

Recruitment of adolescents to virtual clinical trials: experiences from the Health4Me clinical trial

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Recruitment of adolescents to virtual clinical trials: experiences from the Health4Me clinical trial

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Abstract

Background: Preventive interventions are needed to provide targeted health support to adolescents to improve health behaviors. Engaging adolescents in preventive interventions remains a challenge, highlighting the need for innovative recruitment strategies. Given adolescents' lives are intertwined with digital technologies, attention should be focused on these avenues for recruitment. The evolving nature of clinical trials, including the emergence of virtual clinical trials, require new recruitment approaches, which must be evaluated.

Objective: To examine the effectiveness and cost of various digital recruitment strategies for recruiting adolescents to a virtual clinical trial, and to evaluate the progression of participants from screening to enrolment and explore factors associated with non-participation. We do this using the example of the Health4Me Study, a preventive digital health intervention to improve physical activity and nutrition behaviors among adolescents 12-18 years old.

Methods: Participants were recruited into the Health4Me Study via social media advertisements on various contemporary platforms, emails to schools, emails to contacts within known networks and emails to relevant youth organizations. Data was collected from social media advertisements, screening, and recruitment logs. Data analysis included summary and descriptive statistics, as well as Chi-Squared tests to explore factors associated with non-participation.

Results: From 2369 expressions of interest, 390 (16.4%) participants were enrolled. A total of 19 advertisements were placed on social media, and 385 promotional emails were sent to schools, contacts within known networks, and relevant youth organizations. Social media advertisements reached 408,077 unique accounts. Advertisements mostly reached those living in populous states in Australia (75% of unique accounts [306,489/408,077]) and those identifying as female (43.5% of unique accounts [177,698/408,077]). 25% of advertisements were delivered to accounts with uncategorised genders (101,907/408,077). Total cost per participant enrolled was AUD \$3.89 (USD \$2.58). Most participants (85.9%, 1980/2305) found out about the study through Instagram. Differences in screening characteristics between eligible participants who did and did not enrol were found to be statistically significant for gender ($P=.02$) with fewer males and more individuals reporting their gender as 'Other' enrolling than expected than by chance alone. Recruitment method also differed ($P<.001$), with fewer participants enrolling

through Instagram and more enrolling through other methods (e.g. known networks, word of mouth) than expected by chance alone.

Conclusions: In this study we show that virtual clinical trial recruitment was found to be low-cost with the potential to increase trial participation. Social media was the most effective recruitment method, reaching all states and territories, including hard-to-reach populations. Future action is needed to explore recruitment methods which are more effective for males and to build trust among adolescents regarding clinical trial recruitment via social media.

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ABSTRACT

Background: Preventive interventions are needed to provide targeted health support to adolescents to improve health behaviours. Engaging adolescents in preventive interventions remains a challenge, highlighting the need for innovative recruitment strategies. Given adolescents' lives are intertwined with digital technologies, attention should be focused on these avenues for recruitment. The evolving nature of clinical trials, including the emergence of virtual clinical trials, require new recruitment approaches, which must be evaluated.

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Conclusions: In this study we show that virtual clinical trial recruitment was found to be low-cost with the potential to increase trial participation. Social media was the most effective recruitment method, reaching all states and territories, including hard-to-reach populations. Future action is needed to explore recruitment methods which are more effective for males and to build trust among adolescents regarding clinical trial recruitment via social media.

KEYWORDS

Adolescents; clinical trial; recruitment; digital health; prevention

INTRODUCTION

Adolescence is regarded as the second window of opportunity; a critical period to intervene and provide targeted support to improve health outcomes which have a profound impact on health and wellbeing throughout the life course [1]. Failure to invest in primary prevention among today's adolescents will increase the burden of chronic diseases, and the existing sizeable total health expenditure of AUD \$24 billion (USD \$15.9 billion) on potentially avoidable risk factors [2]. It is

important that high quality public health interventions that focus on primary prevention of chronic diseases are tested with adolescents through clinical trials. However, challenges exist with engaging adolescents in preventive interventions including their health system disengagement making them hard to access to deliver such interventions [3], a prevention lens not being appealing to adolescents [4], and their evolving need for autonomy in providing informed consent [5]. Innovative methods to engage adolescents within preventive interventions are needed that can overcome identified barriers. Adolescents' lives are increasingly intertwined with digital technologies such as mobile phones and the internet [6]. With that comes the opportunity to harness developments in digital technologies for innovative preventive interventions [7]. The use of digital methods for recruitment to clinical trials is increasing in popularity. Previous research has focused on comparing social media or other digital strategies to traditional in-person recruitment [8-13], and the use of digital tools for recruitment and retention of clinical trial participants [14, 15]. While research shows that digital recruitment strategies are effective compared to traditional in-person recruitment, limited research is available to understand the efficiency of digital recruitment strategies alone and their impact on clinical trial participants and investigators (e.g. helping investigators identify eligible trial participants) [14]. A previous review identified that Facebook is effective for recruiting adolescent participants [16], and a cross-sectional study revealed that the use of Instagram and Snapchat may also be useful and cost-effective to recruit young people to surveys [17], but limited evidence is available for the use of these contemporary platforms for adolescent recruitment to clinical trials. As more social media platforms become available and others diminish in popularity, it is crucial that research is undertaken to understand their effectiveness for recruiting adolescents to research.

Additional complexities occur when there are no physical recruitment sites, otherwise known as remote [18], decentralized [19], or virtual [20] clinical trials, from hereon in called virtual clinical trials. Virtual clinical trials can leverage digital technologies for participant recruitment and retention, enabling online consent for participants and on-time data collection that is convenient for participants as they do not have to travel to a physical site [21]. Virtual clinical trials among adolescent participants have the potential to overcome some of the previously identified barriers including reaching those who are disengaged with the health system and reaching adolescents directly, allowing them autonomy in making decisions about their health, including providing informed consent (depending on ethics approvals). However, there is limited research to understand digital recruitment strategies for clinical trials among adolescents. Furthermore, it is also important to understand factors which may cause eligible participants not to engage in digital preventive interventions. Reporting will enable future research to tailor recruitment towards the most effective digital strategies and address factors which cause disengagement. Therefore, this study aims: (i) to examine the effectiveness and cost of various digital recruitment strategies for recruiting adolescents to a virtual clinical trial; (ii) to evaluate the progression of participants from screening to enrolment and (iii) explore factors associated with non-participation.

METHODS

The Health4Me study was used as the context for this research. The full protocol is published elsewhere [22]. In brief, the Health4Me Study is a virtual clinical trial, based in Australia, of a community-based, 6-month text message intervention. The intervention aims to improve physical activity and nutrition behaviours among adolescents 12-18 years old. Primary ethics approval was

received from the University of Sydney Human Research Ethics Committee (2022/402) and the trial is registered at the Australia New Zealand Clinical Trials Registry (ANZCTR) ACTRN12622000949785; Date registered: 05/07/2022.

Participants and Eligibility Criteria

Participants were eligible to take part in the Health4Me Study if they were: (1) 12–18 years old inclusive; (2) owned a mobile phone capable of sending and receiving text messages; (3) had an Australian mobile phone number; (4) had sufficient English to read text messages pitched at a 7th grade reading level; and (5) provided electronic consent (or from their parents or guardians if < 14 years old). Participants were excluded from the study if they: (1) had a diagnosis of type 1 or type 2 diabetes mellitus; (2) had a previous or current diagnosis of an eating disorder or were at high risk for an eating disorder as assessed in screening; (3) weight < 25th centile for age; (4) had recent rapid weight loss; (5) had a medical condition which would preclude providing informed consent or ability to comply with the study protocol; (6) were enrolled in an alternative randomised lifestyle management program; (7) were pregnant or planning to become pregnant during the 6-month intervention; and (8) were unable to read English at a 7th grade reading level. The eligibility criteria for the Health4Me Study have been published elsewhere [22].

Given the Health4Me Study was conducted virtually, several steps were embedded to ensure participants could safely enrol into the study. To complete screening procedures, we partnered with the InsideOut Institute for Eating Disorders, a team of researchers and clinician experts in eating disorders based at the University of Sydney. Potential participants first expressed interest to take part in the study by filling out the Expression of Interest (EOI) Form on REDCap which included contact details and screening against the eligibility criteria, as well as screening for eating disorder risk using two validated questionnaires – InsideOut Institute Screener (IOI-S) and Eating Disorders Examination Questionnaire (EDE-Q) [23, 24]. Study specific cut-points were set for the IOI-S (≥ 16) and EDE-Q (> 3 AND any of behavioural items 15-18 endorsed ≥ 1). Potential participants first completed the IOI-S, if they scored below the cut point and met all inclusion criteria, they were sent the e-consent form. However, if participants scored above the cut point on the IOI-S, they were directed to complete an EDE-Q. If potential participants scored under the cut point on the EDE-Q, they were deemed eligible and sent the e-consent form. If a potential participant was detected to be above the cut point on the EDE-Q, they were referred to the InsideOut Institute for Eating Disorders for an assessment to determine suitability to participate by eating disorder expert clinicians (clinical psychologist or registered clinical psychology students with expertise in eating disorders) via phone call. If they received clearance from the eating disorder expert clinicians, they were sent the e-consent form and deemed eligible to enrol in the study. If they did not receive clearance, they were sent an email with various resources for eating disorder support. If a potential participant did not meet other inclusion criteria, they were sent an email explaining why they were ineligible. All participants provided informed e-consent (and from their parents or guardians if < 14 years old) before baseline measures were collected [22]. Participants were randomized once all baseline measures were complete.

Recruitment

The protocol was to enrol 390 participants – 195 per arm – based on detecting a mean difference in moderate to vigorous physical activity [MVPA] minutes per day of 14.8 (control: 42.55 and

intervention: 57.36) with standard deviations (SD) of 21.45 for control and 37.79 for intervention or a 13.37% difference in the proportion of appropriate vegetable consumption (control: 4.85% and intervention: 18.22%) with 90% power and accounting for 30% dropout. The Bonferroni adjusted significance level of 0.025 was used to account for two primary outcomes. The participant information statement detailed that participants would receive an AUD \$30 (USD \$19.90) gift voucher at the completion of all baseline assessments as a reimbursement for their time. A recent review has suggested that financial incentives can be provided to children appropriately and few studies suggest incentives are inherently harmful [25]. Recruitment methods are detailed below.

Recruitment Methods

Recruitment ran from February 2023 to February 2024 using a range of methods including social media advertising on Facebook, Instagram, TikTok and Twitter/X, emails to schools, emails to contacts within known networks and emails to relevant youth organizations. A dedicated study website was also created to establish legitimacy.

Social media advertisements

Initially, study-dedicated Facebook and Instagram pages were established with the study logo, study contact information and detailed the purpose of the study. Posts were made on Instagram to establish the study as an authentic and active social media account. All content and the study logo were co-designed with adolescents [26]. All advertisements were created using ethics approved text and images on Meta Ads Manager, which simultaneously promoted advertisements on Facebook and Instagram or on TikTok for Business, which promoted advertisements on TikTok. Due to restrictions in advertising to people under 18 years of age [27], all advertisements were targeted only for people aged 13-18 years old in Australia. Advertisements on Meta were run for a maximum of two weeks, with a maximum budget of AUD \$20 (USD \$13.30) per day. The single advertisement on TikTok was run for four days, with a lifetime budget of AUD \$50 (USD \$33.20). A single post was made on Twitter/X by a member of the research team. All advertisements linked directly to the study EOI form, hosted on REDCap.

Emails

Emails were sent to schools, known networks and contacts of the research team and, relevant youth organizations e.g. headspace. Emails contained a link to the study website and the study REDCap page.

Study website

Previous formative work by the research team revealed that adolescents desire online health information that is credible and reliable [28]. A study website was created to establish the study as legitimate and to build trust among adolescents. The study website contained the study logo, study contact information, detailed the purpose of the study, how to get involved (including a direct link to the study REDCap page), photographs and names of the key researchers and names of the wider research team. Potential participants could also access the full Participant Information Sheet through the study website.

Data Sources

1. Social media advertisements

Data was available and collected from Meta Ads Manager. For each advertisement, data was

collected on the number of days the advertisement ran, advertisement strategy used, reach, impressions, link clicks, cost per result and total amount spent (\$AUD). De-identified advertisement audience demographic data included location, age, and gender. User's location was based on their state or territory (New South Wales [NSW], Victoria [VIC], South Australia [SA], Queensland [QLD], Western Australia [WA], Northern Territory [NT], Tasmania [TAS] and Australian Capital Territory [ACT]). Age and gender data were based on what social media users disclose on their user profiles and were summarised according to Meta Ads Manager categories (age: 13-17, 18-24; gender: male, female, uncategorised). Data was available and collected from TikTok for Business. For each advertisement, data was collected on the number of days the advertisement ran, reach, impressions, link clicks, cost per result and total amount spent (AUD). Post analytics were available and collected from Twitter/X. For the single post, data was collected on likes, reposts, impressions and link clicks.

2. Recruitment log

A log was kept of all dates on which emails were sent to schools, known networks and contacts and, youth organizations. Data was also collected on the number of people who visited the study REDCap page each day to express interest and the number of enrolments. Detailed notes were kept on the log by the research team.

3. Screening logs

A detailed log was kept of all participant enquiries. The secure online REDCap [29] database collected data including age (12-14/15-18), gender (male, female, other, prefer not to say), high school attendance (yes/no), height and weight (for body mass index [BMI] calculations, categorised as underweight, healthy weight, above a healthy weight and well above a healthy weight) [30, 31] and, recruitment method. The responses for recruitment method included: (1) Facebook; (2) Instagram; (3) Twitter/X; (4) TikTok; (5) Other social media platform; (6) headspace; (7) GP/doctor; (8) Other. The screening log also contained details on eligibility and reasons for exclusion. A further screening log was also collected from the InsideOut Institute for Eating Disorders which kept a detailed log of potential participants requiring screening for eating disorder risk. The secure online REDCap database and allowed both the psychologists and research team to make comments. Potential participants were contacted a maximum of two times by the eating disorder expert clinicians. If contact was not established after two attempts, they were marked as ineligible and sent resources via email.

Data Analysis

Summary statistics regarding social media data are presented. Total costs (\$AUD) are reported for social media advertisements, with the average cost calculated per participant eligible and per participant enrolled. Descriptive statistics for continuous measures, including counts and percentages for recruitment method, were used to summarise the breakdown of potential participants who enquired, and participants screened by the InsideOut Institute for Eating Disorders.

To explore factors associated with non-participation, differences in screening characteristics between eligible participants who did and did not enrol in the study were compared using Chi-squared tests. Significance level was set at 5%. Characteristics included age, gender, BMI, high school attendance and recruitment method. Adjusted Standardised Residuals (ASRs) were used to measure the strength of the difference between observed and expected values. Data were analysed using IBM SPSS

version 29.0 (IBM Corp, Armonk, NY, USA)

RESULTS

Effectiveness and cost of recruitment strategies

A total of 2369 entries were made to the EOI form. Of those, 2305 respondents completed the question asking how they heard about the study. Most (1980/2305, 85.9%) found out about the study through Instagram, followed by Other (182/2305, 7.9%) and then Facebook (112/2305, 4.9%). The full sample size of 390 adolescents was reached in 12 months. A full breakdown of how participants heard about the study is available in Figure 1.

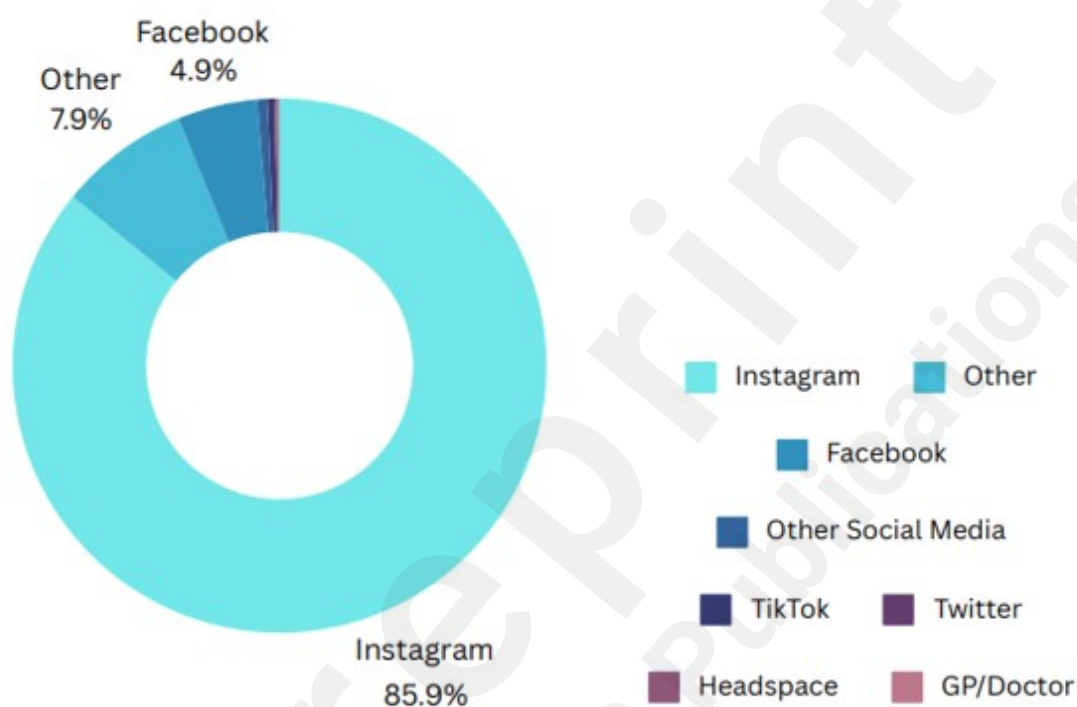


Figure 1: Breakdown of Recruitment Method

For the Health4Me Study, there were 17 advertisements run on Meta Ads Manager over 12 months. The length which the advertisements were running for ranged from 2-18 days, with advertisements running for a total of 146 days. Overall, advertisements reached a total of 408,077 unique Meta accounts, and were viewed >2.3 million times. A cost-per-link-click strategy was employed in 16/17 advertisements, and one employed a cost-per-post-engagement strategy. Across 17 advertisements, 7,211 link clicks were made. Advertisements mostly reached people in NSW, VIC, QLD, accounting for 75% of the audience. Nearly 97% of the advertisement audience was aged 13-17 years old. For gender, advertisements mostly reached females (43.5%) however, a quarter (25%) of the advertisements were delivered to accounts with uncategorised genders. One advertisement was run through TikTok for Business which ran for four days, reached 8,386 unique accounts, and was viewed 14,832 times, with 144 link clicks made. No further data were available. One ad was placed on Twitter/X which was viewed a total of 1,041 times and reposted 11 times, with 15 link clicks made.

The overall cost of social media advertisements run through Meta was AUD \$1,478.63. Cost-per-link-click ranged from AUD \$0.03-\$0.87. The overall cost of the advertisement through TikTok was

AUD \$39.97, with cost-per-link-click at AUD \$0.28. In total, AUD \$1,518.60 was spent on social media advertisements. Cost per eligible participant was AUD\$1.64 (USD \$1.09), and cost per participant enrolled was AUD \$3.89 (USD \$2.58). A full breakdown of all social media data is available in Table 1 and 2.



Table 1: Breakdown of Meta advertisements reach by State/Territory, Age and Gender

| State/Territory | Reach, n (%) |
|------------------------------|----------------|
| New South Wales | 123,543 (30.3) |
| Victoria | 95,954 (23.5) |
| Queensland | 86,992 (21.3) |
| Western Australia | 44,808 (11.0) |
| South Australia | 31,814 (7.8) |
| Northern Territory | 5,633 (1.4) |
| Tasmania | 9,858 (2.4) |
| Australian Capital Territory | 5,377 (1.3) |
| Unknown | 4,098 (1.0) |
| Age | |
| 13-17 | 395,403 (96.9) |
| 18-24 | 12,674 (3.1) |
| Gender | |
| Female | 177,698 (43.5) |
| Male | 128,472 (31.5) |
| Uncategorised | 101,907 (25.0) |
| Total | 408,077 |

Table 2: Breakdown of Social Media Ads for the Health4Me Study through Meta, TikTok and Twitter/X

| Start Date (DD/MM/YYYY) | End Date (DD/MM/YYYY) | Days Ad Live (n) | Ad strategy ^a | Reach ^b | Impressions ^c | Total cost (\$AUD) | Daily Budget (\$AUD) | Link Clicks ^d (n) | Cost per result (\$AUD) | Post Reaction s (n) | Post Saves (n) | Post Shares (n) |
|-------------------------------|--------------------------|---------------------|--------------------------|--------------------|--------------------------|-----------------------|-------------------------|---------------------------------|----------------------------|------------------------|-------------------|--------------------|
| Meta (Instagram and Facebook) | | | | | | | | | | | | |
| 10/02/2023 | 28/02/2023 | 18 | Post engagement | 14128 | 36340 | 112.96 | 10 | 68 | 0.03 | 3184 | 5 | 1 |
| 02/03/2023 | 08/03/2023 | 6 | Link clicks | 88929 | 138404 | 59.87 | 10 | 550 | 0.11 | 28 | 4 | 17 |
| 31/03/2023 | 15/04/2023 | 16 | Link clicks | 70992 | 164879 | 115.66 | 10 | 675 | 0.17 | 76 | 5 | 19 |
| 28/04/2023 | 12/05/2023 | 15 | Link clicks | 86464 | 237153 | 143.30 | 10 | 775 | 0.18 | 106 | 6 | 22 |
| 16/05/2023 | 28/05/2028 | 13 | Link clicks | 93409 | 237016 | 123.73 | 10 | 641 | 0.19 | 78 | 2 | 9 |
| 31/05/2023 | 14/06/2023 | 15 | Link clicks | 117056 | 345260 | 144.00 | 10 | 680 | 0.21 | 208 | 1 | 9 |
| 15/06/2023 | 30/06/2023 | 15 | Link clicks | 110532 | 307182 | 162.05 | 10 | 706 | 0.23 | 127 | 1 | 10 |
| 04/07/2023 | 18/07/2023 | 14 | Link clicks | 96816 | 301837 | 143.73 | 10 | 664 | 0.22 | 69 | 3 | 8 |
| 21/07/2023 | 25/07/2023 | 4 | Link clicks | 72945 | 124063 | 80.86 | 20 | 731 | 0.11 | 113 | 13 | 23 |
| 28/07/2023 | 31/07/2023 | 4 | Link clicks | 64672 | 99327 | 59.77 | 20 | 410 | 0.15 | 66 | 7 | 8 |
| 01/09/2023 | 04/09/2023 | 4 | Link clicks | 49600 | 76721 | 59.99 | 20 | 375 | 0.16 | 41 | 6 | 9 |
| 13/10/2023 | 16/10/2023 | 4 | Link clicks | 44795 | 72066 | 59.99 | 20 | 435 | 0.14 | 51 | 7 | 14 |
| 23/11/2023 | 25/11/2023 | 3 | Link clicks | 18484 | 18995 | 40.00 | 20 | 72 | 0.56 | 3 | - | 3 |
| 01/12/2023 | 03/12/2023 | 3 | Link clicks | 35278 | 36989 | 41.18 | 20 | 85 | 0.48 | - | - | - |
| 16/01/2024 | 21/01/2024 | 6 | Link clicks | 8185 | 13463 | 62.74 | 15 | 103 | 0.61 | 3 | - | 3 |
| 02/02/2024 | 05/02/2024 | 4 | Link clicks | 15311 | 19940 | 44.35 | 15 | 51 | 0.87 | 10 | 1 | 1 |
| 22/02/2024 | 23/02/2024 | 2 | Link clicks | 114365 | 134196 | 24.45 | 20 | 190 | 0.13 | 61 | 1 | - |
| Totals: | | 146 | - | 408,077 | 2,363,831 | 1,478.63 | - | 7,211 | - | 4,224 | 62 | 156 |
| TikTok | | | | | | | | | | | | |
| 25/08/2023 | 29/08/2023 | 4 | N/A | 8386 | 14832 | 39.97 | 10 | 144 | 0.28 | 7 | - | - |
| Twitter | | | | | | | | | | | | |
| 14/02/2024 | - | - | N/A | - | 1041 | - | - | 15 | - | 15 | - | 11 |

^a Post engagement: strategy aims to get users to like, share, comment on or save the advertisement; Link clicks: strategy aims to get users to click

on the advertisement URL link

^b Number of times the advertisement is delivered to a unique account

^c Number of times the advertisement is delivered in total (including being delivered multiple times to one account)

^d Number of times the advertisement URL link was clicked

Emails requesting inclusion in school communications to students were sent to 367 high schools across NSW. One school announced the study at their school assembly. One email was sent to our mailing list of young people who have expressed interest in future research. Emails were sent to 17 other known networks, contacts, and youth organizations. Of those, the research team was made aware that one shared in their GP newsletter, and one shared within their local health district.

Progression of participants from screening to enrolment

Figure 2 shows the progression of participants and drop out points from screening to enrolment. Of the 2369 entries on the EOI form, 655 were immediately excluded. Of the excluded entries, 41 did not have an Australian mobile number. These 41 entries were among the first 100 EOIs and were believed to be bots. After adding a reCAPTCHA to the REDCap screening survey, we received no further suspicious entries. Of the remaining, 462 entries were incomplete, 145 were duplicate entries and 32 withdrew their expression of interest post-screening. In addition, 328 entries were ineligible as they did not meet the inclusion criteria, with reasons for exclusion shown in Figure 2.

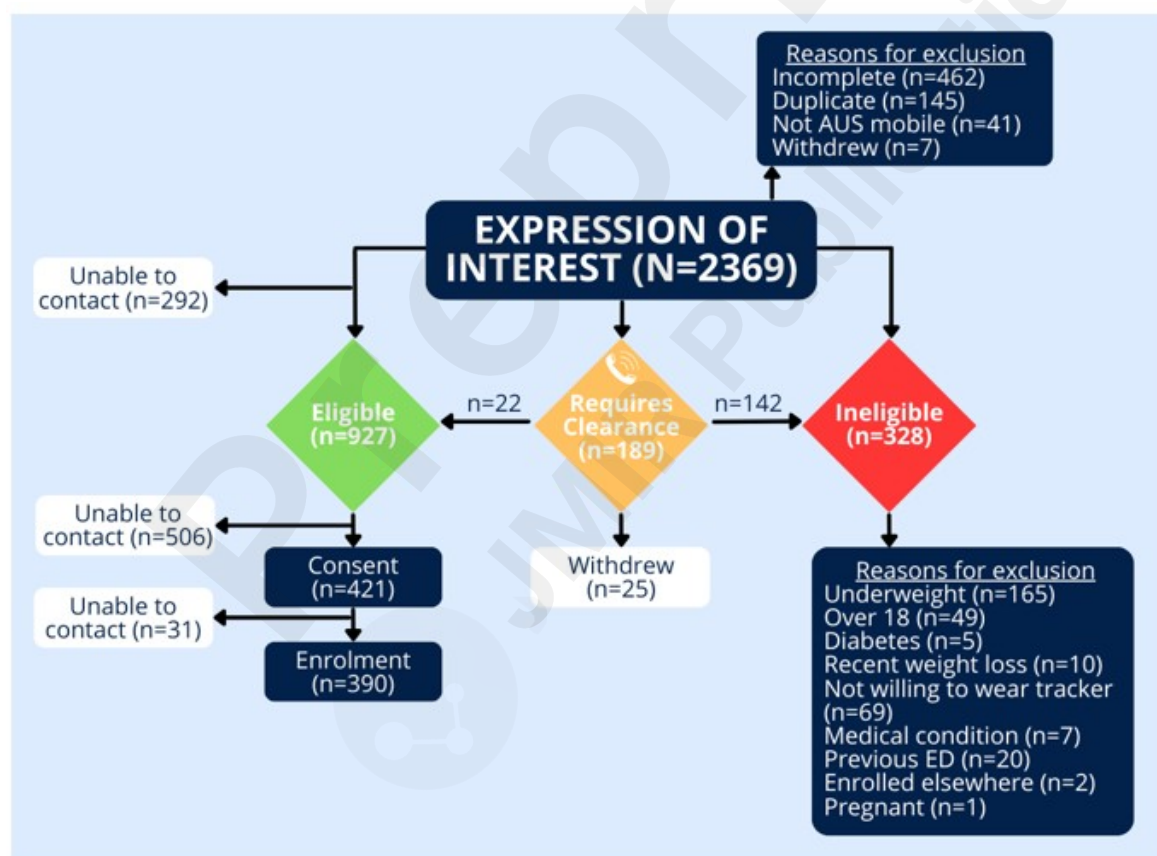


Figure 2: Progression of participants from screening to enrolment

AUS: Australian; ED: Eating Disorder

A total of 481 potential participants scored above the cut-point on the IOI-S. 292 participants but were unable to be contacted to complete the EDE-Q (per protocol for further screening for eating disorder risk). A further 189 potential participants were referred to the InsideOut Institute for assessment from eating disorder expert clinicians. Of those, 104 were unable to

be contacted by the eating disorder expert clinicians, 38 were ineligible post-call as they were assessed as high risk. A further 25 potential participants withdrew at this step and 22 potential participants were assessed as eligible by the psychologist and sent the e-consent form.

927 potential participants were eligible and sent the e-consent form. Of those, 506 were unable to be contacted and the e-consent form was never signed. The e-consent form was signed by 421 participants, and they were sent the baseline surveys, but 31 participants did not commence answering baseline questions, giving 390/2369 (16.4%) participants enrolled in the study.

Factors associated with non-participation

During screening, 537 potential participants were identified as eligible but did not proceed to enrolment, and 390 participants enrolled in the Health4Me Study. Chi-squared tests indicated that there were statistically significant differences in screening characteristics between eligible participants who did and did not enrol in the study for gender and recruitment method. Gender differences were significant (X^2 [3, n=927] = 9.8, $P=.02$), ASRs indicated fewer males and more individuals reporting 'Other' enrolled than expected by chance alone. Additionally, the recruitment method was significant (X^2 [3, n=925] = 17.39, $P<.001$), ASRs indicated fewer participants enrolled through Instagram and more enrolled through other methods (e.g. known networks, word of mouth) than expected by chance alone. No differences were observed for other screening characteristics. A full breakdown of screening characteristics between those who were eligible and did or did not enrol is available in Table 3.

Table 3: Comparison of screening characteristics between those who were eligible who did and did not enrol in the Health4Me Study

| | Total eligible, not enrolled (n=537) | Total enrolled (n=390) | P-value |
|--|--------------------------------------|------------------------|--------------------------------------|
| Age | | | |
| 12-14 | 80 | 41 | X^2 [1, n=927] = 3.83, $P=.05$ |
| 15-18 | 457 | 349 | |
| Gender | | | |
| Male | 166 | 92 | X^2 [3, n=927] = 9.8, $P=.02^*$ |
| Female | 347 | 274 | |
| Other | 11 | 17 | |
| Prefer not to say | 13 | 7 | |
| BMI^a | | | |
| Underweight | 21 | 16 | X^2 [3, n=878] = 2.12, $P=.548$ |
| Healthy weight | 410 | 279 | |
| Above a healthy weight | 60 | 51 | |
| Well above a healthy weight | 21 | 20 | |
| Attending high school | | | |
| Yes | 464 | 339 | X^2 [1, n=927] = 0.52, $P=.819$ |
| No | 73 | 51 | |
| Recruitment Strategy^b | | | |
| Facebook | 18 | 22 | X^2 [3, n=925] = 17.39, $P<.001^*$ |
| Instagram | 470 | 301 | |
| Other social media platform ^c | 4 | 5 | |
| Other ^d | 44 | 61 | |

^a Due to being asked gender during screening and not sex assigned at birth, we are unable to accurately calculate BMI for those who listed their gender as 'Other' or 'Prefer not to say'.

^b One record missing from each for recruitment strategy. Total eligible, not enrolled (n=536), Total enrolled (n=389)

^c Due to small numbers, categories of 'Twitter/X, TikTok and Other social media platform were combined

^d Due to small numbers, categories of headspace, GP/doctor and Other were combined

* Statistically significant

DISCUSSION

Principal Results

The Health4Me Study, aimed at improving physical activity and nutrition behaviours among 12- to 18-year-olds. We received a total of 2369 EOIs and recruited 390/2369 (16.4%) participants in less than 12-months. Social media was the main source of recruitment. The research team did try to engage with schools, known networks and relevant youth organizations via emails with limited success. Social media advertisements through Meta were effective, reaching 408,077 unique accounts across all states and territories in Australia. Overall, social media advertisements were low cost (AUD \$3.89 per participant enrolled).

From screening to enrolment, there were multiple points of drop out. Of the EOIs from potential participants who were eligible (927/2369, 39.1%), statistically significant differences were observed for those who did and did not enrol in terms of gender and recruitment method. Fewer males and more individuals reporting their gender as 'Other' enrolled than expected by chance alone. In addition, fewer individuals enrolled through Instagram and more enrolled through other methods (e.g. known networks, word of mouth) than expected by chance alone.

Comparison with Prior Work

Virtual clinical trials have the potential to address challenges in traditional site-based recruitment and be cost-effective [20]. Yet, prevention programs among adolescents are known to have the lowest recruitment rates [32], and stakeholders have identified that a prevention lens may not be engaging for adolescents [4]. In the Health4Me Study, a digital preventive intervention, we found that the digital recruitment strategies used were effective, recruiting 390 adolescents in less than 12 months. The Health4Me Study was guided by factors associated with successful recruitment from a previous virtual clinical trial [33] including: (i) national recruitment; (ii) self-referrals; (iii) unmet need for trial intervention; (iv) patient and public involvement; (v) regular monitoring and communication; and (vi) reimbursement and early exclusion. In the Health4Me Study we recruited a national sample and participants self-referred into the study. In addition, there are limited prevention programs currently available for adolescents [34] and the intervention and all advertising materials were co-designed with adolescents [26]. We employed a small day-to-day research team who communicated regularly through detailed screening and recruitment logs, and participants were reimbursed through online gift vouchers after completing all study activities at baseline and 6-month follow-up.

The costs reported in this study for social media advertising are lower per enrolled participant than what has previously been reported in reviews (USD \$3-\$628) [9, 35], however these studies mostly report on Facebook and compare social media to traditional in-person recruitment. Limited research is available reporting virtual clinical trial recruitment costs to recruit adolescents. A virtual clinical trial which aimed to prevent and reduce cyberbullying among adolescents that used Instagram for study recruitment found a higher consent rate than the Health4Me Study (24.4% v 16.4%) yet had much higher social media ad costs (USD \$19 v USD \$2.59 per enrolled participant) [36]. It is essential for future virtual clinical trials to report costs associated with recruitment to understand their cost-effectiveness for enrolling participants from the target population.

Virtual clinical trials allow remote access to research, potentially enhancing the diversity of participants, and recruiting from hard-to-reach populations [20]. We observed in the Health4Me Study that more individuals reporting their gender as 'Other' enrolled than expected by chance alone. This 'Other' category captures any gender other than male or female (e.g. non-binary, transgender). In another virtual clinical trial targeting cyberbullying found that nearly half of the participants recruited via Instagram identified as lesbian, gay, or bisexual [36]. We also observed that less eligible males enrolled in the Health4Me Study than expected by chance alone. When looking at the social media advertisements, they reached less males overall. Future efforts should be directed to identifying effective methods to recruit

males to virtual clinical trials.

Another factor considered to attract hard-to-reach participants online is that those interested can self-refer into the study. A previous study which aimed to assess effectiveness of online behavioural therapy for tics among young people found that the majority of participants self-referred from online [33], enabling those who were not under the care of mental health clinicians to be included. The Health4Me Study is unique in that participants who are 15 and older can consent themselves into the study, without the need for parent or guardian consent. This was approved by the ethics committee, with support from our youth advisory group as the Health4Me Study is a low-risk, preventive health intervention. This capacity to self-refer gives adolescents some autonomy around their health, especially given that preventive care is seldom given within primary care to this age group [37].

Within this study, we also found that less eligible adolescents enrolled through Instagram than were expected by chance alone, and more enrolled through other methods (e.g. known networks, word of mouth) than what was expected by chance alone. Hypothesized reasons for this are around trust in health information which adolescents view online, including for clinical trials. Previous reviews show that adolescents often distrust health information found online yet continue to engage with this information [38]. In terms of health information on social media, friends and networks are particularly important for gaining adolescents trust in this space [39]. Future studies planning to recruit adolescents through social media could explore the use of peer referral or endorsement from youth advisors or reputable organizations (e.g. study sponsor) to gain an increased level of trust. In addition, adolescents are acutely aware of how their personal data is being used and building trust and authenticity among this population is vital [28]. Partnerships with known youth health organizations and endorsement of the clinical trial through their own social media accounts may be useful to increase trust among adolescents.

Within the Health4Me Study, we also observed that there were multiple points of drop out from screening to enrolment. The largest point of drop out was those who were eligible and sent the consent form but never responded. For all eligible participants, the research team sent the consent form twice via email, however after no response they were marked 'unable to contact'. Future efforts should be directed to streamlining processes of screening and consent for scalability of future trials. Previous studies have aimed to do this using mobile applications e.g. ResearchKit [40], which is an open-source software framework designed to streamline the process of screening and consenting participants into research studies. Evidence of success is available for research studies among adults [41, 42], yet no outcomes are currently available among adolescents [43].

The second highest rate of drop-out among participants was those who required further screening for a potential eating disorder. Out of 2369 potential participants, 292 (12.3%) did not complete an EDE-Q and were therefore excluded, and 189 (8.0%) required clearance through a phone call with the study psychologist. When compared to the prevalence of eating disorders overall among Australian adolescents, this rate is lower than what has previously been reported (point prevalence of 22.2%) [44]. Thus, screening for eating disorders was not identified as a barrier to enrolment, rather an important safety precaution for potential identification of disordered eating among this population in a preventive intervention.

Limitations

We must acknowledge the limitations in this study. Firstly, there are restrictions on advertising to adolescents via social media and changes are constantly occurring in this space. Though the inclusion criteria for age in this study was 12-to 18-year-olds, social media advertisements are unable to be targeted to adolescents less than 13 years old, as you can only establish a social media account if you are over 13. We also developed advertisements for distribution on Snapchat, however advertising of clinical trials is not allowed on its platform. Secondly, adolescents report that they find recruitment via social media to be feasible and acceptable for recruitment and retention [45, 46]. However, this was not assessed within this study as follow-ups are ongoing. Adolescent perceptions for using social media for recruitment will be assessed in the process evaluation for the Health4Me Study, by assessing retention rates and analysing focus group data. The findings of this study require validation with studies among other adolescent populations.

Conclusions

Within the Health4Me Study we observed that recruitment was most effective via social media, and this was low cost per participant enrolled. Throughout the screening to enrolment process there were multiple points of drop out, and future efforts should be directed towards streamlining screening and enrolment processes for scalability of future trials. In addition, our results highlight the importance of building trust among clinical trials and health information generally among adolescents on social media for future success in recruiting adolescents via this digital strategy.

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CONFLICTS OF INTEREST

None declared.

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ABBREVIATIONS

ACT: Australian Capital Territory
ASRs: Adjusted Standardised Residuals
AUD: Australian Dollar
BMI: Body Mass Index
EDE-Q: Eating Disorder Examination Questionnaire
EOI: Expression of Interest
IOI-S: InsideOut Institute Screener
MVPA: Moderate to Vigorous Physical Activity
NSW: New South Wales
NT: Northern Territory
QLD: Queensland
SA: South Australia
SD Standard Deviation
TAS: Tasmania
VIC: Victoria
WA: Western Australia

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Supplementary Files

Figures

Breakdown of recruitment method.

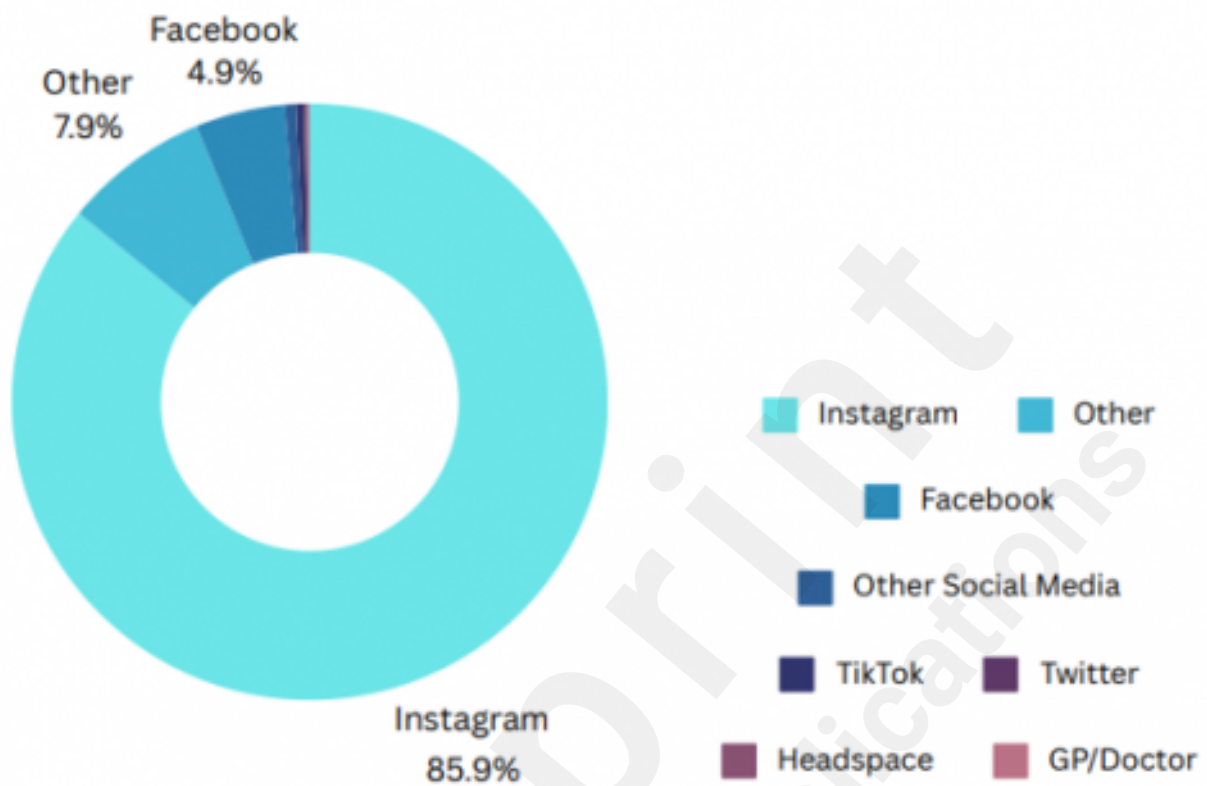


Figure 1: Breakdown of Recruitment Method

Progression of participants from screening to enrolment.

