ZEAL

Zimbabwe Eyecare And Learning: formative research on hyperopia and educational outcomes in primary school children in Zimbabwe.

Funders:
Wellcome Trust
Chen Yet-Sen Family Foundation

STUDY AIM

The aim is to determine whether uncorrected or corrected long-sightedness (hyperopia) has an impact on reading skills, in Grade 2 or Grade 4 school-aged children from Mashonaland Central province of Zimbabwe, compared to age-, gender-, and school-matched children with no refractive error (emmetropia), measured by the Happy Readers V4 reading tool over 6 months.

OBJECTIVES

1. To assess the prevalence of moderate to high hyperopia (≥ +2.00D) among primary school children in Grades 2 and 4, from Mashonaland Central province in Zimbabwe.
2. To accurately detect moderate to high hyperopia (≥ +2.00D) using four screening tests compared to the gold-standard cycloplegic refraction in Grades 2 and 4 primary school children, in Mashonaland Central province, Zimbabwe.
3. To study the association between uncorrected and corrected moderate to high hyperopia (≥ +2.00D) and baseline reading levels in Grades 2 and 4 primary school children, in Mashonaland Central, Zimbabwe.
4. To compare near visual acuity and reading levels at baseline and at 6 months between moderate to high hyperopic (≥ +2.00D) children compared to age-, gender-, and school-matched controls with no vision problems.
5. To compare spectacle compliance among newly diagnosed hyperopic and newly diagnosed myopic (short-sighted) school children in Grades 2 and 4, from Mashonaland Central province of Zimbabwe, at 6 weeks and 14 weeks.

This study implements two study designs: a cross-sectional study and the second approach is a longitudinal intervention study.

MAIN STUDY QUESTION

- What is the prevalence of moderate to high hyperopia (≥ +2.00D) among Grades 2 and 4 primary school children in Mashonaland Central province, Zimbabwe?
- Can our screening tests identify moderate to high hyperopia (≥+2.00D) in an accurate fashion?
- Is moderate to high hyperopia (≥ +2.00D) associated with poor reading levels in Grades 2 and 4 Zimbabwean children compared to age-, gender- and school-matched emmetropic controls?
- Will correction of moderate to high hyperopia (≥ +2.00D) improve reading levels, in Grades 2 and 4 primary school children from Mashonaland Central province, Zimbabwe?
- Does spectacle compliance differ among newly diagnosed hyperopic children and myopic children in Grades 2 and 4, from Mashonaland Central, Zimbabwe?

SETTING

Participants will be recruited from schools selected by the Ministry of Primary and Secondary Education (MoPSE) in Mashonaland Central province in Zimbabwe.

SAMPLE SIZE

We propose to test 2000 primary school children from Mashonaland Central province of Zimbabwe: 1000 Grade 2 school children and 1000 Grade 4 school children. The proposed sample size will allow us to achieve margins of error ranging from 1.5% to 5.0% for hyperopia prevalence in the range of 3 to 15%.

PARTICIPANTS

Inclusion criteria:

- Grades 2 or 4 from the list of selected primary schools by the MoPSE
- Moderate to high hyperopia (≥ +2.00D)
- Emmetropia
- Newly diagnosed myopia (to assess spectacle compliance)

Exclusion criteria:

- Not Grades 2 or 4 and not from the list of selected schools by the MoPSE

- History of systemic disease or ocular disease and/or medications known to have an impact on accommodation
- Known history of developmental learning disability
- Known neurological anomalies (e.g. cerebral palsy, Down syndrome)
- History of previous spectacle wear
- Known behaviour disorder (e.g. ADHD).

RANDOMIZATION

Baseline near visual acuity and reading skills will be assessed by randomising the hyperopic cohort with and without spectacle correction. The randomization sequence will be generated by the study statistician at the Clinical Trials Unit at LVPEI using an online random number generator (www.randomization.com) and concealed until a participant is determined eligible and agrees to participate.

Intervention: Based on the results of the refraction and prescribing guidelines outlined in the study protocol, participants will be provided with two free pairs of spectacles. One pair of spectacles will remain at school.

MAIN STUDY OUTCOME

- Prevalence of moderate to high (≥ +2.00D) hyperopia in Grades 2 and 4 primary school children in Mashonaland Central, Zimbabwe.
- Using the four screening tests to accurately detect moderate to high hyperopia (≥ +2.00D).
- Baseline near visual acuity and reading skills measured using the Happy Readers V4 test.
- Spectacle compliance among newly diagnosed hyperopic and myopic Grade 2 and 4 primary school in Mashonaland Central, Zimbabwe.
- Six-month change in near visual acuity and reading skills measured by the Happy Readers V4 test.

TECHNIQUE FOR MEASUREMENT OF MAIN OUTCOME AND SECONDARY OUTCOMES

The primary analysis will be conducted on all outcome data obtained from all enrolled participants as randomised, i.e., intention-to-treat analysis. Per-protocol analysis will also be conducted as secondary analysis, analysing participants according to treatment they actually received. A detailed Statistical Analysis Plan will be completed and approved before data collection is final.

Primary Outcomes

(i) Prevalence of moderate to high hyperopia (≥ +2.00D)
(ii) The metric or method of measurement to be used: cycloplegic refraction
(iii) Timepoint(s) of primary interest: measured at a single time point
(i) Near visual performance: near acuity measured at 12.5cm/accommodative response/Brückner reflex test/stereopsis
(ii) The metric or method of measurement to be used: laser-etched near vision chart/ QuickSee autorefractor/Arclight/PASS 3+ Stereotest
(iii) Timepoint(s) of primary interest: measured at a single time point
(i) Baseline near visual acuity and reading level
(ii) The metric or method of measurement to be used: conventional near vision chart held at 40cm and the Happy Readers V4 reading test
(iii) Timepoint(s) of primary interest: measured at a single time point
(i) Change in near visual acuity and reading level
(ii) The metric or method of measurement to be used: The conventional near vision chart held at 40cm and the Happy Readers V4 reading test
(iii) Timepoint(s) of primary interest: 6 months
(i) Spectacle compliance
(ii) The metric or method of measurement to be used: unannounced direct observation
(iii) Timepoint(s) of primary interest: 6 weeks and 14 weeks

CAPACITY BUILDING PARTNERSHIPS

CHRISTIAN BLIND MISSION (CBM)

L V PRASAD EYE INSTITUTE

L V PRASAD EYE INSTITUTE CLINICAL TRIALS UNIT

NEW ENGLAND COLLEGE OF OPTOMETRY

NORTHERN IRELAND CLINICAL TRIALS UNIT

PEEK VISION

QUEEN'S UNIVERSITY BELFAST

THE VISION IN PRESCHOOLERS STUDY GROUP

ULSTER UNIVERSITY

UNIVERSITY OF ZIMBABWE

ZIMBABWE OPTOMETRIC ASSOCIATION

CLEARLY INITIATIVES

THE CHEN YET -SEN FAMILY FOUNDATION

BASELINE DATA (POTENTIAL PREDICTORS OF OUTCOME)

Age, gender, education, visual acuity, refractive error in both eyes, ocular examination to rule out other ocular abnormalities, medical disorders, learning or developmental delays, reading performance and spectacle compliance.

PURPOSE OF THE STUDY

The purpose of this study is to prepare for a randomised trial of hyperopia correction in the improvement of children's educational outcomes in Zimbabwe.

OUTLINE OF MAIN ANALYSIS

The primary analysis will use a significance level of <0.05 and will compare the change in reading scores (one of the primary outcomes, with sensitivity analysis including and excluding vision-dependent tests) between the two groups. Both the raw comparison and the comparison adjusting for potential determinants of change in reading performance, such as baseline reading score, age, sex and education (further covariates will be detailed in the Statistical Analysis Plan) will be analysed. Similar methods will be used for other time points and other outcomes that are continuous data.

A health and social care perspective will be adopted for the main analysis and a societal perspective in a sensitivity analysis. Planned subgroup analyses will include the need for glasses, age, gender, and baseline reading assessment.

Statistical modelling will also be performed to explore the effect of combining tests on diagnostic accuracy to detect hyperopia by examining AUC on constructed ROC Curve in order to identify the most accurate diagnostic strategy for moderate to high hyperopia (≥ +2.00D). Appropriate cut-offs on the four tests individually and taken together will be assessed by calculating sensitivity, specificity, positive predictive value and negative predictive value.

Compare those receiving spectacle correction (newly diagnosed hyperopia vs myopia). Gender-disaggregated analysis. Full details of the analyses will be given in the Statistical Analysis Plan.

PILOT STUDY

Prior to the main study, a pilot study would be conducted on 20 participants to standardise the protocols and flow of participants.

TRIAL MANAGEMENT AND OVERSIGHT

TIMELINE

- Protocol development and approvals: 6 months (June, 2021-December, 2022)
- Recruitment: 1 months (February, 2022-June, 2022)
- Experiment: 9 months (June, 2022 to December, 2022)
- Analysis and report writing (not including peer review and approval): 8 months (January, 2023 to September, 2022)

ENGINE
VISION DRIVES DEVELOPMENT

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