PROSPER Full Protocol

Study Identification

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Brief Title: PROSPER

Official Title: PROductivity Study of Presbyopia Elimination in Rural-dwellers (PROSPER)

Study Status

Record Verification: December 2017

Overall Status: Recruiting

Study Start: July 24, 2017 [Actual]

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Study Completion: October 28, 2017 [Actual]

Sponsor/Collaborators

Sponsor: Congdon Nathan

Responsible Party: Sponsor-Investigator

Investigator: Congdon Nathan [cnathan]

Official Title: Professor

Affiliation: Sun Yat-sen University & Queen's University Belfast

Collaborators:

Queen's University, Belfast

Clearly.**W**orld

COMMUNITY EYE CARE FOUNDATION (CECF)

Aravind Eye Care System

University of British Columbia

Amalgamated Plantations Private Limited

VisionSpring

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved Approval Number: LNEH/88/2017

Board Name: Dr. Ashok Mahadik

Board Affiliation: Lion's NAB Eye

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Data Monitoring: Yes

Plan to Share IPD: No

FDA Regulated Intervention: No

Study Description

Brief Summary:

This trial seeks to establish, using a randomized, controlled design, the impact of near eyesight correction on the productivity of presbyopic agricultural workers in India, as measured by weight of tea picked.

I. Background: Importance of research topic, Particular Features of setting

Uncorrected presbyopia is an expensive problem for the world. Lost productivity among adults who need eyeglasses has been estimated to cost the global economy $227 billion every year, [1,2] and illiteracy may lead to a further $3 trillion in annual global economic losses. It has been shown that 74% of illiterate adults failed one or more parts of a vision screening. [3] However, in order to motivate governments, industry and other key stakeholders to invest in solving the problem of uncorrected near vision in adults, higher-

quality data on the productivity impact of correction are needed. Current studies are suggestive, but carefully-performed randomized trials are still lacking in the published literature.

An unpublished University of Michigan (USA) working paper found that correcting near-vision loss with glasses yields an increase in productivity of up to 34%, though no control group was included, and the outcome assessed was not precisely defined. An unpublished impact assessment conducted by Building Resources Across Communities (BRAC), the world's largest NGO in number of staff, concluded that 90% of individuals experiencing near-vision loss in Bangladesh encountered problems with their daily work; and, on average, 23% reported that their income was compromised.[4] In Rwanda, Lifetime Consulting & Partners found that workers with poor vision who did not wear glasses were three times more likely to be asked by supervisors to repeat their work of sorting coffee beans than after receiving and wearing glasses.[4] Again, no control group was included, and this work has not been published. Furthermore, a Dalberg Global Development Advisors study of adults in India who had their vision corrected with glasses found that 65% reported an increase in independence in movement and travel, and 59% reported improved work productivity, [5] but these outcomes were not confirmed quantitatively or objectively. Finally, a population study of 1008 older adult in Shenyang, northern China, found that those with uncorrected presbyopia (69%) were more likely to report diminished accomplishment due to vision ($P = 0.01$, adjusted for age, sex, education, and distance vision) than were those without presbyopia. [6] The impact of correcting presbyopia was not studied in prospective fashion.

In summary, available data are consistent with the idea that correcting presbyopia can lead to significant improvements in productivity among adult workers. However, in the absence of high-quality randomized trials, it is very difficult to be certain about cause and effect: it is equally plausible that the economic burden of poverty could result in failure to purchase glasses, rather than the reverse. Lack of control groups and carefully-defined productivity outcomes in many studies further hinder interpretation. Policy makers and industry partners require more convincing data in order to commit to the support of programs of vision correction.

Features of this setting:

A high proportion (> 50%) of workers have presbyopia in this large workforce, and previous projects by Vision Spring have shown that the large majority of these workers have no presbyopic correction.

The primary outcome (daily weight of tea picked) is measured and recorded by Amalgamated Tea as part of routine practice.

The work population is very stable, and data from previous years have been used for sample size calculations.

The project will be carried out during the high season (July through October) when the amount of tea picked is limited by the labourer and not by growth of the plants. Further,

these agricultural workers are strongly incentivized to pick more tea, because they are paid by weight, and thus gain in income when their personal productivity increases.

II. Experimental plan

Study design: Randomized, investigator-masked controlled trial

Methods to be used:

Population: Presbyopic (generally age >= 40 years) tea workers at the Amalgamated Plantations Pvt Ltd (APPL) in Assam, India.

Baseline data acquisition: Demographic and clinical: Age, sex, contact information, habitual and best corrected visual acuity at near and distance; power of distance and near refractive error in each eye; workers with acuity not improving to 6/7.5 in either eye at distance will undergo dilated fundus examination and will be referred to a local collaborating facility for care if needed. Work productivity: Daily mean weight of tea picked during a 4 weeks baseline period prior to randomisation.

Recruitment and consent: Approximately 1500 APPL workers aged 40 years or more will undergo assessment of above clinical criteria ("Baseline data acquisition") by VisionSpring local staff, assisted by APPL as part of the on-going Clear Vision Workplace program. Those meeting inclusion criteria (see below) will be invited to join to the study and complete informed consent forms. Recruitment will continue until approximately 700 persons have joined the study (see sample size calculations below). Baseline work productivity will be measured as outlined above for a 4-week period).

Inclusion Criteria:

- Employee of APPL for 1 year
- Aged >= 40 years
- Habitual near visual acuity of >= 0.8M (<=6/12) at 40cm in both eyes, correctable to <=0.5M (>=6/7.5) in both eyes with near glasses
- Uncorrected distance vision >= 6/7.5 in the better-seeing eye
- The participant worked and has data available on weight of tea picked for >=10 days in the previous 4 weeks (This will largely exclude men in this setting).
- Ability to give informed consent

Exclusion Criteria:

- Eye disease detected on baseline eye exam
- Current ownership of near correction capable of improving near visual acuity to <= 0.8M (>= 6/12) in either eye
- Unlikely to complete follow-up due to unsatisfactory work performance, plans to move out of the area, etc.

- Need for distance correction to achieve distance vision of >= 6/7.5 in the better-seeing eye.
- Inability to achieve best-corrected visual acuity with spherical power glasses only (that is: need for astigmatic correction to achieve best-corrected near visual acuity)

Persons with eye problems detected on examination will be referred for definitive care at local facilities, and distance refractive errors will be corrected with free bifocals for those with uncorrected VA < 6/12 in the better-seeing eye.

Randomization, Balancing and Intervention: Eligible workers completing baseline productivity assessment will be enrolled into the study, and assigned at random to one of the below groups:

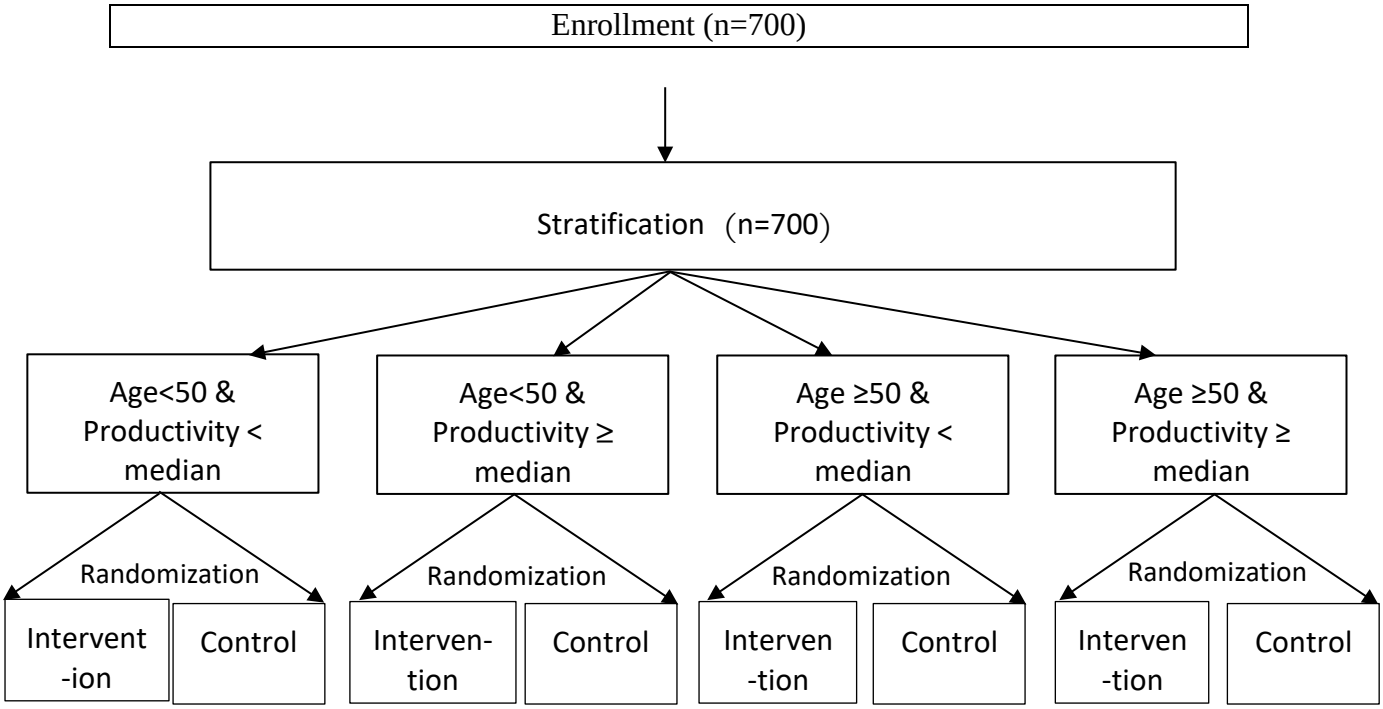
Intervention Group: Will immediately receive a free pair of presbyopic glasses through the Clear Vision Workplace program. These glasses will correct the worker's vision to their usual working distance, and will not correct astigmatism.

Control Group: Will be deferred to receive free presbyopic spectacles after the 12 weeks evaluation period.

Balance of the groups on age and baseline work productivity will be assessed and maintained insofar as possible, and allocation concealment prior to randomisation will be ensured through the use of a secure process so that neither the participant nor the person recruiting them to the study will know in advance whether or not they will receive spectacles immediately or after 12 weeks.

Randomization methodology: Eligible workers completing baseline data collection will be enrolled into the study, and stratified into eight groups according to age (<50, >=50), sex and baseline work productivity (<median, >=median), then participants among each of the eight groups will be assigned at random to one of the study arms as shown in the following figure.

An independent statistician having no contact with participants will generate the randomization sequence using a computer system that is inaccessible until after recruitment. The participants in each stratified group will be assigned to either the intervention or control group in a 1:1 ratio with block size of six. The participants will know their group assignment. However, the APPL staff measuring the weight and quality outcomes will be masked to a worker’s group assignment by having an intermediate person receive the tea from the worker at the weighing station each day.



Main outcome and masking: The daily mean weight of tea picked will be calculated for each worker for the 4 weeks baseline and for the 12 weeks evaluation period. The difference between these two means will be calculated for each worker, and the mean of this value will be calculated for each randomised group, with the main study outcome being the difference between these values for each group. It will not be practical to mask participants to their study group assignment (the investigators do not feel that providing sham near correction of plano power is ethical). However, the APPL staff measuring the weight outcomes will be masked to a worker's group assignment by having an intermediate person receive the tea from the worker and carry it to the weighing station each day. Secondary outcomes will include visual quality of life in both groups, self-reported wear of the study spectacles in the intervention group, self-reported purchase and use of glasses in the control group, independent compliance observations, quality of tea picked (if possible to assess) and the proportion of workers who work than less than 10 days in a month during the 12 weeks evaluation period.

Study hypothesis: Productivity gains in the Intervention Group will be significantly greater than those in the Control Group when the 12 weeks evaluation period is compared to the 4 weeks baseline period.

Sample size calculations: With two-sided significance level of P=0.05, power of 80%, a daily mean of 25.0 (SD: 5.0) kg of tea picked at baseline (among persons working >= 10 days in a month), and allowing for 20% loss to follow-up, a sample size of 160 persons (80 per group) will be sufficient to detect a 10% greater increase in daily mean weight of tea picked in the intervention group compared to the control group (primary outcome). However, in order to have sufficient data to conduct adequately powered analyses to compare the results for persons aged 40 years and above, with those for persons aged at

least 45 years and at least 50 years, we will aim to recruit a total of 700 participants. These subgroup analyses will be important for informing future policy, for example if choices need to be made about which, if any, age groups should be targeted for eyeglasses.

Statistical Plan: The analysis of the primary outcome (as defined above) between randomised groups will be done in intention to treat fashion with and without adjustment for potential determinants of productivity at baseline (including age, age*group interaction, sex, marital status, attitudinal variables and time spent as a tea picker) and during the evaluation period (including self-reported use of glasses in the intervention group and self-reported purchase and use of glasses among the control group). The mean daily data for participants working <10 days in a month during the evaluation period will be excluded from the main analyses in sensitivity analyses to assess the impact of these workers on the overall results (both in relation to the effect estimate and its confidence interval). Co-linearity of potential determinant variables will be checked, in order to avoid including colinear variables together in the final model.

Interaction of age and group will be examined, as it is expected that Interaction group participants will have a greater productivity response, while those in the Control may have less.

Analysis of the main outcome will also include age-stratified analysis of participants (for example, 40-44, 45-49, 50-59, and 60 and above).

Baseline characteristics between the groups will be compared.

Prevalence of presbyopia by age group among all participants will be assessed.

The secondary outcome, visual function quality of life using the VFQ25 will be compared between the two groups, with and without adjustment for baseline characteristics and potential determinants during the evaluation period (such as time since receipt of glasses when the VFQ was administered, in the Intervention group).

Compliance monitoring: Weekly (except for holidays), un-announced examinations of both groups will be carried out, to assess compliance with glasses wear in the Intervention group, and to determine if any participants in the Control group have purchased glasses.

Study Roles and Monitoring: The principal investigator will be responsible for final approval of the study protocol, overall study coordination and completing the UK ethical review. The principal investigator has a long-standing working relationship with VisionSpring (VS) and extensive experience in design and execution of randomised trials on refractive error in settings of limited resources. The principal investigator will visit India on two occasions: During the Study Preparation period and at the time of the Baseline examination. The VS India team will be responsible for coordinating field work. VS has worked in India for 10 years, and with APPL since 2014, and has extensive experience in carrying out presbyopic screening and provision of near spectacles in India and a wide variety of LMIC settings. APPL will provide support for the baseline examination, administration of the intervention and the end line distribution of glasses to the Control

Group. APPL will also be primarily responsible for collection of the primary study outcome (mean daily weight of picked tea) and the secondary outcome of the quality of picked tea in both groups.

Dissemination strategy: The project management team will prepare a dissemination strategy which balances the requirements of academic audiences (peer reviewed journal publications and conference presentations) with those of policy-makers and local patients and practitioners in both the UK and India and our NGO partners. In submitting findings to a range of academic journals, the investigators will focus on internationally-recognized journals with high impact, particularly those such as BMJ and Lancet Global Health with open access policies, making the papers more available to researchers and policy-makers in LMICs. The investigators will collaborate with the Cochrane Eyes and Vision group to help them update reviews on the economic impact of correction of refractive error. At the conclusion of the main trial, principal results will be available in English and several Indian languages and in graphic format on a mobile-friendly project website. Results will also be shared through organizations such as our Indian research partners and various locally-active eye health NGOs.

Funding: Primary funding provided by Clearly (Clearly.World), free glasses provided by VisionSpring (VisionSpring.org).

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Annexure

Ophthalmic Examination Procedures

Key Points

Proceed to Distance visual acuity if:

- Subject is 40yrs or older

Distance Acuity Test

- Chart at 4m distance, 1m above ground
- Consistent lighting (as possible) across trial period
- Pinhole if unaided distance visual acuity is 0.5 LogMAR or worse in either eye

Proceed to near visual acuity if:

- Unaided Distance Acuity is better than 0.5 LogMAR in both eyes OR acuity improves through pinhole

Near Acuity Test

- Chart at 40cm distance, at the level of subject's chin
- Chart held by examiner, subject occludes own eyes using palm of hand
- Maintain 40 cm working distance

Distance refraction

- Retinoscopy end-point is neutrality or fastest 'with' motion (least myopic correction)
- Trial frame refraction end-point is maximum sphere for best corrected acuity

Proceed to near refraction if:

- Habitual near visual acuity of >= 0.8M at 40cm in both eyes

Near Refraction

- Use a 'standardized' tea bush as target
- Let subject determine 'ideal/desired' working distance without trial frame and prior to performing the near refraction
- Measure and record the 'ideal/desired' working distance
- Maintain 'ideal/desired' working distance throughout testing
- Near refraction end-point is the highest plus sphere value (near-point addition) that enables the subject to identify 2-3 leaves and a bud that are appropriate for picking at the 'ideal/desired' working distance.
- Measure acuity at 40cm through near refraction end-point

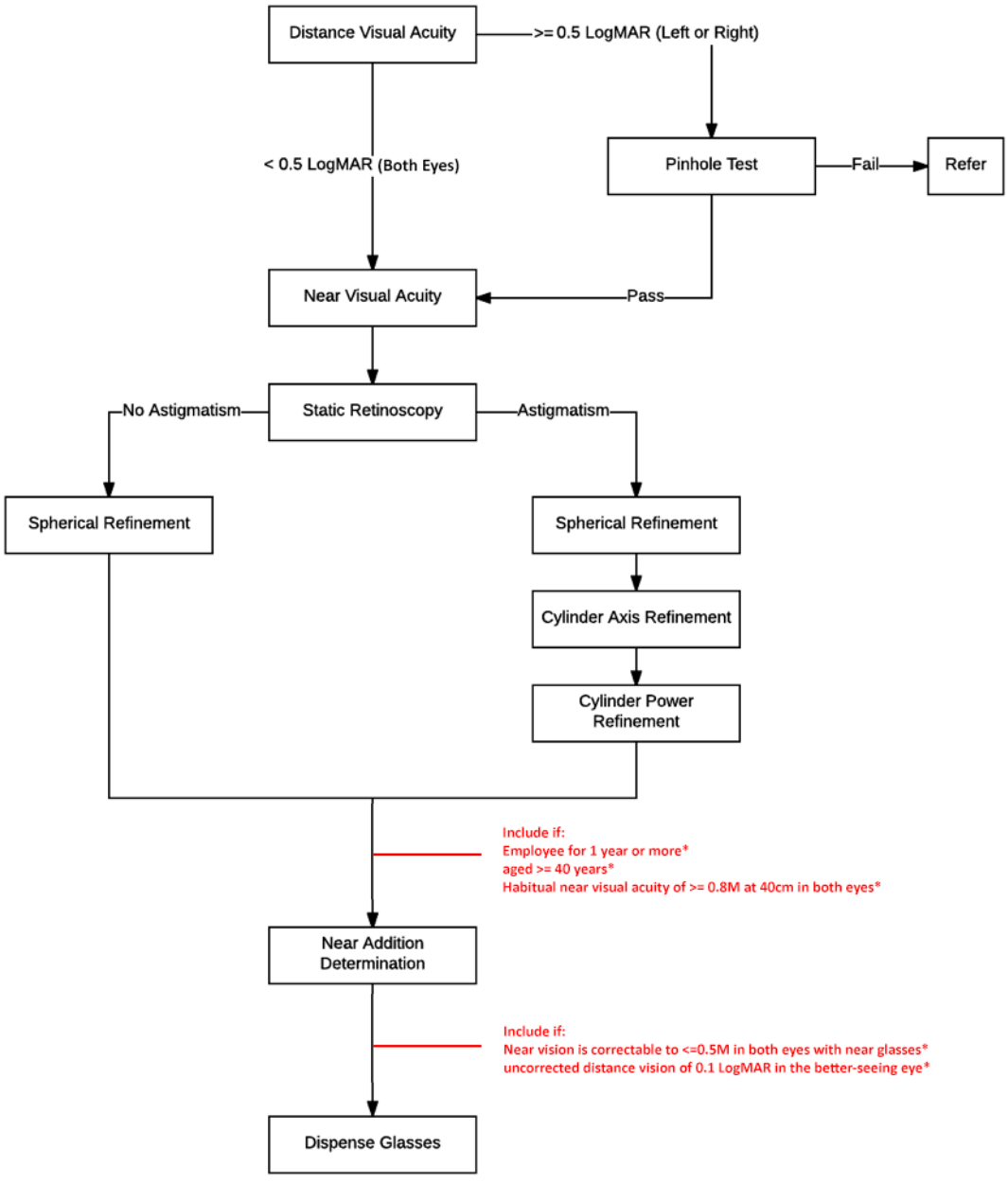
Inclusion Criteria:

Employee of APPL for 1 year; aged >= 40 years; Habitual near visual acuity of >= 0.8M at 40cm in both eyes, correctable to <=0.5M in both eyes with near glasses; uncorrected distance vision of 0.1 LogMAR in the better-seeing eye; the individual has worked and has data available on weight of tea picked for >=10 days in the previous 4 weeks; ability to give informed consent.

Exclusion Criteria:

Eye disease detected on baseline eye exam; current ownership of near correction capable of improving near visual acuity to <= 0.8M (>= 6/12) in either eye ; unlikely to complete follow-up due to unsatisfactory work performance, plans to move out of the area, etc.; need for distance correction to achieve distance vision of 0.1 LogMAR in the better-seeing eye; inability to achieve best-corrected near visual acuity with spherical power glasses only (that is: need for astigmatic correction to achieve best-corrected near visual acuity)

Flowchart



*Corrective eyewear was provided to all employees who required it, irrispective of whether they qualified for the trial or not

Vision Assessment

Distance Visual Acuity

- Distance visual acuity is measured with a printed Tumbling E LogMAR chart based on the "reduced" ETDRS test chart configuration as described by Rosser et al. (2001).
- Distance vision should be measured in a well-lit room or, if no room is available and you find that you must take your measurements outside please ensure that both the subject and the chart are in a shaded area and that all measures are taken to keep lighting consistent across the experiment.
- People waiting to be examined should not be able to see the chart so as to preclude the potential for prior learning.
- The examiner shall ensure than the distance vision chart is located at a distance of 4 metres from the subject. The chart shall be clean and placed approximately 1 metre above the ground.
- Ensure that there are no bright lights directed toward the subject's eyes and check that there are no distracting reflections on the distance vision chart.
- Ensure that the subject is seated comfortably and encourage them not to 'squint' when looking at the chart (a reduction in the palpebral aperture could create a pinhole effect).
- Explain to the subject that you are interested in finding out how far down the chart they can see and that they are welcome to guess if required.
- Show them how to demonstrate the orientation of the E's using their fingers as a means of representing the legs of the letter E.
- Stand next to the chart to point out which letters are being tested.
- Ask the subject to keep both eyes open, but to cover their left eye with the palm of their left hand (without pressing firmly). Ensure that they are not looking between their fingers.
- Show them a single letter from each line starting at the top and work your way down the chart.
- When a letter is misread move two lines up the chart and ask them to identify all the letters on that line.
- If they can identify any two of the three letters on a line they should move onto the line below.
- The test stops when the subject cannot identify more than one letter on a line.
- The subject's distance vision is given by the LogMAR number (0.0 to 1.0) on the right-hand side of the chart next to the last line they were able to identify correctly.
- Record this number on the form provided.
- Repeat the entire procedure for the left eye and record the result.

Pinhole Test

- The pinhole test shall be performed on any eye that scored 0.5 or more on the distance reduced LogMAR chart.
- Ask the subject to keep both eyes open. The examiner shall cover the eye not being examining with the palm of their hand.

- Let the subject hold the Pinhole plate in their hand and encourage them to look through the hole in the centre of it.
- Ask the subject to look at the smallest line of optotypes visible during the distance visual acuity assessment and ask them to identify the letters on that line.
- If their visual acuity improves while viewing the chart through the pinhole plate, then the examiner may continue with the refraction procedures
- If the subject's visual acuity does not improve while looking at the chart through the pinhole plate, then the examiner should refer for further examination

Near Visual Acuity

- Near visual acuity is measured with a printed Tumbling E LogMAR chart based on the "reduced" ETDRS test chart configuration as described by Rosser et al. (2001) and scaled for use at a distance of 40cm.
- The examiner shall hold the chart at the level of the subject's chin and use a ruler to measure out a distance of 40cm between the chart and the subject. It is essential that the subject doesn't move closer or further away from the chart, so the examiner must encourage the subject to remain still.
- The examiner must remain vigilant of movement of the chart closer to - or further away from - the subject to ensure that inaccuracies in the near visual acuity measurement are not introduced.
- Ensure that there are no bright lights directed toward the subject's eyes and that there are no distracting reflections on the near vision chart.
- Ensure that the subject does not 'squint' when looking at the near vision chart (a reduction in the palpebral aperture could create a pinhole effect).
- Ask the subject to keep both eyes open but to cover their left eye with the palm of their left hand.
- Use the back of a pen to show them a single letter from each line starting at the top and work your way down the chart.
- When a letter is misread move two lines up the chart and ask them to identify all the letters on that line.
- If they can identify at least two of the three letters on a line they should move onto the line below.
- The test stops when the subject cannot identify more than one letter on a line.
- The subject's near vision is given by the LogMAR number (0.0 to 1.0) on the righthand side of the chart next to the last line they were able to identify correctly.
- Record this number on form provided.
- Repeat the entire procedure for the left eye and record the result.

Refraction Procedures

Distance Refraction

1. Determine starting point using static retinoscopy
2. Refine retinoscopy result using non-cyclopegic subjective refraction

1. Static Distance Retinoscopy

- Adjust the height of the examination chair so as to ensure that the subject's eyes are at the same level as the examiner's.
- Measure the subject's interpupillary distance.
- Place the trial frame on the subject, ensuring that it is adjusted to the subject's interpupillary distance.
- The examiner shall seat himself/herself such that his/her head blocks the view of the distant target for the eye being examined (ensure that the subject can still see the target with the eye not being examined). This ensures that retinoscopy is performed as close to the visual axis as possible If the subject finds it difficult to ignore the light shining into his/her eye the examiner may move off the line of sight of the eye being examined to facilitate testing.
- The retinoscope shall be is held at the examiner's preferred working distance (usually either 40cm, 50cm or 67cm). Place the collimating lens (the inverse of the retinoscopy working distance in metres) in the trial frame and instruct the subject to keep both eyes open while looking at the target (remind subject that the target may appear blurred).
- Examine the subject's right eye by moving the beam of the retinoscope across the eye and observe the motion of the light reflected off the retina through the pupil.
- Rotate the retinoscope beam through 360 degrees. If the reflex and the beam orientation are not continuous throughout the rotation, the eye is astigmatic, and the principle meridians must be identified.

  Spherical eyes

  - If 'against' motion is observed, place minus lenses in front of the eye in steps of 0.25 D until the motion disappears and neutrality is reached. If 'with' motion is observed, place lenses of positive power in front of the eye in steps of 0.25 D until the motion disappears and neutrality is achieved.

  Astigmatic eyes

  - Rotate the retinoscope beam through 360 degrees. If the reflex and the beam orientation are not continuous throughout the rotation, the eye is astigmatic, and the principle meridians must be identified.
  - Once the orientation of the principle meridians have been identified, the examiner shall selects the least myopic (or most hyperopic) meridian to scope along and neutralizes it through the use or plus or minus spheres.
- The retinoscope beam is then rotated by 90 degrees and the examiner scopes along the remaining meridian (which should have 'against movement').
- Minus cylinder shall then be placed in the trial frame such that its axis lies parallel to the orientation of the retinoscope beam (i.e. parallel to the orientation of the remaining principle meridian).
- Minus cylinder power is added to the trial frame in steps of 0.25 D until neutrality is reached.

- If neutrality cannot be reached leave the eye with the lowest positive (most negative) power that is closest to neutrality (i.e smallest 'with' movement possible)
- Recheck both principle meridians, ensuring that both are 'neutral'.
- Repeat the process for the left eye
- Remove the collimating lenses and proceed to the subjective refraction

2. Non-cycloplegic Subjective Refraction

Spherical Refinement

- The right eye is tested first and then the left eye. The starting refraction determined through static distance retinoscopy shall be placed in the trial frame; the left eye is occluded with an occluder lens and the examiner shall determine the lowest line on the reduced LogMAR chart for which the subject can read at least 2 of 3 letters.
- With the subject focused on the smallest letters that he/she can read, a +0.50 D sphere is held in front of the trial frame over the right eye, and the subject is asked if the lens makes the vision clearer, blurrier, or keeps the vision exactly the same. ("Clearer, Blurrier, or No change" preferred but "Better, Worse, or No change" can be used)
- If vision is clearer or there is no change, the sphere in the trial frame is replaced with a sphere that is 0.50 D more plus or less minus. The subject should be asked to read the letters through the +0.50 challenge lens to demonstrate that vision is indeed clearer or the same.
- The +0.50 D sphere is again held in front of the trial frame over the right eye and the subject is asked again if the lens makes the vision clearer, blurrier, or keeps the vision exactly the same.
- If vision is again clearer or there is no change, the sphere in the trial frame is replaced with a sphere that is 0.50 D more plus or less minus.
- This process of increasing the plus sphere or decreasing the minus sphere in the right eye is repeated until the +0.50 D sphere makes the vision blurrier.
- When the +0.50 D sphere makes the vision blurrier, no additional change in the sphere is made at this time. By this process the highest plus or least minus sphere for best vision is determined.
- After determining the highest plus or least minus sphere, the subject is asked to read the smallest line possible (the reading should be at least as good as the initial reading). A -0.25 D sphere is held in front of the trial frame before the right eye and the subject is asked if the lens allows them to read more optotypes.
- If vision is not improved, the +0.50 D sphere is held in front of the trial frame before the right eye once again to see if the subject will accept more plus.
- If the subject reports that the –0.25 D lens improves vision, the subject is requested to read the smallest line possible while the –0.25 D lens is held in front of the trial frame.
- If there is an actual improvement in acuity and the examiner is convinced that the subject is able to read at least one additional optotype, then the sphere in the trial frame is replaced by a sphere that is 0.25 D less plus or more minus.
- For each change in spherical power, visual threshold must be determined by asking the subject to read the smallest line or letters possible either prior to increasing minus or decreasing plus spherical power (if using a -0.25 D challenge lens) or after the lens power has been changed.

- Minus spherical power is added in –0.25 D increments in this fashion as long as the subject continues to read at least one additional optotype.
- If the subject is unable to read any more optotypes, the sphere is not changed, even if the subject reports that the vision with the extra minus is better or clearer (or sharper and darker or more distinct).
- The final check in the initial sphere evaluation should be the presentation of a +0.50 D sphere to determine if any more plus sphere will be accepted initially.

Cylinder Axis Refinement

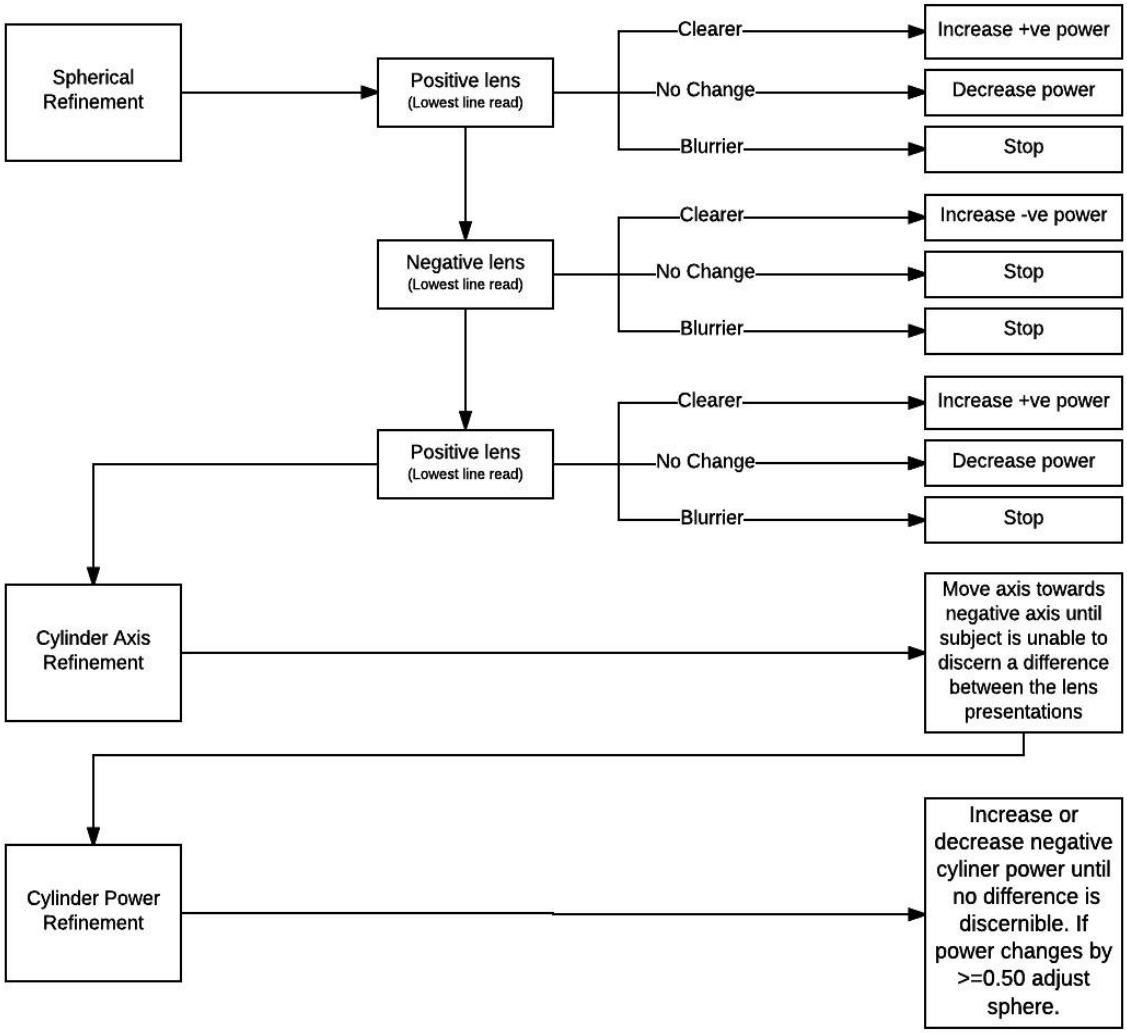
- For purposes of this discussion, only minus cylinder techniques are presented. Plus cylinders may be used instead of minus cylinders to determine the axis and power of the cylinder. If plus cylinders are used, the procedure described must be revised to reflect this change in sign.
- If the starting refraction contains a cylinder correction, changes in cylindrical axis are tested by holding a 0.50 D Jackson Cross Cylinder in front of the trial frame, first with the negative axis 45 degrees to one side of the cylinder axis, and then with the negative axis 45 degrees to the opposite side of the cylinder axis (in most cases, the handle of the Jackson Cross Cylinder lens should be aligned directly over the axis of the cylinder lens in the trial frame).
- Instruct the subject to focus on an optotypes two lines above the smallest line on which he/she can read at least 2 of 3 optotypes.
- Explain to the subject: I am going to show you two views of this “E” and neither view may be clearer than the view you have right now. I would like to know which of the two views is the clearer of the two, or are both views about the same or equally blurry. Ask: Is the “E” clearer on view 1 [flip the lens] or view 2, or are both views about the same or equally blurred?
- Since neither position may produce a clear image, the subject is encouraged to select the orientation that offers the least blur.
- If the subject cannot choose between the two orientations of the Jackson Cross Cylinder at the beginning of this test, the axis of the cylinder is moved 5-15 degrees, first in one direction and then in the other, with the Jackson Cross Cylinder being checked in each position to confirm that the original axis was indeed correct.
- If the subject does prefer one position of the cross cylinder to the other, the axis of the cylinder is moved 5-15 degrees toward the negative axis of the cross cylinder when in the position the subject said was better.
- When the power of the cylinder is low, and/or the subject’s discrimination is poor, larger shifts will produce more clear-cut responses.
- The cross cylinder is tried again with the negative axis 45 degrees to one side of the new cylinder axis and then with the negative axis 45 degrees to the opposite side of the new cylinder axis; the subject is asked which position is the clearer of the two or if the two views are about the same or equally blurry.
- If the subject prefers one position to the other, the axis of the negative cylinder is moved toward the negative axis of the cross cylinder.
- Testing for change of axis is repeated until the subject cannot decide that one position of the cross cylinder is clearer than the other by reporting that both views are about the same or equally blurry.

Cylinder Power Refinement

- Before refining cylinder power, once again establish visual threshold by determining the smallest line or letters the subject can read on the chart. Change in cylinder power is now tested by adding the 0.25 D cross cylinder, first with the negative axis and then with the positive axis coincident with the cylinder axis.
- Again, instruct the subject to focus on an optotype two lines above the smallest line for which the subject could correctly identify 2 of 3 optotypes. Explain to the subject: Once again I am going to show you two views of this "E" and neither view may be clearer than the view you have right now. I would like to know which of the two views is the clearer of the two, or are both about the same or equally blurry. Ask: Is the "E" clearer on view 1 [flip the lens] or view 2, or are both views about the same or equally blurred?
- If the subject prefers the negative axis coincident with cylinder axis, the power of the correcting negative cylinder is increased by an additional -0.25 D.
- If the subject prefers the positive axis coincident with the cylinder, the power of the cylinder is reduced by 0.25 D.
- The process is repeated until the subject cannot choose one of the cross-cylinder positions as clearer than the other (i.e., until both positions are about the same or equally blurred).
- Whenever the cylinder is changed by 0.50 D, a 0.25 D of sphere of opposite sign is added as well (the changing of the sphere occurs during the procedure as soon as the cylinder has been changed by 0.50 D rather than making the adjustment following the completion of the refinement).
- If all cylinder power is removed during cylinder power refinement (i.e., sphere only in the trial frames), check for the presence of astigmatism, following the steps axis refinement above. In addition, if the cylinder power has been changed by more than 0.50 D, the axis should be refined again.

Checking Cylinder When Beginning Refraction is a Sphere

- If the beginning refraction is a sphere and does not contain a cylinder, the presence of astigmatism can be tested by one of two methods:
- Instruct the subject to focus on an optotype one-two lines above the smallest line of optotypes that he/she can read. Using a Jackson Cross Cylinder appropriate for the current acuity (0.25 D for visual acuity of 0.5 or better; 0.5 D for visual acuity poorer than 0.5), test for the presence of cylinder power by placing the cross cylinder with the plus axis alternately at 90 degrees and 180 degrees, and then alternately at 45 degrees and 135 degrees.
    - If the subject reports that the Jackson Cross Cylinder makes the optotype clearer than the spherical correction in any of the four axis locations, insert a cylinder matching the "minus" presentation of the JCC at the preferred axis and continue the refraction by refining the cylinder axis and power, as described above.



Refraction Recheck/Final Sphere Refinement

• The power of the sphere is rechecked according to the sphere refinement protocol above by using +0.25 D and -0.25 D spheres and changing the spherical power by 0.25 D increments of the appropriate sign until the subject reports that the +0.25 lens blurs the vision and the -0.25 does not improve vision. If the sphere is changed at this point by 0.50 D or more, the cylinder axis and power should be rechecked. This process is repeated until no further significant lens changes are made.

Near Refraction

- Remove the trial frame with the distance refraction from the subject's face.
- Ask the subject to stand near a tea bush (representative of the height of the majority of tea bushes likely to be worked on over the course of the study) and assume the stance that they usually use while picking leaves. Instruct them to handle the leaves on the bush as they would while working.
- Ask the subject whether it would be more comfortable to hold their head closer or further away from the bush while working. Remind them that its ok if the leaves on

the bush are blurry at their 'ideal' viewing distance, and that they should not concern themselves with whether they can see well or not because you are going to find out whether glasses can improve their vision. The key consideration here should be that the subject is able to maintain a posture and working distance that will prove comfortable for them over time.

- Measure this distance and record on form
- Measure the distance between the subject's eyes and the leaves and buds (remind the subject to handle the leaves and buds on the table as they would while working)
- Place the trial frame back on the subject's face and use an occluder lens to occlude the left eye.
- It is essential that the subject doesn't move closer or further away from the leaves so the examiner must encourage the subject to remain still. The examiner must remain vigilant of movement of the subject closer to - or further away from - the tea bush to ensure that inaccuracies in the near prescription measurement are not introduced.
- Place a positive sphere with a power equal to the inverse of the working distance (in meters) in the rear lens holder of the trial frame
- With the subject focused on the leaves and buds in their hands, a +0.25 D sphere is held in front of the trial frame over the right eye, and the subject is asked if the lens improves their vision or not.
- If the subject reports that there is no change then increase the add power in the trial frame by +0.25D and repeat the above step.
- The procedure is terminated when the patient reports that the lens makes their vision blurrier.
- The final addition power requirement is determined as the highest positive lens power that allows the subject to identify 2-3 leaves and a bud that are appropriate for picking at their preferred working distance.
- Measure near visual acuity at 40cm through the near end-point using the procedure described under 'Near Visual Acuity' above. This acuity measurement should be recorded while the subject is wearing the lenses that provide their chosen near refraction end-point. Note: given that it is likely that subjects will choose near-point additions that provide optimal vision correction at a distance other than 40cm, this visual acuity measurement is for record keeping purposes only and does not have implicit diagnostic or prognostic value.