A Multicenter, Randomized Controlled Clinical Study Evaluating the Efficacy of Dynamic Spatiotemporal Optical Film (S.T.O.P®KIT) in Retarding Axial Length Growth in Children with Low Hyperopia

Clinical Study Protocol

Protocol Version No. and Date: 1.1/2025.12.29

Clinical Trial Institution:

Shanghai General Hospital / Wang Xiaojuan

Leading Clinical Trial Institution / Coordinating Investigator:

Shanghai General Hospital / Wang Xiaojuan

Clinical Research Protocol Initiated by Investigators of Shanghai General Hospital

(Interventional Study)

Study Title	**A Multicenter, Randomized Controlled Clinical Study Evaluating the Efficacy of Dynamic Spatiotemporal Optical Film (S.T.O.P®KIT) in Retarding Axial Length Growth in Children with Low Hyperopia**
Protocol Version No.	V1.1
Version Date	December 29, 2025
Responsible Department	Department of Ophthalmology
Research Institution	Shanghai General Hospital
Participating Institutions	Research Center 1: Shanghai General Hospital; Research Center 2: The First Affiliated Hospital of Zhengzhou University; Research Center 3: Yantai Yuhuangding Hospital

Signature Page of the Principal Investigator's Protocol

I agree to perform the relevant duties in accordance with Chinese laws, the Declaration of Helsinki, Chinese GCP, and this research protocol, and to personally participate in or directly supervise this clinical study.

I will provide this protocol to all researchers under my responsibility who participate in this study and discuss the protocol and relevant materials with them to ensure they fully understand the research treatment/product and how to conduct this study.

During the implementation of the study, I will strictly adhere to the requirements of this protocol. If modifications to the protocol are necessary, they may only be implemented after notifying and obtaining re-approval or filing consent from the Ethics Committee, unless measures must be taken to protect the safety, rights, and interests of research participants. I will be responsible for making clinically relevant medical decisions, ensuring that research participants receive timely and appropriate treatment in the event of adverse events during the study, and recording and reporting these adverse events in accordance with relevant national regulations.

I guarantee that data will be recorded truthfully, accurately, completely, and in a timely manner, and commit to keeping the personal information and relevant matters of research participants confidential.

Principal Investigator (printed name):

Signature: _____

Institution: Shanghai General HospitalSignature

Date: September 2, 2025

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Version No.	Modification Date	Chapters and Modification Content	Reason for Modification

2. Protocol Summary

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<tr><td>Study Design</td><td colspan="2">This study is designed as a multicenter, parallel-group, open-label, randomized controlled, superiority trial. The randomization method is simple randomization, with grouping performed using a computer-generated random number generator.</td></tr>
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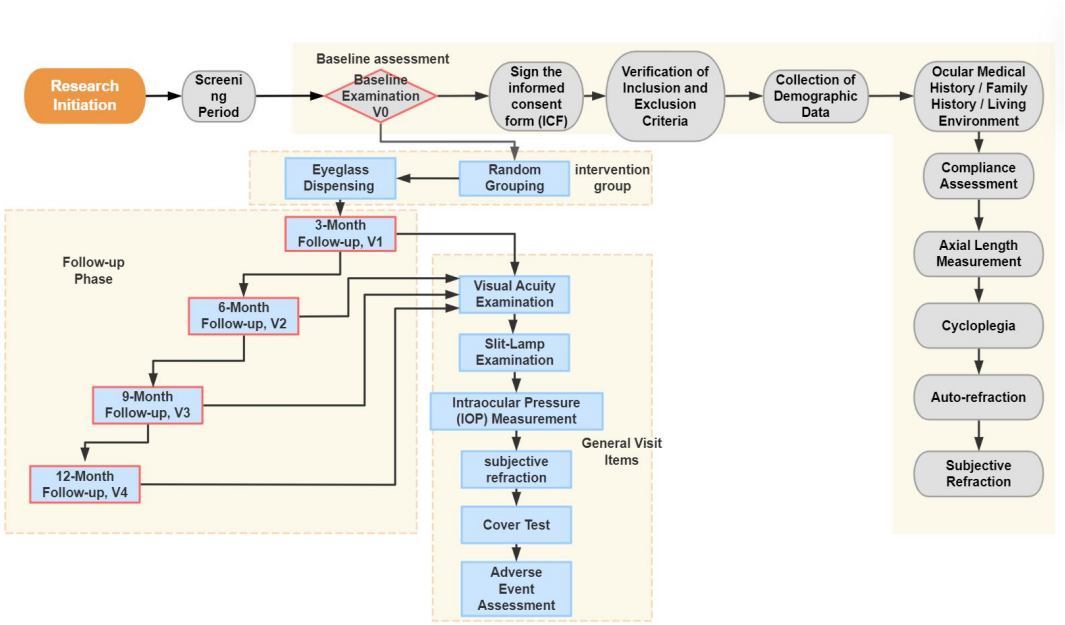
Study Population	Children aged 6-10 years with low hyperopia
Inclusion Criteria	1. Eligible study participants must meet all the following criteria: 1. Age: 6-10 years old; 2. +0.75D ≤ Spherical equivalent power ≤ +3.00D; 3. Anisometropia ≤ 1.50D; 4. Astigmatism ≤ 1.50D; 5. No participation in other myopia prevention and control studies or use of other myopia prevention and control methods (including low-concentration atropine eye drops, defocus eyeglasses, orthokeratology lenses, multifocal soft contact lenses, etc.) within 3 months; 6. Best-corrected visual acuity (BCVA) in both eyes ≥ 0.8 using a standard logarithmic visual acuity chart; 7. Ability to wear frame glasses during near work for at least 6 hours per day; 8. Study participants or their legal representatives sign the informed consent form.
Exclusion Criteria	Study participants meeting any of the following criteria are ineligible for inclusion: 1. Patients with strabismus; 2. Patients with abnormal stereopsis; 3. Comorbidity with other ophthalmic diseases, including developmental abnormalities affecting visual function and refractive status; 4. Previous ocular surgery history; 5. Previous receipt of other myopia control treatments (including orthokeratology lenses, multifocal design soft contact lenses or frame glasses, drug therapy [atropine], visual training, etc.); 6. Current use of medications that may affect pupil size and ocular surface function; 7. Comorbidity with other systemic diseases that may affect visual function

<table>
<tr><td></td><td>or refractive status;
8. Family history of hereditary ophthalmic diseases;
9. Other conditions deemed unsuitable for participation by investigators.</td></tr>
<tr><td>Sample Size</td><td>Experimental group: 90 cases;
Control group: 90 cases;
Total sample size: 180 cases</td></tr>
<tr><td>Study Grouping and Intervention Methods</td><td>Experimental group:
1. First, two pairs of eyeglasses need to be fitted, with S.T.O.P optical films of different phases attached regularly;
2. Follow-up visits are conducted every 3 months, and eyeglasses are replaced at 6 months (with changes in S.T.O.P optical film design and phase);
3. All lenses are plano-spherical and plano-cylindrical lenses (0D sphere, 0D cylinder);
4. Monitoring of axial length, visual acuity, and corresponding ophthalmic examinations are performed.
Control group:
1. No active intervention measures are implemented;
2. Re-examinations are conducted every 3 months.</td></tr>
<tr><td>Study Plan</td><td>1. Change in axial length from baseline to each follow-up visit for each of the experimental and control groups;
2. Difference in the change in spherical equivalent power measured by autorefractometer under cycloplegia from baseline to each follow-up visit between the experimental group and the control group;
3. Difference in visual function between the experimental group and the control group.
<table>
<tr><td>Procedures/Data</td><td>Baseline</td><td>3 Months</td><td>6 Months</td><td>9 Months</td><td>12 Months</td></tr>
</table>
</td></tr>
</table>

	Ocular history/Medical history/Family history/Living environment	-	-	-	-	
	Compliance assessment	√	√	√	√	
	Eyeglass fitting	√	-	√	-	-
	Visual acuity	√	√	√	√	√
	Slit-lamp examination (uncorrected): Ocular assessment	√	√	√	√	√
	Intraocular pressure (IOP)	√	√	√	√	√
	Axial length measurement	√	√	√	√	√
	Cycloplegia	√	-	-	-	√
	Autorefraction (objective refraction)	√	√	√	√	√
	Subjective refraction	-	†	†	†	†
	Cover test at 3m and 40cm	√	√	√	√	√
	Adverse event assessment	√	√	√	√	√
	Ocular	-	-	-	-	

	history/Medical history/Family history/Living environment					
	Compliance assessment	√	√	√	√	
	Eyeglass fitting	√	-	√	-	-
Statistical Analysis Method	Analysis of Covariance (ANCOVA)					
Estimated Study Period	February 1, 2026 (initiation) -August 1, 2027 (completion)					
Notes	1. Indicators such as children's growth and development and refractive status fluctuate naturally over time. A single measurement may be accidental. Four follow-up visits can provide a "dynamic baseline" to help researchers more accurately distinguish between normal fluctuations and true intervention effects. 2. Regular ophthalmic health follow-up and examinations actually provide these children with additional systematic health monitoring opportunities. 3. The process is simplified, with special personnel guiding the examinations, which will not impose an additional burden on parents and children.					

3. Technical Roadmap



4. Research Flow Chart

Procedures/Data	Baseline	3 Months	6 Months	9 Months	12 Months
Ocular history/Medical history/Family history/Living environment	-	-	-	-	
Compliance assessment	√	√	√	√	
Eyeglass fitting	√	-	√	-	-
Visual acuity	√	√	√	√	√
Slit-lamp examination (uncorrected): Ocular assessment	√	√	√	√	√
Intraocular pressure (IOP)	√	√	√	√	√
Axial length measurement	√	√	√	√	√
Cycloplegia	√	-	-	-	√
Autorefraction (objective refraction)	√	√	√	√	√
Subjective refraction	-	†	†	†	†
Cover test at 3m and 40cm	√	√	√	√	√
Adverse event assessment	√	√	√	√	√
Ocular history/Medical history/Family history/Living environment	-	-	-	-	
Compliance assessment	√	√	√	√	

Eyeglass fitting	√	-	√	-	-

5. Research Background

5.1. Current Status of Domestic and Foreign Research

As the focus of myopia management shifts from simply controlling myopia progression to comprehensive management of long-term risks, delaying the age of myopia onset has gradually become an important part of clinical practice in myopia prevention and control. Timely identification of early signs of myopia and implementation of intervention measures are particularly crucial, especially for children at risk of early onset and rapid progression once myopia develops. This conceptual innovation has spawned a series of cutting-edge studies and technological breakthroughs worldwide, advancing myopia management into an era of "prevention before control."

As a country with a high incidence of myopia, China has made breakthrough progress in the field of pre-myopia intervention. The 2025 "Myopia Management White Paper" for the first time established "pre-myopia" ($-0.50D < SE \leq +0.75D$) as a key intervention window, proposing that intervention measures should be initiated immediately when a child's annual myopia progression $\geq$ 0.75D or annual axial length growth $\geq$ 0.20mm. This standard is based on data from national multicenter studies, among which a real-world study conducted by Rao Jing's team confirmed that the use of multifocal defocus lenses (such as DIMS and HLA) in approximately 20 million 6-12-year-old children in the myopia critical state can significantly delay refractive progression and axial length growth, providing high-level evidence-based support for pre-myopia intervention. The rate of myopia progression is fastest around puberty. Wearing defocus glasses at the initial stage of myopia (usually within 100 degrees or just after diagnosis) is equivalent to setting an effective "speed bump" on the "highway" of myopia progression. Early intervention can maximize the inhibition of abnormal elongation of the axial length during the period of rapid growth, gaining valuable time for the entire myopia prevention and control journey.

Numerous clinical studies have confirmed that compared with wearing ordinary single-vision glasses, wearing defocus glasses can delay the annual increase in myopia degree by an average of 50%-60%. This means that a child who originally may have an annual increase of 100 degrees can have the annual increase controlled at 40-50 degrees after persistently wearing defocus glasses. The significance of this delaying effect is extremely important, as it can significantly reduce the

child's future risk of developing high myopia (exceeding 600 degrees), thereby reducing the probability of fundus lesions caused by high myopia (such as retinal detachment, macular degeneration, glaucoma, etc.).

5.2. International Research Trends

Global myopia prevention and control strategies show a trend of diversified development, and the combined application of optical intervention and drug therapy has become a frontier research direction. The research on the mechanism of action of optical defocus technology has been further deepened, and the peripheral retinal hyperopic defocus theory has been verified through primate models, confirming that it can inhibit abnormal axial length growth by regulating the activity of scleral fibroblasts. This discovery provides a solid theoretical basis for the design of defocus lenses.

Evidence-based Basis for Peripheral Defocus in Myopia Prevention and Control:Traditional theory holds that the occurrence and development of myopia are closely related to hyperopic defocus in the peripheral retina.

Emmetropia or hyperopia: Peripheral retinal imaging is in front of the retina, forming myopic defocus, which helps inhibit excessive axial length growth.

Myopia: Peripheral retinal imaging is behind the retina, forming hyperopic defocus, which stimulates axial length elongation and accelerates myopia progression.

Therefore, through specially designed optical products (such as special frame glasses or contact lenses), artificially creating myopic defocus signals in the peripheral retina can theoretically delay axial length growth, thereby controlling myopia.

Experimental Verification: In 2005 and subsequent animal experiments (such as rhesus monkeys, marmosets, etc.), Dr. Earl Smith's team actively manipulated peripheral retinal imaging through optical methods. They found that if the peripheral image focus can be moved from behind the retina to on or in front of the retina (i.e., eliminating or converting to myopic defocus), the axial length growth of experimental animals can be significantly reduced.

Neurophysiological Basis: Studies have also pointed out that the peripheral retina may play a dominant role in regulating eyeball growth, which may be related to factors such as the distribution of its ganglion cells.

The U.S. FDA has accelerated the approval of a number of myopia prevention and control devices

in recent years. Among them, aspheric microlens plano defocus glasses (such as MiYOSMART), as a special optical intervention product for pre-myopia, have obtained EU CE certification. Japan is promoting the research and development of personalized defocus soft contact lens systems, whose patented design achieves precise matching for patients with different pupil sizes by dynamically adjusting the proportion of defocus area (30%-50%) and defocus power (+1.50D-+4.00D). It is worth noting that the synergistic effect of combined therapy has become a research hotspot. A Singaporean clinical trial showed that the combined use of 0.01% atropine and orthokeratology lenses can reduce the risk of myopia progression by an additional 43% compared with single intervention, providing new ideas for the prevention and control of refractory myopia in China.

Table: Comparison of Characteristics of Main Intervention Methods for Pre-myopia

Intervention Type	Representative Products/Protocols	Applicable Stage	Core Advantages	Clinical Efficacy
Optical Intervention	Multifocal defocus frame glasses (DIMS/HLA)	Pre-myopia to low myopia	Non-invasive, worn during the day	Delays myopia progression by 45-60%
Optical Intervention	Aspheric microlens plano glasses	Period of rapid consumption of hyperopic reserve	No need for correction of refractive errors	Reduces myopia incidence by 33%
Drug Intervention	0.04% atropine eye drops	Rapid progression stage (>0.75D/year)	Minimal systemic absorption, convenient to use	Superior to 0.01% atropine and orthokeratology lenses

5.3. Research Value and Significance

5.3.1 Scientific Innovation Value

This project focuses on the optimization of pre-myopia intervention strategies and has significant scientific innovation and clinical transformation value. The study targets the blind spot of

traditional myopia management—the period of rapid consumption of hyperopic reserve (i.e., clinical pre-myopia stage), exploring the control effect of dynamic optical signals in optical intervention methods on preventing children with low hyperopia from rapidly developing into myopia. This research direction fills a key evidence gap: most current studies focus on intervention after myopia has occurred, while research on the prevention and control mechanisms in children with low hyperopia is insufficient, especially the synergistic mechanism of different intervention measures in delaying myopia onset has not been clarified.

6. Research Objectives

6.1. Primary Research Objective

To evaluate whether the experimental group achieves efficacy in preventing myopia progression rate (measured by axial length) compared with the control group.

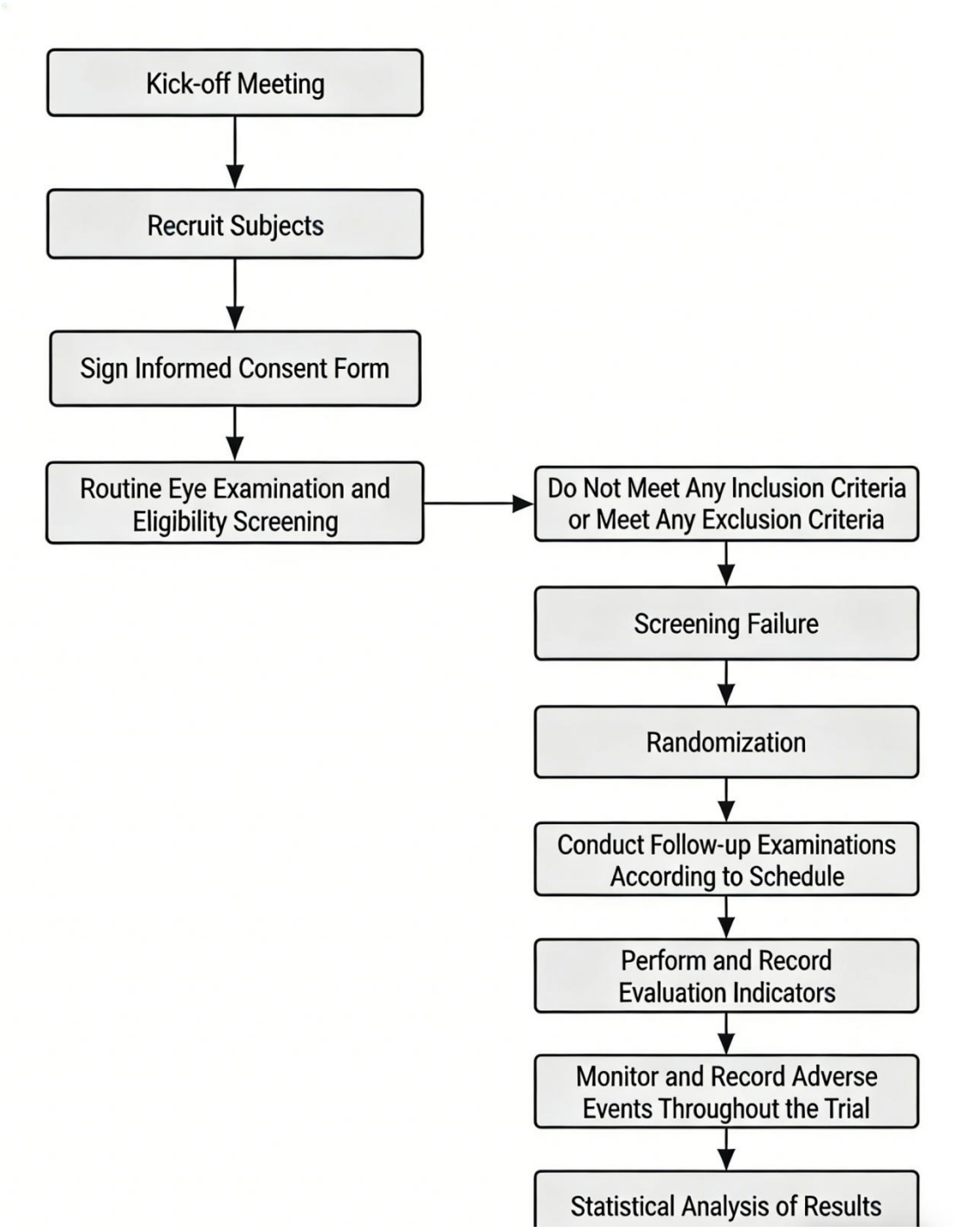
6.2. Secondary Research Objectives

To compare the difference in the change in spherical equivalent power measured by autorefractometer under cycloplegia between the experimental group and the control group.

7. Study Design

This study is designed as a multicenter, parallel-group, open-label, randomized controlled, superiority trial. The randomization method is simple randomization, with grouping performed using a computer-generated random number generator.

7.1 Study Flow Chart



(1) Subjects shall be patients who meet the inclusion and exclusion criteria of the protocol;

(2) Inform subjects of the clinical trial content, and have them understand and sign the Informed Consent Form;

(3) Conduct ocular examinations and screen for eligibility, and randomly assign eligible subjects to corresponding groups with random numbers;

(4) Issue experimental/control products;

(5) Investigators conduct follow-up examinations according to the follow-up schedule, record

follow-up data, and monitor adverse events throughout the trial;

(6) Collate and analyze trial data, and form a clinical trial report.

7.2. Study Implementation (Methods, Content, Procedures, etc.)

After subjects meet the inclusion and exclusion criteria, they shall be followed up in accordance with the clinical trial protocol. During the clinical period, adverse events shall be closely observed and recorded.

The following relevant examinations and operations shall be performed throughout the study:The trial steps are divided into: screening and enrollment, 3 months ± 7 days, 6 months ± 14 days, 9 months ± 14 days, 12 months - 28 days.

7.2.1 Signing of Written Informed Consent Form

- Collect subject information:
  - Concurrent diseases, past medical history, myopia prevention and control intervention history, surgical history, trauma history, etc.;
  - Concomitant medications, and determine whether there is concurrent ophthalmic drug therapy, especially atropine of different concentrations;
  - Conduct ocular examinations:

a. Axial length;

b. Refractive error;

c. Visual acuity, intraocular pressure, fundus color photography, OCT, eye position examination, and slit-lamp examination;

d. Cycloplegia shall be performed only at the baseline visit and at the end of the 12-month trial;

- Verify inclusion/exclusion criteria, and randomly assign eligible subjects to corresponding groups;
- Customize and issue products to the experimental group and the control group.

7.2.2 Follow-up Period

Follow-up visits shall be conducted 30 days, 3 months, 6 months, 9 months, and 12 months after intervention to complete the following assessments:

- Inquire whether any adverse events have occurred since the last follow-up;
- Inquire whether there have been any changes in concomitant medications or treatments since the last follow-up;

- Conduct ocular examinations:

  a. Axial length;

  b. Refractive error;

  c. Visual acuity, compliance assessment, refraction, and slit-lamp examination;

  d. Recording of experimental device defects and protocol deviations;

  e. Schedule the next follow-up visit with the subject.

7.2.3 Unscheduled Visits

Between two follow-up visits, if the subject experiences any discomfort or special conditions (such as any obvious discomfort, damage or loss of study products, etc.) and needs guidance or support from investigators, the subject may return to the research center for an unscheduled follow-up visit. During the unscheduled visit, the reason for the unscheduled visit and the measures taken by the investigator (including examinations or treatments provided, supplementary replacement and issuance of study products, etc.) shall be recorded.

8. Pre-assessment of Project Risks and Benefits

8.1 Risks of Participating in This Study

A very small number of children may experience symptoms such as dizziness, glare, and blurred vision in the initial stage of wearing the glasses. Most children can adapt spontaneously within one week after wearing. If adaptation is really difficult, please inform your research doctor in a timely manner; there are no other known risks at present.

8.2 Benefits of Participating in the Study

Direct benefits: If you agree to participate in this study, you may be able to delay the axial length growth of children through the S.T.O.P®KIT optical film, but we cannot make any promises in this regard.Potential benefits: We hope that the information obtained from your participation in this study can benefit you or other patients with the same condition in the future.In the control group of this trial, subjects who can adhere to completing all follow-up visits as required will receive a pair of dynamic optical films and customized glasses matching their diopter for free at the end of the trial.

9. Study Population

9.1. Inclusion Criteria

1) Patients must meet all the following inclusion criteria to be eligible for the study:

2) Age: 6-10 years old;
3) +0.75D ≤ Spherical equivalent power ≤ +3.00D;
4) Anisometropia ≤ 1.50D;
5) Astigmatism ≤ 1.50D;
6) No participation in other myopia prevention and control studies or use of other myopia prevention and control methods (including low-concentration atropine eye drops, defocus eyeglasses, orthokeratology lenses, multifocal soft contact lenses, etc.) within 3 months;
7) Best-corrected visual acuity (BCVA) in both eyes ≥ 0.8 using a standard logarithmic visual acuity chart;
8) Ability to wear frame glasses during near work for at least 6 hours per day;
9) Study participants or their legal representatives sign the informed consent form.

9.2. Exclusion Criteria

1) Patients meeting any of the following criteria will not be included in the study:
2) Patients with strabismus;
3) Patients with abnormal stereopsis;
4) Comorbidity with other ophthalmic diseases, including developmental abnormalities affecting visual function and refractive status;
5) Previous ocular surgery history;
6) Previous receipt of other myopia control treatments (including orthokeratology lenses, multifocal design soft contact lenses or frame glasses, drug therapy [atropine], visual training, etc.);
7) Current use of medications that may affect pupil size and ocular surface function;
8) Comorbidity with other systemic diseases that may affect visual function or refractive status;
9) Family history of hereditary ophthalmic diseases;
10) Other conditions deemed unsuitable for participation by investigators.

10. Intervention Protocol and Concomitant Treatment

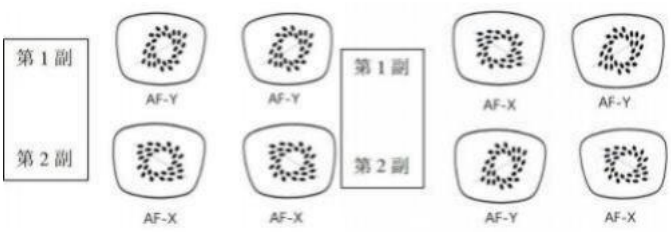
10.1. Study Intervention

Intervention methods:

1) First, two pairs of eyeglasses need to be fitted, with S.T.O.P optical films of different phases

attached regularly;

2) Follow-up visits are conducted every 3 months, and eyeglasses are replaced at 6 months (with changes in S.T.O.P optical film design and phase);
3) Monitoring of axial length, visual acuity, and corresponding ophthalmic examinations are performed;
4) All lenses are plano-spherical and plano-cylindrical lenses (0D sphere, 0D cylinder).



10.2. Concomitant Treatment

There is no concomitant treatment plan.

11. Randomization, Blinding, and Allocation Concealment Methods

11.1. Randomization Method: Simple Randomization

11.1.1 Definition

Simple randomization is the most basic and direct method of random assignment. It ensures that each subject who meets the inclusion criteria has an equal and independent chance of being assigned to any group in the trial (e.g., experimental group or control group).

11.1.2 Purpose

Balancing confounding factors: Theoretically, with a sufficiently large sample size, baseline characteristics (such as age, gender, disease severity) that are known or unknown and may be related to the outcome tend to be evenly distributed among the groups, making the groups comparable.Avoiding selection bias: Preventing investigators or subjects from choosing to enter a specific group based on their own wishes or judgments, thereby affecting the authenticity of the results.Meeting statistical assumptions: Providing a basis for subsequent statistical analyses (such as t-test, chi-square test).

11.1.3 Detailed Operational Description

Determine the allocation ratio: First, determine the expected allocation ratio of each group as 1:1, i.e., the number of subjects in the experimental group and the control group is equal;Generate a random sequence: Use a computer-generated random number sequence (using a true random

number generator or a validated pseudo-random algorithm).

12. Study Endpoints

12.1. Primary Study Endpoint

Difference in the change in axial length from baseline to 12 months after eyeglass fitting between the experimental group and the control group.

12.2. Secondary Study Endpoints

Difference in the change in spherical equivalent power measured by autorefractometer under cycloplegia from baseline to 12 months after eyeglass fitting between the experimental group and the control group.

13. Study Process

13.1. Study Subjects and Grouping

A total of 180 subjects will be included in this study, and evenly divided into the experimental group and the control group according to the randomization principle, with 90 cases in each group. Before enrollment, all subjects will undergo comprehensive ophthalmic examinations, including but not limited to visual acuity test, intraocular pressure measurement, slit-lamp examination, fundus examination, etc., to exclude severe ocular diseases or other factors that may affect the study results. After screening, eligible subjects will be formally included in the study.

13.2. Intervention Measures for the Experimental Group

13.2.1 Eyeglass Fitting and Optical Film Application

Based on the individual ocular parameters of each subject, two pairs of special eyeglasses will be customized for them. These eyeglasses all use plano-spherical and plano-cylindrical lenses (0D sphere, 0D cylinder) to ensure the unity of the basic refractive status. On this basis, S.T.O.P optical films of different phases will be accurately attached to the lenses. This optical film has a unique design and function, which can affect the propagation path and energy distribution of light to a certain extent, thereby potentially regulating the growth and development of the eye.

At the start of the trial, each subject will be provided with the first pair of eyeglasses with S.T.O.P optical films of a specific phase, and instructed on their correct wearing and use.

13.2.2 Follow-up Arrangements and Eyeglass Replacement

A strict follow-up system will be established, and comprehensive follow-up examinations will be conducted for subjects in the experimental group every 3 months. During each follow-up visit,

researchers will conduct a detailed understanding of the subject's eyeglass wearing situation, check for damage or deformation of the eyeglasses, and perform necessary adjustments and maintenance.

When the follow-up period reaches 6 months, the second pair of eyeglasses will be replaced for the subject. This replacement involves not only new lenses but also the redesign and adjustment of the phase of the S.T.O.P optical film. The purpose of this step is to continuously stimulate ocular tissues by changing the phase setting of the optical film, and observe its long-term impact on changes in axial length and visual acuity.

13.3. Monitoring Indicators and Examination Items

Throughout the study, the changes in axial length and visual acuity of the subjects will be closely monitored. As an important indicator reflecting the growth and development of the eyeball, the trend of axial length change is of great significance for evaluating the effect of intervention measures. Visual acuity examination will use a standard logarithmic visual acuity chart to record uncorrected visual acuity and corrected visual acuity respectively.

In addition to the above core indicators, corresponding ophthalmic examinations will also be performed, such as corneal topography, anterior chamber depth measurement, lens transparency assessment, etc. These examinations help to fully understand the structural and functional status of the subject's eyes, detect potential abnormalities in a timely manner, and provide rich data support for subsequent analysis and discussion.

13.4. Control Group Handling Measures

The 90 subjects in the control group will not receive any active intervention measures. However, to ensure the comparability of the study and the completeness of the data, regular re-examinations will also be arranged every 3 months. During the re-examination, only routine ophthalmic examinations will be performed, including basic items such as visual acuity test and intraocular pressure measurement, without any additional treatment or intervention measures. After the completion of the entire trial, subjects in the control group who adhere to completing all follow-up visits as required will receive a pair of dynamic optical films and customized glasses matching their diopter for free.

14. Termination of Study Intervention and Withdrawal/Termination of Study Subjects

14.1. Termination of Study Intervention

14.1.1 Voluntary Withdrawal by Subjects

Definition: Subjects voluntarily request to withdraw from the study due to personal reasons (such as inability to tolerate intervention measures, time conflicts, family factors, etc.).Handling principles: Respect the subject's decision, immediately stop all study intervention measures for them, and complete the final visit record (including vital signs, adverse reactions, and current ocular status).Data retention: Collected data will be included in the Intention-to-Treat (ITT) analysis, but subsequent follow-up will not be mandatory.

14.1.2 Termination Determined by Investigators

Applicable scenarios:

Severe adverse events: Occurrence of severe ocular or systemic adverse reactions related to the study intervention (such as corneal injury, allergic reactions, persistent increase in intraocular pressure);

Major protocol violations: Subjects fail to wear eyeglasses or undergo examinations as required by the protocol, and still do not cooperate after repeated reminders;

Risk of disease progression: Monitoring reveals rapid axial length growth, sharp decline in visual acuity, or other pathological changes requiring emergency medical intervention;

Other medical indications: Aggravation of comorbidities or new diseases affecting study safety.

Handling process: The termination will be decided after evaluation by the principal investigator and the ophthalmology expert team, and reported to the Ethics Committee and the sponsor for filing within 24 hours.

14.2. Withdrawal/Termination of Study Participants

Withdrawal decided by investigators refers to the situation where an enrolled study participant is deemed unsuitable to continue the study during the research process, and the investigator decides that the study participant withdraws from the study.

14.3. Voluntary Withdrawal of Study Participants from the Study

In accordance with the provisions of the Good Clinical Practice (GCP) for Drugs, the Declaration of Helsinki, and the informed consent form, study participants have the right to withdraw from the study midway. If a study participant does not explicitly propose to withdraw from the study but no longer accepts study treatment/drugs or blood collection and is lost to follow-up, it is also considered withdrawal/dropout. If a study participant decides to withdraw, every effort should be

made to complete the withdrawal visit.

14.4. Loss to Follow-up

When a study participant cannot be contacted, research staff must make every effort to contact the study participant to confirm whether the study participant has discontinued the drug/withdrawn from the study and record the reason for withdrawal. To ensure follow-up of study participants, the research center must obtain primary and secondary contact information (such as home, work, and mobile phone numbers) as well as other contact information (such as WeChat) before randomization. In addition, before randomization, the investigator must emphasize the importance of follow-up information to the study participant, and the measures taken during follow-up must be recorded.

14.5. Follow-up Handling After Withdrawal of Study Participants

Investigators must fill in the reason for terminating the study treatment/research drug treatment or withdrawing from the study in the original medical record. They should contact the study participant to complete the early withdrawal visit as much as possible (conduct the withdrawal visit within 7 days of withdrawing from the study), fill in the last follow-up record form for treatment, and record the time of the last receipt of the study treatment/drug as much as possible. For those who withdraw due to adverse events (AEs) and are finally judged to be related to the study treatment/drug after follow-up, it must be recorded in the case report form (CRF). Regardless of the reason, for withdrawn cases, the records in their CRFs should be retained.

15. Adverse Events

15.1. Classification and Severity of Adverse Events

15.1.1 Early Adaptive Reactions (Mild/Self-limiting)

Symptom	Mechanism of Occurrence	Incidence	Treatment Recommendations
Blurred vision/Dizziness	The brain needs to adapt to the optical differences in the peripheral defocus area	Approximately 30%-50%	Gradually extend the daily wearing time (starting from 2 hours and increasing); explain that it is a

			normal phenomenon to eliminate anxiety
Decreased contrast sensitivity	Increased higher-order aberrations affect the recognition of light-dark boundaries	Approximately 20%-40%	Adjust the frame position to ensure the optical center is aligned with the pupil; regularly recheck visual quality
Diminished spatial localization sense	Peripheral visual field distortion interferes with depth perception	Approximately 15%-30%	Avoid fine operations such as driving/working at heights initially; it is recommended to turn on ambient lighting when wearing at night
Decreased contrast sensitivity	Increased higher-order aberrations affect the recognition of light-dark boundaries	Approximately 20%-40%	Adjust the frame position to ensure the optical center is aligned with the pupil; regularly recheck visual quality

15.2. Ocular Tissue Reactions (Requiring Close Monitoring)

15.2.1 Corneal Surface Abnormalities

- Manifestations: Corneal staining (positive fluorescein staining), epithelial microdefects;
- Inducing factors: Lens edge friction, insufficient tear exchange;
- High-risk groups: Patients with a history of dry eye, patients with narrow palpebral fissures;
- Interventions:
- Switch to high oxygen permeability lenses (silicone hydrogel material is preferred);
- Combine with artificial tear therapy (preservative-free formulations are recommended);

- Suspend wearing if necessary until complete recovery.

15.2.2 Conjunctival Hyperemia and Papillary Hypertrophy

- Characteristics: Eyelid conjunctival vascular dilation in a reticular pattern, accompanied by small papillary protrusions;
- Differential diagnosis: Need to exclude giant papillary conjunctivitis (GPC);
- Treatments:

1) Strengthen the lens care process (daily protease removal cleaning);
2) Short-term use of low-concentration steroid eye drops (under the guidance of a physician);
3) Replace lenses of different brands to test tolerance.

15.2.3 Decreased Tear Film Stability

- Detection indicator: Non-invasive tear meniscus height measurement < 0.2mm;
- Warning signs: Recurrent foreign body sensation, burning sensation;
- Solutions:

1) Prefer lenses with wet-angle curing treatment;
2) Use viscous artificial tears before bedtime;
3) Consider using moisture chamber glasses.

15.3. Functional Visual Impairments (Moderate to Severe)

Symptom Cluster	Typical Manifestations	Potential Risks	Treatment Plan
Exacerbated accommodation lag	Difficulty in switching from near work to distance vision after prolonged near work	May accelerate myopia progression	Implement accommodation function training combined with low-concentration atropine medication
Binocular visual function disorders	Decreased stereoscopic acuity, narrowed fusion range	Affect career choices (such as pilots)	Conduct binocular visual function rehabilitation training
Color perception	Mild decrease in	Restrictions on	Provide color

deviation	blue-yellow color discrimination ability	occupations such as art design	correction auxiliary tools

15.4. Follow-up and Recording of Adverse Events

All adverse medical events occurring from the first time the study participant receives the study product until the end of the study/early withdrawal visit will be collected in this study. All adverse events, regardless of severity and causal relationship with the study treatment/research drug, must be recorded by the investigator in the corresponding adverse event page of the CRF.

15.5. Reporting of Adverse Events

From the signing of the informed consent form until the end of the study, all adverse events (whether related to the study treatment/research drug or not) must be recorded in the CRF.

15.6. Reporting of Serious Adverse Events (SAEs)

Any SAEs occurring during the study should follow the SAE reporting procedures specified by Chinese regulations or the Independent Ethics Committee. Investigators should take the following measures:

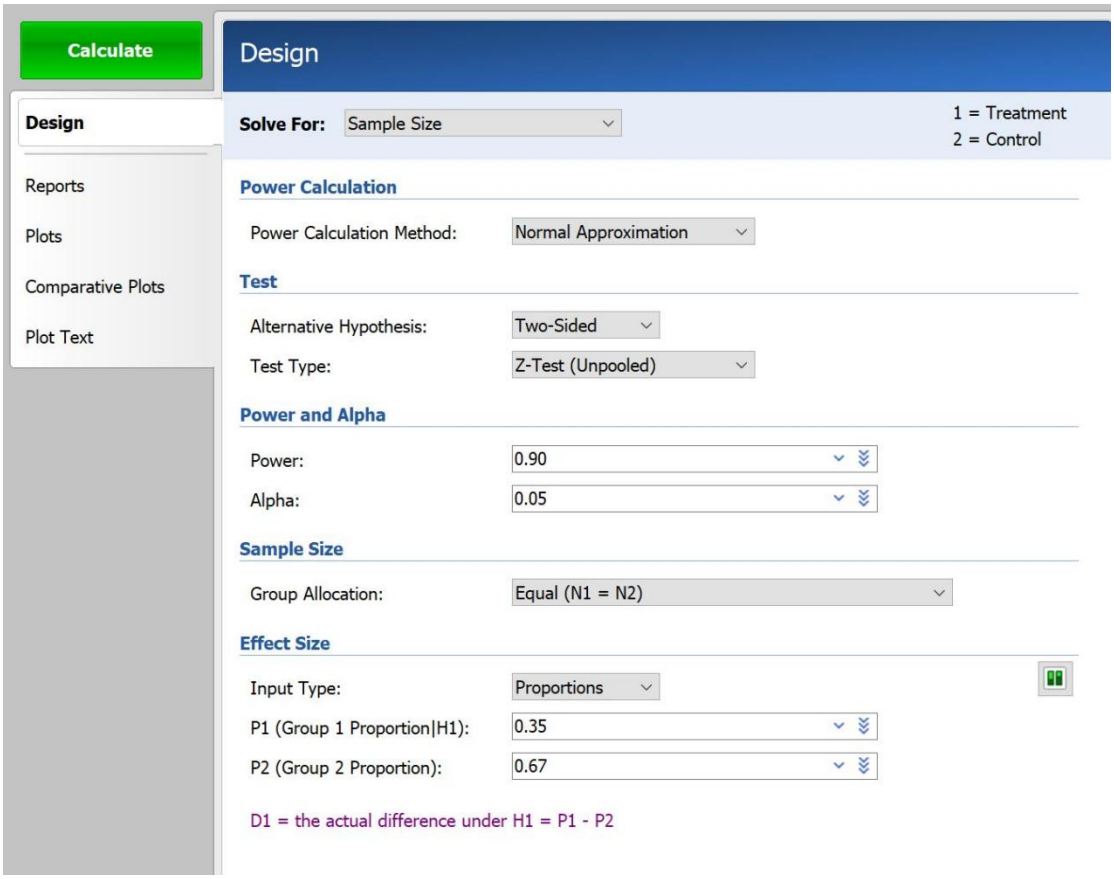
1) Immediately take appropriate medical measures if necessary;
2) Record the SAE in the original documents, the adverse event form of the CRF, and other applicable SAE report forms;
3) The investigator should immediately (within 24 hours of learning of the event) submit the signed and dated SAE report form to the Ethics Committee and copy it to the Clinical Research Center (shiyicss@126.com) in accordance with the requirements of the research center;
4) Follow up and record the course of the event until it resolves, returns to the baseline level, reaches a clinically stable outcome, or the study participant is lost to follow-up.

16. Statistical Analysis

16.1. Basis for Sample Size Determination

The sample size of this study is calculated using PASS software. This study is a randomized controlled trial with two groups: the experimental group and the control group. The axial length of the study subjects is the primary outcome indicator. Referring to the "Expert Consensus on the Application of Axial Length in Myopia Prevention and Control Management (2023)", a yearly axial length growth ≤ 0.20mm is defined as effective control. Based on literature review and

previous clinical trials, the expected effective rate is 67% in the experimental group and 35% in the control group. A two-sided α = 0.05 and a power of 90% are set. Calculations are performed using PASS 15 software.



The total sample size for the two groups is N = 94 cases. Considering the possibility of loss to follow-up and refusal to participate, a dropout rate of 20% is assumed for each group. Therefore, the final total required sample size for the experimental group and the control group is 118 cases, with at least 59 cases in each group.

Dropout-Inflated Sample Size

	Sample Size			Dropout-Inflated Enrollment Sample Size			Expected Number of Dropouts		
Dropout Rate	N1	N2	N	N1'	N2'	N'	D1	D2	D
20%	47	47	94	59	59	118	12	12	24

16.2. Analysis Sets

The Full Analysis Set (FAS) refers to the ideal set of study participants that is as close as possible to the intention-to-treat principle (the primary analysis should include all randomized study participants). This dataset is derived from all randomized study participants with minimal and reasonable exclusions, generally including all randomized study participants who have received at

least one treatment.

16.3. Statistical Analysis Methods

Descriptive statistical methods will be used to summarize and present the baseline data of the study subjects. Continuous variables will be expressed as mean (standard deviation), categorical variables as frequency (constituent ratio), and skewed distributed variables as median (interquartile range). Inter-group comparisons of quantitative indicators will use t-test or Wilcoxon rank-sum test according to the data distribution, categorical indicators will use chi-square test or exact probability method (if chi-square test is not applicable), and ordinal data will use Wilcoxon rank-sum test or CMH test.

17. Data Management

This randomized controlled trial uses paper case report forms (CRFs) for data collection, and a research database will be established through electronic entry subsequently. Data managers will design standardized paper CRFs according to the requirements of the study protocol to ensure clear logic and ease of filling. Special RCT-specific forms such as randomization record forms, treatment allocation forms, compliance assessment forms, primary endpoint assessment forms, and adverse event report forms will be designed, including standardized entry formats and coding rules for all study variables.

The randomization procedure will adopt an independent central randomization system or randomization envelopes to ensure the integrity of allocation concealment. Investigators or clinical research coordinators will be responsible for promptly, truthfully, completely, and accurately recording all relevant data of each study participant during the study in the paper CRFs, including the screening and enrollment process, randomization information, treatment implementation, efficacy evaluation, safety monitoring, compliance evaluation, and dropout/withdrawal, ensuring legible handwriting and accurate information.

Data entry will adopt a double-independent entry mode, with data entry personnel trained in GCP entering data according to the paper CRFs. Special attention will be paid to the accuracy of randomization sequence numbers, consistency of treatment allocation, completeness of primary endpoint data, and accurate classification of adverse events during entry. After the two independent entries are completed, consistency checks will be performed, and inconsistent data items will be verified and corrected to ensure the accuracy of key data.

Data managers will establish a standardized quality control procedure for this study, and regularly perform quality checks through database queries or statistical software scripts, focusing on randomization balance checks, baseline characteristic comparability verification, primary endpoint data completeness assessment, treatment compliance analysis, adverse event report completeness checks, dropout pattern analysis, and missing data impact assessment. Quality control will pay special attention to key data quality issues that may affect the interpretation of trial results.

When data issues are identified, data managers will generate standardized data query forms, detailing the issues to be clarified, including key issues such as randomization procedure execution, treatment allocation accuracy, primary endpoint event determination, adverse event causal relationship assessment, treatment compliance evaluation, and dropout reason analysis. After receiving the query form, the investigator will provide a written response and sign for confirmation. For complex issues involving endpoint event determination, an independent endpoint event assessment committee may make a ruling.

Data entry personnel will make corresponding data modifications and entries according to the investigator's responses. A complete written record of the entire query handling process will be established, including the query content, response process, clinical judgment basis, and final handling results, to ensure the traceability and scientificity of data modifications. Special attention will be paid to the handling of key data queries affecting primary efficacy analysis and safety evaluation.

After all data queries are resolved, data managers will perform the final data cleaning, generate a "clean" dataset and a data quality report. The quality report will include key clinical trial quality indicators such as randomization execution, baseline characteristic balance, primary endpoint data completeness rate, treatment compliance distribution, adverse event occurrence, and dropout/withdrawal analysis. A data audit meeting will then be organized, with the participation of the principal investigator, statistical analysts, data managers, clinical trial monitors, and quality control personnel.

The data audit meeting will comprehensively review the randomization quality, treatment implementation, primary endpoint data quality, safety data completeness, and the impact of missing data on different analysis sets, and make decisions on the handling of outliers and missing data. It will be confirmed that the data quality meets the requirements of ITT analysis,

Per-Protocol Set (PPS) analysis, and safety analysis. Representatives of all parties will sign the data audit resolution based on full discussions, specifically confirming the quality and completeness of the data required for primary efficacy analysis and safety evaluation.

After the data audit is passed, data managers will execute the database locking procedure, establish version control records for the final analysis dataset, generate the ITT analysis set, PPS analysis set, and safety analysis set respectively, and submit the locked data to the statistical analysis team. Paper CRFs will be properly kept as original data, and a complete trial document management system will be established, including randomization records, treatment allocation documents, data collection forms, query handling records, and endpoint event ruling records.

Any data changes required after the database is locked must have sufficient scientific basis and clinical rationality, and can only be executed after the joint signature and approval of the principal investigator, statistician, data manager, and monitor. The complete process of the change and its potential impact on the analysis results will be detailed recorded. The study will establish strict data security and confidentiality measures to maintain the blinding integrity of the blinded trial, restrict data access rights, and de-identify data involving personal identification information to ensure compliance with relevant requirements and regulations.

18. Quality Control

18.1. Protocol Design Quality Control

Before the implementation of the study protocol, investigators will organize experts in related fields such as adolescent myopia prevention and control to demonstrate the study protocol to ensure its scientificity and feasibility. During the study, if necessary, the research team may revise the study protocol in accordance with specified procedures. All revisions must be approved by the Ethics Committee and promptly notified to all study participants.

18.2. Qualification Quality Control of Participating Personnel

The designers of the study protocol must have optometry knowledge/background. The principal investigator should have a medical qualification/background. Data managers should have clinical trial data management experience. Statistical analysts must have a biostatistics background and be familiar with clinical trial statistical analysis methods.

The research team will conduct unified training for all study participants, covering detailed interpretation of the study protocol, standardized operating procedures for equipment, study

participant recruitment and screening criteria, data collection and recording specifications, adverse event identification and reporting procedures, and data management.

For other clinical operators, they must hold professional qualifications in relevant fields (such as practicing nurse, technician qualification certificate, etc.) and have at least 3 years of relevant operational experience. All clinical operators must be familiar with the operational procedures involved in the study, receive unified training, and pass the assessment.

The research team will regularly evaluate the standardization of surgical and clinical operations, and record the quality control of relevant operations to ensure the scientificity and consistency of operations.

18.3. Management and Preservation of Test Data

The research team will completely preserve all original data related to the study, including original readings of test equipment, image data, etc., and properly preserve original documents such as participant questionnaires.

Data in the data collection forms will be derived from and consistent with the original documents. All test results, participant-reported outcomes, and follow-up information will be filled into the database in a timely, accurate, complete, standardized, and truthful manner. Researchers are not allowed to modify data arbitrarily. If corrections are needed due to filling errors, any corrections made will be traced in the data records, and the reason for the correction will be recorded.

Special data managers will be responsible for preserving all relevant materials involved in the study, including original examination and test data, participant screening and enrollment materials, statistical analysis data and reports, etc., for a period of not less than 2 years after the end of the study.

18.4. Statistical Analysis Quality Control

The statistical analysis process and result expression of the study will adopt internationally recognized statistical methods. The research team has formulated a detailed statistical analysis plan in the study protocol, which will be confirmed and refined before the official statistical analysis. Statistical analysts will be independent of the data collection process to ensure the objectivity of the analysis. The statistical analysis report will include detailed methodological descriptions and result interpretations.

18.5. Whole-Process Quality Control

The research team will conduct systematic inspections of the relevant activities and documents of the study, evaluate whether the study is conducted in accordance with the study protocol, standard operating procedures, and relevant regulations, check whether the study data is recorded in a timely, truthful, accurate, and complete manner, and verify whether the distribution, use, and recovery of study drugs comply with the protocol requirements.

Audits will be conducted by independent personnel not directly involved in the study. The first audit is planned to be conducted within 3 months after the study initiation, followed by regular audits every 6 months. The audit content will include the informed consent process, implementation of inclusion/exclusion criteria, standardization of clinical examination operations, completeness of data records, etc.

When study participants fail to conduct the study in accordance with the approved protocol or relevant regulations, the study director will promptly point out and require corrections. All protocol deviations will be recorded, and major deviations will be promptly reported to the Ethics Committee. The research team will establish deviation prevention and correction measures to ensure the continuous improvement of study quality.

19. Ethical Protection and Informed Consent in Clinical Research

Clinical research will comply with the relevant provisions of the World Medical Association's Declaration of Helsinki and the National Health and Family Planning Commission of the People's Republic of China's Measures for the Ethical Review of Biomedical Research Involving Humans, specifically implementing informed consent, protecting privacy, research free of charge and compensation, risk control, protection of special study participants, and principles and requirements for compensation for research-related damages. Before the start of the study, the clinical research will be implemented only after the study protocol is approved by the Ethics Review Committee. Before each study participant is enrolled in the study, the investigator is responsible for fully and comprehensively introducing the purpose, procedures, and potential risks of the study to the study participant and/or their legal representative, and having them sign a written informed consent form. The study participant should be informed that their participation in the clinical research is completely voluntary, and they can refuse to participate or withdraw from the study at any stage of the trial without discrimination or retaliation, and their medical treatment and rights will not be affected. The informed consent form should be retained for inspection as a

clinical research document to effectively protect the personal privacy and data confidentiality of study participants.