimise controlling language (e.g., ordering students around)
		 Remind students about the benefits of high intensity activity
Fair	Sessions provided all students with an	• Encourage self-comparison rather than peer-comparison
	opportunity to experience success	• Encourage students to modify exercises to personal fitness and ability level
		• Treat all students equally and fairly (i.e., high expectations for all)
Enjoyable	Sessions are designed to be enjoyable	Play motivational music during exercise sessions
	and engaging for all students	 Provide students with a variety of HIIT workout options
		• Encourage students to reflect on their post exercise affect (i.e., how they are feeling)
Vote. SAAFE =	= Supportive, Active, Autonomous, Fair, F	Enjoyable teaching principles.