Research Article

The Effects of Enhanced Milieu Teaching With Phonological Emphasis on the Speech and Language Skills of Young Children With Cleft Palate: A Pilot Study

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Purpose: The purpose of this pilot study was to investigate the extent to which a naturalistic communication intervention, enhanced milieu teaching with phonological emphasis (EMT+ PE), improved the language and speech outcomes of toddlers with cleft lip and/or palate (CL/P).

Method: Nineteen children between 15 and 36 months (M=25 months) with nonsyndromic CL/P and typical cognitive development were randomly assigned to a treatment (EMT+PE) or nontreatment, business-as-usual (BAU), experimental condition. Participants in the treatment group received forty-eight 30-min sessions, biweekly during a 6-month period. Treatment was delivered in a university clinic by trained speech language pathologists; fidelity of treatment was high across participants.

Results: Children in the treatment group had significantly better receptive language scores and a larger percentage of consonants correct than children in the BAU group at the end of intervention. Children in the treatment group made greater gains than children in the BAU group on most language measures; however, only receptive language, expressive vocabulary (per parent report), and consonants correct were significant.

Conclusions: The results of this preliminary study indicate that EMT+PE is a promising early intervention for young children with CL/P. Replication with a larger sample and long-term follow-up measures are needed.

lefts of the lip and/or palate (CL/P) occur in approximately 1 of 700 live births in the United States; CL/P is the fourth most commonly occurring birth defect (Cleft Palate Foundation, 2005; Correa & Edmonds, 2002). The population of children with CL/P is heterogeneous, including children whose CL/P is associated with a genetic syndrome and who may have cognitive and other developmental disabilities as well as children who are nonsyndromic and present without other developmental concerns. Two-thirds of children with CL/P have clefting of the lip and/or palate, whereas about one third have cleft palate only. The majority of CL/P cases are unilateral (80%). The primary treatment for children with CL/P is

early surgical repair with concurrent multidisciplinary management of related difficulties in feeding, swallowing, speech, and health-related concerns. Children with CL/P typically have primary surgical repairs before 12 months; however, complex instances of CL/P may require multiple surgeries over several years. The presence of CL/P places children at risk for delayed speech and language development. As a result of the identified differences in speech and language development of infants and toddlers with CL/P, researchers and practitioners have emphasized the need to identify young children with CL/P at risk for speech and language delays and support early speech and language development (Hardin-Jones & Chapman, 2001; Scherer, 2015).

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Toddlers with CL/P: A Population at Risk Speech Delays

Differences in sound production of children with CL/P emerge within the first 6–12 months of life (Chapman, Hardin-Jones, Schulte, & Halter, 2001) as children with CL/P demonstrate differences in both the onset and composition

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of their babbling (Chapman et al., 2001). Young children with CL/P present smaller phonological inventories consisting predominately of vowels, nasals, glides, and glottals produced with labial, velar, or glottal place of articulation (Chapman, 1991; Chapman et al., 2001; Olson, 1965). Young children with CL/P typically do not produce highpressure consonants, such as stop consonants, during the prelinguistic stage of development. Although palate repair reduces vocal limitations in children with CL/P, many children with repaired, nonsyndromic CL/P continue to produce speech errors and present with speech delays into preschool (Jones, Chapman, & Hardin-Jones, 2003). More specifically, many children with CL/P continue to show a preference for sounds produced at the extremes of the vocal tract (e.g., labials, velars, and glottals) while avoiding or not producing other sounds. Oral stop consonants often are limited or not present in young children with CL/P (Chapman et al., 2001; Estrem & Broen, 1989). Furthermore, children may develop compensatory articulation substitution patterns that persist even with treatment (Kuehn & Moller, 2000; Peterson-Falzone, Hardin-Jones, & Karnell, 2001).

Language Delays

Children with CL/P often are delayed in the production of first words and have smaller expressive vocabularies than typically developing (TD) children without CL/P (Broen, Devers, Doyle, Prouty, & Moller, 1998; Chapman, Hardin-Jones, & Halter, 2003; Nagarajan, Savitha, & Subramaniyan, 2009; Richman, Wilgenbusch, & Hall, 2005; Scherer, D'Antonio, & Kalbfleisch, 1999). Possible etiologies of these language delays have included anatomical differences, language delay, phonological disorders, and central nervous system dysfunction (Morris & Ozanne, 2003; Witzel, 1995). Multiple factors may contribute to early language delays in children with CL/P. Production of a less varied sound repertoire may result in less frequent and less intelligible production of words and word approximations. Difficulty in speech production may continue to constrain rate and fluency of children's talk as they move from single words to multiword speech. In addition, the processes by which language development is supported by caregivers in the natural environment may be disrupted for young children with CL/P (Frey, Kaiser, & Scherer, 2017; Scherer & Kaiser, 2010). First, the modelingimitation-feedback sequence (e.g., an adult models new vocabulary, followed by the child imitating the new word, and then the adult providing feedback on the lexical or phonological accuracy of the words) may occur less often for children who are reluctant to attempt words and do not readily imitate adult speech due to their limited speech sound repertoire (Scherer, 1999; Stoel-Gammon, 1989). Second, caregivers' contingent recasting of children's utterances into more advanced and well-formed utterances may be less frequent and less accurate in preserving children's intended meaning when children are highly unintelligible (Frey et al., 2017). Recasts are adult utterances that are (a) contingent upon the child's utterance, (b) share the referential context

and central meaning of that utterance, (c) reformulate sounds, words, or phrases in the child's utterance into a complete and correct utterance, and (d) provide an immediate contrast between the adult's correct recasted form and the incomplete or incorrect form of the child's initial utterance (Fey, Krulik, Loeb, & Proctor-Williams, 1999; Nelson & Welsh, 1998). Parent and clinician use of recasting has been shown to improve broad aspects of language performance including both phonology and grammar (Camarata, 1996, 2010; Camarata & Nelson, 2006; Camarata, Yoder, & Camarata, 2006). Third, children with CL/P practice speech sounds less often; they tend to be low-rate talkers (Frey et al., 2017). From a speech motor fluency perspective, children's limited attempts to use new words may further constrain rapid improvement in phonological production. A lower rate of child talk results in fewer caregiver opportunities to support phonological as well as lexical learning through recasting and expansion (Frey et al., 2017; Stoel-Gammon, 2011).

Speech and Language Skills Over Time

Early speech and language delays persist over time in many children with CL/P (Scherer & D'Antonio, 1995); however, the research on the type and extent of persistent language delays has reported variable outcomes on the basis of the specific population sampled, comparison group, and type of measure (Richman, McCoy, Conrad, & Nopoulos, 2012). At school age, about 25%–34% of children with CL/P continue to present with compensatory sound production errors (Sell et al., 2001), and many children with CL/P remain less intelligible than their same-age peers (Hardin-Jones & Jones, 2005). School-age children with CL/P also evidence specific deficits in language skills such as verbal fluency (Richman & Ryan, 2003), rapid naming (Richman & Ryan, 2003), and phonological memory (Collett, Leroux, & Speltz, 2010) that are predictive of reading ability. Given indications that early speech and language delays are common in children with CL/P and that these delays may persist over time and affect spoken language, reading, academic performance, and social behavior (Richman et al., 2012), there are surprisingly few studies examining early communication interventions for children with CL/P.

Approaches to Intervention

Most interventions for children with clefts have emphasized articulation approaches to improve the production of speech sounds (Peterson-Falzone et al., 2001; Peterson-Falzone, Trost-Cardamone, Karnell, & Hardin-Jones, 2006). Both a sound-by-sound approach that treats one sound at a time and progresses sequentially from isolated sound to syllable, word, phrase, sentence, and conversation levels (Golding-Kushner, 2001; Peterson-Falzone et al., 2001) and a multiple sound approach in which all members of a class of sounds are treated simultaneously (Van Demark & Hardin, 1986) have been used successfully. Pamplona, Ysunza, and Espinosa (1999) compared a sound-by-sound approach to the multiple sound approach

and found that the multiple sound approach resulted in a shorter course of treatment for 3–5-year-olds with CL/P. Pamplona, Ysunza, and Ramirez (2004) compared a multiple sound intervention and whole-language intervention in a small randomized control trial enrolling 30 children with unilateral CL/P, ages 3–7 years. Children in the phonological group received intervention by targeting individual sounds. Children in the whole-language approach participated in play and book reading activities; sounds were treated indirectly by reinforcement of correct sounds and enhancement of their cognitive linguistic organization. Both treatments were effective in reducing compensatory articulation errors when treatments were of similar duration; however, the language-based treatment resulted in better short-term maintenance. The results of these studies suggest that interventions targeting multiple sounds or sounds in the context of language-based activities may be effective to improve sound production in children with CL/P.

Early Naturalistic Speech and Language Interventions for Toddlers with CL/P

Given early onset and the evidence of persistence in speech and language deficits, there is a need for early interventions that are developmentally appropriate for young children with CL/P and that support both speech and language development. Interventions targeting speech sounds in isolation that require repeated practice trials with small sets of isolated sounds are not developmentally appropriate for very young children with CL/P. Furthermore, such interventions do not offer specific support for language development. Naturalistic approaches to speech and language interventions for toddlers simultaneously target speech and language and are grounded in behavior, developmental, and social interactionist theories (Kaiser & Hampton, 2017). These approaches are effective in improving speech and language acquisition because the teaching of speech and language targets occurs in response to the child's interest and intent to communicate. Teaching in response to the child's focus of attention and providing language models in response to a child's communicative intent simulate the effective aspects of dyadic interactions between parents and children that are associated with rapid language development (Kaiser & Hampton, 2017). These child-directed, naturalistic interventions are empirically based and grounded in the developmental sciences and principles of behavior (Schreibman et al., 2015). Only a few studies, however, have investigated naturalistic treatments that target both speech and language for young children with CL/P.

Scherer and colleagues (Scherer, 1999; Scherer, D'Antonio, & McGahey, 2008) examined the effects of vocabulary interventions on speech and language outcomes for toddlers with CL/P. The vocabulary interventions used in these studies included procedures that are based on enhanced milieu teaching (EMT; Kaiser, Hancock, & Hester, 1998) and focused stimulation (Girolametto, Weitzman, & Clements-Baartman, 1998). Scherer (1999), in a multiple

baseline study, reported systematic changes in three children's spontaneous use of target words when sets of comprehended and uncomprehended words were taught using milieu teaching by a speech language clinician. The results were consistent across children and words sets, with small differences associated with children's comprehension of words prior to teaching production. Changes in number of different words, mean length of utterance, and complexity of sound sequences in words were observed in language samples at the end of intervention. In addition, parents reported large changes from pre to post in vocabulary used at home on the MacArthur-Bates Communication Development Inventory (MCDI; Fenson et al., 2007). Given the small sample and single case design, these pre- to postchanges must be interpreted with caution. However, inherent in single-case design methodology, this multiple baseline study controlled for all variables except the manipulation of the independent variable, which provided preliminary evidence of a functional relation between the intervention and language gains. Scherer et al. (2008) trained parents to use focused stimulation procedures to teach two sets of target words to 10 children with CL/P ages 25–35 months. Pre- and posttest language and speech skills of the children in the intervention groups were compared with age, gender, and language ability-matched typical children. The results indicated that children with CL/P increased their productive vocabulary (total words; number of different words in a language sample) and reduced their use of compensatory articulation errors during the intervention. It was not possible to determine the extent to which the increases in vocabulary were due to the intervention alone versus normal development, particularly since the matched TD children showed similar amounts of growth in productive language during the same time period. Although the interpretation of the effects of the intervention procedures on language development was limited by the designs of the studies, one important outcome was an indication that naturalistic or play-based intervention targeting language production could result in positive effects on both speech and language.

In the current study, we implemented a naturalistic language intervention with the added feature of phonological emphasis. The phonological emphasis included modeling words that contained sound targets and recasting children's unintelligible and partially unintelligible utterances using a correct phonological form. The rationale for this approach was twofold. First, given the young age of children, a play-based intervention that taught language in the context of motivating interactions was preferable to a direct instruction approach with massed trials. The naturalistic intervention, EMT, has been shown to be effective in promoting expressive language outcomes in toddlers with significant language impairments (Kaiser & Hampton, 2017; Roberts & Kaiser, 2015). A phonological modeling and recasting component was added to the naturalistic intervention because recasting has been shown to be an effective intervention for improving phonological production in preschoolers with language delays and poor

speech intelligibility (Camarata, Yoder, & Camarata, 2006; Yoder, Camarata, & Gardner, 2005).

EMT With Phonological Emphasis

EMT (Kaiser et al., 1998) is a naturalistic, conversationbased strategy for teaching specific language targets to young children with language impairment. EMT has been demonstrated to increase productive and receptive vocabulary in a range of young children with significant language impairment (Hancock, Kaiser, & Delaney, 2002; Kaiser & Roberts, 2013; Roberts & Kaiser, 2012; Wright, Kaiser, Reikowsky, & Roberts, 2013). EMT is designed to be used during play and routines and is developmentally appropriate for toddlers and young preschoolers (Kaiser & Roberts, 2011). A precursor to EMT, milieu teaching, was used in the study conducted by Scherer (1999) to improve vocabulary and consonant production in toddlers with CL/P. On the basis of the findings from other toddler and preschool populations and the promising outcomes of the Scherer study, a specific version of EMT, which included systematic modeling and recasting of both vocabulary and phonological targets, was developed for the current study. The intervention model, EMT with phonological emphasis (EMT+PE), was designed to teach language and speech sounds concurrently during play interactions between the child and the therapist. The intervention incorporated evidence-based strategies for supporting and teaching early communication (responsive interaction, modeling, expansions, systematic prompting using milieu teaching strategies) as well as targeted modeling and recasting of whole words and speech sounds to provide corrective models. The intervention was differentiated for individual children by teaching vocabulary and sounds consistent with their emerging abilities in both domains.

Research Questions

The purpose of this pilot study was to investigate the effects of the EMT+PE intervention on the speech production and expressive and receptive language skills of toddlers with repaired, nonsyndromic cleft palate. Using a randomized group comparison design, the following research questions were addressed:

- 1. At the end of intervention, did the group of children receiving EMT+PE intervention demonstrate greater gains in language skills than the group who did not receive the EMT+PE intervention?
- 2. At the end of intervention, did the group of children receiving EMT+PE intervention have better speech production than the group who did not receive the EMT+PE intervention?

Method

A small, stratified, randomized design study was conducted to evaluate the effects of EMT+PE on the speech

and language development of young children with non-syndromic, repaired cleft palate.

Participants

A total of 19 children participated in this study. Eight children received the EMT+PE intervention, and 11 children were assigned to the business-as-usual (BAU) control group. Demographic information and participant characteristics are presented in Table 1. Children were recruited for participation in the study at two sites in the southeastern United States continuously between December 2009 and October 2011. Flyers were sent to families of toddlers with cleft palate identified by cleft palate teams at local hospitals and physician's offices, speech and hearing clinics, and through the state early intervention system and regional health departments. Flyers also were distributed to area preschools, childcare centers, and cleft palate support groups. In addition, a description of the study was posted on the project webpage and Facebook page.

Children were included in this study if they (a) were between 15 and 36 months old; (b) had a cognitive scale composite score of 80 or above on the Bayley Scales of Infant and Toddler Development-III (Bayley-III; Bayley, 2006); (c) could produce at least five different words per parent report on the MCDI (Fenson et al., 2007); and (d) demonstrated at least one type of articulatory error during screening on the Profiles of Early Expressive Phonological Skills (PEEPS; Stoel-Gammon & Williams, 2013) and/or during the language sample. These errors could include: (a) a compensatory error on at least one phoneme; (b) a consonant inventory of fewer than five stop or nasal consonants in all positions; and/or (c) errors on at least two stop or nasal consonants. Children were excluded from the sample if they (a) had a sensorineural hearing loss or sound field hearing threshold over 30 dB HL, as measured by an audiologist or confirmed by the medical record; (b) were multilingual or non-English speaking on the basis of parent report; (c) had a syndrome diagnosis from a geneticist; and/or (d) had more than three additional dysmorphic features in addition to the cleft palate. Children did not have to have a diagnosis of a speech or language impairment to be included in the study.

Parents provided written consent for their children to participate in the project. The principal investigator or the project director (a certified speech-language pathologist [SLP]) met with each parent to describe the study, review the written consent form, and answer any questions. The study was conducted under the approval of the institutional review boards at both participating universities.

After the initial screening, children who met the inclusion criteria were assigned to the EMT+PE or the BAU group. Due to the small sample size, assignment to groups was stratified by child gender (male or female) and age at time of screening (≤24 months or >24 months). A random number generator was used to assign participants to groups on the basis of gender and age at screening.

Table 1. Participant characteristics by group at start of study.

	Intervention group		Control group	
Demographics	Frequency	Percent	Frequency	Percent
Total number	8		11	
Gender				
Male	5	62.5	8	72.7
Female	3	37.5	3	27.3
Race/ethnicity				
Caucasian	8	100.0	10	90.9
African American	0	0	1	9.1
Cleft palate type				
Cleft palate only	1	12.5	2	18.2
Unilateral CL/P	5	62.5	6	54.5
Bilateral CL/P	2	25.0	3	27.3
Mother's education level				
High school	3	37.5	0	0
Some college	3	37.5	4	36.4
Four-year degree or more	2	25.0	6	54.5
Unknown	0	0	1	9.1
Annual gross income				
< \$25,000	0	0	2	18.2
\$30,000-\$44,999	3	37.5	1	9.1
\$45,000-\$59,999	0	0	3	27.3
\$60,000-\$74,999	1	12.5	2	18.2
≥ \$75,000	4	50	2	18.2
Unknown	0	0	1	9.1

Note. CL/P = cleft lip and/or palate.

Screening and Assessment

Children were assessed at the start of the study and at the end of intervention (approximately 6 months after initial testing). The exact length of time between preand post assessments varied because of differences in the time required to complete the 48 intervention sessions. Parents completed demographic forms, and a certified SLP or master's level research assistant conducted all child assessments. The SLP and research assistant were trained to criterion on all test protocols prior to the start of the study. Administration of each assessment was video recorded. Scoring for each language assessment was checked for completeness and accuracy by the project coordinator who was not involved in the assessments, and any disagreements in scoring were resolved before a final score was entered. All data were double entered. Due to the pilot status of the study and limited research personnel, staff were not blind to children's treatment status.

Cognitive Skills

Children's cognitive skills were assessed using the Cognitive Scale of the Bayley-III. The Bayley-III is an individually administered, standardized, norm-referenced assessment for children between 1 and 42 months. Items on the Cognitive Scale were written to assess children's sensorimotor development, concept formation, and memory. Internal consistency reliability estimates, as measured by coefficient alpha, for children in the norm sample ranged from 0.79 to 0.97 for the Cognitive Scale. These values

support the internal structure of the scale and the reliability of inferences made from the scores obtained on this measure. The Bayley-III was administered at screening only.

Language Outcome Measures

To assess children's receptive and expressive language skills before and after intervention, (a) standardized, normreferenced assessments were administered; (b) language samples and parent-child interaction sessions were conducted; (c) audio recordings in the natural environment were collected; and (d) information about children's expressive vocabulary was reported by parents.

The Preschool Language Scale–Fourth Edition (PLS-4; Zimmerman, Steiner, & Pond, 2002), a standardized, norm-referenced assessment, was individually administered to assess children's receptive and expressive language skills. The PLS-4 was designed to identify children with potential language delays and can be used with children from birth until 7 years old. The PLS-4 uses a combination of elicited and spontaneous child responses as well as caregiver report to assess children's understanding of language and their communication skills. Three scores were obtained from the PLS-4: (a) an Auditory Comprehension score; (b) an Expressive Communication score; and (c) a Total Language score. Internal consistency reliability estimates, as measured by coefficient alpha, for children between 12 and 36 months in the norm sample ranged from 0.72 to 0.94 for the Auditory Comprehension scale, from 0.88 to 0.94 for the Expressive Communication scale, and from 0.88 to 0.97 for the overall scale. These

values support the internal structure of the scale and the reliability of inferences made from the scores obtained on this measure.

Children's language skills also were assessed through language samples and parent-child interaction sessions. To complete the language sample, the examiner followed a standardized protocol for presenting materials and responding to children's verbal communication during a 20-min play-based language sample session in a clinic room. Because this sample was designed to measure spontaneous language production, the examiner did not introduce any new language during the session but responded to the child by repeating all intelligible child utterances or acknowledging all unintelligible utterances (e.g., if the examiner did not understand the child, she may have said "yeah" or "uhhuh" to acknowledges the child's utterance). Parent-child interaction sessions were conducted during three activities in a clinic room: (a) reading books together for 5 min; (b) sharing a snack for 5 min; and (c) playing with a standard set of toys together for 10 min. Parents were told to interact and play with their children as they "normally would."

Language samples and parent-child interaction sessions were video recorded, transcribed, verified by a second transcriber, and analyzed using the Systematic Analysis of Language Transcripts software (SALT; Miller & Chapman, 2008). For each observation sample, the automated SALT analysis program was used to determine children's mean length of utterance in morphemes (MLUm), total number of words (TNW), and number of different word roots (NDW) used in the sample. In addition, the transcripts from the four observation samples (language sample, snack, book, and play) were merged and analyzed to obtain an overall NDW per minute and MLUm value. The aggregated language sample and parentchild interaction transcripts (a total of 40 min of interaction) were analyzed using SALT standard transcript analysis to calculate children's overall percent of intelligible utterances, which was calculated by the software as the number of fully intelligible utterances divided by the total number of utterances.

The Language Environment Analysis System (LENA; Xu, Yapanel, & Gray, 2009) was used to audio record children's interactions at home and in the community. Children wore LENA recorders on one weekday and one day during the weekend for a minimum of 8 hr each day. Two LENA recordings were obtained at the beginning of the study, and two LENA recordings were obtained after intervention. The LENA software calculated the total number of child vocalizations from the LENA system's algorithm to identify child vocalizations within the recording. Words, babbles, and prespeech communicative sounds were classified by the system as vocalizations. Crying, screaming, laughing, and vegetative sounds (e.g., breathing) were not included in the child vocalization count. Because the length of recording varied across children, number of vocalizations was divided by duration to yield the number of vocalizations per minute.

Reliability studies have been conducted using the LENA (Xu et al., 2009). In a sensitivity study of the accuracy of the LENA system to detect child vocalizations, LENA algorithms correctly identified 75% of human-identified child vocalizations, and only 16% of child nonvocalizations were classified as child vocalizations. The reliability of the LENA, however, may be higher than these estimates due to inherent measurement error in the human-based transcriptions that were used as the comparison measure in the reliability studies (Xu et al., 2009).

In addition to the standardized, norm-referenced and observational measures, parents completed the MCDI (Fenson et al., 2007). The MCDI is a measure of children's expressive vocabulary. The MCDI provides parents with a list of words by category (e.g., animals, toys, food and drink, body parts), and parents indicate whether their children can produce the word. The total number of words selected by the caregiver serves as an estimate of the total number of words in the child's vocabulary. The MCDI has high internal consistency, with a reported coefficient alpha value of .96.

Speech Outcome Measure

The PEEPS was administered to assess the place, voice, and manner of consonant production, accuracy of production (as measured by percentage of consonants correct [PCC]), error patterns, and nasal emission. The PEEPS Basic Word List (40 words) was used for children between 18 and 24 months, and the Expanded Word List (Basic Word List plus an additional 20 words) was used for children between 24 and 36 months. Toys representing each word were presented to the child, and the child was asked: "What is this?" If the child did not spontaneously label the item, the examiner used a sentence completion approach to support the child in labeling the toy within the context of her sentence ("Look, I have a _ [ball]"). If the child did not respond to this strategy, then the examiner modeled the target word ("Say ball"). The accuracy of production of each consonant was scored, and PCC was calculated. All PEEPS protocols were independently scored by two SLPs. Each discrepancy was consensus scored, and the consensus scored protocol was entered in the database.

Experimental Procedures

Treatment Group

Children in the EMT+PE treatment group received intervention during individualized, 30-min play sessions, twice per week, in a clinic room. Children participated in a total of 48 intervention sessions. All sessions were conducted by an SLP trained in EMT+PE strategies. One of the eight children in the EMT+PE group also was receiving outside community-based speech therapy 1 hr per week while participating in the EMT+PE intervention.

The EMT+PE intervention included the components of EMT (Kaiser et al., 1998) with additional phonological

emphasis. When implementing EMT+PE, the therapist (a) selected specific toys on the basis of the child's speech and language targets and arranged the environment to set the stage for therapist-child interactions to increase the likelihood the child would initiate to the therapist (environmental arrangement); (b) modeled specific speech and language targets appropriate to the child's skill level in response to the child's communication and connected to the child's play and interest (modeling and responsive interaction); (c) recasted (repeated) child utterances with accurate production (phonological recast) and expanded child communication forms by adding words to child utterances (expansions); and (d) responded to the child's requests with prompts for elaborated language consistent with the child's targeted skills and reinforced the child's production of the prompted target forms by providing access to requested objects and verbal feedback for communicating (milieu teaching prompts). Additional phonological emphasis was added to the EMT intervention package to prompt speech production through the use of speech recasts. Recasting is the repetition of the child's utterances using the correct form (Camarata, 1996; Camarata & Nelson, 2006). The purpose of the recasts was to provide accurate phonological information in response to a child's incorrect production. These speech recasts naturalistically provided feedback for a child to modify his/her substitution and omission errors (Scherer & Kaiser, 2010).

On the basis of the speech and language assessments administered at entry to the study, individual language and speech sound targets were identified for each child. First, language level targets were determined (i.e., language targets that were single-word utterances, two-word utterances, or three-word utterances). In general, children whose language fell within Brown's (1973) Stage I, had single-word language targets, and children's whose language fell within Brown's Stage II, had two-word language targets. No participants had language targets beyond two words at the start of the study. Participants progressed to two- and three-word language targets during the study. Within each language level, specific language targets were identified after reviewing the transcripts from the child's language sample and play and snack sessions with the caregiver and the child's word inventory reported by parents on the MCDI. Single-word targets might include social words (e.g., hi, bye, peekaboo, please, nightnight), requesting words (e.g., more, help, mine), nouns, action verbs, protoverbs, modifiers, and/or pronouns. Two-word targets might include agent + action, action + object, modifier + noun, preposition + location, and/or a two-word request. To identify speech sound targets, the child's consonant production during the pre-assessment was reviewed. Speech targets were selected on the basis of developmental sequences for consonant production and the child's current use of the sounds in initial, medial, and final positions. On the basis of the child's initial sound inventory (as measured by the PEEPS), developmentally appropriate words that targeted the specific sound in the appropriate position were identified. Many of these words were identified using the word lists from the MCDI. Children typically had three to five language targets and three to five speech targets. Activities, routines, and toys were selected to provide opportunities for the adult to model the target language and sounds in context. Coded and transcribed data from intervention sessions were used to track child acquisition of language and phonological targets on the basis of spontaneous production of words with targeted sounds and utterances spoken during intervention sessions, and phonological and language targets were revised as children acquired skills. When children used speech targets correctly 50% of the time, new speech targets were identified. Single- and two-word utterances primarily were targeted at the start of intervention because the children used few words and few different words during the interactions sampled at the start of the study, and modeling and recasting single words increased the salience of the phonological form. Recasted words were included in multiword expansions when the child's language production level was greater than single words. On average, 34% (SD = 17%) of the words the therapist used during an intervention session included a speech target, and 84% (SD = 13%) of therapist's utterances were at the child's targeted language level.

BAU Group

Children in the BAU group did not receive EMT+ PE intervention but were not prohibited from receiving outside community services. Information regarding the type and amount of community speech and language services children received was collected through parent survey. Six children in the control group received community-based speech and language services; five children in the control group had no reported community-based speech and language services.

Treatment Fidelity

Every fourth intervention session (25% of intervention sessions) was coded for therapist use of EMT+PE strategies. Prior to the start of intervention, criterion levels for implementation of EMT+PE strategies were established. Therapists received extensive training on EMT+PE intervention through practice in the clinic with children with CLP and/or other language impairments not enrolled in the study, review of written materials (research articles, chapters describing the intervention, handouts summarizing intervention strategies), video recorded examples of the intervention implemented by other therapists, and coaching and feedback from senior therapists experienced in the components of the intervention. Therapists had to reach criterion levels of fidelity prior to conducting intervention sessions with participants enrolled in the treatment group.

Therapists' use of EMT+PE strategies exceeded criterion levels across all strategies. Criteria and use of EMT+PE strategies during intervention sessions are summarized in Table 2. These criteria were established through the

Table 2. Fidelity criteria and therapist use of enhanced milieu teaching with phonological emphasis strategies.

Fidelity measure	Description	Criterion (%)	M (SD)
Matched turns	Percentage of therapist's utterances that were in response to a child's communicative attempt or utterance.	>75	98 (2.8)
Talk at child's level	Percentage of therapist's utterances that were at child's language level.	>50	83 (12.5)
Recasted incorrect child utterances	Percentage of child's words containing speech errors that were immediately followed by a therapist's recast of the word(s) containing the speech error(s).	>40	76 (16.7)
Expanded child utterances	Percentage of child's utterances to which the therapist responded by repeating child's utterance and adding one or more words.	>40	55 (16.0)
Time delay strategies	Percentage of correct implementation of time delay episodes.	>80	98 (8.0)
Prompting strategies	Percentage of prompting episodes that were delivered in response to a child's request, followed a system of least-to-most prompts, and ended with therapist providing the desired action or object to the child.	>80	98 (12.4)
Words containing speech targets	Percentage of words therapist used during the session that contained at least one of the child's speech targets.	>25	34 (17.3)

empirical basis of the EMT research literature (see Kaiser & Hampton, 2017). Reliability of coding of EMT+PE strategies was determined by having a second coder code 20% of the intervention fidelity sessions (see Table 2). Interobserver agreement (IOA) was calculated, using the pointby-point method, for the coding of each EMT+PE strategy. To be specific, IOA was calculated for coding of (a) child use of language targets, (b) therapist's matched turns, (c) therapist's recasts and expansions, and (d) therapist's language level. Average agreement across these four coding categories was about 90%. Average percentage of agreement for each coding category was as follows: 90% (SD = 6.65%) for child language targets, 97% (SD = 3.98%)for matched/unmatched turns, 86% (SD = 5.41%) for recasts/expansions, and 88% (SD = 6.60%) for therapist language level. If IOA was below 85% on any coding category within any session, the two coders met to review and discuss each coding discrepancy.

Data Analysis

First, all assessment data were double entered independently by two research assistants into a database. After double data entry was completed, all data were compared, and any disagreements in data entry were resolved by consensus. A clean data file with no data entry errors was created, and data were imported into SPSS Version 19 statistical software package (IBM Analytics, Armonk, NY) for analysis. Next, demographic information and assessment data were summarized and group differences at pretest were examined using chi-square analyses for categorical variables and analysis of variance for continuous variables. Last, to address each research question, a Mann–Whitney U test was used to compare differences in gain scores across measures between the two groups. The Mann–Whitney U test was used due to the small sample size and because the data were not normally distributed. The U statistics, significance values, and postintervention effect sizes were analyzed to investigate the effects of EMT+PE on children's speech and language skills.

To examine the effects of EMT+PE on child language immediately following intervention, eight language gain scores from pre- to postintervention were analyzed: (a) Expressive Communication raw score on the PLS-4; (b) Auditory Comprehension raw score on the PLS-4; (c) NDW used during the language sample; (d) MLUm during the language sample; (e) NDW per minute used across language sample and parent-child interaction sessions; (f) MLUm across language sample and parent-child interaction sessions; (g) number of vocalizations per minute from LENA recordings; and (h) total number of words on the MCDI. To examine the effects of EMT+PE on child speech, two speech outcomes were analyzed: (a) gain in PCC on the PEEPS; and (b) gain in percent intelligibility during the language samples and parent-child interaction sessions. In addition, for each outcome measure, a standardized, mean difference postintervention effect size (d) was calculated using the estimated marginal means for the outcome measure at postintervention (adjusting for pre-intervention scores and child age) and the unadjusted postintervention standard deviation.

Results

Participant characteristics and demographic information are presented in Table 1. Eight children participated in the EMT+PE intervention, their average age at the start of the intervention was 24.3 months (SD = 7.1), and their average age at the time of initial palate repair was 11.5 months (SD = 1.9). Eleven children were assigned to the BAU group. Their mean age at the start of the study was 26.6 months (SD = 7.2), and their average age at the time of palate repair was 11.1 months (SD = 1.4). The average age of mothers in both groups at the start of the study was 29.5 years. No significant differences between participants in the intervention and control groups were observed for gender, race, cleft palate type, mother's education level, annual yearly income, child age at the start of the study, child age at the time of palate repair, or mother's age at the start of the study.

Assessment data for the cognitive, language, and speech measures at the start of the study are presented in Table 3. On average, children in the control group

Table 3. Means and standard deviations for pre- and posttest cognitive, language, and speech measures.

	Pre		Post	
Measure	Intervention	Control	Intervention	Control
Bayley-III cognitive composite score ^a	96.9 (7.5)	103.2 (11.5)	n/a	n/a
PLS-4 AC RS	25.1 (5.4)	31.2 (9.8)	38.1 (7.3)	39.7 (10.0)
PLS-4 AC SS ^a	87.4 (6.6)	104.9 (17.2)	107.0 (11.3)	108.0 (12.7)
PLS-4 EC RS	28.4 (6.7)	33.6 (8.1)	39.4 (7.7)	40.2 (10.4)
PLS-4 EC SS ^a	94.1 (12.3)	106.4 (15.0)	105.3 (9.1)	107.3 (15.1)
PLS-4 Total Language SS ^a	90.0 (10.0)	106.2 (16.8)	106.9 (10.9)	108.8 (14.9)
MCDI total words	182.0 (206.1)	303.9 (290.1)	473.9 (213.8)	432.9 (263.6)
NDW	19.4 (24.7)	35.3 (30.6)	71.0 (44.4)	65.5 (55.5)
NDW per minute ^b	1.3 (1.3)	2.2 (1.7)	3.8 (1.7)	3.7 (2.2)
MLUm ^b	1.2 (0.4)	1.6 (0.7)	2.1 (0.9)	2.4 (1.1)
LENA vocalizations per minute	3.7 (2.2)	3.5 (1.5)	4.1 (1.7)	3.7(1.4)
Percent intelligibility ^b	39.4 (22.1)	45.1 (19.2)	65.1 (23.1)	57.7 (13.7)
PEEPS PCC	31.8 (23.8)	45.7 (19.9)	61.1 (23.8)	58.8 (26.5)

Note. Bayley-III = Bayley Scales of Infant and Toddler Development-III (Bayley, 2006); PLS-4 = Preschool Language Scale—Fourth Edition (Zimmerman et al., 2002); AC = Auditory Comprehension score; RS = raw score; SS = standard score; EC = Expressive Communication score; MCDI = MacArthur—Bates Communication Development Inventory (Fenson et al., 2007); NDW = number of different word roots; MLUm = mean length of utterance in morphemes; LENA = Language Environment Analysis System (Xu et al., 2009); PEEPS = Profiles of Early Expressive Phonological Skills (Stoel-Gammon & Williams, 2013); PCC = percent consonants correct.

performed better than children in the intervention group across all measures at the start of the study. There was a significant difference between groups on total language skills, as measured by the PLS-4, F(1, 17) = 5.89, p = .027. There were no significant differences between the treatment and BAU groups, however, on cognitive skills, F(1, 17) =1.83, p = .19, expressive language, F(1, 17) = 2.48, p = .13, or receptive language skills, F(1, 17) = 2.16, p = .16. In addition, there were no differences between groups in NDW per minute, F(1, 17) = 1.63, p = .22; MLUm, F(1, 17) =1.90, p = .19; or number of vocalizations per min from the LENA recordings, F(1, 13) = 0.031, p = .86. Last, no significant differences between groups were observed for speech intelligibility, F(1, 17) = 0.36, p = .56. Average performance on standardized, norm-referenced language assessments for each group was within average range; however, performance within both groups was highly variable, with standard scores ranging from 67 to 120 on the PLS-4 Auditory Comprehension and 74 to 128 on PLS-4 Expressive Communication scale.

Language Outcomes

End of study assessment data are presented in Table 3. Mann–Whitney U values, significance levels, and effect sizes are presented in Table 4. Significant differences in gains in receptive language skills between groups at the end of intervention were observed, U = 11, p = .006, and significant differences in gains in expressive vocabulary between groups, as measured by total number of words on the MCDI, were observed, U = 15, p = .043. Significant differences between groups were not found for gains in NDW per minute, MLUm, vocalizations per minute, or Expressive Language scores on

the PLS-4. Effect sizes, however, for all language measures were positive, indicating that children in the EMT+PE group performed better at the end of the study than children in the BAU group. Effect sizes ranged from d=0.04 for MLUm to d=0.45 for NDW used during the language sample. Overall, the results indicate that children receiving the

Table 4. Mann–Whitney U values, significance values, and effect sizes for outcome measures.

Outcome Measure	U	Z	р	d
Language outcomes				
PLS-4 EC raw score	22.00	-1.61	.108	0.37
PLS-4 AC raw score*	11.00	-2.74	.006	0.43
MCDI: Total words*	15.00	-2.02	.043	0.40
Aggregated NDW per minute	28.00	-1.32	.186	0.32
Aggregated MLUm	37.00	578	.563	0.04
Language sample NDW	30.00	-1.16	.248	0.45
Language sample MLUm	40.50	289	.772	0.05
LENA vocalizations per minute	12.00	-1.29	.198	0.10
Speech outcomes				
Percent intelligibility	31.50	-1.03	.301	0.62
PEEPS: PCC*	10.00	-2.44	.015	0.47

Note. Effect sizes were calculated using estimated marginal means and unadjusted standard deviations for postintervention group outcome data. PLS-4 = Preschool Language Scale–Fourth Edition (Zimmerman et al., 2002); EC = Expressive Communication score; AC = Auditory Comprehension score; MCDI = MacArthur–Bates Communication Development Inventory (Fenson et al., 2007); NDW = number of different word roots; MLUm = mean length of utterance in morphemes; LENA = Language Environment Analysis System (Xu et al., 2009); PEEPS = Profiles of Early Expressive Phonological Skills (Stoel-Gammon & Williams, 2013); PCC = percent consonants correct.

*p < .05, two-tailed significance test.

^aThese measures have a mean of 100 and a standard deviation of 15. ^bAggregated from language sample, parent–child book, play, and snack transcripts.

EMT+PE intervention made greater gains in language skills across the study than children who did not receive the intervention.

Speech Outcomes

The difference in gain scores on PCC between groups was statistically significant, U = 10, p = .015 (see Table 4). Differences in gains in percent intelligibility, however, were not statistically significant between groups, U = 31.5, p = .301.

Discussion

The presence of CL/P places children at increased risk for speech and language delays. Early communication interventions may decrease the risk of later identified speech and language impairments in young children with CL/P. However, there is a paucity of research on naturalistic speech and language interventions for toddlers with CL/P. The results of this small pilot study suggest EMT+ PE is a promising language and speech intervention for this population. The overall pattern of results is similar to the previous naturalistic intervention studies for toddlers who have CL/P (Scherer, 1999; Scherer et al., 2008) as well as for toddlers with language impairments (Roberts & Kaiser, 2012). Although children in both the EMT+PE and BAU groups entered the study with relatively high language skills, children in the EMT+PE group showed larger gains in both speech and language measures. To be specific, children in the EMT+PE group showed significant improvements in receptive language and expressive vocabulary. There were also changes in productive language measures (NDW, standardized assessment of expressive language, and parent report of words) reflected by moderate effect size differences between groups. In terms of speech outcomes, children in the intervention group made greater gains in percent correct consonants compared with children in the BAU group.

Unlike recent studies of EMT (Kaiser & Roberts, 2013; Roberts & Kaiser, 2012), the current study did not include parents as co-implementers of the intervention. Since this study was a pilot study of the EMT+PE intervention, we chose first to deliver a therapist-implemented intervention to demonstrate the effectiveness and feasibility of the EMT+PE intervention. Kaiser and Roberts (2013) demonstrated that for children with intellectual disabilities, particularly children with autism spectrum disorder, adding parents as co-therapists increased the generalized effects of the EMT intervention. For young children, teaching parents to implement a naturalistic intervention has the potential to increase the dosage and improve outcomes of the interventions. Studies of parent-implemented EMT+PE are a next logical step in developing an intervention to improve outcomes for children with CL/P, particularly since Scherer et al. (2008) demonstrated the feasibility of including parents of children with CL/P in naturalistic interventions.

This study was the first to systematically combine procedures for supporting both language and speech production using two evidence-based strategies (EMT and phonological recasting) in a randomized control trial. EMT+PE is a multicomponent intervention, and the impact of the individual components could not be determined in the current study. In addition, the multicomponent approach was challenging in several ways. Selecting language targets that contained target sounds to embed in naturalistic interactions that fit the child's play level and interests was sometimes difficult. Limiting the number of target words and sounds sometimes constrained the natural qualities of the interaction. Implementing all components of the intervention at high levels of fidelity required a skilled and well-trained interventionist and continuous monitoring of the fidelity of the intervention. In future studies, it may be especially important to analyze the effects of the phonological recasting component by comparing the effects of the naturalistic language intervention (EMT) with and without this component that targets phonological production.

Limitations

There are several important limitations to the study. First, toddlers with nonsyndromic, repaired CL/P are a low incidence population, and thus, the sample size is extremely small. In addition, the groups differed on pretest total language scores. The nonparametric analysis prohibited control of pretest variables, and the variability within and across groups may have affected the outcomes. Given this variability as well as the small sample size, it is essential to replicate this study with a larger sample. Second, the measure of speech outcomes, the PEEPS, is an unstandardized measure without a normative comparison group. Thus, interpretation of the changes in both the treatment and the BAU group relative to normal development is not possible. Measures of speech intelligibility on the basis of transcripts were constrained by the low rate of child talk in the language sample and in the parent-child interactions for some children. The small sample of child words may have led to over or underestimating general intelligibility. Third, some children did not respond to prompts to talk or imitate during the initial PEEPS administration. Thus, it is unknown if children did not have certain consonants in their repertoire at the pretest or if they were unwilling to produce them during an elicitation trial. Although there is no indication of a differential effect for the two experimental groups, the accuracy of the pretest data in describing the production abilities of this sample of children should be questioned. Fourth, some children in both groups were receiving other treatments, and these treatments may have affected overall outcomes (change from pre to post). Six children in the control group were receiving communitybased services; however, only one child in the treatment group received additional services. Last, the sample is limited to middle socioeconomic status children with CL/P who had early cleft repair (before 12 months) and who were nonsyndromic. The generalization of the results of the study are limited to this specific population, although many children with CL/P have genetic or syndromic sources

of CL/P and may have cognitive limitations that would affect the outcomes of the EMT+PE intervention. EMT has been shown to be effective with children with language impairment and significant cognitive impairment (Kaiser & Roberts, 2013); however, the effects of the phonological component of the intervention have not been examined with young children with CL/P who also have cognitive delays.

Implications for Practice

Delivering the blended EMT+PE protocol to teach both language and speech targets in a naturalistic interaction requires preparation. The protocol requires careful selection of speech and language targets that can be taught during play. The activities must interest the child and provide sufficient opportunities for modeling both speech and language targets. The clinician must deliver the intervention with precision while engaging the child in playing with toys and using a conversational style of speaking. In sum, the clinician must be well prepared in terms of her knowledge of child targets and must be fluent in both the EMT and PE components of the intervention to deliver it at high levels of treatment fidelity.

Most children with CL/P in this sample were low-rate talkers at the start of the study. This low rate of productive language poses challenges for both accurate assessment of productive speech and language abilities and delivery of a child-driven naturalistic intervention that teaches in response to the child's communication attempts. Using EMT strategies to increase the rate of talking (e.g., contingent adult responding, imitating child actions while modeling related language, and prompting for functional language) may be necessary before recasting for phonological accuracy can be effective. Children must have a moderate rate of verbal communication so that recasting can be delivered frequently enough to improve speech production. For very-low-rate children, EMT and PE intervention components may be introduced sequentially with initial emphasis on increasing the rate of verbal communication, then modeling and prompting target words with target sounds, then recasting child utterances to promote correct speech production. Effective intervention may require monitoring child verbalizations and adapting the intervention procedure to match the child's production.

Obtaining accurate pretest measures of speech production also was challenging. Typical procedures to stimulate production of speech sounds (asking the child to label objects, directing the child to imitate the word) did not promote attempts to speak in all children. Using multiple measurement contexts to sample speech production (such as the PEEPS, language sample with the clinician, and observation during parent—child interaction) as well as assessing on multiple occasions may be necessary to get a reliable estimate of abilities. Frey et al. (2017) found that children with CL/P were relatively more sensitive to assessment context than TD toddlers and that performance varied

significantly between language samples with a clinician and play interactions with their parents.

Future research should begin by replication of the procedures of the current study. Then, subsequent studies should address how parents can be included in the EMT+PE protocol. Because of the precision required to deliver the full intervention, it is likely that a parent plus therapist model similar to Kaiser and Roberts (2013) would be useful. The therapist would provide intervention directly to the child and teach the parent to use the EMT+PE strategies in everyday interactions at home. The interventionist would monitor child progress in speech and language and guide the parent in adapting the strategies to fit the child's current development. It is expected that children with CL/P will make rapid progress in acquiring words and phrases but may need more practice with speech sounds. Thus, the expert intervention by the therapist would accelerate speech development by teaching sounds in a developmental sequence, and both the parent and therapist would provide support for developing language in the context of interactions.

Data on speech and language outcomes for children with CL/P are somewhat variable. Some but not all children are likely to need intensive and long-term support to develop typical speech and language. Although an early intervention such as EMT+PE could provide an early boost to developing speech and language, the intensity, duration, and focus of intervention may vary across children. There is a need for longitudinal follow up of early interventions for children with CL/P to determine the longer term outcomes and to determine the characteristics of children who may need more intensive or prolonged intervention to optimize speech and language outcomes.

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