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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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TITLE: 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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TITLE: Improving the patient-centred care of children with life-altering skin conditions using an electronic patient-reported feedback intervention (PEDS-ePROM): Protocol for a type 2 hybrid effectiveness-implementation study

ABSTRACT

Introduction

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

Methods and analysis

A hybrid II effectiveness-implementation study will be conducted from February 2020 with children with life-altering skin conditions attending two outpatient clinics at a specialist paediatric children's hospital. A pragmatic randomised controlled trial and mixed methods process evaluation will be completed. Randomisation will occur at the child participant level. Children or caregiver proxies completing baseline PROMs will be randomised to: (1) completion of PROMs plus graphical displays of PROM results to treating clinicians in consultations, versus (2) completion of PROMs without graphical display of PROM results. The primary outcome of the effectiveness trial will be overall health-related quality of life of children using caregiver-proxy report (children < 8 years) and child-report (≥8 years). Secondary outcomes will include other health-related quality of life outcomes (e.g., psychosocial health of

children and caregivers), referrals, hospital resource use and treatment satisfaction. Trial data will be primarily analysed using mixed-effects regression. Analysis of the implementation component will involve inductive thematic analysis of interview data, meeting minutes, observational field notes and written study communication mapped to the Consolidated Framework for Implementation Research.

Ethics and dissemination

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

Trial registration

ACTRN12620000174987

Keywords

Patient-reported outcome measures, quality of life, paediatrics, patient-centred care, implementation

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

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

Aims and objectives

Effectiveness outcomes

The primary effectiveness aim is to determine the short-term effectiveness of implementing PROMs with graphical displays of result summaries, on overall health-related quality of life of children with life-altering skin conditions. Secondary aims will be to examine the effectiveness of the intervention for other health-related quality of life outcomes of children and caregivers, the number and type of referrals to health professionals and treatment satisfaction.

Hypotheses (effectiveness component)

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

Implementation outcomes

The primary implementation aim is to determine the short-term acceptability and sustainability of implementing the interventions.

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 [10]. 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 [11]. 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 [12].

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

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

PEDS-ePROM intervention

The Pediatric Quality of Life Inventory infant and generic scales [15,16] measuring health-related quality of life and a treatment satisfaction item were included as generic measures. Condition-specific health-related quality of life measures selected were the Brisbane Burn Scar Impact Profile [13,17], The CARe parent scale [18], Hemangioma Family Burden questionnaire [19] and Infantile Hemangioma Quality of Life Scale [20]. Selected measures targeted children and their caregivers and a single item targeted siblings. An open-ended option was also available for child and caregiver participants to report their priorities for care. Only PROMs meeting the criteria of content validity supported by involvement of the target group in development were included. Graphical displays of result summaries from the Pediatric Quality of Life Inventory and condition-specific measures of health-related quality of life measure will be presented in consultations for children with skin conditions and their caregivers to treating clinicians. The components of the intervention are reported in Table 1.

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 †

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

* 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

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

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

Sample size estimate

The sample size was based on recruitment feasibility. A retrospective audit of child and caregiver participants of clinic attendees suggested at least 35 participants in each clinic can be recruited in the 6-month intervention period. In terms of the effectiveness randomised controlled trial, if outcome data is available for 70 participants overall, then with 80% power we will be able to detect an effect size for the difference between-arms of 0.68 or greater for overall health-related quality of life at 6-months post-baseline (alpha=0.05).

Interviews will be conducted with the following groups during implementation with numbers of participants represented approximately equally for each clinic: children with a skin condition, their caregivers and treating health professionals. Interviews will continue until saturation (i.e. the point at which no further dimensions, nuances, or insights of issues are identified) [24] building on interview data generated pre-implementation. A greater number of child interviews will be required than caregiver and health professional interviews based on our previous experience obtaining shorter interviews of 15 to 20 minutes in children with burn scars than with caregivers and health professionals.

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,

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

Fidelity

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

Effectiveness evaluation

An intention to treat analysis will be the primary approach but per protocol analyses will be compared to the intention to treat approach to examine the effect of those who didn't receive the intervention as intended. The key sociodemographic and clinical characteristic data that will be examined for baseline differences between the groups will be age, gender, education, household income, socioeconomic status of the neighbourhood where the family reside based on postcode, severity of baseline symptoms and health-related quality of life, body location of the condition, visibility of the condition (scars on the head, neck, face or hands), and time since the skin

condition commenced or injury occurred. The primary comparison will be completed using data from caregivers for children aged younger than 8-years and from children themselves for those aged 8-years or older.

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 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. 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

eligible to have PROM data provided to treating clinicians in the intervention period. The outcomes detailed in Table 2 will be used to determine acceptability and sustainability.

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	1. ≥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].	Electronic data collection for outcome (1) and (2)
		2. ≥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.	Field notes
		3. Phone reminders for PROM completion were required in ≤50% of families.	Field notes and electronic data collection

		4. Technology-related issues with graphical displays of result summaries or ePROM completion were present for ≤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

Consolidated Framework for Implementation Research as overarching themes. The data will be organised into a framework matrix where columns are codes and rows are participants [29]. This analysis is conducted across participants as well as within participants. Steps in framework analysis include familiarization; indexing; charting; and synthesising [29]. Pre-implementation and post-implementation differences will be examined, and themes that emerge in addition to the Consolidated Framework for Implementation Research constructs, will be added to the framework.

Interviews will be audio recorded and transcribed verbatim by study personnel. Recordings will be stored in a coded form on a secure password protected folder within The University of Queensland until coding has been completed, accessible to two of the investigators and a research assistant. The credibility of the analysis will be checked using member checking of the interview data, independent coding of the data by two researchers of at least 20 percent of the data, triangulation of the results across participant groups (managers, treating health professionals, caregiver and child participants), and reflective journaling.

Electronic platform

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

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

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. This framework was identified as a good fit for examining the implementation of PROMs in health service organisations in a recent systematic review of reviews [31] and can assist to understand how the intervention works (i.e., the process by which behaviour change occurs) [32]. More specifically, the current study will seek to understand how the inner setting of the organisation (i.e., organisational culture and structural characteristics) impacts on implementation which has been identified as a research gap [31].

The lack of blinding of treating health professionals and participants in the randomised controlled trial is a limitation although blinding 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 caregiver participants will be blinded 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 [33].

A limitation is the lack of inclusion of families from non-English speaking backgrounds and some cultural groups. Further attention is required to develop and test PROM interventions for families from specific cultural backgrounds which is a challenge in the study setting where people from many 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 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.

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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

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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.

Acknowledgements

Nil

Figure 1 legend

SPIRIT flow diagram for the effectiveness study component*

Word count 3932

STUDY PERIOD				
	Enrolment	**Allocation**	***Post-allocation***	
TIMEPOINT	***-t_1***	**0 Baseline***	***t_1 3-months post-baseline***	***t_2 6-months post-baseline***
ENROLMENT:				
Eligibility screen	X			
Informed consent	X	X		
Allocation		X		
INTERVENTIONS:				
PEDS-ePROM		♦—	—	—♦
ePROM		♦—	—	—♦
EVALUATIONS:				
Sociodemographic details		X		
Clinical characteristics		X		
PEDS-QL (Infant & generic scales)		X	X	X
Brisbane Burn Scar Impact Profile*		X	X	X
CARe Burn Scales*		X	X	X
Haemangioma Family Burden Questionnaire***		X	X	X
Infantile Haemangioma Quality-of-Life Instrument**		X	X	X
Satisfaction with treatment			X	X
Referrals			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.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	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

					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

	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.

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

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	
Funding	#4	Sources and types of financial, material, and other support	28
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	28
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	28
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team,	3, 21

		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

		sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	13,14
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	11, 16
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9,10
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is	14-19

		strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11, 14
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially	12

mechanism		numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	23
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the	Supplementary file 1, 14,15, 17-19

		protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11, 21
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16, 20
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring:	#21a	Composition of data monitoring committee (DMC);	n/a

formal committee		summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	24,15
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	3, 24
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg,	

		investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13, 14, 24
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	28
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	28
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	28
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via	24

		publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	28
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

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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TITLE: 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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Word count 4618

TITLE: Improving the patient-centred care of children with life-altering skin conditions using an electronic patient-reported feedback intervention (PEDS-ePROM): Protocol for a type 2 hybrid effectiveness-implementation study

ABSTRACT

Introduction

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

Methods and analysis

A hybrid II effectiveness-implementation study will be conducted from February 2020 with children with life-altering skin conditions attending two outpatient clinics at a specialist paediatric children's hospital. A pragmatic randomised controlled trial and mixed methods process evaluation will be completed. Randomisation will occur at the child participant level. Children or caregiver proxies completing baseline PROMs will be randomised to: (1) completion of PROMs plus graphical displays of PROM results to treating clinicians in consultations, versus (2) completion of PROMs without graphical display of PROM results. The primary outcome of the effectiveness trial will be overall health-related quality of life of children using caregiver-proxy report. Secondary outcomes will include self-reported overall health-related quality of

life of children, other health-related quality of life outcomes (e.g., caregiver psychosocial health), referrals, and treatment satisfaction. Trial data will be primarily analysed using linear mixed-effects models; and implementation data using inductive thematic analysis of interviews, meeting minutes, observational field notes and study communication mapped to the Consolidated Framework for Implementation Research.

Ethics and dissemination

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

Trial registration

ACTRN12620000174987

Keywords

Patient-reported outcome measures, quality of life, paediatrics, patient-centred care, implementation

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

care [9]. Quality of care outcomes examined were satisfaction with treatment, referral rate, and consultation length.

Implementation outcomes can be examined using an implementation science framework such as The Consolidated Framework for Implementation. This framework has been identified as a 'good fit' for examining the implementation of PROMs in health service organisations in a recent systematic review of reviews that can assist to determine factors that influence implementation [10], and understand how the intervention works (i.e., the process by which behaviour change occurs) [11]. Multi-level influences on implementation can be examined through a focus on individual characteristics of patients, families and clinicians (e.g. knowledge & beliefs about the intervention), as well as organisational and process factors (e.g., engagement) [12].

This paper will report the protocol for a randomised controlled trial and implementation study to test the effectiveness and implementation outcomes of a PROM feedback intervention targeting health-related quality of life, in children with the life-altering skin conditions of burn scars and infantile haemangiomas (termed PEDS-ePROM). The intervention involves the delivery of graphical displays of information from patient-reported outcome measures in routine consultations to encourage communication about the areas displayed. A comparison intervention involves the completion of electronic patient-reported outcome measure data without any graphical display of information (termed ePROM). The need for interventions to improve the health-related quality of life of these children is highlighted by the lower health-related quality of life of children with burn scars across multiple domains even

years after the actual injury compared to children with cancer [13]. At the time of publication, the PEDS-ePROM intervention had been designed and the randomised controlled trial and implementation testing was underway with no findings yet available.

Aims and objectives

The primary effectiveness aim is to determine the short-term effectiveness of implementing PROMs with graphical displays of result summaries, on overall health-related quality of life of children with life-altering skin conditions. Secondary aims will be to examine the effectiveness of the intervention for other health-related quality of life outcomes of children and caregivers, the number and type of referrals to health professionals and treatment satisfaction.

Hypotheses (effectiveness component)

1. The PEDS-ePROM intervention will have a greater effect on overall health-related quality of life than the ePROM intervention, with a consistent direction and similar strength of effect across the clinics and conditions, supporting comparative effectiveness of the intervention.
2. The PEDS-ePROM intervention will increase the number of psychosocial referrals to health professionals and increase proxy-reported satisfaction with treatment.

Implementation outcomes

The primary aim is to determine the short-term acceptability and sustainability of implementing the interventions. The secondary aim is to determine the cost, fidelity and contextual factors related to implementation.

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

health-related quality of life for this group [17]. The design of the randomised controlled trial was based on systematic review findings that identified greater benefits when PROM results were provided to clinicians compared to when results were not provided to clinicians [4]. For the purposes of the current study, PROMs included proxy caregiver measures as young children cannot self-report their quality of life or symptoms.

PEDS-ePROM intervention

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

Table 1. Description of the PEDS-ePROM intervention and ePROM comparison intervention*

Clinic	Mode of administration	PEDS-ePROM intervention Content	Duration	Frequency	ePROM comparison intervention Content	Frequency	Duration	Intervention period
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 -

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 †

* 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.

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 [26]. 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 [26]. 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 caregiver 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) 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 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

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

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

Sample size estimate

The sample size was based on recruitment feasibility. A retrospective audit of child and caregiver participants of clinic attendees suggested at least 35 participants in each clinic can be recruited in the intervention period. In terms of the effectiveness randomised controlled trial, if outcome data is available for 70 participants overall, then with 80% power we will be able to detect an effect size for the difference between-arms of 0.68 standard deviation units or greater for proxy-reported overall health-related quality of life at 6-months post-baseline (alpha=0.05). A between group difference of 0.68 is considered clinically meaningful at the individual level by expert clinicians, as a medium to large effect is regarded as offsetting the burden of completion of ePROMs to patients and families and supporting implementation routinely in clinics. To account for twenty percent attrition expected at 6-month follow-up based on a prior study with children and caregivers completing patient-reported outcome measures in the burns clinic setting [28], recruitment will continue until 88 participants have been randomised to groups.

Interviews will be conducted with the following groups during implementation with numbers of participants represented approximately equally for each clinic: children with a skin condition, their caregivers and treating health professionals. Interviews will continue until saturation (i.e. the point at which no further dimensions, nuances, or insights of issues are identified) [29] building on interview data generated pre-implementation. A greater number of child interviews will be required than caregiver and health professional interviews based on our previous experience of generally obtaining shorter interviews of 15 to 20 minutes in children with burn scars than with caregivers and health professionals.

Evaluation

Effectiveness outcomes

Study outcome measures 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 proxy-report total score) [18,19]. Secondary outcomes will be: (a) 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 [30], child report total score); b) change in the child's psychosocial and physical health across both clinics measured using The Pediatric Quality of Life Inventory; proxy and child report respective subscales; c) change in the child's generic health across both clinics measured using proxy and child report of individual items of the Child Health Utility (CHU-9D) and utility score [25]; d) condition-specific health-related quality of life of the child (overall impact, sensory intensity, sensory

frequency, sensory impact, mobility, daily living, friendships and social interaction, appearance, emotional reactions, and physical symptoms) measured using respective subscales of the Brisbane Burn Scar Impact Profile [burn scar clinic group only]; e) condition-specific health-related quality of life of parents (worry and impact) measured using respective subscales of the Brisbane Burn Scar Impact Profile respective subscales [burn scar clinic group only]; f) condition-specific health-related quality of life of the child (physical symptoms, social interactions, emotional functioning, psychosocial functioning) measured using respective subscales of the Infantile Hemangioma Quality of Life Scale [infantile hemangioma vascular clinic group only]; g) condition-specific health-related quality of life of parents (psychosocial functioning, negative mood, and self-worth) measured using respective subscales of the CARe parent questionnaire [burn scar clinic group only]; h) condition-specific health-related quality of life of parents (relationship and work, budget) measured using the relationships and work dimension and single budget item of the Hemangioma Family Burden questionnaire; i) number and type of referrals for the child or caregiver; and j) caregiver overall satisfaction with treatment. Caregiver overall satisfaction with treatment was based on the finding that significantly more intervention patients reported satisfaction with overall care in a study of children with diabetes, which was the only paediatric study that examined this outcome in a recent systematic review [4]. The number and type of referrals was included as an outcome based on the findings of three paediatric studies identified in a recent systematic review, in which two studies reported an increase in the referral rates in the intervention group, and one study identified no difference in referral rates between intervention and control groups [9]. 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, household income, and postcode; and from children aged 8 years or older or caregivers about their children will include, gender, ethnicity, education level, scar location and comorbidities of the child participants. Clinical data collected from electronic medical records will be percent total body surface area, percent full thickness burn, length of time post-burn, type of healing (e.g., spontaneous skin healing versus split thickness graft), type of burn, and length of time to re-epithelialisation, medications and complications during the study period.

Effectiveness evaluation

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

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

eligible to have PROM data provided to treating clinicians in the intervention period. The implementation outcomes of acceptability and sustainability [31] will be used to determine the overall success of the implementation. The implementation outcomes of acceptability, sustainability, cost, fidelity and contextual factors are detailed in Table 2.

Table 2 Description of the implementation outcomes

Outcome	Detailed description of the outcome	Data type, source and analysis
Acceptability of ePROM interventions and evaluation*	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].* 1. ≥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. ≥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	Quantitative: Electronic study data and administrative data; descriptive analysis 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).

	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)
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.	Qualitative: interview data relating to cost. Quantitative: Study and administrative data, medical records, hospital clinical costings department data.
Fidelity	The extent to which the interventions were delivered and received as intended. 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	Qualitative: Verbal fidelity reports and interviews with children and caregivers, and interviews with health professional participants

	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 [25].	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, 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

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

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

Interviews will be audio recorded and transcribed verbatim by study personnel. Recordings will be stored in a coded form on a secure password protected folder within The University of Queensland until coding has been completed, accessible to

two of the investigators and a research assistant. The credibility of the analysis will be checked using member checking of the interview data, independent coding of the data by two researchers of at least 20 percent of the data, triangulation of the results across participant groups (managers, treating health professionals, caregiver and child participants) and using field notes, and reflective journaling. Microsoft excel (version 16, Microsoft Corporation) and NVivo (version 10, QSR International, Doncaster, Victoria, Australia [37]) will be used to organise and code the data.

Electronic platform

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

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 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].

More specifically, the current study will seek to understand how the inner setting of the organisation (i.e., organisational culture and structural characteristics) impacts on implementation which has been identified as a research gap [10].

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 caregiver 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 [39].

A limitation is the lack of inclusion of families from non-English speaking backgrounds and some cultural groups. Further attention is required to develop and test PROM interventions for families from specific cultural backgrounds which is a challenge in the study setting where people from many 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 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.

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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

STUDY PERIOD				
	Enrolment	**Allocation**	***Post-allocation***	
TIMEPOINT	***-t_1***	**0 Baseline***	***t_1 3-months post-baseline***	***t_2 6-months post-baseline***
ENROLMENT:				
Eligibility screen	X			
Informed consent	X	X		
Allocation		X		
INTERVENTIONS:				
PEDS-ePROM		♦—	—	—♦
ePROM		♦—	—	—♦
EVALUATIONS:				
Sociodemographic details		X		
Clinical characteristics		X		
PEDS-QL (Infant & generic scales)		X	X	X
Brisbane Burn Scar Impact Profile*		X	X	X
CARe Burn Scales*		X	X	X
Haemangioma Family Burden Questionnaire***		X	X	X
Infantile Haemangioma Quality-of-Life Instrument**		X	X	X
Satisfaction with treatment			X	X
Referrals			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.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	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

					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

	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.

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

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

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	
Funding	#4	Sources and types of financial, material, and other support	28
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	28
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	28
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team,	3, 21

		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

		sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	13,14
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	11, 16
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9,10
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is	14-19

		strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11, 14
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially	12

mechanism		numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	23
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the	Supplementary file 1, 14,15, 17-19

		protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11, 21
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16, 20
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring:	#21a	Composition of data monitoring committee (DMC);	n/a

formal committee		summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	24,15
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	3, 24
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg,	

		investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13, 14, 24
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	28
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	28
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	28
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via	24

		publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	28
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

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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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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TITLE: 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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Word count 5242

TITLE: Improving the patient-centred care of children with life-altering skin conditions using an electronic patient-reported feedback intervention (PEDS-ePROM): Protocol for a type 2 hybrid effectiveness-implementation study

ABSTRACT

Introduction

Using patient-reported outcome measures (PROMs) with children have been described as 'giving a voice to the child'. Few studies have examined the routine use of these measures as potentially therapeutic interventions. This study aims to investigate: (1) the *effectiveness* of feedback using graphical displays of information from electronic PROMs (ePROMS) that target health-related quality of life, to improve health outcomes, referrals, and treatment satisfaction; and (2) the *implementation* of ePROMs and graphical displays by assessing acceptability, sustainability, cost, fidelity and context of the intervention and study processes.

Methods and analysis

A hybrid II effectiveness-implementation study will be conducted from February 2020 with children with life-altering skin conditions attending two outpatient clinics at a specialist paediatric children's hospital. A pragmatic randomised controlled trial and mixed methods process evaluation will be completed. Randomisation will occur at the child participant level. Children or parent proxies completing baseline ePROMs will be randomised to: (1) completion of ePROMs plus graphical displays of ePROM results to treating clinicians in consultations, versus (2) completion of ePROMs without graphical display of ePROM results. The primary outcome of the effectiveness trial will be overall health-related quality of life of children. Secondary outcomes will include other health-related quality of life outcomes (e.g., child

psychosocial and physical health, parent psychosocial health), referrals, and treatment satisfaction. Trial data will be primarily analysed using linear mixed-effects models; and implementation data using inductive thematic analysis of interviews, meeting minutes, observational field notes and study communication mapped to the Consolidated Framework for Implementation Research.

Ethics and dissemination

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

Trial registration

ACTRN12620000174987

Keywords

Patient-reported outcome measures, quality of life, paediatrics, patient-centred care, implementation

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

[9]. Quality of care outcomes examined were satisfaction with treatment, referral rate, and consultation length.

Implementation outcomes can be examined using an implementation science framework such as The Consolidated Framework for Implementation Research. This framework has been identified as a 'good fit' for examining the implementation of PROMs in health service organisations in a recent systematic review of reviews that can assist to determine factors that influence implementation [10], and understand how the intervention works (i.e., the process by which behaviour change occurs) [11]. Multi-level influences on implementation can be examined through a focus on individual characteristics of patients, families and clinicians (e.g. knowledge & beliefs about the intervention), as well as organisational and process factors (e.g., engagement) [12].

This paper will report the protocol for a randomised controlled trial and implementation study to test the effectiveness and implementation outcomes of a PROM feedback intervention targeting health-related quality of life, in children with the life-altering skin conditions of burn scars and infantile haemangiomas (termed the PEDS-ePROM study). The intervention involves the delivery of graphical displays of information from electronic PROMs (ePROMs) in routine consultations to encourage communication about the areas displayed and support clinical decision-making. A comparison intervention involves the completion of ePROMs alone without any graphical display of information. The need for interventions to improve the health-related quality of life of these children is highlighted by the lower health-related quality of life of children with burn scars across multiple domains even years

after the actual injury compared to children with cancer [13]. At the time of publication, the intervention had been designed and the randomised controlled trial and implementation testing was underway with no findings yet available.

Aims and objectives

The primary effectiveness aim is to determine the short-term effectiveness of implementing ePROMs with graphical displays of result summaries, on overall health-related quality of life of children with life-altering skin conditions. Secondary aims will be to examine the effectiveness of the intervention for other health-related quality of life outcomes of children and parents, the number and type of referrals to health professionals and treatment satisfaction.

Hypotheses (effectiveness component)

1. The ePROM plus graphical display intervention will have a greater effect on overall health-related quality of life than the ePROM alone intervention, with a consistent direction and similar strength of effect across the clinics and conditions, supporting comparative effectiveness of the intervention.
2. The ePROM plus graphical display intervention will increase the number of psychosocial referrals to health professionals and increase parent proxy-reported satisfaction with treatment compared to the ePROM alone intervention.

Implementation outcomes

The primary aim is to determine the short-term acceptability and sustainability of implementing the interventions. The secondary aim is to determine the cost, fidelity and contextual factors related to implementation.

METHODS AND ANALYSIS

Development of the study design and intervention

The development of the PEDS-ePROM study 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 development strategy using existing research and interviews with parent proxies and children 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 parents 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 that included symptoms and treatment burden were prioritised based on conceptual work from the research team that identified these aspects as central components of health-related quality of life for this group [17]. The design of the randomised

controlled trial was based on systematic review findings that identified greater benefits when PROM results were provided to clinicians compared to when results were not provided to clinicians [4]. Measures of the child's health-related quality of life were completed using parent-proxy and child self-report. The age cut-off for child self-report of 8 years or older was chosen for several reasons: this cut-off was being used in clinical practice in the burn scar clinics in the study setting; the burn scar-specific measures chosen were developed based on this cut-off; and the experience of the clinical and research team had identified that younger children aged 5 to 8 years often had difficulty comprehending the concepts captured in health-related quality of life measures [18]. The difficulty children aged 5 to 8 years may have completing patient-reported outcome measures of health-related quality of life aligns with the findings of other paediatric researchers who identified the strongest evidence was for the broad age-range of 6-8 years as the youngest age children can meaningfully report on a patient-reported outcome [19].

ePROM and graphical display intervention

The Pediatric Quality of Life Inventory infant and generic scales [20,21] measuring health-related quality of life were included as generic measures that were the same across the clinics and conditions. Condition-specific health-related quality of life measures were also included as these measures have been identified as being more responsive to change than generic measures [22]. Condition-specific health-related quality of life measures selected were the Brisbane Burn Scar Impact Profile [17,18], The CARe parent scale [23], Hemangioma Family Burden questionnaire [24] and Infantile Hemangioma Quality of Life Scale [25]. Selected measures targeted children and their parents and a single item targeted siblings. An open-ended option

was also available for child and parent participants to report their priorities for care. Only PROMs meeting the criteria of content validity supported by involvement of the target group in development were included with the exception of the treatment satisfaction item. Graphical displays of result summaries from the Pediatric Quality of Life Inventory and condition-specific measures of health-related quality of life measure will be presented in consultations for children with skin conditions and their parents to treating clinicians. The components of the intervention are reported in Table 1.

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 †

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 †

* 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

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 [29]. This protocol paper has been prepared following the eHealth Consolidated Standards of Reporting Trials (CONSORT) guidelines [30].

Participants

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

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 parents 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 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

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

Sample size estimate

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

clinic can be recruited in the intervention period. In terms of the effectiveness randomised controlled trial, if outcome data is available for 70 participants overall, then with 80% power we will be able to detect an effect size for the difference between-arms of 0.68 standard deviation units or greater for overall health-related quality of life at 6-months post-baseline (alpha=0.05). A between group difference of 0.68 is considered clinically meaningful at the individual level by expert clinicians, as a medium to large effect is regarded as offsetting the burden of completion of ePROMs to patients and families and supporting implementation routinely in clinics. To account for twenty percent attrition expected at 6-month follow-up based on a prior study with children and parents completing patient-reported outcome measures in the burns clinic setting [31], recruitment will continue until at least 88 participants have been randomised to groups. The sample size estimate was based on all participants with data available including parent proxy and child report data. A recent systematic review of health-related quality of life in children with burns identified that parent-proxy and child self-ratings were generally comparable based on generic and burn specific measures [36]. This findings is supported by an additional two trials examining burn scar specific health-related quality of life in the burn scar clinic in this study which were not included in the systematic review [31,32]. These trials identified similar health-related quality of life scores using proxy and child report and for children aged less than 8 years and older than 8 years.

Interviews will be conducted with the following groups during implementation with numbers of participants represented approximately equally for each clinic: children with a skin condition, their parents and treating health professionals. Interviews will continue until saturation (i.e. the point at which no further dimensions, nuances, or

insights of issues are identified) [37] building on interview data generated pre-implementation. A greater number of child interviews will be required than parent and health professional interviews based on our previous experience of generally obtaining shorter interviews of 15 to 20 minutes in children with burn scars than with parents and health professionals.

Evaluation

Effectiveness outcomes

Study outcome measures will be self-completed by children aged 8 years or older and proxy-completed by parents 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 proxy-report total score) [20,21]. Secondary outcomes will be: a) change in the child's psychosocial and physical health across both clinics measured using The Pediatric Quality of Life Inventory; respective subscales; c) change in the child's generic health across both clinics measured using individual items of the Child Health Utility (CHU-9D) and utility score [38]; d) condition-specific health-related quality of life of the child (overall impact, sensory intensity, sensory frequency, sensory impact, mobility, daily living, friendships and social interaction, appearance, emotional reactions, and physical symptoms) measured using respective subscales of the Brisbane Burn Scar Impact Profile [burn scar clinic group only]; e) condition-specific health-related quality of life of parents (worry and impact) measured using respective subscales of the Brisbane Burn Scar Impact Profile respective subscales [burn scar clinic group only]; f) condition-specific health-related quality of life of the child (physical symptoms, social interactions, emotional

functioning, psychosocial functioning) measured using respective subscales of the Infantile Hemangioma Quality of Life Scale [infantile hemangioma vascular clinic group only]; g) condition-specific health-related quality of life of parents (psychosocial functioning, negative mood, and self-worth) measured using respective subscales of the CARe parent questionnaire [burn scar clinic group only]; h) condition-specific health-related quality of life of parents (relationship and work, budget) measured using the relationships and work dimension and single budget item of the Hemangioma Family Burden questionnaire; i) number and type of referrals for the child or parent; and j) parent overall satisfaction with treatment. Parent overall satisfaction with treatment was based on the finding that significantly more intervention patients reported satisfaction with overall care in a study of children with diabetes, which was the only paediatric study that examined this outcome in a recent systematic review [4]. The number and type of referrals was included as an outcome based on the findings of three paediatric studies identified in a recent systematic review, in which two studies reported an increase in the referral rates in the intervention group, and one study identified no difference in referral rates between intervention and control groups [9]. 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 parent 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 parents will include the parent's relationship to the child, level of education, ethnicity, work status, household income,

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

Effectiveness evaluation

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

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 intervention and 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. The analysis population will consist of all participants who have analysable data. To investigate possible effects of informant, age, and gender, a pre-specified subgroup analyses of the primary and secondary health-related quality of life outcomes will be stratified by informant (proxy versus child report), child age (0-24 months versus 2-8 years versus 8+years; except for CHU-9D which will be 3-8 years versus 8+years) and gender (male vs female) to determine whether effect differences exist based on these factors. A sensitivity analysis will be conducted to compare the results of the parent proxy versus child self-report where available.

A sensitivity analysis will also 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. A further sensitivity analysis will investigate the possibility of imbalance in severity of health-related quality of life in the two clinics at baseline. As well as reporting the results for generic health-related quality of life across the clinics, we will also report after stratifying by clinic. 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 eligible to have PROM data provided to treating clinicians in the intervention period. The implementation outcomes of acceptability and sustainability [39] will be used to determine the overall success of the implementation. The implementation outcomes of acceptability, sustainability, cost, fidelity and contextual factors are detailed in Table 2.

Table 2 Description of the implementation outcomes

Outcome	Detailed description of the outcome	Data type, source and analysis
Acceptability of the interventions and evaluation*	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).* 1. ≥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. ≥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	Quantitative: Electronic study data and administrative data; descriptive analysis 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

	interviews and field notes of what was considered acceptable for ongoing implementation of the PROMs routinely in clinical practice in the study clinics and evidence indicating completion rates of 75% were achieved for system-wide implementation of PROMs at a Canadian children's hospital [41].	and packaging, compatability, and relative priority in the implementation phase).
	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, 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)
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.	Qualitative: interview data relating to cost. Quantitative: Study and administrative data, medical records, hospital clinical costings department data.

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

Interpretive Description [42] 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 any specific technique [42]. Interpretive Description is ideal for applied clinical questions and analysis of a wide range of data sources [42]. The analysis builds on what is known in terms of current practices and structures of health services and what is known and not known [42]. Data analysis will be conducted iteratively, concurrently with interviews, with analysis conducted during the implementation phase building on analysis of pre-implementation interviews. Framework analysis [43] will then be applied deductively, mapping the qualitative and quantitative data (e.g., verbatim quotes and descriptive statistics) to the pre-defined key constructs of the Consolidated Framework for Implementation Research as overarching themes. The data will be organised into a framework matrix where columns are codes and rows are participants [43]. This analysis is conducted across participants as well as within participants. Steps in framework analysis include familiarization; indexing; charting; and synthesising [43]. Pre-implementation and post-implementation differences will be examined, and themes that emerge in addition to the Consolidated Framework for Implementation Research constructs, will be added to the framework. Positive and negative participant quotes and descriptive data will be examined separately for each construct in the framework to determine influences on implementation and the strength of each construct, for each clinics as well as across clinics [44]. Once mapping to the Consolidated Framework for Implementation Research has been completed, data that applies to the implementation outcomes of acceptability, sustainability, fidelity and contextual factors will then be summarised.

Interviews will be audio recorded and transcribed verbatim by study personnel. Recordings will be stored in a coded form on a secure password protected folder within The University of Queensland until coding has been completed, accessible to two of the investigators and a research assistant. The credibility of the analysis will be checked using member checking of the interview data, independent coding of the data by two researchers of at least 20 percent of the data, triangulation of the results across participant groups (managers, treating health professionals, parent and child participants) and using field notes, and reflective journaling. Microsoft excel (version 16, Microsoft Corporation) and NVivo (version 10, QSR International, Doncaster, Victoria, Australia [45]) will be used to organise and code the data.

Electronic platform

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

Patient and public involvement

Children aged 8 years and older with life-altering skin conditions, parents 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 parents 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 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, parents, 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 [46]. More specifically, the current study will seek to understand how the inner setting of the organisation (i.e., organisational culture and structural characteristics) impacts on implementation which has been identified as a research gap [10].

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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Author contributions

ZT designed the study with input from SM and RW 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 5242

STUDY PERIOD				
	Enrolment	**Allocation**	***Post-allocation***	
TIMEPOINT	***-t_1***	**0 Baseline***	***t_1 3-months post-baseline***	***t_2 6-months post-baseline***
ENROLMENT:				
Eligibility screen	X			
Informed consent	X	X		
Allocation		X		
INTERVENTIONS:				
PEDS-ePROM		♦—	—	—♦
ePROM		♦—	—	—♦
EVALUATIONS:				
Sociodemographic details		X		
Clinical characteristics		X		
PEDS-QL (Infant & generic scales)		X	X	X
Brisbane Burn Scar Impact Profile*		X	X	X
CARe Burn Scales*		X	X	X
Haemangioma Family Burden Questionnaire***		X	X	X
Infantile Haemangioma Quality-of-Life Instrument**		X	X	X
Satisfaction with treatment			X	X
Referrals			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-	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:

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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11. Wiseman J, Ware RS, Simons M, et al. Effectiveness of topical silicone gel and pressure garment therapy for burn scar prevention and management in children: a randomized controlled trial. *Clin Rehabil* 2019;**34**(1):120-31.

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 SPIRITreporting 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

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	
Funding	#4	Sources and types of financial, material, and other support	28
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	28
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	28
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team,	3, 21

		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

		sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	13,14
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	11, 16
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9,10
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is	14-19

		strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11, 14
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially	12

mechanism		numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	23
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the	Supplementary file 1, 14,15, 17-19

		protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11, 21
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16, 20
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring:	#21a	Composition of data monitoring committee (DMC);	n/a

formal committee		summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	24,15
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	3, 24
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg,	

		investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	13, 14, 24
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	28
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	28
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	28
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via	24

		publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	28
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a