Supplemental Online Content

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Low-concentration Atropine for Myopia Prevention (LAMP-2) Study

Protocol

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Low-concentration Atropine for Myopia Prevention (LAMP-2) Study

Contents

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2. Introduction & background

Myopia is a worldwide public health issue, and is highly prevalent in Hong Kong [1-3]. It is predicted that around half and one-tenth of the world's population will become myopic and highly myopic respectively by year 2025 [4, 5]. Highly myopic individual has excessive eyeball growth and therefore a higher risk of sight-threatening complications, including glaucoma, cataract, retinal detachment, and other stretch-induced degenerative changes of retinal pigment epithelium, choroid and sclera [6]. In China, about 36.5% fourth graders and 65.3% eighth graders have poor eyesight [7]. Prevention of childhood myopia progression is exceedingly important. In view of that, President Xi Jinping has recently remarked the need to control myopia in China for a better children's eye health and bright future [8]. A subsequent national scheme, which was jointly issued by Ministry of Education, the National Health Commission and six other departments, has been announced planning to reduce myopia rate amongst 6-year-olds to 3%, among primary school students to below 38%, and junior and senior high school students below 60% and 70% respectively, by year 2030 [9].

Despite decades of scientific research in the causes of myopia, its exact etiology remains unclear. Environmental pressures, such as the rigorous education system in Hong Kong demanding heavy near work from intensive reading papers or electronic screens, are attributed to the high prevalence of myopia. Electronic device usage is inevitable in children in Hong Kong nowadays. Furthermore, Chinese are at a higher risk of myopia development genetically. [4,5] It is notable that children start to develop myopia as early as age of four, with fast progression phase from age eight to twelve, and then slow down till around age eighteen. Myopia, once developed and progressed, is irreversible. Therefore, timely measure to prevent myopia onset and its progression during aged four to twelve is exceedingly crucial [7].

Different interventions have been attempted to reduce myopic progression, including increasing outdoor time [10-12], optical methods such as bifocal/progressive spectacles [13-16], orthokeratology [17, 18], and defocus spectacles and contact lens [19], and pharmacological methods including atropine eye drops [20-24]. A Cochrane database systemic review concluded that anti-muscarinic agents including atropine eye drop were the most effective anti-myopia treatment [25]. A meta-analysis of 16 different interventions also demonstrated that atropine eye drops confer the best efficacy among all myopia prevention methods [26]. American Academy of Ophthalmology also recommended its use [27].

Atropine is a nonselective muscarinic receptor antagonist with many postulated mechanisms for its anti-myopia actions, including its biochemical effects on retina and sclera for eyeball remodeling [28, 29]. Atropine in the Treatment of Myopia (ATOM 1) study revealed that daily regimen of 1% atropine eye drops reduced myopia progression by 77% when compared with placebo eye drops treatment over a 2-year period [21]. However, side effects included cycloplegia and pupil dilatation resulting in blurred near vision and photophobia respectively. Subsequent ATOM 2 study from the same group showed that lower concentrations of topical atropine (0.5%, 0.1% and 0.01%) one drop nightly over two years were effective in reducing annual myopia progression to -0.3+/-0.6D, -0.38+/-0.6D, and -0.49+/-0.63D, respectively [22]. Because of minimal side effects, and less rebound after stopping the treatment, the authors recommended 0.01% atropine as the optimal concentration [20]. The use of low-concentration atropine is further supported by other groups from United State [30], and Taiwan [31-34]. Nevertheless, the true efficacy and the optimal concentration of this emerging therapy remained unclear.

While current literatures focus on slowing down the myopia progression, only very few is on preventing the onset of myopia. Unfortunately, after the onset of myopia in children, its progression is very difficult to control [35]. It is therefore much more important to prevent the onset of myopia, rather than slowing down the progression. To our knowledge, there is only one study that has evaluated the use of medical intervention to prevent the onset of myopia [35]. In a retrospective study of 24 children in the treatment group using 0.025% atropine nightly versus 26 children in the control group without any intervention, there was a significant lower proportion of onset of myopia along one-year follow-up period in the treatment group versus the control group (21% vs 54%). This study was however limited by its retrospective nature and small sample size [35].

In the past 15 years, our group has been working extensively on myopia research: determining the prevalence of myopia by population-based children eye study [1, 3, 36], identifying risk factors of progression [36-38], genetic factors for myopia [39-44], imaging features of myopic eyes [45, 46], and evaluating different treatment interventions for myopia [20, 24, 47]. PI of this proposal Dr. Jason Yam is PI of Low-Concentration Atropine for Myopia Progression (LAMP) study [24], and an ongoing population-based cohort Hong Kong Children Eye Study [45]. Based on the current evidence, we hypothesize that low-concentration atropine have an effect in preventing the onset of myopia. We propose to conduct a RCT to investigate the effectiveness of using 0.05% atropine and 0.01% atropine comparing with placebo control group to prevent the onset of myopia.

The protocol is complied with the ICH-GCP.

3. Objectives

To determine the effectiveness of using 0.05% and 0.01% atropine in preventing the onset of myopia.

4. Materials & methods

i. Study design

Double blinded randomized clinical trial

Eligible children will be randomized into 3 groups:

- Treatment Group: 0.01% atropine both eyes once daily
- Treatment Group:0.05% atropine both eyes once daily
- Placebo Group: lubricant eye drops both eyes once daily

Children will be offered photochromatic glasses if they experienced glare or their parents were worried of excessive light exposure, or progressive glasses if children experienced difficulty with near vision.

The treatment will be continued for three years.

Cross over treatment for the placebo group after two years onwards:
For the first two years, all the groups remained unchanged
After two years of treatment, children from the placebo group will remain in the placebo group until they have onset of myopia with SE <-0.5D. That is, they will be switched to group 0.05% during the third year once they have onset of myopia.

Treatment group of 0.01% and 0.05% atropine will remain in the same group for three years throughout the whole study period.

ii. Eligibility

Inclusion criteria

- Age 4 to 9
- SE ： 0~ +1.0 D
- Astigmatism: < 1.00 D;
- Anisometropia: < 2.0 D;
- at least one parent whose SER≤-3.00D;
- Informed parental consent.

Exclusion criteria

- Ophthalmic diseases other than refractive errors
- Previous use of treatment of atropine
- Allergy or intolerance to atropine
- Inability to attend regular follow up assessment

iii. Rationale:

- The age limit of 4-9 years old is set because of two reasons:
  1) Age younger than 4 years old will be very difficult for accurate cycloplegic examination and biometry measurement.
  2) Early onset myopes tend to be a fast progressor. Thus age older than 9 will not be included.
- Our on-going population-based study Hong Kong Children Eye Study revealed parental myopia is the most significant predictive factor for children to develop myopia: compared to having both non-myopic parents, having one moderate myopic parent confer 2 folds risk, and having both highly myopic parents 12 folds risk, for children to develop myopia (unpublished data). Therefore, only those children with at least one parent moderate myopic will be recruited.

iv. Sample Size

To calculate the required number of study subjects, we took the estimated myopia onset rate for 0.05%, and 0.01% atropine and placebo groups to be and 6.6%, 14.6%, 20% respectively. The 0.05% atropine group should have the smallest number of myopic onset, thus a minimum of 5 to 10 myopia children should be observed. To detect a difference among treatment groups, a sample size of 375 subjects (125 per group) could achieve 90% power at a 0.05 significance level. By factoring in an attrition rate of 20%, a sample size of 474 subjects (158 per group) would be needed.

v. Study methods

This is a double-blinded randomized control trial, last for three years.

All participating children will be randomized into one of the following groups in 1:1:1 ratio:

v.1 Initial Visit (Appendix C)

Aim:

- To obtain informed consent
- To confirm the eligibility
- To obtain baseline data

History

- Ocular history: history of ocular disease and operation
- Refraction
- Systemic review

Examination (Appendix C)

- Best corrected visual acuity for near and distant (EDTRS) charts
- Near aided visual acuity
- Cover and uncover test to test ocular alignment
- Extraocular movement
- Pupil size
- Intraocular pressure by non-contact tonometry (NCT)
- Measurement of accommodation amplitude by Royal Air Force near point rule
- Instillation of cycloplegic agent
  a. Wash hands.
  b. Tilt patient's head back and make a pouch with the lower cul-de-sac. Install one (1) drop of Mydrin-P and cyclopentolate eye drop. Releases pouch and apply pressure on the inner canthus for a period of ten seconds to minimize systemic absorption. Repeat for the other eye.
  c. After a ten (10) minute interval, repeat step 2.
  d. After a further ten (10) minute interval, repeat step 2 such that a total of three (3) drops of Mydrin-P and cyclopentolate are instilled into each eye.
  e. Perform auto refraction thirty (30) minutes after the last set of drops.

- Cycloplegic autorefraction
  a. Turn the power switch ON. The target rings will appear on the TV monitor.
  b. Set the instrument on the R/K mode. It will be automatically set if this was the mode when the machine was turned off.
  c. Instruct the patient to place his chin on the chin rest and forehead on the headrest gently. Adjust the machine height so that the patient's eye level will meet the eye level indicator when looking straight ahead.
  d. Place the patient's eye in the middle of the TV monitor by manipulating the joystick. Focus on the blinking light by manipulating the joystick back and forth and make sure it is inside the inner target ring.
  e. Instruct the patient to look at the picture and to hold his/her eyes open wide. He/she should refrain from blinking during the measurement procedure.
  f. Press the start button.
  g. Repeat (e&f) for at least 3 readings.
- Choroid thickness measured by DRI Swept Source Optical Coherence Tomography.
- Slit-lamp examination & binocular indirect ophthalmoscopy examination
- Ocular biometry by IOL master
  - Perform six measurements of total axial length, anterior chamber length and corneal curvatures at least 3 measurements are identical or almost identical. Discord outline. Print results.
- Questionnaire
  - Parental history of myopia
  - Parental educational level
  - Self-reported visual function questionnaire

- Questionnaires on amount of near works and out-door activities. (Appendix E)

Randomization
Block randomization will be used to assign consecutive cases into either treatment arm in the proposed RCT. The block size could be 3, 6 or 9 (the actual block size will be kept confidential to all of the investigators and participating staffs except for the statistician who design the randomization strategies). Since age has been shown to be a major factor that associated with the onset of myopia, we will randomize eligible subjects in 8 strata separately (i.e. 1)age 4-6 female in +1.00D≤SE<+0.50D, 2)age 4-6 male in +1.00D≤SE<+0.50D, 3)age 4-6 female in +0.50D≤SE≤0.00D, 4)age 4-6 male in +0.50D≤SE≤0.00D, 5)age 7-9 female in +1.00D≤SE<+0.50D, 6)age 7-9 male in +1.00D≤SE<+0.50D, 7)age 7-9 female in +0.50D≤SE≤0.00D, and 8)age 7-9 male in +0.50D≤SE≤0.00D). Randomization table will be generated and kept confidential by a statistician independently. Only the staff who is designated as the person to obtain the randomization code can get access to the table and assign treatment arms for each study subject. The investigator, the patient and the staff who conducts the follow-up examinations will be kept unaware of the randomization information. In the study design, we have taken into account the possible effect of covariates on the estimated sample size.

Blinding method
- The assignment of groups will not be disclosed to the subjects (including their parents) and investigators.
- All types of eye drops (atropine 0.01%, 0.05% and lubricant) will be contained in the same type of bottle.
- All the optometrists responsible for assessing the study outcomes will be blinded to the treatment given to each of the children.
- The statistician will also be blinded to the assigned treatment for each child.

Dispensing
- Eye drops will be given to children according to randomization

iv.2 Visit 2 at 2 weeks after the treatment (Baseline 2 + assessment of tolerance)
Examination as in visit 1
Cycloplegic refraction at visit 2 will be used as baseline 2 for future comparison of myopia progression if any, as hyperopic shift may occur after commencing atropine eye drops.
Children will be offered photochromatic glasses if they experience glare or their parents are worried about excessive light exposure, or progressive glasses if children experience difficulty with near vision.

iv. 3 Visits 3-11 (Treatment follow-up visits, every 4 months)
- To assess study outcomes
- To assess compliance by history, amount of drug used
- To assess complications
- To update glasses prescription if SE change > 0.75D
- Examination as visit 1.
- After a total of 3 year (Visit 11), the children will be assessed. Treatment

will stop after this visit.

iv. 4 Switch over of placebo group after the second year

The placebo group will be switched to the optimal group (0.05% or 0.01% atropine depending on the pilot data collected from the second year) during the third year when SE ≤ -0.5D. Subject will be kept in the placebo group when SE remains > -0.5D.
0.05% and 0.01% atropine groups will be kept in the respective group during the whole three-year period.

iv. 5 Unscheduled visit

The children are advised to come back for assessment when any problems with the treatments arised, such as deterioration of vision, treatment complications. The children will have detailed examination. New prescription will be given when indicated. When there is severe side effect associated with the treatment, the treatment will be stopped. The children will be asked to come back at the original schedule after the unscheduled visit

iv.6 Visit schedule

Visit 1	Day 0 (Baseline 1)
Visit 2	Week 2 (Baseline 2 + assessment of tolerance)
Visit 3	Month 4 (Treatment follow-up visits)
Visit 4	Month 8 (Treatment follow-up visits)
Visit 5	Month 12 (Treatment follow-up visits)
Visit 6	Month 16 (Treatment follow-up visits)
Visit 7	Month 20 (Treatment follow-up visits)
Visit 8	Month 24 (Treatment follow-up visits)
Visit 9	Month 28 (Treatment follow-up visits)
Visit 10	Month 32 (Treatment follow-up visits)
Visit 11	Month 36 (Treatment follow-up visits)

v. Study outcome & assessment

Efficacy:

- **Primary outcome**: Proportion of onset of myopia and proportion of fast myopia progressor in each group.
- **Secondary outcome**: Myopic progression is measured by change in spherical equivalent refraction (SER). Cycloplegic refraction is assessed by using an auto-refractometer. Eyeball growth is measured by change in axial length, using the IOL master.

Definition of outcome:
Myopia was defined as a spherical equivalent refractive error of at least -0.50D, based on the Refractive Error Study in Children.

Confounding factors (Appendix C):
Age, parental histories of myopia, outdoor activities, rate of myopia progression prior treatment, and initial SER are potential confounding factors of myopic progression.

Safety:

- Questionnaire for self-reported visual function
- Best corrected visual acuity using EDTRS chart
- Intraocular pressures measured by applanation
- Pupil size in room light measured by pupillometer
- Measurement of accommodation amplitude by Royal Air Force near point rule
- Ocular and systemic symptoms
- Ocular signs assessed by slit lamp biomicroscopy and binocular indirect ophthalmoscopy
- Heart rate and blood pressure

vi. Analysis

- Intention-to-treat analysis will be employed.
- The proportion of onset of myopia and proportion of fast myopic progressor in each treatment group are the primary outcome measures. Change from baseline SER and axial length in the treatment group and the control group are the secondary outcome measures. These will be analyzed by multiple regression models. Baseline measurements, treatment group, parental history of myopia, age, and their interaction will be used as factors in the model. The analysis of safety measures made on categorical or frequency scales will be based on chi-square statistics. Analysis of Variance (ANOVA) model will be built up to identify the treatment effect, period effect, carry-over effect and their interaction

vii. Adverse effects & patient withdrawal / exit from study

Atropine is known to occasionally cause the following:

Systemic: tachycardia, respiratory stress, allergic dermatitis
Ocular: increase in IOP, phototoxicity, early presbyopia

These potential side-effects must be closely monitored and quantified. We propose to examine the physical integrity of the cornea, lens and retina. They will be examined with direct examination, serial photography and specular microscopy. In addition, the intraocular pressure is measured with. The data then can be used to project the proportion of the patient population (4-9 year-olds) that may become sensitive to topical atropine.

Ethics considerations

- The atropine trial must be terminated if a better alternative can be identified and having become available.
- For children that are allergy or intolerance to atropine, atropine treatment will be stopped.
- It is well noted that atropine treatment is attended by side effects of mydriasis and cycloplegia. Although short-term and long-term studies revealed few side effects, concerns for retinal phototoxicity are real. Moreover, bifocals do not allow clear vision at all distance and this blurred image might also cause myopic progression. Photochromatic progressive glasses will be prescribed to children for mydriasis and cycloplegia induced by atropine.

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Prevention of Myopia onset using ultra-low dose atropine (PRE-MYO Study)

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2. Introduction & background

Myopia is an important public health issue in Hong Kong, which has one of the highest prevalence rates of myopia in the world, approximately three times that of United States, more than ten times that of Middle East, and nearly twice that in South America [1]. Its prevalence in Hong Kong school children was around 18.3% to 30% at six years of age and 53% to 61.5% at twelve years of age [1-2]. Among preschool children, its prevalence has increased significantly from 2.3% to 6.3% over a ten-year period [3]. The World Health Organization (WHO) recognizes that uncorrected myopia is a major cause of visual impairment [4]. More importantly, myopia is associated with many sight-threatening complications that cannot be prevented by optical correction. These complications include pre-senile cataract, glaucoma, retinal detachment, and characteristic degenerative changes of the sclera, retinal pigment epithelium, and choroid [5]. The degenerative changes are related to mechanical stretching of the involved tissue as the eyeball lengthens in myopic eyes [5]. With all these complications, the increased prevalence of myopia will become a major public health and economic burden.

Despite decades of scientific research in the causes of myopia, its exact etiology remains unclear. Currently, both the genetic and environmental factors are believed to be important risk factors for the development of myopia. Amount of near work and time spent on outdoor activities may be the risk factor and protective factor respectively for myopia development. [6-7] Our group has previously demonstrated that children with a parental history of myopia are more likely to develop myopia [8] and has identified a number of genes associated with myopia [9-14].

Different interventions have been attempted to reduce the myopic progression, including optical under-correction with spectacles [15], bifocal lenses [16], progressive lenses [17] and contact lenses [18]. However, results from these studies are disappointing and no strong evidence in reducing myopia progression has been shown following the use of these measures. Currently, atropine eye drops is the most promising measure to slow down the myopia progression or even prevent its onset. It is a nonselective muscarinic receptor antagonist and there have been many postulated mechanisms for its anti-myopia actions, which include inhibition of accommodation, biochemical remodeling of sclera, and increase in ultraviolet exposure secondary to pupil dilatation [19].

As shown in the Atropine in the Treatment of Myopia (ATOM 1) study, daily regimen of 1% atropine eye drops was found to significantly reduce the progression of myopia by 77% when compared with placebo eye drops treatment over a 2-year period [19]. However, cessation of drug administration led to a partial rebound effect [20]. Additionally, the associated side effects of photophobia due to mydriasis and blurred near vision due to cycloplegia have significantly prohibited wide adoption of atropine use internationally. Recently, the ATOM 2 study showed that a lower concentration of topical atropine (0.5%, 0.1% and 0.01%) one drop nightly over two years may be effective in reducing myopia progression by 75%, 68% and 59% respectively, when compared with the historical placebo group in the ATOM 1 study [21]. Among the groups of 0.5%, 0.1% and 0.01% atropine, the ocular safety profile are much better in the lower dose atropine group, with 70%, 61%, and 6% children requiring progressive glasses respectively.

While current literatures focus on slowing down the myopia progression, only very few is on preventing the onset of myopia. Unfortunately, after the onset of myopia in children, its progression is very difficult to control. [22] It is therefore much more important to prevent the onset of myopia, rather than slowing down the progression. To our knowledge, there is only one study that has evaluated the use of medical intervention to prevent the onset of myopia. [22] In a retrospective study of 24 children in the treatment group using 0.025%

atropine nightly versus 26 children in the control group without any intervention, there was a significant lower proportion of onset of myopia along one year follow-up period in the treatment group versus the control group (21% vs 54%). This study was however limited by its retrospective nature and small sample size. [22]

Work by us

In the past 15 years, our group has been working on determining the prevalence of myopia [1,3], identifying risk factors of progression [8] and genetic factors[9-14] for myopia, and evaluating different treatment interventions for myopia [24-25].

Based on the current evidence, we hypothesize that 0.01% atropine have an effect in preventing the onset of myopia. We propose to conduct a RCT to investigate the effectiveness of using 0.01% low dose atropine comparing with placebo control group to prevent the onset of myopia.

The protocol is complied with the ICH-GCP.

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4. Materials & methods

i. Study design

Double blinded randomized clinical trial

Eligible children will be randomized into 3 groups:

- Treatment Group: 0.01% atropine both eyes once daily
- Treatment Group:0.05% atropine both eyes once daily
- Placebo Group: lubricant eye drops both eyes once daily

Children will be offered photochromatic glasses if they experienced glare or their parents were worried of excessive light exposure, or progressive glasses if children experienced difficulty with near vision.

The treatment will be continued for two years.

Cross over treatment for the placebo group at one year onwards:
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ii. Eligibility

Inclusion criteria

- Age 4 to 9
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- Informed parental consent

Exclusion criteria
- Ophthalmic diseases other than refractive errors
- Previous use of treatment of atropine
- Allergy or intolerance to atropine
- Inability to attend regular follow up assessment

iii. Sample Size

Sample sizes of 100 in control group (lubricant) and 100 in treatment group (0.01% low dose atropine) and 100 in (0.05%low dose atropine), will achieve 90.5% power to detect a difference of 0.29 in the myopia incident rate between the three groups. We assume the incident rate of the control group to be 0.50 and the incident rate of the treatment group to be 0.21, based on the literature. [22] The test statistic used is the two-sided Score test (Farrington & Manning). The significance level of the test will be set to 0.050. A final sample size of 300 (100 in each group) should be used considering a follow-up rate of 90%.

iv. Study methods

iv.1 Initial Visit (Appendix C)

Aim:
- To obtain informed consent
- To confirm the eligibility
- To obtain baseline data

History
- Ocular history: history of ocular disease and operation
- Refraction
- Systemic review

Examination (Appendix C)
- Best corrected visual acuity for near and distant (EDTRS) charts
- Near aided visual acuity
- Cover and uncover test to test ocular alignment
- Extraocular movement
- Pupil size
- Intraocular pressure by non-contact tonometry (NCT)
- Measurement of accommodation amplitude by Royal Air Force near point rule
- Instillation of cycloplegic agent
  a. Wash hands.
  b. Tilt patient's head back and make a pouch with the lower cul-de-sac. Install one (1) drop of Mydrin-P and cyclopentolate eye drop. Releases pouch and apply pressure on the inner canthus for a period of ten seconds to minimize systemic absorption. Repeat for the other eye.
  c. After a ten (10) minute interval, repeat step 2.
  d. After a further ten (10) minute interval, repeat step 2 such that a total of three (3) drops of Mydrin-P and cyclopentolate are instilled into each eye.
  e. Perform auto refraction thirty (30) minutes after the last set of drops.

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a. Turn the power switch ON. The target rings will appear on the TV monitor.
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f. Press the start button.
g. Repeat (e&f) for at least 3 readings.

- Choroid thickness measured by DRI Swept Source Optical Coherence Tomography.
- Slit-lamp examination & binocular indirect ophthalmoscopy examination
- Ocular biometry by IOL master
  - Perform six measurements of total axial length, anterior chamber length and corneal curvatures at least 3 measurements are identical or almost identical. Discord outline. Print results.
  -
- Questionnaire
  - Parental history of myopia
  - Parental educational level
  - Self-reported visual function questionnaire
  - Questionnaires on amount of near works and out-door activities. (Appendix E)

Randomization

Block randomization will be used to assign consecutive cases into either treatment arm in the proposed RCT. The block size could be 4, 6 or 8 (the actual block size will be kept confidential to all of the investigators and participating staffs except for the statistician who design the randomization strategies). Since age has been shown to be a major factor that associated with the onset of myopia, we will randomize eligible subjects in two age groups separately (i.e. age 4-6; and age 7-9). Randomization table will be generated and kept confidential by a statistician independently. Only the staff who is designated as the person to obtain the randomization code can get access to the table and assign treatment arms for each study subject. The investigator, the patient and the staff who conducts the follow-up examinations will be kept unaware of the randomization information. In the study design, we have taken into account the possible effect of covariates on the estimated sample size.

Blinding method

- The assignment of groups will not be disclosed to the subjects (including their parents) and investigators.
- All types of eye drops (atropine 0.01%, 0.05% and lubricant) will be contained in the same type of bottle.
- All the optometrists responsible for assessing the study outcomes will be blinded to the treatment given to each of the children.

- The statistician will also be blinded to the assigned treatment for each child.

Dispensing

- Eye drops will be given to children according to randomization

iv.2 Visit 2 at 2 weeks after the treatment (Baseline 2 + assessment of tolerance)
Examination as in visit 1
Cycloplegic refraction at visit 2 will be used as baseline 2 for future comparison of myopia progression if any, as hyperopic shift may occur after commencing atropine eye drops.
Children will be offered photochromatic glasses if they experience glare or their parents are worried about excessive light exposure, or progressive glasses if children experience difficulty with near vision.

iv. 3 Visits 3-8 (Treatment follow-up visits, every 4 months)

- To assess study outcomes
- To assess compliance by history, amount of drug used
- To assess complications
- To update glasses prescription if SE change > 0.75D
- Examination as visit 1.
- After a total of 2 year (Visit 8), the children will be assessed. Treatment will stop after this visit.

iv. 4 Unscheduled visit

The children are advised to come back for assessment when any problems with the treatments arised, such as deterioration of vision, treatment complications. The children will have detailed examination. New prescription will be given when indicated. When there is severe side effect associated with the treatment, the treatment will be stopped. The children will be asked to come back at the original schedule after the unscheduled visit

iv.5 Visit schedule

Visit 1	Day 0 (Baseline 1)
Visit 2	Week 2 (Baseline 2 + assessment of tolerance)
Visit 3	Month 4 (Treatment follow-up visits)
Visit 4	Month 8 (Treatment follow-up visits)
Visit 5	Month 12 (Treatment follow-up visits)
Visit 6	Month 16 (Treatment follow-up visits)
Visit 7	Month 20 (Treatment follow-up visits)
Visit 8	Month 24 (Treatment follow-up visits)

v. Study outcome & assessment

Efficacy:

- Primary outcome: Proportion of onset of myopia and proportion of fast myopia progressor in each group.

- Secondary outcome: Myopic progression is measured by change in spherical equivalent refraction (SER). Cycloplegic refraction is assessed by using an auto-refractometer. Eyeball growth is measured by change in axial length, using the IOL master.

Confounding factors (Appendix C):

Age, parental histories of myopia, outdoor activities, rate of myopia progression prior treatment, and initial SER are potential confounding factors of myopic progression.

Safety:

- Questionnaire for self-reported visual function
- Best corrected visual acuity using EDTRS chart
- Intraocular pressures measured by applanation
- Pupil size in room light measured by pupillometer
- Measurement of accommodation amplitude by Royal Air Force near point rule
- Ocular and systemic symptoms
- Ocular signs assessed by slit lamp biomicroscopy and binocular indirect ophthalmoscopy
- Heart rate and blood pressure

vi. Analysis

- Intention-to-treat analysis will be employed.
- The proportion of onset of myopia and proportion of fast myopic progressor in each treatment group are the primary outcome measures. Change from baseline SER and axial length in the treatment group and the control group are the secondary outcome measures. These will be analyzed by multiple regression models. Baseline measurements, treatment group, parental history of myopia, age, and their interaction will be used as factors in the model. The analysis of safety measures made on categorical or frequency scales will be based on chi-square statistics. Analysis of Variance (ANOVA) model will be built up to identify the treatment effect, period effect, carry-over effect and their interaction

vii. Adverse effects & patient withdrawal / exit from study

Atropine is known to occasionally cause the following:

Systemic: tachycardia, respiratory stress, allergic dermatitis
Ocular: increase in IOP, phototoxicity, early presbyopia

These potential side-effects must be closely monitored and quantified. We propose to examine the physical integrity of the cornea, lens and retina. They will be examined with direct examination, serial photography and specular microscopy. In addition, the intraocular pressure is measured with. The data then can be used to project the proportion of the patient population (4-9 year-olds) that may become sensitive to topical atropine.

Ethics considerations

- The atropine trial must be terminated if a better alternative can be identified and having become available.
- For children that are allergy or intolerance to atropine, atropine treatment will be stopped.
- It is well noted that atropine treatment is attended by side effects of mydriasis and cycloplegia. Although short-term and long-term studies revealed few side effects, concerns for retinal phototoxicity are real. Moreover, bifocals do not allow clear vision at all distance and this blurred image might also cause myopic progression. Photochromatic progressive glasses will be prescribed to children for mydriasis and cycloplegia induced by atropine.

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Prevention of Myopia onset using ultra-low dose atropine (PRE-MYO Study)

Contents

1. List of Investigators

Principal investigator: Dr. Jason C.S. Yam [1,2,3]
Co-investigators: Dr. LJ Chen[1,3]

1. Department of Ophthalmology & Visual Sciences, The Chinese University of Hong Kong
2. Hong Kong Eye Hospital
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- Questionnaire
  - Parental history of myopia
  - Parental educational level
  - Self-reported visual function questionnaire
  - Questionnaires on amount of near works and out-door activities. (Appendix E)

Randomization

Block randomization will be used to assign consecutive cases into either treatment arm in the proposed RCT. The block size could be 4, 6 or 8 (the actual block size will be kept confidential to all of the investigators and participating staffs except for the statistician who design the randomization strategies). Since age has been shown to be a major factor that associated with the onset of myopia, we will randomize eligible subjects in two age groups separately (i.e. age 4-6; and age 7-9). Randomization table will be generated and kept confidential by a statistician independently. Only the staff who is designated as the person to obtain the randomization code can get access to the table and assign treatment arms for each study subject. The investigator, the patient and the staff who conducts the follow-up examinations will be kept unaware of the randomization information. In the study design, we have taken into account the possible effect of covariates on the estimated sample size.

Blinding method

- The assignment of groups will not be disclosed to the subjects (including their parents) and investigators.
- All types of eye drops (atropine 0.01%, 0.05% andlubricant) will be contained in the same type of bottle.

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- The statistician will also be blinded to the assigned treatment for each child.

Dispensing

- Eye drops will be given to children according to randomization

iv.2 Visit 2 at 2 weeks after the treatment (Baseline 2 + assessment of tolerance)
Examination as in visit 1
Cycloplegic refraction at visit 2 will be used as baseline 2 for future comparison of myopia progression if any, as hyperopic shift may occur after commencing atropine eye drops.
Children will be offered photochromatic glasses if they experience glare or their parents are worried about excessive light exposure, or progressive glasses if children experience difficulty with near vision.

iv. 3 Visits 3-8 (Treatment follow-up visits, every 4 months)

- To assess study outcomes
- To assess compliance by history, amount of drug used
- To assess complications
- To update glasses prescription if SE change > 0.75D
- Examination as visit 1.
- After a total of 1 year (Visit 5), the children will be assessed. Treatment will stop after this visit.

iv. 4 Unscheduled visit

The children are advised to come back for assessment when any problems with the treatments arised, such as deterioration of vision, treatment complications. The children will have detailed examination. New prescription will be given when indicated. When there is severe side effect associated with the treatment, the treatment will be stopped. The children will be asked to come back at the original schedule after the unscheduled visit

iv.5 Visit schedule

Visit 1	Day 0 (Baseline 1)
Visit 2	Week 2 (Baseline 2 + assessment of tolerance)
Visit 3	Month 4 (Treatment follow-up visits)
Visit 4	Month 8 (Treatment follow-up visits)
Visit 5	Month 12 (Treatment follow-up visits)
Visit 6	Month 16 (Treatment follow-up visits)
Visit 7	Month 20 (Treatment follow-up visits)
Visit 8	Month 24 (Treatment follow-up visits)

v. Study outcome & assessment

Efficacy:

- Primary outcome: Proportion of onset of myopia and proportion of fast myopia progressor in each group.
- Secondary outcome: Myopic progression is measured by change in spherical equivalent refraction (SER). Cycloplegic refraction is assessed by using an auto-refractometer. Eyeball growth is measured by change in axial length, using the IOL master.

Confounding factors (Appendix C):

Age, parental histories of myopia, outdoor activities, rate of myopia progression prior treatment, and initial SER are potential confounding factors of myopic progression.

Safety:

- Questionnaire for self-reported visual function
- Best corrected visual acuity using EDTRS chart
- Intraocular pressures measured by applanation
- Pupil size in room light measured by pupillometer
- Measurement of accommodation amplitude by Royal Air Force near point rule
- Ocular and systemic symptoms
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- Heart rate and blood pressure

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- Intention-to-treat analysis will be employed.
- The proportion of onset of myopia and proportion of fast myopic progressor in each treatment group are the primary outcome measures. Change from baseline SER and axial length in the treatment group and the control group are the secondary outcome measures. These will be analyzed by multiple regression models. Baseline measurements, treatment group, parental history of myopia, age, and their interaction will be used as factors in the model. The analysis of safety measures made on categorical or frequency scales will be based on chi-square statistics. Analysis of Variance (ANOVA) model will be built up to identify the treatment effect, period effect, carry-over effect and their interaction

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Atropine is known to occasionally cause the following:

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Prevention of Myopia onset using ultra-low dose atropine (PRE-MYO Study)

Contents

1. List of Investigators

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2. Hong Kong Eye Hospital
3. Prince of Wales Hospital

2. Introduction & background

Myopia is an important public health issue in Hong Kong, which has one of the highest prevalence rates of myopia in the world, approximately three times that of United States, more than ten times that of Middle East, and nearly twice that in South America [1]. Its prevalence in Hong Kong school children was around 18.3% to 30% at six years of age and 53% to 61.5% at twelve years of age [1-2]. Among preschool children, its prevalence has increased significantly from 2.3% to 6.3% over a ten-year period [3]. The World Health Organization (WHO) recognizes that uncorrected myopia is a major cause of visual impairment [4]. More importantly, myopia is associated with many sight-threatening complications that cannot be prevented by optical correction. These complications include pre-senile cataract, glaucoma, retinal detachment, and characteristic degenerative changes of the sclera, retinal pigment epithelium, and choroid [5]. The degenerative changes are related to mechanical stretching of the involved tissue as the eyeball lengthens in myopic eyes [5]. With all these complications, the increased prevalence of myopia will become a major public health and economic burden.

Despite decades of scientific research in the causes of myopia, its exact etiology remains unclear. Currently, both the genetic and environmental factors are believed to be important risk factors for the development of myopia. Amount of near work and time spent on outdoor activities may be the risk factor and protective factor respectively for myopia development. [6-7] Our group has previously demonstrated that children with a parental history of myopia are more likely to develop myopia [8] and has identified a number of genes associated with myopia [9-14].

Different interventions have been attempted to reduce the myopic progression, including optical under-correction with spectacles [15], bifocal lenses [16], progressive lenses [17] and contact lenses [18]. However, results from these studies are disappointing and no strong evidence in reducing myopia progression has been shown following the use of these measures. Currently, atropine eye drops is the most promising measure to slow down the myopia progression or even prevent its onset. It is a nonselective muscarinic receptor antagonist and there have been many postulated mechanisms for its anti-myopia actions, which include inhibition of accommodation, biochemical remodeling of sclera, and increase in ultraviolet exposure secondary to pupil dilatation [19].

As shown in the Atropine in the Treatment of Myopia (ATOM 1) study, daily regimen of 1% atropine eye drops was found to significantly reduce the progression of myopia by 77% when compared with placebo eye drops treatment over a 2-year period [19]. However, cessation of drug administration led to a partial rebound effect [20]. Additionally, the associated side effects of photophobia due to mydriasis and blurred near vision due to cycloplegia have significantly prohibited wide adoption of atropine use internationally. Recently, the ATOM 2 study showed that a lower concentration of topical atropine (0.5%, 0.1% and 0.01%) one drop nightly over two years may be effective in reducing myopia progression by 75%, 68% and 59% respectively, when compared with the historical placebo group in the ATOM 1 study [21]. Among the groups of 0.5%, 0.1% and 0.01% atropine, the ocular safety profile are much better in the lower dose atropine group, with 70%, 61%, and 6% children requiring progressive glasses respectively.

While current literatures focus on slowing down the myopia progression, only very few is on preventing the onset of myopia. Unfortunately, after the onset of myopia in children, its progression is very difficult to control. [22] It is therefore much more important to prevent the onset of myopia, rather than slowing down the progression. To our knowledge, there is only one study that has evaluated the use of medical intervention to prevent the onset of myopia. [22] In a retrospective study of 24 children in the treatment group using 0.025%

atropine nightly versus 26 children in the control group without any intervention, there was a significant lower proportion of onset of myopia along one year follow-up period in the treatment group versus the control group (21% vs 54%). This study was however limited by its retrospective nature and small sample size. [22]

Work by us

In the past 15 years, our group has been working on determining the prevalence of myopia [1,3], identifying risk factors of progression [8] and genetic factors[9-14] for myopia, and evaluating different treatment interventions for myopia [24-25].

Based on the current evidence, we hypothesize that 0.01% atropine have an effect in preventing the onset of myopia. We propose to conduct a RCT to investigate the effectiveness of using 0.01% low dose atropine comparing with placebo control group to prevent the onset of myopia.

The protocol is complied with the ICH-GCP.

3. Objectives

To determine the effectiveness of using 0.01% atropine in preventing the onset of myopia.

4. Materials & methods

i. Study design

Double blinded randomized clinical trial

Eligible children will be randomized into 3groups:

- Treatment Group: 0.01% atropine both eyes once daily
- Treatment Group:0.05% atropine both eyes once daily
- Placebo Group: AIM lubricant both eyes once daily

Children will be offered photochromatic glasses if they experienced glare or their parents were worried of excessive light exposure, or progressive glasses if children experienced difficulty with near vision.

The treatment will be continued for one year.

ii. Eligibility

Inclusion criteria

- Age 4 to 9
- SE > -1.0D and < +1.0 D
- Astigmatism: < 1 D
- Informed parental consent

Exclusion criteria

- Ophthalmic diseases other than refractive errors
- Previous use of treatment of atropine
- Allergy or intolerance to atropine
- Inability to attend regular follow up assessment

iii. Sample Size

Sample sizes of 100 in control group (AIM lubricant) and 100 in treatment group (0.01% low dose atropine) and 100 in (0.05%low dose atropine), will achieve 90.5% power to detect a difference of 0.29 in the myopia incident rate between the two groups. We assume the incident rate of the control group to be 0.50 and the incident rate of the treatment group to be 0.21, based on the literature. [22] The test statistic used is the two-sided Score test (Farrington & Manning). The significance level of the test will be set to 0.050. A final sample size of 300 (100 in each group) should be used considering a follow-up rate of 90%.

iv. Study methods

iv.1 Initial Visit (Appendix C)

Aim:

- To obtain informed consent
- To confirm the eligibility
- To obtain baseline data

History

- Ocular history: history of ocular disease and operation
- Refraction
- Systemic review

Examination (Appendix C)

- Best corrected visual acuity for near and distant (EDTRS) charts
- Near aided visual acuity
- Cover and uncover test to test ocular alignment
- Extraocular movement
- Pupil size
- Intraocular pressure by non-contact tonometry (NCT)
- Measurement of accommodation amplitude by Royal Air Force near point rule
- Instillation of cycloplegic agent
  a. Wash hands.
  b. Tilt patient's head back and make a pouch with the lower cul-de-sac. Install one (1) drop of Mydrin-P and cyclopentolate eye drop. Releases pouch and apply pressure on the inner canthus for a period of ten seconds to minimize systemic absorption. Repeat for the other eye.
  c. After a ten (10) minute interval, repeat step 2.
  d. After a further ten (10) minute interval, repeat step 2 such that a total of three (3) drops of Mydrin-P and cyclopentolate are instilled into each eye.
  e. Perform auto refraction thirty (30) minutes after the last set of drops.

- Cycloplegic autorefraction
  a. Turn the power switch ON. The target rings will appear on the TV monitor.
  b. Set the instrument on the R/K mode. It will be automatically set if this was the mode when the machine was turned off.
  c. Instruct the patient to place his chin on the chin rest and forehead on the headrest gently. Adjust the machine height so that the patient's eye level will meet the eye level indicator when looking straight ahead.
  d. Place the patient's eye in the middle of the TV monitor by manipulating the joystick. Focus on the blinking light by manipulating the joystick back

and forth and make sure it is inside the inner target ring.
e. Instruct the patient to look at the picture and to hold his/her eyes open wide. He/she should refrain from blinking during the measurement procedure.
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Prevention of Myopia onset using ultra-low dose atropine (PRE-MYO Study)

Contents

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2. Introduction & background

Myopia is an important public health issue in Hong Kong, which has one of the highest prevalence rates of myopia in the world, approximately three times that of United States, more than ten times that of Middle East, and nearly twice that in South America [1]. Its prevalence in Hong Kong school children was around 18.3% to 30% at six years of age and 53% to 61.5% at twelve years of age [1-2]. Among preschool children, its prevalence has increased significantly from 2.3% to 6.3% over a ten-year period [3]. The World Health Organization (WHO) recognizes that uncorrected myopia is a major cause of visual impairment [4]. More importantly, myopia is associated with many sight-threatening complications that cannot be prevented by optical correction. These complications include pre-senile cataract, glaucoma, retinal detachment, and characteristic degenerative changes of the sclera, retinal pigment epithelium, and choroid [5]. The degenerative changes are related to mechanical stretching of the involved tissue as the eyeball lengthens in myopic eyes [5]. With all these complications, the increased prevalence of myopia will become a major public health and economic burden.

Despite decades of scientific research in the causes of myopia, its exact etiology remains unclear. Currently, both the genetic and environmental factors are believed to be important risk factors for the development of myopia. Amount of near work and time spent on outdoor activities may be the risk factor and protective factor respectively for myopia development. [6-7] Our group has previously demonstrated that children with a parental history of myopia are more likely to develop myopia [8] and has identified a number of genes associated with myopia [9-14].

Different interventions have been attempted to reduce the myopic progression, including optical under-correction with spectacles [15], bifocal lenses [16], progressive lenses [17] and contact lenses [18]. However, results from these studies are disappointing and no strong evidence in reducing myopia progression has been shown following the use of these measures. Currently, atropine eye drops is the most promising measure to slow down the myopia progression or even prevent its onset. It is a nonselective muscarinic receptor antagonist and there have been many postulated mechanisms for its anti-myopia actions, which include inhibition of accommodation, biochemical remodeling of sclera, and increase in ultraviolet exposure secondary to pupil dilatation [19].

As shown in the Atropine in the Treatment of Myopia (ATOM 1) study, daily regimen of 1% atropine eye drops was found to significantly reduce the progression of myopia by 77% when compared with placebo eye drops treatment over a 2-year period [19]. However, cessation of drug administration led to a partial rebound effect [20]. Additionally, the associated side effects of photophobia due to mydriasis and blurred near vision due to cycloplegia have significantly prohibited wide adoption of atropine use internationally. Recently, the ATOM 2 study showed that a lower concentration of topical atropine (0.5%, 0.1% and 0.01%) one drop nightly over two years may be effective in reducing myopia progression by 75%, 68% and 59% respectively, when compared with the historical placebo group in the ATOM 1 study [21]. Among the groups of 0.5%, 0.1% and 0.01% atropine, the ocular safety profile are much better in the lower dose atropine group, with 70%, 61%, and 6% children requiring progressive glasses respectively.

While current literatures focus on slowing down the myopia progression, only very few is on preventing the onset of myopia. Unfortunately, after the onset of myopia in children, its progression is very difficult to control. [22] It is therefore much more important to prevent the onset of myopia, rather than slowing down the progression. To our knowledge, there is only one study that has evaluated the use of medical intervention to prevent the onset of myopia. [22] In a retrospective study of 24 children in the treatment group using 0.025%

atropine nightly versus 26 children in the control group without any intervention, there was a significant lower proportion of onset of myopia along one year follow-up period in the treatment group versus the control group (21% vs 54%). This study was however limited by its retrospective nature and small sample size. [22]

Work by us

In the past 15 years, our group has been working on determining the prevalence of myopia [1,3], identifying risk factors of progression [8] and genetic factors[9-14] for myopia, and evaluating different treatment interventions for myopia [24-25].

Based on the current evidence, we hypothesize that 0.01% atropine have an effect in preventing the onset of myopia. We propose to conduct a RCT to investigate the effectiveness of using 0.01% low dose atropine comparing with placebo control group to prevent the onset of myopia.

The protocol is complied with the ICH-GCP.

3. Objectives

To determine the effectiveness of using 0.01% atropine in preventing the onset of myopia.

4. Materials & methods

i. Study design

Double blinded randomized clinical trial

Eligible children will be randomized into 3groups:

- Treatment Group: 0.01% atropine both eyes once daily
- Treatment Group:0.05% atropine both eyes once daily
- Placebo Group: 0.9% normal saline both eyes once daily

Children will be offered photochromatic glasses if they experienced glare or their parents were worried of excessive light exposure, or progressive glasses if children experienced difficulty with near vision.

The treatment will be continued for one year.

ii. Eligibility

Inclusion criteria

- Age 4 to 9
- SE > -1.0D and < +1.0 D
- Astigmatism: < 1 D
- Informed parental consent

Exclusion criteria

- Ophthalmic diseases other than refractive errors
- Previous use of treatment of atropine
- Allergy or intolerance to atropine
- Inability to attend regular follow up assessment

iii. Sample Size

Sample sizes of 100 in control group (0.9% normal saline) and 100 in treatment group (0.01% low dose atropine) and 100 in (0.05%low dose atropine), will achieve 90.5% power to detect a difference of 0.29 in the myopia incident rate between the two groups. We assume the incident rate of the control group to be 0.50 and the incident rate of the treatment group to be 0.21, based on the literature. [22] The test statistic used is the two-sided Score test (Farrington & Manning). The significance level of the test will be set to 0.050. A final sample size of 300 (100 in each group) should be used considering a follow-up rate of 90%.

iv. Study methods

iv.1 Initial Visit (Appendix C)

Aim:

- To obtain informed consent
- To confirm the eligibility
- To obtain baseline data

History

- Ocular history: history of ocular disease and operation
- Refraction
- Systemic review

Examination (Appendix C)

- Best corrected visual acuity for near and distant (EDTRS) charts
- Near aided visual acuity
- Cover and uncover test to test ocular alignment
- Extraocular movement
- Pupil size
- Intraocular pressure by non-contact tonometry (NCT)
- Measurement of accommodation amplitude by Royal Air Force near point rule
- Instillation of cycloplegic agent
  a. Wash hands.
  b. Tilt patient's head back and make a pouch with the lower cul-de-sac. Install one (1) drop of Mydrin-P and cyclopentolate eye drop. Releases pouch and apply pressure on the inner canthus for a period of ten seconds to minimize systemic absorption. Repeat for the other eye.
  c. After a ten (10) minute interval, repeat step 2.
  d. After a further ten (10) minute interval, repeat step 2 such that a total of three (3) drops of Mydrin-P and cyclopentolate are instilled into each eye.
  e. Perform auto refraction thirty (30) minutes after the last set of drops.

- Cycloplegic autorefraction
  a. Turn the power switch ON. The target rings will appear on the TV monitor.
  b. Set the instrument on the R/K mode. It will be automatically set if this was the mode when the machine was turned off.
  c. Instruct the patient to place his chin on the chin rest and forehead on the headrest gently. Adjust the machine height so that the patient's eye level will meet the eye level indicator when looking straight ahead.
  d. Place the patient's eye in the middle of the TV monitor by manipulating the joystick. Focus on the blinking light by manipulating the joystick back

and forth and make sure it is inside the inner target ring.
e. Instruct the patient to look at the picture and to hold his/her eyes open wide. He/she should refrain from blinking during the measurement procedure.
f. Press the start button.
g. Repeat (e&f) for at least 3 readings.

- Choroid thickness measured by DRI Swept Source Optical Coherence Tomography.
- Slit-lamp examination & binocular indirect ophthalmoscopy examination
- Ocular biometry by IOL master
  - Perform six measurements of total axial length, anterior chamber length and corneal curvatures at least 3 measurements are identical or almost identical. Discord outline. Print results.
  -
- Questionnaire
  - Parental history of myopia
  - Parental educational level
  - Self-reported visual function questionnaire
  - Questionnaires on amount of near works and out-door activities. (Appendix E)

Randomization

Block randomization will be used to assign consecutive cases into either treatment arm in the proposed RCT. The block size could be 4, 6 or 8 (the actual block size will be kept confidential to all of the investigators and participating staffs except for the statistician who design the randomization strategies). Since age has been shown to be a major factor that associated with the onset of myopia, we will randomize eligible subjects in two age groups separately (i.e. age 4-6; and age 7-9). Randomization table will be generated and kept confidential by a statistician independently. Only the staff who is designated as the person to obtain the randomization code can get access to the table and assign treatment arms for each study subject. The investigator, the patient and the staff who conducts the follow-up examinations will be kept unaware of the randomization information. In the study design, we have taken into account the possible effect of covariates on the estimated sample size.

Blinding method

- The assignment of groups will not be disclosed to the subjects (including their parents) and investigators.
- All types of eye drops (atropine 0.01%, and normal saline 0.9%) will be contained in the same type of bottle.
- All the optometrists responsible for assessing the study outcomes will be blinded to the treatment given to each of the children.
- The statistician will also be blinded to the assigned treatment for each child.

Dispensing

- Eye drops will be given to children according to randomization

iv.2 Visit 2 at 2 weeks after the treatment (Baseline 2 + assessment of tolerance)
Examination as in visit 1
Cycloplegic refraction at visit 2 will be used as baseline 2 for future comparison of myopia progression if any, as hyperopic shift may occur after commencing atropine eye drops.
Children will be offered photochromatic glasses if they experience glare or their parents are worried about excessive light exposure, or progressive glasses if children experience difficulty with near vision.

iv. 3 Visits 3-5 (Treatment follow-up visits, every 4 months)

- To assess study outcomes
- To assess compliance by history, amount of drug used
- To assess complications
- To update glasses prescription if SE change > 0.75D
- Examination as visit 1.
- After a total of 1 year (Visit 5), the children will be assessed. Treatment will stop after this visit.

iv. 4 Unscheduled visit

The children are advised to come back for assessment when any problems with the treatments arised, such as deterioration of vision, treatment complications. The children will have detailed examination. New prescription will be given when indicated. When there is severe side effect associated with the treatment, the treatment will be stopped. The children will be asked to come back at the original schedule after the unscheduled visit

iv.5 Visit schedule

Visit 1	Day 0 (Baseline 1)
Visit 2	Week 2 (Baseline 2 + assessment of tolerance)
Visit 3	Month 4 (Treatment follow-up visits)
Visit 4	Month 8 (Treatment follow-up visits)
Visit 5	Month 12 (Treatment follow-up visits)

v. Study outcome & assessment

Efficacy:

- Primary outcome: Proportion of onset of myopia and proportion of fast myopia progressor in each group.
- Secondary outcome: Myopic progression is measured by change in spherical equivalent refraction (SER). Cycloplegic refraction is assessed by using an auto-refractometer. Eyeball growth is measured by change in axial length, using the IOL master.

Confounding factors (Appendix C):

Age, parental histories of myopia, outdoor activities, rate of myopia progression prior treatment, and initial SER are potential confounding factors of myopic progression.

Safety:

- Questionnaire for self-reported visual function
- Best corrected visual acuity using EDTRS chart
- Intraocular pressures measured by applanation
- Pupil size in room light measured by pupillometer
- Measurement of accommodation amplitude by Royal Air Force near point rule
- Ocular and systemic symptoms
- Ocular signs assessed by slit lamp biomicroscopy and binocular indirect ophthalmoscopy
- Heart rate and blood pressure

vi. Analysis

- Intention-to-treat analysis will be employed.
- The proportion of onset of myopia and proportion of fast myopic progressor in each treatment group are the primary outcome measures. Change from baseline SER and axial length in the treatment group and the control group are the secondary outcome measures. These will be analyzed by multiple regression models. Baseline measurements, treatment group, parental history of myopia, age, and their interaction will be used as factors in the model. The analysis of safety measures made on categorical or frequency scales will be based on chi-square statistics. Analysis of Variance (ANOVA) model will be built up to identify the treatment effect, period effect, carry-over effect and their interaction

vii. Adverse effects & patient withdrawal / exit from study

Atropine is known to occasionally cause the following:

Systemic: tachycardia, respiratory stress, allergic dermatitis

Ocular: increase in IOP, phototoxicity, early presbyopia

These potential side-effects must be closely monitored and quantified. We propose to examine the physical integrity of the cornea, lens and retina. They will be examined with direct examination, serial photography and specular microscopy. In addition, the intraocular pressure is measured with. The data then can be used to project the proportion of the patient population (4-9 year-olds) that may become sensitive to topical atropine.

Ethics considerations

- The atropine trial must be terminated if a better alternative can be identified and having become available.
- For children that are allergy or intolerance to atropine, atropine treatment will be stopped.
- It is well noted that atropine treatment is attended by side effects of mydriasis and cycloplegia. Although short-term and long-term studies revealed few side effects, concerns for retinal phototoxicity are real. Moreover, bifocals do not allow clear vision at all distance and this blurred image might also cause myopic progression. Photochromatic progressive glasses will be

prescribed to children for mydriasis and cycloplegia induced by atropine.

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(The First Original Version Approved by Ethics Committee)

Prevention of Myopia onset using ultra-low dose atropine (PRE-MYO Study)

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Myopia is an important public health issue in Hong Kong, which has one of the highest prevalence rates of myopia in the world, approximately three times that of United States, more than ten times that of Middle East, and nearly twice that in South America [1]. Its prevalence in Hong Kong school children was around 18.3% to 30% at six years of age and 53% to 61.5% at twelve years of age [1-2]. Among preschool children, its prevalence has increased significantly from 2.3% to 6.3% over a ten-year period [3]. The World Health Organization (WHO) recognizes that uncorrected myopia is a major cause of visual impairment [4]. More importantly, myopia is associated with many sight-threatening complications that cannot be prevented by optical correction. These complications include pre-senile cataract, glaucoma, retinal detachment, and characteristic degenerative changes of the sclera, retinal pigment epithelium, and choroid [5]. The degenerative changes are related to mechanical stretching of the involved tissue as the eyeball lengthens in myopic eyes [5]. With all these complications, the increased prevalence of myopia will become a major public health and economic burden.

Despite decades of scientific research in the causes of myopia, its exact etiology remains unclear. Currently, both the genetic and environmental factors are believed to be important risk factors for the development of myopia. Amount of near work and time spent on outdoor activities may be the risk factor and protective factor respectively for myopia development. [6-7] Our group has previously demonstrated that children with a parental history of myopia are more likely to develop myopia [8] and has identified a number of genes associated with myopia [9-14].

Different interventions have been attempted to reduce the myopic progression, including optical under-correction with spectacles [15], bifocal lenses [16], progressive lenses [17] and contact lenses [18]. However, results from these studies are disappointing and no strong evidence in reducing myopia progression has been shown following the use of these measures. Currently, atropine eye drops is the most promising measure to slow down the myopia progression or even prevent its onset. It is a nonselective muscarinic receptor antagonist and there have been many postulated mechanisms for its anti-myopia actions, which include inhibition of accommodation, biochemical remodeling of sclera, and increase in ultraviolet exposure secondary to pupil dilatation [19].

As shown in the Atropine in the Treatment of Myopia (ATOM 1) study, daily regimen of 1% atropine eye drops was found to significantly reduce the progression of myopia by 77% when compared with placebo eye drops treatment over a 2-year period [19]. However, cessation of drug administration led to a partial rebound effect [20]. Additionally, the associated side effects of photophobia due to mydriasis and blurred near vision due to cycloplegia have significantly prohibited wide adoption of atropine use internationally. Recently, the ATOM 2 study showed that a lower concentration of topical atropine (0.5%, 0.1% and 0.01%) one drop nightly over two years may be effective in reducing myopia progression by 75%, 68% and 59% respectively, when compared with the historical placebo group in the ATOM 1 study [21]. Among the groups of 0.5%, 0.1% and 0.01% atropine, the ocular safety profile are much better in the lower dose atropine group, with 70%, 61%, and 6% children requiring progressive glasses respectively.

While current literatures focus on slowing down the myopia progression, only very few is on preventing the onset of myopia. Unfortunately, after the onset of myopia in children, its progression is very difficult to control. [22] It is therefore much more important to prevent the onset of myopia, rather than slowing down the progression. To our knowledge, there is only one study that has evaluated the use of medical intervention to prevent the onset of myopia. [22] In a retrospective study of 24 children in the treatment group using 0.025%

atropine nightly versus 26 children in the control group without any intervention, there was a significant lower proportion of onset of myopia along one year follow-up period in the treatment group versus the control group (21% vs 54%). This study was however limited by its retrospective nature and small sample size. [22]

Work by us

In the past 15 years, our group has been working on determining the prevalence of myopia [1,3], identifying risk factors of progression [8] and genetic factors[9-14] for myopia, and evaluating different treatment interventions for myopia [24-25].

Based on the current evidence, we hypothesize that 0.01% atropine have an effect in preventing the onset of myopia. We propose to conduct a RCT to investigate the effectiveness of using 0.01% low dose atropine comparing with placebo control group to prevent the onset of myopia.

The protocol is complied with the ICH-GCP.

3. Objectives

To determine the effectiveness of using 0.01% atropine in preventing the onset of myopia.

4. Materials & methods

i. Study design

Double blinded randomized clinical trial

Eligible children will be randomized into 2 groups:

- Treatment Group: 0.01% atropine both eyes once daily
- Placebo Group: 0.9% normal saline both eyes once daily

Generally speaking, eye-glasses are not necessary during the study. If children experience glare, blurred vison, difficulty with near vision or their parents are worried about excessive light exposure, children can wear photochromatic glasses or progressive glasses which will be paid by their parents. However, if the doctors believe their symptoms will affect the quality of life and the eye-glasses are necessary, the cost will be covered by the research team.

The treatment will be continued for one year.

ii. Eligibility

Inclusion criteria

- Age 4 to 9
- SE > -1.0D and < +1.0 D
- Astigmatism: < 1 D
- Informed parental consent

Exclusion criteria

- Ophthalmic diseases
- Refractive errors: SE < -1.0D or > +1.0 D
- Previous use of treatment of atropine
- Allergy or intolerance to atropine
- Inability to attend regular follow up assessment

iii. Sample Size

Sample sizes of 56 in control group (0.9% normal saline) and 56 in treatment group (0.01% low dose atropine), will achieve 90.5% power to detect a difference of 0.29 in the myopia incident rate between the two groups. We assume the incident rate of the control group to be 0.50 and the incident rate of the treatment group to be 0.21, based on the literature. [22] The test statistic used is the two-sided Score test (Farrington & Manning). The significance level of the test will be set to 0.050. A final sample size of 128 (64 in each group) should be used considering a follow-up rate of 90%.

iv. Study methods

iv.1 Initial Visit (Appendix C)

Aim:

- To obtain informed consent
- To confirm the eligibility
- To obtain baseline data

History

- Ocular history: history of ocular disease and operation
- Refraction
- Systemic review

Examination (Appendix C)

- Best corrected visual acuity for near and distant (EDTRS) charts
- Near aided visual acuity
- Cover and uncover test to test ocular alignment
- Extraocular movement
- Pupil size
- Intraocular pressure by non-contact tonometry (NCT)
- Measurement of accommodation amplitude by Royal Air Force near point rule
- Instillation of cycloplegic agent
  a. Wash hands.
  b. Tilt patient's head back and make a pouch with the lower cul-de-sac. Install one (1) drop of Mydrin-P and cyclopentolate eye drop. Releases pouch and apply pressure on the inner canthus for a period of ten seconds to minimize systemic absorption. Repeat for the other eye.
  c. After a ten (10) minute interval, repeat step 2.
  d. After a further ten (10) minute interval, repeat step 2 such that a total of three (3) drops of Mydrin-P and cyclopentolate are instilled into each eye.
  e. Perform auto refraction thirty (30) minutes after the last set of drops.

- Cycloplegic autorefraction
  a. Turn the power switch ON. The target rings will appear on the TV monitor.
  b. Set the instrument on the R/K mode. It will be automatically set if this was the mode when the machine was turned off.
  c. Instruct the patient to place his chin on the chin rest and forehead on the headrest gently. Adjust the machine height so that the patient's eye level will meet the eye level indicator when looking straight ahead.
  d. Place the patient's eye in the middle of the TV monitor by manipulating the joystick. Focus on the blinking light by manipulating the joystick back and

forth and make sure it is inside the inner target ring.
e. Instruct the patient to look at the picture and to hold his/her eyes open wide. He/she should refrain from blinking during the measurement procedure.
f. Press the start button.
g. Repeat (e&f) for at least 3 readings.

- Slit-lamp examination & binocular indirect ophthalmoscopy examination
- Ocular biometry by IOL master
  - Perform six measurements of total axial length, anterior chamber length and corneal curvatures at least 3 measurements are identical or almost identical. Discord outline. Print results.
- Questionnaire
  - Parental history of myopia
  - Parental educational level
  - Self-reported visual function questionnaire
  - Questionnaires on amount of near works and out-door activities. (Appendix E)

Randomization

Block randomization will be used to assign consecutive cases into either treatment arm in the proposed RCT. The block size could be 4, 6 or 8 (the actual block size will be kept confidential to all of the investigators and participating staffs except for the statistician who design the randomization strategies). Since age has been shown to be a major factor that associated with the onset of myopia, we will randomize eligible subjects in two age groups separately (i.e. age 4-6; and age 7-9). Randomization table will be generated and kept confidential by a statistician independently. Only the staff who is designated as the person to obtain the randomization code can get access to the table and assign treatment arms for each study subject. The investigator, the patient and the staff who conducts the follow-up examinations will be kept unaware of the randomization information. In the study design, we have taken into account the possible effect of covariates on the estimated sample size.

Blinding method

- The assignment of groups will not be disclosed to the subjects (including their parents) and investigators.
- All types of eye drops (atropine 0.01%, and normal saline 0.9%) will be contained in the same type of bottle.
- All the optometrists responsible for assessing the study outcomes will be blinded to the treatment given to each of the children.
- The statistician will also be blinded to the assigned treatment for each child.

Dispensing

- Eye drops will be given to children according to randomization

Usage and storage of the eye drops

- 1. Wash hands.
- 2. Tilt child's head back and make a pouch with the lower cul-de-sac. Install one (1) drop of the eye drop. Releases pouch and apply pressure on

the inner canthus for a period of ten seconds to minimize systemic absorption. Repeat for the other eye.

- 3. Store eye drops at room temperature. Store away from heat, moisture, and light. Do not store in the bathroom. Keep them out of the reach of children and away from pets.
- 4. The eye drops are only available for participants

iv.2 Visit 2 at 2 weeks after the treatment (Baseline 2 + assessment of tolerance)
Examination as in visit 1
Cycloplegic refraction at visit 2 will be used as baseline 2 for future comparison of myopia progression if any, as hyperopic shift may occur after commencing atropine eye drops.
Generally speaking, eye-glasses are not necessary during the study. If children experience glare, blurred vison, difficulty with near vision or their parents are worried about excessive light exposure, children can wear photochromatic glasses or progressive glasses which will be paid by their parents. However, if the doctors believe their symptoms will affect the quality of life and the eye-glasses are necessary, the cost will be covered by the research team.

iv. 3 Visits 3-5 (Treatment follow-up visits, every 4 months)

- To assess study outcomes
- To assess compliance by history, amount of drug used
- To assess complications
- To update glasses prescription if SE change > 0.75D
- Examination as visit 1.
- After a total of 1 year (Visit 5), the children will be assessed. Treatment will stop after this visit.

iv. 4 Unscheduled visit

The children are advised to come back for assessment when any problems with the treatments arised, such as deterioration of vision, treatment complications. The children will have detailed examination. New prescription will be given when indicated. When there is severe side effect associated with the treatment, the treatment will be stopped. The children will be asked to come back at the original schedule after the unscheduled visit

iv.5 Visit schedule

Visit 1	Day 0 (Baseline 1)
Visit 2	Week 2 (Baseline 2 + assessment of tolerance)
Visit 3	Month 4 (Treatment follow-up visits)
Visit 4	Month 8 (Treatment follow-up visits)
Visit 5	Month 12 (Treatment follow-up visits)

v. Study outcome & assessment

Efficacy:

- Primary outcome: Proportion of onset of myopia and proportion of fast myopia progressor in each group.

- Secondary outcome: Myopic progression is measured by change in spherical equivalent refraction (SER). Cycloplegic refraction is assessed by using an auto-refractometer. Eyeball growth is measured by change in axial length, using the IOL master.

Confounding factors (Appendix C):

Age, parental histories of myopia, outdoor activities, rate of myopia progression prior treatment, and initial SER are potential confounding factors of myopic progression.

Safety:

- Questionnaire for self-reported visual function
- Best corrected visual acuity using EDTRS chart
- Intraocular pressures measured by applanation
- Pupil size in room light measured by pupillometer
- Measurement of accommodation amplitude by Royal Air Force near point rule
- Ocular and systemic symptoms
- Ocular signs assessed by slit lamp biomicroscopy and binocular indirect ophthalmoscopy
- Heart rate and blood pressure

vi. Analysis

- Intention-to-treat analysis will be employed.
- The proportion of onset of myopia and proportion of fast myopic progressor in each treatment group are the primary outcome measures. Change from baseline SER and axial length in the treatment group and the control group are the secondary outcome measures. These will be analyzed by multiple regression models. Baseline measurements, treatment group, parental history of myopia, age, and their interaction will be used as factors in the model. The analysis of safety measures made on categorical or frequency scales will be based on chi-square statistics. Analysis of Variance (ANOVA) model will be built up to identify the treatment effect, period effect, carry-over effect and their interaction

vii. Adverse effects & patient withdrawal / exit from study

Atropine is known to occasionally cause the following:

Systemic: tachycardia, respiratory stress, allergic dermatitis
Ocular: increase in IOP, phototoxicity, early presbyopia

These potential side-effects must be closely monitored and quantified. We propose to examine the physical integrity of the cornea, lens and retina. They will be examined with direct examination, serial photography and specular microscopy. In addition, the intraocular pressure is measured with. The data then can be used to project the proportion of the patient population (4-9 year-olds) that may become sensitive to topical atropine.

- Ethics considerationsThe issue of confidentiality is the major ethical issue, and will be solved by recording the data in a manner that does not allow the participants to be identified (ie. using a non-recognizable code for each patient).
- The atropine trial must be terminated if a better alternative can be identified and having become available.
- For children that are allergy or intolerance to atropine, atropine treatment will be stopped.
- It is well noted that atropine treatment is attended by side effects of mydriasis and cycloplegia. Although short-term and long-term studies revealed few side effects, concerns for retinal phototoxicity are real. Moreover, bifocals do not allow clear vision at all distance and this blurred image might also cause myopic progression. Photochromatic progressive glasses will be prescribed to children for mydriasis and cycloplegia induced by atropine.

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Summary of Amendments History

Protocol: Summary of Amendments History

Original Approved Protocol Version and Date	Version 3, 2nd July 2015
Total Number of Approved Versions	6
Final Approved Protocol Version and Date	Version 8, 20th May 2019

Amended Protocol: Version 4, 27th July 2016				
Current condition *(indicate source document & location)*	**Amendment**	**Proposed by**	**Reason for change**	**Will change increase risk to participants?**
Protocol: Version 3 dated 02 July 2015	Protocol: Version 4 dated 27 July 2016	PI	According to our preliminary investigation in clinic. We found 0.05% Atropine have more significant effect and less side effect. So we add this new dose prevention group.	NA
Informed consent English and Chinese version Version 4 dated on 14 Jul 2015	Informed consent English and Chinese version Version 5 dated on 27 July 2016	PI	Update information	NA

Amended Protocol: Version 5, 20th September 2016				
Current condition *(indicate source document & location)*	**Amendment**	**Proposed by**	**Reason for change**	**Will change increase risk to participants?**
Our study is a double blinded randomized clinical trial, which includes 3 groups. They are treatment group:0.01%atropine group, 0.05%atropine group and placebo group separately. We plan to use 0.9% normal saline as the placebo group eye drop before.	Now we want to amend our control group drug with AIM lubricant instead of 0.9% saline.	PI	The AIM lubricant is a kind of artificial tears. It's main ingredient included sodium chloride 5.5mg/ml(0.55%w/v) and potassium chloride 1.5mg/ml(0.15%w/v). The PH value is more similar to the tears of human and more comfortable for use.	No
Protocol Version 4 dated 24 Mar 2016	Protocol Version 5 dated 20 Sept 2016	PI	Update information	No

Amended Protocol: Version 6, 31st October 2016				
Current condition *(indicate source document & location)*	**Amendment**	**Proposed by**	**Reason for change**	**Will change increase risk to participants?**
Research Protocol (Version 5 dated 20 Sept 2016)	Research Protocol (Version 6 dated 31 Oct 2016)	PI	Information update	No
Participant information sheet	Participant information sheet	PI	Information update	No

(English and Chinese Versions)(Version 5 dated 27 July 2016)	(English and Chinese Versions) (Version 6 dated 29 Oct 2016)			
Informed Consent Form (English and Chinese Versions)(Version 5 dated 27 July 2016)	Informed Consent Form (English and Chinese Versions)(Version 6 dated 29 Oct 2016)	PI	Information update	No
It is proposed as a 1-year study in our previously protocol.	We suggest to extend the treatment period to two years	PI	Two-year treatment period will be better both to the scientific evidence and also to the children participating in our program. We suggest a plan for crossover of treatment groups. After one year of treatment, children from the placebo group will remain in the placebo group until they have onset of myopia with SE <-0.5D. That is, they will be switched to group 0.05%	No

			during the second year once they have onset of myopia. Treatment group of 0.01% and 0.05% atropine will remain in the same group for two years throughout the whole study period.	
There are five scheduled visits.	Add three more scheduled visits. The total number of scheduled visit is eight.	PI	We would like to look at the possibility of myopia occurrence and the variation of participants' situation	No

Amended Protocol: Version 7, 2nd February 2017				
Current condition *(indicate source document & location)*	**Amendment**	**Proposed by**	**Reason for change**	**Will change increase risk to participants?**
Research Protocol (Version 6 dated 29 Oct 2016)	Research Protocol (Version 7 dated 2 Feb 2017)	PI	Information update	No
Participant information sheet (English and Chinese Versions) (Version 6 dated 29 Oct 2016)	Participant information sheet (English and Chinese Versions) (Version 7 dated 3 Feb 2017)	PI	Information update	No
Informed Consent Form	Informed Consent Form	PI	Information update	No

(English and Chinese Versions)(Version 6 dated 29 Oct 2016)	(English and Chinese Versions)(Version 7 dated 3 Feb 2017)			
Current study end date is July 2017	Extend the study end date to Feb 2021	PI	Slow recruitment	No

Amended Protocol: Version 8, 20th May 2019				
Current condition *(indicate source document & location)*	**Amendment**	**Proposed by**	**Reason for change**	**Will change increase risk to participants?**
Current Study title: Prevention of Myopia onset using ultra-low dose atropine. (PRE-MYO Study)	Updated study title: Low-concentration Atropine for Myopia Prevention (LAMP-2) Study	PI	Information updates	No
Research Protocol [Version 7 Date: 2 Feb 2017]	Research Protocol [Version 8 Date: 20 May 2019]	PI	Information updates	No
Participant Information Sheet and Informed Consent Form (English and Chinese versions) [Version 8 Date: 5 July 2017]	Participant Information sheet and Informed Consent Form (English and Chinese versions) [Version 9 Date: 20 May 2019]	PI	Information updates	No

Atropine study follow up visit data sheet [English Version: Version 2; dated 26 May 2015]	Atropine study follow up visit data sheet [English Version: Version 3; dated 21 May 2019]	PI	Information updates	No
PRE-MYO Study Poster [English and Chinese Versions: Version 1 Date: 10 Aug 2017]	PRE-MYO Study Poster [English and Chinese Versions: Version 2 Date: 20 May 2019]	PI	Information updates	No
Current follow up period is 24 months	The follow up period will be extended to 36 months.	PI	Three years' treatment period will be better both to the scientific evidence and also to the children participating in our program. We suggest a plan for crossover of treatment groups after two-year placebo treatment.	No

			After two years of treatment, children from the placebo group will remain in the placebo group until they have onset of myopia with SE ≤ -0.5D. That is, they will be switched to group 0.05% during the second year once they have onset of myopia. Treatment group of 0.01% and 0.05% atropine will remain in the same group for two years throughout the whole study period.	
Current study end date is Feb 2021	Extend study end date to Dec 2022	PI	As we plan to extend the follow up period to 36 months, we need to extend the study end date to Dec 2022	No
Current total sample size is 300	Increase total sample size to 474	PI	To calculate the required number of study subjects,	No

			we took the estimated myopia onset rate for 0.05%, and 0.01% atropine and placebo groups to be and 6.6%, 14.6%, 20% respectively. The 0.05% atropine group should have the smallest number of myopic onset, thus a minimum of 5 to 10 myopia children should be observed. To detect a difference among treatment groups, a sample size of 375 subjects (125 per group) could achieve 90% power at a 0.05 significance level. By factoring in an attrition rate of 20%, a sample size of 474 subjects (158 per group) would be needed.	
Questionnaire	Questionnaire	PI	Change of study title	No

[English Version: Version 2; dated 02 Jun 2015] [Chinese Version: Version 2; dated 02 Jun 2015]	[English Version: Version 3; dated 20 May 2019] [Chinese Version: Version 3; dated 20 May 2019]			

Summary of Questionnaires

1. **NEI VFQ-25 (Chinese)**

2. **Development, Environment & Lifestyle (Chinese)**

3. **Development, Environment & Lifestyle (English)**

PB/IA

美國全國眼科學院
視覺功能問卷 － 25
(VFQ-25)

2000年版本

(訪問版本)

2000年1月

說明：

我將讀出一些句子，內容談及與您視力有關的問題或您對自己視力情況的感受。在每條問題後，我會给您讀出一連串可能的答案。請選擇最能形容您的情況之答案。

請想像自己正在佩戴眼鏡或隱形眼鏡(如有的話)的情況下來回答所有問題。
您需要用多少時間來回答每條問題都可以。

您所有的答案將會保密。您的答案必須盡量準確，我們才能透過這項調查來增進我們對視力問題的認識及它如何影響您的生活質素。請記著：如果您在進行某項活動時需要佩戴眼鏡或隱形眼鏡，請根據已佩戴它們的情況回答以下問題。

視覺功能問卷 – 25

第一部份 – 整體健康及視力

1. 一般來說，您的整體健康屬於*：

讀出答案類別： *(圈出一個答案)*

極佳..... 1

非常好..... 2

良好..... 3

一般..... 4

差..... 5

2. 現時來說，如果雙眼並用(如您需佩戴眼鏡或隱形眼鏡，則根據已佩戴的情況作答)，您認爲自己的視力屬於極佳、良好、一般、差或非常差？或您已完全失明？

讀出答案類別： *(圈出一個答案)*

極佳..... 1

良好..... 2

一般..... 3

差..... 4

非常差..... 5

完全失明..... 6

*如VFQ-25與SF-36或RAND 36-項健康問卷1.0同時使用，則省略第1條問題。

3. 您有多少時候會爲自己的視力擔憂？

讀出答案類別： *(圈出一個答案)*

從來沒有..... 1

少許時間..... 2

有時..... 3

大部分時間..... 4

全部時間.?..... 5

4. 您感到眼睛及它周圍有多大的痛楚或不適(例如灼熱、痕癢或疼痛)？您認爲是：

讀出答案類別： *(圈出一個答案)*

完全沒有..... 1

輕微..... 2

中度..... 3

嚴重，或. 4

非常嚴重?..... 5

第二部份 – 活動困難

以下的問題是關於您在進行某些活動時遇到多大的困難(如您需佩戴眼鏡或隱形眼鏡，則根據已佩戴的情況作答)。

5. 您在閱讀報章上一般的字體時有多大困難？您認爲是：
(如有需要，讀出選項) *(圈出一個答案)*

完全沒有困難 1
有少許困難..... 2
有中度困難..... 3
有極大困難..... 4
因視力的原故已停止此活動..... 5
因其他理由或對所述活動沒有興趣 ,已停止此活動..... 6

6. 您進行在近距離需要看得清楚的工作或嗜好時(例如下廚、縫紉、家居修補或使用手工具)有多大困難？ 您認爲是：
(如有需要，讀出選項) *(圈出一個答案)*

完全沒有困難 1
有少許困難..... 2
有中度困難..... 3
有極大困難..... 4
因視力的原故已停止此活動..... 5
因其他理由或對所述活動沒有興趣，已停止此活動..... 6

7. 因視力的原故，您在放滿物件的架上尋找東西時有多大困難？

(如有需要，讀出選項) *(圈出一個答案)*

完全沒有困難 1

有少許困難..... 2

有中度困難..... 3

有極大困難..... 4

因視力的原故已停止此活動..... 5

因其他理由或對所述活動沒有興趣，已停止此活動..... 6

8. 您在閱讀路牌或店舖名稱時有多大困難？

(如有需要，讀出選項) *(圈出一個答案)*

完全沒有困難 1

有少許困難..... 2

有中度困難..... 3

有極大困難..... 4

因視力的原故已停止此活動..... 5

因其他理由或對所述活動沒有興趣，已停止此活動..... 6

9. 因視力的原故，您在燈光陰暗的環境、或晚上下台階、梯級或行人路邊有多大困難？

(如有需要，讀出選項) *(圈出一個答案)*

完全沒有困難 1

有少許困難..... 2

有中度困難..... 3

有極大困難..... 4

因視力的原故已停止此活動..... 5

因其他理由或對所述活動沒有興趣，已停止此活動..... 6

10. 因視力的原故，您一路走時察覺到兩旁的物件有多大困難？

(如有需要，讀出選項) *(圈出一個答案)*

完全沒有困難 1

有少許困難..... 2

有中度困難..... 3

有極大困難..... 4

因視力的原故已停止此活動..... 5

因其他理由或對所述活動沒有興趣，已停止此活動..... 6

11. 因視力的原故，您要觀察到別人對您所說的話的反應有多大困難？

(如有需要，讀出選項) *(圈出一個答案)*

完全沒有困難 1

有少許困難..... 2

有中度困難..... 3

有極大困難..... 4

因視力的原故已停止此活動..... 5

因其他理由或對所述活動沒有興趣，已停止此活動..... 6

12. 因視力的原故，您在挑選及配襯自己的衣服時有多大困難？

(如有需要，讀出選項) *(圈出一個答案)*

完全沒有困難 1

有少許困難..... 2

有中度困難..... 3

有極大困難..... 4

因視力的原故已停止此活動..... 5

因其他理由或對所述活動沒有興趣，已停止此活動..... 6

13. 因視力的原故，您到別人家中探望他們、在派對或餐廳裏與人共聚有多大困難？

(如有需要，讀出選項) *(圈出一個答案)*

完全沒有困難 1

有少許困難..... 2

有中度困難..... 3

有極大困難..... 4

因視力的原故已停止此活動..... 5

因其他理由或對所述活動沒有興趣，已停止此活動..... 6

A8. 因視力的原故，您在觀看及欣賞電視節目時有多大困難？

(如有需要，讀出選項) *(圈出一個答案)*

完全沒有困難 1

有少許困難..... 2

有中度困難..... 3

有極大困難..... 4

因視力的原故已停止此活動..... 5

因其他理由或對所述活動沒有興趣，已停止此活動..... 6

第三部分：對視力問題的回應

以下的問題是關於您的視力對您所做的事可能產生的影響。就每條問題，請告訴我它對您來說是: 任何時間都正確、大部分時間正確、有時正確、少許時間正確或從來都不正確

(每行圈出1個答案)

讀出答案類別：	任何時間	大部分時間	有時	少許時間	從不
17. 因視力的原故，您能完成的事情是否比您想做的爲少？	1	2	3	4	5
18. 因視力的原故，您能工作或進行其他活動多長時間是否受到限制？	1	2	3	4	5
19. 您的眼睛及它周圍的痛楚或不適 (例如灼熱、痕癢或疼痛) 在多大程度上令您不能做您想做的事？您認爲是：	1	2	3	4	5

就以下每句，請告訴我它對您來說是: 肯定對、大部分對、大部分不對、肯定不對，或您不肯定。

(每行圈出1個答案)

	肯定對	大部分對	不肯定	大部分不對	肯定不對
20. 因視力的原故，我大部分時間都留在家中	1	2	3	4	5
21. 因視力的原故，我很多時間感到沮喪	1	2	3	4	5
22. 因視力的原故，我對自己所做的事情的控制能力少了很多。	1	2	3	4	5
23. 因視力的原故，我需要過度依賴聽別人所告訴我的話。	1	2	3	4	5
24. 因視力的原故，我需要別人給予我許多的幫助。	1	2	3	4	5
25. 因視力的原故，我擔心會做出一些令自己或別人尷尬的事。	1	2	3	4	5

訪問到此結束。非常多謝您的時間及協助。

附錄：自由選擇附加問題

副量表：整體健康

A1. 在一個以0代表情況與死亡一樣差，而10代表可能有的最佳健康狀況的量表上，您會給您的整體健康多少評分？

(圈出一個答案)

0 1 2 3 4 5 6 7 8 9 10

最差 最佳

副量表：整體視力

A2. 在一個以0代表最差的視力，即無異於失明甚或更壞，而10代表視力處於最佳狀態的量表上，您會給您現在的視力多少評分(如您需佩戴眼鏡或隱形眼鏡，則根據已佩戴的情況作答)?

(圈出一個答案)

0 1 2 3 4 5 6 7 8 9 10

最差 最佳

香港中文大學眼科中心
CUHK Eye Centre

香港中文大學醫學院
Faculty of Medicine
The Chinese University of Hong Kong

低濃度阿托品眼藥水在近視發病預防之研究

研究問卷調查

成長, 環境, 生活

（由父母填寫）

編碼: _____

就讀學校：_____

聯繫電話：_____

與小孩的關係: _____

民族：_____

完成日期: ___/___/___

由工作人員填寫:

接受日期：___/___/___
問卷是否完成： 是 / 否
是否有未填項目：是 / 否
審核人員：_____

數據錄入： 是 / 否
錄入人員：_____
重新錄入： 是 / 否
錄入人員：_____

Version 3 Date: 20 May 2019

有關孩子的視力問題

請與你的小朋友一起完成以下問題

1) 你的小朋友有沒有做過視力測試？
   - ☐ 沒有 (請跳至第4題)
   - ☐ 有 ***(_____歲第一次檢查視力)***
   - ☐ 不確定

2) 你的小朋友有定期做眼科常規檢查嗎？（包括視力）
   - ☐ 沒有 (請跳至第4題)
   - ☐ 有
   - ☐ 不確定

3) 多長時間去醫院或眼鏡店檢查一次？
   - ☐ 半年至少一次
   - ☐ 半年一次
   - ☐ 一年一次
   - ☐ 一年少於一次

4) 你的小朋友有沒有以下問題？***請如果有，請說明發病年齡。***

	問題	**發病年齡 (歲)**
☐	近視	
☐	遠視	
☐	散光	
☐	斜視	
☐	弱視	
☐	其它 (請詳述：_____)	
☐	正常(沒有以上情況)	

5) 你的小朋友***現在***有沒有***配戴眼鏡***（包括框架眼鏡、隱形眼鏡）？
   - ☐ 沒有（跳至第 9題）
   - ☐ 有（請在檢查當日帶備眼鏡）

6) 你的小朋友幾歲開始戴眼鏡？ _____歲

7) 小朋友第一副的眼鏡度數是:

眼鏡度數	右眼	左眼
遠視		
近視		
散光		

8) 你的小朋友使用眼鏡的頻率（包括***框架眼鏡***、***隱形眼鏡***）？

- ☐ 所有時間
- ☐ 大部分時間
- ☐ 有時
- ☐ 幾乎不戴
- ☐ 只有當眼睛感到疲倦時才戴

9) 你的小朋友有沒有使用以下方法治療近視？**（可多選）**

- ☐ 雙光眼鏡
- ☐ 漸變鏡
- ☐ 阿托品眼藥水
- ☐ OK 鏡
- ☐ 針灸
- ☐ 以上皆沒有
- ☐ 不確定
- ☐ 其他 (請詳述：_____)

10) 你的小朋友是否遇到過任何下列的情形？

- ☐ 看遠處時視力模糊
- ☐ 重影
- ☐ 眼痛（請列舉發生頻率：_____）
- ☐ 其他（請描述：_____）
- ☐ 以上皆沒有

11) 你的小朋友在閱讀或做近距離的工作時會不會經常頭疼？

- ☐ 會
  如果會，每星期會頭疼次數_____次；
  發生時段（如上午、中午、下午、晚上、其它）_____；
  持續時間_____分鐘
- ☐ 不會
- ☐ 不確定

12) 你的小朋友每個星期會閱讀幾多本書籍或雜誌 (***如果你的小朋友沒有看完一整本書，請將看過的部分相加； 例如：1/2 本 A 書+ 1/2 本 B 書=1 本書***）
每個星期共閱讀_____本

13) 你的小朋友***通常***是在哪裡看書、寫字或畫畫等近距離工作？***(可多選)***

- ☐ 在家裡臥室或書房
- ☐ 在家裡的飯廳或客廳
- ☐ 圖書館 / 補習社

☐ 其他 (請說明：_____)

14) 你的小朋友在家做近距離工作（如：閱讀、寫字或畫畫）時***通常***使用什麼類型的照明設備？***（可多選）***

☐ 檯燈
☐ 天花板吊燈或室內吊燈
☐ 自然光（如太陽光通過窗戶）
☐ 其他 (請說明：_____)

15) 你的小朋友***持續***做近距離工作（如：閱讀、寫字或畫畫）多久之後會休息一陣 ？

☐ 0-15分鐘
☐ 16-30分鐘
☐ 31-45分鐘
☐ 46-60分鐘
☐ 超過60分鐘

16) 你的小朋友通常多久從圖書館借閱或從書店購買一次書籍呢？

☐ 從不
☐ 每個星期少於一次
☐ 大約每個星期一次
☐ 每個星期超過一次

17) 你的小朋友通常怎樣去學校？每程所需時間?

	交通工具類型	**花費時間 (分鐘)**
☐	私家車	
☐	地鐵、巴士	
☐	校巴	
☐	走路	
☐	單車	
☐	其它 (請說明： _____)	

18) 如果你的小朋友是乘坐交通工具（如：私家車、地鐵或巴士）前往學校，他/她通常怎麼打發旅程？（***可多選***）

☐ 看書、學習
☐ 在車上與他人聊天
☐ 玩手持電子產品（如：手機、GameBoy、 iPad、平板電腦）
☐ 睡覺
☐ 看看窗外風景
☐ 其他（請說明：_____ ）

近距離工作的問題

19) 你的小朋友在看書寫字時，臉是否幾乎碰到書？

- ☐ 是
- ☐ 否
- ☐ 不確定

20) 請選擇你的小朋友***看書***、***寫字***的大概距離：

- ☐ 0- < 10 厘米（0-4 < 英吋）
- ☐ 10- < 20 厘米（4- < 8英吋）
- ☐ 20- < 30 厘米（8- < 12英吋）
- ☐ ≥ 30 厘米(≥ 12 英吋）

21) 你的小朋友有否使用以下哪些電子設備？***(可多選)***

- ☐ 手機
- ☐ iPad / 平板電腦
- ☐ 電腦
- ☐ 電視
- ☐ 電子遊戲機（如：X-Box，PlayStation等）
- ☐ 以上皆沒有

22) ***如果有，***他 /她是幾歲開始使用這些電子產品：

電子產品的類型	**年紀 (歲)**
手機	
其他手持電子設備（如：GameBoy，iPad，平板電腦）	
電腦	
電視	
電子遊戲機（如：X-Box， PlayStation等）	

23) 你的小朋友看手持電子設備（如手機，GameBoy， iPad，平板電腦）時距離螢幕幾遠？

- ☐ 從不玩手機或平板電腦
- ☐ 0 - < 10 厘米（0 - < 4英吋）
- ☐ 10 - < 20 厘米（4 -< 8英吋）
- ☐ 20 - < 30 厘米（8- < 12英吋）
- ☐ ≥ 30 厘米 （≥ 12英吋）

24) 你的小朋友看電腦時距離螢幕幾遠？

- ☐ 從不玩電腦
- ☐ 0 - < 25 厘米（0 - < 10呎）
- ☐ 25 - < 50 厘米（10 - < 20呎）
- ☐ 50 - < 100 厘米（20 - < 40呎）
- ☐ ≥ 100 厘米（大於40呎）

25) 你的小朋友看電視時距離電視幾遠？

☐ 從不看電視
☐ < 1 米（小於3呎）
☐ 1-2 米（3-6呎）
☐ < 2-3 米（6-9呎）
☐ ≥ 3 米（大於9呎）

26) 你的小朋友玩電子遊戲機(如: PlayStation)時離螢幕多遠？

☐ 不玩電子遊戲機
☐ < 1 米（小於3呎）
☐ 1-2 米（3-6呎）
☐ < 2-3 米（6-9呎）
☐ ≥ 3 米（大於9呎）

關於學習的問題

請根據小朋友去年的學習成績，填寫下面的問題

27) 小朋友在***年級***裡的排名是多少？ 第____名

28) 小朋友在***班級***裡的排名是多少？ 第____名

29) 小朋友考試最常得到的分數？

☐ A（90 – 100分）
☐ B（80 – 89分）
☐ C（70 – 79分）
☐ D（60 – 69分）
☐ E（50 -59分）
☐ F（<50分）

30) 小朋友學校裡的 老師教書用的板是什麼類型的？（可多選）

☐ 黑板
☐ 白板
☐ 智能板
☐ 其它（請說明：_____）

31) 請選擇其使用的頻率。

	從不（0%）	很少（~25%）	經常(~50%）	大部分（~75%）	總是（~100%）
黑板	☐	☐	☐	☐	☐
白板	☐	☐	☐	☐	☐
智能板	☐	☐	☐	☐	☐
其它 (請說明：____)	☐	☐	☐	☐	☐

睡眠習慣的問題

32) 請填寫在上學時，週末，假期時小朋友每天的睡覺習慣？

	學習日 （星期一至星期五）	**週末 （星期六至星期日）**	**假期 （暑假、寒假、公眾假期）**
睡覺時間	_____：_____上午 / 下午	_____：_____上午 / 下午	_____：_____上午 / 下午
起床時間	_____：_____上午 / 下午	_____：_____上午 / 下午	_____：_____上午 / 下午

33) 你的小朋友晚上睡覺時四周環境亮度：***(請選擇相應亮度)***

	2歲以前	**4歲以前**	**現在**
全暗	☐	☐	☐
夜間照明燈	☐	☐	☐
窗外或走廊的光線	☐	☐	☐
房間燈光	☐	☐	☐

有關你的小朋友的假日

請估計於假期裡，你的小朋友處於室內/戶外的時間（注意：不包括吃飯，睡覺等）。

34) 去年***6個星期的暑假***：

- ☐ 室內為主，每天偶爾長達2小時在戶外
- ☐ 室內和室外時間大致相當
- ☐ 大部份戶外，每天偶爾長達2小時在室內

35) 去年冬天的***4個星期的聖誕假及新年假***：

- ☐ 室內為主，每天偶爾長達2小時在戶外
- ☐ 室內和室外時間大致相當
- ☐ 大部份戶外，每天偶爾長達2小時在室內

36) 其他***公眾假期***(例如佛誕、國慶節等)：

- ☐ 室內為主，每天偶爾長達2小時在戶外
- ☐ 室內和室外時間大致相當
- ☐ 大部份戶外，每天偶爾長達2小時在室內

下面的一些問題是關於去年夏天當你的小孩處於戶外陽光下至少15分鐘後的情形。請想想在這樣情形下你的小孩通常採取的防曬措施。

37) 回想去年夏天，你的小孩經常於早上11時到下午3時之間處於陽光下超過15分鐘嗎？

- ☐ 總是（~100%）
- ☐ 大部分（~ 75%）
- ☐ 經常（~ 50%）
- ☐ 很少 （~ 25%）
- ☐ 從來沒有在陽光下超過15分鐘
- ☐ 不確定

38) 繼續回想去年夏天，你的小孩的皮膚有幾經常在曬傷後第二天仍然是疼痛的或敏感的呢？

- ☐ 總是（~100%）
- ☐ 大部分（~75%）
- ☐ 經常（~ 50%）
- ☐ 很少（~ 25%）
- ☐ 從不（~ 0%）
- ☐ 不確定

39) 回想去年夏天當你的小孩在陽光下超過15分鐘時，你的小孩有幾經常戴了寬沿帽或有後遮物的帽子？

- ☐ 總是（~ 100%）
- ☐ 大部分（~ 75%）
- ☐ 經常（~ 50%）
- ☐ 很少 （~ 25%）
- ☐ 從不（~ 0%）
- ☐ 不確定

40) 繼續回想去年夏天，你的小孩有幾經常使用SPF15或更高防曬指數的防曬霜

- ☐ 總是（~ 100%）
- ☐ 大部分（~ 75%）
- ☐ 經常（~ 50%）
- ☐ 很少 （~ 25%）
- ☐ 從不（~ 0%）
- ☐ 不確定

41) 繼續回想去年夏天，你的小孩有幾經常為了保護自己不被太陽曬傷而穿長袖衣服？

- ☐ 總是（~ 100%）
- ☐ 大部分（~ 75%）
- ☐ 經常（~ 50%）
- ☐ 很少 （~ 25%）
- ☐ 從不（~ 0%）
- ☐ 不確定

日常活動的問題

42) 請選擇你的小朋友在***上學期間***在學校或在家裡所參加的活動以及***每個星期***你的小朋友花在這方面的時間。

一週（七天）的活動情況					
	有	每個星期在這項活動中花費的時間數	活動地點		
			戶外	體育館	教室或更小的室內
a) 舞蹈、體操、武術等	☐	_____小時/星期	☐	☐	☐
b) 田徑	☐	_____小時/星期	☐	☐	☐
c) 游泳	☐	_____小時/星期	☐	☐	☐
d) 足球、英式足球、橄欖球	☐	_____小時/星期	☐	☐	☐
e) 籃球	☐	_____小時/星期	☐	☐	☐
f) 網球、壁球、羽毛球或乒乓球	☐	_____小時/星期	☐	☐	☐
g) 板球、高爾夫球	☐	_____小時/星期	☐	☐	☐
h) 溜冰、滾軸溜冰-	☐	_____小時/星期	☐	☐	☐
i) 棒球、壘球	☐	_____小時/星期	☐	☐	☐
j) 行山、爬山	☐	_____小時/星期	☐	☐	☐
k) 參加青少俱樂部	☐	_____小時/星期	☐	☐	☐
l) 參加宗教活動（如教會）	☐	_____小時/星期	☐	☐	☐
m) 其他，請下面說明	☐	_____小時/星期	☐	☐	☐

43) 在下面的活動中，請選擇你的小朋友平均***每日***花在上面的時間

(**例如**：如果你的小孩每個星期（**星期一至星期五**）參加戶外休閒活動15個小時，**學習日**每天 平均戶外休閒時間=15/5=3小時。）**如果超過3個小時，請在橫線上寫明具體時間**

時間（每日） 分類	學習日（例如：週一至週五）				週末（例如：週六週日）				假期（例如：暑假，聖誕假）			
	從不	少於1小時	1-2小時	大於3小時	從不	少於1小時	1-2小時	大於3小時	從不	少於1小時	1-2小時	大於3小時
a) 室外活動（散步或者踩單車）	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
b) 戶外休閒活動(燒烤、野餐、海灘), 被家長帶領出遊	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
c) 看電視、 DVD	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
d) 玩電子遊戲機（如PlayStation）	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
e) 速描、繪畫、寫作	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
f) 製作手工藝品	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
g) 做飯、製作小東西	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
h) 完成學校的功課	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
i) 休閒閱讀	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
j) 玩樂器	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
k) 用電腦	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
l) 玩電子產品（如：手機、手持遊戲機、平板電腦）	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
m) 和寵物玩、照顧寵物	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
n) 購物、逛街	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時
o) 下象棋、撲克牌、棋盤遊戲	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時	☐	☐	☐	☐ ___小時

有關你的小朋友的生活環境

44) 小朋友的*父母*抽煙嗎？

	媽媽		爸爸
☐	從來不抽	☐	從來不抽
☐	以前抽,現在不抽 (請寫明煙齡:_____ 年)	☐	以前抽,現在不抽 (請寫明煙齡:_____ 年)
☐	現在抽 (請寫明煙齡:_____ 年)	☐	現在抽 (請寫明煙齡:_____ 年)

45) 小朋友*出生後*，*家裡*有人抽煙嗎？

☐ 不抽

☐ 抽（請在下表對應方框內填寫）

	媽媽	爸爸	其他人(請列舉：_____)
每天抽煙數目	_____支	_____支	_____支
煙齡 (小朋友出生後)	_____年	_____年	_____年

46) 請選擇能夠最好描述小朋友的住房情況

☐ 公屋

☐ 私人樓宇 (租)

☐ 私人樓宇(買)

☐ 獨棟別墅 (租/買)

☐ 一層

☐ 兩層

☐ 三層

☐ 宿舍

☐ 合租房 (如:劏房、板間房)

☐ 其它（請說明 : _____）

47) 你家位於樓房的第_____層。

48) 從你家的窗戶往外看，30米以內是否有比你家更高的建築物遮擋視線？

☐ 有

☐ 沒有（請跳至50題）

☐ 不確定（請跳至50題）

49) 如果有建築物遮擋，請估計有多少建築物遮擋，並估計建築物距離你家的距離。
建築物的數量_____座，建築物的距離_____米。

50) 請選擇你家房子的大小。

- ☐ ≤ 200平方呎
- ☐ 201—400 平方呎
- ☐ 401—600平方呎
- ☐ 601—800平方呎
- ☐ 801—1,000平方呎
- ☐ 1,000—1,200平方呎
- ☐ 1,201—1,400平方呎
- ☐ ≥ 1,401平方呎

經濟問題

請選擇合適的選項 , 以港幣作答

51) 家庭每月總收入（請以港幣作答）

- ☐ < $10,000
- ☐ $10,000 – 11,999
- ☐ $12,000 – 14, 999
- ☐ $15,000 – 19,999
- ☐ $20,000 – 24,999
- ☐ $25,000 – 29,999
- ☐ $30,000 – 34,999
- ☐ $35,000 – 39,999
- ☐ $40,000 – 49,999
- ☐ $50,000 – 59,999
- ☐ $60,000 – 79,999
- ☐ $80,000 – 99,999
- ☐ $100,000 – 149,999
- ☐ $150,000 – 199,999
- ☐ ≥ $200,000

52) 家裡同住人數（包括你自己）：_____人

出生史及妊娠至新生兒期

下面問題關於你孩子的出生和早期幾年的情況，如果你有健康手冊（附詳細出生記錄），請你查看。

53) 你的小朋友的出生年月？
____ (日) / ____ (年)

54) 你的小朋友在哪兒出生？
出生的國家：_____出生城市：_____

55) 分娩形式？

- ☐ 正常順產
- ☐ 臀先露
- ☐ 剖腹產
- ☐ 真空吸出術
- ☐ 產鉗助產
- ☐ 其他（請列舉: _____）
- ☐ 不確定

56) 孩子出生時的體重：_____千克/公斤 或者 _____磅 或者 _____ 安士

57) 出生時身長_____厘米

58) 出生頭圍: ____厘米
59) 共懷孕多少週？ ____週
☐ 不確定

60) 懷孕多少週時，你的小朋友出生？
☐ 晚(42週後或更長)
☐ 正常 (37-41 週)
☐ 早產 (32-36 週)
☐ 非常早 (31週或更早)

61) 孩子出生後是否需要深切治療或特別治療嗎？
☐ 是
☐ 否(請跳至63題)
☐ 不確定 (請跳至63題)

62) 你的小朋友接受多長時間的特別治療: _____(天)
請寫下痊癒的時間 ____(日) / ____(月) / ____ (年)

63) 該小朋友是多胞胎嗎？
☐ 不是
☐ 是的，雙胞胎
☐ 是的，三胞胎
☐ 是的，多於三胞胎
☐ 不確定

64) 孩子的母親生了幾個小孩？
☐ 1
☐ 2
☐ 3
☐ 4
☐ 其他：_____

65) 參加普查的小朋友在家排行第幾?
☐ 第一
☐ 第二
☐ 第三
☐ 第四
☐ 其他：_____

66) 媽媽生這個小朋友時的歲數是？
☐ <20
☐ 20-24
☐ 25-29
☐ 30-35
☐ ≥ 40 (***請說明具體 _____ 歲***)

母乳餵養情況的問題

67) 你的小朋友是否接受母乳餵養嗎？

- ☐ 是
- ☐ 否 (請跳至72題)
- ☐ 不確定（請跳至72題）

68) 你的小朋友幾歲開始喝母乳？

- ☐ ≤1個月
- ☐ 2-3個月
- ☐ 4-5個月
- ☐ ≥6個月

69) 你的小朋友接受母乳餵養了多長時間？

- ☐ ≤1個月
- ☐ 2-3個月
- ☐ 4-5個月
- ☐ 6-9個月
- ☐ 9-12個月
- ☐ 大於1年

70) 你的小朋友***半歲前***接受母乳餵養的情況

- ☐ 全母乳（只有母乳）
- ☐ 大部分母乳餵養（母乳為主加非配方輔食如粥或流質食物）
- ☐ 部分母乳（配方奶粉為主及部分母乳）

71) 你的小朋友餵食母乳的方式

- ☐ 直接飲母乳
- ☐ 奶瓶
- ☐ 混合上述兩種方法

母親懷孕時候的健康狀況將影響孩子的發展，所以以下部分我們想知道母親在懷孕時的健康狀況

72) 懷孕時有沒有生病？

- ☐ 沒有
- ☐ 不確定
- ☐ 有（請詳述：

_____

_____）

73) 在懷孕期間母親有沒有發生以下情況：（如果有，請選擇）

	有	沒有	不確定
高血壓 (住院了或是吃藥了)	☐	☐	☐
因糖尿病而注射胰島素	☐	☐	☐
有糖尿病沒注射胰島素	☐	☐	☐
懷孕期間高燒	☐	☐	☐
有德國麻疹	☐	☐	☐
有腮腺炎	☐	☐	☐
有其他健康問題， 請描述_____	☐	☐	☐

74) 懷孕期間母親有沒有抽煙或其他煙草類？

☐ 沒有 (請跳至78題)

☐ 有 (每天抽_____支煙)

☐ 不確定(請跳至78題)

75) 你懷孕的時候什麼時候開始吸煙？

從 ____(日) / ____(月) / ____ (年) 至 ____(日) / ____(月) / ____ (年)

76) 懷孕期間母親多久抽一次煙

☐ 每天

☐ 至少每週一次，不是每天

☐ 一週少於一次

☐ 完全不抽

☐ 不確定

77) 懷孕期間母親有經歷以下情況嗎？

☐ 減少抽煙量

☐ 試著戒煙但沒成功

☐ 成功戒煙

☐ 以上都無

☐ 不確定

78) 懷孕期間家中有沒有吸煙者？

☐ 有，一天在室內吸_____支煙

☐ 沒有

☐ 不確定

79) 懷孕期間母親多久喝一次酒？

☐ 每天

☐ 至少每週一次，不是每天

☐ 一週少於一次

☐ 完全不飲

☐ 不確定

80) 懷孕期間母親有沒有經歷以下情況嗎？

☐ 減少飲酒量
☐ 試著戒酒成功
☐ 成功戒酒
☐ 以上都無
☐ 不確定

81) 若母親懷孕期間有喝酒，請選擇每次飲酒量

（1 = 12 安士啤酒或 5 安士紅酒或 1.5 安士白酒）

☐ 1-2
☐ 2-4
☐ 超過 4

82) 懷孕期間，孩子母親有沒有服用過藥物？

☐ 有（***請填寫下列表格***）
☐ 沒有
☐ 不確定

如果在懷孕期間服用過藥物，請把藥物名稱和服用次數填寫在下表：

	藥物名稱	用藥方式（口服、針劑）	一天次數	一週次數	用藥原因
1					
2					
3					
4					
5					

83) 你的小朋友有被診斷有以下疾病嗎？

☐ 早期發育遲
☐ 過度活躍症或多動症
☐ 癲癇
☐ 腦膜炎
☐ 糖尿病
☐ 唐氏綜合徵
☐ 遺傳性關節眼病綜合症
☐ 弓形蟲
☐ 馬凡氏綜合症
☐ 先天性心臟病
☐ 其他：_____
☐ 不確定
☐ 正常（以上皆沒有）

家庭背景的問題

84) 描述孩子*母親*的工作情況

- ☐ 全職 (包括自僱)
- ☐ 兼職 （包括自僱）
- ☐ 待業 （請跳至86題）
- ☐ 家庭主婦 （請跳至86題）
- ☐ 一邊讀書一邊工作
- ☐ 全職讀書
- ☐ 退休
- ☐ 因健康問題無法工作
- ☐ 退休但有退休金
- ☐ 其它：_____

85) 孩子*母親*的職業:

- ☐ **經理及行政級人員**（如：民意代表、高階主管及 總執行長；行政及商業經理人員；生產及專業服務經理人 員；餐旅、零售及其他場所 服務經理人員)
- ☐ **專業人員**（如：科學及工程專業人員；醫療保健專業人員；教學專業人員；商業及行政專業人員；資訊及通訊專業人員；法律、社會及文化專業 人員）
- ☐ **輔助專業人員**（如：科學及工程專業人員，醫療保健助理專業人員，商業及行政助理專業人 員，法律、社會、文化及有 關助理專業人員；資訊及通訊傳播技術員）
- ☐ **事務支援人員**（如：一般及文書事務人員；顧客服務事務人員；會計、生產、運輸及有 關事務人員；其他事務支援人員）
- ☐ **服務工作及銷售**（如：個人服務工作人員；銷售及展示工作人員；個人照顧工作人員；保安服務工作人員）
- ☐ **農林牧漁勞動者**（如：農藝及園藝作物栽培人 員；動物飼育人員；農牧綜合生產人員；林業生產人員；漁業生產人員）
- ☐ **技藝有關工作人員**（如：營建及有關工作人員；金屬、機具製造及有關 工作人員；手工藝及印刷工作人員；電力及電子設備裝修人 員；其他技藝有關工作人員）
- ☐ **機械設備操作及組裝人員**（如：生產機械設備操作人員；組裝人員；駕駛及移運設備操作人員）
- ☐ **基層技術工及勞力工**（如：清潔工及幫工；農、林、漁、牧業勞力 工；採礦、營建、製造及運輸勞力工；街頭服務工及非餐飲小販；廢棄物服務工及環境清掃工；其他基層技術工及勞力 工）
- ☐ **軍人、員警**（如：軍官；士官； 其他位階軍人）

86) 描述孩子*父親*的工作情況

- ☐ 全職 (包括自僱)
- ☐ 兼職 （包括自僱）
- ☐ 待業 （請跳至88題）
- ☐ 家務工作 （請跳至88題）
- ☐ 一邊讀書一邊工作
- ☐ 其它：_____
- ☐ 全職讀書
- ☐ 退休
- ☐ 因健康問題無法工作
- ☐ 退休但有退休金

87) 孩子*父親*的職業

- ☐ **經理及行政級人員**（如：民意代表、高階主管及 總執行長；行政及商業經理人員；生產及專業服務經理人 員；餐旅、零售及其他場所 服務經理人員)
- ☐ **專業人員**（如：科學及工程專業人員；醫療保健專業人員；教學專業人員；商業及行政專業人員；資訊及通訊專業人員；法律、社會及文化專業 人員）
- ☐ **輔助專業人員**（如：科學及工程專業人員，醫療保健助理專業人員，商業及行政助理專業人 員，法律、社會、文化及有 關助理專業人員；資訊及通訊傳播技術員）
- ☐ **事務支援人員**（如：一般及文書事務人員；顧客服務事務人員；會計、生產、運輸及有 關事務人員；其他事務支援人員）
- ☐ **服務工作及銷售**（如：個人服務工作人員；銷售及展示工作人員；個人照顧工作人員；保安服務工作人員）
- ☐ **農林牧漁勞動者**（如：農藝及園藝作物栽培人 員；動物飼育人員；農牧綜合生產人員；林業生產人員；漁業生產人員）
- ☐ **技藝有關工作人員**（如：營建及有關工作人員；金屬、機具製造及有關 工作人員；手工藝及印刷工作人員；電力及電子設備裝修人 員；其他技藝有關工作人員）
- ☐ **機械設備操作及組裝人員**（如：生產機械設備操作人員；組裝人員；駕駛及移運設備操作人員）
- ☐ **基層技術工及勞力工**（如：清潔工及幫工；農、林、漁、牧業勞力 工；採礦、營建、製造及運輸勞力工；街頭服務工及非餐飲小販；廢棄物服務工及環境清掃工；其他基層技術工及勞力 工）
- ☐ **軍人、員警**（如：軍官；士官； 其他位階軍人）

88) 孩子*母親*的最高學歷

- ☐ **小學以下**
- ☐ 小學
- ☐ 初中
- ☐ 高中
- ☐ 副學士
- ☐ 大學
- ☐ 研究生（包括碩士或博士）

共上學_____年

89) 孩子*父親*的最高學歷

- ☐ 小學以下
- ☐ 小學
- ☐ 初中
- ☐ 高中
- ☐ 副學士
- ☐ 大學
- ☐ 研究生（包括碩士或博士）

共上學_____年

90) 孩子*親生母親*的健康狀況，請選擇其曾經有的或現在有的病症。

- ☐ 高血壓
- ☐ 癌症
- ☐ 氣喘
- ☐ 糖尿病

☐ 心臟病
☐ 腦中風
☐ 其他，請註明：
_____
☐ 不確定
☐ 以上皆沒有

91) 孩子***親生父親***的健康狀況，請選擇其曾經有的或現在有的病症。

☐ 高血壓
☐ 癌症
☐ 氣喘
☐ 糖尿病
☐ 心臟病
☐ 腦中風
☐ 其他，請註明：
_____
☐ 不確定
☐ 以上皆沒有

92) 孩子的***父母或祖父母***中有沒有被診斷出有一下列病症的？（請在橫線上寫明家庭成員如：父親）

☐ 馬凡綜合症（Marfan’ s syndrome ）_____
☐ 唐氏綜合症（Down syndrome） _____
☐ 努南綜合征（矮小症）（Noonan syndrome）_____
☐ 遺傳性關節-眼病綜合征 (Stickler syndrome)_____
☐ 特納綜合征（性腺發育障礙綜合症）（Turner’ s syndrome） _____
☐ 不確定
☐ 以上皆沒有

93) 孩子***親生母親***的眼睛有沒有以下症狀？***（如果有請詳細描述）***

	眼病	**右眼（度）**	**左眼（度）**
☐	近視	_____	_____
☐	遠視	_____	_____
☐	散光	_____	_____
☐	斜視		
☐	弱視		
☐	正常		

94) ***親生父親***的眼睛有沒有以下症狀？***（如果有請詳細描述）***

	眼病	**右眼（度）**	**左眼（度）**
☐	近視	_____	_____
☐	遠視	_____	_____
☐	散光	_____	_____
☐	斜視		
☐	弱視		
☐	正常		

95) 孩子***親生母親***的健康狀況，請選擇其曾經有的或現在有的眼病

眼病種類	**右眼**	**左眼**
老年性黃斑變性(AMD)	☐	☐
白內障	☐	☐
糖尿病黃斑水腫(DME)	☐	☐
糖尿病視網膜病變	☐	☐
青光眼	☐	☐
黃斑裂孔(macular hole)	☐	☐
視網膜脫離	☐	☐
其它(請列舉: _____)	☐	☐
沒有以上情況	☐	
不確定	☐	

96) 孩子***親生父親***的健康狀況，請選擇其曾經有的或現在有的眼病。

眼病種類	**右眼**	**左眼**
老年性黃斑變性(AMD)	☐	☐
白內障	☐	☐
糖尿病黃斑水腫(DME)	☐	☐
糖尿病視網膜病變	☐	☐
青光眼	☐	☐
黃斑裂孔(macular hole)	☐	☐
視網膜脫離	☐	☐
其它(請列舉: _____)	☐	☐
沒有以上情況	☐	
不確定	☐	

97) 孩子***親生父親***被診斷過為弱視（懶惰眼或者一隻眼視力極差）嗎？（任意一眼）

☐ 無

☐ 不確定

☐ 是

如果是，是

哪一隻眼？

☐ 右眼

☐ 左眼

☐ 雙眼

☐ 不確定

診斷時年齡：_____歲；診斷人：_____

曾否接受遮眼治療？

☐ 是

☐ 無

☐ 不確定

98) 孩子***親生母親***被診斷過為弱視（懶惰眼或者一隻眼視力極差）嗎？（任意一眼）

☐ 無

☐ 不確定

☐ 是

如果是，是哪一隻眼？

☐ 右眼

☐ 左眼

☐ 雙眼

☐ 不確定

診斷時年齡：_____歲；診斷人：_____

曾否接受遮眼治療？

☐ 是

☐ 無

☐ 不確定

99) 孩子的***親生母親***被診斷過為斜視嗎？

☐ 無

☐ 不確定

☐ 是

如果是，是哪一隻眼？

☐ 右眼

☐ 左眼

☐ 雙眼

☐ 不確定

診斷時年齡：_____歲；診斷人：_____

她做手術矯正斜視了嗎？

☐ 是

☐ 無

☐ 不確定

100) 孩子的***親生父親***被診斷過為斜視嗎？

☐ 無

☐ 不確定

☐ 是

如果是，是哪一隻眼？

☐ 右眼
☐ 左眼
☐ 雙眼
☐ 不確定

診斷時年齡：_____歲；診斷人：_____

她做手術矯正斜視了嗎？

☐ 是
☐ 無
☐ 不確定

101) 孩子***親生父母***的基本資訊 :

	親生父親	**親生母親**
出生地		
民族		
身高（厘米）		
體重（公斤）		

完成日期: ____(日) / ____(月) / ____ (年)
簽名: _____
與孩子的關係: _____

意見及建議：

_____

_____

聲明（關於保密性）

問卷中的所有資料都將徵得完成者的同意並且保持機密。所有資料只用於低濃度阿托品研究。沒有你的同意，所有訊息都不會公佈及洩漏。這是一份自願填寫的問卷，你和你的孩子不會獲得報酬。
如果你想回收你的個人資訊，請通過以下方式聯絡：

臨牀研究辦公室
香港中文大學眼科及視覺科學學系
香港中文大學眼科中心
電話：3943 5818
圖文傳真：2648 3856
電子郵箱：deptovs@cuhk.edu.hk

謝謝!

香港中文大學眼科中心
CUHK Eye Centre

香港中文大學醫學院
Faculty of Medicine
The Chinese University of Hong Kong

Low-concentration Atropine for Myopia Prevention (LAMP-2) Study

QUESTIONNAIRE

Development, Environment & Lifestyle

(Parental Use)

Serial no.:: _____

School: _____Contact number: _____

Relationship to child: _____

Ethnicity: _____Date of completion: ____/____/____

For staff use only:

Date received: ___/__/___ Data entry: Yes No

Complete Questionnaire: Yes No Entered by:

Missing Data: Yes No Re-entry: Yes No

Verified by: Entered by:

Version 3 Date: 20 May 2019

Vision Questions

Please answer the following questions with your child.

1) Has your child been to an eye examination before?
   - ☐ No (please skip to question 4)
   - ☐ Yes (***please specify: first eye examination at _____ years old***)
   - ☐ Not sure
2) Does your child have eye examinations regularly?
   - ☐ No (please skip to question 4)
   - ☐ Yes
   - ☐ Not sure
3) How often does your child visit the hospital or optical shop to get his or her eyes examined?
   - ☐ At least once half a year
   - ☐ Once half a year
   - ☐ Less than once a year
   - ☐ Once a year
4) What is the condition of your child's eyes? ***Please also indicate the age of onset for each applicable condition.***

	Condition	**Age of onset (years)**
☐	Myopia (short-sightedness)	
☐	Hyperopia (farsightedness)	
☐	Astigmatism	
☐	Strabismus	
☐	Amblyopia	
☐	Others (*please specify:* _____)	
☐	Normal (None of the mentioned conditions above)	

5) Does your child ***currently*** wear ***glasses*** **or** ***contact lenses***?
   - ☐ No (please skip to question 9)
   - ☐ Glasses (<u>please bring them to the eye examination</u>)
6) When did your child start wearing glasses? _____ years old
7) Please indicate your child's first pair of glasses' prescription.

Prescription (diopter)	**Right eye**	**Left eye**
Myopia		
Hyperopia		
Astigmatism		

8) How often does your child wear ***glasses*** or ***contact*** lenses***?***
   - ☐ All the time
   - ☐ Most of the time
   - ☐ Sometimes
   - ☐ Hardly ever
   - ☐ Only when his/her eyes feel tired

9) Has your child ever used any of the following methods to treat myopia? (***Please check all that applies***)

- ☐ Bifocal glasses
- ☐ Progressive glasses
- ☐ Atropine eye drops
- ☐ Orthokeratology glasses
- ☐ Acupuncture
- ☐ None of the above
- ☐ Not sure
- ☐ Others (Please specify: _____)

10) Has your child ever experienced any of following?

- ☐ Blurred vision when looking into the distance
- ☐ Double vision
- ☐ Sore eyes (How often? _____)
- ☐ Other (please describe: _____)
- ☐ None of the above

11) Does your child get headaches when reading or doing close work

- ☐ Yes
  - ☐ If yes, how often___times per week. And what time of the day? _____ (i.e. morning, afternoon, evening etc.)
  - ☐ How long do the headaches usually last? _____ minutes
- ☐ No
- ☐ Not sure

12) How many books or magazines do your child finish reading in a week? (***If your child did not complete the entire whole book, please sum up the parts completed for each book per week; e.g. ½ of book A + ½ book B = 1 book***)

_____books or magazines per week

13) Where does your child do ***most*** of his/her reading or close work?

- ☐ At a quiet location at home (*e.g. bedroom, study*)
- ☐ At another location at home (*e.g. dining room, living room*)
- ☐ In the library or/and tutorial center
- ☐ Other (please describe: _____)

14) What type of lighting is ***normally used*** when your child read or do close work? ***(You may tick more than one box***)

- ☐ Desk lamp
- ☐ Ceiling or room light
- ☐ Natural light (*e.g. sunlight through a window, skylight*)
- ☐ Other (please describe: _____)

15) For how long does your child ***continuously*** read or do close work before taking a break of 5 minutes or longer?

- ☐ 0-15 minutes
- ☐ 16-30 minutes
- ☐ 31-45 minutes

☐ 46-60 minutes

☐ More than 60 minutes

16) How often does your child borrow/buy books from libraries or bookstores?

- ☐ Never
- ☐ Less than once a week
- ☐ Around once a week
- ☐ Greater than once a week

17) Please ***tick the vehicle(s)*** your child usually uses to get to school and indicate the ***duration of travel time***.

	Type of vehicle	**Duration (minutes)**
☐	Car	
☐	Train/bus	
☐	School bus	
☐	Walk	
☐	Bicycle	
☐	Other (please specify: _____)	

18) If your child gets to school in a car, train or bus, what do he/ she usually do during the journey?

- ☐ Read a book/ study
- ☐ Talk to other people in the vehicle
- ☐ Play with hand-held electronic devices (*e.g. mobile phone, Gameboy, iPad/tablet*)
- ☐ Sleep
- ☐ Look outside the window
- ☐ Other (please describe: _____)

Near Work and Distance Questions

19) Does your child place his/her face unusually close to the book while reading/ writing?

- ☐ Yes
- ☐ No
- ☐ Not sure

20) If your child's ***reading/writing*** distance is close, please estimate how close by ticking one box.

- ☐ 0 to < 10 centimeters (0 to < 4 inches)
- ☐ 10 to < 20 centimeters (4 to < 8 inches)
- ☐ 20 to < 30 centimeters (8 to < 12 inches)
- ☐ ≥ 30 centimeters (≥ 12 inches)

21) Does your child have access to any of the following? (***You may tick more than one box***)

- ☐ Mobile phone
- ☐ Hand-held devices (*e.g. Gameboy, iPad/tablet*)
- ☐ Computer
- ☐ Access to television
- ☐ Home Video Game System (*e.g. Xbox, PlayStation, etc.*)

22) ***If applicable***, please indicate how old was your child when he/she started using the follow devices:

Type of devices	**Age (years)**
Mobile phone	
Other hand-held devices (*e.g. Gameboy, iPad/tablet*)	
Computer	
Television	
Home Video Game System (*e.g. X-Box, PlayStation, etc.)*	

23) When your child is using hand-held devices (*e.g. mobile phone, Gameboy, iPad/tablet*), how close to the screen does he/she sit?

- ☐ 0 to < 10 centimeters (0 to < 4 inches)
- ☐ 10 to < 20 centimeters (4 to < 8 inches)
- ☐ 20 to < 30 centimeters (8 to < 12 inches)
- ☐ ≥ 30 centimeters (≥ 12 inches)

24) When your child is using the computer, how close to the computer does your child sit?

- ☐ My child does not watch television
- ☐ 0 to < 25 centimeters (0 to < 10 inches)
- ☐ 25 to < 50 centimeters (10 to < 20 inches)
- ☐ 50 to < 100 centimeters (20 < 40 inches)
- ☐ ≥ 100 centimeters (> 40 inches)

25) When your child is watching television, how close to the television does your child sit?

- ☐ My child does not watch television
- ☐ < 1 meters (less than 3 feet)
- ☐ 1-2 meters (3-6 feet)
- ☐ 2-3 meters (6-9 feet)
- ☐ ≥ 3 meters (greater than 9 feet)

26) When your child plays video games, like PlayStation, how close to the screen does he/she sit?

- ☐ My child does not play video games
- ☐ < 1 meters (less than 3 feet)
- ☐ 1-2 meters (3-6 feet)
- ☐ 2-3 meters (6-9 feet)
- ☐ ≥ 3 meters (greater than 9 feet)

Academic Questions

Please respond to the next two questions in response to your child's last academic year.

27) Where does your child rank in his or her ***grade***? _____
28) Where does your child rank in his or her ***class***? _____
29) What are the two most frequent grades obtained by your child? (***Please select two***)

- ☐ A (90% to 100%)
- ☐ B (80% to 89%)
- ☐ C (70% 79%)
- ☐ D (60% to 69%)
- ☐ E (50% to 59%)
- ☐ F (< 50%)

30) What types of boards are used in your child's class room? (***Please check all that applies***)

- ☐ Blackboard
- ☐ Whiteboard
- ☐ Smart board
- ☐ Other (please specify: _____)

31) Please indicate how often each type of boards is used in the classroom.

	Never (0%)	**Rarely (~25%)**	**Often (~50%)**	**Most (~75%)**	**Always (100%)**
Blackboard	☐	☐	☐	☐	☐
Whiteboard	☐	☐	☐	☐	☐
Smart board	☐	☐	☐	☐	☐
Others (please specify: _____)	☐	☐	☐	☐	☐

Sleeping Habit Questions

32) Please answer the following questions according to a typical day (***weekday/weekend or holiday***).

	Weekdays ***(i.e. Monday to Friday)***	**Weekends** ***(i.e. Saturday and Sunday)***	**Vacation days** ***(i.e. summer, winter break, public holidays)***
Sleeping time	: AM/PM	: AM/PM	: AM/PM
Waking time	: AM/PM	: AM/PM	: AM/PM

33) What type of lighting is normally used in your child's bedroom when he/she is sleeping?

	Before 2 years old	**Before 4 years old**	**Present**
No lights	☐	☐	☐
Night light	☐	☐	☐
Light from adjacent room or window	☐	☐	☐
Room light	☐	☐	☐

Vacation Questions

Please estimate the amount of time your child spends indoor/outdoor during each of the following vacation periods (excluding mealtimes, sleeping etc.)

34) During the ***6 weeks of summer last year:***

- ☐ Mainly indoors and occasionally spending up to 2 hours/day
- ☐ About equal day amount of time indoors and outdoors
- ☐ Mostly outdoors and occasionally spending up to 2 hours/day

35) During the ***4 weeks of winter break (Christmas and Chinese New Year holiday) last year:***

- ☐ Mainly indoors and occasionally spending up to 2 hours/day
- ☐ About equal day amount of time indoors and outdoors
- ☐ Mostly outdoors and occasionally spending up to 2 hours/day

36) During the ***other vacations*** (such as national day, labor day etc.)

- ☐ Mainly indoors and occasionally spending up to 2 hours/day
- ☐ About equal day amount of time indoors and outdoors
- ☐ Mostly outdoors and occasionally spending up to 2 hours/day

The next few questions are about occasions last summer when your child was outside in the sun for at least 15 minutes. Please think about actions your child usually took sun protection these occasions.

37) Thinking back to last summer, how often did your child go out in the sun for more than 15 minutes between 11am to 3pm?

- ☐ Always (~100%)
- ☐ Often (~75%)
- ☐ Sometimes (~50%)
- ☐ Rarely (~25%)
- ☐ Never (0%)
- ☐ Unsure

38) Still thinking of last summer, how often did your child get sunburnt, so his or her skin was sore or tender the next day?

- ☐ Always (~100%)
- ☐ Often (~75%)
- ☐ Sometimes (~50%)
- ☐ Rarely (~25%)
- ☐ Never (0%)
- ☐ Unsure

39) Thinking back to last summer when your child was out in the sun for more than 15 minutes, how often did him/her wear a broad brimmed hat or cap with a black flap?

- ☐ Always (~100%)
- ☐ Often (~75%)
- ☐ Sometimes (~50%)
- ☐ Rarely (~25%)
- ☐ Never (0%)
- ☐ Unsure

40) Still thinking back to last summer, how often did your child apply broad-spectrum sunscreen with an SPF of 15 or more?

- ☐ Always (~100%)
- ☐ Often (~75%)
- ☐ Sometimes (~50%)
- ☐ Rarely (~25%)
- ☐ Never (0%)
- ☐ Unsure

41) Still thinking back to last summer, how often did your child dress in clothing to protect him/her from the sun?

- ☐ Always (~100%)
- ☐ Often (~75%)
- ☐ Sometimes (~50%)
- ☐ Rarely (~25%)
- ☐ Never (0%)
- ☐ Unsure

Activity Questions

42) Please tick the activities your child does ***during the school term*** and the number of ***hours per week*** he/she spends doing the activity. Include activities done ***at school*** and ***outside of school.***

During the 7 Days of the Week					
			Where is this done?		
	Yes	**Number of hours per week spent in this activity**	**Outdoor**	**In a hall or gym**	**In a classroom or smaller**
a) Dancing, gymnastics martial arts	☐	_____hours/week	☐	☐	☐
b) Athletics	☐	_____hours/week	☐	☐	☐
c) Swimming	☐	_____hours/week	☐	☐	☐
d) Football, soccer, rugby, league, AFL	☐	_____hours/week	☐	☐	☐

e) Netball, basketball	☐	_____hours/week	☐	☐	☐
f) Tennis, squash or racquet sports	☐	_____hours/week	☐	☐	☐
g) Cricket, golf	☐	_____hours/week	☐	☐	☐
h) Skating, rollerblading	☐	_____hours/week	☐	☐	☐
i) Baseball/soft ball	☐	_____hours/week	☐	☐	☐
j) Bushwalking, rock climbing	☐	_____hours/week	☐	☐	☐
k) Attending a youth group/club	☐	_____hours/week	☐	☐	☐
l) Attending a religions center	☐	_____hours/week	☐	☐	☐
m) Other, please describe below	☐	_____hours/week	☐	☐	☐

43) Please tick the average number of ***hours per day*** that your child spends doing the following activities (***e.g. if your child does 15 hours of outdoor leisure activities per week, then the average number of hours per weekday is 3 hours***). If your child spends ***more than 3 hours*** on a particular activity, please specify ***the amount of hours spent***.

	On a school weekday				**On a school weekend**				**On a vacation day (e.g. summer and winter break)**			
	Not at all	Less than 1 hour	1-2 hours	3 or more hours	Not at all	Less than 1 hour	1-2 hours	3 or more hours	Not at all	Less than 1 hour	1-2 hours	3 or more hours
a) Out of door activities(in your backyard, walking, riding a bike/scooter)	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours
b) Outdoor leisure activities (*e.g. BBQs, picnic, beach, bushwalk*)	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours
c) Watching T.V/ videos/ DVDs	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours
d) Playing home video game (e.g. *PlayStation)*	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours
e) Drawing, painting and/or writing	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours
f) Hobbies and crafts	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours	☐	☐	☐	☐ _____hours
g) Cooking, making or constructing things	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

				hours				hours				hours
h) School homework	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours
i) Reading books for pleasure	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours
j) Playing musical instruments	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours
k) Using a computer	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours
l) Playing ***hand-held*** electronic devices (*e.g. mobile phone, Gameboy, iPad/tablet*)	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours
m) Playing with and caring for pets	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours
n) Going shopping	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours
o) Playing chess, cards or board games	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours	☐	☐	☐	☐ hours

Living Environment Questions

44) Do your child's ***biological mother*** and ***father*** smoke?

Mother		**Father**	
☐	Never smoked	☐	Never smoked
☐	Previously smoked; does not currently smoke (please specify: _____ years)	☐	Previously smoked; does not currently smoke (please specify: _____years)
☐	Currently smoke (please specify: years)	☐	Currently smoke (please specify: years)

45) ***After the birth of your child***, has anyone smoked inside his or her home?

☐ No

☐ Yes (please complete the table below)

	Mother	**Father**	**Others** *(Please specify:)*
Cigarettes/ay	cigarette	_____ cigarette	cigarette
Years of smoking (after birth of child)	year(s)	_____ year(s)	year(s)

46) Please ***tick*** the box that best describe your child's regular home:

- ☐ Public housing
- ☐ Private flat/unit/apartment (rental)
- ☐ Private flat/unit/apartment (owned)
- ☐ Separate house (rental/owned)
  - ☐ One storey
  - ☐ Two stories
  - ☐ Three stories
- ☐ Dormitories
- ☐ Co-rentals (i.e. subdivided flats, cubical apartments)
- ☐ Others (please specify: _____)

47) On what floor do does your child live on? _____floor

48) From the front door of your child's home, are there buildings within 30 m that are higher than his or her home?

- ☐ Yes
- ☐ No (please skip to question 50)
- ☐ Not applicable (please skip to question 50)

49) Please state the number of buildings higher than your child's home, and estimate their distances from your child's home.

_____buildings

_____meters away from your child's home

50) What is the size of your home?

- ☐ ≤ 200 square feet
- ☐ 201—400 square feet
- ☐ 401—600 square feet
- ☐ 601—800 square feet
- ☐ 801—1,000 square feet
- ☐ 1,000—1,200 square feet
- ☐ 1,201—1,400 square feet
- ☐ ≥ 1,401 square feet

Financial Questions

Please tick the appropriate box and answer the following questions in Hong Kong dollars.

51) What's your family income?

- ☐ <$10,000
- ☐ $10,000 –11,999
- ☐ $12,000 –14,999
- ☐ $15,000 –19,999
- ☐ $20,000 – 24,999
- ☐ $25,000 –29,999
- ☐ $30,000 – 34,999
- ☐ $35,000 – 39,999
- ☐ $40,000 – 49,999
- ☐ $50,000 – 59,999
- ☐ $60,000 – 79,999
- ☐ $80,000 – 99,999
- ☐ $100,000 –144,999
- ☐ $150,000 –199,999
- ☐ ≥ $200,000

52) How many are in your household? (***please include yourself***) _____people

Birth History Questions

If you still have your child's health record, please use it to answer the following questions.

53) When was your child born?
____/____ (*month/ year)*

54) Where was your child born?
Name (country of birth): _____
Name (city of birth): _____

55) Delivery Type:

- ☐ Normal
- ☐ Breech
- ☐ Caesarean
- ☐ Vacuum extraction
- ☐ Forceps
- ☐ Other (please specify:_____)
- ☐ Unsure

56) What was your child's birth weight? grams or pounds ounces
____ ____ ____

57) Birth length: centimeters
____

58) Birth head circumference: centimeters
____

59) What was your child's gestation period ____weeks
☐ unsure

60) Was your child born

- ☐ Late (42 weeks or more)
- ☐ On time (37-41 weeks gestation)
- ☐ Early (32-36 weeks gestation)
- ☐ Very early (31 weeks or less)

61) Was your admitted to a Neonatal Intensive Care Unit (NICU) or Special Care Nursery (SCN) after birth?

- ☐ Yes
- ☐ No (please skip to question 63)
- ☐ Unsure (please skip to question 63)

62) Duration in Neonatal Intensive Care Unit (NICU) or Special Care Nursery (SCN):
_____(days)

What was the date of discharge? / _/
____ ___ ____
day month years

63) Was this a multiple pregnancy? (*e.g. twins or triplets*)

- ☐ No, single birth
- ☐ Yes, twins

64) How many children has the mother given birth to?

- ☐ 1
- ☐ 2
- ☐ 3

65) What's the birth order of your child?

- ☐ 1
- ☐ 2
- ☐ 3

☐ Yes, triplets
☐ Yes, more than triplets
☐ Not sure

☐ 4
☐ Other: ____ child(ren)

☐ 4
☐ Other: _____

66) How old was the mother when she had the child?

- ☐ < 20
- ☐ 20-24
- ☐ 25-29
- ☐ 30-35
- ☐ ≥ 40 (***Please specify: ___years old***)

Breastfeeding Questions

67) Has your child ever been breastfed?

- ☐ Yes
- ☐ No (please skip to question 72)
- ☐ Not applicable (please skip to question 72)

68) At what age was your child first breastfed?

- ☐ ≤ 1 months
- ☐ Between 2-3 months
- ☐ Between 4-5 months
- ☐ ≥ 6 months

69) What is the total time your child was breastfed?

- ☐ ≤ 1 months
- ☐ Between 2-3 months
- ☐ Between 4-5 months
- Between 6-9 months ☐ Between 9-12 months
- ☐ ≥ 1 year

70) What type of breast feeding diet did your child have ***before 6 months old***?

- ☐ Exclusive (breast milk only)
- ☐ Mostly breast milk (non-formula supplements)
- ☐ Partly breast milk (formula supplements)

71) How was your child breastfed?

- ☐ Direct
- ☐ Bottle
- ☐ Mixed ways

The mother's health during pregnancy can influence her child's development. We would like to know about specific conditions the mother may have experienced during the pregnancy.

72) Were there any problems with the pregnancy?

- ☐ No
- ☐ Unsure
- ☐ Yes (If yes, please describe:

_____
_____)

73) During the pregnancy, did the mother: (***Please tick the appropriate box***)

	Yes	**No**	**Unsure**
Have high blood pressure needing treatment? (admission to hospital or medication)	☐	☐	☐
Have diabetes needing insulin injections?	☐	☐	☐
Have diabetes but didn't have insulin injections?	☐	☐	☐
Have a high fever anytime during the pregnancy?	☐	☐	☐
Have Rubella (German measles)?	☐	☐	☐
Have Mumps?	☐	☐	☐
Have other health problems? (*please specify:* _____)	☐	☐	☐

74) During the pregnancy, did the mother ever smoke cigarettes, cigars, pipes or other tobacco products?

- ☐ No (please skip to question 76)
- ☐ Yes (please specify: _____ cigarettes/day)
- ☐ Not applicable

75) When did you smoke during your pregnancy?

From: ____/ ____/ To: / _/

____ ____ ___ ____

day month years *day month years*

76) How often did the mother smoke cigarettes, cigars, pipes or other tobacco product, while she was pregnant with the child?

- ☐ Daily
- ☐ At least weekly, not daily
- ☐ Less often than weekly
- ☐ Try and give up smoking but were unsuccessful

77) During the pregnancy, did the mother:

- ☐ Reduce the amount of tobacco she smoked

☐ Not at all
☐ Don't know
☐ Successfully give up smoking
☐ None of the above
☐ Don't know

78) During the pregnancy, did the mother share a home with people who smoked indoors?
- ☐ Yes (please specify approximately how many cigarettes were smoked indoors/day during the pregnancy: _____)
- ☐ No
- ☐ Not sure

79) How often did the mother consume alcohol while she was pregnant with the child?
- ☐ Daily
- ☐ At least weekly, not daily
- ☐ Less often than weekly
- ☐ Not at all
- ☐ Don't know

80) During the pregnancy, did the mother:
- ☐ Reduce the amount of alcohol consumption
- ☐ Try and give up alcohol but were unsuccessful
- ☐ Successfully give up alcohol
- ☐ None of the above
- ☐ Don't know

81) How much alcohol did the mother consume/sitting?

(***1 standard drink = 12 ounces of beer, 5 ounces of wine, and 1.5 ounces of distilled spirits)***
- ☐ 1-2 drink
- ☐ 2-4 drink
- ☐ More than 4 drinks

82) During the pregnancy, did the mother take any prescribed/ over-the-counter medications?
- ☐ Yes (please complete the table below)
- ☐ No
- ☐ Not applicable

Please list all prescribed/over-the-counter medication.

	Medication Name	**Method of intake (i.e. oral injected)**	**How many times a day**	**Duration in a week**	**Reason for taking**
1					
2					
3					
4					
5					

83) Has your child been diagnosed for following diseases?

- ☐ Delayed development
- ☐ Attention Deficient Hyperactive Disorder or Attention Deficient Disorder
- ☐ Epilepsy
- ☐ Meningitis
- ☐ Diabetes
- ☐ Down Syndrome
- ☐ Stickler Syndrome
- ☐ Toxoplasma
- ☐ Marfan syndrome
- ☐ Congenital heart disease
- ☐ Others (please specify: _____)
- ☐ Not sure
- ☐ Normal

Family Background Questions

Please tick the appropriate box for the following questions

84) How would you describe the ***mother's*** employment status?

- ☐ Employment full-time (*includes self-employment*)
- ☐ Employed part-time (*includes self-employment*)
- ☐ Unemployed (please skip to question 86)
- ☐ Home duties (*i.e. housewife.* Please skip to question 86)
- ☐ Student and working
- ☐ Student and not working
- ☐ Retired
- ☐ Unable to work due to health problems
- ☐ Pension
- ☐ Other (please specify: _____)

85) ***Mother's*** current occupation:

☐ Managers (*e.g. chief executives, senior officials and legislators; administrative and commercial managers; production and specialized services managers; hospitality, retail and other services managers*)

☐ Professionals (*e.g. science and engineering; health professionals; teaching professionals; business and administration; information and communication technology professionals; , legal, social and cultural professionals*)

☐ Technicians and Associate Professionals (*e.g. science and engineering associate, health associate, business and administration, legal, social, cultural, related professionals; information and communication technicians*)

☐ Clerical Support Workers (*e.g. general and keyboard, customer services, numerical and material recording clerks; other clerical support workers*)

☐ Services and Sales Workers (*e.g. personal services, sales, personal care, protective services workers*)

☐ Skilled Agricultural, Forestry and Fishery Workers (*e.g. market-oriented skilled agricultural, market-oriented skill forestry, fishery and hunting workers; substance farmer, fishers, hunters and gatherers*)

☐ Craft and Related Trades Workers (*e.g. building and related trades workers, excluding electricians; metal, machinery and related trades workers; handicraft and printing workers; electrical and electronic trades workers; food processing, woodworking, garment and other craft and related workers*)

☐ Plant and Machines Operators, and Assemblers (e.g. stationary plant and machine operators; assemblers; drivers and mobile plant operators)

☐ Elementary Occupations (*e.g. cleaners and helpers; agricultural, forestry and fisher laborers, labors in mining; laborers in mining, construction, manufacturing and transport; food preparation assistants; street and related sales and services workers; refuse workers and other elementary workers*)

☐ Armed Forces Occupations (*e.g. commissioned armed forces officers; non-commissioned armed forces officers; armed forces occupation, other ranks*)

86) How would you describe the ***father's*** employment status?

☐ Employment full-time (*includes self-employment*)

☐ Employed part-time (*includes self-employment*)

☐ Unemployed (please skip to question 88)

☐ Home duties (*i.e. housewife*. Please skip to question 88)

☐ Student and working

☐ Student and not working

☐ Retired

☐ Unable to work due to health problems

☐ Pension

☐ Other (please specify: _____)

87) ***Father's*** current occupation:

☐ Managers (*e.g. chief executives, senior officials and legislators; administrative and commercial managers; production and specialized services managers; hospitality, retail and other services managers*)

☐ Professionals (*e.g. science and engineering; health professionals; teaching professionals; business and administration; information and communication technology professionals; , legal, social and cultural professionals*)

☐ Technicians and Associate Professionals (*e.g. science and engineering associate, health associate, business and administration, legal, social, cultural, related professionals; information and communication technicians*)

☐ Clerical Support Workers (*e.g. general and keyboard, customer services, numerical and material recording clerks; other clerical support workers*)

☐ Services and Sales Workers (*e.g. personal services, sales, personal care, protective services*

workers)

☐ Skilled Agricultural, Forestry and Fishery Workers (*e.g. market-oriented skilled agricultural, market-oriented skill forestry, fishery and hunting workers; substance farmer, fishers, hunters and gatherers*)

☐ Craft and Related Trades Workers (*e.g. building and related trades workers, excluding electricians; metal, machinery and related trades workers; handicraft and printing workers; electrical and electronic trades workers; food processing, woodworking, garment and other craft and related workers*)

☐ Plant and Machines Operators, and Assemblers (e.g. stationary plant and machine operators; assemblers; drivers and mobile plant operators)

☐ Elementary Occupations (*e.g. cleaners and helpers; agricultural, forestry and fisher laborers, labors in mining; laborers in mining, construction, manufacturing and transport; food preparation assistants; street and related sales and services workers; refuse workers and other elementary workers*)

☐ Armed Forces Occupations (*e.g. commissioned armed forces officers; non-commissioned armed forces officers; armed forces occupation, other ranks*)

88) What is the highest level of education completed by the ***mother***?

- ☐ Never attended school
- ☐ Primary school
- ☐ Junior high school
- ☐ Senior high school
- ☐ Associate degree or higher diploma
- ☐ University, CAE or some other tertiary institute degree
- ☐ Higher degree including a Masters or PhD

Total amount of years spent in school: _____ years

89) What is the highest level of education completed by the ***father***?

- ☐ Never attended school
- ☐ Primary school
- ☐ Junior high school
- ☐ Senior high school
- ☐ Associate degree or higher diploma
- ☐ University, CAE or some other tertiary institute degree
- ☐ Higher degree including a Masters or PhD

Total amount of years spent in school: _____ years

90) Please check all medical conditions the child's ***biological mother*** may have had or currently has:

- ☐ High blood pressure
- ☐ Cancer
- ☐ Asthma
- ☐ Diabetes
- ☐ Heart disease
- ☐ Stroke
- ☐ Other (please describe: _____)
- ☐ Not applicable
- ☐ Unsure

91) Please check all medical conditions the child's ***biological father*** may have had or currently has:

- ☐ High blood pressure
- ☐ Cancer
- ☐ Asthma
- ☐ Diabetes
- ☐ Heart disease
- ☐ Stroke
- ☐ Other (please describe: _____)
- ☐ Not applicable
- ☐ Unsure

92) Have any of the child's biological family members ever been diagnosed with the following? (***Including mother, father, grandparents or any other family member***) ***Please specify which biological family members on the lines below***

- ☐ Marfan's syndrome _____
- ☐ Stickler syndrome _____
- ☐ Noonan syndrome _____
- ☐ Down syndrome _____

- ☐ Turner's syndrome _____
- ☐ Unsure _____
- ☐ Not applicable

93) What's the condition of the child's biological mother's eyes? (***please indicate the prescription where appropriate***)

	Eye diseases	**Right eye (diopters**	**Left eye (diopters)**
☐	Myopia (short-sightedness)	_____	
☐	Hyperopia (farsightedness)	_____	
☐	Astigmatism	_____	
☐	Strabismus		
☐	Amblyopia		
☐	Normal		

94) What's the condition of the child's biological father's eyes? (***please indicate the prescription for each eye where appropriate***)

	Eye diseases	**Right eye (diopters**	**Left eye (diopters)**
☐	Myopia (short-sightedness)	_____	
☐	Hyperopia (farsightedness)	_____	
☐	Astigmatism	_____	
☐	Strabismus	_____	
☐	Amblyopia	_____	
☐	Normal		

95) Please check all ophthalmic disorders the child's ***biological mother*** may have had or currently has:

Type of Ophthalmic disorder	**Right Eye**	**Left Eye**
Age –regulated macular degeneration	☐	☐
Cataract	☐	☐
Diabetic macular edema	☐	☐
Diabetic retinopathy	☐	☐
Glaucoma	☐	☐
Macular hole	☐	☐
Retinal detachment	☐	☐
Others (*please specify*: _____)	☐	☐
Not applicable	☐	
Not sure	☐	

96) Please tick all ophthalmic disorders the child's ***biological father*** may have had or currently has:

Type of Ophthalmic disorder	Right Eye	Left Eye
Age –regulated macular degeneration	☐	☐
Cataract	☐	☐
Diabetic retinopathy	☐	☐
Diabetic macular edema	☐	☐
Glaucoma	☐	☐
Macular hole	☐	☐
Retinal detachment	☐	☐
Others (***please specify:*** _____)	☐	☐
Not applicable	☐	
Not sure	☐	

97) Has the child's ***biological father*** ever been diagnosed with amblyopia? (lazy or weak eye/ poor vision in one eye)?

☐ Yes
☐ No
☐ Not applicable

If yes, which eye(s) was involved?

☐ Right eye ☐ Both eyes
☐ Left eye ☐ Not sure

At what age was diagnosed? _____ years
By whom? _____

Did he wear an eye patch for this condition?

☐ Yes
☐ No
☐ Not sure

98) Has the child's ***biological mother*** ever been diagnosed with amblyopia? (lazy or weak eye/ poor vision in one eye)?

☐ Not applicable
☐ No
☐ Yes

If yes, which eye(s) was involved?

☐ Right eye ☐ Both eyes
☐ Left eye ☐ Not sure

At what age was diagnosed? _____years
By whom? _____

Did she wear an eye patch for this condition?

☐ Yes
☐ No
☐ Not sure

99) Has the child's ***biological father*** ever been diagnosed with strabismus? (squint or turned eye)?

- ☐ Not applicable
- ☐ No
- ☐ Yes

If yes, which eye(s) was involved?

- ☐ Right eye
- ☐ Left eye
- ☐ Both eyes
- ☐ Not applicable

At what age was diagnosed? _____years
By whom? _____

Did he have surgery to correct the squint?

- ☐ Yes
- ☐ No
- ☐ Not sure

100) Has the child's ***biological mother*** ever been diagnosed with strabismus? (Squint or turned eye)?

- ☐ Not applicable
- ☐ No
- ☐ Yes

If yes, which eye(s) was involved?

- ☐ Right eye
- ☐ Left eye
- ☐ Both eyes
- ☐ Not applicable

At what age was diagnosed? _____years
By whom? _____

Did she have surgery to correct the squint?

- ☐ Yes
- ☐ No
- ☐ Not sure

101) Biological parents' basic information:

	Father	**Mother**
Place of birth		
Nationality		
Height (m)		
Weight (kg)		

Date of completion: ☐ / ☐ / ☐

Signature: _____

Relationship to child: _____

Questions/comments: _____

_____

_____

Disclaimer (*Statement of Confidentiality*):

All data that would permit the identification of any person completing the questionnaire will be kept strictly confidential. All information collected will be solely used for the Wan Chai Children Eye Study and will not be disclosed or released for any other purpose without your consent.
You may collect any personal information provided at any time by contacting:

Research Office
Department of Ophthalmology and Visual Sciences
The Chinese University of Hong Kong
Hong Kong Eye Hospital
Telephone: 3943 5813
Fax: 2648 3856
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Thank you!