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The efficacy of early language intervention in mainstream school settings: A Randomised Controlled Trial

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The efficacy of early language intervention in mainstream school settings: A Randomised
Controlled Trial

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Declaration of conflicting interests

Revenue from sales of the *Nuffield Early Language Intervention* programme are used for charitable purposes. The authors declare that they have no financial interests in the programme.

For Peer Review

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Abstract

Background

Oral language skills are a critical foundation for literacy and more generally for educational success. The current study shows that oral language skills can be improved by providing suitable additional help to children with language difficulties in the early stages of formal education.

Methods

We conducted a Randomized Controlled Trial with 394 children in England, comparing a 30-week oral language intervention programme starting in nursery (N=132) with a 20-week version of the same programme starting in Reception (N=133). The intervention groups were compared to an untreated waiting control group (N=129). The programmes were delivered by trained Teaching Assistants working in the children's schools/nurseries. All testers were blind to group allocation.

Results

Both the 20- and 30-week programmes produced improvements on primary outcome measures of oral language skill compared to the untreated control group. Effect sizes were small to moderate (20-week programme: $d=.21$; 30-week programme: $d=.30$) immediately following the intervention and were maintained at follow-up 6 months later. The difference in improvement between the 20-week and 30-week programmes was not statistically significant. Neither programme produced statistically significant improvements in children's early word reading or reading comprehension skills (secondary outcome measures).

Conclusions

This study provides further evidence that oral language interventions can be delivered successfully by trained Teaching Assistants to children with oral language difficulties in

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nursery and Reception classes. The methods evaluated have potentially important policy implications for early education.

Keywords:

Early intervention, Language, Reading, RCT design, Education

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3 It is generally assumed that children enter school with sufficiently well-
4 developed oral language skills to benefit from education. Indeed, language is the medium of
5 instruction in all mainstream schools and, importantly, it is also the foundation of literacy
6 skills (Hulme, Nash, Gooch, Lervåg, & Snowling, 2015; NICHD Early Child Care Research
7 Network, 2005). It follows that children who enter school with poor language skills are at
8 high risk of educational underachievement (e.g. Conti-Ramsden, Durkin, Simkin, & Knox,
9 2009; Roulstone, Law, Rush, Clegg, & Peters, 2011; Snowling, Adams, Bishop, & Stothard,
10 2001). There is particularly strong evidence that a wide range of non-phonological language
11 skills, including vocabulary knowledge and grammatical skills are critically important for the
12 development of reading comprehension (Clarke, Snowling, Truelove, & Hulme, 2010;
13 Fricke, Bowyer-Crane, Haley, Hulme, & Snowling, 2013). We target those skills in the
14 intervention reported here.

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30 Interventions to improve the language skills of children with difficulties in this
31 area are potentially of great educational importance. Studies have typically involved
32 vocabulary training and shared book reading activities. In general, vocabulary interventions
33 produce improvements on measures of directly taught words with moderate effect sizes but
34 generalization is poor. For example, Neuman, Newman, and Dwyer (2011) reported that 12-
35 15 minutes of vocabulary training each day for 'at-risk' preschoolers had negligible effects
36 on a standardized vocabulary measure. More generally, Elleman, Lindo, Morphy, and
37 Compton (2009), in a meta-analysis of vocabulary interventions for children from pre-school
38 to grade 12 both with and without learning difficulties, found small effect sizes for
39 vocabulary measures ($d=.29$, $k=14$), but a large effect size for directly taught skills ($d=.79$,
40 $k=18$).

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The practice of shared book reading, in which a child and adult 'read' a book
together jointly and discuss its contents, appears to be a more promising strategy for boosting

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3 language skills. Lonigan, Shanahan, and Cunningham (2008) reported a large effect of shared
4
5 book reading on measures of oral language ($d=.73$, $k=16$) whether implemented by parents or
6
7 in school settings. Moderate to large effects were also found in a meta-analysis by Mol, Bus,
8
9 de Jong, and Smeets (2008).
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12 A similar picture emerges from studies which have investigated the efficacy of
13
14 speech and language therapy for children's language disorders. A review by Law, Garrett,
15
16 and Nye (2004), excluding interventions of less than 8 weeks duration, found no overall
17
18 effect of language interventions on expressive language skills though there were significant
19
20 effects for both syntax and vocabulary when children with receptive language impairments
21
22 were excluded. None of the therapies improved receptive language abilities. Similar negative
23
24 conclusions come from reviews by Cirrin and Gillam (2008), and Boyle, McCartney, O'Hare,
25
26 and Law (2010), although a review of 'what works' integrating data from treatment studies
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28 with views of parents suggests there are a growing number of language interventions for
29
30 which there is 'indicative' evidence (Law, Roulstone, & Lindsay, 2015). There is therefore an
31
32 urgent need for studies evaluating suitable interventions for use in the early years (before age
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34 6) using rigorous methodologies.
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39 One approach that has been found to be effective in mainstream schools is an
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41 oral language intervention promoting vocabulary, narrative and listening skills, delivered by
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43 trained Teaching Assistants (TAs; Bowyer-Crane et al., 2008). Children receiving this
44
45 intervention shortly after school entry made more progress in vocabulary and grammar than
46
47 children receiving an alternative treatment focusing on phonology and early reading skills
48
49 (see also Bianco et al., 2010). An extension of this approach, starting the intervention before
50
51 school entry and supplementing it with training in pre-reading skills for the final 10 weeks,
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53 reported robust effects on oral language and narrative skills, phoneme awareness and letter
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3 knowledge ($d_s=.30-.83$; Fricke et al., 2013). Children receiving intervention also showed
4
5 significant gains in reading comprehension one year after the intervention finished.
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8 Here we report a replication and extension of the study by Fricke et al. (2013)
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10 in which the UK-based children's communication charity I CAN was licensed to distribute
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12 the programme, and trained and supported TAs in its delivery. We had the following
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14 hypotheses:

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16 1) The intervention would lead to gains in oral language skills for children
17
18 with poor language.
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21 2) We anticipated that the size of the intervention effects would be reduced
22
23 compared to the original trial, given that there is typically a reduction in effect size over
24
25 successive trials (Ioannidis, 2006). This is likely to be particularly the case when the research
26
27 team is not involved in training.
28

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30 3) A subsidiary aim was to compare the extent to which a 30-week
31
32 programme, beginning in the last term of nursery and continuing for 20 weeks in Reception
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34 class, was more effective than simply delivering a 20-week programme starting in Reception
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36 class. We predicted that the 30-week programme would produce larger gains though we had
37
38 no confident predictions about the size of such an effect.
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41 4) Since oral language interventions have been found to promote reading
42
43 comprehension (Clarke, et al., 2010; Fricke et al., 2013), we predicted that the intervention
44
45 group would show improved reading comprehension.
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47 48 **Method**

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50 A randomized controlled trial (RCT) was conducted where children from 34
51
52 nurseries were allocated to a 30-week intervention, a 20-week intervention or a waiting
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54 control group. Children in the 30-week intervention group received the *Nuffield Early*
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56 *Language Intervention* programme (following Fricke et al., 2013). This was delivered for 10
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3 weeks in nursery (last term of preschool in England before entering formal schooling; ages 3-
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5 4) and continued for 20 weeks in Reception (first year of primary school in England; ages 4-
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7 5). The 20-week intervention group received only the final 20 weeks of the intervention in
8
9 their primary schools (Reception), while the waiting control group received their usual school
10
11 provision. It should be noted that this design with children in different conditions nested
12
13 within schools means that there is the possibility of contamination effects. In practice such
14
15 effects seem unlikely to have occurred since nurseries/schools were aware of the importance
16
17 of adhering to the study design. To the extent to which such leakage does occur it can only
18
19 serve to reduce the estimates of the effectiveness of the interventions.
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23 From the beginning of Year 1 (term following post-testing), schools were
24
25 given permission to deliver additional language and literacy support to the waiting control
26
27 group. Fifteen schools opted for TA training to enable delivery of a targeted language and
28
29 literacy intervention provided by the research team to the waiting control group. The
30
31 programme offered was different to the *Nuffield Early Language Intervention* (which would
32
33 not have been age-appropriate). However, by delayed follow-up testing only eight of these
34
35 schools had started to implement it. The remaining 19 schools chose to include children in the
36
37 waiting control group in the school's existing language and reading support programmes.
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40
41 The study was granted ethical approval by UCL's Research Ethics Committee.
42
43 Schools were recruited and trained to deliver the intervention programme by I CAN. Head
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45 teachers gave consent for the intervention to be delivered in their schools, and for screening
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47 assessments. Informed parental consent was obtained for all project phases following
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49 screening.
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52 Children were assessed before the start of intervention at screening (t_0) and
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54 pre-test (t_1), immediately following intervention (post-test, t_2) and at delayed follow-up (t_3 ,
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56 roughly 6 months after t_2). All testers were blind to group allocation. While the waiting
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3 control group remained untreated until post-test, by the time of the delayed follow-up some
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5 of these children had started to receive school-based language and literacy support, though
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7 the specific nature, quality and intensity of this varied widely. The timeline for assessments
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9 and intervention delivery is presented in Figure 1.

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12 -Figure 1 about here-

13 14 **Participants**

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16 In accordance with the CONSORT guidelines (Schulz, Altman, & Moher,
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18 2010) Figure 2 shows details of the recruitment, allocation and flow of participants through
19
20 the study. Sample size was determined based on budget constraints, and a formal power
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22 calculation that showed that with N=120 per arm there was better than 80% power to detect a
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24 difference between groups equivalent to $d=.29$ ($p<.05$, 2-tailed).

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27 Our intervention (Fricke et al., 2013) is designed to improve the oral language
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29 skills of children with language difficulties in mainstream nurseries and Reception classes.
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31 We therefore used an equivalent recruitment procedure to that in our previous study. Three
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33 hundred and two primary schools with attached nurseries in generally disadvantaged areas
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35 and with mainly monolingual English-speaking pupils on their registers were approached by I
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37 CAN with information about the study. Of these, 34 schools (Greater London: 17;
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39 Yorkshire/Nottinghamshire: 17) agreed to take part. All children in these nurseries who were
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41 due to enter school (Reception **in England**) the following academic year were screened.
42
43 Children who were on a school's special educational needs register for difficulties other than
44
45 language, and children learning English as an Additional Language who had not yet acquired
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47 sufficient English language skills to participate in the assessments, were not included in the
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49 screening.
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54 -Figure 2 about here-

Language Intervention in Mainstream Settings 10

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3 Within each school/nursery, 15 children with the lowest mean verbal
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5 composite score based on scaled scores on the screening measures (Child Evaluation of
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7 Language Fundamentals (CELF) Preschool II^{UK} *Sentence Structure* and *Expressive*
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9 *Vocabulary* subtests; Semel, Wiig, & Secord, 2006) were selected as possible participants in
10
11 the study. To validate this initial selection, individual assessments using further language and
12
13 early literacy measures were conducted (*t1*; see below). Up to 12 children in each nursery
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15 (N=394; $M_{\text{age}}=3;11$) were selected to take part in the RCT based on the following criteria; a)
16
17 having the lowest mean verbal composite scores in their school/nursery (derived from z-
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19 scores on screening measures and the British Picture Vocabulary Scale (BPVS; Dunn, Dunn,
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21 & Style, 2009) and b) entering Reception at the same primary school they attended for
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23 nursery. Within each school/nursery children were allocated to either the 30-week
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25 intervention (N=132), the 20-week intervention (N=133) or waiting control groups (N=129).
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27 Group allocation was conducted independently by the Institute for Fiscal Studies and
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29 involved minimisation (Altman & Bland, 2005) for gender, age and the verbal composite
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31 score.
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36 We assessed the number of children in the sample who could be considered to
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38 have clinically significant language difficulties by using standard scores from three
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40 standardized tests administered at screening and pre-test (BPVS, CELF *Expressive*
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42 *Vocabulary*, CELF *Sentence Structure*). The mean standard scores for the sample as a whole
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44 on these tests were: BPVS=86.21 (range 69-118), CELF *Expressive Vocabulary*=86.95
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46 (range 50-145), CELF *Sentence Structure*=78.35 (range 60-120). Thus, the sample recruited
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48 has standardised language scores in the low-average range. However, some 186/394 (47%)
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50 children were at the 14th centile or below on the three tests and 149/394 (38%) were at or
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52 below the 10th centile on all three tests. Thus, a high proportion of the sample had clinically
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54 significant language difficulties.
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Assessment measures

Primary outcome measures were standardized and non-standardized tests of language ability. Early literacy skills (letter-sound knowledge and word reading) and reading comprehension were secondary outcome measures. The same measures as those used in Fricke et al. (2013) were employed where possible to allow direct comparisons. Some additional measures such as statutory data collected by schools are not reported here.

Screening (*t0*), pre- (*t1*), post- (*t2*), and delayed follow-up (*t3*) tests

Language skills

Vocabulary: Expressive vocabulary knowledge was measured using the CELF *Expressive Vocabulary* subtest (*t0*, *t2*, *t3*) and the *Information Score* from the Renfrew Action Picture Test (APT; Renfrew, 2003; *t1-t3*). Receptive vocabulary skills were assessed using the BPVS (*t1-t3*).

Grammar: Grammatical skills were measured using the CELF *Sentence Structure* subtest (*t0*, *t2*, *t3*) and the APT *Grammar Score* (*t1-t3*).

Listening Comprehension: Children's listening comprehension skills were tested by asking children to listen to two short stories adapted from the York Assessment of Reading for Comprehension (YARC, Snowling et al., 2009) and answer questions about them (*t1-t3*).

Taught Vocabulary: A random selection of the vocabulary taught in the nursery and Reception parts of the intervention was assessed using *Picture Naming* (*t1-t3*) and by asking children to provide a definition of words (*Definitions*; *t1-t3*).

Early literacy skills

Letter-sound knowledge: The *Letter-Sound Knowledge* subtest from the YARC (core version *t1*, extended version *t2-t3*; Hulme et al., 2009) was used.

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Word Level Reading: Word level reading accuracy was measured using the YARC *Early Word Reading* subtest (*t1-t3*; Hulme, et al., 2009).

Reading Comprehension: The two beginner passages from the YARC Passage Reading test (Snowling et al., 2009) were used to assess children's reading comprehension (*t3*).

Training and intervention programme

Children allocated to the intervention groups received the *Nuffield Early Language Intervention* which aims to improve children's vocabulary, develop narrative skills, encourage active listening, and build confidence in independent speaking. Children allocated to the 30-week intervention group received the intervention in nursery (10 weeks) and continued in Reception (20 weeks) as described by Fricke et al. (2013). Children allocated to the 20-week intervention group only received the Reception part of the programme.

During the first 10 weeks in nursery, three 20-minute sessions were delivered each week to groups of 2-4 children (total small group intervention time: 10hrs). **Topic areas covered as part of the vocabulary work are 'Family & Friends' (15 sessions) and 'Our House' (15 sessions).** The 20 weeks in Reception consist of 57 30-minute small group sessions (2-4 children) and 37 15-minute individual sessions with children participating in three group and two individual sessions per week (total intervention time: small group 28.5hrs; one-to-one 9.25hrs). In the last 10 weeks the active listening work is extended to incorporate explicit activities to promote phonological awareness and letter-sound knowledge; these programme elements were designed to reinforce the literacy instruction all children receive in school. Whenever possible, phonological awareness and letter-sound knowledge activities incorporated taught vocabulary in order to further consolidate these words. **The topic areas covered in Reception are 'My Body', 'Things we wear', 'People who help us', 'Growing', 'Journey' and 'Time'.** The listening work in the first 20 weeks targets children's active

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3 listening skills and incorporates auditory discrimination, memory, and sequencing as well as
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5 rhyming activities in line with phase 1 of the phonics resource Letters and Sounds (DfES,
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7 2007). In the last 10 weeks, the listening activities are extended to include activities targeting
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9 phonological awareness (blending and segmenting) and letter sound knowledge.
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12 The *Nuffield Early Language Intervention* teaches children using multi-
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14 sensory techniques within a standard framework (see Online Appendix A for details). The
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16 programme was designed with reference to the Primary Framework for Literacy and
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18 Mathematics (DfES, 2006), the Statutory Framework for the Early Years Foundation Stage
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20 (DCSF, 2008), and in consultation with teachers and speech and language therapists. Topics
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22 and vocabulary were selected to cover different word types and vocabulary is taught using a
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24 multi-contextual approach within a repetitive framework that follows established principles
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26 for teaching listening, vocabulary and narrative (e.g., Beck & McKeown, 2007; Beck,
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28 McKeown, & Kucan, 2013; Carroll, Bowyer-Crane, Duff, Hulme, & Snowling, 2011; Locke
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30 2006). Narrative work allows the use of taught vocabulary in connected speech and
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32 introduces children to key story elements and sequencing of events while encouraging
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34 expressive language and grammatical competence.
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39 The intervention was delivered by TAs selected by their nursery/school who
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41 were trained and supported by I CAN. The training content was based on that used in Fricke
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43 et al. (2013). TAs received one day of training prior to delivering the nursery part and two
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45 further training days prior to the Reception part. I CAN also offered telephone support on
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47 request to TAs. The training for this field trial differed from the research trial in two ways: in
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49 contrast to Fricke et al. (2013), TAs did not receive a one-day refresher training before the
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51 last 10-week block in Reception, and the level of support they received during the
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53 intervention phase was much reduced. The role of the research team in delivering the
54
55 intervention was limited to monitoring treatment fidelity and attendance through observations
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of teaching in nursery (one group session) and Reception (two group and two individual sessions), and collecting completed record forms from TAs. Following the observations, feedback was provided and areas of improvement discussed as necessary.

Results

TAs delivered on average 28.44/30 (SD=4.35, Range: 10-30) group sessions to the 30-week intervention group in nursery and 49.17/57 (SD=13.22, Range 10-58) group sessions in Reception. For the 20-week intervention group TAs delivered on average 48.72/57 (SD=13.55, Range: 10-57) group sessions in Reception. The number of sessions each child attended varied considerably (30-weeks: Nursery group sessions: $M=24.69$, $SD=6.37$, Range: 0-30; Reception group sessions: $M=38.51$, $SD=20.62$, Range: 0-57; Individual sessions: $M=21.91$, $SD=15.37$, Range: 0-43; 20-weeks: Reception group sessions $M=41.11$, $SD=19.65$, Range: 0-57; Individual sessions: $M=23.01$, $SD=15.40$, Range: 0-44). Although the range of sessions completed varied widely, preliminary analyses showed no significant relationship between the number of sessions delivered and the degree of improvement on measures of language skills. Data from all children for whom t_2 data are available are included in the analyses.

In addition to recording the number of sessions attended, some teaching sessions were observed to assess treatment fidelity. We graded the quality of teaching of different session components on a 5-point scale with the manual instructions as a reference point (1=several aspects missing/not satisfactory, 2=some aspects missing/not satisfactory, 3=according to manual, 4=according to manual with good use of resources/questions/techniques to support language, 5=according to manual with very good use of resources/questions/techniques). On average, TAs achieved a mean quality rating of 2.83 (SD=0.46, Range 2.00-3.83) for group sessions observations in nursery, 2.95 (SD=0.49, Range 1.80-4.00) in the first ten weeks in Reception, and 3.20 (SD=0.58, Range 2.00-4.43) in

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2
3 the second ten weeks in Reception. Fidelity and quality ratings for individual sessions tended
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5 to be lower than for more manualised group sessions (first ten weeks in Reception: $M=2.74$,
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7 $SD=0.55$, Range 1.20-3.80; second ten weeks: $M=2.83$, $SD=0.56$, Range 1.83-4.00).
8

9
10 Descriptive statistics for all outcome measures at screening, pre-test, post-test
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12 and delayed follow-up for the 30-week intervention, 20-week intervention and waiting
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14 control groups are shown in Table 1. It is clear that the groups are approximately equated on
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16 all measures at screening/pre-test (all $ps>.273$), as expected given allocation with
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18 minimisation for age, gender and verbal composite scores. It is also clear that both the 20-
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20 week and 30-week interventions are associated with improvements on the majority of
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22 language measures although effect sizes differ between measures (30-week intervention:
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24 $ds=.01-.46$; 20-week intervention: $ds=.08-.23$).
25
26

27
28 -Table 1 about here-

29
30 All analyses were performed on an intention-to-treat basis. The majority of the
31
32 analyses were conducted in Stata 14.0 (Stata Corp, College Station, Texas, USA). Structural
33
34 equation models (SEM) were constructed using Mplus 7.4 (Muthen & Muthen, 1998-2015)
35
36 with Full Information Maximum Likelihood estimators to allow for missing data and robust
37
38 (Huber-White) standard errors to allow for the clustering of children within schools. Little's
39
40 MCAR test confirmed that missing data for the language and literacy measures used in the
41
42 SEM models could be considered to be missing completely at random ($\chi^2=22.12$; $df=17$;
43
44 $p=.181$).
45
46

47 48 **Effects of intervention on directly taught skills**

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50 Table 2 shows descriptive statistics for each group on taught vocabulary
51
52 measures and a summary of the effects of intervention. There were effects for both
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54 intervention groups on taught vocabulary measures compared to the waiting control group
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56 which tended to be larger at post-test ($ds=.19-1.07$) than at delayed follow-up ($ds=.08-.66$). In
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contrast, differences between the 30-week and 20-week intervention groups were very small (post-test: $d_s=.04-.15$; delayed follow-up: $d_s=.03-.22$). Differences between groups on directly taught vocabulary measures were assessed in hierarchical linear (ANCOVA) models with initial level of performance on the same measure as covariate, and with varying intercepts and fixed slopes across schools. These models account for the non-independence of observations due to children being clustered within schools. To test the assumption of homogeneity of regression slopes across groups the group x covariate interaction terms were included in initial models but were dropped from the models reported since these effects were not significant and of negligible magnitude. The absence of group by covariate interactions justifies the use of the simpler models with parallel slopes.

-Table 2 about here-

Effects on primary outcomes (standardized and non-standardized measures of oral language)

Our principal interest was to examine the extent to which the interventions produced improvements on a broad language factor defined by our primary outcome measures (i.e. standardized and non-standardized tests of language ability: CELF *Expressive Vocabulary*, CELF *Sentence Structure*, BPVS, *Listening Comprehension*, APT *Information* and *Grammar scores*). Such a measure assesses an underlying language factor that captures the common variance shared by the different language measures. The model used is shown in Figure 3 and provides an excellent fit to the data ($\chi^2 (145)=178.582$, $p=.030$; RMSEA=.024 [90% CI .008-.035]; CFI=.890; TFI=.986). In this model variance in the pre-test, post-test and delayed follow-up language scores is captured by six latent variables (Language Pre-test, Language Post-test, Language Delayed Follow-up, APT Pre-test, APT Post-test, APT Delayed Follow-up). The language pre-test, post-test and delayed follow-up factors reflect shared variance across all language measures at each time point, while the APT factors

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3 account for variance that is shared by APT *Information* and *Grammar* scores but which is not
4
5 shared with the other language measures. The APT factors were included in the model to
6
7 improve fit since the APT measures shared significant variance with each other which was
8
9 not accounted for by the language latent variable (it is likely that the APT factor reflects
10
11 shared measurement variance since both scores come from the same test).
12
13

14 It is notable that the language factors show considerable longitudinal stability
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16 and the APT factors moderate stability. In this model, the unstandardized regression weights
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18 from the language pre-test to the two language post-test factors are fixed to be equal (a Wald
19
20 Test shows that this constraint results in no loss of fit in comparison to a model in which the
21
22 paths were freely estimated; $\chi^2(1)=2.991, p=.084$). Also, each pair of unstandardized
23
24 regression weights from each of the dummy codes (20-week intervention→Language Post-
25
26 test; 20-week intervention→Language Delayed Follow-up and 30-week intervention
27
28 →Language Post-test; 30-week intervention→Language Delayed Follow-up) were fixed to
29
30 be equal. These constraints provide a direct test of whether each of the intervention effects
31
32 differ in size between the immediate and delayed post-tests. Once again imposing these
33
34 constraints resulted in negligible changes in model fit (Wald Test: $\chi^2(2)=0.628, p=.730$)
35
36 confirming that the size of the intervention effects did not differ between the two testing
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38 times.
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43 -Figure 3 about here-
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46 The most critical result from this analysis is that both the 20-week and 30-
47
48 week intervention groups show a significantly greater increase in their scores on the language
49
50 post-test and delayed follow-up factors (controlling for pre-test scores) than the waiting
51
52 control group ($d=.21$ [95% CI .044-.366] and $d=.30$ [95% CI .130-.468] respectively). The
53
54 extent of improvement does not differ between the two intervention groups (Wald test: χ^2
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56 (1)=.842, $p=.359$). A critical assumption for this analysis is that there are equivalent slopes
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3 between language pre-test and language post-test factor scores across groups. Analyses which
4
5 included the interaction terms between pre-test and group dummy codes confirmed that the
6
7 slopes for the intervention groups did not differ significantly from the slope for the waiting
8
9 control group at either post-test (20-week intervention: $\beta=.037$, $p=.236$; 30-week
10
11 intervention: $\beta=.021$, $p=.520$) or at delayed follow up (20-week intervention: $\beta=-.053$,
12
13 $p=.258$; 30-week intervention: $\beta=-.071$, $p=.077$).

16 The clear absence of interactions between group and pre-test scores in these
17
18 analyses confirm that the slopes relating pre-test to post-test language scores do not differ
19
20 between groups. In other words, children with the most severe language difficulties at pre-test
21
22 respond to our intervention to the same degree as children with less severe difficulties. This
23
24 pattern is illustrated in Figure 4.

27 -Figure 4 about here-

29 It should also be noted that the model used here does not display factorial
30
31 invariance (unstandardized loadings on the language factor differ across different testing
32
33 times). This finding shows that the composition of the language factor varies over time
34
35 (possibly partly because the different language tests show different degrees of improvement
36
37 as a result of intervention). One implication of this is that we cannot make strong claims
38
39 about the intervention having effects on a unitary underlying language factor. Nevertheless,
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41 the model gives an estimate of the size of change in language skills produced by our
42
43 interventions when language is assessed by a latent variable with high reliability.
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48 **Effects on secondary outcomes (early literacy and reading comprehension)**

50 We also examined whether the intervention had any effects on early literacy
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52 skills (i.e. letter-sound knowledge and word reading). Table 1 shows descriptive statistics for
53
54 the effects of the intervention on these measures. We constructed a latent variable model for
55
56 literacy, comparable to the one for language, which is shown in Figure 5. The model provides
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3 an excellent fit to the data ($\chi^2(15)=23.235, p=.079$; RMSEA=.037 [90% CI .000-.066];
4
5 CFI=.989; TFI=.980). In this model variance in pre-test and post-test literacy scores is
6
7 captured by three latent variables (Literacy Pre-test, Literacy Post-test, Literacy Delayed
8
9 Follow-up). The literacy factor shows moderate longitudinal stability which is consistent with
10
11 the fact that this is a time of rapid changes in literacy skills, which were very low when first
12
13 assessed in nursery.
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16
17 In this model, the unstandardized regression weights from the literacy pre-test
18
19 to the two literacy post-tests were fixed to be equal as this did not result in a significant loss
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21 of fit (Wald Test: $\chi^2(1)=1.001, p=.317$). Furthermore, each pair of unstandardized regression
22
23 weights from each dummy code to the post-test and delayed follow-up factor were fixed to be
24
25 equal (20-week intervention→Literacy Post-test; 20-week intervention→Literacy Delayed
26
27 Post-test, and 30-week intervention→Literacy Post-test; 30-week intervention→Literacy
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29 Delayed Follow-up). These constraints provide a direct test of whether each of the
30
31 intervention effects differ in size between immediate post-test and delayed follow-up. Once
32
33 again imposing these constraints resulted in negligible changes in model fit ($\chi^2(2)=1.837$,
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35 $p=.399$), confirming that the size of the intervention effects did not differ between the two
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37 testing times.
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42 The most critical result from this analysis is that, as expected from the means
43
44 in Table 2, neither the 20-week nor the 30-week intervention groups show a significantly
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46 greater increase in their scores on the early literacy immediate post-test or delayed follow-up
47
48 factor (controlling for pre-test scores) than the waiting control group ($d=.09$ [95% CI -.131-
49
50 .317] and $d=.13$ [95% CI -.125-.387] respectively). Once again a model with interactions
51
52 between group dummy and Literacy Pre-test confirmed that a model where slopes are
53
54 constrained to be equal is valid. In this model, as in the model for language skills, the literacy
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Language Intervention in Mainstream Settings 20

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3 factor does not show factorial invariance (unstandardized factor loadings vary across testing
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5 times).

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7 -Figure 5 about here-

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10 In addition to word level reading and letter-sound knowledge, we assessed
11
12 intervention effects on reading comprehension when it was first administered at delayed
13
14 follow-up in a hierarchical linear model with children nested within schools (with varying
15
16 intercepts but fixed slopes across schools). Using baseline listening comprehension skill as
17
18 the covariate, there was no sign of a difference between the 20-week intervention and the
19
20 waiting control group (marginal mean group difference=.59, 95% CI -.29-1.49, $z=1.30$,
21
22 $p=.193$) or the 30-week intervention and the waiting control group (marginal mean group
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24 difference=.37, 95% CI -.54-1.28; $z=0.79$, $p=.427$).

25 26 27 28 **Discussion**

29
30 This study evaluated the effectiveness of the *Nuffield Early Language*
31
32 *Intervention* in a field trial. A key aim was to assess the extent to which the programme is
33
34 effective when delivered without the extensive support used in our earlier research trial
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36 (Fricke et al., 2013). A subsidiary aim was to evaluate whether the original 30-week
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38 programme (10 weeks at the end of nursery in England (age 3-4) followed by 20 weeks in
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40 first two terms of primary school, i.e. Reception in England (age 4-5)) differed appreciably
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42 from simply delivering a 20-week programme starting in Reception. The overall pattern of
43
44 results is clear; both the 20- and 30-week programmes produce small improvements on
45
46 standardized tests of oral language skill immediately following the intervention and these
47
48 effects are maintained 6 months later. Although the size of improvements tended to be larger
49
50 for the 30-week programme, this difference was not statistically significant. In contrast to the
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52 effects on oral language, we did not find evidence that the programmes reliably improved
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54 early literacy or reading comprehension skills.
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3 The effects of the 30-week programme on oral language skills is broadly in
4 line with findings from Fricke et al. (2013) though the effects are smaller. The smaller effect
5 sizes likely reflect differences in treatment fidelity (many children in the current study
6 received less than the full “dose” of the programme) and differences in the quality of training
7 and ongoing support given to the TAs in this study compared to our earlier trial (Fricke et al.
8 2013). To put the size of these effects in context, according to the method of reporting
9 favoured by the Education Endowment Foundation (2016) the 30-week programme produced
10 gains in language skills equivalent to roughly 4 months additional progress and the 20-week
11 programme gains of roughly 2 months. For studies of educational interventions at least two
12 organizations (Promising Practices Network, 2007; What Works Clearing House, 2007) have
13 suggested that $d=.25$ should be seen as educationally important although it is also worth
14 noting that smaller effect sizes can in certain circumstances be considered to have high
15 practical importance (see Cooper, 2008).
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32 It is encouraging that the intervention effects are maintained at delayed
33 follow-up, by which time some of the children in the waiting control group were receiving
34 some form of intervention, albeit of highly variable quality and quantity. It is hard to know
35 why some schools preferred not to be trained in the additional language and literacy support
36 that we offered for the waiting control group, or why some who accepted the training delayed
37 its implementation. However, it is encouraging to note that, immediately following the trial,
38 10 schools continued to use the *Nuffield Early Language Intervention* in nursery and/or
39 Reception and a further 9 schools intended to use it again.
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49 We found no statistically significant difference between the 30-week and 20-
50 week programmes. The preschool component of the programme, however, was of limited
51 duration (10hrs) and consisted only of group work with no individual sessions. Further work
52 is needed to establish the best form of language intervention for children in nursery.
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3 The absence of intervention effects on early literacy skills replicates Fricke et
4 al. (2013). This likely reflects the fact that all children were receiving intensive systematic
5 phonics teaching in their schools. In addition, whereas Fricke et al. (2013) found significant
6 improvements in reading comprehension some six months after the end of the intervention,
7 this was not the case in the current study, most likely because the improvements in language
8 skills here are much smaller than those in the earlier study.
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Conclusion

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19 Oral language skills are critical to educational success (Roulstone et al., 2011)
20 and this study provides evidence that the benefits of the *Nuffield Early Language Intervention*
21 (Fricke et al., 2013) are reproducible when training is delivered by an independent
22 organisation, in ‘real world’ educational settings (cf. Savage, Carless, & Erten, 2009). Further
23 research is needed to evaluate whether a more intensive nursery-based language intervention
24 programme would be effective in boosting the language skills of preschool children (we
25 suspect it would). It would also be desirable for future studies to assess the longer term
26 effects of early language interventions and their potential cost effectiveness.
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Key points

- Oral language skills are critical to educational success.
 - Data from an RCT show that both a 30-week language intervention delivered in nursery and Reception classes in England and a 20-week intervention delivered in Reception only can improve oral language skills.
 - The intervention did not bring about reliable gains in early literacy or reading comprehension skills.
 - The findings provide further evidence that oral language interventions can be delivered successfully by TAs working in schools.
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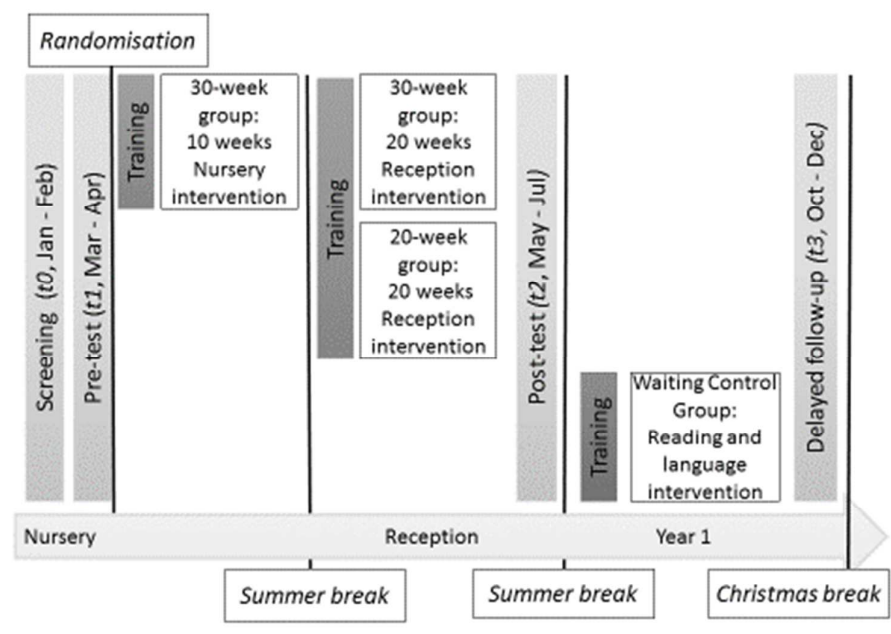


Figure 1: Timeline of project showing assessment, training and intervention phases

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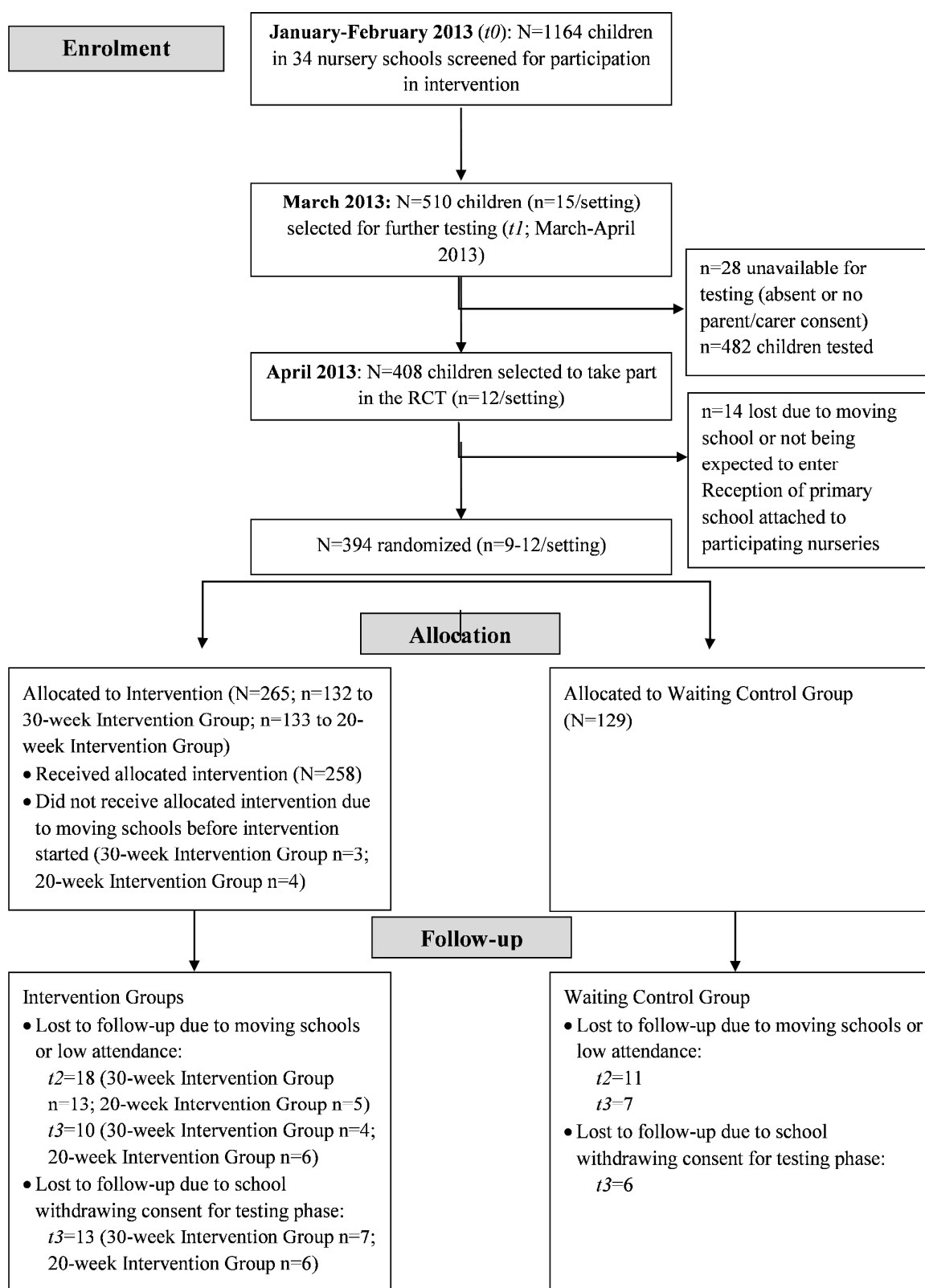


Figure 2: CONSORT diagram showing flow of participants through RCT study

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Table 1

Mean raw scores (SD) for 30-week intervention, 20-week intervention and waiting control groups for primary and secondary outcome measures at screening (t0), pre-intervention (t1), immediately post-intervention (t2) and delayed follow-up (t3; with effect sizes for intervention effects).

| | Reliability | 30-week | | 20-week | | Waiting Control | | Cohen's <i>d</i> | | |
|-------------------------|------------------|--------------|-------|--------------|-------|-----------------|-------|--------------------|-------------------|--------------------|
| | | Intervention | | Intervention | | n=129 | | 30↔ | 30↔ | 20↔ |
| | | n=132 | | n=133 | | | | | | |
| | | <i>M</i> | SD | <i>M</i> | SD | <i>M</i> | SD | 20 | WC | WC |
| Age (months) | | | | | | | | | | |
| • t0 | | 46.01 | 3.40 | 46.08 | 3.57 | 46.16 | 3.59 | | | |
| • t2 | | 61.54 | 3.27 | 61.57 | 3.60 | 61.75 | 3.69 | | | |
| • t3 | | 67.66 | 3.20 | 67.77 | 3.61 | 67.75 | 3.74 | | | |
| Primary Outcomes | | | | | | | | | | |
| CELF-EV | .82 ^a | | | | | | | | | |
| • t0-(40) | | 10.86 | 5.10 | 10.74 | 5.59 | 10.80 | 5.34 | | | |
| • t2-(40) | | 21.00 | 5.74 | 20.77 | 5.90 | 19.60 | 5.98 | 0.02 ¹ | 0.26 ¹ | 0.23 ¹ |
| • t3-(40) | | 24.71 | 6.14 | 24.29 | 5.91 | 22.90 | 6.56 | 0.06 ¹ | 0.34 ¹ | 0.27 ¹ |
| CELF-SS | .78 ^a | | | | | | | | | |
| • t0-(22) | | 6.78 | 3.71 | 6.48 | 3.81 | 6.58 | 3.80 | | | |
| • t2-(22) | | 13.48 | 3.28 | 13.73 | 2.92 | 13.23 | 2.94 | -0.15 ¹ | 0.01 ¹ | 0.16 ¹ |
| • t3-(22) | | 16.23 | 2.78 | 16.14 | 2.68 | 15.97 | 2.91 | -0.06 ¹ | 0.02 ¹ | 0.07 ¹ |
| BPVS | .91 ^a | | | | | | | | | |
| • t1-(168) | | 36.67 | 13.04 | 37.79 | 14.25 | 36.52 | 15.08 | | | |
| • t2-(168) | | 64.54 | 13.09 | 64.29 | 12.77 | 61.79 | 14.32 | 0.10 ¹ | 0.18 ¹ | 0.09 ¹ |
| • t3-(168) | | 74.86 | 9.27 | 73.36 | 12.30 | 72.35 | 11.16 | 0.19 ¹ | 0.17 ¹ | -0.02 ¹ |

Language Intervention in Mainstream Settings 32

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|----|------------------|------------------|------|-------|------|-------|------|--------------------|-------------------|--------------------|
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| 2 | | | | | | | | | | |
| 3 | APT information | .83 ^b | | | | | | | | |
| 4 | | | | | | | | | | |
| 5 | • t1-(40) | 20.70 | 6.38 | 20.02 | 6.08 | 20.44 | 6.00 | | | |
| 6 | • t2-(40) | 28.08 | 4.66 | 28.24 | 4.58 | 27.60 | 4.74 | -0.14 ¹ | 0.04 ¹ | 0.18 ¹ |
| 7 | • t3-(40) | 29.93 | 4.23 | 29.85 | 4.15 | 29.15 | 4.52 | -0.10 ¹ | 0.08 ¹ | 0.19 ¹ |
| 8 | | | | | | | | | | |
| 9 | | | | | | | | | | |
| 10 | APT grammar | .89 ^b | | | | | | | | |
| 11 | | | | | | | | | | |
| 12 | • t1-(38) | 14.33 | 6.31 | 13.53 | 5.96 | 13.89 | 5.59 | | | |
| 13 | • t2-(38) | 22.70 | 4.72 | 22.05 | 5.23 | 21.31 | 4.99 | -0.03 ¹ | 0.16 ¹ | 0.19 ¹ |
| 14 | • t3-(38) | 25.83 | 3.87 | 24.92 | 4.55 | 24.00 | 4.79 | 0.02 ¹ | 0.23 ¹ | 0.22 ¹ |
| 15 | | | | | | | | | | |
| 16 | | | | | | | | | | |
| 17 | | | | | | | | | | |
| 18 | Listening | .99 ^b | | | | | | | | |
| 19 | | | | | | | | | | |
| 20 | comprehension | | | | | | | | | |
| 21 | | | | | | | | | | |
| 22 | • t1-(16) | 1.19 | 1.51 | 1.44 | 1.79 | 1.39 | 1.43 | | | |
| 23 | • t2-(16) | 5.02 | 2.55 | 4.86 | 2.87 | 4.55 | 2.51 | 0.25 ¹ | 0.46 ¹ | 0.15 ¹ |
| 24 | • t3-(16) | 6.62 | 2.96 | 6.42 | 3.07 | 6.25 | 2.47 | 0.27 ¹ | 0.39 ¹ | 0.07 ¹ |
| 25 | | | | | | | | | | |
| 26 | | | | | | | | | | |
| 27 | | | | | | | | | | |
| 28 | Secondary | | | | | | | | | |
| 29 | | | | | | | | | | |
| 30 | Outcomes | | | | | | | | | |
| 31 | YARC-Letter | .95 ^a | | | | | | | | |
| 32 | | | | | | | | | | |
| 33 | Knowledge | | | | | | | | | |
| 34 | | | | | | | | | | |
| 35 | • t1-(17) | 1.60 | 2.71 | 2.14 | 2.96 | 1.79 | 2.58 | | | |
| 36 | • t2-(32) | 27.12 | 3.86 | 26.87 | 5.66 | 26.57 | 5.49 | 0.26 ¹ | 0.28 ¹ | 0.00 ¹ |
| 37 | • t3-(32) | 29.65 | 2.55 | 29.41 | 3.47 | 29.12 | 3.90 | 0.27 ¹ | 0.27 ¹ | -0.02 ¹ |
| 38 | | | | | | | | | | |
| 39 | | | | | | | | | | |
| 40 | YARC-Early | .98 ^a | | | | | | | | |
| 41 | | | | | | | | | | |
| 42 | Word Reading | | | | | | | | | |
| 43 | | | | | | | | | | |
| 44 | • t1-(30) | 0.34 | 2.10 | 0.12 | 0.86 | 0.09 | 0.80 | | | |
| 45 | • t2-(30) | 8.90 | 5.99 | 9.94 | 7.14 | 8.87 | 6.74 | -0.17 ² | 0.00 ² | 0.17 ² |
| 46 | • t3-(30) | 16.20 | 7.98 | 16.27 | 8.53 | 14.72 | 7.63 | -0.01 ² | 0.19 ² | 0.19 ² |
| 47 | | | | | | | | | | |
| 48 | | | | | | | | | | |
| 49 | | | | | | | | | | |
| 50 | YARC-Reading | .77 ^a | | | | | | | | |
| 51 | | | | | | | | | | |
| 52 | Comprehension | | | | | | | | | |
| 53 | | | | | | | | | | |
| 54 | • t3-(16) | 6.34 | 3.42 | 6.84 | 3.44 | 6.28 | 2.94 | -0.15 ² | 0.02 ² | 0.18 ² |
| 55 | | | | | | | | | | |

Note. ()=Maximum raw scores; CELF=Clinical Evaluation of Language Fundamentals, EV=Expressive vocabulary, SS=Sentence structure,

BPVS=British Picture Vocabulary Scale, APT=Action Picture Test, YARC=York Assessment of Reading for Comprehension.

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Language Intervention in Mainstream Settings 33

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Reliability: ^aCronbach's alpha; ^bInterrater reliability

Cohen's *d*: 1=difference in progress between groups divided by pooled initial SD; 2=difference in means at post-test/follow-up divided by pooled SD at post-test/follow-up (pre-test scores were at floor/not available so could not be used)

For Peer Review

Language Intervention in Mainstream Settings 34

Table 2

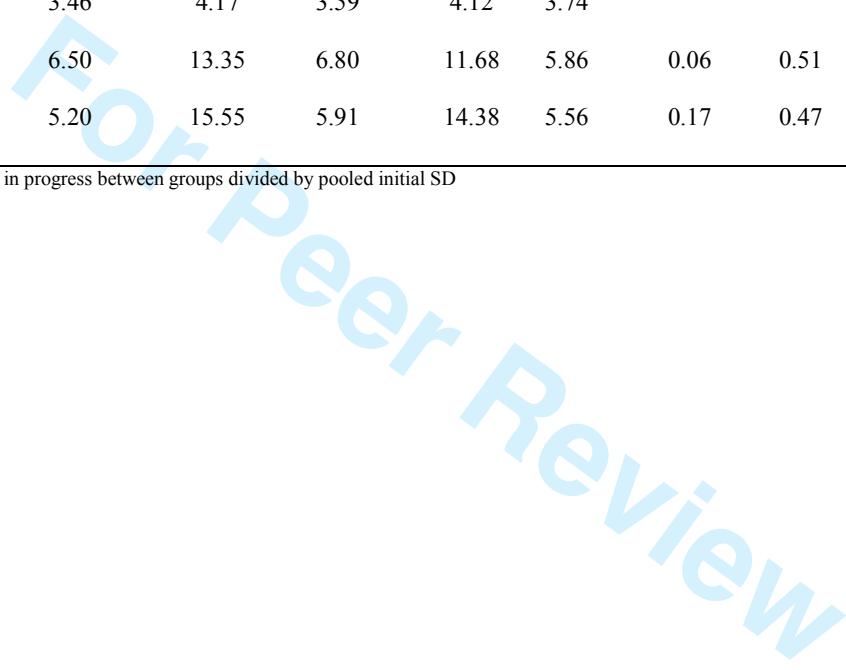
Mean raw scores (SD) and intervention effects for 30-week intervention, 20-week intervention and waiting control groups pre-intervention (t1), immediately post-intervention (t2) and at delayed follow-up (t3) for directly taught vocabulary measures

| | 30-week | | 20-week | | Waiting | | Cohen's d | | | Hierarchical Linear Model | | | |
|-----------------------------|--------------|------|--------------|------|---------|------|-----------|-------|-------|---------------------------|-------|-------|------|
| | Intervention | | Intervention | | Control | | 30↔20 | 30↔WC | 20↔WC | 30↔WC | | 20↔WC | |
| | M | SD | M | SD | M | SD | | | | z | p | z | p |
| Nursery-Expressive Naming | | | | | | | | | | | | | |
| • t1-(14) | 5.43 | 2.44 | 5.50 | 2.40 | 5.49 | 2.35 | | | | | | | |
| • t2-(14) | 9.43 | 1.77 | 9.14 | 1.92 | 8.67 | 1.73 | 0.15 | 0.34 | 0.19 | 3.81 | <.001 | 2.22 | .027 |
| • t3-(14) | 10.59 | 1.58 | 10.12 | 1.84 | 9.91 | 1.64 | 0.22 | 0.31 | 0.08 | 3.30 | .001 | 1.06 | .289 |
| Nursery-Definitions | | | | | | | | | | | | | |
| • t1-(48) | 4.24 | 3.57 | 4.35 | 3.63 | 4.48 | 3.28 | | | | | | | |
| • t2-(48) | 13.97 | 6.45 | 13.67 | 6.44 | 11.56 | 5.60 | 0.09 | 0.84 | 0.73 | 3.55 | <.001 | 2.89 | .004 |
| • t3-(48) | 15.63 | 5.91 | 15.62 | 6.12 | 14.24 | 6.39 | 0.03 | 0.54 | 0.50 | 2.30 | .022 | 2.02 | .043 |
| Reception-Expressive Naming | | | | | | | | | | | | | |
| • t1-(24) | 7.71 | 3.08 | 7.75 | 3.18 | 7.80 | 3.27 | | | | | | | |

Language Intervention in Mainstream Settings 35

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|-----------------------|-------|------|-------|------|-------|------|------|------|------|-------|-------|------|-------|
| • t2-(24) | 14.83 | 3.08 | 14.74 | 3.37 | 11.52 | 2.84 | 0.03 | 1.07 | 1.03 | 10.24 | <.001 | 9.80 | <.001 |
| • t3-(24) | 15.52 | 2.76 | 15.46 | 2.82 | 13.52 | 3.02 | 0.03 | 0.66 | 0.62 | 6.35 | <.001 | 5.93 | <.001 |
| Reception-Definitions | | | | | | | | | | | | | |
| • t1-(54) | 4.03 | 3.46 | 4.17 | 3.59 | 4.12 | 3.74 | | | | | | | |
| • t2-(54) | 13.43 | 6.50 | 13.35 | 6.80 | 11.68 | 5.86 | 0.06 | 0.51 | 0.44 | 2.67 | .008 | 2.05 | .040 |
| • t3-(54) | 16.00 | 5.20 | 15.55 | 5.91 | 14.38 | 5.56 | 0.17 | 0.47 | 0.31 | 2.78 | .005 | 1.75 | .080 |

Note. ()=Maximum raw scores, Cohen's d: difference in progress between groups divided by pooled initial SD



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Language Intervention in Mainstream Settings 36

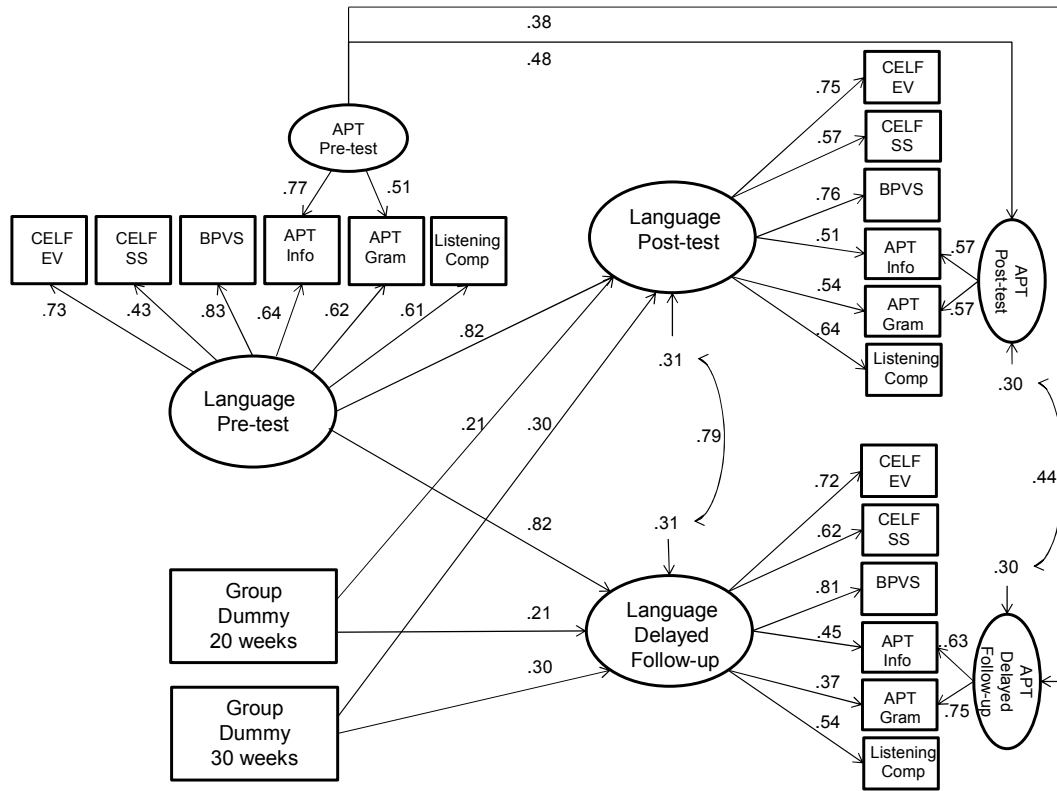


Figure 3: Model showing the effects of the interventions on language skills at immediate post-test and delayed follow-up. Standardized coefficients shown (except for dummy variables where y-standardized values are shown). Robust (Huber-White cluster estimators) standard errors are shown which do not differ appreciably from simple standard errors. A number of covariances between the same measures at adjacent time points were significant and included in the model, but not shown in the diagram. Note. CELF=Clinical Evaluation of Language Fundamentals, EV=Expressive vocabulary, SS=Sentence structure, BPVS=British Picture Vocabulary Scale, APT=Action picture test, Info=Information, Gram=Grammar, Comp=Comprehension.

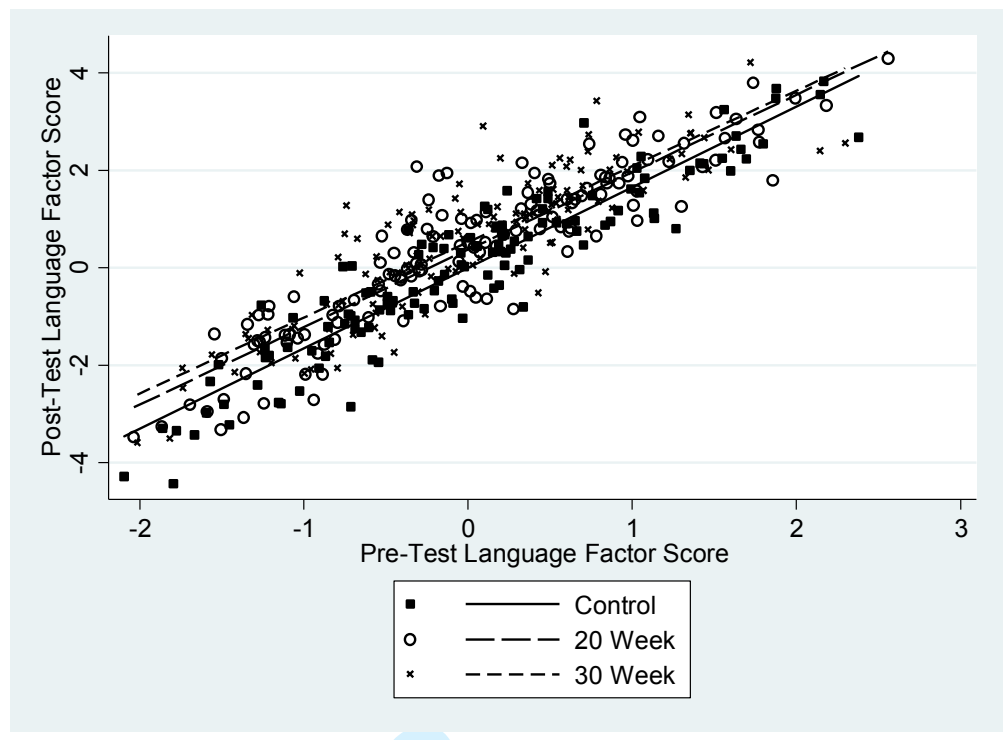


Figure 4: Scatterplot showing the relationship between the outcome variable (post-test language factor score) and the covariate (pre-test language factor score) for the 30- and 20-week intervention and the waiting control groups.

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Language Intervention in Mainstream Settings 38

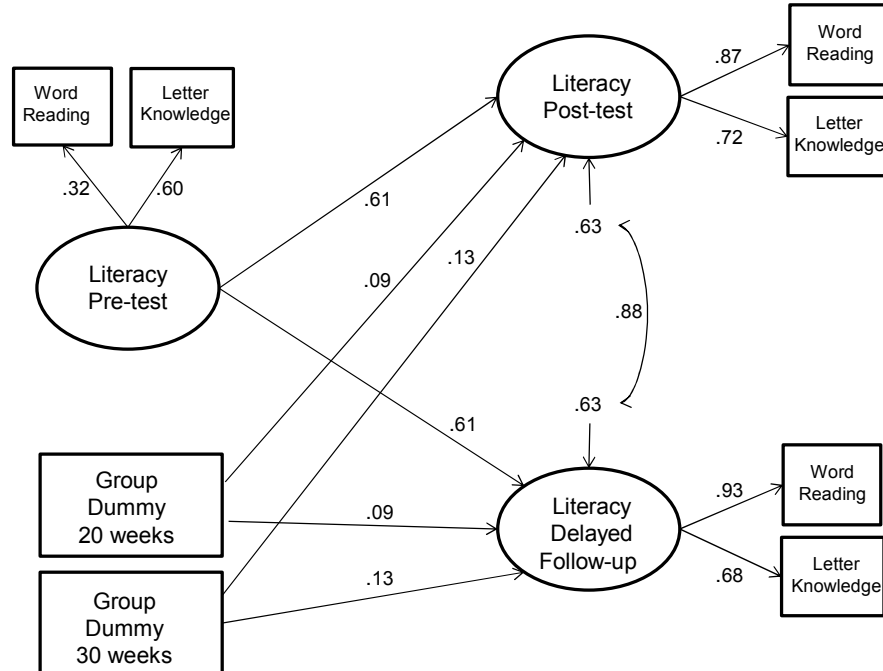


Figure 5: Model showing the effects of the interventions on literacy skills at immediate post-test and delayed follow-up. Standardized coefficients shown (except for dummy variables where y -standardized values are shown). Robust (Huber-White cluster estimators) standard errors are shown which do not differ appreciably from simple standard errors. Some covariances between the same measures at adjacent time points were significant and included in the model, but not shown in the diagram.

Online Appendix A

Table A1

Group and individual session schedule for Nuffield Early Language Intervention programme in Nursery and Reception

| Nursery (10 weeks) | Reception Part 1 (10 weeks) | | Reception Part 2 (10 weeks) | |
|--------------------------------|--|------------------------------|--|---|
| Group session (20 mins) | Group session (25 mins + 5 mins to spend flexibly) | Individual session (15 mins) | Group session (25 mins + 5 mins to spend flexibly) | Individual session (15 mins) |
| Introduction (2 mins) | Introduction incl. Listening Game (3 mins) | Introduction (2 mins) | Introduction (2 mins) | Introduction (2 min) |
| Active Listening Game (3 mins) | | | Letter sounds and phonological awareness (3 mins) | Letter sounds and phonological awareness (4 mins) |
| Vocabulary Teaching (6 mins) | Vocabulary Revision (5 mins) Vocabulary Teaching (5 mins) | Vocabulary Revision (5 mins) | Vocabulary Revision (4 mins) Vocabulary Teaching (5 mins) | Vocabulary Revision (4 mins) |
| Narrative Work (6 mins) | Narrative (10 mins) | Narrative (5 mins) | Narrative (9 mins) | Narrative (4 mins) |
| Plenary (3 mins) | Plenary (2 mins) | Plenary (3 mins) | Plenary (2 mins) | Plenary (1 min) |

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Online Appendix B

Table B1

CONSORT checklist

| Section/Topic | Item No | Checklist item | Reported on page No |
|---------------------------|---------|---|---------------------|
| Title and abstract | | | |
| | 1a | Identification as a randomised trial in the title | 1 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | 3-4 |
| Introduction | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | 5-7 |
| | 2b | Specific objectives or hypotheses | 7 |
| Methods | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | 7-9 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A |
| Participants | 4a | Eligibility criteria for participants | 9-10 |
| | 4b | Settings and locations where the data were collected | 9 |

| | | | |
|----------------|-----|--|---------------|
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 12-14, 29, 39 |
| 7 | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | 11-12 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | N/A |
| Sample size | 7a | How sample size was determined | 9 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | N/A |
| Randomisation: | | | |
| Sequence | 8a | Method used to generate the random allocation sequence | 10 |
| generation | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | 10 |
| Allocation | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), | 10 |
| concealment | | describing any steps taken to conceal the sequence until interventions were assigned | |
| mechanism | | | |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 10 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 8 |

Language Intervention in Mainstream Settings 42

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| | 11b | If relevant, description of the similarity of interventions | 6-7, 12-14 |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | 14, 15, 16, 18 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | N/A |
| Results | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | 30 |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | 30 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 29, 30 |
| | 14b | Why the trial ended or was stopped | N/A |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | 31-32 |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | 15 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | 14-20, 31-32, 34-35, 36, 38 |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | N/A |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre- | N/A |

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specified from exploratory

Harms

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All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)

N/A

Discussion

Limitations

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Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-22

Generalisability

21

Generalisability (external validity, applicability) of the trial findings

20-22

Interpretation

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Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

20-22

Other information

Registration

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Registration number and name of trial registry

N/A

Protocol

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Where the full trial protocol can be accessed, if available

N/A

Funding

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Sources of funding and other support (such as supply of drugs), role of funders

23

