1. ABOUT THE DATASET

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Title: Evaluating an early social communication intervention for young children with Down Syndrome: a feasibility study (ASCEND)

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Organisations: University of Reading

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Description:

This feasibility study aims to estimate the parameters to inform a future randomised controlled trial to test whether an early social communication intervention is effective in improving language skills in young children with Down Syndrome. In a two-arm randomised controlled trial (RCT), with 1:1 randomisation stratified by trial site, children were allocated to receive either the intervention plus standard NHS speech and language therapy, or standard NHS speech and language therapy only.

In the intervention arm, parents/guardians received brief training videos on the parent-based intervention and a manual to follow with their child for 10 weeks.

20 children with Down Syndrome, aged between 11 and 36 months were recruited into the trial and 19 were randomised. The dataset contains the baseline, post-treatment and 6 month follow-up data from 9 participants receiving the intervention (in addition to standard NHS speech and language therapy) and 10 control participants receiving standard NHS speech and language therapy only.

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Related publication:

Stojanovik, V., Pagnamenta, E., Sampson, S., Sutton, R., Jones, B., Joffe, V., Harvey, K., Pizzo, E. and Rae, S. (2024) *Evaluating an early social communication intervention for young children with Down Syndrome (ASCEND): results from a feasibility randomised control trial.* Pilot and Feasibility Studies, 10. 127. <https://doi.org/10.1186/s40814-024-01551-y>

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2. TERMS OF USE

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3. PROJECT AND FUNDING INFORMATION

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Title: Evaluating an early social communication intervention for young children with Down Syndrome: a feasibility study (ASCEND)

Dates: project start 1st August 2019, end date 16th May 2022

Funding organisation: National Institute for Health and Care Research (Research for Patient Benefit)

Grant no: PB-PG-0817-20035

4. CONTENTS

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The sets of Questionnaire measures were collected at baseline (time point 1), immediately post-intervention (Time point 2) and at a 6-month follow-up (time point 3). This dataset includes:

* ASCENDDemographicdetails.csv – contains demographic information about the participating families. These data were collected only at time point 1
* ASCENDTime1CDI.csv- contains raw data from all participants on the Communicative Development Inventory from time point 1 for English
* ASCENDTime1CDIbilingual.csv - contains raw data from the bilingual participants on the Communicative Development Inventory from time point 1 for their other language
* ASCENDTime2CDI.csv - contains raw data from all participants on the Communicative Development Inventory from time point 2 for English
* ASCENDTime2CDIbilingual.csv- contains raw data from the bilingual participants on the Communicative Development Inventory from time point 2 for their other language
* ASCENDTime3CDI.csv- contains raw data from all participants on the Communicative Development Inventory from time point 3 for English
* ASCENDTime3CDIBilingual.csv- contains raw data from the bilingual participants on the Communicative Development Inventory from time point 3 for their other language
* ASCENDHADS.csv – contains raw data from the Hospital Anxiety and Depression Scales at Times points 1, 2, and 3
* ASCENDCSBS.csv- contains raw data from the Communication and Social Behaviour Scale at time points 1, 2, and 3
* ASCENDACQOL.csv – contains raw data from the Adult Quality of Life Questionnaire at time points, 1, 2 and 3
* ASCENDITQOL.csv – contains raw and standard scores on the Toddler Quality of Life Questionnaire at time points 1, 2, and 3
* ASCENDVineland.csv – contains raw, standard and percentile scores on the Vineland Adaptive Behaviour Scale
* DataDictionaryDemographics.xslx – contains all the questions for the demographics questionnaire, providing information about how the questions were scored or coded (where applicable)
* DataDictionaryCDI.xslx – contains all the words and phrases featured on the Communicative Development Inventory
* DataDictionaryHADs.xlsx – contains all the questions and the scoring of the Hospital Infant Anxiety Depression Scale
* DataDictionaryCSBS.xslx – contains all the questions featured in the Communicative and Social Behaviour Scales and the scoring criteria
* DataDictionaryACQOL.xslx – contains all the questions and the scoring of the Adult Quality of Life questionnaire
* DataDictionaryITQOL.xslx – contains all the questions and the scoring of the Infant Toddler Quality of Life questionnaire
* DataDictionaryVineland.xslx – contains a description of the subscales in the Vineland Adaptive Behaviour Scales

5. METHODS

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The study was conducted in 3 NHS sites in England, providing Speech and Language services across three geographical regions: Berkshire, Oxford, and North East London Foundation Trust. Both the questionnaires and the intervention took place at the participants’ homes in their own time with support by telephone and email.

Measures of the child’s language ability were collected at three time points:  1) immediately before the start of the intervention (baseline),  2) immediately after the intervention had been completed (end of treatment) and  3) 6 months post intervention (follow-up).

Participants were randomized following the completion of baseline measures.

Most of the data (Demographics, Infant Toddler Quality of Life Questionnaire (ITQOL) (Landgraf et al., 2013), Adult Quality of Life Questionnaire (AC-QoL) (Elwick et al., 2010), The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1994), and the Communicative Development Inventory (CDI) (Hamilton et al., 2000)) was downloaded from survey tool websites (JISC and Survey Monkey) into an Excel worksheet.

The Communication and Social Behaviour Scale (CSBS) (Wetherby & Prizant, 2002) was completed via a telephone interview and the responses were recorded on a paper copy of the questionnaire. Data was manually entered into an Excel worksheet.

The Vineland Adaptive Behaviour Scale (Sparrow et al., 2016) was completed remotely by parents. The responses were scored automatically online and a report was auto-generated via a web-based platform (Q-Global). The scores were entered manually into an Excel worksheet.

For the ITQOL and ACQOL, where questions were negatively worded or scored, the scores were reversed after downloading the data. Similarly, for the HADS, those questions that were positively worded were reverse-scored.

Data has been anonymized by removing any information which would potentially identify survey respondents (e.g., child’s name in free text responses, date of birth).

- Experimental procedures/protocols

Sum scores for HADS and ACQOL were calculated and classified according to the scoring manual. The standardised scores and percentile ranks were calculated for the Vineland and CSBS according to the manual. The mean and standardised scores were calculated for the ITQOL. For the CDI counts of words that were understood were summed to create a total receptive score. Counts of spoken words/sounds and signs were summed to create a total expressive score.

Adherence to the intervention was monitored by using weekly parent diaries, and via two telephone contacts with parents at weeks 4 and 8 of the intervention, using a standard set of questions to check adherence. Diaries were returned via email and the data was double entered into a REDCap database.

Contamination occurring between the intervention group and the control group was measured. Prior to receiving the study manual (immediately post randomisation for the intervention Group, and following the follow-up assessments for the control group), parents in both groups were asked whether they were familiar with the intervention materials, whether they have discussed the intervention with other parents or seen the manual, and whether they may have carried out any activities as described in the manual. This questionnaire was sent to participants via REDCap.

On completion of the intervention, participants were sent the Parent Satisfaction Questionnaire via REDCap to assess the acceptability of the intervention.

Questionnaire data was entered by the study research assistant and checked independently by the study trial manager.

For a detailed description of the study protocol please refer to the publication below.

Stojanovik V., Pagnamenta E., Seager E., Breen M., Jennings S., Joffe V., Harvey K., Pizzo E. and Perry H. The ASCEND study: protocol for a feasibility study to evaluate an early social communication intervention for young children with Down syndrome. Pilot and Feasibility Studies, 2022 Jan 17;8(1):8. doi: 10.1186/s40814-022-00968-7. PMID: 35039084; PMCID: PMC8762187.

References for all questionnaires

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Hamilton, A., Plunkett, K., & Schafer, G. (2000). Infant vocabulary development assessed with a British communicative development inventory. Journal of Child Language, 27(3),689–705

Landgraf, J. M., Vogel, I., Oostenbrink, R., van Baar, M. E., & Raat, H. (2013). Parent-reported health outcomes in infants/toddlers: measurement properties and clinical validity of the ITQOL-SF47. *Quality of Life Research*, *22*, 635-646.

Sparrow, S.S., Cicchetti, D.V. & Saulnier, C.A. (2016). *Vineland adaptive behaviour scales*. 3rd ed. Vineland: Pearson

Wetherby, A. & Prizant, B. (2002) *Communication and symbolic behaviour scales developmental profile*. 1st ed. Baltimore: Paul H. Brookes

Zigmond, A.S., & Snaith, R.P. (1994). *The hospital anxiety and depression scale*. London: GL Assessment