Health4Life eHealth intervention to modify multiple lifestyle risk behaviours among adolescent students in Australia: a cluster-randomised controlled trial

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Summary

Background Lifestyle risk behaviours are prevalent among adolescents and commonly co-occur, but current intervention approaches tend to focus on single risk behaviours. This study aimed to evaluate the efficacy of the eHealth intervention Health4Life in modifying six key lifestyle risk behaviours (ie, alcohol use, tobacco smoking, recreational screen time, physical inactivity, poor diet, and poor sleep, known as the Big 6) among adolescents.

Methods We conducted a cluster-randomised controlled trial in secondary schools that had a minimum of 30 year 7 students, in three Australian states. A biostatistician randomly allocated schools (1:1) to Health4Life (a six-module, web-based programme and accompanying smartphone app) or an active control group (usual health education) with the Blockrand function in R, stratified by site and school gender composition. All students aged 11–13 years who were fluent in English and attended participating schools were eligible. Teachers, students, and researchers were not masked to allocation. Primary outcomes were alcohol use, tobacco use, recreational screen time, moderate to vigorous physical activity (MVPA), sugar-sweetened beverage intake, and sleep duration at 24 months, measured by self-report surveys, and analysed in all students who were eligible at baseline. Latent growth models estimated between-group change over time. This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619000431123).

Findings Between April 1, 2019, and Sept 27, 2019, we recruited 85 schools (9280 students), of which 71 schools with 6640 eligible students (36 schools [3610 students] assigned to the intervention and 35 [3030 students] to the control) completed the baseline survey. 14 schools were excluded from the final analysis or withdrew, mostly due to a lack of time. We found no between-group differences for alcohol use (odds ratio 1·24, 95% CI 0·58–2·64), smoking (1·68, 0·76–3·72), screen time (0·79, 0·59–1·06), MVPA (0·82, 0·62–1·09), sugar-sweetened beverage intake (1·02, 0·82–1·26), or sleep (0·91, 0·72–1·14) at 24 months. No adverse events were reported during this trial.

Interpretation Health4Life was not effective in modifying risk behaviours. Our results provide new knowledge about eHealth multiple health behaviour change interventions. However, further research is needed to improve efficacy.

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Introduction

Alcohol use, tobacco smoking, recreational screen time, physical inactivity, poor diet, and poor sleep (hereafter referred to as the Big 6) are key risk factors for obesity,[1] mental health disorders,[2] and chronic diseases such as cardiovascular disease, type 2 diabetes, and cancers.[3] The Big 6 are highly prevalent among adolescents; for example, an estimated 81% of people aged 11–17 years globally do not meet recommended physical activity levels.[4] Risk behaviours also commonly co-occur, with more than 80% of adolescents engaging in two or more risk behaviours and more than 35% engaging in three or more.[5] The Big 6 persist over time, increasing the risk of ill health during the life course,[6] and are associated with a substantial economic burden.[7] Effective interventions early in life have large public health and economic benefits,[8] yet most current intervention approaches focus on single risk behaviours and are not always scalable.

Multiple health behaviour change (MHBC) interventions[9] that concurrently target risk behaviours offer an efficient solution for improving adolescent health. Changing one lifestyle behaviour can lead to improvements across multiple behaviours, which can result in an overall healthy lifestyle change.[9] EHealth is defined as the cost-effective and secure use of information and communication technologies in support of health.[10]

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Research in context

Evidence before this study

We conducted a comprehensive search of Ovid MEDLINE, Embase, PsycINFO, and the Cochrane Library databases between Jan 1, 2000, and March 14, 2019, with no language restrictions to identify published studies evaluating school-based eHealth interventions targeting multiple lifestyle risk behaviours. A list of all search terms is provided in the appendix (pp 21–22). Eligible studies included universal (ie, delivered to all students regardless of their level of risk) school-based prevention programmes that targeted two or more of the Big 6 (ie, alcohol use, tobacco smoking, sedentary behaviour [eg, screen time and sitting] , physical activity, diet, and sleep), targeted students aged 11–18 years, were primarily delivered via eHealth methods, and used a randomised controlled trial design (including randomisation at the school-year level or individual-class level) with comparison groups including no intervention, education as usual, or an alternate evidence-based intervention not delivered via eHealth (eg, face to face). Overall, eHealth school-based interventions were effective in improving screen time, physical activity, and fruit and vegetable intake. However, effects were small and short term, and the quality of evidence was low. We found little evidence of an effect on alcohol use and tobacco smoking, or on the intake of fat or sugary drinks and snacks; no study targeted sleep and no study examined all of the Big 6 risk factors. These results highlighted the need for further high-quality trials of co-designed, eHealth, multiple health behaviour change (MHBC) interventions, particularly those targeting substance use, sedentary time, and sleep.

Added value of this study

We conducted a rigorous cluster-randomised controlled trial of an eHealth MHBC intervention (the Health4Life Initiative) to modify the Big 6 chronic disease risk factors among secondary school students. Health4Life was not effective in modifying adolescent risk behaviours; however, it did significantly improve students' knowledge about chronic disease risk factors over a 24-month period and was deemed to be acceptable by students and teachers. Results from this study provide new knowledge about the efficacy of eHealth MHBC interventions for school students and highlight future directions for research.

Implications of all the available evidence

Further research to refine the content of Health4Life and improve uptake of intervention components is required. Implications of this trial for the development of new eHealth MHBC interventions for adolescents include intervening at a younger age, incorporating motivational interviewing and additional skill-building opportunities for prevention efforts, implementing multilevel approaches within the school and home settings, and ongoing consultation with adolescents to optimise engagement with smartphone apps and emerging technology.

Programmes delivered in this way (ie, via internet, computers, tablets, mobile technology, or telehealth) in schools can reach large populations and are readily scalable to meet the needs of young people. However, few eHealth MHBC school-based interventions have been robustly trialled, none target all the Big 6, and effects are typically small and short term.[11] To address these gaps, we co-designed Health4Life with adolescents and educators, to our knowledge the first eHealth school-based MHBC intervention to concurrently target the Big 6. Health4Life uses principles of social-influence, social-cognitive, and self-determination theories, as well as the two-process model of sleep to modify the Big 6 risk behaviours among adolescents.[12] This school-based programme consists of six web-based modules and optional classroom activities delivered during health education lessons in the first year of secondary school (students aged 11–13 years)[12] and an accompanying smartphone app.[13]

The aim of our study was to evaluate the efficacy of Health4Life in modifying the Big 6 lifestyle risk behaviours among adolescents when delivered at the school level. As specified in the published protocol,[14] we hypothesised that Health4Life would be more effective than an active control group (school-based health education as usual) in modifying the Big 6 among adolescents, specifically: reducing alcohol use, tobacco use, sedentary recreational screen time, the decline in moderate to vigorous physical activity (MVPA), sugar-sweetened beverage intake, and increasing sleep among adolescents with short duration, and decreasing sleep among those with long duration.

Methods

Study design

This cluster-randomised controlled trial was conducted in Australian secondary schools. A cluster-randomised design, with the school as the unit of randomisation, was chosen to avoid influence of the control group from the intervention group through student and staff communication. The study was approved by Human Research Ethics Committees of the University of Sydney (2018/882), the University of Queensland (2019000037), Curtin University (HRE2019–0083), and relevant school sector ethics committees. Full details of the study protocol have been reported elsewhere.[14]

Participants

A total of 519 independent, public (government-funded), or Catholic schools were approached across three Australian states. Schools were identified via the publicly available database My School, with those that had fewer than 30 year 7 students excluded. Schools were only approached if the relevant ethics approval had been obtained, and were required to have a minimum of

30 year 7 students (aged 11–13 years) and were recruited across four sites: Greater Sydney (NSW); regional areas of New South Wales; a 100 km radius from Brisbane (QLD); and a 600 km radius from Perth (WA). All year 7 students who were fluent in English and attended participating schools in 2019 were eligible. However, some schools also included their year 8 students (aged 13–14 years). This was requested by the schools and was allowed as year 7 and year 8 are within the same stage of the Australian Health and Physical Education Curriculum. All students were included in analyses. Gender data were self-reported. Response options were "Male", "Female", "Non-binary/Gender Fluid", "Different identity" (in which a text response was allowed), and "Prefer not to say". Due to differing ethical requirements, some schools used opt-out parental consent procedures, whereas others required written and oral opt-in consent. Active student written consent was also required. Consent rates have been reported previously.[15]

Randomisation and masking

Schools were randomly allocated (1:1) to the Health4Life intervention or to the active control group (health education as usual) with the Blockrand function in R version 4.2.1. Randomisation was stratified by site and school gender composition (coeducational, predominately male [>60%], or predominately female [>60%]) and conducted by a biostatistician with no role in school recruitment. The randomisation scheme was weighted by the total pool of available schools per site (37 recruited from New South Wales [including greater Sydney and regional areas], 16 from Western Australia, and 18 from Queensland). As is standard for school-based interventions, students, teachers, and researchers were not masked to allocation.

Procedures

Students were asked to complete an online survey in class at baseline (2019), immediately after the intervention (2019), 12 months after baseline (2020), and 24 months after baseline (2021). As of March, 2023, 36-month data are being cleaned and results will be reported in the future. Absent students were invited to complete the survey remotely. Students were entered into a random prize draw to receive an AUD$100 gift voucher (two per school per assessment).

The intervention group received Health4Life, an eHealth MHBC programme that provides students with simultaneous education about the Big 6, the relationships between them, and their relationship with mental health. It uses a staged model of prevention, comprising universal and selective components.

Universal components were available to all year 7 students in 2019. The school-based programme consists of six online cartoon modules that use co-designed storylines about a group of teenagers and principles of social influence to impart evidence-based information about the Big 6.[12] The cartoons, which are the core content of the intervention, are delivered sequentially during health education lessons (ideally once per week). They are supplemented by web-based, targeted feedback about adherence to national health guidelines and optional online and teacher-delivered activities to reinforce key messages and encourage discussion while allowing teachers flexibility to adapt programme delivery to their needs. The companion smartphone app was designed to encourage behaviour change by prompting students to track their behaviours and providing goal-setting opportunities, motivational quotes, and badges or rewards.[13]

The selective Health4Life+ intervention component provided further education about the Big 6 and used cognitive-behavioural and motivation-enhancement techniques to help develop students' coping strategies and skills to facilitate healthy habits. Delivered via additional modules within the Health4Life app, Health4Life+ was only offered to students who were identified as at increased risk of chronic disease (eg, engaging in two or more of the Big 6) 1 year after the initial intervention, after the 12-month follow-up survey. Further details, including the theoretical underpinnings of the intervention and thresholds for being at increased risk of chronic disease, have been published elsewhere.[12–14]

Control schools implemented health education as usual, which is mandatory in Australian schools. Health education is delivered approximately once per week by teachers to help students to develop the knowledge and skills to lead healthy, safe, and active lives. Teachers from control schools completed a logbook that assessed the amount and format of any education relating to the Big 6 that they delivered.

All students and teachers at schools in the intervention group were asked to complete an online survey about the acceptability and relevance of Health4Life immediately after the intervention. Objective engagement data were also collected via the Health4Life website and app, including the number of modules completed and the frequency and duration of app access.

Students, teachers, and parents were instructed to contact the lead researchers (MT and KEC) or the Manager of the University of Sydney's Human Research Ethics Committee via email or telephone to report adverse events.

Outcomes

Prespecified primary outcomes were change from baseline to 24 months in self-reported measures of the Big 6 risk factors. Full details are in the published study protocol;[14] national health guidelines for each behaviour are detailed in the appendix (p 2).

See Online for appendix

Alcohol use was assessed with a single item and a standard drink pictorial chart: "Have you had a full standard alcoholic drink in the past 6 months?" (0=No, 1=Yes). Tobacco use was measured with a single item: "In the past 6 months, have you tried cigarette smoking, even one or two puffs?" (0=No, 1=Yes). Screen time was

assessed with mean time (hours and minutes) spent engaging in sedentary recreational screen time (ie, time spent on screens during free time, excluding schoolwork) on weekdays and weekends in the past week. The derived screen time variable for analyses was coded as semi-continuous (<2 h per day engaging in screen time was coded as meeting guidelines; >2 h per day was coded with the precise number of hours spent engaging in screen time). MVPA was measured with a single item assessing the number of days in the past week students engaged in 60 min of MVPA. The MVPA variable was coded as semicontinuous (0=meets guidelines, ≥1=number of days the student does not meet guidelines). A single item assessed usual consumption of soft drinks, cordials, or sports drinks per week or day. Energy drinks were not included as they were assessed separately in the current study. A categorical variable was created (0=no risk of excessive sugar-sweetened beverage consumption, 1=low risk [<1 cup of sugar-sweetened beverage per week], 2=some risk [2–4 cups of sugar-sweetened beverage per week], 3=high risk [5 or more cups of sugar-sweetened beverage per week]). Mean sleep duration (hours and minutes) was calculated with a six-item scale assessing usual bedtime, time attempted sleeping, time taken to fall asleep, time awake after sleep onset, final wake time, and time they got out of bed. The derived sleep variable was coded as semicontinuous (0=meets guidelines, ≥1=mean hours the student does not meet or exceeds the guideline).

The secondary outcome reported in this Article was knowledge about the Big 6, which was measured with a 20-item scale developed to reflect the intended content of Health4Life (appendix p 3). The items assessed knowledge of Australian health guidelines for the Big 6, prevalence of alcohol and tobacco use among Australian adolescents (normative perceptions), and physical and mental health effects of the Big 6. Items were summed to produce a total knowledge score. Other secondary outcomes included acceptability and relevance of the intervention, engagement in the website and app, symptoms of mental ill health, daytime sleepiness, insomnia, fruit and vegetable consumption, discretionary food intake, quantity and frequency of alcohol use, quantity and frequency of tobacco use, alcohol-related harms, light physical activity, and future intentions to use health-related behaviours. These outcomes will be reported separately in a future publication.

The post-hoc outcome of composite risk index was created (range 0–6) to represent the number of Big 6 risk factors students engaged in, which is a recommended approach for evaluating MHBC interventions.[16] The scoring used to derive the risk index is detailed in the appendix (p 2).

Statistical analysis

To determine the required sample size, the minimal detectable effect size associated with the risk behaviours at the final timepoint (36 months) was estimated. The α level was set at a conservative 0·006 level on the basis of a Bonferroni correction to account for testing of multiple outcomes. Power was set at 0·80; the correlation among level 1 data (repeated measurements over time within one student) was set at 0·60 and the number of timepoints was set at five. We estimated a mean of 70 students per school from 72 schools would generate a minimum detectable effect size of 0·158 (equivalent to an odds ratio [OR] of 0·75), which was based on the targeted risk behaviour with the lowest anticipated prevalence at baseline (ie, alcohol use). A total of 72 schools would have enabled analysis within each trial site separately; however, this sample size was not achieved due to school withdrawal. Our final sample of 6640 students from 71 schools provides sufficient power to allow overall comparisons between intervention groups in the pooled sample. The sample-size formula used does not require correlations between school-level data; however, it does require correlations between student-level data.[17] As per the recommendations in the formula, this correlation level was set at 0·6.

The primary outcome was analysed in eligible students at baseline. All analyses used latent growth models (LGMs) in Mplus (Muthén & Muthén, Los Angeles, CA, USA) version 8.4. LGMs estimate change over time in a structural equation modelling framework, in which baseline variables are the reference point, latent intercepts denote student starting points, and slopes denote growth over time. An intervention effect was represented by the effect of the intervention group variable on the slope latent factor, which provides an estimate of between-group differences in the change in outcome over time. Different types of LGM were used depending on the distribution of each outcome (ie, semi-continuous, binary, ordinal, or continuous; appendix pp 4–5). The α level was set at a conservative 0·006 level on the basis of a Bonferroni correction to account for testing of multiple outcomes. Model-based intervention effect sizes (ie, ORs, rate ratios, or mean differences) and 95% CIs were estimated at each timepoint with the model constraint command in Mplus. School was included as a cluster variable in all models, accounting for nesting of repeated measurements within students and students within schools. As randomisation was stratified by school gender composition and site, we controlled for assigned sex at birth and school region as covariates in all models. We tested different specifications of time scores (ie, linear, quadradic, and freely estimated) on unconditional LGMs (ie, no covariates) to establish the best fitting time structure and slope estimate interpretation for each outcome (appendix p 14). Model fit was compared with Akaike information criterion, Bayesian information criterion, and sample-size adjusted Bayesian information criterion statistics.

To investigate the effect of attrition on outcomes, a binary variable was created representing those present at baseline only versus those who completed one or more

follow-up surveys. *t*-tests investigated the differences between missing conditions on baseline continuous variables. Binary logistic regressions were used for dichotomous variables and multinomial logistic regressions were used for categorical variables. The LGMs used full-information maximum likelihood (FIML) estimation, treating missing data in accordance with the intention-to-treat principles (ie, including all randomly assigned participants). FIML uses all available information when estimating parameters, is considered superior to traditional methods, and is widely used in LGMs.[18]

A priori exploratory analyses were conducted to assess the effect of intervention dose on outcomes. We used objective online module completion data to derive a dose variable that represented whether students received a sufficient dose (ie, completed all six online modules of the school-based programme) or an insufficient dose (completed fewer than six online modules of the programme) irrespective of their use of the Health4Life app (due to low app uptake). Analyses used the same model specifications as the primary analyses, except with the derived dose variable (0=control group, 1=insufficient dose, 2=sufficient dose) regressed on intercept and slope instead. As these groups were not randomly assigned and intervention dose was probably related to other factors, we used inverse probability weighting to attain unbiased estimates of intervention effects at sufficient and insufficient dose based on propensity scores,[19] defined as the probability of full exposure to the Health4Life intervention based on the observed baseline characteristics of participants (ie, comparisons were

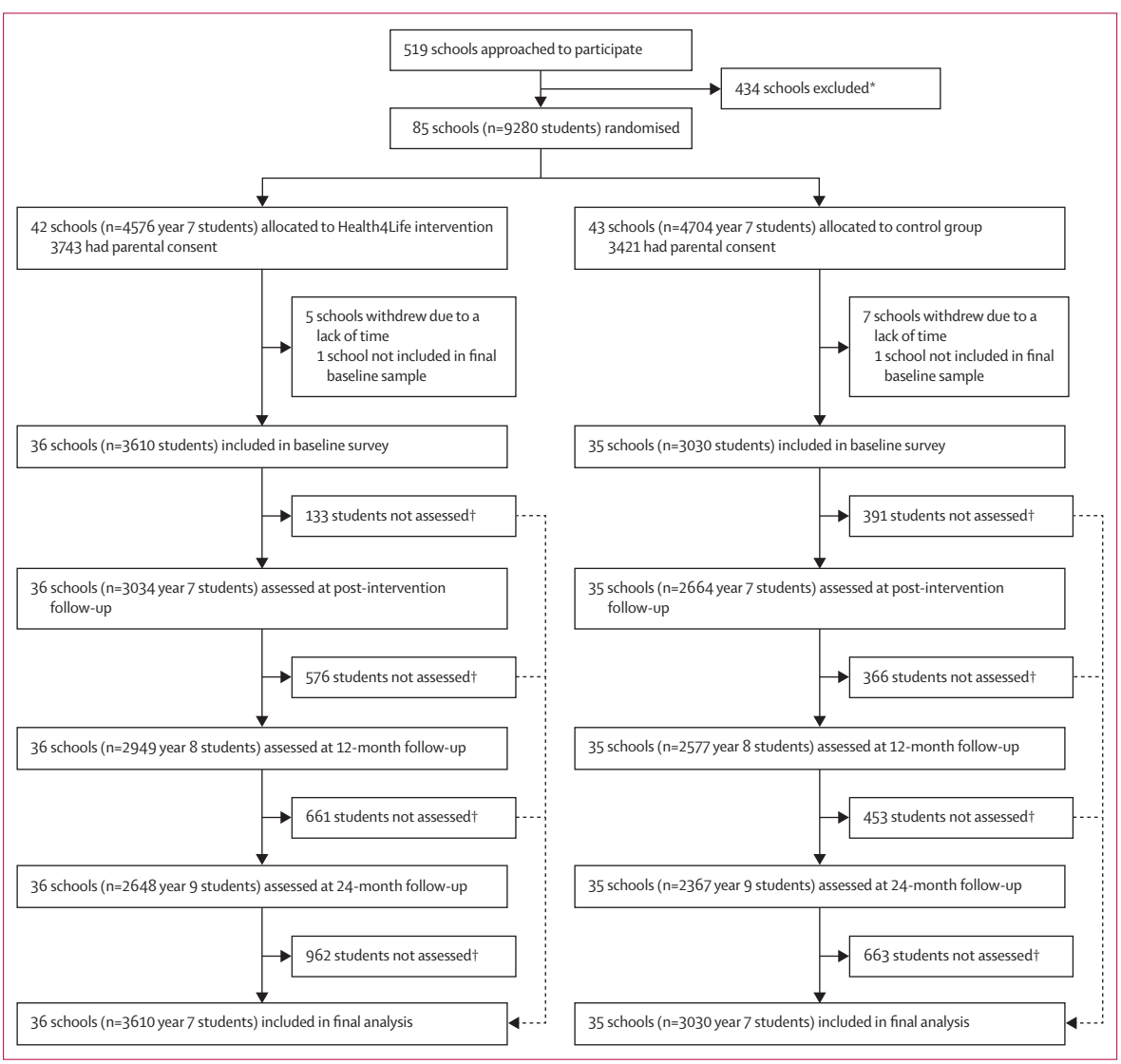

Figure: **Trial profile**
*Schools declined to participate or did not respond. †Students were absent, had insufficient data, moved schools, or declined to participate.

made between the insufficient dose group and control group and between the sufficient dose group and control group, with the three weighted groups similar in all respects at baseline regarding measured variables except for intervention allocation). The propensity score-based mean treatment effect weights were estimated for all students by regressing dose on a set of 26 baseline covariates with the WeightIt package in R version 0.13.1. In accordance with previous research, covariates were baseline measures of all outcomes, demographic variables, and factors associated with the Big 6 (appendix pp 6–9).

In accordance with the study protocol, the data safety and monitoring board comprised the Principal Investigator, Project Coordinator, and project biostatisticians. This trial follows the CONSORT guidelines and was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619000431123).

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, writing of the report, or decision to submit for publication.

Results

Between April 1, 2019, and Sept 27, 2019, we recruited 85 schools, 42 of which were randomly assigned to the Health4Life intervention (4576 students), and 43 to health education as usual (control group; 4704 students; figure). 14 schools withdrew, distributed across the four trial sites and three school types. 6640 students from 71 schools (36 schools assigned to the intervention and 35 to the control) were included in the baseline survey (mean age 12·7 years [SD 0·50]; 3311 [49·9%] were male, 3204 [48·3%] were female, 30 [0·5%] were non-binary or gender fluid, 9 [0·1%] had a different identity, and 69 [1·0%] preferred not to say). Full details of the sample

	Dichotomous variables				Continuous variables			
	Baseline	Post-intervention follow-up	12-month follow-up	24-month follow-up	Baseline	Post-intervention follow-up	12-month follow-up	24-month follow-up
Moderate to vigorous physical activity*								
Control group	2267/2909 (77·9%, 0·008)	1965/2516 (78·1%, 0·008)	1989/2490 (79·9%, 0·008)	1844/2272 (81·2%, 0·008)	3·47 (1·57, 0·03)	3·54 (1·60, 0·04)	3·48 (1·58, 0·04)	3·71 (1·68, 0·04)
H4L group	2702/3489 (77·4%, 0·007)	2186/2876 (76·0%, 0·008)	2236/2830 (79·0%, 0·008)	1903/2452 (77·6%, 0·008)	3·60 (1·60, 0·03)	3·50 (1·57, 0·03)	3·55 (1·64, 0·03)	3·70 (1·71, 0·04)
H4L group *vs* control group	0·98 (0·80 to 1·20)	0·99 (0·97 to 1·01)	0·91 (0·79 to 1·04)	0·82 (0·62 to 1·09)	1·02 (0·97 to 1·08)	1·00 (1·00 to 1·00)	0·99 (0·97 to 1·01)	0·97 (0·93 to 1·01)
Mean daily screen time hours*								
Control group	2542/2954 (86·1%, 0·006)	2150/2559 (84·0%, 0·007)	2253/2509 (89·8%, 0·006)	2115/2264 (93·4%, 0·005)	5·99 (3·58, 0·07)	6·09 (3·83, 0·08)	6·60 (4·03, 0·08)	6·64 (3·93, 0·09)
H4L group	3023/3524 (85·8%, 0·006)	2425/2913 (83·2%, 0·007)	2533/2856 (88·7%, 0·006)	2275/2470 (92·1%, 0·005)	6·52 (4·03, 0·07)	6·35 (4·13, 0·08)	6·79 (4·19, 0·08)	6·93 (4·04, 0·08)
H4L group *vs* control group	0·97 (0·67 to 1·40)	1·03 (0·98 to 1·08)	0·92 (0·82 to 1·03)	0·79 (0·59 to 1·06)	1·04 (0·97 to 1·13)	0·97 (0·89 to 1·06)	0·99 (0·90 to 1·08)	1·00 (0·96 to 1·05)
Mean daily sleep hours*								
Control group	1234/2861 (43·1%, 0·009)	1071/2473 (43·3%, 0·010)	985/2409 (40·9%, 0·010)	787/2194 (35·9%, 0·010)	1·01 (1·01, 0·03)	1·04 (1·14, 0·03)	0·98 (0·95, 0·03)	0·96 (1·04, 0·04)
H4L group	1463/3371 (43·4%, 0·009)	1167/2819 (41·4%, 010)	1052/2724 (38·6%, 0·010)	834/2422 (34·4%, 0·010)	1·01 (1·04, 0·03)	1·01 (1·16, 0·03)	1·06 (1·07, 0·03)	0·99 (0·94, 0·03)
H4L group *vs* control group	0·97 (0·73 to 1·30)	0·997 (0·97 to 1·02)	0·91 (0·75 to 1·12)	0·91 (0·72 to 1·14)	0·97 (0·87 to 1·08)	0·97 (0·84 to 1·12)	1·12 (1·01 to 1·24)	1·13 (0·99 to 1·29)
Alcohol use in the past 6 months								
Control group	71/2879 (2·5%, 0·003)	98/2477 (4·0%, 0·004)	190/2480 (7·7%, 0·005)	342/2264 (15·1%, 0·008)	..	..	..	..
H4L group	110/3467 (3·2%, 0·003)	84/2847 (3·0%, 0·003)	231/2805 (8·2%, 0·005)	408/2439 (16·7%, 0·008)	..	..	..	..
H4L group *vs* control group	0·84 (0·46 to 1·53)	1·03 (0·94 to 1·12)	1·16 (0·70 to 1·92)	1·24 (0·58 to 2·64)	..	..	..	..
Tobacco use in the past 6 months†								
Control group	43/2853 (1·5%, 0·002)	48/2473 (1·9%, 0·002)	95/2470 (3·8%, 0·004)	121/2258 (5·4%, 0·004)	..	..	..	..
H4L group	54/3453 (1·6%, 0·002)	52/2837 (1·8%, 0·002)	108/2782 (3·9%, 0·004)	164/2424 (6·8%, 0·005)	..	..	..	..
H4L group *vs* control group	0·76 (0·36 to 1·57)	1·10 (0·86 to 1·42)	1·50 (0·82 to 2·74)	1·68 (0·76 to 3·72)	..	..	..	..

(Table 1 continues on next page)

	Dichotomous variables				Continuous variables			
	Baseline	Post-intervention follow-up	12-month follow-up	24-month follow-up	Baseline	Post-intervention follow-up	12-month follow-up	24-month follow-up
(Continued from previous page)								
Frequency of sugar-sweetened beverage consumption								
Rarely—control group	1248/2948 (42·3%, 0·009)	1148/2542 (45·2%, 0·010)	1098/2512 (43·7%, 0·010)	1038/2285 (45·4%, 0·010)	..	..	..	..
Rarely—H4L group	1313/3518 (37·3%, 0·008)	1263/2906 (43·5%, 0·009)	1184/2851 (41·5%, 0·009)	1003/2471 (40·6%, 0·010)	..	..	..	..
1 or less per week—control group	978/2948 (33·2%, 0·009)	826/2542 (32·5%, 0·009)	841/2512 (33·5%, 0·009)	700/2285 (30·6%, 0·010)	..	..	..	..
1 or less per week—H4L group	1164/3518 (33·1%, 0·008)	907/2906 (31·2%, 0·009)	887/2851 (31·1%, 0·009)	768/2471 (31·1%, 0·009)	..	..	..	..
2–4 per week—control group	447/2948 (15·2%, 0·007)	364/2542 (14·3%, 0·007)	361/2512 (14·4%, 0·007)	353/2285 (15·4%, 0·008)	..	..	..	..
2–4 per week—H4L group	611/3518 (17·4%, 0·006)	439/2906 (15·1%, 0·007)	471/2851 (16·5%, 0·007)	417/2471 (16·9%, 0·008)	..	..	..	..
5 or more per week—control group	275/2948 (9·3%, 0·005)	204/2542 (8·0%, 0·005)	212/2512 (8·4%, 0·006)	194/2285 (8·5%, 0·006)	..	..	..	..
5 or more per week—H4L group	430/3518 (12·2%, 0·006)	297/2906 (10·2%, 0·006)	309/2851 (10·8%, 0·006)	283/2471 (11·5%, 0·006)	..	..	..	..
H4L group *vs* control group	1·27 (0·92 to 1·76)	1·00 (0·99 to 1·02)	1·01 (0·91 to 1·12)	1·02 (0·82 to 1·26)	..	..	..	..
Composite risk score‡								
Control group	..	..	..	..	2·31 (1·09, 0·02)	2·27 (1·15, 0·02)	2·40 (1·13, 0·02)	2·50 (1·17, 0·02)
H4L group	..	..	..	..	2·37 (1·15, 0·02)	2·23 (1·18, 0·02)	2·41 (1·17, 0·02)	2·51 (1·23, 0·02)
H4L group *vs* control group	..	..	..	..	–0·01 (–0·10 to 0·08)	0·00 (–0·02 to 0·03)	–0·01 (–0·05 to 0·04)	–0·01 (–0·09 to 0·07)
Knowledge of the Big 6‡								
Control group	..	..	..	..	12·25 (3·04, 0·06)	12·54 (3·35, 0·07)	12·58 (3·26, 0·06)	12·53 (3·49, 0·07)
H4L group	..	..	..	..	11·89 (3·09, 0·05)	14·11 (3·77, 0·07)	13·05 (3·58, 0·07)	13·04 (3·63, 0·07)
H4L group *vs* control group	..	..	..	..	–0·36 (–0·73 to 0·01)	1·85 (1·53 to 2·16)	0·97 (0·69 to 1·26)	0·92 (0·62 to 1·21)

Data are number of students who did not meet the guideline recommendation out of the total number of students analysed for each outcome at each timepoint (%, SE), mean (SD, SE), odds ratio (95% CI) for dichotomous variables, and rate ratio (95% CI) or *b* (95% CI) for continuous variables. Odds ratios represent the between-group differences in likelihood of being in a higher risk category for the intervention group compared with the control group. *b*=regression coefficient. H4L=Health4Life intervention. *Data are rate ratio (95% CI). †The variable has four levels and was treated as ordinal. ‡Data are *b* (95% CI).

Table 1: **Raw data for each outcome by time and intervention status, and model-based between-group difference effect size estimates at each timepoint**

characteristics at baseline have been published elsewhere.[15] The number of students who completed the survey over time (figure) and baseline demographics by intervention group (appendix p 10) are provided. The descriptive statistics for outcomes by intervention group are reported (table 1). 6454 (97·2%) of 6640 students provided follow-up data on at least one occasion, and 5698 (85·8%) provided follow-up data on two or more occasions. Baseline characteristics by follow-up status are reported in the appendix (p 11), as are results from the attrition analyses by demographic characteristics and primary outcomes (appendix pp 12–13). Compared with students who completed follow-up surveys, those present at baseline only were more likely to identify as non-binary or gender fluid than male or female and were more likely to report higher truancy and lower grades. Compared with those who dropped out, students who completed follow-up surveys had lower odds of baseline alcohol use, excessive sugar-sweetened beverage intake (>5 cups per week), and not meeting sleep guidelines but higher odds of not meeting MVPA guidelines. There was no evidence of a difference in the odds of attrition between intervention groups for any outcome (appendix p 13). As such, missing at random was assumed. 96 teachers from 32 of the 35 control schools completed the logbook assessing the amount and format of education relating to the Big 6 that they delivered. 90 (94%) of these 96 teachers reported covering one or more of the Big 6 in at least one health education lesson in 2019 (appendix p 1).

Model fit statistics for the best fitting unconditional growth models and specification of time are reported in the appendix (p 15). Due to the high prevalence of not meeting guidelines for screen time and MVPA, most students were modelled in the continuous portion and the dichotomous (guidelines) portion of the model. A summary of parameter estimates and CIs of the LGMs

	Dichotomous portion of model				Continuous portion of model			
	Intercept		Slope		Intercept		Slope	
	OR (95% CI)	p value	OR (95% CI)	p value	RR (95% CI)	p value	RR (95% CI)	p value
Two-part latent growth model								
Moderate to vigorous physical activity								
Insufficient *vs* control group	1·06 (0·78 to 1·43)	0·73	0·74 (0·52 to 1·04)	0·081	0·99 (0·93 to 1·06)	0·82	0·98 (0·90 to 1·07)	0·66
Sufficient *vs* control group	0·94 (0·70 to 1·28)	0·71	0·94 (0·66 to 1·32)	0·71	1·003 (0·95 to 1·06)	0·93	0·99 (0·92 to 1·07)	0·83
Sufficient *vs* insufficient	0·89 (0·65 to 1·23)	0·50	1·27 (0·94 to 1·73)	0·12	1·01 (0·96 to 1·07)	0·71	1·01 (0·94 to 1·09)	0·79
Mean daily screen time								
Insufficient *vs* control group	1·29 (0·39 to 1·53)	0·46	0·82 (0·66 to 1·09)	0·17	1·02 (0·91 to 1·15)	0·69	1·02 (0·89 to 1·17)	0·79
Sufficient *vs* control group	0·90 (0·44 to 1·84)	0·77	0·92 (0·66 to 1·27)	0·61	0·99 (0·90 to 1·10)	0·88	1·01 (0·96 to 1·05)	0·79
Sufficient *vs* insufficient	1·16 (0·75 to 1·79)	0·51	1·12 (0·84 to 1·48)	0·44	0·97 (0·90 to 1·05)	0·42	0·99 (0·93 to 1·05)	0·68
Mean daily sleep hours								
Insufficient *vs* control group	0·96 (0·72 to 1·29)	0·81	0·91 (0·71 to 1·16)	0·45	0·95 (0·81 to 1·11)	0·54	1·15 (1·01 to 1·32)	0·040
Sufficient *vs* control group	1·09 (0·74 to 1·60)	0·70	0·82 (0·57 to 1·18)	0·28	0·92 (0·79 to 1·07)	0·26	1·15 (0·99 to 1·34)	0·062
Sufficient *vs* insufficient	1·13 (0·82 to 1·55)	0·45	0·90 (0·65 to 1·25)	0·53	0·96 (0·84 to 1·10)	0·58	1·00 (0·82 to 1·22)	0·99
Logistic latent growth model								
Alcohol use in the past 6 months								
Insufficient *vs* control group	0·98 (0·41 to 2·34)	0·97	1·03 (0·43 to 2·44)	0·95	..	..	..	..
Sufficient *vs* control group	0·60 (0·23 to 1·52)	0·28	1·98 (0·75 to 5·23)	0·17	..	..	..	..
Sufficient *vs* insufficient	0·61 (0·24 to 1·56)	0·30	1·93 (0·69 to 5·40)	0·21	..	..	..	..
Tobacco use in the past 6 months								
Insufficient *vs* control group	0·79 (0·35 to 1·79)	0·57	2·12 (0·86 to 5·19)	0·10	..	..	..	..
Sufficient *vs* control group	0·82 (0·30 to 2·26)	0·70	1·36 (0·47 to 3·91)	0·57	..	..	..	..
Sufficient *vs* insufficient	1·04 (0·40 to 2·72)	0·94	0·64 (0·24 to 1·70)	0·37	..	..	..	..
Ordinal logistic latent growth model								
Frequency of sugar-sweetened beverage consumption								
Insufficient *vs* control group	1·04 (0·61 to 1·79)	0·88	1·36 (0·98 to 1·89)	0·067	..	..	..	..
Sufficient *vs* control group	1·02 (0·59 to 1·77)	0·94	1·09 (0·85 to 1·41)	0·48	..	..	..	..
Sufficient *vs* insufficient	0·98 (0·62 to 1·56)	0·93	0·80 (0·61 to 1·07)	0·13	..	..	..	..
Continuous latent growth model								
Composite risk score								
Insufficient *vs* control group	−0·04 (−0·16 to 0·08)*	0·52	0·02 (−0·07 to 0·10)*	0·73	..	..	..	..
Sufficient *vs* control group	−0·02 (−0·13 to 0·09)*	0·77	0·01 (−0·10 to 0·11)*	0·90	..	..	..	..
Sufficient *vs* insufficient	0·02 (−0·09 to 0·13)*	0·69	−0·01 (−0·10 to 0·33)*	0·85	..	..	..	..
Knowledge of the Big 6								
Insufficient *vs* control group	−0·29 (−0·71 to 0·13)*	0·18	0·67 (0·39 to 0·94)*	<0·0001†	..	..	..	..
Sufficient *vs* control group	0·02 (−0·41 to 0·44)*	0·94	0·80 (0·48 to 1·13)*	<0·0001†	..	..	..	..
Sufficient *vs* insufficient	0·30 (−0·07 to 0·68)*	0·11	0·14 (−0·10 to 0·37)*	0·25	..	..	..	..

Data are OR (95% CI) or RR (95% CI) unless otherwise specified. Continuous portions of the two-part models were log-transformed. Slope estimates are for mean change in risk behaviours by the 24-month timepoint. *b*=regression coefficient. OR=odds ratio. RR=rate ratio. *Data are *b* (95% CI). †Significant at the p=0·006 level.

Table 2: **Latent growth model parameters and 95% CIs examining the effects of dose of Health4Life intervention on primary and secondary outcomes**

for each outcome is reported in the appendix (p 16). There were no significant effects of the intervention on the odds of alcohol or tobacco use, screen time, MVPA, sugar-sweetened beverage intake, or sleep over 24 months. Similarly, for students who did not meet guidelines (ie, the continuous portion of the model) there was little evidence of an intervention effect on mean days of MVPA, mean daily screen time hours, or mean daily hours of sleep (table 1; appendix p 16). In terms of secondary outcomes, there was little evidence of a between-group difference on mean composite risk scores over time. However, the Health4Life group reported significantly greater mean knowledge of the Big 6 scores over 24 months and at each assessment occasion (table 1; appendix p 16).

Of the 3610 intervention group students, 3157 (87·5%) were in schools with accurate online module completion data for the school-based programme and were included in the dose analyses. Of these 3157 students, 1960 (62·1%) received a sufficient dose and 1197 (37·9%) received an

insufficient dose. 407 (11%) intervention students accessed the universal Health4Life app and five (0·1%) accessed the selective Health4Life+ booster content. Issues with app uptake included restrictive school policies about mobile phone use, concerns about mobile phone storage, and not being aware of the app. The results from the LGMs for each outcome are reported in table 2. Students who received a sufficient dose had significantly greater mean knowledge of the Big 6 scores over 24 months relative to students in the control group, and at each follow-up occasion (appendix p 17). Similarly, compared with students in the control group, students who received an insufficient dose also had greater knowledge of the Big 6 over time and at each survey occasion (appendix p 17). No other outcomes were affected by dose (table 2; appendix p 17). No adverse events were reported during this trial.

2105 students from 33 intervention schools and 118 teachers from 35 intervention schools provided feedback about Health4Life. Overall, most students rated the programme as good or very good (1575 [74·8%] of 2105) and enjoyed the style of learning and the stories presented in the cartoons (1573 [74·7%]). The majority of teachers (99 [84%] of 118) also rated the programme favourably and most (84 [71%]) thought the cartoon stories held student attention well. Feedback on the Health4Life app was provided by 144 students who downloaded the app, of whom 115 (80%) said they would recommend the app to their friends.

Discussion

The hypothesised behavioural changes in the primary outcomes were not observed, with little evidence of group differences for alcohol use, smoking, screen time, MPVA, sugar-sweetened beverage intake, or sleep duration. However, Health4Life was acceptable to students and teachers and significantly improved students' knowledge about chronic disease risk factors over 24 months relative to an active control group. To our knowledge, this is the first study worldwide to evaluate the efficacy of an eHealth MHBC school-based intervention in simultaneously reducing the Big 6 risk factors for chronic disease among adolescents compared with an active control group.

Our results are somewhat consistent with a meta-analysis[11] that showed that eHealth MHBC interventions were not effective in reducing alcohol use, smoking, or sugar-sweetened beverage intake among secondary school students, but were associated with small, short-term improvements in screen time, MVPA, and fruit and vegetable intake. MHBC interventions are theorised to promote behaviour change efficiently and synergistically by increasing self-efficacy to modify risk behaviours.[9] However, by promoting concurrent action in all Big 6 behaviours in only six modules, Health4Life possibly did not cover each risk behaviour in sufficient detail. The OurFutures programmes (formerly Climate Schools), on which Health4Life was modelled, dedicate six lessons to just one behaviour (eg, alcohol use) and have been shown to significantly reduce alcohol use and related harms up to 7 years after the intervention.[20] Although there is mixed evidence to support the superiority of a sequential versus a simultaneous MHBC approach,[21] delivering education about the Big 6 sequentially over more lessons might have increased adolescents' capacity to apply the new skills and knowledge. Future interventions will need to balance providing sufficient education about each risk behaviour and the advantages of simultaneous prevention, such as highlighting relationships between health behaviours and efficiently providing health education in a busy academic curriculum.

One explanation for the null findings in relation to the primary outcomes is that education alone is not sufficient for behaviour change. Health4Life was associated with significant improvements in knowledge about chronic disease risk factors, with effects persisting up to 2 years after intervention delivery regardless of whether students received a sufficient or insufficient dose. This finding indicates that students were capable of learning preventive information about the Big 6. However, this knowledge did not translate into behavioural change. Although education is crucial for explaining why behavioural changes need to be made and for assisting adolescents to make informed health-related decisions,[22] knowledge alone is usually insufficient for behaviour change,[22] suggesting that refinements to intervention content are needed to improve the efficacy of Health4Life. First, although Health4Life included web-based targeted feedback on students' adherence to Australian health guidelines, further adapting to individuals' readiness to change might increase relevance.[9] Second, evidenced-based strategies, such as motivational interviewing, are probably needed to increase motivation to change behaviours.[23] Although the Health4Life+ app included elements of motivational interviewing, app uptake was very low. Including motivational interviewing in the universal school-based programme might have not only promoted behaviour change, but also increased app engagement. Baseline data from a cross-sectional survey indicated that many of the Big 6 were already highly prevalent at baseline (mean age 12·7 years)—eg, 5565 (85·9%) of 6478 students were exceeding screen time guidelines and 4969 (77·7%) of 6398 students were not sufficiently active.[15] Regarding screen time, rates of the Big 6 increased over the course of the trial and throughout the COVID-19 pandemic so that at 24 months (age 14 years), 2275 (92·1%) of 2470 students in the intervention group and 2115 (93·4%) of 2264 in the control group reported excessive screen time. These results suggest that these behaviours are already well entrenched by the first year of secondary school, and that earlier intervention might be warranted. Finally, to modify these behaviours, multilevel approaches are probably required. These approaches could include

additional support and skill-building opportunities in the school setting, such as whole-of-school approaches for MVPA[24] or coaching (eg, from teachers or trained peers) to help students understand the key parts of Health4Life and apply the relevant information to their own lives, which has been shown to improve the effectiveness of and adherence to eHealth interventions.[25] Furthermore, due to the crucial role parents have in influencing adolescent health behaviours,[26] they should be included in intervention efforts. A systematic review showed that parent-based interventions delivered in conjunction with adolescent components were associated with positive programme effects.[27] Notably, 90 (94%) of 96 teachers from control schools reported teaching lessons on one or more of the Big 6 behaviours during the intervention year, thereby making the control condition an active control condition. As such, the null effects on behaviour change suggest that Heath4Life could be equivalent to health education as usual, rather than not effective.

The association between high-quality implementation and intervention outcomes is well recognised in prevention science. An advantage of eHealth interventions, such as Health4Life, is that integral content can be preprogrammed and completion is self-directed by students; therefore, implementation is not dependent on teacher training or skills. Moreover, the flexible nature of online delivery means that students can complete missed lessons at home or in a follow-up lesson, increasing their potential to receive the intervention in full. Despite these benefits, and the intervention being part of the school curriculum and completed under teacher supervision, only 62·1% of students received a sufficient dose of Health4Life. A priori exploratory analyses assessing the effect of dose on outcomes were largely consistent with the primary analyses. There were no differences between students who received a sufficient dose of the intervention and students in the control group on the primary outcomes, and both sufficient and insufficient doses were associated with greater knowledge of the Big 6 over time relative to the control group. The propensity model to predict likelihood of a sufficient dose was constructed through student-level variables and did not include other factors likely to have influenced dose, such as technical issues or teachers' willingness to prioritise intervention delivery among other competing demands. An important next step will be to further examine the effects of student engagement, implementation fidelity, additional acceptability data not included in this Article (eg, qualitative data), and feasibility data on intervention completion and outcomes.

Although we did not specify an a priori threshold for app engagement, uptake of the universal Health4Life app and selective Health4Life+ booster content was low, with 407 (11·3%) of 3610 intervention students accessing the Health4Life app and five (0·1%) accessing the selective Health4Life+ booster content. Although smartphone ownership among adolescents is nearly universal in Australia,[28] engagement with health-related apps among adolescents who are not seeking support to improve their health behaviours remains a challenge. Issues with app uptake in this study included restrictive school policies about mobile phone use, concerns about mobile phone storage, and not being aware of the app.[29] The content of the Health4Life app was co-designed with adolescents and included evidence-based behaviour change techniques.[13] However, strategies to promote the availability of the app and the Health4Life+ additional content were minimal (eg, email prompts and teacher prompts) and not co-designed; promotion strategies after randomisation would probably have increased engagement. Further research and ongoing end-user consultation are needed to better understand how to optimise app uptake and engagement. The staged model of prevention used in Health4Life aimed to deter risk factors from emerging in the first place and to provide additional, ongoing support to adolescents who were already showing indicators of emerging risk of chronic disease to help them improve their health behaviours. Therefore, without sufficient uptake of the app and booster content, the Health4Life intervention was limited to a brief, 6-week, universal intervention. Sustained intervention or prompts could have helped prevent risk behaviours from emerging during the following years or could have provided additional support to reduce those behaviours over the following years. Because of the documented benefits of booster sessions[30] and selective approaches in prevention, implementing additional in-class sessions, such as booster cartoon modules or activities for adolescents at increased risk of chronic disease, could be beneficial.

The social context of a study designed to modify lifestyle risk behaviours during an unprecedented global pandemic is worthy of discussion. Although Health4Life was implemented in 2019, the 12-month and 24-month follow-up assessments and the selective intervention were implemented during the COVID-19 pandemic. Throughout the pandemic, adolescents experienced substantial disruptions to schooling, employment, and peer relationships and effects on health behaviours among youths have been documented worldwide.[31,32] The intermittent and sometimes extended restrictions on movement and social interactions in Australia during 2020–21 might have reduced opportunities for students to apply the new knowledge and skills learned via the intervention in their own lives. For example, organised sport, one of the most common forms of physical activity among adolescents, was often cancelled for periods of time and use of screens to connect with friends and family was sometimes the only option. Furthermore, a longitudinal study published in 2022 suggested the effect of the COVID-19 pandemic on adolescents' risk behaviours extended beyond the acute effects of lockdown periods.[31] There were also increasing mental health problems among adolescents during the pandemic,[33,34]

which are closely inter-related with lifestyle risk behaviours. Therefore, the potential effects of Health4Life on the Big 6 are likely to have been overwhelmed by the physical and social contexts of the COVID-19 pandemic.

Our results should be considered in the context of several limitations. First, due to the scale of the study, objective data collection was not feasible and measurement relied on self-report surveys. As a result, students could have underestimated or overestimated their health behaviours. Second, although our cohort comprises students attending independent, public, and Catholic secondary schools across three Australian states, it is not nationally representative and students were predominantly born in Australia, of middle or upper socioeconomic status, and living in major cities,[15] which limits the generalisability of our results. Future studies should recruit populations with greater cultural and socioeconomic diversity. Finally, due to withdrawal of schools, this trial was not powered to detect differences in effect sizes between the different trial sites across Australia. Therefore, we do not report site-specific intervention effects. However, future exploratory work aims to examine the effects of COVID-19 on our outcomes, as some sites were relatively unaffected by lockdowns (eg, Western Australia) whereas others were considerably affected (eg, New South Wales). Nonetheless, the current study was a rigorous cluster-randomised controlled trial of 6640 Australian adolescents from 71 secondary schools, making it one of the largest school-based studies of its kind. Health4Life was developed in close consultation with end-users,[12,13] it was perceived as relevant and engaging by students and teachers, and implementation was deemed acceptable within a school setting.

The Health4Life intervention was not effective in modifying lifestyle risk behaviours among Australian adolescents. However, results indicated that Health4Life was associated with improved knowledge about six chronic disease risk factors over 24 months. Further research to refine intervention content and improve uptake of the web-based and app-based components is required. Implications for future eHealth MHBC interventions include consideration of the timing of intervention delivery, incorporating parents and motivational enhancement strategies into prevention efforts, and ongoing end-user consultation to optimise engagement with apps and emerging technology.

The Health4Life Team

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Contributors

KEC and NCN led the development of this Article and contributed equally. MT, KEC, NCN, FK-L, CC, LT, TS, MS, KM, BP, DRL, LH, NM, SA, and BS secured funding for this study. KEC and LT led intervention development. KEC and LAG were responsible for ethics and governance, overall trial coordination, and supervision of staff with oversight from MT, NCN, and CC. LAG, BO, SS, KMM, and EH were responsible for recruitment of schools and data collection in New South Wales. SA and NM were responsible for trial coordination, school recruitment, and data collection in Western Australia with assistance from JW and CS. LH was responsible for trial coordination, school recruitment, and data collection in Queensland with assistance from RE and AC. TS, MS, and SO'D were responsible for data analysis and data monitoring. Data were directly accessed and verified by KEC, MS, TS, SO'D, LAG, SS, and BO. All authors had full access to all the data. All authors contributed to developing protocols for the study and reviewed, edited, and approved the final version of the manuscript. All authors had final responsibility for the decision to submit for publication.

Declaration of interests

MT and NCN are developers of OurFutures, the web-based programme (formerly Climate Schools) on which Health4Life was modelled, and are co-directors of CLIMATESchools, a company established to enable the distribution of evidence-based wellbeing resources to schools. FK-L's digital programme SHADE is the subject of licensing arrangements with Magellan Health and Cobalt Therapeutics. FK-L has not received any royalties in relation to these licensing agreements to date, but may receive some in the future. FK-L is a non-executive board member for the Orygen Medical Research Institute, is President of the Society for Mental Health Research, and is a member and Research Committee Chair of the Women in Health Science Committee for the Australian National Health and Medical Research Council. All other authors declare no competing interests.

Data sharing

The statistical analysis code (syntax) and data collected for the study, including de-identified participant data, will be made available to researchers on request to the corresponding author and with appropriate reason when accompanied by study protocol and analysis plan. Data will be shared after the approval of a proposal by a committee of the current research team with a signed data access agreement. Informed consent forms are available in the published protocol (https://bmjopen.bmj.com/content/10/7/e035662).

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