SUPPLEMENTARY INFORMATION

Will a fee for service payment for a young people’s health assessment in general practice increase the detection of risk behaviours and improve health outcomes compared with no fee for service payment? Protocol for a cluster randomized controlled trial (RAd Health Trial)

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APPENDIX 1: – Young Person’s Nested Cohort Study

Aims:
1. To assess the impact of a rebate payment for a young person’s health assessment on the quality of life and health care utilisation of young people attending participating general practices.

Methods:

Study design:
This will be a cohort study of young people recruited from participating practices. Participants will complete a survey at recruitment and be followed up online for up to 24 months providing information, including completing a quality of life instrument, to inform the economic evaluation of the trial. Participants will be asked to give consent to obtain their health care utilisation data (Medicare [Australia’s universal health insurance scheme] and Pharmaceutical Benefits Schedule [Australian government subsidised medicines]) for data linkage to assess their health care use 12 months prior to and during the follow-up period. Recruitment of young people for the cohort study will commence mid-2023.

Inclusion/exclusion criteria:
Young people will be eligible if they are aged 14-24 years and are attending a participating practice for a consultation with a GP at the time of recruitment of the cohort. They will be excluded if there is a language barrier, they are incapacitated due to illness, have an intellectual disability, are aged 14-15 years and attending the clinic on their own without a parent or legal guardian, or there are other circumstances that hinder their ability or their guardian’s ability to give informed consent.

Recruitment and consent:
We will place a research assistant in each practice to recruit a consecutive sample of young people as they attend the practice for a consultation for any reason. Approximately 25 young people per practice will be recruited. We will obtain signed consent from the young people to participate in the cohort study, complete online surveys and give permission to access their administrative health records (Medicare and Pharmaceutical Benefits Schedule) via data linkage. Young people aged 16 to 24 years will be able to provide their own consent to participate. For patients aged 14 and 15 attending with a parent/legal guardian, consent will be obtained from parent/guardian as well as the child.
**Data collection:**

Cohort participants will complete online surveys to provide the following data:

- Health-related quality of life measured using age-appropriate preference-based instruments at baseline (recruitment) and again at 12 months. The AQoL-6D will be applied to those aged 18 and over, while the CHU9D will be used for those aged 14-17 (1).
- Healthcare utilisation data obtained from Medicare and the Pharmaceutical Benefits Schedule via data linkage.
- Demographic, risk and behaviour characteristics and experiences of any health assessments at the participating practices.

Additionally, some will be asked if they would like to participate in an interview as part of the process evaluation (see Appendix 2 – Process Evaluation for further information).

**Sample size:**

A sample size of 1,000 young people recruited from participating practices (average 25 per practice) will allow us to detect a difference of 0.06 in the mean AQoL-6D and CHU9D scores between the two trial arms assuming a standard deviation of 0.235 (1), 80% power, alpha of 5% and ICC of 0.02 and a loss to follow up of 30% (2).

**Analysis:**

The data will be used to inform the economic evaluation as outlined in the main protocol.
REFERENCES


APPENDIX 2: Process Evaluation

Aim:
To assess the implementation of the trial intervention (a rebate payment for a young person’s health assessment) and assess the impact of the intervention on practice operations, staff and patients.

Methods:
Theoretical framework
Our mixed-methods process evaluation will use Normalisation Process Theory (NPT) as a framework to guide our process evaluation (1). NPT helps characterise and explain mechanisms that facilitate or inhibit the implementation and integration of complex interventions. 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). Table 1 below outlines how NPT can be applied to RAd Health and the types of data to be collected for the process evaluation.
Table 1: Overview of Normalisation Process Theory and its application in RAd Health

<table>
<thead>
<tr>
<th>NPT</th>
<th>Coherence</th>
<th>Cognitive participation</th>
<th>Collective action</th>
<th>Reflexive monitoring</th>
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<tbody>
<tr>
<td>Have participants ascribed meaning to the intervention by: 1) Differentiating it from current practices; 2) Understand its objectives, values and benefits; and 3) Comprehend what the individual tasks and responsibilities are?</td>
<td>Are participants willing to invest time and energy into the intervention by: 1) Driving the new practice forward; 2) Contributing to the work; and, 3) Defining the actions and procedures necessary to sustain the practice?</td>
<td>Are participants producing and reproducing the actions required to make the intervention function by 1) Dividing up the labour as needed; and, 2) Integrating protocols into the workplace?</td>
<td>Have participants examined why the intervention is/is not working by 1) Evaluating the effectiveness and usefulness of the intervention; and, 2) Modifying actions to increase effectiveness?</td>
<td></td>
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NPT as applied to RAd Health

| Do the participating GPs and clinic staff understand the benefits of an annual preventive health assessment for young people? What will they do to make sure health assessments for young people happen? Do young people understand what is involved in a health assessment? | Is it feasible to include a young person's health assessment as part of consultation? What is needed to facilitate the conduct of a health assessment? Is it sustainable? Do young people accept the assessments? | Do the participating GPs have the support of the other staff and management to perform health assessments? Is there enough resources or training to do the health assessments and provide young people with necessary information? Are the appropriate staff available to do the health assessments? | Are health assessments happening and increasing in number? Do GPs receive feedback on their performance on health assessments? What is needed to monitor the conduct of health assessments in the practice? |

Process Evaluation data collection

| Semi-structured interviews with GPs, nurses and clinic staff; interviews with young people patients. | Semi-structured interviews with GPs, nurses and clinic staff; interviews with young people. | Semi-structured interviews with GPs, nurses and clinic staff; interviews with young people. | Semi-structured interviews with GPs, nurses and clinic staff; interviews with young people. |
Outcomes

Implementation outcomes will include acceptability (barriers/facilitators), adoption (uptake of health assessments), fidelity (how health assessments were implemented/used), and sustainability (how the uptake of health assessments changes over time). We will also assess the impact associated with rebate payments and undertaking health assessments in the practice. These outcomes will be assessed using data extracted from the medical record, semi-structured interviews with GPs, nurses, practice managers and patients and data monitoring from the research team.

Data collection

Quantitative data: 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™ (2). We will also use these data to monitor the impact of the intervention on the practice including examining: i) the number of young people’s health assessments conducted each year; ii) continuity of care for young people (for example, are patients attending two or more times per year); and, iii) whether the intervention has any impact on the profile of patients attending the practice during the trial – for example, do clinics in the intervention arm see more young people during the intervention period.

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.

Qualitative data: Acceptability of the rebate payments and health assessments will be assessed using semi-structured interviews conducted via Zoom or telephone with approximately 20 GPs, 20 nurses, 20 practice managers and 20 young people. Participants will be purposively sampled from participating practices to ensure representation by age, gender, and geographical
location. Interviews will be conducted about 6 months after commencing the trial and again at 18 months.

Analysis:

Quantitative data: Any changes in the number of health assessments over time, continuity of care or profile of patients attending the clinic will be compared between trial arms using the appropriate regression methods accounting for repeated measures from patients and clustering at the practice level. Further detail about the statistical analysis will be provided in a statistical analysis plan.

Qualitative data: Interview data: Interviews will be transcribed verbatim and two researchers will independently and inductively record codes and sub-codes applied to all data. If consensus on codes is unable to be reached, a third researcher will provide arbitration. Data will be analysed thematically. The triangulation of different sources of information (general practitioners, practice nurses / managers and patients) is consistent with best practice in qualitative research and will strengthen the rigor, validity, and comprehensiveness of this analysis. All interviews will be recorded, transcribed verbatim, and coded using NVivo™. Additionally, interview data will be interpreted using the four elements of NPT – coherence, cognitive participation, collective action and reflexive monitoring – to help us understand why the intervention works or does not work and identify factors that facilitate or inhibit the implementation and integration of rebated health assessments for young people in general practice.
REFERENCES
