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Effectiveness of a school-based universal resilience intervention in reducing tobacco, alcohol and illicit substance use in a population of adolescents: cluster-randomised controlled trial

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ABSTRACT

Objectives: Initiation of tobacco, alcohol and illicit substance use typically occurs during adolescence, with the school setting recommended to reduce adolescent substance use. Strengthening individual (e.g. problem solving) and environmental (e.g. caring relationships at school) resilience protective factors of adolescents has been suggested as a strategy for reducing substance use by adolescents, however few studies have examined this potential. A study was conducted to investigate the effectiveness of a school-based universal 'resilience' intervention in reducing the prevalence of tobacco, alcohol and illicit substance use, and increasing the individual and environmental protective factors of students.

Design: A cluster-randomised controlled trial

Setting: Thirty-Two Australian secondary schools (20 intervention;12 control)

Participants: Cohort of Grade 7 students followed up in Grade 10 (2014; aged 15-16years).

Intervention: A pragmatic intervention involving school staff selection and implementation of available programs and resources targeting individual and environmental 'resilience' protective factors for all Grade 7-10 students was implemented in schools (2012-2014). School staff were provided implementation support.

Measurements: An online survey collected baseline and follow up data for primary outcomes: tobacco (ever, recent) and alcohol (ever, recent, 'risk') use, and secondary outcomes: marijuana and other illicit substance use, and individual (six factor subscales, aggregate) and environmental (three factor subscales, aggregate) protective factor scores. Generalized and linear mixed models examined follow up differences between groups.

Results: Follow-up data from 2105 students (intervention=1261; control=844; 69% of baseline cohort) were analysed. No significant differences were found between intervention and control students for any primary (ever tobacco:OR 1.25,95%CI:0.92,1.68,*p*=0.14; recent tobacco:OR1.39,95%CI:0.84,2.31,*p*=0.19; recent ever alcohol:OR 1.11,95%CI:0.83,1.48,*p*=0.46; alcohol:OR1.13,95%CI:0.78,1.62,*p*=0.51; 'risk' alcohol:OR0.98,95%CI:0.70,1.36,*p*=0.89) or secondary outcomes (marijuana:OR1.12,95%CI:0.74,1.68,*p*=0.57; other illicit

substance:OR1.19,95%CI:0.67,2.10,*p*=0.54; individual protective factors: MD=0,95%CI:-0.07,0.06,*p*=0.89; environmental protective factors: MD:-0.02,95%CI:-0.09,0.06,*p*=0.65).

Conclusions: The universally implemented school-based intervention was not effective in reducing the prevalence of tobacco, alcohol or illicit substance use, or in increasing the protective factors of students.

Trial registration: Australia and New Zealand Clinical Trials Register reference: ACTRN12611000606987

ARTICLE SUMMARY

Strengths and limitations of this study

- This study represents a comprehensive examination using the gold standard study design for school-based studies to investigate the potential of a universal school-based resilience protective factor intervention in reducing the tobacco, alcohol and illicit substance use of adolescents.
- Major strengths of this study include: the cluster-randomised controlled study design, the large sample size of participating students, the collection of individual outcome data as well as process data to assess intervention implementation, and the use of statistical methods that both accounted for the clustering of student outcome data and sensitivity analyses using intention to treat principles which included multiple imputation to account for missing data.
- Although the study found a high rate of student attrition (31%), such attrition is typical for school-based research, did not differ between treatment groups and had little impact on the estimated power of the study (difference of 0.3-0.4%).
- The study was reliant upon adolescent self-report of substance use and subject to the known limitations of self-report in this population. Whilst the planned validation of tobacco use by adolescents was not supported by schools, strategies were implemented to increase the validity of adolescent report including a web-based survey and confidential participation by students.

BACKGROUND

Tobacco, alcohol and illicit substance use are responsible for 9% of the global disease burden,[1] 12% of deaths world-wide,[2] and significant health and societal costs.[3-6] Initiation of tobacco, alcohol and illicit substance use in high income countries generally occurs during adolescence,[7-9] with earlier use associated with greater dependence in adulthood.[1] Whilst data from the United States and Australia show a declining trend in adolescent substance use [9, 10] a considerable proportion of adolescents (aged 11-17 years) continue to report such use; 23%-45% having smoked a cigarette, 43%-74% having consumed an alcoholic drink, and 7%-40% having used an illicit substance.[9-11]

Schools represent an opportune setting for interventions to prevent adolescent substance use as they provide access to large numbers of adolescents for prolonged periods, and have curricula and policies that seek to promote student health and wellbeing.[12, 13] As a consequence, substance use prevention interventions delivered to all students in a school or classroom regardless of risk (that is universal)[14] [15] are common and supported by governments world-wide to reduce the prevalence of adolescent substance use.[16-19] Despite policies recommending comprehensive approaches to substance use prevention address protective factors of substance use[17, 19-21] and 'resilience',[17, 19] such policies do not provide guidance regarding the specific factors or resilience strategies that should be targeted.

Evidence from cross sectional studies suggests a range of individual factors including self-efficacy, problem solving, communication and self-awareness are protective of adolescent substance use; as has evidence regarding environmental factors such as caring relationships with adults and peers, and meaningful participation in home, school and community settings.[22-34] Such factors have similarly been found to be protective of a person's 'resilience',[35-37] most broadly defined as the process of, capacity for, or outcome of successful adaptation in the context of risk or adversity.[37-39] Systematic reviews assessing the effectiveness of school-based universal intervention approaches in

reducing adolescent substance use have not specifically examined the effectiveness of interventions that have focused solely on resilience or such protective factors.[40-42]

Only one controlled trial could be located assessing the effectiveness of such an intervention approach in reducing the prevalence of substance use in adolescent school students. The cluster-randomized controlled trial conducted in 26 Australian secondary schools investigated the effectiveness of a three year whole-of-school intervention delivered by schools targeting a number of individual and environmental protective factors in preventing tobacco, alcohol and marijuana use in a cohort of students.[43] Outcomes were assessed at baseline, mid-intervention (after one year of intervention) and following intervention completion. Despite promising results mid-intervention for tobacco use, at follow up the confidence intervals for the adjusted odd ratios for tobacco, alcohol or marijuana use outcomes indicated a non-significant result.[44] In contrast, a non-controlled pre-post effectiveness trial of a three year universal intervention delivered by schools and focused solely on individual and environmental protective factors showed reductions of up to 50% in the use of tobacco (50% to 27%), alcohol (34% to 17%) and marijuana (16% to 7%) use among cross sections of students in three Australian secondary schools.[45]

Given the limited evidence regarding the effectiveness of universal interventions promoting protective factors as a means of reducing adolescent student substance use, a cluster randomised controlled trial was conducted to determine the effectiveness of a secondary school staff-delivered intervention targeting such protective factors in reducing the prevalence of tobacco and alcohol use (primary outcomes) and marijuana and illicit substance use, and in increasing individual and environmental protective factors (secondary outcomes).

METHODS

Study design and setting

A cluster randomised controlled trial was conducted in secondary schools in one health district of New South Wales, Australia. Outcome assessments were conducted with a cohort of students at

baseline (when students were in Grade 7 - aged 12-13 years) and at follow-up (when students were in Grade 10). Approximately 114,000 people aged 10 to 19 years reside in metropolitan, regional, rural and remote areas within the district.[46, 47] Relevant ethics committee approvals were obtained (Hunter New England Health Ref:09/11/18/4.01; University of Newcastle Ref:H-2010-0029). Further study details have been reported elsewhere.[48]

Participants and recruitment

Schools

A national schools database[49] identified 172 schools with secondary enrolments within the study area. Schools were eligible if they: were a Government or Catholic secondary school located within a socioeconomically disadvantaged local government area,[50] had enrolments in Grades 7 to 10 (aged 12-16 years) and had more than 400 total student enrolments. Schools were ineligible if they were: single gender, independent (private), special needs, selective, central (for students aged 5-18 years) or boarding schools.

Randomisation of schools

Eligible schools were approached in random order until a quota of 32 schools consented. Consenting schools were stratified according to participation in a government disadvantaged schools initiative (yes/no)[51] and school size (medium 400-800/large >800), then randomly allocated to intervention or control in a 20:12 block design ratio by an independent statistician using a random number function in Microsoft Excel prior to baseline data collection.

Students

All students enrolled in Grade 7 (first year at secondary school) were eligible to participate in data collection and active parental consent for student participation was sought via a mailed study information pack. A free call number was provided for parents who wished to decline. After two weeks, non-responding parents were prompted via telephone by school-affiliated staff who were blind to group allocation.

School staff

Selected school staff (deputy principal, head teachers for student welfare and five key subject areas, and the Aboriginal Education Coordinator or other Aboriginal staff member) at each intervention and control school were invited to participate in data collection at follow up.

Intervention

A three-year universal ('whole of school') intervention was delivered to all students in Grades 8 to 10. The intervention, based on a pilot study,[45] involved 16 broad strategies (see Table 1) seeking to build the protective factors of students implemented across the three domains of the Health Promoting Schools framework (Table 1).[52] Each of the 16 broad strategies addressed one or more individual (self-efficacy, problem solving, cooperation/communication, self-awareness, empathy, goals/aspirations) or environmental protective factors (school support, school meaningful participation, community support, community meaningful participation, home support, home meaningful participation, peer caring relationships, pro-social peers). Such protective factors have been found to be correlated with adolescent substance use [53] and align with a 'resilience' approach.[35-37, 54]

A pragmatic intervention approach [55] that involved intervention delivery by school staff as a component of routine school practice was adopted to approximate intervention delivery under 'real world' conditions [55]. Schools were provided with details of existing resources and programs addressing the 16 broad strategy areas from which they could choose to implement. Whilst schools were required to implement programs and resources that addressed each of the 16 broad strategies, they had the flexibility to select which specific program or resource to implement, and the order and manner in which they were implemented.

Table 1. Intervention and implementation support strategies

Intervention strategies by Health Promoting Schools domain

Curriculum, teaching and learning

1. Age-appropriate lessons (9 hours) on individual protective factors across school subjects (e.g. MindMatters[89] or school-developed curriculum resources) [I,a]
2. Non-curriculum programs (9 hours) targeting protective factors (e.g. the Resourceful Adolescent Program)[90] [I,E]
3. Additional program targeting protective factors for Aboriginal students [I,E, a]

Ethos and environment

4. Rewards and recognition program [I,E]
5. Peer support/peer mentoring programs [I,E]
6. Anti-bullying programs [I,E]
7. Empowerment/leadership programs [I,E]
8. Additional empowerment/leadership/mentoring programs for Aboriginal students [I,E,a]
9. Aboriginal cultural awareness strategies [I,.E,a]

Partnerships and services

10. Promotion/engagement of local community organisations/groups/clubs in school (e.g. charity organizations) [E,a]
11. Additional/enhanced consultation activities with Aboriginal community groups [I,E,d]
12. Promotion/engagement of health, community and youth services in the school [I,E,a]
13. Additional/enhanced Aboriginal community organizations promoted or engaged [I,E,d]
14. Referral pathways to health, community and youth services developed and promoted [I,E,a]
15. Strategies to increase parental involvement in school (e.g. school events) [E,a]
16. Information regarding student protective factors provided to parents via school newsletter [I,E,a]

Implementation support strategies

1. Engagement with school community including presentations at school staff meetings regarding planned intervention [b]
2. Embedded staff support:
    - School intervention officer one day a week to support program implementation
    - Project coordinator to liaise with school sectors and support school intervention officers [c]
3. School intervention team formed (new team or re-alignment of existing team, inclusive of school intervention officer and school executive member) to implement intervention
4. Structured planning process to prioritize and select appropriate resources/programs:
    - Needs assessment of student protective factors (when study sample in Grade 7 and 9)
    - Two school community planning workshops and one strategy review workshop [c]
    - School plan to address intervention strategies endorsed by the school executive
5. Intervention implementation guide that described the intervention, planning process, available resources and programs, tools and templates for intervention implementation.
6. Staff mental health training (minimum of one hour per school during staff meetings)
7. AUD $2,000 per year each for:
    - Teacher release time for intervention implementation or professional development
    - Strategies specifically for Aboriginal students [a]
8. Feedback reports regarding student substance use and protective factors, and intervention implementation (termly) [c]
9. An Aboriginal Cultural Steering group was formed comprising of Aboriginal staff from local Aboriginal community organizations and Government Departments to provide Aboriginal cultural advice and direction regarding the study design, implementation, evaluation and dissemination

I To target individual protective factors; E To target environmental protective factors
[a] Implemented in Years 2 and 3 only; [b] Year 1 only; [c] Years 1 and 2 only; [d] Year 3 only
NB. Following publication of the study protocol[48] and based upon advice received from an Aboriginal Cultural Steering Group intervention strategies 3,8,11,13 were added.

To facilitate implementation of intervention strategies, programs and resources, schools were provided with a comprehensive range of support strategies, including an embedded psychology or

education trained implementation support officer; strategies that have been previously reported to facilitate implementation of interventions (Table 1).[56-63]

Control schools implemented usual school curricula and policies which may have included protective factor strategies and resources similar to, or the same as, those systematically provided to the intervention schools, but were not provided with program resources or support. A report describing baseline school-level student substance use and protective factor characteristics was provided to control schools.

Data collection procedures

Student demographic and protective factor characteristics and substance use outcomes

Students completed a confidential web-based survey[64] in class time prior to intervention commencement (baseline: August-November 2011) and immediately following intervention completion (follow up: July-November 2014). Neither the school staff nor researchers were blind to group allocation.

Implementation of strategies targeting protective factors

To assess intervention implementation by intervention schools,[65] research staff reviewed school documents and recorded the delivery of intervention strategies monthly. In addition, at follow up, telephone-based structured interviews were conducted with staff from both groups by interviewers regarding school implementation of intervention strategies and engagement with the intervention during the final year of intervention, School staff from intervention schools were asked their level of engagement with the intervention in the final year.

Measures

Student demographic characteristics

The student survey addressed: age, gender, residential postcode, Aboriginal and/or Torres Strait Islander status, ethnicity, and non-English speaking background.

Student substance use

Substance use outcome data were collected using items from an ongoing Australian triennial survey of school students' health behaviours (Appendix A).[9] Primary outcomes included tobacco (ever and recent) alcohol (ever, recent and 'risky') use. Secondary outcomes included marijuana and other illicit substance use. Planned validation of student self-report of smoking via saliva-based cotinine testing[48, 66] was not conducted due to school policies prohibiting drug testing.

Student individual and environmental protective factors

The Resilience and Youth Development module of the California Healthy Kids Survey was used to measure individual and environmental protective factors .[53] Items for all six individual and three of the environmental factor subscales were selected based on their congruence with the intervention (Appendix A). Aggregate individual and environmental protective factor scores were used as secondary outcome measures.

Consistent with a previous study of the survey,[53] analysis of baseline responses confirmed the subscales were internally consistent and valid (Cronbach alpha coefficients: individual 0.55-0.81; environmental 0.77-0.88). Confirmatory factor analysis[53] demonstrated the subscale factor structure to be a good model fit (comparative fit index 0.92, root mean square error of approximation 0.04).

Implementation of strategies targeting protective factors

The telephone survey of school staff assessed reported implementation of programs and resources in each of the 16 broad strategy areas (Table 1), and staff in during the final year of intervention. Intervention school staff level of engagement was assessed by a single item (not at all/somewhat/moderately/very/unsure).

Sample size

Based on an assumed parental consent rate of 80%,[29, 67] and loss of students to follow-up from Grade 7 to Grade 10 of 25%, it was estimated the cohort would consist of 3,630 Grade 7 students (2,270 intervention, 1,360 control) and 2,720 Grade 10 students at follow up (1,700 intervention, 1,020 control). Assuming 80% power, a 5% significance level, an intra-cluster correlation of 0.01,[45] and Grade 10 control group prevalence of 14% for recent smoking, 36.2% for recent/risk alcohol use, 25% for marijuana use, and 9.3% for other illicit substance use,[68] the study was estimated to be able to detect an absolute reduction in prevalence of 4.8% for recent smoking, 7.0% for recent/risk alcohol use, 6.2% for marijuana use and 3.9% for illicit substance use in intervention compared to control students.

Statistical analysis

Student demographic characteristics

Student-reported residential postcode was used to calculate student socioeconomic status [50] and remoteness of residential location.[69] Characteristics of students (gender, Aboriginality, socioeconomic status, remoteness, baseline substance use and protective factor scores) completing both baseline and follow up surveys were compared to those lost to follow up by logistic regression accounting for potential clustering of students within schools.

Student substance use

Recent tobacco use was defined as having smoked at least one cigarette in the last week, and recent alcohol use as at least one alcoholic drink in the last week (yes/no). The response options for 'risky alcohol use' were dichotomised (either 'none', or 'once'/'twice'/'3-6 times'/'7 or more times'), as were the response options for both marijuana and other illicit substance use (either 'none', or 'once or twice'/'3-5 times'/'6-9 times'/'10-19 times'/'20-39 times'/'40 or more times').

Comparison between groups in the prevalence of substance use at follow up for the cohort Grade 10 students in intervention and control schools was undertaken to determine the effectiveness of the

intervention using generalized linear mixed models (binomial distribution with a logit link). All models included a fixed effect for treatment group (intervention versus control) and a random effect for each school to account for clustering of responses within schools. Models were adjusted for *a priori* selected prognostic variables (age, gender, school type, school size, Aboriginal/Torres Strait Islander status, ethnicity, non-English speaking background, socio-economic status) and odd ratios with 95% Wald confidence intervals calculated. Intra-class correlations were estimated on the logistic scale using the methods described in Eldridge et al.[70]

Sensitivity analyses were undertaken using intention-to-treat principles, where multiple imputation was used to assess the sensitivity of results to missing data under the missing at random (MAR) assumption[71] from students that were lost to follow up or changed schools during the intervention period. The method of chained regression equations was used, imputing 10 data sets separately by treatment group, and pooling the results using Rubin's method.[72]

Student individual and environmental protective factor scores

Student protective factor subscale scores were calculated by averaging the responses to all items in each subscale. Aggregate individual and environmental protective factor scores were calculated by averaging all relevant subscale scores for each student.[53] Scores ranged from 1 to 4, with higher scores more favourable.

Linear mixed models were used to assess the effectiveness of the intervention for the aggregate individual and environmental protective factor scores at follow up. The models included a fixed effect for treatment group (intervention vs control) and a random effect for school to account for clustering of responses within schools. Models were adjusted for the same prognostic variables as per the substance use models. Intra class correlation was estimated as the proportion of the total variance that is due to between cluster variance.

Implementation of strategies targeting protective factors

Descriptive statistics summarised the number of intervention schools implementing each of the 16 broad intervention strategies that targeted protective factors as identified via project records (Intervention Years 1-3). Chi-square and t test analyses examined whether intervention and control schools differed with respect to their reported implementation of protective factor strategies in the final year of intervention.

A criterion for statistical significance of $p \leq 0.05$ was used. All analyses were undertaken using SAS Software Version 9.4.[73]

RESULTS

Sample

Schools

Forty-four of the 47 eligible schools were approached prior to achieving the quota of 32 schools (73% consent rate) (see figure 1). Participating schools included 28 government and four Catholic schools. Of the 32 schools, 21 were medium and 11 were large sized schools. No schools withdrew following allocation.

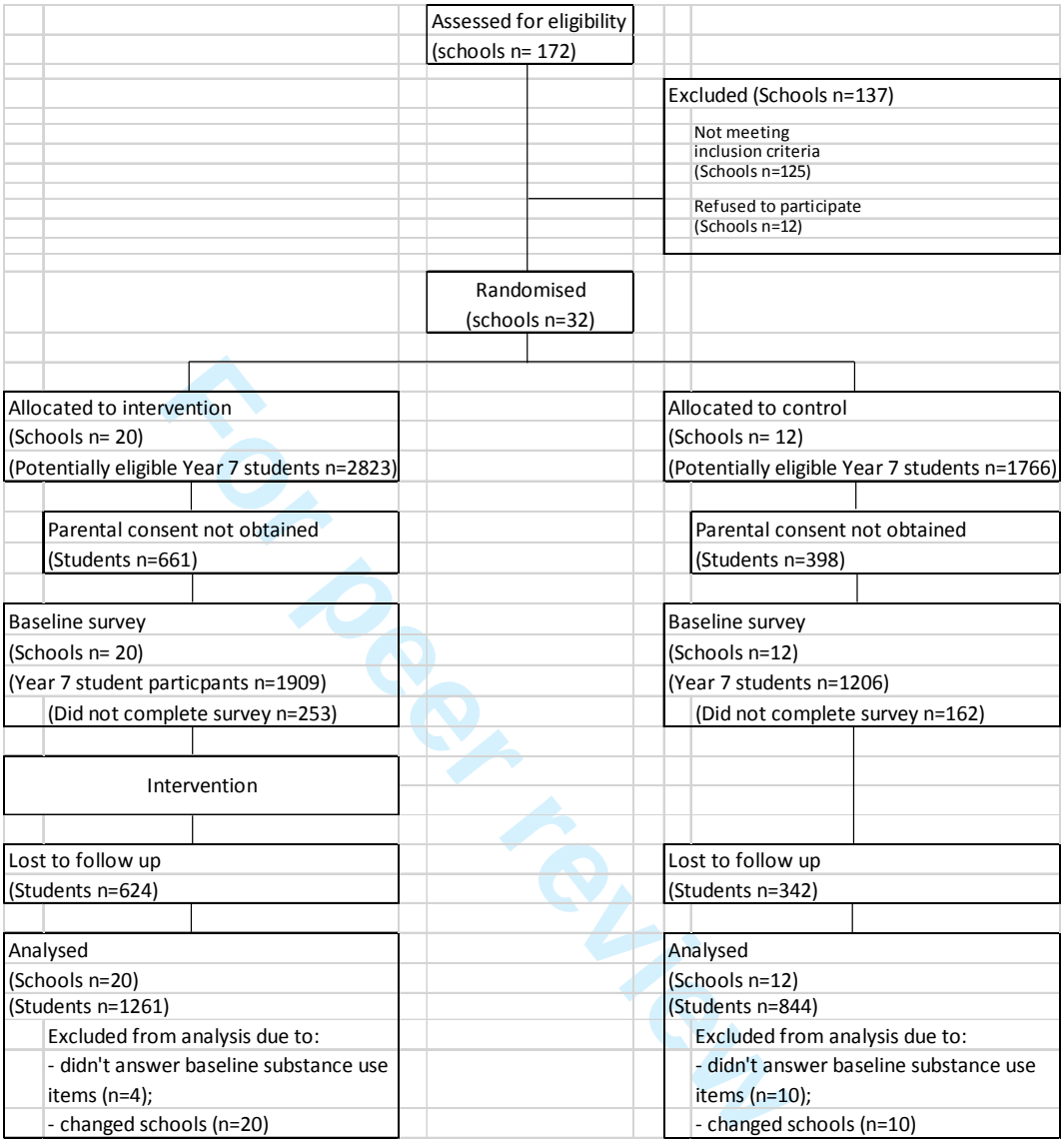

Figure 1. Study flow diagram

Students

At baseline, parental consent was provided for 3530 Grade 7 students (76.9% of enrolled students), of which 3115 students participated in the baseline survey (67.9% of enrolled students; 88.2% of students with parental consent). Follow up data were collected from 2,149 of the students who completed the baseline survey (retention rate 69.0%; intervention 67.3%, control 71.6%) with no differential loss to follow up between intervention and control groups (p=0.1). Reasons for lost to follow up included: students no longer attending school (n=652; 65.5%), absent from school on

follow up survey days (n=207; 20.8%), or unknown reason for currently enrolled students (n=137;13.8%). Students who moved between schools (n=30) and those who participated but did not answer substance use items at baseline (n=14) were excluded resulting in a cohort of 2,105 students for the primary analysis. All 3115 students who completed the baseline survey were included in sensitivity analyses.

The demographic characteristics of students who completed the baseline survey are shown in Table 2. Students who were lost to follow up compared to those who completed both baseline and follow up surveys (the cohort) were more likely to: report use for each substance use measure (tobacco: ever 17.9% v 8.1% $p<0.01$, recent 4.1% v 1.4% $p<.001$; alcohol: ever 37.6% v 26.8% $p<0.01$, recent 8.8% v 4.2% p<.001, 'risky' 8.6% v 3.7% $p<.001$; marijuana: 2.6% v 1% $p=.003$; other illicit substances: 2.0% v 0.6% $p=.003$), and have lower mean individual (2.92 v 3.04 $p<.001$) and environmental protective factor scores (2.88 v 2.98 $p<.001$). Students who were lost to follow up were also more likely to be Aboriginal and/or Torres Strait Islander (18.1% v 10.2%, $p<.001$). There was no difference for any other demographic characteristics.

Table 2. Student demographics, substance use and protective factor characteristics of students participating in baseline survey by group (N=3115)

Student characteristics	Intervention n (%)	Control n (%)
Total students	1909	1206
Male	950 (49.8)	607 (50.3)
Age (mean (SD))	12.6 (0.53)	12.6 (0.53)
Aboriginal and/or Torres Strait Islander*	245 (12.8)	151 (12.6)
Socioeconomic status**		
Low (<990)	1062 (55.6)	718 (59.5)
High (≥990)	847 (44.4)	488 (40.5)
Remoteness (ARIA)**		
Major Cities	744 (39.1)	567 (47.1)
Inner Regional	565 (29.7)	387 (32.1)

Outer Regional/Remote	594 (31.2)	250 (20.8)
Ethnicity		
Other ethnic, cultural or national origin	235 (12.3)	95 (7.9)
Non-English speaking background		
Speak language other than English	119 (6.2)	57 (4.7)
Substance use		
Tobacco use – ever	221 (11.7)	124 (10.5)
Tobacco use – recent	49 (2.6)	21 (1.8)
Alcohol use - ever	615 (32.5)	316 (26.7)
Alcohol use - recent	121 (6.4)	53 (4.5)
Alcohol use – 'risky'	111 (5.9)	50 (4.2)
Marijuana use	34 (1.8)	12 (1.0)
Other illicit substance use	23 (1.2)	8 (0.7)
Protective factor score		
Individual factors (mean (SD))	2.99 (0.48)	3.03 (0.45)
Environmental factors (mean (SD))	2.93 (0.56)	2.96 (0.55)

*Missing for 4 students; **SES and remoteness could not be calculated 5 students postcode missing (4 intv, 1 control)

Substance use

Table 2 shows the proportion of students reporting substance use at baseline. There was no difference between intervention and control students for any measure of substance use at follow up (Table 3), with the same result for intention-to-treat sensitivity analyses (see Appendix B).

Table 3. Intervention versus control group comparisons at follow up (N=2105)

Outcome	Intra class correlations	Intervention group N=1,261	Control group N=844	Intervention v control	
Primary outcomes					
Substance use		n (%)	n (%)	OR (95% CI)	*P*
Tobacco use - ever[a]	0.0182	406 (32.5)	235 (27.9)	1.25 (0.92, 1.68)	.14
Tobacco use - recent[a]	0.0280	148 (11.8)	75 (8.9)	1.48 (0.93, 2.37)	.09
Alcohol use - ever[b]	0.0105	770 (61.8)	494 (58.7)	1.11 (0.83,1.48)	.46
Alcohol use – recent[c]	0.0149	261 (20.9)	156 (18.6)	1.10 (0.77, 1.56)	.60
Alcohol use – 'risky'[d]	0.0152	293 (23.6)	196 (23.4)	1.03 (0.74,1.43)	.86
Secondary outcomes					
Substance use					
Marijuana use[e]	0.0163	193 (15.6)	115 (13.7)	1.18 (0.80,1.72)	.39
Other illicit substance use[e]	0.0368	85 (6.9)	47 (5.6)	1.42 (0.85,2.38)	.23
Protective factor score		Mean (SD)	Mean (SD)	Mean diff (95% CI)	*P*
Individual[g]	0.0011	3.02 (0.48)	3.01 (0.49)	-0.01 (-0.07,0.06)	.87
Environmental[g]	0.0010	2.77 (0.61)	2.76 (0.62)	-0.02 (-0.09,0.06)	.67

[a] 13 missing, [b] 18 missing, [c] 23 missing, [d] 25 missing, [e] 29 missing, [f] 7 missing, [g] 4 missing

Student individual and environmental protective factors

Baseline mean individual and environmental protective factor scores are shown in Table 2. At follow up there was no difference in mean individual or environmental aggregate protective factor scores between intervention and control students (Table 3). Similarly, there was no difference between

intervention and control students in mean scores for any of the individual or environmental protective factor subscales (see Appendix C).

School implementation of strategies targeting protective factors

Review of project records across all three years of the intervention identified 12 of the 20 intervention schools were recorded to have implemented programs or resources in each of the 16 strategy areas every year (see Appendix D for examples of strategies that intervention schools implemented). In each year of the study either 18 or 19 of the 20 intervention schools were recorded to have implemented programs or resources in each of the strategy areas.

A total of 232 of the 256 (91%) school staff completed the telephone survey regarding intervention implementation in the final year of the intervention. Comparison of intervention and control schools reported implementation of intervention strategies in the final year of intervention showed intervention schools were more likely than control schools to have incorporated nine hours of protective factor instruction across at least two school subjects across Grade 7 to 10 (intervention 88% v control 36%, $p<.01$), but not in Grade 10 alone (intervention 88% v control 55%, $p=0.08$) (Appendix E). A higher proportion of Head Teachers at intervention schools reported using resilience resources within curriculum in any Grade than control schools (75% and 49% respectively, $p<0.01$) and the mean number of resilience resources implemented outside of the classroom was higher in intervention compared with control schools (3.1 and 1.2 respectively, $p<0.01$). There were no significant differences between intervention and control schools in the reported implementation of the other 15 strategies (Appendix E). Between 73% and 84% of intervention school staff reported being moderately or very engaged in the final year of the intervention (Aboriginal contact 73.7% (14/19); Deputy 84.2% (16/19); Head Teacher Welfare 83.3% (15/18); Head Teachers Key Learning Areas 76.4% (68/89).

DISCUSSION

This study sought to test the effectiveness of an intervention delivered by schools on a universal basis that focused on enhancing student individual and environmental 'resilience' protective factors as a means of reducing the prevalence of adolescent tobacco, alcohol and illicit substance use. At follow-up, there was no difference in the prevalence of any measure of substance use between intervention and control students, nor was there any difference for aggregate or individual measure of individual and environmental protective factors.

The findings are broadly consistent with evidence from the only other randomised controlled trial of a school-based universal intervention focused solely on promoting the individual and environmental protective factors of adolescent students as a means of reducing substance use.[43] The intervention in that study was similar to that in the current study in terms of: its pragmatic nature; timing (from Grade 8 onwards); duration (3 years); delivery by school staff; strategies (curriculum and school environment); and environmental protective factor content (addressing relationships and meaningful participation at school). However its content differed in terms of a more limited focus on individual protective factors than the current study.[43] Despite promising findings mid-intervention for tobacco use favouring an intervention effect, at follow up the study similarly found no effect of the intervention on tobacco, alcohol or illicit substance use. Additionally, no effect was found for the protective factors measured (school engagement and social relationships), with authors citing insufficient specific intervention content in these areas as a possible explanation.[43]

The hypothesised mechanism of effect for the current study was based on association evidence that an inverse relationship existed between protective factors and substance use.[22-34, 74] As the intervention was ineffective in improving such factors it remains unknown whether the enhancement of such factors can lead to a reduction in the prevalence of adolescent substance use.

Various aspects of the intervention design may have contributed to the null finding for protective factors. First, the universal nature of the intervention without a targeted intervention for students with

lower protective factor scores or with other substance use risk factors may have limited its ability to have a measurable impact. Whilst there is conflicting evidence regarding whether universal, selective or targeted interventions are more effective in reducing substance use,[75-78] the positive findings of one cluster-randomised controlled study undertaken in 43 schools in Hong Kong suggest that an intervention combining both a universal and a targeted approach may be effective. The study reported a positive effect for eight of fourteen targeted protective factors, as well as a reduction in illegal substance use.[79]

Second, the use of a pragmatic intervention approach allowing school staff to select the type, manner and order of implementation of curriculum resources and programs may have contributed to the null study findings as such an intervention approach has been reported to be less likely to be effective than non-pragmatic approaches.[80, 81] Although pragmatic intervention approaches are intended to optimise translation into practice, the potential exists for a loss of intervention integrity and fidelity and hence effectiveness to occur through local adaption.[82, 83]

Third, the use of programs and resources that were also accessible to control schools may have contributed to the null findings due to a lack of differential intervention exposure between groups. The likelihood of such an explanation is heightened by the finding of similar strategy implementation levels in both groups at follow up, with the exception of curriculum-focussed strategies.

Fourth, similar to the conclusion of the Bond study,[43] the duration of the intervention may have been insufficient to impact on student protective factors. As the full intervention was implemented over two years (only two of 16 strategies were delivered in Year 1) the intervention may not have had sufficient time to impact on student protective factors. This possibility is supported by findings from other school-based substance use prevention studies that suggest interventions delivered over 3-4 years rather than 1-2 years may be more effective.[84] Such a conclusion is also supported by a World Health Organisation review of evidence regarding the Health Promoting Schools approach that found interventions of longer duration across a range of outcomes were more effective.[85]

Finally, two additional key design factors that may have limited the intervention effect were the intervention's focus on protective factors only, with no content addressing known risk factors of substance use (such as peer or familial substance use[86]), and a limited focus on family and community-based protective factors (such as caring parental relationships and meaningful community participation), both of which have been reported to be predictors of substance use.[87]

Major strengths of this study included the cluster-randomised controlled study design, the use of implementation support strategies and the large sample size. Although the study found, as for school-based research generally,[88] a high rate of student attrition (31%), such attrition did not differ between treatment groups and had little impact on the estimated power of the study (difference of 0.3-0.4%).

Given the significant policy and practice investment in intervention approaches that seek to enhance student protective factors as a means of reducing adolescent substance use, further research is warranted to investigate the effectiveness of this intervention approach. Similarly, further research is warranted regarding whether universal interventions targeting such factors can be effective when augmented with a targeted intervention component either for those students at elevated risk (i.e. selective) or those who have already initiated substance use (i.e. indicated). Similarly, further research is required to identify intervention approaches that are both capable of being scaled-up to be delivered as part of routine school practice across large populations of secondary schools, and efficacious in reducing adolescent substance use.

AUTHOR CONTRIBUTIONS

RKH conducted the literature search, drafted the manuscript and contributed to study design, data collection, data analysis, data interpretation, and coordination of the study. JW, MF, JB, LW and EC helped draft the manuscript and participated in the conception, design and coordination of the study. JD helped draft the manuscript and participated in the coordination of the study. CL, CO and JA

helped draft the manuscript and conducted data analysis. All authors read and revised the manuscript critically for intellectual content, and approved the final manuscript.

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COMPETING INTERESTS STATEMENT

We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

DATA SHARING STATEMENT

Requests for additional unpublished data should be forwarded to Rebecca.hodder@hnehealth.nsw.gov.au

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APPENDICES

Appendix A: Primary and secondary outcome measures

	Survey item	Response options
Primary outcomes:		
Tobacco use – ever	Have you ever smoked even part of a cigarette? [9]	Yes/No
Tobacco use – recent	Have you smoked a cigarette in the last week? If yes, starting from yesterday please record the number of cigarettes that you smoked on each day of last week[9]	Yes/No 0-99
Alcohol use - ever	Have you ever had a drink of alcohol? E.g. beer, wine or alcopops/pre-mix drinks (do not count sips or tastes)	Yes/No
Alcohol use – recent	Have you had any alcoholic drinks, such as beer, wine or alcopops/pre-mix drinks in the last week? (do not count sips or tastes) If yes, starting from yesterday please record the number of alcoholic drinks that you had on each day of last week[9]	Yes/No 0-99
Alcohol use - 'risky'	In the last 4 weeks, how many times have you had 5 or more alcoholic drinks in a row? [9]	None/Once/Twice/3-6 times/7 or more times
Secondary outcomes:		
Marijuana use	How many times in the last four weeks have you smoked or used marijuana/cannabis (grass, hash, dope, weed, mull, yarndi, ganga, pot, a bong, a joint) [9]	None/Once or twice/3-5 times/6-9 times/10-19 times/20-39 times/40 or more times
Other illicit substance use	How many times in the last four weeks have you used any other illegal drug or pill to get "high", such as inhalants, hallucinogens (eg LSD, acid, trips), amphetamines (eg. speed, ice), ecstasy, cocaine or heroin?	None/Once or twice/3-5 times/6-9 times/10-19 times/20-39 times/40 or more times
Individual protective factors[53]	Cooperation and communication subscale: 2 items; e.g. "I enjoy working together with other students my age"	1: Never true, 2: True some of the time; 3: True most of the time; 4: True all of the time
	Self-efficacy subscale: 4 items; e.g. "I can do most things if I try"	As above
	Empathy subscale: 3 items; e.g. "I try to understand what other people feel and think"	As above
	Problem solving subscale: 3 items; e.g. "When I need help I find someone to talk with"	As above
	Self-awareness subscale: 3 items; e.g. "I understand why I do what I do"	As above
	Goals and aspirations subscale: 3 items; e.g. "I have	As above

	goals and plans for the future"	
Environmental protective factors[53]	School support subscale: 6 items; e.g. "At my school there is an adult who really cares about me"	As above
	School meaningful participation subscale: 3 items; e.g. "At my school, I help decide things like class activities or rules"	As above
	Peer caring relationships subscale: 3 items; e.g. "I have a friend who helps me when I'm having a hard time"	As above

Appendix B: Multiple imputation results (n=3,115)

Outcome	Intervention v control	
Primary outcomes		
Substance use	OR (95% CI)	*P*
Tobacco use - ever	1.11 (0.91, 1.35)	.31
Tobacco use - recent	1.20 (0.89, 1.62)	.23
Alcohol use – ever	1.07 (0.89, 1.27)	.48
Alcohol use – recent	1.07 (0.85, 1.34)	.55
Alcohol use – 'risky'	1.03 (0.82, 1.30)	.81
Secondary outcomes		
Substance use		
Marijuana use	1.12 (0.78, 1.62)	.52
Other illicit substance use	1.27 (0.81, 2.00)	.29

Appendix C: Protective factor subscale results

Outcome	Control group N=844 Mean (SD)	Intervention group N=1,261 Mean (SD)	Intervention v control OR (95% CI)	*P*
Individual protective factor scores				
Cooperation and communication	2.94 (0.68)	2.94 (0.70)	0.01 (-0.08,0.10)	.78
Empathy	3.09 (0.71)	3.09 (0.74)	0.00 (-0.09,0.09)	.97
Goals and aspirations	3.29 (0.67)	3.29 (0.69)	0.00 (-0.10,0.10)	.96
Problem solving	2.73 (0.74)	2.75 (0.73)	0.03 (-0.05,0.11)	.51
Self-awareness	3.02 (0.76)	2.96 (0.75)	-0.05 (-0.13,0.04)	.31
Self-efficacy	3.06 (0.54)	3.03 (0.58)	-0.03 (-0.09,0.04)	.44
Environmental protective factor scores				
School support	2.79 (0.77)	2.79 (0.78)	-0.01 (-0.11,0.08)	.80
Meaningful school participation	2.26 (0.72)	2.23 (0.76)	-0.04 (-0.12,0.05)	.36
Peer caring relationships	3.25 (0.83)	3.25 (0.84)	0.00 (-0.09,0.09)	.99

Appendix D. Examples of strategies that schools implemented to address the intervention strategies

Intervention strategies by Health Promoting Schools domain	Examples of specific programs implemented in intervention sc
Curriculum, teaching and learning	
1. Age-appropriate lessons (9 hours) on individual protective factors across school subjects	MindMatters;[89] SenseAbility;[91] school-developed curricul activities within 'Overcoming Adversity' unit and resilience bo
2. Non-curriculum programs (9 hours) targeting protective factors	The Resourceful Adolescent Program;[90] SenseAbility;[91] res random acts of kindness week.
3. Additional program targeting protective factors for Aboriginal students	Feeling Deadly Not Shame;[92] engagement with Clontarf;[93 Aboriginal yarning groups; Stronger, Smarter program.[95]
Ethos and environment	
4. Rewards and recognition program	Formal acknowledgements of student contribution to the schoo achievements; encouragement of student input in recognition p empowerment awards.
5. Peer support/peer mentoring programs	Peer mentoring; peer tutoring/support; peer mediation; positive bonding camps; Rock and Water.[96]
6. Anti-bullying programs	Buddy schemes; positive bystander programs; positive peer pro RUOK Day); cyberbullying programs (e.g. Cyberia[97]); safe a environment (e.g. Bullying No Way[98]); Project RockIt.[99]
7. Empowerment/leadership programs	Duke of Edinburgh International Awards Youth Program;[100 program.[101]
8. Additional empowerment/leadership/mentoring programs for Aboriginal students	Outdoor learning space and Yarn space for Aboriginal students Cultural Centre[102] to participate in cultural talks and learn ab culture; Dare to Lead Program;[103] Junior AECG.
9. Aboriginal cultural awareness strategies	Aboriginal cultural art project (e.g. Aboriginal mural in school assembly; Connect to Country; display of Acknowledgement o
Partnerships and services	
10. Promotion/engagement of local community organisations/groups/clubs in school (e.g. charity organizations)	Focus on increasing quality and sustainability of partnerships, a communication strategy between schools and external partners sports clubs, Lions and Rotary Clubs, Samaritans, Red Cross).
11. Additional/enhanced consultation activities with Aboriginal community groups	Enhanced consultation activities with Aboriginal Health and A teacher nights held at local Aboriginal Medical Services); Abo partnerships.
12. Promotion/engagement of health, community and youth services in the school	Presentations by Black Dog Institute; promotion of Headspace; officer; Royal Life Saving NSW; the University of Newcastle.
13. Additional/enhanced Aboriginal community organizations promoted or engaged	School presence at local Aboriginal Education Consultative Gr engagement with the Polly Farmer Foundation.
14. Referral pathways to health, community and youth services developed and promoted	Schools websites and newsletters promoted links to various sch Counselling, Year Advisors, School Chaplain, Aboriginal Stud community and youth services (e.g. Kids Helpline, Headspace)
15. Strategies to increase parental involvement in	Parent mentors; expert seminars for parents and school staff on

school (e.g. school events)	people; parent community groups promoted in newsletter.
16. Information regarding student protective factors provided to parents via school newsletter	Newsletters sent home defining resilience protective factors an home; provision of information via school website.

Appendix E. Intervention versus control group implementation of strategies targeting protective factor in the final year of intervention

Intervention strategies by Health Promoting Schools domain	Outcome definition	Interv gr N= % (
Curriculum, teaching and learning		
1. Age-appropriate lessons on individual protective factors across school subjects	≥9hrs classroom resilience instruction across more than 1 KLA (Year 10)*	88.2 (
	≥9hrs classroom resilience instruction across more than 1 KLA (Year 7-10)*	88.2 (
	Head Teachers using any resilience resource in curriculum (including MindMatters and SenseAbility)*	75.3 (
	Head Teachers using MindMatters in curriculum*	42.7 (
	Head Teachers using SenseAbility in curriculum*	13.5 (
2. Non-curriculum programs targeting protective factors	≥9hrs non-classroom resilience instruction (Year 10)**	87.5 (
	At least one resilience program/resource used outside of curriculum**	88.9 (
	Most used resource: MindMatters**	61.1 (
	Number of programs used (Mean (SD)) (Intervention n=18; control n=11)**	3.1 (
3. Additional program targeting protective factors for Aboriginal students	≥9hrs non-classroom resilience instruction (Year 10 Aboriginal students)***	86.7 (
Ethos and environment		
4. Rewards and recognition program	At least one whole school rewards/recognition program****	100 (
5. Peer support/peer mentoring programs	At least one peer support**** (either peer support or buddy program/peer mentoring across all kids in any Year group)	77.8 (
6. Anti-bullying programs	At least one whole school anti-bullying initiative/program****	100 (
7. Empowerment/leadership programs	At least one peer leadership training or one program that students were active participants in all levels of planning and decision making across all kids in any Year group****	83.3 (
8. Additional empowerment/leadership/mentoring programs for Aboriginal students	At least one additional program (peer support, peer leadership, peer mentoring or program that students were active participants in all levels of planning and decision making across) in any Year group for Aboriginal	89.5 (

	students)***	
9. Aboriginal cultural awareness strategies (Examples: Aboriginal cultural art project	At least one cultural awareness strategy for non-Aboriginal students/staff across whole school***	89.5 (
Partnerships and services		
10. Promotion/engagement of local community organisations/groups/clubs in school	Partnership[a] with at least 3 community organizations**	33.4
11. Additional/enhanced consultation activities with Aboriginal community groups	Consultation in the development/running of Aboriginal cultural awareness strategies for non-Aboriginal staff/students)**	84.2 (
12. Promotion/engagement of health, community and youth services in the school	Partnership[a] with at least one health/community services**	61.1 (
13. Additional/enhanced Aboriginal community organizations promoted or engaged	Partnership[a] with at least one Aboriginal local community organization***	36.8
14. Referral pathways to health, community and youth services developed and promoted	Promotion of any health or community services at school**	100 (
15. Strategies to increase parental involvement in school	Implementation of at least 1 parent engagement strategy**	94.4 (
16. Information regarding student protective factors provided to parents via school newsletter	Provided information to parents at least once a term regarding enhancing student resilience****	64.7 (

*Informants were Head Teachers from 5 Key Learning Areas (KLAs);English, Maths, PDHPE, Science, HSIE. Schools with data from Head Teachers from 2 or more KLAs were included (n=17 intervention; n=11 control);
** Informants were Head Teachers Welfare;
*** Informants were designated Aboriginal contact persons for each school. For strategy 3, 9 respondents were excluded as they were unable to estimate hours;
**** Informants were Deputy Principals;
[a]Key informants (Head Teacher Welfare for strategy 10 and 12, and Aboriginal contact person for strategy 13) were asked to nominate up to 5 active partnerships with organisations or services. They were asked whether or not each partnership had a range of characteristics including: a formal agreement on services provided, consistency of the partnership with aims of the School Plan, regular meetings to review and evaluate partnership, service specifically tailored to community needs, multiyear endeavour.

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	2-3
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	4-5
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		**n/a**
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	6-7
	4b	Settings and locations where the data were collected		5-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	9-10

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		n/a
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	6
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	6

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		6
	11b	If relevant, description of the similarity of interventions		n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	11-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		11-12
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	13-14
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	13-14
Recruitment	14a	Dates defining the periods of recruitment and follow-up		9
	14b	Why the trial ended or was stopped		n/a
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	15-16

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	13-14,17
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	17
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		16, Appendix B
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		n/a
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		21
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		19-21
Other information				
Registration	23	Registration number and		1

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	22

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

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3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.

BMJ Open

Effectiveness of a pragmatic school-based universal resilience intervention in reducing tobacco, alcohol and illicit substance use in a population of adolescents: cluster-randomised controlled trial

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Title: Effectiveness of a pragmatic school-based universal resilience intervention in reducing tobacco, alcohol and illicit substance use in a population of adolescents: cluster-randomised controlled trial

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Word count: 4149

ABSTRACT

Objectives: Initiation of tobacco, alcohol and illicit substance use typically occurs during adolescence, with the school setting recommended to reduce adolescent substance use. Strengthening individual (e.g. problem solving) and environmental (e.g. caring relationships at school) resilience protective factors of adolescents has been suggested as a strategy for reducing substance use by adolescents, however few studies have examined this potential. A study was conducted to investigate the effectiveness of a pragmatic school-based universal 'resilience' intervention in reducing the prevalence of tobacco, alcohol and illicit substance use, and increasing the individual and environmental protective factors of students.

Design: A cluster-randomised controlled trial

Setting: Thirty-Two Australian secondary schools (20 intervention;12 control)

Participants: Cohort of Grade 7 students followed up in Grade 10 (2014; aged 15-16years).

Intervention: A pragmatic intervention involving school staff selection and implementation of available programs and resources targeting individual and environmental 'resilience' protective factors for all Grade 7-10 students was implemented in schools (2012-2014). School staff were provided implementation support. **Measurements:** An online survey collected baseline and follow up data for primary outcomes: tobacco (ever, recent) and alcohol (ever, recent, 'risk') use, and secondary outcomes: marijuana and other illicit substance use, and individual (six factor subscales, aggregate) and environmental (three factor subscales, aggregate) protective factor scores. Generalized and linear mixed models examined follow up differences between groups.

Results: Follow-up data from 2105 students (intervention=1261; control=844; 69% of baseline cohort) were analysed. No significant differences were found between intervention and control students for any primary (ever tobacco:OR 1.25,95%CI:0.92,1.68,*p*=0.14; recent tobacco:OR1.39,95%CI:0.84,2.31,*p*=0.19; recent ever alcohol:OR 1.11,95%CI:0.83,1.48,*p*=0.46; alcohol:OR1.13,95%CI:0.78,1.62,*p*=0.51; 'risk' alcohol:OR0.98,95%CI:0.70,1.36,*p*=0.89) or secondary outcomes (marijuana:OR1.12,95%CI:0.74,1.68,*p*=0.57; other illicit substance:OR1.19,95%CI:0.67,2.10,*p*=0.54; individual protective factors: MD=0,95%CI:-0.07,0.06,*p*=0.89; environmental protective factors: MD:-0.02,95%CI:-0.09,0.06,*p*=0.65).

Conclusions: The universally implemented pragmatic school-based intervention was not effective in reducing the prevalence of tobacco, alcohol or illicit substance use, or in increasing the protective factors of students.

Trial registration: Australia and New Zealand Clinical Trials Register reference: ACTRN12611000606987

ARTICLE SUMMARY

Strengths and limitations of this study

- This study represents a comprehensive examination using the gold standard study design for school-based studies to of the potential for a universal school-based resilience protective factor intervention in reducing the tobacco, alcohol and illicit substance use of adolescents.
- Major strengths of this study include: the cluster-randomised controlled study design, the large sample size of participating students, the collection of individual outcome data as well as process data to assess intervention implementation, and the use of statistical methods that both accounted for the clustering of student outcome data and sensitivity analyses of data via intention to treat principles including multiple imputation to account for missing data.
- Although the study found a high rate of student attrition (31%), such attrition is typical for school-based research, did not differ between treatment groups and had little impact on the estimated power of the study (difference of 0.3-0.4%).
- The study was reliant upon adolescent self-report of substance use and subject to the known limitations of self-report in this population. Whilst the planned validation of tobacco use by adolescents was not supported by schools, strategies were implemented to increase the validity of adolescent report including a web-based survey and confidential participation by students.

BACKGROUND

Tobacco, alcohol and illicit substance use are responsible for 9% of the global disease burden,[1] 12% of deaths world-wide,[2] and significant health and societal costs.[3-6] Initiation of tobacco, alcohol and illicit substance use in high income countries generally occurs during adolescence,[7-9] with earlier use associated with greater dependence in adulthood.[1] Whilst data from the United States and Australia show a declining trend in adolescent substance use [9, 10] a considerable proportion of adolescents (aged 11-17 years) continue to report such use; 23%-45% having smoked a cigarette, 43%-74% having consumed an alcoholic drink, and 7%-40% having used an illicit substance.[9-11]

Schools represent an opportune setting for interventions to prevent adolescent substance use as they provide access to large numbers of adolescents for prolonged periods, and have curricula and policies that seek to promote student health and wellbeing.[12, 13] As a consequence, substance use prevention interventions delivered to all students in a school or classroom regardless of risk (that is universal)[14] [15] are common and supported by governments world-wide to reduce the prevalence of adolescent substance use.[16-19] Despite policies recommending comprehensive approaches to substance use prevention address protective factors of substance use[17, 19-21] and 'resilience',[17, 19] such policies do not provide guidance regarding the specific factors or resilience strategies that should be targeted or the manner in which they should be addressed. Possibly as a result, it is reported that schools frequently develop their own programs [22], do not implement evidence-based programs or implement existing evidence-based programs [23] and make significant adaptations to cater for local contexts [24]. The extent to which such an approach can realise its intended benefits has not been reported.

Evidence from cross sectional studies suggests a range of individual factors including self-efficacy, problem solving, communication and self-awareness are protective of adolescent substance use; as has evidence regarding environmental factors such as caring relationships with adults and peers, and meaningful participation in home, school and community settings.[25-37] Such factors have similarly

been found to be protective of a person's 'resilience',[38-40] most broadly defined as the process of, capacity for, or outcome of successful adaptation in the context of risk or adversity.[40-42] Systematic reviews assessing the effectiveness of school-based universal intervention approaches in reducing adolescent substance use have not specifically examined the effectiveness of interventions that have focused solely on resilience or such protective factors.[43-45]

Whilst various studies have assessed the effectiveness of interventions that address resilience protective factors as a component of a broader intervention [46-64] or that combine universal and targeted prevention approaches [59, 60] only one controlled trial could be located assessing the effectiveness of a universal approach focused solely on resilience protective factors in reducing the prevalence of substance use in adolescent school students. The cluster-randomized controlled trial conducted in 26 Australian secondary schools investigated the effectiveness of a three year whole-of-school intervention delivered by schools (i.e. pragmatic) targeting a number of individual and environmental protective factors in preventing tobacco, alcohol and marijuana use in a cohort of students.[48] Outcomes were assessed at baseline, mid-intervention (after one year of intervention) and following intervention completion. Despite promising results mid-intervention for tobacco use, at follow up the confidence intervals for the adjusted odd ratios for tobacco, alcohol or marijuana use outcomes indicated a non-significant result.[47]

Given the limited evidence regarding the effectiveness of universal interventions promoting protective factors as a means of reducing adolescent student substance use, a cluster randomised controlled trial was conducted to determine the effectiveness of a secondary school staff-delivered pragmatic intervention targeting such protective factors in reducing the prevalence of tobacco and alcohol use (primary outcomes) and marijuana and illicit substance use, and in increasing individual and environmental protective factors (secondary outcomes).

METHODS

Study design and setting

A cluster randomised controlled trial was conducted in secondary schools in one health district of New South Wales, Australia. Outcome assessments were conducted with a cohort of students at baseline (when students were in Grade 7 - aged 12-13 years) and at follow-up (when students were in Grade 10). Approximately 114,000 people aged 10 to 19 years reside in metropolitan, regional, rural and remote areas within the district.[65, 66] Relevant ethics committee approvals were obtained (Hunter New England Health Ref:09/11/18/4.01; University of Newcastle Ref:H-2010-0029). Further study details have been reported elsewhere.[67]

Participants and recruitment

Schools

A national schools database[68] identified 172 schools with secondary enrolments within the study area. Schools were eligible if they: were a Government or Catholic secondary school located within a socioeconomically disadvantaged local government area,[69] had enrolments in Grades 7 to 10 (aged 12-16 years) and had more than 400 total student enrolments. Schools were ineligible if they were: single gender, independent (private), special needs, selective, central (for students aged 5-18 years) or boarding schools.

Randomisation of schools

Eligible schools were approached in random order until a quota of 32 schools consented. Consenting schools were stratified according to participation in a government disadvantaged schools initiative (yes/no)[70] and school size (medium 400-800/large >800), then randomly allocated to intervention or control in a 20:12 block design ratio by an independent statistician using a random number function in Microsoft Excel prior to baseline data collection.

Students

All students enrolled in Grade 7 (first year at secondary school) were eligible to participate in data collection and active parental consent for student participation was sought via a mailed study information pack. A free call number was provided for parents who wished to decline. After two

weeks, non-responding parents were prompted via telephone by school-affiliated staff who were blind to group allocation.

School staff

Selected school staff (deputy principal, head teachers for student welfare and five key subject areas, and the Aboriginal Education Coordinator or other Aboriginal staff member) at each intervention and control school were invited to participate in data collection at follow up.

Intervention

A three-year universal ('whole of school') intervention was delivered to all students in Grades 8 to 10. The intervention, based on a pilot study,[71] involved 16 broad strategies (see Table 1) seeking to build the protective factors of students implemented across the three domains of the Health Promoting Schools framework (Table 1).[72] Each of the 16 broad strategies addressed one or more individual (self-efficacy, problem solving, cooperation/communication, self-awareness, empathy, goals/aspirations) or environmental protective factors (school support, school meaningful participation, community support, community meaningful participation, home support, home meaningful participation, peer caring relationships, pro-social peers). Such protective factors have been found to be correlated with adolescent substance use [73] and align with a 'resilience' approach.[38-40, 74]

A pragmatic intervention approach [75] that involved intervention delivery by school staff as a component of routine school practice was adopted to approximate intervention delivery under 'real world' conditions [75]. Schools were provided with details of existing resources and programs addressing the 16 broad strategy areas from which they could choose to implement. Whilst schools were required to implement programs and resources that addressed each of the 16 broad strategies, they had the flexibility to select which specific program or resource to implement, and the order and manner in which they were implemented. This approach is similar to approaches adopted by previous

substance use prevention studies [59, 60, 62], with the exception that selected programs and resources were not required to have been rigorously evaluated.

Table 1. Intervention and implementation support strategies

Intervention strategies by Health Promoting Schools domain

Curriculum, teaching and learning

1. Age-appropriate lessons (9 hours) on individual protective factors across school subjects (e.g. MindMatters[108] or school-developed curriculum resources) [I,a]
2. Non-curriculum programs (9 hours) targeting protective factors (e.g. the Resourceful Adolescent Program)[109] [I,E]
3. Additional program targeting protective factors for Aboriginal students [I,E, a]

Ethos and environment

4. Rewards and recognition program [I,E]
5. Peer support/peer mentoring programs [I,E]
6. Anti-bullying programs [I,E]
7. Empowerment/leadership programs [I,E]
8. Additional empowerment/leadership/mentoring programs for Aboriginal students [I,E,a]
9. Aboriginal cultural awareness strategies [I,.E,a]

Partnerships and services

10. Promotion/engagement of local community organisations/groups/clubs in school (e.g. charity organizations) [E,a]
11. Additional/enhanced consultation activities with Aboriginal community groups [I,E,d]
12. Promotion/engagement of health, community and youth services in the school [I,E,a]
13. Additional/enhanced Aboriginal community organizations promoted or engaged [I,E,d]
14. Referral pathways to health, community and youth services developed and promoted [I,E,a]
15. Strategies to increase parental involvement in school (e.g. school events) [E,a]
16. Information regarding student protective factors provided to parents via school newsletter [I,E,a]

Implementation support strategies

1. Engagement with school community including presentations at school staff meetings regarding planned intervention [b]
2. Embedded staff support:
    - School intervention officer one day a week to support program implementation
    - Project coordinator to liaise with school sectors and support school intervention officers [c]
3. School intervention team formed (new team or re-alignment of existing team, inclusive of school intervention officer and school executive member) to implement intervention
4. Structured planning process to prioritize and select appropriate resources/programs:
    - Needs assessment of student protective factors (when study sample in Grade 7 and 9)
    - Two school community planning workshops and one strategy review workshop [c]
    - School plan to address intervention strategies endorsed by the school executive
5. Intervention implementation guide that described the intervention, planning process, available resources and programs, tools and templates for intervention implementation.
6. Staff mental health training (minimum of one hour per school during staff meetings)
7. AUD $2,000 per year each for:
    - Teacher release time for intervention implementation or professional development
    - Strategies specifically for Aboriginal students [a]
8. Feedback reports regarding student substance use and protective factors, and intervention implementation (termly) [c]
9. An Aboriginal Cultural Steering group was formed comprising of Aboriginal staff from local Aboriginal community organizations and Government Departments to provide Aboriginal cultural advice and direction regarding the study design, implementation, evaluation and dissemination

I To target individual protective factors; E To target environmental protective factors

[a] Implemented in Years 2 and 3 only; [b] Year 1 only; [c] Years 1 and 2 only; [d] Year 3 only
NB. Following publication of the study protocol[67] and based upon advice received from an Aboriginal Cultural Steering Group intervention strategies 3,8,11,13 were added.

To facilitate implementation of intervention strategies, programs and resources, schools were provided with a comprehensive range of support strategies, including an embedded psychology or education trained implementation support officer; strategies that have been previously reported to facilitate implementation of interventions (Table 1).[76-83]

Control schools implemented usual school curricula and policies which may have included protective factor strategies and resources similar to, or the same as, those systematically provided to the intervention schools, but were not provided with program resources or support. A report describing baseline school-level student substance use and protective factor characteristics was provided to control schools.

Data collection procedures

Student demographic and protective factor characteristics and substance use outcomes

Students completed a confidential web-based survey[84] in class time prior to intervention commencement (baseline: August-November 2011) and immediately following intervention completion (follow up: July-November 2014). Neither the school staff nor researchers were blind to group allocation.

Implementation of strategies targeting protective factors

To assess intervention implementation by intervention schools,[85] research staff reviewed school documents and recorded the delivery of intervention strategies monthly. In addition, at follow up, telephone-based structured interviews were conducted with staff from both groups by interviewers regarding school implementation of intervention strategies and engagement with the intervention during the final year of intervention, School staff from intervention schools were asked their level of engagement with the intervention in the final year.

Measures

Student demographic characteristics

The student survey addressed: age, gender, residential postcode, Aboriginal and/or Torres Strait Islander status, ethnicity, and non-English speaking background.

Student substance use

Substance use outcome data were collected using items from an ongoing Australian triennial survey of school students' health behaviours (Appendix A).[9] Primary outcomes included tobacco (ever and recent) alcohol (ever, recent and 'risky') use. Secondary outcomes included marijuana and other illicit substance use. Planned validation of student self-report of smoking via saliva-based cotinine testing[67, 86]' was not conducted due to school policies prohibiting drug testing.

Student individual and environmental protective factors

The Resilience and Youth Development module of the California Healthy Kids Survey was used to measure individual and environmental protective factors .[73] Items for all six individual and three of the environmental factor subscales were selected based on their congruence with the intervention (Appendix A). Aggregate individual and environmental protective factor scores were used as secondary outcome measures.

Consistent with a previous study of the survey,[73] analysis of baseline responses confirmed the subscales were internally consistent and valid (Cronbach alpha coefficients: individual 0.55-0.81; environmental 0.77-0.88). Confirmatory factor analysis[73] demonstrated the subscale factor structure to be a good model fit (comparative fit index 0.92, root mean square error of approximation 0.04).

Implementation of strategies targeting protective factors

The telephone survey of school staff assessed reported implementation of programs and resources in each of the 16 broad strategy areas (Table 1), and staff in during the final year of intervention.

Intervention school staff level of engagement was assessed by a single item (not at all/somewhat/moderately/very/unsure).

Sample size

Based on an assumed parental consent rate of 80%,[32, 87] and loss of students to follow-up from Grade 7 to Grade 10 of 25%, it was estimated the cohort would consist of 3,630 Grade 7 students (2,270 intervention, 1,360 control) and 2,720 Grade 10 students at follow up (1,700 intervention, 1,020 control). Assuming 80% power, a 5% significance level, an intra-cluster correlation of 0.01,[71] and Grade 10 control group prevalence of 14% for recent smoking, 36.2% for recent/risk alcohol use, 25% for marijuana use, and 9.3% for other illicit substance use,[88] the study was estimated to be able to detect an absolute reduction in prevalence of 4.8% for recent smoking, 7.0% for recent/risk alcohol use, 6.2% for marijuana use and 3.9% for illicit substance use in intervention compared to control students.

Statistical analysis

Student demographic characteristics

Student-reported residential postcode was used to calculate student socioeconomic status [69] and remoteness of residential location.[89] Characteristics of students (gender, Aboriginality, socioeconomic status, remoteness, baseline substance use and protective factor scores) completing both baseline and follow up surveys were compared to those lost to follow up by logistic regression accounting for potential clustering of students within schools.

Student substance use

Recent tobacco use was defined as having smoked at least one cigarette in the last week, and recent alcohol use as at least one alcoholic drink in the last week (yes/no). The response options for 'risky alcohol use' were dichotomised (either 'none', or 'once'/'twice'/'3-6 times'/'7 or more times'), as were the response options for both marijuana and other illicit substance use (either 'none', or 'once or twice'/'3-5 times'/'6-9 times'/'10-19 times'/'20-39 times'/'40 or more times').

Comparison between groups in the prevalence of substance use at follow up for the cohort Grade 10 students in intervention and control schools was undertaken to determine the effectiveness of the intervention using generalized linear mixed models (binomial distribution with a logit link; analysis as treated). All models included a fixed effect for treatment group (intervention versus control) and a random effect for each school to account for clustering of responses within schools. Models were adjusted for *a priori* selected prognostic variables (age, gender, school type, school size, Aboriginal/Torres Strait Islander status, ethnicity, non-English speaking background, socio-economic status) and odd ratios with 95% Wald confidence intervals calculated. Intra-class correlations were estimated on the logistic scale using the methods described in Eldridge et al.[90]

Sensitivity analyses were undertaken according to intention-to-treat principles, where multiple imputation was used to assess the sensitivity of results to missing data under the missing at random (MAR) assumption[91] from students that were lost to follow up or changed schools during the intervention period. The method of chained regression equations was used, imputing 10 data sets separately by treatment group and pooling the results using Rubin's method.[92] Specifically, we used the chained regression equations method of generating 10 complete datasets; logistic regression models were used for categorical (binomial, ordinal or multinomial) variables and linear regression models were used for continuous variables. The imputation model included all substance abuse outcomes, together with all variables that were in the analysis model and treatment group.

Student individual and environmental protective factor scores

Student protective factor subscale scores were calculated by averaging the responses to all items in each subscale. Aggregate individual and environmental protective factor scores were calculated by averaging all relevant subscale scores for each student.[73] Scores ranged from 1 to 4, with higher scores more favourable.

Linear mixed models were used to assess the effectiveness of the intervention for the aggregate individual and environmental protective factor scores at follow up. The models included a fixed effect for treatment group (intervention vs control) and a random effect for school to account for clustering of responses within schools. Models were adjusted for the same prognostic variables as per the substance use models. Intra class correlation was estimated as the proportion of the total variance that is due to between cluster variance.

Implementation of strategies targeting protective factors

Descriptive statistics summarised the number of intervention schools implementing each of the 16 broad intervention strategies that targeted protective factors as identified via project records (Intervention Years 1-3). Chi-square and t test analyses examined whether intervention and control schools differed with respect to their reported implementation of protective factor strategies in the final year of intervention.

A criterion for statistical significance of $p \leq 0.05$ was used. All analyses were undertaken by an independent statistician using SAS Software Version 9.4.[93]

RESULTS

Sample

Schools

Forty-four of the 47 eligible schools were approached prior to achieving the quota of 32 schools (73% consent rate) (see figure 1). Participating schools included 28 government and four Catholic schools. Of the 32 schools, 21 were medium and 11 were large sized schools. No schools withdrew following allocation.

Insert figure 1 here

Students

At baseline, parental consent was provided for 3530 Grade 7 students (76.9% of enrolled students), of which 3115 students participated in the baseline survey (67.9% of enrolled students; 88.2% of students with parental consent). Follow up data were collected from 2,149 of the students who completed the baseline survey (retention rate 69.0%; intervention 67.3%, control 71.6%) with no differential loss to follow up between intervention and control groups (p=0.1). Reasons for lost to follow up included: students no longer attending school (n=652; 65.5%), absent from school on follow up survey days (n=207; 20.8%), or unknown reason for currently enrolled students (n=137;13.8%). Students who moved between schools (n=30) and those who participated but did not answer substance use items at baseline (n=14) were excluded resulting in a cohort of 2,105 students for the primary analysis. All 3115 students who completed the baseline survey were included in sensitivity analyses.

The demographic characteristics of students who completed the baseline survey are shown in Table 2. Students who were lost to follow up compared to those who completed both baseline and follow up surveys (the cohort) were more likely to: report use for each substance use measure (tobacco: ever 17.9% v 8.1% p<0.01, recent 4.1% v 1.4% p<.001; alcohol: ever 37.6% v 26.8% p<0.01, recent 8.8% v 4.2% p<.001, 'risky' 8.6% v 3.7% p<.001; marijuana: 2.6% v 1% p=.003; other illicit substances: 2.0% v 0.6% p=.003), and have lower mean individual (2.92 v 3.04 p<.001) and environmental protective factor scores (2.88 v 2.98 p<.001). Students who were lost to follow up were also more likely to be Aboriginal and/or Torres Strait Islander (18.1% v 10.2%, p<.001). There was no difference for any other demographic characteristics.

Table 2. Student demographics, substance use and protective factor characteristics of students participating in baseline survey by group (N=3115)

Student characteristics	Intervention n (%)	Control n (%)
Total students	1909	1206

Male	950 (49.8)	607 (50.3)
Age (mean (SD))	12.6 (0.53)	12.6 (0.53)
Aboriginal and/or Torres Strait Islander*	245 (12.8)	151 (12.6)
Socioeconomic status**		
Low (<990)	1062 (55.6)	718 (59.5)
High (≥990)	847 (44.4)	488 (40.5)
Remoteness (ARIA)**		
Major Cities	744 (39.1)	567 (47.1)
Inner Regional	565 (29.7)	387 (32.1)
Outer Regional/Remote	594 (31.2)	250 (20.8)
Ethnicity		
Other ethnic, cultural or national origin	235 (12.3)	95 (7.9)
Non-English speaking background		
Speak language other than English	119 (6.2)	57 (4.7)
Substance use		
Tobacco use – ever	221 (11.7)	124 (10.5)
Tobacco use – recent	49 (2.6)	21 (1.8)
Alcohol use - ever	615 (32.5)	316 (26.7)
Alcohol use - recent	121 (6.4)	53 (4.5)
Alcohol use – 'risky'	111 (5.9)	50 (4.2)
Marijuana use	34 (1.8)	12 (1.0)
Other illicit substance use	23 (1.2)	8 (0.7)
Protective factor score		
Individual factors (mean (SD))	2.99 (0.48)	3.03 (0.45)
Environmental factors (mean (SD))	2.93 (0.56)	2.96 (0.55)

*Missing for 4 students; **SES and remoteness could not be calculated 5 students postcode missing (4 intv, 1 control)

Substance use

Table 2 shows the proportion of students reporting substance use at baseline. There was no difference between intervention and control students for any measure of substance use at follow up (Table 3), with the same result for intention-to-treat sensitivity analyses (see Appendix B).

Table 3. Intervention versus control group comparisons at follow up (N=2105)

Outcome	Intra class correlations	Intervention group N=1,261	Control group N=844	Intervention v control	
Primary outcomes					
Substance use		n (%)	n (%)	OR (95% CI)	*P*
Tobacco use - ever[a]	0.0182	406 (32.5)	235 (27.9)	1.25 (0.92, 1.68)	.14
Tobacco use - recent[a]	0.0280	148 (11.8)	75 (8.9)	1.48 (0.93, 2.37)	.09
Alcohol use - ever[b]	0.0105	770 (61.8)	494 (58.7)	1.11 (0.83,1.48)	.46
Alcohol use – recent[c]	0.0149	261 (20.9)	156 (18.6)	1.10 (0.77, 1.56)	.60
Alcohol use – 'risky'[d]	0.0152	293 (23.6)	196 (23.4)	1.03 (0.74,1.43)	.86
Secondary outcomes					
Substance use					
Marijuana use[e]	0.0163	193 (15.6)	115 (13.7)	1.18 (0.80,1.72)	.39
Other illicit substance use[e]	0.0368	85 (6.9)	47 (5.6)	1.42 (0.85,2.38)	.23
Protective factor score		Mean (SD)	Mean (SD)	Mean diff (95% CI)	*P*
Individual[g]	0.0011	3.02 (0.48)	3.01 (0.49)	-0.01 (-0.07,0.06)	.87
Environmental[g]	0.0010	2.77 (0.61)	2.76 (0.62)	-0.02 (-0.09,0.06)	.67

[a] 13 missing, [b] 18 missing, [c] 23 missing, [d] 25 missing, [e] 29 missing, [f] 7 missing, [g] 4 missing

Student individual and environmental protective factors

Baseline mean individual and environmental protective factor scores are shown in Table 2. At follow up there was no difference in mean individual or environmental aggregate protective factor scores between intervention and control students (Table 3). Similarly, there was no difference between

intervention and control students in mean scores for any of the individual or environmental protective factor subscales (see Appendix C).

School implementation of strategies targeting protective factors

Review of project records across all three years of the intervention identified 12 of the 20 intervention schools were recorded to have implemented programs or resources in each of the 16 strategy areas every year (see Appendix D for examples of strategies that intervention schools implemented). In each year of the study either 18 or 19 of the 20 intervention schools were recorded to have implemented programs or resources in each of the strategy areas.

A total of 232 of the 256 (91%) school staff completed the telephone survey regarding intervention implementation in the final year of the intervention. Comparison of intervention and control schools reported implementation of intervention strategies in the final year of intervention showed intervention schools were more likely than control schools to have incorporated nine hours of protective factor instruction across at least two school subjects across Grade 7 to 10 (intervention 88% v control 36%, $p<.01$), but not in Grade 10 alone (intervention 88% v control 55%, $p=0.08$) (Appendix E). A higher proportion of Head Teachers at intervention schools reported using resilience resources within curriculum in any Grade than control schools (75% and 49% respectively, $p<0.01$) and the mean number of resilience resources implemented outside of the classroom was higher in intervention compared with control schools (3.1 and 1.2 respectively, $p<0.01$). There were no significant differences between intervention and control schools in the reported implementation of the other 15 strategies (Appendix E). Between 73% and 84% of intervention school staff reported being moderately or very engaged in the final year of the intervention (Aboriginal contact 73.7% (14/19); Deputy 84.2% (16/19); Head Teacher Welfare 83.3% (15/18); Head Teachers Key Learning Areas 76.4% (68/89).

DISCUSSION

This study sought to test the effectiveness of a pragmatic intervention delivered by schools on a universal basis that focused on enhancing student individual and environmental 'resilience' protective factors as a means of reducing the prevalence of adolescent tobacco, alcohol and illicit substance use. At follow-up, there was no difference in the prevalence of any measure of substance use between intervention and control students, nor was there any difference for aggregate or individual measure of individual and environmental protective factors.

The findings were broadly consistent with evidence from the only other randomised controlled trial of a school-based universal intervention focused solely on promoting the individual and environmental protective factors of adolescent students as a means of reducing substance use.[48] The intervention in that study was similar to that in the current study in terms of: its pragmatic nature; timing (from Grade 8 onwards); duration (3 years); delivery by school staff; strategies (curriculum and school environment); and environmental protective factor content (addressing relationships and meaningful participation at school). However its content differed in terms of a more limited focus on individual protective factors than the current study.[48] Despite promising findings mid-intervention for tobacco use favouring an intervention effect, at follow up the study similarly found no effect of the intervention on tobacco, alcohol or illicit substance use. Additionally, no effect was found for the protective factors measured (school engagement and social relationships), with authors citing insufficient specific intervention content in these areas as a possible explanation.[48]

The hypothesised mechanism of effect for the current study was based on association evidence that an inverse relationship existed between protective factors and substance use.[25-37, 94] As the intervention was ineffective in improving such factors it remains unknown whether the enhancement of such factors can lead to a reduction in the prevalence of adolescent substance use.

Various aspects of the intervention design may have contributed to the null finding for protective factors. First, the universal nature of the intervention without a targeted intervention for students with lower protective factor scores or with other substance use risk factors may have limited its ability to

have a measurable impact. Whilst there is conflicting evidence regarding whether universal, selective or targeted interventions are more effective in reducing substance use,[95-98] the positive findings of one cluster-randomised controlled study undertaken in 43 schools in Hong Kong suggest that an intervention combining both a universal and a targeted approach may be effective. The study reported a positive effect for eight of fourteen targeted protective factors, as well as a reduction in illegal substance use.[60]

Second, the use of a pragmatic intervention approach allowing school staff to select the type, manner and order of implementation of curriculum resources and programs may have contributed to the null study findings as such an intervention approach has been reported to be less likely to be effective than non-pragmatic approaches.[99, 100] Although pragmatic intervention approaches are intended to optimise translation into practice, the potential exists for a loss of intervention efficacy, integrity and fidelity to occur through local selection and adaption of programs.[101, 102]Such findings suggest that the common practice of schools developing and adapting programs [22-24], an intervention approach assessed in this trial, may not realise the intended substance use reduction benefits.

Third, the use of programs and resources that were also accessible to control schools may have contributed to the null findings due to a lack of differential intervention exposure between groups. The likelihood of such an explanation is heightened by the finding of similar strategy implementation levels in both groups at follow up, with the exception of curriculum-focussed strategies. It is unclear whether contamination with respect to awareness of programs and resources between intervention and control schools was an issue as it was not specifically assessed, however the cluster-randomised design at least in part may have reduced this risk.

Fourth, similar to the conclusion of the Bond study,[48] the duration of the intervention may have been insufficient to impact on student protective factors. As the full intervention was implemented over two years (only two of 16 strategies were delivered in Year 1) the intervention may not have had sufficient time to impact on student protective factors. This possibility is supported by findings from

other school-based substance use prevention studies that suggest interventions delivered over 3-4 years rather than 1-2 years may be more effective.[103] Such a conclusion is also supported by a World Health Organisation review of evidence regarding the Health Promoting Schools approach that found interventions of longer duration across a range of outcomes were more effective.[104]

Finally, two additional key design factors that may have limited the intervention effect were the intervention's focus on protective factors only, with no content addressing known risk factors of substance use (such as peer or familial substance use[105]), and a limited focus on family and community-based protective factors (such as caring parental relationships and meaningful community participation), both of which have been reported to be predictors of substance use.[106]

Major strengths of this study included the cluster-randomised controlled study design, the use of implementation support strategies and the large sample size. Although the study found, as for school-based research generally,[107] a high rate of student attrition (31%), such attrition did not differ between treatment groups and had little impact on the estimated power of the study (difference of 0.3-0.4%).

Given the significant policy and practice investment in intervention approaches that seek to enhance student protective factors as a means of reducing adolescent substance use, further research is warranted to investigate the effectiveness of this intervention approach. Further research is also warranted regarding whether universal interventions targeting such factors can be effective when augmented with a targeted intervention component either for those students at elevated risk (i.e. selective) or those who have already initiated substance use (i.e. indicated). Similarly, further research is required to identify intervention approaches that are both capable of being scaled-up to be delivered as part of routine school practice across large populations of secondary schools, and efficacious in reducing adolescent substance use.

AUTHOR CONTRIBUTIONS

RKH conducted the literature search, drafted the manuscript and contributed to study design, data collection, data analysis, data interpretation, and coordination of the study. JW, MF, JB, LW and EC helped draft the manuscript and participated in the conception, design and coordination of the study. JD helped draft the manuscript and participated in the coordination of the study. CL, CO and JA helped draft the manuscript and conducted data analysis. All authors read and revised the manuscript critically for intellectual content, and approved the final manuscript.

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COMPETING INTERESTS STATEMENT

We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

DATA SHARING STATEMENT

Requests for additional unpublished data should be forwarded to

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FIGURES

Figure 1. Study flow diagram

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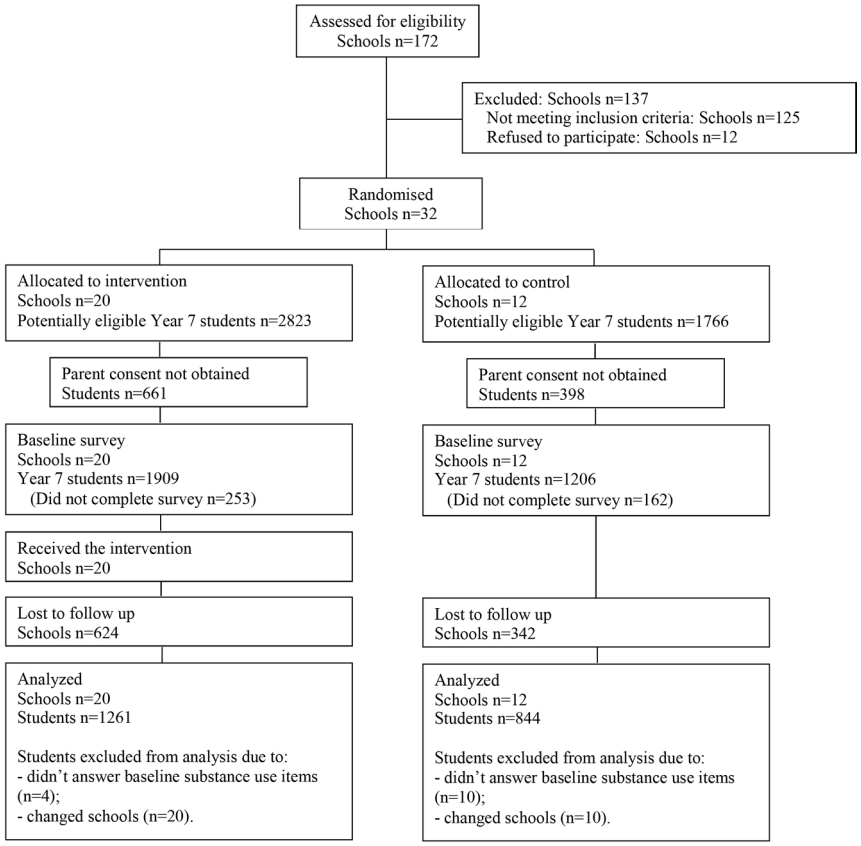

Figure 1. Study flow diagram

166x233mm (300 x 300 DPI)

APPENDICES

Appendix A: Primary and secondary outcome measures

	Survey item	Response options
Primary outcomes:		
Tobacco use – ever	Have you ever smoked even part of a cigarette? [9]	Yes/No
Tobacco use – recent	Have you smoked a cigarette in the last week? If yes, starting from yesterday please record the number of cigarettes that you smoked on each day of last week[9]	Yes/No 0-99
Alcohol use - ever	Have you ever had a drink of alcohol? E.g. beer, wine or alcopops/pre-mix drinks (do not count sips or tastes)	Yes/No
Alcohol use – recent	Have you had any alcoholic drinks, such as beer, wine or alcopops/pre-mix drinks in the last week? (do not count sips or tastes) If yes, starting from yesterday please record the number of alcoholic drinks that you had on each day of last week[9]	Yes/No 0-99
Alcohol use - 'risky'	In the last 4 weeks, how many times have you had 5 or more alcoholic drinks in a row? [9]	None/Once/Twice/3-6 times/7 or more times
Secondary outcomes:		
Marijuana use	How many times in the last four weeks have you smoked or used marijuana/cannabis (grass, hash, dope, weed, mull, yarndi, ganga, pot, a bong, a joint) [9]	None/Once or twice/3-5 times/6-9 times/10-19 times/20-39 times/40 or more times
Other illicit substance use	How many times in the last four weeks have you used any other illegal drug or pill to get "high", such as inhalants, hallucinogens (eg LSD, acid, trips), amphetamines (eg. speed, ice), ecstasy, cocaine or heroin?	None/Once or twice/3-5 times/6-9 times/10-19 times/20-39 times/40 or more times
Individual protective factors[73]	Cooperation and communication subscale: 2 items; e.g. "I enjoy working together with other students my age"	1: Never true, 2: True some of the time; 3: True most of the time; 4: True all of the time
	Self-efficacy subscale: 4 items; e.g. "I can do most things if I try"	As above
	Empathy subscale: 3 items; e.g. "I try to understand what other people feel and think"	As above

	Problem solving subscale: 3 items; e.g. “When I need help I find someone to talk with”	As above
	Self-awareness subscale: 3 items; e.g. “I understand why I do what I do”	As above
	Goals and aspirations subscale: 3 items; e.g. “I have goals and plans for the future”	As above
Environmental protective factors[73]	School support subscale: 6 items; e.g. “At my school there is an adult who really cares about me”	As above
	School meaningful participation subscale: 3 items; e.g. “At my school, I help decide things like class activities or rules”	As above
	Peer caring relationships subscale: 3 items; e.g. “I have a friend who helps me when I'm having a hard time”	As above

Appendix B: Multiple imputation results (n=3,115)

Outcome	Intervention v control	
Primary outcomes		
Substance use	OR (95% CI)	*P*
Tobacco use - ever	1.11 (0.91, 1.35)	.31
Tobacco use - recent	1.20 (0.89, 1.62)	.23
Alcohol use – ever	1.07 (0.89, 1.27)	.48
Alcohol use – recent	1.07 (0.85, 1.34)	.55
Alcohol use – 'risky'	1.03 (0.82, 1.30)	.81
Secondary outcomes		
Substance use		
Marijuana use	1.12 (0.78, 1.62)	.52
Other illicit substance use	1.27 (0.81, 2.00)	.29

Appendix C: Protective factor subscale results

Outcome	Control group N=844 Mean (SD)	Intervention group N=1,261 Mean (SD)	Intervention v control OR (95% CI)	*P*
Individual protective factor scores				
Cooperation and communication	2.94 (0.68)	2.94 (0.70)	0.01 (-0.08,0.10)	.78
Empathy	3.09 (0.71)	3.09 (0.74)	0.00 (-0.09,0.09)	.97
Goals and aspirations	3.29 (0.67)	3.29 (0.69)	0.00 (-0.10,0.10)	.96
Problem solving	2.73 (0.74)	2.75 (0.73)	0.03 (-0.05,0.11)	.51
Self-awareness	3.02 (0.76)	2.96 (0.75)	-0.05 (-0.13,0.04)	.31
Self-efficacy	3.06 (0.54)	3.03 (0.58)	-0.03 (-0.09,0.04)	.44
Environmental protective factor scores				
School support	2.79 (0.77)	2.79 (0.78)	-0.01 (-0.11,0.08)	.80
Meaningful school participation	2.26 (0.72)	2.23 (0.76)	-0.04 (-0.12,0.05)	.36
Peer caring relationships	3.25 (0.83)	3.25 (0.84)	0.00 (-0.09,0.09)	.99

Appendix D. Examples of strategies that schools implemented to address the intervention strategies

Intervention strategies by Health Promoting Schools domain	Examples of specific programs implemented in intervention schools per strategy
Curriculum, teaching and learning	
1. Age-appropriate lessons (9 hours) on individual protective factors across school subjects	MindMatters;[108] SenseAbility;[110] school-developed curriculum resources (e.g. Student activities within 'Overcoming Adversity' unit and resilience booklets).
2. Non-curriculum programs (9 hours) targeting protective factors	The Resourceful Adolescent Program;[109] SenseAbility;[110] resilience meta-language posters; random acts of kindness week.
3. Additional program targeting protective factors for Aboriginal students	Feeling Deadly Not Shame;[111] engagement with Clontarf;[112] Sista Speak; Bro Speak;[113] Aboriginal yarning groups; Stronger, Smarter program.[114]
Ethos and environment	
4. Rewards and recognition program	Formal acknowledgements of student contribution to the school outside academic and sporting achievements; encouragement of student input in recognition processes; resilience and student empowerment awards.
5. Peer support/peer mentoring programs	Peer mentoring; peer tutoring/support; peer mediation; positive relationship and year group bonding camps; Rock and Water.[115]
6. Anti-bullying programs	Buddy schemes; positive bystander programs; positive peer programs; anti-bullying day (e.g. RUOK Day); cyberbullying programs (e.g. Cyberia[116]); safe and supportive school environment (e.g. Bullying No Way[117]); Project RockIt.[118]
7. Empowerment/leadership programs	Duke of Edinburgh International Awards Youth Program;[119] Positive lifestyles program.[120]
8. Additional empowerment/leadership/mentoring programs for Aboriginal students	Outdoor learning space and Yarn space for Aboriginal students; excursions to Yamuloong Cultural Centre[121] to participate in cultural talks and learn about traditional Aboriginal culture; Dare to Lead Program;[122] Junior AECG.
9. Aboriginal cultural awareness strategies	Aboriginal cultural art project (e.g. Aboriginal mural in school hall); NAIDOC week formal assembly; Connect to Country; display of Acknowledgement of Country.

Partnerships and services	
10. Promotion/engagement of local community organisations/groups/clubs in school (e.g. charity organizations)	Focus on increasing quality and sustainability of partnerships, and development of effective communication strategy between schools and external partners (including local churches and sports clubs, Lions and Rotary Clubs, Samaritans, Red Cross).
11. Additional/enhanced consultation activities with Aboriginal community groups	Enhanced consultation activities with Aboriginal Health and Aboriginal parents (e.g. parent-teacher nights held at local Aboriginal Medical Services); Aboriginal Elder and community partnerships.
12. Promotion/engagement of health, community and youth services in the school	Presentations by Black Dog Institute; promotion of Headspace; Beyond Blue; Police liaison officer; Royal Life Saving NSW; the University of Newcastle.
13. Additional/enhanced Aboriginal community organizations promoted or engaged	School presence at local Aboriginal Education Consultative Group (AECG) meetings; engagement with the Polly Farmer Foundation.
14. Referral pathways to health, community and youth services developed and promoted	Schools websites and newsletters promoted links to various school-based services (e.g. School Counselling, Year Advisors, School Chaplain, Aboriginal Student Support); and other health, community and youth services (e.g. Kids Helpline, Headspace).
15. Strategies to increase parental involvement in school (e.g. school events)	Parent mentors; expert seminars for parents and school staff on supporting resilience in young people; parent community groups promoted in newsletter.
16. Information regarding student protective factors provided to parents via school newsletter	Newsletters sent home defining resilience protective factors and how to support such factors at home; provision of information via school website.

Appendix E. Intervention versus control group implementation of strategies targeting protective factor in the final year of intervention

Intervention strategies by Health Promoting Schools domain	Outcome definition	Intervention group N=20 % (n/N)	Control group N=12 % (n/N)	*P* value
Curriculum, teaching and learning				
1. Age-appropriate lessons on individual protective factors across school subjects	≥9hrs classroom resilience instruction across more than 1 KLA (Year 10)*	88.2 (15/17)	54.5 (6/11)	0.08
	≥9hrs classroom resilience instruction across more than 1 KLA (Year 7-10)*	88.2 (15/17)	36.4 (4/11)	0.01
	Head Teachers using any resilience resource in curriculum (including MindMatters and SenseAbility)*	75.3 (67/89)	49.1 (27/55)	0.002
	Head Teachers using MindMatters in curriculum*	42.7 (38/89)	30.9 (17/55)	0.20
	Head Teachers using SenseAbility in curriculum*	13.5 (12/89)	0 (0/55)	0.004
2. Non-curriculum programs targeting protective factors	≥9hrs non-classroom resilience instruction (Year 10)**	87.5 (14/16)	77.8 (7/9)	0.60
	At least one resilience program/resource used outside of curriculum**	88.9 (16/18)	81.8 (9/11)	0.60
	Most used resource: MindMatters**	61.1 (11/18)	18.2 (2/11)	0.05
	Number of programs used (Mean (SD)) (Intervention n=18; control n=11)**	3.1 (1.83)	1.2 (0.87)	0.004
3. Additional program targeting protective factors for Aboriginal students	≥9hrs non-classroom resilience instruction (Year 10 Aboriginal students)***	86.7 (13/15)	100.0 (5/5)	1.0

Ethos and environment				
4. Rewards and recognition program	At least one whole school rewards/recognition program****	100 (19/19)	100 (10/10)	1.0
5. Peer support/peer mentoring programs	At least one peer support**** (either peer support or buddy program/peer mentoring across all kids in any Year group)	77.8 (14/18)	90.9 (10/11)	0.62
6. Anti-bullying programs	At least one whole school anti-bullying initiative/program****	100 (19/19)	100 (10/10)	1.0
7. Empowerment/leadership programs	At least one peer leadership training or one program that students were active participants in all levels of planning and decision making across all kids in any Year group****	83.3 (15/18)	100 (11/11)	0.27
8. Additional empowerment/leadership/mentoring programs for Aboriginal students	At least one additional program (peer support, peer leadership, peer mentoring or program that students were active participants in all levels of planning and decision making across) in any Year group for Aboriginal students)***	89.5 (17/19)	70.0 (7/10)	0.31
9. Aboriginal cultural awareness strategies (Examples: Aboriginal cultural art project	At least one cultural awareness strategy for non-Aboriginal students/staff across whole school***	89.5 (17/19)	70.0 (7/10)	0.30
Partnerships and services				
10. Promotion/engagement of local community organisations/groups/clubs in school	Partnership[a] with at least 3 community organizations**	33.4 (6/18)	18.2 (2/11)	0.67
11. Additional/enhanced consultation activities with Aboriginal community groups	Consultation in the development/running of Aboriginal cultural awareness strategies for non-Aboriginal staff/students)**	84.2 (16/19)	60.0 (6/10)	0.19

12. Promotion/engagement of health, community and youth services in the school	Partnership[a] with at least one health/community services**	61.1 (11/18)	45.5 (5/11)	0.47
13. Additional/enhanced Aboriginal community organizations promoted or engaged	Partnership[a] with at least one Aboriginal local community organization***	36.8 (7/19)	20.0 (2/10)	0.40
14. Referral pathways to health, community and youth services developed and promoted	Promotion of any health or community services at school**	100 (18/18)	100 (11/11)	1.0
15. Strategies to increase parental involvement in school	Implementation of at least 1 parent engagement strategy**	94.4 (17/18)	100.0 (11/11)	1.0
16. Information regarding student protective factors provided to parents via school newsletter	Provided information to parents at least once a term regarding enhancing student resilience****	64.7 (11/17)	44.4 (4/10)	0.42

*Informants were Head Teachers from 5 Key Learning Areas (KLAs);English, Maths, PDHPE, Science, HSIE. Schools with data from Head Teachers from 2 or more KLAs were included (n=17 intervention; n=11 control);
** Informants were Head Teachers Welfare;
*** Informants were designated Aboriginal contact persons for each school. For strategy 3, 9 respondents were excluded as they were unable to estimate hours;
**** Informants were Deputy Principals;
[a]Key informants (Head Teacher Welfare for strategy 10 and 12, and Aboriginal contact person for strategy 13) were asked to nominate up to 5 active partnerships with organisations or services. They were asked whether or not each partnership had a range of characteristics including: a formal agreement on services provided, consistency of the partnership with aims of the School Plan, regular meetings to review and evaluate partnership, service specifically tailored to community needs, multiyear endeavour.

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	2-3
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	4-5
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		**n/a**
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	6-7
	4b	Settings and locations where the data were collected		5-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	9-10

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		n/a
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	6
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	6

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		6
	11b	If relevant, description of the similarity of interventions		n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	11-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		11-12
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	13-14
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	13-14
Recruitment	14a	Dates defining the periods of recruitment and follow-up		9
	14b	Why the trial ended or was stopped		n/a
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	15-16

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	13-14,17
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	17
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		16, Appendix B
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		n/a
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		21
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		19-21
Other information				
Registration	23	Registration number and		1

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	22

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

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BMJ Open

Effectiveness of a pragmatic school-based universal resilience intervention in reducing tobacco, alcohol and illicit substance use in a population of adolescents: cluster-randomised controlled trial

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Title: Effectiveness of a pragmatic school-based universal resilience intervention in reducing tobacco, alcohol and illicit substance use in a population of adolescents: cluster-randomised controlled trial

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Word count: 4149

ABSTRACT

Objectives: Initiation of tobacco, alcohol and illicit substance use typically occurs during adolescence, with the school setting recommended to reduce adolescent substance use. Strengthening individual (e.g. problem solving) and environmental (e.g. caring relationships at school) resilience protective factors of adolescents has been suggested as a strategy for reducing substance use by adolescents, however few studies have examined this potential. A study was conducted to investigate the effectiveness of a pragmatic school-based universal 'resilience' intervention in reducing the prevalence of tobacco, alcohol and illicit substance use, and increasing the individual and environmental protective factors of students.

Design: A cluster-randomised controlled trial

Setting: Thirty-Two Australian secondary schools (20 intervention;12 control)

Participants: Cohort of Grade 7 students followed up in Grade 10 (2014; aged 15-16years).

Intervention: A pragmatic intervention involving school staff selection and implementation of available programs and resources targeting individual and environmental 'resilience' protective factors for all Grade 7-10 students was implemented in schools (2012-2014). School staff were provided implementation support.

Measurements: An online survey collected baseline and follow up data for primary outcomes: tobacco (ever, recent) and alcohol (ever, recent, 'risk') use, and secondary outcomes: marijuana and other illicit substance use, and individual (six factor subscales, aggregate) and environmental (three factor subscales, aggregate) protective factor scores. Generalized and linear mixed models examined follow up differences between groups.

Results: Follow-up data from 2105 students (intervention=1261; control=844; 69% of baseline cohort) were analysed. No significant differences were found between intervention and control students for any primary (ever tobacco:OR 1.25,95%CI:0.92,1.68,*p*=0.14; recent tobacco:OR1.39,95%CI:0.84,2.31,*p*=0.19; recent ever alcohol:OR 1.11,95%CI:0.83,1.48,*p*=0.46; alcohol:OR1.13,95%CI:0.78,1.62,*p*=0.51; 'risk' alcohol:OR0.98,95%CI:0.70,1.36,*p*=0.89) or secondary outcomes (marijuana:OR1.12,95%CI:0.74,1.68,*p*=0.57; other illicit substance:OR1.19,95%CI:0.67,2.10,*p*=0.54; individual protective factors: MD=0,95%CI:-0.07,0.06,*p*=0.89; environmental protective factors: MD:-0.02,95%CI:-0.09,0.06,*p*=0.65).

Conclusions: The universally implemented pragmatic school-based intervention was not effective in reducing the prevalence of tobacco, alcohol or illicit substance use, or in increasing the protective factors of students.

Trial registration: Australia and New Zealand Clinical Trials Register reference: ACTRN12611000606987

ARTICLE SUMMARY

Strengths and limitations of this study

- This study represents a comprehensive examination using the gold standard study design for school-based studies to of the potential for a universal school-based resilience protective factor intervention in reducing the tobacco, alcohol and illicit substance use of adolescents.
- Major strengths of this study include: the cluster-randomised controlled study design, the large sample size of participating students, the collection of individual outcome data as well as process data to assess intervention implementation, and the use of statistical methods that both accounted for the clustering of student outcome data and sensitivity analyses of data via intention to treat principles including multiple imputation to account for missing data.
- Although the study found a high rate of student attrition (31%), such attrition is typical for school-based research, did not differ between treatment groups and had little impact on the estimated power of the study (difference of 0.3-0.4%).
- The study was reliant upon adolescent self-report of substance use and subject to the known limitations of self-report in this population. Whilst the planned validation of tobacco use by adolescents was not supported by schools, strategies were implemented to increase the validity of adolescent report including a web-based survey and confidential participation by students.

BACKGROUND

Tobacco, alcohol and illicit substance use are responsible for 9% of the global disease burden,[1] 12% of deaths world-wide,[2] and significant health and societal costs.[3-6] Initiation of tobacco, alcohol and illicit substance use in high income countries generally occurs during adolescence,[7-9] with earlier use associated with greater dependence in adulthood.[1] Whilst data from the United States and Australia show a declining trend in adolescent substance use [9, 10] a considerable proportion of adolescents (aged 11-17 years) continue to report such use; 23%-45% having smoked a cigarette, 43%-74% having consumed an alcoholic drink, and 7%-40% having used an illicit substance.[9-11]

Schools represent an opportune setting for interventions to prevent adolescent substance use as they provide access to large numbers of adolescents for prolonged periods, and have curricula and policies that seek to promote student health and wellbeing.[12, 13] As a consequence, substance use prevention interventions delivered to all students in a school or classroom regardless of risk (that is universal)[14] [15] are common and supported by governments world-wide to reduce the prevalence of adolescent substance use.[16-19] Despite policies recommending comprehensive approaches to substance use prevention address protective factors of substance use[17, 19-21] and 'resilience',[17, 19] such policies do not provide guidance regarding the specific factors or resilience strategies that should be targeted or the manner in which they should be addressed. Possibly as a result, it is reported that schools frequently develop their own programs [22], do not implement evidence-based programs or implement existing evidence-based programs [23] and make significant adaptations to cater for local contexts [24]. The extent to which such an approach can realise its intended benefits has not been reported.

Evidence from cross sectional studies suggests a range of individual factors including self-efficacy, problem solving, communication and self-awareness are protective of adolescent substance use; as has evidence regarding environmental factors such as caring relationships with adults and peers, and meaningful participation in home, school and community settings.[25-37] Such factors have similarly been found to be protective of a person's 'resilience',[38-40] most broadly defined as the process of, capacity for, or outcome of successful adaptation in the context of risk or adversity.[40-42]

Various randomised controlled trials have assessed the effectiveness of resilience protective factor interventions on substance use[43]. These have primarily addressed either resilience protective factors as a component of a broader intervention approach, [44-60] combined universal and targeted interventions,[61, 62] combined parent and school-based strategies,[63] or involved elementary school aged students only.[64] However only one controlled trial that assessed the effectiveness of a universal school-based intervention focused solely on the enhancement of both individual and environmental resilience protective factors in reducing the prevalence of adolescent or secondary school-aged students substance use. The cluster-randomized controlled trial conducted in 26 Australian secondary schools, investigated the effectiveness of a three year whole-of-school intervention delivered by schools (i.e. pragmatic) targeting a number of individual and environmental protective factors in preventing tobacco, alcohol and marijuana use in a cohort of students.[46] Outcomes were assessed at baseline, mid-intervention (after one year of intervention) and following intervention completion. Despite promising results mid-intervention for tobacco use, at follow up the confidence intervals for the adjusted odd ratios for tobacco, alcohol or marijuana use outcomes indicated a non-significant result.[45]

Given the limited evidence regarding the effectiveness of universal interventions promoting protective factors as a means of reducing adolescent student substance use, a cluster randomised controlled trial was conducted to determine the effectiveness of a secondary school staff-delivered pragmatic intervention targeting such protective factors in reducing the prevalence of tobacco and alcohol use (primary outcomes) and marijuana and illicit substance use, and in increasing individual and environmental protective factors (secondary outcomes).

METHODS

Study design and setting

A cluster randomised controlled trial was conducted in secondary schools in one health district of New South Wales, Australia. Outcome assessments were conducted with a cohort of students at baseline (when students were in Grade 7 - aged 12-13 years) and at follow-up (when students were in Grade 10). Approximately 114,000 people aged 10 to 19 years reside in metropolitan, regional, rural and remote areas within the

district.[65, 66] Relevant ethics committee approvals were obtained (Hunter New England Health Ref:09/11/18/4.01; University of Newcastle Ref:H-2010-0029). Further study details and assessment of other registered outcomes are reported elsewhere.[67, 68]

Participants and recruitment

Schools

A national schools database [69] identified 172 schools with secondary enrolments within the study area. Schools were eligible if they: were a Government or Catholic secondary school located within a socioeconomically disadvantaged local government area,[70] had enrolments in Grades 7 to 10 (aged 12-16 years) and had more than 400 total student enrolments. Schools were ineligible if they were: single gender, independent (private), special needs, selective, central (for students aged 5-18 years) or boarding schools.

Randomisation of schools

Eligible schools were approached in random order until a quota of 32 schools consented. Consenting schools were stratified according to participation in a government disadvantaged schools initiative (yes/no)[71] and school size (medium 400-800/large >800), then randomly allocated to intervention or control in a 20:12 block design ratio by an independent statistician using a random number function in Microsoft Excel prior to baseline data collection (the number of intervention schools were increased from planned 12 to 20 following stakeholder consultation).

Students

All students enrolled in Grade 7 (first year at secondary school) were eligible to participate in data collection and active parental consent for student participation was sought via a mailed study information pack. A free call number was provided for parents who wished to decline. After two weeks, non-responding parents were prompted via telephone by school-affiliated staff who were blind to group allocation.

School staff

Selected school staff (deputy principal, head teachers for student welfare and five key subject areas, and the Aboriginal Education Coordinator or other Aboriginal staff member) at each intervention and control school were invited to participate in data collection at follow up.

Intervention

A three-year universal ('whole of school') intervention was delivered to all students in Grades 8 to 10. The intervention, based on a pilot study,[72] involved 16 broad strategies (see Table 1) seeking to build the protective factors of students implemented across the three domains of the Health Promoting Schools framework (Table 1).[73] Each of the 16 broad strategies addressed one or more individual (self-efficacy, problem solving, cooperation/communication, self-awareness, empathy, goals/aspirations) or environmental protective factors (school support, school meaningful participation, community support, community meaningful participation, home support, home meaningful participation, peer caring relationships, pro-social peers). Such protective factors have been found to be correlated with adolescent substance use [74] and align with a 'resilience' approach.[38-40, 75]

A pragmatic intervention approach [76] that involved intervention delivery by school staff as a component of routine school practice was adopted to approximate intervention delivery under 'real world' conditions [76]. Schools were provided with details of existing resources and programs addressing the 16 broad strategy areas from which they could choose to implement. Whilst schools were required to implement programs and resources that addressed each of the 16 broad strategies, they had the flexibility to select which specific program or resource to implement, and the order and manner in which they were implemented. This approach is similar to approaches adopted by previous substance use prevention studies [58, 61, 62], with the exception that selected programs and resources were not required to have been rigorously evaluated.

Table 1. Intervention and implementation support strategies

Intervention strategies by Health Promoting Schools domain
Curriculum, teaching and learning
1. Age-appropriate lessons (9 hours) on individual protective factors across school subjects (e.g. MindMatters[77] or school-developed curriculum resources) [I,a]
2. Non-curriculum programs (9 hours) targeting protective factors (e.g. the Resourceful Adolescent Program)[78] [I,E]
3. Additional program targeting protective factors for Aboriginal students [I,E, a]
Ethos and environment
4. Rewards and recognition program [I,E]
5. Peer support/peer mentoring programs [I,E]
6. Anti-bullying programs [I,E]
7. Empowerment/leadership programs [I,E]
8. Additional empowerment/leadership/mentoring programs for Aboriginal students [I,E,a]

9. Aboriginal cultural awareness strategies [I,E,a]

Partnerships and services

10. Promotion/engagement of local community organisations/groups/clubs in school (e.g. charity organizations) [E,a]
11. Additional/enhanced consultation activities with Aboriginal community groups [I,E,d]
12. Promotion/engagement of health, community and youth services in the school [I,E,a]
13. Additional/enhanced Aboriginal community organizations promoted or engaged [I,E,d]
14. Referral pathways to health, community and youth services developed and promoted [I,E,a]
15. Strategies to increase parental involvement in school (e.g. school events) [E,a]
16. Information regarding student protective factors provided to parents via school newsletter [I,E,a]

Implementation support strategies

1. Engagement with school community including presentations at school staff meetings regarding planned intervention [b]
2. Embedded staff support:
    - School intervention officer one day a week to support program implementation
    - Project coordinator to liaise with school sectors and support school intervention officers [c]
3. School intervention team formed (new team or re-alignment of existing team, inclusive of school intervention officer and school executive member) to implement intervention
4. Structured planning process to prioritize and select appropriate resources/programs:
    - Needs assessment of student protective factors (when study sample in Grade 7 and 9)
    - Two school community planning workshops and one strategy review workshop [c]
    - School plan to address intervention strategies endorsed by the school executive
5. Intervention implementation guide that described the intervention, planning process, available resources and programs, tools and templates for intervention implementation.
6. Staff mental health training (minimum of one hour per school during staff meetings)
7. AUD $2,000 per year each for:
    - Teacher release time for intervention implementation or professional development
    - Strategies specifically for Aboriginal students [a]
8. Feedback reports regarding student substance use and protective factors, and intervention implementation (termly) [c]
9. An Aboriginal Cultural Steering group was formed comprising of Aboriginal staff from local Aboriginal community organizations and Government Departments to provide Aboriginal cultural advice and direction regarding the study design, implementation, evaluation and dissemination

I To target individual protective factors; E To target environmental protective factors
[a] Implemented in Years 2 and 3 only; [b] Year 1 only; [c] Years 1 and 2 only; [d] Year 3 only
NB. Following publication of the study protocol[67] and based upon advice received from an Aboriginal Cultural Steering Group intervention strategies 3,8,11,13 were added.

To facilitate implementation of intervention strategies, programs and resources, schools were provided with a comprehensive range of support strategies, including an embedded psychology or education trained implementation support officer; strategies that have been previously reported to facilitate implementation of interventions (Table 1).[79-86]

Control schools implemented usual school curricula and policies which may have included protective factor strategies and resources similar to, or the same as, those systematically provided to the intervention schools, but were not provided with program resources or support. A report describing baseline school-level student substance use and protective factor characteristics was provided to control schools.

Data collection procedures

Student demographic and protective factor characteristics and substance use outcomes

Students completed a confidential web-based survey[87] in class time prior to intervention commencement (baseline: August-November 2011) and immediately following intervention completion (follow up: July-November 2014). Neither the school staff nor researchers were blind to group allocation.

Implementation of strategies targeting protective factors

To assess intervention implementation by intervention schools,[88] research staff reviewed school documents and recorded the delivery of intervention strategies monthly. In addition, at follow up, telephone-based structured interviews were conducted with staff from both groups by interviewers regarding school implementation of intervention strategies and engagement with the intervention during the final year of intervention, School staff from intervention schools were asked their level of engagement with the intervention in the final year.

Measures

Student demographic characteristics

The student survey addressed: age, gender, residential postcode, Aboriginal and/or Torres Strait Islander status, ethnicity, and non-English speaking background.

Student substance use

Substance use outcome data were collected using items from an ongoing Australian triennial survey of school students' health behaviours (Appendix A).[9] Primary outcomes included tobacco (ever and recent) alcohol (ever, recent and 'risky') use. Secondary outcomes included marijuana and other illicit substance use. Planned validation of student self-report of smoking via saliva-based cotinine testing[67, 89], was not conducted due to school policies prohibiting drug testing.

Student individual and environmental protective factors

The Resilience and Youth Development module of the California Healthy Kids Survey was used to measure individual and environmental protective factors .[74] Items for all six individual and three of the environmental factor subscales were selected based on their congruence with the intervention (Appendix A). Aggregate individual and environmental protective factor scores were used as secondary outcome measures.

Consistent with a previous study of the survey,[74] analysis of baseline responses confirmed the subscales were internally consistent and valid (Cronbach alpha coefficients: individual 0.55-0.81; environmental 0.77-0.88).[90] Confirmatory factor analysis[74] demonstrated the subscale factor structure to be a good model fit (comparative fit index 0.92, root mean square error of approximation 0.04).

Implementation of strategies targeting protective factors

The telephone survey of school staff assessed reported implementation of programs and resources in each of the 16 broad strategy areas (Table 1), and staff in during the final year of intervention. Intervention school staff level of engagement was assessed by a single item (not at all/somewhat/moderately/very/unsure).

Sample size

The sample size was calculated on the basis of 24 schools (i.e. 12 in each group). Based on an assumed parental consent rate of 80%,[32, 91] and loss of students to follow-up from Grade 7 to Grade 10 of 25%, it was estimated the cohort would consist of 2,720 Grade 7 students (1,360 in each group) and 2,040 Grade 10 students at follow up (1,020 in each group). Assuming 80% power, a 5% significance level, an intra-cluster correlation of 0.01,[72] and Grade 10 control group prevalence of 14% for recent smoking, 36.2% for recent/risk alcohol use, 25% for marijuana use, and 9.3% for other illicit substance use,[92] the study was estimated to be able to detect an absolute reduction in prevalence of 4.8% for recent smoking, 7.0% for recent/risk alcohol use, 6.2% for marijuana use and 3.9% for illicit substance use in intervention compared to control students.

Statistical analysis

Student demographic characteristics

Student-reported residential postcode was used to calculate student socioeconomic status [70] and remoteness of residential location.[93] Characteristics of students (gender, Aboriginality, socioeconomic status, remoteness, baseline substance use and protective factor scores) completing both baseline and follow up surveys were compared to those lost to follow up by logistic regression accounting for potential clustering of students within schools.

Student substance use

Recent tobacco use was defined as having smoked at least one cigarette in the last week, and recent alcohol use as at least one alcoholic drink in the last week (yes/no). The response options for 'risky alcohol use' were dichotomised (either 'none', or 'once'/'twice'/'3-6 times'/'7 or more times'), as were the response options for both marijuana and other illicit substance use (either 'none', or 'once or twice'/'3-5 times'/'6-9 times'/'10-19 times'/'20-39 times'/'40 or more times').

Comparison between groups in the prevalence of substance use at follow up for the cohort Grade 10 students in intervention and control schools was undertaken to determine the effectiveness of the intervention using generalized linear mixed models (binomial distribution with a logit link; analysis as treated). All models included a fixed effect for treatment group (intervention versus control) and a random effect for each school to account for clustering of responses within schools. Models were adjusted for *a priori* selected prognostic variables (age, gender, school type, school size, Aboriginal/Torres Strait Islander status, ethnicity, non-English speaking background, socio-economic status) and odd ratios with 95% Wald confidence intervals calculated. Intra-class correlations were estimated on the logistic scale using the methods described in Eldridge et al.[94]

Sensitivity analyses were undertaken according to intention-to-treat principles, where multiple imputation was used to assess the sensitivity of results to missing data under the missing at random (MAR) assumption[95] from students that were lost to follow up or changed schools during the intervention period. The method of chained regression equations was used, imputing 10 data sets separately by treatment group and pooling the results using Rubin's method.[96] Specifically, this involved a chained regression equations method of generating 10 complete datasets; logistic regression models were used for categorical (binomial,

ordinal or multinomial) variables and linear regression models were used for continuous variables. The imputation model included all substance use outcomes, together with all variables that were in the analysis model and treatment group.

Student individual and environmental protective factor scores

Student protective factor subscale scores were calculated by averaging the responses to all items in each subscale. Aggregate individual and environmental protective factor scores were calculated by averaging all relevant subscale scores for each student.[74] Scores ranged from 1 to 4, with higher scores more favourable.

Linear mixed models were used to assess the effectiveness of the intervention for the aggregate individual and environmental protective factor scores at follow up. The models included a fixed effect for treatment group (intervention vs control) and a random effect for school to account for clustering of responses within schools. Models were adjusted for the same prognostic variables as per the substance use models. Intra class correlation was estimated as the proportion of the total variance that is due to between cluster variance.

Implementation of strategies targeting protective factors

Descriptive statistics summarised the number of intervention schools implementing each of the 16 broad intervention strategies that targeted protective factors as identified via project records (Intervention Years 1-3). Chi-square and t test analyses examined whether intervention and control schools differed with respect to their reported implementation of protective factor strategies in the final year of intervention.

A criterion for statistical significance of $p \leq 0.05$ was used. All analyses were undertaken by an independent statistician using SAS Software Version 9.4.[97]

RESULTS

Sample

Schools

Forty-four of the 47 eligible schools were approached prior to achieving the quota of 32 schools (73% consent rate) (see figure 1). Participating schools included 28 government and four Catholic schools. Of the 32 schools, 21 were medium and 11 were large sized schools. No schools withdrew following allocation.

Insert figure 1 here

Students

At baseline, parental consent was provided for 3530 Grade 7 students (76.9% of enrolled students), of which 3115 students participated in the baseline survey (67.9% of enrolled students; 88.2% of students with parental consent). Follow up data were collected from 2,149 of the students who completed the baseline survey (retention rate 69.0%; intervention 67.3%, control 71.6%) with no differential loss to follow up between intervention and control groups (p=0.1). Reasons for lost to follow up included: students no longer attending school (n=652; 65.5%), absent from school on follow up survey days (n=207; 20.8%), or unknown reason for currently enrolled students (n=137;13.8%). Students who moved between schools (n=30) and those who participated but did not answer substance use items at baseline (n=14) were excluded resulting in a cohort of 2,105 students for the primary analysis. All 3115 students who completed the baseline survey were included in sensitivity analyses.

The demographic characteristics of students who completed the baseline survey are shown in Table 2. Students who were lost to follow up compared to those who completed both baseline and follow up surveys (the cohort) were more likely to: report use for each substance use measure (tobacco: ever 17.9% v 8.1% p<0.01, recent 4.1% v 1.4% p<.001; alcohol: ever 37.6% v 26.8% p<0.01, recent 8.8% v 4.2% p<.001, 'risky' 8.6% v 3.7% p<.001; marijuana: 2.6% v 1% p=.003; other illicit substances: 2.0% v 0.6% p=.003), and have lower mean individual (2.92 v 3.04 p<.001) and environmental protective factor scores (2.88 v 2.98 p<.001). Students who were lost to follow up were also more likely to be Aboriginal and/or Torres Strait Islander (18.1% v 10.2%, p<.001). There was no difference for any other demographic characteristics.

Table 2. Student demographics, substance use and protective factor characteristics of students participating in baseline survey by group (N=3115)

Student characteristics	Intervention n (%)	Control n (%)

Total students	1909	1206
Male	950 (49.8)	607 (50.3)
Age (mean (SD))	12.6 (0.53)	12.6 (0.53)
Aboriginal and/or Torres Strait Islander*	245 (12.8)	151 (12.6)
Socioeconomic status**		
Low (<990)	1062 (55.6)	718 (59.5)
High (≥990)	847 (44.4)	488 (40.5)
Remoteness (ARIA)**		
Major Cities	744 (39.1)	567 (47.1)
Inner Regional	565 (29.7)	387 (32.1)
Outer Regional/Remote	594 (31.2)	250 (20.8)
Ethnicity		
Other ethnic, cultural or national origin	235 (12.3)	95 (7.9)
Non-English speaking background		
Speak language other than English	119 (6.2)	57 (4.7)
Substance use		
Tobacco use – ever	221 (11.7)	124 (10.5)
Tobacco use – recent	49 (2.6)	21 (1.8)
Alcohol use - ever	615 (32.5)	316 (26.7)
Alcohol use - recent	121 (6.4)	53 (4.5)
Alcohol use – 'risky'	111 (5.9)	50 (4.2)
Marijuana use	34 (1.8)	12 (1.0)
Other illicit substance use	23 (1.2)	8 (0.7)
Protective factor score		
Individual factors (mean (SD))	2.99 (0.48)	3.03 (0.45)
Environmental factors (mean (SD))	2.93 (0.56)	2.96 (0.55)

*Missing for 4 students; **SES and remoteness could not be calculated 5 students postcode missing (4 intv, 1 control)

Substance use

Table 2 shows the proportion of students reporting substance use at baseline. There was no difference between intervention and control students for any measure of substance use at follow up (Table 3), with the same result for intention-to-treat sensitivity analyses (see Appendix B).

Table 3. Intervention versus control group comparisons at follow up (N=2105)

Outcome	Intra class	Intervention	Control group	Intervention v control

	correlations	group N=1,261	N=844		
Primary outcomes					
Substance use		n (%)	n (%)	OR (95% CI)	*P*
Tobacco use - ever[a]	0.0182	406 (32.5)	235 (27.9)	1.25 (0.92, 1.68)	.14
Tobacco use - recent[a]	0.0280	148 (11.8)	75 (8.9)	1.48 (0.93, 2.37)	.09
Alcohol use - ever[b]	0.0105	770 (61.8)	494 (58.7)	1.11 (0.83,1.48)	.46
Alcohol use – recent[c]	0.0149	261 (20.9)	156 (18.6)	1.10 (0.77, 1.56)	.60
Alcohol use – 'risky'[d]	0.0152	293 (23.6)	196 (23.4)	1.03 (0.74,1.43)	.86
Secondary outcomes					
Substance use					
Marijuana use[e]	0.0163	193 (15.6)	115 (13.7)	1.18 (0.80,1.72)	.39
Other illicit substance use[e]	0.0368	85 (6.9)	47 (5.6)	1.42 (0.85,2.38)	.23
Protective factor score		Mean (SD)	Mean (SD)	Mean diff (95% CI)	*P*
Individual[g]	0.0011	3.02 (0.48)	3.01 (0.49)	-0.01 (-0.07,0.06)	.87
Environmental[g]	0.0010	2.77 (0.61)	2.76 (0.62)	-0.02 (-0.09,0.06)	.67

[a] 13 missing, [b] 18 missing, [c] 23 missing, [d] 25 missing, [e] 29 missing, [f] 7 missing, [g] 4 missing

Student individual and environmental protective factors

Baseline mean individual and environmental protective factor scores are shown in Table 2. At follow up there was no difference in mean individual or environmental aggregate protective factor scores between intervention and control students (Table 3). Similarly, there was no difference between intervention and control students in mean scores for any of the individual or environmental protective factor subscales (see Appendix C).

School implementation of strategies targeting protective factors

Review of project records across all three years of the intervention identified 12 of the 20 intervention schools were recorded to have implemented programs or resources in each of the 16 strategy areas every year (see Appendix D for examples of strategies that intervention schools implemented). In each year of the study either 18 or 19 of the 20 intervention schools were recorded to have implemented programs or resources in each of the strategy areas.

A total of 232 of the 256 (91%) school staff completed the telephone survey regarding intervention implementation in the final year of the intervention. Comparison of intervention and control schools reported implementation of intervention strategies in the final year of intervention showed intervention schools were more likely than control schools to have incorporated nine hours of protective factor instruction across at least two school subjects across Grade 7 to 10 (intervention 88% v control 36%, $p<.01$), but not in Grade 10 alone (intervention 88% v control 55%, $p=0.08$) (Appendix E). A higher proportion of Head Teachers at intervention schools reported using resilience resources within curriculum in any Grade than control schools (75% and 49% respectively, $p<0.01$) and the mean number of resilience resources implemented outside of the classroom was higher in intervention compared with control schools (3.1 and 1.2 respectively, $p<0.01$). There were no significant differences between intervention and control schools in the reported implementation of the other 15 strategies (Appendix E). Between 73% and 84% of intervention school staff reported being moderately or very engaged in the final year of the intervention (Aboriginal contact 73.7% (14/19); Deputy 84.2% (16/19); Head Teacher Welfare 83.3% (15/18); Head Teachers Key Learning Areas 76.4% (68/89).

DISCUSSION

This study sought to test the effectiveness of a pragmatic intervention delivered by schools on a universal basis that focused on enhancing student individual and environmental 'resilience' protective factors as a means of reducing the prevalence of adolescent tobacco, alcohol and illicit substance use. At follow-up, there was no difference in the prevalence of any measure of substance use between intervention and control students, nor was there any difference for aggregate or individual measure of individual and environmental protective factors.

The findings were broadly consistent with evidence from the only other randomised controlled trial of a school-based universal intervention focused solely on promoting the individual and environmental protective factors of adolescent students as a means of reducing substance use.[46] The intervention in that study was similar to that in the current study in terms of: its pragmatic nature; timing (from Grade 8 onwards); duration (3 years); delivery by school staff; strategies (curriculum and school environment); and environmental protective factor content (addressing relationships and meaningful participation at school). However its content differed in terms of a more limited focus on individual protective factors than the current study.[46] Despite promising findings mid-intervention for tobacco use favouring an intervention effect, at follow up the study similarly found no effect of the intervention on tobacco, alcohol or illicit substance use. Additionally, no effect was found for the protective factors measured (school engagement and social relationships), with authors citing insufficient specific intervention content in these areas as a possible explanation.[46]

The hypothesised mechanism of effect for the current study was based on association evidence that an inverse relationship existed between protective factors and substance use.[25-37, 90] As the intervention was ineffective in improving such factors it remains unknown whether the enhancement of such factors can lead to a reduction in the prevalence of adolescent substance use.

Various aspects of the intervention design may have contributed to the null finding for protective factors. First, the universal nature of the intervention without a targeted intervention for students with lower protective factor scores or with other substance use risk factors may have limited its ability to have a measurable impact. Whilst there is conflicting evidence regarding whether universal, selective or targeted interventions are more effective in reducing substance use,[98-101] the positive findings of one cluster-randomised controlled study undertaken in 43 schools in Hong Kong suggest that an intervention combining both a universal and a targeted approach may be effective. The study reported a positive effect for eight of fourteen targeted protective factors, as well as a reduction in illegal substance use.[62]

Second, the use of a pragmatic intervention approach allowing school staff to select the type, manner and order of implementation of curriculum resources and programs may have contributed to the null study

findings, as such an intervention approach has been reported to be less likely to be effective than non-pragmatic approaches.[102, 103] Although pragmatic intervention approaches are intended to optimise translation into practice, the potential exists for a loss of intervention efficacy, integrity and fidelity to occur through local selection and adaptation of programs.[104, 105]The intervention relied, at least in part, upon both schools and teachers selecting from a large number of readily available resources and programs that address resilience protective factors, very few of which are evidence-based, and schools implementing them well. The study findings suggest that the common practice of schools developing and adapting programs [22-24], an intervention approach assessed in this trial, may not realise the intended substance use reduction benefits.

Third, the use of programs and resources that were also accessible to control schools may have contributed to the null findings due to a lack of differential intervention exposure between groups. The likelihood of such an explanation is heightened by the finding of similar strategy implementation levels in both groups at follow up, with the exception of curriculum-focussed strategies. It is unclear whether contamination with respect to awareness of programs and resources between intervention and control schools was an issue as it was not specifically assessed, however the cluster-randomised design at least in part may have reduced this risk.

Fourth, similar to the conclusion of the Bond study,[46] the duration of the intervention may have been insufficient to impact on student protective factors. As the full intervention was implemented over two years (only two of 16 strategies were delivered in Year 1) the intervention may not have had sufficient time to impact on student protective factors. This possibility is supported by findings from other school-based substance use prevention studies that suggest interventions delivered over 3-4 years rather than 1-2 years may be more effective.[106] Such a conclusion is also supported by a World Health Organisation review of evidence regarding the Health Promoting Schools approach that found interventions of longer duration across a range of outcomes were more effective.[107]

Finally, three additional design factors may have limited the intervention effect: the intervention's focus on protective factors only, with no content addressing known risk factors of substance use (such as peer or familial substance use[108]); the limited focus on family and community-based protective factors (such as

caring parental relationships and meaningful community participation), both of which have been reported to be predictors of substance use; [109] and the reported low test-retest reliability of the resilience protective factor measurement tool, which may have led to instability in student responses over time.[74]

Major strengths of this study included the cluster-randomised controlled study design, the use of implementation support strategies and the large sample size. Although the study found, as for school-based research generally,[110] a high rate of student attrition (31%), such attrition did not differ between treatment groups and had little impact on the estimated power of the study (difference of 0.3-0.4%).

Given the significant policy and practice investment in intervention approaches that seek to enhance student protective factors as a means of reducing adolescent substance use, further research is warranted to investigate the effectiveness of this intervention approach. Further research is also warranted regarding whether universal interventions targeting such factors can be effective when augmented with a targeted intervention component either for those students at elevated risk (i.e. selective) or those who have already initiated substance use (i.e. indicated). Similarly, further research is required to identify intervention approaches that are both capable of being scaled-up to be delivered as part of routine school practice across large populations of secondary schools, and efficacious in reducing adolescent substance use.

AUTHOR CONTRIBUTIONS

RKH conducted the literature search, drafted the manuscript and contributed to study design, data collection, data analysis, data interpretation, and coordination of the study. JW, MF, JB, LW and EC helped draft the manuscript and participated in the conception, design and coordination of the study. JD helped draft the manuscript and participated in the coordination of the study. CL, CO and JA helped draft the manuscript and conducted data analysis. All authors read and revised the manuscript critically for intellectual content, and approved the final manuscript.

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COMPETING INTERESTS STATEMENT

We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

DATA SHARING STATEMENT

Requests for additional unpublished data should be forwarded to Rebecca.hodder@hnehealth.nsw.gov.au

FIGURES

Figure 1. Study flow diagram

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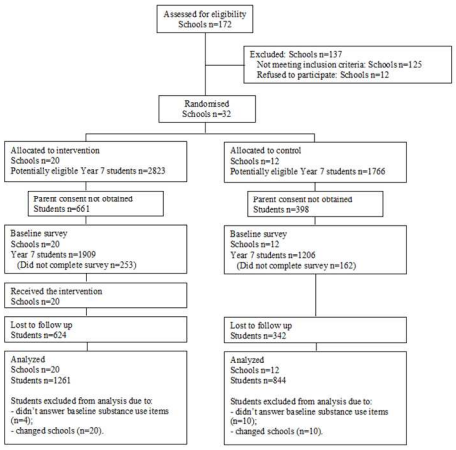

Figure 1. Study flow diagram

APPENDICES

Appendix A: Primary and secondary outcome measures

	Survey item	Response options
Primary outcomes:		
Tobacco use – ever	Have you ever smoked even part of a cigarette? [1]	Yes/No
Tobacco use – recent	Have you smoked a cigarette in the last week? If yes, starting from yesterday please record the number of cigarettes that you smoked on each day of last week[1]	Yes/No 0-99
Alcohol use - ever	Have you ever had a drink of alcohol? E.g. beer, wine or alcopops/pre-mix drinks (do not count sips or tastes)	Yes/No
Alcohol use – recent	Have you had any alcoholic drinks, such as beer, wine or alcopops/pre-mix drinks in the last week? (do not count sips or tastes) If yes, starting from yesterday please record the number of alcoholic drinks that you had on each day of last week[1]	Yes/No 0-99
Alcohol use - 'risky'	In the last 4 weeks, how many times have you had 5 or more alcoholic drinks in a row? [1]	None/Once/Twice/3-6 times/7 or more times
Secondary outcomes:		
Marijuana use	How many times in the last four weeks have you smoked or used marijuana/cannabis (grass, hash, dope, weed, mull, yarndi, ganga, pot, a bong, a joint) [1]	None/Once or twice/3-5 times/6-9 times/10-19 times/20-39 times/40 or more times
Other illicit substance use	How many times in the last four weeks have you used any other illegal drug or pill to get "high", such as inhalants, hallucinogens (eg LSD, acid, trips), amphetamines (eg. speed, ice), ecstasy, cocaine or heroin?	None/Once or twice/3-5 times/6-9 times/10-19 times/20-39 times/40 or more times
Individual protective factors[2]	Cooperation and communication subscale: 2 items; e.g. "I enjoy working together with other students my age"	1: Never true, 2: True some of the time; 3: True most of the time; 4: True all of the time
	Self-efficacy subscale: 4 items; e.g. "I can do most things if I try"	As above
	Empathy subscale: 3 items; e.g. "I try to understand what other people feel and think"	As above

	Problem solving subscale: 3 items; e.g. “When I need help I find someone to talk with”	As above
	Self-awareness subscale: 3 items; e.g. “I understand why I do what I do”	As above
	Goals and aspirations subscale: 3 items; e.g. “I have goals and plans for the future”	As above
Environmental protective factors[2]	School support subscale: 6 items; e.g. “At my school there is an adult who really cares about me”	As above
	School meaningful participation subscale: 3 items; e.g. “At my school, I help decide things like class activities or rules”	As above
	Peer caring relationships subscale: 3 items; e.g. “I have a friend who helps me when I'm having a hard time”	As above

Appendix B: Multiple imputation results (n=3,115)

Outcome	Intervention v control	
Primary outcomes		
Substance use	OR (95% CI)	*P*
Tobacco use - ever	1.11 (0.91, 1.35)	.31
Tobacco use - recent	1.20 (0.89, 1.62)	.23
Alcohol use – ever	1.07 (0.89, 1.27)	.48
Alcohol use – recent	1.07 (0.85, 1.34)	.55
Alcohol use – 'risky'	1.03 (0.82, 1.30)	.81
Secondary outcomes		
Substance use		
Marijuana use	1.12 (0.78, 1.62)	.52
Other illicit substance use	1.27 (0.81, 2.00)	.29

Appendix C: Protective factor subscale results

Outcome	Control group N=844 Mean (SD)	Intervention group N=1,261 Mean (SD)	Intervention v control OR (95% CI)	*P*
Individual protective factor scores				
Cooperation and communication	2.94 (0.68)	2.94 (0.70)	0.01 (-0.08,0.10)	.78
Empathy	3.09 (0.71)	3.09 (0.74)	0.00 (-0.09,0.09)	.97
Goals and aspirations	3.29 (0.67)	3.29 (0.69)	0.00 (-0.10,0.10)	.96
Problem solving	2.73 (0.74)	2.75 (0.73)	0.03 (-0.05,0.11)	.51
Self-awareness	3.02 (0.76)	2.96 (0.75)	-0.05 (-0.13,0.04)	.31
Self-efficacy	3.06 (0.54)	3.03 (0.58)	-0.03 (-0.09,0.04)	.44
Environmental protective factor scores				
School support	2.79 (0.77)	2.79 (0.78)	-0.01 (-0.11,0.08)	.80
Meaningful school participation	2.26 (0.72)	2.23 (0.76)	-0.04 (-0.12,0.05)	.36
Peer caring relationships	3.25 (0.83)	3.25 (0.84)	0.00 (-0.09,0.09)	.99

Appendix D. Examples of strategies that schools implemented to address the intervention strategies

Intervention strategies by Health Promoting Schools domain	Examples of specific programs implemented in intervention schools per strategy
Curriculum, teaching and learning	
1. Age-appropriate lessons (9 hours) on individual protective factors across school subjects	MindMatters;[3] SenseAbility;[5] school-developed curriculum resources (e.g. Student activities within 'Overcoming Adversity' unit and resilience booklets).
2. Non-curriculum programs (9 hours) targeting protective factors	The Resourceful Adolescent Program;[4] SenseAbility;[5] resilience meta-language posters; random acts of kindness week.
3. Additional program targeting protective factors for Aboriginal students	Feeling Deadly Not Shame;[6] engagement with Clontarf;[7] Sista Speak; Bro Speak;[8] Aboriginal yarning groups; Stronger, Smarter program.[9]
Ethos and environment	
4. Rewards and recognition program	Formal acknowledgements of student contribution to the school outside academic and sporting achievements; encouragement of student input in recognition processes; resilience and student empowerment awards.
5. Peer support/peer mentoring programs	Peer mentoring; peer tutoring/support; peer mediation; positive relationship and year group bonding camps; Rock and Water.[10]
6. Anti-bullying programs	Buddy schemes; positive bystander programs; positive peer programs; anti-bullying day (e.g. RUOK Day); cyberbullying programs (e.g. Cyberia[11]); safe and supportive school environment (e.g. Bullying No Way[12]); Project RockIt.[13]
7. Empowerment/leadership programs	Duke of Edinburgh International Awards Youth Program;[14] Positive lifestyles program.[15]
8. Additional empowerment/leadership/mentoring programs for Aboriginal students	Outdoor learning space and Yarn space for Aboriginal students; excursions to Yamuloong Cultural Centre[16] to participate in cultural talks and learn about traditional Aboriginal culture; Dare to Lead Program;[17] Junior AECG.
9. Aboriginal cultural awareness strategies	Aboriginal cultural art project (e.g. Aboriginal mural in school hall); NAIDOC week formal assembly; Connect to Country; display of Acknowledgement of Country.

Partnerships and services	
10. Promotion/engagement of local community organisations/groups/clubs in school (e.g. charity organizations)	Focus on increasing quality and sustainability of partnerships, and development of effective communication strategy between schools and external partners (including local churches and sports clubs, Lions and Rotary Clubs, Samaritans, Red Cross).
11. Additional/enhanced consultation activities with Aboriginal community groups	Enhanced consultation activities with Aboriginal Health and Aboriginal parents (e.g. parent-teacher nights held at local Aboriginal Medical Services); Aboriginal Elder and community partnerships.
12. Promotion/engagement of health, community and youth services in the school	Presentations by Black Dog Institute; promotion of Headspace; Beyond Blue; Police liaison officer; Royal Life Saving NSW; the University of Newcastle.
13. Additional/enhanced Aboriginal community organizations promoted or engaged	School presence at local Aboriginal Education Consultative Group (AECG) meetings; engagement with the Polly Farmer Foundation.
14. Referral pathways to health, community and youth services developed and promoted	Schools websites and newsletters promoted links to various school-based services (e.g. School Counselling, Year Advisors, School Chaplain, Aboriginal Student Support); and other health, community and youth services (e.g. Kids Helpline, Headspace).
15. Strategies to increase parental involvement in school (e.g. school events)	Parent mentors; expert seminars for parents and school staff on supporting resilience in young people; parent community groups promoted in newsletter.
16. Information regarding student protective factors provided to parents via school newsletter	Newsletters sent home defining resilience protective factors and how to support such factors at home; provision of information via school website.

Appendix E. Intervention versus control group implementation of strategies targeting protective factor in the final year of intervention

Intervention strategies by Health Promoting Schools domain	Outcome definition	Intervention group N=20 % (n/N)	Control group N=12 % (n/N)	*P* value
Curriculum, teaching and learning				
1. Age-appropriate lessons on individual protective factors across school subjects	≥9hrs classroom resilience instruction across more than 1 KLA (Year 10)*	88.2 (15/17)	54.5 (6/11)	0.08
	≥9hrs classroom resilience instruction across more than 1 KLA (Year 7-10)*	88.2 (15/17)	36.4 (4/11)	0.01
	Head Teachers using any resilience resource in curriculum (including MindMatters and SenseAbility)*	75.3 (67/89)	49.1 (27/55)	0.002
	Head Teachers using MindMatters in curriculum*	42.7 (38/89)	30.9 (17/55)	0.20
	Head Teachers using SenseAbility in curriculum*	13.5 (12/89)	0 (0/55)	0.004
2. Non-curriculum programs targeting protective factors	≥9hrs non-classroom resilience instruction (Year 10)**	87.5 (14/16)	77.8 (7/9)	0.60
	At least one resilience program/resource used outside of curriculum**	88.9 (16/18)	81.8 (9/11)	0.60
	Most used resource: MindMatters**	61.1 (11/18)	18.2 (2/11)	0.05
	Number of programs used (Mean (SD)) (Intervention n=18; control n=11)**	3.1 (1.83)	1.2 (0.87)	0.004
3. Additional program targeting protective factors for Aboriginal students	≥9hrs non-classroom resilience instruction (Year 10 Aboriginal students)***	86.7 (13/15)	100.0 (5/5)	1.0

Ethos and environment				
4. Rewards and recognition program	At least one whole school rewards/recognition program****	100 (19/19)	100 (10/10)	1.0
5. Peer support/peer mentoring programs	At least one peer support**** (either peer support or buddy program/peer mentoring across all kids in any Year group)	77.8 (14/18)	90.9 (10/11)	0.62
6. Anti-bullying programs	At least one whole school anti-bullying initiative/program****	100 (19/19)	100 (10/10)	1.0
7. Empowerment/leadership programs	At least one peer leadership training or one program that students were active participants in all levels of planning and decision making across all kids in any Year group****	83.3 (15/18)	100 (11/11)	0.27
8. Additional empowerment/leadership/mentoring programs for Aboriginal students	At least one additional program (peer support, peer leadership, peer mentoring or program that students were active participants in all levels of planning and decision making across) in any Year group for Aboriginal students)***	89.5 (17/19)	70.0 (7/10)	0.31
9. Aboriginal cultural awareness strategies (Examples: Aboriginal cultural art project	At least one cultural awareness strategy for non-Aboriginal students/staff across whole school***	89.5 (17/19)	70.0 (7/10)	0.30
Partnerships and services				
10. Promotion/engagement of local community organisations/groups/clubs in school	Partnership[a] with at least 3 community organizations**	33.4 (6/18)	18.2 (2/11)	0.67
11. Additional/enhanced consultation activities with Aboriginal community groups	Consultation in the development/running of Aboriginal cultural awareness strategies for non-Aboriginal staff/students)**	84.2 (16/19)	60.0 (6/10)	0.19

12. Promotion/engagement of health, community and youth services in the school	Partnership[a] with at least one health/community services**	61.1 (11/18)	45.5 (5/11)	0.47
13. Additional/enhanced Aboriginal community organizations promoted or engaged	Partnership[a] with at least one Aboriginal local community organization***	36.8 (7/19)	20.0 (2/10)	0.40
14. Referral pathways to health, community and youth services developed and promoted	Promotion of any health or community services at school**	100 (18/18)	100 (11/11)	1.0
15. Strategies to increase parental involvement in school	Implementation of at least 1 parent engagement strategy**	94.4 (17/18)	100.0 (11/11)	1.0
16. Information regarding student protective factors provided to parents via school newsletter	Provided information to parents at least once a term regarding enhancing student resilience****	64.7 (11/17)	44.4 (4/10)	0.42

*Informants were Head Teachers from 5 Key Learning Areas (KLAs); English, Maths, PDHPE, Science, HSIE. Schools with data from Head Teachers from 2 or more KLAs were included (n=17 intervention; n=11 control);
** Informants were Head Teachers Welfare;
*** Informants were designated Aboriginal contact persons for each school. For strategy 3, 9 respondents were excluded as they were unable to estimate hours;
**** Informants were Deputy Principals;
[a]Key informants (Head Teacher Welfare for strategy 10 and 12, and Aboriginal contact person for strategy 13) were asked to nominate up to 5 active partnerships with organisations or services. They were asked whether or not each partnership had a range of characteristics including: a formal agreement on services provided, consistency of the partnership with aims of the School Plan, regular meetings to review and evaluate partnership, service specifically tailored to community needs, multiyear endeavour.

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Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	2-3
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	4-5
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		**n/a**
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	6-7
	4b	Settings and locations where the data were collected		5-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	9-10

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		n/a
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	6
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	6

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		6
	11b	If relevant, description of the similarity of interventions		n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	11-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		11-12
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	13-14
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	13-14
Recruitment	14a	Dates defining the periods of recruitment and follow-up		9
	14b	Why the trial ended or was stopped		n/a
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	15-16

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	13-14,17
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	17
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		16, Appendix B
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		n/a
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		21
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		19-21
Other information				
Registration	23	Registration number and		1

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	22

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.