Cover Page

Official Title：

Evaluation of a Contextual, Behavioral, and Cognitive-Based Program to Improve Ophthalmic Compliance in Children and Adolescents with Special Needs

NCT Number：

NCT06717282

Study Type: Interventional (Single-arm, Pre–Post)
Version: Final
Date: 2026-01-19

Study Protocol and Statistical Analysis Plan

1. Background and Rationale

Children and adolescents with special needs, including autism spectrum disorder, developmental delay, and intellectual disability, present a significantly higher prevalence of visual problems compared with typically developing peers. Early ophthalmic assessment and regular follow-up are essential; however, cooperation during ophthalmic examinations remains a major barrier. Sensory hypersensitivity, motor limitations, attentional difficulties, and cognitive challenges frequently prevent completion of standard ophthalmic assessments.

Clinical experience and prior evidence suggest that structured interventions integrating contextual familiarization, behavioral reinforcement, and task-oriented cognitive support may improve cooperation during ophthalmic examinations and enhance participants' ability to complete examinations that require higher levels of cognitive engagement.

This study therefore evaluates a contextual, behavioral, and cognitive–based ophthalmic adaptation program designed to enhance ophthalmic compliance in children and adolescents with special needs.

2. Study Objectives

To evaluate the effectiveness of a contextual, behavioral, and cognitive–based ophthalmic adaptation program in improving cooperation during ophthalmic examinations and visual functional performance following the intervention.

3. Study Design

This study is a single-arm, pre–post interventional clinical trial. All eligible participants receive the intervention. Outcomes are assessed before and after completion of the intervention. Participants with complete pre- and post-intervention data are included in the final analysis.

4. Study Setting

Recruitment and assessments are conducted at the Vision Center for People with Special Needs, National Taiwan University Hospital.

5. Participants

Inclusion Criteria

Participants must meet all the following criteria:

(1) Aged 2 to 18 years.
(2) Diagnosed with or suspected of autism spectrum disorder, developmental delay, or intellectual disability.
(3) Demonstrated difficulty cooperating with routine ophthalmic examinations in general ophthalmology settings due to cognitive, behavioral, or emotional factors.

Exclusion Criteria

Participants will be excluded if they meet the following criterion:

- Children or adolescents with developmental delays or disabilities who can complete routine ophthalmic examinations or standard vision screenings during regular ophthalmology visits or school-based health screenings without specialized support.

6. Sample Size and Analysis Population

A total of 20 participants are enrolled. Participants with complete pre- and post-intervention outcome data are included in the final statistical analysis.

7. Study Procedures

Baseline Assessment

Before intervention, participants undergo assessment using:

(1) Visual Function Battery for Children with Special Needs (VFB-CSN)
(2) Near Detection Scale (NDS)
(3) Functional Vision Questionnaire (FVQ)
(4) Ophthalmic Compliance and Adaptation Questionnaire
(5) Parent-reported measures (Vineland Adaptive Behavior Scales–III, CASD-C, Sensory Profile, HVFQI)

Intervention

Participants receive six individual one-hour sessions, typically once every two weeks, delivered by occupational therapists specialized in visual rehabilitation. Intervention components include:

(1) Contextual strategies (environmental familiarization)
(2) Behavioral strategies (positive reinforcement)
(3) Cognitive strategies (visual supports and structured instruction)

Post-intervention Assessment

All baseline outcome measures are re-administered following completion of the intervention.

8. Outcome Measures

Primary Outcome

Change in overall visual functional performance (VFB-CSN).

Secondary Outcomes

Change in ophthalmic examination compliance as measured by the Ophthalmic Compliance and Adaptation Questionnaire.

9. Statistical Considerations

9.1 Analysis Population

The analysis population includes participants who completed both pre-intervention and post-

intervention assessments. Participants with incomplete outcome data were excluded from the final statistical analysis.

9.2 Outcome Measures

Primary Outcome

Change in overall visual functional performance and subscale scores as measured by the Visual Function Battery for Children with Special Needs (VFB-CSN).

Secondary Outcome

Change in ophthalmic examination compliance as measured by the Ophthalmic Compliance and Adaptation Questionnaire.

9.3 Descriptive Statistics

Descriptive statistics are used to summarize participant demographic characteristics and baseline clinical measures. Continuous variables are presented as means and standard deviations, and categorical variables are presented as frequencies and percentages, as appropriate.

9.4 Inferential Statistical Analysis

Given the small sample size and the expected non-normal distribution of outcome measures, non-parametric statistical tests are used to compare pre-intervention and post-intervention outcomes.

Comparisons between pre- and post-intervention scores for the primary and secondary outcomes are conducted using appropriate non-parametric methods for paired data.

9.5 Significance Level

All statistical tests are two-tailed. Statistical significance is defined as a p-value of less than 0.05.

9.7 Statistical Software

All statistical analyses are performed using standard statistical software (e.g., SPSS).

10. Ethics and Human Subjects Protection

This study was reviewed and approved by the Institutional Review Board. Written informed consent was obtained from caregivers prior to participation.

11. Data Management and Confidentiality

All data are de-identified and securely stored. Access is restricted to authorized research personnel.

12. Consistency Statement

This protocol represents the final version reviewed and approved prior to data analysis. All analyses are conducted in accordance with the predefined Statistical Analysis Plan.