# Statistical Analysis Plan

## PROSPER III (PROductivity Study of Presbyopia Elimination among aRtisans: a mixed methods randomised trial on the effect of providing near glasses on workplace retention of Indian textile workers)

### DOCUMENT HISTORY

| Version | Date | Edited by | Comments | Timing in relation to unblinding |
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| 1.0 | 7 June 2020 | GM | Approved by signatories, updated to version 1.0 | Prior to trial registration |
| 2.0 | 25 March 2024 | GM | Change to inclusion and exclusion criteria, removal of TSC and DMEC, Interim analysis by trial statistician, subgroup analysis, sensitivity analysis, Consort diagram. | After trial registration |

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# 2. INTRODUCTION

This document details the proposed presentation and analyses for the main analysis reporting results from the USAID and Clearly funded randomised controlled trial PROSPER III (PROductivity Study of Presbyopia Elimination among aRtisans: a randomised trial on the effect of providing near glasses on workplace retention of Indian textile workers). The results reported in this publication will follow the strategy set out here. Subsequent analyses of a more exploratory nature will not be bound by this strategy, although they are expected to follow the broad principles described. The principles are not intended to curtail exploratory analysis (for example, to decide cut- points for categorisation of continuous variables), nor to prohibit accepted practices (for example, data transformation prior to analysis); rather they are intended to establish the rules that will be followed, as closely as possible, when analysing and reporting on the trial and the qualitative sub-study.

The analysis plan will be available on request when the principal manuscripts are submitted for publication. Suggestions for subsequent analyses by journal editors or referees will be considered carefully and carried out, as far as possible, in line with the principles of this analysis plan.

Any deviations from the data analysis plan will be described and the rationale given in the final report of the trial. The analysis will be carried out by an identified, appropriately qualified and experienced statistician, who will ensure the integrity of the data during processing. Examples of such procedures include quality control and evaluation procedures.

# 3. PERSONNEL

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# 4. BACKGROUND INFORMATION

## 4.1 Rationale

PROSPER III is a mixed methods randomised controlled trial (RCT) assessing the effect of reading glasses on the retention of presbyopic textile workers in Bangalore, India. PROSPER

III's primary approach is a randomized controlled trial (RCT), and the secondary or embedded approach is a descriptive qualitative study.

## 4.2 Objectives of the trial

Globally, 3 billion people do not have the eyeglasses they need to earn, learn, travel safely in traffic and participate in civic life. Among these, 1.1 billion people lack a simple pair of reading glasses to correct impaired near vision, called presbyopia.[1] Presbyopia, the essentially universal decline in unaided near vision that occurs with aging, is the world's most common cause of vision impairment. Loss of accommodation (ability to change focus from distance to near) due to presbyopia can begin as early as age 30 years, commonly becomes functionally apparent by 40, and is essentially complete by 55, meaning that presbyopia is most common at the height of the working years. The correction of presbyopia is both safe and affordable: requiring nothing more than a pair of reading glasses to restore vision at near. Despite this, only approximately 10% of people in need of reading glasses in low and middle-income countries actually have them.

Data from the International Labour Organization shows that the rate of having a job among people over the age of 40 in low- and middle-income countries is declining. Our previous randomized trials in India[2] demonstrated that the provision of free reading spectacles significantly improved the productivity of agricultural workers on a tea plantation over the course of a harvest season. The PROSPER trial enrolled 751 adults (mean age 47 years) with uncorrected presbyopia in Assam, India, and showed significantly higher productivity among workers randomized to receive free glasses compared to Controls (21.7% relative productivity increase; effect size 1.01 [95% CI 0.86–1.16]; p<0.0001). Intervention-group compliance with study glasses reached 84.5% by closeout. Regression model predictors of greater productivity increase included intervention group membership (an extra 5.25 kg of tea leaves picked per day [95% CI 4.60–5.91], p<0.0001) and, among intervention participants, older age (p=0.039) and better compliance with the intervention (p<0.0001). PROSPER I revealed a significant interaction between age and study group for the main study outcome. Older participants in the intervention group had significantly greater productivity increases than younger participants. Older participants in the control group, having more pronounced, uncorrected presbyopia, were less able than their younger peers to take advantage of higher crop yields during the peak high season, resulting in lower productivity increases. This strong interaction of age and productivity with study group adds to the biological plausibility of the results of PROSPER I. To place these results into perspective, the relative productivity increase in the productivity of workers receiving reading glasses was as large as or larger than that reported for any other health intervention trial in low-income and middle-income countries.[3-5]

In light of the above findings, PROSPER III will assess whether free reading glasses are able to extend the productive working life of workers (i.e increase retention) in textile factories in Bangalore, India. We hypothesise that worker retention over the 18-month evaluation period will be greater in the Intervention compared to the Control group. Additional qualitative data will be collected to enhance understanding of factors affecting retention of study subjects (textile workers aged 30 years and above with uncorrected presbyopia who are employed by Shahi Exports Private Limited in Karnataka, India).

## 4.3 Trial design

PROSPER III is an investigator-masked, multi-centre mixed methods randomized controlled trial.

## 4.4 Eligibility

### 4.4.1 Inclusion criteria

Shahi employees will be eligible to participate if:

- they are aged 30 years or older
- have presbyopia, defined as an unaided near visual acuity of N6.3 or worse in both eyes
- have worked in the production department for 6 weeks or more
- they require a new pair of glasses to improve their near vision
- they have a corrected near visual acuity of N4 or better in both eyes

### 4.4.2 Exclusion criteria

Shahi employees will be ineligible to participate if:

- have ocular pathology in either eye detected during the eye examination, or history of such disease based on self-report
- have a low likelihood of completing follow-up in the study due to current plans to move out of the area or leave employment at Shahi during the follow-up period

## 4.5 Interventions

Eligible participants will be randomly assigned to Intervention or Control Groups (1:1). Intervention group participants will receive free reading glasses after undergoing a vision screening at the factories, which will mark the beginning of the assessment period. In addition to receiving free reading glasses, participants in the Intervention Group will be eligible for free replacement glasses in the event of loss or damage throughout the trial. Control group participants will receive free reading glasses at the end of the assessment period (18 months after the beginning of the assessment period). An interim analysis will be performed by the trial statistician. If the Trial Management Group (TSG) terminates the trial on the recommendation of the trial statistician, then Control Group participants will receive free reading glasses at trial closure. The trial will be investigator-masked, but not participant-masked, because the investigators do not feel provision of zero-power glasses to the control group is ethical. However, participants will have limited knowledge of the study hypothesis, limiting potential placebo effects.

## 4.6 Definition of primary and secondary outcomes

### 4.6.1 Primary outcome

The primary objective of the study is to estimate the effect of the provision of free reading glasses on the retention of textile workers employed in Shahi's sewing department. The time-to-event endpoint for PROSPER III is defined as the time between randomization to

Intervention or Control Group and loss of employment at Shahi. Employment status for each participant will be assessed from trial entry to closure as recorded in Shahi's Human Resource Management Database.

### 4.6.2 Secondary outcomes

The secondary outcomes are:

- reasons given by supervisor and colleagues of former sew-ers (separately) for workers no longer being employed at Shahi
- proportions of sew-ers who state they are satisfied or very satisfied with work, feel valued or very valued at work, and are likely or very likely to stay with current employer
- change in self-assessed productivity
- self-report of having been approached by their assigned Captain and/or a supervisor
- change in attitude towards eye health, glasses wear and uptake of eyecare services
- changes in skill grade and associated change in wage
- adherence with spectacle wear
- Quality of Life using the THRIVE Near Vision Quality of Life tool.
- intervention cost-effectiveness

## 4.7 Hypothesis framework

PROSPER III is a superiority trial comparing glasses wear to non-wear. Analysis of the trial will entail calculation of treatment effect measures and confidence intervals to assess the difference between the two arms.

## 4.8 Sample size & power

Previous retention trials in this setting have showed 18-20% of overall likelihood of attrition at 5 months follow-up, 50% overall likelihood of attrition at 12 months, 60% at 18 months, 70% at 24 months. Assuming a work retention rate of 50% at 1 year and 40% at 18 months in the Control group, we anticipate that our glasses intervention will increase retention by 20% in the Intervention group at 1 year (hazard of 0.8). Data analysis using a Cox proportional hazard model with 2-sided significance at the 5% level and 80% power yields a total sample size of 1,260 (630 in each group). No correction for attrition is required as attrition is the outcome and therefore no attrition from the sample is possible.

## 4.9 Intervention allocation

Consenting participants eligible for the trial will be divided into four strata according to age (<median, ≥median), work tenure at the textile factory (<median, ≥median). Participants in each stratum will be randomized 1:1 with block size of four to either the Intervention or Control Groups. The randomisation sequence will be generated by the researchers at Good Business Lab and concealed until a worker is determined eligible and has agreed to participate. The field team will have a list provided by the textile factories of potential participants, their current age, tenure and baseline productivity. Study personnel will access the random assignment for each participant according to the correct age-tenure stratum only at the time of enrolment.

### 4.10 Data collection schedule

#### 4.10.1 Data collection before trial

Demographic data will be collected through Shahi's Human Resource database and clinical information will be collected using VisionSpring's Eye Examination Form (Annexe 1).

#### 4.10.2 Data collection during trial

Wage and employment status data will be collected on a daily basis from Shahi's Human Resource division. Employment status data will be assessed on a weekly basis over the 18-month intervention period. Intervention costs will be collected by VisionSpring and assessed at the end of the trial intervention period. Secondary outcome data will be collected using the following data collection forms

- Baseline Assessment (following eye examination)
- Endline Assessment (at the end of the 18-month intervention period)
- Spectacle Wear Compliance (on a weekly basis over the 18-month intervention period)
- Self-assessment of productivity by workers enrolled in the trial (once at the start and at the end of the study)
- Supervisor assessment of worker productivity for workers enrolled in the trial (once at the start and at the end of the study)
- Identification of trial participants leaving the employ of Shahi will occur every two months and telephone interviews will be scheduled in two phases (7 months and 16 months after the start of assessment period)

### 4.11 Interim analyses and stopping rules

An interim analysis on the primary outcome will be performed by the trial statistician. In the light of interim data on the trial's outcomes, adverse event data, accumulating evidence from other trials and any other relevant evidence, the statistician will inform trial management if in their view there is proof beyond reasonable doubt that the data indicate that any part of the protocol under investigation is either clearly indicated or contra-indicated, either for all participants, or for a particular subgroup of trial participants. Unless modification or cessation of the trial is recommended by the trial statistician, the investigators, collaborators, and administrative staff will remain ignorant of the results of the interim analysis. The accumulating trial data by arm and interim analyses will be confidential and will only be viewed by the principal investigator upon the recommendation of the trial statistician. The TMG will not be routinely privy to these interim reports. The trial statistician will make recommendations to the TMG based on the interim data.

### 4.12 Trial reporting

The trial will be reported according to the principles of the CONSORT statement.

## 5. PROTOCOL DEVIATIONS

A protocol deviation is defined as a failure to adhere to the protocol such as the wrong intervention being administered, incorrect data being collected and documented, errors in applying inclusion/exclusion criteria or missed follow-up visits due to error.

### 5.1 Major

The following will be defined as major protocol deviations:

- Enrolled workers have not provided Informed Consent
- Data considered fraudulent

### 5.2 Minor

The following will be defined as minor protocol deviations:

#### 5.2.1 Participants randomised in error

- Employees < 35 years, or employed < 6 weeks, or not employed in the sewing department assigned to Intervention Group

#### 5.2.2 Participants who do not receive allocated intervention

- Workers in the Intervention Group not receiving glasses
- Workers in the Control Group received glasses from VisionSpring (workers in the Control Group deciding to purchase glasses from an external eyecare service provider during the course of the study will not be considered a protocol deviation, and their data will be analysed under the Intention-to-treat principle)

## 6. ADHERENCE TO THE INTERVENTION

Adherence to the intervention will be assessed through observation of spectacle wear while working. Adherence will be measured surreptitiously on a weekly basis. The enumerators assessing spectacle wear compliance are GBL staff members familiar to Shahi workers but are not revealed to be collecting glasseswear adherence data to ensure minimum modification of compliance behaviour in present of enumerators.

## 7. ANALYSIS POPULATIONS

### 7.1 Primary analysis strategy

All outcomes will be assessed by Intention-to-treat (ITT): participants will be analysed in the groups into which they were randomly allocated, i.e. comparing the outcomes of all workers allocated to the Intervention Group with workers allocated to the Control Group, regardless of allocation received.

### 7.2 Descriptive analysis population

Baseline demographic and clinical characteristics will be reported for all workers randomised for whom we have data available, excluding protocol deviations randomised in error where Informed Consent has not been obtained.

# 8. DESCRIPTIVE ANALYSES

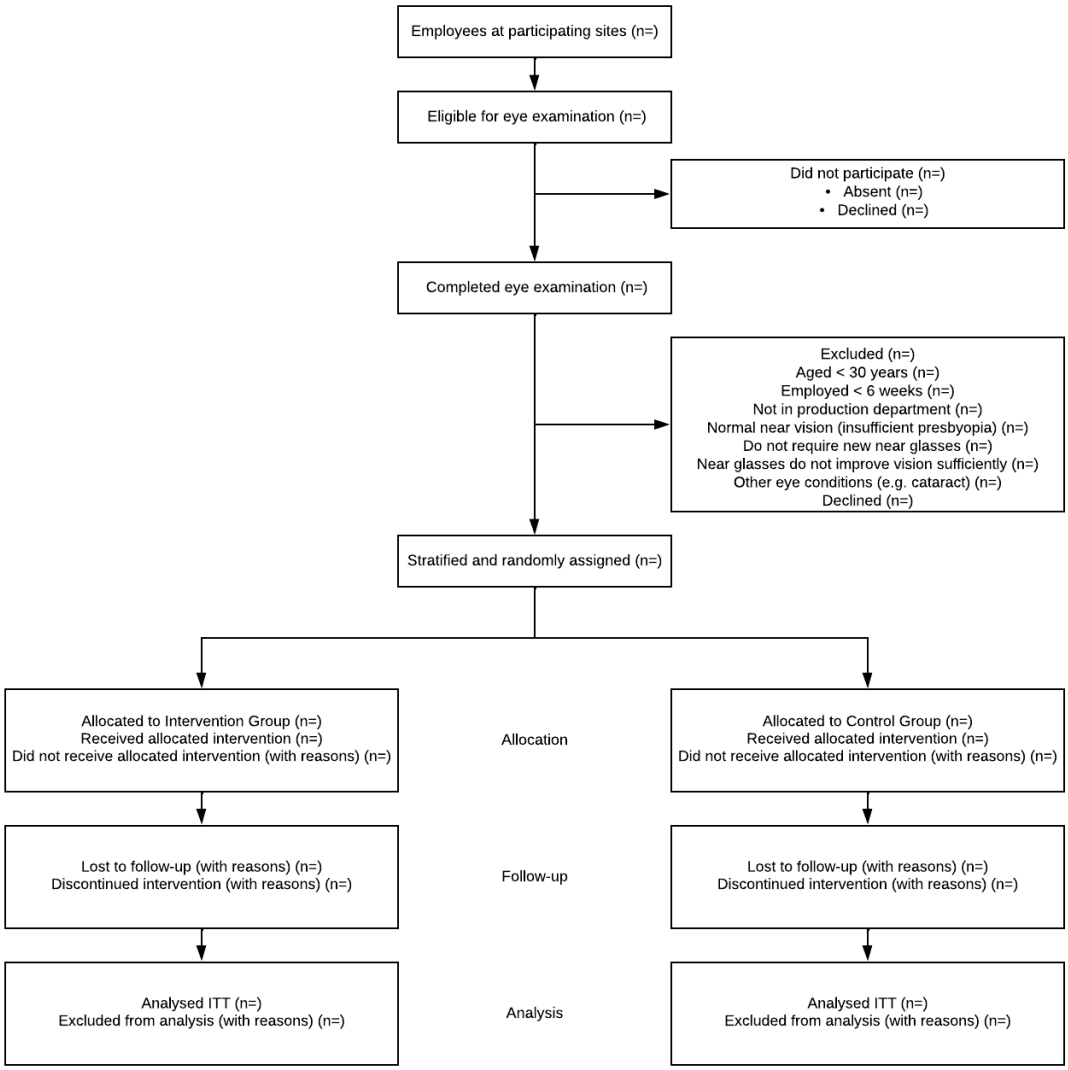
## 8.1 Representativeness of trial population and participant throughput

The flow of participants through each stage of the trial will be summarised using a CONSORT diagram (see below). We will report the numbers of participants:

- at participating sites
- eligible for eye examination
- examined
- stratified and randomly assigned
- received intended intervention
- withdrawals
- randomised in error

included in the analysis

**CONSORT Flow Diagram**




## 8.2 Baseline comparability of randomised groups

Participants in randomised groups will be described separately with respect to the following characteristics at trial entry:

- age
- sex
- education level
- marital status
- number of children and dependants
- median wage compared to urban Bangalore and urban India
- near vision quality of life (THRIVE tool)
- uncorrected visual acuity in each eye separately at distance and both eyes together at near
- urban or rural factory

- mean power of near correction required
- baseline work productivity
- worker self-efficacy
- attitudes towards vision correction
- access to local eyecare services
- history of uptake of eyecare services

Numbers (with percentages) for binary and categorical variables and means (and standard deviations), or medians (with lower and upper quartiles) for continuous variables will be presented; there will be no tests of statistical significance performed nor confidence intervals calculated for differences between randomised groups on any baseline variable.

### 8.3 Losses to follow-up

Whilst high degrees of loss-to-follow-up can lead to biased estimates of the intervention effect (particularly when there is differential drop out between intervention arms, which is related to the intervention) we anticipate minimal loss-to-follow-up with respect to the primary outcome and for secondary outcomes. In the case of the primary outcome, loss of employment at Shahi, “loss to follow-up” is in and of itself an endpoint. We will perform complete-cases analyses in each case. With respect to the covariates, we anticipate a small (<2%) amount of missing data. As the anticipated amount of missing data is small, we will analyse the data using a complete-case analysis.

### 8.4 Adherence to intervention

The percentage of glasses wear adherence per week will be reported for the duration of the trial.

## 9. COMPARATIVE ANALYSES

### 9.1 Analysis of primary and secondary outcomes

We will calculate the Cox proportional hazard ratio for the rate of retention between Treatment and Control groups with and without adjustment for the following co-variates: age, work tenure, spectacle wear compliance, self-reported self-efficacy, rural vs urban factory, hostel vs non hostel residence, marital and parental status, skill grade (if not too highly colinear with work tenure), work attendance. Linear regression analyses will be performed on potential determinants of primary and secondary outcomes. The study group and all significant variables with p values less than 0·20 in simple regression analyses will be included in multiple regression models. Histograms, normal quantile plots (QQ Plot), and the Shapiro-Wilk normality test will be used to test the normality assumption in regression models. For the Visual Quality of Life (THRIVE) tool, a composite score (eleven items) and near activities sub-score (five items) will be created on 0–100 scales. Intervention costs will comprise the screening test, glasses (and any replacement thereof) as well as direct and indirect costs to the company for facilitating workplace-based sight tests. We will report cost effectiveness distinguishing between study costs and program costs.

The analysis of primary and secondary outcomes will be adjusted for the minimisation factors (age, work tenure at the textile factory, efficiency during baseline assessment) to

account for the correlation between treatment groups introduced by balancing the randomisation.[5] Both the crude unadjusted and adjusted estimates will be presented, but the primary inference will be based on the adjusted analysis.

For multiple imputation of missing data in assessing primary outcomes we will create 20 copies of the data, in which missing values shall be imputed by chained equations, and the datasets will be averaged.

### 9.2 Pre-specified subgroup analysis

The consistency of the effect of the intervention across specific subgroups will be assessed using the statistical test of interaction. Note that this study was not designed to have sufficient power to test for interaction terms in these subgroup analyses; we will interpret the results with caution. Pre-specified subgroup analyses include:

- Sex
- Skill grade (<median, ≥median)
- Degree of Presbyopia (early presbyopia, reading glass powers < 1.25D; moderate presbyopia, 1.25D <= reading glasses powers < 2.00D, advanced presbyopia: reading glasses powers >=2.00D)
- Age group (35 to 39years, 40 to 49 years, 50 years and older)
- Compliance rate observed in the factory (<median, ≥median)
- Presenting binocular near visual acuity of N8 and worse

Subgroup analysis will be performed on the primary outcome and mean efficiency outcomes.

### 9.3 Sensitivity analysis

We will conduct additional “post-hoc” analyses in which we will adjust for additional pre-specified potential confounders (table 1 below). The pre-specified confounders will be included in the models even when no baseline imbalance exists. We have limited the inclusion of potential confounding variables to those that we surmise to be the most important based on the investigators’ assessment of clinical plausibility. This approach has been chosen since confounder selection strategies which are based on collected data, for example selecting confounders using preliminary statistical tests, result in models with poor statistical properties such as incorrect type I error rates.[6-9] Those confounders that are highlighted as having a significant impact in the subgroup analyses will also be included in these analyses to assess the impact on the treatment effect.

Table 1:

| **Level** | **No.** | **Confounder** |
|---|---|---|
| Patient | 1 | Age (years, continuous) |
| | 2 | Sex (Male/Female) |

| | | |
|---|---|---|
| Site | 3 | Rural/Urban |

Some workers leave the workforce temporarily to take up higher paying seasonal or temporary work, with the intention of returning to the factory workforce after several months away. These workers undergo rigorous performance testing before being permitted to re-join the factory workforce. As the reason for leaving the workforce temporarily is not related to reduced productivity, we feel it is important to include a sensitivity analysis of the primary outcome that takes seasonal and temporary work patterns into account. To this end, in addition to the pre-specified sensitivity analyses outlined above, we will conduct supplementary analyses of the primary outcome that will focus on participants who exited the factory to pursue other seasonal or temporary employment opportunities at the conclusion of the 18-month primary data collection period, but who return to their positions in the factory within a four-month period after the conclusion of primary data collection.

### 9.4 Significance levels and adjustment of p-values for multiplicity

For the primary and secondary outcome, including subgroup analyses, a 95% confidence interval will be calculated.

### 9.5 Procedure for accounting for missing, unused, and spurious data

Missing data will be described, for example, by presenting the number and percentage of individuals in the missing category. All data collected on data collection forms will be used, since only essential data items will be collected.

### 9.6 Exclusion of data

Before data are locked for statistical analysis, a blinded review of all data will take place. Any decision to exclude a subject or single observation from the statistical analysis is the joint responsibility of the PROSPER III trial statistician, the international trial manager and the Chief Investigator. Exclusion of data from analyses will be used restrictively and normally no data should be excluded from the full analysis set. The subjects or observations to be excluded, and the reasons for their exclusion will be documented and signed by those responsible before database lock. The subjects and observations excluded from analysis sets, and the reason for this, will be described in the clinical trial report. Any observation excluded from the analysis database will be documented before database lock with the reason for exclusion provided.

### 9.7 Statistical software employed

Stata, version 18

## 10. QUALITATIVE SUB-STUDY

One of the hypotheses being tested in PROSPER III is providing glasses to correct presbyopia in sewing operators in India can reduce attrition. The RCT will collect data comparing the attrition rates of Intervention and Control group subjects; however, this will not explain why

sewing operators have left their jobs, and the role that vision plays in that decision. This qualitative sub-study will provide this additional information.

### 10.1 Research Design

The descriptive qualitative study design is frequently used in mixed methods research because its outcome – a straightforward report on methods and findings close to participants' own voices – makes it relatively easy to integrate quantitative and qualitative findings. Furthermore, our aim is to highlight the voice of sew-ers who have left Shahi during the study rather than develop a theoretical model or explore pre-determined factors thought to affect their decisions.

### 10.2 Sample and Sample Size

The sampling frame or set of potential participants will be all PROSPER III subjects who leave the employ of Shahi before the end of the study. A criterion-based purposive sampling framework will be used for selecting the respondents for interviews to expand the range of variation in responses while allowing for identifying similarities and differences. The criteria used to create the strata for the sub sample would be:

- Early leavers vs late leavers (with relation to the start of the study)
- Treatment status
- Power of glasses (Low - Visual acuity <=N6.3; Moderate >=N8)

In a descriptive qualitative study, approximately 20 participants can provide enough data to reach informational redundancy or data saturation (the point when no new information emerges from the last round of data collected) and theoretical saturation (the point when the researchers identify themes or categories with enough data to support their interpretations of each one). If some participants do not provide rich data, then additional persons must be recruited to reach saturation. Because we will be selecting participants from each of the 8 categories based on the criterion strata's, we will increase the total sample size to 40 persons, planning for an additional five interviews if needed. The sample for each category would range between 3-6 depending upon the quality of response we get. The sampling framework for selecting the participants is described in table 2.

Table 2:

| CRITERIA | CATEGORIES | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| When left trial | Early (2rd – 6th month) | | | | Later (12th - 15th month) | | | |
| Treatment status | Control Group | | Intervention Group | | Control Group | | Intervention Group | |
| Prescription strength | low | moderate | low | moderate | low | moderate | low | moderate |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Sample size per category | 3-6 | 3-6 | 3-6 | 3-6 | 3-6 | 3-6 | 3-6 | 3-6 |

Administrative data from Shahi indicate that about 20% of their workers leave after 5 months of employment, 50% after 12 months and 60% after 18 months. Assuming that the attrition rate for sew-ers is similar, we will have a large enough sampling frame to identify and enroll 40-45 participants.

### 10.3 Recruitment

Using administrative data at the enrolled factories, we will identify job leavers between the 2nd to 6th month, and 12th to 15th month, compare the lists with the enrolment list for PROSPER III, and create a random-ordered list of job leavers to invite into this sub-study. A research team member will attempt to contact each person via telephone on the list in sequence, making up to three calls before declaring them 'unreachable' and removing their name from the recruitment list. Since there are cases of workers rejoining the factory within a few months, the enumerator will administer a short call reading out the information sheet (Annex 10) which mentions the purpose of the call and to check if they are planning to rejoin. Those who are planning to rejoin the factory within the next 6 months would be excluded from the qualitative study. Those who do not intend to return to the factory would be eligible for the qualitative survey. These workers would be informed of their eligibility and would be read out the Information Sheet which provides the information regarding their rights as a participant of the study. If the worker agrees to participate in the interview, their oral consent will be obtained, and they will be administered the interview as per the interview instrument sheet.

### 10.4 Time Period

Since the study seeks to explore the reasons behind workers leaving the factory and if vision issues are one of them, it is crucial to explore if workers leaving at the beginning of the study were more likely to be suffering from vision problems and the impact they had on their work, as compared to those who left later into the study. For this purpose the study would be conducted in two phases, the first phase would follow up on workers who have left the factory between 2- 6 months. The second phase of interviews would be conducted for workers who have left the factory between the 12-15th month.

### 10.5 Data Collection

We will use a standardized protocol to back-translate the relevant documents (sub-study information sheet, consent form and interview guide). Using the first draft version of the instruments, we will pilot test them for acceptability and clarity with three to five participants in each of the study languages. We will use feedback from the pilot test participants to revise the instruments and test them again with one person for each language, making final adjustments as needed. T he interviewer will call the worker to: a)

review the sub-study information sheet, b) ensure the worker is eligible and still wants to be interviewed, and c) conduct the phone interview or schedule it for another time. The interviewer will use the semi-structured interview guide and record (with prior permission) the oral consent and interview. The telephonic interview will be conducted using the Exotel plug-in for SurveyCTO, which allows the form to make calls, the call would be recorded on the Exotel server, which would be only accessible to the GBL research team.

### 10.6 Data Analysis

The recorded interviews will be deidentified before being shared to an experienced bilingual transcriber who will transcribe the recording in the language used in the interview (Hindi, Kannada), and an accuracy check will be conducted by the GBL team member by comparing the audio and written versions of the interview. The bilingual translator will also produce an English-language version of each transcript, conferring with the interviewer to ensure accuracy.

The transcripts would be analysed using the Qualitative Content Analysis +Framework method. The analysis would be carried out in the following steps.

#### 10.6.1 Prepare working transcripts.

**To start, we will create** working copies of each transcript, add line numbers (to help contextualise quotes during analysis), set aside less relevant statements and label each meaning unit (quote) with an anonymous source code (e.g. 'Int-6' = 6th participant from the Intervention Group).

#### 10.6.2 Familiarisation

Analysis would be done by two or three researchers who will independently work with the transcripts and then confer until reaching consensus. The researchers will start by independently reading the whole document several times in order to become familiar with the information it contains. While reading the transcript from an interview, notes can be made on the margins which can be revisited later during the analysis.

#### 10.6.2 Produce analysis matrices

The researchers will create a blank table for each topic from the interview guide that they will populate with relevant quotes from transcripts (one quote per row). The tables will consist of five columns, one for the row number, another for the quote where we paste relevant statement or quote from the working transcript with the line number and source code; one column for the summary of the quote's meaning , the fourth column would be for the code which is to be developed from the meaning statements and finally the fifth column would be for the sub-code. The researchers will work independently on their own matrices and will then review the codes together and develop an agreed-upon list of codes.

pic.

### 10.6.3 Create the Codebook

A new word document labelled “Codebook” (the Analytical Framework) would be developed wherein the researcher would list each Code in alphabetical order along with any accompanying Sub-codes, then a brief definition of the Code/Sub-code and a sample quote that illustrates the Code/Sub-code. Every time the codebook is updated, the version number of each iteration of the document would be noted in the title page along with the date and source transcripts.

### 10.6.4 Creating Categories from codes

A new document which is a second version of the matrices would be created. The researchers would identify Codes/Sub-codes that seem to “belong together” and group them into a category keeping the category names short and factual. Categories express the manifest (visible) content in the data, or what is visible and obvious, and answers the questions of “Who? What? When? or Where?” Since there can be overlap between codes and categories, sub-categories can be created to bridge codes and categories.

### 10.6.5 Interpreting the data

The researchers would create a word document which contains the frequency table listing each category and codes for each topic. The frequency table will chart the data based on the Categories, listed in rank order from most to least frequently used, and the Codes/Subcodes they contain plus frequency counts. Illustrative quotes for each Category, particularly for the most frequently used Codes/Subcodes, will be provided under each frequency table along with a brief paragraph describing the meaning of the findings displayed in the frequency table.

An overall matrix would be created to chart the results as a single frequency table per Category along with an overall statement with supportive quotes based on the summary of findings from each transcript.

### 10.6.8 Write report

The researchers will prepare a report on methods used to collect and analyse the data, as well as findings from both the qualitative content analysis (salience and relevance of categories within each topic) and thematic analysis.

## 10.7 Outcomes

- A rank-ordered list of reasons sew-ers have left Shahi or the textile industry
- A report on the role that poor near vision (uncorrected presbyopia) has on sew-ers’ productivity, self-efficacy and job leaving
- Material for wider dissemination to academic audiences through presentations at conferences and publications in peer-reviewed journals

### 10.8 Rigour

We will take several steps to ensure the qualitative sub-study is rigorous by following standard procedures aimed to fulfil the four criteria of excellence for qualitative research.

#### 10.8.1 Credibility

Credibility (equivalent to internal validity) will be ensured through: a) prolonged and varied engagement with participants throughout the entire PROSPER III study; b) seeking referential adequacy by collecting documents and field notes that describe the study context; c) triangulation (the use of multiple data types and sources regarding worker attrition, and multiple investigators and perspectives); and d) producing high-quality findings through following a well-designed protocol for the sub-study, training the investigators, having an experienced qualitative researcher analyse field notes and analytic memos, and peer debriefing about the procedures and findings with qualitative experts not involved with the study.

#### 10.8.2 Transferability

Transferability (equivalent to external validity or generalizability) will be enhanced by a) providing a rich description of methods, context, and findings; b) ensuring that sampling to data saturation was achieved; and c) data collection and analysis are done in a transparent way. This will allow others to decide if the methods and findings could be transferred to their setting or population (case-to-case generalization) or added to the literature on the study subject.

#### 10.8.3 Dependability

Dependability (findings would be similar if the same cohort of participants, analysts and contexts existed) will be developed by maintaining a rich description of study methods and an audit trail or copy of all documents generated during the sub-study to allow others to inspect the methods used to reach study concisions. Other methods include stepwise replication of the data analysis procedures through assessing coding accuracy and inter-coder reliability.

#### 10.8.4 Confirmability

Confirmability (confidence that results can be corroborated by other researchers with similar participants, methods, and instruments) will be enhanced by triangulation (explained above), presenting information on the researchers and their positionality (e.g., experience with the research topic or study participants). Researchers will keep a ‘reflexive journal’ and share their experiences with the team at regular meetings, ensuring that their perspective does not overshadow the views and experiences of participants.

## 11. SAFETY DATA ANALYSIS

### 11.1 Serious adverse events

Serious adverse events will be listed by allocation as well as allocation received.

## 12. ADDITIONAL EXPLORATORY ANALYSIS

Any analyses not specified in the analysis protocol will be exploratory in nature and a 2-sided significance level of 0.01 will be used with 99% confidence intervals.

## 13. DEVIATION FORM ANALYSIS DESCRIBED IN PROTOCOL

None at present

## 13. REFERENCES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## 14. APPROVAL

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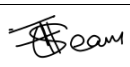
|---|---|---|
| Senior Statistician | Lovemore Sigwadhi | |
| |  | |
| Chief Investigator | Nathan Congdon | |
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