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Doctoral Thesis

**Experiences of Transition to Secondary School in Children with a Cleft Lip and/or
Palate**

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Statement of Total Word Count for the Thesis

	Main Text	Appendices <i>(including references, tables & figures)</i>	Total
Thesis Abstract	299	-	299
Part 1: Literature Review	7,965	7,529	15,494
Part 2: Research Paper	7,933	5,519	13,452
Part 3: Critical Appraisal	3,996	1,061	5,057
Part 4: Ethics Section	5,060	16,555	21,615
Total	25,253	30,664	55,917

Thesis Abstract

This thesis explores the lived experiences of children who were born with a cleft lip and/or palate (CL/P) and their parents from a qualitative perspective. It includes a literature review, research paper, critical appraisal and ethics section. The literature review is a meta-synthesis of parents' lived experience of raising a child with CL/P. Data from 12 papers were synthesised using a meta-ethnographic approach. Four over-arching themes describe parents' experiences; (1) adapting to a changed future, (2) social aspects of parenting a child with CL/P, (3) parents' experiences of treatments, and (4) empowerment and personal growth. Findings add to current understandings by highlighting processes of adaptation and re-adaptation, the value of peer support, the emotional burden of the continued treatment journey, issues regarding power in healthcare settings, and empowerment and personal growth. The research paper explores the secondary school transition experiences of children with CL/P in order to understand how they experience and make sense of this critical phase. Six participants took part in semi-structured interviews and their data were analysed using interpretative phenomenological analysis (IPA). Four themes describe participants' transition experiences; (1) managing and valuing difference: the impact on self-worth and identity, (2) managing and valuing difference within the social context, (3) disclosure and the process of informing others about CL/P, (4) developing positive peer relationships. Findings suggest that children with CL/P experience psychological and social challenges during the transition period. However, they also utilise many coping strategies in order to develop resilience during this time. Implications for services supporting children and their families during this period are discussed. The critical appraisal expands upon some of the practical, methodological, and ethical issues encountered during the research process. It describes how these issues were addressed and serves as a reflective guide to researchers conducting research with similar populations.

Declaration

This thesis describes research carried out between January 2015 and April 2017 for the Doctorate in Clinical Psychology Programme at the Division of Health Research, Lancaster University. The work presented here is my own, except where due reference is made. This thesis has not been submitted for the award of any higher degree elsewhere.

Name: Rachael Faulkner

Date: 23rd April 2017

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SECTION ONE

LITERATURE REVIEW

The Experience of Parenting a Child with a Cleft Lip and/or Palate: A Meta-Synthesis

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Abstract

Objective: There has been a wealth of research into the psychosocial aspects of caring for a child with CL/P, including a focus on parents' lived experiences. The aim of this literature review was to contribute to current understanding via the integration of this research evidence into a cohesive whole.

Design and Procedure: A qualitative meta-synthesis was conducted using a meta-ethnographic framework (Noblit and Hare, 1988; Britten et al., 2002). Systematic database searches were carried out to identify all suitable studies as per the inclusion criteria. Quality appraisals were completed using the Critical Appraisal Skills Programme (CASP; 2013). Finally, data from included studies were extracted and findings synthesised.

Studies: 12 papers which used a qualitative or mixed-methods design to explore aspects of parents' experiences of having a child with CL/P were included in this meta-synthesis.

Results: Four overarching meta-themes describe parents' experiences: (1) adapting to a changed future, (2) social aspects of parenting a child with CL/P, (3) parents' experiences of treatments, and (4) empowerment and personal growth.

Conclusions: Findings add to current understandings by highlighting processes of adaptation and re-adaptation, the value of peer support, the emotional burden of the continued treatment journey, issues regarding power in healthcare settings, and empowerment and personal growth. Findings are of value to clinical psychologists and other healthcare professionals supporting parents of children with CL/P.

Keywords: caregivers; cleft lip and/or palate; CL/P; empowerment; literature review; lived experiences; meta-synthesis; parents; parenting; psychosocial; qualitative; resilience; visible difference.

Cleft Lip and/or Palate

A 'cleft lip and/or palate' (CL/P), which is a split or opening on the upper lip and/or roof of the mouth, is one of the most commonly occurring congenital differences affecting approximately one in every 700 children¹ (Abramowicz et al., 2003; Mossey et al, 2009). Effects on the child's feeding, appearance, speech, and hearing can lead to long-lasting consequences for physical health and psychosocial adjustment (Hunt et al., 2005; Shkoukani et al., 2013). Therefore, children with CL/P typically require extensive specialist multidisciplinary team (MDT) input (which includes a clinical psychologist) from birth through to adulthood to optimise physical and psychosocial development (Chuo et al, 2008; Mossey et al, 2009).

CL/P is thought to result from a combination of genetic and environmental factors, however, in most cases occurs in children with no family history of CL/P or other congenital differences (Murray, 2002; Dixon et al., 2011). The diagnosis of CL/P can therefore be an unexpected and shocking event for parents² (Johansson and Ringsberg, 2004; Nusbaum et al., 2008). Furthermore, the ongoing experience of caring for a child with CL/P can be stressful for parents as they negotiate the challenges of feeding difficulties, attending regular hospital appointments, and supporting their child through intensive treatments and surgical interventions (Tisza and Gumpertz, 1962; Nelson et al., 2012a).

Parental functioning has been shown to influence the psychological outcomes of children with chronic health conditions (see Drotar (1997) for a review of the literature). Understanding parental adjustment to having a child with CL/P is therefore crucial to ensuring clinical psychologists working within cleft services are best able to promote

¹ Prevalence varies nationally. Overall international prevalence= 9.92 per 10,000 with 95% confidence interval of 9.70-10.14 (IPDTC, 2011).

² For ease of reading the term 'parents' is used throughout as an umbrella term for any individual that is the sole or joint caregiver to a child with CL/P.

psychological wellbeing, prevent mental health difficulties, and identify and support those in need of psychological intervention (Lockhart, 2003; Hearst, 2007).

Parents' Experiences of CL/P: Current Understandings

Over the last few decades there has been a wealth of research into the psychosocial aspects of caring for a child with CL/P. Findings predominantly highlight the negative consequences to the parent. Speltz et al. (1993) report that mothers of children with craniofacial differences including CL/P, experience increased stress, reduced feelings of competence in their interactions with their child, and increased marital conflict, compared to normative data. Decreased social support is also described, and is associated with increased maternal depression (Sank et al., 2003). Greater levels of parental anxiety regarding the child and the child's future are also documented (Brantley and Clifford, 1980).

More recently, there has been a shift within the literature to focus on positive parental adjustment and resilience. A number of subsequent studies report the range of positive outcomes that parents of a child with CL/P experience, including; a better understanding of the self and compassion towards others, increased feelings of coping and optimism, enhanced emotion regulation and communication skills, greater adaptability (for example, the ability to overcome difficult challenges), a greater sense of belonging and spirituality, and higher levels of social support (Eiserman, 2001; Baker et al., 2009). Good social support has also been found to predict less psychological distress, less impact on the wider family, and greater positive parental adjustment (Bradbury and Hewison, 1994; Baker et al., 2009).

In an attempt to aggregate and make sense of the large and varied evidence base two separate narrative literature reviews of the existing quantitative and qualitative literature within this field have been conducted (Nelson et al., 2012a; Leemreis et al., 2014). In the first, Nelson et al. (2012a) highlight that much of the existing literature focuses on parents'

needs and experiences around the time of the diagnosis and/or birth of their child, with themes of shock, loss and mourning being commonly highlighted both in surveys and in qualitative studies (e.g. Bradbury and Hewison, 1994; Black et al., 2009; Chuachareon et al., 2009). Studies exploring parental experiences of services at this time are also common with few studies exploring issues in later childhood. Overall, this review highlights that despite a large body of literature within this general field, the in-depth qualitative examination of parents' perspectives is lacking. In particular, very little research has considered the father's perspective, and Nelson et al (2012a) suggest that further research into parental experiences as children with CL/P develop throughout childhood is needed. In the second review, Leemreis et al. (2014) took a broader focus and included parents of children with a range of visible facial differences, including skin disorders and craniofacial differences such as CL/P. Nonetheless, findings again highlight the emotional consequences (including both positive and negative factors) parents experience following the diagnosis of a child with a visible facial difference (Bradbury and Hewison, 1994; van Staden and Gerhardt, 1995; Baumann and Braddick, 1999). Findings also indicate a process of adaptation and reorganisation that parents undergo after an initial mourning period. However, again there is little emphasis on the continued parenting journey throughout childhood and the review authors suggest that future research should explore risk and resilience factors from both qualitative and quantitative perspectives to better inform understandings of psychological adjustment in parents of children with visible facial differences, such as CL/P.

Rationale for the Current Meta-Synthesis

Narrative reviews provide a useful way of arranging, summarising, and putting into context evidence of different types (for instance, both qualitative and quantitative research) and have utility to policy makers and commissioners (Barnett-Page and Thomas, 2009). However, narrative approaches are criticised for being primarily 'descriptive' in their focus

(Dixon-Woods et al., 2006) and for their lack of success in identifying deeper meaning within the data (Lucas et al., 2007; Barnett-Page and Thomas, 2009). In contrast, meta-synthesis (whereby the findings of a body of qualitative research are synthesised) is proposed as a literature review method that enables the integration of qualitative research into a cohesive ‘whole’ in which the result is greater than the sum of its parts (Noblit and Hare, 1988). It is argued that via meta-synthesis it is possible to produce novel interpretations which have greater explanatory power than could be achieved via narrative reviews (Britten et al., 2002; Campbell et al., 2003; Barnett-Page and Thomas, 2009).

In the time since the Nelson et al. (2012a) and Leemreis et al. (2014) reviews there has been an increase in qualitative literature addressing parental experiences of raising a child with CL/P beyond the point of diagnosis, including a number of studies exploring fathers’ perspectives. Therefore, a meta-synthesis of this literature is now viable. Subsequently, this meta-synthesis aimed to systematically identify all studies which explored the lived experiences of parenting a child with CL/P and integrate the results of these studies into a useful whole. Increased knowledge and understanding of the psychosocial lived experiences (including both risk and resilience factors) of parents is crucial to the ongoing development of family-orientated services that are sensitive to the needs of young people and their parents. It is therefore intended that findings will inform the planning and delivery of psychological services for young people with CL/P and their parents.

Method

Approach

The aim of this literature review was to contribute to current knowledge and understanding of the lived experiences of parenting a child with CL/P via the synthesis of existing qualitative research. A qualitative meta-synthesis was conducted using the seminal

interpretative meta-ethnographic framework established by Noblit and Hare (1988) and adapted for health research by Britten et al. (2002). Meta-ethnography provides a framework for bringing together research findings from a range of different qualitative studies to produce a set of ‘third-order’ constructs, or synthesised themes, which provide novel interpretations about the phenomena of interest, whilst remaining true to the original ‘first-order’ (participant level) and ‘second-order’ (study author level) constructs (Britten et al., 2002, p.209; Pope et al., 2007). In this review, first-order constructs are participants’ descriptions of their experiences of having and/or raising a child with CL/P, second-order constructs are the theoretical interpretations made by the original study authors, and third-order constructs represent the synthesis of this information into overarching meta-themes.

Search Strategy

The starting point for a meta-ethnography is the identification of a review question, search terms, and inclusion and exclusion criteria, to enable the systematic identification of relevant literature (Noblit & Hare, 1988). The Context How Issues Population (CHIP) tool (Shaw, 2010; figure one) was used to aide comprehensiveness and help identify free-text search terms. The primary review question to be addressed was “what are the lived experiences of parenting a child with CL/P?”

[INSERT FIGURE 1 HERE]

A systematic literature search was conducted in August 2016 using the following databases; Academic Search Complete (covering a range of disciplines including social sciences and humanities; searchable years 1934-present), British Nursing Index (covering British nursing, midwifery and allied-health journals; 1992-present), CINAHL (nursing and allied-health disciplines; 1937-present); EMBASE via Ovid (biomedical disciplines; 1974-2016), Medline (general medical disciplines; 1946-present) and PsycINFO (psychology and

allied-health disciplines; 1806-present). Free-text search terms (Table one) were combined using Boolean operators and where available, database subject mapping, thesaurus, and mesh-heading functions were used to expand search results, and limiters applied to increase applicability of results. An updated database search was conducted in November 2016 (using the original search strategy) to identify any more recently published papers prior to synthesis.

[INSERT TABLE 1 HERE]

Database searches yielded 1187 results. The title and keywords of returned results were reviewed and only papers that appeared relevant to the review question (n=206) were retained. The abstracts of remaining papers were then subject to further review with papers not meeting the inclusion criteria being discarded (n=55). At this stage remaining papers from all database searches were combined and duplicates were removed. Next, the full texts of the remaining papers (n=62) were obtained and checked against the inclusion and exclusion criteria. A diagrammatic representation of the search process (adapted from Moher et al., 2009) is presented in figure two.

[INSERT FIGURE 2 HERE]

Papers were retained for inclusion if they; (1) included parents that have had and/or raised a child born with a CL/P, and had a substantial focus on the psychosocial issues surrounding this, (2) used a qualitative design for data collection and analysis and evidenced findings with participant quotations, and (3) were published in peer reviewed journals³. Papers were excluded if they: (1) were not available in an English language version⁴; (2) focused solely on parents' experiences of services; (3) focused exclusively on parents' experiences of receiving a diagnosis of CL/P and did not also explore parents' lived experiences of 'raising' a child with CL/P; (4) also included health conditions other than

³ The peer review process serves as an initial stage of quality assessment.

⁴ This was due to a lack of resources for translation of papers.

CL/P and presented the dataset such that it was not possible to determine which results related exclusively to experiences of parenting a child with CL/P.

Examples of discarded papers include Klein et al. (2006) which also included mothers of children with other craniofacial anomalies and Hsieh et al. (2013) which explored the experiences of expectant mothers following prenatal diagnosis of CL/P and therefore did not incorporate broader parenting experiences.

Characteristics of the Studies

Twelve papers (presented in table two and referred to throughout by study numbers (S1-S12) for clarity) were identified for the meta-synthesis. Of these 12 papers, 10 were not included in either of the previous literature reviews (Nelson et al., 2012a; Leemreis et al., 2014), S3 was included in both reviews, and S6 was only included in Leemreis et al. (2014).

[INSERT TABLE 2 HERE]

The 12 included papers were published between 2004 and 2016 and drew on 11 different samples. Two studies (S6 and S7) used the same sample, however, both met the inclusion criteria and had different research questions. Six studies used European samples (four in the UK, one in Sweden, one in Norway), four papers used samples in the USA, one in Nigeria, and one in Brazil. Samples ranged in size from 12-118. Participants included a range of 'parent' types, including: mothers, fathers, and adoptive parents. Studies employed a range of data collection methods including focus groups (S1), telephone interviews (S2, S8, S11-S12), and face to face interviews (S3-S10). Three studies (S1, S8 and S10) used mixed-methods; however, qualitative data was extractable from quantitative analysis. All papers present some form of thematic analysis of their results guided by a range of different methods including: content analysis (n=1), extended case method (n=1), framework analysis (n=1), thematic analysis (n=2), phenomenological approaches (n=3), and grounded theory

techniques (n=4). Whilst the included studies draw on different methodologies and epistemologies, each study was deemed to offer valuable insight into the lived experiences of parenting a child with CL/P.

Quality Appraisal

Quality appraisals were carried out using the Critical Appraisal Skills Programme (CASP; 2013) to assess the methodological robustness of each study. The CASP is a concise, easy to use, checklist which allows for the systematic quality appraisal of health related research. The CASP comprises ten questions. Questions one and two are screening questions designed to screen out studies not relevant to the review topic. Questions 3-10 cover aspects of research design, data collection and analysis, ethical conduct, and implications of study findings. The rating system developed by Duggleby et al. (2010) was applied to determine scores for each question in relation to each study. Questions 3-10 were rated according to three-point rating scale as 'weak', 'moderate' or 'strong'. A weak score (1 point) was given to studies that provided little or no explanation for a particular issue, for example, how the sample was identified and participants recruited to the study was not mentioned. A moderate score (2 points) was given when the particular issue was addressed but procedural details regarding this were lacking, for instance, studies that stated ethical issues were considered with no further explanation of this. A strong score (3 points) was awarded where study authors provided sufficient explanation and justification of the particular issue in question; for instance, providing a clear rationale and detailed steps for how data analysis was carried out, including examples (where relevant). Scores from each of the eight questions were added together and a total score (scores could range from 8-24) was assigned. To ensure rigour, four papers were appraised by an external rater (clinical psychologist). Inter-rater agreement was 90%. Differences were discussed and a final score was agreed upon. CASP (2013) results are presented in table three.

[INSERT TABLE 3 HERE]

There is much debate regarding how, or if at all, to apply quality assessment tools within qualitative meta-syntheses. Much of this debate centres on the epistemological polarities between quantitative (an area in which quality appraisal is considered essential) and qualitative research, limitations in the quality reporting of qualitative papers due to journal word count restrictions, and the arbitrary use of rating scales and cut-off criteria (Mays and Pope, 2000; Pope et al., 2007; Barnett-Page and Thomas, 2009). Accordingly, the decision was taken not to exclude studies on the basis of perceived 'quality' as long as they passed the initial two CASP (2013) screening questions (which all studies did). Instead, CASP (2013) results were used to enable consideration of the relative strengths and weakness of each study in the final synthesis. For instance, areas of weakness were identified within S1 and S3, including a failure to consider the relationship between the researcher and the participants, and minimal description of the process of data analysis. However, findings within this review are supported by papers scoring across the range of scores given to the studies, and therefore no themes are reliant on weaker-scoring studies.

Data Synthesis

Data synthesis began with the reading and re-reading of each study to ensure familiarity with the data (Noblit & Hare, 1988). Completing quality appraisals and summarising methodological information also aided familiarisation. Next, the findings from each study were reviewed in detail and all data relevant to the research question were extracted (Noblit & Hare, 1988). This involved developing a list of relevant original study themes and author interpretations, along with participant quotations from each study. Notes regarding initial interpretations about the data and emerging themes were also added (see

appendix 1-B). These notes were then used to compare and contrast the data, resulting in initial ideas regarding how the study findings were related.

In meta-ethnographic synthesis, studies can be brought together into a cohesive whole or ‘translated’ in one of three ways; reciprocal translations, refutational translations, or by forming a line of argument (Barnett-Page & Thomas, 2009). Reciprocal translations are when the themes from individual studies are conceptually analogous to one another and as such, can be combined to form overarching concepts. Conversely, where study themes are contradictory, refutational translations can be used to explore and account for these contradictions. Finally, a ‘line of argument’ synthesis involves building findings from individual studies together into a ‘bigger picture’ to develop an overarching understanding of the whole that both links and explains findings (Barnett-Page & Thomas, 2009). In this review, initial examinations of study themes indicated that study findings were related by forming a line of argument. To illustrate this, a wide range of both positive and negative experiences of support were highlighted in S2-5 and S9-12, however when considered together there was a broader sense of parents’ wider social experiences of raising a child with CL/P and the impact this had on adjustment and coping.

Initial emerging themes were developed by drawing together the data from the original studies into shared concepts. At this stage, 13 emerging themes were identified (appendix 1-C). These initial themes were then reviewed and following supervision from a health psychologist experienced in meta-synthesis, amalgamated into the final four overarching themes. Final overarching themes are presented in the results section and encapsulate a higher level ‘third-order’ understanding of the lived experiences of parenting a child with CL/P, whilst also retaining the integrity of the original author and participant interpretations (see appendix 1-D).

Results

Data synthesis yielded four overarching meta-themes, which comprised a total of 10 sub-themes. Overarching themes include: (1) adapting to a changed future, (2) social aspects of parenting a child with CL/P, (3) parents' experiences of treatments, and (4) empowerment and personal growth. The contribution that each study made to overarching themes and their respective sub-themes are provided in table four.

[INSERT TABLE 4 HERE]

Theme One: Adapting to a Changed Future

Having a child with a CL/P could be a shocking and unexpected event for parents. Here, parents' experiences of this unexpected event and the process of adaptation they went through to adjust to, and accept the 'changed' future without the anticipated 'perfect' child are presented. This also includes consideration of the further period of parental re-adaptation that follows appearance-altering interventions.

The unexpected loss of the 'perfect' child. The experience of finding out about a child's diagnosis of CL/P was addressed in seven of the reviewed papers (S1, S3-4, S7, S10-12). Six papers included parents that had received the diagnosis prenatally via ultrasound screening (S1, S3-4, S7, S11-12) and four included those who found out following birth (S3, S7, S11, S12)⁵. Parents had not anticipated that their child might be born with a CL/P and subsequently experienced a deep sense of shock on receiving the diagnosis (S1, S3, S4, S11, S12); *"My first reaction was shock. I wasn't really prepared. We didn't think we'd have a child with a cleft palate"* (S3; p.167). Parents who had a CL/P themselves anticipated their child having CL/P to some extent, but still described feelings of shock (S12).

⁵ It was unclear when parents in S10 received their child's diagnosis of CL/P.

This shock can be understood as a loss of the anticipated ‘perfect’ child (S1, S3; S7, S11, S12); “*it’s very difficult to take in that the child you thought was “perfect” in inverted commas [quotation marks], turns out that they’re not perfect as defined by the medical professionals*” (S7; p.305). This loss led to grief and sadness; “*you can’t help but feel sad when you see someone walking around with a perfect baby*” (S1; p.361). Parents also grappled with paradoxical feelings of despair regarding their child’s ‘imperfection’, whilst simultaneously feeling unconditional love towards their child (S1, S3, S7); “*It was a funny feeling. I thought he was ugly but sweet at the same time*” (S3; p.167).

Perceived insensitive reactions from healthcare professionals added to the emotional shock (S11, S12); “*offering us a termination within 10 minutes of finding out...that was the most upsetting thing...*” (S11; p.33). However, positive professional support was also noted and seemed to help parents emotionally process the diagnosis; “*the consultant was brilliant, she spent a lot of time with us...she helped us take it all in*” (S11; p.33).

Developing understanding and personal meaning. Upon receiving the diagnosis, parents began to develop a personal understanding of what having a child with CL/P meant to them (S3, S4, S7, and S10-12). Collecting information about CL/P was one means of doing this (S4, S10, and S11). This was especially important given that many parents described a lack of prior understanding about CL/P. Parents utilised various sources for acquiring information including: healthcare professionals, patient information leaflets, social media and the wider internet (S4, S10, S11). Increased knowledge facilitated coping as parents felt more in control of the situation; “*I absorb the information I can get. It’s a way to cope and handle it*” (S4; p.70). However, S11 highlighted that the internet could increase distress as unregulated websites often presented worst-case scenarios.

A further way in which parents developed understanding and personal meaning was to make favourable comparisons (S3, S7, and S10-12). Parents compared CL/P to other health issues and considered CL/P to be a minor issue, not a disability; *“we don't see it as a handicap, more as a flaw”* (S3; p.168). Making comparisons allowed parents to reframe their experiences and increased a sense of coping; *“there are some things that happen in life that make you see things for what they really are. I was catching the bus to work and I saw this little girl who had spina bifida. She was very, very poorly and it made me think, you know what, I'm actually quite lucky”* (S11; p.36).

Re-adaptation to the child's changed appearance. Overtime parents became accustomed to, and accepting of, their child's 'different' appearance. They considered the CL/P and any treatment devices (such as those used in nasopalveolar moulding [NAM]) to be a natural extension of their child's identity; *“I think I am used to it now, whenever he does rip it out...kinda like looking at somebody who normally wears glasses when they take them off”* (S2; p.2418-2419). A further period of parental adjustment was required following the commencement of treatment (S2, S3, and S10-11). This was most notable following surgical intervention as parents described the profound changes that surgery made to their child's appearance; *“he looked like a completely different little boy, it was almost as if you'd lost one and gained another that you didn't really know...I still haven't come to terms with it”* (S11; p.36). However parents of children undergoing non-surgical interventions, such as NAM, which produced more gradual changes also commented on the emotional impact of their child's altered appearance; *“I'm... blown away...how big of a difference it was... you don't realize how it's closing when I see him every day, but to see... It was just amazing...”* (S2; p.2418). It seemed that some parents had anticipated an emotional reaction to their child's changed appearance, however, others did not. Nonetheless, parents were broadly satisfied with the outcome of treatments and were able to re-adapt to their child's altered appearance;

“we had no expectations that he would be a perfect child. We knew it might take a couple of operations before it looked good. But we were lucky – it turned out really well” (S3; p.170).

Theme Two: Social Aspects of Parenting a Child with CL/P

Parenting a child with CL/P raises many social challenges for parents. Here, parents' lived experiences of social stigma, the way in which parents managed these experiences, and their experiences of social support are presented. .

Social Stigma. Findings from seven studies (S1, S3-4, S6-7, S11-12) suggest that parents anticipated that their child might not be accepted by family, peers and other acquaintances because of their CL/P. Parents worried that this might lead to the social isolation of the child and themselves (S6, S7, S11). However, there was a mixed picture regarding parents' actual experiences of stigma and social isolation. Two studies (S3, S11) suggest that parents' families and close friends were largely accepting of their child and their CL/P, as one mother explained; *“my mum came to the maternity ward. She picked him up and held him and established a very special relationship with him right from the start. She said he was lovely and had such a beautiful head” (S3; p.169).* Such reactions were important to parents as they demonstrated unconditional support and acceptance. In contrast, findings from S1, S3, S7, and S11-12, highlight that social stigma was commonplace. Some parents in these studies experienced overt stigmatizing reactions; *“my mother-in-law said he is a bastard and I should throw him away...” (S1; p.120).* Whereas other parents described more subtle experiences of stigma, such as others keeping their distance from the child; *“we used to have friends that haven't been to see us. I don't think they dare” (S3; p.169).*

Stigmatising reactions typically resulted in feelings of blame and shame. This was most apparent in parents who had a CL/P themselves; *“my father-in-law blamed me...” (S12;*

p.428). However, such feelings were also experienced by parents without CL/P and increased parents' sense of isolation and difference from others (S1, S11).

Parents managed stigmatising reactions in different ways, often reflecting the attributions they made about the stigmatising reactions, as well as the difficult emotional reactions (e.g. shame and blame) they experienced. For instance, parents that considered others to be well intentioned but lacking understanding tended to orientate towards informing others and addressing curiosity, as one father explained; *"you could tell if people were interested, so we'd say, 'yeh, he's got a cleft lip and palate, but don't go worrying about it.' You'd break the ice straight away"* (S11; p.35). Conversely, parents that interpreted stigma as hurtful and isolating adopted more avoidant coping styles such as avoiding social situations or attempting to hide their child's face from others to avoid disclosure of the CL/P (S1, S7); *"I avoided my family, even during my sister's wedding... I can't let them see my child like this"* (S1; p.120).

Parents' experiences of social support. The provision of good social support from relatives, friends, other parents of children with CL/P, and healthcare professionals aided parental coping. However, parents' experiences of support and the way in which they engaged in this varied. While the data and interpretations provided within the reviewed papers did not indicate the precise factors which accounted for this variation, it is likely that familial acceptance, provision by specialist cleft services, and parents' own coping styles all influenced experiences of support.

Practical and emotional support from family and friends improved coping (S10, S11), particularly in times of high stress and vulnerability (S10). However, findings suggest that as parents had to adjust to and accept their child's CL/P (see theme one), so too did other family members and friends. This affected the availability of support in the initial stages following

diagnosis; *“once we'd gone through breaking the news and getting over the upset...we had absolute total support”* (S11; p.35).

The value of peer support from other parents of children with CL/P was highlighted in several studies (S2, S5, S9-11). Peer support systems typically developed informally in clinic waiting rooms, although some parents were put in touch with other parents by their cleft service. Such relationships facilitated a sense of comradery and ‘togetherness’; *“I always loved talking to people... who'd been through the process, just to see what they had been through, how it compared and just to get that support from people who had been through it”* (S2; p.2418). Talking to parents further ahead in the treatment journey was also beneficial and provided parents with feelings of hope and motivation.

An important function of peer relationships was the reciprocity and shared empathy experienced (S5, S9-12). Parents could learn about and understand their own experiences whilst simultaneously helping others in a similar situation (S9-12); *“... it's nice to give back and help others. I know when you're in that boat and you have questions and it's all unfamiliar, it's nice to have somebody to ask those things to”* (S9; p646.). Parents with CL/P themselves could provide an added ‘unique perspective’ to such relationships, however, there was also a tendency for these parents to feel taken for granted when approached by services to provide support to other parents (S12).

Experiences of support from healthcare professionals were mixed. In the weeks following the birth parents were mostly supported by non-specialist healthcare professionals (e.g. maternity staff, health visitors) who were experienced as caring but lacking understanding (S3-4, S11); *“It was tough... I got different advice on every shift... and there were three shifts a day... you do not know who you should listen to...”* (S4; p.69). This resulted in parents feelings abandoned and isolated in this early period; *“we were promised*

the support would be there straight away, but for two weeks nobody came to see him or check how we were coping...” (S11; p.33). In the longer term, good support from specialist MDTs increased psychological resilience and coping (S2, S5, S9-10). However, findings from S11 suggest that emotional support is often aimed towards mothers and fathers could feel “*forgotten about*” (S11; p.35). Nonetheless, fathers may also be more likely to decline any support offered due to a perceived need to ‘put on a brave face’ and remain ‘strong’ for their partner; “*all the way through I was trying to be...positively optimistic...keeping it together and helping my wife to come to terms with everything...*” (S11; p.35).

Theme Three: Parents’ Experiences of Treatments

Parents experienced their child’s treatment journey to be emotionally and psychologically difficult. They felt a moral obligation to pursue treatments in the best interest of their child despite these difficulties. Here, parents’ experiences of their child’s treatment journey and their experiences of the cleft team during this journey are presented.

The long and arduous treatment journey. Parents’ experiences of CL/P treatments, including non-surgical treatments (such as NAM) and/or repeated surgical interventions, were described in nine studies (S2, S5-12). The overall treatment journey was characterised by intense periods of treatment and recovery, broken by quieter periods of waiting. Waiting periods provided families/parents freedom and relief; “*the first year of his life has just been one big blur...we’re enjoying the smooth bit in between, but we know there’s lots to come*” (S11; p.37). Despite this, the ongoing nature of treatment meant that the treatment journey held a constant disruptive presence in the background of family life which parents experienced as stressful, anxiety-provoking, and emotionally burdensome; “*It occupied our lives for a long time, there was regular treatment and it was a big feature of life*” (S11; p.37).

Underpinning parent's struggles with the treatment journey was a sense of uncertainty resulting from a lack of clarity regarding the progression of the treatment journey and the outcome of treatments (S5, S7, S10); *"I keep on saying to [speech and language therapist], 'Do you think she needs another operation?' and she says, 'Let's just see how we go. She's doing fine now...' But does she need another operation is all I want to know..."* (S7; p.352). Uncertainty began at diagnosis and continued throughout childhood and adolescence as parents struggled to imagine an end-point to treatment. Nonetheless, findings point to a peak in uncertainty prior to the child's first surgical intervention, which was described as a daunting yet important milestone; *"it's [the first surgery] something that I've been looking forward to quite a lot...it's the first hurdle to cross..."* (S11; p.36). This was especially true for parents using NAM treatments as surgery meant an end to this and a subsequent reduction in the burden of care.

As the treatment journey progressed, the nature of uncertainty evolved. Parents became more familiar with the treatment process and therefore, it became easier to manage. However, their concerns for the impact of treatments on the child grew (S7, S11); *"she's going to be a lot older than her previous surgeries...I think that will hit us hard because her level of understanding will be very different"* (S11; p.36).

Balancing treatment burdens with 'doing the best' for the child. Parents described feeling a moral sense of duty to do the *"right thing"* (S6; p.799) for their child (S2, S6-8, S11); *"when it's your child you just want the best for them don't you?"* (S6; p.798). Taking advantage of every available treatment option was seen as an instinctive way for parents to fulfil their moral duty to their child (S6, S7, S11); *"however far we need to go, if it takes till she's 18 and leaves home, that's how far we'll go"* (S6; p.799). However, parents' sense of duty to seek treatments was paradoxical to their movement towards unconditional acceptance of their child (see theme one); *"I'm keen that his cleft doesn't define him... if further*

treatment isn't compulsory and he's happy looking a bit different, that's absolutely fine" (S11; p.37). In addition, parents wanted to protect their child from the physical and emotional pain of treatment, and subsequently experienced conflict in their decision making; *"given that our son wasn't talking and we had to interpret his needs, if you're not able to figure out a need... then you might think about whether it's the right time for surgery"* (S8; p.447-448). Feelings of guilt following the repeated pursuit of surgical treatments were common (S6, S7, S11); *"we knew at the back of our minds we needed to do something. You always know, don't you, that what is best, what your heart tells you or your head tells you, are two different things?"* (S7; p.350).

Relationship with the cleft team. Four studies (S6-7, S10-11) highlighted the close yet complex relationship that parents had with the cleft team throughout their child's treatment journey. On the one hand, a confidence and deep-seated trust in the cleft team allowed parents to 'surrender' their child to the team to pursue what they considered to be necessary surgical treatments despite the surgical and emotional risks (S6, S7, S11); *"you know the surgical team do this day in, day out...and they do it extremely well"* (S11; p.37). However, viewing them as 'faultless experts' had several consequences. Firstly, parents appeared to have unrealistic expectations regarding surgical outcomes (S6, S10); *"...after the surgery, he is gonna be a perfect baby, and he won't have any disabilities"* (S10; p.6). Secondly, parents experienced feelings of powerlessness in their relationship with healthcare professionals (S6, S11). This was especially evident when clinic visits were held with the whole MDT, as parents described how it could feel intimidating to voice any concerns in such settings (S11). Power imbalances also influenced parents' sense of choice in their child's treatment journey and led to parents feeling as if they had to follow the recommendations of the cleft team, even for surgeries considered elective in nature; *"...if he [orthodontist] thinks that's the right thing, then who am I to judge it...if they think it's the*

right way to go, then who are we to disagree?” (S6; p.801). Despite this, some parents described being able to find a balance between trusting professionals to help guide decision making whilst remaining ultimately responsible for decisions affecting their child’s care; *“at the end of the day it was mine and her dad’s decision...” (S6; p.801).*

Theme Four: Empowerment and Personal Growth

Findings from six studies (S4-5, S9-12) suggest that parents underwent a process of personal growth and empowerment when adapting to, and coping with the challenges of parenting a child with CL/P. This theme describes the journey to empowerment and highlights how it influences parents’ personal identity.

The journey to empowerment. The empowerment process started with parents feeling as if they lacked the necessary skills and abilities to manage the many challenges involved in parenting a child with CL/P; *“In the beginning it is very difficult because you don't know how to handle it...” (S5; p.496).* However, remaining disempowered was not an option for parents due to their need to ‘do the right thing’ for their child (theme three). Therefore, parents sought ways to establish a sense of control and coping; *“... From being completely paralyzed... to be acting... here I actually have to do it myself... I'm certainly not the person who is sitting there waiting... I go into action myself!” (S4; p.70).* Increasing one’s knowledge (S10), being selective in which advice to take from others (S4), and standing up for one’s own decisions with healthcare professionals (for example, whether or not to continue with breastfeeding despite difficulties [S4]) were all ways in which parents sought action. This ‘action’ led to sense of empowerment for parents. This was especially apparent in two of the studies which explored parents’ experiences of NAM treatment (S9, S10). Findings from these studies suggest that the intensity of the NAM treatment regime and the requirement for parents to be actively involved in this regime fostered a sense of purpose

and agency. This contrasts with aspects of surgical interventions which, as highlighted in theme three, typically involved a sense of ‘surrendering’ and disempowerment.

As parents became more confident with aspects of their child’s care regime, the initial anxiety and stress regarding ‘getting it right’ decreased and parents began to feel more proficient and in control of their child’s treatment; “[*My stress with NAM decreased definitely after the first week. Just familiarity and comfort in doing it. It wasn’t as foreign. It was a little less scary in that regard... I became less nervous*]” (S10; p.5). Increasing confidence and skill also led to a sense of ‘mastery’ (S9, S10), which was boosted by positive feedback from healthcare professionals; “[*to hear the doctor who was working on the very device [NAM] say, "You're doing a good job. You're doing what you're supposed to. It looks like it's supposed to," is rewarding*]” (S9; p.644).

A better parent: Personal growth. Findings from three studies (S9, S11-12) indicated that parents believed they had become better, more grounded, and more understanding individuals and parents as a result of their experiences. As one parent explained; “[*having babies before, it was a lot like having blinkers on...this opens your eyes to what else is out there.*]” (S11; p.37). This again influenced a positive parental identity and sense of empowerment. Personal growth was particularly evident for parents who were themselves born with a CL/P; “[*my son has given me huge strength, just to cope. Through him I've learned a huge amount from the other side*]” (S12; p.430). This suggested that parents felt they had been able to adapt to their circumstances in a way that enabled them to develop psychological resilience.

Discussion

This meta-synthesis is the first to draw together qualitative findings concerning parents’ lived experiences of raising a child with CL/P. The meta-synthesis enabled data

relevant to this topic to be drawn from a wide range of studies exploring different aspects of parents' more general experiences. Meta-syntheses increase the accessibility of qualitative findings to clinicians, researchers and policy makers (Finfgeld, 2003). Therefore, a considerable strength of this review is that qualitative findings regarding parents' lived experiences of CL/P from a range of published papers are integrated in a single report.

Consistent with previous reviews in this field (Nelson et al., 2012a; Leemreis et al., 2014) findings from theme one highlighted parents' experiences of loss, accompanied by feelings of shock, following the detection of CL/P in their child. Findings also described the process of adaptation that parents underwent in order to accept the reality of their changed future without their imagined 'perfect child'. However, findings from this meta-synthesis add to existing understanding by demonstrating that parents acquired this acceptance by developing understanding and personal meaning of CL/P, part of which involved favourably comparing ones' own situation to others. Findings also demonstrated that parents underwent a further period of re-adaption following appearance-altering interventions in order to re-accept their child's changed appearance.

With regards to parents' social experiences (theme two), findings mirrored Nelson et al. (2012a) by showing that parents experienced stigmatising reactions to their child's CL/P, which led to feelings of shame and blame, and that parents managed this in different ways. Nelson et al. (2012c) suggested differences in the management of stigma are gender-related. However, within this meta-synthesis such differences are understood in relation to the attributions that parents made about their experiences as well as the emotional reactions (e.g. shame and blame) they experienced. Further consideration of any gender-related differences is limited by the lack of studies exploring the perspectives of both mothers and fathers. Whilst a number of studies in this review did include data from fathers, and one study (Stock and Rumsey, 2015a) focused exclusively on the fathers' perspective; fathers continue to be

underrepresented in research. This is of concern given that fathers are more likely to feel that their emotional needs are “forgotten about”, more likely to keep emotional difficulties hidden, and less likely to accept emotional support (Stock and Rumsey, 2015a). Future researchers should continue to explore the perspectives of fathers in order to better understand their experiences and help ensure that services are best able to meet their needs. Findings from theme two also build on previous review findings by highlighting the value of good social support in helping parents negotiate the social and emotional challenges they faced. In particular, reciprocal peer support from other parents of children with CL/P was advantageous to parents’ sense of coping and personal growth. Furthermore, parents who were themselves born with a CL/P felt that they could add a unique and valuable perspective to such peer relationships. Peer support systems typically developed informally, however, clinicians working in cleft services may wish to consider further ways to support the informal development of peer support networks, for example, via networking events and/or ‘buddy’ systems. However, caution should be applied when approaching parents with CL/P to take part in such networks to ensure that they feel valued and appreciated.

The application of social comparison theory (SCT), originally proposed by Festinger (1954), may help explain the process of parental adaptation and re-adaptation in the context of parents’ broader social experiences. It is beyond the scope of this review to fully discuss the complex processes underlying the theory, however, in brief, SCT proposes that individuals evaluate their own social and personal worth in relation to others, at both an individual and group level, in order to reduce feelings of uncertainty, develop a stronger sense of self, and orientate towards self-improvement (Festinger, 1954; Wood, 1989). Wood (1989) adds that the wider social environment in which an individual exists will also influence these comparisons. Future researchers may therefore wish to consider the

application of SCT in their own research and work towards developing a model of adjustment and adaptation in parents of children with CL/P.

Existing reviews from Nelson et al. (2012a) and Leemreis et al. (2014) highlighted that treatments placed an emotional strain on parents and impacted family quality of life. The current review adds to this by providing a more in-depth account of parents' experiences of their child's treatment journey (theme three). Findings suggested it is the ongoing nature of treatments throughout childhood which created a particular emotional burden for parents. Furthermore, this was underpinned by uncertainty regarding treatment outcomes and future treatment plans. Providing parents with information about future treatment plans in addition to a focus on current plans may help reduce feelings of uncertainty. Additionally, parents experienced conflict in their decision-making as they attempted to balance the burdens of treatment with their sense of duty to do the 'right thing' for their child. In the longer-term this could lead to feelings of guilt, which parents attempted to sanction by surrendering a perceived decision-making responsibility to clinicians. Clinical psychologists working in cleft services could support parents and the wider team in negotiating such conflict. Clinicians should also be mindful of power imbalances within their relationships with parents, and where possible, seek to reduce these. For instance, findings suggest it preferable for clinic appointments to be held on a one-one basis with individual members of the MDT.

Findings from theme four (empowerment and personal growth) demonstrated that despite the psychological and social challenges of caring for a child with CL/P, parents were able to adapt to their circumstances and thrive. Active involvement in the child's treatment regime likely supported the empowerment process, as did the provision of good social support. However, only one paper included in this meta-synthesis directly explored mechanisms of empowerment (Martins et al., 2013). Further research exploring this, including ways to support this process is therefore recommended.

Limitations

A key focus of this meta-synthesis was parents' experiences of CL/P throughout their child's childhood and adolescence. Included papers sampled parents' of children from a wide age range (1.5 months – 25 years) due to a paucity of papers which exclusively sampled a more homogenous age-range of children (for example, children of school-age). Therefore, it is recognised that findings present a broad account of parents' overall experiences of raising a child with CL/P and more specific conclusions regarding parents' experiences in later childhood/adolescence are limited. Nelson et al. (2012c) reported parental concerns regarding the impact of CL/P on their child's social and psychological functioning as their child became older and approached transition points, such as the move to secondary school, college, work and/or adult services. However, there was insufficient data regarding this to warrant a meta-theme in this synthesis, thus, further research is needed.

Conclusions

This meta-synthesis highlights the breadth of experiences that parents encountered when raising a child with CL/P. Findings add to current understandings by highlighting: processes of adaptation and subsequent re-adaptation following treatments; the value of peer support in enhancing coping and adjustment; the emotional burden of the continued treatment journey (including issues regarding power imbalances with healthcare professions); and the development of empowerment and personal growth. Findings and suggested clinical implications are of value to clinical psychologists and other healthcare professionals supporting parents of children with CL/P.

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Figure Legends

Figure 1: CHIP tool (Shaw, 2010) analysis

Table 1: Free-text search terms

Figure 2: Diagrammatic Representation of Search Strategy

Table 2: Methodological Summary of Included Papers

Table 3: Quality Appraisal of Included Review Papers

Table 4: Contribution of Each Study to Meta-Synthesis Themes

Figure 1. CHIP tool analysis adapted from Shaw (2010)

CHIP	Key questions to consider	Possible search terms
<u>C</u> ontext	What is the context? In what way is this context of interest to you?	cleft lip and palate; cleft lip; cleft palate; cleft; CLP; craniofacial anomaly; CFA; orofacial.
<u>H</u> ow	What methods have been used in previous studies?	Qualitative approaches; ethnographic studies; interviews; focus groups; action research; thematic analysis; grounded theory; interpretive phenomenological analysis; IPA; narrative analysis; content analysis; framework analysis.
<u>I</u> ssues	What issues are you interested in?	Having a child with a CL/P; experiences of diagnosis; raising a child with CL/P; CL/P and parenthood.
<u>P</u> opulation	What sector of the population interests you?	Parents; mothers; fathers; carers; caregivers; family; families; guardians.

Table 1. Free-text search terms applied to each database

Free-text search terms	
1	(parent* OR mother* OR father* OR family OR families OR adopt* OR foster* OR carer* OR caregiver* OR guardian*)
2	(cleft lip and palate* OR cleft lip* OR cleft palate* OR cleft* OR CLP* OR craniofacial* OR CFA OR cranio-facial* OR orofacial* OR oro-facial*)
3	Qualitative OR interview* OR focus group* OR action research OR ethnograph* OR thematic anal* OR grounded theory OR interpretive phenomol* OR narrative anal* OR content anal* OR framework anal*

Figure 2. Diagrammatic Representation of Search Process

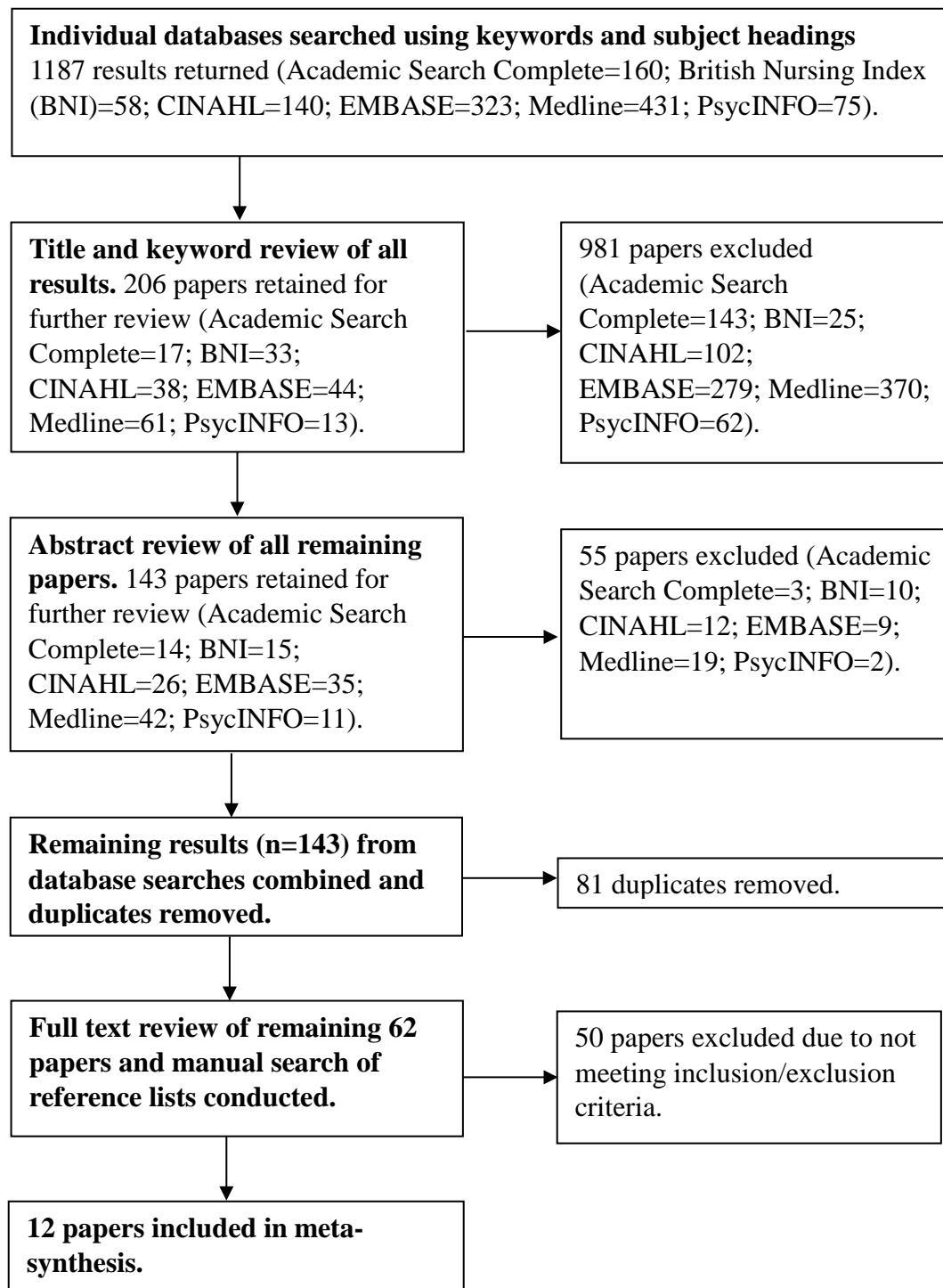


Table 2. Methodological Summary of Included Papers

Study	Author(s)	Year	Location	Study Aims	Participants	Data Collection	Data Analysis
S1	Awoyale et al.	2016	Nigeria	To identify qualitative factors that affect quality of life in family caregivers of children with CL/P.	22 caregivers of children with CL/P took part in the qualitative aspect of the study.	Mixed methods – qualitative component used focus groups	Qualitative component used framework Analysis
S2	Hopkins et al.	2016	USA	To explore the experience of parents caring for an infant with a cleft lip and palate receiving nasoalveolar moulding (NAM).	12 parents (eight mothers and four fathers) of infants with cleft lip and palate currently receiving (n=3) or recently completed (n=5) NAM.	Informal semi-structured interviews via telephone	Phenomenological approach
S3	Johansson and Ringsberg	2004	Sweden	To describe parents' experiences of having a child with CL/P with a focus on social and mental support.	20 parents (20 mothers and 12 fathers) of children aged 1.5 months to five years with CL/P.	Face to face interviews guided by a broad topic guide.	Phenomenological approach
S4	Lindberg and Berglund	2014	Norway	To describe the experiences of feeding for mothers of children born with CL/P and to determine how mothers cope with the challenges relating to feeding.	12 mothers of children with CL/P aged 3 – 13 months. All mothers had attended a class for families with new-born babies with CL/P	Face to face interviews with broad open ended questions	Phenomenological approach
S5	Martins et al.	2013	Brazil	To identify the empowerment mechanisms that families of children with cleft lip and palate (CLP) have developed or enhanced to be resilient against the adversity of CLP.	10 families of children with CLP up to three years of age (five interviews with both the mother and father; five with just the mother).	Semi-structured interviews conducted face to face in participants' homes	Content analysis
S6	Nelson et al.	2012b	UK	To explore how mothers and fathers experience and manage decision making during their child's cleft treatment.	27 families (comprised of 8 couples, three fathers, and 16 mothers) of children with CL/P aged 20 weeks to 21 years.	Face to face semi-structured interviews.	Grounded Theory

S7	Nelson et al	2012c	UK	To explore the emotional and social experiences of mothers and fathers caring for children with CL/P at different ages from birth to young adulthood.	27 families (total n=35 comprised of 8 couples, three fathers, and 16 mothers) of children with CL/P aged 20 weeks to 21 years.	Face to face semi-structured interviews.	Grounded Theory
S8	Shipe et al.	2015	USA	(a) To describe the experiences of families of adopted children with CL/P undergoing cleft treatment; (b) identify psychosocial attributes that signal optimal timing for surgery; (c) identify modifiable factors that can improve the experiences of families undergoing post-adoption surgery.	20 interviews with caregivers of children with CL/P adopted from outside the USA. (11 interviews with the mother only; three with the father only; six with mother and father dyad).	Mixed methods; qualitative component consisted of semi-structured interviews conducted face to face (n=12) or via telephone (n=8).	Mixed methods; qualitative component used grounded theory.
S9	Sischo et al.	2015a	USA	To present a conceptual framework of caregiver coping and adaptation to early cleft care using NAM.	68 caregivers of infants with nonsyndromic CL/P who elected to have NAM. Children aged 7 weeks – 13month – longitudinal design)	Face to face semi-structured interviews conducted at 1-week post NAM insertion, pre lip surgery, and post palate surgery/routine follow up for children with CL only.	Grounded Theory
S10	Sischo et al.	2015b	USA	To understand caregivers' responses to early CL/P care for their infants.	118 caregivers of infants (less than seven months old) with nonsyndromic CL/P. Participants were in one of two treatment groups; (1) traditional care, (2) traditional care + NAM.	Mixed methods; semi-structured face to face interviews conducted at three time-points; (1) beginning of treatment, (2) pre lip surgery and (3) post palate surgery.	Mixed methods – qualitative component used the extended case method.
S11	Stock and Rumsey	2015a	UK	To explore the impact of having a child born with a CL/P from the father's perspective.	15 fathers of children aged 4.5 months to 25 years born with CL/P.	Semi-structured telephone interviews.	Thematic analysis
S12	Stock and Rumsey	2015b	UK	To explore experiences of parents who were themselves born with a CL/P.	24 parents (13 mothers, 11 fathers) with CL/P themselves (8 with children with CLP, 16 with children without CLP).	Semi-structured telephone interviews.	Thematic analysis

Table 3. Quality Appraisal of Included Review Papers

CASP (2013) Questions ⁶	Assigned Study Number											
	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12
Q3. Is the research design appropriate for the study aims?	2	3	2	3	2	3	3	2	3	3	3	3
Q4. Is the recruitment strategy appropriate for the study aims?	2	3	3	2	2	3	3	3	2	2	3	3
Q5. Was data collected in a way that addressed the research issue?	2	3	3	3	3	2	2	3	3	2	2	2
Q6. Is the researcher-participant relationship adequately considered?	1	2	1	1	1	1	2	2	1	1	2	2
Q7. Have ethical issues been sufficiently considered?	2	2	2	3	2	2	3	3	3	2	3	3
Q8. Was data analysis sufficiently rigorous?	1	3	1	3	3	3	3	2	3	3	3	3
Q9. Is there a clear statement of findings?	2	3	3	3	3	3	3	3	3	3	3	3
Q10. What is the value of the research?	2	3	2	3	2	3	3	3	3	2	3	3
Total (range 8-24)	14	22	17	21	18	20	22	21	21	18	22	22

⁶ Scoring Key: Questions 3-10 were rated on a three-point rating scale; weak (1), moderate (2), strong (3).

Table 4. Contribution of Each Study to Meta-Synthesis Themes

	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12
Theme 1: Adapting to a Changed Future	X	X	X	X			X			X	X	X
• The unexpected loss of the ‘perfect’ child	X		X	X			X			X	X	X
• Developing understanding and personal meaning			X	X			X			X	X	X
• Re-adaptation to the child’s changed appearance		X	X							X	X	
Theme 2: Social Aspects of Parenting a Child with CL/P	X	X	X	X	X	X	X		X	X	X	X
• Social stigma	X		X	X		X	X				X	X
• Parents’ experiences of social support		X	X	X	X				X	X	X	X
Theme 3: Parents’ Experiences of Treatment		X			X	X	X	X	X	X	X	X
• The long and arduous treatment journey		X			X	X	X	X	X	X	X	X
• Balancing treatment burdens with ‘doing the best’ for the child		X				X	X	X			X	
• Relationship with the cleft team						X	X			X	X	
Theme 4: Empowerment and Personal Growth				X	X				X	X	X	X
• The journey to empowerment				X	X				X	X		
• A better parent: personal growth									X		X	X

Section One Appendices

- 1-A Manuscript Preparation Guidelines
- 1-B Data Extraction: An example from S1
- 1-C Data Synthesis: Initial Emerging Themes
- 1-D Data Synthesis: An Example of How Original Author and Participant Interpretations Contribute Towards Final Over-Arching Themes

Appendix 1-A

Manuscript Preparation Guidelines



The Cleft Palate-Craniofacial Journal

MANUSCRIPT PREPARATION

GENERAL INFORMATION

SCOPE

The Cleft Palate-Craniofacial Journal (CPCJ) is directed to a multidisciplinary readership of clinicians and scientists interested in craniofacial anomalies, including cleft lip and cleft palate. The CPCJ publishes original research articles, clinical reports, brief communications, articles related to new ideas or innovations, letters to the editor, editorials, invited book reviews, and meeting announcements.

CONTACT INFORMATION

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Two independent peer reviews are typically solicited. At the discretion of the Section Editor, a third review by a biostatistician may also be solicited. The Editor is responsible for all final decisions regarding acceptance or rejection, recommendations for revision, and final editing. Manuscripts will be evaluated according to various criteria, including scientific methodology, level of evidence, novelty, clarity, and conciseness. Accepted articles describing novel findings or methods and with high levels of evidence may be advanced in the publication queue

at the discretion of the Editor.

All submitted articles are “double-blinded” to ensure an unbiased review. Reviewers will not have access to author names or affiliations. Authors will not have access to reviewer names or affiliations.

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Authors are required to disclose, in a cover letter accompanying their manuscript, any relevant conflict of interest, including direct or indirect financial interests they may have in the materials or subject matter dealt with in the manuscript. This information will be held in confidence by the Editor during the review process, but at the discretion of the Editor, may be included in publication of an accepted manuscript.

GROUP AUTHORSHIP

The CPCJ allows research groups to be recognized in submitted manuscripts. Authors should identify both the group name and the individual authors who accept responsibility for the article (e.g., Smith A, Johnson R, Williams T; The CleftCran Research Group). The named individuals must meet the full criteria and requirements for authorship as described in the Author Responsibility section above. Other research group members who do not qualify for authorship may be listed in an Acknowledgement.

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types of publication including but not limited to print, visual, electronic, or broadcast media. Consent forms should be uploaded as an 'Additional Information' file at submission.

HUMANS AND ANIMALS IN RESEARCH

For manuscripts describing the results of experimental studies on humans, authors must include a statement in the Methods section of the manuscript that a Human Subjects or Institutional Review Board (IRB) approved the study and that informed consent was obtained. While informed consent might not be required for consecutive case series and/or retrospective chart review reports, these are still considered research given that the objective of your report is to generalize the findings. As such, they require Humans Subjects Review Board approval. If a formal IRB is not available, the authors must state so in a cover letter accompanying the submission, and include a statement in the manuscript that principles outlined in the Declaration of Helsinki were followed. Information regarding the Declaration of Helsinki may be found at <http://www.wma.net/en/30publications/10policies/b3/>.

All research involving animals must follow published guidelines for use of laboratory animals (<http://www.apa.org/science/leadership/care/guidelines.aspx>). Compliance with these guidelines should be indicated in the Methods section of the manuscript, along with Institutional Review Board approval if appropriate.

MANUSCRIPT PREPARATION

SUBMISSION CATEGORIES

Original Articles: Reports of original clinical or basic science data pertaining to prevalence, causes, mechanisms, diagnosis, course, treatment, and prevention, including systematic reviews and meta-analysis that represent a new contribution to the field. Limit: 7 typeset pages as they appear in the journal (about 7,000 manuscript words, with up to 6 figures or tables combined).

NEW IN 2016: *What I (We) Do:* Introduce new solutions to clinical problems. Novelty and quality of illustrations and videos (when appropriate) are key ingredients. Authors should include a brief (50-75 words) abstract with the following format: Background (what is the issue/problem), solution, what I/we did that is new. Also include 3-5 key words. If no patient identifiable data are included, no IRB form is necessary. Limit: 2 typeset pages as they appear in the journal (about 1,000 words, with up to 3 figures or tables combined, and up to 5 references).

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Brief Communications: Preliminary or limited results of original research pertaining to prevalence, causes, mechanisms, diagnosis, course, treatment, and prevention. Limit: 3 typeset pages as they appear in the journal (about 3,000 manuscript words, with up to 3 figures or tables combined).

Ethics/Health Policy: *Ethical and Legal Reports* are original articles which examine issues of ethics or the law arising in cleft and craniofacial care and research. *Health Policy Reports* are original articles which examine social, political and economic issues arising in cleft and craniofacial care or research. Limit: 3 typeset pages as they appear in the journal (about 3,000 manuscript words, with up to 3 figures or tables combined).

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Letters to the Editor: Comments in the form of letters that express differences of opinion or supporting views of recently published CPCJ content. Limit: 1.5 typeset pages as they appear in the journal (about 1,500 manuscript words, with up to 1 figure or table).

Editorials: Brief substantiated commentaries on subjects of interest to the CPCJ readership. Editorials should be narrative in form. Limit: 1.5 typeset pages as they appear in the journal (about 1,500 manuscript words, with up to 1 figure or table).

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1. Title Page

The Title Page (submitted separately from the manuscript) must include (in the following order):

- Title (maximum 20 words) ; should be informative, relevant, and concise
- Author names with *no more than* three highest attained degrees, in the order that they will appear in print
- Academic rank or position, and institutional affiliation for each author
- Name, address, telephone number, fax number, and email address of the corresponding author, who will receive all editorial communication and reprint requests.
- If applicable, statement that manuscript was presented orally at a professional meeting, including the name, date, and location of the meeting.
- Credits and appropriate grant numbers if the study was supported by an agency.
- Running title (less than 8 words).
- If applicable, statement acknowledging all forms of financial support
- If desired, any other acknowledgements (e.g. individuals assisting with conduct of the study but not qualifying for authorship).

To ensure that the article is blinded, please do not include author names or affiliations, or any other identifying information in any portion of the manuscript other than this Title Page.

2. Manuscript

Page 1: Title

The first page of the manuscript text file should include only the title used on the Title Page (above).

Page 2: Abstract

Original articles and ideas and innovations articles should include a structured abstract of no longer than 250 words (including Key Words) with the following headings and information, as applicable. Structured abstracts of no longer than 150 words should be used for data-based Brief Communications articles.

Structured Abstract:

Objective: State the main question or objective of the study and the major hypothesis tested, if any.

Design: Describe the design of the study indicating, as appropriate, use of randomization, blinding, criterion standards for diagnostic tests, temporal direction (retrospective or prospective), etc.

Setting: Indicate the study setting, including the level of clinical care (for example, primary or tertiary; private practice or institutional).

Patients, Participants: State selection procedures, entry criteria, and numbers of participants entering and finishing the study.

Interventions: Describe the essential features of any intervention, including the methods and duration of administration.

Main Outcome Measure(s): The primary study outcome measures should be indicated as planned before data collection began. If the hypothesis being reported was formulated during or after data collection, this fact should be clearly stated.

Results: Describe measurements that are not evident from the nature of the main results and indicate any blinding. If possible, the results should be accompanied by confidence intervals (most often the 95% interval) and the exact level of statistical significance. For comparative studies, confidence intervals should relate to the differences between groups. Absolute values should be indicated when risk changes or effect sizes are given.

Conclusions: State only those conclusions of the study that are directly supported by data, along with their clinical application (avoiding overgeneralization) and/or whether additional study is required before the information should be used in clinical settings. Equal emphasis must be given to positive and negative findings of equal scientific merit.

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Key Words: A short list of the key words that reflects the article's content.

Clinical reports should include an unstructured abstract of no longer than 100 words, including Key Words, describing the objective, essential features and uniqueness of the case being presented, and conclusions. Non-data-based Brief Communications and Ethics, Legal, or Health Policy reports should include an unstructured abstract of no longer than 100 words, including Key Words.

Page 3:

Where applicable, divide the body of the manuscript into the Introduction, Methods, Results, Conclusion, and References.

The CPCJ follows guidelines published in the *American Medical Association Manual of Style*. Manuscripts should be typed double-spaced with 1" margins, left justified, and use a standard 12-point font. Pages should be numbered consecutively in the upper right hand corner, beginning with the second page. Do not print a running title. Turn off the word processing program's hyphenation feature and "smart quotes" feature before typing. Headings must be used to designate the major divisions of the manuscript. Up to three levels of headings may be used.

Statistics

If a statistical analysis is conducted, explanation of the methods used must precede the Results section in the manuscript. Unusual or complex analysis methods should be referenced.

Units of Measure/ Abbreviations

The metric system is preferred for expressing units of measure. Abbreviations may be used for terms. The full term for each abbreviation should appear at its first use in the text, unless the abbreviation is a standard unit of measure. Abbreviations used in a table must be explained in a footnote below the table. For a list of standard abbreviations, consult the Council of Biology Editors Style Guide (available from the Council of Science Editors, 9650 Rockville Pike, Bethesda, MD 20814; <http://www.councilscienceeditors.org/>) or other standard sources.

The table below lists standard accepted abbreviations for typical cleft type classifications and study groups. Other abbreviations may be proposed for classifications and groups not listed.

<u>ABBREVIATION</u>	<u>USED TO DESCRIBE A SUBJECT GROUP THAT INCLUDES:</u>
CL	cleft lip (excludes (1) cleft lip and alveolus, (2) cleft lip and palate, and (3) cleft palate)
CP	cleft palate only (excludes (1) cleft lip and (2) cleft lip and palate)
CLP	cleft lip and palate (excludes (1) cleft lip and (2) cleft palate)
CL±P	cleft lip with or without cleft palate = cleft lip + cleft lip and palate (excludes cleft palate)
CP±L	cleft palate with or without cleft lip = cleft lip and palate + cleft palate (excludes cleft lip)
CL/P	cleft lip and/or cleft palate = cleft lip + cleft lip and palate + cleft palate (no exclusions)
CL±A	cleft lip with or without cleft alveolus = cleft lip + cleft lip and alveolus (excludes (1) cleft lip, (2) cleft lip and palate, and (3) cleft palate)
CP±A	cleft palate with or without cleft alveolus (excludes (1) cleft lip, (2) cleft lip and alveolus, and (3) cleft lip and palate)

TERMS THAT MAY BE ADDED TO THE ABBREVIATIONS ABOVE (IF APPROPRIATE):

i	isolated
I	incomplete
U	unilateral
B	bilateral
SM	submucous

Phonetic Symbols

Authors who use phonetic symbols are required to use Unicode-compliant fonts in their manuscripts. This will ensure the symbols display properly both during peer review and in the final published article. Examples of acceptable fonts include Charis SIL, Doulos SIL, and Gentium Unicode. Times New Roman is also acceptable, as it includes most IPA symbols and is Unicode compliant.

Citations/ReferencesSingle Author Article

Citation: Mantel (1963) or (Mantel, 1963)

Reference: Mantel N. Chi-square tests with one degree of freedom; extensions of the Mantel-Haenszel procedure. *J Am Stat Assoc.* 1963;58:690-700.

Two Author Article

Citation: Rasheed and Munshi (1996) or (Rasheed and Munshi, 1996)

Reference: Rasheed SA, Munshi AK. Electromyographic and ultrasonographic evaluation of the circum-oral musculature in children. *J Clin Pediatr Dent.* 1996;20:305-311.

Three Or More Author Article

Citation: Lilja et al. (2000) or (Lilja et al., 2000)

Reference: Lilja J, Elander A, Lohmander A, Persson C. Isolated cleft palate and submucous cleft palate. *Oral Maxillofac Surg Clin N Am.* 2000;12:455-468.

Two or more works by the same first author in the same year

Citation: Smith (1975a), Smith (1975b) or (Smith, 1975a) etc

Reference: Smith RC. Long term effects of smoking on fetal development. *Teratology* 1975a;42:75-84.

Monograph

Citation: Bardach (1967) or (Bardach, 1967)

Reference: Bardach J. *Cleft Lip and Palate* (Monograph). Warsaw: Polish Institute of Medical Publications; 1967.

Thesis

Citation: Dowden (1992)

Reference: Dowden PA. The Effects of Listener Training on the Speech Intelligibility of Severely Dysarthric Individuals. Seattle, WA: University of Washington; 1992. Dissertation.

Book

Citation: McWilliams et al. (1990) or (McWilliams et al., 1990)

Reference: McWilliams BJ, Morris HL, Shelton RL. *Cleft Palate Speech*. Philadelphia: BC Decker; 1990: 40-49. (only list pages if specific pages are cited).

Chapter in Book

Citation: Eliason (1990) or (Eliason, 1990)

Reference: Eliason MJ. Neuropsychological perspectives of cleft lip and palate. In: Bardach J, Morris HL, eds. *Multidisciplinary Management of Cleft Lip and Palate*. Philadelphia: WB Saunders; 1990:825–831.

Conference Presentation

Citation: Parke and Sawin (1975) or (Parke and Sawin, 1975)

Reference: Parke RD, Sawin DB. Infant characteristics and behavior as elicitors of maternal and paternal responsivity in the newborn period. Presented at the Meeting of the Society for Research in Child Development; April 1975; Denver, Colorado.

Website

Citation: World Health Organization (2005)

Reference: World Health Organization. International database on craniofacial anomalies. Available at: www.who.int/genomics/anomalies/. Accessed June 27, 2005.

When multiple references are cited simultaneously in the text, they should be arranged in chronological order, for example: (Smith, 1975; Jones et al., 1981; Brown, 1986). References should be double-spaced, and listed in alphabetical order (unnumbered) according to the surname of the first author. For articles with more than ten authors, include only the first ten author names in the reference list, followed by “et al.”.

Figure Legends

A list of figure legends must be included on a separate page at the end of the manuscript article file. The legend should explain each figure as concisely as possible. Do not include figure legends in your figure art file. Figure legends are not included in the word count limit.

Tables

Tables should be numbered consecutively using Arabic numerals. Each table should have an appropriate title and explanation at its head. Abbreviations used in a table must be explained in a footnote below the table. Submit tables as separate files, with one table per file, in either .doc (text) or .xls (spreadsheet) format.

Figures

All figures and illustrations must be original photographs or artwork. For figures or illustrations reprinted from published work, the author must obtain written permission from the copyright holder and upload that permission as an “Additional Information” file at submission. Figures should be numbered consecutively in the order in which they appear in the manuscript, using Arabic numerals. A “List of Figure” Legends must be included on a separate page following the body of the manuscript. The legend should explain each figure in detail. Authors will be responsible for the following charges for each color figure submitted: \$75.00 for online only; \$400.00 for both online and print for ACPA members or \$500.00 for non-members. A single figure may include multiple images (a, b, c, etc.) but all must appear on the same page.

Figures should be submitted in one of the following formats: tif (preferable), eps, jpg, pdf. Each figure should be submitted as a separate file. Composite figures made up of more than one image should be submitted as separate files (e.g. Fig 1A, Fig 1B). However, composite figures should contain a single legend describing the contents of all figures in the composite.

Refer to the Digital Art Specifications document at www.cpcjournal.org (see “For Authors”) for image resolution, size, and format requirements. For symbols that must be explained, please use a key that can be shot with the figures. Do not include symbols in the figure legend. Authors may be charged if artwork must be generated to incorporate figure symbols into the figure legend.

Figures submitted at lower than the required resolutions stated above will be allowed for review purposes. However, the publication process for accepted manuscripts will be delayed until acceptable images have been submitted.

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Video clips that contribute significantly to the manuscript may be submitted in either avi, mov, or mpeg formats. Videos should be submitted at the desired reproduction size and length, but should not exceed 6 MB in

size. If submitting avi files, the files must be compressed. Authors are solely responsible for all editing of video clips. Each video file must be accompanied by a still image from the video that conforms to the figure resolution and size requirements outlined above for figures. This image will be published in the print version of the journal in place of the video. Please indicate in the figure legend that the still image has an associated video file. Both the print-version figure and the video must share the same file name (e.g., Figure1.jpg and Figure1.mov). A List of Video Legends” should be prepared on a separate page at the end of the manuscript article file. *Video submissions are strongly encouraged, particularly for articles dealing with surgical techniques.*

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Appendix 1-B

Data Extraction: An Example from S1

Author Theme Titles	Author Interpretations, Metaphors and/or Key Phrases	Representative Participant Quotes	My Initial Comments and Interpretations
Reaction to the birth of a cleft child	<ul style="list-style-type: none"> • Expressions of ‘shock’ and ‘sad’. • Baby considered an alien. • Being more aware of occurrence of clefts results in less severe reactions. • Experiencing mixed feelings towards the baby, both happiness and despair. 	<p><i>“As a pharmacist I had heard of cleft, so when the doctor told me he had a cleft palate. I was sad and tears just flowed as I sobbed.”</i></p> <p><i>“I wasn’t really prepared.... I felt he was ugly but he was still my baby... nothing else was wrong apart from the split lip.”</i></p>	<ul style="list-style-type: none"> • Diagnosis of cleft at birth a shocking and overwhelming experience. • Difficult reactions towards the baby – impact on bonding? • Positive and negative emotions experienced simultaneously. • Preparation and awareness reducing extent of shock?
Information about care processes	<ul style="list-style-type: none"> • Inadequate and correct information made caring for the baby difficult. • Poor access to services was highlighted especially in the rural areas. • Health workers were reported not to show empathy. This increased emotional strain. • Most parents were however happy with surgical repair. 	<p><i>“The nurse on duty sent me with a referral letter and no information. I cried all the way to the hospital carrying my baby in the four hour journey. I got there and the first words the nurse I met said was to come back the next week, clinic had closed. I was very sad”</i></p> <p><i>“I knew I didn’t have a perfect baby, I hoped the doctors knew what they were doing and now that it is healing, I’m happy; I can live my life now”</i></p>	<ul style="list-style-type: none"> • Lack of information and support from healthcare professionals adding to the challenge of caring for a baby • Feeling abandoned by professionals • Lack of support and empathy from professionals is isolating. • Significance of surgery – allowing parents to move on and live their life.
Challenges of caregiving’	<ul style="list-style-type: none"> • Hidden challenges relating to finances, social and emotional aspects. 	<p><i>“I am very ashamed: I can’t take him out till the repair is done. My mother-in-law said he is a bastard and I should throw him away. My neighbours whisper when they see me, they keep finding reasons to come into my house and greet our baby. My husband only understands and comforts me, but it has not been easy.”</i></p>	<ul style="list-style-type: none"> • An isolating experience - the many challenges of being a caregiver for a child with CL/P (e.g. financial, social and emotional) not recognised by others. • Stigma and shame – hiding the child from family for fear of others reactions.
Coping mechanisms’	<ul style="list-style-type: none"> • Participants still adjusting to the family acceptance of the child. • Participants had to stop work and could not attend social function. • Hiding the child for fear of stigma. 	<p><i>“I avoided my family, even during my sister’s wedding... I can’t let them see my child like this”</i></p> <p><i>“Covering the baby’s face and head... has helped me go out occasionally. I tell them he is sleeping.”</i></p>	<ul style="list-style-type: none"> • The stigma and shame of CL/P. • Attempting to hide CL/P to avoid the stigma and shame. • Fear of negative reactions from others.

Appendix 1-C

Data Synthesis: Initial Emerging Themes

Emerging Theme	Descriptive Theme Title
1	An unexpected event: the loss of an expected 'perfect' child
2	Social stigma and acceptance
3	Developing understanding and acceptance
4	Re-adaptation following treatment
5	Managing the long and arduous journey of treatment
6	Trusting and depending on the cleft team
7	Balancing treatment burdens with wanting the best for the child
8	Being a good parent: doing the best for the child
9	Experiences of support
10	Impact on parents' relationships
11	Relationship with the child
12	Personal growth and empowerment: impact on parental identity and self-worth
13	Looking to the future: parents' hopes and fears for the child

Appendix 1-D

Data Synthesis: An Example of How Original Author and Participant Interpretations Contributed Towards Final Meta-Themes

Overarching Theme One: Adapting to a ‘changed’ future’				
Theme Title	Study	Original Author Theme Titles	Key Author Interpretations	Representative Participant Quotation(s)
<i>Sub-theme:</i> The unexpected loss of the expected ‘perfect’ child’	S1	Reaction to the birth of a cleft child	<ul style="list-style-type: none"> • Expressions of ‘shock’ and ‘sad’. • Baby considered an alien. • Experiencing mixed feelings towards the baby – happiness and despair. 	<i>“I wasn’t really prepared.... I felt he was ugly but he was still my baby... nothing else was wrong apart from the split lip.”</i>
	S3	Unexpected event: having a child with CLP - ‘first meeting with the child’	<ul style="list-style-type: none"> • Parents shocked when they first saw their baby. But others did not react strongly. • The child was seen as both ugly and sweet at the same time. 	<i>My first reaction was shock. I wasn't really prepared. We didn't think we'd have a child with a cleft palate. It was a funny feeling. I thought he was ugly but sweet at the same time. (Mo)</i>
	S4	Being a capable and good mother	<ul style="list-style-type: none"> • Mothers reported feelings of shock and great concern about feeding at the time of diagnosis in pregnancy. 	<i>It was overwhelming because all thoughts came at the same time... what will she look like... how can I feed her... how will others react?</i>
	S7	Conflicting Emotions	<ul style="list-style-type: none"> • News of a child’s cleft brought a simultaneous mixture of grief about the impairment and delight about having a new-born. • Parents expressed disappointment about the imperfection associated with their child having a cleft. 	<i>“. . . It’s very difficult to take in that the child you thought was “perfect” in inverted commas [quotation marks], turns out that they’re not perfect as defined by the medical professionals.</i>
	S11	Appraisals of the Cleft; Variations in Care and Support	<ul style="list-style-type: none"> • Antenatal diagnosis extremely upsetting, not just because fathers had been told their child had a cleft but also due to the often insensitive way in which this information was delivered. • The immediate offer of a termination following diagnosis was distressing. 	<i>My partner was crying her eyes out and we were left alone in this room. Then a staff nurse put a piece of paper in front of us and I will always remember it said, "how to deal with a disabled child."</i>
	S12	Reactions to their child’s diagnosis; Factors Affecting Parental Adjustment	<ul style="list-style-type: none"> • Having had children without CL/P previously or receiving their child’s diagnosis of cleft in the postnatal period increased shock. • Professionals had been insensitive at times. 	<i>I was devastated. People say things like, “Oh there’s so much that can be done nowadays” . . . but I know how painful it is to get there, and how long the journey is. I just felt sad for her, really.</i>

SECTION TWO

RESEARCH PAPER

Experiences of Transition to Secondary School in Children with Cleft Lip and/or Palate

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(excluding reference lists, tables, figures and appendices)

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Abstract

Objective: The transition to secondary school may be particularly challenging for children with cleft lip and/or palate (CL/P). However, there is an absence of research examining this topic. This study explored the secondary school transition experiences of children with CL/P in order to understand how they experience and make sense of this critical phase and inform the development of services supporting children and their families during this period.

Design: A qualitative design was used in which data were collected via semi-structured interviews and analysed using interpretative phenomenological analysis (IPA).

Setting: Participants were recruited from a NHS specialist cleft service that covers a large geographical area in England and North Wales, United Kingdom.

Participants: Six participants with CL/P (aged 11-12 years old) in their first 12 months following transition to secondary school.

Results: Four themes describe participants' transition experiences; (1) 'managing and valuing difference: the impact on self-worth and identity', (2) 'managing and valuing difference within the social context', (3) 'disclosure and the process of informing others about CL/P', (4) 'developing positive peer relationships'.

Conclusions: Children with CL/P experience a number of psychosocial challenges during the transition to secondary school. Clinical psychologists working in cleft services should attend to these issues when supporting children with CL/P (and their families) in preparing for this transition to foster resilience and adjustment.

Keywords: children; cleft lip and/or palate; CL/P; experiences; interpretative phenomenological analysis; IPA, qualitative; resilience, school transition; visible difference.

Cleft Lip and/or Palate

Cleft Lip and/or Palate (CL/P)¹ is one of the most common types of congenital difference (Murray, 2002; Mossey et al., 2009) with a prevalence of 9.25 (UK) and 10.20 (US) per 10,000 births² (International Perinatal Database of Typical Oral Clefts (IPDTC), 2011). A CL/P is a gap or opening in the lip and/or mouth, which occurs when areas of the face do not fully join during foetal development. Clefts are usually repaired surgically in early infancy, however further procedures are often required as children grow. Additionally, children with CL/P typically experience a range of additional difficulties, including; feeding and dental problems, otitis media with effusion (glue ear), recurrent ear infections, hearing and speech difficulties and/or visible facial differences (Shkoukani et al., 2013).

Despite the above problems, research evidence presents a mixed picture regarding psychosocial adjustment in young persons with CL/P (Hunt et al., 2005). A number of studies have found that children and adolescents with CL/P have superior self-esteem, more positive social experiences, and a better quality of life compared to those without CL/P (Carroll and Shute, 2005; Locker et al., 2005; Kramer et al., 2009; Feragen et al., 2010). Conversely, a large number of studies suggest young people born with CL/P experience higher rates of anxiety and depression, and lower self-esteem (including dissatisfaction with appearance and/or speech) compared to peers without CL/P (Ramstad et al., 1995; Thomas et al., 1997; Hunt et al., 2007; Murray et al., 2010). It is unclear as to precisely why some individuals cope better with CL/P than others. Methodological weaknesses and inconsistencies in the literature may account for some of these differences. For instance, Hunt et al. (2005) highlight a number of issues including; the lack of appropriate controls and longitudinal studies, a

¹ CL/P is used throughout to refer to cleft lip, cleft palate, and cleft lip and palate, unless otherwise specified.

² Prevalence varies nationally. Overall international prevalence= 9.92 per 10,000 with 95% confidence interval of 9.70-10.14 (IPDTC, 2011).

reliance on proxy reports from parents/teachers, and the use of a wide variety of questionnaires measuring aspects of psychological functioning.

Psychosocial Wellbeing during the Transition to Secondary School

Starting secondary school is a significant transitional event for many children (Wassell et al., 2007) and presents opportunities for new experiences, friendships, and positive challenges (Sirsch, 2003; Pratt and George, 2005; Jindal-Snape and Miller, 2008). However, moving from the small, personal and familiar environment of primary school, to the larger and unfamiliar setting of secondary school requires adjustment, and can be a daunting and challenging time for children (Zeedyk et al, 2003).

As children embark upon this transition, they experience disruptions in peer relationships (Zeedyk et al., 2003; Pratt and George, 2005; Rice et al., 2011). Incidences of bullying can also increase as individuals seek to establish status within social groups (Pellegrini and Long, 2002). Subsequently, negative effects on self-esteem and anxiety during are widely documented (Brown and Armstrong, 1982; Wigfield et al., 1991; Pellegrini and Long, 2002). Individuals with low self-esteem and previous experiences of bullying are more likely to experience a ‘difficult’ transition. Additionally, ‘difficult’ transitions predict persisting psychosocial and educational difficulties, such as depression, poor peer relationships and lower attainment (West et al., 2010). Accordingly, the transition to secondary school is considered a ‘critical’ period (Sirsch, 2003; Treasury, 2003; Griebel and Berwanger, 2006).

Transition to Secondary School in Children with Cleft Lip and/or Palate

There is increasing recognition that the transition to secondary school may be particularly challenging for individuals with craniofacial differences (CFD) such as CL/P and

concerns regarding the potential for teasing and/or bullying are highlighted (Hearst, 2007; Rumsey and Harcourt, 2007; Division of Clinical Psychology (DCP), 2010; Tierney et al., 2015). Furthermore, a number of studies report high rates of teasing and/or bullying in children of primary school-age with CL/P (Semb et al., 2005; Lorot-Marchand et al., 2015; Feragen and Stock, 2016), which as highlighted is a risk factor for a difficult transition.

During the transition to secondary school, there is an increased desire for acceptance from peers (Pratt and George, 2005). Indeed, Marshman et al. (2009) found that many young people with a range of CFD (including CL/P) developed appearance-related concerns around the time of their transition to secondary school. 'Making a good impression' was also seen as important, with individuals often attempting to conceal their CFD or seek corrective treatments ahead of their transition to minimise the potential for negative peer interactions (Marshman et al., 2009).

Edwards et al. (2011) proposed that the way children with CFD present themselves in social interactions significantly affects the 'first impressions' others make about them. While positive social skills and expressiveness are important in the reduction of stigma and development of positive peer relationships (Edwards et al., 2011), this is something that young people with CFD may find difficult. Additionally, children (from the general population) tend to judge individuals with speech difficulties more negatively than individuals without speech difficulties (Lass et al., 1991).

A further example of the difficulties encountered by secondary school-age children with CL/P is provided by Kapp-Simon and McGuire (1997), who observed the social interactions of children with a visible CFD (including CL/P) alongside peers without CFD during school lunch breaks. They found that children with CFD were less likely to initiate social interactions, more likely to be on the peripheral of group conversations, and less likely

to receive positive peer responses. Specific problems with attentional difficulties such as self-control, concentration difficulties, and impulsivity have also been indicated (Slifer et al., 2003), which may have implications for an individual's ability to 'settle in' to their new environment.

The above literature indicates particular issues that children CL/P may encounter when transitioning to secondary school and with which they may need support. Within the UK, where the current study is set, specialist cleft services operate on a regional basis to provide holistic, multidisciplinary input to individuals and their families to optimise feeding, growth, speech and language skills, and social and psychological wellbeing (Chuo et al., 2008; Mossey et al., 2009; NHS England, 2013). Clinical psychologists form an integral part of this multidisciplinary team (MDT; Clinical Standards Advisory Group, 1998), promoting psychological wellbeing, preventing mental health difficulties in children and their families, and identifying and providing support to those in need of psychological intervention (Lockhart, 2003; Hearst, 2007; Chuo et al., 2008).

UK cleft service specifications state that the provision of psychological support should be available to all children with CL/P and their families prior to the transition to secondary school (NHS England, 2013). However, specific recommendations regarding this support are not provided and subsequently regional variation exists (Rumsey and Harcourt, 2007). In addition, the evidence base on which to develop such recommendations is lacking, due to an absence of research examining the secondary school transition experiences of children with CL/P. Further research regarding the psychosocial issues and lived experiences of children with CL/P during this period is paramount for ensuring that services are best able to meet the needs of children and their families.

In order to address the evidence gap, the present study sought to explore the lived experiences of children with CL/P when transitioning to secondary school, in order to illuminate how they experience and make sense of this critical phase. The purpose of this is to inform the development of cleft and related services as well as the practice of clinical psychologists and other health professionals working with children with CL/P.

Method

Design

This research aimed to understand the lived experiences of children with CL/P when transitioning to secondary school. A qualitative design allowed for the in-depth, idiographic examination of participants' experiences within an exploratory framework. This inductive approach was apposite given the dearth of empirical studies within this area.

Interpretative phenomenological analysis (IPA; Smith et al., 2009) was selected as the most appropriate methodological approach to address the research aims due to its underlying principles of phenomenology, hermeneutics and idiography. Phenomenology involves understanding the meaning of lived experience, hermeneutics encompasses the interpretation of bodies of text, such as research interview transcripts, and idiography concerns the sense an individual makes about their lived experience and the essence of what this experience is like for them. IPA is therefore interested in the lived experiences of individual participants alongside any recurring experiences for a particular, well-defined group (Smith, 1996; Smith et al., 1997; Smith et al., 2009). A number of published IPA studies with samples of children of a similar age to this present study (Griffiths et al., 2011; Majors, 2013; Watson et al., 2016) indicate that children of this age can provide experiential accounts of their own sense-making and thus IPA is a suitable methodological approach.

Consistent with the principals of IPA, data were obtained via one-to-one semi-structured interviews with participants. This enabled participants to share their experiences in a flexible and individualised way whilst ensuring that detailed, autobiographical accounts focused on the research aim.

Sampling and Recruitment

Unlike quantitative research that often demands large sample sizes, Smith et al. (2009) argue that for IPA studies it is advantageous to focus on small, homogenous samples to balance time-intensive depth of detail and interpretation with the idiographic analysis of cases. Whilst there is no 'ideal' sample size for an IPA study (Smith and Osborn, 2003), Smith et al. (2009) assert that 4-10 participants is appropriate for professional doctorate level research. Additionally, a growing number of single case and small n (1-4) IPA studies have been published in peer-reviewed journals (Robson, 2002; Bramley and Eatough, 2005; Eatough and Smith, 2006). Therefore, the present study sought a sample size and composition consistent with the parameters of IPA.

To help ensure homogeneity (that is, a common set of experiential features of research concern) in this study, purposive sampling was utilised. Individuals were eligible to take part if they were born with a CL/P and they transitioned from primary to secondary school, within the UK, in the previous 12 months. Individuals were excluded from the study if they were not educated in a mainstream setting.

Recruitment took place via one UK-based regional cleft service, which split over two NHS trust sites, covered a large geographical area. The relevant cleft teams identified and

contacted the parents/carers of all individuals (n=247)³ likely to meet the inclusion criteria supplying written information about the study by post. Advertisement posters were also displayed in clinic waiting rooms and parents/carers of interested individuals were asked to contact the researcher directly to express an interest in the study.

Participants

The sample comprised one group of six participants (1 female, 5 male). All participants were born with a CL/P, and at the point of participation, all were aged 11-12 years old and had transitioned to secondary school within the last 12 months. Salient participant characteristics are summarised (table one) and case studies providing contextual information are appended (2-A).

[INSERT TABLE 1 HERE]

Data Collection

Data were collected via a single face-to-face interview with each participant lasting an average of 48 minutes (range 41-63 minutes). Interviews took place at the participants' home, and all opted to have their parent/carer present. A semi-structured approach was utilised in which I, as the researcher, facilitated an exploratory discussion with participants about their experiences of school transition. An interview schedule (Section 4) comprised of broad open-ended questions was developed following consultation with a health psychologist with expertise in qualitative research (academic supervisor) and a clinical psychologist working with the study population (field supervisor) and was used flexibly to guide interviewing. Examples of questions included 'What has it been like growing up with a cleft?' and 'Can

³ Total number of according to cleft service database records. Total comprises two school cohorts at site 1 (n1=77; n2=92) and one school cohort at site 2 (n=79).

you tell me what it was like starting your new school?’ Follow up questions such as; ‘Can you tell me more about that?’ prompted participants to develop their accounts. The interview schedule facilitated a consistent approach to questioning, whilst allowing the exploration of nuances in participants’ experiences in a conversational manner. Interviews were audio recorded and subsequently transcribed. Following transcription of the first interview, supervision was obtained from the academic supervisor and feedback was utilised to refine research-interviewing skills. For instance, in subsequent interviews I tried to refrain from summarising participant accounts to minimise disruptions to the conversational flow.

Data Analysis

Data were analysed using IPA, guided by Smith et al. (2009). Firstly, each transcript was read a number of times to aid familiarisation. Initial coding of the data was then conducted individually for each participant. This involved annotating the left margin of each transcript with exploratory comments that highlighted anything of interest to the research question from a psychological perspective. This included a summary of the thoughts, feelings and actions shared by the participant and any preliminary interpretations about phenomena (Smith et al., 2009, p83-90). Next, the right margin was used to summarise the fundamental essence of the data in the form of key words and phrases that constituted ‘emergent themes’ (Appendix 2-A). Emergent themes reflect an initial understanding about the participant’s experience taking into account both the ‘first order’ participant words alongside the ‘second order’ author interpretations (Smith et al., 2009, p91-92).

In order to develop the depth and complexity of interpretations, emergent themes were drawn together into a coherent structure across each participant’s account as a whole. Here, each emergent theme was written onto a post-it note, and themes that were similar or somehow related were then spatially grouped together and those that were divergent were

separated and re-grouped where applicable. Themes that did not fit any groups were discarded. The product was a set of super-ordinate themes that captured the essence of the participant's experience (Smith et al., 2009 p92, 96-99). Narrative summaries were then written for each super-ordinate theme to provide a coherent and detailed summary of each theme and help retain the voice of each participant in subsequent stages (see Appendix 2-B; Smith et al., 2009, p99). Analysing participants' data individually, one participant at a time, enabled openness to nuances and the emergence of new themes throughout analysis.

The next stage of analysis involved bringing together super-ordinate themes into a set of overarching concepts (Smith et al., 2009, p100). Super-ordinate themes from each participant were collated and reviewed so that patterns across the sample could be examined. This included a focus on both similarities and divergences, within and across the data. At this stage, supervision from the academic supervisor helped ensure methodological rigour and face validity. Recommendations, such as the separation of psychological and social aspects of 'difference' (themes one and two), were incorporated as theme development continued. Connected themes were combined and modified theme titles assigned to each overarching theme (Smith et al., 2009, p101). Appendix 2-C illustrates this and demonstrates how participant level super-ordinate and emergent themes contributed to final overarching themes. Finally, succinct yet rich narrative accounts of each overarching theme encompassing the data in its entirety were developed. These accounts form the results and are evidenced by extracts from between four and six participants for each theme which exceeds Smith's (2011, pg17) 'acceptable' criteria for reporting IPA studies with a similar sample size.

Reflexivity

In IPA, research findings are co-constructed via the interface between the researcher and the participant (Shaw, 2010). Reflexive practice is essential to enable the researcher to

acknowledge the impact that their own assumptions may have on findings (Larkin et al., 2006; Smith et al., 2009). Smith et al. (2009) provides a framework for data analysis that encourages the researcher to identify and then temporarily set aside their own preconceptions in order to privilege participant accounts. Accordingly, I recorded an audio diary throughout the research process and kept a reflective log to enable consideration of the process and content of data collection and analysis and aid reflexivity. A transcribed excerpt from this audio diary is appended (appendix 2-D).

Ethical Issues

The UK 'National Research Ethics Service' granted approval for this study and ethical issues were considered throughout the research process. Fully informed written parental consent and participant assent was provided ahead of participation and efforts were made to minimise participant distress (see sections three and four for further discussion).

Results

Four overarching themes (presented diagrammatically in figure one) describe participants' experiences of transition to secondary school; (1) managing and valuing difference: the impact on self-worth and identity; (2) managing and valuing difference within the social context; (3) disclosure and the process of informing others; (4) developing positive peer relationships. To aid readability basic transcription conventions are used (table two).

[INSERT FIGURE 1 HERE]

[INSERT TABLE 2 HERE]

Theme One: Managing and Valuing Difference: The Impact on Self-worth and Identity

Theme one describes participants' sense of feeling different from their peers as a result of their CL/P, the impact that this had their self-worth and identity, and how they managed this during the transition to secondary school.

All participants thought that their CL/P meant that they were in some way different from peers, for example, having a different appearance (Ruby and Tyler), sounding different (Josh and George), or a general sense of being different (Ethan and Harry). This was due to the rarity of CL/P, as most stated they did not know anyone else with CL/P at either their primary or secondary school. The transition to secondary school magnified participants' sense of difference and brought 'difference' into conscious reflection. Some considered difference to be special and/or something to feel proud of; *"I look different and I had braces [before anyone else did] ... I felt different but not in a bad way, I was kind of proud"* (Ruby; 169-178). Such views positively influenced self-worth. However, feeling different was also paradoxically experienced as emotionally challenging, with feelings of discomfort, embarrassment, and isolation being common; *"no one knows what it's like, and no one knows what it feels like and it's a bit like I wish someone, just one person knew what it felt like"* (George; 351-352). Negative emotional reactions were driven by an underlying sense of undesirability, and a belief in the 'truth' of this undesirability; *"this boy came up to me... for no reason he called me fat nose... I was really embarrassed... the fact that he kind of, I can't explain it, like, the fact that it was kind of almost true"* (Ruby; 4-15). However, because most participants both positively and negatively appraised their CL/P and sense of difference, the impact that negative social interactions had on self-worth was complex. To highlight this, on the one hand Josh indicated that he considered his difference to be special and interesting to others; *"I knew people were happy about me and like they were fascinated*

by me, by my cleft palate, cause like it's not like a great population of people with them" (Josh; 339-340). However, feeling different from his peers also resulted in feelings of inadequacy. For instance, Josh often used language laden with negative connotations such as "dodgy" (Josh; 45) and "hole mouth" (Josh; 49) to describe his CL/P and experiences of difference during his transition. In viewing his cleft as integral to his identity, Josh felt more threatened by negative stereotypes (real or perceived) surrounding his difference. These contradictory and complex patterns appeared across most participants. Subsequently, it seemed that feeling 'different' was neither a wholly positive nor negative experience for participants and could be both: "*sometimes it's good being different, sometimes I don't mind it that much, and sometimes I like being different*" (Ruby; 459-460).

Participants attempted to cope with feelings of difference during their transition by highlighting shared interests and experiences with peers (without CL/P) to enable them to feel 'less different'. In doing this, some participants also began to notice the wide range of individual difference that exists in others. Understanding the 'normality of difference' encouraged a positive view of difference, which in turn fostered a positive sense of self; "*I'm different from other people and I don't mind that... it can be a bit of appearance, and personality..., like my nose is a bit different I know that, and I think my personality is [different]. Well everyone's personality is kind of different... It's a good thing, because if we were all the same, we would get tired of it... same personality and everything, and then everyone would just go crazy and it would be horrible.*" (Tyler; 402-411). A further strategy adopted by two participants (Ruby and Ethan), particularly when faced with external threats such as bullying, was to seek validation through reflecting on their own positive attributes. These focused on participants' constructions of how they considered themselves a 'good person' as opposed to physical characteristics; "*I had done [some charity fundraising] to*

help others and it made me feel a bit better about myself...the fact that... it didn't matter how I looked, just that I had done something good for other people" (Ruby; 73-79).

Overall, participants felt 'different' from their peers due to their CL/P. However, the experience of difference was multifaceted and thus experienced both positively and negatively by participations throughout their transition. That is, participants' relationship with difference was not stable but fluctuated across time and contexts depending on participants' relationship with their personal identity and their social interactions. Participants adopted a range of strategies to enable them to manage feelings of difference during their transition.

Theme Two: Managing and Valuing Difference within the Social Context

Theme two describes the ways in which participants' managed their 'difference' within the social context during the transition period to facilitate a sense of social acceptance.

As participants embarked upon their transition to secondary school, they worried about the impact that their CL/P would have on their social experiences. Most participants were apprehensive about negative appraisal and concerns regarding bullying were apparent, especially amongst participants with previous experiences of teasing/bullying; *"I was sort of a bit worried, if I would get bullied about it... I didn't want people to know and then pick on me because I had that [CL/P] like in case they called me names or I was different and they might make fun of that" (George; 81-85).*

Participants adopted a range of strategies to manage their sense of difference from peers during their transition. Some sought to minimise or hide their 'difference' from others to limit negative peer appraisal. For instance, Josh explained how he initially avoided shouting during sports lessons at his new school to try to prevent others from noticing he sounded different; *"I didn't like shouting in rugby. I didn't want to make my voice [obvious*

to others] so that people ask what's wrong with my voice" (Josh; 308-309). However, hiding one's difference contradicted beliefs that difference can be positive. For instance, in addition to hiding his difference, Josh also described using his cleft palate as a means of impressing peers; "I show them [the scars in] my mouth... they are all impressed" (Josh; 13-17). This again highlights the complex relationship that participants had with a sense of difference, both personally (as described in Theme 1) and socially.

Hiding/minimising CL/P from peers was not an option for those participants such as Ruby and Ethan, that had a more visible CL/P, and both described experiencing appearance related teasing/bullying shortly after starting secondary school. Teasing/bullying during the transition period was experienced as emotionally difficult as it threatened participants' sense of feeling accepted in their new environment. As Ethan shared; *"two girls in my [class] were making fun of me because of my appearance... it made me angry and upset... I was shocked because I didn't really think that people would be like that [at secondary school]" (Ethan; 139-155). To cope with this, these individuals avoided being the centre of attention, preferring smaller peer groups that would afford a sense of safety. Having good support when issues arose was also important. For instance, both Ruby and Ethan stated that having supportive parents and teachers meant that they felt able to report the bullying and seek the help they needed; "I went out and told the teacher, and they told them off quite badly... it made me cry [to repeat it to the teacher] but I think it helped... I thought that if she wasn't [going to] get into trouble then she was going to do it again" (Ruby; 36-40).*

Participants also sought a sense of 'social normalisation' to reduce the threat of feeling different during the transition period. For instance, George described how he was just the same as his peers (without CL/P) because he could do all the same things as them. Alternatively, Josh described how he would attempt to fit in with peers by reciprocating

teasing regarding physical characteristics to normalise and trivialise teasing he received and be seen by others as 'the same'. For instance; *"I'd call them and they'd call me ... I'd call them peg leg or something, so we'd just call each other's illnesses"* (Josh; 48-50).

Additionally, Tyler found that he was able to normalise his experiences of difference by meeting other peers with a CL/P at a specialist CL/P school transition group. *"I remember going to the school [transition group] thing at the hospital and I met a few people... it was good, seeing other kids with a cleft lip... it was just nice to see other people like that"* (Tyler; 276-291). Feeling the same as others reduced feelings of isolation and increased a sense of connectivity, which participants linked to adjusting and coping during their transition.

In summary, participants worried that 'difference' might affect their ability to fit in and feel accepted by peers. Active attempts to seek a sense of 'normalisation', establish connections with peers, and gain support from others facilitated adjustment and coping despite initial anxieties.

Theme Three: Disclosure and the Process of Informing Others about CL/P

Theme three describes the process of informing others about CL/P during transition to secondary school, and the different ways in which participants managed 'disclosure'.

As participants started secondary school, they noticed that new peers and teachers had little understanding of CL/P and in some cases this led to incorrect assumptions being made; *"someone once asked me if it was a car crash, and I was like NO!"* (Ruby; 220). The novelty of CL/P invoked curiousness from others and most were asked questions about their CL/P. Most participants interpreted this curiousness as a genuine, friendly attempt by peers to understand more about CL/P. These participants orientated towards informing others about CL/P to increase understanding, and put others at ease. However, not all agreed. Ruby and George both considered CL/P to be a private matter and therefore experienced questioning as

invasive; *“I kind of wanted it to be private, I just didn’t want everyone knowing... because like, I think it might have given me another reason to be singled out”* (Ruby; 253-260).

Accordingly, Ruby and George sought to maintain their privacy; however, this was often difficult given the visibility of their CL/P. Subsequently, Ruby tended to ignore or divert attention away from her CL/P to enable her to retain some control in disclosure; *“I tried to ignore them I was like ‘pardon what did you say?’ and then tried to think of a way to avoid answering it... sometimes I just shrugged and walked off”* (Ruby; 184-207).

Sharing with peers was largely spontaneous and in response to peer questioning; *“I told them because they asked me”* (Tyler; 40). Participants took a ‘matter of fact’ approach, describing in literal terms what having a CL/P means; *“I say I was born with it, I was just born with a hole”* (Harry; 286). This approach was influenced by discussions with healthcare professionals during clinic visits and broader family discourses; *“I just explained everything that my mum and dad had told me and that I had heard from the doctors”* (Ethan; 65-66). Having support from pre-existing friends was also beneficial when explaining to new peers. Josh described how pre-existing friends understood enough information to explain CL/P to others, whilst lacking an emotional connection that might make talking about CL/P difficult; *“my friends told my new friends... they explained it probably better than me... they put more detail, like about my operations, and how much pain I was in... cause like I was a bit nervous and they wasn’t because it’s not them* (Josh; 173-183).

Participants also experienced difficulties informing others. Most felt unprepared to talk about their CL/P, due to having little prior experience of informing others. Participants felt that they themselves lacked a comprehensive understanding of CL/P, which resulted in feelings of inferiority for not ‘knowing better’; *“I didn’t know what myself had, so like I felt a bit silly... like because I was born with it... and I didn’t even understand it, I felt a bit silly.”* (George; 68-74). However, participants became more confident in talking about their CL/P as

they had more practice in doing so; *“I done it once, it felt ok to do it again”* (Josh; 185). Positive reactions from others also boosted participants’ confidence in informing others; *“I opened up and sort of told someone and it made me feel better to think that they weren’t doing anything about it”* (George; 214-216). A number of participants also described practicing potential responses to peer questioning ahead of their transition to increase a sense of preparedness. For instance, George described how he got the idea of practicing *“comebacks”* (George; 322) to unwanted questioning after reading a children’s novel about visible facial difference.

Finally, the decision to disclose was not necessarily a straightforward decision with participants indicating ambivalence regarding how much they shared and with whom. Timing was also an important consideration. Josh described a need to inform others (especially teachers) early on to alleviate misunderstandings; *“if I tell [my teacher early on about how CL/P affects my voice] then he won’t pull me up on it in the future”* (Josh; 192). Conversely, both George and Ruby only shared their experiences with close friends several weeks/months into the new school year once positive peer relationships were established; *“I made friends and then I trusted them so I thought I could tell them... I thought if they really are my friends they wouldn’t really laugh or anything”* (George; 89-92).

In summary, participants experienced curiosity and questioning from peers, and most felt unprepared to respond to this. Participants’ management of disclosure varied markedly. Nonetheless, a focus on increasing preparedness reduced anxieties regarding disclosure.

Theme Four: Developing Positive Peer Relationships

Theme four illuminates the influence that CL/P had on participants’ experiences of developing positive peer relationships during the transition period and the ways in which participants negotiated the challenges they faced at this time.

All participants started secondary school with some, but not all of their peers from primary school, except Harry as his family relocated shortly before the transition. Developing positive peer relationships and feeling accepted by new peers was a pivotal aspect of participants' transitions. However, participants worried about whether their CL/P would affect their ability to make friends and feel included; "*the thing is, the fact I look different, people might judge me on the way I look, not the way I am because they don't want to know me because I look different*" (Ruby; 482-484). However, meeting new peers was also an exciting prospect and most described looking forward to making new friends and feeling optimistic about peer success; "*I was hoping I was going to make friends*" (Harry; 110).

A key driver behind participants' emphasis on developing positive peer relationships was ensuring access to peer support to reduce a sense of vulnerability; "*...if you are with people you don't feel as vulnerable, even if they are not strong or anything you still don't feel as vulnerable as when you are alone....*" (Tyler; 431-432).

Participants utilised a number of different resources and strategies to assist in the development of positive peer relationships. Maintaining links with old friends whilst building new relationships helped foster a sense of familiarity and connection. Having a few close friends from primary school transitioning to the same secondary school and/or making a few new friends early on in the transition process was also helpful. Participants utilised existing friendships as a safe base through which to further extend peer networks; "*having friends who are friends with other people and having things in common then meeting them*" (Harry; 215-216). Older peers were a key resource when navigating the challenges of starting secondary school. Older peers included school organised 'buddies' (Ethan), and informally developed acquaintances such as older siblings of friends (Josh).

Further strategies included emphasising commonalities with peers to avoid and/or minimise any observable CL/P related differences and attempting to be seen as ‘nice’ and likable; *“if you are friendly to people you get more friends... it’s just being friendly is nice”* (Tyler; 97-98). Making a good impression early on in the transition process was also important to participants. As was portraying confidence and self-acceptance; *“I make new friends every day, every step I take... lots of people follow me... because I act all confident”* (Josh; 303-306), and *“because I accept it [CL/P] as part of me so they do the same of me.”* (Josh; 21-22). A number of participants also described pre-selecting new friends according to perceived ‘friendliness’ to avoid potentially threatening social experiences such as bullying; *“there has been a few [peers] that I have not bothered going near because they look like they would be mean... you don’t want to go near them ‘cause you feel like they will be a bit hostile...”* (Tyler; 236-240). However, choosing the ‘correct’ friends required a judgment based on perceived rather than actual characteristics, which contradicted participants’ own desires to not be taken at ‘face value’.

Developing positive peer relationships required a significant amount of effort. Despite this, all participants described how they felt their efforts had paid off as they had successfully established a number of ‘true friendships’ with new peers. ‘True friends’ were those that participants felt a sense of shared unconditional acceptance and respect with; *“I do think about [being different] quite a lot but when I am with my friends I don’t really think about it that much because they don’t really make fun of me, otherwise I wouldn’t be their friend”* (Ruby; 477-480). Peer support from ‘true friends’ was considered to be reciprocal with participants emphasising that they too provided support and encouragement to peers (without CL/P) highlighting that the need for peer support goes beyond CL/P related issues.

Developing positive peer relationships was a pivotal yet challenging aspect of participants' transition experiences. Nonetheless, participants adopted a range of strategies to enable them to establish new and successful friendships.

Discussion

This research aimed to understand the lived experiences of children with CL/P when transitioning from primary to secondary education. The in-depth examination of participant accounts guided by IPA resulted in four overarching themes. Together these themes highlight the range of psychological and social challenges that participants faced; specifically, the impact that feeling 'different' had on participants' sense of identity and self-worth, and on their social interactions with peers during the transition period. Findings also highlight the many ways in which participants adapted to and coped with these challenges.

Underpinning themes one and two was the notion of 'difference'. In line with previous studies, participants expressed a sense of being different from peers because of their CL/P (Chapado, 2000; Chetpakdeechit et al., 2009). However, findings from this study also highlight that participants' personal relationship with 'difference' was complex and at times, contradictory. The transition to secondary school magnified feelings of difference, and concerns regarding fitting in and being accepted increased. However, as with Egan et al. (2011) the use of active coping strategies (such as, talking about CL/P to increase understanding in others, accessing support from parents, teachers and peers, and maintaining a focus on one's own positive attributes) facilitated positive adjustment.

Developing positive peer relationships was important to participants during the transition and was seen as a way to reduce a sense of vulnerability and increase feelings of resilience and acceptance. This is consistent with the existing literature, which suggests that having a 'close friend' may offer protection against teasing and bullying (Hodges et al., 1999;

DCP, 2010; Acquah et al., 2016). However, findings from themes three and four also highlight the many social challenges that participants had to negotiate when developing positive peer relationships. A widespread lack of awareness and understanding of CL/P was apparent in participants' descriptions of interactions with peers (and in some cases, teachers). Unsolicited curiosity and questioning about their CL/P was commonplace, and participants felt unprepared as to how to respond to this attention. Experiences of teasing and bullying during the transition period were also highlighted by a number of participants, which mirrors existing research evidence (Turner et al., 1997; Chapados, 2000; Carroll and Shute, 2005; Locker et al., 2005). However, unlike previous studies (Chapados, 2000), participants largely felt supported by teachers when bullying did occur. In addition, whilst bullying was consistently considered to be a painful emotional experience; teasing could be seen to strengthen peer relationships depending on the individual's perception of it, as also highlighted by Carroll and Shute (2005). Therefore, the attributions that an individual makes about the challenges they face during the transition period, and their sense of preparedness and confidence in dealing with these challenges are likely to influence adjustment.

Overall, the varied experiences reported in this study reflect the existing literature, which shows that some individuals struggle, whilst others cope well with CL/P (Hunt et al., 2007). However, findings from this study add to existing understanding by demonstrating that coping is not necessarily a binary construct. Much of the existing literature tends to focus on the negative aspects of difference. However, this approach is arguably too simplistic. The application of psychological resilience theory may further current understanding.

Numerous definitions of psychological resilience have been proposed (see Rutter, 1987; Luthar et al., 2000; Masten, 2001). However, all of these definitions encompass two components; the presence of adversity, and positive adjustment and adaptation. Early

research into resilience centred on identifying traits and qualities that may facilitate thriving in spite of adversity. Good self-esteem, autonomy, and social support are routinely cited as some of the many protective factors (Garmezy, 1985; Rutter, 1987; Garmezy, 1991). Since then researchers have shifted focus to the underlying processes involved in resilience and multiple models are proposed. Fletcher and Sarkar (2013) provide a useful overview and critique of these models, and suggest that despite differences between various models, common features exist, including the notion that resilience is a dynamic and changeable process and that within this process a range of determinants impact upon resilience. To illustrate this, Richardson's (2002) metatheory of resilience proposed that the process of resilience commences with a state of balance and stability. This balance is disrupted if the individual has inadequate resources to protect against adverse life events. Reintegration occurs as the individual begins to adjust to the circumstances in one of four ways: (1) resilient reintegration, whereby a new higher level of balance is achieved; (2) homeostatic reintegration, which focuses on getting through the adversity; (3) loss reintegration, in which negative consequences result in a lower level of balance; (4) dysfunctional reintegration, whereby maladaptive coping strategies develop.

Applied to the findings of the present study, the process of resilience for participants began at primary school where participants were comfortable and settled. The transition to secondary school was a period of adversity for participants, however, participants had a range of protective resources they could draw upon to buffer against the challenges they faced. Reintegration occurred relatively swiftly and by the point of interview all participants had adjusted to their new circumstances. Whilst the present study did not explicitly explore the way in which participants reintegrated, it can be hypothesised that all participants formed either resilient or homeostatic reintegration.

Clinical Implications

Targeted specialist transition programmes for children with CL/P offered by local cleft services (Maddern et al., 2006; NHS England, 2013) have a key role in increasing preparedness. However, only one participant from this study attended such a programme. Whilst participation in such programmes was not a focus of this study, findings may nonetheless illuminate barriers to attendance. Firstly, participants broadly felt that they coped well during the transition period despite apparent challenges. It is therefore likely that these individuals did not consider there to be any benefit from attending specialist support programmes. Secondly, as highlighted in themes one and two, participants had a complex relationship with 'difference' and at various points during the transition period participants distanced themselves from their 'difference' in order to feel more confident in their ability to fit in and establish positive peer relationships. The act of distancing may explain why some individuals choose not to engage in specialist support at this time.

Clinical psychologists working in cleft services should consider alternative ways of supporting children with CL/P through the transition to secondary school, in addition to existing programmes, in order to reach a wider audience. This could include a greater emphasis on the role of parents in supporting children at home to increase preparedness, for example, practicing responses to peer questioning and/or supporting parents to share information about their child's CL/P with the new school to increase understanding amongst teachers. The development of age-appropriate mobile phone/tablet based apps incorporating material from specialist cleft transition programmes may also help normalise the process of transition preparation by removing it from a hospital-based environment (which may reinforce a sense of difference) and placing it into an accessible format that children can access at their own pace.

A focus on increasing understanding of CL/P in the general school population, and normalising difference more broadly, could also help further improve transition experiences of children with CL/P. Indeed, evidence suggests that children respond well to school-based programmes aimed at raising awareness of appearance related issues (Lovegrove and Rumsey, 2005). Within the UK, most schools already implement general transition programmes for all pupils starting secondary school (Evangelou et al., 2008). One participant in this study discussed how as part of this general transition preparation, his school were set the task of reading a children's novel called 'Wonder' about a boy who was born with Treacher Collins syndrome and a cleft palate. Whilst this initially increased curiosity from peers, feelings of preparedness, acceptance and normalisation also increased. Clinical psychologists working in cleft and/or other paediatric services could therefore work with local schools to develop more inclusive transition programmes that have a broader focus on normalising difference and supporting inclusivity for all pupils.

Limitations

Participants in this study were self-selecting (via parent gatekeepers). It is therefore possible that only those individuals that felt they had coped well with the transition to secondary school opted to take part. Furthermore, it was initially anticipated that participants would opt to take part in the interview individually without the presence of their parent/carer due to the greater level of confidentiality that this would afford. However, all participants chose to have their parent/carer present during the interview. Both of these factors may have influenced findings via participants focusing primarily on the more positive aspects of their experiences. Nonetheless, despite themes of coping and resilience being emphasised within the results, participants also described the many challenges they faced, suggesting that the sample, and the nature of experiences shared during the interview, were not overly biased.

Furthermore, in some instances the presence of a parent/carer seemed to enhance participant self-disclosure, as parents were able to gently prompt participants about aspects of their experience and/or provide emotional comfort and support whilst allowing the focus of the interview to remain on the participant.

It is acknowledged that there is a wide range of time since transition at the point in which participants participated in the study (2-11 months). The rationale for including this range was to allow for a broader and more detailed picture regarding participants' experiences of the transition period as a whole to emerge. Data from all participants (regardless of time post-transition) contributed towards each overarching theme.

Historically, researchers have avoided using in-depth qualitative interviews (such as those advocated within IPA and used in the present study) with child participants, due to concerns that children lack the necessary cognitive and verbal skills to share their sense making about a particular phenomenon (Docherty and Sandelowski, 1999). However, most of the participants within the present study were able to self-reflect on their experiences with ease. Methods such as rephrasing the question, showing interest, and prompting the participant to elaborate their account, facilitated the collection of rich and meaningful data. Therefore, IPA is a suitable approach for participants of a similar age to the present study.

A further limitation concerns the generalisability of qualitative research to other contexts and demographic groups (Myers, 2000). Nonetheless, this research is the first to examine the lived experiences of children when transitioning to secondary school and provides useful clinical implications and directions for further research. The accumulation of similar studies overtime may allow for further generalisations of the data (Smith et al., 1995).

Directions for Future Research

This study highlights several areas requiring further research. Firstly, research utilising longitudinal designs that follow participants through the transition process could enhance findings from the present study and further explore the impact of transition to secondary school in children with CL/P. Specifically, research exploring the underlying processes of resilience at this time are recommended. Exploration of the efficacy of specific transition preparation programmes (both specialist CL/P and general school-based) would also be advantageous. Finally, future research into the ‘complex and dynamic personal relationship difference’ highlighted in this study, may help further understanding into the specific factors affecting resilience more generally.

Conclusions

This novel, exploratory study provides insight into the lived experiences of children with CL/P when transitioning to secondary school. Findings highlight that issues regarding difference, and peer reactions and relationships, pose challenges for children with CL/P during this time. Findings also highlight the range of coping strategies that enabled participants to develop resilience during the critical school transition period. Clinical psychologists working in cleft services should attend to these factors when supporting young people with CL/P (and their families) in preparing for the transition to secondary school and consider broader ways of further enhancing resilience and coping.

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Figure Legends

Table 1: Participant characteristics

Table 2: Transcription style conventions used in participant quotations

Figure 1: Diagrammatic representation of study themes

Table 1: Participant Characteristics

Participant*	Gender	Age	Cleft Type	Time since transition at interview	Additional Information
Josh	Male	12	Cleft palate with minor speech difficulties	11 months	<ul style="list-style-type: none"> • Chose to attend a different secondary school from older sibling • Described self as very self-confident
Ethan	Male	11	Visible cleft lip and palate	2 months	<ul style="list-style-type: none"> • Additional congenital health difficulties (including renal problems) • Several past and recent experiences of appearance related bullying.
Harry	Male	11	Visible cleft lip and palate with speech difficulties	5 months	<ul style="list-style-type: none"> • Transitioned from an out of area primary school (due to family relocation) and therefore did not know any peers at secondary school prior to transition.
George	Male	11	Sub-mucous cleft palate with previous speech difficulties	6 months	<ul style="list-style-type: none"> • Mother works in a teaching role at old primary school. • Read 'Wonder' a children's novel about visible facial difference by Raquel Jaramillo (Palacio, 2012) as part of school transition process.
Ruby	Female	11	Visible cleft lip and palate	6 months	<ul style="list-style-type: none"> • Experiences of appearance related bullying. • Described self as 'self-conscious about appearance • Previous psychological input from local cleft service for pre-operative anxiety
Tyler	Male	12	Visible cleft lip and palate	7 months	<ul style="list-style-type: none"> • Attended a school transition group for people with CL/P at local cleft service and a mainstream transition summer school at new secondary school.

* NB. Pseudonyms are used.

Figure 1: Diagrammatic representation of study themes

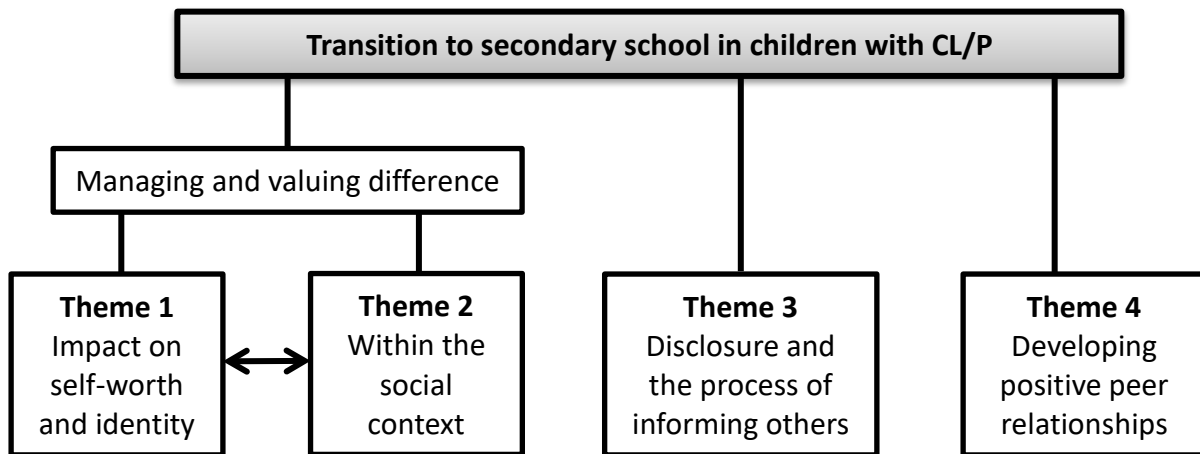


Table 2: Transcription style conventions used in participant quotations

Style Convention	Usage
[text]	Additional text added to aid clarity
...	Text that has been edited/deleted for the purposes of presenting only material central to the point of interest
<u>TEXT</u>	Denotes participant emphasising a point by shouting/exclaiming

Section 2 Appendices

- 2-A Participant case studies
- 2-B Initial coding of the data: An extract from the analysis of Josh's transcript
- 2-C A narrative summary of a superordinate theme: An example taken from Josh's theme two: 'managing and valuing difference'
- 2-D Illustration of how participant level super-ordinate themes and key emergent theme codes mapped on to final over-arching themes.
- 2-E Transcribed excerpt from reflective audio diary.

Appendix 2-A

Participant Case Studies

Josh

Josh, 12 years old, was born with a cleft palate. He perceived that he sounded different from peers because of his cleft palate; however, speech difficulties were not overly apparent during the interview. Josh described himself as very confident and well-liked by peers. Josh chose to attend a different secondary school from his older sibling so that he could attend the same school as several pre-existing friends. He also had two younger siblings. None of his siblings had a CL/P.

Ethan

Ethan, 11 years old, was born with visible cleft lip and palate (which affected his speech) and additional congenital health difficulties including renal problems. Ethan reported two significant episodes of bullying (one at primary school, one at secondary school). Ethan had one younger sibling (without a CL/P).

Harry

Harry, 11 years old, was born with a visible cleft lip and palate, which affected his speech. Harry's family relocated shortly prior to his transition to secondary school, therefore, he started secondary school without any of his peers from primary school. Harry did not have any siblings.

George

George, 11 years old, was born with a sub-mucous cleft palate. He described having previous speech difficulties that much improved following surgery and speech and language therapy. George perceived his cleft palate to be largely invisible to others, except when attempting to eat/drink certain foods (e.g. ice cream and milkshakes). George had an older sister (without a CL/P) who attended the same secondary school as him. As part of the school transition process, George and his school peers read 'Wonder' a children's novel about visible facial difference by Raquel Jaramillo (Palacio, 2012).

Ruby

Ruby, aged 11, was the only female in the sample. Ruby had a visible cleft lip and palate and described feeling self-conscious about her appearance as a result. Ruby described several experiences of appearance-related bullying throughout primary and secondary school. She reported receiving previous psychological input from her local cleft service for pre-operative anxiety, which she described as beneficial. Ruby had two younger brothers (without a CL/P).

Tyler

Tyler, aged 12, was born with a visible cleft lip and palate. In preparing to transition to secondary school, Tyler attended a mainstream 'summer camp' at his new secondary school. He also attended a school transition preparation group for people with CL/P run by his local cleft service. Tyler had been at his secondary school for seven months at interview. It is unknown whether Tyler had any siblings.

Appendix 2-B

Initial Data Coding: An Extract from ‘Josh’s’ Transcript Demonstrating Annotated Exploratory Comments and Emergent Themes

Exploratory Comments	(Line Numbers) Transcript Excerpt	Key Coding & Emergent Themes
<p>Opening statement drawing attention to the pain and operations – wanting to share this with me – are the operations significant to the participant? Why? Does being open foster acceptance? – others must understand to be able to accept? Not scared of what? – What does being scared/not scared mean? Being open is important in helping other accept it and just get on with it. Need for me to understand and accept? Acceptance = getting on with it, not making a deal out of it? Wanting to be seen as someone who is able to get on with it. How does it feel when peers question the difference? No big deal? Respond in a matter of fact approach to dealing with questions and explaining difference. Lack of understanding from peers – questioning difference. Matter of fact approach to explaining what a cleft is. Meaning of scars as “impressive” – something to show off and be proud off? Use of scars to impress others and increase popularity? Highlighting difference from others. Positive experience of others in relation to the cleft. Views self-acceptance as important in encouraging acceptance from others– role modelling acceptance to others. Not knowing people at high school initially</p>	<p>1 I: so first of all I was wondering if you could tell me a little bit about what it was like being 2 born and growing up with a cleft palate generally. 3 P: It was just bit painful the operations but I’m open about it so it’s good and people accept 4 it. 5 I: What made it easy to be open about it? 6 P: Just that I’m not scared about it. It’s just like because I’m open people accept it they will 7 just move on with it. 8 I: So when you say open? 9 P: With school friends and that. 10 I: And how do you be open? Do you talk about it or...? 11 P: Well people ask me why my voice changes from low to high I just say I have got a cleft 12 palate, and they go what’s one of them and then I say when I was born I had a hole in the top 13 of my mouth and they are all like have you got any scars? So I show them. 14 I: Do you? 15 P: I show them my mouth. 16 I: So you show them your scars and 17 P: They are all impressed. 18 I: They are impressed. So being open and kind of talking about it with others and not being 19 afraid of answering questions helps. And have you ever had times when people haven’t been 20 so good about it, or you had difficulties with it? 21 P: No cause people are really nice about it, because like me because I accept it as part of me 22 so they do the same of me. 23 I: so accepting people for who they are is important. 24 P: yer 25 I: so thinking back now to about guess this time last year, so you started school last year, so 26 this time last year when you had just left your primary school and you were just about to 27 start high school can you remember what sort of things you thought about starting high 28 school.</p>	<p>Highlighting the pain of operations – creating impact Being open fosters acceptance. Others must understand to accept. Feeling confident/not scared Openness helps others accept. Acceptance = getting on with it and not making a deal out of it Peers question difference. Matter of fact approach to dealing with questions. Lack of understanding from peers – questioning difference. Matter of fact approach. Scars impress others. Something to show off and be proud of. Scars increase popularity. Self-acceptance facilitated acceptance from others. Acceptance from other and self is important. Making friends helped reduce anxiety. Anxiety towards other people’s reaction towards the cleft.</p>

<p>causing feelings of anxiety, but this changed over time. Making friends helped to reduce anxiety. Feelings of anxiety not just related to not knowing other people, also specific concerns and anxieties relating to other people's reaction towards the cleft. Worries about the thoughts, and behaviours of others in relation to the cleft. Worries about being singled out and reactions of others. Potential for negative appraisal impacting upon ability to 'fit in' causing concern. Worried about the potential for rumours with the consequence of not being accepted by peers. But worries not founded. What is the meaning behind the term 'dodgy'? General sense of being accepted at primary school, yet fears of this being different in high school. Cleft as something to 'poke fun at' between friends. Feels acceptable when with friends? Contrast between the cleft being 'accepted' and it being 'fair game' as a target amongst friends. Use of word "peg leg" brings to mind stereotypical images of disability/difference. What is the meaning of the term illness in this context? Is cleft as an illness?</p>	<p>29 P: just a bit worried for like going in because I didn't know much people in the year 7 class 30 but then as the year went on I made more friends. 31 I: so feeling worried at first because you didn't know anybody but then over time that felt ok 32 because you knew more people. 33 Mum: he was a bit worried, weren't you about what other people would say about your 34 speech 35 P: yer I was a bit worried like if people like 'why's he talking like that' 36 I: mmmm 37 P: but like no one did. 38 I: ok so when you were worried about it, what sort of things did you think about? 39 P: like what would they say, and what they would think it was and if they would say 40 something to me. 41 I: ok, so you were worried that people might notice it, and then if they notice it, they might 42 think 'what's that?' and say things? 43 P: yer 44 I: what sort of things were you worried people might say? 45 P: just like, spreading things about that I have a dodgy voice and that but no one did in the 46 end. 47 I: and did anyone do that at primary school? 48 P: no I had like me fallouts with me friends and then like I'd call them and they'd call me 49 and then people would call me 'hole mouth' when we fall out and I'd call them peg leg or 50 something, so we'd just call each other's illnesses. 51 I: ok, and do you think that you were falling out because of the cleft or because of something 52 else...? 53 P: nah just because friends fall out.</p>	<p>Thoughts about other people's negative reactions towards the cleft causes worry.</p> <p>Worried about the potential for rumours to be spread with the consequence of not being accepted by peers. Negative connotations of language used to describe cleft. Cleft as something to 'poke fun at' between friends (banter). Contrast between the cleft being 'accepted' and it being 'fair game' as a target amongst friends. Stereotypical images of disability/difference. Cleft as a disability/illness. Cleft as something to 'poke fun at'. Contrast between the cleft being 'accepted' and it being 'fair game' as a target amongst friends. Cleft as a disability/illness.</p>
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Appendix 2-C

A Narrative Summary of a Superordinate theme: An Example taken from ‘Josh’

Narrative Summary of Superordinate Theme ‘Managing and Valuing Difference’	Quotes (line numbers)	Emergent Themes
<p>This theme summarises Josh’s experiences feeling different from his peers because of his cleft palate and the way in which he seemed to respond to this difference both during his transition to high school and more generally. It seemed that in many ways Josh was proud of how his cleft palate set him out as being different from his peer and helped contribute to his unique identity as an individual. In this respect, Josh viewed difference as something to be broadly celebrated, something which was also reinforced by others during times of success and achievement ‘in spite of difference’, such as when Josh won a communication skills award in primary school. In addition, Josh viewed his difference as being special and talked about it as a means of impressing his peers, for example by ‘showing off’ his scars. Overall, this seemed to boost Josh’s self-confidence. Therefore, it is possible that viewing oneself as being different was in some way advantageous and protective to Josh during his transition to high school in that it boosted his self-confidence and enabled him to connect successfully with peers. Incongruously, there was also a sense that for Josh, being different from his peers was to some extent undesirable. For instance, when describing his experiences of difference during his transition to high school, Josh often used words such as ‘dodgy’, ‘hole mouth’ and ‘illnesses’ which seemed to hold negative connotations for Josh. It is possible that because Josh viewed his cleft as a fundamental part of his identity, he felt more threatened by any negative stereotypes (real or perceived) surrounding his difference. Josh described how his friends from his primary school tended not to notice any difference. Or at least, where difference was</p>	<p>“Well people ask me why my voice changes from low to high I just say I have got a cleft palate, and they go what’s one of them”. (lines 11-12)</p> <p>“They are all like have you got any scars? So I show them...I show them my mouth... they are all impressed.” (13-17)</p> <p>“I was a bit worried like if people like “why’s he talking like that””(35)</p> <p>“[<i>worried about peers</i>] spreading things about that I have a dodgy voice and that but no one did in the end.” (45-46)</p> <p>“I had like me fallouts with me friends and then like I’d call them and they’d call me and then people would call me ‘hole mouth’ when we fall out and I’d call them peg leg or something, so we’d just call each other’s illnesses.” (48-50)</p> <p>“...’cause Jake... and jack my mate’s brother, and he looked after me and my best mate.... [it] felt good cause I knew nobody would [<i>pick on me because of my cleft</i>], and he is hard and could look after someone. (97-100)</p> <p>“As a child Tamsin knew she would like correct me on my words, she like helped me speak a lot better.... cause like if I said juice, she would be like to say JUICE and would sit me down until I said juice properly....[it was] a bit weird, because like she is not an adult and she would correct me, but good growing up because it’s helped me lots. So like I can speak properly. (232-236).</p> <p>“...it worked didn’t it, cause I got the confident communicator award didn’t I...cause like I didn’t think I would get it because</p>	<ul style="list-style-type: none"> • Peers questioning the difference emphasises the difference. • Scars are impressive – a thing to be shown off. • Anxiety about others reaction to the cleft – concerns about acceptance • Difference holds negative connotations (‘dodgy’) • Cleft viewed as an illness/disability: a sense of inadequacy • Cleft name calling ‘fair game’ between friends. • Need for protection from peers • Family support in trying to reduce the level of difference • Changes in sibling relationship as a result of difference • Challenging stereotypes

noticed, there was a sense that Josh felt confident in knowing that there was an absence of critical judgment in relation to the difference. However, it seemed that when Josh started high school, thoughts relating to difference as ‘undesirable’ were of greater concern for Josh than perhaps they had been previously. Subsequently, Josh described ways in which he sought to minimise and or hide the extent to which he was viewed as different from others. For instance, Josh described instances in which he had avoided shouting during sports at school to try and prevent others from being able to notice he sounded in anyway ‘different’. This also maps onto a more general attempt by Josh and his family throughout his life to reduce the degree of apparent difference perceivable by others, for example through the use of informal ‘speech therapy’ to reduce observable differences. Additionally, it also seemed that Josh and his wider family held a shared ‘normalising’ belief about Josh’s cleft as being different, but not significantly so. This normalising belief seemed to influence how Josh responded to potential challenges in relation to difference. For instance, Josh described how if peers attempted to point out Josh’s difference, or tease him because of it, he tended to respond by reciprocating this behaviour towards them, thus seeking to normalise difference.

most people with a cleft palate or cleft lip are quieter but I just like I just went for the award and got better.” (235-256)
 “people sometimes say have you cut yourself, and I’m like no it’s my birth mark. It’s like a strawberry, a little heart and a leaf” (267-268)
 “I didn’t like shouting in rugby. I didn’t want to make my voice, people ask what’s wrong with my voice” (308-309).
 “It’s better now, because people know about it and they don’t look at me strange, so everyone I grew up with, James my best mate, he says now because we grew up together he can’t notice the difference in my voice because he grew up with it.” (312-313)
 “...people congratulated me for getting on with it, and they wanted to look at me stitches, like where are your new stitches.” (336-337)
 “I knew people were happy about me and like they were fascinated by me by my cleft palate, cause like it’s not like a great population of people with them. (339-340)
 “yer, but like they [*the braces*] fixed in the one day anyway so I didn’t need them again. I tightened the loads overnight and just fixed them by myself. It hurt my teeth though. (343-344).

and assumptions about people born with a cleft.

- Achieving in spite of cleft.
- Difference is part of your identity/ proud to be different.
- Trying to hide the difference to avoid others asking questions.
- Old friends don’t notice difference.
- Positive recognition for others for coping with challenges of cleft.
- Being different is special/interesting.

Appendix 2-D

Participant Level Super-ordinate Themes Mapped on to Over-arching Themes

	Overarching Themes			
	Theme 1: Managing and valuing ‘difference’ - The impact on self-worth and identity	Theme 2: Managing and valuing difference within the social context	Theme 3: Disclosure and the process of informing others about CL/P	Theme 4: Developing positive peer relationships
Josh	The impact of difference of self-worth and confidence	Managing and valuing difference amongst peers	Shared understanding: Gaining acceptance by normalising cleft experience	Building positive peer relationships
Ethan	Identity and difference – understanding the meaning of cleft	Appearance related bullying: a difficult and embarrassing experience, yet support helps.	A need to share with others to increase understanding a be true to oneself.	Changing peer relationships – from loss to developing new positive peer relationships
Harry	Noticing and dealing with feeling ‘different’	Noticing and dealing with difference from peer	Breaking Taboo	Importance of peer relationships and social support
George	Negotiating the spectrum of difference	Wanting to feel the same as others	The impact of developing positive peer relationships on decision -making regarding disclosure	The gradual process of developing peer relationships and establishing trust.
Ruby	The evolving personal relationship with difference: seeking self-acceptance	Finding acceptance of difference when difference is visible	Managing privacy when difference is visible	The effort of fitting in: working hard to develop positive peer relationships
Tyler	Embracing difference: “I’m different from other people and I don’t mind that”	Finding ways to fit in and feel the same as others	An openness to difference	The importance of establishing new friendships to reduce vulnerability and feel connected

Appendix 2-E

Transcribed Excerpt from the Reflective Audio Diary

The following is an excerpt from my reflective diary, which was audio recorded immediately following the research interview with my first participant 'Josh':

"I have just completed the interview with Josh, a bubbly and confident boy. Josh had a cleft palate only and my initial thought on meeting him was that you probably would not know it, unless Josh was to tell you. Interestingly though I was surprised by how much of Josh's interview focused on his sense of difference, particularly in relation to his speech, as to me it really was not that obvious. However, I also noticed that Josh felt his cleft did not hold him back in anyway in his social interactions and during his transition to secondary school, and in many ways it did not matter for him. I guess Josh just sees it as a natural part of who he is as a person. For instance, Josh talked about how he was no different from his peers, yet also talked about how he was actually quite proud of his cleft and how he would show it off as a way of impressing others. He even wanted to show it off to me and showed me the scar in his mouth. I think I was surprised how cleft could be really important and at the same time, not at all important to an individual. I wonder whether this paradox will come up in future interviews. I was also struck by how confident Josh was, and how happy he was to tell me about his experiences. Obviously, Josh volunteered to take part in this research, he even told me that his reason for doing that was that he was coping so well and he wanted to be able to share his experiences to help other with CL/P that might not be coping so well..."

SECTION THREE

CRITICAL APPRAISAL

**Reflections on a Qualitative Analysis of Experiences of Transition to Secondary School
in Children with Cleft Lip and/or Palate**

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(excluding tables and figures, reference lists and appendices)

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(Appendix 1-A).

Reflections on a Qualitative Analysis of Experiences of Transition to Secondary School in Children with Cleft Lip and/or Palate

The research presented in section two of this thesis provides a novel account of the lived experiences of children with a cleft lip and/or palate (CL/P) when transitioning to secondary school. Findings support existing arguments that suggest this transition is a critical period in the lives of young people in general, and that children with CL/P may face many additional psychological and social challenges at this time as a result of their CL/P. Additionally, the research presented in section two contributes to current understanding as it is concluded that children with CL/P draw upon coping strategies and resources which enable them to develop psychological resilience and effectively adapt to the challenges of transition.

The salient strengths and limitations of this study are acknowledged in the main research report. However, the constraints of the traditional academic format for presenting research limits further discussion of the wider issues around the research process. This critical appraisal therefore supplements the research report to allow for a more in-depth consideration of broader research issues. In this critical appraisal I expand upon my rationale for selecting the chosen research topic and methodological approach, and discuss some of the practical, ethical and methodological issues encountered. It is hoped that this critical appraisal contextualises the research for the reader and serves as a reflective guide to others carrying out work with children in similar settings.

Selecting a Research Topic and Methodology

My interest in this area of research developed following a conversation with my field supervisor (a clinical psychologist working within a specialist cleft service) regarding her experience of delivering school transition preparation groups for children with CL/P and their parents as recommended by national service specifications (NHS England, 2013). During this

conversation it emerged that despite positive feedback from children and their parents regarding the utility of these groups, anecdotally, there was little reported change in psychosocial wellbeing. Keen to understand possible explanations for this, I explored the literature and found an absence of studies directly addressing the issue of secondary school transition in children with CL/P. The need for research exploring this was therefore apparent. Furthermore, when looking at the broader literature regarding psychosocial functioning in children with CL/P, I noticed several recurrent methodological limitations which influenced the direction of my own research. Firstly, researchers have historically orientated towards 'problem-focused' constructs of psychosocial functioning operationalised via the use of 'objective' measures normed against 'healthy' controls (see Hunt et al., 2005). Such approaches overlook more positive aspects of psychosocial functioning which have been identified in children with CL/P (see Eiserman, 2001; Feragen et al., 2009; Feragen et al., 2010), and fail to convey the more subtle nuances and complexities of participants' lived experiences. Secondly, existing research within the field of CL/P has largely ignored the perspectives of children. For instance, a review of existing qualitative research within this field conducted by Sharif et al. (2013) found only two studies which included child or adolescent participants. Additionally, the use of proxy respondents (e.g. parents and teachers) in empirical studies is common, despite significant discrepancies between proxy reports and young person self-reports (Hunt et al., 2005). Therefore, it was important that my own study would facilitate children to share their own perspectives regarding the transition to secondary school and directly contribute to the advancement of understanding via active participation in research. A qualitative approach was chosen to enable exploratory examination of this novel topic (Barker et al., 2015) without the imposition of preconceived constructs of psychosocial functioning.

I initially considered a narrative methodology to guide the research design and analysis. Narrative approaches originate from the fields of sociology, anthropology, psychology, history and literature, and aim to explore the lives and experiences of a small number of participants via the literary re-telling of their own life stories (Daiute and Lightfoot, 2004; Creswell, 2012). However, narrative approaches focus primarily on how participants tell their stories and thus fail to explain the fundamental essence of a lived experience or phenomenon in the way that phenomenological approaches can (Creswell, 2012; Van Manen, 2016). Phenomenological approaches have particular relevance within the field of health psychology as research adopting such approaches can explore and understand the processes in which a well-defined group of individuals experience a particular phenomenon such as living with a health condition (Smith, 1996). Therefore, phenomenological approaches have greater clinical utility to clinicians working with such populations (Creswell, 2012). Indeed, a large number of published papers exploring participants' experiences of living with a health condition adopt phenomenological approaches such as interpretative phenomenological analysis (IPA; Griffiths et al., 2011; Osborn and Smith, 2015; McKenzie et al., 2016; Smith et al., 2017). Alternatively, grounded theory approaches aim to develop new theories which are grounded in the data of a larger number of participants (typically 20-60 individuals; Creswell, 2012), which, given the exploratory aims of my research, was not my intention. I hoped to understand the essence of how a small group of individuals (children with CL/P) experience a particular phenomenon (the transition to secondary school), and to identify areas in need of further exploration. Consistent with these aims, I considered a phenomenological approach to be most appropriate, and selected IPA guided by Smith et al. (2009) as a framework.

Practical, Ethical and Methodological Issues

Conducting research with children raises multiple practical, ethical and methodological issues. Kirk (2007) provides a detailed consideration of these issues; however, prominent issues relevant to this study are discussed here. More general methodological issues encountered during the research process are also discussed.

Recruiting Participants to the Study

Recruitment took place via one UK-based regional cleft service which was split over two NHS trust sites. This approach was selected as the services in question already held database records of all children with a CL/P that had transitioned to secondary school within the last year (and therefore potentially met the inclusion criteria). It was believed that this would facilitate swift recruitment, however, three rounds of recruitment were completed (two at site one, and one at site two), in which invitations were sent out to 247 potentially suitable individuals, before the desired sample of 4-10 participants was reached. Additionally, it was necessary to obtain approval for minor amendments from the Research Ethics Committee to enable recruitment to continue beyond the initial proposed endpoint to ensure sufficient participant numbers. This was time-consuming and delayed other research tasks.

One potential barrier to recruitment was that during the first round of recruitment, invites were sent during the school summer holidays. Therefore, potential participants had already been at secondary school for 11 months and experiences of the transition period may have been less salient at this point. Additionally, it is likely that families were busy during the school holidays and therefore less able to volunteer time for research. Consequently, in subsequent recruitment rounds I made the deliberate decision to delay sending invitations to avoid clashes with holiday periods. This seemed beneficial and increased opt in rates. In retrospect, I would have considered using alternative recruitment methods, such as via social

media and the Cleft Lip and Palate Association (a UK-wide voluntary organisation for individuals with CL/P and their families), to reach a wider, potentially more engaged, audience and avoid the delays of obtaining research and development approval for each NHS site. Future researchers might also benefit from exploring different ways of engaging with potential participants outside of NHS settings.

Power Imbalances

Article 12 of the United Nations Convention on the Rights of the Child states that children have a right to participate in research (UNCRC, 1989). However, the adult-centricity of most societies places adults in the more powerful ‘authoritarian’ position and children in the less powerful position. This can lead to power imbalances between child participants and adult researchers, impacting a child’s ability to freely and honestly participate in research (Morrow and Richards, 1996; Punch, 2002; Alderson, 2001; Kirk, 2007). O’Kane (2000) provides a range of helpful recommendations to reduce power imbalances with child participants including ensuring that: study information is age-appropriate; that children are given a choice regarding participation (including specifics regarding the location, timing and format of any participation); and that children are consulted regarding the research process. In my own study, age-appropriate study materials (participant information sheet, consent form, and interview schedule) were developed in consultation with the field supervisor to ensure accessibility. It would have been advantageous to also consult with a group of potential participants during the development stages of the study to establish their views on the suitability of the study design and associated materials. However, I took the decision to forgo consultation with potential participants for pragmatic reasons owing to the limited time frame available for this research, the lack of direct access to potential participants (which was managed via local collaborators within cleft services due to ethical reasons), and the need to

proceed with recruitment and data collection in a timely manner to ensure that participants met the inclusion criteria (less than 12 months since transition).

The setting for the research is also an important consideration in relation to power. It is suggested that conducting research within the child's home environment may reduce the child's perception of the researcher as a figure of authority; however, this may compromise privacy (Marshman and Hall, 2008). Conversely, the greater privacy of clinical settings may be outweighed by the potential or perceived power imbalance (Marshman and Hall, 2008). The self-presentation of the researcher should also be considered. Harden et al. (2000) cautions that business suits and formal attire may increase power imbalances; whereas, overly informal dress may lack credibility with the child's parent(s). In my research, I gave participants the choice regarding the timing and location of the research interview (including who they would like to be present during the interview as per O'Kane, 2000). All participants chose to be interviewed in their own home. However, on reflection I wonder how much choice participants actually had regarding this, as arrangements for the research interviews were unavoidably discussed and made with parent gate-keepers. Regarding self-presentation, I decided to wear jeans and a blouse when meeting participants as an attempt to be approachable yet professional. I also took my NHS identification badge with me as proof of identity; however, I chose not to wear this to prevent being seen as a figure of authority. Furthermore, whilst the home environment itself was outside of my control, where possible I sat with participants on a sofa as opposed to at a table which I felt would place a physical barrier between the participant and I, potentially increasing a sense of power imbalance.

I feel that the measures I took to minimise any power imbalances were largely successful as for the most part, rapport was easy to establish and participants seemed willing and able to freely share their perspectives with me. However, there were a number of issues which I feel may have continued to contribute to power imbalances. Firstly, the presence of

participants' parent(s) during the interview (see section titled 'managing participant distress' for rationale) resulted in 2:1 ratio of 'powerful' adult to 'less powerful' child and reduced the sense of privacy available to participants. Secondly, the interview format itself which was chosen and developed by adult researchers may have influenced power dynamics. Alternative methods of data collection in addition to the research interview may have further reduced power imbalances and may have potentially allowed for additional perspectives to emerge within the data. For instance, Darbyshire et al. (2005) advocate the use of games and physical activity within focus group settings to 'free' children from participant bias and mapping exercises, in which children are encouraged to draw and/or move around in the physical space to represent their ideas non-verbally. Alternative approaches include the use of 'photovoice', a method developed by Wang and Burris (1997) to allow participants to document aspects of their lives through photographic images. Such methods were not used in the present study as IPA advocates the use of semi-structured interviews as the 'gold standard' for data collection (Smith and Osborn, 2003). Nonetheless, following completion of the research process I reflected on the limitations of relying exclusively on traditional 'adult' orientated methods. Subsequently, I argue that IPA methodology should evolve to also include scaffolding approaches alongside more traditional methods to minimise power imbalances. Smart phone based diary apps could incorporate photovoicing with functions such as pre-set questions, free-text options and video diaries to generate 'real-time' insights into participant experiences which could then be explored further at interview. Future researchers examining the views of child participants using IPA may wish to consider such approaches when working to minimise power imbalances in their own research.

Informed Consent

Access to child participants tends to be via parent/carer gate-keepers, particularly for studies involving participants under 16 years of age (Harden et al., 2000). Again this

highlights issues regarding power imbalances in research and raises questions regarding a child's ability to freely consent or refuse to their participation. With this in mind, I initially intended to ask the children participating in my study to offer fully informed written consent (should they decide to take part), alongside parental consent in line with the Research Ethics Guidebook (2017). However, one of the few stipulations of the REC was that participants should instead be asked to assent to their parental consent because of their age (i.e. less than 16 years old). I considered this to contradict my agenda to ensure child-centred ethical research practice as the concept of assent refers to an agreement given by children who understand some, but not all of the points required for consent and therefore, by definition are unable to give consent (Research Ethics Guidebook, 2017). When contemplating how to proceed I acknowledged that in order to complete a study with child participants I needed to work within the parameters of existing systems and thus conceded to this change from consent to assent to obtain ethical approval. Additionally, I felt that as the researcher it was ultimately my responsibility to ensure that participants were fully informed about the study and that they felt valued and included, yet free to make decisions on their own behalf, irrespective of whether they were providing consent or assent. Accordingly, I sat with each participant and went through the young persons' version of the information sheet and consent form with them. Parents/carers were present and I provided a space for parents to ask questions and discuss any aspects of the research with their child, however, I emphasised that participants were free to make their own decisions regarding participation.

Managing Participant Distress

When embarking on this research project I was aware of the potential emotional impact on participants (Drury et al., 2007). Draucker et al. (2009) advocate the use of 'distress protocols' to safeguard the wellbeing of participants when researching sensitive topics. Details regarding the distress protocol devised for this study are described in section

four (p.16-17); however in brief, participants were able to choose whether they wanted their parent/carer to be present during the interview for the purposes of providing emotional support and helping them feel more comfortable, and participants were informed of their right to stop the interview at any point. Access to further assessment and/or ongoing support from local cleft psychologists was also available if required.

During research interviews all participants described difficult emotional experiences when discussing the challenges they faced during the transition period. The distress protocol provided me with reassurance that safeguards were in place should a participant become especially distressed during the interview. Subsequently, for the most part I felt confident in my direction of encouraging participants to share these difficult experiences with me for the purposes of understanding their lived experiences. However, at times I found it challenging to balance encouraging participants to deepen their descriptions of these difficult experiences to ensure rich and meaningful data, whilst simultaneously being mindful of minimising distress. This dilemma was most apparent for me during the interview with Tyler¹ who, despite being largely upbeat during his interview, became very upset and tearful when asked about his experiences of leaving primary school. The following excerpt from my reflective audio diary recorded following the interview with Tyler illustrates the conflict I experienced:

“...I initially struggled to know how far to push Tyler when he was talking about leaving primary school. It was clearly a difficult experience for him at the time, although I was unable to get a sense of what this was about as he seemed reluctant or unable to talk about it. However, it was also obvious that it was emotionally distressing for Tyler to remember these experiences in the moment and I was mindful that at the end of the interview I would be leaving him to process any potentially difficult feelings on his own. The researcher in me wanted to ask more to better

¹ All names are pseudonyms.

understand these difficult emotions, however, the clinician in me wanted to help Tyler manage this distress. I tried to take the lead from Tyler as much as possible, and reminded myself of the purpose of the interview. Initially, I felt uncertain about how much to keep pushing or whether I should back off, but as his distress increased and he started sobbing, I felt an immediate shift and it suddenly felt most appropriate to stop the questioning and focus instead on minimising the distress. Action point: review this when transcribing the interview and discuss with supervisor to see if I still feel that it was right to stop asking questions at that point.”

When I reviewed the relevant section of the interview transcript (appendix 3-A), I noticed the shift from pursuing data to managing distress occurred very swiftly. I also noticed that despite the intensity of Tyler’s distress, he quickly ‘recovered’ and once again immersed himself in the interview, albeit with a slightly different topic focus.

Throughout clinical psychology training I have developed comprehensive skills in conducting both clinical work and research. Whilst there is a distinction between clinical interviews (which aim to develop an understanding of a client’s experience to facilitate therapeutic change) and research interviews (which aim to develop an understanding of the participant’s perspective on their experiences), there are also commonalities in the interview skills required for both and overlaps in the roles of the researcher and the therapist (Gale, 1992; Hart and Crawford-Wright, 1999; Drury et al., 2007; Targum, 2011). Indeed, some researchers from non-clinical backgrounds report feeling they lack the necessary skills or training to manage more therapeutic elements of research such as working with emotions (Dickson-Swift et al., 2006). Clinical psychologists (including trainees) can therefore be of great value when conducting research on potentially sensitive topics. However, Dickson-Swift et al (2006) also found that researchers with professional clinical training can feel a sense of conflict between the different roles of researcher and clinician.

Personally, I found my 'dual role' as a trainee clinical psychologist to be advantageous and simultaneously challenging. I was able to utilise my clinical skills to attend to, and manage Tyler's distress with empathy and compassion, whilst maintaining a clear focus on the purposes of the research interview to prevent a blurring of boundaries. However, I found myself having transitory thoughts of wanting, but being unable, to offer further therapeutic input to participants such as Tyler. Further consideration of the issues prior to undertaking this research, including an awareness of how participating in research interviews can in itself be of therapeutic value to participants (see Rossetto, 2014) may have helped me feel more prepared for managing this dynamic. Future researchers from both clinical and non-clinical backgrounds should therefore consider the impact that their training and experience may have on the research process.

Addressing Sample Homogeneity and Managing the Volume of Data

It is recommended that IPA samples should be fairly homogenous to allow for the analysis of psychological similarities and differences within a well-defined group of participants (Smith and Osborn, 2003; Smith et al., 2009). It could be argued that the homogeneity of participants in this study was questionable as five participants were male, whereas only one participant was female (Ruby), and participants had a range of different cleft types with varying visibility to others. Additionally, participants reported a wide range of difference in their lived experiences and ways of coping during the transition period.

The cleft registry & audit network (CRANE) database is a national register of children born with a CL/P in the UK (excluding Scotland) each year. The pool of individuals invited to take part in this study is likely to be representative of this registry. Figures from the 2016 report show that most individuals born with a CL/P were male (57%). There are also significant gender differences in cleft type ($p < 0.001$). Cleft lip (CL), and cleft lip and palate

(CLP) are more prevalent in males (CL=68%; unilateral CLP=65%; bilateral CLP=63%).

Whereas, cleft palate (CP) is more prevalent in females (53%). These figures may account for some of the differences in the composition of the research sample, however, it is unlikely that they explain all of the differences. As such, it is unknown why more males volunteered to take part in the study than females.

I considered removing Ruby's data from the data set to minimise heterogeneity. However, Smith and Osborn (2003) state there can be considerable variation across participant super-ordinate themes and 'doing' IPA involves the negotiation of such divergences alongside any commonalities within the data. Once I reached the stage of completing the participant level data analysis, I spent time examining the commonalities and divergences across participants. I felt that the differences across participants' experiences added richness to the data and provided insight into the complexity of participants' transition experiences. Therefore, I felt that excluding participant data from the results would have been arbitrary and would have detracted from the value of findings. Subsequently, one of the main challenges I faced was finding a way to succinctly write up the overarching themes in a way that captured the shared essence of participants' experiences whilst retaining individual nuances and divergences from all six participants. I found this process to be laborious as each participant shared an interesting and meaningful account of their experiences and I felt a duty to present this data as fully as possible.

Initial drafts of study results were significantly longer than the available word count. Therefore, numerous phases of editing were required before reaching the final study themes. Focusing on the central research question helped me appraise which themes were vital to include and which aspects of the data were more superfluous. Having discussions with supervisors regarding to the use of the word limit, and the novelty and interest of findings

from a clinical perspective, was also beneficial. Finding time to have some distance from writing and then returning to it with a clearer sense of how to present the results also helped.

As a result of the editing process I decided to cut an overarching theme titled '*Getting on with it: The Process of Evolving Confidence and Resilience*' from the final report. This theme described how many of the coping strategies that participants adopted during the transition period had developed throughout their childhood as a whole to enable them to adapt to and cope with the broader challenges of growing up with CL/P. I decided that whilst this theme provided useful context to the wider process of developing resilience, it was slightly peripheral to participants' transition experiences and therefore removing it created space for more direct transition-related experiences.

Conclusions

This critical appraisal explores some of the practical, ethical and methodological issues I encountered during the research process and highlights how I addressed these issues in the current study. In conclusion, it is possible to conduct successful IPA studies with children on potentially distressing topics, provided that such issues are attended to sensitively. Researchers conducting work with similar populations may therefore find this critical appraisal useful when planning their own work.

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Section 3 Appendices

3-A Excerpt from Tyler's Interview Transcript

Appendix 3-A

Excerpt from Tyler's Interview Transcript

Line	Transcript
205	Interviewer: What about leaving primary school, how did that feel?
206	Participant: It was a bit sad but it wasn't that bad.
207	Interviewer: What was sad about it?
208	Participant: I dunno, just like your friends
209	Interviewer: What was sad about your friends?
210	Participant: Mmm [starts crying]
211	Interviewer: Are you ok?
212	Participant: [crying heavily]
213	Participant's Mother: It's ok, it's alright [hugs participant and then leaves room]
214	Interviewer: We don't need to talk about it if it feels too hard.
215	Participant: No.
216	Interviewer: You don't want to talk about it?
217	Participant: No.
218	Participant's Mother [returns with a box of tissues] It's ok, there you go.
219	Interviewer: I'm sorry to ask difficult questions, we don't need to keep talking about
220	that if you don't want to. [deliberate pause] was there anything else you wanted to
221	talk about leaving primary school?
222	Participant: Ummm not really no.
223	Interviewer: Shall we move on?
224	Participant: Yeh.
225	Interviewer: Okay, so understanding it was perhaps a bit difficult leaving primary
226	school, but from what you were saying before it sounds like the start of your new
227	school has gone well so far and you have been doing really well in starting to make
228	new friends. How are you feeling now about the rest of your time at your new school?
229	Participant: Yeh I like it.
230	Interviewer: Why is that?
231	Participant: They go on about GCSEs a lot and how like if we start doing some of
232	the tests now and all that stuff it will be good for us when we get to year 11.

SECTION FOUR

ETHICS SECTION

Transition to Secondary School in Children with Cleft Lip and/or Palate

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(excluding tables, reference lists, and appendices)

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Research Protocol**Version 3 - 12/05/2015**

Study Title:	Experiences of Transition to Secondary School in Children with Cleft lip and/or palate
Principal Investigator:	Rachael Faulkner, Trainee Clinical Psychologist, Lancaster University
Academic Supervisor:	Dr Craig Murray, Lancaster University
Field Supervisors:	[REDACTED] [REDACTED]
Affiliation:	Lancaster University

Introduction

Cleft Lip and/or Palate (CL/P)

The term 'cleft lip and/or palate' (CL/P) refers to a heterogeneous group of common congenital craniofacial anomalies that occur in approximately 1 in every 700 births (Mossey, Little, Munger, Dixon & Shaw, 2009; Murray, 2002). A 'cleft' is a split or gap in the upper lip on either one side (unilateral) or both sides (bilateral) and/or roof of the mouth. A cleft occurs when separate areas of the face and/or mouth do not fully join together during foetal development (Cleft Lip and Palate Association (CLAPA), n.d.). The precise cause of CL/P is not presently known, however, emerging evidence suggests a complex combination of genetic and environmental factors (Dixon, Marazita, Beaty & Murray, 2011; Mossey et al, 2009; Vieira, 2008).

Clefts are usually repaired surgically in early infancy (CLAPA, 2003), however, further procedures are often required as a child grows and can continue into early adulthood (Shkoukani, Chen & Vong, 2013). Individuals born with a CL/P may also experience a range of additional difficulties including; feeding difficulties, chronic glue ear, recurrent ear infections, hearing difficulties, dental cavities, displaced teeth, speech difficulties and psychosocial problems (Mersch, 2014; Mossey et al, 2009; Shkoukani et al, 2013). Subsequently, individuals often require specialist multidisciplinary input throughout their lifespan, particularly during childhood and adolescence to optimise feeding, appearance, facial growth, speech and language skills and wellbeing (Mossey et al, 2009; Shkoukani et al, 2013). This typically includes input from plastic surgeons, maxillofacial surgeons, speech and language therapists, clinical nurse specialists, clinical psychologists, paediatric dentists, orthodontists, audiologists, ward staff and clinical geneticists (Chuo et al, 2008; CLAPA, 2003; Mossey et al, 2009).

Psychosocial Wellbeing in Individuals with CL/P

Hunt, Burden, Hepper and Johnston (2005) conducted a literature review of 64 papers which explored psychosocial difficulties in individuals with CL/P. They argue that there is a general misconception that individuals with a CL/P experience psychological distress as a result of the CL/P. They conclude that individuals with CL/P do not experience significant psychosocial difficulties as a result of the CL/P. Conversely, overall psychosocial functioning is considered good. However, some specific problems may be more prevalent than in individuals without CL/P (Hunt et al, 2005). These difficulties include behavioural problems, depression, anxiety, and satisfaction with appearance and speech (Hunt et al, 2005).

More recent evidence suggests that children born with CL/P may experience more teasing and bullying and have lower self-esteem compared to their peers (Hunt, Burden, Hepper, Stevenson & Johnston, 2007). For instance, Hunt et al (2007) found that parents of children with CL/P report that their child is more anxious, has lower self-esteem, and is less satisfied with their physical appearance and speech compared to reports from parents of children without CL/P. Significantly higher incidences of teasing were also reported ($p < 0.001$; Hunt et al, 2007). Similarly, Murray et al (2010) found that school-age children with CL/P (up to the age of 7 years old) tended to spend more time alone, experienced more bullying and negative interactions with peers, and seemed more anxious and withdrawn compared to their peers without cleft lip and/or palate. However, Berger and Dalton (2009) found that adolescents (aged 11- 16 years old) with CL/P did not report increased psychosocial difficulties compared to their peers; despite reporting experiences of teasing and bullying, feeling not understood or heard, embarrassed and self-conscious. Nonetheless, research exploring quality of life in domains such social functioning, schooling, and family and friends, is lacking (Klassen et al, 2012).

Matsumoto (2009) suggests that the 'meaning of self' for children with cleft lip and/or palate changes throughout the developmental stages. This may indicate that as children with CL/P develop and become adolescents their narrative of having a visible difference changes in some way. Despite this, there is a paucity of research qualitatively exploring children's and young people's experiences of having a CL/P. One study, by Hall, Gibson, James and Rodd (2013) looked at children's (with CL/P) general life stories and explored how they experience specific aspects of the condition and related treatment. However, to date no studies have explored how children with CL/P experience the transition from primary school to high school, which research indicates can be a daunting and difficult time for many children (Maher, 2010; Zeedyk et al, 2003).

Rationale for the Proposed Research

This research project will seek to qualitatively explore the lived experiences of young people (aged 11-12 years) with CL/P when transitioning to high school. It is anticipated that findings will enhance understanding of how young people with CL/P experience this transition and may inform interventions to support young people with CL/P during this transition. Findings will therefore be of relevance to clinical psychologists and other health professionals working with children and young people with CL/P. Findings may also help to inform the development of services for children and young people with CL/P nationally.

Method

Design

This research project will utilise a qualitative design to explore participants' experiences of transitioning to high school. Data will be collected via a single one-to-one interview between the participant and the researcher. Each interview will last approximately 1 hour, although interviews may be shorter or longer depending on how long the

participant needs to express their experiences. A semi-structured approach to interviewing will be utilised, this will allow for a consistent approach throughout data collection, whilst also allowing for the idiosyncrasies of participants' experiences to be explored and captured. Data will be analysed qualitatively using Interpretative Phenomenological Analysis (IPA).

Participants

The sample will be purposive and will consist of one group of participants. It is likely that the sample will be fairly homogenous. This is because whilst the exact nature of CL/P may be heterogeneous, and participants may come from a range of cultural and socio-economic backgrounds, all participants share the experience of being born with a CL/P, and will be (mostly) 11-12 years old, and in their first year of high school.

Approximately 10 participants will be recruited to this study from a total population pool of circa 1000¹ young people, although recruitment will be phased according to region. To be included in the study, participants must have been born with a cleft lip and/or palate and have transitioned to a mainstream high-school from a mainstream primary school within the United Kingdom (UK) in the last 12 months. Whilst there is no specific age criteria for inclusion, it is anticipated that the majority of participants will be 11 – 12 years old as this is the typical age that young people start high school. Individuals will not be excluded from the study on the grounds of physical or learning disabilities; however, they must attend a mainstream high school in order to meet the inclusion criteria. Individuals will therefore be excluded from the study if they are not educated in a mainstream high school setting; for example, if they are home schooled, attend a special school or attend a three tier school system. The rationale for excluding this group of young people is that

these individuals are likely to have considerably different experiences of school related transitions.

Materials

All individuals identified as meeting the inclusion criteria will be sent a recruitment pack in the post. The recruitment packs will comprise of an invitation letter (Appendix 4-A) which will be addressed to the parent/carer of the potential participant, a participant information sheet – parent/carer version (Appendix 4-B), a participant information sheet- young person leaflet (Appendix 4-C), and response form (Appendix 4-D). A second letter (Appendix 4-E) may also be sent if required, in accordance with the recruitment strategy (detailed below). All information sent to potential participants and their parents/carers will be sent by the cleft team (direct care team) on the researcher's behalf to ensure that the researcher does not have access to any patient data prior to participants opting into the study. Potential participants and their parents/carers will be informed of this via the participant information sheets. Posters (Appendix 4-F) containing recruitment information may also be displayed in cleft clinic waiting rooms and/or other local site areas as agreed by the relevant research and development (R&D) departments. An electronic version of the poster and information sheets may also be displayed on cleft service websites and/or newsletters, in accordance with R&D agreement.

A confirmation letter (Appendix 4-G) will be sent to all individuals that opted into the study to confirm details regarding the time, date and location in which their interview will take place. These letters will be addressed to both the young person and their parent/carer and will be sent via email to individuals that have an email address, or posted (where time allows) to individuals that do not have an email address. In addition, acknowledgement letters (Appendix 4-H) will be sent to any individuals, and their parents/carers, that opted in but

were not selected for inclusion in this study. Both the confirmation and acknowledgement letters will be sent by the researcher as these will only be sent to individuals that have expressed an interest in the study and have provided their contact details to the researcher.

A parent/carer consent form (Appendix 4-I) and a young person consent form (Appendix 4-J) will also be used to record confirmation of consent. An interview schedule (Appendix 4-K) will loosely guide the direction of questioning during interviews to help maintain a consistent approach. The interview schedule has been developed in consultation with the field supervisors (a clinical psychologist working within a specialist cleft service). All recruitment and participant materials have also been reviewed by field and academic supervisors to help ensure that information is informative yet accessible and appropriate for its intended purpose.

A mobile phone (on loan from Lancaster University) will be used to allow potential participants and/or their parents/carers to contact the researcher and vice versa, for the purposes of this study. A digital dictaphone will be used to audio record interviews.

Recruitment Protocol

Within the UK and Ireland, specialist cleft services operate on a regional basis, providing specialist input for all individuals born with a cleft lip and/or palate across their lifespan. Within this study, recruitment will take place via these specialist cleft services to help ensure that all individuals that meet the inclusion criteria are invited to take part in this study. However, due to the large estimated population size and the comparatively small sample size required for this qualitative study (approximately 10 participants), a phased recruitment strategy will be utilised according to geographic location for pragmatic reasons.

In the first phase, recruitment will be conducted via the [REDACTED]

[REDACTED] According to the CRANE database (2013), this region has the largest number of individuals with a cleft lip and/or palate registered overall. It is also the region closest to the chief investigator's base and thus will significantly reduce time and associated travel costs. However, if after this initial phase sufficient recruitment has not been obtained (approximately 10 participants) then further recruitment phases will seek to recruit via further specialist cleft services until sufficient participant numbers have been obtained. The relevant research and development (R&D) and site specific approval will be sought for each phase only once that phase is instigated. These subsequent phases will be rolled out as follows:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Within each phase the local cleft team (direct care team) will identify all individuals that meet the inclusion criteria (as indicated above). Recruitment packs, which will have been prepared in advance by the researcher, will then be sent via post to the parents/carers of all identified individuals by a member of the cleft team (cleft coordinator, assistant psychologist or equivalent). Address labels will be added to the packs prior to posting by the cleft team, to ensure that only the direct care team has access to patient data. The

recruitment packs will be addressed to the parent/carer of the young person (potential participant). However, within the pack there will be two sets of project information; a parent/carer version and an accompanying young person (participant) version. This will allow the parent/carer to read the project information before deciding whether or not to pass on the information to their child and discuss with them.

In addition to the recruitment packs, posters displaying key study information may be displayed in local clinic area for example, in clinic waiting rooms, on service websites and/or in any relevant service newsletters/leaflets or equivalent, pending local R&D approval. Potential participants may also be told about the study by their clinician and/or another member of the direct care team when they attend the clinic for appointments, only if it is considered to be appropriate at the time by the clinician. In this case, the clinician will be advised to approach the young person's parent/carer in the first instance and provide them with a copy of the participant information sheet. It is then up to the parent/carer to decide whether information about the study can also be shared with the young person.

Individuals invited to take part in the study will be asked to opt in (by phone, email or post) within two weeks of receiving the recruitment pack. A freepost addressed envelope will be provided for this purpose. Individuals will be advised (in the information sheet) that they can discuss the research further with the chief investigator via phone or email prior to opting in if preferred. They will also be able to discuss the research with the field supervisor and/or other clinical psychology colleagues if desired, although the clinician may advise the participant to seek further information from the chief investigator.

If approximately 10 participants have not been recruited to the study within the first two weeks after the recruitment pack was sent, a second letter will be sent to remind participants of the study. This second letter will be sent by the cleft team on the researcher's

behalf to all individuals that were initially invited to the study. This will not only ensure that the researcher does not have access to patient data, but in addition, also ensures that the cleft team is not able to establish whom has/has not responded thus far.

If approximately 10 participants have not been recruited to the study after a further one week, the researcher will apply for R&D and site specific approval to begin the next phase of recruitment. Recruitment will be conducted using the same approach throughout each phase until approximately 10 participants have been recruited to the study. All advertising materials used (e.g. posters etc.) will remain in situ at each site until all recruitment has ceased. The point at which recruitment ceases will be determined by the chief investigator. When recruitment ceases, the chief investigator will inform all local collaborators that recruitment is no longer active, and advise them to ensure that all publication of the study from that site ceases.

Protocol for the Selection of Participants

Participants will be recruited to the study using a phased opportunist selection process. In which, the initial selection of participants will take place immediately at the end of the initial two week recruitment period within each phase. If at this point there is a low response rate, all individuals that have thus far opted into the study will be selected for inclusion and the researcher will contact all of these individuals to arrange a suitable interview appointment. At this point, recruitment will continue as per the recruitment strategy outlined above until approximately 10 participants have been recruited to the study. Conversely, if any point there is a high response rate to invitation (e.g. greater than 10) then the researcher will select participants according to their availability, geographical location, and/or participant characteristics. Selection of participants according to participant availability and/or geographical location may facilitate swift data collection and minimize

travel expenses. Selection according to participant characteristics may help ensure homogeneity of participants, which is ideal for data analysis within an IPA framework.

The researcher will contact selected participants using the contact details that the participant supplied (on the response form) to arrange a convenient time and location for the interview to take place with the participant. Confirmation letters will be sent to participants to confirm the above. Where possible, confirmation letters will be emailed to participants, alternatively, these may be posted. In the instance of a high response rate it may be that not all of those that expressed an interest in the study are selected for participation. Any individuals not selected for participation will be contacted by the researcher via an acknowledgement letter sent by email or post, to inform them of this decision and to thank them for their input.

Data Collection

Data collection will occur during a single meeting with the participant. This will take place at either the participant's home address or on NHS trust premises at the participant's nearest/usual cleft clinic, depending on participant preference. Where possible, data collection will be scheduled outside of school hours (e.g. evenings, weekends and school holidays) to minimize disruption to the young person's education. Participant expenses up to a maximum of £20 per participant will be paid in accordance with the guidelines outlined in the Lancaster University Doctorate in Clinical Psychology (DCLinPsy) handbook².

Before participating in the study, both the young person and their parent/carer will be asked to provide fully informed consent. Data will be then be collected via a single one-to-one interview between the young person and the chief investigator. The rationale for conducting one-one interviews is to allow the young person to express their own personal experiences without any bias or influence from their parent/carer. However, if the

young person would prefer, their parent/carer will be allowed to be present during the interview. Whilst this may influence the data, it is hoped that this will help increase participation rates and ensure that the young person feels at ease during participation. It is anticipated that each interview will last approximately 60 minutes, although they will be guided by the young person and may therefore be shorter or longer in duration. The content of each interview will be guided using an interview schedule. Interviews will be audio recorded.

Data Analysis

Audio recordings of participant interviews will be transcribed verbatim to aid analysis. Transcripts will then be analysed using IPA, guided by Smith, Flowers and Larkin (2009). Smith et al (2009) argue that when individuals experience significant events and transitions in their life, they reflect on these events in order to make sense of their experiences. IPA provides a framework for the qualitative analysis of data that allows the researcher to explore and examine participant reflections and understand participants' meaning making, whilst also acknowledging the active interpretative role of the researcher (Smith et al, 2009). The process of data analysis will be discussed during supervision with the academic supervisor (Dr. Craig Murray) from Lancaster University to ensure reliability and validity of analysis.

Data Storage

Whilst the project is taking place the chief investigator (Trainee Clinical Psychologist) will be responsible for ensuring that all project data will be stored securely. Accordingly, audio recordings will be uploaded to an encrypted password protected file on the encrypted Lancaster University drive as soon as possible after each interview and then deleted from the dictaphone. Once transcribed, audio files will be

permanently deleted. During transcription all identifying information will be changed or redacted to maintain participant anonymity and confidentiality. Anonymised transcripts will be saved in an encrypted password protected file on the university drive for the duration of the data analysis process. Any personal data collected during the study (e.g. consent forms, response forms, participant contact details and any other project data) will be stored temporarily in a locked cabinet located within a secure location on university site until it is possible to scan it electronically and save as an encrypted password protected file on the encrypted university drive. All identifiable personal data will be saved in a separate encrypted password protected files and then deleted/destroyed as soon as possible once no longer needed, with the exception of consent forms (details of which are described below).

Once the study is completed project data (anonymised transcripts and consent forms) will be scanned and saved electronically in individual encrypted password protected files. Data will then be transferred securely to the DCLinPsy Research Coordinator using the ZendTo file transfer software and will be stored in a password-protected file space on the encrypted university server for 10 years from the date of submission. All data will be deleted after 10 years. The safe storage and deletion of all project data will be carried out by the DCLinPsy Research Coordinator. The data custodian (DCLinPsy Research Director) will assume ultimate responsibility for safety of the data.

Ethical, Risk and Practical Issues

Ethical Approval

This study has undergone a peer review process at Lancaster University which comprised of a panel of peer Trainee Clinical Psychologists, members of the Lancaster University Public Involvement Network, and Doctorate in Clinical Psychology Research Staff. Approval will be obtained from the Research Support Office (RSO) at Lancaster and

the relevant local National Health Service (NHS) Research and Development (R&D) departments. Ethical approval will be obtained from the National Research Ethics Service (NRES) via the Integrated Research Application System (IRAS). Copies of submitted IRAS forms and subsequent research ethics committee (REC) & R&D approvals are appended.

Consent

Before participating in the study, participants and their parents/carers will both be required to provide fully informed consent. In obtaining informed consent, the young person and their parent/carer will be asked to re-read the relevant version of the participant information sheet explaining what participation involves. A young person version and a parent/carer version of the participant information sheet will be provided. Participant information sheets and consent forms will be discussed verbally with participants and their parent/carer to ensure understanding, and participants and their parent/carer will be able to discuss any questions with the researcher prior to deciding whether to consent to the study. After reading the participant information sheets and discussing any questions with the researcher, the young person's parent/carer will then be asked to consent to their child's participation. The young person themselves will also be asked to consent to their participation. As such, data collection will only go ahead if both the young person and their parent/carer agree to the young person's participation. This will be evidenced by the signing of consent forms (both a young person and a parent/carer version will be provided). Participants and their parent/carer(s) will be able to withdraw their consent, without specifying a reason, at any time up until two weeks after their interview has taken place. Within this time period, all participant data will be removed from the study and destroyed, however, after this period, data will remain in the study. This information is shared

with participants and their parent/carer in the information sheets and participants and their parent/carer will be reminded of this verbally prior to the start of the interview.

Participant Wellbeing

It is anticipated that participants will not experience any harm or distress as a result of taking part in this study. To help facilitate well-being participants can choose to complete the interview alone with the chief investigator, or if they prefer, their parent/carer may also be present during the interview. Nonetheless, if concerns regarding the participant's well-being are raised by the participant and/or their parent/carer, or noted by the researcher during an interview, the researcher will contact the designated local collaborator as soon as possible to discuss these concerns and agree upon a course of action. In the first instance, participant details will not be disclosed to the field supervisor to maintain participant confidentiality. However, if necessary, confidentiality may be breached to ensure participant safety and wellbeing is maintained. This information is shared in the participant information sheets and participants and their parent/carer will be reminded of this verbally prior to the start of the interview. If participants require follow up input, this will be offered by the local specialist cleft service of which the participant is a patient. The researcher will advise the participant and their parent/carer how to seek further input from their local specialist cleft service and with consent, the researcher may instigate a referral on their behalf.

If at any point during data collection the participant and/or their parent/carer is highly distressed or there is any indication of risk to self or others, the researcher will, where safe to do so, attempt to alleviate any immediate distress. Additionally, if necessary the researcher will contact the emergency services to ensure that an immediate emergency support is in place. Furthermore, the researcher will contact the designated field supervisor and/or local collaborator as soon as possible to discuss concerns and seek further advice. Local

safeguarding policies will be adhered to at all times. Again, this information is shared in the participant information sheets.

Lone Working

Data collection interviews may be conducted in participants' homes. Therefore, it is likely that the researcher will undertake some lone working during this study. As a substantive LCFT employee and Lancaster University DClInPsy Trainee, the chief investigator will abide by the LCFT lone working policy and the Lancaster University lone working guidance at all times whilst undertaking data collection. Additionally, a lone working protocol has been developed to help ensure the safety of the researcher when undertaking lone working and as such, the following measures will be adhered to:

(1) Before undertaking lone working the 'lone worker' must;

- Find a 'buddy' to partner with during the interviews. The buddy should be a colleague, for instance, a peer trainee clinical psychologist or field supervisor. The buddy should be contactable by phone for the expected duration of the interview and should be able to check on the lone workers progress as needed.
- Inform the buddy of the date and time of the interview and how long it is expected to last, the specific time the buddy should expect to hear from you by, mobile numbers (both personal and work mobile) and the academic supervisor for the project.
- Provide the buddy with a sealed envelope containing the participant name, address and contact number and details of where the interview will take place (if not at the participant address), the car make, model and registration and any emergency contact details.
- Immediately prior to undertaking lone working, ensure that mobile phones are fully charged and the car has sufficient fuel for a return journey.

(2) When arriving at the interview location, the lone worker should;

- Park the car in a manner that facilitates a swift exit and once parked, check that you have suitable phone network coverage.
- If the participant has any pets that make you feel uncomfortable, politely ask if they can be put in another room during the interview.
- Sit as near to your exit as possible.
- Inform the participant how long the interview is expected to last and that you will have to call your colleague if you need more time.
- Ensure that your phone is visible (but on silent) throughout the meeting so that you can see if your buddy is trying to contact you at any point.
- If you feel that you are at risk at any point during the interview make your excuses and leave as soon as possible.
- If you feel that you are in danger and cannot leave, text or call your buddy using the code word Mavis to let them know that you are in trouble (e.g. “could you let Mavis know I’m running late for our appointment.”) Your buddy will then initiate the emergency protocol.
- At the end of the interview (or after you have safely left the participants house), and once you are safely in your car with the doors locked, phone the buddy to inform them of your safety.

(3) When being a buddy for a lone worker, the buddy should:

- Legibly record the details that the lone worker supplied you with.
- Ensure that either (a) your mobile phone has sufficient network coverage and is fully charged, or (b) you have access to a landline for the duration of the interview and you have shared this number with the lone worker.

- Ensure that you have access to the sealed envelope that the lone worker provided you with at the time of the scheduled interview.
- If you have not heard from the lone worker by the agreed time, phone them on both numbers (personal and work). If they do not answer your call, send a text message to both numbers asking them to contact you as soon as possible.
- If you have not been able to make contact with your buddy, contact the academic supervisor for further guidance. If you cannot contact the supervisor and/or you are still concerned, open the sealed envelope, contact the police and share the information with the police.
- If the interview goes according to plan, you should return the unopened envelope to the lone worker for them to safely destroy.

Funding and Expenses

This research project will incur some expenses. These are likely to include; mobile phone credit (to respond to participant enquires), participant travel expenses up to a maximum of £20 per participant, researcher travel expenses (for mileage exceeding the researcher's home to base distance), stationary and postage for recruitment packs and reminder letters (approximately 120 of each in the first phase of recruitment³), and stationary and postage for confirmation letters and acknowledgement letters, although where possible these will be emailed. All equipment and research expenses will be provided by Lancaster University in accordance with the guidelines outlined in the DClinPsy online handbook.

Timescales

This research project will run in accordance with the timescales presented in Table 1.

[Insert Table 1 Here]

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Figure Legends

Table 1: Timescales for the study

Table 1: Timescales for the study

Activity	Date
Submit ethics proposal to RSO (university)	March 2015
Submit ethics proposal to IRAS (NHS).	April 2015
Obtain IRAS and local R&D approval	April 2015
Recruitment & data collection	May-June 2015
Transcription of data & data analysis	May-July 2015
Prepare & submit draft report	August 2015
Submit final thesis.	September 2015
Submit paper for publication	Within 12 months of completion

Section 4 Appendix

4-A	Participant Invitation Letter
4-B	Participant Information Sheet – Parent/Carer Version
4-C	Participant Information Sheet- Young Person Leaflet
4-D	Expression of Interest Response Form
4-E	Second Participant Invitation Letter
4-F	Study Poster
4-G	Confirmation Letter
4-H	Acknowledgement Letter
4-I	Consent Form – Parent/Carer Version
4-J	Consent Form – Young Person Version
4-K	Interview Schedule
4-L	NHS Ethics Integrated Research Application System (IRAS) Form
4-M	NRES REC Favourable Opinion with Conditions Letter
4-N	NRES REC Conditions Met Letter
4-O	Research and Development (R&D) Approval Letter (Service 1)
4-P	R&D Approval Letter (Service 2)
4-Q	NRES REC Minor Amendments Approval Letter

**Experiences of Transition to High School in Young People with a Cleft Lip and/or
Palate - Parent/Carer Invitation Letter****Researcher: Rachael Faulkner (Trainee Clinical Psychologist)**

Dear Parent/Carer

My name is Rachael Faulkner and I am a Trainee Clinical Psychologist on the Doctorate in Clinical Psychology programme at Lancaster University. This letter has been given or sent to you by [REDACTED] therefore, please be aware that I have not had access to any of your personal details.

I am conducting research exploring the experiences of young people with a cleft lip and/or palate when starting high school. This is an important area to research because although some services offer support groups to prepare and support young people with a cleft lip and/or palate with their transition to high school, very little is known about how young people actually experience this transition. Knowing more about the experiences of transition to high school in young people with a cleft lip and/or palate would therefore help cleft services further support young people and their families with this transition. Therefore, in this study I would like to talk to young people that were born with a cleft lip and/or palate about their recent experiences of starting high school.

Along with this letter, I have included a parent/carers information sheet, which will tell you more about the study, including what will be involved if you do support your child to take part. I have also included a young person's participant information sheet, which summarises the key information. I would be grateful if you could take a few minutes to read all the enclosed information and if you feel it is appropriate, discuss the information with your child. If after reading the enclosed information, you and your child feel that they might like to take part in this study, please reply using the enclosed response form within the next two weeks. If there is anything you would like to discuss in relation to this study, please feel free to contact me either by email (r.faulkner2@lancaster.ac.uk) or by telephone on [REDACTED]

The cleft clinic may send a further reminder letter in about two weeks' time. This second letter will be sent to everyone that has been invited to take part in the study as the cleft centre will not be told who has/hasn't responded to this letter. I apologise for any inconvenience this may cause.

Thank you for taking the time to read this letter.
Yours sincerely,

Rachael Faulkner

Trainee Clinical Psychologist, Lancaster University

Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate - Parent/Carer Information Sheet

Researcher: Rachael Faulkner (Trainee Clinical Psychologist)

What is the study about?

The aim of this study is to ask young people with a cleft lip and palate about their recent experiences of starting high school.

Why am I being approached?

I would like to collect information from young people with a cleft lip and/or palate that have started high school in the last 12 months. You are being approached because [REDACTED] has identified you as being a parent or carer of a young person with a cleft lip and/or palate that has recently started high school. [REDACTED] has given out this information sheet on my behalf. Therefore, I do not have access to any patient records or contact details belonging to you and/or your child.

What will my child be asked to do if they take part?

If, with your permission, your child decides that they would like to take part in this study, I will arrange to meet with you and your child at a place and time that is convenient for you both. This can be in your home or at your local cleft clinic. During this meeting, we will talk about what is involved in the study and I will answer any questions that you both have.

If at this point, your child still wishes to take part in the study, you will both be asked to provide informed consent and sign a consent form to evidence this. Your child will only be able to participate in this study if both you and your child are happy for them to do so. You are also both able to withdraw consent at any point up to 2 weeks after the interview has taken place and any data collected will be destroyed and not used. After this point the data will remain in the study. You do not need to give a reason to withdraw from the study.

After you have both provided informed consent, you will be asked to leave the room and the interview with your child will begin. If your child prefers, you can be present during the interview. However, as it is your child's experiences I am interested in, you will not be asked to take part. The interview will be an informal chat about your child's experiences of starting high school. The whole meeting will last approximately 1 hour. With consent, the interview will be audio recorded on a dictaphone. This recording will only be used to help me analyse the data. It will not be used for any other purposes and will be deleted as soon as I have transcribed the data.

Will my data be confidential?

All data collected during this study will be kept completely confidential. The only people that will have access to the data are the researchers conducting this project; they are Dr. Craig Murray (Academic Supervisor, Lancaster University) and myself (Rachael Faulkner, Chief Investigator). The cleft team will not have access to your child's data. The only exception to this is if either you or your child tells me anything that makes me think that your child, or someone else, are at significant risk of harm. In this case, I will have to break confidentiality and speak to [REDACTED] from the cleft clinic about this. Where possible, these concerns will be shared with you prior to being passed on.

All data will be stored safely and securely as follows;

- Whilst the study is being conducted, data will be stored electronically in an encrypted file on a password-protected computer that only I (Rachael Faulkner, Chief Investigator) will be able to access. Any paper data, such as completed consent forms, will be stored in a locked filing cabinet held in a secure location at Lancaster University only until it is possible to scan and electronically store this data, at which point all paper copies will be destroyed.
- Once the study has been completed anonymised interview transcripts, consent forms, and any coded data produced during analysis, will be stored electronically in encrypted password protected files by the Doctorate in Clinical Psychology Research Coordinator for 10 years after the end of study. At the end of the storage period, all data will be deleted/destroyed.

What will happen to the results?

Data from your child's interview will be anonymised, collated with other participants' responses, and analysed to produce a set of findings. Findings will be summarised and reported in my Doctorate in Clinical Psychology thesis. A summary of findings will be shared with your local cleft clinic and any other cleft clinics that have taken part in this study. If you would like, a copy of this summary report can also be sent to you. Findings may also be submitted for publication in an academic or professional journal and/or may be presented at any relevant conferences or events. Direct quotations from your child's interview may be used in any reports or publications; however, these will be anonymised so that you and your child cannot be identified.

Are there any risks?

It is anticipated that your child will not experience any significant harm or distress when taking part in this study. Every effort will be made to ensure that the topics are approached and discussed sensitively. However, your child (and/or you, if present) will be able to stop the interview at any time without giving a reason. Furthermore, if at any point during the interview your child appears to be experiencing distress I will check with them whether they wish to continue.

If your child experiences any distress either prior to, during, or following the interview you are encouraged to inform the researcher and/or your local cleft clinician who can arrange for further support to be provided.

Are there any benefits to taking part?

There are no direct benefits to either you or your child as a result of taking part in this study. However, you will be reimbursed for any travel expenses that you incur whilst taking part in this study, up to a maximum of £20.

Who has reviewed the project?

This study has been reviewed and approved by [REDACTED] Research Ethics Committee on behalf of the National Research Ethics Service (NRES). Approval has also been obtained from Lancaster University's Research Support Office and the Research and Development (R&D) department at your local cleft clinic.

Where can I obtain further information about the study?

If you have any questions about the study, please contact the main researchers:

Chief Investigator	Academic Supervisor
Rachael Faulkner (Trainee Clinical Psychologist) Division of Health Research Furness College Lancaster University Lancaster, LA1 4YG Email: r.faulkner2@lancaster.ac.uk Phone: [REDACTED]	Dr Craig Murray (Deputy Research Director & Senior Lecturer) Division of Health Research Furness College Lancaster University Lancaster, LA1 4YG Email: c.murray@lancaster.ac.uk Phone: 01524 592730

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Research Director (Doctorate in Clinical Psychology)	Associate Dean for Research (External to the Doctorate in Clinical Psychology Department)
Jane Simpson Doctorate in Clinical Psychology Division of Health Research Furness College Lancaster University Lancaster, LA1 4YG Tel: (01524) 592730 Email: j.simpson@lancaster.ac.uk	Professor Paul Bates Faculty of Health and Medicine Division of Biomedical and Life Sciences Lancaster University Lancaster LA1 4YD Tel: (01524) 593718 Email: p.bates@lancaster.ac.uk

Thank you for taking the time to read this information sheet.

**Experiences of Transition to High School in Young People with a Cleft Lip
and/or Palate - Young Persons Information Leaflet**

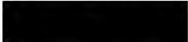

Researcher: Rachael Faulkner (Trainee Clinical Psychologist)

What is it?

Hello, my name is Rachael Faulkner. As part of my training to be a Clinical Psychologist I am doing some research about what it is like to leave primary school and start high school for young people who were born with a cleft lip and/or palate.

I would like to invite you to take part in this research. However, before you decide if you would like to take part, it is important that you understand what is involved. Please read this leaflet carefully, it tells you about the research. It may also be helpful to talk to your parents/carers about it.

Why are you asking me?

I would like to talk to young people who were born with a cleft lip and/or palate that have started high school within the last year. I have asked the cleft clinic at  send this leaflet out to everyone that they think might be able to help with this research.  have not given me any of your details.

Do I have to take part?

No. It is completely up to you whether you take part. I will not tell the cleft clinic who takes part. Your decision will not affect your care from the cleft clinic.

Do I need permission from my parent/carer?

Yes. If you do decide to take part, you will need permission from your parent/carer. I will ask you and your parent/carer to sign a form to say that you are both happy for you to take part.

What will I be asked to do?

If you decide to take part, I will arrange to meet at your house or your local cleft centre. During this meeting, we will talk about your cleft lip and/or palate, and what it was like for you leaving primary school and starting high school. I will ask you some questions about your experiences. I am interested in hearing what you have to say and there are no right or wrong answers. I will record our conversation so that I can write up it up later. No one else will listen to the recording and it won't be used for anything else. After our conversation has finished, you will not need to do anything else.

How long will it take?

Our meeting will last about 1 hour, but we can take as many breaks as you like.

Can my parent/carer stay with me?

At the start of the meeting, I would like to meet with you and your parent/carer so that we can all talk together about what the study involves. After this, I will ask your parent/carer to leave the room while we chat about your experiences of starting high school. However, if you prefer, your parent/carer can stay with you during our chat but they won't be able to join in with the conversation. This is because I am only interested in your views and not the views of your parent/carer.

Can I change my mind?

Yes. You can stop the meeting at any time. You don't have to give me a reason. Changing your mind will not affect your care from the cleft clinic in anyway.

Will it be private?

Yes. Everything that we talk about during our conversation will be private. I might use some of your words in my report when I write up the findings to help explain things, but I won't use your real name. If you like, you can choose a pretend name for me to use instead.

However, if you tell me anything that makes me worried about your safety, or the safety of someone else, I will have to share this with one of the psychologists at your cleft clinic. If I do have to share

what you say, I will always try to tell you about this first, and I will only share what is necessary.

What will happen to the results?

When our meeting has finished I will go away on type up what you said during our conversation. I will change your name and any other key details so that no one can tell that it is you. I will then combine what you said with what other young people said and I will pick out the key themes from everyone's responses. These key themes will be the findings from this research project. I will then write a report that explains these findings, and submit this report to Lancaster University as part of my coursework. I might also share this report with staff at your local cleft clinic, and with staff that work in any other cleft clinics.

Where will the information be kept?

I will keep all the information I collect as part of this project in a locked cupboard or in a password-protected file on a secure computer network whilst the research takes place.

How long will the information be kept for?

After the research is finished and the report is submitted, the information will be stored in a password-protected file on a secure computer network for 10 years. After 10 years, the information will be deleted.

Are there any risks?

If you have had a difficult time starting high school, you might find some questions or topics upsetting to talk about. However, I will try my best to make sure we only talk about things you feel comfortable talking about. We can take breaks during the conversation. You can also choose not to answer any of the questions. You can stop the conversation at any time without giving a reason. At the end, we can talk about how you found the conversation and I can suggest ways that you can get more support if you need it.

Will I be paid for taking part?

No, unfortunately I cannot pay you for taking part. However, I can pay your travel expenses if you travel to the meeting.

Is anyone checking this project?

Craig Murray at Lancaster University is supervising this research. This research has also been checked by Lancaster University, a research ethics committee, and the research and development department at [REDACTED]

If you have any complaints, please contact Jane Simpson (Division of Health Research, Lancaster University). Her phone number is 01524 592730 and her email address is: j.simpson@lancaster.ac.uk.

How can I find out more or get involved?

If you have any questions about the study, or would like to take part, please contact me on [REDACTED]

You can also fill in the response form that was sent to your parent/carer with this leaflet and send it to me in the post using the envelope provided. I will then get in contact with you to arrange a time to meet.

My contact details are:

Rachael Faulkner
 Trainee Clinical Psychologist
 Department of Clinical Psychology
 Division of Health Research
 Furness College
 Lancaster University
 Lancaster
 LA1 4YG

Email: r.faulkner2@lancaster.ac.uk

Phone: [REDACTED]

Thanks For Reading

Appendix 4-D

Doctorate in
Clinical Psychology

Lancaster
University



Faculty of
Health & Medicine

Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate - Response Form

Researcher: Rachael Faulkner (Trainee Clinical Psychologist)

Thank you for taking the time to read all the enclosed information. If your child is interested in taking part in the study titled 'Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate', **please complete the following form and return it to me by 1st August 2015.**

You can return your response form to me by email at r.faulkner2@lancaster.ac.uk, or by post using the enclosed envelope. The freepost address to send your response to is:

Rachael Faulkner
FREEPOST: RTAU-SYXU-YCZZ
Department of Clinical Psychology
Furness College
Bailrigg
LANCASTER
LA1 4YG

Once I have received your response, I will contact you to arrange a suitable time to meet with you and your child to discuss the research further and complete the interview with your child. If there is a high response I may not be able to interview everyone. If this is the case I will contact you by email or letter to let you know. If either you or your child would like to discuss anything with me before deciding whether to take part, please do not hesitate to contact me by phone on [REDACTED] or email (r.faulkner2@lancaster.ac.uk).

Yours sincerely,

Rachael Faulkner (Trainee Clinical Psychologist)

Response Form

My child would like to take part in the study exploring '**experiences of transition to high school in young people with a cleft lip and/or palate**'. Please contact me to arrange an interview.

Parent/Carer name: _____ Phone number: _____

Young person name: _____

Email or postal address: _____

The best time to contact me is: Morning / Afternoon / Evening / Weekends

Please send to r.faulkner2@lancaster.ac.uk or Rachael Faulkner, FREEPOST: RTAU-SYXU-YCZZ, Clinical Psychology, Furness College, Bailrigg, Lancaster, LA1 4YG.

**Experiences of Transition to High School in Young People with a Cleft Lip and/or
Palate - Follow up Letter**

Researcher: Rachael Faulkner (Trainee Clinical Psychologist)

Dear Parent/Carer

I recently wrote to you about some research that I am conducting. The aim of this research is to find out more about how young people with a cleft lip and/or palate experience the transition from primary school to high school. To do this, I would like to interview young people that were born with a cleft lip and/or palate about their recent experiences of starting high school.

I am sending this letter to remind you how you can contact me. If, with your permission, your child would like to take part in this study, please reply using the attached response form by 1st August 2015.

If there is anything you would like to discuss in relation to this study, please feel free to contact me either by email (r.faulkner2@lancaster.ac.uk) or by telephone on [REDACTED]

Please be aware that this letter has been sent to you by [REDACTED] on my behalf. Therefore, I have not had access to any of your personal details. If you have already contacted me about taking part in the study, or if you are not interested in taking part, then please disregard this letter.

Thank you for taking the time to read this letter.

Yours sincerely,

Rachael Faulkner

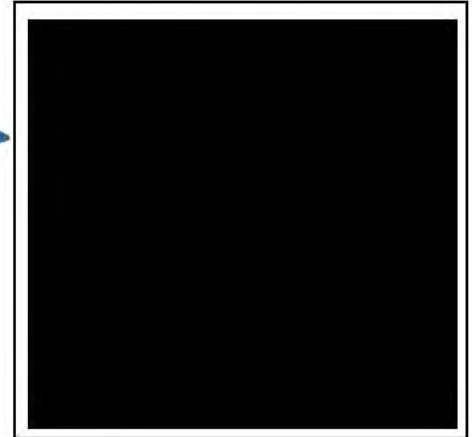
Trainee Clinical Psychologist, Lancaster University

Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate

Researcher: Rachael Faulkner (Trainee Clinical Psychologist)

Hello, my name is Rachael Faulkner. I am a Trainee Clinical Psychologist at Lancaster University.

I am researching how young people with a cleft lip and/or palate experience the transition from primary school to high school.



Could you help?

I would like to talk to young people with a cleft lip and/or palate about their recent experiences of starting high school.

You/your child can get involved in this study if you/they:

- Were born with a cleft lip and/or palate, and
- Started high school in the last 12 months.



If you/your child are interested in taking part in this study, or you would like more information, please contact me by phone or email on:

- 
- r.faulkner2@lancaster.ac.uk



This study is approved by  Research Ethics Committee.

Appendix 4-G

Doctorate in
Clinical Psychology

Lancaster
University



**Experiences of Transition to High School in Young People with a Cleft Lip and/or
Palate - Confirmation Letter**

Researcher: Rachael Faulkner (Trainee Clinical Psychologist)

Dear *(Young Person and Parent/Carer)*

Thank you for agreeing to take part in my research. Our meeting will be:

Date: _____

Time: _____

Place: _____

At the start of our meeting, we will spend some time all together - you, me and your parent/carer. We will talk about what the research is about and what it involves. You and your parent/carer will also be able to ask me questions that you have about the research.

When you and your parent/carer have all the information, I will ask you both to decide if you want to continue or not. If you are both happy to continue, I will ask you both to sign a form. I will then ask your parent/carer to wait outside and we will start the conversation bit of the research. If you want, your parent/carer can stay with you during this bit. The whole meeting will last about 1 hour, but we can stop for breaks if we need to.

If you change your mind and no longer want to take part in the study then that is ok. You do not need to give me a reason. If you need to cancel or rearrange our meeting for any reason, then please let me know as soon as you can. My contact details are:

Phone: [REDACTED]

Email: r.faulkner2@lancaster.ac.uk

I look forward to meeting with you.

Yours sincerely,

Rachael Faulkner

Trainee Clinical Psychologist, Lancaster University

**Experiences of Transition to High School in Young People with a Cleft Lip and/or
Palate - Acknowledgement Letter**

Researcher: Rachael Faulkner (Trainee Clinical Psychologist)

Dear (Young Person and Parent/Carer),

Thank you very much for offering to take part in my research project.

I am writing to let you know that unfortunately I am not able to meet with you as part of this project. This is because there has been a lot of interest in this research and I cannot meet with everybody that has said their interested. I am sorry about this, and I would like to say thank you for your interest.

When the research is finished, I will write a summary report of the findings. If you would like to receive a copy of this report, please let me know and I will make sure I send you a copy. My contact details are at the end of this letter.

If you are finding starting high school difficult, or you have any other problems that you would like to talk to someone about, your cleft clinic may be able to help. Please ask your parent/carer to contact your cleft clinic for support.

If you have any questions, or would like to talk about this letter then please contact me. You can contact me by phone on [REDACTED] or by email at r.faulkner2@lancaster.ac.uk.

I wish you all the best.

Yours sincerely,

Rachael Faulkner (Trainee Clinical Psychologist)

Lancaster University

**Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate -
Parent/Carer Consent Form****Researcher: Rachael Faulkner (Trainee Clinical Psychologist)**

Your child is being asked if he/she would like to take part in research looking at how young people with a cleft lip and/or palate experience the transition to high school. Because your child is under 16, they need your permission to take part. Before you make your decision, please read both versions of the participant information sheet. If you have any questions or concerns please discuss these with Rachael Faulkner (the chief investigator). If you are happy to consent to your child's participation, please read the statements below and tick if you agree, then sign below.

	<i>Please tick if you agree</i>
I have read the information sheets and fully understand what my child's participation would involve.	
My child and I have had the opportunity to ask questions and have them answered.	
I understand that participation is voluntary and that both my child and I can withdraw consent at any time up to two weeks after participation in the study, without giving a reason, and without medical care or legal rights being affected.	
I understand that my child's interview will be audio recorded and then typed into an anonymised transcript for data analysis purposes.	
I understand that audio recordings will only be kept until the data has been transcribed.	
I understand that the information from my child's interview will be pooled with other participants' responses, anonymised and may be published.	
I consent to anonymised information and quotations from my child's interview being used in reports, conferences and training events.	
I understand that both my child and I can withdraw our consent at any time during data collection or up to 2 weeks after data collection has taken place, and that any data collected will be deleted/destroyed and not included in the research.	
I understand that any information my child and I give will remain strictly confidential unless it is thought that there is a risk of harm to my child or others, in which case the researcher will need to share this information with the field supervisor/local collaborator.	
I consent to Lancaster University storing anonymised, written transcriptions of my child's interview, the consent forms and any coded data, in a secure encrypted password protected file on the Lancaster University server for 10 years after the study has finished.	
I consent to my child's participation in this study.	

Parent/Carer Name: _____ Signature _____ Date _____

Researcher Name: _____ Signature _____ Date _____



**Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate -
Young Person Assent Form**

Researcher: Rachael Faulkner (Trainee Clinical Psychologist)

You are being asked if you would like to take part in research about what it is like to leave primary school and start high school for young people who were born with a cleft lip and/or palate. Before you decide, please read the participant information leaflet and ask Rachael (the researcher) about any questions you have. If you then decide you want to take part, please ask your parent/carer to help you complete this form.

	<i>Please tick if you agree</i>
I read the information sheet and I understand what taking part involves.	
I was able to ask questions about the research and have them answered.	
I understand that it's my decision if I take part or not and that my decision will not affect my care from the cleft clinic.	
I know that my parent/carer has had to give their permission for me to take part.	
I know that my parent/carer or I can change our minds at any time during the meeting or up to 2 weeks after, and we don't have to give a reason. If we change our minds, anything that I/we say will not be used in the study.	
I understand that my conversation with the researcher will be recorded but the recording will only be used to help the researcher remember what was said and that this will be deleted as soon as possible.	
I understand that the researcher might use some of my words in the report to explain the findings but my name will be changed so that no one can tell it's me.	
I know that everything I say will be kept private unless the researcher is worried about my safety or the safety of someone else. If the researcher is worried she will tell one of the clinical psychologists at the cleft clinic.	
I am happy for Lancaster University to keep my data in a password-protected file on a secure computer network for 10 years after the study has finished.	
I am happy to take part in this study.	

Participant Name: _____ **Signature** _____ **Date** _____

Researcher Name: _____ **Signature** _____ **Date** _____

Appendix 4-K

Experiences of Transition to High School in Children with a Cleft Lip and/or Palate

Interview Schedule

- Introductions (5 minutes – all timings are approximate)
- Explaining the study and answering questions (10 minutes)
- Obtaining informed consent (5 minutes)

Sample questions: *(Please note, these questions are to be used as a guide only, other questions may be asked and this guide may be amended throughout the interview process.)*

- **Can you tell me a little bit about your cleft lip and/or palate?**
 - What has it been like growing up with a cleft?
 - Did you ever talk about your cleft with other children/teachers at primary school?
 - If so, what did you talk about?
 - Did anyone ask you about your cleft?
 - If so, how did you deal with this?

- **Do you remember how you felt before you started your new school?**
 - How did you feel about leaving your old school?
 - Did you visit your new school beforehand? If so, what did you think, how did you feel?
 - What did you think your new school would be like when you started?
 - How did that make you feel?
 - Was it like that?
 - How did that make you feel?
 - What did you do?
 - Did you talk to anyone about starting high school? (e.g. friends, parents/carers/teachers/the cleft clinic (e.g. transition group)/ anyone else?)
 - If yes, what did you talk about?
 - Did this make you feel better/worse? Why?

- **Can you tell me what it was like starting your new school?**
 - What was the best bit of starting your new school?
 - Did you struggle with anything?
 - What was the most difficult bit for you?
 - Would anything have helped with this?
- **What was it like in the first few days/weeks?**
 - How did you feel?
 - Friends?
 - New people?
 - Teachers?
 - Family?
- **Did anything change later after these first few days/weeks?**
 - Old friends?
 - New friends?
 - Other people at school?
 - Teachers?
 - Family?
 - School work
- **How do you feel about your new school now?**
 - Do you like it? If so, why do you like/not like it?
 - Is there anything you don't like?
 - Would you change anything? If so, what?
 - What difference would this make?
 - What do you hope the rest of your time at this school will be like?
- **Was there anything that might have made changing schools easier/less worrying?**
 - If so, what do you think could help?
 - Who would be best to help with this? (e.g. teachers, parents/carers, the cleft clinic, older people with a cleft)

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)

Transition to High School in Young People with Cleft Lip/Palate

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- England
-
-
- Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England
 Scotland
 Wales
 Northern Ireland
 This study does not involve the NHS

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
 Social Care Research Ethics Committee
 Research Ethics Committee
 Confidentiality Advisory Group (CAG)
 National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

- Yes No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

- Yes No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

- Yes No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

- Yes No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- Yes No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

Yes No

9. Is the study or any part of it being undertaken as an educational project?

Yes No

Please describe briefly the involvement of the student(s):

The student will be the Chief Investigator in this project. The student will also undertake all other aspects of this study including design, recruitment, data collection, data analysis and reporting of results. The student is a final year Trainee Clinical Psychologist undertaking this project as part of the Doctorate in Clinical Psychology and will work under the supervision of [REDACTED]

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

Yes No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

Yes No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

Yes No

Integrated Research Application System
Application Form for Research involving qualitative methods only



Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting [Help](#).

Please define any terms or acronyms that might not be familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
 Transition to High School in Young People with Cleft Lip/Palate

Please complete these details after you have booked the REC application for review.

REC Name:

████████████████████

REC Reference Number:
 15/EM/0257

Submission date:
 22/05/2015

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate.

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Miss	Rachael	Faulkner
Address	Faculty of Health & Medicine, Clinical Psychology - Division of Health Research		
	Floor C, Furness College		
	Lancaster University, Lancaster		
Post Code	LA1 4YG		
E-mail	r.faulkner2@lancaster.ac.uk		
Telephone	██████████		
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate in Clinical Psychology (DClinPsy)

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title Forename/Initials Surname
	Dr C Murray
Address	Faculty of Health & Medicine, Clinical Psychology - Division of Health Research Floor C, Furness College Lancaster University, Lancaster
Post Code	LA1 4YG
E-mail	c.murray@lancaster.ac.uk
Telephone	+44 (0)1524 592730
Fax	

Please state which academic supervisor(s) has responsibility for which student(s):

Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)

Academic supervisor(s)

Student 1 Miss Rachael Faulkner

Dr C Murray

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- Student
 Academic supervisor
 Other

A3-1. Chief Investigator:

	Title Forename/Initials Surname
	Miss Rachael Faulkner
Post	Trainee Clinical Psychologist
Qualifications	BSc(Hons) Psychology
Employer	Lancashire Care NHS Foundation Trust
Work Address	Faculty of Health & Medicine, Clinical Psychology - Division of Health Research Floor C, Furness College Lancaster University, Lancaster
Post Code	LA1 4YG
Work E-mail	r.faulkner2@lancaster.ac.uk
* Personal E-mail	

Work Telephone [REDACTED]
 * Personal Telephone/Mobile
 Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?

This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	[REDACTED]	[REDACTED]	[REDACTED]
Address	[REDACTED]		
	[REDACTED]		
	[REDACTED]		
Post Code	[REDACTED]		
E-mail	[REDACTED]		
Telephone	[REDACTED]		
Fax			

A5-1. Research reference numbers. Please give any relevant references for your study:

Applicant's/organisation's own reference number, e.g. R & D (if available):

Sponsor's/protocol number:

Protocol Version:

Protocol Date:

Funder's reference number:

Project website:

Additional reference number(s):

Ref.Number	Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

Yes No

Please give brief details and reference numbers.

n/a

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

This research project aims to find out how young people who were born with a cleft lip and/or palate experience the transition from primary school to high school. In doing this, the project researcher would like to interview approximately 10 young people with a cleft lip and/or palate about their experiences of starting high school. It is hoped that findings will be of use to clinical psychologists who work in cleft services, particularly when supporting young people with a cleft lip and/or palate during school transitions.

To be eligible to take part in the study individuals must have been born with a cleft lip and/or palate, and have transitioned to a mainstream high-school from a mainstream primary school within the United Kingdom in the last 12 months. There is no set age criteria, however, it is likely that most participants will be 11 – 12 years old as this is the typical age that young people start high school. Individuals that do not attend a mainstream high school (e.g. those that are home schooled, attend a special school, or attend a three tier school system) are not eligible to take part in this study.

Participants will be asked to take part in one interview with the researcher which will last approximately one hour. During the interview participants will be asked questions about what it was like leaving primary school and starting high school. Participants can decide to take part in the interview at their home, or at their local cleft service. After this interview, participants do not need to do anything else, however, the study will continue until approximately 10 participants have taken part in the study.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

RECRUITMENT:

Potential participants will be recruited to the study via [REDACTED]
[REDACTED]
[REDACTED]

The local cleft team (direct care team) will identify all individuals that meet the inclusion criteria (as indicated above). Recruitment packs, which will have been prepared in advance by the researcher, will then be sent via post to the parents/carers of all identified individuals by a member of the cleft team (cleft coordinator, assistant psychologist or equivalent). Address labels will be added to the packs prior to posting by the cleft team, to ensure that only the direct care team has access to patient data. The recruitment packs will be addressed to the parent/carer of the young person (potential participant). However, within the pack there will be two sets of project information; a parent/carer version and an accompanying young person (participant) version. This will allow the parent/carer to read the project information before deciding whether or not to pass on the information to their child and discuss with them.

In addition to the recruitment packs, posters displaying key study information may be displayed in local clinic area for example, in clinic waiting rooms, on service websites and/or in any relevant service newsletters/leaflets or equivalent, pending local R&D approval. Potential participants may also be told about the study by their clinician and/or another member of the direct care team when they attend the clinic for appointments, only if it is considered to be appropriate at the time by the clinician. In this case, the clinician will be advised to approach the young person's parent/carer in the first instance and provide them with a copy of the participant information sheet. It is then up to the parent/carer to decide whether information about the study can also be shared with the young person.

Individuals invited to take part in the study will be asked to express any interest in the study by phone, email or post within two weeks of receiving the recruitment pack. A freepost addressed envelope will be provided for this purpose. Individuals will be advised (in the information sheet) that they can discuss the research further with the chief investigator via phone or email prior to opting in if preferred. They will also be able to discuss the research with the field supervisor and/or other clinical psychology colleagues if desired, although the clinician may advise the participant to seek further information from the chief investigator.

If approximately 10 participants have not been recruited to the study within the first two weeks after the initial invitation letter was sent, a second letter will be sent to remind potential participants about the study. This second letter will be sent by the cleft team on the researcher's behalf to all individuals that were initially invited to the study. This will not only

ensure that the researcher does not have access to patient data, but in addition, also ensures that the cleft team is not able to establish whom has/has not responded thus far.

If approximately 10 participants have not been recruited to the study after a further one week, the researcher will apply for R&D and site specific approval to begin the next phase of recruitment. Recruitment will be conducted using the same approach throughout each phase until approximately 10 participants have been recruited to the study. All advertising materials used (e.g. posters etc.) will remain in-situ at each site until all recruitment has ceased. The point at which recruitment ceases will be determined by the chief investigator. When recruitment ceases the chief investigator will inform all local collaborators and advise them to cease advertisement of the study and ensure that any remaining advertisement materials are removed from public display.

CONSENT:

Before participating in the study, participants and their parents/carers will both be required to provide fully informed consent.

In obtaining informed consent, the young person and their parent/carer will be asked to re-read the relevant version of the participant information sheet explaining what participation involves. A young person version and a parent/carer version of the participant information sheet will be provided. Participant information sheets and consent forms will also be discussed verbally with participants and their parent/carer to ensure understanding. Participants and their parent/carer will also be able to discuss any questions that they have with the researcher prior to deciding whether or not to consent to take part in the study.

After re-reading the participant information sheets and discussing any questions with the researcher, the young person's parent/carer will then be asked to consent to their child's participation. The young person themselves will also be asked to consent to their participation. As such, data collection will only go ahead if both the young person and their parent/carer agree to the young person's participation. This will be evidenced by the signing of consent forms (both a young person and a parent/carer version will be provided).

Participants and their parent/carer(s) will be able to withdraw their consent, without specifying a reason, at any time up until two weeks after their interview has taken place. During this period, relevant data will be removed from the study and destroyed, however, after this point data will remain in the study. This information is shared with participants and their parent/carer in the information sheets and participants and their parent/carer will be reminded of this verbally prior to the start of the interview.

PARTICIPANT WELL-BEING:

It is anticipated that participants will not experience any harm or distress as a result of taking part in this study. To help facilitate well-being participants can choose to complete the interview alone with the chief investigator, or if they prefer, their parent/carer may also be present during the interview.

Nonetheless, if concerns regarding the participant's well-being are raised by the participant and/or their parent/carer, or noted by the researcher during an interview, the researcher will contact the designated field supervisor [REDACTED] and/or local collaborator as soon as possible to discuss these concerns and agree upon a course of action. In the first instance, participant details will not be disclosed to the field supervisor to maintain participant confidentiality. However, if necessary, confidentiality may be breached to ensure participant safety and well-being. This information is shared in the participant information sheets and participants and their parent/carer will be reminded of this verbally prior to the start of the interview. If participants require follow up input, this will be offered by the local specialist cleft service of which the participant is a patient. The researcher will advise the participant and their parent/carer how to seek further input from their local specialist cleft service and with consent, the researcher may instigate a referral on their behalf.

Similarly, if at any point during data collection the participant and/or their parent/carer is highly distressed or there is any indication of risk to self or others, the researcher will, where safe to do so, attempt to alleviate any immediate distress. Additionally, if necessary the researcher will contact the emergency services to ensure that an immediate emergency support is in place. Furthermore, the researcher will contact the designated field supervisor and/or local collaborator as soon as possible to discuss concerns and seek further advice. Local safeguarding policies will be adhered to at all times. Again, this information is shared in the participant information sheets.

RISKS TO THE RESEARCHER:

Data collection interviews may be conducted in participants' homes. Therefore, it is likely that the researcher will undertake some lone working during this study. As a substantive [REDACTED] employee and doctoral student on the Lancaster University Doctorate in Clinical Psychology (DClinPsy) programme,

the researcher will abide by the [REDACTED] lone working policy and the Lancaster University lone working guidance (copies of which are appended to the research protocol) at all times whilst undertaking data collection. Subsequently, a lone working protocol (appended to the research protocol) has been developed to help ensure the safety of the researcher when undertaking lone working. In brief this involves the researcher ensuring that a buddy (colleague) is aware of when they will be undertaking lone working and has access to any relevant information in the case of an emergency (please refer to lone working protocol appended to the research protocol for full details).

A6-3. Proportionate review of REC application *The initial project filter has identified that your study may be suitable for proportionate review by a REC sub-committee. Please consult the current guidance notes from NRES and indicate whether you wish to apply through the proportionate review service or, taking into account your answer to A6-2, you consider there are ethical issues that require consideration at a full REC meeting.*

Yes - proportionate review No - review by full REC meeting

Further comments (optional):

This study will involve interviewing young people that were born with a cleft lip and/or palate (age approximately 11-12 years old) about their experiences of starting high school. Interviewing will take place on one occasion, after which there will be no further input required from participants. It is not anticipated that participants will experience any distress as a result of taking part in this study.

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. Please tick all that apply:

- Case series/ case note review
- Case control
- Cohort observation
- Controlled trial without randomisation
- Cross-sectional study
- Database analysis
- Epidemiology
- Feasibility/ pilot study
- Laboratory study
- Metanalysis
- Qualitative research
- Questionnaire, interview or observation study
- Randomised controlled trial
- Other (please specify)

This project will use qualitative methods only. Data (interviews with young people) will be analysed using Interpretative Phenomenological Analysis (IPA).

A10. What is the principal research question/objective? Please put this in language comprehensible to a lay person.

How do young people born with a cleft lip and/or palate (CLP) experience the transition from mainstream primary to secondary education?

A11. What are the secondary research questions/objectives if applicable? Please put this in language comprehensible to a lay person.

Are the experiences of transition to high school in young people born with a cleft lip and/or palate (CLP) mostly positive,

negative or mixed?

Do young people born with a CLP feel that having a CLP impacts upon their experiences of transition to high school? If so, how?

What, if anything, might assist a young person with CLP when transitioning to high school?

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

A 'cleft' is a split or gap in the upper lip on either one side or both sides, and/or roof of the mouth. A cleft occurs when separate areas of the face and/or mouth do not fully join together during foetal development (Cleft Lip and Palate Association (CLAPA), n.d.). A 'cleft lip and/or palate' (CLP) occurs in approximately 1 in 700 births (Mossey, Little, Munger, Dixon & Shaw, 2009; Murray, 2002). This figure means that approximately 1000 babies are born with a CLP in the UK each year (CRANE, 2013).

Clefts are usually repaired surgically in early infancy (CLAPA, 2003), however, further procedures are often required throughout childhood and early adulthood (Shkoukani, Chen & Vong, 2013). Individuals born with a CLP may also experience a range of additional difficulties including; feeding difficulties, chronic glue ear, recurrent ear infections, hearing difficulties, dental cavities, displaced teeth, speech difficulties and psychosocial problems (Mersch, 2014; Mossey et al, 2009; Shkoukani et al, 2013). Subsequently, individuals often require specialist care throughout their lifespan, particularly during childhood and adolescence to optimise feeding, appearance, facial growth, speech and language skills and wellbeing (Mossey et al, 2009; Shkoukani et al, 2013). This care typically includes input from plastic surgeons, maxillofacial surgeons, speech and language therapists, clinical nurse specialists, clinical psychologists, paediatric dentists, orthodontists, audiologists, ward staff and clinical geneticists (Chuo et al, 2008; CLAPA, 2003; Mossey et al, 2009).

Following a review of 64 papers which explored psychosocial difficulties in individuals with CLP, Hunt, Burden, Hepper and Johnston (2005) conclude that overall psychosocial functioning in people with CLP is good. However, some specific problems may be more common than in individuals without CLP (Hunt et al, 2005). These difficulties include behavioural problems, depression, anxiety, and satisfaction with facial appearance and speech (Hunt et al, 2005). To add to this, more recent evidence suggests that children born with CLP may experience more teasing and bullying and have lower self-esteem compared to their peers without CLP (Hunt, Burden, Hepper, Stevenson & Johnston, 2007). Similarly, Murray et al (2010) found that school-age children with CLP (up to the age of 7 years old) tended to spend more time alone, experienced more bullying and negative interactions with peers, and seemed more anxious and withdrawn compared to their peers without cleft lip and/or palate. However, in another study, adolescents (aged 11- 16 years old) with CLP did not report increased psychosocial difficulties compared to their peers; despite reporting experiences of teasing and bullying, feeling not understood or heard, embarrassed and self-conscious (Berger & Dalton; 2009).

Matsumoto (2009) suggests that the 'meaning of self' for children with CLP changes as they get older. This may indicate that as children with CLP develop and become adolescents their narrative of having a visible difference changes in some way, yet it is not clear why this is. Furthermore, there is a lack of qualitative research exploring children's and young people's experiences of having a CLP, particularly during periods of transition or change. Specifically, to date no studies have explored how children with CLP experience the transition from primary school to high school, which research indicates can be a daunting and difficult time for many children (Maher, 2010; Zeedyk et al, 2003). Therefore, this study will explore the experiences of young people (aged 11-12 years) with CLP when transitioning to high school. It is anticipated that findings will enhance understanding of how young people with CLP experience this transition and may inform interventions to support young people with CLP during this transition. Findings will therefore be of relevance to clinical psychologists and other health professionals working with children and young people with CLP. Findings may also help to inform the development of services for children and young people with CLP nationally.

References:

Berger, Z. E., & Dalton, L. J. (2009). Coping with a cleft: Psychosocial adjustment of adolescents with a cleft lip and palate and their parents. *The Cleft Palate–Craniofacial Journal*, 46, 435– 443. doi: 10.1597/08-093.1

Chuo, C. B., Searle, Y., Jeremy, A., Richard, B. M., Sharp, I., & Slator, R. (2008). The continuing multidisciplinary needs of adult patients with cleft lip and/or palate. *The Cleft Palate-Craniofacial Journal*, 45(6), 633-638. Retrieved from <http://www.cpcjournal.org/doi/full/10.1597/07-048.1>

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Hunt, O., Burden, D., Hepper, P., & Johnston, C. (2005). The psychosocial effects of cleft lip and palate: a systematic review. *The European Journal of Orthodontics*, 27(3), 274-285. doi:10.1093/ejo/cji004

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Maher, D. (2010). Supporting students' transition from primary school to high school using the internet as a communication tool. *Technology, Pedagogy and Education*, 19(1), 17-30. doi:10.1080/14759390903579216

Matsumoto, M. (2009). Characteristics of meaning of self among people with cleft lip and/or palate. *Japanese Journal of Developmental Psychology*, 20(3), 234-242.

Mersch, J. (2014). Cleft Palate and Cleft Lip. Retrieved from <http://www.medicinenet.com/script/main/art.asp?articlekey=43116>

Mossey, P. A., Little, J., Munger, R. G., Dixon, M. J., & Shaw, W. C. (2009). Cleft lip and palate. *The Lancet*, 374(9703), 1773-1785. doi:10.1016/S0140-6736(09)60695-4

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Shkoukani, M. A., Chen, M., & Vong, A. (2013). Cleft lip—a comprehensive review. *Frontiers in Pediatrics*, 1. doi:10.3389/fped.2013.00053

Zeedyk, M. S., Gallacher, J., Henderson, M., Hope, G., Husband, B., & Lindsay, K. (2003). Negotiating the transition from primary to secondary school perceptions of pupils, parents and teachers. *School Psychology International*, 24(1), 67-79. doi: 10.1177/0143034303024001010

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Design:

This research project will utilise a qualitative design to explore participants' experiences of transitioning to high school. Data will be collected via a single one-to-one interview between the participant and the researcher. A semi-structured approach to interviewing will be utilised, this will allow for a consistent approach throughout data collection, whilst also allowing for the idiosyncrasies of participants' experiences to be explored and captured. Each interview will last approximately 1 hour, although interviews may be shorter or longer depending on how long the participant needs to express their experiences. Data will be analysed qualitatively using Interpretative Phenomenological Analysis (IPA). The sample will be purposive and will consist of one group of participants. It is likely that the sample will be fairly homogenous in nature as whilst participants may come from a range of cultural and socio-economic backgrounds, all participants will have been born with a cleft lip and/or palate (CLP), and will be (mostly) 11-12 years old and in their first year of high school.

Participants:

Approximately 10 participants will be recruited to this study from a total population pool of around 1000 young people (CRANE Database, 2013), although recruitment will be phased [REDACTED]. To be included in the study, participants must have been born with a CLP and have transitioned to a mainstream high-school from a mainstream primary school within the United Kingdom (UK) in the last 12 months. Whilst there is no specific age criteria for inclusion, it is anticipated that the majority of participants will be 11 – 12 years old as this is the typical age that young people start high school. Individuals will not be excluded from the study on the grounds of physical or learning

disabilities, however, they must attend a mainstream high school in order to meet the inclusion criteria. Individuals will therefore be excluded from the study if they are not educated in a mainstream high school setting; for example, if they are home schooled, attend a special school or attend a three tier school system. The rationale for excluding this group of young people is that these individuals are likely to have vastly different experiences of school related transitions.

Recruitment Protocol:

Within the UK and Ireland, specialist cleft services operate on a regional basis, providing specialist input for all individuals born with a cleft lip and/or palate across their lifespan. Within this study, recruitment will take place via these specialist cleft services to help ensure that all individuals that meet the inclusion criteria are invited to take part in this study. However, due to the large estimated population size and the comparatively small sample size required for this qualitative study (approximately 10 participants), a phased recruitment strategy will be utilised according to [REDACTED]

In the first phase, recruitment will be conducted via [REDACTED]

[REDACTED] however, if after this initial phase sufficient recruitment has not been obtained (approximately 10 participants) then further recruitment phases will seek to recruit via further specialist cleft services until sufficient participant numbers have been obtained. These subsequent phases will be rolled out in the following order;

Phase 2: [REDACTED]

Phase 3: [REDACTED]

Phase 4: [REDACTED]

Phase 5: [REDACTED]

Phase 6: [REDACTED]

Phase 7: [REDACTED]

The relevant research and development (R&D) and site specific approval will be sought for each phase only once that phase is instigated.

Within each phase the local cleft team (direct care team) will identify all individuals that meet the inclusion criteria (as indicated above). Recruitment packs, which will have been prepared in advance by the researcher, will then be sent via post to the parents/carers of all identified individuals by a member of the cleft team (cleft coordinator, assistant psychologist or equivalent). The recruitment packs will be addressed to the parent/carer of the young person (potential participant). However, within the pack there will be two sets of project information; a parent/carer version and an accompanying young person (participant) version. This will allow the parent/carer to read the project information before deciding whether or not to pass on the information to their child and discuss with them. Copies of all study materials are appended to this application as per the guidelines.

Address labels will be added to the packs prior to posting by the cleft team, to ensure that only the direct care team has access to patient data. Individuals invited to take part in the study will be asked to opt in (by phone, email or post) within two weeks of receiving the recruitment pack. A freepost addressed envelope will be provided for this purpose.

Individuals will be advised in the information sheet that they can discuss the research further with the chief investigator via phone or email prior to opting in if preferred. They will also be able to discuss the research with the field supervisor (and/or other cleft team colleagues) if desired, although clinicians may advise the participant to seek further information from the chief investigator. In addition to the recruitment packs, posters displaying key study information may be displayed in local clinic area (e.g. in clinic waiting rooms), on service websites and/or in any relevant service newsletters/leaflets or equivalent, pending local R&D approval.

If approximately 10 participants have not been recruited to the study within the first two weeks after the recruitment pack was sent, a second letter may be sent to remind potential participants about the study. This second letter will again be sent by the cleft team on the researcher's behalf to all individuals that were initially invited to the study. This will not only ensure that the researcher does not have access to patient data, but in addition, also ensures that the cleft team is not able to establish whom has/has not responded thus far.

If approximately 10 participants have not been recruited to the study after a further one week, the researcher will apply for R&D and site specific approval to begin the next phase of recruitment. Recruitment will be conducted using the same approach throughout each phase until approximately 10 participants have been recruited to the study. All advertising materials used (e.g. posters and leaflets.) will remain in-situ at each site until all recruitment has ceased. The point at which recruitment ceases will be determined by the chief investigator. At this point, the chief investigator will contact all local collaborators and advise them to cease recruitment and remove all remaining study advertising materials from display.

Protocol for the selection of participants:

Participants will be recruited to the study using a phased opportunist selection process. In which, the initial selection of participants will take place immediately at the end of the initial two week recruitment period within each phase. If at this point there is a low response rate, all individuals that have thus far opted into the study will be selected for inclusion and the researcher will contact all of these individuals to arrange a suitable interview appointment. At this point, recruitment will continue as per the recruitment strategy outlined above until approximately 10 participants have been recruited to the study.

Conversely, if any point there is a high response rate to invitation (e.g. greater than 10) the researcher will select individuals for inclusion according to their availability, geographical location, and/or participant characteristics. Selection of participants according to participant availability and/or geographical location may facilitate swift data collection and minimize travel expenses. Selection according to participant characteristics may help ensure homogeneity of participants, which is ideal for data analysis within an IPA framework.

The researcher will contact selected participants using the contact details that the participant supplied (on the response form) to arrange a convenient time and location for the interview to take place with the participant. Confirmation letters will be sent to participants to confirm the above. Where possible, confirmation letters will be emailed to participants, alternatively, these may be posted.

In the instance a high response rate it may be that not all of those that expressed an interest in the study are selected for participation. Any individuals not selected for participation will be contacted by the researcher via an acknowledgement letter which will be sent via email or post, to inform them of this decision and to thank them for their input.

Data Collection:

Data collection will occur during a single meeting with the participant. This will take place at either the participant's home address or on NHS trust premises at the participant's nearest/usual cleft clinic, depending on participant preference. Where possible, data collection will be scheduled outside of school hours (e.g. evenings, weekends and school holidays) to minimize disruption to the young person's education. For interviews conducted within participant homes, the [REDACTED] Lone Working Policy [REDACTED] Lone Working Guidance, and the lone worker protocol will be adhered to.

Before participating in the study, the young person and their parent/carer will be asked to re-read the participant information sheet. Participant information sheets will also be relayed verbally to ensure full understanding and any questions that the young person and/or their parent/carer may have will be addressed. The young person's parent/carer will then be asked to consent to their child's participation. The young person themselves will be asked to assent to their participation. As such, data collection will only go ahead if both the young person and their parent/carer agree to the young person's participation. This will be evidenced by the signing of consent and assent forms.

Any participants claiming travel expenses will then be asked to complete an expenses form. Participant expenses up to a maximum of £20 per participant will be paid in accordance with the guidelines outlined in the Lancaster University Doctorate in Clinical Psychology (DClinPsy) handbook. The relevant section of which can be viewed at; http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/new/onlinehandbook/research_expenses/.

Data will be then be collected via a single one-to-one interview between the young person and the chief investigator. The rationale for conducting one-one interviews is to allow the young person to express their own personal experiences without any bias or influence from their parent/carer. However, if the young person would prefer, their parent/carer will be allowed to be present during the interview. Whilst this may influence the data, it is hoped that this

will help increase participation rates and ensure that the young person feels at ease during participation. It is anticipated that each interview will last approximately 60 minutes, although they will be guided by the young person and may therefore be shorter or longer in duration. The content of each interview will be guided using an interview schedule. Interviews will be audio recorded using a digital dictaphone.

Data Analysis:

Audio recordings of participant interviews will be transcribed verbatim to aid analysis. Transcripts will then be analysed using IPA, guided by Smith, Flowers and Larkin (2009). IPA provides a framework for the qualitative analysis of data that allows the researcher to explore and examine participant reflections and understand participants' meaning making, whilst also acknowledging the active interpretative role of the researcher (Smith et al, 2009). The product of data analysis will be a set of key codes and themes which will form the basis of study findings. The process of data analysis will be discussed during supervision with the academic supervisor (Dr. Craig Murray) from Lancaster University to ensure reliability and validity of analysis.

References:

CRANE Database. (2013). Annual Report on Cleft Lip and/or Palate 2013. On behalf of the Cleft Development Group. Retrieved from [https://www.crane-database.org.uk/publications/2013_annual_report .pdf](https://www.crane-database.org.uk/publications/2013_annual_report.pdf)

Smith, J. A., Flowers, P., & Larkin, M. (2009). Interpretative phenomenological analysis: Theory, method and research. London, UK. Sage.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings
- None of the above

Give details of involvement, or if none please justify the absence of involvement.

Members of the Lancaster University Public Involvement Network (LUPIN) were involved in a peer review process for the initial proposed design of this research. Recommendations from this peer review were taken into consideration and adopted accordingly.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

To be included in the study, participants must;

- (a) have been born with a cleft lip and/or palate
- (b) have transitioned to a mainstream high-school from a mainstream primary school within the United Kingdom (UK) in the last 12 months.

N.B. There is no specific age criteria for participants in this study, however, it is anticipated that most participants will be 11-12 years old as this is the typical age that young people transition to high school.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Individuals will be excluded from the study if;

- (a) they are not educated in a mainstream high school setting (e.g. if they are home schooled, attend a special school or attend a three tier school system).

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Seeking consent	1	0	10 - 15 minutes	The chief investigator (CI) will meet with each participant and their parent/carer. Participants and their parent/carers will be asked to re-read participant information sheets, discuss any questions or concerns with the CI and then sign a consent form (parent/carer and young person versions will be provided) to confirm consent.
Interview	1	0	1 hour	Participants will be asked to take part in one semi-structured interview with the CI which will last approximately 60 minutes in duration in which they will be asked questions about their experience of starting high school. Parents/carers may also be present during the interview if this is preferred by the participant and/or their parent/carer.

A21. How long do you expect each participant to be in the study in total?

Each participant will take part in one interview with the chief investigator. The interview will last approximately 1 hour, although interviews may be shorter or longer depending on how much the participant wishes to share with the researcher. After completion of this one interview, participation will be complete.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

POTENTIAL RISKS:

It is not anticipated that there are any risks to participants when taking part in this study. Furthermore, participation is unlikely to cause any harm or distress.

To help facilitate well-being, participants can choose to complete the interview alone with the chief investigator, or if they prefer, their parent/carer may also be present during the interview.

Nonetheless, if concerns regarding the participant's well-being are raised by the participant and/or their parent/carer, or noted by the researcher during an interview, the researcher will contact the designated field supervisor [REDACTED] and/or local collaborator as soon as possible to discuss these concerns and agree upon a course of action. In the first instance, participant details will not be disclosed to the field supervisor to maintain participant confidentiality. However, if necessary, confidentiality may be breached to ensure participant safety and wellbeing is maintained. This information is shared in the participant information sheets and participants and their parent/carer will be reminded of this verbally prior to the start of the interview.

If participants require follow up input, this will be offered by the local specialist cleft service of which the participant is a patient. The researcher will advise the participant and their parent/carer how to seek further input from their local specialist cleft service and with consent, the researcher may instigate a referral on their behalf.

If at any point during data collection the participant and/or their parent/carer is highly distressed or there is any indication of risk to self or others, the researcher will, where safe to do so, attempt to alleviate any immediate distress. Additionally, if necessary the researcher will contact the emergency services to ensure that an immediate emergency support is in place. Furthermore, the researcher will contact the designated field supervisor and/or local collaborator as soon as possible to discuss concerns and seek further advice. Local safeguarding policies will be adhered to at all times. Again, this information is shared in the participant information sheets.

BURDENS:

The only potential burdens to participants in this study is the time required to allow for participation, and the possibility of incurring expenses. To minimize this burden, interviews will be arranged at a location convenient to the participant. This will be either their home address, or at their local cleft clinic. Both locations will be familiar to participants and suitably accessible. Interviews will also be scheduled at a time to suit participants. If interviews are held at participant's local cleft clinic, then where possible interviews will be scheduled to occur before or after any routine appointments to reduce participant travel. Alternatively, where possible interviews will be arranged outside of school times (e.g. after school, or during weekends and holidays) to minimize disruption to education. A range of different time slots will be made available to increase the likelihood that interviews can take place at a time that is convenient for participants. Furthermore, any expenses incurred by participants as a direct result of their participation in the study (e.g. travel and parking) will be reimbursed up to a maximum of £20 per participant in accordance with the Lancaster University research expenses guidelines available from:

http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/new/onlinehandbook/research_expenses/

To further reduce financial burden on participants, a free post addressed envelope will be provided for potential participants to return expression of interest forms. Similarly, if participants wish to speak to the researcher via telephone (to discuss aspects of the research), the researcher will offer to call the participant at a time convenient to them, to minimize any inconvenience and/or associated telephone costs.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

Yes No

If Yes, please give details of procedures in place to deal with these issues:

Participants will primarily be asked about their experiences of starting high school, therefore questions will not be highly emotive in nature. Please refer to the interview schedule for examples of questions. However, participants will also be asked about their experiences of having a cleft lip and/or palate in relation to starting high school, and for some individuals this may be a sensitive, embarrassing or upsetting topic.

The researcher conducting the interviews is a final year trainee clinical psychologist and has a wealth of experience in conducting clinical assessments and interviews, and in working with individuals (including young people) that are experiencing a wide range of uncomfortable emotions (including acute distress). Therefore the researcher will respond sensitively and reflexively to participants' needs to contain any uncomfortable emotions. If participants become upset during the interview they will at this point be reminded of their right to withdraw consent and end the interview early should they wish to do so.

A24. What is the potential for benefit to research participants?

There are no direct benefits to participants when taking part in this study. However, participants will be reimbursed (up to a maximum of £20 per participant) for any expenses incurred, in accordance with the Lancaster University research expenses policy. They may also enjoy taking part in the interview with the researcher.

A26. What are the potential risks for the researchers themselves? (if any)

Data collection interviews may be conducted in participants' homes. Therefore, it is likely that the researcher will undertake some lone working during this study. [REDACTED]

[REDACTED], the chief investigator will abide by the [REDACTED] lone working policy and the [REDACTED] lone working guidance at all times whilst undertaking data collection.

Accordingly, the researcher will assume responsibility for their own safety in accordance with [REDACTED]. Subsequently, a lone working protocol has been developed by the researcher to help ensure their

safety when undertaking lone working. In brief this involves the researcher ensuring that a buddy (colleague) is aware of when they will be undertaking lone working and has access to any relevant information in the case of an emergency (please refer to the lone working protocol for full details).

Copies of all lone working policies and protocols are appended accordingly.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

No one outside of the direct care team will have access to patient records. Patient records will only be accessed by the direct care team and this will be for recruitment purposes only; to identify which patients meet the inclusion criteria, and for accessing their contact details so that recruitment packs can be sent. Patient case notes will not be reviewed. Contact details will not be passed on to researchers outside of the direct care team.

During recruitment, a member of the local cleft team (cleft coordinator, assistant psychologist or equivalent) will identify all individuals that meet the inclusion criteria. The direct care team will send out recruitment packs to identified individuals on the researchers behalf to ensure that only the direct care team has access to patient data.

Individuals invited to take part in the study will be asked to contact the researcher directly by phone, email or post, to express an interest in the study, should they wish to do so, within two weeks of receiving the recruitment pack. Accordingly, the researcher will only have access to patient contact details (and not their medical records) when they contact the researcher directly to express an interest.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

Yes No

Please give details below:

Potential participants will be identified by the direct care team. The direct care team will then contact the parents/carers of potential participants about the study on the researchers behalf via a posted recruitment pack. The direct carer team may also approach the parents/carers of potential participants when they attend the cleft clinic for routine appointments with their child. Researchers outside of the direct care team will not have access to any patient records at any point during the research. Researchers outside of the direct care team will not have access to patient contact details prior to them expressing an interest in the study.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

Yes No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

Subject to local R&D approval at each site, recruitment posters and leaflets will be displayed within the Cleft Services (NHS trust site) from which recruitment is taking place. A copy of the poster may also be displayed on the cleft service patient website.

A29. How and by whom will potential participants first be approached?

The parents/carers of potential participants will be sent a recruitment pack including an invitation letter addressed to the parent/carer, a parent/carer participant information sheet, a young person participant information sheet, and an expression of interest form (response form). This will allow the parent/carer to read the project information before deciding whether or not to pass on the information to their child and discuss with them.

Recruitment packs will have been written and prepared by the chief investigator but will be sent by the direct care team on the researcher's behalf. This information is shared with potential participants and their parent/carers in the information sheets.

In addition to the recruitment packs, posters displaying key study information may be displayed in local clinic area, for example, in clinic waiting rooms, on service websites and/or in any relevant service newsletters/leaflets or equivalent, pending local R&D approval. Potential participants may also be told about the study by their clinician and/or another member of the direct care team when they attend the clinic for appointments, only if it is considered to be appropriate at the time by the clinician. In this case, the clinician will be advised to approach the young person's parent/carer in the first instance and provide them with a copy of the participant information sheet. It is then up to the parent/carer to decide whether information about the study can also be shared with the young person.

The researcher will never contact potential participants unless potential participants have directly indicated their permission to be contacted by the researcher. Potential participants can express their permission for the researcher to contact them by returning the response form (expression of interest form) to the researcher or by contacting the researcher by phone, email or post for more information.

A30-1. Will you obtain informed consent from or on behalf of research participants?

Yes No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Prior to taking part in the study, a parent/carer of each participant will be asked to provide informed consent for their child to take part in this study. The young person themselves will also be asked to consent to their participation. Participation will therefore only take place if both the young person and their parent/carer are willing for the young person to take part. To ensure that consent is fully informed, the participant and their parent/carer will be asked to re-read the relevant participant information sheet (both a young person and a parent/carer version are provided to ensure accessibility). Participant information sheets will also be relayed verbally to ensure full understanding, and any questions or concerns that the participant and/or their parent/carer may have will be addressed. Consent will be evidenced by the signing of consent forms (both parent/carer and participant versions will be used).

Participants and their parent/carer(s) will also be able to withdraw their consent, without specifying a reason, at any time up until two weeks after they have taken part in the study. During this period all participant data will be removed from the study and destroyed. However, after this two week period data will remain in the study. This information is shared in the participant information sheets.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

Yes No

A31. How long will you allow potential participants to decide whether or not to take part?

Potential participants and their parents/carers will be asked to express an interest in the study within two weeks of the recruitment packs being sent. A further reminder letter may be sent, in which case potential participants and their parent/carer will be given a further week to consider expressing an interest. An expression of interest does not infer consent, and therefore, potential participants and their parents/carers will have the further time before meeting with the researcher to further consider whether or not to take part.

On meeting the researcher, the researcher will ask potential participants and their parent/carer to re-read the study information and then discuss any questions or concerns that they may have with the researcher. If at this point, potential participants and their parents/carers are happy to proceed informed consent will be obtained from both the

participant and their parent/carer and the interview (data collection) will commence immediately. However, a further appointment can be arranged should either the participant or parent/carer wish to have more time to consider whether or not to take part.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?(e.g. translation, use of interpreters)

Funding is not available to send out materials in multiple languages. Therefore in the first instance study materials will only be provided in English. However, funding can be accessed from Lancaster University (in accordance with their research expenses guidelines downloadable from http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/new/onlinehandbook/research_expenses/) if requests are received from potential participants to translate materials and/or provide interpreters. [REDACTED]

The researcher acknowledges the ethical implications of this, however, in practice it is unlikely that this will affect inclusivity as anecdotally clinicians from phase one services [REDACTED] [REDACTED] advice that they rarely used translators and interpreters for written materials within their clinical work.

Should the use of translated materials be required further ethical and research and development approval will be obtained.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.

- The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- The participant would continue to be included in the study.
- Not applicable – informed consent will not be sought from any participants in this research.
- Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

Each participant will take part in one interview with the researcher lasting approximately one hour in duration. Continued capacity to consent throughout the interview can therefore be assumed. After the data collection interview has taken place the researcher will have no further contact with participants therefore continued monitoring beyond the initial data collection interview is not practicable.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?(Tick as appropriate)

- Access to medical records by those outside the direct healthcare team
- Electronic transfer by magnetic or optical media, email or computer networks
- Sharing of personal data with other organisations
- Export of personal data outside the EEA
- Use of personal addresses, postcodes, faxes, emails or telephone numbers

- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:
 - Manual files including X-rays
 - NHS computers
 - Home or other personal computers
 - University computers
 - Private company computers
 - Laptop computers

Further details:

The chief investigator (Trainee Clinical Psychologist) conducting this study who is external to the direct care team will not have access to any patient details or records. The researcher will only have access to potential participant and their parent/carers contact details once they have expressed an interest in the study and contacted the researcher directly to share their contact details. Contact details will only be used for purposes of contacting potential participants to further discuss the study and/or arrange data collection. Contact details will be securely stored (see latter questions for more information) and will only be held for as long as needed. Contact details will not be used for other purposes and will not be shared with anyone else.

Direct quotations from participants may be used within the reporting of results to illustrate findings. It is likely that a written report of findings will be published in a peer review journal and/or at relevant conferences or similar. All participant quotations will be suitably anonymised, for instance, real names will be replaced with pseudonyms and potentially identifying place names, dates and events will be redacted.

Audio recordings will be used to record participant interviews for the purposes of aiding data analysis only. Recordings will not be used for any other purposes and will be deleted as soon as transcription has been completed.

All data generated as part of this study including participant contact details will be stored safely and securely. Please see answer to A37 for details.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Confidentiality of data during recruitment:

The cleft team (direct care team) will be responsible for identifying which individuals meet the inclusion criteria. Patient identifiable information should be on a strict need to know basis. Therefore, patient data will not be shared outside of the direct care team. In addition, only individuals that would normally have access to patient data as part of their job role will access patient data for the purpose of this study. Furthermore, only the least amount of information required will be accessed to check suitability for the study as per the inclusion criteria and to access patient contact details. When members of the cleft team (direct care team) access patient data for the purposes of identifying potential participants they will be working within their usual role. Therefore, they will be familiar with their responsibilities in compliance with the law and will adhere to the NHS Confidentiality Code of Practice downloadable from; <http://systems.hscic.gov.uk/infogov/codes/confcode.pdf>

Confidentiality during data collection and analysis:

The chief investigator (Trainee Clinical Psychologist) will also work in accordance with the NHS Confidentiality Code of Practice when handling participant data. Again only necessary personal data will be used and this will only be retained for as long as necessary. For instance, participant contact details will be used for purposes of arranging interviews. Once interviews have been completed, contact details will be deleted/destroyed.

At the point of transcription all data will be suitably anonymised so participants will be unidentifiable in the data. For instance, names will be changed as will any distinguishable information. During the study all participant data, and any other data produced as part of the study (e.g. transcripts, coding, consent forms etc.) will be stored securely in an encrypted password protected file on the encrypted Lancaster University computer drive.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the*

direct care team, please justify and say whether consent will be sought.

During recruitment stages potential participants will be identified by the direct care team. Individuals external to the direct care team will not have access to personal data and will not be involved in identifying potential participants.

During data collection and analysis, the researcher (external to the direct care team) will have access to limited personal data and only when this is supplied directly by participants and/or potential participants and their parents/carers. This personal data will consist of contact details only. The researcher will not have access to personal medical records at any stage during this study.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- Less than 3 months
 3 – 6 months
 6 – 12 months
 12 months – 3 years
 Over 3 years

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

- Yes No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
 Participant's parents/carers will be able to claim a reimbursement of expenses up to a maximum of £20 per participant to cover the cost of travel and parking. Expenses will be paid in accordance with the guidelines outlined in the Lancaster University Doctorate in Clinical Psychology (DClinPsy) handbook .
 The relevant section of the DClinPsy handbook can be viewed at;
http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/new/onlinehandbook/research_expenses/.

No other incentives or payments will be offered for taking part in this study.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

- Yes No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

- Yes No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

- Yes No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

Yes No

Please give details, or justify if not registering the research.

This research study will not be registered on a public database. However, if the study is published at a later date, the title and abstract would be available on the publisher's website.

Registration of research studies is encouraged wherever possible.

You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? Tick as appropriate:

- Peer reviewed scientific journals
- Internal report
- Conference presentation
- Publication on website
- Other publication
- Submission to regulatory authorities
- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- No plans to report or disseminate the results
- Other (please specify)

The findings of this project will be written up as part fulfillment of the researcher's doctoral thesis (Doctorate in Clinical Psychology). It is also anticipated that a report will be submitted for publication in a peer reviewed journal. Findings may also be presented as a verbal and/or poster presentation at relevant conferences and a summary report of findings will be shared with participating services.

A53. Will you inform participants of the results?

Yes No

Please give details of how you will inform participants or justify if not doing so.

During data collection participants and their parents/carers will be asked if they would like to receive a summary of findings. At the end of the study a brief accessible summary of key findings will be sent directly to those that requested it. Individual feedback on findings will not be possible due to the fact that all data will be made anonymous at the point of analysis. The summary report will also be shared with the services that took part in the study and therefore participants will also be able to access a summary of findings directly from the service at a later date should they wish to do so.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? Tick as appropriate:

- Independent external review
- Review within a company
- Review within a multi-centre research group

- Review within the Chief Investigator's institution or host organisation
- Review within the research team
- Review by educational supervisor
- Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

This study has undergone a peer review process at Lancaster University which comprised of a panel of peer Trainee Clinical Psychologists, members of the Lancaster University Public Involvement Network, and Doctorate in Clinical Psychology Research Staff.

Further review of the design has been carried out through supervision with the Academic Supervisor and the field supervisor. Approval has also been obtained from the Lancaster University Research Support Office.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 10

Total international sample size (including UK): 10

Total in European Economic Area:

Further details:

The study will only recruit participants within the United Kingdom. Approximately 10 participants in total will be recruited to this study.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

This study will only use qualitative methodology, therefore, formal sample size calculations were not required. It is anticipated that a sample size of approximately 10 participants should ensure that there is sufficient data to generate a set of overarching themes, derived from emerging themes within the data. Smaller sample sizes are considered appropriate for research projects using interpretative phenomenological analysis (IPA) to ensure that a degree of richness in participant accounts is preserved. Thus a sample size of much larger than 10 participants may result in a reduction of richness and depth within the findings.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

This study will use interpretative phenomenological analysis (IPA) as a framework in which to conduct qualitative data analysis. Audio recordings of participant interviews will be transcribed verbatim to aid analysis. Transcripts will then be analysed using IPA, guided by Smith, Flowers and Larkin (2009). Smith et al (2009) argue that when individuals experience significant events and transitions in their life, they reflect on these events in order to make sense of their experiences. IPA provides a framework for the qualitative analysis of data that allows the researcher to explore and examine participant reflections and understand participants' meaning making, whilst also acknowledging the active interpretative role of the researcher (Smith et al, 2009). The process of data analysis will be discussed during supervision with the academic supervisor (Dr. Craig Murray) from Lancaster University to ensure reliability and validity of analysis.

References:

Smith, J. A., Flowers, P., & Larkin, M. (2009). Interpretative phenomenological analysis: Theory, method and research. London, UK. Sage.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.

	Title	Forename/Initials	Surname
Post	[Redacted]	[Redacted]	[Redacted]
Qualifications	[Redacted]		
Employer	[Redacted]		
Work Address	[Redacted]		
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
Post	[Redacted]	[Redacted]	[Redacted]
Qualifications	[Redacted]		
Employer	[Redacted]		
Work Address	[Redacted]		
Post Code	[Redacted]	[Redacted]	[Redacted]
Telephone	[Redacted]	[Redacted]	[Redacted]
Fax	[Redacted]	[Redacted]	[Redacted]
Mobile	[Redacted]	[Redacted]	[Redacted]
Work Email	[Redacted]	[Redacted]	[Redacted]

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status: NHS or HSC care organisation Commercial status:
 Academic
 Pharmaceutical industry
 Medical device industry
 Local Authority
 Other social care provider (including voluntary sector or private organisation)
 Other

If Other, please specify:

Contact person

Name of organisation [REDACTED]
 Given name [REDACTED]
 Family name [REDACTED]
 Address [REDACTED]
 Town/city [REDACTED]
 Post code [REDACTED]
 Country [REDACTED]
 Telephone [REDACTED]
 Fax [REDACTED]
 E-mail [REDACTED]

Is the sponsor based outside the UK?

Yes No

legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

- Funding secured from one or more funders
 External funding application to one or more funders in progress
 No application for external funding will be made

What type of research project is this?

- Standalone project
 Project that is part of a programme grant
 Project that is part of a Centre grant
 Project that is part of a fellowship/ personal award/ research training award
 Other

Other – please state:

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

Yes No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

[REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]

Mobile

Details can be obtained from the NHS R&D Forum website: <http://www.rdforum.nhs.uk>

A69-1. How long do you expect the study to last in the UK?

Planned start date: 23/02/2015

Planned end date: 28/12/2015

Total duration:

Years: 0 Months: 10 Days: 6

A71-2. Where will the research take place? (Tick as appropriate)

- England
 Scotland
 Wales
 Northern Ireland
 Other countries in European Economic Area

Total UK sites in study 2

Does this trial involve countries outside the EU?

Yes No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:

- NHS organisations in England 2
 NHS organisations in Wales
 NHS organisations in Scotland
 HSC organisations in Northern Ireland
 GP practices in England
 GP practices in Wales
 GP practices in Scotland
 GP practices in Northern Ireland
 Social care organisations
 Phase 1 trial units
 Prison establishments
 Probation areas
 Independent hospitals
 Educational establishments
 Independent research units
 Other (give details)

Total UK sites in study:

2

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? Please tick box(es) as applicable.

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (NHS sponsors only)
- Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

Participants in this study will be in their first year of high school. Whilst age of transition to high school may vary it is anticipated that the majority of participants will be aged 11-12 years old. This research project aims to look at the experiences of transition to high school in individuals with a cleft lip and/or palate. Therefore, asking individuals that have recently transitioned to high school (within the last year) will help enhance quality of data by ensuring that participants can recall their experiences.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

No control group will be used.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

Before participating in the study, participants and their parents/carers will both be required to provide fully informed consent.

In obtaining informed consent, the young person and their parent/carer will be asked to re-read the relevant version of the participant information sheet explaining what participation involves. A young person version and a parent/carer version of the participant information sheet will be provided. Participant information sheets and consent forms will also be discussed verbally with participants and their parent/carer to ensure understanding, and participants and their parent/carer will be able to discuss any questions that they have with the researcher prior to deciding whether or not to consent to take part in the study.

After reading the participant information sheets and discussing any questions with the researcher, the young person's parent/carer will then be asked to consent to their child's participation. The young person themselves will also be asked to consent to their participation. As such, data collection will only go ahead if both the young person and their parent/carer agree to the young person's participation. This will be evidenced by the signing of consent forms (both a young person and a parent/carer version will be provided).

Participants and their parent/carer(s) will also be able to withdraw their consent, without specifying a reason, at any time up until two weeks after they have taken part in the study. During this period all participant data will be removed from the study and destroyed. However, after this two week period data will remain in the study. This information is shared in the participant information sheets. This information is shared with participants and their parent/carer in the information sheets and participants and their parent/carer will be reminded of this verbally prior to the start of the interview.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

All young people in the study will be of a similar age (11-12 years) therefore only one set of participant information sheets for young people will be provided.

The readability of all information within this study for young people has been checked by the field supervisors [REDACTED] [REDACTED] to ensure accessibility to the population. An additional version will be available for parents/carers. Information will also be shared verbally with potential participants prior to obtaining consent to help ensure informed understanding.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.

Research site		Investigator/ Collaborator/ Contact	
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
 - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
 - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
 - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
 - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
 - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- Chief Investigator
 Sponsor

- Study co-ordinator
- Student
- Other – please give details
- None

Access to application for training purposes (*Not applicable for R&D Forms*)

Optional – please tick as appropriate:

I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Miss Rachael Faulkner on 11/05/2015 15:23.

Job Title/Post: Trainee Clinical Psychologist
Organisation: Lancaster University/ Lancashire Care NHS Foundation Trust
Email: r.faulkner2@lancaster.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

Please note: The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by An authorised approver at [REDACTED] n 21/05/2015 16:41.

Job Title/Post: [REDACTED]

Organisation: [REDACTED]

Email: [REDACTED]

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.
2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.
3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.
4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Craig Murray on 11/05/2015 15:50.

Job Title/Post: Senior Lecturer
Organisation: Lancaster University
Email: c.murray@lancaster.ac.uk

Appendix 4-M: NHS REC Favorable Opinion with Conditions Letter



Health Research Authority

29 May 2015

Miss Rachael Faulkner
 Faculty of Health & Medicine, Clinical Psychology - Division of Health Research
 Floor C, Furness College
 Lancaster University, Lancaster
 LA1 4YG

Dear Miss Faulkner,

Study title:	Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate.
REC reference:	15/EM/0257
IRAS project ID:	174020

The Proportionate Review Sub-committee of the NRES Committee reviewed the above application on 29 May 2015.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager [redacted] circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

- The researcher's name and designation must be added to the Participant-facing documents, beneath the title of the study.

- The Young Person Consent Form should be called the Young Person Assent Form
- Point number nine on the Parent / Carer Consent form must be changed to read 'unless there is a risk of harm to my child', not '...a risk of harm to myself'.
- Point number eight on the Parent / Carer Consent form is different to point number five on the Assent form. These points should be combined so each form has all of the information provided.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion”).

Summary of discussion at the meeting

Social or scientific value; scientific design and conduct of the study

The Sub-Committee queried whether the researcher is seeking approval for all seven phases of the study, or only the first phase. The researcher was contacted and stated that this approval would only cover phase one of the study, and that subsequent phases would only be utilized if additional recruitment is needed. The researcher confirmed that an amendment would be submitted in this situation.

Care and protection of research participants; respect for potential and enrolled participants’ welfare and dignity

The Sub-Committee queried whether interviewing a child alone could pose a safeguarding risk to the researcher. The researcher was contacted and she explained that although it is recommended that the child’s parent/guardian is absent, this may not always be preferable to the child or the parent/guardian. She confirmed that she will allow the participants to make this decision. The researcher noted that she appreciated the concern for her own wellbeing, and assured the Sub-Committee that both she and her supervisor agree her level of training and clinical experience with children will ensure that the lone interviews will be appropriate.

The Sub-Committee agreed that although this study concerns a potentially vulnerable group, the researcher has addressed the sensitive issues.

Informed consent process and the adequacy and completeness of participant information

The Sub-Committee noted some typographical errors in the Participant Information Sheet and Consent form.

Suitability of the applicant and supporting staff

The Sub-Committee contacted the researcher to ask whether she held a current Disclosure and Barring Service (DBS) certificate. The researcher confirmed that she does hold a DBS certificate.

Approved documents

The documents reviewed and approved were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Recruitment Poster]	1	10 March 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [LU Liability Insurance]	n/a	21 May 2015
Interview schedules or topic guides for participants [Interview schedule]	3	31 March 2015
IRAS Checklist XML [Checklist_22052015]		22 May 2015
Letter from sponsor [LU Indemnity Cover Letter]	n/a	21 May 2015
Letters of invitation to participant [Parent/Carer Invite Letter]	2	18 March 2015
Letters of invitation to participant [Second follow up letter]	2	18 March 2015
Other [Participant Expression of Interest Form]	1	26 February 2015
Other [Confirmation of Interview Letter]	1	10 March 2015
Other [Acknowledgement Letter to individuals not selected for participation]	2	18 March 2015
Other [Participant Expenses Claim Form]	1	10 April 2015
Other [LCFT lone working policy]	HS 007	01 July 2013
Other [Lancaster University Lone Working Guidance]	n/a	22 May 2007
Other [Lone Worker Protocol]	1	13 March 2015
Other [LU public liability letter]	n/a	21 May 2015
Participant consent form [Consent Form - Young Person Version]	2	11 May 2015
Participant consent form [Consent Form - Parent/Carer Version]	2	11 May 2015
Participant information sheet (PIS) [Young Person PIS]	2	18 February 2015
Participant information sheet (PIS) [Parent/Carer PIS]	3	11 May 2015
REC Application Form [REC_Form_22052015]		22 May 2015
Research protocol or project proposal [Research Protocol]	V3	11 May 2015
Summary CV for Chief Investigator (CI) [Summary CV Rachael Faulkner - CI]	2	10 May 2015
Summary CV for supervisor (student research) [Summary CV Dr Craig Murray - Project Supervisor]	1	11 May 2015

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee’s best wishes for the success of this project.

15/EM/0257

Please quote this number on all correspondence



Enclosures: List of names and professions of members who took part in the review
“After ethical review – guidance for researchers”

Copy to:



NRES Committee [REDACTED]

Attendance at PRS Sub-Committee of the REC meeting on 29 May 2015

Committee Members:

Name	Profession	Present	Notes
[REDACTED]	[REDACTED]	[REDACTED]	
[REDACTED] (Chair)	[REDACTED]	Yes	
[REDACTED]	[REDACTED]	Yes	

Also in attendance:

Name	Position (or reason for attending)
[REDACTED]	[REDACTED]

Appendix 4-N: NHS REC Conditions Met Letter



Health Research Authority

03 June 2015

Ms Rachael Faulkner
 Faculty of Health & Medicine, Clinical Psychology - Division of Health Research
 Floor C, Furness College
 Lancaster University, Lancaster
 LA1 4YG

Dear Ms Faulkner,

Study title:	Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate.
REC reference:	15/EM/0257
IRAS project ID:	174020

Thank you for your letter of June 2nd 2014. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 29 May 2015.

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Recruitment Poster]	2	01 June 2015
Letters of invitation to participant [Parent/Carer Invite Letter]	3	01 June 2015
Letters of invitation to participant [Second follow up letter]	3	01 June 2015
Other [Participant Expression of Interest Form]	2	01 June 2015
Other [Confirmation of Interview Letter]	2	01 June 2015
Other [Acknowledgement Letter to individuals not selected for participation]	3	01 June 2015
Participant consent form [Consent Form - Young Person Version]	3	01 June 2015
Participant consent form [Consent Form - Parent/Carer Version]	3	01 June 2015
Participant information sheet (PIS) [Young Person PIS]	3	01 June 2015
Participant information sheet (PIS) [Parent/Carer PIS]	4	01 June 2015

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Recruitment Poster]	2	01 June 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [LU Liability Insurance]	n/a	21 May 2015
Interview schedules or topic guides for participants [Interview schedule]	3	31 March 2015
Letter from sponsor [LU Indemnity Cover Letter]	n/a	21 May 2015
Letters of invitation to participant [Parent/Carer Invite Letter]	3	01 June 2015
Letters of invitation to participant [Second follow up letter]	3	01 June 2015
Other [Participant Expenses Claim Form]	1	10 April 2015
Other [LCFT lone working policy]	HS 007	01 July 2013
Other [Lancaster University Lone Working Guidance]	n/a	22 May 2007
Other [Lone Worker Protocol]	1	13 March 2015
Other [LU public liability letter]	n/a	21 May 2015
Other [Participant Expression of Interest Form]	2	01 June 2015
Other [Confirmation of Interview Letter]	2	01 June 2015
Other [Acknowledgement Letter to individuals not selected for participation]	3	01 June 2015
Participant consent form [Consent Form - Young Person Version]	3	01 June 2015
Participant consent form [Consent Form - Parent/Carer Version]	3	01 June 2015
Participant information sheet (PIS) [Young Person PIS]	3	01 June 2015
Participant information sheet (PIS) [Parent/Carer PIS]	4	01 June 2015
REC Application Form [REC_Form_22052015]		22 May 2015
Research protocol or project proposal [Research Protocol]	V3	11 May 2015
Summary CV for Chief Investigator (CI) [Summary CV Rachael Faulkner - CI]	2	10 May 2015
Summary CV for supervisor (student research) [Summary CV Dr Craig Murray - Project Supervisor]	1	11 May 2015

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/EM/0257

Please quote this number on all correspondence

Yours sincerely,




E-mail: [REDACTED]

Copy to: [REDACTED]

[REDACTED]

[REDACTED]



Ms Rachael Faulkner
Faculty of Health & Medicine, Clinical
Psychology - Division of Health Research
Floor C, Furness College
Lancaster University, Lancaster
LA1 4YG

10th July 2015

RE: Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate
REC Ref: 15/EM/0257
R&D Ref: 15/09/RE

Dear Ms Faulkner,

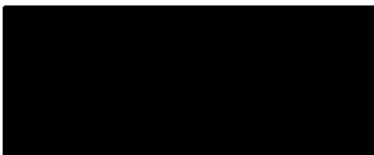
Thank you for submitting the above application to the Research & Development Office. It has now been reviewed against the requirements of the Research Governance Framework for Health and Social Care and relevant legislation. I am pleased to confirm that following completion of these checks approval is now granted for the study to commence within the [redacted] Foundation Trust.

All NHS Trusts are performance managed by the National Institute for Health Research (NIHR) by benchmarks which measure the time taken to recruit the first patient into a research study and the local site's recruitment to time and target. All investigators within the Trust are supported by Data Managers within the Clinical Research Business Unit who can interpret these benchmarks for you and advise you on the timing and format in which data should be submitted to the CRBU. **R&D approval is conditional upon these data being submitted in a timely fashion each month.**

It will be the responsibility of the local Principal Investigator to comply with the responsibilities laid down, in the Research Governance Framework for Health and Social Care, by the Department of Health. Please see the enclosed leaflet for further information.

A full copy of the Research Governance Framework for Health and Social Care can also be obtained from the Department of Health website at www.doh.gov.uk or the R&D Office.

Yours sincerely



Director of Research



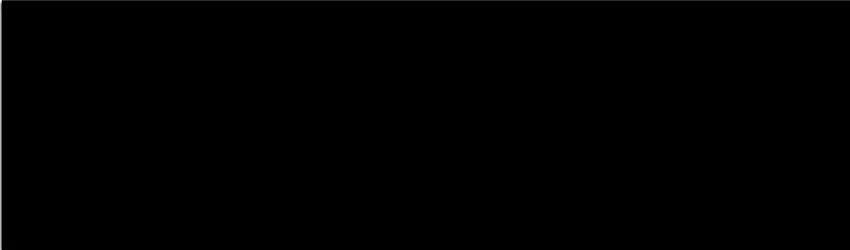
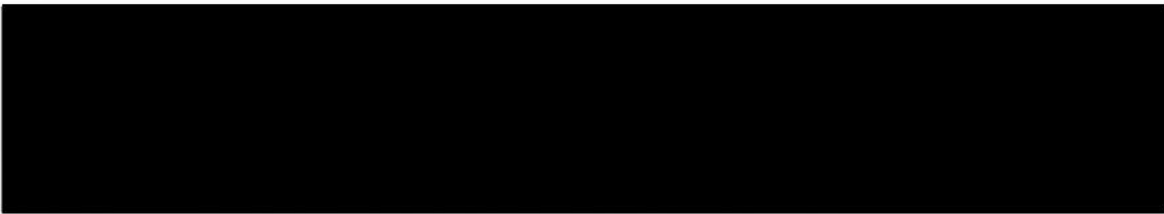
INVESTOR IN PEOPLE

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

It is the principal investigator's responsibility to ensure that:

- The dignity, rights, safety and well being of participants are given priority at all times by the research team.
- The research is carried out in accordance with the research governance framework.
- When a study involves participants under the care of a doctor, nurse or social worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate and agree to retain overall responsibility for their care.
- When the research involves user or carer or a child, looked after or receiving services under the auspices of the local authority, that the agency director or her deputy agrees to the person (and/or their carer) being invited to participate and is fully aware of the arrangements for dealing with any disclosure or other relevant information.
- Unless participants or the relevant research ethics committee request otherwise participants' care professionals are given information specifically relevant to their care which arises in the research.
- The study complies with all legal and ethical requirements.
- A Material Transfer Agreement is in place with the receiving organisation for any samples sent outside of the Trust.
- Each member of the research team is qualified by education, training and experience to discharge his/her role in the study.
- Students and new researchers have adequate supervision, support and training.
- The research follows the protocol approved by the research committee.
- Any proposed changes or amendments to or deviations from the protocol are submitted for approval to the ethics committee, the research sponsor and any other appropriate body.
- Procedures are in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage.
- Arrangements are made for the appropriate archiving of data when the research has finished.
- The findings from the work are opened to critical review through the accepted scientific and professional channels.
- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants.
- All data and documentation associated with the study are available for audit at the request of an auditing authority.





4th September 2015



PIN: R04004

REC Reference: 15/EM/0257

Research Study: Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate.

Thank you for submitting the above study for NHS R&D permission. **Lancaster University** is the Sponsor for this study which **is not** on the NIHR portfolio.

I am pleased to confirm that the Research Office has now received all necessary documentation, and the appropriate governance checks have been undertaken. This letter is issued subject to the research team complying with the attached conditions, Trust SOPs, the DH Research Governance Framework, and any other applicable regulatory requirements. This approval is in relation to the documentation listed.

The target for this study is:

- 70 Day from Valid Submission to 1st Patient Recruited: **13 November 2015**

You are required to keep R-Peak (Research Management database) updated with recruitment figures and inform the Research Office when the status of your trial changes.

I would like to take this opportunity to wish you well with your research.

Yours sincerely



Incorporating:-
Manchester Royal Eye Hospital • Manchester Royal Infirmary • Royal Manchester Children's Hospital
Saint Mary's Hospital • Trafford Hospitals • University Dental Hospital of Manchester
Community Services



Documents Acknowledged/Approved

Document	Version	Date
Recruitment Poster	2	01 June 2015
LU Liability Insurance		21 May 2015
Interview Schedule	3	31 March 2015
LU Indemnity Cover Letter		21 May 2015
Parent/Carer Invite Letter	3	01 June 2015
Second follow up letter	3	01 June 2015
Participant Expenses Claim Form	1	10 April 2015
LCFT lone working policy	HS 007	01 July 2013
Lancaster University Lone Working Guidance		22 May 2007
Lone Worker Protocol	1	13 March 2015
LU public liability letter		21 May 2015
Participant Expression of Interest Form	2	01 June 2015
Confirmation of Interview Letter	2	01 June 2015
Acknowledgement Letter to individuals not selected for participation	3	01 June 2015
Consent Form – Young Person	3	01 June 2015
Consent Form – Parent/Carer	3	01 June 2015
Young Person PIS	3	01 June 2015
Parent/Carer PIS	4	01 June 2015
Research Protocol	3	11 May 2015
CI CV – Rachael Faulkner	2	10 May 2015
Project Supervisor CV – Dr Craig Murray	1	11 May 2015
REC Form		21 May 2015
REC Approval Letter		03 June 2015

Conditions of Approval:-

- All researchers involved in the study need to have received training appropriate to their role covering aspects of Research Governance or Good Clinical Practice (GCP). Trust policy states GCP training needs to be renewed every 3 years.
- The Research Office must be informed of: (please forward copies of amended documents by email)
 - The actual start date of the project
 - Any amendments sent to the MHRA or Research Ethics Committee
 - Any changes to the management of the project
 - Any extensions to the project, and associated additional funding, if applicable.
- The Research Office must be notified immediately of all Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) via email [redacted] or Research Office fax: [redacted] and/or by copy of official notification to the regulatory authorities (NRES, MHRA as applicable).
- All research taking place on CMFT Trust premises is subject to the Trust monitoring programme, either as part of the annual 10% audit requirement or "triggered" monitoring¹. The Chief and/or Principal Investigator is required to make him/herself available for any monitoring visit, on a mutually agreed date.
- All Principal Investigators are required to complete and submit an annual self-assessment at the request of the Research Office.
- All Principal Investigators are required to provide recruitment (accrual) data to the Research Office monthly via R-Peak.
- The Research Office must be given a minimum three months' notice, in writing, if the Principal Investigator leaves the employment [redacted]
- The Research Office must receive immediate notification if the Principal Investigator is unable to continue to fulfil his/her duties as PI for other reason e.g. long-term sickness
- Any evidence of fraud &/or misconduct must be immediately brought to the attention of the Research Office either via the Incident Reporting system, or by direct communication.
- If you intend to store biological samples after the study has ended you must contact the HTA Licence Manager [redacted] to discuss HTA licensing requirements.

Failure to comply with any of the above may result in withdrawal of approval for the project and the immediate cessation of the research. Persistent failure to comply may result in disciplinary action.

18 January 2016

[REDACTED]
 Faculty of Health & Medicine, Clinical Psychology - Division of Health Research
 Floor C, Furness College
 Lancaster University, Lancaster
 LA1 4YG

Dear Miss Faulkner

Study title:	Experiences of Transition to High School in Young People with a Cleft Lip and/or Palate.
REC reference:	15/EM/0257
Amendment date:	06 January 2016
IRAS project ID:	174020

Thank you for your letter of 06 January 2016, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

<i>Document</i>	<i>Date</i>
Notice of Minor Amendment [Study extension until May 31st 2016]	06 January 2016
Other [Email Notification]	06 January 2016

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

15/EM/0257:	Please quote this number on all correspondence
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Yours sincerely

[Redacted signature]

[Redacted name]

REC Assistant

Email:

[Redacted email address]

Copy to:

[Redacted copy to list]