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Improving the patient-centred care of children with life-altering skin conditions using feedback from electronic patient-reported outcome measures: Protocol for a hybrid effectiveness-implementation study (PEDS-ePROM)

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2
3 **TITLE: Improving the patient-centred care of children with life-altering skin**
4 **conditions using feedback from electronic patient-reported outcome**
5 **measures: Protocol for a hybrid effectiveness-implementation study (PEDS-**
6 **ePROM)**
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3 **TITLE: Improving the patient-centred care of children with life-altering skin**
4 **conditions using an electronic patient-reported feedback intervention (PEDS-**
5 **ePROM): Protocol for a type 2 hybrid effectiveness-implementation study**
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12 **ABSTRACT**

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14 **Introduction**

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17 Using patient-reported outcome measures (PROMs) with children have been
18 described as 'giving a voice to the child'. Few studies have examined the routine use
19 of these measures as potentially therapeutic interventions with children. The study
20 aim is to investigate: (1) the *effectiveness* of a patient-centred care intervention using
21 feedback from electronic PROMs (PEDS-ePROM intervention) on health outcomes,
22 referrals, and treatment satisfaction; and (2) the *implementation* of PEDS-ePROM by
23 assessing acceptability and sustainability of the intervention and study processes.
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33 **Methods and analysis**

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35 A hybrid II effectiveness-implementation study will be conducted from February 2020
36 with children with life-altering skin conditions attending two outpatient clinics at a
37 specialist paediatric children's hospital. A pragmatic randomised controlled trial and
38 mixed methods process evaluation will be completed. Randomisation will occur at
39 the child participant level. Children or caregiver proxies completing baseline PROMs
40 will be randomised to: (1) completion of PROMs plus graphical displays of PROM
41 results to treating clinicians in consultations, versus (2) completion of PROMs
42 without graphical display of PROM results. The primary outcome of the effectiveness
43 trial will be overall health-related quality of life of children using caregiver-proxy
44 report (children < 8 years) and child-report (≥ 8 years). Secondary outcomes will
45 include other health-related quality of life outcomes (e.g., psychosocial health of
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3 children and caregivers), referrals, hospital resource use and treatment satisfaction.
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5 Trial data will be primarily analysed using mixed-effects regression. Analysis of the
6
7 implementation component will involve inductive thematic analysis of interview data,
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9 meeting minutes, observational field notes and written study communication mapped
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11 to the Consolidated Framework for Implementation Research.
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17 **Ethics and dissemination**

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19 Ethical approval was obtained from Children's Health Queensland Human Research
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21 Ethics Committee (HREC/2019/QCHQ/56290), The University of Queensland
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23 (2019002233), and Queensland University of Technology (1900000847).
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26 Dissemination will occur through stakeholder groups, scientific meetings and peer-
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28 reviewed publications.
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33 **Trial registration**

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35 ACTRN12620000174987
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38 **Keywords**

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41 Patient-reported outcome measures, quality of life, paediatrics, patient-centred care,
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43 implementation
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ARTICLE SUMMARY

Strengths and limitations of this study

- New evidence of the effectiveness and implementation of patient-reported outcome measures in the routine clinical care of children and caregivers with skin conditions will be generated which has received limited attention.
- Stakeholders representing multiple perspectives (children, caregivers, health professionals) were involved in the development of the intervention and process evaluation.
- Lack of ability to blind participants to the outcomes and contamination of the control group are potential biases.

INTRODUCTION

The routine use of patient-reported outcome measures (PROMs), or proxy-report measures, as part of routine clinical care has been identified as a means of driving change in healthcare systems, to ensure the unique voice of the patient is heard [1,2]. Potential benefits are improvements in shared decision-making, communication with health professionals and adherence to recommended treatments [3]. PROMs are defined as questionnaires completed by a patient with a health condition about their own health and treatment. For the purposes of the current study, PROMs include proxy caregiver measures as young children cannot self-report their quality of life or symptoms.

A recent systematic review identified that the effectiveness of PROM interventions for people with health conditions compared to usual care has been positive in adequately powered studies [4]. Few trials have been conducted in children. Only 2 of 22 included randomised controlled trials were conducted in children, one focussed on children with diabetes and one on children with cancer [5,6]. Two more recent paediatric cluster randomised controlled trials investigated PROMs used with children with severe mental health conditions attending child and adolescent psychiatric services [7,8]. Only one of the four paediatric trials identified positive effects of the PROM intervention. The positive effects were for psychosocial health-related quality of life but not physical health-related quality of life in children with diabetes [5].

This paper will report the protocol for a randomised controlled trial and implementation study to test the effectiveness, acceptability and sustainability of a

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3 PROM intervention in children with the life-altering skin conditions of burn scars and
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5 infantile haemangiomas. The need for interventions to improve the health-related
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7 quality of life of these children is highlighted by the lower health-related quality of life
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9 of children with burn scars across multiple domains even years after the actual injury
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11 compared to children with cancer [9]. At the time of publication, the PROM
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13 intervention to be tested had been designed (termed PEDS-ePROM) and the
14
15 randomised controlled trial and implementation testing was underway with no
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17 findings yet available.
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21 **Aims and objectives**

22 Effectiveness outcomes

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24 The primary effectiveness aim is to determine the short-term effectiveness of
25
26 implementing PROMs with graphical displays of result summaries, on overall health-
27
28 related quality of life of children with life-altering skin conditions. Secondary aims will
29
30 be to examine the effectiveness of the intervention for other health-related quality of
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32 life outcomes of children and caregivers, the number and type of referrals to health
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34 professionals and treatment satisfaction.
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40 *Hypotheses (effectiveness component)*

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- 43 1. The PEDS-ePROM intervention will lead to effect estimates from generic health-
44 related quality of life measures in a consistent direction and have a similar strength
45 of effect across the clinic and conditions, supporting comparative effectiveness of
46 the intervention.
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 - 48 2. The PEDS-ePROM intervention will have a greater effect on overall health-related
49 quality of life than the ePROM intervention.
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57 Implementation outcomes

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3 The primary implementation aim is to determine the short-term acceptability and
4 sustainability of implementing the interventions.
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7 **METHODS AND ANALYSIS**

8 **Development of the study design and intervention**

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10 The development of the PEDS-ePROM trial and intervention was conducted from
11 May 2019 to January 2020. We initiated preliminary discussion with clinicians in
12 clinical areas to identify which measures were already being used routinely in
13 practice. Systematic reviews and paediatric literature regarding the use of PROMs
14 were also reviewed. Interview guides were developed to identify health outcomes
15 that are meaningful and of high priority to children, their families and health
16 professionals in the PROM intervention [10]. The nine core questions from the
17 International Society of Quality of Life (ISOQOL) user guide and the companion
18 guide areas were addressed in the interviews [11]. This strategy has been identified
19 as important to improve the engagement of children and young people such that
20 fewer items are missed and responses accurately reflect their experiences and
21 cognitive ability [12].
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Interviews were conducted with children with life-altering skin conditions, their
caregivers and treating health professionals in two phases as part of the pre-
implementation planning, with interview questions mapped to the Consolidated
Framework for Implementation Research. In the first phase the most appropriate
outcomes and PROMs were identified. In the second phase the content validity of
chosen PROMs was confirmed. Potential barriers and benefits to implementation
were identified in both phases. For children with burn scars and their families,
measures of health-related quality of life specific to scarring were prioritised to

1
2
3 include symptoms and treatment burden based on conceptual work from the
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5 research team that identified these aspects as central components of health-related
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7 quality of life for this group [13]. Theory-based interventions also tend to be more
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9 effective than non-theory based interventions [14]. The design of the randomised
10
11 controlled trial was based on systematic review findings that identified greater
12
13 benefits when PROM results were provided to clinicians compared to when results
14
15 were not provided to clinicians [4].
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18 19 **PEDS-ePROM intervention**

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21 The Pediatric Quality of Life Inventory infant and generic scales [15,16] measuring
22
23 health-related quality of life and a treatment satisfaction item were included as
24
25 generic measures. Condition-specific health-related quality of life measures selected
26
27 were the Brisbane Burn Scar Impact Profile [13,17], The CARE parent scale [18],
28
29 Hemangioma Family Burden questionnaire [19] and Infantile Hemangioma Quality of
30
31 Life Scale [20]. Selected measures targeted children and their caregivers and a
32
33 single item targeted siblings. An open-ended option was also available for child and
34
35 caregiver participants to report their priorities for care. Only PROMs meeting the
36
37 criteria of content validity supported by involvement of the target group in
38
39 development were included. Graphical displays of result summaries from the
40
41 Pediatric Quality of Life Inventory and condition-specific measures of health-related
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43 quality of life measure will be presented in consultations for children with skin
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45 conditions and their caregivers to treating clinicians. The components of the
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47 intervention are reported in Table 1.
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Table 1. Description of the PEDS-ePROM intervention and ePROM comparison intervention*

Clinic	Mode of administration	PEDS-ePROM intervention			ePROM comparison intervention			Intervention period
		Content	Duration	Frequency	Content	Duration	Frequency	
Burn scar clinic	Administered remotely using email or by a research occupational therapist in the clinic setting. PROM data collected electronically on a device at home or on an Apple iPad in the clinic.	PEDS-QL generic and infant scales BBSIP CARE scales	Approx. 15 mins for child and caregiver participants to complete ePROMs prior consultations. Up to 15 mins to download, print and deliver ePROMs & graphical displays to consultations***.	Delivered in consultations up to 1x/mth. Based on usual care likely to be delivered 2-3x.	ePROMs delivered and completed as per PEDS-ePROM intervention group. No graphical summaries provided in consultations‡.	Approximately 15 mins for child and caregiver participants to complete ePROMs prior to each consultation.	As per PEDS-ePROM intervention	Baseline - 6 mths †
Vascular clinic	As per burn scar clinic	PEDS-QL infant scales	Approx. 10 mins for caregiver participants to	Up to 1x/mth, likely 1-2x **.	ePROMs delivered and completed as	Approximately 10 mins for child and	As per PEDS-	Baseline - 6 mths †

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Hemangioma	complete	per PEDS-	caregiver	ePROM
Family Burden	ePROMs prior to	ePROM	participants to	intervention
questionnaire	each	intervention	complete	
Infantile	consultation.	group. No	ePROMs prior	
Haemangioma	Up to 10 mins to	graphical	to each	
Quality-of-Life	download, print	summaries	consultation.	
Instrument	and deliver	provided in		
	ePROMs &	consultations‡.		
	graphical			
	displays to			
	consultations***.			

* Based on the Template for Intervention Description and Replication (TIDieR) guidelines

† Post-baseline

‡ Graphical summaries provided to child and caregiver participants and entered into medical records at the end of the study

** Children with ulcerated haemangiomas may receive intervention more frequently

*** Graphical summaries provided to child and caregiver participants at the end of the study

PROM, patient-reported outcome measure; ePROMs, electronic patient-reported outcome measures; PEDS-QL, Pediatric Evaluation of Quality of Life Inventory; approx., approximately; mins, minutes; mth, months

Method for completing PROMs

Electronically-delivered PROMs were identified as the best option for getting patients to complete the measures at home prior to consultations to reduce the burden of administration of measures and result summaries during busy clinics. The PROMs will be administered via a weblink sent to caregiver participants in an email in the three days prior to their appointment. If the questionnaires are not completed via the weblink, child and caregiver participants will be offered a further opportunity to complete the questionnaires using an iPad up to 30 minutes prior to their consultation at the outpatient clinic while they are waiting for their consultation. Phone calls will be used to remind caregiver participants to complete the PROMs. The PROMs and graphical display of result summaries will be generated using the online survey software program Qualtrics^{XM} [21] and presented to treating health professionals immediately prior to appointments. Copies of the electronically completed PROMs and graphical displays of result summaries will be stored in medical records.

Context

The setting will be two outpatient clinics at a major metropolitan quaternary-level children's hospital in Australia; a burns clinic and a vascular anomalies clinic. Caregivers (or their children with skin conditions if aged 8 years or older) will be consecutively approached and recruited, and the intervention delivered prior to and at these clinics. The catchment of the hospital includes inhabitants from rural, regional and metropolitan areas including those from surrounding islands. Recruitment commenced in January 2019. The first participant was randomised to receive the intervention in March 2020.

Research design

A hybrid type 2 effectiveness-implementation design will be used which blends evaluating intervention effectiveness and understanding implementation of the intervention simultaneously [22]. Benefits of this design include reduced lag time for uptake of the results into routine clinical practice and understanding the barriers and benefits to implementation [22]. A pragmatic two-arm randomised controlled trial will be conducted using block randomisation in random blocks of 4, 6 or 8 stratified by clinic, with child participants as the unit of randomisation; and an embedded qualitative process evaluation involving interviews with clinicians, and child and caregiver participants. The randomisation sequence will be prepared by statistician independent from the study and will be concealed using sequentially numbered, opaque, sealed envelopes with tamper proof tape prepared by a person independent from the study.

The randomised controlled trial arms will be: (1) PROM completion plus graphical display of result summaries to clinicians (intervention group) versus; (2) PROM completion without graphical display of result summaries to clinicians (comparison group).

Baseline PROM measurement will occur before randomisation. PROM measurement will occur prior to or at one or more subsequent hospital appointments over the following 6-months and follow-up measurement will occur at 3-months and 6-months post-baseline if these timepoints differ from data collection timepoints during consultations with health professionals. Child and caregiver participants will be masked to the hypotheses. A Standard Protocol Items Recommendations for

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Interventional Trials (SPIRIT) flow diagram has been used to report the schedule for enrolment, interventions and evaluations for the effectiveness component of the study (Figure 1).

The study design and evaluation plan have been informed by the Consolidated Framework for Implementation Research which considers reasons for successful implementation or problems and can be used to understand the mechanism of action of the intervention. This framework also covers the physical and social environment, values, individual motivation and capacity factors which are considered important for the intervention being tested and has been derived from 33 theories relating to implementation [23]. This Protocol paper has been prepared following the eHealth Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Participants

Inclusion criteria

Children with burn scars and infantile haemangiomas, aged 16 years or younger at the time of recruitment, who require ongoing management in the hospital setting, and their caregivers aged 18 years or older will be included. Ongoing management is defined as children who require one or more ongoing consultations beyond baseline for the prevention or management of skin conditions as determined by treating clinicians at baseline. Treating clinicians will also be asked to determine children's ability to complete PROMs electronically based on their physical condition and knowledge of the family (i.e., to determine if bilateral hand burns would prevent sufficient movement of their hands to use an iPad).

Exclusion criteria

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3 Children and caregivers will not be eligible to participate if they are involved with
4 child protection services and it is difficult to obtain consent, where circumstances
5 interfere with the participant's ability to give informed consent (i.e., diminished
6 understanding or comprehension), or where there is difficulty speaking or
7 understanding written English as the PROMs are only available for the study in
8 English.
9

16 Sample size estimate

17
18 The sample size was based on recruitment feasibility. A retrospective audit of child
19 and caregiver participants of clinic attendees suggested at least 35 participants in
20 each clinic can be recruited in the 6-month intervention period. In terms of the
21 effectiveness randomised controlled trial, if outcome data is available for 70
22 participants overall, then with 80% power we will be able to detect an effect size for
23 the difference between-arms of 0.68 or greater for overall health-related quality of life
24 at 6-months post-baseline ($\alpha=0.05$).
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38 Interviews will be conducted with the following groups during implementation with
39 numbers of participants represented approximately equally for each clinic: children
40 with a skin condition, their caregivers and treating health professionals. Interviews
41 will continue until saturation (i.e. the point at which no further dimensions, nuances,
42 or insights of issues are identified) [24] building on interview data generated pre-
43 implementation. A greater number of child interviews will be required than caregiver
44 and health professional interviews based on our previous experience obtaining
45 shorter interviews of 15 to 20 minutes in children with burn scars than with
46 caregivers and health professionals.
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Evaluation

Effectiveness outcomes

Study outcomes will be self-completed by children aged 8 years or older and proxy-completed by caregivers for younger children. The primary outcome assessed will be change in the child's generic overall health across both clinics measured using The Pediatric Quality of Life Inventory (PedsQL™ 4.0 Generic Core and Infant Scales) [15,16] subscales of psychosocial, physical and overall health and the Child Health Utility (CHU-9D) [25]. Secondary outcomes will be: a) change in other health-related quality of life outcomes (e.g., child physical health, The Pediatric Quality of Life Inventory), child psychosocial health (The Pediatric Quality of Life Inventory); b) resource use from the perspective of the health service based on the cost of implementing the intervention will be recorded for patients in each group. In addition, healthcare resource utilisation for co-interventions for skin treatment (e.g. medicines, complementary treatments, and details of hospital presentations), will be collected from several sources including medical records, and the hospital clinical costings department for corroboration and analysis; c) number and type of referrals for the child or caregiver; and d) caregiver satisfaction with treatment. A description of each of the outcomes and psychometric properties of outcomes are reported in Supplementary File 1. Adverse effects of the PROM interventions will be monitored using the self-report of caregiver and child participants (where appropriate), treating health professionals as well as by monitoring of the PROM data by investigators.

Other outcomes

Sociodemographic data collected from or about caregivers will include the caregiver's relationship to the child, level of education, ethnicity, work status,

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3 household income, and postcode; and from children aged 8 years or older or
4 caregivers about their children will include, gender, ethnicity, education level, scar
5 location and comorbidities of the child participants. Clinical data collected from
6 electronic medical records will be percent total body surface area, percent full
7 thickness burn, length of time post-burn, type of healing (e.g., spontaneous skin
8 healing versus split thickness graft), type of burn, and length of time to re-
9 epithelialisation, medications and complications during the study period.

19 Fidelity

20 Fidelity of the intervention will be records kept by researchers regarding the number
21 of participants who completed ePROMs as scheduled, the number randomised to
22 receive graphical displays of result summaries versus the number of participants
23 who actually received graphical displays of result summaries during consultations,
24 and missing PROM data on Qualtrics^{XM} [21]. Immediately after face-to-face
25 consultations caregivers and children (where appropriate) will be requested to
26 verbally report the topics that were discussed during the consultation mapped to the
27 graphical display of result summaries.

39 Effectiveness evaluation

40 An intention to treat analysis will be the primary approach but per protocol analyses
41 will be compared to the intention to treat approach to examine the effect of those
42 who didn't receive the intervention as intended. The key sociodemographic and
43 clinical characteristic data that will be examined for baseline differences between the
44 groups will be age, gender, education, household income, socioeconomic status of
45 the neighbourhood where the family reside based on postcode, severity of baseline
46 symptoms and health-related quality of life, body location of the condition, visibility of
47 the condition (scars on the head, neck, face or hands), and time since the skin
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3 condition commenced or injury occurred. The primary comparison will be completed
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5 using data from caregivers for children aged younger than 8-years and from children
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7 themselves for those aged 8-years or older.
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9 10 Effectiveness analysis

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13 Primary outcome comparison at 6-month post-baseline will be based on overall health
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15 from the Pediatric Evaluation of Quality of Life Inventory between the PEDS-ePROM
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17 and ePROM comparison group using linear mixed-effects models that account for
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19 repeated observations from the same child and clustering within clinics and within
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21 treating health professionals. Covariables will be included for potentially confounding
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23 variables if any differences between groups are identified for key sociodemographic
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25 and clinical characteristics at baseline.
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30 A sensitivity analysis will be conducted using imputation techniques to replace non-
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32 ignorable data that is considered to be missing at random over the follow-up period, to
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34 determine whether bias is likely in the complete case analysis. Secondary outcome
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36 comparisons will be conducted at 6-months post-baseline using linear mixed models
37
38 where appropriate. Multi-level or nested hierarchical analysis will examine the effect
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40 of clinic and treating health professional effects by examining patient clustering
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42 within clinics, and surgeons and occupational therapists clustered within clinics. The
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44 amount and type of missing data will be reported using descriptive statistics. Data
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46 analysis will be conducted using Stata 16.0 (Statacorp, College Station, TX, USA).
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50 Implementation outcomes

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52 Implementation will be considered successful if graphical displays of result
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54 summaries are presented to treating clinicians immediately prior to more than 85% of
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56 consultations where a patient is randomised to receive a report, and if PROMs and
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58 summaries are filed in electronic medical records for more than 75% of patients
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3 eligible to have PROM data provided to treating clinicians in the intervention period.
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5 The outcomes detailed in Table 2 will be used to determine acceptability and
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8 sustainability.
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For peer review only

Table 2 Description of the outcomes included in the implementation process evaluation

Outcome	Participant of focus	Detailed description of the outcome	Source of data
Acceptability of ePROM interventions for families of children with health conditions and treating clinicians*	Child and caregiver	<ol style="list-style-type: none"> 1. $\geq 80\%$ of families will take < 15 minutes to complete the ePROMs as previous research has identified that PROMs that are fast to complete are most acceptable to clinicians and families [26]. 2. $\geq 50\%$ of families completed ePROMs across all scheduled consultations that were eligible to be included in the study intervention period, where consultations eligible to be included were limited to one consultation over any 1-month period. Based on pre-intervention phase interviews and what was considered acceptable for ongoing implementation of the PROMs routinely in clinical practice in the clinics. 3. Phone reminders for PROM completion were required in $\leq 50\%$ of families. 	<p>Electronic data collection for outcome (1) and (2)</p> <p>Field notes</p> <p>Field notes and electronic data collection</p>

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4. Technology-related issues with graphical displays of result summaries or ePROM completion were present for $\leq 10\%$ of families across all eligible appointments.

Sustainability of ePROM interventions and evaluation

Child and caregiver

The extent to which the ePROM intervention was maintained or continued in routine clinical practice at the end of the study.

Interviews with child, caregiver and health professional participants.
Field notes

* Children ≥ 8 years will self-report; caregivers will provide proxy-reports for children aged < 8 years except for satisfaction with treatment which will only be self-reported by caregivers.

ePROMs, electronic patient-reported outcome measures

Implementation evaluation

Acceptability and sustainability of the intervention will be evaluated using interviews, health service and missing data, observational field notes of meetings and each clinic attended or planned, meeting minutes and study emails. Acceptability is defined as the perception among stakeholders that a treatment, service, practice or innovation is agreeable or satisfactory [27]. Sustainability is defined as the extent that a newly implemented treatment is maintained within a service setting's ongoing, stable operations [27]. The data from these sources will be mapped to the Consolidated Framework for Implementation Research [23]. This framework can be used to understand barriers and facilitators to implementing the intervention within an organisation which can assist in determining the sustainability and potential scaling up of the intervention. Factors related to implementation delivery that might have impacted on the intervention effectiveness will also be examined to understand whether and how the expected outcomes were achieved, and the reasons for this.

Implementation analysis

Interpretive Description [28] will be used to analyse the data initially. This qualitative analysis uses elements from several other qualitative methodologies including phenomenology, grounded theory, and ethnography without focusing on any specific technique [28]. Interpretive Description is ideal for applied clinical questions and analysis of a wide range of data sources [28]. The analysis builds on what is known in terms of current practices and structures of health services and what is known and not known [28]. Data analysis will be conducted iteratively, concurrently with interviews, with interviews conducted during the implementation phase building on analysis of pre-implementation interviews. Framework analysis [29] will then be applied deductively, mapping the data to the pre-defined key constructs of the

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3 Consolidated Framework for Implementation Research as overarching themes. The
4 data will be organised into a framework matrix where columns are codes and rows
5 are participants [29]. This analysis is conducted across participants as well as within
6 participants. Steps in framework analysis include familiarization; indexing; charting;
7 and synthesising [29]. Pre-implementation and post-implementation differences will
8 be examined, and themes that emerge in addition to the Consolidated Framework for
9 Implementation Research constructs, will be added to the framework.
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22 Interviews will be audio recorded and transcribed verbatim by study personnel.

23 Recordings will be stored in a coded form on a secure password protected folder
24 within The University of Queensland until coding has been completed, accessible to
25 two of the investigators and a research assistant. The credibility of the analysis will
26 be checked using member checking of the interview data, independent coding of the
27 data by two researchers of at least 20 percent of the data, triangulation of the results
28 across participant groups (managers, treating health professionals, caregiver and
29 child participants), and reflective journaling.
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40 Electronic platform

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42 The electronic survey platform Qualtrics^{XM} [21] was chosen to administer the
43 PROMs and to provide graphical displays of result summaries based on visual
44 aesthetics of the graphical displays compared to other survey programs and prior
45 experience of the investigators using the program. Features of the program that were
46 important for administration of the chosen surveys and study design were the ability
47 to have open-ended text, email distribution, ability to send reminders, display
48 longitudinal responses, a recoding values function, automated scoring functionality,
49 and links to NVivo software [30] for coding open text responses.
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Patient and public involvement

Children aged 8 years and older with life-altering skin conditions, caregivers of children with life-altering skin conditions and treating health professionals in the study setting were involved in all study phases including development of the intervention, process evaluation, study design and implementation evaluation. These stakeholder groups reported on the burden of the planned intervention, potential time required to participate and acceptability of follow-up intervals in pre-implementation interviews. Plans include forming a stakeholder reference group to inform the interpretation and sustainability of the study findings.

DISCUSSION

To our knowledge studies of PROM interventions have not previously focused on children with life-altering skin conditions. A pragmatic approach has been taken to maximise relevance to the clinical context including limiting exclusion criteria, and developing and delivering an intervention that has limited interference with the running of very busy outpatient clinics. If the intervention is shown to have promising short-term results then secondary prevention impacts particularly on emotional health of caregivers may be likely and the benefits higher in the longer term which will be examined in the future.

An outcome of the proposed study may be refinement of the PEDS-ePROM intervention based on mapping to the Consolidated Framework for Implementation Research which may identify additional elements that should be considered. The findings will also likely inform the design of a multisite cluster effectiveness-implementation study of a patient-reported outcome measure intervention in these children which may reduce the risk of contamination bias [8]. Information obtained

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3 will inform ongoing efforts in paediatric care to use patient-reported outcome
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5 measures as part of routine clinical care.
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7 8 **Strengths and limitations**

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10 Strengths of the study include the involvement of stakeholders representing multiple
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12 perspectives (children, caregivers, health professionals) in the development of the
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14 intervention and the process evaluation, and the focus of the intervention and
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16 process evaluation on health-related quality of life. The use of the Consolidated
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18 Framework for Implementation Research is also a strength. This framework was
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20 identified as a good fit for examining the implementation of PROMs in health service
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22 organisations in a recent systematic review of reviews [31] and can assist to
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24 understand how the intervention works (i.e., the process by which behaviour change
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26 occurs) [32]. More specifically, the current study will seek to understand how the
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28 inner setting of the organisation (i.e., organisational culture and structural
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30 characteristics) impacts on implementation which has been identified as a research
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32 gap [31].
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40 The lack of blinding of treating health professionals and participants in the
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42 randomised controlled trial is a limitation although blinding is not possible as the
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44 outcomes are patient or proxy-reported and it will be clear to most participants when
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46 results are presented in consultations. However, child and caregiver participants will
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48 be blinded to the hypotheses. Potential contamination bias has also been raised as a
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50 possibility in trials of this nature where several clinics within a facility are included, as
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52 treating health professionals' awareness of issues that should be focused on may be
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54 raised, diluting the impact of the intervention [33].
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3 A limitation is the lack of inclusion of families from non-English speaking
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5 backgrounds and some cultural groups. Further attention is required to develop and
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7 test PROM interventions for families from specific cultural backgrounds which is a
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9 challenge in the study setting where people from many cultural backgrounds are
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11 seen. Specifically, people of Aboriginal and Torres Strait Islander descent were not
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13 involved in the development process thus the intervention and study design may not
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15 be acceptable for this group of people and should be established.
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18 19 **Ethical approval and dissemination**

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21 Ethical approval has been received from Children's Health Queensland Hospital and
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23 Health Service Human Research Ethics Committee (HREC/19/QCHQ/56290), The
24
25 University of Queensland (2019002233), and Queensland University of Technology
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27 (1900000847).
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33 Written consent will be obtained from caregiver and treating health professional
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35 participants once written and verbal information has been provided. Caregivers will
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37 be encouraged to discuss the study with children who can communicate with their
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39 caregivers prior to consent being obtained. Adverse effects will be reported to the
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41 Children's Health Queensland Hospital and Health Service and Human Research
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43 Ethics Committees.
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9 **Author contributions**

10 ZT designed the study with input from SM for the effectiveness evaluation, GH for
11 the implementation evaluation, and RK and MS for integrating with existing clinical
12 processes. ZT drafted the protocol and SM, MS, TZ, RW and RK critically revised
13 the manuscript.
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22 **Funding statement**

23 This work was supported by a Health Services Research grant from the Children's
24 Hospital Foundation, Brisbane, grant number 50297. The funder had no input into
25 the design or conduct of the study.
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32 **Competing interests statement**

33 ZT, MS and RK developed the Brisbane Burn Scar Impact Profile which was
34 included as a scar-specific measure in this study. MS and RK were clinical staff
35 members of the health service where the study will be conducted at the time of
36 submission.
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45 **Data sharing statement**

46 The final trial dataset will be available to chief investigators. The final trial dataset
47 may be accessed with approval from the investigators if steps are undertaken to
48 preserve the confidentiality of the data.
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54 **Acknowledgements**

55 Nil
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58 **Figure 1 legend**

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3 SPIRIT flow diagram for the effectiveness study component*
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5 **Word count 3932**
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For peer review only

STUDY PERIOD				
	<i>Enrolment</i>	<i>Allocation</i>	<i>Post-allocation</i>	
TIMEPOINT	-t₁	0 Baseline*	t₁ 3-months post-baseline	t₂ 6-months post-baseline
ENROLMENT:				
Eligibility screen	X			
Informed consent	X	X		
Allocation		X		
INTERVENTIONS:				
<i>PEDS-ePROM</i>		◄	—————	►
<i>ePROM</i>		◄	—————	►
EVALUATIONS:				
<i>Sociodemographic details</i>		X		
<i>Clinical characteristics</i>		X		
<i>PEDS-QL (Infant & generic scales)</i>		X	X	X
<i>Brisbane Burn Scar Impact Profile**</i>		X	X	X
<i>CARe Burn Scales**</i>		X	X	X
<i>Haemangioma Family Burden Questionnaire***</i>		X	X	X
<i>Infantile Haemangioma Quality-of-Life Instrument***</i>		X	X	X
<i>Satisfaction with treatment</i>			X	X
<i>Referrals</i>			X	X

*Baseline measures completed prior to randomization; ≥2nd appointment vascular clinic, ≥1st appointment scar clinic; ** burn scar clinic only; *** vascular clinic only

Figure 1

Supplementary File 1 Details of the outcomes in the intervention and effectiveness evaluation

Outcome	Outcome measure	Participant of focus	Domains, subscales, items or versions used in the study	Used in study intervention or evaluation	Description	Psychometrics
Generic health-related quality of life	CHU-9D	Child	3 to 5 years (parent proxy) 5 to 7 years (parent proxy version) 7 to 8 years (parent proxy) > 8 years version (child)	Evaluation	A measure of health-related quality of life that can be used with child aged 3 years and older. The parent proxy version for children aged 3 to 5 years has 10 items with an additional item on overall health compared to 9-item versions for other versions.	A reliable and valid measure recommended for economic evaluations in paediatric settings [1-3]. 3-5 year version has not yet been validated (personal communication, Katherine Stevens). The item on schoolwork/homework has been modified.
Generic health-related quality of life (primary outcome measure)	PEDS-QL 4.0 Generic and Infant Scales	Child	All items	Evaluation and intervention	Generic 4.0 scale: 23 items, 4 domains (physical, emotional, social and school functioning), 3 summary scores (psychosocial health, physical health, total score). Scores will be transformed on a 0 to 100 and scored as recommended by the developers (Mapi Research Trust and Varni, 2017, scaling and scoring, version 17, available from	Validation (including reproducibility and responsiveness testing) supported for children with acute and chronic conditions including those in a hospital setting [4,5].

<http://www.pedsqol.org/PedsQL-Scoring.pdf>, accessed 11.05.2020).

Condition-specific health-related quality of life	The Brisbane Burn Scar Impact Profile	Child and caregiver	All items	Evaluation and intervention	Groups of items measured were overall impact of burn scars; frequency and impact of itch, pain and other sensations; school, play and daily activities (includes mobility and activities of daily living items); friendships and social interactions; appearance; emotional reactions; physical symptoms; and parent and family concerns.	Content validity (children with burn scars and caregiver involvement in development) [6]. Psychometric testing in children and caregivers has largely supported longitudinal validity, reproducibility and responsiveness from around the time of wound healing [7,8].
Condition-specific health-related quality of life	CARe Burn Scales	Caregiver	15 items	Evaluation and intervention	Self-worth and negative mood parent scale items.	Content validity (caregivers of children with burns involved in development). Further validity testing is underway but not yet published (personal communication, Catrin Griffiths).
Condition-specific health-related quality of life		Child and caregiver	4 items	Evaluation and intervention	Four items from the 20-item questionnaire were included. Three items forming the relationship and work dimension were included (e.g.,	Structural validity: internal coherence (Cronbach's α : 0.93). Construct validity: correlation with mental

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					time spent with other children, impact of the haemangioma on career and stopping work). In addition the single item on budget and financial resources was included.	dimension of the Short-Form-12 (r = -0.75), and Psychological General Well-Being Index (r = -0.61). Discriminant validity: significant differences were found according to the size and location of the infantile haemangioma [9].
Condition-specific health-related quality of life	Infantile Haemangioma Quality-of-Life Instrument	Child and caregiver	All items of the final measure	Evaluation and intervention	The 29 final items were included: 5 items targeting the child and the remainder targeting the caregiver. 4 subscales: child physical symptoms, child social interactions, parent emotional functioning, and parent psychosocial functioning.	Content validity (with parents involved in the development), test-retest reliability and structural validity supported [10].
Satisfaction with treatment	Study specific	Caregiver	N/A	Evaluation	An 11-point condition specific numeric rating scale with anchors of very dissatisfied to very satisfied will be asked similar to the numeric rating scale used in a previous study by the authors with children with burn scars and their caregivers [11] at 3-months and 6-months post-baseline.	N/A
Referrals	Study specific	Child and caregiver	N/A	Evaluation	The number and type of referrals for child and caregiver	N/A

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participants to health professionals during 6-month intervention period. Referrals will be those made by health professional participants receiving result summaries in their consultations. Taken from medical records.

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

Reporting Item

Page Number

Administrative

information

Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
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1	Trial registration	#2a	Trial identifier and registry name. If not yet	3
2			registered, name of intended registry	
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6	Trial registration:	#2b	All items from the World Health Organization Trial	n/a
7			Registration Data Set	
8	data set			
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11	Protocol version	#3	Date and version identifier	
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15	Funding	#4	Sources and types of financial, material, and other	28
16			support	
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19				
20	Roles and	#5a	Names, affiliations, and roles of protocol	28
21			contributors	
22	responsibilities:			
23				
24	contributorship			
25				
26				
27				
28	Roles and	#5b	Name and contact information for the trial sponsor	n/a
29				
30	responsibilities:			
31				
32	sponsor contact			
33				
34	information			
35				
36				
37				
38	Roles and	#5c	Role of study sponsor and funders, if any, in study	28
39			design; collection, management, analysis, and	
40	responsibilities:		interpretation of data; writing of the report; and the	
41			decision to submit the report for publication,	
42	sponsor and funder		including whether they will have ultimate authority	
43			over any of these activities	
44				
45				
46				
47				
48				
49				
50				
51				
52	Roles and	#5d	Composition, roles, and responsibilities of the	3, 21
53			coordinating centre, steering committee, endpoint	
54	responsibilities:		adjudication committee, data management team,	
55				
56	committees			
57				
58				
59				
60				

and other individuals or groups overseeing the trial,
if applicable (see Item 21a for data monitoring
committee)

Introduction

Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	12
Methods:			
Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study	11

1		sites can be obtained	
2			
3			
4	Eligibility criteria	#10 Inclusion and exclusion criteria for participants. If	13,14
5		applicable, eligibility criteria for study centres and	
6		individuals who will perform the interventions (eg,	
7		surgeons, psychotherapists)	
8			
9			
10			
11			
12			
13	Interventions:	#11a Interventions for each group with sufficient detail to	8-10
14	description	allow replication, including how and when they will	
15		be administered	
16			
17			
18			
19			
20			
21	Interventions:	#11b Criteria for discontinuing or modifying allocated	n/a
22	modifications	interventions for a given trial participant (eg, drug	
23		dose change in response to harms, participant	
24		request, or improving / worsening disease)	
25			
26			
27			
28			
29			
30			
31	Interventions:	#11c Strategies to improve adherence to intervention	11, 16
32	adherence	protocols, and any procedures for monitoring	
33		adherence (eg, drug tablet return; laboratory tests)	
34			
35			
36			
37			
38			
39	Interventions:	#11d Relevant concomitant care and interventions that	9,10
40	concomitant care	are permitted or prohibited during the trial	
41			
42			
43			
44	Outcomes	#12 Primary, secondary, and other outcomes, including	14-19
45		the specific measurement variable (eg, systolic	
46		blood pressure), analysis metric (eg, change from	
47		baseline, final value, time to event), method of	
48		aggregation (eg, median, proportion), and time point	
49		for each outcome. Explanation of the clinical	
50		relevance of chosen efficacy and harm outcomes is	
51			
52			
53			
54			
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56			
57			
58			
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1		strongly recommended	
2			
3			
4	Participant timeline	#13 Time schedule of enrolment, interventions	Figure 1
5		(including any run-ins and washouts), assessments,	
6		and visits for participants. A schematic diagram is	
7		highly recommended (see Figure)	
8			
9			
10			
11			
12			
13	Sample size	#14 Estimated number of participants needed to achieve	14
14		study objectives and how it was determined,	
15		including clinical and statistical assumptions	
16		supporting any sample size calculations	
17			
18			
19			
20			
21			
22			
23	Recruitment	#15 Strategies for achieving adequate participant	11, 14
24		enrolment to reach target sample size	
25			
26			
27			
28			
29	Methods:		
30			
31	Assignment of		
32			
33	interventions (for		
34			
35	controlled trials)		
36			
37			
38	Allocation:	#16a Method of generating the allocation sequence (eg,	12
39	sequence	computer-generated random numbers), and list of	
40		any factors for stratification. To reduce predictability	
41	generation	of a random sequence, details of any planned	
42		restriction (eg, blocking) should be provided in a	
43		separate document that is unavailable to those who	
44		enrol participants or assign interventions	
45			
46			
47			
48			
49			
50			
51			
52			
53			
54			
55	Allocation	#16b Mechanism of implementing the allocation	12
56	concealment	sequence (eg, central telephone; sequentially	
57			
58			
59			
60			

1	mechanism		numbered, opaque, sealed envelopes), describing	
2				
3			any steps to conceal the sequence until	
4				
5			interventions are assigned	
6				
7				
8	Allocation:	#16c	Who will generate the allocation sequence, who will	12
9				
10	implementation		enrol participants, and who will assign participants	
11				
12			to interventions	
13				
14				
15	Blinding (masking)	#17a	Who will be blinded after assignment to	23
16				
17			interventions (eg, trial participants, care providers,	
18				
19			outcome assessors, data analysts), and how	
20				
21				
22				
23	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	n/a
24				
25	emergency		permissible, and procedure for revealing a	
26				
27	unblinding		participant's allocated intervention during the trial	
28				
29				
30				
31	Methods: Data			
32				
33	collection,			
34				
35	management, and			
36				
37	analysis			
38				
39				
40				
41	Data collection plan	#18a	Plans for assessment and collection of outcome,	Supplementary
42				
43			baseline, and other trial data, including any related	file 1, 14,15, 17-
44				
45			processes to promote data quality (eg, duplicate	19
46				
47			measurements, training of assessors) and a	
48				
49			description of study instruments (eg,	
50				
51			questionnaires, laboratory tests) along with their	
52				
53			reliability and validity, if known. Reference to where	
54				
55			data collection forms can be found, if not in the	
56				
57				
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1		protocol	
2			
3			
4	Data collection plan:	#18b Plans to promote participant retention and complete	11
5			
6	retention	follow-up, including list of any outcome data to be	
7			
8		collected for participants who discontinue or deviate	
9			
10		from intervention protocols	
11			
12			
13	Data management	#19 Plans for data entry, coding, security, and storage,	11, 21
14			
15		including any related processes to promote data	
16			
17		quality (eg, double data entry; range checks for data	
18			
19		values). Reference to where details of data	
20			
21		management procedures can be found, if not in the	
22			
23		protocol	
24			
25			
26			
27			
28	Statistics: outcomes	#20a Statistical methods for analysing primary and	16, 20
29			
30		secondary outcomes. Reference to where other	
31			
32		details of the statistical analysis plan can be found,	
33			
34		if not in the protocol	
35			
36			
37			
38	Statistics: additional	#20b Methods for any additional analyses (eg, subgroup	17
39			
40	analyses	and adjusted analyses)	
41			
42			
43	Statistics: analysis	#20c Definition of analysis population relating to protocol	17
44			
45	population and	non-adherence (eg, as randomised analysis), and	
46			
47	missing data	any statistical methods to handle missing data (eg,	
48			
49		multiple imputation)	
50			
51			
52			
53	Methods: Monitoring		
54			
55			
56	Data monitoring:	#21a Composition of data monitoring committee (DMC);	n/a
57			
58			
59			
60			

1	formal committee		summary of its role and reporting structure;	
2				
3			statement of whether it is independent from the	
4				
5			sponsor and competing interests; and reference to	
6				
7			where further details about its charter can be found,	
8				
9			if not in the protocol. Alternatively, an explanation of	
10				
11			why a DMC is not needed	
12				
13				
14				
15	Data monitoring:	#21b	Description of any interim analyses and stopping	n/a
16				
17	interim analysis		guidelines, including who will have access to these	
18				
19			interim results and make the final decision to	
20				
21			terminate the trial	
22				
23				
24				
25	Harms	#22	Plans for collecting, assessing, reporting, and	24,15
26				
27			managing solicited and spontaneously reported	
28				
29			adverse events and other unintended effects of trial	
30				
31			interventions or trial conduct	
32				
33				
34				
35	Auditing	#23	Frequency and procedures for auditing trial	n/a
36				
37			conduct, if any, and whether the process will be	
38				
39			independent from investigators and the sponsor	
40				
41				
42	Ethics and			
43				
44	dissemination			
45				
46				
47				
48	Research ethics	#24	Plans for seeking research ethics committee /	3, 24
49				
50	approval		institutional review board (REC / IRB) approval	
51				
52				
53	Protocol	#25	Plans for communicating important protocol	
54				
55	amendments		modifications (eg, changes to eligibility criteria,	
56				
57			outcomes, analyses) to relevant parties (eg,	
58				
59				
60				

1		investigators, REC / IRBs, trial participants, trial	
2		registries, journals, regulators)	
3			
4			
5			
6	Consent or assent	#26a Who will obtain informed consent or assent from	13, 14, 24
7		potential trial participants or authorised surrogates,	
8		and how (see Item 32)	
9			
10			
11			
12			
13	Consent or assent:	#26b Additional consent provisions for collection and use	n/a
14	ancillary studies	of participant data and biological specimens in	
15		ancillary studies, if applicable	
16			
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18			
19			
20			
21	Confidentiality	#27 How personal information about potential and	28
22		enrolled participants will be collected, shared, and	
23		maintained in order to protect confidentiality before,	
24		during, and after the trial	
25			
26			
27			
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30			
31	Declaration of	#28 Financial and other competing interests for principal	28
32	interests	investigators for the overall trial and each study site	
33			
34			
35			
36	Data access	#29 Statement of who will have access to the final trial	28
37		dataset, and disclosure of contractual agreements	
38		that limit such access for investigators	
39			
40			
41			
42			
43			
44	Ancillary and post	#30 Provisions, if any, for ancillary and post-trial care,	n/a
45	trial care	and for compensation to those who suffer harm	
46		from trial participation	
47			
48			
49			
50			
51	Dissemination	#31a Plans for investigators and sponsor to communicate	24
52	policy: trial results	trial results to participants, healthcare professionals,	
53		the public, and other relevant groups (eg, via	
54			
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publication, reporting in results databases, or other
 data sharing arrangements), including any
 publication restrictions

Dissemination [#31b](#) Authorship eligibility guidelines and any intended n/a
 policy: authorship use of professional writers

Dissemination [#31c](#) Plans, if any, for granting public access to the full 28
 policy: reproducible protocol, participant-level dataset, and statistical
 research code

Appendices

Informed consent [#32](#) Model consent form and other related n/a
 materials documentation given to participants and authorised
 surrogates

Biological [#33](#) Plans for collection, laboratory evaluation, and n/a
 specimens storage of biological specimens for genetic or
 molecular analysis in the current trial and for future
 use in ancillary studies, if applicable

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 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

BMJ Open

Improving the patient-centred care of children with life-altering skin conditions using feedback from electronic patient-reported outcome measures: Protocol for a hybrid effectiveness-implementation study (PEDS-ePROM)

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Primary Subject Heading:	Paediatrics
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2
3 **TITLE: Improving the patient-centred care of children with life-altering skin**
4 **conditions using feedback from electronic patient-reported outcome**
5 **measures: Protocol for a hybrid effectiveness-implementation study (PEDS-**
6 **ePROM)**
7
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55 Word count 4618
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4
5 **TITLE: Improving the patient-centred care of children with life-altering skin**
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7 **conditions using an electronic patient-reported feedback intervention (PEDS-**
8
9 **ePROM): Protocol for a type 2 hybrid effectiveness-implementation study**
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13

14 **ABSTRACT**

15
16 **Introduction**

17
18 Using patient-reported outcome measures (PROMs) with children have been
19 described as 'giving a voice to the child'. Few studies have examined the routine use
20 of these measures as potentially therapeutic interventions. This study aims to
21 investigate: (1) the *effectiveness* of feedback from electronic PROMs (PEDS-
22 ePROM intervention) that target health-related quality of life, to improve health
23 outcomes, referrals, and treatment satisfaction; and (2) the *implementation* of PEDS-
24 ePROM by assessing acceptability, sustainability, cost, fidelity and context of the
25 intervention and study processes.
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37 **Methods and analysis**

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39 A hybrid II effectiveness-implementation study will be conducted from February 2020
40 with children with life-altering skin conditions attending two outpatient clinics at a
41 specialist paediatric children's hospital. A pragmatic randomised controlled trial and
42 mixed methods process evaluation will be completed. Randomisation will occur at
43 the child participant level. Children or caregiver proxies completing baseline PROMs
44 will be randomised to: (1) completion of PROMs plus graphical displays of PROM
45 results to treating clinicians in consultations, versus (2) completion of PROMs
46 without graphical display of PROM results. The primary outcome of the effectiveness
47 trial will be overall health-related quality of life of children using caregiver-proxy
48 report. Secondary outcomes will include self-reported overall health-related quality of
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3 life of children, other health-related quality of life outcomes (e.g., caregiver
4 psychosocial health), referrals, and treatment satisfaction. Trial data will be primarily
5 analysed using linear mixed-effects models; and implementation data using
6 inductive thematic analysis of interviews, meeting minutes, observational field notes
7 and study communication mapped to the Consolidated Framework for
8 Implementation Research.
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19 **Ethics and dissemination**

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21 Ethical approval was obtained from Children's Health Queensland Human Research
22 Ethics Committee (HREC/2019/QCHQ/56290), The University of Queensland
23 (2019002233), and Queensland University of Technology (1900000847).
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28 Dissemination will occur through stakeholder groups, scientific meetings and peer-
29 reviewed publications.
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35 **Trial registration**

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37 ACTRN12620000174987
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41 **Keywords**

42
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44 Patient-reported outcome measures, quality of life, paediatrics, patient-centred care,
45 implementation
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ARTICLE SUMMARY

Strengths and limitations of this study

- New evidence of the effectiveness and implementation of patient-reported outcome measures in the routine clinical care of children with skin conditions and their caregivers will be generated which has received limited attention.
- Stakeholders representing multiple perspectives (children, caregivers, health professionals) were involved in the development of the intervention and process evaluation.
- Lack of ability to mask participants to the outcomes and contamination of the control group are potential biases, although child and caregiver participants were masked to the hypotheses.

INTRODUCTION

The routine use of patient-reported outcome measures (PROMs), or proxy-report measures, as part of routine clinical care has been identified as a means of driving change in healthcare systems, to ensure the unique voice of the patient is heard [1,2]. Potential benefits are improvements in shared decision-making, communication with health professionals and adherence to recommended treatments [3]. PROMs are defined as questionnaires completed by a patient with a health condition about their own health and treatment.

A recent systematic review identified that the effectiveness of PROM interventions for people with health conditions compared to usual care has been positive in adequately powered studies [4]. Few trials have been conducted in children. Only 2 of 22 included randomised controlled trials were conducted in children, one focussed on children with diabetes and one on children with cancer [5,6]. Two more recent paediatric cluster randomised controlled trials investigated PROMs used with children with severe mental health conditions attending child and adolescent psychiatric services [7,8]. Only one of the four paediatric trials identified positive effects of the PROM intervention. The positive effects were for psychosocial health-related quality of life but not physical health-related quality of life in children with diabetes [5].

The implementation of the PROMs in routine paediatric care has also recently been investigated in a systematic review, with increased identification and discussion around health-related quality of life (HRQOL) reported, particularly in psychosocial and emotional domains, but with mixed results regarding the impact on quality of

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3 care [9]. Quality of care outcomes examined were satisfaction with treatment, referral
4 rate, and consultation length.
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10 Implementation outcomes can be examined using an implementation science
11 framework such as The Consolidated Framework for Implementation. This
12 framework has been identified as a 'good fit' for examining the implementation of
13 PROMs in health service organisations in a recent systematic review of reviews that
14 can assist to determine factors that influence implementation [10], and understand
15 how the intervention works (i.e., the process by which behaviour change occurs)
16 [11]. Multi-level influences on implementation can be examined through a focus on
17 individual characteristics of patients, families and clinicians (e.g. knowledge & beliefs
18 about the intervention), as well as organisational and process factors (e.g.,
19 engagement) [12].
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35 This paper will report the protocol for a randomised controlled trial and
36 implementation study to test the effectiveness and implementation outcomes of a
37 PROM feedback intervention targeting health-related quality of life, in children with
38 the life-altering skin conditions of burn scars and infantile haemangiomas (termed
39 PEDS-ePROM). The intervention involves the delivery of graphical displays of
40 information from patient-reported outcome measures in routine consultations to
41 encourage communication about the areas displayed. A comparison intervention
42 involves the completion of electronic patient-reported outcome measure data without
43 any graphical display of information (termed ePROM). The need for interventions to
44 improve the health-related quality of life of these children is highlighted by the lower
45 health-related quality of life of children with burn scars across multiple domains even
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3 years after the actual injury compared to children with cancer [13]. At the time of
4
5 publication, the PEDS-ePROM intervention had been designed and the randomised
6
7 controlled trial and implementation testing was underway with no findings yet
8
9 available.

11 **Aims and objectives**

12
13
14 The primary effectiveness aim is to determine the short-term effectiveness of
15
16 implementing PROMs with graphical displays of result summaries, on overall health-
17
18 related quality of life of children with life-altering skin conditions. Secondary aims will
19
20 be to examine the effectiveness of the intervention for other health-related quality of
21
22 life outcomes of children and caregivers, the number and type of referrals to health
23
24 professionals and treatment satisfaction.

25 *Hypotheses (effectiveness component)*

- 26
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31
32 1. The PEDS-ePROM intervention will have a greater effect on overall health-
33
34 related quality of life than the ePROM intervention, with a consistent direction
35
36 and similar strength of effect across the clinics and conditions, supporting
37
38 comparative effectiveness of the intervention.
39
40
41 2. The PEDS-ePROM intervention will increase the number of psychosocial
42
43 referrals to health professionals and increase proxy-reported satisfaction with
44
45 treatment.
46

47 **Implementation outcomes**

48
49 The primary aim is to determine the short-term acceptability and sustainability of
50
51 implementing the interventions. The secondary aim is to determine the cost, fidelity
52
53 and contextual factors related to implementation.
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METHODS AND ANALYSIS

Development of the study design and intervention

The development of the PEDS-ePROM trial and intervention was conducted from May 2019 to January 2020. We initiated preliminary discussion with clinicians in clinical areas to identify which measures were already being used routinely in practice. Systematic reviews and paediatric literature regarding the use of PROMs were also reviewed. Interview guides were developed to identify health outcomes that are meaningful and of high priority to children, their families and health professionals in the PROM intervention [14]. The nine core questions from the International Society of Quality of Life (ISOQOL) user guide and the companion guide areas were addressed in the interviews [15]. This strategy has been identified as important to improve the engagement of children and young people such that fewer items are missed and responses accurately reflect their experiences and cognitive ability [16].

Interviews were conducted with children with life-altering skin conditions, their caregivers and treating health professionals in two phases as part of the pre-implementation planning, with interview questions mapped to the Consolidated Framework for Implementation Research. In the first phase the most appropriate outcomes and PROMs were identified. In the second phase the content validity of chosen PROMs and process evaluation were confirmed. Potential barriers and benefits to implementation were identified in both phases. For children with burn scars and their families, measures of health-related quality of life specific to scarring were prioritised to include symptoms and treatment burden based on conceptual work from the research team that identified these aspects as central components of

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2
3 health-related quality of life for this group [17]. The design of the randomised
4
5 controlled trial was based on systematic review findings that identified greater
6
7 benefits when PROM results were provided to clinicians compared to when results
8
9 were not provided to clinicians [4]. For the purposes of the current study, PROMs
10
11 included proxy caregiver measures as young children cannot self-report their quality
12
13 of life or symptoms.
14
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16 17 18 19 **PEDS-ePROM intervention**

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21 The Pediatric Quality of Life Inventory infant and generic scales [18,19] measuring
22
23 health-related quality of life were included as generic measures that were the same
24
25 across the clinics and conditions. Condition-specific health-related quality of life
26
27 measures were also included as these measures have been identified as being more
28
29 responsive to change than generic measures [20]. Condition-specific health-related
30
31 quality of life measures selected were the Brisbane Burn Scar Impact Profile [17,21],
32
33 The CARE parent scale [22], Hemangioma Family Burden questionnaire [23] and
34
35 Infantile Hemangioma Quality of Life Scale [24]. Selected measures targeted
36
37 children and their caregivers and a single item targeted siblings. An open-ended
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39 option was also available for child and caregiver participants to report their priorities
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41 for care. Only PROMs meeting the criteria of content validity supported by
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43 involvement of the target group in development were included with the exception of
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45 the treatment satisfaction item. Graphical displays of result summaries from the
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47 Pediatric Quality of Life Inventory and condition-specific measures of health-related
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49 quality of life measure will be presented in consultations for children with skin
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51 conditions and their caregivers to treating clinicians. The components of the
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53 intervention are reported in Table 1.
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Table 1. Description of the PEDS-ePROM intervention and ePROM comparison intervention*

Clinic	Mode of administration	PEDS-ePROM intervention			ePROM comparison intervention			Intervention period
		Content	Duration	Frequency	Content	Duration	Frequency	
Burn scar clinic	Administered remotely using email or by a research occupational therapist in the clinic setting. PROM data collected electronically on a device at home or on an Apple iPad in the clinic.	PEDS-QL generic and infant scales BBSIP CARE scales	Approx. 15 mins for child and caregiver participants to complete ePROMs prior consultations. Up to 15 mins to download, print and deliver ePROMs & graphical displays to consultations***.	Delivered in consultations up to 1x/ mth. Based on usual care likely to be delivered 2-3x.	ePROMs delivered and completed as per PEDS-ePROM intervention group. No graphical summaries provided in consultations‡.	Approximately 15 mins for child and caregiver participants to complete ePROMs prior to each consultation. Up to 5 minutes to download, print and deliver ePROM.***	As per PEDS-ePROM intervention	Baseline - 6 mths †
Vascular	As per burn	PEDS-QL	Approx. 10 mins	Delivered in	ePROMs	Approximately	As per	Baseline -

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clinic	scar clinic	infant scales Hemangioma Family Burden questionnaire Infantile Haemangioma Quality-of-Life Instrument	for caregiver participants to complete ePROMs prior to each consultation. Up to 10 mins to download, print and deliver ePROMs & graphical displays to consultations***.	consultations up to 1x/mth. Based on usual care likely 1-2x **.	delivered and completed as per PEDS- ePROM intervention group. No graphical summaries provided in consultations‡.	10 mins for child and caregiver participants to complete ePROMs prior to each consultation. No printing required.***	PEDS- ePROM intervention	6 mths †
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* Based on the Template for Intervention Description and Replication (TIDieR) guidelines

† Post-baseline

‡ Graphical summaries provided to child and caregiver participants and entered into medical records at the end of the study

** Children with ulcerated haemangiomas may receive intervention more frequently

*** Graphical summaries provided to child and caregiver participants at the end of the study

PROM, patient-reported outcome measure; ePROMs, electronic patient-reported outcome measures; PEDS-QL, Pediatric Evaluation of Quality of Life Inventory; approx., approximately; mins, minutes; mth, months

Method for completing PROMs

Electronically-delivered PROMs were identified as the best option for getting patients to complete the measures at home prior to consultations to reduce the burden of administration of measures and result summaries during busy clinics. The PROMs will be administered via a weblink sent to caregiver participants in an email in the three days prior to their appointment. If the questionnaires are not completed via the weblink, child and caregiver participants will be offered a further opportunity to complete the questionnaires using an iPad prior to their consultation at the outpatient clinic while they are waiting for their consultation where possible. Caregiver proxy-report will continue throughout the study for any child who turns eight years of age after the first caregiver proxy-report. Phone calls will be used to remind caregiver participants to complete the PROMs. The PROMs and graphical display of result summaries will be generated using the online survey software program Qualtrics^{XM} [25] and presented to treating health professionals immediately prior to appointments. Copies of the electronically completed PROMs and graphical displays of result summaries will be stored in medical records.

Context

The setting will be two outpatient clinics at a major metropolitan quaternary-level children's hospital in Australia; a burns clinic and a vascular anomalies clinic. Caregivers (or their children with skin conditions if aged 8 years or older) will be consecutively approached and recruited, and the intervention delivered prior to and at these clinics. The catchment of the hospital includes inhabitants from rural, regional and metropolitan areas including those from surrounding islands.

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3 Recruitment commenced in January 2019. The first participant was randomised to
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5 receive the intervention in March 2020.
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10 **Research design**

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12 A hybrid type 2 effectiveness-implementation design will be used which blends
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14 evaluating intervention effectiveness and understanding implementation of the
15
16 intervention simultaneously [26]. Benefits of this design include reduced lag time for
17
18 uptake of the results into routine clinical practice and understanding the barriers and
19
20 benefits to implementation [26]. A pragmatic two-arm randomised controlled trial will
21
22 be conducted using block randomisation in random blocks of 4, 6 or 8 stratified by
23
24 diagnostic group (i.e., infantile haemangiomas, burn scars), with child participants as
25
26 the unit of randomisation; and an embedded qualitative process evaluation involving
27
28 interviews with clinicians, and child and caregiver participants. The randomisation
29
30 sequence will be prepared by a statistician independent from the study and will be
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32 concealed using sequentially numbered, opaque, sealed envelopes with tamper
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34 proof tape prepared by a person independent from the study.
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42 The randomised controlled trial arms will be: (1) PROM completion plus graphical
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44 display of result summaries to clinicians (intervention group) versus; (2) PROM
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46 completion without graphical display of result summaries to clinicians (comparison
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48 group).
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53 Baseline PROM measurement will occur before randomisation. PROM measurement
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55 will occur prior to or at one or more subsequent hospital appointments over the
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57 following 6-months and follow-up measurement will occur at 3-months and 6-months
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3 post-baseline if these timepoints differ from data collection timepoints during
4 consultations with health professionals. Child and caregiver participants will be
5 masked to the hypotheses. A Standard Protocol Items Recommendations for
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post-baseline if these timepoints differ from data collection timepoints during consultations with health professionals. Child and caregiver participants will be masked to the hypotheses. A Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) flow diagram has been used to report the schedule for enrolment, interventions and evaluations for the effectiveness component of the study (Figure 1).

The study design and evaluation plan have been informed by the Consolidated Framework for Implementation Research. This framework covers the physical and social environment, values, individual motivation and capacity factors which are considered important for the intervention being tested and has been derived from 33 theories relating to implementation [27]. This Protocol paper has been prepared following the eHealth Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Participants

Inclusion criteria

Children with burn scars and infantile haemangiomas, aged 0 to 16 years at the time of recruitment, who require ongoing management in the hospital setting, and their caregivers aged 18 years or older will be included. Ongoing management is defined as children who require one or more ongoing hospital consultations with clinicians at the study setting beyond baseline in the 6-month post-baseline intervention period for the prevention or management of skin conditions as determined by treating clinicians at baseline. Treating clinicians will also be asked to determine children's ability to complete PROMs electronically based on their physical condition and

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3 knowledge of the family (i.e., to determine if bilateral hand burns would prevent
4 sufficient movement of their hands to use an iPad).
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8 9 Exclusion criteria

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11 Children and caregivers will not be eligible to participate if they are involved with
12 child protection services and it is difficult to obtain consent, where circumstances
13 interfere with the participant's ability to give informed consent (i.e., diminished
14 understanding or comprehension), or where there is difficulty speaking or
15 understanding written English as the PROMs are only available for the study in
16 English.
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24 25 Sample size estimate

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27 The sample size was based on recruitment feasibility. A retrospective audit of child
28 and caregiver participants of clinic attendees suggested at least 35 participants in
29 each clinic can be recruited in the intervention period. In terms of the effectiveness
30 randomised controlled trial, if outcome data is available for 70 participants overall,
31 then with 80% power we will be able to detect an effect size for the difference
32 between-arms of 0.68 standard deviation units or greater for proxy-reported overall
33 health-related quality of life at 6-months post-baseline ($\alpha=0.05$). A between
34 group difference of 0.68 is considered clinically meaningful at the individual level by
35 expert clinicians, as a medium to large effect is regarded as offsetting the burden of
36 completion of ePROMs to patients and families and supporting implementation
37 routinely in clinics. To account for twenty percent attrition expected at 6-month
38 follow-up based on a prior study with children and caregivers completing patient-
39 reported outcome measures in the burns clinic setting [28], recruitment will continue
40 until 88 participants have been randomised to groups.
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3 Interviews will be conducted with the following groups during implementation with
4 numbers of participants represented approximately equally for each clinic: children
5 with a skin condition, their caregivers and treating health professionals. Interviews
6 will continue until saturation (i.e. the point at which no further dimensions, nuances,
7 or insights of issues are identified) [29] building on interview data generated pre-
8 implementation. A greater number of child interviews will be required than caregiver
9 and health professional interviews based on our previous experience of generally
10 obtaining shorter interviews of 15 to 20 minutes in children with burn scars than with
11 caregivers and health professionals.
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26 **Evaluation**

27 Effectiveness outcomes

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29 Study outcome measures will be self-completed by children aged 8 years or older
30 and proxy-completed by caregivers for younger children. The primary outcome
31 assessed will be change in the child's generic overall health across both clinics
32 measured using The Pediatric Quality of Life Inventory (PedsQL™ 4.0 Generic Core
33 and Infant Scales proxy-report total score) [18,19]. Secondary outcomes will be: (a)
34 change in the child's generic overall health across both clinics measured using The
35 Pediatric Quality of Life Inventory (PedsQL™ 4.0 Generic Core and Infant Scales
36 [30], child report total score); b) change in the child's psychosocial and physical
37 health across both clinics measured using The Pediatric Quality of Life Inventory;
38 proxy and child report respective subscales; c) change in the child's generic health
39 across both clinics measured using proxy and child report of individual items of the
40 Child Health Utility (CHU-9D) and utility score [25]; d) condition-specific health-
41 related quality of life of the child (overall impact, sensory intensity, sensory
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3 frequency, sensory impact, mobility, daily living, friendships and social interaction,
4 appearance, emotional reactions, and physical symptoms) measured using
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6 respective subscales of the Brisbane Burn Scar Impact Profile [burn scar clinic group
7
8 only]; e) condition-specific health-related quality of life of parents (worry and impact)
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10 measured using respective subscales of the Brisbane Burn Scar Impact Profile
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12 respective subscales [burn scar clinic group only]; f) condition-specific health-related
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14 quality of life of the child (physical symptoms, social interactions, emotional
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16 functioning, psychosocial functioning) measured using respective subscales of the
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18 Infantile Hemangioma Quality of Life Scale [infantile hemangioma vascular clinic
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20 group only]; g) condition-specific health-related quality of life of parents
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22 (psychosocial functioning, negative mood, and self-worth) measured using
23
24 respective subscales of the CARE parent questionnaire [burn scar clinic group only];
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26 h) condition-specific health-related quality of life of parents (relationship and work,
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28 budget) measured using the relationships and work dimension and single budget
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30 item of the Hemangioma Family Burden questionnaire; i) number and type of
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32 referrals for the child or caregiver; and j) caregiver overall satisfaction with treatment.
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40 Caregiver overall satisfaction with treatment was based on the finding that
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42 significantly more intervention patients reported satisfaction with overall care in a
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44 study of children with diabetes, which was the only paediatric study that examined
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46 this outcome in a recent systematic review [4]. The number and type of referrals was
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48 included as an outcome based on the findings of three paediatric studies identified in
49
50 a recent systematic review, in which two studies reported an increase in the referral
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52 rates in the intervention group, and one study identified no difference in referral rates
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54 between intervention and control groups [9]. A description of each of the outcomes
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56 and psychometric properties of outcomes are reported in Supplementary File 1.
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3 Adverse effects of the PROM interventions will be monitored using the self-report of
4 caregiver and child participants (where appropriate), treating health professionals as
5 well as by monitoring of the PROM data by investigators.
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11 Other outcomes

12 Sociodemographic data collected from or about caregivers will include the
13 caregiver's relationship to the child, level of education, ethnicity, work status,
14 household income, and postcode; and from children aged 8 years or older or
15 caregivers about their children will include, gender, ethnicity, education level, scar
16 location and comorbidities of the child participants. Clinical data collected from
17 electronic medical records will be percent total body surface area, percent full
18 thickness burn, length of time post-burn, type of healing (e.g., spontaneous skin
19 healing versus split thickness graft), type of burn, and length of time to re-
20 epithelialisation, medications and complications during the study period.
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35 Effectiveness evaluation

36 An intention to treat analysis will be the primary approach but per protocol analyses
37 will be compared to the intention to treat approach to examine the effect of those
38 who didn't receive the intervention as intended. The key sociodemographic and
39 clinical characteristic data that will be examined for baseline differences between the
40 groups will be age, gender, education, household income, socioeconomic status of
41 the neighbourhood where the family reside based on postcode, severity of baseline
42 symptoms and health-related quality of life, body location of the condition, visibility of
43 the condition (scars on the head, neck, face or hands), and time since the skin
44 condition commenced or injury occurred. The primary comparison will be completed
45 using data from caregivers for children aged younger than 8-years.
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Effectiveness analysis

Primary outcome comparison at 6-month post-baseline will be based on overall health from the Pediatric Evaluation of Quality of Life Inventory between the PEDS-ePROM and ePROM comparison group using linear mixed-effects models that account for repeated observations from the same child and clustering within clinics and within treating health professionals. Covariables will be included for potentially confounding variables if any differences between groups are identified for key sociodemographic and clinical characteristics at baseline.

A sensitivity analysis will be conducted using imputation techniques to replace non-ignorable data that is considered to be missing at random over the follow-up period, to determine whether bias is likely in the complete case analysis. Secondary outcome comparisons will be conducted at 6-months post-baseline using linear mixed-effects models where appropriate. Multi-level or nested hierarchical analysis will examine the effect of clinic and treating health professional effects by examining patient clustering within clinics, and surgeons and occupational therapists clustered within clinics. The amount and type of missing data will be reported using descriptive statistics. The maximum potential effect of the intervention with children will be analysed according to the treatment actually received (an 'as treated' analysis incorporating treatment dose received). Data analysis will be conducted using Stata 16.0 (Statacorp, College Station, TX, USA).

Implementation outcomes

Implementation will be considered successful if graphical displays of result summaries are presented to treating clinicians immediately prior to more than 85% of consultations where a patient is randomised to receive a report, and if PROMs and summaries are filed in electronic medical records for more than 75% of patients

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3 eligible to have PROM data provided to treating clinicians in the intervention period.
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5 The implementation outcomes of acceptability and sustainability [31] will be used to
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7 determine the overall success of the implementation. The implementation outcomes
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9 of acceptability, sustainability, cost, fidelity and contextual factors are detailed in

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12 Table 2.
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For peer review only

Table 2 Description of the implementation outcomes

Outcome	Detailed description of the outcome	Data type, source and analysis
Acceptability of ePROM interventions and evaluation*	<p>The acceptability of the ePROM interventions and evaluation by families of children with health conditions and treating clinicians including content, complexity, delivery and relative advantage [31].*</p> <ol style="list-style-type: none"> 1. $\geq 80\%$ of families will take <15 minutes to complete the ePROMs as previous research has identified that PROMs that are fast to complete are most acceptable to clinicians and families [32]. 2. $\geq 50\%$ of families completed ePROMs across all scheduled consultations that were eligible to be included in the study, where consultations eligible to be included were limited to one consultation over any 1-month period. Based on pre-intervention phase interviews and field notes of what was considered acceptable for ongoing implementation of the PROMs routinely in clinical practice in the study clinics and 	<p>Quantitative: Electronic study data and administrative data; descriptive analysis</p> <p>Qualitative: interview and field note data; thematic analysis including mapping to CFIR innovation constructs (e.g., relative advantage, adaptability, complexity, cost in the pre-implementation and implementation stages).</p>

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evidence indicating completion rates of 75% were achieved for system-wide implementation of PROMs at a Canadian children’s hospital [33].

- 3. Phone reminders for PROM completion were required in ≤50% of families. This outcome was based on feedback from clinicians in the pre-implementation phase indicating that phone call reminders for this type of intervention are a burden to clinicians and may impact uptake by clinicians.
- 4. Technology-related issues with graphical displays of result summaries or ePROM completion were present for ≤10% of families across all eligible appointments.
- 5. ≥75% of participants eligible to have ePROM data provided to treating clinicians had intervention ePROMs and graphical displays filed in electronic medical records.

Sustainability of ePROM interventions and evaluation

The extent to which the ePROM intervention (or a modification of the intervention) was continued or planned to be continued in routine clinical practice at the end of the study, and barriers and facilitators of sustained use.

Qualitative: Interviews with child, caregiver and health professional participants and field notes; analysed using

thematic analysis and mapping to CFIR (e.g., knowledge and beliefs about the intervention, design quality and packaging, needs and resources)

Qualitative: interview data relating to cost.

Quantitative: Study and administrative data, medical records, hospital clinical costings department data.

Qualitative: Verbal fidelity reports and interviews with children and caregivers, and interviews with health professional participants

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15 Cost

The cost of implementing the intervention for patients in the intervention and control groups based on resource use from the perspective of the health service.

Data for healthcare resource utilisation for co-interventions for skin treatment (e.g. medicines, complementary treatments), and details of hospital presentations), will be included.

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29 Fidelity

The extent to which the interventions were delivered and received as intended.

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1. Dose of the intervention: Child and caregiver verbal report of the topics on the graphical displays of ePROM results that were discussed during the

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consultation in the intervention group, immediately after the consultation.

and field notes

2. Dose of the intervention: percentage of eligible consultations for each participant where ePROM data was completed in advance of the consultation as scheduled.

Quantitative: Study data, descriptive analysis

3. The number (percentage) of participants randomised to receive graphical displays of result summaries versus the number of participants who actually had graphical displays of result summaries delivered to consultations.

4. Amount and type of missing intervention-related ePROM data on Qualtrics^{XM} [25].

Contextual factors

Barriers and facilitators to multi-level implementation of the intervention and the evaluation; at the individual level, clinic level, hospital level, and outside the hospital setting.

Qualitative: Interviews with child, caregiver and health professional participants; and field notes analysed using thematic analysis and mapping to CFIR (e.g., culture, networks and

communication,
implementation cost)

* Children ≥ 8 years will self-report; caregivers will provide proxy-reports for children aged < 8 years except for satisfaction with treatment which will only be self-reported by caregivers.

ePROMs, electronic patient-reported outcome measures; CFIR, Consolidated Framework for Implementation Research

For peer review only

Implementation evaluation

Implementation outcomes will be evaluated using interviews; health service, administrative, clinical costings and missing data; observational field notes of meetings and each clinic attended or planned; meeting minutes and study emails; and fidelity reports. Acceptability is defined as the perception among stakeholders that a treatment, service, practice or innovation is agreeable or satisfactory [31]. Sustainability is defined as the extent that a newly implemented treatment is maintained within a service setting's ongoing, stable operations [31]. The data from these sources will be mapped to the Consolidated Framework for Implementation Research [27]. This framework can be used to understand barriers and facilitators to implementing the intervention at the level of individuals, the organisational level and settings external to the organisation which can assist in determining the sustainability and potential scaling up of the intervention. Factors related to implementation delivery that might have impacted on the intervention effectiveness will also be examined to understand whether and how the expected outcomes were achieved, and the reasons for this.

Fidelity of the intervention will be taken from study records kept by researchers.

Immediately after face-to-face consultations caregivers and children (where appropriate) will be requested to verbally report the graphical display topics that were discussed during the consultation in the intervention group.

Implementation analysis

Interpretive Description [34] will be used to thematically analyse the data. This qualitative analysis uses elements from several other qualitative methodologies including phenomenology, grounded theory, and ethnography without focusing on

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3 any specific technique [34]. Interpretive Description is ideal for applied clinical
4 questions and analysis of a wide range of data sources [34]. The analysis builds on
5 what is known in terms of current practices and structures of health services and
6 what is known and not known [34]. Data analysis will be conducted iteratively,
7 concurrently with interviews, with analysis conducted during the implementation
8 phase building on analysis of pre-implementation interviews. Framework analysis
9 [35] will then be applied deductively, mapping the qualitative and quantitative data
10 (e.g., verbatim quotes and descriptive statistics) to the pre-defined key constructs of
11 the Consolidated Framework for Implementation Research as overarching themes.
12 The data will be organised into a framework matrix where columns are codes and
13 rows are participants [35]. This analysis is conducted across participants as well as
14 within participants. Steps in framework analysis include familiarization; indexing;
15 charting; and synthesising [35]. Pre-implementation and post-implementation
16 differences will be examined, and themes that emerge in addition to the
17 Consolidated Framework for Implementation Research constructs, will be added to
18 the framework. Positive and negative participant quotes and descriptive data will be
19 examined separately for each construct in the framework to determine influences on
20 implementation and the strength of each construct, for each clinics as well as across
21 clinics [36]. Once mapping to the Consolidated Framework for Implementation
22 Research has been completed, data that applies to the implementation outcomes of
23 acceptability, sustainability, fidelity and contextual factors will then be summarised.

24 Interviews will be audio recorded and transcribed verbatim by study personnel.
25 Recordings will be stored in a coded form on a secure password protected folder
26 within The University of Queensland until coding has been completed, accessible to
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3 two of the investigators and a research assistant. The credibility of the analysis will
4 be checked using member checking of the interview data, independent coding of the
5 data by two researchers of at least 20 percent of the data, triangulation of the results
6 across participant groups (managers, treating health professionals, caregiver and
7 child participants) and using field notes, and reflective journaling. Microsoft excel
8 (version 16, Microsoft Corporation) and NVivo (version 10, QSR International,
9 Doncaster, Victoria, Australia [37]) will be used to organise and code the data.

19 Electronic platform

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21 The electronic survey platform Qualtrics^{XM} [25] was chosen to administer the
22 PROMs and to provide graphical displays of result summaries based on visual
23 aesthetics of the graphical displays compared to other survey programs and prior
24 experience of the investigators using the program. Features of the program that were
25 important for administration of the chosen surveys and study design were the ability
26 to have open-ended text, email distribution, ability to send reminders, display
27 longitudinal responses, a recoding values function, automated scoring functionality,
28 and links to NVivo software [37] for coding open text responses.

39 Patient and public involvement

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41 Children aged 8 years and older with life-altering skin conditions, caregivers of
42 children with life-altering skin conditions and treating health professionals in the
43 study setting were involved in all study phases including development of the
44 intervention, process evaluation, study design and implementation evaluation. These
45 stakeholder groups reported on the burden of the planned intervention, potential time
46 required to participate and acceptability of follow-up intervals in pre-implementation
47 interviews. Plans include forming a stakeholder reference group to inform the
48 interpretation and sustainability of the study findings.

DISCUSSION

To our knowledge studies of PROM interventions have not previously focused on children with life-altering skin conditions. A pragmatic approach has been taken to maximise relevance to the clinical context including limiting exclusion criteria, and developing and delivering an intervention that has limited interference with the running of very busy outpatient clinics. If the intervention is shown to have promising short-term results then secondary prevention impacts particularly on emotional health of caregivers may be likely and the benefits higher in the longer term which will be examined in the future.

An outcome of the proposed study may be refinement of the PEDS-ePROM intervention based on mapping to the Consolidated Framework for Implementation Research which may identify additional elements that should be considered. The findings will also likely inform the design of a multisite cluster effectiveness-implementation study of a patient-reported outcome measure intervention in these children which may reduce the risk of contamination bias [8]. Information obtained will inform ongoing efforts in paediatric care to use patient-reported outcome measures as part of routine clinical care.

Strengths and limitations

Strengths of the study include the involvement of stakeholders representing multiple perspectives (children, caregivers, health professionals) in the development of the intervention and the process evaluation, and the focus of the intervention and process evaluation on health-related quality of life. The use of the Consolidated Framework for Implementation Research is also a strength. Theory-based interventions tend to be more effective than non-theory based interventions [38].

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3 More specifically, the current study will seek to understand how the inner setting of
4 the organisation (i.e., organisational culture and structural characteristics) impacts on
5 implementation which has been identified as a research gap [10].
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12 The lack of masking of treating health professionals and participants in the
13 randomised controlled trial is a limitation although masking is not possible as the
14 outcomes are patient or proxy-reported and it will be clear to most participants when
15 results are presented in consultations. However, child and caregiver participants will
16 be masked to the hypotheses. Potential contamination bias has also been raised as
17 a possibility in trials of this nature where several clinics within a facility are included,
18 as treating health professionals' awareness of issues that should be focused on may
19 be raised, diluting the impact of the intervention [39].
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33 A limitation is the lack of inclusion of families from non-English speaking
34 backgrounds and some cultural groups. Further attention is required to develop and
35 test PROM interventions for families from specific cultural backgrounds which is a
36 challenge in the study setting where people from many cultural backgrounds are
37 seen. Specifically, people of Aboriginal and Torres Strait Islander descent were not
38 involved in the development process thus the intervention and study design may not
39 be acceptable for this group of people and should be established.
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49 **Ethical approval and dissemination**

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51 Ethical approval has been received from Children's Health Queensland Hospital and
52 Health Service Human Research Ethics Committee (HREC/19/QCHQ/56290), The
53 University of Queensland (2019002233), and Queensland University of Technology
54 (1900000847).
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Written consent will be obtained from caregiver and treating health professional participants once written and verbal information has been provided. Caregivers will be encouraged to discuss the study with children who can communicate with their caregivers prior to consent being obtained. Adverse effects will be reported to the Children's Health Queensland Hospital and Health Service and Human Research Ethics Committees.

For peer review only

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Author contributions

ZT designed the study with input from SM for the effectiveness evaluation, GH for the implementation evaluation, and RK and MS for integrating with existing clinical processes. ZT drafted the protocol and SM, MS, TZ, RW and RK critically revised the manuscript.

Funding statement

This work was supported by a Health Services Research grant from the Children's Hospital Foundation, Brisbane, grant number 50297. The funder had no input into the design or conduct of the study.

Competing interests statement

ZT, MS and RK developed the Brisbane Burn Scar Impact Profile which was included as a scar-specific measure in this study. MS and RK were clinical staff members of the health service where the study will be conducted at the time of submission.

Data sharing statement

The final trial dataset will be available to chief investigators. The final trial dataset may be accessed with approval from the investigators if steps are undertaken to preserve the confidentiality of the data. Additional information regarding criteria for accessing data are available from the study investigators.

Acknowledgements

Nil

Figure 1 legend

SPIRIT flow diagram for the effectiveness study component*

Word count 4618

Supplementary File 1 Details of the outcomes in the intervention and effectiveness evaluation

Outcome	Outcome measure	Participant of focus	Domains, subscales, items or versions used in the study	Used in study intervention or evaluation	Description	Psychometrics
Generic health-related quality of life	CHU-9D	Child	3 to 5 years (parent proxy) 5 to 7 years (parent proxy version) 7 to 8 years (parent proxy) > 8 years version (child)	Evaluation	A measure of health-related quality of life that can be used with child aged 3 years and older. The parent proxy version for children aged 3 to 5 years has 10 items with an additional item on overall health compared to 9-item versions for other versions.	A reliable and valid measure recommended for economic evaluations in paediatric settings [1-3]. 3-5 year version has not yet been validated (personal communication, Katherine Stevens). The item on schoolwork/homework has been modified.
Generic health-related quality of life (primary outcome measure)	PEDS-QL 4.0 Generic and Infant Scales	Child	All items	Evaluation and intervention	Generic 4.0 scale: 23 items, 4 domains (physical, emotional, social and school functioning), 3 summary scores (psychosocial health, physical health, total score). Scores will be transformed on a 0 to 100 and scored as recommended by the developers (Mapi Research Trust and Varni, 2017, scaling and scoring, version 17, available from	Validation (including reproducibility and responsiveness testing) supported for children with acute and chronic conditions including those in a hospital setting [4,5].

<http://www.pedsqol.org/PedsQL-Scoring.pdf>, accessed 11.05.2020).

Condition-specific health-related quality of life	The Brisbane Burn Scar Impact Profile	Child and caregiver	All items	Evaluation and intervention	Groups of items measured were overall impact of burn scars; frequency and impact of itch, pain and other sensations; school, play and daily activities (includes mobility and activities of daily living items); friendships and social interactions; appearance; emotional reactions; physical symptoms; and parent and family concerns.	Content validity (children with burn scars and caregiver involvement in development) [6]. Psychometric testing in children and caregivers has largely supported longitudinal validity, reproducibility and responsiveness from around the time of wound healing [7,8].
Condition-specific health-related quality of life	CARe Burn Scales	Caregiver	15 items	Evaluation and intervention	Self-worth and negative mood parent scale items.	Content validity (caregivers of children with burns involved in development). Further validity testing is underway but not yet published (personal communication, Catrin Griffiths).
Condition-specific health-related quality of life	Haemangioma Family Burden Questionnaire	Child and caregiver	4 items	Evaluation and intervention	Four items from the 20-item questionnaire were included. Three items forming the relationship and work dimension were included (e.g.,	Structural validity: internal coherence (Cronbach's α : 0.93). Construct validity: correlation with mental

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					time spent with other children, impact of the haemangioma on career and stopping work). In addition the single item on budget and financial resources was included.	dimension of the Short-Form-12 (r = -0.75), and Psychological General Well-Being Index (r = -0.61). Discriminant validity: significant differences were found according to the size and location of the infantile haemangioma [9].
Condition-specific health-related quality of life	Infantile Haemangioma Quality-of-Life Instrument	Child and caregiver	All items of the final measure	Evaluation and intervention	The 29 final items were included: 5 items targeting the child and the remainder targeting the caregiver. 4 subscales: child physical symptoms, child social interactions, parent emotional functioning, and parent psychosocial functioning.	Content validity (with parents involved in the development), test-retest reliability and structural validity supported [10].
Satisfaction with treatment	Study specific	Caregiver	N/A	Evaluation	An 11-point condition specific numeric rating scale with anchors of very dissatisfied to very satisfied will be asked similar to the numeric rating scale used in a previous study by the authors with children with burn scars and their caregivers [11] at 3-months and 6-months post-baseline.	N/A
Referrals	Study specific	Child and caregiver	N/A	Evaluation	The number and type of referrals for child and caregiver	N/A

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participants to health professionals during 6-month intervention period, including psychosocial referrals. Referrals will be those made by health professional participants receiving result summaries in their consultations. Taken from medical records. Psychosocial referrals include referrals to social work, psychology, a general practitioner, or other health professional; where the referral is clearly for psychosocial support other than that provided by the health professionals delivering consultations in the effectiveness evaluation.

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

Reporting Item

Page Number

Administrative

information

Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
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1	Trial registration	#2a	Trial identifier and registry name. If not yet	3
2			registered, name of intended registry	
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6	Trial registration:	#2b	All items from the World Health Organization Trial	n/a
7			Registration Data Set	
8	data set			
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11	Protocol version	#3	Date and version identifier	
12				
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15	Funding	#4	Sources and types of financial, material, and other	28
16			support	
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20	Roles and	#5a	Names, affiliations, and roles of protocol	28
21			contributors	
22	responsibilities:			
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24	contributorship			
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28	Roles and	#5b	Name and contact information for the trial sponsor	n/a
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30	responsibilities:			
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38	Roles and	#5c	Role of study sponsor and funders, if any, in study	28
39			design; collection, management, analysis, and	
40	responsibilities:		interpretation of data; writing of the report; and the	
41			decision to submit the report for publication,	
42	sponsor and funder		including whether they will have ultimate authority	
43			over any of these activities	
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52	Roles and	#5d	Composition, roles, and responsibilities of the	3, 21
53			coordinating centre, steering committee, endpoint	
54	responsibilities:		adjudication committee, data management team,	
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56	committees			
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and other individuals or groups overseeing the trial,
if applicable (see Item 21a for data monitoring
committee)

Introduction

11	Background and	#6a	Description of research question and justification for	5
12	rationale		undertaking the trial, including summary of relevant	
13			studies (published and unpublished) examining	
14			benefits and harms for each intervention	
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21	Background and	#6b	Explanation for choice of comparators	5
22	rationale: choice of			
23	comparators			
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28	Objectives	#7	Specific objectives or hypotheses	6
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31	Trial design	#8	Description of trial design including type of trial (eg,	12
32			parallel group, crossover, factorial, single group),	
33			allocation ratio, and framework (eg, superiority,	
34			equivalence, non-inferiority, exploratory)	
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41	Methods:			
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43	Participants,			
44	interventions, and			
45	outcomes			
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51	Study setting	#9	Description of study settings (eg, community clinic,	11
52			academic hospital) and list of countries where data	
53			will be collected. Reference to where list of study	
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1		sites can be obtained	
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4	Eligibility criteria	#10 Inclusion and exclusion criteria for participants. If	13,14
5		applicable, eligibility criteria for study centres and	
6		individuals who will perform the interventions (eg,	
7		surgeons, psychotherapists)	
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13	Interventions:	#11a Interventions for each group with sufficient detail to	8-10
14	description	allow replication, including how and when they will	
15		be administered	
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21	Interventions:	#11b Criteria for discontinuing or modifying allocated	n/a
22	modifications	interventions for a given trial participant (eg, drug	
23		dose change in response to harms, participant	
24		request, or improving / worsening disease)	
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31	Interventions:	#11c Strategies to improve adherence to intervention	11, 16
32	adherence	protocols, and any procedures for monitoring	
33		adherence (eg, drug tablet return; laboratory tests)	
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39	Interventions:	#11d Relevant concomitant care and interventions that	9,10
40	concomitant care	are permitted or prohibited during the trial	
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44	Outcomes	#12 Primary, secondary, and other outcomes, including	14-19
45		the specific measurement variable (eg, systolic	
46		blood pressure), analysis metric (eg, change from	
47		baseline, final value, time to event), method of	
48		aggregation (eg, median, proportion), and time point	
49		for each outcome. Explanation of the clinical	
50		relevance of chosen efficacy and harm outcomes is	
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1		strongly recommended	
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4	Participant timeline	#13 Time schedule of enrolment, interventions	Figure 1
5		(including any run-ins and washouts), assessments,	
6		and visits for participants. A schematic diagram is	
7		highly recommended (see Figure)	
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13	Sample size	#14 Estimated number of participants needed to achieve	14
14		study objectives and how it was determined,	
15		including clinical and statistical assumptions	
16		supporting any sample size calculations	
17			
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23	Recruitment	#15 Strategies for achieving adequate participant	11, 14
24		enrolment to reach target sample size	
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29	Methods:		
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31	Assignment of		
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33	interventions (for		
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35	controlled trials)		
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39	Allocation:	#16a Method of generating the allocation sequence (eg,	12
40	sequence	computer-generated random numbers), and list of	
41		any factors for stratification. To reduce predictability	
42	generation	of a random sequence, details of any planned	
43		restriction (eg, blocking) should be provided in a	
44		separate document that is unavailable to those who	
45		enrol participants or assign interventions	
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55	Allocation	#16b Mechanism of implementing the allocation	12
56		sequence (eg, central telephone; sequentially	
57	concealment		
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1	mechanism		numbered, opaque, sealed envelopes), describing	
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3			any steps to conceal the sequence until	
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5			interventions are assigned	
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8	Allocation:	#16c	Who will generate the allocation sequence, who will	12
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10	implementation		enrol participants, and who will assign participants	
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12			to interventions	
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15	Blinding (masking)	#17a	Who will be blinded after assignment to	23
16				
17			interventions (eg, trial participants, care providers,	
18				
19			outcome assessors, data analysts), and how	
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23	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	n/a
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25	emergency		permissible, and procedure for revealing a	
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27	unblinding		participant's allocated intervention during the trial	
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31	Methods: Data			
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33	collection,			
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35	management, and			
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37	analysis			
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41	Data collection plan	#18a	Plans for assessment and collection of outcome,	Supplementary
42				
43			baseline, and other trial data, including any related	file 1, 14,15, 17-
44				
45			processes to promote data quality (eg, duplicate	19
46				
47			measurements, training of assessors) and a	
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49			description of study instruments (eg,	
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51			questionnaires, laboratory tests) along with their	
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53			reliability and validity, if known. Reference to where	
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55			data collection forms can be found, if not in the	
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57				
58				
59				
60				

1		protocol	
2			
3			
4	Data collection plan:	#18b Plans to promote participant retention and complete	11
5			
6	retention	follow-up, including list of any outcome data to be	
7			
8		collected for participants who discontinue or deviate	
9			
10		from intervention protocols	
11			
12			
13	Data management	#19 Plans for data entry, coding, security, and storage,	11, 21
14			
15		including any related processes to promote data	
16			
17		quality (eg, double data entry; range checks for data	
18			
19		values). Reference to where details of data	
20			
21		management procedures can be found, if not in the	
22			
23		protocol	
24			
25			
26			
27			
28	Statistics: outcomes	#20a Statistical methods for analysing primary and	16, 20
29			
30		secondary outcomes. Reference to where other	
31			
32		details of the statistical analysis plan can be found,	
33			
34		if not in the protocol	
35			
36			
37			
38	Statistics: additional	#20b Methods for any additional analyses (eg, subgroup	17
39			
40	analyses	and adjusted analyses)	
41			
42			
43	Statistics: analysis	#20c Definition of analysis population relating to protocol	17
44			
45	population and	non-adherence (eg, as randomised analysis), and	
46			
47	missing data	any statistical methods to handle missing data (eg,	
48			
49		multiple imputation)	
50			
51			
52			
53	Methods: Monitoring		
54			
55			
56	Data monitoring:	#21a Composition of data monitoring committee (DMC);	n/a
57			
58			
59			
60			

1	formal committee	summary of its role and reporting structure;	
2			
3		statement of whether it is independent from the	
4			
5		sponsor and competing interests; and reference to	
6			
7		where further details about its charter can be found,	
8			
9		if not in the protocol. Alternatively, an explanation of	
10			
11		why a DMC is not needed	
12			
13			
14			
15	Data monitoring:	#21b Description of any interim analyses and stopping	n/a
16			
17	interim analysis	guidelines, including who will have access to these	
18			
19		interim results and make the final decision to	
20			
21		terminate the trial	
22			
23			
24			
25	Harms	#22 Plans for collecting, assessing, reporting, and	24,15
26			
27		managing solicited and spontaneously reported	
28			
29		adverse events and other unintended effects of trial	
30			
31		interventions or trial conduct	
32			
33			
34			
35	Auditing	#23 Frequency and procedures for auditing trial	n/a
36			
37		conduct, if any, and whether the process will be	
38			
39		independent from investigators and the sponsor	
40			
41			
42	Ethics and		
43			
44	dissemination		
45			
46			
47			
48	Research ethics	#24 Plans for seeking research ethics committee /	3, 24
49			
50	approval	institutional review board (REC / IRB) approval	
51			
52			
53	Protocol	#25 Plans for communicating important protocol	
54			
55	amendments	modifications (eg, changes to eligibility criteria,	
56			
57		outcomes, analyses) to relevant parties (eg,	
58			
59			
60			

1		investigators, REC / IRBs, trial participants, trial	
2		registries, journals, regulators)	
3			
4			
5			
6	Consent or assent	#26a Who will obtain informed consent or assent from	13, 14, 24
7			
8		potential trial participants or authorised surrogates,	
9			
10		and how (see Item 32)	
11			
12			
13	Consent or assent:	#26b Additional consent provisions for collection and use	n/a
14			
15	ancillary studies	of participant data and biological specimens in	
16		ancillary studies, if applicable	
17			
18			
19			
20			
21	Confidentiality	#27 How personal information about potential and	28
22			
23		enrolled participants will be collected, shared, and	
24			
25		maintained in order to protect confidentiality before,	
26			
27		during, and after the trial	
28			
29			
30			
31	Declaration of	#28 Financial and other competing interests for principal	28
32			
33	interests	investigators for the overall trial and each study site	
34			
35			
36	Data access	#29 Statement of who will have access to the final trial	28
37			
38		dataset, and disclosure of contractual agreements	
39			
40		that limit such access for investigators	
41			
42			
43			
44	Ancillary and post	#30 Provisions, if any, for ancillary and post-trial care,	n/a
45			
46	trial care	and for compensation to those who suffer harm	
47			
48		from trial participation	
49			
50			
51	Dissemination	#31a Plans for investigators and sponsor to communicate	24
52			
53	policy: trial results	trial results to participants, healthcare professionals,	
54			
55		the public, and other relevant groups (eg, via	
56			
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58			
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publication, reporting in results databases, or other
 data sharing arrangements), including any
 publication restrictions

Dissemination [#31b](#) Authorship eligibility guidelines and any intended n/a
 policy: authorship use of professional writers

Dissemination [#31c](#) Plans, if any, for granting public access to the full 28
 policy: reproducible protocol, participant-level dataset, and statistical
 research code

Appendices

Informed consent [#32](#) Model consent form and other related n/a
 materials documentation given to participants and authorised
 surrogates

Biological [#33](#) Plans for collection, laboratory evaluation, and n/a
 specimens storage of biological specimens for genetic or
 molecular analysis in the current trial and for future
 use in ancillary studies, if applicable

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 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

BMJ Open

Improving the patient-centred care of children with life-altering skin conditions using feedback from electronic patient-reported outcome measures: Protocol for a hybrid effectiveness-implementation study (PEDS-ePROM)

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Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Patient-centred medicine, Rehabilitation medicine, Dermatology, Health services research
Keywords:	PAEDIATRICS, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Paediatric dermatology < DERMATOLOGY, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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2
3 **TITLE: Improving the patient-centred care of children with life-altering skin**
4 **conditions using feedback from electronic patient-reported outcome**
5 **measures: Protocol for a hybrid effectiveness-implementation study (PEDS-**
6 **ePROM)**
7
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9

10
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2
3 **TITLE: Improving the patient-centred care of children with life-altering skin**
4 **conditions using an electronic patient-reported feedback intervention (PEDS-**
5 **ePROM): Protocol for a type 2 hybrid effectiveness-implementation study**
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11
12 **ABSTRACT**
13

14 **Introduction**
15

16 Using patient-reported outcome measures (PROMs) with children have been
17 described as 'giving a voice to the child'. Few studies have examined the routine use
18 of these measures as potentially therapeutic interventions. This study aims to
19 investigate: (1) the *effectiveness* of feedback using graphical displays of information
20 from electronic PROMs (ePROMS) that target health-related quality of life, to
21 improve health outcomes, referrals, and treatment satisfaction; and (2) the
22 *implementation* of ePROMs and graphical displays by assessing acceptability,
23 sustainability, cost, fidelity and context of the intervention and study processes.
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35 **Methods and analysis**
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37 A hybrid II effectiveness-implementation study will be conducted from February 2020
38 with children with life-altering skin conditions attending two outpatient clinics at a
39 specialist paediatric children's hospital. A pragmatic randomised controlled trial and
40 mixed methods process evaluation will be completed. Randomisation will occur at
41 the child participant level. Children or parent proxies completing baseline ePROMs
42 will be randomised to: (1) completion of ePROMs plus graphical displays of ePROM
43 results to treating clinicians in consultations, versus (2) completion of ePROMs
44 without graphical display of ePROM results. The primary outcome of the
45 effectiveness trial will be overall health-related quality of life of children. Secondary
46 outcomes will include other health-related quality of life outcomes (e.g., child
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3 psychosocial and physical health, parent psychosocial health), referrals, and
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5 treatment satisfaction. Trial data will be primarily analysed using linear mixed-effects
6
7 models; and implementation data using inductive thematic analysis of interviews,
8
9 meeting minutes, observational field notes and study communication mapped to the
10
11 Consolidated Framework for Implementation Research.
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17 **Ethics and dissemination**

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19 Ethical approval was obtained from Children's Health Queensland Human Research
20
21 Ethics Committee (HREC/2019/QCHQ/56290), The University of Queensland
22
23 (2019002233), and Queensland University of Technology (1900000847).
24
25

26 Dissemination will occur through stakeholder groups, scientific meetings and peer-
27
28 reviewed publications.
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32

33 **Trial registration**

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35 ACTRN12620000174987
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38 **Keywords**

39
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41 Patient-reported outcome measures, quality of life, paediatrics, patient-centred care,
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43 implementation
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ARTICLE SUMMARY

Strengths and limitations of this study

- New evidence of the effectiveness and implementation of electronic patient-reported outcome measures (ePROMs) in the routine clinical care of children with skin conditions and their parents will be generated which has received limited attention.
- Stakeholders representing multiple perspectives (children, parents, health professionals) were involved in the development of the intervention and process evaluation.
- Lack of ability to mask participants to the outcomes and contamination of the control group are potential biases, although child and parent participants were masked to the hypotheses.

INTRODUCTION

The routine use of patient-reported outcome measures (PROMs), or proxy-report measures, as part of routine clinical care has been identified as a means of driving change in healthcare systems, to ensure the unique voice of the patient is heard [1,2]. Potential benefits are improvements in shared decision-making, communication with health professionals and adherence to recommended treatments [3]. PROMs are defined as questionnaires completed by a patient with a health condition about their own health and treatment.

A recent systematic review identified that the effectiveness of PROM interventions for people with health conditions compared to usual care has been positive in adequately powered studies [4]. Few trials have been conducted in children. Only 2 of 22 included randomised controlled trials were conducted in children, one focussed on children with diabetes and one on children with cancer [5,6]. Two more recent paediatric cluster randomised controlled trials investigated PROMs used with children with severe mental health conditions attending child and adolescent psychiatric services [7,8]. Only one of the four paediatric trials identified positive effects of the PROM intervention. The positive effects were for psychosocial health-related quality of life but not physical health-related quality of life in children with diabetes [5].

The implementation of PROMs in routine paediatric care has also recently been investigated in a systematic review, with increased identification and discussion around health-related quality of life reported, particularly in psychosocial and emotional domains, but with mixed results regarding the impact on the quality of care

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2
3 [9]. Quality of care outcomes examined were satisfaction with treatment, referral
4 rate, and consultation length.
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10 Implementation outcomes can be examined using an implementation science
11 framework such as The Consolidated Framework for Implementation Research. This
12 framework has been identified as a 'good fit' for examining the implementation of
13 PROMs in health service organisations in a recent systematic review of reviews that
14 can assist to determine factors that influence implementation [10], and understand
15 how the intervention works (i.e., the process by which behaviour change occurs)
16 [11]. Multi-level influences on implementation can be examined through a focus on
17 individual characteristics of patients, families and clinicians (e.g. knowledge & beliefs
18 about the intervention), as well as organisational and process factors (e.g.,
19 engagement) [12].
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35 This paper will report the protocol for a randomised controlled trial and
36 implementation study to test the effectiveness and implementation outcomes of a
37 PROM feedback intervention targeting health-related quality of life, in children with
38 the life-altering skin conditions of burn scars and infantile haemangiomas (termed
39 the PEDS-ePROM study). The intervention involves the delivery of graphical
40 displays of information from electronic PROMs (ePROMs) in routine consultations to
41 encourage communication about the areas displayed and support clinical decision-
42 making. A comparison intervention involves the completion of ePROMs alone
43 without any graphical display of information. The need for interventions to improve
44 the health-related quality of life of these children is highlighted by the lower health-
45 related quality of life of children with burn scars across multiple domains even years
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3 after the actual injury compared to children with cancer [13]. At the time of
4
5 publication, the intervention had been designed and the randomised controlled trial
6
7 and implementation testing was underway with no findings yet available.
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10 11 12 **Aims and objectives**

13
14 The primary effectiveness aim is to determine the short-term effectiveness of
15
16 implementing ePROMs with graphical displays of result summaries, on overall
17
18 health-related quality of life of children with life-altering skin conditions. Secondary
19
20 aims will be to examine the effectiveness of the intervention for other health-related
21
22 quality of life outcomes of children and parents, the number and type of referrals to
23
24 health professionals and treatment satisfaction.
25
26

27 28 *Hypotheses (effectiveness component)*

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30
31
32 1. The ePROM plus graphical display intervention will have a greater effect on overall
33
34 health-related quality of life than the ePROM alone intervention, with a consistent
35
36 direction and similar strength of effect across the clinics and conditions, supporting
37
38 comparative effectiveness of the intervention.
39
40 2. The ePROM plus graphical display intervention will increase the number of
41
42 psychosocial referrals to health professionals and increase parent proxy-reported
43
44 satisfaction with treatment compared to the ePROM alone intervention.
45
46

47 48 **Implementation outcomes**

49
50 The primary aim is to determine the short-term acceptability and sustainability of
51
52 implementing the interventions. The secondary aim is to determine the cost, fidelity
53
54 and contextual factors related to implementation.
55
56

57 58 **METHODS AND ANALYSIS**

59 60 **Development of the study design and intervention**

1
2
3 The development of the PEDS-ePROM study and intervention was conducted from
4 May 2019 to January 2020. We initiated preliminary discussion with clinicians in
5
6 clinical areas to identify which measures were already being used routinely in
7
8 practice. Systematic reviews and paediatric literature regarding the use of PROMs
9
10 were also reviewed. Interview guides were developed to identify health outcomes
11
12 that are meaningful and of high priority to children, their families and health
13
14 professionals in the PROM intervention [14]. The nine core questions from the
15
16 International Society of Quality of Life (ISOQOL) user guide and the companion
17
18 guide areas were addressed in the interviews [15]. This development strategy using
19
20 existing research and interviews with parent proxies and children has been identified
21
22 as important to improve the engagement of children and young people such that
23
24 fewer items are missed and responses accurately reflect their experiences and
25
26 cognitive ability [16].
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35 Interviews were conducted with children with life-altering skin conditions, their
36
37 parents and treating health professionals in two phases as part of the pre-
38
39 implementation planning, with interview questions mapped to the Consolidated
40
41 Framework for Implementation Research. In the first phase the most appropriate
42
43 outcomes and PROMs were identified. In the second phase the content validity of
44
45 chosen PROMs and process evaluation were confirmed. Potential barriers and
46
47 benefits to implementation were identified in both phases. For children with burn
48
49 scars and their families, measures of health-related quality of life specific to scarring
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51 that included symptoms and treatment burden were prioritised based on conceptual
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53 work from the research team that identified these aspects as central components of
54
55 health-related quality of life for this group [17]. The design of the randomised
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3 controlled trial was based on systematic review findings that identified greater
4 benefits when PROM results were provided to clinicians compared to when results
5 were not provided to clinicians [4]. Measures of the child's health-related quality of
6 life were completed using parent-proxy and child self-report. The age cut-off for child
7 self-report of 8 years or older was chosen for several reasons: this cut-off was being
8 used in clinical practice in the burn scar clinics in the study setting; the burn scar-
9 specific measures chosen were developed based on this cut-off; and the experience
10 of the clinical and research team had identified that younger children aged 5 to 8
11 years often had difficulty comprehending the concepts captured in health-related
12 quality of life measures [18]. The difficulty children aged 5 to 8 years may have
13 completing patient-reported outcome measures of health-related quality of life aligns
14 with the findings of other paediatric researchers who identified the strongest
15 evidence was for the broad age-range of 6-8 years as the youngest age children can
16 meaningfully report on a patient-reported outcome [19].
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ePROM and graphical display intervention

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39 The Pediatric Quality of Life Inventory infant and generic scales [20,21] measuring
40 health-related quality of life were included as generic measures that were the same
41 across the clinics and conditions. Condition-specific health-related quality of life
42 measures were also included as these measures have been identified as being more
43 responsive to change than generic measures [22]. Condition-specific health-related
44 quality of life measures selected were the Brisbane Burn Scar Impact Profile [17,18],
45 The CARE parent scale [23], Hemangioma Family Burden questionnaire [24] and
46 Infantile Hemangioma Quality of Life Scale [25]. Selected measures targeted
47 children and their parents and a single item targeted siblings. An open-ended option
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3 was also available for child and parent participants to report their priorities for care.
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5 Only PROMs meeting the criteria of content validity supported by involvement of the
6
7 target group in development were included with the exception of the treatment
8
9 satisfaction item. Graphical displays of result summaries from the Pediatric Quality of
10
11 Life Inventory and condition-specific measures of health-related quality of life
12
13 measure will be presented in consultations for children with skin conditions and their
14
15 parents to treating clinicians. The components of the intervention are reported in
16
17
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19 Table 1.
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For peer review only

Table 1. Description of the ePROM plus graphical display and ePROM alone interventions*

Clinic	Mode of administration	ePROM + graphical display (intervention group)			ePROM alone (comparison group)			Intervention period
		Content	Duration	Frequency	Content	Duration	Frequency	
Burn scar clinic	Administered remotely using email or by a research occupational therapist in the clinic setting. PROM data collected electronically on a device at home or on an Apple iPad in the clinic.	PEDS-QL generic and infant scales BBSIP CARE scales	Approx. 15 mins for child and parent participants to complete ePROMs prior consultations. Up to 15 mins to download, print and deliver ePROMs & graphical displays to consultations.	Delivered in consultations up to 1x/ mth. Based on usual care likely to be delivered 2-3x.	ePROMs delivered and completed as per intervention group. No graphical summaries provided in consultations‡.	Approximately 15 mins for child and parent participants to complete ePROMs prior to each consultation. Up to 5 minutes to download, print and deliver ePROM.	As per intervention group	Baseline - 6 mths †

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Vascular clinic	As per burn scar clinic	PEDS-QL infant scales Hemangioma Family Burden questionnaire Infantile Haemangioma Quality-of-Life Instrument	Approx. 10 mins for parent participants to complete ePROMs prior to each consultation. Up to 10 mins to download, print and deliver ePROMs & graphical displays to consultations.	Delivered in consultations up to 1x/mth. Based on usual care likely 1-2x **.	ePROMs delivered and completed as per intervention group. No graphical summaries provided in consultations‡.	Approximately 10 mins for child and parent participants to complete ePROMs prior to each consultation. No printing required.	As per intervention group	Baseline - 6 mths †
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* Based on the Template for Intervention Description and Replication (TIDieR) guidelines [26]

† Post-baseline

‡ Graphical summaries provided to child and parent participants and entered into medical records at the end of the study

** Children with ulcerated haemangiomas may receive intervention more frequently

PROM, patient-reported outcome measure; ePROMs, electronic patient-reported outcome measures; PEDS-QL, Pediatric Evaluation of Quality of Life Inventory; approx., approximately; mins, minutes; mth, months

Method for completing PROMs

Electronically-delivered PROMs were identified as the best option for getting patients to complete the measures at home prior to consultations to reduce the burden of administration of measures and result summaries during busy clinics. The ePROMs will be administered via a weblink sent to parent participants in an email in the three days prior to their appointment. If the questionnaires are not completed via the weblink, child and parent participants will be offered a further opportunity to complete the questionnaires using an iPad prior to their consultation at the outpatient clinic while they are waiting for their consultation where possible. Parent proxy-report will continue throughout the study for any child who turns eight years of age after first completion using parent proxy-report. Phone calls will be used to remind parent participants to complete the ePROMs. The ePROMs and graphical display of result summaries will be generated using the online survey software program Qualtrics^{XM} [27] and presented to treating health professionals immediately prior to appointments. Copies of the ePROMs and graphical displays of result summaries will be stored in medical records.

Context

The setting will be two outpatient clinics at a major metropolitan quaternary-level children's hospital in Australia; a burns clinic and a vascular anomalies clinic. Parents (and their children with skin conditions if aged 8 years or older) will be consecutively approached and recruited, and the intervention delivered prior to and at these clinics. The catchment of the hospital includes inhabitants from rural, regional and metropolitan areas including those from surrounding islands. Recruitment commenced in January 2019. The first participant was randomised to receive the intervention in March 2020.

Research design

A hybrid type 2 effectiveness-implementation design will be used which blends evaluating intervention effectiveness and understanding implementation of the intervention simultaneously [28]. Benefits of this design include reduced lag time for uptake of the results into routine clinical practice and understanding the barriers and benefits to implementation [28]. A pragmatic two-arm randomised controlled trial will be conducted using block randomisation in random blocks of 4, 6 or 8 stratified by diagnostic group (i.e., infantile haemangiomas, burn scars), with child participants as the unit of randomisation; and an embedded qualitative process evaluation involving interviews with clinicians, and child and parent participants. The randomisation sequence will be prepared by a statistician independent from the study and will be concealed using sequentially numbered, opaque, sealed envelopes with tamper proof tape prepared by a person independent from the study.

The randomised controlled trial arms will be: (1) ePROM completion plus graphical display of result summaries to clinicians (intervention group) versus; (2) ePROM completion alone without graphical display of result summaries to clinicians (comparison group).

Baseline PROM measurement will occur before randomisation. PROM measurement will occur prior to or at one or more hospital appointments over the following 6-months and follow-up measurement will occur at 3-months and 6-months post-baseline if these timepoints differ from data collection timepoints during consultations with health professionals. Child and parent participants will be masked to the

1
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3 hypotheses. A Standard Protocol Items Recommendations for Interventional Trials
4 (SPIRIT) flow diagram has been used to report the schedule for enrolment,
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6 (SPIRIT) flow diagram has been used to report the schedule for enrolment,
7
8 interventions and evaluations for the effectiveness component of the study (Figure
9
10 1).

11
12
13
14 The study design and evaluation plan have been informed by the Consolidated
15
16 Framework for Implementation Research. This framework covers the physical and
17
18 social environment, values, individual motivation and capacity factors which are
19
20 considered important for the intervention being tested and has been derived from 33
21
22 theories relating to implementation [29]. This protocol paper has been prepared
23
24 following the eHealth Consolidated Standards of Reporting Trials (CONSORT)
25
26 guidelines [30].
27
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30 31 32 **Participants**

33
34 Participants for the effectiveness trial will be consecutively sampled. A previous study
35
36 by the author team using this sampling in the study setting with the same population
37
38 [31, 32] demonstrated representation of the burn scar study population [33].
39
40 Participants for the implementation study component will be purposively sampled with
41
42 representation of parents across both clinics, those who responded positively and
43
44 negatively to the intervention, and children across different age-groups or their parents
45
46 where possible.
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49

50 51 52 **Inclusion criteria**

53
54 Children with burn scars and infantile haemangiomas, aged 0 to 16 years at the time
55
56 of recruitment, who require ongoing management in the hospital setting, and their
57
58 parents aged 18 years or older will be included. Ongoing management is defined as
59
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2
3 children who require one or more ongoing hospital consultations with clinicians at the
4 study setting beyond baseline in the 6-month post-baseline intervention period for the
5 prevention or management of skin conditions as determined by treating clinicians at
6 baseline. Treating clinicians will also be asked to determine children's ability to
7 complete PROMs electronically based on their physical condition and knowledge of
8 the family (i.e., to determine if bilateral hand burns would prevent sufficient movement
9 of their hands to use an iPad).

20 Exclusion criteria

21
22 Children and parents will not be eligible to participate if they are involved with child
23 protection services and it is difficult to obtain consent, where circumstances interfere
24 with the participant's ability to give informed consent (i.e., diminished understanding
25 or comprehension), or where there is difficulty completing the PROMs due to
26 difficulty speaking or understanding written English. Participants who have difficulty
27 speaking or understanding written English will be excluded as it was difficult to
28 anticipate in advance the languages that might be required for ePROMs due to the
29 cultural diversity of patients seen in the setting; as multiple ePROMs were being
30 administered (four with no or few translations available) with most not developed or
31 tested using culturally diverse groups which is an important criteria for establishing
32 cross-cultural validity [34,35]; as funding was not available for purchasing available
33 translations of up to US\$500 per translation; and as the interventions were not
34 developed with these people thus it was unclear whether the interventions would
35 meet the needs of these potential participants.

54 Sample size estimate

55
56
57 The sample size was based on recruitment feasibility. A retrospective audit of child
58 and parent participants of clinic attendees suggested at least 35 participants in each
59
60

1
2
3 clinic can be recruited in the intervention period. In terms of the effectiveness
4
5 randomised controlled trial, if outcome data is available for 70 participants overall,
6
7 then with 80% power we will be able to detect an effect size for the difference
8
9 between-arms of 0.68 standard deviation units or greater for overall health-related
10
11 quality of life at 6-months post-baseline ($\alpha=0.05$). A between group difference of
12
13 0.68 is considered clinically meaningful at the individual level by expert clinicians, as
14
15 a medium to large effect is regarded as offsetting the burden of completion of
16
17 ePROMs to patients and families and supporting implementation routinely in clinics.
18
19 To account for twenty percent attrition expected at 6-month follow-up based on a
20
21 prior study with children and parents completing patient-reported outcome measures
22
23 in the burns clinic setting [31], recruitment will continue until at least 88 participants
24
25 have been randomised to groups. The sample size estimate was based on all
26
27 participants with data available including parent proxy and child report data. A recent
28
29 systematic review of health-related quality of life in children with burns identified that
30
31 parent-proxy and child self-ratings were generally comparable based on generic and
32
33 burn specific measures [36]. This findings is supported by an additional two trials
34
35 examining burn scar specific health-related quality of life in the burn scar clinic in this
36
37 study which were not included in the systematic review [31,32]. These trials identified
38
39 similar health-related quality of life scores using proxy and child report and for
40
41 children aged less than 8 years and older than 8 years.
42
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51 Interviews will be conducted with the following groups during implementation with
52
53 numbers of participants represented approximately equally for each clinic: children
54
55 with a skin condition, their parents and treating health professionals. Interviews will
56
57 continue until saturation (i.e. the point at which no further dimensions, nuances, or
58
59
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1
2
3 insights of issues are identified) [37] building on interview data generated pre-
4
5 implementation. A greater number of child interviews will be required than parent and
6
7 health professional interviews based on our previous experience of generally
8
9 obtaining shorter interviews of 15 to 20 minutes in children with burn scars than with
10
11 parents and health professionals.
12
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16

17 **Evaluation**

18 Effectiveness outcomes

19
20 Study outcome measures will be self-completed by children aged 8 years or older
21
22 and proxy-completed by parents for younger children. The primary outcome
23
24 assessed will be change in the child's generic overall health across both clinics
25
26 measured using The Pediatric Quality of Life Inventory (PedsQL™ 4.0 Generic Core
27
28 and Infant Scales proxy-report total score) [20,21]. Secondary outcomes will be: a)
29
30 change in the child's psychosocial and physical health across both clinics measured
31
32 using The Pediatric Quality of Life Inventory; respective subscales; c) change in the
33
34 child's generic health across both clinics measured using individual items of the
35
36 Child Health Utility (CHU-9D) and utility score [38]; d) condition-specific health-
37
38 related quality of life of the child (overall impact, sensory intensity, sensory
39
40 frequency, sensory impact, mobility, daily living, friendships and social interaction,
41
42 appearance, emotional reactions, and physical symptoms) measured using
43
44 respective subscales of the Brisbane Burn Scar Impact Profile [burn scar clinic group
45
46 only]; e) condition-specific health-related quality of life of parents (worry and impact)
47
48 measured using respective subscales of the Brisbane Burn Scar Impact Profile
49
50 respective subscales [burn scar clinic group only]; f) condition-specific health-related
51
52 quality of life of the child (physical symptoms, social interactions, emotional
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3 functioning, psychosocial functioning) measured using respective subscales of the
4 Infantile Hemangioma Quality of Life Scale [infantile hemangioma vascular clinic
5 group only]; g) condition-specific health-related quality of life of parents
6 (psychosocial functioning, negative mood, and self-worth) measured using
7 respective subscales of the CARE parent questionnaire [burn scar clinic group only];
8 h) condition-specific health-related quality of life of parents (relationship and work,
9 budget) measured using the relationships and work dimension and single budget
10 item of the Hemangioma Family Burden questionnaire; i) number and type of
11 referrals for the child or parent; and j) parent overall satisfaction with treatment.
12
13 Parent overall satisfaction with treatment was based on the finding that significantly
14 more intervention patients reported satisfaction with overall care in a study of
15 children with diabetes, which was the only paediatric study that examined this
16 outcome in a recent systematic review [4]. The number and type of referrals was
17 included as an outcome based on the findings of three paediatric studies identified in
18 a recent systematic review, in which two studies reported an increase in the referral
19 rates in the intervention group, and one study identified no difference in referral rates
20 between intervention and control groups [9]. A description of each of the outcomes
21 and psychometric properties of outcomes are reported in Supplementary File 1.
22
23 Adverse effects of the PROM interventions will be monitored using the self-report of
24 parent and child participants (where appropriate), treating health professionals as
25 well as by monitoring of the PROM data by investigators.
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54 Other outcomes

55 Sociodemographic data collected from or about parents will include the parent's
56 relationship to the child, level of education, ethnicity, work status, household income,
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3 and postcode; and from children aged 8 years or older or parents about their children
4 will include, gender, ethnicity, education level, scar location and comorbidities of the
5 child participants. Clinical data collected from electronic medical records will be
6 percent total body surface area, percent full thickness burn, length of time post-burn,
7 type of healing (e.g., spontaneous skin healing versus split thickness graft), type of
8 burn, and length of time to re-epithelialisation, medications and complications during
9 the study period.

19 Effectiveness evaluation

21 Descriptive statistics will be used to report the characteristics of the sample. The
22 number of participants excluded based on the exclusion criteria will also be reported
23 (e.g., difficulty speaking English). An intention to treat analysis will be the primary
24 approach but per protocol analyses will be compared to the intention to treat
25 approach to examine the effect of those who didn't receive the intervention as
26 intended. The key sociodemographic and clinical characteristic data that will be
27 examined for baseline differences between the groups will be age, gender,
28 education, household income, socioeconomic status of the neighbourhood where the
29 family reside based on postcode, severity of baseline symptoms and health-related
30 quality of life, body location of the condition, visibility of the condition (scars on the
31 head, neck, face or hands), and time since the skin condition commenced or injury
32 occurred. Baseline differences in informant (parent proxy and child self-report) will
33 also be examined between the groups.

51 Effectiveness analysis

54 Primary outcome comparison at 6-month post-baseline will be based on overall
55 health from the Pediatric Evaluation of Quality of Life Inventory between the
56 intervention and comparison group using linear mixed-effects models that account
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1
2
3 for repeated observations from the same child and clustering within clinics and within
4
5 treating health professionals. Covariables will be included for potentially confounding
6
7 variables if any differences between groups are identified for key sociodemographic,
8
9 and clinical characteristics at baseline. The analysis population will consist of all
10
11 participants who have analysable data. To investigate possible effects of informant,
12
13 age, and gender, a pre-specified subgroup analyses of the primary and secondary
14
15 health-related quality of life outcomes will be stratified by informant (proxy versus
16
17 child report), child age (0-24 months versus 2-8 years versus 8+years; except for
18
19 CHU-9D which will be 3-8 years versus 8+years) and gender (male vs female) to
20
21 determine whether effect differences exist based on these factors. A sensitivity
22
23 analysis will be conducted to compare the results of the parent proxy versus child
24
25 self-report where available.
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33 A sensitivity analysis will also be conducted using imputation techniques to replace
34
35 non-ignorable data that is considered to be missing at random over the follow-up
36
37 period, to determine whether bias is likely in the complete case analysis. A further
38
39 sensitivity analysis will investigate the possibility of imbalance in severity of health-
40
41 related quality of life in the two clinics at baseline. As well as reporting the results for
42
43 generic health-related quality of life across the clinics, we will also report after
44
45 stratifying by clinic. Secondary outcome comparisons will be conducted at 6-months
46
47 post-baseline using linear mixed-effects models where appropriate. Multi-level or
48
49 nested hierarchical analysis will examine the effect of clinic and treating health
50
51 professional effects by examining patient clustering within clinics, and surgeons and
52
53 occupational therapists clustered within clinics. The amount and type of missing data
54
55 will be reported using descriptive statistics. The maximum potential effect of the
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3 intervention with children will be analysed according to the treatment actually
4 received (an 'as treated' analysis incorporating treatment dose received). Data
5
6 analysis will be conducted using Stata 16.0 (Statacorp, College Station, TX, USA).
7
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9

10 Implementation outcomes

11
12 Implementation will be considered successful if graphical displays of result
13
14 summaries are presented to treating clinicians immediately prior to more than 85% of
15
16 consultations where a patient is randomised to receive a report, and if PROMs and
17
18 summaries are filed in electronic medical records for more than 75% of patients
19
20 eligible to have PROM data provided to treating clinicians in the intervention period.
21
22 The implementation outcomes of acceptability and sustainability [39] will be used to
23
24 determine the overall success of the implementation. The implementation outcomes
25
26 of acceptability, sustainability, cost, fidelity and contextual factors are detailed in
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31 Table 2.
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Table 2 Description of the implementation outcomes

Outcome	Detailed description of the outcome	Data type, source and analysis
Acceptability of the interventions and evaluation*	<p>The acceptability of the ePROM interventions and evaluation by families of children with health conditions and treating clinicians including content, complexity, delivery and relative advantage [39] and reflecting and evaluating (including the ability to meet needs of people who have difficulty speaking or understanding written English in the future).*</p> <ol style="list-style-type: none"> 1. $\geq 80\%$ of families will take < 15 minutes to complete the ePROMs as previous research has identified that PROMs that are fast to complete are most acceptable to clinicians and families [40]. 2. $\geq 50\%$ of families completed ePROMs across all scheduled consultations that were eligible to be included in the study, where consultations eligible to be included were limited to one consultation over any 1-month period. Based on pre-intervention phase 	<p>Quantitative: Electronic study data and administrative data; descriptive analysis</p> <p>Qualitative: interview and field note data; thematic analysis including mapping to CFIR innovation constructs (e.g., relative advantage, adaptability, complexity, cost in the pre-implementation and implementation stages; and reflecting and evaluating, design quality</p>

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3
4 interviews and field notes of what was considered and packaging,
5 acceptable for ongoing implementation of the PROMs compatability, and
6 routinely in clinical practice in the study clinics and relative priority in the
7 evidence indicating completion rates of 75% were implementation phase).
8 achieved for system-wide implementation of PROMs at
9 a Canadian children's hospital [41].
10
11
12
13

- 14 3. Phone reminders for PROM completion were required
15 in $\leq 50\%$ of families. This outcome was based on
16 feedback from clinicians in the pre-implementation
17 phase indicating that phone call reminders for this type
18 of intervention are a burden to clinicians and may
19 impact uptake by clinicians.
20
21 4. Technology-related issues with graphical displays of
22 result summaries or ePROM completion were present
23 for $\leq 10\%$ of families across all eligible appointments.
24
25 5. $\geq 75\%$ of participants eligible to have ePROM data
26 provided to treating clinicians had intervention ePROMs
27 and graphical displays filed in electronic medical
28 records.
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3 Sustainability of ePROM
4 interventions and
5 evaluation
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The extent to which the ePROM intervention (or a modification of the intervention) was continued or planned to be continued in routine clinical practice at the end of the study, and barriers and facilitators of sustained use.

Qualitative: Interviews with child, parent and health professional participants and field notes; analysed using thematic analysis and mapping to CFIR (e.g., knowledge and beliefs about the intervention, design quality and packaging, needs and resources)

24 Cost
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The cost of implementing the intervention for patients in the intervention and control groups based on resource use from the perspective of the health service.

Qualitative: interview data relating to cost.

Data for healthcare resource utilisation for co-interventions for skin treatment (e.g. medicines, complementary treatments), and details of hospital presentations), will be included.

Quantitative: Study and administrative data, medical records, hospital clinical costings department data.

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Fidelity

The extent to which the interventions were delivered and received as intended.

1. Dose of the intervention: Child and parent verbal report of the topics on the graphical displays of ePROM results that were discussed during the consultation in the intervention group, immediately after the consultation.
2. Dose of the intervention: percentage of eligible consultations for each participant where ePROM data was completed in advance of the consultation as scheduled.
3. The number (percentage) of participants randomised to receive graphical displays of result summaries versus the number of participants who actually had graphical displays of result summaries delivered to consultations.
4. Amount and type of missing intervention-related ePROM data on Qualtrics^{XM} [27].

Qualitative: Verbal fidelity reports and interviews with children and parents, and interviews with health professional participants and field notes

Quantitative: Study data, descriptive analysis

Contextual factors

Barriers and facilitators to multi-level implementation of the intervention and the evaluation; at the individual level, clinic level, hospital level, and outside the hospital setting.

Qualitative: Interviews with child, parent and health professional participants; and field notes analysed using thematic analysis and mapping to CFIR (e.g., culture, networks and communication, implementation cost)

* Children ≥ 8 years will self-report; parents will provide proxy-reports for children aged < 8 years except for satisfaction with treatment which will only be self-reported by parents.

ePROMs, electronic patient-reported outcome measures; CFIR, Consolidated Framework for Implementation Research

Implementation evaluation

Implementation outcomes will be evaluated using interviews; health service, administrative, clinical costings and missing data; observational field notes of meetings and each clinic attended or planned; meeting minutes and study emails; and fidelity reports. Acceptability is defined as the perception among stakeholders that a treatment, service, practice or innovation is agreeable or satisfactory [39]. Sustainability is defined as the extent that a newly implemented treatment is maintained within a service setting's ongoing, stable operations [39]. The ways in which the needs of people with difficulty speaking or understanding written English can best be addressed in the future will be explored in interviews as part of understanding acceptability and sustainability, as these groups were excluded from participation. The data from these sources will be mapped to the Consolidated Framework for Implementation Research [29]. This framework can be used to understand barriers and facilitators to implementing the intervention at the level of individuals, the organisational level and settings external to the organisation which can assist in determining the sustainability and potential scaling up of the intervention. Factors related to implementation delivery that might have impacted on the intervention effectiveness will also be examined to understand whether and how the expected outcomes were achieved, and the reasons for this.

Fidelity of the intervention will be taken from study records kept by researchers.

Immediately after face-to-face consultations parents and children (where appropriate) will be requested to verbally report the graphical display topics that were discussed during the consultation in the intervention group.

Implementation analysis

1
2
3 Interpretive Description [42] will be used to thematically analyse the data. This
4
5 qualitative analysis uses elements from several other qualitative methodologies
6
7 including phenomenology, grounded theory, and ethnography without focusing on
8
9 any specific technique [42]. Interpretive Description is ideal for applied clinical
10
11 questions and analysis of a wide range of data sources [42]. The analysis builds on
12
13 what is known in terms of current practices and structures of health services and
14
15 what is known and not known [42]. Data analysis will be conducted iteratively,
16
17 concurrently with interviews, with analysis conducted during the implementation
18
19 phase building on analysis of pre-implementation interviews. Framework analysis
20
21 [43] will then be applied deductively, mapping the qualitative and quantitative data
22
23 (e.g., verbatim quotes and descriptive statistics) to the pre-defined key constructs of
24
25 the Consolidated Framework for Implementation Research as overarching themes.
26
27 The data will be organised into a framework matrix where columns are codes and
28
29 rows are participants [43]. This analysis is conducted across participants as well as
30
31 within participants. Steps in framework analysis include familiarization; indexing;
32
33 charting; and synthesising [43]. Pre-implementation and post-implementation
34
35 differences will be examined, and themes that emerge in addition to the
36
37 Consolidated Framework for Implementation Research constructs, will be added to
38
39 the framework. Positive and negative participant quotes and descriptive data will be
40
41 examined separately for each construct in the framework to determine influences on
42
43 implementation and the strength of each construct, for each clinics as well as across
44
45 clinics [44]. Once mapping to the Consolidated Framework for Implementation
46
47 Research has been completed, data that applies to the implementation outcomes of
48
49 acceptability, sustainability, fidelity and contextual factors will then be summarised.
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3 Interviews will be audio recorded and transcribed verbatim by study personnel.
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5 Recordings will be stored in a coded form on a secure password protected folder
6
7 within The University of Queensland until coding has been completed, accessible to
8
9 two of the investigators and a research assistant. The credibility of the analysis will
10
11 be checked using member checking of the interview data, independent coding of the
12
13 data by two researchers of at least 20 percent of the data, triangulation of the results
14
15 across participant groups (managers, treating health professionals, parent and child
16
17 participants) and using field notes, and reflective journaling. Microsoft excel (version
18
19 16, Microsoft Corporation) and NVivo (version 10, QSR International, Doncaster,
20
21 Victoria, Australia [45]) will be used to organise and code the data.
22
23
24

25 26 Electronic platform

27
28 The electronic survey platform Qualtrics^{XM} [27] was chosen to administer the
29
30 PROMs and to provide graphical displays of result summaries based on visual
31
32 aesthetics of the graphical displays compared to other survey programs and prior
33
34 experience of the investigators using the program. Features of the program that were
35
36 important for administration of the chosen surveys and study design were the ability
37
38 to have open-ended text, email distribution, ability to send reminders, display
39
40 longitudinal responses, a recoding values function, automated scoring functionality,
41
42 and links to NVivo software [45] for coding open text responses.
43
44
45

46 47 Patient and public involvement

48
49 Children aged 8 years and older with life-altering skin conditions, parents of children
50
51 with life-altering skin conditions and treating health professionals in the study setting
52
53 were involved in all study phases including development of the intervention, process
54
55 evaluation, study design and implementation evaluation. These stakeholder groups
56
57 reported on the burden of the planned intervention, potential time required to
58
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1
2
3 participate and acceptability of follow-up intervals in pre-implementation interviews.

4
5 Plans include forming a stakeholder reference group to inform the interpretation and
6
7 sustainability of the study findings.
8
9

10 11 12 **DISCUSSION**

13
14 To our knowledge studies of PROM interventions have not previously focused on
15
16 children with life-altering skin conditions. A pragmatic approach has been taken to
17
18 maximise relevance to the clinical context including limiting exclusion criteria, and
19
20 developing and delivering an intervention that has limited interference with the
21
22 running of very busy outpatient clinics. If the intervention is shown to have promising
23
24 short-term results then secondary prevention impacts particularly on emotional
25
26 health of parents may be likely and the benefits higher in the longer term which will
27
28 be examined in the future.
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34
35 An outcome of the proposed study may be refinement of the intervention based on
36
37 mapping to the Consolidated Framework for Implementation Research which may
38
39 identify additional elements that should be considered. The findings will also likely
40
41 inform the design of a multisite cluster effectiveness-implementation study of a
42
43 patient-reported outcome measure intervention in these children which may reduce
44
45 the risk of contamination bias [8]. Information obtained will inform ongoing efforts in
46
47 paediatric care to use patient-reported outcome measures as part of routine clinical
48
49 care.
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53 **Strengths and limitations**

54
55 Strengths of the study include the involvement of stakeholders representing multiple
56
57 perspectives (children, parents, health professionals) in the development of the
58
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1
2
3 intervention and the process evaluation, and the focus of the intervention and
4 process evaluation on health-related quality of life. The use of the Consolidated
5 Framework for Implementation Research is also a strength. Theory-based
6
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9
10 interventions tend to be more effective than non-theory based interventions [46].
11
12 More specifically, the current study will seek to understand how the inner setting of
13 the organisation (i.e., organisational culture and structural characteristics) impacts on
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17 implementation which has been identified as a research gap [10].
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22 The lack of masking of treating health professionals and participants in the
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The lack of masking of treating health professionals and participants in the
randomised controlled trial is a limitation although masking is not possible as the
outcomes are patient or proxy-reported and it will be clear to most participants when
results are presented in consultations. However, child and parent participants will be
masked to the hypotheses. Potential contamination bias has also been raised as a
possibility in trials of this nature where several clinics within a facility are included, as
treating health professionals' awareness of issues that should be focused on may be
raised, diluting the impact of the intervention [47].

A limitation is the lack of inclusion of children and parents who have difficulty
speaking or understanding English. Further attention is required to develop and test
ePROM interventions for families from specific cultural backgrounds which is a
challenge in the study setting where people from diverse cultural backgrounds are
seen. Specifically, people of Aboriginal and Torres Strait Islander descent were not
involved in the development process thus the intervention and study design may not
be acceptable for this group of people and should be established.

Ethical approval and dissemination

Ethical approval has been received from Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/19/QCHQ/56290), The University of Queensland (2019002233), and Queensland University of Technology (1900000847).

Written consent will be obtained from parent and treating health professional participants once written and verbal information has been provided. Parents will be encouraged to discuss the study with children who can communicate with their parents prior to consent being obtained. Adverse effects will be reported to the Children's Health Queensland Hospital and Health Service and Human Research Ethics Committees.

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52 **Author contributions**

53
54 ZT designed the study with input from SM and RW for the effectiveness evaluation,
55
56 GH for the implementation evaluation, and RK and MS for integrating with existing
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2
3 clinical processes. ZT drafted the protocol and SM, MS, TZ, RW and RK critically
4 revised the manuscript.
5
6
7

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9
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11 Hospital Foundation, Brisbane, grant number 50297. The funder had no input into
12 the design or conduct of the study.
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18 **Competing interests statement**

19
20 ZT, MS and RK developed the Brisbane Burn Scar Impact Profile which was
21 included as a scar-specific measure in this study. MS and RK were clinical staff
22 members of the health service where the study will be conducted at the time of
23 submission.
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31 **Data sharing statement**

32
33 The final trial dataset will be available to chief investigators. The final trial dataset
34 may be accessed with approval from the investigators if steps are undertaken to
35 preserve the confidentiality of the data. Additional information regarding criteria for
36 accessing data are available from the study investigators.
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45 **Acknowledgements**

46 Nil
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48 **Figure 1 legend**

49 SPIRIT flow diagram for the effectiveness study component*
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51 **Word count 5242**
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STUDY PERIOD				
	<i>Enrolment</i>	<i>Allocation</i>	<i>Post-allocation</i>	
TIMEPOINT	<i>-t₁</i>	0 <i>Baseline*</i>	<i>t₁</i> <i>3-months</i> <i>post-baseline</i>	<i>t₂</i> <i>6-months</i> <i>post-baseline</i>
ENROLMENT:				
Eligibility screen	X			
Informed consent	X	X		
Allocation		X		
INTERVENTIONS:				
<i>PEDS-ePROM</i>		◄	—————	►
<i>ePROM</i>		◄	—————	►
EVALUATIONS:				
<i>Sociodemographic details</i>		X		
<i>Clinical characteristics</i>		X		
<i>PEDS-QL (Infant & generic scales)</i>		X	X	X
<i>Brisbane Burn Scar Impact Profile**</i>		X	X	X
<i>CARe Burn Scales**</i>		X	X	X
<i>Haemangioma Family Burden Questionnaire***</i>		X	X	X
<i>Infantile Haemangioma Quality-of-Life Instrument***</i>		X	X	X
<i>Satisfaction with treatment</i>			X	X
<i>Referrals</i>			X	X

*Baseline measures completed prior to randomization; ≥2nd appointment vascular clinic, ≥1st appointment scar clinic; ** burn scar clinic only; *** vascular clinic only

Figure 1

Supplementary File 1 Details of the outcomes in the intervention and effectiveness evaluation

Outcome	Outcome measure	Participant of focus	Domains, subscales, items or versions used in the study	Used in study intervention or evaluation	Description	Psychometrics
Generic health-related quality of life	CHU-9D	Child	All items 3 to 5 years (parent proxy) 5 to 7 years (parent proxy) 7 to 8 years (parent proxy) ≥ 8 years version (child)	Evaluation	A measure of health-related quality of life that can be used with child aged 3 years and older. The parent proxy version for children aged 3 to 5 years has 10 items with an additional item on overall health compared to 9-item versions for other versions.	A reliable and valid measure recommended for economic evaluations in paediatric settings [1-3]. 3-5 year version has not yet been validated (personal communication, Katherine Stevens). The item on schoolwork/homework has been modified.
Generic health-related quality of life (primary outcome measure)	PEDS-QL 4.0 Generic and Infant Scales	Child	All items 2-4 years (parent proxy) 5-7 years (parent proxy) 8-12 years (child self-report) 13-18 years (child self-report)	Evaluation and intervention	Generic 4.0 scale: 23 items, 4 domains (physical, emotional, social and school functioning), 3 summary scores (psychosocial health, physical health, total score). Scores will be transformed on a 0 to 100 and scored as recommended by the developers (Mapi Research Trust and Varni, 2017, scaling and scoring,	Validation (including reproducibility and responsiveness testing) supported for children with acute and chronic conditions including those in a hospital setting [4,5].

version 17, available from <http://www.pedsql.org/PedsQL-Scoring.pdf>, accessed 11.05.2020).

Condition-specific health-related quality of life	The Brisbane Burn Scar Impact Profile	Child and caregiver	All items Children < 8 years (parent proxy) Children 8-18 (child self-report)	Evaluation and intervention	Groups of items measured were overall impact of burn scars; frequency and impact of itch, pain and other sensations; school, play and daily activities (includes mobility and activities of daily living items); friendships and social interactions; appearance; emotional reactions; physical symptoms; and parent and family concerns.	Content validity (children with burn scars and caregiver involvement in development) [6]. Psychometric testing in children and caregivers has largely supported longitudinal validity, reproducibility and responsiveness from around the time of wound healing [7,8].
Condition-specific health-related quality of life	CARe Burn Scales	Caregiver	15 items Parent self-report	Evaluation and intervention	Self-worth and negative mood parent scale items.	Content validity (caregivers of children with burns involved in development). Further validity testing is underway but not yet published (personal communication, Catrin Griffiths).
Condition-specific health-related quality of life	Haemangioma Family Burden Questionnaire	Child and caregiver	4 items Parent proxy and parent self-report	Evaluation and intervention	Four items from the 20-item questionnaire were included. Three items forming the relationship and work	Structural validity: internal coherence (Cronbach's α : 0.93). Construct validity:

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related
quality of life

dimension were included (e.g., time spent with other children, impact of the haemangioma on career and stopping work). In addition the single item on budget and financial resources was included.

correlation with mental dimension of the Short-Form-12 ($r = -0.75$), and Psychological General Well-Being Index ($r = -0.61$). Discriminant validity: significant differences were found according to the size and location of the infantile haemangioma [9].

Condition-specific health-related quality of life

Infantile Haemangioma Quality-of-Life Instrument

Child and caregiver

All items of the final measure (parent proxy and parent self-report)

Evaluation and intervention

The 29 final items were included: 5 items targeting the child and the remainder targeting the caregiver. 4 subscales: child physical symptoms, child social interactions, parent emotional functioning, and parent psychosocial functioning.

Content validity (with parents involved in the development), test-retest reliability and structural validity supported [10].

Satisfaction with treatment

Study specific

Caregiver

Single item Parent self-report

Evaluation

An 11-point condition specific numeric rating scale with anchors of very dissatisfied to very satisfied will be asked similar to the numeric rating scale used in a previous study by the authors with children with burn scars and their

N/A

					caregivers [11] at 3-months and 6-months post-baseline.	
Referrals	Study specific	Child and caregiver	N/A	Evaluation	The number and type of referrals for child and caregiver participants to health professionals during 6-month intervention period, including psychosocial referrals. Referrals will be those made by health professional participants receiving result summaries in their consultations. Taken from medical records. Psychosocial referrals include referrals to social work, psychology, a general practitioner, or other health professional; where the referral is clearly for psychosocial support other than that provided by the health professionals delivering consultations in the effectiveness evaluation.	N/A

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

	Reporting Item	Page Number
Administrative information		
Title	#1 Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

1	Trial registration	#2a	Trial identifier and registry name. If not yet	3
2			registered, name of intended registry	
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6	Trial registration:	#2b	All items from the World Health Organization Trial	n/a
7			Registration Data Set	
8	data set			
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11	Protocol version	#3	Date and version identifier	
12				
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14				
15	Funding	#4	Sources and types of financial, material, and other	28
16			support	
17				
18				
19				
20	Roles and	#5a	Names, affiliations, and roles of protocol	28
21			contributors	
22	responsibilities:			
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24	contributorship			
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28	Roles and	#5b	Name and contact information for the trial sponsor	n/a
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30	responsibilities:			
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32	sponsor contact			
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34	information			
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38	Roles and	#5c	Role of study sponsor and funders, if any, in study	28
39			design; collection, management, analysis, and	
40	responsibilities:		interpretation of data; writing of the report; and the	
41			decision to submit the report for publication,	
42	sponsor and funder		including whether they will have ultimate authority	
43			over any of these activities	
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52	Roles and	#5d	Composition, roles, and responsibilities of the	3, 21
53			coordinating centre, steering committee, endpoint	
54	responsibilities:		adjudication committee, data management team,	
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56	committees			
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and other individuals or groups overseeing the trial,
if applicable (see Item 21a for data monitoring
committee)

Introduction

Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	12
Methods:			
Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study	11

1		sites can be obtained	
2			
3			
4	Eligibility criteria	#10 Inclusion and exclusion criteria for participants. If	13,14
5		applicable, eligibility criteria for study centres and	
6		individuals who will perform the interventions (eg,	
7		surgeons, psychotherapists)	
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13	Interventions:	#11a Interventions for each group with sufficient detail to	8-10
14	description	allow replication, including how and when they will	
15		be administered	
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21	Interventions:	#11b Criteria for discontinuing or modifying allocated	n/a
22	modifications	interventions for a given trial participant (eg, drug	
23		dose change in response to harms, participant	
24		request, or improving / worsening disease)	
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31	Interventions:	#11c Strategies to improve adherence to intervention	11, 16
32	adherence	protocols, and any procedures for monitoring	
33		adherence (eg, drug tablet return; laboratory tests)	
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39	Interventions:	#11d Relevant concomitant care and interventions that	9,10
40	concomitant care	are permitted or prohibited during the trial	
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44	Outcomes	#12 Primary, secondary, and other outcomes, including	14-19
45		the specific measurement variable (eg, systolic	
46		blood pressure), analysis metric (eg, change from	
47		baseline, final value, time to event), method of	
48		aggregation (eg, median, proportion), and time point	
49		for each outcome. Explanation of the clinical	
50		relevance of chosen efficacy and harm outcomes is	
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1		strongly recommended	
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4	Participant timeline	#13 Time schedule of enrolment, interventions	Figure 1
5		(including any run-ins and washouts), assessments,	
6		and visits for participants. A schematic diagram is	
7		highly recommended (see Figure)	
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13	Sample size	#14 Estimated number of participants needed to achieve	14
14		study objectives and how it was determined,	
15		including clinical and statistical assumptions	
16		supporting any sample size calculations	
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23	Recruitment	#15 Strategies for achieving adequate participant	11, 14
24		enrolment to reach target sample size	
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29	Methods:		
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31	Assignment of		
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33	interventions (for		
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35	controlled trials)		
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39	Allocation:	#16a Method of generating the allocation sequence (eg,	12
40	sequence	computer-generated random numbers), and list of	
41		any factors for stratification. To reduce predictability	
42	generation	of a random sequence, details of any planned	
43		restriction (eg, blocking) should be provided in a	
44		separate document that is unavailable to those who	
45		enrol participants or assign interventions	
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55	Allocation	#16b Mechanism of implementing the allocation	12
56		sequence (eg, central telephone; sequentially	
57	concealment		
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1	mechanism		numbered, opaque, sealed envelopes), describing	
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3			any steps to conceal the sequence until	
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5			interventions are assigned	
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8	Allocation:	#16c	Who will generate the allocation sequence, who will	12
9				
10	implementation		enrol participants, and who will assign participants	
11				
12			to interventions	
13				
14				
15	Blinding (masking)	#17a	Who will be blinded after assignment to	23
16				
17			interventions (eg, trial participants, care providers,	
18				
19			outcome assessors, data analysts), and how	
20				
21				
22				
23	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	n/a
24				
25	emergency		permissible, and procedure for revealing a	
26				
27	unblinding		participant's allocated intervention during the trial	
28				
29				
30				
31	Methods: Data			
32				
33	collection,			
34				
35	management, and			
36				
37	analysis			
38				
39				
40				
41	Data collection plan	#18a	Plans for assessment and collection of outcome,	Supplementary
42				
43			baseline, and other trial data, including any related	file 1, 14,15, 17-
44				
45			processes to promote data quality (eg, duplicate	19
46				
47			measurements, training of assessors) and a	
48				
49			description of study instruments (eg,	
50				
51			questionnaires, laboratory tests) along with their	
52				
53			reliability and validity, if known. Reference to where	
54				
55			data collection forms can be found, if not in the	
56				
57				
58				
59				
60				

1		protocol	
2			
3			
4	Data collection plan:	#18b Plans to promote participant retention and complete	11
5			
6	retention	follow-up, including list of any outcome data to be	
7			
8		collected for participants who discontinue or deviate	
9			
10		from intervention protocols	
11			
12			
13	Data management	#19 Plans for data entry, coding, security, and storage,	11, 21
14			
15		including any related processes to promote data	
16			
17		quality (eg, double data entry; range checks for data	
18			
19		values). Reference to where details of data	
20			
21		management procedures can be found, if not in the	
22			
23		protocol	
24			
25			
26			
27			
28	Statistics: outcomes	#20a Statistical methods for analysing primary and	16, 20
29			
30		secondary outcomes. Reference to where other	
31			
32		details of the statistical analysis plan can be found,	
33			
34		if not in the protocol	
35			
36			
37			
38	Statistics: additional	#20b Methods for any additional analyses (eg, subgroup	17
39			
40	analyses	and adjusted analyses)	
41			
42			
43	Statistics: analysis	#20c Definition of analysis population relating to protocol	17
44			
45	population and	non-adherence (eg, as randomised analysis), and	
46			
47	missing data	any statistical methods to handle missing data (eg,	
48			
49		multiple imputation)	
50			
51			
52			
53	Methods: Monitoring		
54			
55			
56	Data monitoring:	#21a Composition of data monitoring committee (DMC);	n/a
57			
58			
59			
60			

1	formal committee		summary of its role and reporting structure;	
2				
3			statement of whether it is independent from the	
4				
5			sponsor and competing interests; and reference to	
6				
7			where further details about its charter can be found,	
8				
9			if not in the protocol. Alternatively, an explanation of	
10				
11			why a DMC is not needed	
12				
13				
14				
15	Data monitoring:	#21b	Description of any interim analyses and stopping	n/a
16				
17	interim analysis		guidelines, including who will have access to these	
18				
19			interim results and make the final decision to	
20				
21			terminate the trial	
22				
23				
24				
25	Harms	#22	Plans for collecting, assessing, reporting, and	24,15
26				
27			managing solicited and spontaneously reported	
28				
29			adverse events and other unintended effects of trial	
30				
31			interventions or trial conduct	
32				
33				
34				
35	Auditing	#23	Frequency and procedures for auditing trial	n/a
36				
37			conduct, if any, and whether the process will be	
38				
39			independent from investigators and the sponsor	
40				
41				
42	Ethics and			
43				
44	dissemination			
45				
46				
47				
48	Research ethics	#24	Plans for seeking research ethics committee /	3, 24
49				
50	approval		institutional review board (REC / IRB) approval	
51				
52				
53	Protocol	#25	Plans for communicating important protocol	
54				
55	amendments		modifications (eg, changes to eligibility criteria,	
56				
57			outcomes, analyses) to relevant parties (eg,	
58				
59				
60				

1		investigators, REC / IRBs, trial participants, trial	
2		registries, journals, regulators)	
3			
4			
5			
6	Consent or assent	#26a Who will obtain informed consent or assent from	13, 14, 24
7		potential trial participants or authorised surrogates,	
8		and how (see Item 32)	
9			
10			
11			
12			
13	Consent or assent:	#26b Additional consent provisions for collection and use	n/a
14	ancillary studies	of participant data and biological specimens in	
15		ancillary studies, if applicable	
16			
17			
18			
19			
20			
21	Confidentiality	#27 How personal information about potential and	28
22		enrolled participants will be collected, shared, and	
23		maintained in order to protect confidentiality before,	
24		during, and after the trial	
25			
26			
27			
28			
29			
30			
31	Declaration of	#28 Financial and other competing interests for principal	28
32	interests	investigators for the overall trial and each study site	
33			
34			
35			
36	Data access	#29 Statement of who will have access to the final trial	28
37		dataset, and disclosure of contractual agreements	
38		that limit such access for investigators	
39			
40			
41			
42			
43			
44	Ancillary and post	#30 Provisions, if any, for ancillary and post-trial care,	n/a
45	trial care	and for compensation to those who suffer harm	
46		from trial participation	
47			
48			
49			
50			
51	Dissemination	#31a Plans for investigators and sponsor to communicate	24
52	policy: trial results	trial results to participants, healthcare professionals,	
53		the public, and other relevant groups (eg, via	
54			
55			
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58			
59			
60			

publication, reporting in results databases, or other
 data sharing arrangements), including any
 publication restrictions

Dissemination [#31b](#) Authorship eligibility guidelines and any intended n/a
 policy: authorship use of professional writers

Dissemination [#31c](#) Plans, if any, for granting public access to the full 28
 policy: reproducible protocol, participant-level dataset, and statistical
 research code

Appendices

Informed consent [#32](#) Model consent form and other related n/a
 materials documentation given to participants and authorised
 surrogates

Biological [#33](#) Plans for collection, laboratory evaluation, and n/a
 specimens storage of biological specimens for genetic or
 molecular analysis in the current trial and for future
 use in ancillary studies, if applicable

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 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)