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BACKGROUND

It is estimated that cleft lip and/or palate (CLP) occurs in approximately 1 in 700 live births (Vieira, 2008). From infancy until early adulthood, care is provided by a large multidisciplinary team. The core members of the team as defined by the Clinical Standards Advisory group (CSAG, 1998) are cleft surgeons, speech and language therapists, orthodontists, paediatric dentists and nurses. In recognition of the challenges of CLP, and following the centralisation of cleft care in the UK (Sandy et al., 1998), it was recommended that psychologists be included in every multidisciplinary cleft team.

Psychologists play an important role in the care of both children and adults with a cleft. Looking and/or sounding different to their peers, as well as the ongoing burden of treatment, can pose a number of challenges throughout an individual's life (Rumsey and Stock, 2013). Other family members may also require psychological support, to cope with the emotions surrounding a diagnosis of CLP and its treatment implications (Nelson, Kirk, Caress and Glenny, 2012). Literature exploring the psychosocial adjustment of those affected by CLP has produced conflicting findings. While some studies suggested that individuals with a cleft are more at risk of developing difficulties than their peers (Noar, 1991; 1992; Turner et al, 1997), others have found no differences between this group and the general population (Hunt et al, 2005; Collett and Speltz, 2006; Berger and Dalton, 2009). While these differences may be partly attributable to the multifactorial nature of psychosocial adjustment, a lack of consensus and comparability in relation to the methodology employed is also likely to play a role (Rumsey and Stock, 2013).

Nonetheless, some particular areas of difficulty have been identified. Those with CLP may present with a number of cognitive, emotional and behavioural concerns (Endriga and Kapp-Simon, 1999), including difficulties with learning and development (Lockhart, 2003), a higher risk of rejection from peers (Hearst & Middleton, 1997), a tendency to withdraw and internalise problems (Pope & Snyder, 2005), dissatisfaction with appearance (Billaud Feragen & Borge, 2010), unrealistic expectations of cleft-related surgery (Cadogan and Bennum, 2011) and anxiety, depression and low self-esteem associated with facial difference more generally (Thompson & Kent, 2001). Individuals with CLP may therefore benefit from general support to improve quality of life and self-concept, increase social support, reduce social isolation and manage social anxiety. In addition, targeted interventions may be required to address concerns specifically linked to CLP. A recent review of the psychosocial difficulties experienced by those born with a cleft identified the need to address specific issues such as the management of appearance concerns, including expectations of surgery and orthodontic work and difficulties such as teasing and bullying (Stock & Rumsey, 2013).

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Despite this important role in the provision of care for children and families affected by CLP, evaluation of psychology services in reducing psychosocial difficulties has thus far been limited to internal audit data produced by individual clinics within the UK. This may be due in part to the tendency of clinicians to take a personalised approach to the content of interventions, in order to ensure that each individual receives support tailored to their own needs. While this level of flexibility is important, greater coherence in the development and evaluation of appropriate interventions would increase effectiveness and allow for direct comparisons. In addition, the James Lind Alliance (JLA) (a National Institute for Health Research (NIHR) organisation which engages patients and clinicians in setting priorities for future research) recently identified the effectiveness and timing of psychosocial interventions to be the top ranking priority in CLP research (JLA, 2012).

An up-to-date and systematic review of the literature, with a specific focus on the effectiveness of psychosocial interventions in CLP is clearly required. This current review aims to address this need by specifically assessing the most useful approaches to psychosocial interventions within CLP.

AIMS & OBJECTIVES

This systematic review aimed to 1) assess the evidence to support the effectiveness or efficacy of psychosocial therapy interventions compared to no intervention, 2) assess whether the focus and theoretical approach affect the relative effectiveness or efficacy of interventions (examples include, but are not limited to, cognitive behavioural therapy, solution-focussed therapy, mindfulness, person-centred therapy, and 3) assess whether the timing of psychosocial interventions and the frequency of sessions affect psychosocial outcomes in the short and longer term.

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METHODS

Search Strategy

The search aimed to identify all studies relating to psychosocial interventions for children or adults with cleft or parents of children with clefting. An extensive search strategy was used to search 10 databases, including MEDLINE, EMBASE, PsychINFO, and Cochrane central register of Controlled trials (CENTRAL) (See Appendix A for full search strategy and list of databases). The search was conducted on 11th June 2013. No language restrictions were applied. In addition websites including National Institute of Clinical Excellence (NICE) and the metaRegister of Controlled Trials (mRCT) were searched and reference lists of included papers were also searched. Search criteria were adapted to suit the search terms of each individual database.

Inclusion Criteria

Study design

Eligible studies included both randomised and non-randomised controlled trials. Observational comparative studies, either within or between groups, were also eligible for inclusion.

Population

Individuals with non syndromic cleft lip and/or cleft palate with/without cleft alveolus or individuals with syndromes with no known developmental delay (e.g. Sticklers, hemifacial microsomia) were eligible for inclusion. Intervention studies for parents of children with clefts were also eligible for inclusion. Studies containing less than 90% children or adults with cleft lip and/or palate, or their parents, were excluded unless they reported results separately for those with cleft lip and/or palate, or raw data was available upon request from the authors.

Intervention

For the purposes of this review, a psychosocial intervention was defined as any attempt to develop solutions to the challenges individuals may experience to their psychological wellbeing when interacting with any element of the social environment. Within cleft care there is great variety in terms of the content and measurement of appropriate interventions. Therefore all interventions addressing psychosocial adjustment were included within the review.

Comparators

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Studies that compared any psychosocial intervention with no intervention, or that compared different psychosocial interventions, or psychosocial interventions at different points in time were eligible for inclusion.

Outcomes

Any outcome measures related to psychosocial functioning were eligible for inclusion within the review.

Analysis

The authors used a qualitative approach to synthesise data across studies (Dixon-Woods et al., 2005) and focused on three main areas: theoretical or therapeutic perspective, method of delivery (setting, person delivering the intervention) and timing of the intervention (age of intervention, intensity and frequency of the intervention). Where possible meta-analyses were performed on primary outcome measures (e.g. preoccupation with appearance, anxiety, depression, confidence, quality of life, social integration, well-being). Mean differences (MDs) or Standard Mean differences (SMDs) together with 95% confidence intervals (CIs) were extracted. Effect sizes and confidence intervals were plotted using forest plots where appropriate. Study authors were contacted for additional information where necessary and possible.

Assessment of Risk of Bias

Two reviewers (HW & AM) independently assessed bias in both trials and observational studies. Trials were assessed using the Cochrane Risk of Bias tool (Higgins & Green, 2011) to rate each of the following five components as high, low or unclear risk of bias: 1) method of sequence generation (how the randomisation sequence was generated, e.g. random number table), 2) method of allocation concealment (how the randomisation was concealed from researchers/clinicians), 3) method of blinding of the outcome assessor (how the study ensured the outcome assessor did not know to which condition the participant had been allocated), 4) selective reporting of outcome data (not reporting all outcomes in the results that are mentioned in the methods or failing to use standard outcome measures within a particular field of research) and 5) completeness of outcome data (were all attritions accounted for and was an intention to treat analysis performed?).

In the case of psychosocial interventions, it is not possible for the treating clinicians or participants to be blind to their treatment allocation, therefore, adequate blinding was considered to have taken place if both data analysis and outcome assessment were blinded. Selective reporting of outcome data was considered to have taken place when papers only reported outcomes which had a favourable result or if the outcome measures assessed did not include standard measures that experts in the area would expect to have been reported.

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In the case of observational studies two reviewers (AB & AM) used the RAMbo assessment tool (Chen & Wang, 2009) to assess the quality of randomisation (R), whether missing data was accounted for (A) and whether the type of measurement was appropriate (M).

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RESULTS

Search Results

The search results identified 2320 potential references for inclusion. After duplicates were removed, this was reduced to 1367 unique papers. Four independent reviewers (AB, MP, NS & HW) checked the remaining list for inclusion and identified 23 possible references for inclusion based on titles and abstracts. On retrieval of the full papers, two reviewers (AB & MP) independently identified **eight potentially eligible papers (seven studies)** that met the inclusion criteria. This process can be seen in Figure 1.

Excluded studies

Of the eight papers identified for as potentially eligible for inclusion, six papers could only be included in the narrative synthesis of this review (Robinson et al, 1996; Newell & Clarke 2000; Pelchat et al, 2004; 1999; Maddern et al, 2006; Kleve et al, 2002). These studies met all inclusion criteria, except that they did not contain data from at least 90% participants with cleft, or 90% parents with cleft. The authors sought to retrieve the cleft-only participant data from each of these studies. However, due to the age of the papers this data was no longer readily available. Therefore, these papers were excluded from the analysis below, but are included in the narrative synthesis.

Included Studies

Two studies were included within the review (Kapp-Simon et al, 2005; Bessell et al, 2012). As with the excluded studies, each contained less than 90% participants with cleft. The Kapp-Simon (2005) paper focused on children with craniofacial conditions; the judgement was therefore made that the findings from this study were likely to be relevant to children with cleft more specifically. The Bessell et al (2012) paper was included, as it was possible to access the raw cleft participant data provided by the first author, and to focus the analysis on participants with a cleft. As this paper was written by the first author of this review, data extraction and risk of bias assessments were conducted by three different reviewers (MP, AM & HW) to ensure objectivity was maintained.

Risk of Bias Assessment

Two papers were assessed using the Cochrane risk of bias assessment tool (Higgins & Green, 2011): Bessell et al, (2012) and Newell & Clarke (2000).

Randomisation Procedure & Allocation Concealment: Both papers were found to be of low risk of bias with regards to randomisation sequence and sequence allocation (See table 1).

Blinding of outcome assessment: Both studies were found to be of low risk of bias.

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Attrition: All rates of attrition were adequately documented in the papers.

Selective reporting of outcome measures: All outcomes reported in the studies were reported in the results.

RAMbo Assessment of observational studies

The remaining six papers were assessed for bias using the RAMbo assessment technique (Chen & Wang, 2009).

Randomisation: None of the six studies employed true randomisation procedures. All studies were therefore rated at high risk of bias (see table 2).

Accountability of participants: All studies provided information about missing participants where possible, although detailed information about the reasons for drop outs was not included in the studies. No drop outs were present in the Kapp-Simon et al (2005) study. Unfortunately in the Robinson et al (1996) study, the rate of attrition at follow-up was so high that an insufficient number of participants were included in the study. Therefore, this study was rated at high risk of bias.

Measurement: Although in the Robinson et al (1996) study the outcome measures were both objective and appropriate, and reported in sufficient detail, the statistical analyses were not suitable to the study, with the researchers failing to carry out multiple comparisons. It is unclear from the Pelchat et al (1999; 2004) studies who was responsible for data analysis and a self-designed questionnaire was used rather than a validated questionnaire. The other papers were found to have adequate and appropriate measurement (Maddern et al, 2006; Kapp-Simon et al, 2005; Kleve et al, 2002).

Analysis

Only one of the studies with usable data was a randomised controlled trial (RCT) (Bessell et al, 2012). As within this study the total number of participant with cleft = 8, and as there were no comparison studies, it was not possible or appropriate to perform a meta-analysis. Instead, a narrative synthesis was conducted on the two included studies and the six studies where data for CLP alone were not available.

Description of Studies

Therapeutic approach

Cognitive-Behavioural Therapy: Five studies assessed the effectiveness of a CBT-based approach (Bessell et al 2012; Maddern et al, 2006; Pelchat 2004; 1999; Kleve et al 2002; Newell & Clarke, 2000). These studies assessed CBT-based interventions in a range of adults with visible differences (Bessell et al, 2012; Maddern et al, 2006; Kleve et al, 2002; Newell &

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Clarke, 2000) or parents of children with CLP or Downs Syndrome (Pelchat et al 1999;2004). See Table 4 for details.

Social Skills Training: Two studies assessed the effectiveness of social skills training (Kapp-Simon et al; Robinson et al, 1996), whilst an additional study included a mixed CBT and SST approach (Bessell et al., 2012). Of these studies two assessed the effects of this model in adults with visible difference, whilst the final study assessed an SST approach in adolescents with craniofacial conditions. See Table 4 for details.

Method of Delivery

Self-help: Two of the included studies assessed the effectiveness of self-help interventions. The Bessell et al (2012) paper compared face-to-face delivery of a CBT intervention against an online delivery with minimal facilitation from an assistant psychologist or counsellor. The Newell & Clarke (2000) intervention consisted of a CBT-based self-help booklet consisting of 18 A5 pages. The self-help booklet was mailed to participants for them to use in their own homes.

Group-based (facilitated): Two studies adopted a group-based approach to intervention. The Kapp-Simon et al (2005) study assessed the effectiveness of a group-based social skills intervention for adolescents. The setting of the Kapp-Simon intervention was unclear or by whom it was delivered. Robinson et al (1996) assessed the effectiveness of a group-based social skills workshop for individuals with visible differences. No information was provided about who delivered the intervention.

Face-to-face individual: Four studies assessed the effectiveness of individual CBT-based interventions (Bessell et al, 2012; Maddern et al, 2006; Pelchat 2004; 1999, Kleve et al, 2002). The Bessell et al (2012) paper also assessed the effectiveness of a face-to-face delivery of a CBT/SST intervention administered by a trained counsellor or an assistant psychologist. This intervention took place within clinics. Maddern et al (2006) assessed the effectiveness of a face-to-face CBT delivery for children with visible differences delivered by a clinical psychologist or assistant psychologist within clinics. Pelchat (2004; 1999) assessed the effectiveness of an individual parent support programme for parents of children with CLP or downs syndrome delivered by nurses partially in clinics and partially at home. Kleve et al. (2002) evaluated the effectiveness of a CBT-based therapy to address the psychosocial issues experienced by adults with visible differences. The intervention was delivered by the clinical psychology team at Outlook, Bristol.

The findings above suggest a CBT or SST, or combined approach is most appropriate for this population, but the limited sample sizes make it difficult to draw any firm conclusions. Due to the differences in methodological design, it was also difficult to draw any firm conclusions about the optimal delivery of psychosocial interventions. Each intervention was delivered

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using different facilitators. Therefore, the review cannot recommend whether any particular individuals should be responsible for delivering these psychosocial interventions.

Timing of Intervention

This review attempted to identify the optimal duration and intensity of intervention. The studies included within this review generally varied in duration from two sessions (Robinson et al, 1996), through to 12 sessions (Kapp-Simon et al, 2005). Full details of intervention duration can be found in Table 4.

Where stated, the intensity of the interventions also varied from daily (Robinson et al, 1996) to weekly (Bessell et al, 2012; Kleve et al, 2002). The length of sessions varied from one hour (Bessell et al, 2012) to whole days (Robinson et al, 1996) (see Table 4 for full details of intensity).

Due to the differing intensity and duration across the studies, it is difficult to draw any firm conclusions regarding the optimal length and intensity of therapy. However, most studies opted for between 6 - 10 sessions administered weekly for 1-1.5 hours. Therefore, it would seem reasonable to conclude that this is the minimum intensity and duration required to lead to clinically significant changes. This also matches recommendations for the minimum intensity of therapies in the general population (Roth & Fonagy, 2005).

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DISCUSSION

Summary of results

This systematic review identified only two papers that matched the majority of the inclusion criteria. One paper focused on addressing appearance-related concerns amongst adults with visible differences, including adults with CLP, and the second paper reported a social skills intervention for adolescents with a variety of craniofacial conditions, including CLP. Only one intervention was tested using a RCT design, whilst the other was an observational study. Overall only 28 participants with cleft or other craniofacial anomalies were represented within the two papers. Therefore, the two studies did not provide sufficient data to draw any firm conclusions regarding the best forms of psychosocial interventions for either adults or children affected by CLP, the optimal method of delivery or intensity and timing of intervention.

Therapeutic approach

The interventions included within the current systematic review focused on social skills training or CBT, or a combination of the two approaches. Evidence from the wider psychological literature suggests that CBT and SST may prove useful intervention models to address many of the concerns experienced by those with CLP. Social skills training for the general population have been found to be effective at increasing social support, through increasing social communication, and also reduce social isolation (Roth & Fonagy 2006). SST has also been highly effective in addressing social anxiety, and is a technique that has been used in the general population for many years, both with adults (Roth and Fonagy, 2006) and children and adolescents (Roth et al, 2002). SST can also help individuals to manage teasing and bullying by boosting self-confidence and improving social communication (Roth et al, 2002). There is also an argument that helping to increase individuals' social support network and increase their social contact with others will in turn improve their quality of life, at least in relation to social elements (Kapp-Simon et al, 2005). The use of the SST and CBT approaches are supported by two systematic reviews assessing interventions for those with visible differences more generally (Bessell & Moss, 2007; Jenkinson et al, in submission). The poor methodological quality of the papers included in both these reviews and the small numbers of participants involved, made it difficult to draw any firm conclusions, but both reviews highlighted SST as a potentially useful technique for managing appearance concerns. The reviews also concluded that the incorporation of elements of CBT into these interventions had the greatest potential to promote adjustment.

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Specific issues in CLP may include the burden of multidisciplinary care, the impact of multiple surgeries, or, as a cleft can be associated with additional challenges such as speech and language difficulties, hearing loss and/or delays in cognitive development, the additive effects of these factors may result in distress. Further investigation is required to highlight the best models for intervention in this specific area.

Method of Delivery

Methods of delivery fit broadly within the following categories; group self-help, group-healthcare facilitated, individual self-help or individual facilitated intervention. Future research should assess which techniques of delivery are most appropriate for patients and families.

The question of how interventions are delivered and the optimum duration and intensity depends at least in part on the degree of psychosocial distress the individual is experiencing (Roth & Fonagy, 2006) . At lower levels of distress, less intense, perhaps remote forms of intervention may be suitable, whereas moderate-to-severe levels of distress more intensive face-to-face support is needed (National Institute for Health Research, 2007). This tiered model of psychological care is based on the concept that following assessment/screening for psychological distress the individual is matched to an appropriate level of intervention based on level of distress and expressed need.

Timing of intervention

Evidence from the wider psychological literature based on CBT and SST vary considerably in length from 6 to 20+ sessions (Roth & Fonagy, 2006). In some cases of low-level distress, it may be that six sessions will be sufficient to promote effective coping. However, in the case of individuals experiencing extreme distress a longer term intervention may be required. The intensity of an intervention may also vary depending upon the degree of distress. Most CBT/SST approaches employ weekly or bi-weekly sessions (Roth & Fonagy, 2006). This model ensures that clients have enough time between each session to engage in at home assignments and to reflect adequately on the intervention sessions, but does not leave such a large period of time to run the risk of clients forgetting basic information or feeling unsupported (Roth & Fonagy, 2006). Despite this, there may be occasions, especially towards the end of the intervention when sessions become less regular and perhaps move to monthly sessions to provide individuals with “top up” support (Carr, 2009). The exact number of sessions required will always depend to some extent on individual need (Roth & Fonagy, 1996). In the absence of evaluations of interventions specifically relating to cleft, guidance can only be drawn from the results of evaluations of interventions for people challenged by other conditions.

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Study Design

All systematic reviews base the evidence for intervention models on a hierarchy of methodological designs (Centre for Reviews and Dissemination (CRD), 2001). The gold standard for evidence of effectiveness is taken from high quality RCTs with large sample sizes. Although RCTs are the gold standard, they are not always possible to execute. In these instances observational studies can provide useful evidence, but they should be conducted to the highest methodological standard with samples sizes based on calculations that allow the detection of realistic and clinically important effects. One way of ensuring larger sample sizes when working with a small population is to engage in multi-centre trials to increase access to participants. Although multidisciplinary cleft services (in the UK) are well-placed to achieve this, the lifelong nature of CLP, the complexity of psychosocial adjustment and the broad range of therapeutic approaches practised provide challenges for the clinical and research communities. An important step will be to achieve a consensus between clinicians and researchers in relation to the elements to be targeted by therapeutic intervention, and in the measures used to evaluate change, as well as substantial cooperation to achieve the necessary designs and sample sizes is needed.

Limitations of the Review

The review conducted a comprehensive literature search across numerous relevant databases. All inclusion assessments were checked by at least two researchers. Additionally, reference sections of identified papers were also checked. In addition no language restrictions were applied. Therefore, it is unlikely that this review failed to include any studies conducted within this area.

Implications for practice

This review was unable to provide any evidence to support any specific model of psychosocial intervention in relation to the therapeutic approach, the duration of the intervention, the age at which interventions should be conducted and the, setting, intensity and delivery of the interventions. As the need to identify effective psychological interventions was identified as the top priority in the recent James Lind Alliance Priority Setting Exercise (need a ref), a programme of research should be put in place to underpin this work. Clinicians and researchers will need to collaborate in efforts to **identify the factors which may contribute to the development and maintenance of distress and of resilience in those affected by CLP, in order to target these factors through interventions. A consensus will need to be achieved in relation to the content and timing of interventions and in the choice of the measures used to assess the efficacy of these interventions.**

Implications for research

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Researchers within the field of psychosocial intervention face **many challenges** in addressing the key uncertainties within the literature and in developing adequately designed studies that are well reported. In order for reviews to be most useful in the future it is important that there are studies conducted that formally assess therapeutic approaches and evaluate the effectiveness of psychosocial interventions. These papers need to include detailed information about the intervention and its underlying therapeutic approach. It is also necessary to describe the intervention setting, who provided it, and the frequency and intensity of the intervention in sufficient details to allow for replication (Abraham et al, 2008). Where possible, future studies should take the form of RCTs and use core outcome measures as standard. These core outcome measures may include generic measures to assess adjustment in relation to other conditions and norm groups, and specific measures to tap into the issues that are particularly relevant to CLP.

Conclusion

In identifying only eight papers suitable for a systematic review of psychosocial interventions in the field of CLP, the findings of this review have limited clinical value, however, it does bring into sharp focus the current lack of research and consensus in the area. On the basis of the available research findings and evidence from the wider psychological literature, this review has highlighted that SST and CBT approaches are worthy of further investigation as techniques for addressing many of the difficulties associated with having a cleft, however, the review has also highlighted that a broader programme of work is necessary to inform the content and timing of future interventions. In light of the recent JLA priority setting exercise, it is clear that such a research programme is a priority in order to provide evidence-based interventions to address the challenges faced by families, children and adults affected by CLP. **Discussion is 7+ pages – it is way too long – I think it needs to be about half this length – it needs structure so flows better and so it doesn't repeat the introduction of the results section - and it needs to be much punchier – this is a JLA priority and the current RCT evidence base is based on eight people!**

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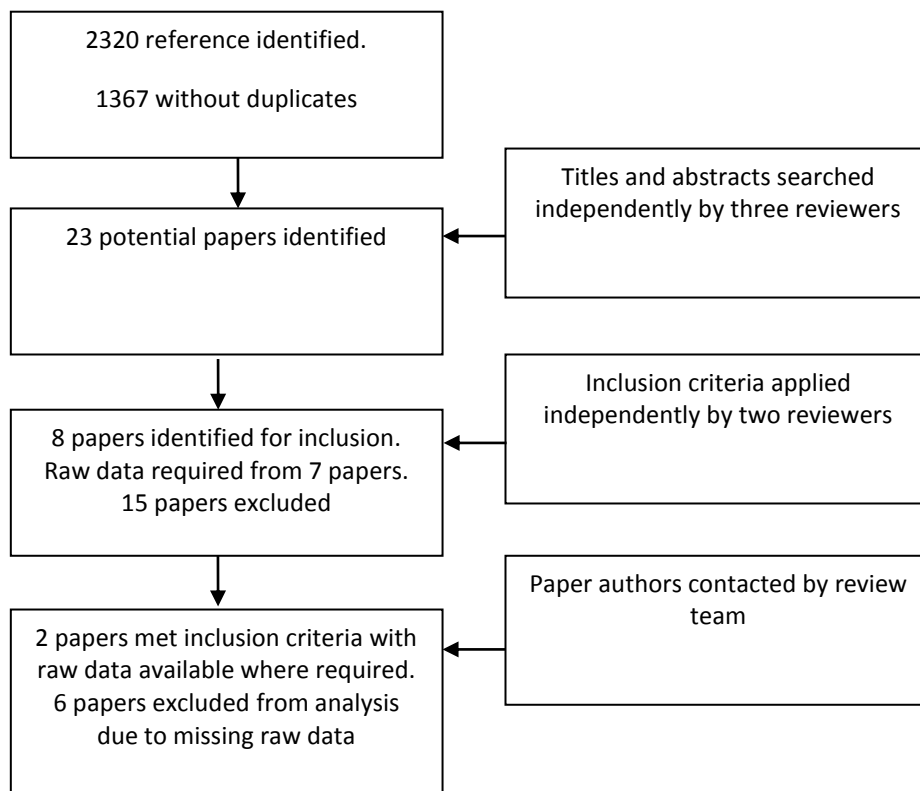


Figure 1: Diagram of review process

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Table 1: Risk of bias in RCTs

Study	Study Design	Sequence Generation	Allocation Concealment	Method of blinding of outcome assessor	Completeness of outcome data	Reporting of outcome data
Bessell et al (2012)	RCT	Low	Low	Low	Low	Low
Newell & Clarke (2000)	RCT	Low	Low	Low	Low	Low

Low = low risk of bias, High = high risk of bias, unclear = information in the paper not sufficient to assess risk of bias

Table 2: Risk of bias observational studies

Study	Study Design	Randomisation Procedure	Attrition	Measurement
Maddern et al, 2006	Observational	High	Low	Low
Pelchat et al (2004;1999)	Observational	High	Low	High
Kapp-Simon et al (2005)	Observational	High	Low	Low
Kleve et al (2002)	Observational	High	Low	Low
Robinson et al (1996)	Observational	High	High	High

Low = low risk of bias, High = high risk of bias, unclear = information in the paper not sufficient to assess risk of bias

Table 3: Study characteristics of included studies

Study	N	Location	Population	Age	Study Design	Intervention	Comparator interventions	Setting	Facilitator	Intensity	Duration	Follow-up
Bessell et al 2012	8 (f)	United Kingdom	Adults with any visible difference	18+	RCT	8 wkly, 60 min CBT/SST	No treatment control 8 wkly, 60 min SST/CBT face-to-face	Clinic	Therapist/self help	8 weekly sessions	1 hour	6 month post-intervention
Newell & Clark 2000	106 (88 f = 5)	United Kingdom	dermatology/plastic surgery outpatients	18+	RCT	CBT	no treatment control	home	Self-help	N/A	N/A	3 months after distribution
Maddern et al (2006)		United Kingdom	Children with any form of disfigurement		Ob							
Kapp-Simon et al (2005)	20 (11 girls)	United States	C hildren with craniofacial conditions	12-14 yrs	Ob	12, 90 min SST group sessions	Waiting list control					None
Pelchat et al (2004;1999)					Ob							
Kleve et al, 2002	36 (27 F)	United Kingdom	Adults with visible differences	17-72 yrs	Ob	CBT	No Control	Clinic	Therapist	3-6 sessions	Not stated	6 month post-intervention
Robinson et al 1996	64 (41 f)	United Kingdom	Adults with visible differences	2-3 yrs	Ob	SST	No control	clinic	Therapist	2 day workshop	Full days	6-month post-

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Appendix A: Sample search strategy (for Medline) and databases searched

The following search terms will be used to identify articles. Only English language papers will be considered. The Databases will be searched using the MEDLINE database strategy outlined below. This approach will be adapted to run on the other selected databases.

Medline strategy:

Cleft Palate/ (15858)

2 Cleft Lip/ (11262)

3 hare lip\$.tw. (92)

4 harelip\$.tw. (341)

5 Palatoschisis.tw. (83)

6 cleft lip\$.tw. (8300)

7 cleft palate\$.tw. (8313)

8 orofacial\$ cleft\$.tw. (544)

9 facial cleft\$.tw. (824)

10 oral cleft\$.tw. (441)

11 craniofacial cleft\$.tw. (107)

12 Velopharyngeal Insufficiency/ (1336)

13 Velopharyngeal Insufficiency.tw. (534)

14 or/1-13 (22163)

15 exp Adaptation, Psychological/ (88681)

16 exp Psychotherapy/ (133902)

17 exp Counseling/ (28798)

18 "Self-Help Groups"/ (7073)

19 "Social Support"/ (42051)

20 ((psychosocial\$ or psycho-social\$) adj5 (intervention\$ or treatment\$ or therap\$ or program\$)).tw. (6601)

21 counsel\$.tw. (54194)

22 (behavi\$ adj5 (therap\$ or treatment\$ or program\$ or intervention\$)).tw. (36684)

23 (cognitiv\$ adj5 (therap\$ or treatment\$ or program\$ or intervention\$)).tw. (15149)

24 (psychologic\$ adj5 (therap\$ or treatment\$ or program\$ or intervention\$)).tw. (9679)

25 (mindfulness adj5 (therap\$ or treatment\$ or program\$ or intervention\$)).tw. (347)

26 "Early Intervention (Education)"/ (1312)

27 Patient Education as Topic/ (62111)

28 support group\$.tw. (3710)

29 self-help.tw. (3764)

30 psychotherap\$.tw. (26937)

31 group therap\$.tw. (3177)

32 Social Adjustment/ (19616)

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- 33 person-cent\$ therap\$.tw. (5)
- 34 solution-based therap\$.tw. (0)
- 35 or/15-34 (412834)
- 36 14 and 35 (668)

The databases will be searched from 1937 to present. In cases where databases do not go back as far as 1937, searches will be conducted from inception. The following databases will be searched: Medline, Embase, Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CCTR), Web of Science, Database of Abstracts of Reviews of Effects (DARE), National Institute of Clinical Excellence (NICE), Psychinfo, and CINAHL.