Effect of brief verbal intervention (BVI) on the quality of optometry service by using unannounced standardized patient (USP) with refractive error: study protocol for a randomized controlled trial (RCT)

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Abstract

Background: Improper refractive correction can be harmful to eye health, aggravating the burden of vision impairment. During most optometry clinical consultations, practitioner-patient interactions play a key role. Maybe it is feasible for patients themselves to do something to get high-quality optometry. But the present empirical research on the quality improvement of eye care needs to be strengthened. The study aims to test the effect of brief verbal intervention (BVI) through patient on the quality of optometry service.

Methods: This study will take unannounced standardized patient (USP) with refractive error as the core research tool, both in measurement and intervention. The USP case and the checklist will be developed through a standard protocol and assessed for validity and reliability before its full use. USP will be trained to provide standardized responses during optical visits, and receive baseline refraction by the skilled study optometrist who will be recruited within each site. A multi-arm parallel-group randomized trial will be used, with one common control and three intervention groups. The study will be performed in four cities, Guangzhou and three cities in Inner Mongolia, China. A total of 480 optometry service providers (OSP) will be stratified and randomly selected and divided into four groups. The common control group will receive USP usual visits (without intervention), and three intervention groups will separately receive USP visits with three kinds of BVI on the patient side. A detailed outcome evaluation will include the optometry accuracy, optometry process, patient satisfaction, cost information and service time. Descriptive analysis will be performed for the survey results, and the difference of outcomes between interventions and control providers will be compared and statistically tested using generalized linear models (GLMs).

Discussion: This research will help policy makers understand the current situation and influencing factors of refractive error care quality, and then implement precise policies; at the same time, explore short and easy interventions for patients to improve the quality of optometry service.

Trial registration: Chinese Clinical Trial Registry ChiCTR2200062819, ChiCTR2200062820. Registered on August 19, 2022.


Administrative Information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).
<table>
<thead>
<tr>
<th><strong>Title</strong> {1}</th>
<th>Effect of brief verbal intervention (BVI) on the quality of optometry service by using unannounced standardized patient (USP) with refractive error: study protocol for a randomized controlled trial (RCT)</th>
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<td><strong>Trial registration</strong> {2a and 2b}</td>
<td>Chinese Clinical Trial Registry ChiCTR2200062819, ChiCTR2200062820. Registered on August 19, 2022.</td>
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<td><strong>Protocol version</strong> {3}</td>
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</table>
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| **Role of sponsor** {5c} | This is a researcher initiated clinical trial. Therefore, the funding sources had no role in writing the manuscript and will not have any role during its execution, analysis, interpretation of the data or decision to submit results. There are no conflicts of interest. |

**Introduction**

**Background and rationale** {6a}

**Refractive error and optometry**

In 2019, an estimated 2.2 billion people worldwide were vision impaired, and at least 1 billion of them could have been prevented or cured [1]. Myopia is the predominant type of refractive error, and uncorrected refractive error is the leading cause of avoidable visual impairment worldwide [1, 2]. The incidence of myopia is increasing rapidly in China which also has one of the largest numbers of patients with refractive error [2, 3]. Wearing spectacles provides a cost-effective way to correct refractive error, and optometry is an essential part of refractive correction [4]. However, they are prescribed or dispensed by a wide range of eye care providers, including primary eye care clinicians, ophthalmic personnel,
optometrists, ophthalmologists, and personnel without any formal training or professional certification [5]. In addition, the optometry service and functions carried out by each of eye care providers is largely dependent on the demand for services and financial incentives in different kinds of eye care facilities, potentially compromising the quality of eye care [6].

Global health faces enormous challenges in providing high-quality eye care in low and middle-income countries [1, 7, 8]. Uncorrected or improperly corrected refractive errors greatly affect patients’ health and quality of life, even bring a huge economic burden to society [9]. Despite the potential negative effects of poor eye care, few researchers have conducted researches on this issue in China. A few studies have discovered a high rate of inaccuracy of spectacle prescriptions. Nearly half (48.8%) of children in rural Guangdong with glasses had an absolute difference in prescription by ≥1.00D and 17.7% by ≥2.00D [10]. Among children who received optometry in rural western China, 9.1% had poor vision due to inappropriate refractive correction [11]. This study also suggested that rural optometrists were overly dependent on computerized optometry and could not effectively improve vision with subjective optometry. A survey in Shanghai showed that 26.05% of children from migrant families wore inaccurate glasses [12].

**Unannounced standardized patients**

Previous studies have showed the prevalence of blindness and visual impairment, and the proportion due to uncorrected or improperly corrected refractive errors. Because of the potential observation bias, these studies may provide limited information on the quality of local optometry service. We need a methodology and criteria for establishing quality indicators. In recent years, the unannounced standardized patient (USP) has been increasingly used for healthcare quality measurement in developing countries [13-15]. The USP methodology as the gold standard for quality assessment [16, 17] in clinical practice has the following advantages of being: a) an objective and direct assessment of care in real visit; b) unannounced and thus having no Hawthorne effect (also referred to as the observer effect, in that individuals modify an aspect of their behaviors in response to their awareness of being observed [18]; c) standardized in case presentation and thus providing a natural control for case mix; and d) immediate in terms of recording assessment results and thus having less recall bias. Furthermore, the use of USPs enables us to conduct a randomized controlled trial with multi-arms by creating an experiment condition of the USP case while holding other USP factors constant.

USP encounters were validated as an effective way of measuring reproducibility refractive error within optometry [19]. The first study to use USP to assess the quality of optometry service in China was a cross-sectional survey conducted by Sean et al in Shaanxi [6], which reported a 25.6% inaccuracy (≥1.00D absolute difference) in optometry prescriptions, higher than the 18.4% found in a previous study that did not use SP methods in rural western China [11]. Sean et al also found that public hospitals provided poorer quality in optometry services compared with private optical shops. Compared with hospitals which generally prescribe rather than dispense spectacles, private optical shops mainly profit
from spectacle sales and thus may be incentivized to provide better optometry service to reduce after-sales services for patients with uncomfortable spectacles.

But this USP study still offers areas for improvement. The study used vector dioptic distance (VDD) alone as an outcome indicator for quality. However, VDD has not been validated as a proxy for patients' refractive tolerance [20], thus, VDD should be used in conjunction with a measure for vision comfort [5, 21]. Otherwise, we need another more reliable indicator, such as optimally prescribed spectacles (or optimal spectacle prescription), for measuring optometry quality (more on the section of method).

**Brief verbal intervention**

However, those cross-sectional studies only describe current situation, without continuing to explore the quality improvement of eye care. Along with the promotion of the Healthy China Initiative, eye health policy in the new era has gradually shifted towards high-quality development of eye care. But the change of the policy system is a complex and difficult process, requiring multiple inputs and reforms in various aspects. While the national policy system is undergoing continuous reform, it is beneficial to explore how patients themselves can shape the quality of care during the patient-practitioner interactions. Brief verbal intervention (BVI) is an easy and effective method commonly used in primary health services such as in smoking cessation interventions and reducing alcohol intake [22]. In this study we will use USP to test the effectiveness of BVI in improving optometry service. The USP allows us to vary a component of USP (i.e., a different line a USP use as a form of BVI) across providers while holding other USP elements constant, thus the measurement differences among the providers can be ascribed to that only varying component.

**Objectives (7)**

In summary, the objectives of the study are: 1) to assess the quality of the structure, process, and outcomes of optometry service; 2) to analyze the factors that influence the quality of optometry service; and 3) to assess the effectiveness of patient-based BVI on improving the quality of optometry service.

**Trial design (8)**

The study is designed as a prospective, single-blind, multi-center, noninferiority, randomized controlled trial with four arms - three intervention groups versus a common control group with 1:1:1:1 allocation of the participating optometry service providers (OSPs).

**Methods: Participants, Interventions And Outcomes**

**Study setting (9)**

The study will be carried out in Guangzhou and Inner Mongolia, China. Guangzhou is the capital city of Guangdong Province, representing a well-developed metropolitan in the south. Inner Mongolia autonomous region has less medical resources, representing relatively underdeveloped land in China. We chose three cities in Inner Mongolia, which are Bayannur (west), Hohhot (central) and Xinganmeng (east).
Optometry service providers (OSPs) are considered for inclusion if they meet the criteria as defined below. In each location we will draw a representative sample of eligible OSPs using stratified and simple random sampling.

**Eligibility criteria (10)**

**Inclusion criteria for service providers**

Participants must meet the following criteria to be eligible for the study:

- OSPs in Guangzhou and Inner Mongolia, consisting of general hospitals with ophthalmology department, ophthalmology specialty hospitals or clinics, and optical shops.

- Any personnel providing optometry services, as licensed optometrists and ophthalmologists or not, at the above-mentioned institutions.

**Exclusion criteria for service providers**

Optical services meeting any of the following criteria will be excluded from the study:

- Providers providing Internet-based services only.

- Providers providing optometry service solely for contact lens only.

**Inclusion criteria for USPs**

USPs must meet the following criteria to be eligible for the study:

- People with refractive error profile of interest (myopia or myopia with astigmatism), and good ocular health.

- Fluent native speakers of the primary language of the district,

- Having a good memory.

**Exclusion criteria for USPs**

If the USPs meet any of the following criteria, they will not be eligible for the study:

- Having prior refractive eye surgery or had eye surgery within the last three months.

- Having manifest or intermittent strabismus, or amblyopia.

- People with any ocular or health conditions that can cause variable spectacle prescription.

**Who will take informed consent? (26a)**
At recruitment, all USPs must sign the informed consent electronically through a web-link sent by our emails. We have obtained a waiver for informed consent from the OSPs as the process may compromise the sample representation due to possible participant self-selection. We meet the criteria of consent waiver for the USP studies as stipulated by the medial ethics: 1) data analysis will only be performed at the aggregated level rather than targeting individual participants; 2) de-identification for the participating individuals and institutions will be fully implemented; and 3) services performed on USPs are not critical services where resources must be protected for the real patients [23].

Additional consent provisions for collection and use of participant data and biological specimens (26b)

No biological specimens will be collected and no additional consent will be sought.

Interventions

Explanation for the choice of comparators (6b)

The control group of optical services will receive usual USP visits, while the intervention groups will receive usual USP visits plus a form of BVIs. In the usual USP visit, the customer requests for an optometry for the spectacle prescription but will otherwise make no other proactive lines. Although a schedule will be developed for each USP to visit sampled OSPs, most visits will be drop-in visits with no prior appointment unless it is a required procedure by the OSP, for example, when USPs have to register online in advance to visit the ophthalmology department of the hospital. The usual USP visit is chosen as the control, because the purpose is to investigate whether patient's BVI will change practitioner's behavior and thereby affect the quality of optometry service. It should also be noted that the assessment results in the control group will serve as the cross-sectional survey results of the quality of optometry service.

Intervention description (11a)

The USP will execute three different forms of BVIs. For each, the USP will deliver exactly the same rendition of the USP cases other than a proactive line before undergoing the eye examination that represents the content of an assigned BVI. The three BVIs are informed by three respective underlying theories: qualification requirement, patient knowledge and social monitoring. In Group A, the USPs will say “I would like to ask for a qualified professional to do the examination/optometry.” or something like that, to create a qualification requirement for better service. In Group B, the USPs will say “I learned from a TV health program that subjective refraction is a critical component” to show patients’ knowledge in appropriate procedures. In Group C, the USPs will say “I am a blogger and will share my experience on Internet” to create a scenario of social monitoring. Except for the first opening statement and BVI, the USPs will not offer any other lines unless prompted by a providers' question or instruction. They will also provide only standard answers and responses strictly according to the USP scripts.

Criteria for discontinuing or modifying allocated interventions (11b)
BVIs are brief intervention that will be started and concluded with a single USP visit so we expect few or no cases of discontinuing an allocated intervention. In the case a provider refuses to provide optometry service, the USP will record the reason and visit a replacement provider with similar characteristics.

**Strategies to improve adherence to interventions (11c)**

The intervention will be delivered by highly trained USPs even though they are also real patients. Meanwhile, we will check the quality of USPs’ rendition of their roles and scripts through the voice recordings that the USPs will secretly take during each optical visit with their smartphones. Thus, we expect high level of adherence to the research protocols.

**Relevant concomitant care permitted or prohibited during the trial (11d)**

Not applicable. In our study, relevant concomitant care and interventions are not considered.

**Provisions for post-trial care (30)**

Not applicable for the provider participants as the intervention - BVI will conclude right after each USP visit. However, in one of our future trials, we are considering sending a quality summary to each institutions that the USP has visited to assess whether such an “audit and feedback” may help improve the quality of care.

**Outcomes (12)**

**Optimal spectacle prescription**

Refration of each USP will be conducted prior to the launch of the field visits by the skilled optometrist who will be recruited within each setting to conduct individual refraction. For example, the baseline refraction in Guangzhou will be conducted by experienced optometrists from Zhongshan Ophthalmic Center at Sun Yat-Sen University, the state key laboratory of ophthalmology. Each item of the expert prescription will be used as the “optimal spectacle prescription” (Table 1) for a given USP. The tolerance limits (Table 1) are developed from published studies [5, 24-26] and evaluated through experts’ consensus.

**Table 1 Criteria for optimal spectacle prescription**
Component of spectacle prescription & Tolerance limits compared with baseline prescription

<table>
<thead>
<tr>
<th>Component</th>
<th>Tolerance limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spherical power</td>
<td>±0.50DS</td>
</tr>
<tr>
<td>Cylindrical power</td>
<td>±0.50DC</td>
</tr>
<tr>
<td>Cylindrical axis</td>
<td></td>
</tr>
<tr>
<td>(if baseline cylinder power ≤ −0.50DC)</td>
<td>±7°</td>
</tr>
<tr>
<td>(if baseline −0.50DC to ≤ −1.50DC)</td>
<td>±5°</td>
</tr>
<tr>
<td>(if baseline −1.50DC)</td>
<td>±2°</td>
</tr>
<tr>
<td>Pupil distance</td>
<td>±2mm</td>
</tr>
<tr>
<td>Corrected visual acuity</td>
<td>±0.1</td>
</tr>
</tbody>
</table>

DS=diopter sphere, DC=diopter cylinder

**Primary outcomes: optometry accuracy**

The primary outcome is optometry accuracy, a dichotomous variable of spectacle prescription. The prescription of a specific USP visit will be considered "accurate" if all of its readings fall within the tolerance limits in Table 1 to the optimal spectacle prescription. Otherwise, they will be judged as inaccurate prescription.

**Secondary outcomes: indicators for optometry service process**

We will also assess providers' adherence to best practice in optometry services as the secondary outcomes, such as the percentage of guideline recommended procedures performed. We developed the following technical process indicators based on the guideline recommendations [27]: whether practitioners perform subjective optometry, try on adjustments, check old glasses, etc., and whether the operation is standardized and completed. A technical quality assessment checklist will be developed and the USP will complete this checklist right after each optical visit. In addition to those technical process of optometry, we will also evaluate patient experience, cost and service time. The patient-centered eye care in the optometry or ophthalmology will be assessed with a revised patient perspective patient-centeredness (PPPC-R) rating scale by USP [28, 29]. Table 2 summarizes all outcomes to be collected.

**Table 2 Outcomes and their definitions**
<table>
<thead>
<tr>
<th>Name</th>
<th>Definition</th>
<th>Nature</th>
<th>How it is assessed</th>
<th>By whom</th>
</tr>
</thead>
<tbody>
<tr>
<td>optometry accuracy</td>
<td>whether it is optimally prescribed for spectacle</td>
<td>primary</td>
<td>spectacle prescription</td>
<td>USP and companion</td>
</tr>
<tr>
<td>completion of process items</td>
<td>the percentage of recommended procedures performed</td>
<td>secondary</td>
<td>quality checklist</td>
<td>USP and companion</td>
</tr>
<tr>
<td>patient experience score</td>
<td>whether it is patient-centered</td>
<td>secondary</td>
<td>PPCP-R rating scale</td>
<td>USP</td>
</tr>
<tr>
<td>cost</td>
<td>optometry fees, prices of recommended lenses and frames</td>
<td>secondary</td>
<td>data collection form</td>
<td>USP and companion</td>
</tr>
<tr>
<td>service time</td>
<td>optometry time and waiting time</td>
<td>secondary</td>
<td>data collection form</td>
<td>USP and companion</td>
</tr>
</tbody>
</table>

Participant timeline (13)

The study subjects (optical services and the refractionists) are not informed for participation, thus they will be visited unannounced by USP. We will recruit USPs and train them, implementing interventions in different groups. Figure 1 presents an explicit flow chart of this study.

Sample size (14)

We calculated the sample size based on the proportion of optometry accuracy, which is the primary outcome in this study. According to the previous literature [5], the proportion of optometry accuracy is 44.1% in the control group (receiving usual USP visits), and proportions in the intervention groups (receiving usual USP visits plus BVIs) are supposed to be 66.1% (when assuming the effect size of 0.22). Accounting for multiple comparisons of proportions (the proportion of optometry accuracy) for treatments vs. a control [30], the overall alpha is set to be 0.05, thus a level of significance is 0.0167 (0.05/3) by using Bonferroni adjustments. In this study, we set the power of each test at 0.9, all groups have the same sample size. And finally, a total of 456 USP visits is required, each OSP is corresponded to a USP visit. Considering 5% of dropout and/or missing data, the number of participants adds up to a total of 480 participants. The sample size required for the control group and each of the intervention group is 120 respectively. The sample size calculation was performed using PASS 15 software (NCSS, Kaysville, UT, USA).

Recruitment (15)

We will develop the sampling frame of all OSPs who meet our inclusion and exclusion criteria by crawling the data of Gaode Map, which is the leading map service App which has the advantage of capturing both registered and non-registered optical shops in China. We will select the sample of OSPs with stratified and simple random sampling. We will recruit USPs by posting job announcements on campus posters.
and social media and also through our existing USP network. The USPs will be paid for participation and reimbursed for other related expenses.

**Assignment of interventions: allocation**

**Sequence generation (16a)**

The sample of OSPs will be randomly assigned to the control or the intervention groups with a 1:1:1:1 allocation. The randomization schedule will be computer-generated and stratified by service type (such as hospitals and optical shops). A stratified randomization is used to ensure that the four groups have a similar distribution in type as this characteristic may substantially affect the outcomes.

**Concealment mechanism (16b)**

The allocation of OSPs will be conducted by a statistician otherwise not related to the research. Other than a code for each service provider and the service type, the statistician will have no other identifying information of the sampled participants.

**Implementation (16c)**

After stratified random sampling, the allocation sequence will be generated by computer, and the randomization for each group will be initiated by the researcher. The USPs will be enrolled by the researcher and assigned randomly to the OSPs in each group. To balance confounding factor of individual USP, each USP will be assigned to four groups for equal visits.

**Assignment of interventions: blinding**

**Who will be blinded (17a)**

The study subjects (OSPs) will be blinded to their allocation status as we have obtained a waiver for their informed consent. The USPs will not be blinded as they will need to implement BVIs according to the allocation status. The outcome assessors and data analysts will be blinded to reduce subjective analysis.

**Procedure for unblinding if needed (17b)**

As no informed consent will be sought, unblinding on the side of OSPs is highly unlikely if possible at all. But if that occurs, a replacement of provider with similar characteristics will be identified for a replacement visit.

**Data collection and management**

**Plans for assessment and collection of outcomes (18a)**

We will collect a variety of quality of eye care information and other related explanatory variables. Donabedian's classification of quality of care (structure, process and outcome) will be used for quality
evaluation [31]. The quality of structure level includes: personnel qualification (whether the practitioner is qualified and professionally certified) and equipment layout (whether the facility's hardware meet the requirements of optometry and whether its layout is appropriate), etc. This kind of information will be obtained from publicly available websites, promotional materials and USP on-site observations.

Almost all data will be collected through the USP visit to the OSPs. The USP will visit each provider along with a companion as “friend”. While the USP is under examination by the practitioner, the companion will observe the equipment environment and the optometry procedures. When conditions permit, the companion will record right away the key information on the smartphone, pretending sending WeChat messages. At the end of each visit, the USP will ask for a spectacle prescription. The USP and the companion will work together to complete the quality checklist and other data forms on the smartphone within 15 minutes of the end of the optometry service. Both the USP and companion will secretly voice record the conversation during the visit with their smartphones.

**Plans to promote participant retention and complete follow-up (18b)**

Not applicable. The intervention in the study is instant and involves no follow-ups.

**Data management (19)**

All data collected will be entered into the Research Electronic Data Capture (REDCap) system. REDCap is a free and powerful cloud-based tool for data collection, storage and management [32]. REDCap will also track any changes to the data in an audit trail and be able to fully de-identify the data. REDCap has bank-level security features and only the investigators involved in this study can access the data. All forms collected for this study, including the signed consent forms, will be stored on REDCap system safely and conveniently.

**Confidentiality (27)**

Research data will be stored using a study identification code for each USP visit. A code will also be assigned to each visited OSP. Some identification information such as institutional names, GPS coordinates and license number for the providers will be collected. However, full de-identification will be implemented before data analyses. No service provider or practitioner identification details will be reported in publications or any other public spaces.

Information about potential USP participants will be collected through the application form, which will be used to check the patient’s eligibility to participate in this study and will not be shared. The collected personal information will be safely stored on REDCap with strict access controls.

**Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use (33)**

Not applicable. We plan to collect no biological specimens.
Statistical methods

Statistical methods for primary and secondary outcomes (20a)

Data will be analyzed on an intention-to-treat (ITT) basis to compare primary and secondary outcomes in the originally assigned groups. Baseline characteristics for each group will be descriptively presented using mean (standard deviation, SD) or median (interquartile range, IQR) for continuous variables depending on the distribution, and frequency (percent) for categorical variables. Primary outcome (optometry accuracy) and secondary outcomes will be analysed using generalized linear models (GLMs). Binomial distribution and identity link function will be used for binary outcomes, Poisson distribution and identity link function will be used for count outcomes, and normal distribution and identity link function will be used for continuous outcomes. Effects (risk differences for binary and count outcomes, and mean differences for continuous outcomes) with corresponding two-sided 95% confidence intervals will be estimated. Missing data will be imputed using multiple imputation in the GLMs. Sensitivity analysis will be performed by covariate adjusted analysis using GLMs with baseline characteristics as covariates. Cost effectiveness analyses will be performed and cost effectiveness ratios will be calculated using bootstrapping techniques. Statistical significance will be considered to be present when the P value is <0.05. IBM SPSS (version 20) and SAS (version 9.4, SAS Institute) will be used for all statistical analyses.

Interim analyses (21b)

Not applicable. There are no planned interim analyses.

Methods for additional analyses (e.g. subgroup analyses) (20b)

Subgroup analyses will be performed, based on type of service (hospitals and optical shops) and types of practitioners (such as liscenced vs. un-liscenced practitioners).

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data (20c)

We expect the number of withdrawals to be low because the intervention is delivered by the USP and the service provider will receive the intervention passively. Additionally, the intervention will be conducted over a brief period of one USP visit thus without post-visit follow-ups. All data will be entered into the REDCap system immediately after the visit. Furthermore, the voice recording will help record and check the data even long time after the visit. Thus, we expect to have minimum (if any) missing data. A maximum dropout and/or missing data of 5% is considered in our sample size calculation. We will analyze the data according to the ITT principle.

Plans to give access to the full protocol, participant level-data and statistical code (31c)

The datasets used and/or analyzed during the current study will be made available by the corresponding author upon reasonable request after completion and publication.
Oversight and monitoring

Composition of the coordinating centre and trial steering committee (5d)

The study will be coordinated between Southern Medical University and Inner Mongolia Medical University. Day to day support for the trial is provided by:

- Principle investigator: lead the study design and supervise the conduct of the trial; revise the protocol and amendments; approve final protocol.

- Executive Investigator: develop research proposal and protocol; select and recruit USPs; conduct sample randomization and allocation; advise on study design and statistical analyses.

- Data manager: organize data capturing system; safeguard data quality; perform statistical analyses.

- Study coordinator: register trial; train USPs; obtain informed consent; coordinate optical service visits; assess quality of the USP visit.

- Study optometrist: develop "optimal spectacle description"; help train USPs.

The study team meets every two weeks. There is no trial steering committee or stakeholder involvement group.

Composition of the data monitoring committee, its role and reporting structure (21a)

As the study does not involve any medications or invasive examinations or treatment, we expect minimum harm to the participants. The USPs and their companions will also be encouraged to report any irregularities or concerns through a feedback system. Thus we do not create an independent data monitoring committee for this study.

Adverse event reporting and harms (22)

Possible harms to the optometry provider include inadvertent disclosure of their identity which along with their USP quality assessment information may adversely affect their business and public image or even lead to regulatory attention. However, we will take strong measures as prior described to protect provider information. Possible adverse event to the USPs may include potential confrontations between the USP and the provider once their anonymity is exposed and potential harm to their eye should the practitioners perform their eye examination in a harmful way. However, all USPs will be intensively trained to present a letter with phone contact information from the university to explain their research roles in case of possible confrontation and also to avoid potentially harmful examination.

Frequency and plans for auditing trial conduct (23)

Monitoring of trial conduct will be performed continuously.
**Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees)**

Protocol modifications will be communicated to the relevant parties in the form of an amendment. In case amendments concern or affect USP participants in any way, they will be informed about the changes. If needed, additional consent will be requested and registered. Also, on-line trial registries will be updated accordingly.

**Dissemination plans**

The results of this research will be presented at scientific meetings and disclosed completely in international peer-reviewed journals. Both positive and negative results will be reported. USPs can receive a laymen summary of the results in case they opted-in to receive outcomes on a study level.

**Discussion**

This randomized controlled trial is designed to investigate the effect of BVI by USP on the quality of optometry service. The outcomes will include optometry accuracy, provider adherence to best practice in conducting optometry, and structural elements of the OSPs. The results of this study will not only provide valuable information on the quality of optometry service and identify specific opportunity for quality improvement, but also provide much-needed empirical evidence to aid policy-makers, education institutions and service providers on how to ensure that optical services provide quality eye care. The findings can be especially helpful for people with refractive error to obtain proper refraction and good service as BVIs can potentially be self-implemented by patients. The use of USPs in this study provides a reliable way of measuring and changing quality of the services.

**Limitations**

There are several limitations that should be considered. First, we will not be able to afford buying spectacles due to limited budgets. The results of data can only reflect the provided optometry service quality, not the whole refractive error care. Second, we don’t consider young children, only use adult USPs (aged 18 or up) in the study as the mydriatic optometry is an invasive examination that cannot be ethically implemented in the USP study. Third, our USP have real profile of refractive error with various diopters, so different USPs may cause individual difference. We will minimize the potential bias by assigning each USP into the four groups in addition to the random assignment of OSPs. Training will be provided to ensure each USP plays their roles consistently except BVI across groups.

**Strengths**

This randomized controlled trial will provide insight into the effect of BVI in optical visit. By use of usual visit without BVI as a control group, we will gain insight into the current situation of the quality of optometry service. We focus on the technical quality and patient-centeredness, with the gold standard of practice assessment. And USP is a promising tool to not only assess quality but also implement quality
improvement intervention. Our study can provide an important contribution to the understanding of refractive error care and the role of BVI as a quality-improvement method, and also provide methodological practice of USPs to future researchers.

**Trial status**

The current protocol is version 3.0 of October 30th, 2022. The USP recruiting started in September 2022. The anticipated end date of the study is April 1st, 2023.

**Abbreviations**

BVI  
brief verbal intervention  
USP  
unannounced standardized patient  
RCT  
randomized controlled trial  
VDD  
vector dioptric distance  
OSP  
optometry service provider  
REDCap  
Research Electronic Data Capture  
SD  
standard deviation  
IQR  
interquartile range  
GLM  
generalized linear models.

**Declarations**

**Acknowledgements**

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**Authors’ contributions (31b)**
HJL and JQL are the main authors of the proposal and protocol, who designed the study and wrote the manuscript. XSC, YJL and RTZ provided substantial contributions to the conception and implementation of the study. HYL, WJH and SYL determined the sample size and planned the statistical analysis. NZ, LPZ, QZ, SSL, CPL and YYX provided contributions to develop the design of the study. All authors read and approved this manuscript. DX is the principal investigator. He edited the manuscript and oversaw revisions to the protocol.

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Availability of data and materials {29}

Only the investigators will have full access to the final datasets. The datasets used and/or analyzed during the current study will be made available from the corresponding author upon reasonable request.

Ethics approval and consent to participate {24}

The study has been approved by Medical Ethics Committee of Inner Mongolia Medical University (YKD202201082) and Biomedical Ethics Committee of Southern Medical University (NYLS [2022] No.21). We have ethics approvals of a waiver for obtaining service owner or clinician informed consent. As specified above, the optical services will be unknown to their enrolment in this study so as to avoid opt-in bias. That is why the visit is called unannounced. The USP study meets the ethical standards that it conducts de-identified and aggregated analysis only (not violating clinician privacy), it uses non-emergency settings only (not wasting scare resource), and the “deception” of the USP is necessary to prevent “priming” the research subject. But written, electronic informed consent will be obtained from the USPs and potential harms have been explained.

Consent for publication {32}

Not applicable. This manuscript does not contain individual personal data from participants.

Competing interests {28}

The authors declare that they have no competing interests.

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References


Figures

![Flow chart of the study](image)

**Figure 1**

Flow chart of the study