Communication interventions for autism spectrum disorder in minimally verbal children (Review)

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[Intervention Review]

Communication interventions for autism spectrum disorder in minimally verbal children

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A B S T R A C T

Background

Autism spectrum disorder (ASD) has an estimated prevalence of around 1.7% of the population. People with ASD often also have language difficulties, and about 25% to 30% of children with ASD either fail to develop functional language or are minimally verbal. The ability to communicate effectively is an essential life skill, and difficulties with communication can have a range of adverse outcomes, including poorer academic achievement, behavioural difficulties and reduced quality of life. Historically, most studies have investigated communication interventions for ASD in verbal children. We cannot assume the same interventions will work for minimally verbal children with ASD.

Objectives

To assess the effects of communication interventions for ASD in minimally verbal children.

Search methods

We searched CENTRAL, MEDLINE and Embase as well as 12 other databases and three trials registers in November 2017. We also checked the reference lists of all included studies and relevant reviews, contacting experts in the field as well as authors of identified studies about other potentially relevant ongoing and unpublished studies.

Selection criteria

Randomised controlled trials (RCTs) of communication-focused interventions for children (under 12 years of age) diagnosed with ASD and who are minimally verbal (fewer than 30 functional words or unable to use speech alone to communicate), compared with no treatment, wait-list control or treatment as usual.

Data collection and analysis

We used standard Cochrane methodological procedures.

Main results

This review includes two RCTs (154 children aged 32 months to 11 years) of communication interventions for ASD in minimally verbal children compared with a control group (treatment as usual). One RCT used a verbally based intervention (focused playtime intervention; FPI) administered by parents in the home, whereas the other used an alternative and augmentative communication (AAC) intervention (Picture Exchange Communication System; PECS) administered by teachers in a school setting.

The FPI study took place in the USA and included 70 participants (64 boys) aged 32 to 82 months who were minimally verbal and had received a diagnosis of ASD. This intervention focused on developing coordinated toy play between child and parent. Participants received 12 in-home parent training sessions for 90 minutes per session for 12 weeks, and they were also invited to attend parent advocacy coaching sessions. This study was funded by the National Institute of Child Health and Human Development, the MIND Institute Research Program and a Professional Staff Congress-City University of New York grant. The PECS study included 84 minimally verbal participants (73 boys) aged 4 to 11 years who had a formal diagnosis of ASD and who were not using PECS beyond phase 1 at baseline. All children attended autism-specific classes or units, and most classes had a child to adult ratio of 2:1. Teachers and parents received PECS training (two-day workshop). PECS consultants also conducted six half-day consultations with each class once per month over five months. This study took place in the UK and was funded by the Three Guineas Trust.

Both included studies had high or unclear risk of bias in at least four of the seven 'Risk of bias' categories, with a lack of blinding for participants and personnel being the most problematic area. Using the GRADE approach, we rated the overall quality of the evidence as very low due to risk of bias, imprecision (small sample sizes and wide confidence intervals) and because there was only one trial identified per type of intervention (i.e. verbally based or AAC).

Both studies focused primarily on communication outcomes (verbal and non-verbal). One of the studies also collected information on social communication. The FPI study found no significant improvement in spoken communication, measured using the expressive language domain of the Mullen Scale of Early Learning expressive language, at postintervention. However, this study found that children with lower expressive language at baseline (less than 11.3 months age-equivalent) improved more than children with better expressive language and that the intervention produced expressive language gains in some children. The PECS study found that children enrolled in the AAC intervention were significantly more likely to use verbal initiations and PECS symbols immediately postintervention; however, gains were not maintained 10 months later. There was no evidence that AAC improved frequency of speech, verbal expressive vocabulary or children's social communication or pragmatic language immediately postintervention. Overall, neither of the interventions (PECS or FPI) resulted in maintained improvements in spoken or non-verbal communication in most children.

Neither study collected information on adverse events, other communication skills, quality of life or behavioural outcomes.

Authors' conclusions

There is limited evidence that verbally based and ACC interventions improve spoken and non-verbal communication in minimally verbal children with ASD. A substantial number of studies have investigated communication interventions for minimally verbal children with ASD, yet only two studies met inclusion criteria for this review, and we considered the overall quality of the evidence to be very low. In the study that used an AAC intervention, there were significant gains in frequency of PECS use and verbal and non-verbal initiations, but not in expressive vocabulary or social communication immediately postintervention. In the study that investigated a verbally based intervention, there were no significant gains in expressive language postintervention, but children with lower expressive language at the beginning of the study improved more than those with better expressive language at baseline. Neither study investigated adverse events, other communication skills, quality of life or behavioural outcomes. Future RCTs that compare two interventions and include a control group will allow us to better understand treatment effects in the context of spontaneous maturation and will allow further comparison of different interventions as well as the investigation of moderating factors.

PLAIN LANGUAGE SUMMARY

Are communication interventions effective for minimally verbal children with autism spectrum disorder?

Background

Autism spectrum disorder (ASD) is a condition that is characterised by difficulties with the social aspects of communication, and repetitive and restricted interests and behaviours (e.g. repetitive body movements such as hand flapping, sensory sensitivities and circumscribed interests). People with ASD commonly also have language difficulties, and around 25% to 30% of children are unable to use verbal language to communicate or are minimally verbal (use fewer than 30 words). The ability to communicate is a crucial life skill, and difficulties with communication can have a range of negative consequences such as poorer academic performance, poorer quality of life and behavioural difficulties. Communication interventions generally aim to improve children's ability to communicate either through speech or by supplementing speech with other means (e.g. sign language or pictures).

What did we look at?

We searched 18 databases and trials registers in November 2016 and updated the search in November 2017.

What did our study find?

We identified two trials involving 154 minimally verbal children who had ASD (aged 32 months to 11 years). The studies randomly divided participants into those that received a communication intervention and a control group that did not receive the intervention but received treatment as usual in the community. Both studies focused primarily on communication outcomes (verbal and non-verbal). One of the studies also collected information on social communication. Neither study collected information on adverse events, other communication skills, quality of life or behavioural outcomes.

One study looked at an alternative and augmentative communication (ACC) intervention (Picture Exchange Communication System; PECS), which teachers gave the children in school. This intervention was conducted over five months and involved teacher training and consultation. PECS is a staged approach where children are taught to exchange a single picture of a desired item or action to another person who then responds to the request. The system progresses toward putting pictures together in sentences and using these sentences in a variety of ways such as commenting and answering questions. This study included 84 participants (73 boys) aged 4 to 11 years and was funded by the Three Guineas Trust. The other study looked at a verbally based intervention (focused playtime intervention; FPI), which is a home-based parent education programme that aims to promote coordinated play with toys between parents and their children. This study included 70 participants (64 boys) aged 32 months to 82 months and was funded by a Clinical and Patient Educators Association grant (HD35470) from the National Institute of Child Health and Human Development, the MIND Institute Research Program, and a Professional Staff Congress-City University of New York grant.

Main results

There is limited evidence that verbally based and AAC interventions improve spoken and non-verbal communication in minimally verbal children with ASD. Both studies included in this review reported gains in aspects of verbal or non-verbal communication (or both) for some children immediately after the intervention. Neither of the interventions resulted in improvements in verbal or non-verbal communication that were maintained over time for most children. We rated the overall quality of the evidence as very low because we only found two eligible studies, and they involved few participants. Furthermore, both studies had some methodological limitations that increased their risk of bias.

Recommendations

There is currently limited evidence that verbally based and ACC interventions improve expressive communication skills in minimally verbal children with ASD aged 32 months to 11 years. Additional trials that use communication interventions and compare the effects of these interventions to a control group are urgently required to build the evidence base.

SUMMARY OF FINDINGS

Summary of findings for the main comparison.   Summary of findings: focused playtime intervention versus treatment as usual for minimally verbal children with autism spectrum disorder

Focused playtime intervention versus treatment as usual for minimally verbal children with autism spectrum disorder

Patient or population: minimally verbal children with autism spectrum disorder

Settings: child's home (study set in California, USA)

Intervention: focused playtime intervention

Comparison: treatment as usual

Outcomes	Impact	Number of participants (studies)	Quality of the evidence (GRADE)
Spoken communication Measured by: Mullen Scale of Early Learning: Expressive Language Index (MSEL: log (base 2) transformed age equivalent scores) Follow-up: 20 to 21 weeks	No significant main effect of functional playtime intervention on expressive language outcomes (t (df = 57) = 1.21, P = 0.23)	70 (1 RCT)	$\oplus\ominus\ominus$ **Very low**[a,b]
Non-verbal communication/AAC	No data were reported for this outcome		
Combined spoken and non-verbal communication/AAC	No data were reported for this outcome		
Adverse events	No data were reported for this outcome		
Social communication and pragmatic language skills	No data were reported for this outcome		
Other communication skills	No data were reported for this outcome		
Quality of life for the individual or their family and parent satisfaction	No data were reported for this outcome		
Non-core aspects of behaviour and function	No data were reported for this outcome		

CI: confidence interval.

GRADE Working Group grades of evidence
High quality: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low quality: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded one level for risk of bias (rated as unclear or high risk of bias on 4/7 domains).
[b]Downgraded two levels for imprecision due to small sample size and only one trial identified for comparison.

Summary of findings 2.   Summary of findings: Picture Exchange Communication System (PECS) versus treatment as usual for minimally verbal children with autism spectrum disorder

Picture Exchange Communication System (PECS) versus treatment as usual for minimally verbal children with autism spectrum disorder			

Patient or population: minimally verbal children with autism spectrum disorder

Settings: school (autism-specific schools and units in South East London, UK)

Intervention: PECS (teacher training and consultation; 2 groups: immediate treatment group and delayed treatment group)

Comparison: control (classes where teachers had not received any active direct, in class training/consultancy with PECS consultants)

Outcomes	Relative effect* (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)
Spoken communication Measured by: frequency of speech, including non-word vocalisations (expressed as rates per minute)[a] Follow-up: 2 school terms[b]	There was no significant main effect of the PECS intervention on frequency of speech (OR 1.10, 95% CI 0.46 to 2.62, P = 0.83)	84 (1 RCT)	⊕⊖⊖⊖ **Very low**[c,d]
Non-verbal communication/AAC Measured by: frequency of use of PECS symbols (expressed as rates per minute)[a] Follow-up: 2 school terms[b]	Children in the PECS group were 3.90 times more likely to be in a higher PECS-use category than children in the control group (OR 3.90, 95% CI 1.75 to 8.68, P < 0.001)	84 (1 RCT)	⊕⊖⊖⊖ **Very low**[c,d]
Combined spoken and non-verbal communication/AAC Measured by: verbal and non-verbal initiations (expressed as rates per minute)[a] Follow-up: 2 school terms[b]	Children in the PECS group were 2.73 times (OR 2.73, 95% CI 1.22 to 6.08, P < 0.05 (specific P value not reported in paper)) more likely to to be in the higher initiation-rate category than the control group	84 (1 RCT)	⊕⊖⊖⊖ **Very low**[c,d]
Adverse events	No data were reported for this outcome		
Social communication or pragmatic language Measured by: reciprocal social interaction (ADOS-G domain scores)[a] Follow-up: 2 school terms[b]	There was no significant main effect of the PECS intervention on reciprocal social interaction OR 0.55 (95% CI 0.25 to 1.19, P = 0.13)	84 (1 RCT)	⊕⊖⊖⊖ **Very low**[c,d]
Other communication skills	No data were reported for this outcome		
Quality of life for the individual or their family and parent satisfaction	No data were reported for this outcome		
Non-core aspects of behaviour and function	No data were reported for this outcome		

The **relative risk** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

AACADOS-G: Autism Diagnostic Observation Schedule - Generic; **CI**: Confidence interval; **OR**: odds ratio; **PECS**: Picture Exchange Communication System; **RCT**: Randomised controlled trial.

GRADE Working Group grades of evidence
High quality: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low quality: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low quality: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Only one outcome measure is reported for each outcome in this table (although further outcome measures were collected by the studies). Outcomes Measures were chosen based on how clinically meaningful they were.
[b]7.5 to 10.7 months after the baseline assessment.
[c]Downgraded one level for risk of bias (rated as unclear or high risk of bias on 4/7 domains).
[d]Downgraded two levels for imprecision due to small sample size, wide CI and only one trial identified for comparison.

BACKGROUND

Description of the condition

Autism spectrum disorder (ASD) is one of the most common neurodevelopmental disabilities. Data from the Autism and Developmental Disabilities Monitoring (ADDM) Network, an active surveillance system in the USA, has reported an increase in prevalence from 6.7 per 1000 in the year 2000 to 16.9 per 1000 in 2014 (Baio 2018). Similar increasing trends have also been observed worldwide (Croen 2002; Gillberg 1999; Lai 2014; May 2017).

ASD is characterised by social communication difficulties and repetitive, restricted behaviours and routines. A clinical diagnosis of ASD is based on observed behavioural criteria, defined in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), currently in its fifth edition (APA 2013). Genetic causes for autism are increasingly being identified (Stessman 2017), and the environment is also thought to play a role (Chaste 2012; Modabbernia 2017).

The most recent edition of the DSM removed language difficulties as a core feature of ASD (APA 2013). However, a significant proportion of children with ASD experience difficulties acquiring spoken language. The severity of these difficulties varies considerably. Most children with ASD acquire language during the preschool years (Anderson 2007; Howlin 2009), typically by five years of age (Tager-Flusberg 2005). However, 25% to 30% of children with ASD fail to develop any functional spoken language or remain minimally verbal (Anderson 2007; Norrelgen 2015; Rose 2016; Tager-Flusberg 2013). Language difficulties in children with ASD can result in a number of adverse sequelae, including behavioural difficulties (Bott 1997; McClintock 2003; Sigafoos 2000), poor adaptive functioning skills and poor social skills (Anderson 2007; Baghdadli 2007; Hudry 2010). This can result in reduced quality of life and fewer opportunities to participate in the community. Specifically, in some studies of individuals with ASD who are minimally verbal, communication impairment has been found to predict higher levels of aggression (Hartley 2008; Matson 2008), and in one study, up to 25% of minimally verbal children with ASD were found to show an increase in aberrant behaviours such as social withdrawal during adolescence (Lord 2010). Furthermore, self-injurious behaviour has also been negatively associated with expressive language in children with ASD (Baghdadli 2003).

There has been a lack of consensus regarding the definition of the term 'minimally verbal'. For example, Tager-Flusberg 2013 proposed benchmark criteria to identify this group; the first stage is 'pre-verbal', and the next stage is 'first words' where the child is required to have an age-equivalence of greater than 15 months for vocabulary and pragmatic abilities. Kasari 2013 defines minimally verbal children as those with "a very small repertoire of spoken words or fixed phrases that are used communicatively" (p 480). Others describe this group as children who use no words or single words (Thurm 2015). A number of studies have used definitions provided by diagnostic tools. For example, the Autism Diagnostic Interview - Revised (ADI-R) is a structured parent interview for diagnosing ASD. Based on parent report about the child's language abilities on some of the interview questions, the ADI-R can group individuals into different levels. For example, "no phrase speech and greater than or equal to three words but single words used on a daily basis" would be coded as a one, and "no speech used on a daily basis and less than a 5 word vocabulary" would be coded as a two (Rutter 2003). For the purposes of this review, we define minimally verbal children as those having fewer than 30 functional words and/or being unable to use speech alone to communicate, despite being of an age where one would expect them to use language (i.e. mental age of greater than two years). This working definition encompasses many specific definitions used across studies.

To date, research has not been able to identify a consistent reason why some children with ASD fail to acquire verbal language, although several hypotheses have been proposed. Further to the underlying genetic and environmental markers of ASD and language, researchers have applied structural and functional imaging or neurophysiological techniques to examine potential abnormalities in the brain structures of children with ASD to explain language outcomes (De Fossé 2004; Freitag 2009; Just 2004; Kumar 2010; Stanfield 2008). It remains unclear, however, how these structural and functional changes directly explain the language difficulties that occur in children with ASD.

Further to the neural underpinnings of language and ASD, some researchers have focused on cognitive mechanisms impacting verbal development in these children. Cognitive ability (IQ) and difficulties with social communication skills seem to be influential contributors (Norrelgen 2015). For example, one study found non-verbal cognitive ability, gestures and imitation to be the strongest predictors of later expressive language ability in children with ASD (Luyster 2008). Joint attention skills may also have an impact on the development of language in children with ASD. Joint attention has been defined as the ability to respond to social interaction bids from others and the ability to initiate social interaction with others, as well as the co-ordination of these two skills (Alessandri 2005; Mundy 2007). A number of studies have found joint attention to be predictive of later language abilities in both children with ASD and in typically developing children (e.g. Charman 2003; Mundy 1990; Mundy 2007). Consequently, a number of intervention programmes have considered joint attention (Dawson 2010; Kasari 2012; Lawton 2012). Another study found that vocal and motor imitation, along with joint attention, were more impaired in children with ASD who had not developed language by five years of age (Luyster 2008; Thurm 2007). It has been proposed that childhood apraxia of speech may cause some children with ASD to fail to develop verbal communication; however, to date, there has been limited evidence to support this hypothesis (Pickett 2009; Schoen 2011; Shriberg 2011).

Whilst aetiological mechanisms are poorly understood, arguably more work has been conducted on prognostication of outcomes in these children. Studies suggest that early acquisition of speech and language (by five years of age) is predictive of more favourable outcomes, such as adaptive and social functioning, in later years (Anderson 2007). There is some evidence that communication interventions are less effective if applied after five years of age (Pickett 2009). Some children develop spoken language during adolescence (12 years of age and above) (Wodka 2013); the chance of this happening is less likely than at younger ages (Tager-Flusberg 2013). These differential responses to intervention based on a child's age warrant further research, stratified by different age groups (preschool age or school age).

Description of the intervention

To date, there is no consensus regarding the most appropriate and effective communication intervention for children with ASD who are minimally verbal. This Cochrane Review will focus on interventions that target the acquisition and development of communication skills delivered directly during social-communicative interactions between the child with ASD and another person (usually a therapist). As such, the review will not include pharmaceutical interventions, dietary interventions, or interventions delivered to children through other means without another person facilitating this intervention (e.g. through computers, other forms of technology or animals). In brief, we will include the following four categories of communication interventions in this review: verbally based communication interventions; augmentative and alternative communication (AAC) interventions; combined communication interventions (verbally based intervention plus ACC); and comprehensive interventions with a communication focus. The first three are language-focused interventions that address specific communication skills, whereas the final approach is a comprehensive treatment model. We categorised the interventions based on our expertise in the area, clinical reasoning (typically interventions are described as verbal, AAC or both/multimodal), and what is known about the mechanisms around interventions for minimally verbal children with ASD.

Verbally based communication interventions

Verbally based interventions use verbal strategies to improve the use of sounds, words and sentences to express oneself. They range from naturalistic, child-centred and developmental-pragmatic approaches (e.g. Gutstein 2002), to structured and more didactic methods based on discrete trial training (DTT; e.g. Delprato 2001; Paul 2013); for an overview, see Paul 2008 and Prizant 1998. Responsive Education Prelinguistic Milieu Teaching (RPMT) is an approach that uses modelling of communicative behaviour and correction of child responses, time delay (waiting for the child to initiate or respond) and incidental teaching in natural environments. This approach capitalises on the child's natural interests (Yoder 2006a). Some novel approaches are also being evaluated to see if these may address the specific difficulties experienced by minimally verbal children with ASD (e.g. Rapid Motor Imitation Antecedent, a programme that has been adapted from the DTT model) (Paul 2013).

AAC interventions

AAC interventions refer to a variety of non-verbal communication methods to help minimally verbal children with ASD acquire and develop speech and language skills (Ganz 2004; Kasari 2014; Merinda 2009). AAC also provides children with an alternative means of communicating if they are unable to do so through speech. There are two main types of AAC: aided and unaided. Aided systems use supplementary materials, including graphic symbols such as picture books, texture-based systems such as Braille, and speech-generating devices (SGD) that produce digitalised speech. Unaided systems use manual signs and graphic gestures; these may be formal such as sign language and key word signs, or informal such as idiosyncratic movements. Some AAC interventions incorporate structured and hierarchical behavioural approaches. The Picture Exchange Communication System (PECS; Bondy 1998), for example, includes six phases of teaching; the child moves up

the hierarchy as they make progress. In the first phase the child is physically prompted to make specific requests for items they want using pictures, and in the final, most advanced phase, the child uses the pictures to communicate independently. In recent years, the use of new technologies, such as smartphones, iPads and tablets, has burgeoned. A systematic review of tablet computers and portable media devices that had been adapted to serve as SGD found that the devices usually facilitated verbal ability and that language acquisition was faster for individuals using SGDs compared to manual signs or low-technology AAC (Lorah 2015).

Combined communication interventions (verbally based intervention plus AAC)

Combined programmes, sometimes referred to as 'total communication' interventions, use components from both verbally based communication interventions and AAC interventions. The Hanen More than Words programme (Sussman 2001), for example, is a parent training programme that teaches parents to use strategies (e.g. comment on the child's interests, use AAC, use cues to encourage turn-taking) in their everyday routines to help their child to communicate. The Means, Opportunities, Reasons and Expectations (MORE) programme is another approach that uses both verbally based communication interventions and AAC interventions (Emerson 2013).

Comprehensive interventions with a communication focus

A broad range of comprehensive programmes for ASD have been developed. These target a range of developmental skills in addition to communication, such as cognition, behaviour, play, emotional regulation and social skills. Pivotal Response Training is an example of a naturalistic behavioural intervention, which facilitates stimulus and response generalisation, increases spontaneity, reduces prompt dependency and increases motivation (Koegel 2006). Other examples of comprehensive interventions include the Denver Model (and Early Start Denver Model) (Rogers 2000; Rogers 2009), the Relationship Development Intervention (Gutstein 2002), the Learning Experience and Alternative Program (LEAP; Strain 1998), the Treatment and Education of Autistic and Related Communication Handicapped Children (TEACCH) programme (Mesibov 2005), the Social Communication, Emotional Regulation Transactional Support (SCERTS) model (Prizant 2006), and applied behaviour analysis (Lovaas 1987; Reichow 2009).

Comprehensive programmes, most of which have not been adapted for use in children who are minimally verbal, go beyond the scope of the current review. We will only include such programmes if they have been adapted, so that the focus is on communication and the primary aim of the study is to improve communication skills. An example of the type of intervention that may be included is that used in a recently published trial by Kasari 2014. This trial combined Joint Attention, Symbolic Play, Engagement and Regulation intervention with Enhanced Milieu Teaching (JASP + EMT) to improve communicative spoken language in minimally verbal children. Similarly, we will only include parent-mediated interventions, such as the Parent-Mediated Communication Focused Treatment (PACT; Green 2010) and the Hanen More than Words programme (Sussman 2001), if the intervention targets communication and the aims of the study are communication specific.

Each of the approaches above use different mechanisms to improve speech acquisition and development in minimally verbal children

(see How the intervention might work section). Consequently, we had planned to conduct separate subgroup analyses to explore these different types of interventions further (classified in the manner stated above, or even more precisely, depending on the number of studies included in each subgroup).

How the intervention might work

Verbally based communication interventions

The underlying theory behind many verbally based interventions is that the lack of verbal communication originates from other inherent areas of difficulty in ASD, including reduced levels of social motivation, reduced attention to child-directed speech, immaturity of speech motor development and generally poor imitation skills. Limitations in all of these domains, if serious enough, may lead to severe language impairment. If this theory is correct, an intervention that focuses specifically on speech production together with more intensive and orientated guidance from caregivers, may be enough to trigger the speech learning process. Similarly, efforts that seek out approaches for reciprocal interaction mediated by word exchanges might also work through 'tuning on' or 'tuning up' the expressive language system (Schoen 2011; Shriberg 2011).

AAC interventions

There are a number of theories as to why AAC systems may facilitate vocal production. First, based on the principle of automatic reinforcement, AAC interventions may form an interactive reinforcement system that increases the effectiveness of speech production (Millar 2006). Essentially, if the spoken word and its symbol are presented simultaneously along with a reinforcer, minimally verbal children might begin to produce approximations of the word. Second, for those children with deficits in motor skills or cognitive function, mastering other skills for establishing basic communication may help them to conquer the difficulties encountered during vocal production (Romski 1996). Third, it has been proposed that AAC interventions may reduce the pressure for children to communicate verbally, and, in doing so, reduce demands on auditory-vocal channels and indirectly increase the chances of spontaneous vocal production (Kasari 2014).

Comprehensive interventions with a communication focus

Some comprehensive programmes have been adapted to specifically target communication. For instance, PRT was designed to target 'pivotal' areas of a child's development (including motivation, response to multiple cues, self-management, and the initiation of social interactions) (Koegel 2006). Pivotal behaviours are central to a broad range of areas of a child's functioning and, when promoted, may lead to improvements in verbal communication. In addition, parent-mediated communication interventions aim to enhance parent-child interactions by increasing parental sensitivity and responsiveness to the child's communication needs. Through a range of interaction strategies, such as routines and familiar, repetitive language and pauses, the child's prelinguistic and early language skills may improve (Green 2010; Sussman 2001). Finally, JASPER interventions may help develop the child's verbal skills by promoting the child's play skills and attention to social interaction (Kasari 2013).

Why it is important to do this review

The ability to communicate is an essential life skill. Communication is key to forming and maintaining relationships, performing academically and enabling people to participate and function in their community. Difficulties communicating can also have an impact on family quality of life and stress. The evidence suggests that 25% to 30% of children with ASD will remain minimally verbal when they reach school age (Anderson 2007; Norrelgen 2015; Tager-Flusberg 2013). Historically, most studies that have investigated communication interventions for children with ASD have focused on the language development of verbal children. Little attention has been given to children who are minimally verbal (Kasari 2013; Paul 2013; Tager-Flusberg 2013), with the exception of a workshop on the topic of minimally verbal children with ASD organised by the National Institutes of Health (NIH) in 2010, which signalled the critical need for greater research focus in this area (NIH 2010). At present there is no consensus on what the most effective intervention approach for minimally verbal children with ASD may be. We cannot assume that interventions that work for verbal children will also work for children who are minimally verbal, so a systematic review to evaluate the existing evidence on interventions for this population is needed.

A number of reviews have investigated communication interventions for children with ASD (e.g. Goldstein 2002; Kim 2009; Thunberg 2013). None of these reviews have focused specifically on children with ASD who are minimally verbal. The existing reviews have not systematically reviewed the quality of included studies, making it difficult to judge risk of bias for each included study. This Cochrane Review will use a more comprehensive range of databases to search the literature, apply different inclusion criteria compared to the previous reviews, and provide the most up-to-date information on the available evidence on interventions for minimally verbal children with ASD.

In this review, we aim to address two main questions. First, are communication interventions beneficial for minimally verbal children with ASD and, if so, which type of intervention is the most effective? Second, do the outcomes of preschool and school-age children with ASD differ when such interventions are applied? This review will provide a summary of the available evidence on interventions for children with ASD who are minimally verbal. This will assist decision-making around the types and amount of intervention for this group of children as well as inform the planning of resources to support them. This information is highly relevant for clinicians, service-providers, families and policymakers.

O B J E C T I V E S

To assess the effects of communication interventions for ASD in minimally verbal children.

M E T H O D S

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs).

Types of participants

We included participants that met the following four criteria.

1. They had received a diagnosis of ASD, autism, autistic disorder, Asperger's syndrome, pervasive developmental disorder (PDD) and PDD - not otherwise specified (PDD-NOS). The diagnosis must have been made using standard diagnostic criteria, such as the Childhood Autism Rating Scale (CARS; Schopler 1986), Gilliam Autism Rating Scale (GARS; Gilliam 1995), Autism Diagnostic Interview - Revised (ADI-R; Lord 1994), Autism Diagnostic Observation Schedule (ADOS; Lord 2000), or the Diagnostic Interview for Social and Communication Disorders (DISCO; Wing 2002), or by using established diagnostic criteria such as the *International Classification of Diseases* (ICD; WHO 1992) or the DSM (APA 2013).

2. They were under 12 years of age.

3. They were minimally verbal, defined in any of the following ways: having fewer than 30 functional words (Kasari 2013), being unable to use speech alone to communicate (described as being non-verbal, having little or no speech, complex communication needs, severe communication impairment), or both.

4. They were at a cognitive level where one would expect them to use words (i.e. mental age of greater than 12 months, as measured by non-verbal developmental quotient or IQ). This was to ensure they were not pre-verbal.

We did not exclude participants if they had comorbidities (e.g. attention deficit hyperactivity disorder (ADHD), epilepsy) in addition to ASD.

Types of interventions

Language-focused interventions that primarily aimed to improve spoken communication (expressive language or speech, or both) or use of non-verbal communication (e.g. AAC) compared with no intervention, wait-list control or treatment as usual. We excluded studies that had other treatment controls (i.e. where one intervention is directly compared to another in the RCT) because there is still no standard or established communication intervention for minimally verbal children with ASD and therefore no reference intervention. Eligible interventions included the following.

1. Verbally based communication interventions (such as Prelinguistic Milieu Teaching (PMT; Yoder 2006a), Discrete Trial Training (DTT; Lovaas 1987), Prompts for Restructuring Oral Muscular Phonetic Targets (PROMPT; Chumpelik 1984)).

2. AAC interventions (such as Picture Exchange Communication System (PECS; Bondy 1998), SGDs, sign language).

3. Combined communication interventions (verbally based communication and AAC interventions).

4. Comprehensive (multi-modal) interventions that aim to improve spoken communication or AAC ability, or both.

We excluded studies that used comprehensive interventions for ASD that targeted a range of developmental skills (such as fine motor skills) unless the aims of the study were specifically focused on spoken communication or the use of AAC, or both. Equally, we only included parent training programmes if they had a specific focus on spoken communication, use of AAC or both.

We excluded interventions that focused on improving social skills as a primary aim, although social communication may have been a secondary outcome. We excluded interventions that required physical support from a third party for the child to communicate; for example, Facilitated Communication, described by Biklen 1990, and Rapid Prompting Method (HALO 2016). We only included interventions that involved the child communicating independently.

Types of outcome measures

Primary outcomes

1. Spoken communication (expressive language or speech, or both), measured using formal standardised assessments, standardised parent-report checklists and tools, novel instruments (newly designed scales specific to a study), language samples and vocabulary counts. Spoken communication could have been in the form of sounds, words and phrases or sentences, and used in a variety of ways (e.g. to request, comment).

2. Non-verbal communication or AAC, measured by, for example, the phase of PECS (Bondy 1998), frequency of use of vocabulary on a speech generating device, number of initiations using PECS or the number of key word signs a child uses.

3. Combined spoken and non-verbal communication. This refers to measures that do not distinguish whether they are spoken or non-verbal. For example, the outcome 'frequency of initiations' may include both spoken and unspoken initiations.

4. Adverse events (e.g. increased stress in parents or increased anxiety in the child in response to completing a particular intervention), measured by tools such as the Parenting Stress Index (Abidin 1995) or the Spence Children's Anxiety Scale (Spence 1998).

Secondary outcomes

1. Social communication and pragmatic language skills, measured using tools such as the ADOS social interaction domain or the Early Social Communication Scales (Lord 2000; Mundy 2003).

2. Other communication skills (e.g. adaptive communication), measured by, for example, the Vineland Adaptive Behavior Scales - Second Edition (VABS-II; Sparrow 2005).

3. Quality of life for the individual or their family (e.g. emotional well-being and support) and parent satisfaction, measured by either standardised instruments, such as the Parenting Stress Index (Abidin 1995), Beach Family Quality of Life Scale (Beach Center on Disabilities 2006), tools such as Focus on the Outcomes of Communication Under Six (Thomas-Stonell 2013), or by novel instruments invented by the study designers.

4. Non-core aspects of behaviour and function (e.g. non-verbal cognition, challenging behaviours, self-mutilation and aggression), measured either by standardised instruments or by novel instruments invented by the study designers.

Search methods for identification of studies

Electronic searches

We searched the electronic databases and trials registers listed below in November 2016 and updated the searches in November 2017. We did not use any date or language restrictions, and we sought translations of non-English language papers and assessed them for potential inclusion in the review, as necessary.

1. Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 10), in the Cochrane Library, and which includes the

![Cochrane Library logo] Trusted evidence.
Informed decisions.
Better health.

Cochrane Database of Systematic Reviews

Cochrane Developmental, Psychosocial and Learning Problems Group Specialized Register (searched 8 November 2017).

2. MEDLINE Ovid (1946 to October week 4 2017).

3. MEDLINE In-Process & Other Non-Indexed Citations Ovid (searched 7 November 2017).

4. MEDLINE Epub Ahead of Print Ovid (searched 7 November 2017).

5. Embase Ovid (1974 to 7 November 2017).

6. CINAHL Plus EBSCOhost (Cumulative Index to Nursing and Allied Health Literature; 1937 to 8 November 2017).

7. PsycINFO Ovid (1967 to December week 1 2017).

8. ERIC EBSCOhost (Education Resources Information Center; 1966 to 8 November 2017).

9. Conference Proceedings Citation Index - Science Web of Science (CPCI-S; 1990 to 7 November 2017).

10. Conference Proceedings Citation Index - Social Sciences & Humanities Web of Science (CPCI-SS&H; 1990 to 7 November 2017).

11. SpeechBITE (speechbite.com; all available years; searched 8 November 2017).

12. Epistemonikos (epistemonikos.org; all available years; searched 8 November 2017).

13. Cochrane Database of Systematic Reviews (CDSR; 2017, Issue 11), part of the Cochrane Library (searched 8 November 2017).

14. Database of Abstracts of Reviews of Effect (DARE; 2015, Issue 2), part of the Cochrane Library (searched 17 November 2016, which was the final issue of DARE; new records are no longer being added).

15. WorldCat (worldcat.org; all available years; searched 8 November 2017).

16. ClinicalTrials.gov (clinicaltrials.gov; all available years; searched 8 November 2017).

17. ISRCTN Registry (www.isrctn.com; all available years; searched 8 November 2017).

18. World Health Organization International Clinical Trials Registry Platform (WHO ICTRP; who.int/ictrp/en; all available years; searched 8 November 2017).

The search strategies are in Appendix 1.

Searching other resources

We checked the reference lists of all included studies and relevant reviews for additional references. In addition, we asked experts in the field to provide details of ongoing clinical trials and any relevant unpublished material not captured by our Electronic searches. We also contacted authors of identified trials to ask if they knew of any other published or unpublished studies that our searches missed.

Data collection and analysis

Table 1 summarises the methods we had planned to use, as per our published protocol (Brignell 2016), but which did not employ or were not relevant to this review. We may use these preplanned methods in subsequent updates of this review.

Selection of studies

Two review authors (AB, KC) independently screened titles and abstracts identified by our searches for potentially relevant studies. Of those deemed potentially relevant, the same review authors obtained and independently assessed the full text against the inclusion criteria (Criteria for considering studies for this review). We resolved any disagreements through discussion or, if required, by consulting a third review author (AM).

We identified and excluded duplicates, and collated multiple reports of the same study so that each study, rather than each report, was the unit of interest in the review. We listed all excluded studies and the reasons for their exclusion in Characteristics of excluded studies tables.

We recorded the selection process in sufficient detail to produce a PRISMA flow diagram (Liberati 2009).

Data extraction and management

We extracted data on each of the following criteria from each included study.

1. Methods (study design, total duration, number of study centres and location, study setting, withdrawals, date of study).

2. Participants (number (N), mean age, age range, sex, severity of condition, diagnostic criteria, inclusion criteria, exclusion criteria).

3. Interventions (intervention, comparison, concomitant intervention, excluded interventions).

4. Outcomes (primary and secondary outcomes specified and collected, time points reported).

5. Notes (funding for trial, or any notable conflicts of interest of trial authors).

Two review authors (AB, KC) independently extracted data from the included studies and recorded them in the Characteristics of included studies tables. We resolved disagreements by consensus or by involving a third review author (AM).

One review author (AB) manually inputted the data from the data collection form into Review Manager 5 (RevMan 5) (ReMan 2014). A second review author (KC) spot-checked study characteristics for accuracy against the trial report. Once completed, both reviewers (AB, KC) double checked that they had entered the data correctly, by comparing the study reports with how the data were presented in the systematic review.

Assessment of risk of bias in included studies

Two review authors (AB, KC) independently assessed the risk of bias of each included study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* and set out in Appendix 2 (Higgins 2017). The same two review authors consulted a third assessor (AM) to resolve any differences of opinion. Both reviewers assessed the risk of bias for each included study across the following seven domains and assigned ratings of low, high or unclear risk of bias: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other potential sources of bias.

Where available, we have provided a quote from the study report together with a justification for the judgement in the 'Risk of bias' table (beneath the Characteristics of included studies table). We summarised the 'Risk of bias' judgements across different studies for each of the domains listed above by graph and by text in the Risk of bias in included studies section of the review. Where information

on risk of bias related to unpublished data or correspondence with a trial author, we noted this in the 'Risk of bias' table.

When considering the effects of interventions, we took into account the risk of bias for the studies that contributed to that outcome.

Measures of treatment effect

Dichotomous outcomes

We calculated odds ratios (OR) for dichotomous variables (e.g. clinical improvement or no clinical improvement) and presented these with 95% confidence intervals (CI).

Ordinal outcomes

We presented ordinal outcomes directly as ordinal data, and presented assumed (control) and corresponding (intervention) risk compared for each ordinal value separately. We presented data as corresponding risk per 1000. We did not transform ordinal data into continuous or dichotomous data due to the skew of the data and the nature of the ordinal scales (an arbitrary cut-point would not be as clinically meaningful as the full ordinal scale).

Continuous outcomes

For continuous data, we calculated mean differences (MD) as long as studies used the same measurement, or standardised mean differences (SMDs) when studies use different scales, together with their corresponding 95% CI. We ensured that higher scores for continuous outcomes had the same meaning for the particular outcome, explained the direction to the reader, and reported where we reversed the directions if this was necessary. If a study did not report standard deviations (SD) or standard errors, we contacted the corresponding author of the study to obtain this information. If necessary, we sought to calculate effect estimates from t statistics, analysis of variance (ANOVA) tables or other statistics, as appropriate.

Unit of analysis issues

We encountered no unit of analysis problems. Howlin 2007 was a cluster-randomised trial (with 17 clusters), and the analysis took clustering into account. See Table 1 and Brignell 2016 for the methods reported in our published protocol for managing unit of analysis issues should they arise in subsequent updates of this review.

Dealing with missing data

For studies without complete reports (studies identified by abstract only), or without complete information in full reports (critical data could not be found in report), we contacted investigators or study sponsors to obtain the missing data, where possible. We documented any details provided by the study authors and used for further analysis. Table 1 summarises the methods we had planned to use, as per our published protocol (Brignell 2016), but which did not employ or were not relevant to this review. We may use these preplanned methods in subsequent updates of this review.

Assessment of heterogeneity

We assessed clinical heterogeneity by examining differences between the two included studies. We examined participant characteristics, timing and type of interventions or controls, as well as types of outcomes measured (see Description of studies in the Results section below).

Assessment of reporting biases

We were unable to assess reporting bias as planned (Brignell 2016), as there were too few studies.

Data synthesis

We were unable to conduct our analyses as planned because of the small number of studies that met inclusion criteria for this review (see Table 1 for unused methods and Brignell 2016). Given that no comparison included more than one study, it was not appropriate to synthesise the data into one meta-analysis. Instead, we have presented the results of each included study separately and conducted 'Risk of bias' assessment on each study.

Subgroup analysis and investigation of heterogeneity

When an individual study provided information on our prespecified subgroups, we examined differences visually, by inspecting their CI; non-overlapping CIs indicate a statistically significant difference in effect between subgroups.

We were not able to conduct our preplanned subgroup analyses (Brignell 2016), as there were too few studies for meta-analyses. See Table 1 for details on these planned subgroup analyses.

Sensitivity analysis

We were unable to conduct our preplanned sensitivity analyses (Brignell 2016), as there were too few studies for meta-analyses. See Table 1 for details on these planned sensitivity analyses.

'Summary of findings' tables

We created 'Summary of findings' tables using the software developed by the GRADE working group for our two main comparisons (GRADEpro 2015): PECS or FPI versus treatment as usual. We included the following outcomes, assessed immediately postintervention, in the tables: spoken communication; non-verbal communication or AAC; combined verbal and non-verbal communication or AAC; adverse events; social communication and pragmatic language skills; other communication skills; quality of life for the individual or their family and parent satisfaction; and non-core aspects of behaviour and function.

Two review authors (HS, AB) independently assessed the overall quality of the body of evidence using the GRADE approach (GRADE 2004; Guyatt 2008); AM arbitrated any disagreements. Using this approach, the same two authors graded the quality of the evidence for each outcome as high, moderate, low or very low, according to the presence of the following criteria: limitations in the design and implementation of studies; indirectness of evidence; unexplained heterogeneity or inconsistency of results; imprecision of results; and high probability of publication bias. We presented these ratings in the 'Summary of findings' tables and provided our reasons for downgrading the quality of the evidence in the footnotes.

R E S U L T S
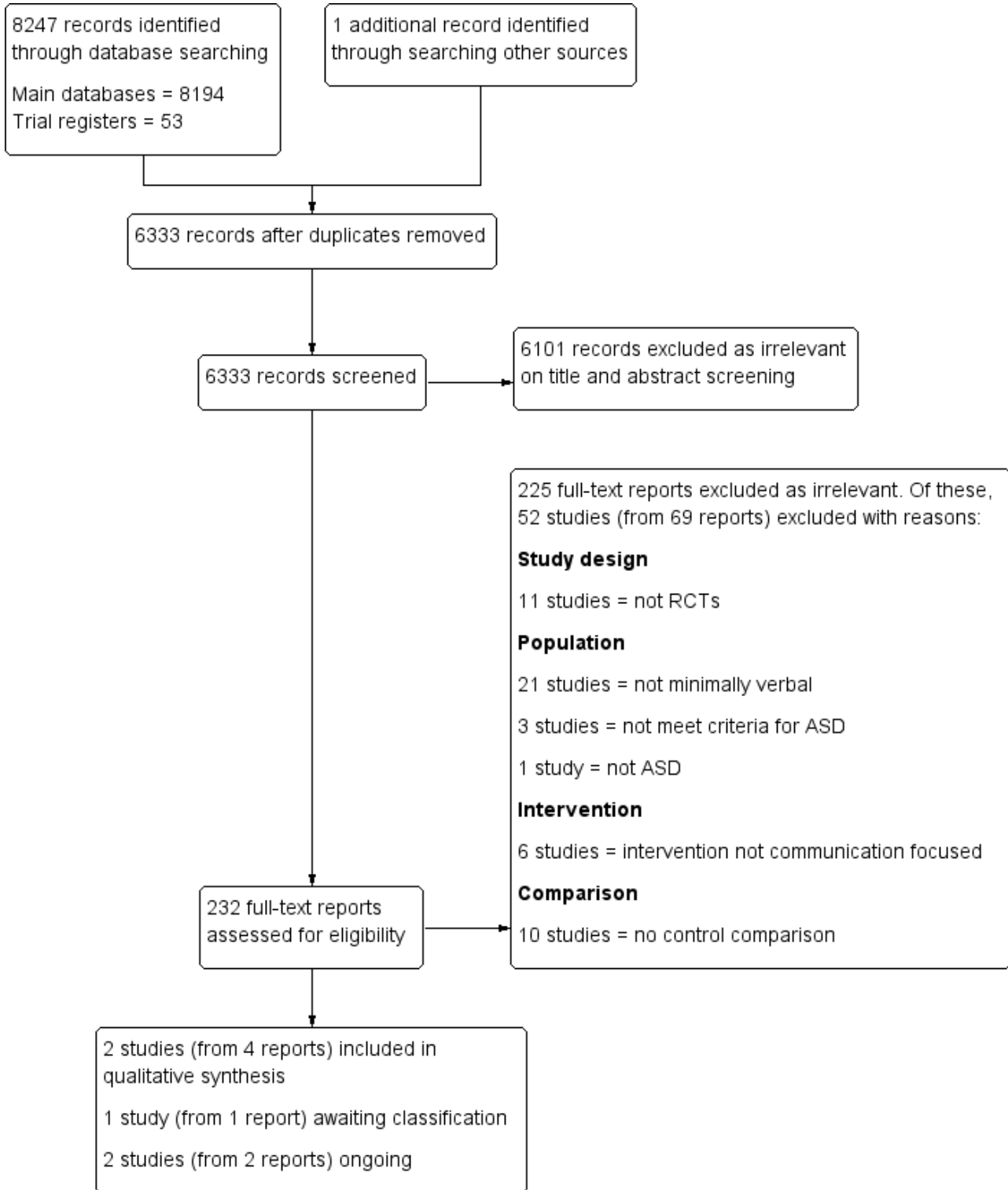
Description of studies

Results of the search

The search yielded 8248 records. Of these, 1915 records were duplicates, and we judged 6101 to be irrelevant based on their titles and abstracts, mostly because they were not RCTs. We retrieved and assessed the full-text reports of the remaining 232 records.

Of these, 69 appeared to be eligible for inclusion (Criteria for considering studies for this review). However, on closer inspection and discussion between three review authors (AB, KC, AM), we decided that only two studies (from four reports) met our inclusion criteria. Additionally, one study (from one report) is awaiting classification, and two trials are ongoing (i.e. they have been registered but do not yet have results). See Figure 1.

Figure 1.   Study flow diagram.

8247 records identified through database searching

Main databases = 8194
Trial registers = 53

1 additional record identified through searching other sources

6333 records after duplicates removed

6333 records screened

6101 records excluded as irrelevant on title and abstract screening

225 full-text reports excluded as irrelevant. Of these, 52 studies (from 69 reports) excluded with reasons:

Study design

11 studies = not RCTs

Population

21 studies = not minimally verbal

3 studies = not meet criteria for ASD

1 study = not ASD

Intervention

6 studies = intervention not communication focused

Comparison

10 studies = no control comparison

232 full-text reports assessed for eligibility

2 studies (from 4 reports) included in qualitative synthesis

1 study (from 1 report) awaiting classification

2 studies (from 2 reports) ongoing

Included studies

Two studies met our inclusion criteria for this review (Howlin 2007; Siller 2013). See the Characteristics of included studies for full details of each study.

Study design

Howlin 2007 was an open-label, cluster-RCT (17 clusters) in which the unit of randomisation was the school classroom (average class size of five children). Siller 2013 was a standard, single-blinded RCT (blind to assessor).

Participants

Both included studies aimed to include children with ASD who had limited or no use of spoken language. However, their inclusion criteria had differences in their definition of spoken language, as well as the age range of participants: Howlin 2007 included children aged 4 to 11 years, whereas Siller 2013 included children aged six years or younger.

Verbally based intervention

Siller 2013 included 70 children (64 boys, 6 girls), with a mean age of 58.3 months (SD 12.7) in the intervention group and 55.9 months (SD 11.9) in the control group. The study included children with limited or no use of spoken language (generally fewer than 25 words and no phrases), and whose mothers were fluent in English and who lived within a 90-minute driving distance to the lab. All children had a previous diagnosis of ASD, which was confirmed in the study using both the ADI-R and ADOS-G. All children met the criteria for autistic disorder on the ADI-R, with 64 meeting the criteria for autistic disorder on the ADOS. The remaining five children were classified as having ASD. One child did not complete the ADOS.

AAC intervention

Howlin 2007 included 84 children (73 boys, 11 girls), with a mean age of 73.1 months (SD 15.8) in the immediate treatment group, 86.6 months (SD 12.7) in the delayed treatment group, and 85.6 months (SD 3.6) in the no treatment group. The study recruited children from 17 classes (clusters) and required that each class had a minimum of three children meeting the following criteria: children had little or no functional language (i.e. not exceeding single words/productions), no evidence of sensory impairment, and were not using PECS beyond phase 1 (i.e. could only exchange symbols with prompting). All children had a formal clinical diagnosis of autism (i.e. they met the criteria for ASD on the ADOS). Notably, Howlin 2007 used multiple intervention groups (i.e. one immediate treatment group and one delayed treatment group, compared to one control (no treatment) group).

Interventions

The two included studies examined different interventions: Howlin 2007 utilised an AAC intervention and Siller 2013 utilised a verbally based intervention. No studies that utilised combined or comprehensive interventions met our inclusion criteria (see Criteria for considering studies for this review section).

Verbally based intervention

Siller 2013 compared focused playtime intervention (FPI) to a control group. FPI is capacity-building approach that promotes coordinated toy play between the parent and child. There is an ordered sequence of eight topics. Both the parent and clinician were involved in first half of the session, but only the parent conducted therapy in the second half of the session. Both intervention and control groups were invited to a parent advocacy group. Information was collected on the non-project services and school programmes attended by both groups 12 months before the study, between intake and exit, and between exit and follow-up.

AAC intervention

Howlin 2007 compared the PECS intervention to a control group, and administered the intervention within a school context. PECS is an intervention that involves teaching an individual to exchange pictures with other people for desired objects or activities, thereby facilitating the child's ability to initiate communication. There are a series of phases that are arranged in a hierarchy of increasing difficulty. In this study teachers and parents received PECS training (two-day workshop or 13 hours) followed by consultation. The active treatment period began about one week after training. PECS consultants conducted six half-day consultations with each class once per month over five months. The consultants recommended and demonstrated strategies to improve children's use of PECS in the classroom, monitored teachers' progress, and provided systematic feedback on implementation of PECS. The classroom teachers were not completely naïve to PECS, but generally their prior use of PECS had been minimal and limited to the first phase of PECS, which included supporting (scaffolding) the child to make requests (Howlin 2007).

Outcome measures

Both included studies used different tools to measure our primary outcomes of spoken and non-verbal communication, and neither study mentioned adverse events in their reports (Howlin 2007; Siller 2013).

Verbally based intervention

Siller 2013 used the expressive language subtest of the Mullen Scale of Early Learning (MSEL) to assess language change over time. The MSEL is a developmental assessment tool that measures a range of developmental areas. It contains two language subtests: expressive and receptive language. Siller 2013 used age-equivalent scores and collected measures at baseline, after the 12-week intervention, and 12 months after the completion of the intervention.

Siller 2013 did not measure any of our secondary outcomes.

AAC intervention

Howlin 2007 videotaped daily snack sessions for a maximum of 15 minutes and coded three variables: frequency of child communicative initiations; frequency of use of PECS symbols; and frequency of speech (including non-word vocalisations). Frequencies were expressed as rates per minute. The trial also included standardised measures based on the Expressive One Word Picture Vocabulary Test and the British Picture Vocabulary Scales. These scales were completed three times throughout the study; at baseline after randomisation, after two school terms (7.5 to 10.7 months after baseline assessments), and at the follow-up assessment (10.4 months after the end of intervention for the immediate treatment group, 7.1 months after the end of intervention for control group, and 4.6 months after the end of intervention for the delayed treatment group).

Regarding the secondary outcomes, Howlin 2007 evaluated change in social communication over time using two scores from the ADOS-G: the communication domain score and the reciprocal social interaction (RSI) domain score. Howlin 2007 did not measure any of our other secondary outcomes.

Funding

The Three Guineas Trust provided funding support for one study (Howlin 2007). The other study, Siller 2013, was supported by a Clinical and Patient Educators Association grant (HD35470) from the National Institute of Child Health and Human Development, the MIND Institute Research Program, and a Professional Staff Congress-City University of New York grant.

Excluded studies

Of the 69 full-text reports that appeared to meet our inclusion criteria (Criteria for considering studies for this review), 11 had two or more publications (as noted in the reference list of Excluded studies). After grouping together multiple reports of the same study, we identified 52 unique studies. We excluded all 52 studies for the following reasons.

1. Study design: we excluded 11 studies because they were not RCTs (D'Elia 2014; Jalili 2014; Mandell 2013; Rogers 2006; Sallows 2005; Schroder 2015; Serret 2017; Stock 2013; Sweeney 2016; Vernay 2017; Zeina 2015).

2. Population: we excluded 25 studies due to ineligible participants; in 19 studies participants did not meet the prespecified definition of 'minimally verbal' (Aldred 2004; Casenhiser 2013; Chang 2016; Elder 2011; Fletcher-Watson 2013; Flores 2014; Fteiha 2017; Hardan 2015; Ingersol 2012; Jemison Pollard 2010; Kaale 2014; Kaiser 2013; Kasari 2006; Oosterling 2010; Pickles 2016; Reitzel 2013; Roberts 2011; Solomon 2014; Venker 2012); 2 studies included participants with low language levels, but the inclusion criteria and descriptive characteristics did not specify that the children were 'minimally verbal' (Landa 2011; Kasari 2015); 3 studies did not use prespecified ASD diagnostic criteria (Martins 2013; Simpson 2013; Smith 2000); and 1 study included participants without ASD (Romski 2010).

3. Intervention: we excluded six studies due to ineligible interventions; four studies used a broader intervention programme without a specific communication focus (Drew 2002; Tonge 2014; Wetherby 2014; Whelan 2010), and two studies did not include communication-focused interventions (Field 2001; Wong 2010).

4. Comparator: we excluded 10 studies due to lack of control comparator (Goods 2013; Gould 2015; Kasari 2014; Paul 2013; Sandiford 2013; Schriebman 2014; Yoder 1988; Yoder 2006b; NCT01018407; NCT01751698). Although all 10 RCTs specifically focused on communication interventions for minimally verbal children with ASD, they did not have a control group for comparison. Rather, they compared one type of intervention to another. These studies compared a range of interventions, including one type of verbally based intervention versus another type of verbally based intervention, and an AAC intervention versus a verbally based intervention. These studies are listed below.

Verbally based intervention versus another type of verbally based intervention

Six studies compared a verbally based intervention with another type of verbally based intervention. Paul 2013 compared Milieu Communication Training versus a Rapid Motor Imitation Antecedent intervention. Sandiford 2013 compared melodic based communication therapy with traditional speech and language therapy. Gould 2015 compared a Joint Attention, Symbolic Play, Engagement and Regulation (JASPER) intervention versus Discrete Trial Training (DTT); the primary outcomes were based around play, but investigators also collected language outcomes. In a pilot study by Goods 2013, all participants received behaviour-based interventions at school 30 hours per week. Fifteen children who were minimally verbal were randomised into a control or intervention group, which consisted of substitution of JASPER intervention for the behaviour-based intervention for 30 minutes, twice weekly for three months. We also excluded two ongoing studies: NCT01751698 and NCT01018407. One of these is investigating DTT versus an interpersonal developmental approach (NCT01018407), and the other is comparing DTT versus JASP + EMT (NCT01751698).

AAC intervention versus verbally based intervention

Four studies compared an AAC intervention to a verbally based intervention. Two studies compared the PECS to a different intervention; one compared PECS to Responsive Education and Prelinguistic Milieu Teaching (Yoder 2006b), and the other compared PECS to Pivotal Response Training (Schriebman 2014). Kasari 2014 administered a JASP + EMT intervention for all participants but added an SGD intervention to one of the groups. One study compared four groups who received signing alone, speech therapy alone, simultaneous signing plus speech therapy, and alternating signing plus speech therapy (Yoder 1988).

See Table 2 for further details on studies comparing two different interventions. Note, we have not included ongoing studies in the table, as they do not yet have results.

Studies awaiting classification

Based on title and abstract, one conference paper, Gilbert 2012, appeared to meet our inclusion criteria (Criteria for considering studies for this review). However, the study authors did not confirm if it did, and we were not able to obtain further detail or data. The study authors reported the participants were also part of a larger, ongoing study (see the Characteristics of studies awaiting classification table for details). This study compared a verbally based intervention to a control group.

Ongoing studies

Two trials met our inclusion criteria but are not yet completed (NCT02291172; NCT02464527). See the Characteristics of ongoing studies tables for details on these studies.

Risk of bias in included studies

Please see the 'Risk of Bias' tables (under Characteristics of included studies tables) for details of the risk of bias in each included study, and Figure 2 for a tabular summary. We judged one study, Howlin 2007, to be at low risk of bias in three domains (selection (random sequence generation), attrition and reporting bias); high risk of bias in two domains (performance and detection

bias); and unclear risk of bias in two domains (selection (allocation concealment) and other potential sources of bias). We judged the other study, Siller 2013, to be at low risk of bias in three domains (detection, attrition and reporting bias); high risk of bias in one domain (performance bias); and unclear risk of bias in three domains (selection (random sequence generation and allocation concealment) and other potential sources of bias).

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Allocation

Sequence generation

We considered one study, Howlin 2007, to be at low risk of bias in this domain. In this school-based study, classes were stratified according to size. In each stratum, classes were randomly allocated to one of the three conditions using an online randomisation programme (www.random.org). We judged the other study, Siller 2013, to be at unclear risk of bias in this domain as they did not report details of how randomisation was completed. In this study, to ensure that two out of every four consecutive children were assigned to the control group, the children were randomised in blocks of four.

Allocation concealment

Neither study reported on how the individuals were informed of their allocation to intervention or control groups; for example, by using sealed envelopes (Howlin 2007; Siller 2013). The nature of these included studies makes it impossible to blind the participants or people administering the intervention to their group allocation. Consequently, we rated both studies at unclear risk of bias in this domain.

Blinding

Blinding of participants and personnel (performance bias)

We considered both studies to be at high risk of performance bias (Howlin 2007; Siller 2013). Participants and personnel were aware of allocation to intervention or control groups in both studies.

Blinding of outcome assessment (detection bias)

We judged one study to be at low risk of detection bias (Siller 2013). Staff conducting assessments or coding were blinded to group assignment, and prior to all outcome assessment sessions, parents were reminded not to reveal their group assignment to the assessment staff. We judged the other study, Howlin 2007, to be at high risk of detection bias, as assessors were not blinded to group assignment. The study authors stated in the manuscript that this was because of financial and personnel limitations.

Incomplete outcome data

We rated both included studies to be at low risk of attrition bias (Howlin 2007; Siller 2013). In Siller 2013, three participants dropped out from the intervention group and two from the control group at the one year follow-up point (Siller 2013). Analyses were conducted on an intention-to-treat basis using multiple imputations to deal with the missing data. Statistical analysis comparing those lost to follow-up and those who remained found that participants who dropped out of the study took longer to complete the intervention period and received fewer autism-specific, non-project services in the community, on average. These differences were then statistically corrected. In Howlin 2007, one child from the immediate treatment group moved away after the trial started, and seven children in the delayed treatment group moved out of classes prior to the start of the intervention. These children did complete assessments, and participants were analysed on an intention-to-treat basis (Howlin 2007).

Selective reporting

We rated both studies to be at low risk of reporting bias as all outcomes reported in the study had been prespecified in the prospective trial registration/protocol (Howlin 2007; Siller 2013). Neither study, however, reported data on adverse events.

Other potential sources of bias

We considered both trials to be at unclear risk of other bias (Howlin 2007; Siller 2013). It is difficult in autism spectrum research to control for interventions being obtained in the local community, and neither trial collected detailed information on any additional interventions received by the control groups. In addition, Howlin 2007 reported that some classes in the control arm may have been using some PECS. Treatment fidelity may also have been an issue, although the study authors argue it was intended as a pragmatic trial. The cluster-randomised controlled design has the potential to introduce biases through differential recruitment of participants within each cluster and methodological difficulties in applying the intention-to-treat approach. In the Howlin 2007 study, differential recruitment was unlikely to have taken place, as all children enrolled in each class received the intervention allocated to the class, and there was no opt-out of any children. However, the Howlin 2007 study had withdrawal of both one whole cluster as well as individual participants within a cluster, along with the addition of one child to the cluster part way through the trial. It is unclear how to analyse these participants from an intention-to-treat perspective and the effect of any bias introduced.

Effects of interventions

See: **Summary of findings for the main comparison** Summary of findings: focused playtime intervention versus treatment as usual for minimally verbal children with autism spectrum disorder;

Summary of findings 2 Summary of findings: Picture Exchange Communication System (PECS) versus treatment as usual for minimally verbal children with autism spectrum disorder

We included two studies in this review, both of which utilised different types of intervention: Howlin 2007 utilised an AAC (PECS) intervention, whereas Siller 2013 utilised a verbally based, play-based (FPI) intervention. No studies met our inclusion criteria for the remaining two intervention types (combined interventions and comprehensive interventions). There was substantial clinical heterogeneity between the included studies, including varied age ranges and inclusion criteria, and different outcome measures (standardised language scores versus coded verbal and non-verbal behaviours). There was also methodological heterogeneity in the trial designs (one cluster RCT and one standard RCT). Thus, we decided that it was not appropriate to pool the data in meta-analysis, and consequently have provided a narrative description of the results below.

FPI versus treatment as usual

The primary outcome described below is taken from the same study with 70 children (Siller 2013).

Primary outcomes

Spoken communication

Siller 2013 measured expressive language using the expressive language domain of the Mullen Scale of Early Learning developmental assessment tool. This study reported that the main effect for FPI was not significant (t (df = 57) = 1.21, P = 0.23; very low-quality evidence, Summary of findings for the main comparison). Exploratory analysis found that baseline measures of expressive language (specifically 24 children who entered the study with expressive language ability under the 11.3-month level) moderated a significant, medium-to-large effect, accounting for approximately 25% of the variance in the children's subsequent language gains.

Adverse events

Siller 2013 reported no data on adverse events.

Siller 2013 did not measure our other primary (non-verbal communication or AAC, or combined verbal and non-verbal communication or AAC) or secondary outcomes (social communication and pragmatic language skills; other communication skills; quality of life for the individual or their family and parent satisfaction; non-core aspects of behaviour and function).

PECS versus treatment as usual

All primary and secondary outcomes described below come from the same, single study with 84 children (Howlin 2007).

Primary outcomes

Spoken communication

Frequency of speech (including non-word vocalisations)

Howlin 2007 found no significant main effect of PECS on frequency of speech (OR 1.10, 95% CI 0.46 to 2.62, P = 0.83; very low-quality evidence, Summary of findings 2).

Expressive vocabulary

Howlin 2007 found no significant main effect of PECS on expressive vocabulary (OR 1.01, 95% CI 0.89 to 1.15, P = 0.87).

Non-verbal communication or AAC: frequency of use of PECS symbols

Howlin 2007 reported a significant main effect of PECS on frequency of use of PECS symbols immediately postintervention. Children in the PECS group were 3.90 times (OR 3.90, 95% CI 1.75 to 8.68, P < 0.001; very low-quality evidence, Summary of findings 2) more likely to to be in the higher PECS-use category than the control group from time point 1 (baseline) to time point 2 (7.5 to 10.7 months after baseline). However, the main effect was not maintained at the 10-month follow-up (time point 3) for the group who had the intervention earlier, with these children being no more likely than the control group to be in a higher PECS-rate category (OR 1.56, 95% CI 0.46 to 2.62, P = 0.48).

Combined verbal and non-verbal communication or AAC: frequency of child communicative initiations (included both verbal and non-verbal initiations)

Howlin 2007 reported a significant main effect of PECS on the frequency of communicative initiations immediately postintervention. Children in the PECS group were 2.73 times more likely to to be in the higher initiation-rate category than the control group from time point 1 to time point 2 (OR 2.73 95% CI 1.22 to 6.08, P < 0.05 (specific P value not reported in paper); very low-quality evidence, Summary of findings 2). However, the main effect was not maintained at the 10-month follow-up for the group that had the intervention earlier, with these children being no more likely than the control group to have a higher initiation rate (OR 1.08, 95% CI 0.30 to 3.90, P = 0.91).

Adverse events

Howlin 2007 reported no data on adverse events.

Secondary outcomes: social communication and pragmatic language skills

Howlin 2007 found no evidence of a significant main effect of PECS immediately postintervention on ADOS communication domain scores (OR 0.52, 95% CI 0.24 to 1.12, P = 0.10) or on the RSI domain scores (OR 0.55, 95% CI 0.25 to 1.19, P = 0.13). However, at the 10-month follow-up of the immediate treatment group, there was a significant main effect for RSI scores on the ADOS (OR 0.28, 95% CI 0.09 to 0.89, P < 0.05 (specific P value not reported in paper)). PECS was associated with a decrease in severity scores on this domain, with children being 3.57 times (OR) more likely to be in the lower ordinal category (less severe difficulties) on the RSI scale.

Subgroup analysis and investigation of heterogeneity

We included only two studies in this review (Howlin 2007; Siller 2013), investigating different types of interventions. Thus, we were not able to conduct subgroup analyses or assess heterogeneity as we had planned (Brignell 2016); see Table 1 for methods archived for use in future updates. Both included studies provided limited information on subgroups (Howlin 2007; Siller 2013). Neither study provided the specific subgroup information prespecified in our protocol (Brignell 2016); however, one study provided information that was related to baseline language capability (Siller 2013). In this study, authors conducted exploratory moderator analyses to assess whether the baseline characteristics of the children modified

treatment gains. They found that baseline measures of expressive language moderated effects on residual gain scores in expressive language (t (df = 57) = −2.47, P < 0.05). For 24 children with expressive language below a 11.3-month level at baseline, effect size estimates indicated a medium-to-large effect: f^2 = 0.25 (range 0.09 to 0.36). We have reported analyses conducted by the study authors as we did not have the data required to see if the CI overlapped.

Quality of the evidence

Overall, based on the GRADE criteria (GRADE 2004), we rated the quality of the evidence for all reported outcomes as very low. For one study, Siller 2013, we downgraded the quality of the evidence by one level for risk of bias (rated at unclear or high risk of bias on 4/7 domains) and by two levels for imprecision due to small sample size and because there was only one trial for comparison (see Summary of findings for the main comparison). For the other study, Howlin 2007, we downgraded the quality of the evidence by one level for risk of bias (rated at unclear or high risk of bias on 4/7 domains) and by two levels for imprecision due to small sample size, wide CIs, and because there was only one trial for comparison (see Summary of findings 2).

D I S C U S S I O N

Summary of main results

We identified and included in this review two studies (N = 154) that met our inclusion criteria (Howlin 2007; Siller 2013). We were not able to pool the data from these studies in a meta-analysis because they used different types of communication interventions. One study assessed a verbally based intervention (FPI) versus a control group that involved parent training (Siller 2013), whereas the other study assessed an AAC intervention (PECS) administered by teachers versus a control group (Howlin 2007).

The study that examined a verbally based intervention (FPI) versus a control group, Siller 2013, found no significant effect for the intervention group on spoken communication (assessed with expressive language age-equivalent scores). However, a further exploratory analysis found that children with relatively lower expressive language ability at baseline (specifically, less than 11.3 months age-equivalent) benefited more from the intervention than children with better expressive language at baseline. The authors concluded that parents of children with relatively better language may require additional strategies to FPI.

The other study that assessed an AAC intervention (PECS) versus a control group, Howlin 2007, found that children in the PECS group were significantly more likely to use verbal communicative initiations and PECS symbols more frequently immediately postintervention. However, this effect was not maintained for either of these two outcomes at the follow-up assessment 10 months later. This study did not find a significant effect of PECS for frequency of speech or for expressive and receptive vocabulary based on standardised tools (Howlin 2007). Of interest, the study found no effect for the secondary outcomes of communication and RSI ADOS scores immediately postintervention; however, PECS was associated with a decrease in RSI severity score (i.e. less severe deficits in RSI skills) at the 10-month follow-up point.

Neither study found an effect on the primary outcome that was maintained over time, and neither study provided information on

adverse effects of interventions. It was possible there was some contamination in one of the included studies (Howlin 2007), as some teachers designated to the control group may still have been using some PECS, as it was not a requirement that PECS use be ceased for the control group. Furthermore, children in the control group in the Siller 2013 study may also have been accessing treatments in the community. This may have impacted the strength of the findings in each study and should be considered when interpreting our results.

The findings from Siller 2013 on moderators of interventions raises important questions around variation in treatment response. Given the substantial heterogeneity in ASD and wide range of underpinning factors that may be at play in preventing a child from talking, it is not surprising that children respond differently to different interventions (see Hudry 2017, Trembath 2014 and Vivanti 2014 for further discussion around predictors of treatment response). One approach that may facilitate a better understanding of who responds better to which intervention is to compare two interventions and investigate child factors that may moderate outcomes from each one. This approach has been used in several studies of children with ASD who are minimally verbal (e.g. Paul 2013; Yoder 2006b), and these studies have identified factors that may be important in predicting a child's response to different interventions. For example, Paul 2013 found that children with a receptive language age-equivalent below 18 months were more likely to do better with the Rapid Motor Imitation Antecedent training, whereas those scoring above 18 months were more likely to do better with Milieu Communication Training. Furthermore, Yoder 2006b found that Responsive Education and Prelinguistic Milieu Teaching increased the frequency of generalised turn-taking and generalised initiating joint attention more than PECS, but that the increase in generalising joint attention only occurred for children who had at least some initiating joint attention at baseline. PECS, however, increased the children's ability to make generalised requests more than Responsive Education and Prelinguistic Milieu Teaching for those children who had limited ability to initiate joint attention at baseline. Our understanding of who responds to what type of intervention is still in its infancy, but studies such as these have the potential to help us to move further toward personalising currently available interventions.

We identified two studies that compared interventions to control groups; however, it is important to note that there are 10 other trials focused on communication interventions for minimally verbal children with ASD that compared two different interventions (rather than using a control group). These studies make contributions to the literature, but we excluded them based on our study protocol (Brignell 2016), in which we specified that we would only include studies that compared an intervention to a control. We could not include these studies in the data analysis for our review, but several showed positive results (e.g. Goods 2013; Kasari 2014; Paul 2013; Yoder 1988), providing some indirect evidence for interventions in minimally verbal children with ASD. Such studies help us to parse the heterogeneity in the minimally verbal population with ASD by showing that, while different treatments may not be effective for all children in this population, they may improve expressive language in certain subgroups. At the highest level, however, these studies suggest that expressive language can at least be improved in some minimally verbal children with ASD and point the way to future work to more carefully identify the baseline characteristics of children who may

respond to one or another therapy. We have provided detail on these studies in this review because we recognise their value to the field of interventions in minimally verbal children with ASD (see Table 2).

Overall completeness and applicability of evidence

This review provides up-to-date evidence on communication interventions for children with ASD who are minimally verbal. We identified only two studies with a total of 154 participants. One study was conducted at the children's homes, the other at school, and both studies had good applicability. We found data extraction and analysis difficult because of the absence of a uniform tool for outcome measurement, as well as the non-standardised design in one study (cluster-RCT with multiple groups). Moreover, we were unable to examine some important outcomes, such as adverse events and functional communication skills. No studies that employed comprehensive or combined interventions met our inclusion criteria, so we were unable to draw any conclusions about the evidence for these interventions. Overall, we conclude that the completeness of current evidence is low. Across all outcomes, available data are insufficient to show whether verbally based or AAC interventions (specifically PECS and FPI) are effective at increasing verbal or augmentative communication skills in minimally verbal children with ASD.

Quality of the evidence

Using the GRADE approach (GRADE 2004), we considered the overall quality of the evidence to be very low. We downgraded all outcomes by at least two points due to imprecision (only two trials identified, both of which had small sample sizes) and inconsistency (large CIs). The studies did not always report sufficient detail to allow assessment of risk bias.

Potential biases in the review process

We did not note any obvious biases in this review. To minimise bias, two review authors independently screened the records, extracted data, and assessed the risk of bias and quality of evidence. With the exception of one study that could not be classified due to lack of detail around inclusion criteria (Characteristics of studies awaiting classification), we included all studies that met our inclusion criteria (Criteria for considering studies for this review). A limitation of this review is that we did not include studies that included treatment-to-treatment comparisons. These studies make up most intervention trials for children who are minimally verbal. However, we followed our prior, published protocol of this review (Brignell 2016), and we have reported details of the treatment-to-treatment comparison trials in a separate table (see Table 2).

Agreements and disagreements with other studies or reviews

We did not identify any other studies or reviews.

AUTHORS' CONCLUSIONS

Implications for practice

This review identified two RCTs that used a communication intervention in minimally verbal children with ASD and included a control group. There was limited evidence that communication interventions (AAC and verbally based) improve aspects of communication for minimally verbal children with ASD. In the study

that used an AAC intervention (PECS), children in the intervention group were more likely to use verbal or non-verbal communicative initiations and PECS symbols than the control group immediately after the intervention. In the study that used a verbally based intervention, children did not make significant improvements in their expressive language as a group; however, a subgroup of children did improve. Both studies had methodological limitations, and we rated the overall quality of the evidence as very low. The search used in this review also identified 10 RCTs that compared one or more interventions in minimally verbal children with ASD but did not have a control or treatment-as-usual comparison group (Goods 2013; Gould 2015; Kasari 2014; NCT01018407; NCT01751698; Paul 2013; Sandiford 2013; Schriebman 2014; Yoder 1988; Yoder 2006b). These studies did not meet our inclusion criteria (Criteria for considering studies for this review), but they make a contribution to the literature in the field of ASD in minimally verbal children. Clinicians, families and consumers should be aware of the lack of evidence for the effectiveness of communication interventions for minimally verbal children with ASD. If they choose to use these interventions, they should carefully monitor the child's progress and adapt as indicated.

Implications for research

Our review may be viewed as having inclusion criteria that were too strict to capture the aforementioned 10 studies (Goods 2013; Gould 2015; Kasari 2014; NCT01018407; NCT01751698; Paul 2013; Sandiford 2013; Schriebman 2014; Yoder 1988; Yoder 2006b), as well as other studies that used non-RCT designs (e.g. single-case design studies). While the inclusion of these studies was beyond the scope of the current review, a systematic review of such studies that employs appropriate statistical methods for treatment-to-treatment comparisons, along with an assessment of study quality, would be desirable. Future studies that compare two interventions but also include a control group will allow us to better understand effects in the context of spontaneous maturation as well allow comparison of two interventions. Control groups can include treatment as usual or wait-list controls, and these types of groups avoid the ethical challenges around withholding intervention for

such a high-needs group. To increase sample sizes and improve the evidence base, intervention studies that include children with a range of language abilities could potentially present the results of the minimally verbal children as a separate subgroup, or studies could use subsamples of children who have genetic diagnoses (and are at greater risk for being minimally verbal).

Appropriate outcome measures that are sensitive to change are required because currently available standardised tools are not well suited to study outcomes in minimally verbal children. In addition, studies should investigate other important outcomes, such as function and participation, social communication, adaptive communication skills, quality of life and behaviour, along with primary measures of communication. Economic implications should also be evaluated. Studies will need to be creative in developing novel approaches to interventions that are closely linked to our developing understanding of the aetiology and neurobiology of ASD and related disorders, the ultimate goal being tailored interventions based on child and family characteristics, needs and strengths. This review found that most studies of minimally verbal children have focused on the preschool and early primary school years, and there is an urgent need for studies in older children who remain minimally verbal. While the literature has emphasised the importance of being able to speak before five years of age on later outcomes (e.g. Pickett 2009), we cannot assume that children over the age of five years do not make the same progress with intervention, or that interventions for younger children are appropriate and effective for older children.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Howlin 2007

Methods	**Design**: cluster-randomised-controlled trial with school as the randomisation unit (schools randomised into 3 groups: immediate treatment group (ITG), delayed treatment group (DTG), and no treatment group (NTG))
	Date of study: not stated but study published in 2007
	Duration of study:
	1. ITG: time point 1-time point 3 mean 17.9 months (SD 0.5)
	2. DTG: time point 1-time point 3 mean 14.6 months (SD 1.9)
	3. NTG: time point 1-time point 3 mean 15.3 months (SD 0.7)
	Setting: greater London and South East England, UK. A total of 17 classes with > 4 children in each class were enrolled in the study. All children were attending autism-specific classes or units. Most had child:adult ratio of 2:1. All classes followed the national curriculum. Teaching approaches differed but most took an eclectic approach utilising pictures and visuals and structured teaching.
Participants	**Sample size**: 84 (note, n = 88 after randomisation but one ITG class (n = 4) withdrew before baseline assessment)
	1. ITG: 5 classes, n = 26
	2. DTG: 6 classes, n = 30
	3. NTG: 6 classes, n = 28
	Withdrawals: 1 class withdrew after randomisation. 1 child withdrawn from NTG (failed to meet diagnostic criteria after baseline assessments done), and 1 child joined the DTG. 1 child form ITG moved away following intervention and before final assessment. 7 children moved out of DTG pre-intervention but completed final assessments.
	Sex:
	1. ITG: 21 boys, 5 girls

Howlin 2007 *(Continued)*

  2. DTG: 27 boys, 3 girls
  3. NTG: 25 boys, 3 girls

Age:

  1. ITG: mean 73.1 months (SD 15.8, range 47.3–106.3)
  2. DTG: mean 86.6 months (SD 12.7, range 62.0–113.5)
  3. NTG: mean 85.6 months (SD 13.6, range 61.0–122.1)

Inclusion criteria*:

  1. Children with a formal clinical diagnosis of autism (meets criteria for ASD on ADOS)
  2. Little or no functional language (i.e. not exceeding single words/productions)
  3. No evidence of sensory impairment
  4. Aged between 4 years and 11 years
  5. Not using PECS beyond phase 1 (i.e. can only exchange symbols with prompting)

  *Each class required minimum of 3 children meeting the above criteria

Exclusion criteria:

  1. Children without a diagnosis of ASD
  2. Children who were in a classroom where there were fewer than 3 children meeting inclusion criteria

Interventions	**Intervention**: PECS
	
	  1. ITG: 7.6 months (approximately 2 terms) of PECS training followed by a 10.4 month follow-up period
	  2. DTG: 7.5 months of no treatment/baseline followed by 7.1 months of PECS training
	
	Control: NTG; 15.3 months with no PECS training
	
	Administration: intervention and assessments occurred in the school setting. Teachers and parents received PECS training (2-day workshop or 13 h) followed by consultation. The active intervention period began about 1 week after training. PECS consultants conducted 6 half-day consultations with each class once per month over 5 months. The consultants recommended and demonstrated strategies to improve children's use of PECS in the classroom, monitored teachers' progress and provided systematic feedback on implementation of PECS. Note, classroom teachers were not completely naïve to PECS, but generally the use of this was minimal and limited to phase I scaffolded requesting.

Outcomes	**Primary outcomes**
	
	Researchers videotaped daily snack session for maximum of 15 min. Three variables were coded:
	
	  1. Frequency of child communicative initiations
	  2. Frequency of use of PECS symbols
	  3. Frequency of speech (including non-word vocalisations); frequencies expressed as rates per minute
	
	Secondary outcomes
	
	These included standardised measures: Expressive One Word Picture Vocabulary Test, British Picture Vocabulary Scales completed 3 times through the study. The Communication and Reciprocal Social Interaction Domain scores of the ADOS-G were also used.
	
	Timing of outcome measurement: children were filmed/assessed at baseline, after the end of the first intervention period, and after the end of the second intervention period

Notes	**Comment**: none **Funding source**: supported by the Three Guineas Trust. Pyramid UK also supported the project (by providing the PECS consultants). It is unclear if these consultants were paid.

Howlin 2007 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	**Comment**: 15/18 class groups excluded due to fewer than 3 eligible children in the same classroom. Classes were stratified according to size. In each stratum, classes were randomly allocated to 1 of the 3 conditions using an online randomisation programme (www.random.org).
Allocation concealment (selection bias)	Unclear risk	**Comment**: study does not mention how allocation was performed
Blinding of participants and personnel (performance bias) All outcomes	High risk	**Comment**: participants and personnel were aware of allocation. It is not possible to perform blinding as placebo not possible for this type of trial **Quote**: "Because of financial and personnel limitations… assessors (and videotape coders, see below) were not blind to group assignment" (p 476)
Blinding of outcome assessment (detection bias) All outcomes	High risk	**Comment**: staff conducting assessments or coding (or both) were not blinded to group assignment. See directly above.
Incomplete outcome data (attrition bias) All outcomes	Low risk	**Comment**: 1 child from the immediate treatment group moved away after the trial started, and 7 children in the delayed treatment group moved out of classes prior to the intervention starting. Analyses were conducted on an intention-to-treat basis. Did not compare those who dropped out to those who remained in terms of characteristics
Selective reporting (reporting bias)	Low risk	**Comment**: all measures reported in the published trial protocol were reported in the Results section. Does not state whether adverse outcomes were collected in protocol or paper
Other bias	Unclear risk	**Comment**: PECS may have been used to some extent in the control group. Also, there may be bias due to the cluster-randomised control design of the study; however, the extent of this bias is unclear (see Risk of bias in included studies for more details). **Quote**: "it was not possible to collect ongoing measures of treatment fidelity… [but] this is of less importance for pragmatic effectiveness studies than for efficacy studies." (p 479)

Siller 2013

Methods	**Design**: randomised controlled/clinical trial
	Date of study: data collected between 2004 and 2007
	Duration of study:
	1. intervention: mean 147 days (SD 41, range 91–279)
	2. control: mean 141 days (SD 43, range: 78–255)
	Follow-up assessment scheduled approximately 12 months after exit (mean 13.9 months (SD 4.7, range 9–32))
	Setting: Los Angeles, California
Participants	**Sample size**: 70 (36 intervention, 34 control)

Siller 2013 *(Continued)*

Withdrawals:

1. Intervention: 2/36 dropped out prior to exit assessment and 3/36 dropped out prior to follow-up
2. Control: 1/34 dropped out prior to exit assessment and 2/34 dropped out prior to follow-up

Sex: 64 boys, 6 girls

Age:

1. intervention: mean 58.3 months (SD 12.7)
2. control: mean 55.9 (SD 11.9)

Inclusion criteria:

1. Children with ASD aged 6 years and younger
2. Limited or no use of spoken language (generally fewer than 25 words and no phrases)
3. Mother fluent in English and within 90-min driving distance to lab
4. Previously diagnosed ASD and confirmed in study using ADI-R and ADOS-G. All children met criteria for autistic disorder on ADI-R, whereas 64 met criteria for autistic disorder on the ADOS, and 5 were classified as having autism spectrum disorder on the ADOS-G. One child did not complete the ADOS.

Exclusion criteria: not stated

Interventions	**Intervention**: focused playtime intervention (FPI). FPI is capacity building approach that promotes co-ordinated toy play between the parent and child. There is an ordered sequence of 8 topics. Both parent and clinician are involved in the first half of the session, then only parent in second half (further details are provided in the report). Participants received 12 in-home training sessions lasting 90 min per session for 12 weeks. They were also invited to attend parent advocacy coaching sessions. **Control group**: invited to attend parent advocacy coaching sessions **Administration**: 3 assessments conducted; 2 in UCLA lab and 1 at home. Information was collected on the non-project services and school programmes attended by intervention and control groups: 12 months before study, between intake and exit, and between exit and follow-up. No significant differences were found between groups.
Outcomes	**Primary outcomes** 1. Maternal synchronisation (percentage of verbal behaviours that were synchronised with both children's attention and action, divided by the percentage of time children attended to toys) 2. Mullen Scale of Early Learning expressive language age equivalent (log (2) transformed) **Timing of outcome measurement**: measures collected at baseline, after 12-week intervention and 12 months after completion of intervention
Notes	**Comment**: none **Funding source**: study was supported by CPEA grant (HD35470) from the National Institute of Child Health and Human Development, the MIND Institute Research Program, and a PSC-CUNY grant

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	**Comment**: children were randomised in clusters of 4 to ensure groups had equal numbers; however, the method is not described
Allocation concealment (selection bias)	Unclear risk	**Comment**: study does not mention how allocation was performed

Siller 2013 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	**Comment**: participants and personnel were aware of allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	**Comment**: staff conducting assessments or coding (or both) were blinded to group assignment, and prior to all outcome assessment sessions, parents were reminded not to reveal their group assignment to the assessment staff
Incomplete outcome data (attrition bias) All outcomes	Low risk	**Comment**: some participants dropped out (3 intervention, 2 control). Analyses were conducted on an intention-to-treat basis. Multiple imputation analysis done to take into account missing data or those lost to follow-up. Statistical analysis comparing those lost to follow-up to those who remained found that participants who dropped out of the study took longer to complete the intervention period and received fewer autism-specific, non-project services in the community, on average. These differences were then corrected for statistically.
Selective reporting (reporting bias)	Low risk	**Comment**: all measures reported in the published trial protocol were reported in the Results section; however, it does not state whether adverse outcomes were collected in protocol or paper
Other bias	Unclear risk	**Comment**: did not report on any other possible interventions that may have been received by control group (e.g. through the community)

ADI-R: Autism Diagnostic Interview-Revised; **ADOS**: Autism Diagnostic Observtion Schedule; **ADOS-G**: Autism Diagnostic Observtion Schedule- Generic;
ASD: autism spectrum disorder; **CPEA**: Clinical and Patient Educators Association; **PSC-CUNY**: Professional Staff Congress-City University of New York; **PECS**: Picture Exchange Communication System; **SD**: standard deviation; **UCLA**: University of California, Los Angeles.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Aldred 2004	Not minimally verbal. Most children > 50 words on CDI. 8 children in each group described as "high-functioning"
Casenhiser 2013	Not minimally verbal. Mean PLS expressive language age = 24.5 months (SD = 12.7) in intervention group and 24.7 months (SD = 12.6) in control group. Mean length of utterance = 1.3 (SD = 0.5)
Chang 2016	Not minimally verbal
D'Elia 2014	Not an RCT
Drew 2002	Not a communication-focused intervention. Broader training programme. Young cohort. Age: 21–23 months. 22/24 were non-verbal, others used single words. CDI mean number of words produced = 6.8 (SD 20.9) in intervention group and 6.6 (SD 13.7) in control group
Elder 2011	Not minimally verbal. Mean number of intelligible words = 40.9 at baseline
Field 2001	Focused specifically on imitation rather than being a communication intervention
Fletcher-Watson 2013	Not minimally verbal. Mean number of words = 142 at baseline
Flores 2014	Not minimally verbal. Some children spoke in sentences

Study	Reason for exclusion
Fteiha 2017	Not minimally verbal: "mild degree of autism". A proportion of sample have > 19 words
Goods 2013	No control group. Treatment comparison (30 hours ABA ± JASPER)
Gould 2015	No control group. Treatment comparison (JASPER vs DTT)
Hardan 2015	Not minimally verbal. Minimally verbal was not a required inclusion criteria. Mean number words produced on CDI at baseline = 137.1 (SD 118.1) and 169.5 (SD 134.2)
Ingersol 2012	Not a language outcome. JA and social-emotional functioning outcomes. Not minimally verbal. Mean PLS expressive language age = 17.3 months (SD 5.5, range 9–23 months); NVMA = 20.8 months (SD 6.6, range 8–30 months)
Jalili 2014	Not an RCT. Groups homogenised based on CARS scores
Jemison Pollard 2010	Intervention was not language focused. Study used a music intervention that aimed to improve social skills
Kaale 2014	Not minimally verbal. Mean RDLS expressive language age = 18.8 months (SD 10.5) in intervention group and 24.9 months (SD 12.8) in control group. Minimally verbal was not an inclusion criteria
Kaiser 2013	Not minimally verbal. Mean length of utterance = 1.4 units (units include the total number of words and morphemes per utterance)
Kasari 2006	Not minimally verbal. Mean MSEL expressive language age = 20.6 months (SD 6.51) in JA group, 21.43 months (SD 7.59) in SP group, and 19.41 months (SD = 7.70) in control group
Kasari 2014	No control group. Treatment comparison (JASPER ± SGD)
Kasari 2015	No control group. Treatment comparison (JASPER vs PEI). Mean MSEL expressive language age = 14.09 months (SD 6.84) in JASPER group and 14.98 months (SD 7.02) in PEI group. Minimally verbal was not an inclusion criteria
Landa 2011	No control group. Treatment comparison (intervention given to both groups ± IS intervention). Mean MSEL expressive language T score = 23.92 (SD 5.50) for IS group and 25.92 (SD = 8.12) in non-IS group. Expressive language change was a secondary outcome. Minimally verbal was not an inclusion criteria
Mandell 2013	Not an RCT. Treatment comparison (STAR vs structured teaching)
Martins 2013	Did not use required ASD diagnostic criteria
NCT01018407	No control group. Treatment comparison (DTT vs interpersonal developmental approach)
NCT01751698	No control group. Treatment comparison (DTT vs JASP-EMT)
Oosterling 2010	Not minimally verbal. CDI mean number of "words said" = 106.8 (SD 122) in intervention group and 101.7 (SD 110) in control group
Paul 2013	No control group. Treatment comparison (RMIA vs MCT)
Pickles 2016	Not minimally verbal. 64% were assessed using ADOS modules 2 & 3 (i.e. using > single words)
Reitzel 2013	Not minimally verbal. Mean MSEL expressive language age = 16 months (SD 8) in intervention group and 21.5 (SD 9.2) in control group. Mean visual reception score on MSEL = 29.0 (SD 9.2) in intervention group and 22.4 (SD 8.2) in control group. Mean ratio IQ = 42.5 (SD 12.0) in intervention group

Study	Reason for exclusion
	and 31.1 (SD 10.6) in control group. Used standard scores on communication subscale of VABS for outcomes
Roberts 2011	Not minimally verbal
Rogers 2006	Not an RCT. Single-subject design. Treatment comparison (Denver Model vs PROMPT)
Romski 2010	Not all ASD. Sample included minimally verbal children without ASD (e.g. Down Syndrome and cerebral palsy)
Sallows 2005	Not an RCT
Sandiford 2013	No control group. Treatment comparison (melodic intonation therapy vs traditional speech therapy)
Schriebman 2014	No control group. Treatment comparison (PECS vs pivotal response training)
Schroder 2015	Not an RCT
Serret 2017	Not an RCT
Simpson 2013	Did not use required ASD diagnostic criteria
Smith 2000	Did not use required ASD diagnostic criteria
Solomon 2014	Not minimally verbal. CDI mean number words produced = 76 (SD 54) for intervention group and 78 (SD 70) for control group
Stock 2013	Not an RCT
Sweeney 2016	Not an RCT
Tonge 2014	Not a communication-focused intervention. Broader parent education programs. PEAC, PEBM, control group
Venker 2012	Not minimally verbal. CDI mean number words produced = 108.2 (SD 151, range 0–385)
Vernay 2017	Not an RCT
Wetherby 2014	Not a communication-focused intervention but targeted a range of skills, including autism symptoms. Does not specify minimally verbal. Very young (16–20 months old) children diagnosed with ASD. MSEL T scores = 29.61 (SD 11.22) for individual and 28.68 (SD 10.95) for group intervention. No control group. Compared 2 modes of intervention: individual vs group ESI using the SCERTS curriculum
Whelan 2010	Not a communication-focused intervention. Broader intervention. NVMA < 24 months and child using computer programme for a significant proportion of intervention
Wong 2010	Not a language-focused intervention. Aim of study was focused on preverbal skills. Lower range for NVMA < 12 months. Minimally verbal not an inclusion criteria although children do appear to be minimally verbal based on text
Yoder 1988	No control group. Treatment comparison (4 interventions: sign alone, speech alone, simultaneous, alternating)
Yoder 2006b	No control group. Treatment comparison (RPMT vs PECS)

Study	Reason for exclusion
Zeina 2015	Not an RCT. Three comparison groups based on IQ level

ABA: applied behaviour analysis; **ADOS**: Autism Diagnostic Observation Schedule; **ASD**: autism spectrum disorder; **CARS**: Childhood Autism Rating Scale; **CDI**: Communicative Development Inventory; **DTT**: Discrete Trial Training; **ESI**: Early Social Interation project; **IQ**: intelligence quotient; **IS**: interpersonal synchrony; **JA**: joint attention; **JASPER**: Joint Attention, Symbolic Play, Engagement and Regulation; **JASP-EMT**: Joint Attention, Symbolic Play and Enhanced Milieu Teaching; **MCT**: Milieu Communication Training; **MLU**: mean length of utterance; **MSEL**: Mullen Scales of Early Learning; **NVMA**: nonverbal mental age; **PEAC**: Partnerships between Education and Autism Communities; **PEBM**: Parent Education and Behaviour Management; **PECS**: Picture Exchange Communication System; **PEI**: psychoeducational intervention; **PLS**: Preschool Language Scale; **PROMPT**: Prompts for Restructuring Oral Muscular Phonetics Targets; **RCT**: randomised controlled trial; **RDLS**: Reynell Developmental Language Scales; **RMIA**: Rapid Motor Imitation Antecedent training; **RPMT**: Responsive Education and Prelinguistic Mileu Teaching; **SCERTS**: Social Communication, Emotional Regulation Transactional Support; **SD**: standard deviation; **SGD**: speech generating device; **SP**: symbolic play; **STAR**: Strategies for Teaching based on Autism Research; **VABS**: Vineland Adaptive Behaviour Scales.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Gilbert 2012

Methods	**Design**: group design with randomised treatment and wait-list control
	Date of study: 2012
	Duration of study: not stated. 32 weeks of intervention then follow-up
	Setting: Hofstra University, Hempstead, USA
Participants	**Sample size**: not stated
	Withdrawals: not stated
	Sex: not stated
	Mean age: 6 years 10 months
	Inclusion criteria
	1. Fewer than 10 spontaneous words
	2. Limited reciprocity, gesture, eye contact, and joint attention
	Exclusion criteria: not stated
Interventions	**Intervention**: Milieu Communication Treatment
	Control: age- and ability-matched wait-list control group
	Administration: not stated
	Duration: 32 weeks
Outcomes	**Outcomes**: detailed outcome measures not provided. Authors state they measured individual differences on specified pre-linguistic behaviours
Notes	**Comment**: This is an abstract from conference proceedings. The study appears to be eligible for inclusion but we could only extract limited detail from the abstract. We contacted the authors but were unable to obtain the necessary detail to classify the study as included or excluded.
	Funding source: not stated

ASD: autism spectrum disorder.

Characteristics of ongoing studies *[ordered by study ID]*

NCT02291172

Trial name or title	**Public title**: Comprehensive communication intervention for minimally verbal children with autism
	Official title: Comprehensive communication intervention for minimally verbal children with autism
Methods	**Design**: randomised, single-group assignment
	Duration of study: 4 months
	Setting: Nashville, Tennessee, USA
Participants	**Sample size**: 74 enrolled
	Sex: male and female children eligible for inclusion
	Age: range 36 months to 54 months
	Inclusion criteria:
	1. Diagnosis of ASD as confirmed by the ADOS
	2. Mental age of 18 months (measured on the Mullen Scales of Early Learning)
	3. Expressive vocabulary < 10 words
	4. Age 36–54 months
	5. English as primary language spoken at home
	6. Parents willing to participate in parent training
	Exclusion criteria:
	1. Major medical conditions other than ASD (i.e. genetic disorders such as Down syndrome)
	2. Sensory disabilities (blindness or deafness)
	3. Motor disabilities (e.g. cerebral palsy)
Interventions	**Intervention**: a blend of JASP + EMT using SGDs with parent training intervention with the addition of individualised DTT to teach receptive language, imitation, and joint attention when children lack these skills at entry
	Control: business as usual
	Administration: this is a 3-month (42 session) intervention. Children will be assessed at 4 time points: preintervention, postintervention, 2 months postintervention, and 4 months postintervention.
Outcomes	**Primary outcome**: spontaneous communicative utterances (time frame: 12 weeks), measured from a naturalistic language sample
Starting date	September 2014
	Status: recruitment completed
Contact information	**Name**: Ann Kaiser
	Position: Susan W Gray Professor of Education and Human Development
	Address: Department of Special Education, Vanderbilt University
Notes	**Comment**: further detail available at clinicaltrials.gov/show/NCT02291172

NCT02464527

Trial name or title	**Public title**: Stimulus-stimulus pairing study (SSP) **Official title**: A pilot feasibility study to increase vocal language in minimally verbal children diagnosed with autism spectrum disorders
Methods	**Design**: randomised, parallel assignment **Duration of study**: 6–12 weeks (intervention 6 weeks, control (wait-list) wait 6 weeks and then receive the 6-week intervention) **Setting**: Emory University
Participants	**Sample size**: 16 enrolled **Sex**: male and female children eligible for inclusion **Age**: range 24 months to 47 months **Inclusion criteria**: 1. diagnosis of autism 2. currently do not emit vocalisations or minimally verbal 3. aged 24–47 months 4. willingness of the participant's parent/guardian to bring their child to the Marcus Autism Center for 1-h appointments, 5 days a week, for 6 weeks **Exclusion criteria**: children with significant problem behaviour that interferes with structured intervention
Interventions	**Intervention**: SSP, consisting of sounds and words being systematically paired with delivery of a preferred item **Control**: wait-list control **Administration**: participants in the SSP l attend clinic-based sessions for 1 h per day, 5 days per week, for 6 weeks. The SSP procedure will consist of sounds and words being systematically paired with delivery of a preferred item. The participants will be recorded by a vocal recorder by the parent/guardian at home or in the community.The wait-list control group will wait for 6 weeks; children will not receive any treatment during this period. The wait-list control group will then receive the SSP procedure (delayed procedure) after the 6-week wait.
Outcomes	**Primary outcomes** 1. Change in frequency of target vocalisations or approximations (or both) at home (time frame: week 1, week 6). Vocalisation data will be collected in the home via the vocal recorder device. Target vocalisation is when the participant emits the target sound or word. Change is defined as the difference in the number of vocalisations at week 1 and week 6. 2. Change in parent-reported vocalisations (time frame: week 1, week 6). A parent-rated checklist will assess their child's vocal language, and parents will rate improvement as a yes or no question on the checklist at week 1 and week 6. 3. Feasibility of intervention assessed by reliability of delivery by therapists (time frame: week 6). The number of times SSP is reliably delivered by the therapist to the participant during the intervention period of 6 weeks will be assessed. Reliable delivery consists of the therapist pairing sounds and words with preferred items in accordance to the protocol.

NCT02464527 *(Continued)*

4. Acceptability of SSP by parents (time frame: week 6). The level of compliance and willingness of the parents/guardian to bring the participants to the sessions will be assessed. Acceptability is when the parent/guardian brings the participant to the clinic for the sessions for 1 h a day, 5 days per week, for 6 weeks

Starting date	June 2014
	Status: recruitment completed
Contact information	**Name**: Alice Shillingsburg
	Position: Assistant Professor
	Address: Emory University
Notes	**Comment**: further detail available at clinicaltrials.gov/show/NCT02464527
	Funding source: Emory University

ADOS: Autism Diagnostic Observation Schedule; **ASD**: autism spectrum disorder; **DTT**: discrete trial training; **JASP + EMT**: Joint Attention, Symbolic Play, Engagement and Enhanced Milieu Teaching; **SGD**: speech generating device; **SSP**: stimulus-stimulus pairing.

ADDITIONAL TABLES

Table 1. Unused methods

Method	Approach
Types of outcomes	We will synthesise results for the following time points: at the end of intervention, one year after the end of intervention, and after more than one year of follow-up.
Measures of treatment effects	**Dichotomous data**
	If a study only presents data for the change from baseline to follow-up in the published report, we will contact the corresponding author of the study to obtain data at each time point.
	Multiple outcomes
	If included studies provide multiple, interchangeable measures of the same construct at the same time point, we will calculate the average SMD across the outcomes and the average estimated variances for continuous variables; for dichotomous measures, we will choose only the most reliable measure based on the authors' statement or our judgement (e.g. measures from the most commonly used scales). If included studies report the same outcomes (measured by the same scale/tool) differently (e.g. as a dichotomous variable in one study but as a continuous variable in another), we will attempt to transform them to uniform variables using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017). In case a well-established cut-off point exists, we will transform continuous data to dichotomous data. Otherwise, we will require detailed information from the study authors when they reported dichotomous results. Alternatively, we will use the SMD (or log odds ratios) and their standard errors to combine dichotomous and continuous data, when possible, using the generic inverse variance method in Review Manager 5 (RevMan 5; ReMan 2014). If we are unable to transform the variables (e.g. the study authors do not reply to our request) or to combine them appropriately, we will conduct separate analyses on the variables with different formats.
Unit of analysis issues	**Cluster-randomised trials**
	We will include cluster-RCTs along with individual-RCTs in the analysis. We will assess cluster-RCTs carefully (in terms of recruitment bias, baseline imbalance, loss of clusters and comparability with individually RCTs) for potential unit-of-analysis errors. If it is unclear whether or not an included

Table 1. Unused methods *(Continued)*

study applied proper controls for clustering, we will contact the corresponding author for further details. If the study does not use appropriate controls, we will request individual participant data from the study authors and reanalyse the data using appropriate multilevel models. We will perform the analyses according to the approach described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will analyse effect sizes and standard errors using the generic inverse method in RevMan 5 (ReMan 2014). To adjust for clustering (reducing the size of effect of each clustered trial to its 'effective sample size'), we will use an estimate of the intracluster correlation coefficient (ICC) extracted from the trial, as described in Higgins 2011. Where we can derive ICCs from other sources, we will state this clearly in the Results section and we will conduct a sensitivity analysis to investigate the effects of variation in the ICC (see 'Sensitivity analysis' section below).

Studies with multiple intervention arms

If a single included trial reports multiple intervention arms, we will only include the relevant arms. If more than one intervention arm is relevant to our review, we will first estimate if they are sufficiently similar to be combined. For instance, arms with the same intervention but different frequency of application, or arms with essentially the same intervention but with minor modifications in each group, can be treated as a whole intervention group. If so, we will combine all eligible intervention groups and compare them with the combined results of eligible control groups, thus making single, pair-wise comparisons. Where two comparisons (e.g. intervention A versus control and intervention B versus control) are required to be entered into the same meta-analysis separately, we will halve the number of participants in the control group to avoid double counting the participants.

Dealing with missing data	For studies with missing data due to loss of follow-up/attrition, we will conduct analyses using the intention-to-treat (ITT) approach. We will impute the outcomes for the missing participants using both a 'best-case' and 'worst case' scenario for dichotomous data. In the case that the missing data are continuous variables (i.e. no mean or standard deviation (SD) reported), we will attempt to calculate them using the standard errors, confidence intervals (CI) and t values, according to the methods described in Higgins 2011. If we are unable to retrieve or derive the missing data, we will describe the missing data for each trial included in the review in the 'Risk of bias' tables (beneath the 'Characteristics of included studies' tables); and if the proportion is large (greater than 20%), we will consider downgrading the quality level of the body of evidence. We will discuss the extent to which missing data can affect the results and mention it in the Authors' conclusions section. We will conduct a sensitivity analysis to explore the impact of including studies with high levels of missing data in the overall assessment of effect (see 'Sensitivity analysis' section below), using the strategy described in Deeks 2017.
Assessment of heterogeneity	We will perform tests for heterogeneity using the Chi^2 test, to assess whether observed differences in results are compatible with chance alone. Furthermore, we will use the I^2 statistic to quantify inconsistency across studies. We will define the presence of heterogeneity by a P value of less than 0.10 from the Chi^2 test and an I^2 statistic value of greater than 50%, as described in Deeks 2017. We are aware that, in the case of small sample size or few included studies, a non-significant result of heterogeneity analyses must not be taken as evidence of no heterogeneity. We will explore possible sources of heterogeneity by subgroup analysis and investigation of heterogeneity (see 'Subgroup analysis and investigation of heterogeneity' section below) and sensitivity analysis (see 'Sensitivity analysis' section below).
Assessment of reporting bias	Where we are able to pool outcome data from 10 trials or more, we will draw a funnel plot (intervention effect estimate versus standard error of intervention effect estimate), to examine the possibility of reporting bias. If we find funnel plot asymmetry, we will further investigate clinical heterogeneity of studies as a possible explanation. We will use the 'contour-enhanced' funnel plot (Peters 2008), to distinguish asymmetry due to publication bias from that due to other factors; asymmetry is more likely caused by factors other than by publication bias when the supposed missing studies are in areas of higher statistical significance.
Data synthesis	We will use RevMan 5 to pool all eligible trials that apply communication interventions on minimally verbal children compared to no intervention or usual treatment (ReMan 2014). In the primary analyses, we will pool data from all types of interventions together. Given that we expected to find

Table 1. Unused methods *(Continued)*

	substantial clinical heterogeneity — the included interventions will have been designed according to different theories and approaches — we will pool the available data using a random-effects model, weighted by the inverse of the variance estimate, as described in Deeks 2017. We will report the estimate of the between-study variance in a random-effects meta-analysis (known as Tau^2). We will conduct separate analyses for different types of interventions using subgroup analyses (see 'Subgroup analysis and investigation of heterogeneity' section directly below).
Subgroup analysis and investigation of heterogeneity	We will use the approach developed by Borenstein 2008, to formally investigate differences between two or more subgroups. This method conducts a standard test for heterogeneity across subgroup results rather than across individual study results, and has been implemented in RevMan 5 (ReMan 2014). If we identify a small number of studies or small sample sizes (or both), we will use caution when we interpret the subgroup analyses and will discuss the limitations of the findings (e.g. potential for confounding) to avoid over-interpretation of the results. For ethical reasons, most intervention studies in the field of ASD do not conduct RCTs using a 'true' control group (i.e. one group that receives an intervention and the other receives no intervention at all). Most studies use a treatment as usual (TAU) control group. TAU means the children may be receiving a range of interventions in the community (e.g. one session of speech pathology per week), but these interventions are not an intervention arm in the randomised controlled trial. We will discuss the limitations of interpreting data when a study has used TAU control groups. We will examine the following data presented in the included studies by conducting subgroup analyses. 1. Age: preschool (aged under five years with more than two years mental age) versus school-aged children (aged 6 to 12 years with more than 2 years mental age) 2. Baseline language capability: children with ASD who have different language levels at baseline (totally non-verbal versus 1 to 10 functional words; non-verbal versus 10 to 20 functional words) 3. Type of intervention: verbally based interventions, AAC interventions, combined interventions, comprehensive interventions with a communication focus 4. Duration of intervention: number of weeks 5. Dose of intervention: number of hours per week
Sensitivity analysis	We will perform sensitivity analyses to assess the impact of each of the following on the effect estimate. 1. Performance of missing data imputation based on a 'best-case' or 'worst case' scenario assumption of missing data 2. Exclusion of unpublished studies 3. Exclusion of studies at high risk or unclear risk of bias (related to randomisation, blinding or attrition) 4. Exclusion of studies with high levels of missing data 5. Fixed-effect model versus a random-effects model 6. Variations in the intracluster correlation coefficient (ICC) (where we have derived ICC's from other sources)

AAC: augmentative and alternative communication interventions; **ASD**: autism spectrum disorder; **RCT**: randomised controlled trial; **SMD**: standardised mean difference; **TAU**: treatment as usual.

Communication interventions for autism spectrum disorder in minimally verbal children (Review)

Table 2.   Characteristics of excluded randomised comparison trials

Author	Study Design	Participants	Intervention type	Intervention dose/duration	Outcome measures	Outcomes	Methodological issues
Goods 2013	Pilot randomised comparison trial	15 children with autism. Mean age 4.56 years months (SD 0.85); developmental quotient 31.81. All had < 10 spontaneous functional words (parent report). All attending non-public school and receiving minimum of 30 h ABA/week	ABA only group versus JASPER + ABA	12 weeks. Both had 30 h of ABA but 1 group had substitution of JASPER for 30 min, twice a week	MSEL (development). RDLS (receptive/expressive language). Classroom observation measure (engagement states, spontaneous use of gesture in 20-min free play). ESCS (joint attention, requesting gestures). Structured Play Assessment (play types and diversity)	Significant differences and large effect sizes between groups, with the intervention group having: more play diversity (d = 0.81); less time unengaged (d = 1.63); more initiating, more requesting gestures (d = 1.51). No significant difference in initiating joint attention and requesting gestures. No significant group difference in receptive/expressive language baseline to exit	Small sample and 3 children discontinued. Measured expressive language with RDLS, which assesses a range of language skills so hard to know if vocabulary specifically improved. No traditional control group (all children were receiving intensive ABA intervention) so hard to know if maturation or true treatment effects
Gould 2015	Treatment comparison trial	65 minimally verbal (< 30 spontaneous, non-echoed words heard during entry assessments) children with ASD. Age 33–54 months. Cognitive level ≥ 12 months	DTT versus JASPER	6 months total. 4 months of sessions × 5 days a week, 1 month of sessions × 3 days a week, one month of sessions ×2 days a week. Each session was 60 min. Parent training also included	MSEL (receptive and expressive language). Main outcome measure was frequency and type of play (structured play assessment)	Changes in symbolic play types predicted improvement in receptive (b = 0.89, t (df = 60) = 2.50, P = 0.015) and expressive language (b = 0.51, t (df = 60) = 3.02, P = 0.04).	Study mainly focused on play behaviours as outcomes, although language outcomes were also collected

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| Kasari 2014 | Randomised trial: SMART design (sequential multiple assignment randomised trial) | 61 minimally verbal (< 20 spontaneous different words in 20 min) children with autism. 51 boys; 10 girls. Mean age 6.31 years. Receptive language > 24 months. Excluded those with major medical conditions, sensory or motor disability, uncontrolled seizures, proficient use of SGD. Mean Brief IQ 68.18 (SD 18.96) | JASP + EMT versus JASP +EMT+SGD | First phase: 12 weeks (24 sessions × 1 h each) for each group. SGD was used to model speech 50% of the time in the JASP + EMT + SGD group. Second phase: parents were included in the 24 sessions. For second phase, slow responders had 1 of 3 adapted interventions: intensity of JASP + EMT increased (3 h per week for 12 weeks); addition of SGD to the JASP + SGD (1 h per week for 12 weeks); or intensity of JASP + EMT + SGD increased (3 h per week for 12 weeks). Early responders continued with same phase-1 intervention | 20-min natural language sample (both verbal utterances and SGD-produced utterances were counted). Primary outcome = total number spontaneous communicative utterances (TSCU), including comments, requests and protests. Secondary outcome = total number of different word roots (TDWR) and total number of comments (TCOM) | JASP + EMT + SGD intervention group (versus starting with JASP + EMT alone) had greater TSCU at week 24 (P < 0.01). Average TSCU at week 24 for JASP + EMT + SGD = 61.9 utterances (95% CI 52.8 to 71.0) and JASP + EMT = 40.3 utterances (95% CI 32.7 to 48.0). Approximately double the rate of communicative utterance per minute at baseline. Moderate-to-large effect size (0.62). JASP + EMT + SGD group had greater TDWR (P = 0.04) and TCOM (P < 0.01) at week 24. Small-to-moderate effect sizes (0.29 for TDWR and 0.44 for TCOM). For all outcomes JASP + EMT + SGD were superior at week 12 in adaptive interventions. For adapted interventions for slow responders, beginning with JASP + EMT and adding the SGD component and intensifying the JASP + EMT + SGD intervention led to greater TSCU (42.7, 95% CI 33.2 to 52.3) than the intensifying JASP + EMT (39.6, 95% CI 28.5 to 50.7), but there was no significant difference between the groups. Overall response rate was 70% by week 12 (77.7% in JASP + EMT + SGD versus 62.2% in JASP + EMT group), which was not statistically significant. Approximately 6.5 children needed to be treated initially with the JASP + EMT + SGD rather than the JASP + EMT for 1 additional child to respond by 12 weeks. Adding in the SGD later for slow responders to JASP + EMT alone was not as effective as having the SGD at the beginning. | Only enrolled 2/3 of intervention targets. The smaller sample size may impact statistical power. No control group so hard to know if maturation or true treatment effects |

Paul 2013	Treatment comparison trial (quasi-randomised)	22 children with autistic disorder or PDD-NOS (module 1 ADOS), with < 15 spontaneous words reported by parents measured on CSBS Caregiver Questionnaire and noted during 20-min play observation and on CSBS behavioural observation. Expressive language < 18 months age-equivalent on VABS. Non-verbal mental age of at least 12 months (Mullen Visual Reception Scale). Generalised motor imitation. Excluded those with uncorrected vision or hearing disability. Mean age 4.3 years (SD 1.2) in RMIA group (6 boys, 4 girls), and 3.5 years (SD0.8) years in MCT group (11 boys, 1 girl)	RMIA versus MCT	36 x 45-min sessions over 12 weeks. Maintenance assessment occurred 3–6 months postintervention	Tager-Flusberg 2009 criteria for making progress with intervention from 1 stage to another	No significant differences between the two intervention groups on any of the outcomes at postintervention or maintenance assessments. On average, the RMIA group produced significantly more words and used more language in everyday situations postintervention than before, and maintained these gains 3 to 6 months postintervention. Similar findings for MCT group; however, significant improvement in VABS expressive language scales was not seen. RMIA group: 5/10 met Tager-Flusberg et al benchmark - VABS EL age-equivalent of > 15 months, parent report > 30 word on CDI, more than 7 different words types on CSBS play session, expression of at least 2 different communicative intentions with words and 4 different consonants used in CV syllables. All 5 children retained or exceeded these gains at maintenance assessment. MCT group: 5/12 met Tager-Flusberg et al benchmark - VABS expressive age-equivalent of > 15 months, parent report of > 20 words on CDI, more than 5 different word types on CSBS play session, expression of 2 different communicative intentions in words and 4 different consonants used in CV syllables. All 5 children retained or exceeded these levels at maintenance assessment. In a moderator analysis, children with higher joint attention scores pre-intervention improved more than children with lower joint attention scores, regardless of intervention group. Receptive language age equivalent of around 18 months was an important cut point, with those below 18 months more likely to do better with RMIA, and those scoring above 18 months more likely to do better with MCT.	No control group so hard to know if maturation or true treatment effects. Small sample size limits statistical power and strict inclusion criteria means cannot generalise to all minimally verbal children with ASD. Design not fully randomised as child allocated non-randomly to MCT group if unable to master the preintervention motor imitation skills required for the RMIA group. This may have biased findings in favour of RMIA group.

Communication interventions for autism spectrum disorder in minimally verbal children (Review)

Cochrane Database of Systematic Reviews

Table 2. Characteristics of excluded randomised comparison trials *(Continued)*

Sandiford 2013	Randomised comparison trial	12 children with autism (11 boys, 1 girl). Non-verbal (≤ 10 words used on a daily basis and no functional speech). Excluded if receiving speech therapy externally, or has severe hearing or vision impairment	MBCT versus TSLT	Both groups received 5 weeks of intervention. 4 × 45-min individual sessions were provided each week	Number of verbal attempts, number of correct words, number of words reported by the parent, and number of imitative attempts. To measure number of verbal attempts and number of correct words over time, a criterion-referenced vocabulary test was developed by the study. This was given at baseline, the beginning of each intervention week and finally, at the end of intervention	Both groups made significant progress with intervention in number of verbal attempts (P < 0.001), number of correct words (P = 0.04) and number of imitative attempts (P = 0.02) following intervention. The MBCT group progressed significantly in number of verbal attempts after weeks 1–4 and number of correct words after weeks 1 and 3. The TSLT group progressed significantly after weeks 4 and 5. No significant differences in number of verbal attempts or number of correct words between groups postintervention. A significant number of new words were heard at home for the MBCT group (P = 0.04). Children in the MBCT group had more imitative attempts (P = 0.03) relative to the TSLT group.	Small sample size, especially after some lost to attrition. Not all children completed all sessions. No follow-up assessment. No control group so hard to know if maturation or true treatment effects
Schriebman 2014	Randomised comparison trial	39 children with autism (34 boys, 5 girls). Mean age 29.7 months (SD 5.67). Had < 9 intelligible words. No prior PRT or PECS training. No evidence of primary mental retardation or major neurological or sensory impairment	PRT versus PECS	258 h of intervention (for both the PRT or PECS group). For the first 15 weeks parents participated in 2 × weekly, 2-h parent education sessions. Child received five × 2-h sessions/week at home	Spoken language (MSEL: Expressive Language Scale). Spoken vocabulary (EOWVT and the MacArthur Bates Communicative Developmental Inventories). Adaptive communication (Vineland Adaptive Behaviour	For each measure, a main effect of time indicated improvement in spoken language, adaptive communication, and spoken vocabulary. When collapsed across conditions, gains on the measures from pre- to postintervention to follow-up were statistically significant. In many cases, effect sizes were quite large, especially for vocabulary. There was no main effect of intervention type found on any measure. 12/19 children in the PECS group reached stage 6 PECS, 2 reached stage 5, 2 reached stage 3, and 1 reached stage 2.	No control group so hard to know if maturation or true treatment effects. No maintenance/follow-up assessment. A significant proportion of children were at basal on EOWVT tool. Some of the coders were not blinded to

Table 2.   Characteristics of excluded randomised comparison trials *(Continued)*

				Scales). AAC (phase of PECS; score of 1–6). Parent satisfaction (survey)			child's intervention assignment
Yoder 1988	Randomised comparison trial with 4 different interventions	60 children with (moderate to severe) autism. ≤ 25 word vocabulary (established by parent questionnaire). Expressive/receptive ages ≤ 28 months on SICD tool, hearing and vision WNL. Mean age 5.0–5.6 years. Mean NVIQ 40.5–44.4	4 interventions were compared: speech alone, sign alone, simultaneous presentation of sign and speech, and alternating presentation of sign and speech	Language training: 90 individual sessions daily for 40 min	Total number of different child-initiated spoken words observed during the 40-min training sessions. Words had to be initiated by child and used for an intentional purpose. Could not be echolalia or imitated directly from adult	There was a significant effect after controlling for verbal imitation level (P < 0.05). Children in the sign-alone group (mean 0.78 (SD 0.62)) used significantly fewer spontaneous words than the other 3 groups (Scheffd's D = 0.39, P = 0.01). The effects of speech alone (mean 1.25 (SD 0.67)), simultaneous presentation of sign and speech (mean 1.01 (SD 0.78)) and alternating presentation of sign and speech (mean 0.97 (SD 0.64)) were not significantly different to each other. Children with higher verbal imitation scores used more spontaneous words regardless of intervention group. Verbal imitation ability and vocabulary size predicted later spontaneous words in the sign alone group. Age (P < 0.001), IQ (P < 0.01), and verbal imitation level (P < 0.001) predicted use of spontaneous words (P < 0.001) in the other 3 groups.	Relatively small samples once divided into 4 groups (n = 15 each). Implications for statistical analyses. No control group so hard to know if maturation or true treatment effects
Yoder 2006b	Randomised comparison trial	36 children with ASD (33 autism and 3 PDD-NOS). Mean age 33.6 (SD 8.4, range 21–54). Mean NVMA 18.6 (SD 3.7, range 11.5–26.5). 31 boys, 5 girls. Minimally verbal ≤ 20 different words used cumulatively during 3 communication samples. Ex-	RPMT versus PECS	3 × 20-min sessions per week for 6 months. Parents also offered up to 15 h training	15-min, semi-structured, free-play with examiner where spoken communication measures (frequency of non-imitative spoken acts and number of different non-imitative words) were collected. The free-play measures were repeated	PECS was more effective than RPMT in increasing the number of non-imitative spoken communication acts (Cohen's d = 1.15) and number of different non-imitative words used (d = 1.12) postintervention. Moderate effect sizes. At 6 months follow-up, the growth rate of the number of different non-imitative words was faster in the PECS than the RPMT group for children who had relatively higher object exploration at baseline. Children with relatively low object exploration at baseline improved faster when in the RPMT group than in the PECS group. Effects were not maintained 6 months after the end of intervention	No control group so hard to know if maturation or true treatment effects. Examiners and coders not blind to intervention assignment

cluded if severe sensory or motor impairments or if primary language at home was not English	at the end of intervention and 6 months after the end of intervention

ABA: applied behaviour analysis; **ADOS**: Autism Diagnostic Observation Schedule; **CARS**: Childhood Autism Rating Scale; **CDI**: MacArthur Bates communicative development inventories; **CSBS**: Communication and Symbolic Behavior Scales; **DTT**: discrete trial training; **EL**: expressive language; **EMT**: Enhanced Milieu Teaching; **ESI**: Early Social Interaction project; **EOWVT**: Expressive One Word Picture Vocabulary Test;**ESCS**: Early Social Communication Scales; **FPI**: focused playtime intervention;**IS**: Interpersonal Synchrony intervention;**JA**: joint attention intervention; **JASP**: joint attention and symbolic play intervention; **JASPER**: joint attention, symbolic play, engagement and regulation intervention; **MBCT**: melodic based communication therapy; **MCT**: Milieu Communication Training; **MIT**: Melodic Intonation Therapy; **MLU**: mean length of utterance; **MSEL**: Mullen Scales of Early Learning; **NVIQ**: non-verbal intelligence quotient; **NVMA**: non-verbal mental age;**PDD-NOS**: pervasive developmental disorder - not otherwise specified;**PEAC**: Parent Education and Counselling intervention; **PEBM**: Parent Education and Behaviour Management Program;**PECS**: Picture Exchange Communication System; **PEI**: Psychoeducational Intervention; **PLS**: Preschool Language Scales; **PRT**: Pivotal Response Training; **RDLS**: Reynell Developmental Language Scales; **RL**: receptive language; **RMIA**: Rapid Motor Imitation Antecedent intervention; **RPMT**: Responsive Education and Prelinguistic Milieu Teaching; **SCERTS**: Social Communication, Emotional Regulation, and Transactional Supports; **SD**: standard deviation; **SGD**: Speech Generating Device; **SP**: Symbolic Play intervention; **STAR**: Strategies for Teaching based on Autism Research; **TS(L)T**: traditional speech (and language) therapy; **VABS**: Vineland Adaptive Behaviour Scales; **WNL**: within normal limits (age appropriate).

A P P E N D I C E S

Appendix 1. Search strategies

Cochrane Central Register of Controlled Trials (CENTRAL), in the Cochrane Library, and which includes the Cochrane Developmental, Psychosocial and Learning Problems Specialised Register

Searched: 17 November 2016 (340 records); 8 November 2017 (41 records)

#1[mh "child development disorders,pervasive"]
#2[mh ^"Developmental Disabilities"]
#3pervasive next development* next disorder*
#4(pervasive near/3 child*)
#5(PDD or PDDs or PDD-NOS or ASD or ASDs)
#6autis*
#7asperger*
#8kanner*
#9"childhood schizophrenia"
#10Rett*
#11{or #1-#10}
#12[mh Communication]
#13[mh "communication disorders"]
#14[mh "language development disorders"]
#15[mh "Language Development"]
#16[mh "nonverbal communication"]
#17[mh "Verbal Behavior"]
#18[mh "Verbal learning"]
#19((communicat* or speech or language) near/5 (need* or dysfunction* or impair* or disabil* or disabl* or delay*))
#20(minimal* near/1 (speech* or verbal*))
#21(limited near/1 (speech* or verbal*))
#22(nonverbal or non-verbal or "no speech")
#23(pre NEXT linguistic or prelinguistic)
#24[mh vocabulary]
#25(vocabular* or lexicon*)
#26functional next word*
#27[mh Mutism]
#28(mute or mutism)
#29{or #12-#28}
#30#11 and #29 in Trials [Note: Final line of search 2016]
#31#11 and #29 Publication Year from 2016 to 2017, in Trials [Note: Final line of search 2017]

MEDLINE Ovid

Searched: 17 November 2016 (2118 records); 8 November 2017 (41 records)

1 exp child development disorders, pervasive/
2 Developmental Disabilities/
3 pervasive development$ disorder$.tw,kf.
4 (pervasive adj3 child$).tw,kf.
5 (PDD or PDDs or PDD-NOS or ASD or ASDs).tw,kf.
6 autis$.tw,kf.
7 asperger$.tw,kf.
8 kanner$.tw,kf.
9 childhood schizophrenia.tw,kf.
10 Rett$.tw,kf.
11 or/1-10
12 exp Communication/
13 exp communication disorders/
14 language development disorders/
15 exp Language Development/
16 nonverbal communication/
17 Verbal Behavior/
18 exp Verbal learning/

19 ((communicat$ or speech or language) adj4 (need$ or dysfunction$ or impair$ or disabil$ or disabl$ or delay$)).tw,kf.
20 (minimal$ adj1 (speech$ or verbal$)).tw,kf.
21 (limited adj1 (speech$ or verbal$)).tw,kf.
22 (nonverbal or non-verbal or "no speech").tw,kf.
23 (pre-linguistic or prelinguistic).tw,kf.
24 vocabulary/
25 (vocabular$ or lexicon$).tw,kf.
26 functional word$.tw,kf.
27 Mutism/
28 (mute or mutism).tw,kf.
29 or/12-28
30 randomized controlled trial.pt.
31 controlled clinical trial.pt.
32 randomi#ed.ab.
33 placebo$.ab.
34 drug therapy.fs.
35 randomly.ab.
36 trial.ab.
37 groups.ab.
38 or/30-37
39 exp animals/ not humans.sh.
40 38 not 39
41 11 and 29 and 40
42 remove duplicates from 41 [Note: Final line of search 2016]
43 Limit 42 to ed=20161101-20171026 [Note:Final line of search 2017]

MEDLINE In-Process & Other Non-Indexed Citations Ovid

Searched: 17 November 2016 (240 records); 8 November 2017 (128 records after deduplication with previous set)

1 pervasive development$ disorder$.tw,kf.
2 (pervasive adj3 child$).tw,kf.
3 (PDD or PDDs or PDD-NOS or ASD or ASDs).tw,kf.
4 autis$.tw,kf.
5 asperger$.tw,kf.
6 kanner$.tw,kf.
7 childhood schizophrenia.tw,kf.
8 Rett$.tw,kf.
9 or/1-8
10 ((communicat$ or speech or language) adj4 (need$ or dysfunction$ or impair$ or disabil$ or disabl$ or delay$)).tw,kf.
11 (minimal$ adj1 (speech$ or verbal$)).tw,kf.
12 (limited adj1 (speech$ or verbal$)).tw,kf.
13 (nonverbal or non-verbal or "no speech").tw,kf.
14 (pre-linguistic or prelinguistic).tw,kf.
15 (vocabular$ or lexicon$).tw,kf.
16 functional word$.tw,kf.
17 (mute or mutism).tw,kf.
18 or/10-17
19 9 and 18
20 (random$ or trial$ or control$ or group$ or blind$ or placebo$ or prospective or meta-analysis or systematic review or RCT).mp.
21 19 and 20

MEDLINE Epub Ahead of Print Ovid

Searched: 17 November 2016 (62 records); 8 November 2017 (51 records after deduplication with previous set)

1 pervasive development$ disorder$.tw,kf.
2 (pervasive adj3 child$).tw,kf.
3 (PDD or PDDs or PDD-NOS or ASD or ASDs).tw,kf.
4 autis$.tw,kf.
5 asperger$.tw,kf.
6 kanner$.tw,kf.
7 childhood schizophrenia.tw,kf.
8 Rett$.tw,kf.

9 or/1-8

10 ((communicat$ or speech or language) adj4 (need$ or dysfunction$ or impair$ or disabil$ or disabl$ or delay$)).tw,kf.

11 (minimal$ adj1 (speech$ or verbal$)).tw,kf.

12 (limited adj1 (speech$ or verbal$)).tw,kf.

13 (nonverbal or non-verbal or "no speech").tw,kf.

14 (pre-linguistic or prelinguistic).tw,kf.

15 (vocabular$ or lexicon$).tw,kf.

16 functional word$.tw,kf.

17 (mute or mutism).tw,kf.

18 or/10-17

19 9 and 18

20 (random$ or trial$ or control$ or group$ or blind$ or placebo$ or prospective or meta-analysis or systematic review or RCT).mp.

21 19 and 20

Embase Ovid

Searched: 17 November 2016 (1532 records); 8 November 2017 (157 records after deduplication with previous set)

1 exp autism/

2 (PDD or PDDs or ASD or ASDs).tw.

3 autis$.tw.

4 asperger$.tw.

5 kanner$.tw.

6 childhood schizophreni$.tw.

7 Rett$.tw.

8 developmental disorder/

9 pervasive development$ disorder$.tw.

10 (pervasive adj3 child$).tw.

11 or/1-10

12 interpersonal communication/

13 communication skill/

14 language ability/

15 exp communication disorder/

16 language development/

17 speech disorder/

18 exp verbal behavior/

19 nonverbal communication/

20 developmental language disorder/

21 ((communicat$ or speech or language) adj4 (need$ or dysfunction$ or impair$ or disabil$ or disabl$ or delay$)).tw,kw.

22 (limited adj1 (speech$ or verbal$)).tw,kw.

23 (nonverbal or non-verbal or "no speech").tw,kw.

24 (pre-linguistic or prelinguistic).tw,kw.

25 (vocabular$ or lexicon$).tw,kw.

26 functional word$.tw,kw.

27 mutism/

28 (mute or mutism).tw,kw.

29 or/12-28

30 11 and 29

31 Randomized controlled trial/

32 controlled clinical trial/

33 Single blind procedure/

34 Double blind procedure/

35 triple blind procedure/

36 Crossover procedure/

37 (crossover or cross-over).tw.

38 ((singl$ or doubl$ or tripl$ or trebl$) adj1 (blind$ or mask$)).tw.

39 Placebo/

40 placebo.tw.

41 prospective.tw.

42 factorial$.tw.

43 random$.tw.

44 assign$.ab.

45 allocat$.tw.

46 volunteer$.ab.
47 or/31-46
48 30 and 47
49 remove duplicates from 48

CINAHL Plus EBSCOhost (Cumulative Index to Nursing and Allied Health Literature)

Searched: 17 November 2016 (924 records); 8 November 2017 (98 records after deduplication with previous set)

S1 (MH "Child Development Disorders, Pervasive+")
S2 pervasive development* disorder*
S3 pervasive n3 child*
S4 (PDD or PDDs or PDD-NOS or ASD or ASDs)
S5 autis*
S6 asperger*
S7 kanner*
S8 childhood schizophrenia
S9 Rett*
S10 (MH "Developmental Disabilities")
S11 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10
S12 (MH "Communication+")
S13 (MH "Communicative Disorders")
S14 (MH "Language Disorders")
S15 (MH "Language Development")
S16 (MH "Nonverbal Communication+")
S17 (MH "Verbal Behavior")
S18 ((communicat* or speech or language) n5 (need* or dysfunction* or impair* or disabil* or disabl* or delay*))
S19 (minimal* n1 (speech* or verbal*))
S20 (limited n1 (speech* or verbal*))
S21 (nonverbal or non-verbal or "no speech")
S22 (pre-linguistic or prelinguistic)
S23 (MH "Vocabulary")
S24 (vocabular* or lexicon*)
S25 functional word*
S26 (MH "Mutism")
S27 (mute or mutism)
S28 S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27
S29 S11 AND S28
S30 (MH "Clinical Trials+")
S31 MH random assignment
S32 (MH "Meta Analysis")
S33 (MH "Crossover Design")
S34 (MH "Quantitative Studies")
S35 PT randomized controlled trial
S36 PT Clinical trial
S37 (clinical trial*) or (control* N2 trial*)
S38 ("follow-up study" or "follow-up research")
S39 (prospectiv* study or prospectiv* research)
S40 (evaluat* N2 study or evaluat* N2 research)
S41 (MH "Program Evaluation")
S42 (MH "Treatment Outcomes")
S43 TI(single N2 mask* or single N2 blind*) OR AB(single N2 mask* or single N2 blind*)
S44 TI((doubl* N2 mask*) or (doubl* N2 blind*)) OR AB((doubl* N2 mask*) or (doubl* N2 blind*))
S45 TI ((tripl* N2 mask*) or (tripl* N2 blind*)) or ((trebl* N2 mask*) or (trebl* N2 blind*)) OR AB((tripl* N2 mask*) or (tripl* N2 blind*)) or ((trebl* N2 mask*) or (trebl* N2 blind*))
S46 random*
S47 S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46
S48 S29 AND S47

PsycINFO Ovid

Searched: without limits 18 December 2017 (884 records)

1 exp pervasive developmental disorders/

2 Developmental disabilities/
3 pervasive development$ disorder$.tw.
4 (pervasive adj3 child$).tw.
5 autis$.tw.
6 asperger$.tw.
7 (autis$ or ASD or ASDs).tw.
8 Rett$.tw.
9 Kanner$.tw.
10 (PDD or PDDs or PDD-NOS).tw.
11 childhood schizophren$.tw.
12 or/1-11
13 exp Communication Disorders/
14 exp Language Disorders/
15 Language Development/
16 Language Delay/
17 nonverbal communication/
18 oral communication/
19 verbal communication/
20 verbal ability/
21 ((communicat$ or speech or language) adj3 (need$ or dysfunction$ or impair$ or disabil$ or disabl$ or delay$)).tw,id.
22 (minimal$ adj1 (speech$ or verbal$)).tw,id.
23 (limited adj1 (speech$ or verbal$)).tw,id.
24 (nonverbal or non-verbal or "no speech").tw,id.
25 (pre-linguistic or prelinguistic).tw,id.
26 vocabulary/
27 (vocabular$ or lexicon$).tw,id.
28 (mute or mutism).tw,id.
29 or/13-28
30 12 and 29
31 clinical trials/
32 random sampling/
33 placebo/
34 Experiment controls/
35 ((clinic$ or control$) adj (study or trial$ or experiment$)).tw,id.
36 ((compar$ or control$ or experiment$ or treat$) adj3 (subjects or group$)).tw,id.
37 ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$)).tw,id.
38 exp program evaluation/
39 exp treatment outcomes/
40 exp treatment effectiveness evaluation/
41 (random$ or RCT).tw,id.
42 or/31-41
43 30 and 42

ERIC EBSCOhost (Education Resources Information Center)

Searched: 17 November 2016 (1205 records); 8 November 2017 (50 records after deduplication with previous set)

S1 DE "Developmental Disabilities"
S2 DE "Pervasive Developmental Disorders" OR DE "Asperger Syndrome" OR DE "Autism"
S3 (pervasive development* disorder* or PDD or PDDs)
S4 (autis* or ASD or ASDs)
S5 Asperger*
S6 Rett*
S7 Kanner*
S8 childhood schizophren*
S9 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8
S10 DE "Communication Disorders"
S11 DE "Language Impairments"
S12 DE "Language Acquisition"
S13 DE "Interpersonal Communication"
S14 DE "Augmentative and Alternative Communication"
S15 DE "Nonverbal Communication"
S16 DE "Communication Problems"

S17 ((communicat* or speech or language) n5 (need* or dysfunction* or impair* or disabil* or disabl* or delay*))
S18 (minimal* n1 (speech* or verbal*))
S19 (limited n1 (speech* or verbal*))
S20 (nonverbal or non-verbal or "no speech")
S21 (pre-linguistic or prelinguistic)
S22 DE "Verbal Ability"
S23 DE "Speech Skills"
S24 (pre-linguistic or prelinguistic)
S25 DE "Communication Skills"
S26 DE "Communication Strategies"
S27 DE "Vocabulary Development"
S28 DE "Vocabulary Skills"
S29 (vocabular* or lexicon*)
S30 functional word*
S31 (mute or mutism)
S32 S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31
S33 S9 AND S32
S34 DE "Meta Analysis" OR DE "Evaluation Research" OR DE "Control Groups" OR DE "Experimental Groups" OR DE "Longitudinal Studies" OR DE "Followup Studies" OR DE "Program Effectiveness" OR DE "Program Evaluation"
S35 TI (random* or trial* or EXPERIMENT* OR PROSPECTIVE* OR longitudinal or BLIND* or CONTROL*) OR AB (random* or trial* or PROSPECTIVE* OR EXPERIMENT*or longitudinal or BLIND* or CONTROL*)
S36 S34 OR S35
S37 S33 AND S36

Conference Proceedings Citation Index - Science Web of Science (CPCI-S)

Searched: 17 November 2016 (58 records); 8 November 2017 (12 records after deduplication with previous set)

#21 #20 AND #19
#20 TS=(random* or trial* or control* or group* or placebo* or prospectiv* or assign* or "meta-analysis" or "systematic review" or RCT)
#19 #18 AND #9
#18 #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10
#17 TS=(mute or mutism)
#16 TS=("functional word*")
#15 TS=(vocabular* or lexicon*)
#14 TS=(pre-linguistic or prelinguistic)
#13 TS=(nonverbal or non-verbal or "no speech")
#12 TS=(limited near/1 (speech* or verbal*))
#11 TS=(minimal* near/1 (speech* or verbal*))
#10 TS=((communicat* or speech or language) near/5 (need* or dysfunction* or impair* or disabil* or disabl* or delay*))
#9 #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1
#8 TS=(Rett*)
#7 TS=("childhood schizophrenia")
#6 TS=(Kanner*)
#5 TS=(asperger*)
#4 TS=(autis*)
#3 TS=(PDD or PDDs or PDD-NOS or ASD or ASDs)
#2 TS=(pervasive near/3 child*)
#1 TS= ("pervasive development* disorder* ")

Conference Proceedings Citation Index - Social Sciences & Humanities Web of Science (CPCI-SS&H)

Searched: 17 November 2016 (51 records); 8 November 2017 (7 records after deduplication with previous set)

#21 #20 AND #19
#20 TS=(random* or trial* or control* or group* or placebo* or prospectiv* or assign* or "meta-analysis" or "systematic review" or RCT)
#19 #18 AND #9
#18 #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10
#17 TS=(mute or mutism)
#16 TS=("functional word*")
#15 TS=(vocabular* or lexicon*)
#14 TS=(pre-linguistic or prelinguistic)
#13 TS=(nonverbal or non-verbal or "no speech")

#12 TS=(limited near/1 (speech* or verbal*))
#11 TS=(minimal* near/1 (speech* or verbal*))
#10 TS=((communicat* or speech or language) near/5 (need* or dysfunction* or impair* or disabil* or disabl* or delay*))
#9 #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1
#8 TS=(Rett*)
#7 TS=("childhood schizophrenia")
#6 TS=(Kanner*)
#5 TS=(asperger*)
#4 TS=(autis*)
#3 TS=(PDD or PDDs or PDD-NOS or ASD or ASDs)
#2 TS=(pervasive near/3 child*)
#1 TS= ("pervasive development* disorder* ")

speechBITE (speechbite.com)

Searched: 18 November 2016 (17 records); 8 November 2017 (3 records after deduplication with previous set)

Advanced search:

keywords minimally verbal AND Population = autistic spectrum disorders AND Research design = RCT
keywords non verbal AND Population = autistic AND Research design = RCT
keywords nonverbal AND Population = autistic AND Research design = RCT
keywords pre-verbal AND Population = autistic AND Research design = RCT
keywords preverbal AND Population = autistic AND Research design = RCT
keywords prelinguistic AND Population = autistic AND Research design = RCT
keywords pre linguistic AND Population = autistic AND Research design = RCT

Epistemonikos (epistemonikos.org)

Searched: 18 November 2016 (23 records); 8 November 2017 (3 records after deduplication with previous set)

(title:(autis* OR Asperg* OR ASD OR pervasive) OR abstract:(autis* OR Asperg* OR ASD OR pervasive)) AND (title:("minimally verbal" OR "non verbal" OR "nonverbal" OR mute OR mutism) OR abstract:("minimally verbal" OR "non verbal" OR "nonverbal" OR mute OR mutism))

Cochrane Database of Systematic Reviews (CDSR), part of the Cochrane Library

Searched: 18 November 2016 (5 records); 8 November 2017 (2 records after deduplication with previous set)

#1[mh "child development disorders, pervasive"]
#2[mh ^"Developmental Disabilities"]
#3(pervasive next development* next disorder*):ti,ab
#4(pervasive near/3 child*):ti,ab
#5(PDD or PDDs or PDD-NOS or ASD or ASDs):ti,ab
#6autis*:ti,ab
#7asperger*:ti,ab
#8kanner*:ti,ab
#9"childhood schizophrenia":ti,ab
#10Rett*:ti,ab
#11{or #1-#10}
#12[mh Communication]
#13[mh "communication disorders"]
#14[mh "language development disorders"]
#15[mh "Language Development"]
#16[mh "nonverbal communication"]
#17[mh "Verbal Behavior"]
#18[mh "Verbal learning"]
#19((communicat* or speech or language) near/5 (need* or dysfunction* or impair* or disabil* or disabl* or delay*)):ti,ab
#20(minimal* near/1 (speech* or verbal*)):ti,ab
#21(limited near/1 (speech* or verbal*)):ti,ab
#22(nonverbal or non-verbal or "no speech"):ti,ab
#23(pre-linguistic or prelinguistic):ti,ab
#24 [mh vocabulary]
#25(vocabular* or lexicon*):ti,ab
#26 (functional next word*):ti,ab
#27[mh Mutism]

#28(mute or mutism):ti,ab
#29{or #12-#28}
#30 #11 and #29 in Cochrane Reviews (Reviews and Protocols)

Database of Abstracts of Reviews of Effect (DARE), part of the Cochrane Library

Searched: 18 November 2016 (27 records). Not searched in 2017 as this was DARE's final issue.

#1[mh "child development disorders, pervasive"]
#2[mh ^"Developmental Disabilities"]
#3(pervasive next development* next disorder*):ti,ab
#4(pervasive near/3 child*):ti,ab
#5(PDD or PDDs or PDD-NOS or ASD or ASDs):ti,ab
#6autis*:ti,ab
#7asperger*:ti,ab
#8kanner*:ti,ab
#9"childhood schizophrenia":ti,ab
#10Rett*:ti,ab
#11{or #1-#10}
#12[mh Communication]
#13[mh "communication disorders"]
#14[mh "language development disorders"]
#15[mh "Language Development"]
#16[mh "nonverbal communication"]
#17[mh "Verbal Behavior"]
#18[mh "Verbal learning"]
#19((communicat* or speech or language) near/5 (need* or dysfunction* or impair* or disabil* or disabl* or delay*)):ti,ab
#20(minimal* near/1 (speech* or verbal*)):ti,ab
#21(limited near/1 (speech* or verbal*)):ti,ab
#22(nonverbal or non-verbal or "no speech"):ti,ab
#23(pre-linguistic or prelinguistic):ti,ab
#24 [mh vocabulary]
#25(vocabular* or lexicon*):ti,ab
#26 (functional next word*):ti,ab
#27[mh Mutism]
#28(mute or mutism):ti,ab
#29{or #12-#28}
#30#11 and #29 in Other Reviews

WorldCat (www.worldcat.org)

Searched: 18 November 2016 (0 records); 8 November 2017 (1 record)

kw:((MINIMALLY VERBAL or NONVERBAL or NON VERBAL or mute) AND (autis* or asperg*)) AND format=thesis/dissertation

ClinicalTrials.gov (clinicaltrials.gov)

Searched: 18 November 2016 (17 records); 8 November 2017 (3 records first posted from 18 November 2016 to 8 November 2017)

Advanced search: Search terms | non verbal OR nonverbal OR minimally verbal OR mute | Interventional Studies | Autism OR ASD OR Asperger OR PDD OR " pervasive developmental " | Child

ISRCTN Registry (www.isrctn.com)

Searched: 18 November 2016 (1 records); 8 November 2017 (2 records)

VERBAL within Condition: AUTISM AND Participant age range: Child

World Health Organization International Clinical Trials Registry Platform (WHO ICTRP; who.int/ictrp/en)

Searched: 18 November 2016 (22 records); 8 November 2017 (2 records registered since previous search)

TITLE verbal OR nonverbal OR mute OR speech
AND
CONDITION autistic OR autism OR asd

Appendix 2. 'Risk of bias' criteria

Random sequence generation

1. Low risk of bias: the sequence generation process was truly random; for example, a random number table or computer random number generator was used
2. High risk of bias: the sequence generation process was non-random; for example, allocation by judgement of the clinician or preference of the participant
3. Unclear risk of bias: there was insufficient information about the sequence generation process to permit a judgement of low or high risk of bias

Allocation concealment

1. Low risk of bias: allocation of participants was done using central allocation or sequentially numbered, opaque, sealed envelopes
2. High risk of bias: the allocation sequence was known to the investigators or participants
3. Unclear risk of bias: the trial was described as randomised, but the method used to conceal the allocation was not described

Blinding of participants and personnel

1. Low risk of bias: blinding of participants and key study personnel was ensured and it was unlikely that blinding was broken, or unlikely a lack of blinding would influence the outcome (or both)
2. High risk of bias: blinding of participants and key study personnel was not done or was broken, and outcomes were likely to be influenced by the lack of blinding
3. Unclear risk of bias: the term 'blinding' was mentioned but no details were given for who was blinded and how the blinding was ensured to permit a judgement of low or high risk of bias

Blinding of outcome assessment

1. Low risk of bias: the outcome assessors were blinded to the intervention received by the participants, or the outcome was unlikely to be influenced by lack of blinding
2. High risk of bias: no blinding of outcome assessment was mentioned but measurement was likely to be influenced by lack of blinding, or blinding could have been broken
3. Unclear risk of bias: the term 'double-blinded' was mentioned but no details were given with regards to how the outcome assessors were blinded to the intervention received by the participants

Incomplete outcome data

1. Low risk of bias: there were no missing outcome data, or the reasons for missing data were unlikely to be related to the true study outcome, or the numbers and reasons were balanced across intervention groups
2. High risk of bias: there were missing outcome data and the reasons were likely to be related to the true study outcome with either imbalance in numbers or reasons for missing data across intervention groups
3. Unclear risk of bias: there was insufficient reporting of attrition or exclusion, or both, to permit a judgement of low or high risk of bias

Selective outcome reporting

We assessed the possibility of selective outcome reporting by checking study protocols, if available, and comparing the outcomes listed in the protocol with the published study report.

1. Low risk of bias: it is clear that all of the study's prespecified and expected outcomes of interest were reported in the prespecified way
2. High risk of bias: not all the study's prespecified outcomes were reported, or one or more primary outcomes were reported in a way that was not prespecified, or one or more reported primary outcomes were not prespecified, or one or more outcomes of interest in the review were reported incompletely so that they could not be entered in a meta-analysis, or the study failed to include the results of a key outcome that was expected to have been reported
3. Unclear risk of bias: there was insufficient information to permit a judgement of low or high risk of bias

Other bias

1. Low risk of bias: the study appeared to be free of other sources of bias
2. High risk of bias: there was at least one problem in the study that could put it at risk of bias; for example, the study was claimed to be fraudulent, or there was extreme baseline imbalance
3. Unclear risk of bias: there was a lack of information to permit a judgement of low or high risk of bias

CONTRIBUTIONS OF AUTHORS

Protocol

HS conceived the protocol.
AB, HS, JZ, DL and CS designed the protocol.
AB and HS co-ordinated the protocol.
AB, HS and JZ designed the search strategies.
AB, HS, JZ, CS and AM wrote the protocol.
AB, DL and AM provided general advice on the protocol.
AB, HS, JZ and DL performed previous work that was the foundation of the current study.

Review

AB and KC screened all records and identified included and excluded studies. AM arbitrated any disagreements.
AB, HS and JZ retrieved missing abstracts and full-text reports.
AB and KC compiled studies and extracted data on excluded studies.
AB and KC extracted data for the 'Characteristics of included studies' tables and assessed risk of bias of included studies. AM arbitrated any disagreements.
AB and HS extracted data for the 'Summary of findings' tables and conducted the GRADE assessment. AM arbitrated any disagreements.
AB wrote the first draft of the review.
AM, KC, HS and CS provided feedback on the draft manuscript.
AB drafted feedback in response to reviewers.

Amanda Brignell is the guarantor for this review.

DECLARATIONS OF INTEREST

SOURCES OF SUPPORT

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

1. **Authorship**
   a. Amanda Brignell now works for Murdoch Children's Research Institute.
   b. Huan Song now works for the University of Iceland.
   c. DongHao Lu was an author on the protocol (Brignell 2016), but not the review.

2. Types of participants
   a. We reduced the minimum non-verbal mental age from at least 24 months to at least 12 months. This was based on clinical reasoning, previous studies, and experts in minimally verbal children with ASD who had used 12 months as the non-verbal mental-age cut-off point (e.g. Paul 2013).

3. Types of outcome measures
   a. We added 'combined spoken and non-verbal communication/AAC' as an outcome because some studies do not collect or report on spoken and non-verbal outcomes separately. For example, one of the outcomes measured in one study, Howlin 2007, was 'frequency of initiations', and this could include both spoken or non-verbal initiations.

4. Measures of treatment effect
   a. We added information on how we would present ordinal outcomes in the 'Summary of findings' tables. We had not previously described the methods for dealing with ordinal data, so it was necessary to explain this.
   b. We also present the OR rather than the RR in the review, as we were not able to extract the RR from the data presented in the trial report.

5. Electronic searches
   a. We searched two additional Ovid MEDLINE segments which are updated daily: MEDLINE In-Process & Other Non-Indexed Citations, and MEDLINE EPub Ahead of Print. We also searched Database of Abstracts of Reviews of Effect (DARE), and the ISRCTN Registry.

6. We report methods that we had planned in our protocol, Brignell 2016, but did not use in the review in Table 1.

INDEX TERMS

Medical Subject Headings (MeSH)

*Nonverbal Communication; Autism Spectrum Disorder [*complications]; Language Development Disorders [complications] [*therapy]; Language Tests; Language Therapy [*methods]; Parents [education]; Play Therapy [*methods]; Randomized Controlled Trials as Topic; School Teachers; Teacher Training; Treatment Outcome

MeSH check words

Child; Child, Preschool; Female; Humans; Male