Rationale and study protocol for 'Switch-off 4 Healthy Minds' (S4HM): A cluster randomized controlled trial to reduce recreational screen-time in adolescents.

Mark J. Babic[1], Philip J. Morgan[1], Ronald C. Plotnikoff[1], Chris. Lonsdale[2], Narelle Eather[1], Geoff Skinner[3], Amanda L. Baker[4], Emma Pollock[1] and David R. Lubans[1].

[1]Priority Research Centre in Physical Activity and Nutrition, University of Newcastle, Newcastle, NSW, Australia.

[2]Institute for Positive Psychology and Education, Australian Catholic University, Strathfield, NSW, Australia.

[3]Faculty of Science and IT, University of Newcastle, Newcastle, NSW, Australia.

[4] School of Medicine and Public Health, University of Newcastle, Newcastle, NSW, Australia.

*Corresponding author: Associate Professor David Lubans

Phone: 4985 4255

Email addresses: David.Lubans@newcastle.edu.au

Postal address: University Drive, Callaghan NSW 2308. Priority Research Centre for Physical Activity and Nutrition ATC 303.

MB: Mark.Babic@uon.edu.au
PM: Philip.Morgan@newcastle.edu.au
RP: Ronald.Plotnikoff@newcastle.edu.au
CL: Chris.Lonsdale@acu.edu.au
NE: Narelle.Eather@newcastle.edu.au
GS: Geoff.Skinner@newcastle.edu.au
AB: Amanda.Baker@newcastle.edu.au
EP: Emma.Pollock@newcastle.edu.au
DL: David.Lubans@newcastle.edu.au

ABSTRACT

Introduction: Excessive recreational screen-time (i.e., screen use for entertainment) is a global public health issue associated with adverse mental and physical health outcomes. Considering the growing popularity of screen-based recreation in adolescents, there is a need to identify effective strategies for reducing screen-time among adolescents. The aim of this paper is to report the rationale and study protocol for the 'Switch-off 4 Healthy Minds' (S4HM) study, an intervention designed to reduce recreational screen-time among adolescents.

Methods: The S4HM intervention will be evaluated using a cluster randomized controlled trial in eight secondary schools (N=321 students) in New South Wales, Australia. The 6-month multi-component intervention will encourage adolescents to manage their recreational screen-time using a range of evidence-based strategies. The intervention is grounded in Self-Determination Theory (SDT) and includes the following components: an interactive seminar for students, eHealth messaging, behavioral contract and parental newsletters. All outcomes will be assessed at baseline and at 6-months (i.e., immediate post-test). The primary outcome is recreational screen-time measured by the Adolescent Sedentary Activity Questionnaire (ASAQ). Secondary outcomes include: self-reported psychological well-being, psychological distress, global physical self-concept, resilience, pathological video gaming and aggression, and objectively measured physical activity (accelerometry) and body mass index (BMI). Hypothesized mediators of behavior change will also be explored.

Discussion: The S4HM study will involve the evaluation of an innovative, theory-driven, multi-component intervention that targets students and their parents, and is designed to reduce recreational screen-time in adolescents. The intervention has been designed for scalability and dissemination across Australian secondary schools.

Keywords: Screen, Behavior, School, Physical activity.

Introduction

Over the past 20 years, young people's recreational screen-time (screen-based entertainment) has increased rapidly [1-3]. Recreational screen-time refers to the time spent using electronic devices such as televisions, computers, video games, and multimedia devices (e.g., tablets / iPads / iPod / iPhones) for entertainment purposes. The majority of young Australians[4], Europeans[5], and North Americans[5, 6] exceed the screen-based recreational guidelines of less than 2-hours per day [7]. Specifically relating Australian secondary students; 42% of girls and 45% of boys spend 2-4 hours per day engaged in screen recreation[4]. Comparably, 69% of girls and 71% of boys from the Netherlands, 68% of girls and 74% of boys from England, 60% of girls and 65% of boys from Canada exceed screen-time recommendations[8]. The existing high levels of screen-time represent an immediate public health concern, as evidence suggests that excessive recreational screen-time (> two hours) is positively associated with a range of adverse physical and mental health outcomes including; obesity[9, 10], hypertension[11], increased aggressive behavior, decreased empathy, reduced pro social behavior [12] and depression[13-15].

Given that sedentary behaviors established during adolescence have shown to track into adulthood [14], it is important to intervene at an early age. Schools provide convenient access to the majority of young people and possess the necessary facilities, personnel and ethos to engage youth [16]. Although there is strong evidence suggesting that interventions delivered in the school setting can improve health behaviors in young people, school-based interventions that include a parental component appear to be more successful [17, 18]. Parents influence their children's lifestyle behaviors in a number of ways including, parental regulation, rule setting [19-22], reinforcing positive behaviors, parental concerns [23] and role modeling [24]. Indeed, parents may provide the key to reducing screen-time in young people as aspects of the family and home environments appear to be related to the amount of screen use [25]. For example, in the 'Health In Adolescents' study, parental regulation of screen behaviors was associated with changes in screen-time [19]. Consequently, empowering parents with specific strategies to manage their children's screen-time may assist in promoting healthier lifetime behaviors [26].

Adolescence represents a period of increasing autonomy, as young people are provided with more freedom over their discretionary time [27], and increased opportunities to make choices and pursue goals[28]. Although it has been suggested adolescents find it challenging to manage their recreational screen-time, a recent study demonstrated

amotivation was positively associated with self-reported screen-time, while both controlled and autonomous motivation were inversely associated with screen-time,[29]. Adolescents, who understand and value the importance of limiting their screen-time, engage in less screen-time than those who are not concerned with the consequences of excessive screen-time which is consistent with the principles of SDT[30]. Based on the high levels of recreational screen-time observed among adolescents across the globe and the adverse health outcomes associated with such behaviors, there is an urgent need to develop and evaluate interventions to reduce screen-time in adolescents. Therefore, the aim of this paper is to provide the rationale and study description for the Switch-off 4 Healthy Minds (S4HM) school-based intervention.

2 Methods/Design

2.1 Study design

The S4HM intervention will be evaluated using a cluster randomized controlled trial (RCT). The 6-month intervention will target male and female adolescents in Grade 7 (first year of secondary school) in Catholic schools in New South Wales, Australia (2014). One school consists of only female students, the remaining seven are co-educational. Assessments were conducted at baseline [April-June (Term 2) 2014], and will be repeated post-program [August-December (Term 4) 2014]. The design, conduct and reporting for this RCT will adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for clustered trials[31]. Ethics approval for the study was obtained from the Human Research Ethics Committees of the University of Newcastle, Newcastle-Maitland Catholic Schools Office and the Diocese of Broken Bay. School principals, parents and students (hereafter referred to as participants) provided written informed consent.

2.2 Sample size calculation

A power calculation was conducted to determine the sample size required to detect changes in the primary outcome [i.e., recreational screen-time from the ASAQ][32]. Calculations were based on 80% power with alpha levels set at $p < 0.05$, using an intraclass correlation coefficient (ICC) of 0.03 and a standard deviation of 91 minutes, based on a previous school-based study[33]. Using the 'design effect', an estimate was made on the extent to which the sample size should be inflated to accommodate for the homogeneity in the clustering of effects at the school level. It was calculated that a study

sample of N = 320 students (i.e., 40 students from 8 schools) would provide adequate power to detect a between group difference of 42 minutes per day of recreational screen time. Outcomes will be analyzed using linear mixed models which are robust to the biases of missing data, however, based on our previous studies we will achieve a retention rate of at least 80%.

2.3 Setting and screening of participants

Eligible schools were low fee paying independent secondary schools located in the Newcastle, Hunter, and Central Coast areas of NSW. All eligible schools (N = 20) were sent an information letter inviting them to participate in the study. The first eight schools to provide written consent were recruited into the study (see Figure 1). All students in grade 7 at the study schools were invited in Term 1, 2014, to complete a screen-time eligibility questionnaire. The questionnaire asked students to report their time spent using screen-based recreation on a typical school day. Students were considered eligible to participate in the study if they reported ≥ 2 hours/day of recreational screen-time. During this visit, students who satisfied the eligibility criteria were provided with an overview of the study and invited to participate. Information and consent letters were sent home with students and the first 40 students from each school to return signed consent letters were recruited into the study.

2.4 Blinding and randomization

Once baseline assessments were conducted, schools were randomized to one of two study arms (i) S4HM intervention group or (ii) control group. Schools were matched according to their size, location and socio-economic status using the Socio-Economic Indexes for Areas index of relative socio-economic disadvantage [34] and then pairs of schools were randomly allocated to one of the two study groups using a computer-based random number-producing algorithm. This method ensured an equal chance of allocation to each group. The randomization was conducted by a researcher not involved in the current project. Assessors will be blinded to group allocation at post-test.

2.5 Intervention

S4HM is grounded in Self-determination Theory (SDT)[30] tenets and is designed to increase adolescents' autonomous motivation [29] to limit their recreational screen-time by satisfying their basic psychological needs for autonomy, competence, and relatedness. Autonomy refers to an individual's need to feel in control of their behaviours and

goals[30], while competence refers to the need to gain mastery of tasks and learn different skills[30]. Finally, relatedness refers to an individual's desire to experience a sense of belonging and attachment to other people[30]. The S4HM intervention components, behavior change strategies and hypothesized mediators are described in Table 1.

Students' autonomy to limit their recreational screen-time will be targeted using a variety of strategies. For example, participants will be provided with an opportunity to specify their preferred technological social media to receive their eHealth messaging from the following: Twitter, Facebook, Kik or text messages. Through newsletters, parents will be encouraged to include their children in designing household screen-time rules and to give their children choice relating consequences of exceeding screen-time limits. Perceptions of competence will be supported using positive reinforcement throughout the study, self-monitoring, goal setting to reduce recreational screen-time and behavioral contracts. Such strategies will allow for a positive reflection on abilities and may assist in building competence. Feelings of relatedness will be targeted by encouraging participants to make connections through face-to-face meetings and competing with others in screen-time reduction challenges, including family and friends throughout the study. In addition, participants will be encouraged to share the social media messaging information with their friends (face-to-face), whilst challenging participants to include friends or relatives in proposed physical challenges. Encouraging a network of support provides safety and supports growth; such strategies are aimed to provide a sense of belonging. A key feature of the support provided will be the encouragement of rules, as providing instructions have been found to be significantly inversely associated with screen-time [21]. Additionally, advice on role modelling to parents will also be an important factor, as parent and child levels of screen viewing are strongly related [24].

Parents will receive hard copies of the monthly newsletters in the mail. Six newsletters have been developed for parents to help support them whilst managing their children's screen-time. The newsletters provide parents with information and various tips, strategies and research regarding limiting recreational screen-time and the consequences of excessive screen-time. Parents will also be provided with conflict resolution strategies to help with any arguments that may arise as a result of reducing screen-time. In addition, the fifth newsletter will include a behavior contract and a list of potential screen-time rules

2.6 Control group

To prevent possible compensatory rivalry and resentful demoralization, the control schools will be provided with the program after the follow-up assessments.

Table 1: Intervention components, behavior change techniques and targeted constructs in the S4HM intervention

Intervention component	Dose	Description	Behavior change strategies	Hypothesized mediators
1) Interactive seminar	Once at the start of the intervention (60 minutes)	The interactive seminar will be delivered by a member of research team to students during school hours. The session will focus on the consequences of excessive screen-time and the benefits of reducing screen-time. Students will be given the opportunity to ask any questions and interact throughout the session using Turning point™ interactive polling.	▪ Information on consequences ▪ Prompt intention formation ▪ Provide instruction ▪ General encouragement	▪ Motivation to limit screen-time ▪ Perceived autonomy ▪ Perceived competence ▪ Perceived relatedness
2) *eHealth*	50 prompts over 6 months. Bi-weekly	Participants will select their preferred method for receiving eHealth messages from the following: Twitter, Facebook, Kik or text messages. Messages will address the consequences of excessive screen-time and the importance of self-management (self-monitoring screen-time and goal setting for increasing/decreasing behaviors).	▪ Provide information about behavior health link ▪ Prompt self-monitoring of behaviors ▪ Prompt barrier identification ▪ Prompt specific goal setting	▪ Motivation to limit screen-time

3) Behavioral contract	Once	Students will be asked to sign a screen-time behavioral contract in the second month of the intervention. The contract provided describes appropriate replacement behavior and encourages the creation of a list of; potential screen-time rules, benefits of limiting screen-time, possible barriers of limiting screen-time, possible solutions to such barriers and consequences of exceeding screen-time limits.	▪ Prompt specific goal setting ▪ Prompt identification as a role model	▪ Motivation in school sport ▪ Perceived autonomy ▪ Perceived competence
4) Parental newsletters	6 over 6 months (1 per month)	The newsletters will be sent to parents and focus on: household screen-time rules, consequences of excessive screen-time, strategies to manage parent/child conflict arising from screen-time rules and home challenges to reduce recreational screen-time. For example, setting clear rules, placing limits on screen-time, and not having screen-based media in bedrooms will aim to encourage fewer hours of screen-time in adolescents.	▪ Provide information about behavior health link ▪ Prompt self-monitoring of behaviors ▪ Prompt specific goal setting ▪ Information on consequences ▪ General encouragement	▪ Perceived competence ▪ Physical activity behavioral strategies ▪ Motivation to limit screen-time

2.7 Outcomes:

All assessments will be conducted by trained research assistants at the study schools. Prior to baseline data collection, research assistants participated in an assessment workshop ~~before baseline data collection~~. A protocol manual with detailed instructions for conducting assessments was used by research assistants during baseline data collection and will be used during follow-up assessments.

2.7.1 Primary outcome:

2.7.1.2 Recreational screen-time:

Recreational screen-time was measured using the Adolescent Sedentary Activity Questionnaire (ASAQ) [32]. The ASAQ requires participants to report the time they spend doing the following activities during a normal school week: i) watching televisions, ii) watching DVD's/videos, iii) using the computer for fun, iv) using tablets/ iPads/iPods/iPhones etc. (the final category was added to the original measure). Total recreational screen-time is then determined as the sum of time spent in each of the screen time categories~~screen behavior~~. The ASAQ has excellent reliability (Cronbach's α = .78 and .90 for girls and boys in grade 8 respectively)[32], and is considered a comprehensive measure of sedentary behaviors among young people [32].

2.8.2 Secondary outcomes:

2.8.2.1 Psychological distress

The 10-item Kessler Psychological Distress Scale [35] was used to provide a global measure of distress. The K10 is based on questions about anxiety and depressive symptoms experienced in the past four weeks [36]. Scores range from 10 to 50. Scores under 20 indicates likelihood to be well, 20-24 an individual is likely to have a mild mental disorder, 25-29 indicates a possibility of having moderate mental disorder and individuals with scores of 30 and over are suspected to have a severe mental disorder[36]. The K10 has shown excellent reliability (Cronbach's α = .93)[35] in Australians aged >18.

2.8.2.2 Pathological video game use

Gentile's pathological video gaming scale [37] was employed to gather information regarding video-gaming habits and parental involvement in gaming and to determine who met clinical-

style criteria for pathological gaming. The scale contains 11 questions pertaining to cognitions and behaviors indicative of pathological gaming (e.g., 'Have you ever lied to family or friends about how much you play video games?'). Students responded either 'Yes' (=1), 'No' (=0), or 'Sometimes' (=0.5) to each question. A sum total of ≥6 qualifies a subject as a pathological gamer. Gentile's pathological video gaming scale has reported high reliability for U.S. adolescents aged 8-18 (Cronbach's α= .78)[37].

2.8.2.3 Aggression

Aggressive behavior was assessed using an aggression scale designed for young adolescents [38]. Students were asked to report how many times in the last week they engaged in 11 specific aggressive behaviors (e.g., 'I teased students to make them angry'). Responses range from 0 to 6 or more times per week for each aggressive behavior. Items were summed to produce a total aggression score (possible range 0 to 66). This scale has demonstrated satisfactory content and construct validity in both adolescent females and males (Cronbach's α = .87)[38].

2.8.2.4 Psychological well-being

The Strength and Difficulties Questionnaire (SDQ) [39] is a brief behavioral screening questionnaire for 3-16 year olds. The 25 items are divided between five scales; emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and prosocial behavior, all of which identify problems with; conduct, emotions, peer relations and hyperactivity[40]. A self-report version of the SDQ has also been validated in children of 11 years or over [41]. The SDQ reported acceptable reliability in European sixth, seventh and eighth graders (Cronbach's α = .88)[41].

2.8.2.5 Global physical self-concept

The global physical self-concept subscale from the Physical Self-Description Questionnaire (PSDQ)[42] was used to provide a measure of self-concept in the physical domain. Students were asked to respond on a 6-point scale (1 = 'False', to 6 = 'True') how true each statement was for them (e.g., 'I am a physically strong person'). The PSDQ provides a reliable method for measuring physical self-concept in adolescents (Cronbach's α = .88) [42].

2.8.2.6 Household screen-time rules

Household screen-time rules were measured using items developed by Ramirez et al. [21]. Students were required to respond 'No', 'Sometimes', or 'Yes' for each of the five items relating to screen-time rules within their family home (e.g., '*In your home do your parents/caregivers have the following rules about screen use? i.e., No recreational screen-time before homework'*). The items were originally designed to apply specifically to TV/DVD or computer use and were adapted to apply to all screen-time devices. The kappa statistic was used to assess reliability of the dichotomous responses for the rules items and agreements on rules between parent and adolescent. Parent and adolescent reliability and agreement for rules regarding sedentary behaviours vary. Parents' test-retest reliability coefficients are reported to be consistently higher for each item (κ range: .44–.70) as compared with adolescents' (κ range: .43–.61)[21].

2.8.2.7 Motivation to limit recreational screen-time

The Motivation to Limit Screen-time Questionnaire (MLSQ) [29] was used to assess participants' motivation for limiting their recreational screen-time. The MLSQ contains 9 questions relating to the three broad motivational regulations outlined in SDT (i.e., autonomous motivation, controlled motivation, and amotivation) [30]. A positive score represents autonomous motivation to limit screen-time. The MLSQ has demonstrated satisfactory construct validity and test–retest reliability in adolescent boys (Cronbach's α = .82).

2.8.2.8 Physical Activity

Physical activity was assessed using GENEActiv (Model GAT04, Activinsights Ltd, Cambridgeshire England) wrist worn accelerometers. The devices were worn by participants during waking and sleeping hours and water activities for seven consecutive days. Data were collected and stored in five second epochs. GENEActiv wrist worn accelerometers have displayed acceptable intra-and inter-instrumental reliability and provide a valid and reliable estimate of physical activity in young people [43, 44]. Thresholds for the classification of activity intensity were taken from recent research undertaken using the GENEActiv accelerometers [43, 44]. ~~Wrist worn devices have the potential for higher subject compliance and cut-points for adolescents [43](Cronbach's α = .88)[43].~~

2.8.2.9 Body mass index

Height and weight. Weight was measured to the nearest 0.1 kg without shoes, in light clothing using a portable digital scale (Model no. UC-321PC, A&D Company Ltd, Tokyo Japan) and height was recorded to the nearest 0.1 cm using a portable stadiometer (Model no. PE087, Mentone Educational Centre, Australia). BMI was calculated using the standard equation (weight [kg] / height $[m]^2$) and BMI z-scores were calculated using the 'LMS' method[45].

2.9 Process evaluation

Process data will be collected to complement the outcome data. Process measures including; retention, adherence, feasibility and satisfaction will be collected from parents and students using a process evaluation questionnaire (e.g., reading newsletters and using suggested strategies to reduce screen-time) and a satisfaction questionnaire for the students (e.g., reading prompts, responses to wearing the accelerometers and using suggested strategies to reduce screen-time).

3.0 Statistical methods

Statistical analyses of the primary and secondary outcomes will be conducted with linear mixed models using IBM SPSS Statistics for Windows, Version 20.0 (2010 SPSS Inc., IBM Company Armonk, NY) and alpha levels will be set at $p < 0.05$. The models will be used to assess the impact of treatment (S4HM or control), time (treated as categorical with levels baseline and 6-months) and the group-by-time interaction, these three terms forming the base model. The models will be specified to adjust for the clustered nature of the data and will include all randomized participants in the analysis. Mixed models are robust to the biases of missing data and provide an appropriate balance of Type 1 and Type 2 errors [46]. Mixed model analyses are consistent with the intention-to-treat principle, assuming the data are missing at random [47]. Differences between completers and those who drop out of the study will be examined using Chi-square and independent samples t-tests. Multiple imputations will be considered as a sensitivity analysis if the dropout rate is substantial. Hypothesized mediators of physical activity and screen-time rules will be examined using multilevel linear analysis and a product-of-coefficients test [48]. Moderators of intervention effects will be explored using linear mixed models with interaction terms for the following: i) sex (boys and girls), ii) SES (based on participants' household postcode SES), iii) weight status (healthy weight, overweight/obese), and iv) baseline recreational screen-time (2 hours/ day of screen-

time or > 2 hours/day) Subgroups analyses will be conducted if significant ($p < 0.1$) interaction effects are identified.

4. Results

The study design and flow is presented in Figure 1. Of the schools that were contacted, eight consented to participate and one declined. Eligibility screening was completed by 1107 students, of whom 918 (83%) were considered eligible. The recruitment target of 40 students per school was achieved in seven of the eight schools and a total of 323 students completed baseline assessments.

5. Discussion

Recreational screen-time use among adolescents has increased at an exponential rate and the majority of young people in developed nations exceed the screen-time recommendations [3]. A number of well-designed[10, 49] studies have found individuals spending >2 hours a day in front of televisions, are more likely to have higher blood pressure[49] and cholesterol levels[10]. Additionally studies have shown a significant dose-response relationship between screen-time and various adverse health outcomes including: risks of type II diabetes, cardiovascular disease and all-cause mortality[13]. Excessive screen-time not only affects an individual's physical health, it is inversely associated with indicators of mental health [50], such as self-esteem [51]. Adverse effects are further demonstrated in a recently published article which described 'Facebook Depression' as preteens and teens are experiencing classic symptoms of depression from spending excessive time on social media sites [52]. Therefore, reducing screen-time is a potential strategy to prevent and treat health concerns[53].

Reducing screen-time has been identified as a key strategy for improving the physical and psychosocial health of young people [13, 54]. The current evidence base of effective interventions is limited. Although screen-time is often targeted in lifestyle interventions focused on increasing physical activity and improving dietary behaviors, no previous intervention has focused solely on reducing recreational screen-time in adolescents. Recent systematic reviews have demonstrated that multi-component interventions targeting screen-time can achieve small, but statistically significant decreases in young people's screen-time [55, 56]. This is a notable finding as the determinants of physical activity and screen-time are indeed different, and unique strategies may be required to modify specific lifestyle behaviors as one intervention strategy may not cover the diverse needs of various subgroups[57].

Interventions designed for specific groups have been suggested and trialled with differing results[57]. Notably, it is of additional concern that previous lifestyle interventions studies have focused on reducing television viewing [58] and have largely ignored the other forms of recreational screen-time, such as video game playing and using the internet for social media, which are particularly popular among young people.

Therefore, identifying strategies to reduce the time that young people spend engaged in recreational screen-time is a challenging endeavor. Although previous studies have achieved some success in reducing television viewing in child populations[1, 53], few studies have successfully reduced screen-time in adolescents. The S4HM intervention will target students in the first year of secondary school and eligible students will be those who are currently exceeding screen-time recommendations. Of the few systematic reviews examining intervention strategies to limit screen-time in adolescents [1, 55]; none have examined strategies to discourage parents from placing TVs in their children's bedrooms or remove TV's [53]. Recommendations have been made to specifically address the removal of TV's from children's bedrooms in order to reduce screen-time in young people [53]. In response to such findings, S4HM will provide advice to parents and adolescents regarding the positioning and time allowances of TV using both newsletters and social media prompts. Studies have also found parental rules and limits on screen-time may reduce screen-time [21, 59]. Demonstrated in a recent systematic review and meta-analysis; multi-component interventions may be the most effective way to reduce recreational screen-time among adolescents, thus its presence in S4HM [1].

Increasing parental awareness of the consequences of excessive screen-time may assist in achieving screen-time behavior change in adolescent populations [53]. S4HM aims to support parents through monthly newsletters containing information on; household rules, dangers of social media, video game addiction, consequences of excessive screen-time and the importance of role-modelling. Each of the concepts are designed to engage and educate parents and their children, as previous studies have identified closer family communication and improved school performance as a result of reducing screen use in adolescents [60]. S4HM aims to provide information regarding various skills parents can adopt, or continue to use, in order to reduce recreational screen-time. S4HM aims to provide such guidance through suggestions of developing constructive practical alternatives to screen-time.

To the authors' knowledge, this is the first intervention to incorporate a social media component into a screen-time reduction intervention; however the student has to choose that option. However, the strategies to reduce recreational screen-time that will be used in the S4HM intervention were originally tested in obesity prevention programs targeting adolescent boys [33, 61] and girls [62] from secondary schools in the Hunter Region, NSW, Australia. The 'Nutrition and Enjoyable Activity for Teen Girls' (NEAT Girls) study was a multi-component school-based intervention developed in reference to Bandura's Social Cognitive Theory (SCT) [63]. NEAT Girls was designed to target specific mediators of physical activity and nutrition behavior and participants were low-active adolescent girls attending schools in low-income communities. Similarly, 'Active Teen Leaders Avoiding Screen-time' (ATLAS) was conducted in 14 secondary schools with 361 adolescent boys, considered to be 'at risk' of obesity, based on their self-reported physical activity and screen-time. Both the NEAT Girls [29] and ATLAS [61] interventions resulted in significant reductions in recreational screen-time of approximately 30 minutes/day.

6. Conclusion

This paper has outlined the rationale and study protocol for the S4HM recreational screen-time reduction intervention for adolescents. The intervention has a strong theoretical foundation and incorporates novel strategies to decrease recreational screen-time. The S4HM intervention will also improve our understanding of psychological and cognitive mechanisms of behavior change through the assessment of a number of potential mediators. Improved understanding of these relationships could help in developing interventions to promote general well-being among adolescents.

Author's contributions

DRL, PJM, RCP, NE, GS, AB obtained funding for the research. All authors contributed to developing the protocols and reviewing, editing, and approving the final version of the paper. DRL, PJM, RCP, CL, GS and MB developed the intervention materials. MB and EP were responsible for data collection and cleaning. DRL is the guarantor and accepts full responsibility regarding the conduct of the study and the integrity of the data. All authors have read and approved the final manuscript.

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Figures:

Figure 1: Study design and flow