Headsprout Early Reading® in Special Schools (HERiSS): a randomised control trial
Evaluation Protocol
Evaluator: The University of Warwick
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Education Endowment Foundation

PROJECT TITLE	Headsprout® Early Reading in Special Schools (HERiSS) – a randomised control trial.
DEVELOPER (INSTITUTION)	Bangor University
EVALUATOR (INSTITUTION)	The University of Warwick
PRINCIPAL INVESTIGATOR(S)	Dr Samantha Flynn & Dr Louise Denne
PROTOCOL AUTHOR(S)	Dr Louise Denne, Dr Emily Roberts-Tyler, Dr Samantha Flynn, Dr Tom Bailey, Dr Paul Thompson
TRIAL DESIGN	Two-arm cluster randomised controlled trial with random allocation at school level
TRIAL TYPE	Efficacy
PUPIL AGE RANGE AND KEY STAGE	5 – 11 yrs (KS 1 & 2)
NUMBER OF SCHOOLS	99 (at design stage)
	55 (at randomisation stage)
NUMBER OF PUPILS	891 (at design stage)
	385 (at randomisation stage)
PRIMARY OUTCOME MEASURE AND SOURCE	Reading skills (DIBELS)
SECONDARY OUTCOME MEASURE AND SOURCE	Reading fluency (DIBELS), Reading self-concept scale, adapted from Chapman and Tunmer,1995)

1. Protocol version history

VERSION	DATE	REASON FOR REVISION
1.0	16.11.2021	N/A

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2. Study rationale and background

Much research that aims to teach children with special educational needs and/or disabilities (SEND) to read has focused on how to recognise words (sight word instruction) without teaching the individual letter/sound components and decoding skills (phonics instruction). Although some approaches to sight word instruction can effectively teach individual target words, research using these approaches demonstrates issues with generalising these skills to be able to develop functional conventional reading skills (references 1,2,3,4,5).This, coupled with a lack of training in an effective and systematic way of teaching reading to children in special schools (6) has led to insufficient teaching effectiveness to enable pupils to access and benefit from phonics-based early reading intervention, and a lack of adaptation of programmes to provide sufficient support for delivering programmes effectively for children with SEND. These, potentially surmountable learning challenges, can be perceived as indicating that pupils with SEND cannot learn conventional early reading skills.

The ability to read is a critical life skill (7). The considerable attainment gap in reading for children with SEND increases across the key stages (8) and translates to poorer post-secondary outcomes related to employment, housing, and social engagement for people with Intellectual Disabilities (ID) (9). As such there is a compelling need for research into the development and evaluation of evidence-based methods that target literacy skills, that can be delivered in schools effectively, and result in improved outcomes.

Recent evidence indicates that explicit, systematic, and intensive instruction in the early primary years for children considered 'at-risk' of reading difficulties, can have significant and sustained effects on reading skills (10). Further, increasing evidence indicates many children with an ID can benefit from phonics-based instruction (11,12,13). The ability to decode (learning correspondences between written and spoken sounds and being able to read these fluently at both a word and sentence level) is an essential component to becoming a proficient reader. As outlined in the widely supported conceptual framework proposed as the Simple View of Reading (14), decoding alone is not sufficient for proficient reading (i.e., understanding what is being read), but decoding skills are an essential element of early reading instruction to enable future proficient reading. Considerable evidence for early phonics instruction also supports this notion.

Headsprout® Early Reading (HER®) is a computer-based, targeted reading programme that has been designed to teach beginning readers skills and strategies using phonics instruction. It includes instruction in phonemic awareness, print awareness, phonics, sounding out, segmenting, and blending, and reading with comprehension (this is consistent with recommendations from the Rose reviews (15) and the EEF SEND guidance report (16)) delivered in 80 episodes. HER® utilises highly effective instructional principles (employed in Direct Instruction; 17,18), including teaching consistent elements before exceptions, basic strategies to mastery, and easy skills prior to more difficult skills. HER® begins with highly stable phonetic elements: the first 33 elements introduced are regular in >85% of the words in which they appear (e.g., s, ee, an, ish, out, ing, old). Fluency practice then allows for mastery of decoding strategies before introducing less stable elements (e.g., k,oo, ay, ow).. HER® also employs sophisticated adaptive learning technology—instruction adapts to individual responses, providing additional instruction or practice, and high levels of response and feedback.

HER® was developed, and has mostly been tested, in groups of children in mainstream schools (aged 4-7) (19). In addition to the formative evaluations conducted by the programme developers, randomised studies evaluating HER® with children aged 4-7 years in mainstream schools (19,37,38) found those receiving HER® demonstrated greater improvements in reading than those not receiving the intervention. Where available, effect sizes indicated medium and large effects across most measures of reading accuracy and word recognition in these studies. For example, in one study, Cohen's d effect sizes ranged from 0.34 to 1.67, with the majority of the effect sizes being close to or above 1 (19).
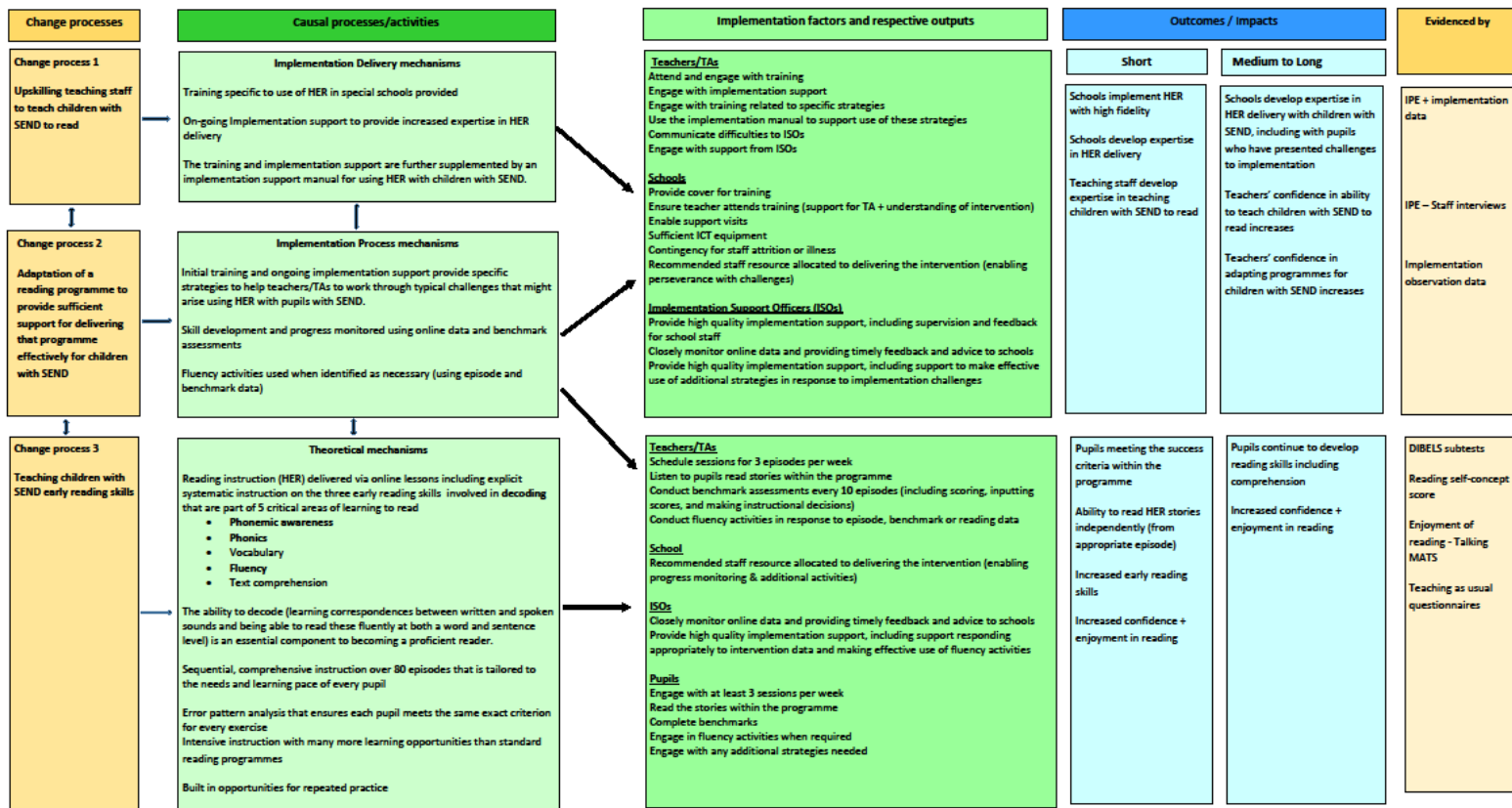
Recently, the programme has been delivered with children with SEND (aged 5-19) and shown similar results - it is also possible to teach early reading skills to children with SEND (21,22). A recent feasibility and pilot research employing a pre-test post-test group design with 26 participants (6) half of which were randomised into receive HER and half did not, researchers explored and trialled important aspects of a Randomised Control Trial (RCT) evaluation to inform a full-scale RCT with children with ID in special schools in the UK. In addition to informing the design of a future study (e.g., 85% retention, longer intervention period, effective training and support), there was also a significant difference between reading outcomes for those in the HER® group compared with 'education as usual', with large effect sizes for reading accuracy and increases in reading age in favour of the HER® group Although this is a positive indication of potential effects of the programme, the main focus of this small scale feasibility and pilot research was to inform a future RCT.

Another study (20) randomly assigned 55 pupils attending a single school for children with severe intellectual and developmental disability to either an HER® group as supplementary instruction, or a waitlist control. Phoneme Segmentation Fluency scores at follow-up were 1.82 times higher in the Intervention group (p = .012) in comparison to the Reading-as-Usual group. Nonsense Word Fluency scores at follow-up were 2.27 times higher in the Intervention group (p =.006) when compared to the Reading-as-Usual group.

In the above studies with children with SEND, HER® was either delivered or supported by a team of trained researchers and included additional support strategies specifically targeting the additional needs of children with SEND. These strategies have been manualised into an accompanying support manual for teaching staff supporting children using HER®. Having shown that it is possible to teach children with SEND early reading skills in small pilot studies, Headsprout Early Reading® in Special Schools (HERiSS) aims to evaluate whether it is possible to deliver HER® at a larger scale by teachers and teaching assistants.

HERiSS Logic Model (Working Document)

Context (Problem): There is a lack of training in an effective and systematic way of teaching reading to children in special schools. This has led to insufficient teaching effectiveness to enable pupils to access and benefit from phonics-based early reading intervention and a lack of adaptation of programmes to provide sufficient support for delivering programmes effectively for children with SEND.
These potentially surmountable learning challenges can be perceived as indicating that pupils with SEND cannot learn conventional early reading skills.

Change processes	Causal processes/activities	Implementation factors and respective outputs	Outcomes / Impacts		Evidenced by

Change process 1

Upskilling teaching staff to teach children with SEND to read

Implementation Delivery mechanisms

Training specific to use of HER in special schools provided

On-going Implementation support to provide increased expertise in HER delivery

The training and implementation support are further supplemented by an implementation support manual for using HER with children with SEND.

Teachers/TAs
Attend and engage with training
Engage with implementation support
Engage with training related to specific strategies
Use the implementation manual to support use of these strategies
Communicate difficulties to ISOs
Engage with support from ISOs

Schools
Provide cover for training
Ensure teacher attends training (support for TA + understanding of intervention)
Enable support visits
Sufficient ICT equipment
Contingency for staff attrition or illness
Recommended staff resource allocated to delivering the intervention (enabling perseverance with challenges)

Implementation Support Officers (ISOs)
Provide high quality implementation support, including supervision and feedback for school staff
Closely monitor online data and providing timely feedback and advice to schools
Provide high quality implementation support, including support to make effective use of additional strategies in response to implementation challenges

Short

Schools implement HER with high fidelity

Schools develop expertise in HER delivery

Teaching staff develop expertise in teaching children with SEND to read

Medium to Long

Schools develop expertise in HER delivery with children with SEND, including with pupils who have presented challenges to implementation

Teachers' confidence in ability to teach children with SEND to read increases

Teachers' confidence in adapting programmes for children with SEND increases

IPE + implementation data

IPE – Staff interviews

Implementation observation data

Change process 2

Adaptation of a reading programme to provide sufficient support for delivering that programme effectively for children with SEND

Implementation Process mechanisms

Initial training and ongoing implementation support provide specific strategies to help teachers/TAs to work through typical challenges that might arise using HER with pupils with SEND.

Skill development and progress monitored using online data and benchmark assessments

Fluency activities used when identified as necessary (using episode and benchmark data)

Change process 3

Teaching children with SEND early reading skills

Theoretical mechanisms

Reading instruction (HER) delivered via online lessons including explicit systematic instruction on the three early reading skills involved in decoding that are part of 5 critical areas of learning to read
- Phonemic awareness
- Phonics
- Vocabulary
- Fluency
- Text comprehension

The ability to decode (learning correspondences between written and spoken sounds and being able to read these fluently at both a word and sentence level) is an essential component to becoming a proficient reader.

Sequential, comprehensive instruction over 80 episodes that is tailored to the needs and learning pace of every pupil

Error pattern analysis that ensures each pupil meets the same exact criterion for every exercise
Intensive instruction with many more learning opportunities than standard reading programmes

Built in opportunities for repeated practice

Teachers/TAs
Schedule sessions for 3 episodes per week
Listen to pupils read stories within the programme
Conduct benchmark assessments every 10 episodes (including scoring, inputting scores, and making instructional decisions)
Conduct fluency activities in response to episode, benchmark or reading data

School
Recommended staff resource allocated to delivering the intervention (enabling progress monitoring & additional activities)

ISOs
Closely monitor online data and providing timely feedback and advice to schools
Provide high quality implementation support, including support responding appropriately to intervention data and making effective use of fluency activities

Pupils
Engage with at least 3 sessions per week
Read the stories within the programme
Complete benchmarks
Engage in fluency activities when required
Engage with any additional strategies needed

Pupils meeting the success criteria within the programme

Ability to read HER stories independently (from appropriate episode)

Increased early reading skills

Increased confidence + enjoyment in reading

Pupils continue to develop reading skills including comprehension

Increased confidence + enjoyment in reading

DIBELS subtests

Reading self-concept score

Enjoyment of reading - Talking MATS

Teaching as usual questionnaires

Contextual factors:

Ability of schools to provide the infrastructure and resources necessary to support implementation.
School characteristics: school/class size, setting of HER® within schools, timetabling of HER®/Teaching Assistant time, IT support and availability, ease of intervention manual use, selection of Teaching Assistants.
Motivation of teachers/TAs to deliver the intervention.
Pupil characteristics: prior reading skill, receipt of free school meals, type of primary need, and whether English is their first language.

Key moderator: Receipt of free school meals

Using a mixed methods approach (collecting quantitative and qualitative data as outlined below) this study aims to test the effectiveness of HER® in special schools for pupils aged between 5 and 11, Key Stages 1 & 2 (KS1 & KS2) who are lacking in prior reading skills, delivered by teachers and Teaching Assistants (TAs). Bangor University will be recruiting participants and delivering the programme and the University of Warwick is responsible for its evaluation. Bangor University will recruit 60 special schools across England. Schools will be randomly assigned (see Randomisation below) to either an intervention or teaching as usual group. The evaluation team will collect pre- and post-test data from all pupils, which measure their reading skills and their reading self-concept. The evaluation will include speaking to teachers and pupils about their experiences of using HER® and ask pupils about their feelings about reading both before and after HER®.

This will be one of the first large-scale cluster RCTs to explore the effects of phonics instruction on the reading skills of pupils with SEND. This may give us useful quality information about the future use of HER® in special schools. It will also be the first to ask KS1 & KS2 pupils with SEND about their experiences of using HER®, and this will help us to understand how pupils feel about using the programme.

3. Intervention

HERiSS involves evaluating the effectiveness of an intervention using HER® delivered by staff in special schools. The intervention will begin following training in September 2021 and continue through until the end of May 2022. The intervention is aimed at pupils aged between 5 and 11 years in KS1 & KS2 who have been identified by school teaching staff as lacking early reading skills.

The intervention involves three change processes (see attached logic model):

- Upskilling teaching staff to support children with SEND to read using the HER programme
- The adaptation of the HER® programme by providing additional support (an implementation support manual) such that it can be effectively delivered to children with SEND
- Teaching children with SEND early reading skills

There are four key components to the intervention. These include the causal mechanisms (delivery, process and theory) needed to effect change:

1) Training staff (teachers and TAs) to oversee the delivery of HER® to children in their school. Digital training resources will be provided to all schools in the intervention group. These will take staff approximately 3-4 hours to access. Following this, two live online workshops will be conducted to follow up on key aspects of programme delivery. Each of these will be approximately 2 hours. Ad hoc training will be provided to schools where, e.g., identified staff were ill and missed the main training delivery. All schools in the intervention group will be offered a choice of dates for the training to be completed in September 2021. All members of staff involved in the delivery of HER® are expected to engage with the digital training resources and at least one member of staff per school is expected to attend the two webinars. Any staff turnover directly involving the individuals allocated to deliver the programme would receive access to the digital training resources and be given a training

session during a school visit. Schools will not be able to begin to use HER® until they have confirmed that all staff involved in HERiSS have accessed the digital training resources and at least one member of staff has attended the two webinars. The evaluation team will attend at least one session of each of the two webinars provided.

2) The delivery of HER® with between 5 and 15 pupils per school. Based on a combination of small group episode delivery and 1:1 work as required, implementation of HER® with the maximum 15 pupils would require between 10 and 20 hours per week. It is therefore necessary for it to be timetabled accordingly and for two staff members to be allocated to HER® delivery for this study, to enable reliable implementation each week.

HER® involves sequential, comprehensive instruction that is tailored to the needs and learning pace of every pupil. Pupils work through activities in an online programme which adapts instruction in response to their answers. Activities are designed to be engaging and resemble computer games. There are 80 computer-delivered lessons and, depending on individual children and their needs, sessions typically take between 10 and 30 minutes. Stories are available throughout the programme and can be read within the online episodes as well as outside of the Headsprout® sessions (these are available as printable books). Benchmark assessments take place after every 10 episodes and take the form of a story. School staff listen to each child read the story individually and rate the reading. These ratings and other monitoring activities are used to decide if the child needs to work on the additional 1:1 fluency activities.

Reading instruction includes explicit systematic instruction on the three early reading skills involved in decoding that are part of 5 critical areas of learning to read:

- **Phonemic awareness**
- **Phonics**
- Vocabulary
- **Fluency**
- Text comprehension

Following benchmark assessments and based on previous research findings (21, 22) some pupils may require additional 1:1 fluency activities. These fluency activities include specific aims (e.g., 30 words of passage ready correctly in a minute) which increase as the programme progresses to ensure true mastery of the reading skills being taught.

The extent to which this is different to usual practice will vary across schools. Many special schools use reading programmes that include some form of phonics instruction, although very few have had training specific to reading instruction with children with SEND. However, they are unlikely to be using programmes in which the core instruction is delivered via the computer, employing explicit fluency-based instruction in phonics and decoding strategies. They are also unlikely to be using a programme that has been piloted specifically with children with SEND, and which includes support strategies relevant to their pupils.

3) The provision, to all schools in the intervention group, of an implementation support manual specifically designed for using HER® with children with SEND; this will provide additional support for high quality implementation and includes suggestions for additional 1:1 fluency exercises.

4) Ongoing implementation support provided by the Implementation Support Officers (ISOs) via a combination of in-person (when possible) and on-line/telephone support. ISOs have

previous experience providing educational support in SEN contexts, and will receive training in both HER delivery and effective implementation support for HER. They will also be in close contact with the delivery team lead and will receive fortnightly supervision meetings to discuss implementation challenges in their allocated schools (see section 9.1 for details). Support provided by ISOs will include supervision and feedback for school staff, effective use of additional strategies in response to implementation challenges, and the close monitoring of online data providing timely feedback to schools in respect of this.

The support model involves schools receiving fortnightly supervision, including one school visit (when possible) every 4 weeks.

Those schools allocated to the HER® arm will implement HER® across one school year, post randomisation and attendance by at least 3 members of staff at the training (see above).

The intervention assumes the ability of schools to provide the infrastructure and resources necessary to support implementation including timetabling HER®/TA time, IT support and availability, the motivation of teachers/TAs to deliver the intervention, the motivation and ability of the pupils to participate in the intervention. The implementation support is designed to monitor and address issues in relation to these assumptions.

Those schools in the teaching as usual (control) group will continue to offer reading instruction as usual. Control group schools will receive two payments totalling £1000: £250 on completion of pre-test assessments, and £750 on completion of post-test assessments.

All schools will be asked to sign a memorandum of understanding. This outlines the responsibilities of each school and their staff members, whether in the intervention or control group. This aims to ensure that schools in the teaching as usual group do not attempt to buy HER® and implement it themselves during the school year, and that schools in the intervention group allocate the resources and commitment needed for implementation with fidelity. This will be monitored via the teacher questionnaire to be administered both before and after the intervention period.

Table 1: TIDieR

Aspect of TIDieR	Exemplification relating to the evaluation
Brief name	HERiSS
Why: Rationale, theory and/or goal of essential elements of the intervention	Children with SEND have been taught early reading skills in small pilot studies using an on-line reading programme Headsprout (HER)®. HERiSS aims to evaluate whether it is possible to deliver HER® at a larger scale by teachers and teaching assistants.
Who: Recipients of the intervention	Pupils in special schools aged between 5 and 11 years in KS1 & KS2 who have been identified by school teaching staff as lacking early reading skills.
What: Physical or informational materials used in the intervention	Headsprout® Early Reading (HER®) - a computer-based, targeted reading programme. An implementation support manual specifically designed for using HER® with children with SEND

What: Procedures, activities and/or processes used in the intervention	Teacher/TA training in the use of HER® The delivery of HER® 3x per week per pupil Additional activities where needed as set out in the implementation support manual Teacher/TA participation in bi-weekly support sessions (by telephone/video call and in situ where possible 1 x per month) delivered by ISOs.
Who: Intervention providers/implementers	Trained teachers and teaching assistants will be responsible for implementation assisted by Implementation Support Officers provided by the delivery team
How: Mode of delivery	On-line computer programme
Where: Location of the intervention	Special schools in classrooms/computer labs depending on school resources (this has not been specified)
When and how much: Duration and dosage of the intervention	The intervention will begin following training in September 2021 and ISO support will continue through until the end of May 2022. Dosage is defined as the delivery of the intervention 3 x per week per pupil for the duration of the intervention.
Tailoring: Adaptation of the intervention	No adaptations have been made to HER® but the implementation support manual provides additional support for high quality implementation and includes suggestions for additional 1:1 fluency exercises
How well (planned): Strategies to maximise effective implementation	Bi-weekly sessions with ISOs will include supervision and feedback for school staff, effective use of additional strategies in response to implementation challenges, and the close monitoring of online data providing timely feedback to schools in respect of this.

4. Impact evaluation

4.1 Research questions

4.1.1   Primary research question (PRQ)

1)   What is the impact of Headsprout Early Reading® (HER®) on the reading skills of KS1 and KS2 pupils in special schools?

4.1.2   Secondary research questions (SRQ)

2)   What is the impact of HER® on the reading self-concept of pupils (including reading for pleasure/spontaneous reading)?
3)   What is the impact of HER® on the different components of reading fluency (e.g., letter naming fluency, phonemic segmentation fluency, nonsense word fluency, oral reading fluency, and word reading fluency)?

4.1.3   Additional/exploratory research questions

4)   Does the impact of HER® differ with pupils' prior reading skill, age (school year) receipt of free school meals, type of primary need, and whether English is their first language?

Table 1: Trial design

Trial design, including number of arms		Two-arm cluster randomised controlled trial
Unit of randomisation		School
Stratification variables (if applicable)		School size (>=70 pupils vs <70 pupils)
Primary outcome	variable	Primary outcome: Pupils' reading skills
	measure (instrument, scale, source)	A composite score derived from DIBELS® (Pupil testing)
Secondary outcome(s)	variable(s)	Components of reading fluency (e.g., letter naming fluency, phonemic segmentation fluency, nonsense word fluency, word reading fluency, and oral reading fluency.) Pupils' reading self-concept (including reading for pleasure/spontaneous reading)
	measure(s) (instrument, scale, source)	DIBELS® component analysis (Pupil testing) Reading self-concept scale (Pupil questionnaire)
Baseline for primary outcome	variable	Pupils' ability to read (sound out words – not comprehension)
	measure (instrument, scale, source)	A composite score derived from DIBELS®
Baseline for secondary outcome	variable	Pupils' reading self-concept (including reading for pleasure/spontaneous reading) Components of reading fluency (e.g., letter naming fluency, phonemic segmentation fluency, nonsense word fluency, word reading fluency, and oral reading fluency)
	measure (instrument, scale, source)	Reading self-concept scale (Pupil questionnaire) DIBELS® component analysis (Pupil testing)

An efficacy trial will run over one academic year involving KS1 and KS2 pupils in special schools across England. This efficacy trial will be a two-armed cluster RCT (cRCT). Schools will be randomly assigned to either intervention or 'teaching as usual' (control) groups. For the control group, literacy lessons will be conducted as normal. Schools receiving the intervention and associated training will implement HER® with a group of eligible pupils (see *Sample* for eligibility) including access to the delivery team's "implementation manual" and on-going support throughout the intervention as described above. For the schools receiving the intervention, this will replace any phonics instruction that would otherwise be implemented with the participating pupils.

4.3 Randomisation

Prior to randomisation, schools will be asked to sign a Memorandum of Understanding (MOU) (as suggested in the EEF Recruitment and Retention pack). This will include permission to access data gathered by HER®, consent to be randomised and commit to the outcome (treatment or control), allowing time and space for testing and ensuring three staff can attend training and deliver HER® (where appropriate).

Following baseline testing, schools will be allocated to the intervention or control groups (1:1) through a process of minimisation (adaptive stratified sampling). This is an effective procedure for small sample sizes that also ensures that intervention arms are balanced with respect to predefined factors as well as for the number of participants in each group. It will additionally allow researchers to immediately notify participating schools of their allocation, thus facilitating planning and minimising waiting times. Using the software Minim, the minimisation process will individually allocate schools to one of the groups. We anticipate one key balancing factor:

> School size. Based on median value from the DfE (2018) data, we anticipate that larger special schools will have at least 70 pupils and smaller schools fewer than 70 pupils

Minimisation will be completed by a member of the evaluation team who will remain independent from delivery and testing, as recommended in the EEF Randomised Trials in Education document. All members of the testing team will remain blinded to school/pupil allocation throughout the trial. Any incidents of unblinding will be reported to the evaluation team and this will be recorded in the study database and final evaluation report.

4.4 Participants

There are 1033 special schools (between 15 and 301 pupils in size) in England (24). To ensure recruitment of enough pupils per school to make providing HER® viable, all schools in a geographical spread around the Midlands, Central and North England will be invited to complete a screening form. This form will have instructions to contact the delivery team if schools have at least five, and up to fifteen pupils at KS1 and/or KS2 who meet clearly described pupil eligibility criteria:

Pupils who do not have a reading ability beyond the level of HER® and can:
- sit at a computer for up to 10 minutes
- understand and follow one or two-step instructions
- imitate spoken sounds/words
- respond to feedback (praise or correction)
- use some self-initiated speech (in English) (single words to short sentences).

Schools will be provided with a short paragraph of text taken from the programme to determine whether pupils have a sufficiently low level of decoding skills.

4.5 Sample size calculations

Table 2: Sample size calculations (following attrition)

		Design stage		Randomisation stage	
		OVERALL	**FSM**	**Overall**	**FSM**
Minimum Detectable Effect Size (MDES)		0.298	0.327	.412	0.461
Pre-test/ post-test correlations	level 1 (pupil)	0.50	0.50	0.50	0.50
Intracluster correlations (ICCs)	level 2 (class)	0.40	0.40	.40	.40
	level 3 (school)	0.10	0.10	.10	.10
Alpha		0.05	0.05	0.05	0.05
Power		0.8	0.8	0.8	0.8
One-sided or two-sided?		Two-sided	Two-sided	Two-sided	Two-sided
Average cluster size		9	3.89	7	3.02
Number of schools	Intervention	49	49	27	27
	Control	50	50	28	28
	Total	99	99	55	55
Number of pupils	Intervention	441	191	189	82
	Control	450	194	196	85
	Total	891	385	385	167

*based on previous data showing that around 43% of FSM pupils in state-funded special schools (see https://explore-education-statistics.service.gov.uk/find-statistics/school-pupils-and-their-characteristics).

Working on a conservative we estimated that 15% of all pupils in a special school may be eligible for HER®, and so we estimated that we would be able to recruit between 5 and 15 primary age pupils from most special schools in selected regions in England. We anticipated that this number of pupils will be manageable for two staff (a trained teacher and Teaching Assistant (TAs)) per school delivering HER®.

The trial was originally designed with the aim to recruit 110 schools and randomise 99 (assuming 10% attrition) to detect a minimum detectable effect size of 0.298. However, the recruitment was heavily disrupted by school closures and despite extending recruitment by one year, the delivery team was experiencing difficulties with recruitment. As such, we

redesigned the project with the aim to randomise 60 schools (30 schools in each study arm). Calculations are based on 80% power, a (two-sided) significance level of 5%, with (following pupil-level attrition, *see below*) an average of 2.33 pupils within each class, and an average of 3 classes within each school at follow-up. Although this is a relative unknown in the case of special schools, we have cautiously accounted for an intracluster correlation coefficient (ICC) as high as .40 at the class level and .10 at the school level, in accordance with guidance (25,26). We have allowed for an estimated correlation of pre and post-intervention scores (both on the same DIBELS® composite test) on the outcome of .5, representing a strong correlation between the two time-points.

The power calculation results in a minimum detectable effect size of .416.

We have allowed for a 10% attrition rate for schools (for both groups), and one pupil per school lost to attrition (11.1% pupil level attrition from average of 8 pupils initially [slightly lower than the originally expected 10] recruited per <u>retained</u> school) in retained schools across the trial. Our drop-out rate is considered as a somewhat conservative estimate, as whilst both lower and higher rates of attrition have been observed in extant studies of the HER® intervention (28, 29) this is a relative unknown with respect to large-scale studies in a special school setting. We have prepared the above sample size calculations and the remainder of this protocol under the assumption that 60 schools will be recruited (with 54 schools retained) and 8 pupils recruited within each school (with an average of 7 pupils retained) to achieve a sample of 378 pupils (after attrition at both the school and pupil level) and have budgeted as such. Power analyses were calculated using the PowerUp! Excel tools designed by Ding and Maynard (2013) (30).

4.6 Outcome measures

4.6.1   Baseline

Baseline measures are:
- The Dynamic Indicators of Basic Early Literacy Skills® 8th edition (DIBELS®)
- A reading self-concept questionnaire (adapted from The Reading Self-concept Scale; Chapman and Tunmer, 1995) (31)

All baseline assessments will be conducted on-line by a team of research assistants trained to use each measure and who have also received training in working with children with SEND. Pupils' characteristics, such as school year, first language, receipt of school meals, and primary need will also be collected at baseline from participating schools to inform the exploratory subgroup analyses.

4.6.1.1 Reading skills

The DIBELS® is a short assessment, taking approximately 20-30 minutes to administer per pupil by a trained individual. The Year 2 version of the DIBELS® with the Oral Reading Fluency Component will be used. It assesses fluency in five core components: Letter Naming, Phonemic Segmentation, Nonsense Word, Word Reading, Oral Reading. The DIBELS® provides data on the number of correct responses per minute to assess the above skills, and as such it can be used to

measure improvement in each of the core components. The Early Childhood Research Institute on Measuring Growth and Development (ECRI-MGD) examined reliability and validity of the DIBELS® in a four-year, longitudinal research study and found that all DIBELS® measures displayed adequate reliability (23). The DIBELS® testing and scoring materials are widely available and free to use, was used in HER® pilot studies in UK special schools (19, 22) and does not require piloting.

The DIBELS® is an appropriate assessment as it tests the outcomes (increased early reading skills and functional reading skills) highlighted in the HERiSS Logic Model (Phonemic awareness, Phonics, and Fluency) and avoids likely limitations of standardised score reading tests with this population.

The evaluation team will be using an adapted version of the DIBELS® to enable the assessment to be conducted online. This has been necessary because of UK government guidance in respect of the COVID-19 pandemic. In the adapted version the DIBELS® pupil assessment materials have been put onto a PowerPoint presentation replicating the order of letters/words and the fonts of the original materials. The key difference is that letters/words are presented individually (i.e. slide by slide) rather than on a whole page as is the case with materials used face-to-face. The reason for this is that in face-to-face delivery, the assessor points to the letters/words one by one as the pupils progress through the testing materials. This is not possible remotely. The materials for on-line delivery were developed and piloted by a team at the University of Warwick for another HER® study which is currently being conducted. To check the suitability for delivery of the materials in a school setting the materials were further piloted with four pupils who met the eligibility criteria for HERiSS at a special school in London.

4.6.1.2 Reading self-concept

A brief (less than 5 minutes) survey of reading self-concept will be undertaken with pupils pre and post-intervention. As no such measure suitable for children in special schools currently exists, an adapted version of an existing survey (The Reading Self-concept Scale; Chapman and Tunmer, 1995) (31) to include scales with adjusted response formats (e.g., thumbs up/thumbs down) and suitable for delivery on-line will be used. The self-concept subscale includes 6 items across three categories: competence, attitude and difficulty. This adapted version has been piloted in a special school in London and is appended to the protocol.

4.6.2 Primary outcome

The composite score of DIBELS® will be used as the primary outcome to gather data on pupils' reading skills. It will be used to answer the primary research question **1** and partly answer secondary research questions 3 and 4. The DIBELS® includes several versions of each of the component measures to be used in case of any interruptions during initial testing e.g., fire alarms) and for post data collection purposes.

4.6.3 Secondary outcomes

The reading self-concept measure will be repeated post-intervention and used as a secondary outcome measure to in part answer secondary research question **2**. Baseline and post intervention data collection will be one year apart. The measure is short and asks questions about a child's feelings about and attitudes towards reading. There are no right answers, and the risk of testing effects is low.

All DIBELS® components will be repeated post-intervention and used as secondary outcome measures to address secondary research question **3** and part answer question **4.**

All post-intervention assessments will be conducted on-line by a team of research assistants, blind to the group allocation, trained to use each measure and who have also received training in working with children with SEND.

4.7. Compliance

Compliance is defined as:

1. All Teachers/TA's supporting pupils through HERiSS have been through the digital training (this item will be scored dichotomously 'Yes/No')
2. At least one member of staff attending the two webinars (this item will be scored dichotomously 'Yes/No')
3. At least 2 trained members of staff overseeing implementation to the end of the academic year (this item will be scored dichotomously 'Yes/No')
4. Schools engaging with ISO provided fortnightly supervision (attending at least 70% of scheduled sessions) and with monthly ISO visits in schools (attending 70% scheduled sessions) (this item will be dichotomously scored, 'Yes' if 70% of supervision were held and 70% of ISO visits in schools were attended, 'No' otherwise)
5. Teachers following recommendations from ISO sessions including using the activities outlined in the HER® manual (measured using a 4-point rating completed by ISOs following each visit). (this item will be turned into a dichotomous measure with a 4 (used most of the time) as 'Yes' and 1-3 (no evidence, rarely used, sometime used) being 'No'.
6. Time-tabling 3 HER® sessions per pupil per week[1] (this item will be scored dichotomously scored 'Yes'/'No'.

The delivery team (ISOs) under supervision from the team from Bangor) will complete a brief (one-side) compliance proforma during each of their monthly implementation support visits, gathering data including: if the visit took place as planned, staff present, engagement with digital resources (on-going), implementation challenges, and whether implementation manual adaptations are used. These data will be analysed descriptively and used to partly answer SRQ 5 and 6.

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[1] The HER® team recommends 3 sessions per week

4.8. Analysis

An intention-to-treat (ITT) approach will be used (including all randomised schools and pupils in the analysis), accounting for clustering at the school and classroom levels, specifying random intercepts. We anticipate using general linear mixed models, based on the distribution of the primary outcome variable, composite score, given that DIBELS® test produces continuous outcome (cf. 21). ICCs (at both the classroom and school level) will be calculated for the null model (i.e. that without covariates) at both pre-test and post-test. The primary analysis will examine mean follow-up DIBELS® composite scores, adjusting for the respective baseline measure; and the prognostic factors (within the randomisation) of school size, with the covariate of interest specified as a dichotomous treatment/control variable. This adjusted mean difference (and the 95% confidence interval) will be examined to compare the intervention and control groups. The effect size will likely be calculated using the standardised mean differences (and accompanying 95% confidence intervals to account for uncertainty in the estimates)) for continuous outcome and reported as Hedge's g.. Secondary outcomes will be analysed using the appropriate generalised linear mixed models with relation to the nature of the outcome variable (as again, all DIBELS® outcomes are count outcomes, although the reading self-concept measure is linear). In the case of the self-concept secondary outcome, effect sizes will be calculated using Hedges' g; with the difference in means between the intervention and control groups in the numerator, divided by the pooled unconditional variance of these two groups in the denominator. All other outcome measures will report expected counts or rate ratios as the effect size of interest.

Table 3: Compliance definitions for compliance analyses

Compliance items	Full	Partial (a)	Partial (b)
1		2 out of 3	
2			
3	6 out of 6		4 out of 5
4		1 out of 2	
5			
6		✓	✗

To ascertain the influence of non-compliance on the predictions made by the ITT, an instrumental variable approach will be utilised. Specifying two binary compliance indicators, full compliance and partial compliance, defined as exceeding a proportion of the six binary response questions for compliance. A separate instrumental variables analysis will be conducted for each compliance scenario to investigate the influence of full compliance and partial compliance (see Table 3). As recommended by the EEF, a Two Stage Least Square approach will be used to estimate the model and Huber-White standard errors reported which are robust to clustering. The R packages 'ivpack' and 'ivreg' will be used to implement the two-stage instrumental variable analysis.

The justification of using two scenarios for partial compliance is follows:

Compliance measure 6 is the only measure that is HER® specific and recommended by the Headsprout team. Compliance measures 1 to 3 relate to training and 4 and 5 relate to ISO support and the additional strategies (HERiSS specific) that are a part of the HERiSS intervention.

Partial compliance for scenario a includes measure 6 and at least one from each of the training and additional support measures (to a total of 4).

Partial compliance for scenario b includes 4 out of 5 of measures 1-5. This scenario is included as compliance measure 6 is not entirely within the control of schools - 3 sessions per week per pupil may be timetabled but schools cannot guarantee that pupils will be present/engage in the timetabled session on a particular day.

Robustness checks will add a number of additional covariates (namely pupils' school, type of primary need, EAL, and FSM) to the model.

To assess the balance of the intervention and control groups; all the aforementioned covariates will be compared across the two groups, as specified in a cross-tabulation; with 2x2 chi-square analyses utilised to test for statistically significant differences; with the exception of the continuous variable pupil age, in which case means, standard deviations will be specified alongside an independent samples t-test. Differences in primary and secondary outcome scores at baseline will be detailed as effect sizes (30).

Subgroup analyses will first analyse the impact of the intervention on the FSM sub-group (alone), for both primary and secondary outcomes, to ascertain the size of treatment effects for FSM pupils. A further subgroup analysis will analyse the interaction of FSM and the treatment effect on the primary and secondary outcomes; to examine whether the treatment effect is conditional on FSM eligibility.

With respect to missing data, if over 5% of cases are missing, a generalised linear mixed model will be run, specifying missingness as the outcome variable. It is plausible that data may be missing at random based on type of primary need, EAL, and baseline pupil reading ability i.e. DIBELS® composite score; and therefore, these variables will be used as covariates in the prediction of missingness. Should data be found to be missing at random, then a multiple imputation model will be run including those covariates found to be predictive of missingness. Sensitivity analysis will compare the imputed model to the ITT analysis.

To ascertain the influence of non-compliance on the predictions made by the ITT, an instrumental variable approach will be utilised, specifying group allocation as the instrumental variable through instrumental variables regression (two-stage least squares regression) (see 4.7), defined at the school level. As recommended by the EEF, a Two Stage Least Square approach will be used to estimate the model.

4.9. Longitudinal follow-ups

Due to the low numbers of pupils in special schools who are typically able to take part in standardised reading tests at the end of KS2, it is not anticipated that suitable data will be available for any longitudinal follow-up of our analyses. Therefore, no follow-up analyses are planned.

5. Implementation and process evaluation

5.1 Research questions

5)   How well was HER® implemented? Did schools comply with the intervention as defined in 4.7 (above)?

6)   What are the barriers and facilitators for good implementation? (e.g., school/class size, setting of HER® within schools, timetabling of HER®/Teaching Assistant time, IT support and availability, ease of intervention manual use, selection of Teaching Assistants)

7)   Can HER® be delivered to KS1 and KS2 pupils in special schools with high fidelity, and what is the usual dosage?
   a. How many HER® episodes do pupils access/complete per week, and throughout the intervention?
   b. How are the adaptations in the implementation manual used for pupils undertaking HER®?
   c. What is the relationship between fidelity to HER® and the impact of HER® on pupils' reading skills?

8)   To inform future research in special schools
   a. what are the most effective approaches   for recruiting special schools and pupils to participate in an RCT?
   b. what are the retention rates of schools and pupils? What are the reasons for drop-out of schools/pupils?

9)   How does HER® differ from reading teaching as usual?

10)   What are pupils' and teachers' experience of, attitudes towards, and perceptions of the HER® programme, as well as its impact?

5.2 Research methods and analysis

Implementation (both delivery and process mechanisms) is the critical aspect of this study. Evidence suggests that it is possible to teach pupils with SEND the early reading skills necessary to become proficient at reading. Whether that can be delivered at scale and via school staff and within the weekly curriculum is the underlying question in the HERiSS logic model.

Using a mixed-method approach the implementation and process evaluation will include data about the fidelity to the intervention, perceptions of pupils and teachers, an understanding of teaching as usual and will advise on implications and considerations for a future effectiveness trial.

5.2.1 Implementation fidelity and dosage

Fidelity and dosage data will be gathered directly from HER®, (HER® software allows for an analysis at pupil level) including episode accuracy scores, frequency of episodes, use of benchmarks, and benchmark scores.

High fidelity is defined as

1. Evidence of at least 80% fidelity for the data collected about both:
    a. Repeating episodes when required, and
    b. Benchmark assessments were completed and acted on appropriately (with either a continuation, repetition of an episode, or a fluency activity)

Dosage is defined as completing 3 sessions per week per pupil.

5.2.2 Interviews with pupils who have received HER®

Interviews will be conducted with at least 15 pupils from at least 10 schools in the intervention group to establish what they liked and disliked about HER®. A sampling framework will be used to sample pupils with a range of ages, primary needs, and initial reading scores. A communication tool developed for use with children with limited communication skills, *Talking Mats*, will be used to ask pupils about whether they liked/disliked elements of HER® and how they feel about reading including both confidence and enjoyment. The interviews will be conducted by Dr Flynn who has experience of using Talking Mats. It may be necessary for a member of school staff to be present in these Talking Mats interviews to support pupils, but the interviewer will be mindful to ensure that this does not lead to contamination of the data. These data will be used to partly answer SRQ **10**.

We will analyse these data using mixed-methods, by quantitatively coding the Talking Mats responses into a three-point scale (e.g., like, unsure, dislike) and using any verbal and non-verbal (e.g., speed of making choices, hesitation, changing responses) responses to qualitatively contextualise the Talking Mats responses.

5.2.3 Pre- and post-intervention teacher survey

A pre- and post-intervention survey will be sent to teachers in all schools (intervention and control) to establish what teaching as usual is for literacy before and during the intervention period (including standard literacy activities, school IT facilities and expertise, usual use of IT for teaching pupils). These data will be quantitatively described which will be used to partly answer SRQ **9**.

5.2.4 Interviews with teachers

To understand the mechanisms that might contribute to/explain the outcomes of the efficacy trial, semi-structured telephone interviews with 12-15 teachers from at least 10 schools in the intervention group will be used to gather in-depth data about topics including attitudes/perceptions of delivering HER®, barriers and facilitators to delivering HER®, perceptions of the training and subsequent support provided (by ISOs and by school leadership), the usefulness of the HER® manual and confidence in teaching children with SEND to read and more generally. Whilst all schools will be invited to take part in the interviews the delivery team will check that the sample includes schools that have experienced both face to face and remote ISO visits. These will be conducted by Dr Denne. A structured qualitative approach (e.g., Framework Analysis) will be used to analyse these data to partly answer SRQ **6** and **10**.

5.2.5 Interviews with ISOs

ISO input is a key component of implementation compliance. Information in respect of compliance will be captured by ISOs in monthly visits (face to face or remote) but will also be explored using semi-structured telephone interviews which will be used to gather in-depth data about topics including ISO perceptions of the facilitators and barriers to implementation in special school settings, attitudes/perceptions of schools' engagement with additional support provided (the HER® manual and ISO recommendations) and support provided by school leadership. All ISOs will be invited to take part in the interviews. These will be conducted by Dr Denne. A structured qualitative approach (e.g., Framework Analysis) will be used to analyse these data to partly answer SRQ 5 and 6.

5.2.5 School and pupil recruitment and retention data

Working with the delivery team, who will be recruiting schools to the trial, a database of how many schools were approached, how many were recruited, school and pupil retention figures at all stages, and reasons for attrition (if given) will be maintained. The recruitment and retention log will follow guidelines in the EEF Recruitment pack. These data will be analysed descriptively and used to partly answer SRQ **8**.

Table 3: IPE methods overview

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation/ logic model relevance
Quantitative	Direct from HER®	Data at pupil level (up to480)	Descriptive	SRQ 7	Dosage and fidelity critical to success of underpinning theoretical mechanisms
Quantitative	Direct observation (ISO visits in schools where possible)	HER® sessions (all pupils)	Descriptive	SRQ 5, 6 and 7	Dosage and fidelity critical to success of underpinning theoretical mechanisms
Qualitative (survey)	Survey	All schools (to be completed by one teacher at each school)	Descriptive	SRQ 9	Key to understanding if the intervention has resulted in the change processes identified
Qualitative (Interview)	Interview (Talking Mats)	At least 15 pupils across 12 schools	Mixed method	SRQ 10	Pupil's perceptions are a key component of change processes 3 and associated outputs
Qualitative (Interview)	Interview (Semi-structured)	12-15 teachers across10 schools	Structured qualitative approach	SRQ 6 and 10	Teacher's perceptions are a key component of change processes 1 and 2

Qualitative (Interview)	Interview (Semi-structured)	4 ISOs	Structured qualitative approach	SRQ 5 and 6	ISO perceptions & experiences are a key component of change processes 1 and 2
Quantitative	Direct observation (where possible)	Data collected by Delivery team responsible for recruitment & retention	Descriptive	SRQ 5,7 and 8	Useful information for future studies on a larger scale

6. Cost evaluation

A full economic analysis of the intervention has not been included in this study. However, the evaluation will collect the following cost data to enable schools to decide whether to invest in the programme

1) Personnel for the implementation of the programme. This data will be collected by the delivery team, primarily through ISO visits – the number of staff members involved at each school, the numbers of HER® sessions delivered per school and the staff time involved, the time the number of person days per school delivered by ISOs.

2) Personnel during training for the implementation of the programme. This data will be collected by the delivery team at the point of delivery and will include the length of time spent per school in training, the number of school staff involved in training, the administrative time spent to set up each training session and the time involved per school on the part of each trainer.

3) Programme costs. This data will be collected by the delivery team and will include the costs of travel for each ISO visit per school and the costs of telephone support for each school over the duration of the intervention.

4) Facilities, equipment and materials. This data will be collected by the delivery team and will include the cost of the HER® licence per school, the cost of the provision of the HER® support manual per school, and the costs to schools of reproducing support materials when needed (collected during ISO visits).

5) Other programme inputs. The ISOs will keep note of any other costs arising as a result of the delivery of the intervention.

7. Ethics and registration

The BERA ethical guidelines (2018) and the University of Warwick's strict research Code of Practice will be adhered to at all times. Ethical approval was obtained from the Humanities & Social Sciences Research Ethics Committee (HSSREC) at the University of Warwick on . Wednesday, 11 December 2019 ref: HSSREC 37/19-20.

The trial is registered at ISRCTN, registration number ISRCTN46208295.

The delivery and evaluation teams will abide by the data protection principles set out in the General Data Protection Regulation (GDPR, 2018). Before randomisation, an information sheet with an opt-in consent form will be sent to parents of pupils selected by schools to participate. After receiving the information sheet, parents will be able to consent to their child participating in testing for the evaluation and having their data included in the analyses. The delivery team will work with schools to encourage parents to return consent forms in a timely manner. In the information sheet, parents will be encouraged to contact the evaluation team with any questions about testing. Parents will have the option to withdraw their child's data at any point during the trial, and this will be made clear in the information sheet.

Both the delivery and evaluation teams will have access to the participant database (schools and pupil data), which will be encrypted and held securely on departmental servers. Only the evaluation team will have access to the trial database (pre and post intervention data collected). Participant information will be treated confidentially, and all participants will be informed of their right to withdraw from testing and/or inclusion of their data in the evaluation at any stage. No person or school will be identifiable in the reporting of this trial.

8. Data protection

For the purposes of conducting the evaluation to assess the impact of HER®, Bangor University and the University of Warwick will become data controllers and processor of personal data of pupils (e.g., pupil names, data from the HER® programme) obtained from schools.

The University of Warwick will be a data controller for all data collected as part of the evaluation.

At the end of the trial, the University of Warwick will share the data with EEF's data archive[2] processor through secure data portals, where the data will be encrypted and saved to secure servers for further analysis. At that point EEF will become the data controller and the University of Warwick will no longer have any responsibility for the data.

The legal basis for processing personal data for this project is informed consent. The delivery and evaluation teams will securely delete all personal data within six months of the project finishing. The University of Warwick will retain the data from this project until Spring 2031 to permit further analysis.

All schools' data will be treated with the strictest confidence and will be transferred securely and saved in secure locations only accessible by the delivery and evaluation teams in line with GDPR and the Data Protection Act 2018. Neither individual participant names nor the names of participating schools will appear in any report arising from this project.

The data will be shared with the Department for Education (DfE), the EEF, EEF's archive manager, the Office for National Statistics and potentially other research teams, subject to the appropriate approvals. Data will be matched with the National Pupil Database (NPD) for analysis after the

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[2] likely within the Secure Research Service provided by the Office for National Statistics

trial. Further matching to the NPD other administrative data may take place during subsequent research to better understand the impact of the project.

Education Endowment Foundation will act as the data controller for the archive, which is managed on their behalf by FFT and held in the ONS Secure Research Service. The archive does not contain any information that can be used to directly identify an individual pupil. For example, the archive does not include names, addresses or dates of birth. The archive does contain the Pupil Matching Reference (PMR) which is an identifier used by the DfE to enable the linking of archive data to the NPD.

9. Personnel

9.1 Delivery Team

Dr Emily Roberts-Tyler, Principal Investigator, School of Educational Sciences, Bangor University, leading school and staff recruitment, training of schools, and provision of implementation support and supervision of ISOs during the trial.

Professor Carl Hughes, Co-investigator, School of Educational Sciences, Bangor University, part of the advisory group supporting school and staff recruitment, and implementation support during the trial.

Dr Corinna Grindle, Co-investigator, part of the advisory group supporting school and staff recruitment, and implementation support during the trial, and part of the team training Headsprout schools, The Centre for Behaviour Solutions.

Dr Claire McDowell, Co-investigator, part of the advisory group supporting school and staff recruitment, and implementation support during the trial, and part of the team training Headsprout schools, Ulster University.

Nationwide Team of Implementation Support Officers. The ISOs will be employed by Bangor University, and trained and supervised by the delivery team lead and advisory group. ISOs will have previous experience providing educational support in SEN contexts, and will receive training in both HER delivery and effective implementation support for HER. They will also be in close contact with the delivery team lead and will receive fortnightly supervision meetings to discuss implementation challenges in their allocated schools.

9.2 Evaluation Team

Dr Samantha Flynn, Joint Principal Investigator, CEDAR, The University of Warwick

Dr Louise Denne, Joint Principal Investigator, CEDAR, The University of Warwick

Professor Richard P. Hastings, Co-investigator, mentor for Flynn & Denne and lead on RCTs, CEDAR, The University of Warwick.

Dr Paul Thompson, Lead statistician, CEDAR, The University of Warwick

Dr Rebecca Morris, Co-investigator and lead on Education, CES, The University of Warwick

Nationwide team of postgraduate *ad hoc* researchers

10. Risks

Risk	Likelihood	Magnitude of Impact	Mitigation
Fail to recruit enough schools	Low[3] – informal approaches to schools indicate interest in the study	High	The delivery team has a data base of all special schools in the UK. Schools will be contacted directly as well as through existing special school networks such as the NASS. The project is also being advertised on social media and University of Warwick and the EEF websites
Schools do not identify enough pupils that meet eligibility criteria	Medium	Medium	Being very clear with schools what the eligibility criteria is and why they are important prior to them signing up to the project. Schools are asked to ensure they are confident they would have at least 5 pupils meeting these criteria prior to signing up[4].
Schools do not attend training sessions	Low	Medium	The memorandum of understanding which schools are being asked to sign makes clear the importance of attending the training session. The delivery team will work closely with schools to ensure compliance with this requirement. Ad hoc training sessions will be provided to schools where, e.g. identified staff were ill and missed the main training delivery. Schools will not have access to the programme until they have received the training.
Reduced dosage of the programme due to delay in schools accessing the programme	Low	Medium/high	The delivery team will ensure clear communication with schools to ensure staff attend training sessions or provide ad hoc training in a timely manner.
Schools do not implement HER: adherence, dosage, fidelity	Low	Medium/high	The support structure built into the intervention is designed to maximise fidelity – schools will be given an implementation support manual and receive fortnightly supervision from ISO's including one site visit per month (where possible) so the risk is low.

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[3] At the design stage of the project (pre-Covid-19) the anticipated risk was low. The additional pressure on schools during the pandemic has meant that, although interested, some schools have decided not to participate.

[4] Due to the delayed start to the trial is that previously eligible pupils have moved on from KS2 into KS3, and are therefore no longer eligible. In some cases, this has resulted in schools being unable to participate due to insufficient numbers of eligible pupils. Generally speaking, not being able to include KS3 pupils has resulted in some very interested schools not being able to find sufficient numbers of pupils. This aspect of the eligibility criteria might want to be revisited in future trials.

Schools are not retained	Low	High	The memorandum of understanding which schools are being asked to sign make clear the importance of committing to the duration of the study. Fortnightly supervision from ISOs is designed to troubleshoot (including identifying motivation issues on the part of pupils/staff) and identify schools that may be at risk of withdrawing from the study. This means that swift action can be taken to bolster commitment to the trial, tailored to the school's issues. If schools are determined to withdraw, The delivery team will try their best to keep them in the evaluation (i.e., agree that schools withdrawing from the intervention will still facilitate post-testing), wherever possible. The incentive paid to schools in the control group is staggered to encourage retention: The first payment of £250 will be paid following pre-test assessments, and the second payment of £750 will be paid following post-test assessments.
Staff turnover in schools	High – experience in schools suggests that we are highly likely to encounter this	High	Whilst the memorandum of understanding can reiterate the need for schools to allocate teachers/TAs to the study this cannot prevent staff turnover. Schools are being asked to send 3 members of staff to the training to mitigate against this. The purpose of having 3 staff at the training, one being a teacher, is that they would have some understanding between them to allow them to continue delivery. Any staff turnover directly involving the individuals allocated to deliver the programme would receive a training session during a school visit from an ISO. The delivery team would be aware if trained teachers were to leave the school due to the frequent ISO contact
Schools in teaching as usual group access HER®	Low	High	The memorandum of understanding which schools are being asked to sign makes clear the importance of not accessing HER® until the end of the study. This will be emphasised during recruitment. It is possible that in the post testing it will be clear if a school has used HER® (children talk about it). In addition, the TAU survey which will be distributed to schools post intervention is likely to pick up any schools using HER®
Evaluation team unable to conduct baseline and post intervention assessments within the time frame allocated.	Medium	High	A team of ad hoc research assistants will be recruited to maximise the evaluation team's capacity to conduct all necessary assessments within the time frames given. We will monitor recruitment of schools and of ad hoc RAs carefully so that we can recruit sufficient RAs to complete the testing in time.

Risk that post intervention RAs are unblinded to the group allocation	Medium (evidence of info re HER® in classrooms, children discussing it etc)	Medium	Prior to post-testing staff will be asked not to reveal participation to the testers. It is not possible to ask pupils not to talk about the study – any instances of unblinding will be recorded.

11. Timeline

	Team responsible	Date
Updated proposal and budget	Warwick	Sep 19
Develop study materials	Warwick (Bangor)	Aug – March 21
Recruitment	Bangor	Dec 19 – May 2021
Parental consent obtained	Bangor	April 2021 – July 2021
Pupil personal data collected	Bangor	April 2021 – July 2021
School TAU data collected	Warwick	April 2021 – July 2021
Baseline pupil data collection	Warwick	April 2021 – July 2021
Randomisation	Warwick	April 2021 – July 2021
Training resources released and live session	Bangor	Sept 21
Intervention delivery	Bangor	Sept 21 – mid May 22
Post-intervention pupil data collection	Warwick	End of May – mid July 22
Post-intervention qualitative data collection	Warwick	End of May – mid July 22
Data analysis and write up	Warwick	Mid July –Dec 22
EEF report first draft due	Warwick	Nov 22
Final report due	Warwick	Jul 23

12. References

1. Katims, D. S. (2000). Literacy instruction for people with mental retardation: Historical highlights and contemporary analysis. Education and Training in Mental Retardation and Developmental Disabilities, 35, 3-15
2. Browder, D. M., Wakeman, S. Y., Spooner, F., Ahlgrim-Delzell, L., & Algozzine, B. (2006). Research on reading instruction for individuals with significant cognitive disabilities. Exceptional Children, 72, 392–408
3. Joseph, L.M., & Seery, M.E. (2004). Where is the phonics? : A review of the literature on the use of phonetic analysis with students with mental retardation. Remedial and special education, 25, 88-94

4. Dessemontet, R. S., Martinet, C., de Chambrier, A.-F., Martini-Willemin, B.-M. & Audrin, C. (2019) 'A meta-analysis on the effectiveness of phonics instruction for teaching decoding skills to students with intellectual disability.' Educational Research Review, 26, pp. 52–70.

5. Reichow B, Lemons CJ, Maggin DM, Hill DR. Beginning reading interventions for children and adolescents with intellectual disability. Cochrane Database of Systematic Reviews 2019, Issue 12. Art. No.: CD011359. DOI: 10.1002/14651858.CD011359.pub2.

6. Roberts-Tyler, E. J., Hughes, J. C., Hastings, R. P. (2019). Evaluating a computer-based reading programme with children with Intellectual Disabilities: feasibility and pilot research. Journal of Research in Special Educational Needs, https://doi.org/10.1111/1471-3802.12458

7. Marchand-Martella, N. E., Slocum, T. A., & Martella, R. C. (2004). Introduction to direct instruction. London: Pearson Education Inc.

8. DfE, 2018:http://dera.ioe.ac.uk/id/eprint/31668

9. Parkin, Kennedy, Long, Hubble & Powell (2018) Support for people with a learning disability Briefing paper Number: 07058 House of Commons https://researchbriefings.parliament.uk/ResearchBriefing/Summary/SN07058

10. M.D. Coyne, E.J. Kame'enui, D.C. Simmons, B.A. Harn (2004) Beginning reading intervention as inoculation or insulin: First-grade reading performance of strong responders to kindergarten intervention. Journal of Learning Disabilities, 37 (2) pp. 90-104
    http://dx.doi.org/10.1177/00222194040370020101

11. Allor, J.H., Mathes, P.G., Roberts, J.K., Cheatham, J.P. and Champlin, T.M. (2010), Comprehensive reading instruction for students with intellectual disabilities: Findings from the first three years of a longitudinal study. Psychol. Schs., 47: 445-466. https://doi.org/10.1002/pits.20482

12. Bradford, S., Shippen, M. E., Alberto, P., Houchins, D. E., & Flores, M. (2006). Using Systematic Instruction to Teach Decoding Skills to Middle School Students with Moderate Intellectual Disabilities. Education and Training in Developmental Disabilities, 41(4), 333–343. http://psycnet.apa.org/record/2006-21512-002

13. Sermier Dessemontet et al., 2019 The Profiles and Patterns of Progress in Numerical Skills of Elementary School Students with Mild and Moderate Intellectual Disability, International Journal of Disability, Development and Education, DOI: 10.1080/1034912X.2019.1608915

14. Gough, P. B., and Tunmer, W. E. 1986. Decoding, reading, and reading disability.RASE: Remedial and Special Education 7:6–10.

15. Rose, Jim, Department for Children, Schools and Families (DCSF), corp creator. (2009) Identifying and teaching children and young people with dyslexia and literacy difficulties: an independent report.

16. EEF: https://educationendowmentfoundation.org.uk/evidence-summaries/teaching-learning-toolkit/phonics/)

17. Schieffer et al., 2018: DOI: 10.3102/0034654317751919

18. Kinder et al., 2005: https://www.nifdi.org/docman/journal-of-direct-instruction-jodi/volume-5-winter-2005/469

19. Tyler, E.J., Hughes, J.C., Beverley, M. et al. Improving early reading skills for beginning readers using an online programme as supplementary instruction. Eur J Psychol Educ 30, 281–294 (2015). https://doi.org/10.1007/s10212-014-0240

20. Grindle, C., Murray, C., Hastings, R. P., Bailey, T., Forster, H., Taj, S., Hughes, C. J. (in preparation). Headsprout® Early Reading for children with severe intellectual disabilities: A single blind randomized controlled trial.

21. Grindle, C.F., Carl Hughes, J., Saville, M., Huxley, K. and Hastings, R.P. (2013), Teaching Early Reading Skills To Children With Autism Using Mimiosprout Early Reading. Behav. Intervent., 28: 203-224. https://doi.org/10.1002/bin.1364

22. Emily J. Tyler, John C. Hughes, Meadhbh M. Wilson, Michael Beverley, Richard P. Hastings, Bethan M. Williams; Teaching Early Reading Skills to Children with Intellectual and Developmental Disabilities Using Computer-Delivered Instruction: A Pilot Study. Journal of International Special Needs Education 1 March 2015; 18 (1): 1–11. doi: https://doi.org/10.9782/2159-4341-18.1.

23. Good, R.H., Kaminski, R.A., Shinn, M., Bratten, J., Shinn, M., Laimon, D., Smith, S., & Flindt, N. (2004). Technical Adequacy of DIBELS: Results of the Early Childhood Research Institute on measuring growth and development (Technical Report, No. 7). Eugene, OR: University of Oregon

24. DfE, 2018: https://www.gov.uk/government/statistics/special-educational-needs-in-england-january-2018

25. Allen, R., Jerrim, J., Parameshwaran, M., & Thompson, D. (2018). Properties of commercial tests in the EEF database. *EEF Research Paper*,

26. Demack, S. (2019). Properties of commercial tests in the EEF database. EEF Research Paper.

27. Cohen J. (1988). Statistical Power Analysis for the Behavioral Sciences. New York, NY: Routledge Academic

28. Morena, L. (2011). Evaluating the impact of Headsprout on the reading achievement of English language learners (Doctoral dissertation, University of Georgia).

29. Storey, C., McDowell, C., & Leslie, J. C. (2019). Headsprout Early Reading for Specific Literacy Difficulty: A Comparison Study. Journal of Behavioral Education, 1-15.

30. Dong, N., & Maynard, R. (2013). PowerUp!: A tool for calculating minimum detectable effect sizes and minimum required sample sizes for experimental and quasi-experimental design studies. Journal of Research on Educational Effectiveness, 6(1), 24-67.

31. Chapman, J. W., & Tunmer, W. E. (1995). Development of young children's reading self-concepts: An examination of emerging subcomponents and their relationship with reading achievement. Journal of Educational Psychology, 87(1), 154–167. https://doi.org/10.1037/0022-0663.87.1.154

32. Coxe, S. (2018, February). *Effect size measures for nonlinear count regression models.* Poster presented at the ASA Conference of Statistical Practice, Portland, Oregon.

33. Hayes, A. F. (2017). Introduction to mediation, moderation, and conditional process analysis: *A regression-based approach*. Guilford Publications.

34. Huffstetter, M. et al (2010). Effects of a computer-based reading program on the early reading and oral language skills of at-risk preschool children. Journal of Education for Students Placed at Risk, 15, 279– 298.

35. Twyman, J., Layng, J., & Layng, Z. (2011). The likelihood of instructionally beneficial, trivial, or negative results for kindergarten and first grade learners who complete at least half of Headsprout Early Reading. Behavioral Technology Today, 6, 1-13.

Appendix 1: The Dynamic Indicators of Basic Early Literacy Skills® 8th edition (DIBELS®)

PDF
DIBELS 8th G1
Scoring booklet.pdf

Appendix 2: Adapted Reading Self-concept Scale

Adapted Reading Self Concept Scale

Researcher Score Sheet

Instructions:

I'm going to read some things to you. They are all about reading. I want you to tell me if they are what you think about reading (thumbs up) or not what you think about reading (thumbs down).

Item questions

Tick the box that corresponds with the participant's response.

Question	Yes	No
I need help to read * (D)		
I can read words (C)		
Reading is easy (D)		
Reading makes me happy (A)		
I get words wrong when I read* (C)		
I don't like reading (A)*		

TOTAL SCORE: _____