

Shaping children’s sentences: trialling visual support for children with language difficulties using the SHAPE CODING system in mainstream primary schools

Submission date 14/05/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/05/2024	Overall study status Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/06/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims
Developmental Language Disorder (DLD) affects 7% of children; approximately two in every mainstream classroom. However, specialist Speech and Language Therapy (SLT) services for children with DLD are very limited, thus the effectiveness and efficiency of an intervention need to be maximised through the identification of appropriate targets and effective procedures and delivery of an appropriate dosage. Children with DLD have particular difficulties with grammar, which affects their ability to communicate with others and access the academic curriculum. Previous studies indicate that SLT intervention can improve the production of grammar in children with DLD. The SHAPE CODING system is a highly individualised intervention for children with DLD (and indeed wider language disorders), which teaches children the rules of grammar using the support of a visual system which represents the different aspects of grammar with shapes (for groups of words in a sentence playing different roles), colours (for different word classes, e.g., nouns, verbs, adjectives), arrows (for tenses) and lines (for singular versus plural). The effectiveness of SLTs using the system to improve the language of children with (D)LD has been evaluated in specialist settings. The intervention has recently been developed to include individualised identification of targets and detailed intervention steps <https://shapecoding.com/resources>. A recent study showed that this approach, together with a feedback hierarchy, was effective at improving the use of the targeted constructions in children (aged 7-10 years) with severe levels of DLD in a special school. Indeed, this method was more efficient than the previous methods used in the school, with the SLT focusing on 2-4 times as many targets over 2 terms. A pilot study was also carried out that investigated the feasibility of SLT delivery of the same intervention in mainstream primary schools with 7 children with DLD in years 3/4 (aged 7-8 years) in two mainstream primary schools with similar results. This study aims to investigate the effectiveness of the SHAPE CODING intervention in new settings with new interventionists and with a wider age group (aged 5-10 years) by carrying out a randomised control trial in mainstream schools.

Who can participate?

Children in school years 1-5 (aged 5-9 years old) at the start of the intervention who are either already on an SLT caseload or for whom there are concerns about their language development. Only children with difficulties with expressive grammar will be included, so the study will exclude those standard scores in the typical range on either of the two standardised grammar tests

What does the study involve?

The study team will partner with SLT practices that provide SLT services to schools. They will approach schools they work in and ask if they would like to participate in the project. If the headteacher consents, the SLT will then collaborate with the school to identify children who will be in years 1-5 (aged 5-9 years old) at the start of the intervention, and who are already on the SLT caseload, or for whom there are concerns about language development. The parents of these children will be sent an information sheet and consent form.

For children whose parents consent, the SLT will meet with the children to gain their consent and will then administer two standardized assessments (Structured Photographic Expressive Language Test - 3; Clinical Evaluation of Language Fundamentals (CELF)-5, Formulated Sentences subtest) to ensure that grammar is an area of difficulty. Those with a standard score above 95 on the SPELT-3 or above 6 on the CELF-5 Formulated Sentences subtest will be excluded from the study, as they are unlikely to benefit from the intervention.

Participants will then be randomly assigned to an intervention versus control group. Those in the intervention group will receive 20 half-hour sessions of 1:1 SLT intervention focusing on individualised grammatical targets, using the SHAPE CODING system. The SHAPE CODING system is a highly individualised intervention for children with DLD (and indeed wider language disorders), which teaches children the rules of grammar using the support of a visual system which represents the different aspects of grammar with shapes (for groups of words in a sentence playing different roles), colours (for different word classes, e.g., nouns, verbs, adjectives), arrows (for tenses) and lines (for singular versus plural). The intervention has recently been developed to include individualised identification of targets and detailed intervention steps <https://shapecoding.com/resources>. Those in the control group will receive usual support (intervention for other areas of speech and language, an SLT programme or school intervention).

What are the possible benefits and risks of participating?

It is hoped that the participants in the intervention group will benefit from an intervention which aims to enhance their understanding and use of a range of grammatical structures in English. This should increase their access to the school curriculum and improve their everyday interactions with others. However, children in the intervention arm will miss lessons to participate in this research.

Children in the control group will not receive the intervention for grammar during the two terms of the project. However, detailed information will be gathered about their language that can be used to inform their support following the completion of the project. They can continue to have intervention as usual in other areas of speech, language and communication.

Where is the study run from?

The study is a partnership between University College London and Moor House School & College. The research team will also partner with SLT services in the South East.

When is the study starting and how long is it expected to run for?
December 2023 to December 2031

Who is funding the study?
Moor House School & College

Who is the main contact?
Dr Susan Ebbels, ebbelss@moorhouseschool.co.uk

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Susan Ebbels

ORCID ID

<http://orcid.org/0000-0003-0402-6227>

Contact details

Moor House School & College, Mill Lane
Oxted
United Kingdom
RH8 9AQ
+44 (0)1883 712271
ebbelss@moorhouseschool.co.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Shaping children's sentences: for children aged 5-10 years with language difficulties in mainstream primary schools, do those receiving intervention using the SHAPE CODING system make greater gains than those in a control group who receive usual support (intervention for other areas of speech and language, an SLT programme or school intervention) on expressive language as measured by a grammar factor combining six grammatical measures

Study objectives

H1: Participants in the intervention group will show significantly greater improvement following intervention relative to those in the control group in their grammatical abilities as measured on a combined grammar factor.

H2: Participants in the intervention group will show significantly greater improvement following intervention relative to those in the control group on a standardised measure of sentence formulation.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 04/03/2024, UCL Research Ethics Committee (UCL REC) (Research and Innovation Services, 2 Taverton St, London, WC1E 6BT, United Kingdom; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 23949/002

Study design

Multicentre interventional single-blind randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Intervention aiming to improve expressive language in children with language difficulties (including Developmental Language Disorder, DLD)

Interventions

This study aims to investigate the effectiveness of SHAPE CODING intervention for children with language difficulties (including DLD) aged 5-10 years old in mainstream schools by carrying out a 4-stage sequential design study. The study team will partner with private speech and language therapy practices that provide Speech and Language Therapy (SLT) services to schools. They will approach schools they work in and ask if they would like to participate in the project. If the headteacher consents, the SLT will then collaborate with the school to identify children who will be in years 1-5 (aged 5-9 years old) at the start of the intervention, and who are already on the SLT caseload, or for whom there are concerns about language development. The parents of these children will be sent an information sheet and consent form.

For children whose parents consent, the SLT will meet with the children to gain their consent and will then administer two standardized assessments (Structured Photographic Expressive Language Test - 3; Clinical Evaluation of Language Fundamentals (CELF)-5, Formulated Sentences subtest) to ensure that grammar is an area of difficulty. Those with a standard score above 90 on the SPELT-3 or above 6 on the CELF-5 Formulated Sentences subtest will be excluded from the study, as they are unlikely to benefit from the intervention.

The study uses the R package “carat” to carry out adaptive covariate randomisation using Hu and Hu’s randomisation using the command-line user interface to assign participants to groups sequentially. The study will use a biased coin probability of 0.85 and the following covariates (with double weight assigned to SLT):

- Year group (1, 2, 3, 4, 5)
- SLT (1, 2, 3, 4, 5, 6, 7, 8, 9, 10)
- CELF Formulated Sentences raw score (0-15, 16-20, 21-26)

Those in the intervention group will receive 20 half-hour sessions of 1:1 Speech and Language Therapy (SLT) intervention focusing on individualised grammatical targets, using the SHAPE CODING system. The SHAPE CODING system is a highly individualised intervention for children with DLD (and indeed wider language disorders), which teaches children the rules of grammar using the support of a visual system which represents the different aspects of grammar with shapes (for groups of words in a sentence playing different roles), colours (for different word classes, e.g., nouns, verbs, adjectives), arrows (for tenses) and lines (for singular versus plural). The intervention has recently been developed to include individualised identification of targets and detailed intervention steps <https://shapecoding.com/resources>.

Those in the control group will receive usual support (intervention for other areas of speech and language, an SLT programme or school intervention).

Intervention Type

Behavioural

Primary outcome measure

The creation of a grammar factor is assessed using the following measures at pre- and post-intervention in both the intervention and control groups:

1. Raw score on the SPELT-3
2. ACE narrative syntax raw score
3. Receptive grammar: TROG-E blocks passed
4. Three measures of grammatical accuracy and complexity in narratives (ERRNI – Story B) and ACE narrative combined):
 - 4.1. Mean length of utterance (MLU)
 - 4.2. Clausal density (number of clauses/number of utterances)
 - 4.3. Grammatical errors per utterance

Secondary outcome measures

Semantics, morphology, syntax, and pragmatics measured using the CELF-5 Formulated Sentences raw score at pre- and post-intervention in both the intervention and control groups

Overall study start date

01/12/2023

Completion date

31/12/2031

Eligibility

Key inclusion criteria

Current inclusion criteria as of 28/06/2024:

1. Children in school years 1-5 (aged 5-9 years old) at the start of the intervention
2. Either already on the SLT caseload or there are concerns about their language development
3. Difficulties with expressive grammar with a standard score below 95 on the SPELT-3, and a scaled score below 7 on the CELF-5 Formulated Sentences subtest

Previous inclusion criteria:

1. Children in school years 1-5 (aged 5-9 years old) at the start of the intervention
2. Either already on the SLT caseload or there are concerns about their language development
3. Difficulties with expressive grammar with a standard score below 90 on the SPELT-3, and a scaled score below 7 on the CELF-5 Formulated Sentences subtest

Participant type(s)

Learner/student, Service user

Age group

Child

Lower age limit

5 Years

Upper age limit

10 Years

Sex

Both

Target number of participants

Following our sequential analysis design plan, our target sample size is up to 260 participants in total, with interim analyses conducted at $n = 40$, $n = 80$ and $n = 140$.

Key exclusion criteria

1. Children with a standard score above 90 on the SPELT-3, or
2. Children with above 6 on the CELF-5 Formulated Sentences subtest

Date of first enrolment

20/05/2024

Date of final enrolment

01/06/2030

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University College London

United Kingdom

WC1E 6BT

Study participating centre

Moor House School & College

Mill Lane

Hurst Green

Oxted

United Kingdom

RH8 9AQ

Sponsor information

Organisation

University College London

Sponsor details

UCLH/UCL Joint Research Office, part of the Research Directorate

4th Floor, West

250 Euston Road

London

London

England

United Kingdom

NW1 2PG

+44 (0) 20 7679 2000

pushpsen.joshi1@nhs.net

Sponsor type

University/education

Website

<https://www.ucl.ac.uk/>

ROR
<https://ror.org/02jx3x895>

Funder(s)

Funder type
University/education

Funder Name
Moor House School & College

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2032

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository, the Open Science Framework at: <https://osf.io/adxcz>. Consent is obtained from both children and their parents. All shared data will be anonymised.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (other)		17/04/2024	15/05/2024	No	No
Statistical Analysis Plan		17/04/2024	16/05/2024	No	No