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Asking children and young people about their general health and well being as part of routine clinical outpatient care - a pilot randomised controlled trial

Submission date
15/01/2024

Recruitment status
No longer recruiting

Registration date
21/01/2024

Overall study status
Completed

Last Edited
16/03/2026

Condition category
Other

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sometimes it can be hard for children and young people to talk about how their overall health and life is going. Answering some set questions might help. Additionally, filling out a general health questionnaire might help the service providers at the hospital outpatient clinics to better care for children and young people. This study aims to find out if asking children and young people about their general health using a standard set of questions, called the 'EQ-5D-Y-5L', at their outpatient appointments, is feasible and acceptable, and if it improves the way health care is provided.

Who can participate?
Children and young people aged 4 to 17 years (inclusive) who have an appointment with one of the participating outpatient appointments during the 5-week trial period are eligible to take part. The service providers (i.e., doctors and nurses) who treat children aged 4 to 17 years (inclusive) attending the participating outpatient clinics are also eligible to take part.

What does the study involve?
Children and young people who choose to take part in the study will be in one of two groups: a group who is asked to complete a general health questionnaire as part of their appointment at The Royal Children’s Hospital or a group not asked to complete the general health questionnaire. These group allocations will be decided by chance, similar to tossing a coin. There will be an equal chance of being in either group. This is called randomisation. Additionally, children and young people who choose to take part in the study, alongside their parent /caregiver, will be asked to complete three 5-minute online surveys:
Survey 1) Before outpatient clinic appointment and before any intervention (known as a 'baseline' survey),
Survey 2) 1 day after outpatient clinic appointment (known as a 1-day follow-up survey), and
Survey 3) 4 weeks after your appointment (known as a 4-week follow-up survey).

Service providers who take part in the study will be asked to complete a 1-minute weekly online survey, and a final 10-minute online follow-up survey. Service providers will also be asked to take part in a qualitative focus group after the completion of the trial.

What are the possible benefits and risks of participating?
We cannot guarantee that participants will get any benefits from this project. However, there is a chance that participants will be assisted by answering the general health questionnaire if they are randomly allocated to the group asked to complete this questionnaire. The time patients /caregivers and service providers spend on this study may be an inconvenience. Patients /caregivers will receive a $20 online gift voucher after completing the final follow-up survey (approximately 4-weeks after your hospital appointment). Service providers will receive a coffee vouchers after completing the final follow-up survey and/or focus group.

Where is the study run from?
The Royal Children's Hospital Melbourne, Murdoch Children's Research Institute and the University of Melbourne (Australia)

When is the study starting and how long is it expected to run for?
June 2023 to August 2024

Who is funding the study?
EuroQol Research Foundation (the Netherlands)

Who is the main contact?
Renee Jones, reneej1@student.unimelb.edu.au

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
RCH HREC #103264

Study information

Scientific Title
A pilot randomised controlled trial of a generic Paediatric Patient Reported Outcome Measure (P-PROM) intervention for use in Routine Outpatient Care for Kids (ROCK)

Acronym
P-PROM ROCK Pilot RCT Study

Study objectives
The use of a generic paediatric patient reported outcome measure (P-PROM) intervention in routine outpatient care at The Royal Children's Hospital will be feasible, acceptable, and useful compared with standard care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/01/2024, The Royal Children's Hospital Melbourne, Human Research Ethics Committee (50 Flemington Road, Melbourne, 3052, Australia; +61 3 9345 5044; rch.ethics@rch.org.au), ref: HREC/103264/RCHM-2024

Study design
Pilot single centre non-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Children in this study may have a range of chronic health conditions. Participating children will be from the following specialist paediatric outpatient clinics: asthma clinic, sleep clinic, encopresis clinic, and chronic constipation clinic.

Interventions
Current interventions as of 13/06/2024:
Randomisation will occur at the child level, whereby patients in participating outpatient clinics who have an outpatient appointment in the 10-week trial period, consented to take part, and completed the baseline survey will be randomly allocated to either the control (standard care) or intervention arm (generic P-PROM) at a 1:1 ratio. Randomisation will be done using an online tool.

Participating child patients allocated to the intervention arm will be asked to complete a generic P-PROM, the EQ-5D-Y-5L, prior to their outpatient clinic appointment. The patient will then be asked to highlight any domain(s) they would like to discuss with their service provider at their upcoming appointment. The results of this P-PROM will be displayed back to the patient and their treating service provider. If the patient highlighted any domain(s) for discussion, this will appear as an alert on the display shown to the service provider. After completing the generic P-PROM, patients will automatically receive resources to support getting help for any concerns they might have with any of the domains covered by the EQ-5D-Y-5L. Service providers will also receive resources and training. The intervention was co-designed with key stakeholders, including clinicians, caregivers of patients, and adolescent patients.

Participating child patients allocated to the control arm will receive standard care, whereby they will attend their appointment as usual.

The trial will run for a 5-10 week period in each outpatient clinic (depending on the frequency of clinics), however, the treatment period for each child is the time associated with their appointment at the outpatient clinic. The follow-up for each child will be at least 4-weeks after their appointment.

All participating child participants or the caregivers of child participants will be asked to complete a baseline questionnaire (pre-appointment), a 1-day post-appointment questionnaire and a 4-week post-appointment questionnaire. All participating service providers will be asked to complete a weekly survey and a post-trial follow-up survey (completed after the 5-week trial period). Participating service providers will also be asked to take part in a post-trial focus group.

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and a 4-week post-appointment questionnaire. All participating service providers will be asked to complete a weekly survey and a post-trial follow-up survey (completed after the 5-week trial period). Participating service providers will also be asked to take part in a post-trial focus group.

Intervention Type
Behavioural

Primary outcome(s)
Acceptability outcomes:
1. patient/caregiver reported attitude about completing the generic P-PROM, measured by asking patients/caregivers a question adapted from the TFA in the 1-day follow-up survey.
2. patient/caregiver reported burden to complete the generic P-PROM, measured by asking patients/caregivers a question adapted from the TFA in the 1-day follow-up survey.
3. patient/caregiver reported relevance of generic P-PROM questions, measured by asking patients/caregivers a question adapted from a previous similar P-PROM study in the 1-day follow-up survey.
4. patient/caregiver reported ease understanding the summary display of the generic P-PROM results, measured by asking patients/caregivers a question adapted from a previous similar P-PROM study in the 1-day follow-up survey.
5. patient/caregiver reported perceived usefulness of generic P-PROM results in the clinical encounter, measured by asking patients/caregivers a question adapted from the TFA and a previous similar P-PROM study in the 1-day follow-up survey.
6. patient/caregiver reported perceived opportunity cost of discussing the generic P-PROM in the clinical encounter, measured by asking patients/caregivers a question adapted from the TFA in the 1-day follow-up survey.
7. patient/caregiver reported perception of intervention coherence of the generic P-PROM (i.e., clarity regarding how generic P-PROM could improve child's care), measured by asking patients /caregivers a question adapted from the TFA in the 1-day follow-up survey.
8. patient/caregiver reported self-efficacy completing the generic P-PROM in future, measured by asking patients/caregivers a question adapted from the TFA in the 1-day follow-up survey.
9. patient/caregiver reported helpfulness of resources provided alongside the generic P-PROM, measured by asking patients/caregivers a study designed question in the 1-day follow-up survey.
10. patient/caregiver reported acceptability of completing and using generic P-PROM in outpatient care, measured by asking patients/caregivers a question adapted from the TFA in the 1-day follow-up survey.
11. patient/caregiver reported ease using the patient portal system to complete the generic P-PROM, view results, and view resources, measured by asking patients/caregivers a study designed question in the 1-day follow-up survey and by data automatically captured via portal (such as time taken to complete and number of clicks).
12. service provider reported ease locating generic P-PROM results, measured by asking service providers a study designed question in the follow-up survey.
13. service provider reported ease interpreting results of generic P-PROM, measured by asking service providers a study designed question in the follow-up survey.
14. service provider reported usefulness of results in clinical encounter, measured by asking service providers a question adapted from the TFA in the follow-up survey. Also measured by asking service providers a study designed question in a weekly during trial survey.
15. service provider reported intervention coherence of generic P-PROM (i.e., clarity regarding how generic P-PROM could improve care provided to children), measured by asking service providers a question adapted from the TFA in the follow-up survey.
16. service provider reported helpfulness of training at beginning of trial, measured by asking service providers a study designed question in the follow-up survey.

17. service provider reported helpfulness of resources document (clinician decision support tool/ clinician & family resources), measured by asking service providers a study designed question in the follow-up survey.
18. service provider reported confidence addressing patient concerns arising from the generic P-PROM, measured by asking service providers a study designed question in the follow-up survey.
19. service provider reported attitude about use of generic P-PROM in routine outpatient care, measured by asking service providers a question adapted from the TFA in the follow-up survey.
20. service provider reported burden using generic P-PROM in routine outpatient care, measured by asking service providers a question adapted from the TFA in the follow-up survey.
21. service provider reported self-efficacy using generic P-PROM in outpatient care routinely in future, measured by asking service providers a question adapted from the TFA in the follow-up survey.
22. service provider reported opportunity cost of using generic P-PROM in outpatient care, measured by asking service providers a question adapted from the TFA in the follow-up survey.
23. service provider reported acceptability of using generic P-PROM in outpatient care, measured by asking service providers a question adapted from the TFA in the follow-up survey.
24. service provider perception on acceptability of intervention measured via qualitative focus groups.

Added 13/06/2024:
25. patient/caregiver perception on the acceptability of intervention measured via qualitative interviews

Feasibility of the generic P-PROM intervention, measured by:
1. the proportion of patients allocated to the intervention who actually complete the generic P-PROM.
2. the proportion of patients/caregivers allocated to the intervention who report wanting to discuss at least one of the domains of the generic P-PROM with their service provider.
3. the proportion of generic P-PROM results opened or viewed by a service provider where a generic P-PROM result was available.
4. format of generic P-PROM completion (via patient portal system (web versus app) or paper).
5. calculating the resources required to implement the intervention, including electronic medical record team support time, clinician time for training, clinician time to discuss and action generic P-PROM results, and researcher time to get patients/caregivers to complete generic P-PROM. Resources will be converted into Australian dollars to provide an estimate of intervention cost.
6. additional consultation time arising from the generic P-PROM intervention compared to standard care, based on service provider report in a weekly survey and follow-up survey (study designed question). Additionally, based on research assistant's recording the duration of a random subset of face-to-face encounters.
7. service provider perception on feasibility of intervention from qualitative focus groups.

Added 13/06/2024:
8. patient/caregiver perception on feasibility of intervention measured via qualitative interviews.

Key secondary outcome(s))

1. the discussion of relevant quality-of-life domains in clinical encounter, measured by asking patients/caregivers if quality of life domains that were relevant to them were discussed in their most recent clinical encounter in the 1-day follow-up survey (study design question). Additionally, this will be measured by assessing notes from the electronic medical record that indicate relevant quality of life domains were discussed with patient.
2. holistic care provided in clinical encounter, measured by asking patients/caregivers if their most recent clinical encounter included discussion of aspects of health beyond just the physical

condition they were present for (such as emotional, social, school, hobbies, and spiritual wellbeing) in the 1-day follow-up survey (study designed question).
3. new health problem detected, measured by calculating the proportion of clinical encounters in which a new health problem was detected for a patient, based on patient/caregiver report in the 1-day follow-up survey and from electronic medical record notes that indicate a new problem was identified.
4. change in practice or support provided to patient (i.e., change medication, referral, connection with support service, connection with online resource) for a health/quality of life problem(s) in their most recent clinical encounter. Measured by asking patients/caregivers a study designed question in the 1-day follow-up survey and by assessing electronic medical record noted about if support was provided.
5. patient satisfaction with care in routine outpatient care based on responses to patient satisfaction questionnaire (PSQ).
6. patient - clinician communication, measured by asking patients/caregivers a study designed question in the 1-day follow-up survey.
7. improvements in child health related quality of life, measured using the CHU9D and based on change between baseline and 4-week follow-up.

Completion date
01/08/2024

Eligibility

Key inclusion criteria
All participants must meet one of the following criteria to be enrolled in this trial:
1. Is a child aged 4-17 years (inclusive) at the time of randomisation and who has an appointment (either new or review and either face to face or telehealth) with one of the participating outpatient clinics during the 5-week trial period.
2. Is a service provider (including clinicians, nurses, allied health staff) who provides outpatient care to children aged 4-17 years (inclusive) in one of the participating outpatient clinics during the trial period.

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
4 years

Upper age limit
100 years

Sex
All

Total final enrolment
87

Key exclusion criteria
1. Patient with a social flag on their electronic medical record (because they will not be able to access the patient portal system).
2. Any participant not able to communicate in English or require a translator as per their electronic medical record (because the patient portal system is only available in English).

Date of first enrolment
14/02/2024

Date of final enrolment
26/05/2024

Locations

Countries of recruitment
Australia

Study participating centre
The Royal Children's Hospital, Melbourne
50 Flemington Road
Melbourne
Australia
3052

Sponsor information

Organisation
Murdoch Children's Research Institute

ROR
https://ror.org/048fyec77

Funder(s)

Funder type
Charity

Funder Name
EuroQol Research Foundation

Alternative Name(s)
EuroQol Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/02/2026	13/02/2026	Yes	No
Results article		13/03/2026	16/03/2026	Yes	No
Statistical Analysis Plan	version 1	19/01/2024	19/01/2024	No	No