


Development of a longitudinal multicentre cohort of children with small area scalds: a feasibility study.

LOOP 

Long-term Outcomes Of Paediatric Scalds

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Executive summary

Background:

Scalds are the most common type of thermal injury in children. These injuries are painful, and carry a risk of lifelong scarring, with associated physical, psychological consequences and long-term healthcare requirements.

Risk factors for scarring are poorly understood and there is variability in scarring in children with small area scalds. Scar formation is likely to have genetic determinants. A better understanding of the role of genetic factors would enable personalised patient management in burns care.

There is currently little information on how scarring affects psychosocial outcomes in children and their carers over time. A greater level of knowledge would mean that appropriate support could be offered to those who were most likely to be affected.

Aims:

- To determine the feasibility of undertaking a longitudinal burn cohort study to assess the impact of genetic make-up on long-term scarring in children of less than or equal to five years of age with small area scalds (Body Surface Area (BSA) < 10%) in England and Wales.
- To increase understanding of how to predict risk factors for poor psychosocial adjustment amongst young children and parents after small area burn injuries.

Methods: This was a mixed methods project incorporating systematic literature reviews, qualitative analysis of interviews and workshops with parents of children with burns, quantitative data analysis of routinely collected data in burn services, on-site audit, and working collaboratively with a range of stakeholders including health professionals, researchers and charity representatives.

Work package 1: Clinical stakeholder involvement

The aim of this work package was to ensure that the work undertaken and plans for a future cohort study were relevant and of high quality. A steering group comprising researchers, multidisciplinary health professionals and charity representatives met three times during the project to monitor progress and adherence to the study aims and advise on all aspects of the study design. We also worked closely with the Cleft Collective, conducting a similar study in children with cleft palate.

Work package 2: Parent involvement

This work package aimed to involve and engage with parents of children who experienced a burn. Interviews and workshops were conducted with parents of children who had a small area scald when they were under 6 years old. Parents gave feedback on the study aims, inclusion criteria, timing and methods of recruitment, methods of DNA sampling, strategies for retaining participants, inputted into the design of a parent information sheet and advised on the study name and choice of logo.

Parent information sheet: A draft information sheet for parents of eligible participants for a future pilot or full cohort study was developed.

Work package 3: Literature review and international collaborations

A scoping review of the methodology used in studies of genetic influence on the development of keloid scarring in children and adults after acute wounding identified nine studies, five of which were conducted in burns. The review informed our recommendations about the design of a future

cohort study – a prospective cohort design, recruiting a large sample of ethnically diverse participants and following them up for at least 12 months.

Work package 4: Outcomes

This package of work aimed to agree the primary (scar quality) and secondary outcomes for the study including measurement tools and timepoints. The work undertaken included systematic reviews - the frequency of use and content of scar quality scales; the proportion of children with scalds who develop scarring; psychosocial outcomes in patients and carers. A health economist was also consulted with regards to costs and any other economic outcomes. The POSAS tool was identified as the most suitable tool to assess scarring (with some possible adaptation for use with children) with follow up at standard NHS timepoints for at least two years. The CARE Burn Scales were chosen as the most suitable measure of burn-specific health-related quality of life.

Recruitment: The work undertaken regarding recruitment cut across the other work programmes. It aimed to explore the likely number of participants that could be recruited into a longitudinal cohort study for children with small area scalds. It involved audit of the number of children presenting to two sites, a literature review of the numbers of children who experience scarring after a scald, an analysis of scar clinic data and a national audit. A total of 2,189 children meeting the study eligibility criteria were seen in UK burns clinics over a 12 month period and approximately 17% of these children would be expected to develop scarring.

Work package 5: Data collection forms were developed for the future study.



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Work package 6: Principles for a full study

Principles for the full study were developed based on the work carried out and agreed with the steering group and input from the parent involvement group.

- *Study design:* prospective longitudinal cohort study with length of follow up of a minimum of two years
- *Population:* children under six years of age, who experienced a scald of <10% BSA including a range of different ethnicities and skin types.
- *Outcomes:* Scar quality assessed by the POSAS 2.0. Burn specific health-related quality of life assessed by the CARE Burn Scales.
- *Time points:* six weeks, three months, six months, one year and annually thereafter.
- *Other data to be collected:* age at time of burn, sex, %BSA, ethnicity, burn location on body, number of surgical procedures, wound infections, use of scar management treatments.

Table of abbreviations

Abbreviation	Definition
E&W	England and Wales
PI	Parent Involvement
SSG	Study steering group
COSB	Core Outcome Set for Burn care research
PROM	Patient Reported Outcome Measure
CAR	Centre for Appearance Research
HES	Hospital Episode Statistics
ALSPAC	Avon Longitudinal Study of Parents and Children
iBID	International Burn Injury Database
BOSS	Burns Objective Scar Scale
HCP	Health care professional
CARe Burns Scales	Suite of self-report burn specific patient reported outcome measures
WP	Work package
PPI	Parent Involvement
%BSA	Percentage Body Surface Area (size of burn)

Background

Children account for approximately half of all burns and scalds seen in European hospitals^{1,2}, with scalds being the most common type of thermal injury³. These injuries are painful, and carry a risk of lifelong scarring, with associated physical, psychological consequences and long-term healthcare requirements.

The incidence of scarring after burn injury has been estimated at between 32% and 72%⁴. Risk factors for scarring are poorly understood. It is known that burn size, a healing time longer than 14 days, and a requirement for multiple operations are independently associated with poor quality scarring⁵. However, children with small area scalds without these risk factors still scar differently⁶⁻¹¹. It is difficult to predict which burn wound will result in hypertrophic scarring and therefore preventive measures such as pressure therapy, splinting and silicones have become routine practice for all deep, extended-healing burns in most burn services. This results in potentially unnecessary treatment and hospital visits for families and costs to the NHS⁷.

Scar formation is likely to have genetic determinants⁶⁻¹². A deeper understanding of how scarring quality is influenced by genetic (and environmental) factors would enable personalised patient management in burn care. To increase knowledge about the link between genetic and other risk factors for poor scarring after burn injury, a longitudinal study is needed that follows up a cohort of patients with similar-type burns over time to determine scarring outcomes with standardised data collection on potential risk factors of interest.

Scarring, and interventions aiming to reduce scarring, can be very challenging for those affected, and are known to impact on quality of life in children¹³⁻¹⁶. A burn injury often also has a significant impact on their parents/carers^{17,18} who are usually the injured child's main source of support. However, there is currently little information on how scarring affects psychosocial outcomes in children, and their parents, over time¹⁰, and what factors influence their adjustment post-burn. This knowledge would allow appropriate and targeted support to be offered to those who are negatively affected.

This grant from the Scar Free Foundation has allowed us to determine the need for, the principles and practicality of a future cohort study of genetic and other risk factors for poor scarring and to examine the psychosocial impact of scarring over time in children with small area scalds.

Aims and objectives

The project had two *aims*:

1. To determine the feasibility of undertaking a full longitudinal burn cohort study to assess the impact of genetic make-up on long-term scarring in children of less than or equal to five years with small area scalds (Body Surface Area (BSA) < 10%) across England and Wales.
2. To increase understanding of how to predict risk factors for poor psychosocial adjustment amongst young children and parents after the same small area scald injuries.

The specific *objectives* were as follows (modified from the application form after discussion with study team, steering group and review of the literature):

1. *Learning*:

- a. Assess published work on a) burn cohort studies of the effect of DNA on scar quality in children and b) longitudinal assessment of psychosocial adjustment to burn scars in young children and their parents/carers, through systematic/literature reviews.
 - b. Engage with researchers involved with the set up and running of the Cleft Collective feasibility and cohort studies, to learn more about their experiences of using parent involvement (PI), in terms of patient literature design, approaching families, recruitment and management of taking and storage of biological samples.
2. *Acceptability:*
 - a. Answer the question: can we recruit eligible patients/parents?
 - b. Work with parents and carers to determine the acceptability of a longitudinal cohort study following up young children with small area scalds.
 - c. Work with parents and carers to determine the recruitment and retention strategy.
 - d. Understand the acceptability of bio-sample collection to families of burned children.
 - e. Work with multidisciplinary health care professionals (HCPs) who have undertaken similar work to understand barriers to recruitment and to collecting the biological samples.
 3. *Recruitment numbers:*
 - a. Agree eligibility criteria for participants through clinical discussion and the literature.
 - b. Gain estimates for potential sample sizes
 - i. Work with the national burn database (iBID) to understand admission numbers across services in England and Wales (E&W).
 - ii. Undertake PI (Parent Involvement) work to understand potential sample sizes.
 - c. Undertake PI work to assess potential barriers to recruitment.
 - d. Understand how to achieve on-going engagement of families to ensure longer-term follow-up and parent/child retention.
 4. *Evaluation and Refinement of Data Collection Procedures and Outcome Measures:*
 - a. Agree outcomes and outcome measures for a full study.
 - b. Understand whether the outcome measures will be appropriate for the study population.
 - c. Agree methods and timing for assessing scarring, psychosocial adjustment, measures for evaluating health economic outcomes, and to support intervention usage.
 5. *Practicality:*
 - a. Design data collection forms' planning, including data on clinical interventions (acute and longer-term), interventional compliance, adverse events and environmental factors that may impact on scar quality.
 - b. Assess time needed to discuss the study with and consent families.
 - c. Understand the ability of participants or parents to complete the outcome measures.
 - d. Understand the feasibility of biological sample collection.
 6. *Implementation:*
 - a. To achieve "buy-in" for a full cohort study from the multidisciplinary burn community.
 - b. Identify potential members of an on-going PI group.
 - c. Make plans for future funding of a longitudinal cohort study.

Methods used and structure of the report

A range of methods have been used within the project including literature reviews, qualitative analysis of interviews and workshops with parents of children with burns, quantitative data analysis of routinely collected data in burn services, on-site audit, and working collaboratively with a range of stakeholders including international health professionals, researchers and charity representatives.

The remainder of the report is organised into themes, each of which relates to a package of work carried out. The aims of each package are described together with further details of the methodology used and the main findings and conclusions.

Work package 1: Clinical stakeholder involvement

The aim of this programme was to ensure that the work undertaken and the resulting plans for a future cohort study were relevant and of high quality through regular engagement with a broad range of relevant multidisciplinary clinical stakeholders throughout the duration of the project.

A steering group was convened at the start of the project comprising researchers, burn surgeons, physiotherapist, paediatric clinical psychologist, senior burns research nurse and a representative of the Children's Burns Trust. The steering group was led by an independent chair (Mr D Collins, consultant burns surgeon, Chelsea and Westminster Hospital NHS Foundation Trust). The role of the steering group was to ensure adherence (or agree the reasons for non-adherence) to the study protocol, monitor progress of the study, consider the safety and confidentiality of study participants and advise on all aspects of the study and design of the future cohort study as a 'critical friend'. Three meetings of the steering were held (February, June and October 2021). A full list of the steering group members can be found in Appendix 1.

The work for the project involved a number of discussions with the Cleft Collective (School of Oral and Dental Sciences, University of Bristol) whose research programme includes longitudinal cohort studies of children and families affected by a cleft of the lip and/or palate. Genetic and psychological information is being collected as part of these studies. A member of the Cleft Collective was on the steering group. We had regular contact with the team (via email and a meeting in December 2021) who shared their experiences with us on the content of the parent information sheet, collection of DNA samples, recruitment and retention of families and potential funding sources for a future cohort study.

Work package 2: Parent Involvement

This programme of work aimed to involve and engage with parents of children who had previously experienced a burn. We invited feedback on the research team's proposals including the research question, study inclusion criteria, data collection methods, study materials and recruitment methods, and invited suggestions for the study name and logo. We gathered this information through a series of individual interviews and small group workshops. Given the ongoing challenges presented by the COVID pandemic, all PI work during the feasibility study took place remotely (via telephone, Microsoft Teams, according to University regulations and PI members' preferences).

Specifically, we invited parents/carers of children with burn injuries who had previously taken part in research conducted by members of the Centre for Appearance Research (CAR) and had expressed an interest in receiving information about future burns-related research being carried out by CAR members. Approximately 80 adults were identified from this existing database and contacted via phone or email, depending on the preference specified when taking part in previous research. In addition, organisations working to support children with burn injuries, and their parents, (e.g.

Children's Burns Trust) promoted the opportunity to be involved in this work. Those who were potentially interested in being involved were invited to contact the researchers for more information. Given the potentially sensitive and emotive issues around their experiences of their child's injury and its consequences, PI work with parents initially involved individual interviews (conducted by the Research Fellow, Pippa Tollow).

Individual interviews were conducted with 16 parents (15 female and one male) of children who had a small area scald when they were under six years of age. Mean participant age was 35.5 years (range 24-46 years) and the mean child age at the time of injury was two years (range 9 months – 4 years).

Semi-structured interviews were guided by an interview schedule including initial questions about the participant and their child's experience of treatment and support relating to the burn. The researcher then gave the participant further information about the proposed 'burns cohort study', followed by questions relating to the parent's attitudes towards these research topics, appropriate timing to approach parents about research, barriers and facilitators to taking part in research, and their attitudes towards specific elements of the proposed study design (e.g., frequency of follow-up). Interviews were conducted via telephone or video, audio recorded and transcribed verbatim. The transcripts were analysed using Reflexive Thematic Analysis (Braun & Clarke, 2021) to identify major themes relating to parents' attitudes towards a longitudinal cohort study and factors that might influence their participation. Parents emphasised the importance of researchers acknowledging that the burn may have been traumatic, aligning the research with the burn experience (for example, more frequent participation in the first year following the burn with decreasing participation requirements in subsequent years), that research should be a reciprocal relationship between families and the researchers, and the importance of participants feeling like they are contributing to change. Participants also made suggestions about the timing of recruitment, methods of DNA sampling and the need for clear information about why DNA data was being collected and how it would be stored.

Two workshops were then held with three of the parent interviewees (a fourth parent contributed via one-to-one phone calls due to a lack of internet access). The first workshop involved an introduction to patient/parent involvement (PI), information about the research team, and discussion of how parents' feedback would contribute to this research. The study design was discussed in detail and the parents gave detailed feedback on each element of the study - including suggestions regarding acceptability of the design, practicalities of taking part in research, and maximising participant recruitment and retention. In the second workshop, the Patient Information Sheet (PIS) was considered, and potential logos/acronyms (including feedback on the researcher-suggested 'burn code' logo/acronym) were discussed. Parents were satisfied with suggested outcome assessment time points for the study and indicated that they would prefer to complete all questionnaires online or via post rather than having to make extra hospital visits to do so. They also suggested that regular contact with study participants (e.g., through newsletters with study progress and personal contact) was important and would help with participant retention. Clarity around DNA sample storage was also highlighted as being very important. The most popular study name was 'Long-term Outcomes of Paediatric Scalds (LOOPS)'. Parents preferred the logo shown in Figure 1 below. A 'PI Impact Log', was also produced and updated throughout the PI work, containing the full list of recommendations made by parents in the interviews and workshops.

Figure 1. Proposed study logo



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The parents who took part in this work reported finding it a very interesting, engaging and worthwhile activity, and have expressed interest in being involved in future work to support a full cohort study taking place. This might include being involved in preparing future bids for funding, to ensure that future research continues to put the views of parents of children with burns at the centre of all aspects of the research. The team agreed that it would be important to continue to engage regularly with PI representatives as the work towards a full burns cohort study develops.

Parent Information Sheet

As part of the project, a initial draft parent information sheet has been developed which would be used in the future pilot or full cohort study. The content of the form is based on the principles of the future cohort study agreed over the course of the project and developed in consultation with the multi-disciplinary project steering group, the parent involvement group and other relevant organisations and individuals (Cleft Collective and Children's Burns trust).



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Work package 3: Literature reviews and international collaborations

Literature reviews

A scoping review of the methodology used in studies of genetic influences on the development of keloid or hypertrophic scarring in adults and children after acute wounding.

A scoping review (a type of research synthesis that aims to map the literature on a particular topic) was conducted with the aim of identifying and summarizing the volume and methodology used in studies of genetic influences on the development of keloid or hypertrophic scarring in adults or children after acute wounding. The broader population of acute wounds and all ages was chosen as we expected to find very few studies conducted in burns patients and were not aware of any that solely recruited children.

The questions addressed by the review were:

- What types of study design have been used?
- What are the characteristics of participants included in the studies?

- How long have studies followed up participants after the initial wound?
- Which tools have been used to assess scarring?
- What other factors have been considered by studies when modelling the effects of genetic variation on subsequent scarring?
- Has the proposed burn cohort study been undertaken before?

A range of electronic bibliographic databases in medicine and biology were searched to April 2020 (Medline, EMBASE, Web of Science, BIOSIS, PROSPERO, The HuGE Navigator (database of genetic association studies) and the GWAS Catalogue, which captures genome-wide association studies (GWAS) using search terms for keloid and hypertrophic scarring combined with terms for genetics. Studies eligible for inclusion were cohort studies (prospective or retrospective) and case control studies that examined the association between one or more genetic variations and the development of keloid or hypertrophic scarring in patients of any age or race and after any type of acute wound.

Nine studies were identified that were eligible for inclusion, five of which recruited patients with burns and four with surgical wounds. All were published between 2012 and 2019. No other acute wound studies were identified that met the inclusion criteria. The characteristics of included studies are shown in Table 1.

Table 1. Characteristics of studies included in the scoping review

	Sood 2015a²⁴	Sood 2015b²³	Sood 2016²²	Thompson 2013²⁵	Wallace 2019²⁶	Gao 2014²⁷	Ilies 2019²⁸	Kulawczuk 2014²⁹	Ward 2012³⁰
Study Design	Cohort	Cohort	Cohort	Cohort	Cohort	Cohort	Nested case control	Case control	Cohort
Country	USA	USA	USA	USA	Australia and UK	China	Romania	Poland	Australia
Dates	2007-14	2007-13	2007-14	-	-	-	-	2009-12	2007-8
Number of Centres	Single	Single	Single	-	Multicentre	Single	Single	Single	Multicentre
Study Type	Candidate gene association	GWAS	Candidate gene association	Candidate gene association	EWAS	Candidate gene association	Candidate gene association	Candidate gene association	Candidate gene association
Polymorphism(s) investigated	8 MC1R SNPs	Genome wide	2146 MAPK-pathway SNPs	rs36228499 in the p27kip1 gene	Exome wide	p53 codon-72 SNPs	null alleles of the isoforms GSTT1 and GSTM1	C(-509)T in the promoter region of the TGF-β1 gene (rs1800469)	rs8110090 in TGFbeta1
Population	Burns	Burns	Burns	Burns	Burns	Surgical wounds	Surgical wounds	Surgical wounds	Surgical wounds
Inclusion Criteria	Adults ≥18 with DPT burns or delayed healing ≥ 2 w	Adults ≥18 with DPT burns or delayed healing ≥ 2 w	Adults ≥18 with DPT burns or delayed healing ≥ 2 w	Adults ≥18 at risk of HTS due to depth and healing time	Adult/Child hospital admission, outpatient treatment or HTS treatment	Caesarean section	Adult >18 Caesarean section with no complications	Cardiac surgery	WA Melanoma Health (population-based) Study participants, adult ≥ 18 with invasive cutaneous melanoma

	Sood 2015a ²⁴	Sood 2015b ²³	Sood 2016 ²²	Thompson 2013 ²⁵	Wallace 2019 ²⁶	Gao 2014 ²⁷	Ilies 2019 ²⁸	Kulawczuk 2014 ²⁹	Ward 2012 ³⁰
Exclusion Criteria	-	-	-	-	>1 acute burn history, treated outside WA, previous keloid	Pathological scar or tumours	Unable to followup, incision overlaps previous surgery or trauma	-	-
Setting	Burns centre	Burns centre	Burns centre	-	Outpatient clinics, burn wards	Hospital	Gynaecology clinic	-	-
Outcome Assessed	HTS	HTS	HTS	HTS	HTS	HTS, keloids	HTS	Keloids	HTS
Scar assessment tool	VSS	VSS height subscale	VSS	VSS	mVSS	No (clinical assessment)	SCAR and POSAS	VSS	VSS
Length of Follow up	≥6 m	6-12 m	6-12 m ¹	6-12 m	3, 6, 12 m	12-18 m	6 m	- ²	≥6 m
No. included in analyses/enrolled in study	425/568	538/638	538/638	300/Unclear	665/953	260/260	54/72	73/100	202/874
Sample size Calculation?	Yes	Yes	No	Yes (post-hoc)	Yes	No	No	No	No
Adequately powered?	Yes	Yes	-	Yes	Yes	-	-	-	-

HTS = hypertrophic scarring; POSAS = Patient and Observer Scar Assessment Scale¹⁹; SCAR = Scar Cosmesis Assessment and Rating scale²⁰; VSS = Vancouver Scar Scale²¹; mVSS = modified Vancouver Scar Scale.

All five burn wound studies used a prospective cohort design, where participants were recruited at the time of wounding and followed-up to evaluate scarring. All studies aimed to predict hypertrophic scarring (no studies of keloid scarring in burns patients were identified). Three looked at the association of one or more candidate genes with the development of scarring, one was a genome-wide association study²³ and one an exome-wide association study. Inclusion criteria required burn wound participants to be adults (≥ 18 years) in four studies with no age threshold in the fifth. All five studies evaluated scarring using the Vancouver Scar Scale (VSS) but there was variability in how the studies operationalised the tool. The median time of final scar assessment ranged from 6.4 to 10.4 months.

Of the four surgical wound studies, two used a prospective cohort design and two had retrospective case-control designs (where participants were selected for the study based on the presence or absence of scarring). Two studies focused on the role of genetic variation in the development of hypertrophic scarring, one of keloid scarring, and one of both hypertrophic and keloid scarring (although no cases of keloid scarring were detected). All explored the association of one of more candidate genes with the development of scarring. There were no genome wide association studies identified. Participants in all four acute surgical wound studies were ≥ 18 years. Surgery was caesarean section in two studies, cardiac surgery in one study and melanoma excision in the final study. Two of the surgical wound studies assessed scarring using the VSS, another used the patient and observer scar assessment scale (POSAS) and Scar Cosmesis Assessment and Rating (SCAR) Scale. The fourth study did not use a rating scale, instead classifying scars as normal, hypertrophic or keloid based on defined clinical features. Length of follow up was six months in one study, 12-18 months in a second, a mean of 13 months in the third study and unclear in the final study.

Other risk factors considered by studies included age and sex of patients, size and location of the burn, ethnicity, time to healing, infections, other medical conditions, body mass index (BMI), number of surgical procedures and use of scar management techniques.

Several methodological weaknesses were observed across the body of evidence included in the review. Few studies reported a sample size calculation. Most genes contributing to complex disorders are associated with only a very modest increase in disease risk, and so large samples are needed to detect these with sufficient power. The sample sizes in the identified studies tended to be small and several studies had a high proportion of missing data (participants could not be included in the analyses due to missing genetic or scar quality data). Most studies had only a short length of follow up that did not allow scars to fully mature (only one study clearly reported that all participants had been followed up for at least a year). Finally, a lack of ethnic diversity was observed amongst study participants; more than three quarters of included participants were white in five of the six studies that reported information about race.

Based on this review, several **recommendations about the design of a future study** were made. Such a study should use a prospective cohort design, recruit a large sample of participants from ethnically diverse populations and follow up participants for at least twelve months. The systematic review was published in the Journal *Advances in Wound Care* in July 2021²².

Other literature reviews

Four other literature reviews were carried out as part of the project and are described in further detail in other sections of this report:

- Review of psychosocial outcomes used in longitudinal studies of young children with burns and their parents (described under 'Work package 4: Outcomes').

- Review of scales commonly used to assess scar quality and their content (described under ‘Work package 4: Outcomes’).
- Review of the length of time that burn scars take to mature (described under ‘Work package 4: Outcomes’).
- Review of the proportion of children with a scald who develop a scar (described under ‘Work package 4: Outcomes’).

Work package 4: Outcomes

This programme of work aimed to agree the primary (scar quality) and secondary outcomes for the study, including measurement tools and timepoints.

Review of scales commonly used to assess scar quality and their content

A recently published systematic review of the content of commonly used scar quality assessment tools was identified and relevant information extracted from it²³. The aims of the review were:

1. To provide an overview of the content of outcome measurement instruments that measure scar quality in different types of scars (burns, surgical, keloid and necrotising fasciitis)
2. To determine the frequency with which instruments and included items are used.

The electronic bibliographic databases PubMed and EMBASE were searched to October 2018. Any study that used or reported a scar quality outcome measurement instrument was eligible for inclusion. Scar quality measurement tools were those that measured at least one characteristic of scar quality and defined how the characteristic(s) were quantified.

440 studies met the inclusion criteria in the above Carriere review. The majority (88%) were studies in which the outcome measurement instruments were used to clinically evaluate patients. Clinometric studies (those that look at measurement properties of a scale, such as its reliability or validity) accounted for seven percent of studies. 160 studies (36%) were in burns patients. Only 30 (7%) studies focused only on children (49% of studies were in adults and 33% in mixed age groups).

The majority of tools used in the studies were clinician-rated (59% of instances of tool use). Patient-reported scales were used 37% of the time and combined tools, in 4% of cases. The most frequently used clinician-reported tools were the POSAS observer-scale (versions 1 or 2) and the VSS. The most frequently used patient-reported tools were the POSAS patient-scale, the Burn Specific Health Scale-brief and the Appearance scale of the Patient Scar Assessment Questionnaire/Dermatology Life Quality Index/ University of North Carolina “4P” Scar Scale (the latter two scales were only used on a small number of occasions). Combined tools were rarely used, but the most frequent versions were modified versions of the VSS and the Kyoto Scar Scale.

Table 2 shows the five most frequently included items (and their order) for all three types of scale. The most frequently included items in clinician-reported scar scales are thickness, pigmentation, vascularity, pliability and surface irregularity. Patient-reported tools commonly include items to assess sensory characteristics of the scar such as pain and itch. The heterogeneity in the content of instruments that measure the same construct (scar quality) identified by this review suggests that there is a lack of consensus among patients, clinicians, and researchers on the most important characteristics of scar quality (Tables 2-5).

Table 2. Content of most frequently used observer-rated scales

	Vascularity / Redness	Pigmentation	Thickness / Elevation / Height	Relief / Surface irregularities	Pliability / Texture	Distortion / Surface area
POSAS, observer scale	X	X	X	X	X	
POSAS, observer scale 2	X	X	X	X	X	X
VSS	X	X	X		X	

Table 3. Content of most frequently used patient-rated scales

	Vascularity / Redness	Pigmentation	Colour	Thickness	Relief / Wrinkled / Lumpy	Texture / Roughness	Pliability / Stiffness	Shiny	Pain	Itch	Stinging	(Hyper)sensitivity	Discomfort	Sensitive for temperature
BSHS-b												X		X
DLQI									X	X	X		X	
POSAS, patient Scale			X	X	X		X		X	X				
PSAQ, appearance	X	X	X	X	X	X		X						

Table 4. Content of most frequently used combination scales

	Redness/vascularity	Pigmentation	Thickness/Elevation/Height	Palpability	Itch	Pain
Kyoto scar Scale	X		X	X		
mVSS (Nedelec)	X	X	X	X	X	X
mVSS(Olivera)	X	X	X	X	X	X

Table 5. Five most frequently included items in different types of outcome measurement instruments

Type of instrument	Order of most frequently assessed items				
	First	Second	Third	Fourth	Fifth
Clinician-reported	Thickness	Pigmentation	Vascularity	Pliability	Surface irregularity
Patient-reported	Pain	Itch	Colour	Thickness	Pliability
Combination	Vascularity	Thickness	Itch	Pliability	Pain

Review of the length of time that burn scars take to mature

A systematic review was conducted by the study team of studies that report the length of time that burn scars take to mature. The purpose of the review was to determine the length of follow up needed in the future cohort study.

We searched two electronic databases (Medline and Embase) to May 2021. To be included in the review, studies had to be in acute thermal burns, have a follow up period of a minimum of six months and describe the progression of burn scars over time, with a minimum of two measurements of scar quality using a validated scale. Studies could be prospective or retrospective.

Twenty-three studies were identified as suitable for inclusion. Only two studies were identified that followed up participants until wound maturity, one in adults and one in children and both with patients with medium sized burns (10-40% BSA). Average time to scar maturation ranged from 8 to 12.4 months across the cohorts included in the studies, although some scars took considerably longer than this (with a maximum of 19 months). Further details of these studies can be found in Table 6.

Twenty-one studies were identified that reported the results of scar assessments at two or more time points. Results were usually expressed as an average (mean or median) scar quality score for the cohort of participants at each timepoint. A statistically significant difference in scar quality between two time points would suggest that, on average, scars are still maturing at the earlier timepoint. Very few of these studies followed up participants beyond 12 months. Findings were very heterogeneous with some studies finding evidence of scar maturation beyond a 3, 6 or 12-month time point and others providing no evidence of a difference. For studies in patients with smaller burns (<10% TBSA) the evidence of changes in scar quality beyond 3 and 6 months was mixed. Studies of larger burns (10-40% or >40%) were more likely to show evidence of continuing scar maturation beyond these time points. There was also evidence for changes beyond 12 months in studies where participants had greater than 40% TBSA. Further details of these studies can be found in Table 7.

The conclusions of the review are limited by the evidence identified. Only two studies directly addressed the question. Most of the evidence identified merely enabled a comparison of average scar scores at two different time points (Table 7). Sample sizes were small in many of the included studies and there were often large amounts of missing data, meaning that many studies were likely to be underpowered to detect a difference. Change was inferred from statistically significant differences in average scar scores, which obscures individual differences in scar maturation. The large number of participants lost to follow up may have also introduced bias into the results (e.g., if participants who were more satisfied with their scars did not attend follow up appointments).

Our findings highlight the need for further longitudinal cohort studies to assess time to scar maturation following thermal burns. Future studies should recruit a large cohort of participants and follow up participants for at least two years and until all scars are mature incorporating regular assessments of scarring using validated methods of assessment.

Table 6: Characteristics of two studies that measured time to scar maturation

Study details	Participants	Details of burn	Interventions/treatments received	Results reported
<p>Name: Chang 1995</p> <p>Study dates: 01/06/1991 - 01/06/1993</p> <p>Number enrolled: (n=105)</p> <p>Study aim: To determine the influence of pressure garment therapy on the rate of burn wound maturation</p>	<p>Inclusion: All patients admitted with burns whose wounds required more than 14 days to close or who required grafting for closure.</p> <p>Exclusion: Burns involving the face and hands</p> <p>Age group: Adults</p> <p>Age: 31 +/- 2.4 yrs (PGT group), 26 +/- 2.06 (non-PGT group)</p> <p>Male/Female: 80% male (PGT group), 88% male (non-PGT group)</p> <p>Ethnicity: Not reported</p>	<p>Cause of burn: Unclear</p> <p>Depth of burn: Unclear</p> <p>TBSA %: 21.7 +/- 2.2 (PGT group), 19.1 +/- 1.8 (NPGT group)</p> <p>Requirement for surgery: Yes (most, however exact numbers not reported)</p>	<p>Interventions received as part of study: Pressure garment therapy</p> <p>Other treatments received: Grafting, pressure therapy in 64/122 patients</p> <p>Complications: None mentioned</p>	<p>Definition of scar maturation: Wounds were considered mature when less than 10% of the entire wound area exhibited scar hypertrophy or hyperaemia</p> <p>Method of assessment: VSS</p> <p>Timing of assessment: 267 days (PGT group), 273 (non-PGT group)</p> <p>Results: Group 1: mean 242.5±140, median 266 days Group 2: mean 265.7 ±137.8, median 273 days</p>
<p>Name: Schwanholt 1994</p> <p>Study dates: Aug-90 - Mar-92</p> <p>Number enrolled: (n=63)</p>	<p>Inclusion: paediatric patients aged 6 months to 16 years who received sheet skin grafts on extremities</p> <p>Exclusion: n.r.</p> <p>Age group: Paediatric</p>	<p>Cause of burn: Unclear</p> <p>Depth of burn: Unclear</p> <p>TBSA %: Mean (range): 0-3 yrs 21% (3-39%), 4-11 years</p>	<p>Interventions received as part of study: None (looking at scarring in 3 different age categories: 1) 0-3 years old, 2) 4-11 years old, 3) 12-18 years old)</p> <p>Other treatments received: Early excision, sheet grafting, dressings and pressure garments</p>	<p>Comments on scar maturation: The time when erythema diminished to normal, and the sheet graft was as flat and pliable as normal skin. For completion of the study a score of zero ad to be obtained on each assessment area at two consecutive visits.</p>

<p>Study aim: To examine variance in burn scar maturation among different paediatric groups.</p>	<p>Age: 0-3 years, n=21; 4-11 years n=9, 12-18 years n=14 (based on those completing the study)</p> <p>Male/Female: Not reported</p> <p>Ethnicity: Not reported</p>	<p>16% (5-27%), 12-18 years 21% (2.5-44%)</p> <p>Requirement for surgery: Yes (all) - nb: sheet grafts not meshed grafts</p>	<p>Complications: None mentioned</p>	<p>Method of assessment: Modified VSS, graft height, pliability and vascularity</p> <p>Timing of assessment: Evaluated every 1-3 months until scar maturity. Range from 6 to 19 months.</p> <p>Results: Mean +/- SEM 1) 10.60 +/- 0.96 months, 2) 12.44 +/- 1.28 months, 3) 9.32 +/- 1,16 months (followed up until scar maturation)</p>
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Table 7: Summary of studies that compared scar quality at two time points

Study name	n	Age group	TBSA category	Scar scale(s)	Time comparison	Evidence of a change in scar quality
Change in scar quality beyond 3 months:						
Gee Kee (2016)	43	Paediatric	<10%	POSAS	3 months versus 6 months	No
Rashaan (2017)	21	Paediatric	<10%	POSAS	3 months versus 6 months	Mixed results
Bloemen (2012)	86	Adults	<10%	POSAS	3 months versus 12 months	Mixed result
Goei (2017)	180	Mixed	<10%	POSAS	3 months versus >18 months	Yes
Isaac (2016)	44	Adults	10-40%	VSS	3 months versus 12 months	Yes
Lagus (2013)	10	Adults	10-40%	VSS	3 months versus 12 months	Unclear
Sood (2015)	10	Adults	10-40%	mVSS	3 months versus 12 months	Mixed results
Zakine (2012)	15	Adults	10-40%	VSS	3 months versus 12 months	Yes
Change in scar quality beyond 6 months:						
Gorga (1999)	248	Paediatric	<10%	VSS	6 months versus 12 months	No
Karlsson (2020)	39	Paediatric	<10%	VSS, POSAS	6 months versus 12 months	Yes
Noordenbos (1999)	28	Mixed	<10%	VSS	6 months versus 12 months	No
van der Wal (2012)	474	Mixed	<10%	POSAS	6 months versus 12 months	Yes
Jarrett (2008)	86	Adults	10-40%	MAPS	6 months versus 12 months	Yes
Li (2015)	60	Mixed	10-40%	VSS	6 months versus 30 months	Yes
Akita (2017)	8	Adults	>40%	VSS and MSS	6 months versus 12 months	Yes
Herndon (2018)	226	Paediatric	>40%	mVSS	6 months versus 12 months	Mixed
Change in scar quality beyond 12 months:						
Yim (2011)	32	Mixed	>40%	VSS	6 months versus 12 months	Yes
Branski (2007)	20	Paediatric	>40%	Hamilton Scale	12 months versus 18-24 months	No
Oliveira (2005)	62	Paediatric	>40%	mVSS	12 versus 18-24 months	Unclear
Barret (1999)	94	Paediatric	>40%	SSS	12 months versus 2 year versus 4 years	12 months Yes 2 years Unclear
Steinstraesser (2011)	43	Adults	not reported	mVSS	12 versus 18 months	No

Review of psychosocial outcomes used in longitudinal studies of young children with burns and their parents

A literature review exploring longitudinal studies of psychosocial outcomes in children with burns was carried out. This review aimed to identify what psychosocial outcome measures have been used, and what burn-specific measures would be suitable for a future cohort study. A recent systematic review of quality of life in children after burn injuries published by Spronk et al (2018)²⁴ identified 27 studies, including 9 longitudinal studies of health related quality of life in children under 18 years of age. This review found that all longitudinal studies suggested improvement of health-related quality of life (HRQL) over time, but problems were reported in the longer term on the domains of “(parental) concern” and “appearance”. The review noted the relatively low number of studies exploring HRQL in children after burns (especially under 4 years).

Our review found a dearth of relevant published studies since this systematic review. We conclude that few studies have explored parental wellbeing, and those that have been conducted are often cross-sectional or focus on extreme distress/post-traumatic stress disorder (PTSD) (an issue that our PI work, described above, identified as being an important element of parents’ experiences). Previous studies explored predictors of child HRQL, with the focus on burn characteristics, comorbidities and demographics). There has been very little exploration of predictors of parental wellbeing or psychological predictors of child HRQL.

Regarding outcome measures, a systematic review of health-related quality of life measures was published by Legemate et al (2020)²⁵, and Griffiths et al (2015)²⁶ published a systematic review of outcome measures used in child and adolescent burns research. We presented three burn specific health-related quality of life tools that were developed for use in child research to the study steering group. The consensus was that the CARE Burn Scales should be used in the future cohort study. These include a parent-report measure to assess outcomes for children under eight years of age, and a measure to assess parents’ own wellbeing and outcomes. The full set of CARE Burn Scales include measures for young people (aged 8-17 years) and adults, meaning that appropriate measures are available to be used throughout any long-term data collection within a future cohort study. The CARE Burn Scales were developed and are used within UK burn care services. They are the most commonly used tool in the UK currently and are also recommended by the British Burns Association (BBA). This tool was also discussed by the PI group who felt that all of the questions were relevant and that it would not be a burden to complete.

The proposed research questions for psychosocial research within a full cohort study are:

- How do children's and parents’ wellbeing change over time after a scald?
- What factors predict children’s and parents’ wellbeing after a scald?

In addition to the CARE Burn Scale measures of child and parent wellbeing (which would be the main outcomes measures), we would also collect data on non-burn-specific aspects of child (PedsQL) and parental well-being (stress, parenting difficulty, mood) and predictors of psychosocial adjustment (e.g. support, psychological flexibility, fear of negative evaluation).

Health Economic outcomes

Discussions with the health economics team at the University of Bristol (J. Thorn), covered plans for a full longitudinal cohort study. This would include the following: to estimate the cost of care, we would collect data on the resources needed for patients to pass through each of the different burn care pathways, from the perspectives of the NHS (e.g. surgery, medication), the patients themselves or their parents/carers (e.g. travel to appointments), and society (e.g. productivity losses from parents altering work patterns). Data would be collected using clinic records where possible, and from parents via proxy self-report questionnaires.

Summary

Following discussion with the project steering group, the consensus was that the **Patient and Observer Scar Assessment Scales version 2 (POSAS v2)** are most suitable to assess scar outcomes in the future cohort study. The literature supports their use and these are the tools that are most commonly used in practice and show good correlation with cutometer scores (an objective method of measuring scar quality). However, the POSAS tool may require some adaption for use as there is not a parent-reported version available.

The findings of the review of scar maturation studies indicate that a high quality prospective longitudinal study of scar maturation is needed. Following discussion with the steering group and the above literature review, the consensus was that **follow-up should ideally be at least two years**. The group decided that a future cohort study should use NHS timepoints for follow up (six weeks, three months, one year and annually thereafter as dictated by clinical need) and maintain patient follow-up for as long as possible (but at least two years).

Very few studies of health-related quality of life in children after burns exist, especially for very young children. There has also been limited exploration of parental well-being for children with these injuries. The consensus of the steering group was that the **CARe Burn Scales** should be used in the future cohort study. Further evidence of the psychometric properties and responsiveness of the CARe Burn Scales (child (parent-report), young person and parent forms) has recently been published (Griffiths et al, 2021)²⁷. This is commonly used in the UK currently and is recommended by the British Burns Association (BBA). This tool was also discussed by the PI group who felt that all of the questions were relevant and that it would be acceptable to complete.

Recruitment

The work carried out around recruitment cut across the other work programmes, but is reported as a separate topic in this report for ease of reading. The work aimed to explore the likely number of participants that could be recruited into a longitudinal cohort study for children with small area scalds. We sought to determine:

1. The numbers of children under six years of age who present with scalds of < 10% BSA.
2. The proportion of these children who are likely to develop scarring.
3. The proportion of presenting children/families who would consent to taking part.

Numbers of children under six years of age who present with scalds

To quantify the number of eligible children/families, data was obtained from the International Burn Injury Database (iBID) for two potential study sites (Bristol Royal Hospital for Children and Alder Hey Children's Hospital, Liverpool). Data included the numbers of children presenting with burns in

March-April 2021 and numbers of these who were under six years old and had experienced a scald of <10% BSA who presented on a week day during office hours (when recruitment would be more likely to take place).

The results both audits are shown in table 8 below.

Table 8. Results of audits of eligible children at Alder Hey Children’s Hospital and Bristol Royal Hospital for Children

	Alder Hey	Bristol
Total no.	25	68
Age in months (mean, s.d.)	20.8 (s.d. 15.5)	mean 25.7 (s.d. 14.8)
Age in months (Range)	1 to 60	2.2 to 70.1
Male	15 (60%)	35 (51.5%)
Female	10 (40%)	33 (48.5%)
Ethnicity	White British 18 (72%); White other 2 (8%); Black African 1 (4%); Chinese 1 (4%); White and Black African 1 (4%); Any other ethnic group 2 (8%)	Not available
TBSA (median and IQR)	2 (1 - 4)	Median 1% (0.5% to 5%)
TBSA range	0.1 - 13%	0.01 to 8.04%
TBSA < 1%	5 (20%)	29 (42.7%)
TBSA 1-5%	16 (64%)	17 (25%)
TBSA 5-10%	3 (12%)	22 (32.4%)
TBSA >10%	1 (4%)	0 (0%)
Seen on a weekday	18 (72%)	47 (69.1%)
Seen during office hours	12 (48%)	43 (63.2 %)

The results would suggest (based on presenting during office hours) that there would be 55 participants meeting the eligibility criteria that could potentially be recruited across the two sites over the two-month period. This would equate to 330 potential participants per year for two sites.

National data was also obtained from the iBID database for the year April 2020 to March 2021. The numbers of children under six years presenting with a small area scald were provided broken down by BSA category and by date of injury (shown in Tables 9 and 10 below).

Table 9. Number of children under six years with a scald broken down by BSA (iBID)

Burn Surface area	Number of children	Percentage
0%	16	0.48
0-0.9%	883	26.6
1-4%	1896	57.13
5-9%	381	11.48
10-14%	56	1.69
15-19%	26	0.78
20-29%	6	0.18
30-39%	1	0.03
70-100%	1	0.03

Not recorded	53	1.6
Total	3319	100

Table 10: Number of children under six years with a scald broken down by day of injury (iBID)

Injury day	Number of children
Mon	421
Tues	456
Wed	497
Thurs	478
Fri	435
Sat	492
Sun	519
Not recorded	21
Grand Total	3319

A total of 3,319 children under six years presented to burns services in England with a scald during the period April 2020 to March 2021. Of these children, 95.7% (3176/3319) had a BSA of less than 10%. It was not possible to obtain the date of presentation and so date of injury was used as a proxy for this (the majority of children with a burn present on the day of their injury). The total number of children injured on a weekday was 2,287. Based on the assumption that 95.7% of these children would have a BSA < 10%, the number of children nationally that would be eligible to participate in the study would be 2,189 per year. Table 11 below details the number of children that presented for each of the years from April 2014 onwards. The annual numbers of children under six years presenting with scalds has remained constant over this period so it would be expected that future years would see similar numbers.

Table 11. Number of children under six presenting with a scar by year (iBID)

Year	Number of children
2014/2015	3152
2015/2016	3051
2016/2017	2994
2017/2018	3194
2018/2019	2971
2019/2020	3248
2020/2021	3319

Proportion of children with scalds who are likely to develop scarring

Two pieces of work were carried out to address this question:

1. A review of the published literature.
2. An analysis of Salisbury burns service iBID and local scar clinic data.

1. Review of the published literature

A literature review was carried out to identify studies that followed-up children who experienced a scald and report the numbers of those patients who experienced scarring. This literature review was done alongside the review of scar maturation studies reported in Work Package 4. A single search of two bibliographic databases (Medline and Embase, searched to May 2021) was carried out to identify studies relevant to either review.

The characteristics of the five studies meeting the inclusion criteria are shown in Table 12, below. Only one study had a prospective design; this was a pilot RCT with a very small sample size (n=13). Four studies were retrospective with a combined total of 722 participants. Three of the five studies reported the number of patients requiring scar management, rather than who had a scar. These numbers may therefore be an underestimate of the actual scarring incidence.

The percentage of children who developed scarring after a scald in the identified studies ranged from 16 – 47%. Participants in the identified studies tended to have larger burns and/or required skin grafting or surgery, so a higher proportion of children who develop a scar might be expected relative to the population of interest in our study (BSA <10%).

Table 12. Characteristics of studies of scarring in children with scalds

Study	Population	TBSA (%)	Age (months)	Outcome
Prospective study				
Wood (2012), Australia n=13 follow-up: 6 months	Children with scald >2% TBSA whose burn anticipated to benefit from surgery.	median 4 (IQR: 3.5–8).	Median 2 yrs 1mo. (IQR: 1 year 3 months to 6 year 11 months), range 8 months to 9 years	VSS scores reported individually for each (range 0 – 9, median 4)
Retrospective studies				
Brans (1994), Netherlands. n=45. Follow-up: 2-5 years	<14 yrs, all treated with allografts	Mean 10.2 (range 3-23)	Mean 23 (range 6-71)	Moderate: 9 (20%) Severe: 12 (27%) No scarring: 24 (53%)
Collin (2006), UK, n=125, follow-up: n.r.	<16 yrs, bathwater scalds. 14.4% required grafts	Mean 9.3, (s.d. 9.15, range 0.5 to 45)	Mean 35.7 (s.d.27.23)	Required scar management: 23 (18%) No scar management: 102 (82%)
Dewar (2004). Australia n= 152, follow-up: n.r.	Children with hot beverage scalds. 18% required skin grafts	Median 4 (range 0.25 to 32)	median 17.5 (range, 3 months to 11.5 years)	Required scar management: 39 (26%) No scar management: 113 (74%)
Lavigne (2016), Australia n=400 Follow-up: unclear	Children with scalds due to hot beverage or starchy liquid	n.r.	hot beverage: median 18.2 (IQR 14.1, 27.8) starch: median 51.4 (IQR 18.7, 102.3)	Required ongoing- scar management: 64 (16%) No scar management: 336 (84%)

Analysis of Salisbury burns service and scar clinic data

Data was obtained from iBID on the numbers of children presenting to the Salisbury burns service (example Burn Unit following national referral guidance) who were under six years old and had experienced a scald of < 10% BSA between January 2015 and July 2021. Data was also obtained for participants who attended the Salisbury scar clinic during the same time period.

Further information on the two samples can be seen in Table 13 below. Between January 2015 and July 2021, 798 patients were seen by the burns service who were under six years old and had experienced a scald of $\leq 10\%$ TBSA. One hundred and thirty four patients were seen by the scar clinic in this same time period, suggesting that approximately 16.8% (134/798) children will experience some degree of scarring. It should be noted that this figure may be an underestimate as some children with small scars may not be referred to or seen in the scar clinic.

Table 13. Summary of data from Salisbury burn service and scar clinic

	iBID data	Clinic data
Total no.	798	127
Age in months (mean, s.d.)	23.1 (14.3)	24.7(14.4)
Age in months (Range)	0-70	2 to 68
Male	454 (55.8%)	69 (54.3%)
Female	353 (44.2%)	58 (45.7%)
% TBSA (median and IQR)	2 (1-3)	3 (2-5.5)
TBSA range	0-10	0.5 - 10
TBSA < 1%	131 (16.4%)	5 (3.9%)
TBSA 1-5%	570 (71.4%)	77 (60.6%)
TBSA 5-10%	97 (12.2%)	45 (35.4%)

Footnote: Seven patients had missing TBSA data. Percentage of scalds resulting in a scar: 127/798 = 15.9%. Including missing TBSA data: 134/798 = 16.8%

Proportion of presenting children/families who would consent to take part in a cohort study

Data was collected at the Bristol Royal Hospital for Children in November and December 2021. Parents of children who would meet the inclusion criteria for the study were shown the participant information sheet and asked to indicate if they would have been willing to take part in the study if it was taking place. This exercise was informed by the feedback from the PI work which confirmed the acceptability of the inclusion criteria and the timing at which parents would be asked about taking part in a cohort study.

Parents were asked to complete 3 questions following review of the PIS.

1. If you had been approached in the first few days following the injury do you think you would have agreed to take part? Yes / No
2. If no, what would have put you off?
If yes, is there anything in particular that you find particularly of interest?
3. Is there anything you would like to suggest?

The questions were given to six parents during their outpatient appointments or from the outreach nursing team. Unfortunately, only one parent feedback form was returned (see note below).

Responses to above questions;

2. "I feel research is so important to help develop care and how we treat patients. So happy to help with this"

3. "I found all the information provided really helpful – also the leaflet was very informative. I felt very well supported and access to advice if needed."

Note: this task proved difficult during the COVID pandemic as the hospital was very busy with patients and decreased staff. This would need to be noted and resourced appropriately for a future study under similar conditions.

Work programme 5: Data and Data linkage

Discussions were had with colleagues from the University of Bristol and the iBID chair who had attempted to link project data from the Case Report Form (CRF) to Hospital Episode Statistics (HES) data from NHS digital. It was agreed that this was costly and took a number of years to achieve. It was agreed that data should be collected through CRFs entered into a database and to link this with the national burn injury database (iBID) (routinely collected data).

Note: iBID is matched against HES data annually.

Work programme 6: Principles for the full study

As a result of the work packages detailed above, the following principles of a future cohort study were agreed:

- *Study design:* prospective longitudinal cohort study with length of follow up of a minimum of two years
- *Population:* children under six years, who experienced a scald of <10% TBSA including a range of different ethnicities and skin types.
- *Outcomes:* Scar Quality assessed by the POSAS 2.0. Burn specific health-related quality of life assessed by the CARE Burn Scales.
- *Time points:* six weeks, three months, six months, one year and annually thereafter.
- *Other data to be collected:* age at time of burn, sex, %TBSA, ethnicity, burn location, number of surgical procedures, wound infections, use of scar management treatments.

Dissemination

The findings of this project are included in this final report which is submitted to the Scar Free Foundation. It will also be disseminated to all steering group members.

Results have also been disseminated through publications:

- Davies P, Cuttle L, Young A. A scoping review of the methodology used in studies of genetic influences on the development of keloid or hypertrophic scarring in adults and children after acute wounding. *Advances in Wound Care*. 2021 May 11(ja).
- Parent involvement work. Submitted to *Scars Burns and Healing*, January 2022.
- Systematic review of time to scar maturation. Submitted to *Burns and Trauma*, February 2022.
- Final project publication: to be completed.

Two abstract presentations have been submitted to the annual British Burn Association (BBA) meeting, taking place in Bristol in May 2022.

Future plans: work from this project will be used to support an application to the NIHR Programme Grant for Applied Research for a longitudinal cohort study as described in this report.

Acknowledgements

We would like to acknowledge the help and support of the parents involved in this study, Mr Ken Dunn (Chair iBID), the members of the Steering Committee listed below, and the Cleft Collective.

Members of the Steering Committee

Name	Role
Declan Collins	Chair. Consultant in Plastic and Reconstructive Surgery
Isabel Jones	Deputy chair. Consultant Burns and Plastic Surgeon
Amber Young	Principle Investigator. Consultant Paediatric Anaesthetist. Senior Research Fellow.
Diana Harcourt	Co-Director of the Centre for Appearance Research (CAR), University of the West of England.
Sian Falder	Consultant Burn Surgeon
Alison Tweddle	Operations Manager. Children's Burns Trust
Kerry Humphries	Cleft Collective Project Manager
Mark Brewin	Clinical burn scarring and laser scientist
Marie-Claire Whyte	Paediatric Clinical Psychologist
Sarah Smailes	Consultant Physiotherapist
Simon Booth	Senior Burns Research Nurse

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