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Will a fee-for-service payment for a young people's health assessment in general practice increase the detection of health risk behaviours and health conditions? Protocol for a cluster randomised controlled trial (RAd Health Trial)

Jane S Hocking ,[1] Cathy Watson,[1] Patty Chondros,[2] Susan M Sawyer ,[3,4] Jemimah Ride,[1,5] Meredith Temple-Smith,[2] Douglas Boyle,[2] Rachel Skinner,[6] George C Patton ,[3,4] Megan S C Lim ,[7,8] Jane Pirkis ,[1] Caroline Johnson ,[2] Sara Newton,[1] Amelia Wardley,[1] Grant Blashki,[9] Rebecca Guy,[10] Kim Dalziel,[1] Lena Sanci[2]

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For numbered affiliations see end of article.

Correspondence to
Jane S Hocking;
jhocking@unimelb.edu.au

ABSTRACT

Introduction Adolescence is a period of major transition in physical, cognitive, social and emotional development, and the peak time for the onset of mental health conditions, substance use disorders and sexual and reproductive health risks. Prevention and treatment during this time can improve health and well-being now and into the future. However, despite clinical guidelines recommending annual preventive health assessments for young people, health professionals cite lack of consultation time and adequate funding as key barriers. This trial aims to determine whether a specific fee-for-service ('rebate payment') for a young person's health assessment, is effective and cost-effective at increasing the detection and management of health risk behaviours and conditions among young people.

Methods and analysis This cluster randomised controlled trial will be conducted in Australian general practice. 42 general practices (clusters) will be randomly allocated 1:1 to either an intervention arm where general practitioners receive a rebate payment for each annual health assessment undertaken for 14–24-year-olds during a 2 year study period, or a control arm (no rebate). The rebate amount will be based on the Medical Benefits Schedule (Australia's list of health professional services subsidised by the Australian Government) currently available for similar age-based assessments. Our primary outcome will be the annual rate of risk behaviours and health conditions recorded in the patient electronic health record (eg, alcohol/drug use, sexual activity and mental health issues). Secondary outcomes include the annual rate of patient management activities related to health risks and conditions identified (eg, contraception prescribed, sexually transmitted infection tests ordered). A process evaluation will assess acceptability, adoption, fidelity and sustainability of the rebate; an economic evaluation will assess its cost-effectiveness. Analyses will be intention-to-treat.

Ethics and dissemination Ethics approval has been obtained from University of Melbourne Human and Research Ethics Committee (2022-23435-29990-3). Findings will be published in peer-reviewed journals.

Trial registration number ACTRN12622000114741

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Our state-of-the-art data extraction tool, GHRANITE, will extract outcome data from the electronic medical record minimising measurement and non-response bias.
⇒ Our mixed-method process evaluation will provide insights from general practitioners (GPs), practice nurses, practice managers and patients about the practical aspects of rebated health assessment in general practice and help us understand why they do or do not work at improving the detection of risk behaviours and health conditions among young people.
⇒ Our rebate payment intervention targets GPs with negligible patient involvement and does not address other barriers to young people's health in general practice including worry about confidentiality, embarrassment in disclosing health concerns and lack of knowledge about available services which may impact young people's health outcomes.
⇒ Our rebate payment intervention only targets one funding mechanism for young people's health assessments in general practice, fee-for-service and may not be relevant to other funding models.

INTRODUCTION

Adolescence and young adulthood are periods of major transition in physical, cognitive, social and emotional development that can establish the foundation for health across the life course.[1] It is the peak time for the onset of mental health conditions, substance use disorders, injuries and sexual and reproductive health risks, which can have lasting effects in later life. Prevention and treatment of these problems during this time can provide a 'triple-dividend' through benefits for adolescent health and well-being now, into future adult life and for the next generation of children.[2] Healthy young people can also stimulate economic growth through increased productivity and reduced health expenditure. For every dollar invested in young people's health, there is an estimated 10-fold health, social and economic return.[3]

Primary healthcare can play a key role in supporting young people during these transitions by optimising their clinical encounters to include screening for physical and mental health conditions and high-risk behaviours, and by intervening where risks or health conditions are identified. A systematic review found that adolescent health assessments in primary care resulted in significant improvements in many health outcomes, including substance use, diet, sexual health and preventive activities.[4] Others have shown that preventive health assessments for young people can improve their health outcomes and quality of care by including comprehensive screening and counselling leading to greater detection of risks and health conditions.[5–9]

Globally, there have been calls for increased funding to support young people's health,[3 10] and the importance of adolescent health in achieving the Sustainable Development Goals has gained global recognition with adolescent health and development now included in the Global Strategy for Women's Children's and Adolescents Health.[11] Yet inadequate funding continues to be a major barrier to supporting young people's health and indeed to supporting primary healthcare in general.[3 12] In the USA, young people are recommended to have an annual health assessment, but lack of insurance, deficiencies in scope of insurance benefits, high-cost sharing and inadequate provider payments are associated with low uptake and inequity in access.[13] In Australia, while guidelines recommend regular preventive health assessments for young people,[14] the primary care funding model does not provide sufficient consultation time to support primary care to conduct comprehensive assessments.

Primary care funding models vary considerably both within and between high-income countries. A common funding model and the main one used in Australian general practice is fee-for-service where healthcare providers are reimbursed for each individual service provided.[12] However, in Australia, despite urgent calls for this to be introduced, there is currently no fee-for-service payment available for a young person's health assessment.[15 16] Robust evidence about the effectiveness and cost-effectiveness of such a payment would greatly enhance the likelihood of its implementation in Australia. We report here the protocol for a cluster randomised controlled trial (RCT) of a fee-for-service payment for a young person's (aged 14–24 years) health assessment in general practice.

Aims

The primary aim is to determine whether a fee-for-service payment (hereafter referred to as a rebate) for a young person's health assessment in general practice increases the detection of risk behaviours and health conditions above that observed in general practices where a rebate is not provided.

Secondary aims include determining whether a rebate payment (1) increases management activity such as testing for sexually transmissible infections, contraceptive prescription, mental health plans and referrals; (2) is acceptable to healthcare providers and patients and (3) is cost-effective.

We hypothesise that the detection and management of risk behaviours and health conditions will be increased by providing general practice with a payment that will fund a longer consultation for a young person's health assessment leading to improved health outcomes in the short term and into adulthood (see figure 1).

The Australian context

Australia's universal health insurance scheme (Medicare) provides funding for primary care services largely as a fee-for-service model, through the Medicare Benefits Schedule (MBS). In Australia, most primary care is delivered through general practice with over 6500 practices across the country. The MBS is a list of medical services (known as item numbers) for which the Australian government will pay a Medicare rebate to provide patients with financial assistance towards the cost of their medical services. While general practitioners (GPs) are able to set their own fees for their services including charging patients above the MBS rebate, most (78%) consultations are charged at the MBS rebate with no additional cost to the patient.[17] There is currently no MBS item number for a young person's health assessment, yet Australian clinical guidelines recommend that adolescents have regular preventive health checks including assessment of mental health, sexual health, alcohol and drug use, injury prevention and body mass index.[14] MBS does provide rebate payments for preventive health assessments in particular population groups including a 45–49-year-olds health assessment, a once off assessment to detect and prevent chronic disease.[18] These age-based rebates fund consultations of up to more than 60 min duration and are more efficient for the practice as they allow a practice nurse to assist with collecting information, taking routine measurements (eg, blood pressure) and providing patients with information under the supervision of the GP.

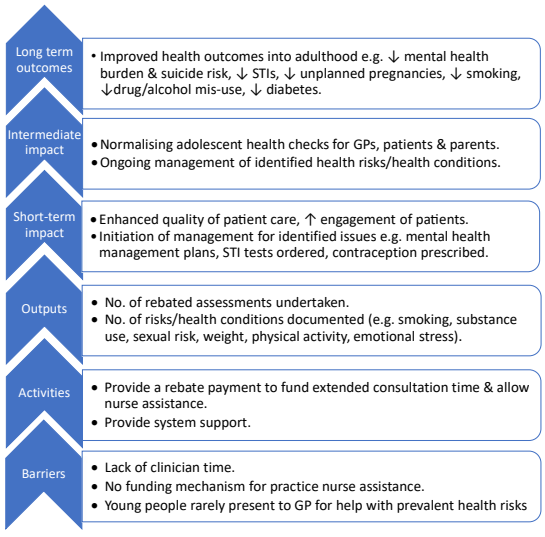

Figure 1 Programme logic for rebated health assessments in general practice. GPs, general practitioners; STIs, sexually transmissible infections.

METHODS

Design and setting

The Rebate for Adolescent Health Trial (RAd Health Trial) is a cluster RCT with the intervention allocated at the general practice level (cluster) (1:1) and the outcome measured at the patient record level. Practices will be randomised to receive the intervention (a rebate payment for each young person's health assessment) or control (no rebate payment) and asked to conduct annual preventive health assessments for patients aged 14–24 years. This age group was selected because it represents young people who should be targeted for a number of preventive health activities each year as per Australian guidelines.[14] Although the intervention is at the GP level at the point of care with their patient, the entire practice was chosen as the unit of randomisation to minimise the risk of contamination between intervention and control within a practice. GPs will be recruited and will provide signed consent as trial participants.

The trial will include a nested cohort study of 1000 young people aged 14–24 years recruited from participating practices about 6 months after randomisation. The purpose of this cohort is to collect quality of life and administrative health utilisation data to inform the cost-effectiveness evaluation of the trial. These young people will be followed online over an up to 24 month period (see online supplemental appendix S1 for further detail about the methodology of the nested cohort study).

A parallel process evaluation will be conducted to assess implementation of the trial intervention and assess the impact of the intervention on practice operations, staff and patients.

General practices will be recruited from both rural and metropolitan areas of Australia. Recruitment of practices and GPs commenced late 2022. The intervention period will be up to 2 years duration (see figure 2).

A RAd Health Trial Advisory Committee has been convened to oversee the trial, monitor and advise on its progress. Membership of the committee includes representatives from professional bodies (eg, Royal Australian College of General Practitioners), adolescent health experts, GPs, nurses, adolescents and parents.

Inclusion and exclusion criteria

General practices

Practices will be eligible for participation if they have (1) at least 600 consultations each year with 14–24-year-olds; (2) use *Medical Director* or *Best Practice* programmes as their electronic health records software, as these are compatible with our data extraction tool GRHANITE (see below for further detail) and (3) consent to instal GRAHNITE on their medical records software.

General practitioners

All GPs working at participating clinics will be eligible to be trial participants as the intervention is applied to the GP; only those who consent to participate will be eligible to receive the rebate payment.

Practice nurses

As per MBS rules, nurses working at participating practices will be able to assist with health assessments if the practice permits, but will not be considered trial participants.

Young people attending the general practice

Young people aged 14–24 years of age attending participating general practices will be eligible to have an annual preventive health assessment, but will not be considered trial participants.

Recruitment and consent

Practice and GPs

We will use several methods to advertise the trial and recruit practices. We will advertise the trial in electronic

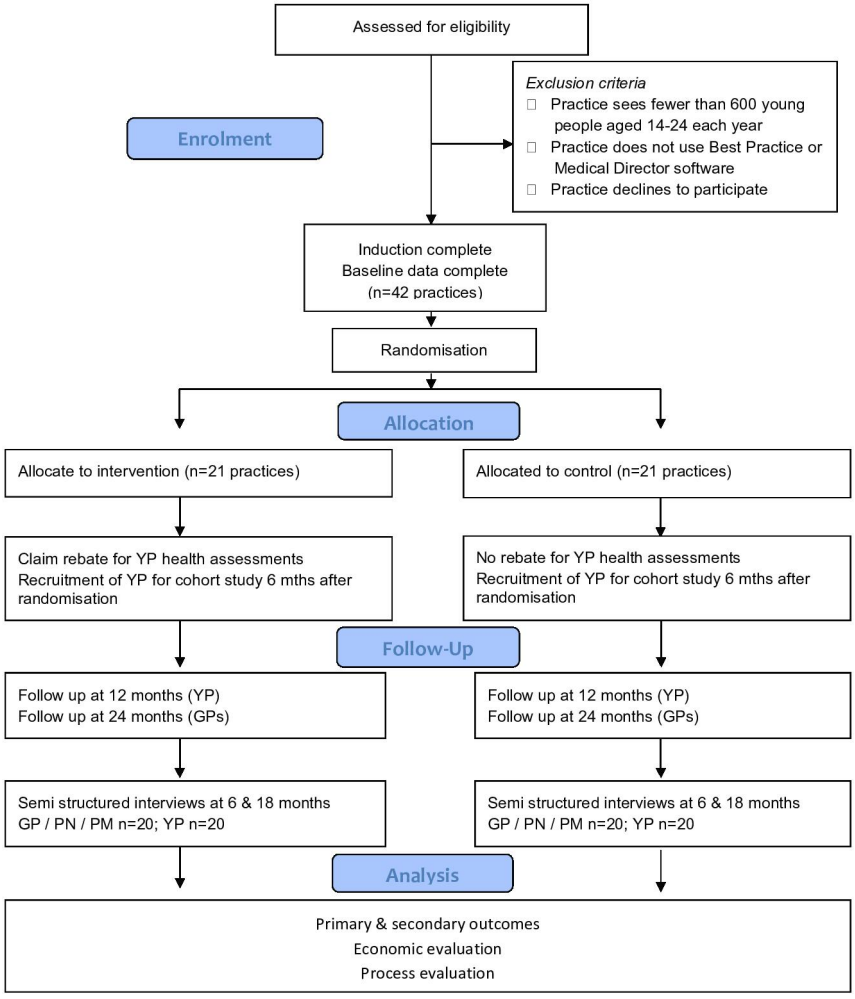

Figure 2 Flow diagram of RAd Health Trial. GP, general practitioner; YP, young person; PN, practice nurse; PM, practice manager

newsletters distributed via regional health authorities known as Primary Health Networks and the Victorian Primary Care Practice-based Research Network, a network managed by the University of Melbourne that facilitates general practice-based research. We will also promote the trial via our professional networks including our research partners and via social media such as Twitter and Facebook. Practices interested in learning more about the trial will be encouraged to contact the research team.

Recruitment officers at Victorian Primary Care Practice-based Research Network will compile a list of practices whom they will contact directly, informing them about the trial and inviting them to participate. Practices will be approached in no particular order until the required sample size is recruited. Recruitment officers will phone the practice to discuss the trial and assess eligibility, and if interested, attend a clinic meeting (either in person or via video-conferencing) to discuss the trial and obtain consent to participate. As the intervention, rebate payment for a young person's health assessment, is applied to the GP, they will be invited to participate in the trial and be required to sign a consent form. GPs who commence work at practices during the trial will be invited to participate and sign up as the trial progresses.

Practice nurses

Nurses will not be recruited nor consented to participate as the trial intervention is not applied to them and they will not be able to claim a rebate payment. However, as nurses may assist in undertaking health assessments in some clinics, a sample of nurses will be invited to undertake a qualitative interview as part of the process evaluation (see below for further detail) to explore the acceptability of rebate payments and health assessments to nurses.

Young people attending the general practice

Young people attending participating general practices during the trial, regardless of whether or not they have a health assessment are not considered to be trial participants as the intervention (rebate payment) is applied to the GP and only non-identifiable patient data will be collected from the patient electronic health record. However, young people who participate in the nested cohort study will provide signed consent when they

Table 1 MBS item numbers*

MBS #701	MBS #703	MBS #705	MBS #707
<30 min $65.00	30 to <45 min $151.05	45 to <60 min $208.40	60+ min $294.45

*Rebate value based on that available on 08 August 2023
MBS, Medicare Benefits Schedule.

are recruited about six months after each practice is randomised (see online supplemental appendix S1).

Intervention

GPs in intervention practices will receive a rebate payment for each health assessment they conduct with a young person. Health assessments should be conducted in accordance with clinical guidelines.[14] They will be eligible to receive one payment per patient per year. The rebate will be based on the Medical Benefits Schedule rebate payment currently available for a 45–49-year-old health assessments (MBS items: 701, 703, 705 and 707). These rebates vary according to the duration of the consultation (see table 1) and in accordance with MBS rules, will allow for a nurse to assist. At the commencement of the trial, the research team will meet with the GPs and practice staff to explain how the rebate will work. The rebate payment will be paid weekly, via electronic payment, which is consistent with Medicare reimbursement arrangements for practices.

Control

GPs in control practices will not receive any rebate payments and will be asked to conduct health assessments with young people as per clinical guidelines[14] and their usual practice.

Resource and support package

GPs in both intervention and control arms will receive a resource and support package ('resource pack') that includes education and training to undertake a young person's health assessment. This was developed in consultation with GPs, practice nurses and practice managers.[19] Prior to randomisation, GPs will be asked to complete a trial induction providing them with some training to conduct a young person's health assessment as per clinical guidelines.[14] Only those GPs in the intervention group who complete the trial induction will be eligible to receive rebate payments. There are currently no training requirements for GPs to claim rebates for similar age-based health assessments in Australia. Practice nurses will have access to the resource pack and encouraged to undertake the training, particularly if they will be assisting with health assessments. The resource pack will be available in an online repository accessible via the electronic health record.

The resource pack includes a young person's health assessment screening template to facilitate record keeping during the assessment. It will be embedded in the electronic health records software and used to guide the assessment. Similar health assessment templates are available for other MBS-rebated health assessments such as the 45–49-year-old assessments.[20] While there are no requirements for GPs to use these templates, MBS recommends that they are used to aid record keeping of health assessments. Our young person's health assessment screening template covers the recommended preventive care activities for young people as per Australian guidelines.[14]

We will use Normalisation Process Theory (NPT), to guide the implementation of the intervention and support package in participating practices and the subsequent process evaluation, helping us understand the cognitive and social processes used by staff to establish the health assessments and how successfully they are integrated into routine practice.[21] NPT helps characterise and explain mechanisms that facilitate or inhibit the implementation and integration of interventions in practice. The theory has four elements—coherence (understanding of the intervention by clinic staff), cognitive participation (commitment to and engagement with the intervention), collective action (work carried out to make the intervention function) and reflexive monitoring (evaluation of the intervention). Further information about the application of NPT in RAd Health is provided in online supplemental appendix S2.

Outcomes

Primary outcome

Our primary outcome will be the rate per year of risk behaviours, and health conditions detected and recorded in the patient electronic health record. The numerator is a count of the number of risks or health conditions recorded; the denominator is the number of unique patients seen during the 2 years postrandomisation. The risks and health conditions will include those recommended to be checked during a young people's health assessments[14] (eg, alcohol/drug use, smoking, sexual activity and mental health). Each separate risk factor or health condition recorded will be included—for example, if a person is recorded to be using marijuana and amphetamines, then this will be counted as two separate risks. We have selected the detection of risk behaviours and health conditions as our primary outcome because if these are detected early, the GP can initiate management plans to reduce the risk of future adverse health outcomes (see figure 1). These data will be extracted from the electronic health records within each practice using our data extraction tool, GRHANITE (see below).

Secondary outcome

The rate per year of patient management activities conducted and recorded in the patient electronic health record. The numerator is a count of the number of patient management activities; the denominator is the number of unique patients seen during the 2 years postrandomisation. The patient management activities

will include those that are related to risk and behaviours recorded such as tests done for sexually transmitted infections, contraception prescription, age and risk-group specific vaccinations prescribed, mental health plans initiated or health education/counselling provided, as per guidelines.[14] These data will be extracted from the electronic health records within each practice using our data extraction tool, GRHANITE.

Process outcomes

The following process outcomes will be assessed.

1. Acceptability (barriers/facilitators) of health assessments.
2. Adoption—uptake of health assessments.
3. Fidelity—how health assessments are implemented in the practice.
4. Sustainability—how the uptake of health assessments changes over time.

These process outcomes will be assessed using data extracted from the medical record and semistructured interviews with GPs, nurses, practice managers and patients. Further detail is provided in online supplemental appendix S2.

Adverse events monitoring

Practices, GPs and patients will be advised to notify the RAd Health team via email or telephone of any adverse events related to the trial. The investigator team will take responsibility for monitoring adverse events and determining in consultation with relevant ethics committee what, if any steps that need to be taken to minimise further adverse events.

Sample size

Thirty-eight practices (with a minimum of 600 young people attending each practice per year) will allow us to detect a 20% relative increase in the rate of risks or health conditions detected per young person between the two trial arms with 90% power and 5% alpha level for a two-sided test, given the baseline rate is 2.0 in the control arm. The baseline rate assumes around 90% of young people attending the practice currently have at least one risk behaviours and health conditions (such as sexual activity, smoking, unsafe alcohol use, drug use and emotional distress), based on our earlier adolescent health trial.[22] This sample size will allow us to detect a 50% increase in our secondary outcome, the rate of management activities assuming a baseline rate of 0.5 per person in the control arm. We have assumed a conservative intracluster correlation (ICC) of 0.06 for outcomes based on our previous trials.[22 23] We will recruit 42 practices to allow for up to four practices closing or withdrawing over the trial period. Table 2 shows the impact of sample size on potential results for the trial.

Randomisation

Randomisation of the practices will take place after completion of the induction programme (figure 2). Practices will be randomly allocated to the two trial arms in a 1:1 ratio, using a computer-generated allocation sequence set up by a statistician who is not involved in the recruitment of practices or data collection. Randomisation will be stratified by the (1) the location of the practice (rural/regional vs metropolitan), and; (2) billing practice of the practice (bulk-bill where there is no-copayment from the patient vs other, where the patient is required to make a copayment in addition to the Medicare fee). Permuted blocks of random sizes will be used to ensure balance of the number of practices allocated to each arm. The permuted block sizes will not be released until practices have all been recruited ensure allocation concealment.

Allocation concealment

Concealment of the computer-generated randomisation sequence until allocation will minimise selection bias. The permuted block sizes will not be released until practices have all been recruited to ensure allocation concealment. The random allocation sequence will be embedded within research electronic data capture (REDCap, a secure web application for managing studies)[24] using the randomisation module. When consent is obtained, GP induction activities completed and baseline data measured for participating practices, the research staff will enter the practice characteristics (including, unique identifier, clinic name, postcode, rural/regional or metropolitan location and whether the practice is bulk billing only or not) into REDcap, and practices will be randomised. Research staff will then notify practices of their allocation.

Blinding

Given the nature of the trial, it will not be possible to blind the practices and their staff nor the research staff liaising with the practices about trial arm allocation. A statistician, other than the one who set up the randomisation, will conduct a blinded analysis of the outcomes. The use of GRHANITE to extract the primary outcome from the electronic health record will capture all health records minimising measurement and non-response bias. It will also provide data from both intervention and control practices in a way that cannot be subverted.

Table 2 Number of practices required to detect a difference in the number of risks or health conditions per young person between trial arms

Number of risks/health conditions detected in control arm compared with intervention arm	80% power	90% power
1.8 vs 2.2 per person	30 practices	42 practices
2.0 vs 2.4 per person	28 practices	38 practices
2.2 vs 2.6 per person	26 practices	34 practices

Patients attending participating practices will be made aware that the practice is taking part in a young person's health trial via information leaflets or posters available in the waiting room but will not be told whether it is an intervention or control practice.

Data collection

Primary and secondary outcome data

Study data will be collected utilising our data extraction tool GRHANITE, which was developed by The University of Melbourne and allows for the collection of research data in compliance with strict technical and governance protocols.[25] This tool has been utilised to ethically and safely collect deidentified data for research for long-established surveillance programmes[26 27] and was used to collect outcome data for a large cluster RCT of a chlamydia testing intervention in 130 general practices.[23]

Demographic details, knowledge attitudes and practices of participating GPs

At enrolment, practice managers will be asked to complete a survey describing characteristics of the practice (location of practice, profile of staff and patients at the practice (eg, age, sex), billing practice of the practice (eg, whether they charge patients additional fees or not). Prior to randomisation, GPs will complete a survey collecting information about their sociodemographic characteristics, their educational qualifications and experience in general practice, and assess their knowledge, attitudes and practices regarding young people's health. This information will be used for a baseline comparison of trial arms.

Process outcomes

Adoption (uptake) and sustainability (how uptake of health assessments changes over time) of rebate payments and health assessments will be assessed using patient data extracted from the electronic health record using our data extraction tool GRHANITE.[25] Fidelity of the intervention will be assessed using an implementation checklist that monitors implementation of trial procedures, completion of trial induction, use of trial materials, implementation and use of the electronic health assessment template and management of rebate payments invoices and disbursement. Acceptability of the rebate payments and health assessments will be assessed using s*emistructured interviews* conducted via Zoom or telephone with approximately 20 GPs, 20 nurses, 20 practice managers and 20 young people. Further detail about process outcomes, data collection and analysis is provided in online supplemental appendix S2 .

Statistical analysis

Descriptive statistics will be used to compare practice (eg, number of practice staff /billing profile), GP (eg, age, sex) and patient profiles by trial arm at baseline. Data analysis will be intention-to-treat, with practices analysed according to their randomised arm.

Primary and secondary outcomes

The ratio of the rate of risks recorded or activities performed between the two arms will be estimated using Poisson-mixed effects regression, with random effects for practices and individuals (to account for repeated outcomes measured for a young person). In all models, baseline rate of outcomes over the 12 months prior to randomisation and stratification factors will be treated as fixed effects. Stratification factors are as follows: (1) the location of the practice (rural/regional vs metropolitan); and (2) billing practice of the practice (bulk-billing vs copayment). Estimates of the intervention effect for the outcomes will be reported as rate ratio with 95% CIs and p-values). The absolute (between-arm difference of rates) and relative (rate ratio) estimated effect sizes will be presented with their respective 95% CI, and the p-value.

ICC of the clustering effects for the key baseline variables estimated with the generalised mixed-effects models will also be reported with 95% CIs.

A detailed statistical analysis plan will be prepared prior to the trial analysis, which will elaborate on supplementary analyses, including sensitivity analyses, non-adherence analysis and exploratory data analyses and the handling of missing outcome data.

Process outcomes

Please see online supplemental appendix S2 for further information about analysis of process outcomes.

Economic evaluation

The economic evaluation will be conducted from (1) the public healthcare sector perspective and (2) the societal perspective. It will account for both the cost of the intervention (including rebates and practice costs such as training and resources) and potential changes in healthcare activity resulting from detection and management of risks, as well as consequent health impacts, bringing these together in terms of cost per quality-adjusted life year (QALY) gained for the intervention arm compared with control. The base case time horizon will be the period of the trial, with an alternate analysis extrapolating beyond the trial period using trial data regarding detection of risks, data on short-term health outcomes and associated healthcare utilisation from the cohort, combined with information from the scientific literature about the longer-term impact on health outcomes, quality of life and cost. The economic modelling will follow standard Medical Services Advisory Committee (MSAC) standards and guidelines for the evaluation of new MBS item numbers,[28] resulting in an incremental cost-effectiveness ratio for the intervention compared with control. This will enable comparison with established funding precedents. One-way and probabilistic sensitivity analyses will be conducted to examine the impact of key assumptions. Cost-effectiveness in terms of the primary trial outcome will also be conducted (cost per risk/health condition identified) to allow for comparison between the cohort and the full trial sample.

The economic evaluation will use the following data:

- From the nested cohort study of young people
  - QALY and healthcare utilisation data (see online supplemental appendix S1).
- From the RAd Health trial:
  - The cost of education and training materials developed.
  - Cost of rebate payments and administrative costs associated with providing the payments.
  - General practice services used by all 14-year-old to 24-year-old attending participating practices during the trial—for example, types of consultations billed (eg, standard consultation and mental health plans), investigations ordered (eg, sexually transmitted infection tests ordered) and prescriptions (eg, contraception and vaccination). These data will be obtained from the general practice electronic medical record using our GRHANITE data collection tool.

Healthcare unit costs will be based on national average prices and productivity costs on national wage data.

Patient and public involvement

GPs, practice nurses and practice managers and young people have been involved in the design of the trial and preparation of the resource pack and health assessment template. Focus groups were conducted with GPs (n=11), practice nurses (n=9) and practice managers (n=3)[19] and separately also with young people (n=11) to identify the educational and training needs of clinicians to conduct the health assessments and determine what support young people would want. We also developed the health assessment template in consultation with GPs and practice nurses and pilot tested it with three GPs and three practice nurses across five clinics to ensure its acceptability, usability and integration within the electronic medical record. Further involvement is via our RAd Health Trial Advisory Committee which includes GPs (n=2), practice nurses (n=1), representatives from professional bodies (n=4), parents (n=2) and adolescents (n=2). This committee meets annually with 6 monthly updates.

Trial status

This trial is registered with the Australian New Zealand Clinical Trial Register and conforms to Consort guidelines.[29] Ethics approval has been obtained from The University of Melbourne Human and Research Ethics Committee (2022-23435-29990-3). Recruitment for this trial commenced in October 2022 and is anticipated that it will be completed late 2023. The intervention period will be of up to 2 years with trial due to be reported in 2026.

Ethics and dissemination

Ethics approval has been obtained from University of Melbourne Human and Research Ethics Committee (2022-23435-29990-3). All digital data will be stored within a restricted-access folder on a network drive that is internal to The University of Melbourne and is only accessible to select project staff. All hard copy data will be stored in a locked filing cabinet at The University of Melbourne. Study materials will be kept for 5 years after publication of the study results after which point, they will be destroyed. All data collected and analysed will pertain to the RAd Health Trial only. Trial results will be presented to the RAd Health Advisory Committee to seek their feedback on interpretation of results and advice regarding dissemination. Findings will be published in peer-reviewed scientific journals and presented at national and international conferences. Further stakeholder engagement will take place via our professional networks.

DISCUSSION

To our knowledge, this trial will provide the first RCT evidence of the effectiveness and cost-effectiveness of a fee-for-service (rebate) payment for a young person's health assessment in general practice. General practice should play a key role in supporting young people's healthy transition from adolescence to adulthood by optimising their clinical encounters to undertake preventive health assessments. However, lack of adequate funding continues to be a major barrier to general practice supporting young people's health.[3 12] This trial will provide the evidence about whether a common funding mechanism used for primary care, fee-for-service, is effective at improving the quality of care and health outcomes for young people.

This trial has several strengths. First, our use of the state-of-the-art data extraction tool GHRANITE will enable collection of deidentified primary outcome data that do not require patient consent, minimises bias and ensures that our trial reflects the real world of health assessments in general practice. Second, our process evaluation will provide insights from stakeholders about practical aspects of how the rebated health assessment for young people works in real life and help us understand why they do or do not work at improving the detection of risk behaviours and health conditions among young people. Third, our economic evaluation will strengthen the trial by determining the cost-effectiveness of a rebate payment, vital for translation.

There are also limitations. First, the intervention will target GPs, with negligible patient involvement which some consider is necessary for sustaining change over time in primary care.[30] Second, our trial does not necessarily address the other barriers to young people's health in general practice including concern about confidentiality, embarrassment in disclosing health concerns and a lack of knowledge about available services.[8 31 32] However, our process evaluation and nested cohort study of young people will help us understand the impact of health assessments on young people and what is needed to make them more acceptable and effective. Third, the intervention targets only one funding mechanism for young people's health assessments in primary care and may not be relevant to other funding models. However, this is the

primary funding mechanism for health assessments in Australian general practice and the evidence generated by this trial is necessary to respond to growing calls to introduce this fee-for-service item number in the Australian setting.

Author affiliations
[1]Melbourne School of Population and Global Health, The University of Melbourne, Melbourne, Victoria, Australia
[2]Department of General Practice, The University of Melbourne, Melbourne, Victoria, Australia
[3]Centre for Adolescent Health, The Royal Children's Hospital Melbourne, Parkville, Victoria, Australia
[4]Department of Paediatrics, The University of Melbourne, Melbourne, Victoria, Australia
[5]Health Economics Group, Monash University, Melbourne, Victoria, Australia
[6]University of Sydney, Sydney, New South Wales, Australia
[7]Burnet Institute, Melbourne, Victoria, Australia
[8]Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Victoria, Australia
[9]Nossal Institute for Global Health, University of Melbourne, Melbourne, Victoria, Australia
[10]Sexual Health Program, The Kirby Institute, University of New South Wales, Sydney, New South Wales, Australia

Twitter Susan M Sawyer @SusanSawyer01

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ORCID iDs
Jane S Hocking http://orcid.org/0000-0001-9329-8501
Susan M Sawyer http://orcid.org/0000-0002-9095-358X
George C Patton http://orcid.org/0000-0001-5039-8326
Megan S C Lim http://orcid.org/0000-0003-3136-6761
Jane Pirkis http://orcid.org/0000-0002-2538-4472
Caroline Johnson http://orcid.org/0000-0002-4755-7514

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