LONG/ FULL TITLE OF THE STUDY

Shape Bias Training as a Vocabulary Intervention for Late Talkers

SHORT TITLE OF THE STUDY

Vocabulary Intervention for Late Talkers

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Vocabulary Intervention for Late Talkers
Research protocol

1 Background

Most studies regarding language acquisition have focused on understanding when and how infants learn words. It is known that at 24 months, typically developing infants know and produce between 200 and 300 words (Jones & Smith, 2005; MacRoy-Higgins, Shafer, Fahey, & Kaden, 2016) and add to their vocabularies from 22 to 37 words each month (Vuksanovic & Bjekic, 2013). It is also during the first years of life that some principles that promote vocabulary learning are developed. The shape bias, which is a tendency to infer that objects that share the same shape will also share the same name, is the one that has been studied the most. At 24 months, typically developed infants present a shape bias and use it as a strategy to generalize words (Jones, 2003; Weismer, Venker, Evans, & Jones Moyle, 2013). In contrast, Late Talkers do not exhibit this preference and present a difficulty in organizing objects by shape (Jones, 2003). It has also been found that teaching typically developed infants a shape bias before the end of the second year of life boosts their vocabulary development (Smith, Jones, Landau, Gershkoff-Stowe, & Samuelson, 2002). Despite this, the possibility of teaching Late Talkers this principle and its effect on their vocabulary and language development has not been explored.

1.1. The shape bias in typical language development

During the first years of life, infants learn and produce mainly words related to object names. Several studies have suggested that between 18 and 24 months, infants learn that novel words can be generalized or extended on the basis of visual properties, especially on the basis of shape, which is known as the 'shape bias' (Borgström, Torkildsen, & Lindgren, 2015; Landau, Smith, & Jones, 1998; Perry & Samuelson, 2011). This bias is a tendency to extend names to objects that share the same shape and not other visual properties such as colour, texture or size (Dansereau, 2016; Hupp, 2015). For example, two round objects can be called "ball" because of their shape even if both objects have different colours, sizes or textures. A shape bias is a useful strategy because object categories tend to be organised by shape (Graham, Williams, & Huber, 1999) and shape is a perceptual feature that can be identified quicker than other visual properties (Landau, Smith, & Jones, 1988).

1.2. The shape bias in Late Talkers

Late Talkers are infants that show a limited expressive language characterized by less than 50 words by the age of 2 in the absence of a physiological, cognitive or genetic disorder that may

account for this delay (Macroy-Higgins & Montemarano, 2015; Rescorla, 2011; Weismer et al., 2013). Late Talkers tend to be below the 15th percentile of expressive vocabulary (Colunga & Smith, 2008) and represent from 10% to 15% of the total infant population (Tsybina & Eriks-Brophy, 2007). Some of these infants "catch up", but others show persistent language difficulties throughout their lives.

Interestingly, Late Talkers do not exhibit a shape bias (Colunga & Sims, 2011; Weismer et al., 2013). This might contribute to their language delay and to their difficulty of adding new words to their vocabulary, even though this is unlikely the only cause of their language delay. A family history of language delay and limited interaction between parent/guardian and infant are likely other important factors (Girolametto, Weitzman, & Earle, 2013).

The three conventional approaches followed for Late Talkers are 'wait and see', 'watch and see', and 'early intervention'. The 'wait and see' approach means no action or intervention, and it is advised to wait until the infant is older to see whether a language delay is indeed present (Girolametto et al., 2013). The 'watch and see' approach consist of monitoring the infant's language development and evaluate it every 3 to 6 months (Preston et al., 2010) to assess if intervention is required or if the infant "catches up". The 'early intervention' approach consists of actively working with the infant to help them to develop their language.

The typical intervention for Late Talkers consists of a series of meetings with a speech and language therapist in group or individual sessions providing language and communication stimulation as well as providing parents and guardians with ideas for how to support their children's language development at home. Most of these interventions tend to include techniques such as focused stimulation, modelling target words (Cable & Domsch, 2011), general language stimulation and milieu teaching (Finestack & Fey, 2013). For focused stimulation, the parent or carer establishes a joint focus with the child by producing an object's name (e.g. "ball"), a comment (e.g. "Look!") or a two-word utterance (e.g. "big ball") (Cable & Domsch, 2011). The technique of modelling target words consist of repeatedly mentioning words to the child in an informal, play-like context (Cable & Domsch, 2011). The general language stimulation technique consists of creating a rich environment in which the child can experience different objects and activities (Finestack & Fey, 2013) such as reading books, playing, helping in everyday activities, etc. Finally, the milieu teaching consists of identifying specific goals and, with the use of naturalistic settings or activities, encourage the child to attempt to use target words or behaviours (Finestack & Fey, 2013). Considering these techniques used in Late Talkers interventions, it appears that many of them aim at teaching the infants specific words or communication patterns they do not know.

1.3. The shape bias as a strategy to boost vocabulary acquisition

Besides being a characteristic of typical language development, evidence suggests that very young typically developing infants that do not have a shape bias yet can be taught to use it as a cue to generalize novel labels, and importantly, that this can have a positive effect on their general word learning. A study by Smith et al. (2002) showed that 17-month-olds can be taught to generalize names to objects that share the same shape. During 7 weeks, infants were presented with sets of novel objects with novel names based on the objects' shape. After this training phase, infants extended the names of both the trained and completely new unfamiliar objects on the basis of shape. Importantly, using a vocabulary checklist filled in by the infants' parents, the study also found that the infants' vocabulary had grown significantly faster over the course of the intervention than that of a control group of infants who did not receive the intervention.

2. The present study

Given the evidence of the benefits of teaching infants a shape bias for their language development and the lack of a shape bias in Late Talkers, the present study will assess if Late Talkers can be taught a shape bias and benefit from it in their vocabulary and language development. Such an intervention can potentially function as a powerful alternative to teaching children specific words. Considering the positive results obtained by Smith et al. (2002) with typically developing children, this intervention programme might help Late Talkers develop a useful attention bias for word learning.

3. Research Questions

3.1. Primary objectives

The main objectives of the present study are:

A. To investigate whether it is possible to teach Late Talkers to attend to objects' shapes as a useful property for learning and generalizing novel object labels.
B. To assess the benefits that this intervention programme has on Late Talkers' short-term vocabulary development compared to an intervention where infants will be taught specific words ('specific word' intervention).
C. To assess the benefits of the intervention programme on language and cognitive development one year after the intervention compared to the 'specific word' intervention.

3.2. Secondary objectives

As a secondary objective, the study will investigate whether some children are more receptive to the shape bias intervention programme than others. More specifically, we will:

D. Assess whether the success of teaching Late Talkers a shape bias for noun extension is related to their sensitivity to object shape similarities.
E. Assess whether the success of teaching Late Talkers a shape bias for noun extension is related to their ability of sustain their attention to novel objects that are presented to them.

3.3. Primary outcome measures

Objective A), i.e. whether children have learned a shape bias, will be assessed by means of a noun extension test with novel names and objects never heard and seen before by the infants at the end of the intervention programme.

Objective B), i.e. whether the intervention programme benefits infants' general vocabulary development, will be assessed with a vocabulary checklist filled in by the parents/guardians before and after both types of intervention. We will compare the vocabulary growth in the group of children that took part in the shape bias intervention programme with that of the group of children that took part in the 'specific word' intervention. A significant larger increase in the shape bias intervention compared to the 'specific word' intervention will provide information regarding the success or efficacy of the shape bias intervention.

Objective C), i.e. whether the shape bias intervention has a "long-term" effect on language development and cognitive abilities. Receptive and expressive language, and cognitive abilities, such as visual spatial skills and working memory, will be assessed at one year after the end of the intervention programme.

3.4. Secondary outcome measures

Objective D), i.e. whether children are more receptive to the shape bias intervention if they are sensitive to shape similarities, will be assessed by relating children's ability to sort objects by shape before the intervention and their ability to extend object labels by shape after the intervention.

Objective E), i.e. whether children' are more receptive to the shape bias intervention if they can sustain their attention to novel objects, will be assessed by relating children's sustained attention during the presentation of a video showing a person presenting and moving novel objects before the intervention, their attention to the novel objects during the intervention, and their ability to extend object labels by shape after the intervention.

4. Method

4.1. Participants

We will recruit a minimum of 30 infants between 2 and 4 years old, identified as Late Talkers (children with a moderate or severe language delay) by Speech and Language therapists working for the Birmingham Community Healthcare NHS Foundation Trust.

4.1.1. Inclusion criteria

- Children (boys and girls) between 24 and 48 months.
- Children from Birmingham and its surrounding areas.
- Monolingual English native speakers
- Children with a moderate or severe language delay, as diagnosed by a Speech and Language Therapist of the Birmingham Community Healthcare NHS Foundation Trust.

4.1.2. Exclusion criteria

- Children with a developmental, physiological, neurological or cognitive disorder that could explain their language delay.
- Children with a mild language delay, as diagnosed by a Speech and Language Therapist of the Birmingham Community Healthcare NHS Foundation Trust.
- Children that speak or know another language different than English, either as first or additional language.

4.1.3. Participant identification and recruitment

We will recruit children via the Speech and Language Therapy Services from the Birmingham Community Healthcare NHS Foundation Trust. Parents/guardians of children that have been referred to these services are invited to attend an individual screening session. In this session, children are evaluated and divided into three categories: children with a mild language delay, children with a moderate delay, and children with a severe delay. Only children with a severe language delay are invited to take part in a subsequent intervention programme run by the NHS services, while it could currently take up to a year between the initial assessment and the start of the intervention. Parents/guardians of children with mild or moderate language delays are provided with guidance on how to support their child's language development and to contact the services again if the child seems to continue to lag behind their peers in their language development.

Parents/guardians of children that fulfil our inclusion exclusion criteria above (i.e. have either a moderate or severe language delay among other criteria) will be provided by the speech and language therapist with a brochure/leaflet (Appendix 1.1) about the present study at the end of the

initial assessment. The therapist will inform them that they can contact us in order to see whether the child might be able to participate in our study. In case of children with a diagnosis of severe language delay, the intervention will take place during the time that they wait for the start of their intervention conducted by the NHS services. They will be informed by the therapist and through the study brochure that their participation will not affect the services provided to them by the Birmingham Community Healthcare NHS Foundation Trust and that they will still receive an evaluation/intervention appointment with them in the future as planned.

The brochure (see Appendix 1.1) will contain information about the study, and the Chief Investigator/Researcher's contact details. If parents/guardians are interested, they can contact the Chief Investigator or researcher. If the children meet the inclusion and exclusion criteria and if capacity allows, they will be invited to take part in the present study at the Infant and Child Lab at the University of Birmingham.

4.1.4. Consent

Parents/guardians will consent their willingness to take part in the study on behalf of their children. The will receive a detailed information sheet (see Appendix 1.2) and a verbal summary of the study by the researcher at the beginning of the initial session of the intervention programme. After this summary and before commencing the first training/testing, they will be asked to sign a consent form (see Appendix 1.3). This consent form states the activities the child will be introduced to and the duration. It emphasizes that participation is completely voluntary, that the parent/guardian can withdraw his/her child from the study at any time up to 1 month after the final session of the intervention programme and without giving any reason, and that this will not have any impact on any services provided by the Birmingham Community Healthcare NHS Foundation Trust in the future. Parents will also be informed that a follow up study will be conducted and will be asked to provide a separate signature if they agree to be contacted in the future to follow up on the progress of their child or not. With regards to the infants, a simple explanation (age appropriate) of the tasks will be provided to them. Afterwards, infants will be asked if they want to "play" with the researcher.

4.1.5. Withdrawing criteria

Parents/guardians can fully withdraw their infants from the study at any stage and up to 1 month after the final session of the intervention programme without the need of providing any explanation. If this happens, all existing paper forms and electronic data related to the infants will be destroyed and their details in the participant database will be deleted. They will therefore not be contacted for any follow-up study. Parents/guardian can also decide not to take part in the follow-up study, either

by not signing the agreement for the follow-up contact on the initial consent form or by informing the researcher when being contacted to make arrangements for the follow-up testing. As with the intervention programme, parents/guardians can withdraw their children from the follow-up study at any time up to 1 month after the completion of the follow-up test. Parents will be informed that their decision to withdraw from the study will not affect any services provided to them by the Birmingham Community Healthcare NHS Foundation Trust.

4.2. Study design

Infants will be randomly allocated to one of two groups: shape training group or specific word training group. Over a series of 9 weekly sessions, all infants will be assessed on different tasks that can be divided into 5 stages: Vocabulary and developmental assessments, initial cognitive assessments, training sessions, first-order generalization test, higher-order generalization test. Depending on the group that the children will be in, they will receive either a shape training or a specific word training. Other assessments (initial assessments, cognitive assessments, first-order generalization test and higher-order generalization test) will be identical across the groups. Additionally, a follow up study will be conducted after one year of completion of the intervention programme. A table describing the intervention procedure is provided in Figure 1. Details of the tasks are given below.

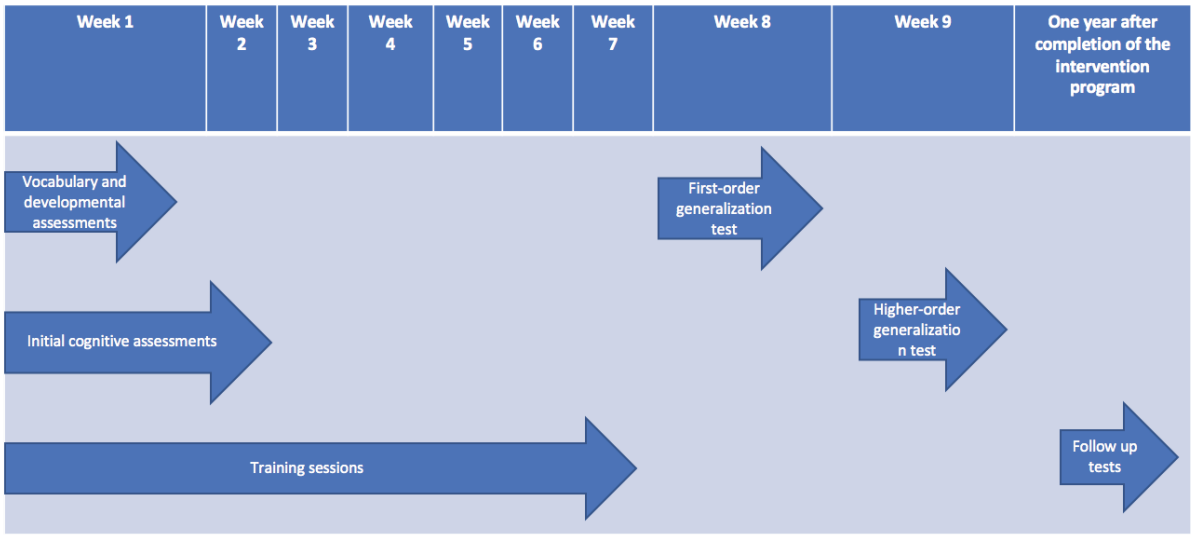

Figure 1. Timeline of intervention programmes.

4.3. Tests and procedure of intervention programme

4.3.1. Vocabulary and developmental assessments. At session 1, parents/guardians will fill in a socioeconomic and general development questionnaire (see Appendix 1.5). The

information provided in this questionnaire will double-check the inclusion/exclusion criteria. It will also be used to check whether the intervention was only successful in a sub-group of the infants (e.g. those without a family history of language problems). In the first and last session, parents/guardians will also be asked to fill in the UK-CDI Words and Gestures questionnaire, a vocabulary checklist of words and phrases that infants might know and use (Alcock, Meints, & Rowland, 2017; see Appendix 1.4). This will allow us to compare language development during the intervention programme between the two intervention groups.

4.3.2. Initial cognitive assessments: The initial cognitive assessments will be presented during the first two sessions. During week 1, infants will be assessed with a shape sorting task and an attention task. The sorting task will last no more than 5 minutes and will be used to assess if before the training programme, infants are sensitive to the shape of objects and can group objects by shape. Infants will be presented with 16 novel objects differing in shape, colour and texture and asked to sort them into groups. How to sort (namely by shape) will be shown to them with the means of examples. The attention task will last 3 minutes and will assess infants' joint and sustained attention. This will be achieved by monitoring their eye movements during the presentation of five short video clips (35 seconds each) of a person looking at and moving unusual novel objects. For this task, participants will sit on their parent/guardian's lap in front of a computer screen. Eye movement will be monitored with a remote eye tracker (see Figure 2). The parent will wear blacked-out glasses so that their behaviour cannot affect the infants' eye gazes.

At week 2, infants' visual spatial abilities and working memory will be assessed using the Wechsler Preschool & Primary Scale of Intelligence - Fourth UK Edition (WPPSI-IV UK). This test will last about 20 minutes and will be used to rule out any potential cognitive delay.

Figure 2. Attention task. Infants will watch five short videos and eye movements will be monitored with a remote eye tracker.

4.3.3. Training sessions

4.3.3.1. Shape training: During the first seven weeks, infants will be presented with four novel words paired with four novel sets of objects (total duration 15 minutes). Each set will consist of two exemplars with the same shape but with different colours and textures. Each set will be presented with sentences such as "*Look! It is a kiv. Do you want to play with the kiv?, Let's play with the kiv"*. Half way through the presentation of the exemplars, the researcher will bring out a third contrasting object. This contrasting object will be presented with the sentence "*Oh no, this is not a kiv"* and will be taken away immediately. The other three sets of novel exemplars will be presented in the same manner.

4.3.3.2. 'Specific word' training: This training will resemble a typical word learning intervention. During the first seven weeks infants will be introduced to 28 real common objects and their names (e.g. biscuit, trousers, slide), randomly divided into 7 sets of four words. During each session, infants will be presented with one of the sets and each session will have a total duration of 15 minutes. The target words have been selected from the Wordbank database, an open database that lists the proportion of children that know a specific word at a specific age. Twenty-eight words that 80% of the total child population at 25 months know were randomly selected as target words. Each session will consist of a 15 min play session in which each object name will be presented at least 10 times and each object name will be mentioned at least 10 times. Additionally, techniques such as focused stimulation and modelling target words, which have proved to be useful for word learning, will be used.

4.3.4. First-order generalization: At week 8 infants in both groups will be assessed as to whether they have learned that objects that have the same shape share the same name. They will be presented with each exemplar used during the training sessions accompanied by three novel toys. These three objects will share only one visual property with the training objects (colour, shape or texture). The three objects will be placed on a table and the researcher will say "*This is a kiv, Can you show me the other kiv?"* while he/she shows the infant one of the exemplars used during the 7 training weeks. All infants will be tested on each trained object with the same procedure. This test will last 8 minutes.

4.3.5. Higher-order generalization: At week 9, all infants will be assessed with four pairs of novel objects different to the ones used in previous sessions. The same procedure as the one for the first-order generalization will be followed and it will also last 8 minutes. This test will assess if infants have learned a general rule that one can extend novel labels based on shape similarities.

At the end of the study and independent of the type of intervention that the children took part in, parents/guardians will be asked about their thoughts about the development and implementation of the study, as well as about possible changes they made at home or any activities (such as music or dancing sessions) that their infants attended to while they were part of the study (see Appendix 1.6). Additionally, they will receive a Participant Debrief Sheet with more information about the specific intervention programme that their child received (see Appendix 1.7).

4.4. Procedure of follow up study

A follow up study will be conducted one year after the start of the intervention programme in order to assess the long-term effects of the intervention in language and cognitive development. For this follow up study children's language, and cognitive abilities, will be assessed. The British Picture Vocabulary Scale (BPVS3) will be used to assess receptive language. In this test the child will listen to a word and will have to select from a set of pictures, the image that corresponds to that word. The Wechsler Preschool & Primary Scale of Intelligence - Fourth UK Edition (WPPSI-IV UK) will be used to assess infant´s visual spatial skills and working memory. In this test, the child will be asked to recreate different figures using blocks and to view animal cards on a zoo layout for a specified time, remember where they are located, and then place each card in the previously viewed location.

5. Ethical considerations

5.1 Research Ethics Committee review and reports

Before the start of the recruitment process, approval will be sought from the ethics committee of the University of Birmingham in addition to an NHS Research Ethics Committee. Additionally, each year an annual progress report will be submitted by the Chief Investigator to the NHS Research Ethics Committee until study completion. When the study is concluded, the Chief Investigator will notify the Research Ethics Committee and one year after this, the chief Investigator will submit a final report with the results of the study.

5.2 Peer review

A research proposal of the present study was reviewed by a colleague of the Chief investigator at the School of Psychology at the University of Birmingham as part of the main researcher's progress review of her PhD project. The project was discussed in a formal viva voce in which feedback regarding the research questions, methodology and design was provided. The reviewer is not involved in the study in any way, but was chosen because of his expertise in the field of developmental psychology, which includes developmental experimental design and the recruitment and testing of child participants.

5.3 Public and Patient Involvement

The study was presented to the NIHR Clinical Research Network: West Midlands – Young Person´s Steering Group (YPSG) in a meeting held at the University of Birmingham. In this meeting, the Chief Investigator and Main Researcher explained the study, its main objectives, methodology and importance for the field. Additionally, the Chief Investigator and Main Researcher presented the recruitment flyer, the information sheet for parents and the consent form. The members of the Young Person's Steering Group provided feedback on how to improve these documents in terms of readability and informativeness. Furthermore, they also provided ideas on how to explain the tasks to the infants in a child friendly language. At the end of the study there will be a second meeting with this group to report on the study's findings.

5.4 Indemnity and Participants payment

Parents will be offered reimbursement for travel expenses for every session that they attend at the Infant and Child Laboratory. Infants will receive a sticker every session they attend and will also receive a book or toy worth not more than £5 after attending all nine sessions.

5.5 Risk assessment

Participating in this research study does not represent a greater risk than what infants are exposed to in their everyday environment. The stimuli used are toy-like objects made from paper, clay, and string, the videos are short and age appropriate, and the procedures imitate play sessions. Even though the tasks are child-friendly and interesting, children will be encouraged to continue performing a task if they do not seem motivated. If positive encouragement fails or the child seems uncomfortable or distressed, the researcher will stop the task and/or session, and will give the child his/her reward. The session might be rescheduled if deemed useful and with the approval of the parent/guardian.

The tasks require the child to sit on the parent's/guardian's lab, on a child´s chair or on the floor, which will minimize the risk of any falls. The testing area will be child-friendly (eg. electrical sockets covered) and small objects or objects that are not safe for a small child (e.g. scissors, medicines) will be removed from the room prior to the arrival of the participants. Some children might suffer from food allergies, and as in consequence, any food (like biscuits or tea offered to the parents) will be kept in a secure place away from the children. Parents will be present at all times and it will be ensured that all researchers have undergone a DBS check for working with children.

Due to the constant contact between researcher and children, there is a minor risk of contagious diseases such as colds or stomach bugs. In order to minimize the risk, the researcher will wash their hands before and after each session with alcohol based hand wash, and all items that the child might touch, such as toys, chairs and tables, will be cleaned and disinfected after every session. There are no risks to the environment or society arising from this research.

Parents/guardians will be informed at session 1 that if during any of the sessions the child or parent/guardian discloses information that might lead the researcher to think that the child or anyone else is at risk, or is being abused, then this information will have to be disclosed to the research team and the relevant authorities. If it is something serious that occurs during the testing session, the assessments will be stopped and the Chief Investigator will be informed immediately. In both cases, the government advice on the procedures for these events will be followed (as outlined at https://www.education.gov.uk/publications/standard/publicationDetail/Page1/DFES-04319-2006).

5.6 Data protection and confidentiality

All researchers involved in the study will comply with the requirements of the Data Protection Act 1998 regarding collection, storage, processing and disclosure of personal information and will uphold the Act's core principles which state that all data must be:

A. Fairly and lawfully processed
B. Processed for specified purposes
C. Adequate, relevant and not excessive
D. Accurate
E. Not kept longer than necessary
F. Processed in accordance with the subject's data rights
G. Secure from unauthorised access or alteration
H. Not transferred to countries without adequate data protection

In order to maintain confidentiality, each participant will receive a participant code formed by an unrelated sequence of characters. During the collection and analysis of date, any data related to the participant will be identified by this code. The documents/hard copies containing the linking code with the personal information will be stored separately from all data in a locked cabinet (when used hard copies) or in a password protected computer and in a password protected/encrypted file (when stored electronically).

The Chief investigator will act as the data custodian. If data is shared with the sponsor or research team, it will not contain information that could lead to the identification of a specific participant. However, personal data will need to be shared with the researcher who conducts the follow-up study in order to contact the parents/guardians. But any newly collected data will again be marked by the participant ID.

5.7 Protocol compliance

This protocol will be strictly followed when implementing the study described. Planned deviations to the protocol are not allowed. When an accidental protocol deviation occurs, a record will be kept with the details of the deviation. This form will be submitted to the Chief Investigator and Sponsor immediately and the Chief investigator will keep this form in a locked cabinet at one of the offices of the University of Birmingham.

Constant deviations will be considered as serious breaches to the protocol. If this occurs, the Chief Investigator and sponsor will be informed in writing. Actions that have an effect on the safety or integrity of the participants or the safety of the trial will also be considered as serious breaches of protocol and if this occur, the Sponsor and Chief Investigator will also be informed immediately.

5.8 Amendments

If at any stage an amendment is required, the Chief investigator will submit a written request to the Sponsor explaining any changes and their reasons. The Sponsor will review the request and will decide if it is a substantial amendment or a minor one. An amendment will be considered as substantial if it affects the safety or integrity of the participants, if it affects the scientific value of the study or if it is related to the conduct or management of the study. If a substantial amendment to the protocol or documents that supported the original application is required, a notice of amendment will be submitted to the review body from whom the original approval was received. If the amendment is non-substantial or minor, the appropriate form will also be submitted.

Each amendment will be included in the protocol. A document explaining the amendment and the reasons for it will be included in an appendix. The number of amendments done in a specific

version of the protocol will be stated in the last digit(s) of the protocol version number. For example, if the protocol version is 1.02, there will be two amendments done to that version.

6 Statistics and data analysis

6.1 Sample size calculation

We are aiming to recruit and test 30 participants. This number is based on similar studies that have assessed language development in children. Additionally, a formal size calculation was used. The calculation showed that in order to achieve a power of 0.8 with a medium effect size and an error probability of 0.05, (a minimum of) 24 participants that finish the study needed to be recruited. Considering that some participants might not finish the whole study and their data might to be used, we will aim to recruit at least 30 participants.

6.2 Planned recruitment rate

Recruitment rate was discussed between the Chief Investigator, the Main Researcher and a Speech and Language Therapist of the Birmingham Community Healthcare NHS Foundation Trust. Considering the number of Late Talkers that the Trust assesses each month that fall into the target group of this project, it is expected to recruit an average of five infants per month and all participants within 12 months.

6.3 Statistical analysis plan

Only data of infants that have completed the intervention will be fully analysed. Nevertheless, when possible, the total population assessed and the reason why certain participants did not finish the study (e.g. decided to withdraw, moved away, stopped attending) will be noted and reported in the study report. A full analysis of the data will be conducted once all data has been collected, which we anticipate to be after about 1 year of commencement of the study.

6.3.1 Summary of baseline data

From the total number of assessments and tasks, results from five of them will be used as baseline data or descriptive statistics. These five assessments are: Vocabulary checklist, Socioeconomic and general development questionnaire, attention task, sorting task, initial working memory assessment, and initial visual spatial abilities assessment. The description of the variables analysed on each assessment and how they will be reported is as follows.

A. Vocabulary assessment: Parents will fill out this checklist before (and after) the intervention and the total number of words that the infant understands and the total number of words they

produce will be registered as continuous variables and will be considered as the baseline language ability before the intervention programme.

B. Socioeconomic and general development questionnaire: This questionnaire will provide information regarding general child development, language delay family history, and family status. A number of different types of variables will be collected: nominal variables (e.g. occupation) and ordinal variables (e.g. infant's order of birth). These variables will be used for descriptive statistics. They are potentially interesting as predictor variables, but the sample size is likely too small to draw any strong conclusions.
C. Attention measure: With this measure, we will assess the fixation duration (number of milliseconds an infant looks) towards a novel object that is moved. The object will be moved for 25 seconds (25000 ms) and the infant's total looking time towards the screen will be registered. This variable will be registered as a continuous variable and used as a predictor of the primary outcome measures.
D. Sorting task: This will be registered as a categorical variable. Infants will sort objects and depending on their sorting tendency they will be assigned to one of four categories: preference for shape, preference for colour, preference for texture, no preference. This variable will be used as a predictor of the primary outcome measures.
E. Working memory and visual spatial abilities: Using the Wechsler Preschool & Primary Scale of Intelligence - Fourth UK Edition (WPPSI-IV UK), infants working memory and spatial abilities will be assessed and compared to a standardized mean of the UK infant population. These variables will be used to assess in a non-verbal manner the participant´s cognitive skills to rule out any possible cognitive delay.

6.3.2 Primary outcome analysis

During weeks 8 and 9 of the study infants will be assessed with two forced choice tasks where they will have to extend object names to new exemplars based on visual commonalities. We will assess the statistical difference between the response pattern and chance (using t-tests). This will show whether infants have learned to extend object names by shape similarities. The factors that predict the number of noun extensions based on shape as well as vocabulary growth will be assessed using mixed effect model analyses. The most important factors tested in the models will be the number of words known before the intervention, the intervention type (shape training vs specific word training), attention measures (pre-test and attention during training), and sorting task measure. The outcome of these analyses will show whether the shape bias intervention has led to a larger vocabulary growth than the specific word intervention (as a control intervention). It will also assess the role of attention in word learning and whether only infants that pay attention to novel items

presented to them or infants that are sensitive to shape similarities between objects can acquire a shape bias. Only data of infants that complete the intervention will be analysed.

Regarding the follow up study, infants' vocabulary and cognitive abilities will be assessed. This with the aim of analysing if there are any long-term effects of each intervention and infants continue learning words and potentially "catching up", or if the intervention programmes are only beneficial while they are being implemented. The cognitive assessments will be used to assess whether the intervention has an effect on visual spatial skills and working memory. In both cases, it will be done by comparing the infants results to the standardized mean of UK infant population. Similarly, infant´s result in the follow up language assessment will be compared to the standarized mean of UK infant population.

6.3.3 Secondary outcomes analysis

As mentioned before, a mixed effect model analysis will be conducted and two of the factors introduced in this model will be the attention measure and the sorting task. With this, we will assess the role of attention and sorting abilities in word learning with the objective of knowing if only infants with certain attention patterns and/or infants that are sensitive to shape similarities can develop a shape bias.

7 Data management

7.1 Data handling and archiving

All data generated during this research will be stored at the Psychology Department at the University of Birmingham. All documents and files with sensitive information will be stored securely in a locked cabinet. Sensitive data stored electronically will be held in password protected computers and electronic files will also be password protected. Files linking participants' sensitive information with their participants' code will be kept in an independent file stored separately from the rest of the files and will be passport protected. Anonymised data will not be password protected since they will not contain any sensitive information, but will still be kept in a password protected computer (of electronic data) or a locked cabinet (if on paper).

7.2 Access to data

Only the Chief Investigator and Main Researcher will have access to the questionnaires, assessments and case report forms, i.e. any sensitive data. The research team and Sponsor will have access only to the anonymized data, which means that they will only be able to access data that does

not contain participants ID or any personal information that could lead to the identification of any participant.

7.3 Data record retention

Data will be stored as long as involved researchers are active in this research area and for at least 10 years after the first publication of the data, unless participants request otherwise. After this period of time, every 5 years the data will be evaluated and if it is still relevant for research purposes, it will be kept, and if not, it will be destroyed.

7.4 Access to the final study dataset

Only the Chief Investigator, Main Researcher and Research team will have access to the complete dataset of the study. Research data and results will be available to the sponsor and the general public if requested. The latter can be obtained from the Chief Investigator or the Main Researcher, however, all data will be anonymized.

8 Dissemination policy

8.1 Dissemination policy

Intellectual property and intellectual property rights belong to the University of Birmingham. However, the Chief investigator and Main researcher will have the right to publish or present any of the study data in research articles, at conferences or as part of presentations. Funding bodies will be acknowledged within the publications, but they will not have any rights over the data.

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