

PROTOCOL

Enriching communication environments for children attending early childhood education centres in Western Sydney

Protocol Number (if applicable): *We intend to register this trial with the
Australian New Zealand Clinical Trials Registry*

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Authors:

Alison Britton¹
Sarah Masso^{2,3}
Tricia McCabe^{2,4}
Natalie Munro²
Fiona Aghajanian¹
Vanessa Lau¹
Alicia Horesh¹
Heather Faulkner¹
Emma Campbell¹

¹Integrated and Community Health, Western Sydney Local Health District

²Faculty of Medicine and Health, The University of Sydney

³The School of Teacher Education, Charles Sturt University

⁴South Western Sydney Local Health District

Sponsor:

Western Sydney Local Health District

Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

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1. GLOSSARY OF ABBREVIATIONS & TERMS

Abbreviation	Description (using lay language)
ECEC	Early Childhood Education Centre
WSLHD	Western Sydney Local Health District
The Training	Modified Learning Language and Loving it™ Program (modification approved by the Hanen Centre®)
SP	Speech Pathologist
Educator	Early Childhood Educator

2. STUDY SITES

2.1 STUDY LOCATION/S

Site	Address	Contact Person	Phone	Email
Speech Pathology Services, Child and Family Health, Integrated and Community Health	Western Sydney Local Health District	Alison Britton	0409 469 902	alison.britton@health.nsw.gov.au

3. FUNDING AND RESOURCES

3.1 SOURCE/S OF FUNDING

This study is supported, in part, by funding received from the Paediatric Innovation Fund from NSW Health awarded to Britton, Lau, Masso, Munro, McCabe, Gott, Faulkner, & Horesh (2019-2021). Speech Pathologists involved in the project are employed by Western Sydney Local Health District and The University of Sydney.

All Speech Pathologists delivering the modified version of the Learning Language and Loving It™ program were trained by the Hanen Centre®. This training was paid for by a ClubGRANTS grant from Dooleys Lidcombe Catholic Club (2018) and the Paediatric Innovation Fund grant (listed above). All trained Hanen-certified Speech Pathologists pay an annual fee to the Hanen Centre® in order to maintain certification. Despite this financial relationship, the Hanen Centre® has no oversight over the current research study.

4. INTRODUCTION/BACKGROUND INFORMATION

4.1 LAY SUMMARY

This project will investigate the impact of a professional development training program, (herein called the Training) for early childhood educators that has a focus on improving their communication interactions with children in their care. The Training is a modified version of Learning Language and Loving It™ developed by the Hanen Centre®. It was modified by the current research team to suit the needs of the local community. The modification has been approved by the Hanen Centre®. Previous research by the current team established that educators reported increased confidence using trained interaction strategies following the Training. The current study will evaluate the direct change in child and educator language use during communication interactions before and after the Training. We hypothesise that participation in the Training leads to positive child and educator communication outcomes including an increase in the number of interaction skills used by educators following Training, and the length of utterances and complexity of words used by children during these interactions.

Eligible educators and children will be paired by centre of attendance and language background. Children will be aged 24-42 months and have typically-developing communication skills. Twenty-four educator-child pairs will be recruited in two groups: Group A and Group B. Each group of educators will receive the 8-week Training in two separate stages; Group A in Stage 1 and Group B in Stage 2. This will allow for control and follow-up comparisons to be completed (see Figure 1).

Demographic information will be collected from educator and child participants before any training commences. In addition, 15-minute educator-child interactions will be video recorded at four time-points within their early childhood education centre (ECEC). Measures will examine the extent to which educators use target interaction strategies and the way children use language in these interactions. This project will help to address a critical gap in knowledge about whether this modification of the Learning Language and Loving it™ Program has a direct impact on children's communication outcomes.

4.2 INTRODUCTION

There is considerable evidence to suggest that professional development with early childhood educators can have a positive impact on children's communication skills (Markussen-Brown et al., 2017; Masso et al., in preparation). It is understood from previous research that when educators are responsive communicators, the language development of young children is supported by the quality of their interactions (Girolametto, Weitzman & Greenberg, 2006). However, previous research has not considered the effectiveness of professional development training for educators in culturally- and linguistically diverse communities. Further, the direct impacts of the current local adaptation of the Training on child and educator interaction behaviour have not been measured.

The current project is Phase 3 of a study entitled Growing Little Language Learners; Phase 1 and 2 were completed in 2020. In Phase 1, a locally-developed adaptation of an established Training was modified in consultation with a community reference group. In Phase 2, the Training was implemented with 36 Educators in the local community; 71% of educators were multilingual with 25 different languages spoken amongst the group. The current project (Phase 3) will allow us to examine the impact of this integrated model of care on improving the communication outcomes of children.

The current project will be conducted across a 20-month period, commencing in mid-2021. There will be five time points and two stages of educator Training. Participating educators will only complete the Training in one of the two stages.

The study will investigate whether children and their educators change their communication behaviours following the Training and whether the amount of change during the training stage is commensurate with change during the stage where no training is received. We hypothesise that there will be a greater magnitude of communication behaviour change during a period of training (as opposed to a period of time when no training is provided).

Through this investigation, we will determine whether new models of care being implemented by Western Sydney Local Health District (WSLHD) are initiating the expected, positive change in the quality of early childhood communication environments in the local area. The outcomes of this study will support decision making regarding the effectiveness of the Training and therefore the value of future implementation of the Training across communities.

4.3 BACKGROUND INFORMATION

Most children aged 2-3 years old in Australia attend formal or informal childcare with as many as 71% of both age groups reported to attend child care (Australian Bureau of Statistics, 2017). Despite attending childcare, many children in Western Sydney are vulnerable to communication difficulties and health inequities due to cultural and linguistic diversity, socioeconomic vulnerabilities, and access to quality communication environments in their early education centre. A recent review on the state of ECEC care in Cumberland City Council area found that the quality of care in this local government area is lower than the state average, with just 20% of centres rated as exceeding the National Quality Standard, compared to 32% of centres across Australia (Cred Consulting, 2019). Traditional models of care are unable to meet the needs of vulnerable communities as long waiting lists and limited services threaten the wellbeing of children at greatest risk of long-term communication, social, and academic disadvantage. Previous research suggests that high quality child care environments positively impact the language development of children from these low-income backgrounds (McCartney, Dearing & Taylor, 2003).

Child and Family speech pathologists of WSLHD have established a new model of integrated care that provides an evidence-based professional development training to early childhood educators in the local community. This Training – Learning Language and Loving It™ (Hanan Centre®, locally modified with permission) – has improved educator confidence in identifying children with delayed communication and knowing what to do when a communication difficulty was suspected (Britton et al., in preparation). Furthermore, educators reported increased confidence using a wide range of interaction skills to support communication development.

The training has been adapted from a well-established training program developed by the Hanan Centre® in Canada. However, evaluations of the standard training (i.e., Flowers et al., 2007; Giromalletto et al., 2003; McDonald et al., 2015) and subsequent adaptations by other research teams around the world (i.e., Cabell et al., 2011; Piasta et al., 2012) have failed to consider the impact of this type of training on multilingual educators and the multilingual/multicultural children in their care. No previous investigations have considered the impact of this training on the communication behaviours of a diverse range of language speakers in their educator and/or child populations. The current investigation, therefore, serves two purposes: (1) to establish whether the locally adapted Training has a direct impact on educator and child communication behaviours during periods when educators are, and are not, engaging in the Training, and (2) to establish whether any changes in communication

behaviours are consistent in English and any additional language/s shared by educators and the children in their care.

Educators have access to a large number of children. They are therefore well-positioned to provide high quality communication opportunities to children of all language abilities. As a result, the potential magnitude of the impact they can have on children in ECECs is far greater than any single speech pathologist could provide through traditional methods. Furthermore, the significant and far-reaching impacts of early language intervention and prevention in the early years are well-established. The results of the current study will inform future ongoing implementation of this training and/or guidance for early childhood educators and education centres in the local area, with a view to improve the communication environments for all children in Western Sydney.

The Training

In 2019, the Speech Pathology team within the Child and Family, Integrated and Community Health service of WSLHD began providing training to early childhood educators in the local area. The training is based on the Learning Language and Loving It™ training developed by the Hanen Centre®. Learning Language and Loving It™ is a valid, evidence-based professional development program which addresses the pivotal role of the early childhood educator in facilitating children's social, language and literacy skills. This program uses the most current research in the areas of childhood education, language development and adult learning to promote developmentally appropriate interactions which are associated with positive language and literacy outcomes for the young children who attend child care. The Training that will be provided as a part of the current study has been adapted locally, through discussion with a local reference group of educators, directors, local council representatives and service providers to suit the needs of the local community. The subsequent adaptation has been approved by The Hanen Centre® and is the first adaptation to be trialed with a distinctly culturally and linguistically diverse population. The Training includes educator attendance at five workshop sessions with a group of their peers and three 1-on-1 coaching sessions in their early childhood education centre workplace with a speech pathologist from WSLHD. This is a truncated version of the full Learning Language and Loving It™ training which involves eight workshop sessions and six video feedback sessions. The modifications were made to make implementation more feasible given educator work commitments, availability for out-of-hours training, and speech pathology resources.

The aim of the Training is to teach early childhood educators responsive interaction strategies that are known to promote the social and communication development of young children and determine the impact of these strategies on children's language production. These strategies include: (1) Child-oriented strategies to support children to engage in conversation and initiate new interactions, (2) Interaction-promoting strategies that can facilitate the extension of language opportunities during individual and group interactions, and (3) Language modelling strategies that expand on children's current communication abilities to increase the complexity of their communication in familiar and unfamiliar communication contexts.

If restrictions and policies surrounding arising from the COVID-19 pandemic impact the planning and implementation of the training, the training may be delivered online. The Hanen Centre® has created an online version of the program which is equivalent in content, structure and duration.

5. STUDY OBJECTIVES

5.1 RESEARCH QUESTIONS

This study will include two primary research questions relative to each participant group. Secondary research questions have also been identified for each participant group. Primary and secondary research questions are listed below.

5.1.1 Was the magnitude of change in children’s mean length of utterance greater during a period of educator training when compared to a control period with no training (Stage 1 comparison)?

5.1.1.1 Was the magnitude of change in children’s mean length of utterance during a training period comparable to a post-training follow up period (Stage 2 comparison)?

5.1.2 Was the magnitude of change in overall educator interaction skills observed greater during a period of educator training when compared to a control period with no training (Stage 1 comparison)?

5.1.2.1 Was the magnitude of change in overall educator interaction skills observed during a training period comparable to a post-training follow up period (Stage 2 comparison)?

5.2 PRIMARY OBJECTIVES

To establish whether children’s mean length of utterance during educator interactions is impacted by educator participation in the Training *and* whether early childhood educators participating in the Training demonstrate a greater change in their use target interaction skills when interacting with children in their care within a training period compared to a period of no training.

5.3 SECONDARY OBJECTIVES

Secondary objectives of the current research include determining the change in children’s linguistic productivity (number of words said, number of conversational initiations, and number of conversational turns) and complexity (vocabulary diversity) during periods when their educator is, and is not, attending the Training. All objectives will be achieved through observation of educator/child interactions at four time points (Time 2-5 described in section 5.6.1).

5.4 OUTCOME MEASURES

This research includes two primary outcome measures: (1) mean length of utterance¹ demonstrated by the child, and (2) a composite score of overall interaction strategies demonstrated by the target educator. These measures are consistent with previous research investigating children’s language development and adult-child interactions (Girolametto, Weitzman, & Greenberg, 2003; Girolametto, Sussman, & Weitzman, 2007; Piasta et al, 2012).

The outcome measures for the current study will be gathered from four 15-minute interactions between educator-child dyads collected before and after each training period. A difference score for each outcome measure will be calculated for each stage of training (differences between Time 2 and

¹ Mean length of utterance is a well-established measure of child language first described by Brown (1973). The calculation of mean length of utterance is based on the average number of morphemes produced per child utterance. It is an appropriate measure of language for young children (Ezeizabarrena & Fernandez, 2018).

Time 3 will produce Difference Score 1; change between Time 4 and Time 5 will produce Difference Score 2; time points are described in Figure 1 below).

Primary Outcome Measures:

The primary outcome measure for educators will be the change in the composite score of overall interaction strategies demonstrated by the target educator in a 15-minute interaction with a child during a training period and during a period of no training. Eight target interaction strategies were defined by Speech Pathologists in WSLHD, with reference to the Teacher Interaction and Language Rating Scale (TILRS; Girolametto, Weitzman, & Greenberg, 2000) and the Conversational Responsiveness Assessment and Fidelity Tool (CRAFT; Friel, Wiggins, & Justice, 2007). Target interaction skills include three Child-oriented strategies, two Interaction-promoting strategies and three Language-modeling strategies. **Child-oriented strategies** include: (1) Encourages child to initiate by observing, waiting expectantly and listening, (2) Responds to the child's initiation with animation and specific language, and (3) Adjusts their position so that they are face to face with the child. **Interaction-promoting strategies** include: (4) Uses a variety of questions to stimulate conversations, and (5) Encourages turn taking. **Language-modeling strategies** include: (6) Uses a variety of vocabulary, (7) Expands the child's utterances by recasting and adding ideas, and (8) Extends the child's utterances by giving information about the topic. Each of these eight strategies will be coded as 'absent' (0) or 'present' (1) for each 30 second segment of the 15-minute interaction. An average will be taken for each strategy across all segments of the video. Then, all average scores will be summed to create a composite score of use of interaction strategies by educators. The presence of these skills will be coded by two members of the research team. These two members will score two video samples independently and meet to reach consensus on the presence of each strategy based on these two videos. The remaining video samples will be randomly allocated and coded by one of these two researchers; each of the two researchers will code 50% of the video samples each. Inter- and intra-rater reliability will be calculated based on 10% of the recorded samples.

The Primary outcome measure for children will be the change in mean length of utterance within a 15-minute interaction with an educator during an educator training period compared to a period of no training.

Secondary Outcome Measures:

The secondary outcome measures for educators will be the difference in the frequency with which the educator uses each of the target interaction strategies in the 15-minute interaction with a child. Target interaction strategies are listed above in Primary Outcome Measures. Difference scores for each of these average scores of presence or absence of the strategy will be compared.

The secondary outcome measures for children will be difference scores for four measures of linguistic productivity or 'talkativeness': (1) total number of words said, (2) number of communication initiations, (3) number of conversational turns, and (4) vocabulary diversity (a measure of linguistic complexity). These will be obtained via computerised conversational language analysis of the 15-minute interaction with an educator. Difference scores for each of these measures will be calculated and compared.

Study Design

5.5 STUDY DESIGN DIAGRAM

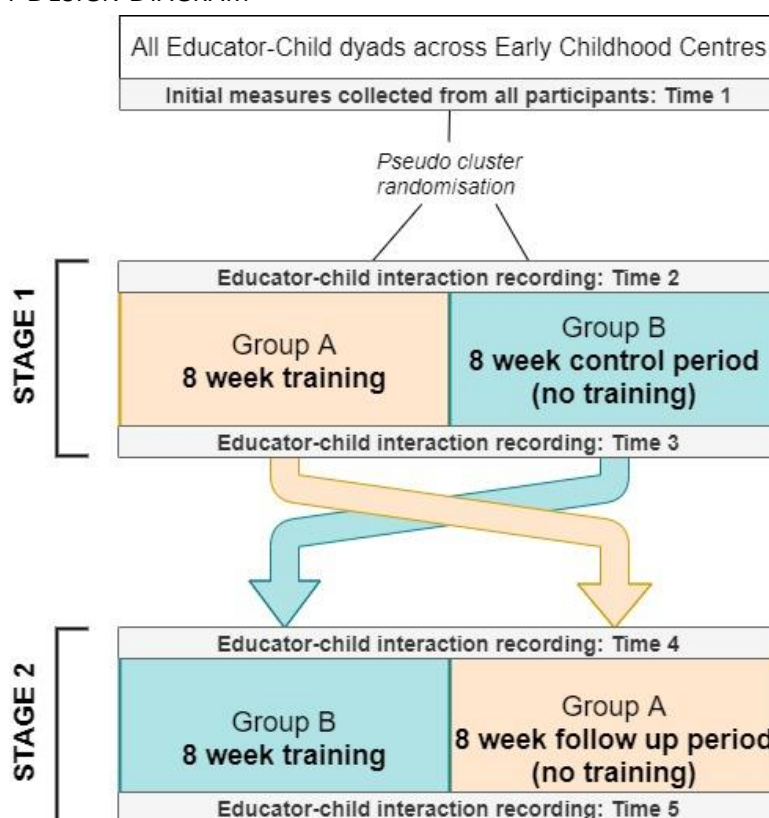


Figure 1. Study Design flow chart

5.6 STUDY TYPE & DESIGN & SCHEDULE

This project will utilise an intervention-controlled, cross-over study design with two groups (see Figure 1). It will be a single-site study, completed within Integrated and Community Health in WSLHD and will be conducted across multiple ECECs within WSLHD .

Early childhood educators from ECECs within the Cumberland City Council Local Government Area will be enrolled to participate in the Training before the commencement of the current research. The Training is a continuing service that is currently provided by the speech pathology team in Child and Family Health within WSLHD. Two training stages will be conducted in 2021 and will form Stage 1 and Stage 2 of the current study.

All educators who are enrolled to attend the Training in 2021 will be invited to participate in the current study (see [Recruitment procedure](#) for further details). Following educator consent, each consenting educator will be paired with a child who meets the study inclusion criteria (see [Inclusion Criteria](#)) and educator-child dyads will be formed. These dyads will then be randomised in to one of two groups at the ECEC level: (1) Group A will receive training in Stage 1, (2) Group B will receive training in Stage 2 (see [Fig. 1](#)). Given this research design, only Group B will have a control period (8 weeks) and only Group A will have a follow-up period (8 weeks), in which no training is provided. Educators who do not provide consent to participate in the current study will still receive the training. No data will be gathered for the purposes of this research from participants who did not provide consent.

The study population will be adult early childhood educators who are enrolled in the Training and children (aged 24-42 months) with typically developing speech and language skills in their care at an ECEC within the Cumberland City Council Local Government Area. Young children (aged 24-42

months) were selected as the population of interest for the current study due to the influence of Trained adult interaction strategies on language learning in children this age.

5.6.1 Research time frame

The timeframe for the current study will be 20 months from the time of recruitment until the end of the final stage of data collection. Data will be collected at five time points for all participant dyads: (1) recruitment and screening of participants (Time 1), (2) before Stage 1 Training (Time 2), (3) after Stage 1 Training (Time 3), (4) before Stage 2 Training (Time 4), and (5) after Stage 2 Training (Time 5) (see Table 1). Both training stages will be 8-weeks in length and there will be a five-week period between Stage 1 and Stage 2 within which Time 3 and Time 4 data will be collected from all dyads. Analysis and dissemination will continue for approximately 12 months from the completion of data collection.

Table 1. Research Time Frame

Study Time Frame	2021						2022
	Apr- Jun	Jul	Jul- Sep	Sep	Oct- Dec	Dec	Jan- Dec
Time 1: Recruitment and screening	2 mths						
Time 2: Data collection before Stage 1		1-2 wks					
Stage 1: Training implemented with Group A			8-wks				
Time 3: Data collection after Stage 1				1-2 wks			
Time 4: Data collection before Stage 2				1-2 wks			
Stage 2: Training implemented with Group B					8-wks		
Time 5: Data collection after stage 2						1-2 wks	
Data analysis and dissemination							12 mths

Time 1 will include the collection of demographic information about Educator and Child participants and confirmation of child eligibility to participate in the research. Times 2-5 are for the purpose of collecting outcome measure data. Difference scores on the primary and secondary outcome measures will be calculated between Time 2 and Time 3 (Difference Score 1, Stage 1) and Time 4 and Time 5 (Difference Score 2, Stage 2). Data for the current study will be collected from video recordings of adult-child interactions completed at Times 2, 3, 4 and 5. Data will include the extent to which the educator demonstrates interaction strategies and the language productivity and complexity demonstrated by the child in each dyad (see Table 2 for the data collection schedule). The inclusion of post-training evaluation of interactions at Time 4 and 5 is to determine the maintenance of interaction strategies demonstrated by Educators in Group A as well as any change in children’s language during a period of no active Educator training.

All analysed data will be de-identified and stored in this de-identified form for the purposes of all analysis. Only the video recordings will be identifiable for the life of the project as video samples cannot be de-identified of all identifiable information. All data, including video samples and extracted data will be re-identifiable only by a member of the research team, employed by WSLHD. It will be re-identified for limited purposes (i.e., to provide a report to the child’s family member at a future date as requested). See a detailed description of data storage protocols during and after the study period in [Section 9](#).

5.6.2 Data collection schedule

Time 1. Following Educator consent, the Educator Demographic Questionnaire (see Appendix A) will be used to collect demographic information from educators during Time 1 via a Microsoft Teams survey or as a hard-copy. This survey requests the disclosure of information related to the educator’s age, gender, country of birth, languages spoken, language proficiency, work history, and education. Following parent consent, demographic information will be gathered

for child participants during Time 1 using questions from the routine demographic questionnaire of the LHD (see Appendix B). At least two other tasks will be conducted for child participants at Time 1. Firstly, the Preschool Language Scales Screener (PLS screener; Zimmerman, Steiner, & Pond, 2011) (Appendix C), a 10-minute screener to identify possible communication impairment, will be completed with the child by a member of the research team in their ECEC, with the Speech Pathologist administering the screener via videoconference due to the impacts of the pandemic. Second, the communication section of the Ages and Stages Questionnaire (ASQ; Squires, Bricker & Twombly, 2009) (Appendix D) will be completed with the child's parent via phone. For multilingual child participants, the BabyLabs Language Exposure Questionnaire (Cattani et al., 2014) (Appendix E) will be completed with the child's parent via phone (see Table 2).

Time 2-5. Fifteen-minute interactions within each educator-child dyad will be video recorded at these four time points. These interactions will take place at the ECEC they attend. Recordings will be viewed and coded by a named member of the research team for the purpose of analysis and outcome measures will be obtained (Appendix F). All interactions will be recorded in the ECEC attended by both the educator and the child. No home visits will be required for the current study. Furthermore, each educator will complete the routine educator Training Survey before and after their training period. That is, Group A will complete the survey at Times 2 and 3 and Group B will complete the questionnaire at Times 4 and 5.

5.6.3 Data management

All participant data will be de-identified, with each participant assigned a participant number. Individual identifiable results will not be reported to participants or reported in an identifying form within published journal articles or presentations. A master document will be established to link participant numbers with identifying participant details. This document will be password protected and stored on the WSLHD server. The linking document will only be accessible by WSLHD research partners named on the project. See a detailed description of data storage protocols during and after the study period in [Section 9](#).

5.6.4 Student involvement in the project

This protocol *may* be used towards an honours student project in the future. If this change is proposed by the research team, the student will be supervised by a member of the university team and a member of the WSLHD team. An amendment to the current protocol would be submitted to the HREC for consideration in the event of student involvement in this protocol.

5.7 STANDARD CARE AND ADDITIONAL TO STANDARD CARE PROCEDURES

The data collection schedule and an indication of whether tasks are routine/standard care or additional are provided in Table 2 below.

Table 2. Data collection schedule for the current study

Entity	Data/Tool	Procedure	Time	Routine ^a or additional	Time
Educator	Consent	Returned via email	-	Additional	Before Time 1
Child	Parental consent				
Educator	Demographic information (Appendix A)	Completed online or on paper	5 mins	Additional	Time 1
Child	Demographic Information (Appendix B)		30 mins	Additional	Time 1

Child	ASQ communication section (Appendix D)	Phone call with a member of the research team			
Child	BLEQ (Appendix E) (<i>multilingual children only</i>)				
Child	PLS Screener (Appendix C)	Directly screened by a Speech Pathologist via videoconference at the child's centre	10 mins	Additional	Time 1
Educator	Training survey	Completed online or on paper	10 mins (x2)	Routine	Pre and post training
Educator/child dyad	Conversational interactions: analysed with Educator Interaction Strategies: Video Observation Tool (Appendix F) and conversational analysis	Video recording at the ECEC	15 mins (x4)	Additional	Time 2, 3, 4, 5

Note. ^a Routine data will be collected to support the implementation of the professional development program with all attendees. Only the data from consenting attendees will be evaluated. Additional data is data that is collected only for the purposes of this research to evaluate the feasibility of this program. None of the additional data will be collected from participants who do not provide consent. ASQ = Ages and Stages Questionnaire (ASQ; Squires, Bricker & Twombly, 2009), BLEQ = BabyLabs Language Exposure Questionnaire (BLEQ; Cattani et al., 2014), PLS = Preschool Language Scales Screener (PLS screener; Zimmerman, Steiner, & Pond, 2011).

5.8 RANDOMISATION

Centres participating in the Training will indicate availability for either or both of the training periods. We will use the random number generator at <https://www.random.org/integers/> to allocate centres who indicate availability for both stages. Therefore, pseudo-cluster randomisation will be implemented, as centres who are available in one time period only will not be randomised for pragmatic reasons. Randomisation will occur at the cluster or centre level to avoid cross-contamination effects between trained and untrained educators. This will occur after educators and children have been recruited in to the current study. This pseudo-randomization is required for the current, pragmatic study.

Masking of educators to training (+training) and no training (-training) conditions is not possible as they are actively participating in the training. The speech pathologist who analyses interaction skills will be blinded to which time point the video is recorded in and the condition that the educator is assigned to (+ training or –training). Therefore, this is a single blinded study.

5.9 STUDY METHODOLOGY

As described above, the current study will include data collected at five time-points (see research time frame in Table 1). The procedures for the current study are listed in the data collection schedule in Table 2.

6. STUDY POPULATION

6.1 RECRUITMENT PROCEDURE

There will be two types of participants in the current study: Educators and Children. Once educators ($n = 24$) and eligible children ($n = 24$) are recruited, educators and children will be paired, as feasible,

by centre of attendance and language background to form dyads. The recruitment for each participant group is detailed in the sections below.

6.1.1 Educator recruitment

All educators who are enrolled to participate in Training provided by WSLHD speech pathologists will be invited to participate in the current study. All educators will be contacted via email (Appendix G) by an investigator on the research team. The email to potential participants will include the Educator Participant Information Sheet (Appendix H) and the Educator Consent Form (Appendix I). Educators who do not respond to this email will be sent a follow-up email one week later by the research team. If no response is received from an invited educator, no further contact will be made by the research team and the enrolled educator will continue in the Training without participation in the current study. If an educator responds with a signed consent form, they will be a participant of the current study and will be sent the Educator Demographic Questionnaire (at Time 1, see Appendix A). In the case of multilingual educators, all reasonable efforts will be made to match educators with child participants who are enrolled in their ECEC and share a non-English language with the Educator to allow for code-switching during interaction sessions as deemed appropriate by the Educator.

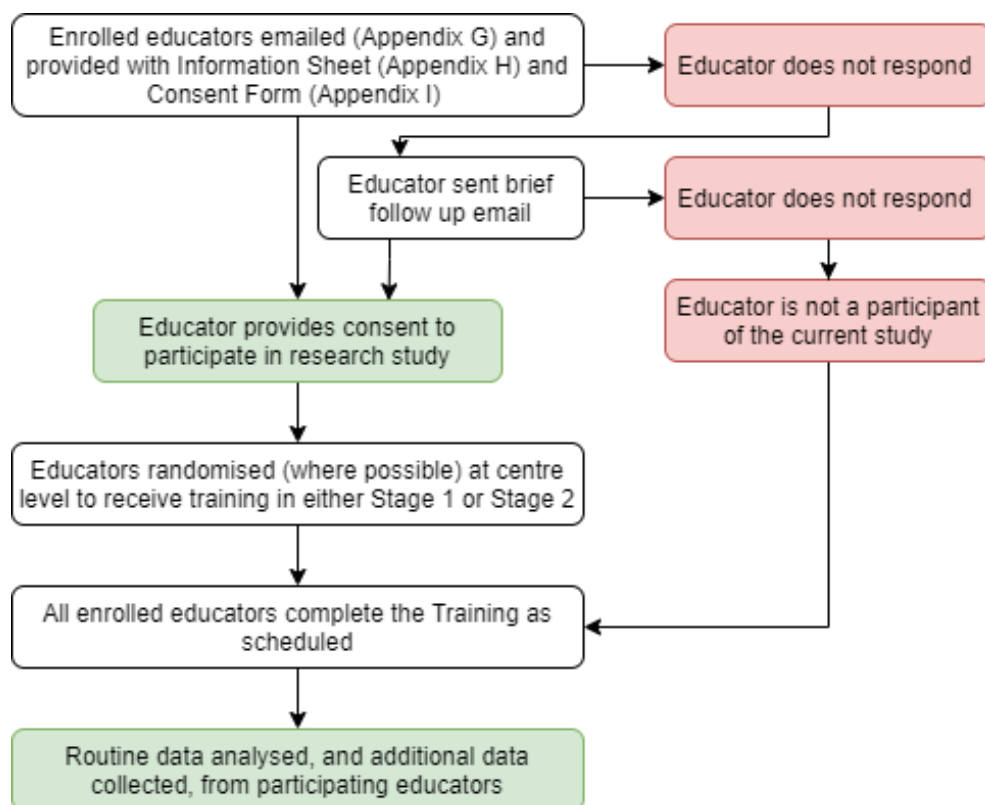


Figure 2. Educator recruitment. Relevant appendices are G, H and I.

6.1.2 Child recruitment

Following consent obtained by an educator, the research team will contact ECEC directors via phone (Appendix J) to advise of an educator participant at their centre and to seek support in identifying possible child participants who may meet the first two inclusion criteria specified below (i.e., correct age and no parental concerns regarding communication development). The research team will provide an email transcript (Appendix K) which centre directors will send to parents of potential child participants with the Parent Participant Information Sheet (Appendix L) and the Parent Consent Form (Appendix M) attached. If no responses are received from any

parents at the educator’s ECEC within 1 week, the research team will briefly call the director to follow up. If no responses are received from parents following this, the educator will be withdrawn from the study. In the event of between-stage child dropout, the Centre director will be asked to contact alternate potential child participants consistent with the initial child recruitment procedure.

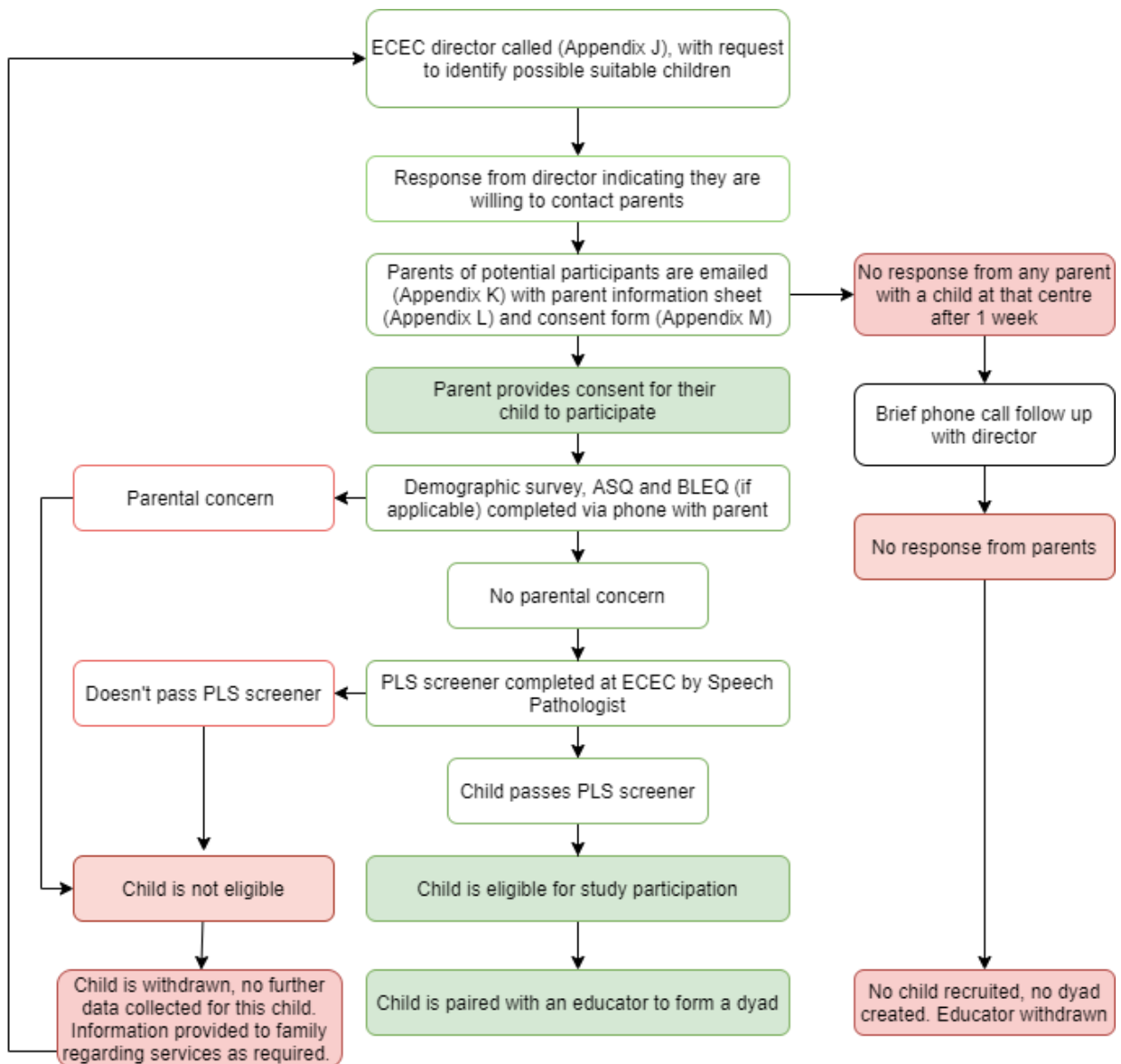


Figure 3. Child recruitment. Relevant appendices are J, K, L and M

6.2 INCLUSION CRITERIA

Inclusion criteria will differ for educators and children who participate in this study. The inclusion criteria for each participant group are described below.

6.2.1 Educator inclusion criteria

Inclusion criteria for educators will include consent to participate in all stages of the study and anticipated completion of the Training program. No limitations on Educator participation will be made based on prior training or level of education. Routine early childhood educator training at both TAFE and University levels does not cover the content of the Training provided as

described for the current study. Group comparisons will be conducted at baseline to ensure homogeneity in group variability based on level of Education.

6.2.2 Child inclusion criteria

The inclusion criteria for child participants are: (1) aged 24-42 months and attend the consenting educator's ECEC at least one day per week, (2) no parental concerns about speech and/or language development, (3) no concerns identified based on the child's performance on the Communication section of the Ages and Stages Questionnaire (ASQ; Squires, Bricker & Twombly, 2009) (Appendix D) completed with a parent in an initial phone call, and (4) no concerns identified based on the Preschool Language Scales Screener (PLS; Zimmerman, Steiner, & Pond, 2011) (Appendix C) completed with a speech pathologist via videoconference at the child's ECEC. Eligibility will be confirmed after consent has been received from interested parents and the child's screening has been completed at the centre.

The ASQ screens children for concerns about overall development and can be a first step to identify children who require further evaluation for developmental concerns. It is a parent evaluation checklist that is suitable to screen the behaviour and functional communication development of children. Eligibility will also be determined based on children's performance on the PLS Screener, a direct screening assessment of language skills that is suitable to complete with children from birth to 8 years of age. The ASQ and PLS screener tools are both valid for the target sample of the current study. Parents of multilingual children will also be interviewed with questions from the BLEQ to establish the proportion of language exposure the child receives in all languages. The BLEQ will not be used to establish eligibility but will be used to gather information about the proportion of English and additional language exposure.

6.3 EXCLUSION CRITERIA

Exclusion criteria are only present for child participants in this study. Children will be excluded if: (1) their parent expresses concern about development based on the ASQ or, (2) the child does not pass the communication screening using the PLS Screener.

6.4 CONSENT

Written consent will be obtained from educators and a legal guardian of child participants (see Appendix I and M respectively). Consent will be provided directly to the research team or via centre directors; speech pathologists providing the training will not be aware of the consent process and will be initially blinded to educators and child participants. Assent will also be obtained from child participant at each stage of the research (including the initial language screening).

It is possible that the educators and/or caregivers of potential child participants will have English as a second or additional language. Due to this, the participant information and consent forms are written in simple English and all documentation provides contact information for the research team if the educator/caregiver wishes to ask questions about the research prior to participation. Also, given that consent is an opt-in process for the current study, we do not expect families who do not understand the documentation to provide consent.

7. PARTICIPANT SAFETY AND WITHDRAWAL

7.1 RISK MANAGEMENT AND SAFETY

While this research is considered low risk, no research can be considered absent of risk. Possible perceived risks for educators could include concerns about data being shared with their employer. This risk will be mitigated by advising all educators (via the participant information sheet) that no individual data will be shared with their employer. Only group data will be shared and individual participant will not be identifiable.

One possible risk for parents who provide consent for their child to participate in the study but who are subsequently withdrawn due to either (1) parental concern on the ASQ or, (2) the child failing the PLS-screener, may become distressed. Speech pathologists are well trained to support families who are faced with the possibility that their child has delayed communication development. All researchers on this team are experienced in supporting families and providing additional resources to assist families to seek further assessment if required.

Risks to children are minimal. Assent will also be obtained from child participants at each stage of the research (including the initial language screening). Child or educator distress when recording will be mitigated through delaying the recording until an alternative, more suitable time and discussion with the research team.

One final risk, which is present with any research or clinical activity conducted with children, is the disclosure of any event or activity that may relate to the protection and safety of the child involved. All members of the research team are qualified speech pathologists and mandatory reporters who are familiar with the procedures to report events that meet the child protection threshold of significant risk of harm. Caregivers are informed of the obligation of research staff to share information as required by law within the participant information sheet (page 3).

The principal investigator and a number of authors on this protocol have completed the Good Clinical Practice training. All named researchers will complete the Good Clinical Practice training before the commencement of data collection.

7.2 ADVERSE EVENT REPORTING

Any adverse events occurring during the course of this study will be reported to the appropriate authority. This may include Western Sydney Local Health District, the Sydney Children's Hospital Network Human Research Ethics Committee and/or the ECEC in which the data for the current study will be collected. A serious adverse event may include any breaches in data confidentiality or storage security. In the case of this event, the breach will be reported to WSLHD and SCHN HREC within 24 hours of the identification of this breach. Serious participant adverse events may include a child receiving an injury during the videoconference screening and/or video recording. Although the chance of these events are minimal due to the nature of the data collection, any incident observed by a member of the research team will be reported to the centre director immediately and to the relevant authority within the LHD within 24 hours.

7.3 HANDLING OF WITHDRAWALS

Educators who provide consent but for whom a suitable child pair cannot be identified will be withdrawn from the current study. Children will be withdrawn if they do not assent to any stage of data collection (after appropriate attempts to reschedule video recordings). Participating educators and the consenting guardian of participating children can withdraw their consent at any time

throughout the duration of this study. Data already collected from withdrawn participants may be included in descriptive analysis of the intended participant sample. Data from withdrawn participants will be removed from group-comparison analysis.

7.4 REPLACEMENTS

Educator and child participants may be replaced if they withdraw (or are withdrawn) between Stages of the research (either before Stage 1, or between Stage 1 and Stage 2). Participants will not be replaced if they withdraw within Stage 1 or Stage 2. Missing data will be removed pairwise in the event of within-stage dropout. In the event of considerable withdrawals and a compromised sample size, a second wave of data collection may be proposed (following HREC approval) to retain required sample size.

8. STATISTICAL METHODS

8.1 SAMPLE SIZE ESTIMATION, JUSTIFICATION, AND CALCULATION

The sample size will be 24 Child-Educator dyads. A target of 12 dyads will be in Group A and 12 will be in Group B. This sample size is selected as a pragmatic threshold due to the likely enrolment of 24-28 educators per training period with an approximate 50% recruitment rate. A sample size larger than 24 dyads is not feasible for the context of the current study. This calculation also allows for dropout of 10% which is consistent with previous similar investigations. This sample size is also comparable to other similar studies in early childhood education (cf McDonald et al., 2015).

Previous data with comparable outcome measures was used to estimate the intra-class correlation (ICC) in a similar setting of educators grouped by centre. For most outcome measures, the ICC was estimated to be 0.1 or lower. Assuming two educators per centre (cluster), with six centres per treatment, a standard deviation in change score of 0.3 (Piastra et al., 2012; Berry-Kravis et al., 2013), an ICC of 0.1, alpha 0.05 and power 0.8, the study should be powered to detect a difference of 0.358. This is comparable to the difference in change score of 0.4 that was previously observed (Piastra et al., 2012).

8.2 STATISTICAL METHODS TO BE UNDERTAKEN

All questionnaire data will be collected via Microsoft Teams and exported in raw format for processing in R or SPSS. Demographic information (including age, languages spoken, language proficiency, educator level of education, educator years of experience, and child communication measures [ASQ and PLS]) will be described for all dyad participants. Two multiple linear regression analyses will be conducted to address the primary aim (Stage 1 contrast) and our secondary aim (Stage 2 contrast). The outcome (dependent variable) for both analyses will be children's mean length of utterance Difference Score across each Stage. Independent variables will be Group allocation (A or B) and cluster (ECEC). This analysis plan will allow for the primary investigation to be conducted on data collected in Stage 1. This primary analysis will investigate the impact of group allocation (Training [Group A]; Control [Group B]) and cluster (Educator Centre) on children's language output (Mean Length of Utterance). The secondary investigation will be conducted on data collected in Stage 2. This secondary analysis will investigate the impact of group allocation (No-training follow-up [Group A]; Training [Group B]) and cluster (Educator centre) on children's language output.

Intention-to-treat analysis will be completed in the event of educator drop-out from the training. If appropriate, per-protocol analysis will be completed to investigate the primary and secondary outcomes.

9. DATA SECURITY & HANDLING

9.1 DETAILS OF WHERE RECORDS WILL BE KEPT & HOW LONG THEY WILL BE STORED

Different data storage procedures will be used during data collection (9.1.1) and after data collection is complete (9.1.2). See the details for each below.

9.1.1 Data storage during the periods of data collection

Routine data (i.e., Educator training surveys) will be stored by WSLHD according to standard data management practices within the Health District. These data will be available to speech pathologists implementing the program, as it is a part of the routine data collection for the implementation of this professional development program. Data from consenting educators will be copied from the routine storage location, de-identified and stored in a secure, password protected file only accessible to members of the research team.

Additional data (i.e., child screening data and video files) will be de-identified (where possible, see Ancillary Data provisions below) and stored in a restricted access folder, separate to the routine data collected from Educators. These data will only be accessible to members of the research team. A master document will be established to link participant numbers with identifying participant details. This document will be password protected and stored on the WSLHD server; the linking document will only be accessible by WSLHD research partners named on the project. It will be re-identifiable by linking the number to the participant name using a master document.

9.1.2 Data storage after the period of data collection

All data gathered for the research will be stored by WSLHD. Data will be kept in a secure drive, only accessible to the research team. Identifiable research data will be password protected. No personal identification information will be recorded in the raw data files. As such, data will never be recorded using identifying information. Only the principal investigators from the research team will have access to any personal participant information and data. Identifiable information about all participants will be stored on a password-protected excel document within a secure folder. It will only be accessible by named members of the research team. Participants will be advised via the participant information sheets that any identifying information about participants will be stored within WSLHD according to WSLHD and NSW Health Policy and Procedures.

On completion of the project, long term storage of data will be managed by WSLHD. The data and all related documentation will be managed in accord with WSLHD Corporate Records Management Policy (WSYD-POLY201465). Only the researchers named on this application will have access to the data. Data will be stored for a minimum of 15 years after the date of publication or termination of the study, or until the youngest participant turns 25.

9.2 CONFIDENTIALITY AND SECURITY

All documents will be held in strict confidence by study investigators and not released to any third party without written approval of investigators.

9.3 ANCILLARY DATA

Video files cannot be completely de-identified due to the identifying nature of recorded images. These will be stored with separate participant identification numbers and stored by Western Sydney Local Health District according to standard data management practices within the Health District. Only named members of the research team will have access to these files and will only access them for the purposes described in this proposal (or subsequent amendments).

10. APPENDIX

List of Attachments included:

Appendix Name	Document Name	Version Number	Date (e.g., 18 January 2012)
Appendix A	Educator Demographic Questionnaire	1	23 February 2021
Appendix B	Child Demographic Questionnaire	1	26 February 2021
Appendix C	Preschool Language Screener Form	1	23 February 2021
Appendix D	Ages and Stages Questionnaire: Communication section	1	26 February 2021
Appendix E	BabyLabs Language Exposure Questionnaire Form	1	26 February 2021
Appendix F	Educator Interaction Strategies: Video Observation Tool	1	26 February 2021
Appendix G	Email transcript: Invitation to educators for study participation	1	26 February 2021
Appendix H	Educator Participant Information Sheet	1	26 February 2021
Appendix I	Educator Consent Form	1	26 February 2021
Appendix J	Phone Call Transcript- To Directors to Identify Potential Child Participants	1	26 February 2021
Appendix K	Email transcript- To Parent to Invite Child to Participate	1	26 February 2021
Appendix L	Parent Participant Information Sheet	2	28 April 2021
Appendix M	Parent Consent Form	1	26 February 2021
Appendix N	Accessible Parent Participant Information Sheet	2	22 June 2021

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