Trial Evaluation Protocol

Glasses in Classes

Evaluator (institution): University of Nottingham

Principal investigator(s): Professor Roisin P. Corcoran

PROJECT TITLE	Glasses in classes: A cluster-randomised controlled trial to evaluate the effects of a school-based intervention to improve academic achievement, visual acuity, and adherence to glasses wear in young children in a disadvantaged multi-ethnic community
DEVELOPER (INSTITUTION)	NHS Bradford Teaching Hospitals Foundation Trust
EVALUATOR (INSTITUTION)	University of Nottingham
PRINCIPAL INVESTIGATOR(S)	Professor Roisin P. Corcoran
PROTOCOL AUTHOR(S)	Professor Roisin P. Corcoran, Dr. Michael Adkins
TRIAL DESIGN	Two-arm cluster randomised controlled trial with random allocation at school level
STUDENT AGE RANGE AND KEY STAGE	Reception (4–5year olds), Early Years Foundation Stage
NUMBER OF SCHOOLS	100
NUMBER OF PUPILS	700
PRIMARY OUTCOME	Reading achievement
SECONDARY OUTCOME	Reading achievement, mathematics achievement, visual acuity

Protocol version history

VERSION	DATE	REASON FOR REVISION
1.2 [*latest*]		
1.1		
1.0 [*original*]		*[leave blank for the original version]*

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Intervention Summary

Template for Intervention Description and Replication (TIDieR): Glasses in Classes (GiC)

- **Why (rationale/theory):** Eyesight development in children occurs within the first 7–8 years of life, with visual acuity (VA) reduction indicating potentially associated conditions including refractive error (glasses required), amblyopia (lazy eye), and/or strabismus (squint) (Daw, 1998). Amblyopia is a developmental disorder of vision where VA is reduced despite wearing the prescribed glasses, early detection and treatment is indicated. Amblyopia is reported to have a prevalence of between 1–4% (Attebo, Mitchell, & Cumming, 1998). The UK National Screening Committee (UK NSC) recommends child visual screening during the first year of school entry, at age 4–5 years (National Screening Committee, 2013), as part of the Child Health Promotion programme (Department of Health, 2009). This is provided by local health services and results are only shared with families. Following vision screening, children confirmed to have reduced VA follow a clinical pathway which includes referral for an ophthalmic examination (cycloplegic refraction and fundus examination) to determine the presence of refractive error (need for glasses) and to rule out eye disease (Public Health England, 2019). The principal treatment for decreased VA generally consists of the wearing of glasses (Stewart, Moseley, Fielder, & Stephens, 2004). However, children who fail to attend follow-up ophthalmic examinations and those who fail to adhere to glasses wear are unlikely to improve their level of VA, affecting their early reading and mathematics achievement. In high poverty communities, prior research suggests a significant number (30%) of young children identified as having a treatable sight deficit either failed to go to an optometrist or fail to wear their prescribed glasses (Bruce et al., 2018a; Corcoran, 2019; Li et al., 2010). Parents have reported school-based interventions are important to support glasses wear in young children, but it is unclear if this would be effective. Research in China and the US have shown provision of glasses to schools is more effective than provision of prescriptions to parents in improving children's vision, and is associated with better educational outcomes (Collins et al., 2016; Glewwe, West, & Lee, 2018; Nie, Pang, Sylvia, Wang, & Rozelle, 2018). Research suggests that the implemented intervention frequently differs from the intervention as designed. It is therefore essential to understand the extent to which school-based interventions are implemented as intended (Corcoran, 2018a; 2018b; Corcoran, Cheung, Kim, & Chen, 2018). The purpose of this study is to examine the impact of a school-based intervention to support glasses wear in young children (share vision screening results with school and provision of additional glasses to be kept in school) on academic achievement, VA, and adherence to glasses wear. Consent to share results of vision screenings with schools may mean schools can more effectively support families through the health pathway. Sharing the vision screening results with schools could also mean that more parents will be encouraged to obtain the glasses prescription and the spare glasses, and improve the adherence of wearing glasses. This could have a positive impact on children's achievement in both reading and mathematics.

- **Who (recipients):** Reception year children will receive vision screening in autumn of 2019. Schools will be randomly assigned to two conditions, either to receive the intervention (treatment) or business-as-usual (control). Children who fail the vision screening in the schools randomly assigned to receive the school-based support will be compared to children who fail the vision screening in control schools.

- **What (materials):** The following is included: Training materials for school staff; campaign materials for families; secure and GDPR compliant systems for recording withdrawals from the project; sharing data and tracking progress on the referral pathway; school-based system to ensure children wear their glasses in school; spare glasses are made available as needed; and an attendant monitoring process for wear.

- **What (procedures):** At the start of the reception year, parents from the treatment and control schools will receive an information letter about the study, with the right to withdraw their children from the study. Children will then receive a vision screening, along with academic pretests. Schools will then be randomly assigned to conditions. Vision screening results will be revealed (Pass/Fail) and letters will be sent to parents with instructions to go to the optician (this applies to both intervention and control groups); if they attend the appointment, they will receive a pair of home glasses. For the intervention group only, vision coordinators will be trained (after pretests are completed). If the parents and children attend the appointment at the opticians, a spare pair of glasses will be sent to the school and will be made available in the classroom. The intervention will run for the academic school year, with teachers ensuring children prescribed glasses wear them, and that their spare pair are available if they attend school without their home pair, as well as working with families to prioritise glasses wear at home. Parents are asked to report to schools if the home glasses are lost or broken and they will be asked to attend the optometrist with their children for the fitting of the replacement glasses. School glasses replacement will be organized by the intervention team, once informed by the school. Number of replacement glasses will be monitored by the developer.

- **Who (implementers):** Distributing information sheets and recording withdrawals will be the responsibility of a designated school 'Vision Coordinator' – this can be a member of SMT or class teachers, TAs, or SENCO. Reception year staff will be responsible for checking and ensuring identified children wear glasses during the school day.

- **How (mode of delivery):** Information sheets and withdrawal forms will be distributed to allow the sharing of prescription data for all reception year children, and all reception children to receive an in-school vision screening. Families of children who fail vision screening will be prompted in writing and in person as needed to attend refractive appointments and obtain glasses for home wear. School staff, using spare glasses if personal pair are not present in the school, will ensure glasses wear in class.

- **Where (setting):** In school (vision screening), in health services settings (Bradford Royal Infirmary – refractive appointment and community optometrists – refractive appointment, dispensing and fitting of all glasses for both home and school use) and in reception year classroom settings (wearing spare glasses).

- **When and how much (duration and dosage):** The intervention will be promoted to parents prior to the beginning of reception year, information sheets and withdrawal forms distributed to allow the sharing of vison screening data sought in September and October of reception year (i.e., by putting forms in book bags and promoting through family contact). Glasses will be ordered from November onwards and the provision of spare glasses to intervention schools will take place by January 2020. For the remainder of the school year children's glasses wear will be monitored via a daily check, likely linked to morning registration.

- **Tailoring (adaptation):** Schools can adapt the process for daily checking that children prescribed glasses wear them to accommodate their method of registration (such as by paper or via electronic means). They may also introduce various approaches to ensuring follow up appointments are met, including accompanying children to hospital or optometrist appointments as appropriate.

Study rationale and background

Eyesight development in children occurs within the first 7–8 years of life, with the presence of reduced VA in young children potentially indicating conditions such as *refractive* error, strabismus, and/or amblyopia (Bruce et al., 2018a; Daw, 1998; Dobson, 1993). There is growing consensus that vision problems may be a potentially treatable component of mathematics and reading difficulty (Collins et al., 2016; Kiely, Crewther, & Crewther, 2001; Granet, 2011; Levine, 1984; Lubkin, 1968; Solan et al., 2004). As part of the Child Health Promotion programme (Committee, 2009), the UK NSC recommends visual screening for children during their first year of school entry, with glasses wear being

the principal treatment recommended for reduced vision. Children who fail to attend follow-up ophthalmic examinations and those who fail to adhere to glasses wear are unlikely to improve their level of VA, affecting their early reading and mathematics (Bruce et al., 2018a).

Prior research suggests that disadvantaged children are more likely to experience higher prevalence of vision problems and less likely to receive the treatment and eyeglasses they need (Bodack, Chung, & Krumholtz, 2010; Collins et al., 2016). The root cause is often misidentified, and pupils are often provided inappropriate interventions, which are both costly and ineffective. Randomised controlled trials in the US and China have demonstrated that the provision of free glasses to children is more effective than prescriptions provision in improving children's vision, and that this could support better academic outcomes, including reading and mathematics (Evans, Morjaria, & Powell, 2018; Glewwe et al., 2018). In the UK, health services screen for vision problems in reception year and disseminate results to parents, but not schools. Approximately 15% of pupils fail the screening and a third do not obtain the glasses or the prescription needed (Bruce & Outhwaite, 2013). Reports suggest that the adherence of glasses wearing in children from disadvantaged backgrounds is very low (Collins et al., 2016). Even if a student does receive glasses, they may be broken, lost, or not worn in school (Messer, Mitchell, Twelker, & Crescioni, 2012). Clearly, solving vision difficulties is not simply an issue of screening pupils or providing eyeglasses. If schools have access to vision screening results, and resources to remedy vision problems (e.g., spare glasses made available in school), they could help ensure that children that need glasses receive and wear them. A school-based intervention may lead to significant positive improvements in pupils' mathematics and reading achievement, especially in disadvantaged communities.

The purpose of this study is to examine the impact of a school-based intervention to support glasses wear in young children (which involves sharing vision screening results with school and provision of additional glasses to be kept in school) on their reading and mathematics achievement. The causal mechanisms of this effect such as attendance for eye appointments, adherence to glasses wear in young children following vision screening, and improvement in VA will also be examined. The effect of the intervention on academic achievement and VA in the child's first year (reception class) of school will be measured. This cluster randomised study will consist of two groups. The treatment group (50 schools), with approximately 350 pupils in need of glasses, will be randomised to receive the intervention over the academic year; the control group (50 schools) will receive business-as-usual care.

This study will evaluate the introduction of a school-based intervention to support the wearing of glasses in young children and measure subsequent improvement of the child's vision and academic achievement. Ophthalmic treatment for the children participating in the trial will not change. However, the children in the intervention schools will receive additional school-based support to wear their glasses. This intervention has not been tested in the UK using a rigorous RCT approach although elements of the intervention have been studied previously within the Bradford setting (Bruce & Outwaite, 2013; Bruce et al., 2018a; Bruce, Sanders, & Sheldon, 2018b; Cassetti, Sanders, & Bruce 2019). This study will contribute to the future design of school-based children's eye services, which aim to improve student outcomes including academic achievement.

Impact evaluation

Research questions

The evaluation will address the following primary research question:

- What is the impact on the reading achievement (letter-word identification) of pupils in reception classes participating in *Glasses in Classes* as opposed to participating in a business-as-usual control group?

In addition, the evaluation will address the following exploratory secondary research questions:

- What is the impact on the mathematics and reading achievement (word attack) of pupils in reception classes participating in *Glasses in Classes* as opposed to participating in a business-as-usual control group?
- What is the impact of *Glasses in Classes* in comparison to business-as-usual control group on student mathematics and reading achievement among pupils eligible for FSM (defined as any student who has ever been classified as in receipt of free school meals)?

- What is the impact on the visual acuity of pupils in reception classes participating in *Glasses in Classes* as opposed to participating in a business-as-usual control group?
  Table 1 outlines the outcomes, baseline measures, sample, and contrasts relevant to the study.

Design

The impact evaluation will involve a cluster randomised multi-level/hierarchical controlled trial involving schools in the Bradford metropolitan area (see Table 2). All schools in the Bradford area (*n* = ~160) are eligible and will be contacted with the aim to recruit 100 schools (50 treatment = T; 50 control = C). It is expected that schools will average close to full two reception classes with approximately 27 pupils per class[1]. All reception pupils (2019–2020) in both treatment and control schools will undergo vision screening assessment, but only a sub-sample of pupils (~15%, Bruce, Kelly, Chambers, Barrett, Bloj, Bradbury, & Sheldon, 2018) who fail the vision screening assessment will be included in the intention-to-treat (ITT) analysis and contribute to the pre and posttests. Results from the vision screening test will be shared with the evaluation team immediately so that pretesting can be arranged for the specific pupils. Baseline reading and mathematics achievement for pupils in reception classes will be assessed in autumn 2019, prior to intervention implementation, and before random assignment. Posttests will be administered in spring 2020 (see Figure 1). The ITT sample will include the pupils in reception classes in 2019, who are enrolled in the intervention schools at the point of random assignment. Pupils not enrolled at the point of random assignment are considered *joiners*. The final analysis sample will exclude the joiners, but they will receive the intervention as usual. Figure 1 outlines the intervention process.

[1] This was calculated from the comparing school performance website, where we were able to take the total roll and divide each school by the number of year groups served. The legal maximum per class is 30 pupils in primary school, with the current average of 27.3 across English primary schools (DfE, 2019). The average number of pupils per year is 47, and 73% of the schools in the area have year groups greater than 30. Therefore, 24% of schools have year groups larger than 60. It is therefore a realistic assumption that most schools will include 2 or more classes.

Table 1

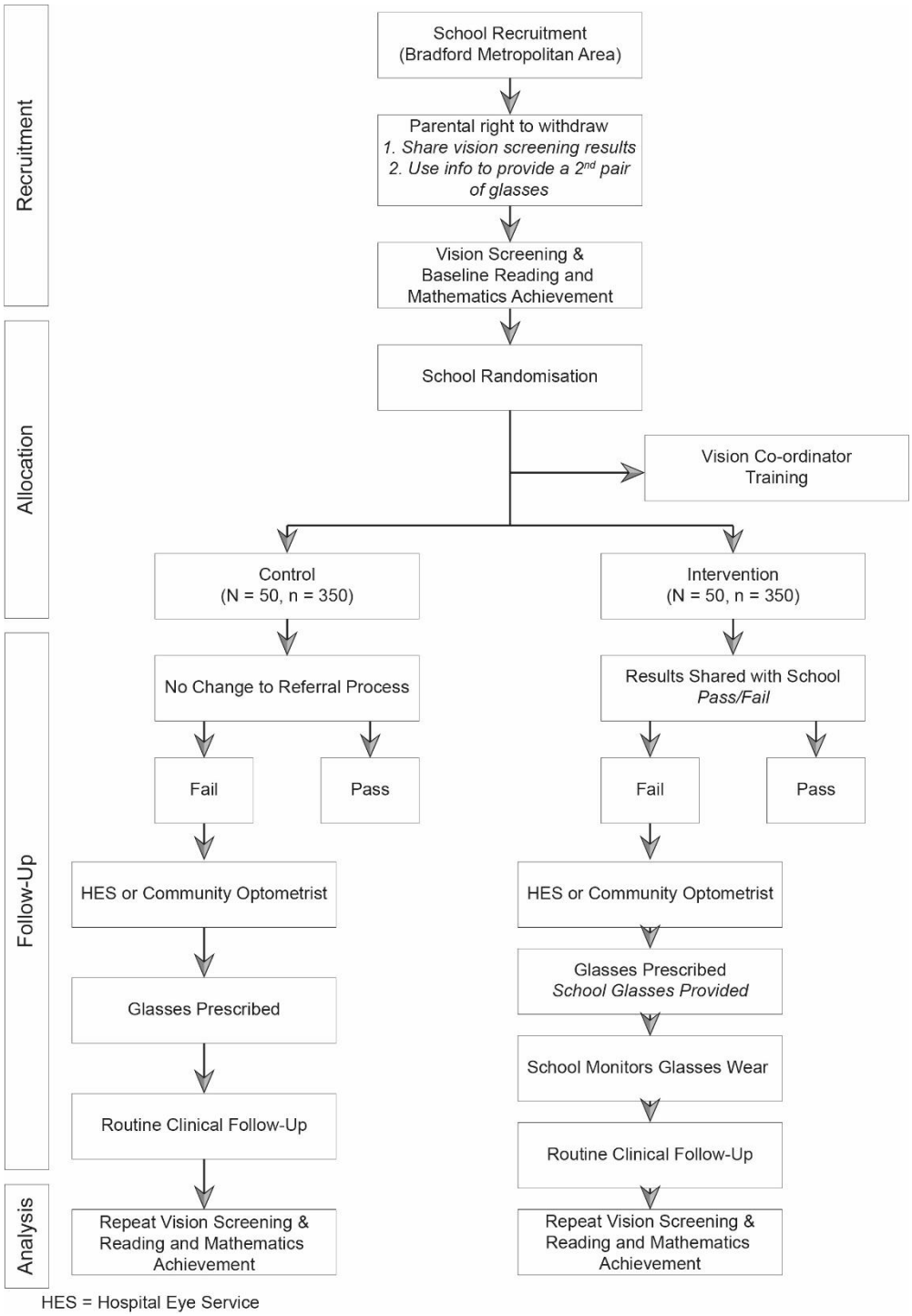
Study Contrast Table

Contrast	Design	Treatment		Control	Outcome			Baseline	
		Description	Grade	Description	Domain	Measure	Timing	Measure	Timing
Confirmatory-Letter-Word Identification-Sample-Year 1 (Primary outcome)	RCT with schools randomized to experimental groups	[GiC] All students who need eyeglasses, treatment, posttest year 1	Reception	[Business-as-usual] All students who need eyeglasses, posttest year 1	Reading achievement	Woodcock-Johnson IV Letter-Word Identification [Continuous]	Spring 2020 end of reception	Woodcock-Johnson IV Letter-Word Identification [Continuous]	Fall 2019 start of reception
Exploratory-Word Attack-Sample-Year 1 (Secondary outcome)	RCT with schools randomized to experimental groups	[GiC] All students who need eyeglasses, treatment, posttest year 1	Reception	[Business-as-usual] All students who need eyeglasses, posttest year 1	Reading achievement	Woodcock-Johnson IV Word Attack [Continuous]	Spring 2020 end of reception	Woodcock-Johnson IV Word Attack [Continuous]	Fall 2019 start of reception
Exploratory-Applied Problems -Sample-Year 1	RCT with schools randomized to	[GiC] All students who need eyeglasses, treatment, posttest year 1	Reception	[Business-as-usual] All students who need eyeglasses,	Mathematics achievement	Woodcock-Johnson IV Applied Problems [Continuous]	Spring 2020 end of reception	Woodcock-Johnson IV Applied Problems [Continuous]	Fall 2019 start of reception

(Secondary outcome)	experimental groups			posttest year 1					
Exploratory-Visual Acuity-Sample-Year 1 (Secondary outcome)	RCT with schools randomized to experimental groups	[GiC] All students who need eyeglasses, treatment, posttest year 1	Reception	[Business-as-usual] All students who need eyeglasses, posttest year 1	Visual acuity	logMAR [Continuous]	Spring 2020 end of reception	logMAR [Continuous]	Fall 2019 start of reception
Exploratory-Letter-Word Identification, Word Attack, Applied Problems, VA-FSM Sample-Year 1	RCT with schools randomized to experimental groups	[GiC] FSM Sample of students who need eyeglasses, treatment, posttest year 1	Reception	[Business-as-usual] FSM Sample of students who need eyeglasses, posttest year 1	-	Word Identification, Word Attack, Applied Problems, VA [Continuous]	Spring 2020 end of reception	Word Identification, Word Attack, Applied Problems, VA [Continuous]	Fall 2019 start of reception

Figure 1

Projected Sample Flow-Chart (Consort Diagram[2])



[2] Flow chart template from Schulz, Altman, and Moher (2010).

Table 2

RCT Design Parameters

Trial type and number of arms		Two-arm, cluster randomised
Unit of randomisation		School
Stratification variables (if applicable)		N/A
Primary outcome	variable	Reading achievement
	measure (instrument, scale)	Woodcock-Johnson IV Letter-Word Identification (Continuous)
Secondary outcome(s)	variable(s)	Reading achievement, Mathematics achievement, Visual acuity
	measure(s) (instrument, scale)	Woodcock-Johnson IV Word Attack (continuous); Woodcock-Johnson IV Applied Problems (continuous); logMAR (continuous)

Randomisation

The proposed design involves a randomised multi-level/hierarchical trial, with school level randomisation using a simple randomisation process. School assignment will be completed for all schools in autumn 2019 for a total of 100 schools (50 control, 50 treatment).

Participants

All regular state primary schools (academies, free schools, and local authority managed) from the Bradford Metropolitan area with a reception class are eligible for inclusion. All children are eligible within the reception year for vision screening (as per standard practice). The main impact analysis will focus on children who fail the vision screening test in the intervention group compared to those who fail the vision screening test in the control group. These children will be recruited through participating schools that have signed a Memorandum of Understanding (MOU).

Sample size calculations

The trial has been designed to maximise the possibility of detecting a small effect size, within a specified geographical area. The power analysis involved a significant number of sensitivity analyses conducted with a range of assumptions (varying ICCs, pre-post correlation, number of schools, etc.) and software – in particular MLPowSim (Browne, Golalizadeh Lahi, & Parker, 2009), PowerUpR (Bulus, Dong, Kelcey, & Spybrook, 2018), and Optimal Design (Raudenbush, 2011). The analyses discussed below use PowerUpR, which provides a more precise estimate than the more limited options available in Optimal Design. Our power calculations are detailed in

Table 3 below.

Table 3

Sample Size Estimates

		OVERALL	FSM
MDES		0.195	0.22
Pretest/ posttest correlations	level 1 (student)	0.88[3]	0.88
	level 2 (class)	-	-
	level 3 (school)	0.62	0.62
Intracluster correlations (ICCs)	level 2 (class)	-	-
	level 3 (school)	0.15[4]	0.15
Alpha		0.05	0.05
Power		0.8	0.8
One-sided or two-sided?		Two-sided	Two-sided
Average cluster size		7[5]	3
Number of schools	Intervention	50	50
	Control	50	50
	Total	100	100
Number of pupils	Intervention	350	150

[3] Villareal (2015) undertook a test review of the WJIV standard battery of tests and found correlations in the range of .83-.95. In the Woodcock Johnson IV manual, test-retest correlations were between 0.83–0.95 for the age 7–11 group (p. 94). However, these sort of test-retest reliability analyses tend to be over very short periods (e.g., one day).

[4] We have selected an ICC of 0.15 as this represents a trade-off in that the schools are centred on a specific small geographical region, but on the other hand recognises that some EEF trials amongst early years have been higher at 0.17–0.19.

[5] 15% of the average primary school year group of 47. We estimate that around a third of the pupils will be on FSM (DfE, 2019).

	Control	350	150
	Total	700	300

Outcome measures

The outcome measures for the primary and secondary outcomes are the Woodcock-Johnson IV Letter-Word Identification, the Woodcock-Johnson IV Word Attack, Woodcock-Johnson IV Applied Problems (Schrank, McGrew, & Mather, 2014), and logarithm of Minimum Angle of Resolution (logMAR). The measures have been selected as they satisfy What Works Clearing House standards (WWC, 2017). Specifically, the tests demonstrate face validity and reliability; are not overaligned with the intervention, and will be administered in the intervention and control groups in the same manner. These standardised performance-based measures are widely used and have been used previously in large-scale trials with a similar age group (Corcoran & Ross, 2014; Corcoran, & Ross, 2015; Corcoran, Ross, Irby, Tong, Lara-Alecio, & Guerrero, 2015).

The Woodcock-Johnson IV Tests of Achievement were internationally normed across multiple age groups (McGrew, LaForte, & Schrank, 2014). Letter-Word Identification is designed to test reading and decoding. Each pupil is provided with visual (i.e., text) stimuli and are required to identify printed letters and words. The response is oral, that is letter names and words. Letter-Word Identification was chosen as the primary outcome measure based on prior research with a similar population (Bruce et al., 2018a). Applied Problems tests quantitative knowledge, mathematical achievement, and quantitative reasoning. Pupils are provided with auditory questions and visual (i.e., numeric and text) stimuli and are required to perform mathematics calculations, providing an oral response comprising of numbers and words. Finally, Word Attack is designed to test reading decoding, auditory processing, and phonetic coding. The stimuli are visual (i.e., words) and pupils are tasked to read phonically and provide pronunciations of pseudo words (McGrew et al., 2014, pp. 127–128). For the analyses, raw scores will be converted to age-standardised scores.

The Keeler crowded logMAR test is the recommended test for performing vision screening in young children. VA will be measured at a three-meter distance using the LogMAR Crowded Test (Keeler, Windsor, UK), with four letters per line, and each letter designated a score of 0.025; therefore, the score total per line represents 0.10 log unit. (The lower the score the higher the VA). A matching card is used when testing children ages 4 to 5 years, therefore knowledge of letters is not a prerequisite for test performance.

Pre and posttests will be conducted based on one-to-one tests carried out in schools by UoN appointed staff, with training will be provided prior to pretest and posttest data collection. Demographic data will be collected along with supplementary data from the National Pupil Database to check for data quality, as well as to provide updates on FSMever for the KS1 follow-on study.

The evaluator will conduct all major evaluation aspects, including random assignment, collection, and analysis and reporting of data for the impact analysis. The PI has discussed with the developer the importance of adherence to the EEF independence evaluation guidelines.

Analysis plan

The primary analysis focuses on reading achievement measured by the Woodcock-Johnson IV Letter-Word Identification scale. This will be administered in summer 2020, in addition to three secondary outcomes – reading achievement measured by the Woodcock-Johnson IV Word Attack scale; mathematics achievement measured by the Woodcock-Johnson IV Applied Problems scale; and VA measured by the logMAR.

The proposed analyses are summarised next and will be detailed separately in the statistical analysis plan.

MAIN OUTCOME

The analysis of the main outcome will be conducted on an ITT basis. The varying intercept model is as follows:

$$y_{ij} = \beta_{0j} + \beta_1 Treatment_{ij} + \beta_2 Pre - test_{ij} + u_{0j} + \epsilon_{ij}$$
$$u_{0j} \sim \mathcal{N}(0, \sigma^2_{school})$$
$$e_{ij} \sim \mathcal{N}(0, \sigma^2_y)$$

This can be understood as follows. The posttest score for the i^{th} student in the j^{th} school is equal to the grand mean score (β_{0j}), the impact of a binary indicator denoting treatment received (β_1) which is coded as 0 or 1, the impact of the mean-centred normally distributed pre-test (β_2), the school-level error term (u_{0j}), and finally the student-level error term (ϵ_{ij}). The two error terms each receive their own probability distribution which are normally distributed and centred on 0, with the two variance parameters estimated from the data (σ^2_{school} and σ^2_y).

Effects sizes will be calculated using Hedges *g*. This is calculated as the mean difference between the treatment and control group and divided by the square root of the total variance. The equation is presented below:

$$ES = \frac{\bar{Y}_{Treatment} - \bar{Y}_{Control}}{(\sigma^2_{school} + \sigma^2_y)}$$

SUBGROUP ANALYSIS

Additional models will be fitted, which will include the 'FSM ever' entitlement (defined as any student who has ever been classified as in receipt of free school meals). This will be fitted as an interaction model in the following form:

$$y_{ij} = \beta_{0j} + \beta_1 Treatment_{ij} + \beta_2 Pre{-}test_{ij} + \beta_3 FSM_{ij} + \beta_4 FSM * Treatment_{ij} u_{0j} + \epsilon_{ij}$$
$$u_{0j} \sim \mathcal{N}(0, \sigma^2_{school})$$
$$e_{ij} \sim \mathcal{N}(0, \sigma^2_y)$$

SECONDARY OUTCOMES

The three secondary outcomes: Woodcock-Johnson IV Word Attack scale, Woodcock-Johnson IV Applied Problems scale, and logMAR will be modelled in the same manner as the primary analysis based on intention to treat and estimate effect sizes using the same formula as above. Should there be a significant effect on both the Woodcock-Johnson and VA measures, we will conduct a follow-on analysis investigating the mediating impact of VA on academic outcomes.

Implementation and Process Evaluation

UoN will implement a robust fidelity of implementation protocol that evaluates adherence to GiC, and explicitly focuses on objective fidelity of implementation measures. The evaluation plan includes questions that provide information about for whom and under what conditions intervention impacts are observed. These questions address the fidelity of implementation (RQ1), change of teacher use of intervention strategies (RQ2), perceptions of GiC amongst school senior leadership, teachers, and parents (RQ3), cost effectiveness (RQ4) and finally unintended consequences (RQ5). The research questions for the process evaluation are presented below:

Research questions

1. Are key components of *Glasses in Classes* implemented with fidelity across schools? What percentage of *Glasses in Classes* schools have high fidelity of implementation according to the fidelity of implementation protocol?
2. What is the impact of *Glasses in Classes* on teachers' use of intervention strategies in comparison to business-as-usual schools?
3. How do principals, parents, and teachers perceive the effectiveness of *Glasses in Classes*? What types of structures and partnerships need to be in place to help deliver Glasses in Classes to large numbers of school at scale?
4. How cost-effective is *Glasses in Classes*?
5. Are there any unintended consequences of *Glasses in Classes* in the intervention group?

Observable indicators that map to the key components of GiC logic model in Figure 2 will be used to evaluate the fidelity of implementation. Table 4 outlines the key indicators including school vision coordinators attendance at training sessions (recorded using attendance logs), glasses ordered (recorded using optometrists' payment receipts for the dispensing of glasses), and provision of intervention in classrooms for children prescribed glasses. Criteria representing school level performance will be used to rate fidelity of implementation and investigate the extent to which GiC is implemented as intended for the treatment schools. For indicators, as defined in a fidelity matrix, a school-level fidelity of implementation threshold will be defined. Aggregate fidelity scores will be calculated for the key components by computing the schools with high fidelity of implementation.

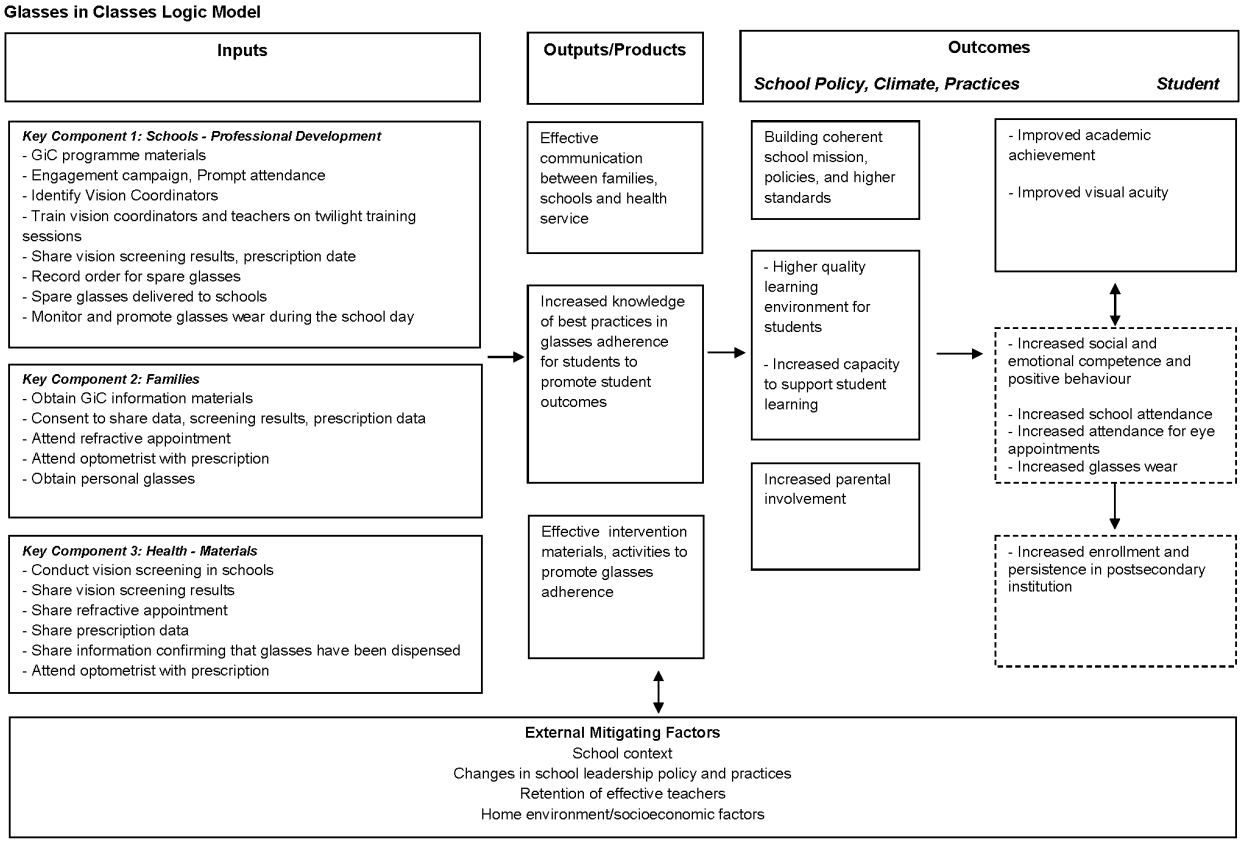
Another feature of the process and implementation evaluation will include qualitative measurement of stakeholders' perceptions of GiC. To investigate perceptions about GiC, surveys will be administered online via Qualtrics.

Finally, the implementation and process evaluation will include six case studies of schools (three compliant schools and three non-compliant schools) to investigate how GiC schools use skills to change their schools' functioning to increase student achievement and barriers. These schools will be selected from the population of treatment schools based on their engagement, reported participation, and willingness to participate. The six case study schools will specifically target three higher fidelity schools and three lower fidelity school to provide case studies of success and challenges. In addition to the data collection measures used for all control and treatment schools (e.g., student achievement data, surveys, etc.), qualitative focus group data will be collected for case study schools including additional measures. One focus group with three to five parents per case study school (three compliant schools and three non-compliant schools) will be conducted in person to examine perceptions and reactions to *Glasses in Classes*. In the non-compliant schools, some parents that did not take their children to the optometrists will be selected. Figure *2*

Table 4 and Table 5 shows the measures to be used.

Figure 2

Glasses in Classes Logic Model[6]



[6] Text in dashed line rectangles represents hypothesised long-term outcomes not measured in the current trial.

Table 4

Fidelity Matrix Glasses in Classes Treatment Schools 2019–2020

Indicators	Definition	Unit	Source	Collection of data[7]	Thresholds for fidelity of implementation	Adequate implementation threshold
Key Component 1: Schools - Professional Development Indicator	1-day group training over 12-months	Vision Coordinators	Attendance Logs	UoL/BIHR	0 = No vision coordinator attends one day training 1 = Vision coordinator attends one day training	Implementation with fidelity = Score of 1 Percentage with a score of 1
Key Component 2: Families Indicator	Attend optometrist with prescription	Parent/Primary care giver	Attendance logs	UoL/BIHR	Percentage attendance: 0 = <80% Attend optometrist with prescription 1= 80-89% Attend optometrist with prescription. 2= 90-100% Attend optometrist with prescription	Implementation with fidelity = Score of 2 (i.e., attend optometrist with prescription) Percentage with a score of 2
Key Component 3: Health - Materials Indicator	Each child receives two pairs of personal glasses	Child/ school	Optometrist payment receipts for the dispensing of glasses	UoL/BIHR	0 = No glasses 1 = Incomplete set (e.g., one pair) 2 = Full set (two pairs)	Implementation with fidelity = score of 2 Percentage of children with a score of 2

[7] UoL – University of Leeds and BIHR (delivery team), UoN – University of Nottingham (evaluation team)

Table 5

Implementation and Process Evaluation Measures

Outcome Measure	Instrument	To whom it is administered	Who administers	Post-test
Detailed information on glasses wearing and availability of eyeglasses	Online survey administered via Qualtrics	Teachers	UoN	05/20
Training session rating of quality	Brief online survey administered via Qualtrics	Vision Coordinators at treatment schools	UoN	11/19
Training session quality	Observations of two training sessions using observation rubric	Vision Coordinators at treatment schools	UoN	11/19
Parent focus group recording perceptions of *Glasses in Classes*	One focus group (three to five participants) per case study school conducted in person to examine perceptions and reactions to *Glasses in Classes*	Select three to five parents in case study treatment schools	UoN	04/20
Semi-structured interview with principals recording perceptions of *Glasses in Classes*	Six semi-structured interviews conducted via phone to examine perceptions and reactions to *Glasses in Classes*	Select six principals in case study treatment schools	UoN	05/20
Business-as-usual control and treatment diffusion	Online survey of control school administered via Qualtrics	All school coordinators in the control group	UoN	11/19 05/20
Cost Evaluation	Online survey administered via Qualtrics	Program developers	UoN	06/20

Cost evaluation

The GiC costing information will be collected from the developer at the end of the study. Costing will account for the total programme implementation excluding the evaluation costs. Information provided will include:

(i) the average cost per child for the school glasses (GiC);
(ii) the average cost per child for breakages and/or loss of the school glasses;
(iii) the no. of contacts by health team liaising (phone or visit) with the vision co-ordinator in addition to the planned monthly feedback;
(iv) the no. of contacts the vision co-ordinator for each school has with parents to follow-up glasses wear.

The cost per year per school will be calculated based on the total number of schools that participate in the trial as outlined in EEF cost guidance (EEF, 2015). The total cost per student will be estimated according to the number of students in the treated school per year. Cost ratings will be based on an approximate cost of GiC implementation per year per pupil.

Ethics and Registration

GiC relies on the collection of sensitive health data, alongside academic achievement data from very young children in an early year setting. Undertaking the research requires a robust approach to research ethics. Given the level of risk involved, full reviews of the project ethics were sought from both health (NHS Bradford Teaching Hospitals Foundation Trust- IRAS 253681) and academic ethical review boards (University of Nottingham - CPMS 41579). The respective ethics review boards approved the study.

The trial will be independently and publicly registered by the University of Nottingham through the International Standard Randomised Controlled Trial Number organisation (ISRCTN) at www.controlled-trials.com.

Schools and parents will be provided with information sheets and privacy notices, which describe why and how the study will be conducted, detailed justification for the information collected and under what basis the data will be processed. Additional forms will be provided to the parents to allow them to withdraw their children from the study.

Data Protection

The research will comply with the Data Protection Act (2018) and General Data Protection Regulations (2016). The project will work towards University of Nottingham and NHS Bradford Teaching Hospitals Foundation Trust ethical standards. We shall process data under the legal basis outlined in article 6(1)(e), "necessary for the performance of a task carried out in the public interest or in the exercise of official authority." For special category data our additional legal justification for processing, as required by article 9 of the GDPR, is article 9(2)(j), "processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1)."

The research team shall ensure that safeguards for managing personal data are in place. Specifically, we shall only process the minimum necessary data, utilise pseudonymisation techniques, ensure data is collected and stored in a secure manner as outlined by the University of Nottingham's *Handling Restricted Data Policy* and work to the University of Nottingham's research ethics standards. We shall also ensure that all research participants are provided with a privacy notice highlighting how we will use the data they provide.

In line with University of Nottingham standards, the university may store the data for up to 25 years after the project. Data will be stored securely in a password-protected folder that is accessible to authorised persons only. Names of children and schools will not be released in associated research reports. The data will be shared with the Department for Education (DfE), the EEF's archive manager and in anonymised form with the Office for National Statistics and potentially other research teams, subject to the appropriate approvals. Further matching with the National Pupil database and other

administrative data may take place during subsequent research to better understand the impact of the project.

The trial parties have the following roles and responsibilities in the collection and management of data:

- The University of Nottingham will act as data controller throughout the evaluation period, up to and including successful submission of evaluation data to the archive (having passed internal FFT checks) and deletion of the data.
- Bradford Institute for Health Research and the University of Leeds will act as joint data controllers up to the point of data archiving and deletion. In the case of the achievement data, Bradford Institute for Health Research and the University of Leeds are data processors.
- Education Endowment Foundation will act as the data controller for the archive
- Fisher Family Trust will act as the data processor for the long-term archive.

Personnel

The team is made up of:

- Professor Roisin P. Corcoran (Principal Investigator) is Chair in Education at the University of Nottingham. She will lead the project, research design, reporting, stakeholder relations, and dissemination.
- Dr. Michael Adkins is a Post-Doctoral Research Fellow at the University of Nottingham. He will be responsible for the data analysis of the impact evaluation and assisting with report-writing.
- Dr. Sheila Evans, Post-Doctoral Research Fellow at the University of Nottingham, will be responsible for fieldwork relating to the GiC process evaluation and assisting with report-writing.
- Research assistants will be responsible for coordinating day-to-day aspects of the project, under the direction of the PI, including maintaining contact with schools, data collection, coding, GDPR compliance, recruitment materials.

The delivery team is made up of:

- Professor Mark Mon-Williams is Chair in Cognitive Psychology at the University of Leeds, and is Professor of Psychology at the Bradford Institute of Health Research, and Professor of Paediatric Vision at The Norwegian Centre for Vision. He is the advisor to the delivery team and link to the Born in Bradford data platform.
- Dr. Alison Bruce is Director of Vision Research, Bradford Institute for Health Research, Bradford Hospitals NHS Trust. She will lead the delivery of the study, research design, data collection and data transfer to the evaluation team.
- Dr. Emily Williams is a Post-Doctoral Research Fellow at the University of Leeds. She will be responsible for GiC delivery process, school engagement, and assisting with report-writing.
- Mrs Jenny Cheung-Crossley is an Advanced Orthoptist who will be responsible for co-ordinating the vision screening team (research orthoptists) and will be responsible for liaising between community and hospital based ophthalmic services.
- Research orthoptists will be responsible for vision screening in schools as directed by the Advanced Orthoptist, including data collection and GDPR compliance.

Risks

Business-as-usual schools will not be exposed to GiC intervention prior to study completion. Control schools will only receive business-as-usual services and supports. Threats to the delivery of the trial will be minimised via the following mechanisms:

1. Project delivery team will explain ramifications of participating in a randomised controlled trial to the school partners.
2. Schools will be required to sign an MOU indicating they are willing to participate in a randomised controlled trial and agree to the terms of contract agreement.

An online survey of control school will be used to monitor any potential treatment diffusion. However, it is not anticipated that the confounds outlined will take place in this study.

Other risks include loss of evaluation staff. However, the University of Nottingham has a large experienced staff team with ample expertise available as needed. Another risk includes failure to recruit an adequate number of schools. The timeline for recruitment is brief, given that schools will need to be in a position to have been randomised and the intervention promoted by mid-October in the 2019/20 academic year. To mitigate this risk, we suggest to over-recruit schools. Similarly, the work in September and October 2019 will be a short time scale to ensure that glasses can be ordered and delivered for the beginning of January 2020. Our process evaluation includes a robust fidelity of implementation protocol to minimize this risk. The risk analysis is presented below in Table 6

Risk Analysis Table 6.

Table 6

Risk Analysis

Risk	Likelihood	Impact	Contingency plan
Inadequate schools recruited and reduced power	Moderate	Moderate	Compensation will be given to schools for completing pre and post-tests (£750 for controls and £250 for treatment groups). All schools are required to sign an MOU in spring 2019.
Different opinions on study design	Moderate	Moderate	UoN staff are experienced evaluators and work with intervention developers flexibly and expeditiously to ensure the study design is robust and meets standards for independence.
Data protection	Low	High	UoN have robust data protection and procedures in place
Attrition of schools and pupils	Low	Low	Appropriate compensation to schools. Allow ample time for testing and revisit schools if some pupils are absent on the data of testing. Ensure schools have a good understanding of the randomisation procedure, what the trial involves and ensure they will participate in the post-test evaluation activities even if they drop out from the intervention
Fidelity of implementation	Low	Low / Moderate	Development team monitor throughout process evaluation. Glasses will be ordered from November onwards and the provision of spare glasses to affected children will take place for the remainder of the school year via a daily check, likely linked to morning registration. Schools will implement a process for daily checking that children prescribed glasses wear them to accommodate their method of registration (such as by paper or via electronic means). They may also introduce various approaches to ensuring follow up appointments are met, including accompanying children to hospital or optometrist appointments as appropriate.

Timeline

Table 7 outlines the timeline for GiC.

Table 7

Key Dates and the Organisation Responsible for Study Activities

Dates	Activity	Staff responsible/ leading
November 2018-April 2019	Evaluation set-up completed, recruitment material finalised, ethics submitted	UoN/UoL/BIHR
April -June 2019	School recruitment, Expression of Interest and Memorandum of Understandings received	UoL/BIHR
July-August 2019	Trial protocol, agreement and trial registration completed	UoN
September 2019	Pupil withdrawal notifications received	UoL/BIHR
October 2019	Pupil data collected from settings and visual acuity and academic baseline testing completed	UoN/UoL/BIHR
October 2019 – November 2019	Randomisation completed	UoN
October 2019 – November 2019	Letters distributed to parents for eye appointments where appropriate, and glasses ordered	UoN/UoL/BIHR
December 2019-June 2020	Glasses delivered to schools, school monitoring of eye glass wear	UoL/BIHR
March-May 2020	IPE surveys distributed and case studies conducted	UoN
May-June 2020	Pupil visual acuity and academic post-testing completed	UoN
September 2020-June 2022	Optional: School monitoring of eye glass wear, glasses replaced as needed. School coordinators, teachers, parents instructed to notify the developer if glasses are lost or broken	UoL/BIHR
2020	Submission of draft report to the EEF	UoN
March-May 2021	Submission of final edited EEF report, submission of data to the EEF archive and updating of ISRCTN trial registry with results	UoN
September-December 2022	Optional longitudinal post-test: KS1 data collected from schools/Requested from NPD	UoN
May-June 2021	Optional longitudinal post-test: Pupil visual acuity post-testing completed, school monitoring of eye glass wear	UoL/BIHR

May-June 2022	Optional longitudinal post-test: Pupil visual acuity and academic post-testing completed, school monitoring of eye glass wear	UoL/BIHR/UoN
November 2022	Optional follow up: Analysis of Key Stage 1 data from NPD/ schools	UoN
February-March 2023	Submission of final addendum report	UoN

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