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STUDY PROTOCOL

# Impact of Meditation on Improving Quality of Life Among Glaucoma Patients: A Study Protocol

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**Purpose:** The primary objective of this study is to assess the feasibility of administering an online meditation program compared to usual care to glaucoma patients to improve mental health outcomes such as quality of life, depression, anxiety, and sleep quality. The secondary objective of this study is to improve mental health outcomes among glaucoma patients.

**Patients and Methods:** This is a study protocol for a 12-week randomized control trial employing a mixed methods design. Glaucoma patients will be recruited from the Ivey Eye Institute in St. Joseph's Hospital Center. Eligible patients will include glaucoma patients of at least 75 years of age. Consented participants will be randomized to an online meditation group or usual care group in blocks of 4, or 2 per arm. Patients assigned to the online meditation group will undergo guided meditation sessions led by a meditation instructor via Microsoft Teams. Patients randomized to the usual care arm will undergo their usual glaucoma treatment. All study questionnaires including feasibility metrics, SF-12, CES-D, HADS-A and PSQI will be administered to both treatment groups at week 1, week 3, week 6, and week 12. Following study conclusion, feasibility metrics will be sent to participants in the intervention arm. In addition, patients randomized to the usual care arm will be given the opportunity to enroll in the meditation program after the 12 week study period, but no data will be collected.

**Discussion and Conclusion:** To the best of the authors' knowledge, this study is the first of its kind to assess the feasibility of administering an online meditation intervention to glaucoma patients. If the findings from this study demonstrate positive results in favor of the treatment, this will be used to justify larger clinical trials and eventually, the integration of online meditation into the standard of care for glaucoma patients.

**Keywords:** feasibility study, pilot study, mindfulness, eye disease

## Introduction

Glaucoma is a group of eye diseases resulting in loss of vision and potential blindness. It is characterized by damage to the optic nerve and the loss of retinal ganglion cells and is often associated with elevated intraocular pressure. Glaucoma is currently the leading cause of irreversible blindness worldwide.[1] In 2020, 4.1 million and 3.6 million adults over the age of 50 suffered from mild to severe visual impairment and blindness, respectively, induced by glaucoma.[1] Nonetheless, the worldwide burden of glaucoma is likely underestimated given that glaucoma can remain asymptomatic until later stages in disease progression.[2]

There is a breadth of literature pointing to a relationship between glaucoma and symptoms of depression,[3–5] altered mood,[6] disturbed sleep,[3] anxiety,[3–5] and self-reported non-compliance of glaucoma treatment.[7] Based on the results of a systematic review, glaucoma patients were most commonly afflicted with depression and anxiety with rates ranging from 7% to 57% and 12% to 49%, respectively.[8] Compared to those without visual impairment, visually impaired individuals were nearly twice as likely to experience depression.[9] The severity of these psychological conditions seems to be influenced by demographic characteristics, glaucoma severity, and treatment duration.[8]

There are several factors that underpin the relationship between glaucoma and decreased quality of life. Evidence from an Indian population demonstrated that newly diagnosed glaucoma patients suffered from decreased quality of life



Received: 31 May 2025
Accepted: 7 October 2025
Published: 1 December 2025

(QOL) 3 months following treatment initiation compared to a group of otherwise healthy controls that visited the hospital for refractive error.[10] This may be a consequence of the looming threat of blindness and the apprehension of the necessity for lifelong treatment. Furthermore, simply being in a hospital setting on a regular basis may induce stress, anxiety, and depression.[11] Many glaucoma patients also suffer from a loss of independence. In one study, 23% of glaucoma patients voluntarily discontinued driving.[12] Those who continued to drive nonetheless refrained from driving at night or in the rain.[12,13] Despite this, glaucoma patients are at greater risk of being in a driving accident.[14–18] In addition, glaucoma patients read slower than their healthy counterparts.[19,20] Glaucoma patients moreover suffer from poorer facial recognition that has detrimental effects on their social life.[21] Taken together, the functional impairments brought about by glaucoma[22] may make it challenging for patients to access care.

Meditation directs an individual to become consciously aware of their internal experiences and thoughts in a non-judgemental manner.[23–25] It is thought to improve mental health by addressing maladaptive patterns of thinking such as reaction to and rumination of thoughts, physical sensations, and emotions.[24] Meditation has been shown to improve depression,[26–28] anxiety,[26,27] and stress[29,30] among a wide range of patient populations. Among glaucoma patients specifically, there is evidence that meditation improves quality of life[30] and decreases intraocular pressure.[30–33] Given the increasing familiarity of technology among older adults,[34] an online meditation intervention may be a feasible method to treat mental health among glaucoma patients.

To date, there has not been a study that has investigated the effectiveness of online meditation compared to usual care in improving mental health among glaucoma patients. The primary objective of this study is to assess the feasibility of conducting a study evaluating an online meditation intervention versus usual care for glaucoma patients. The secondary objective of this study is to assess the impact of meditation on QOL, sleep quality, depression, and anxiety in glaucoma patients compared to usual care.

# Methodology

## Ethics Approval

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. This study was registered with ClinicalTrials.gov (NCT 05697094). This study protocol was approved by the Health Science Research Ethics Board (HSREB) of Western University (ID: 121484).

## Study Design

To assess the feasibility of administering a virtual meditation program to enhance the QOL and mental health of glaucoma patients, a masked, 12-week RCT employing a mixed-method design will be conducted. Patients with a diagnosis of glaucoma aged 75 and older will be eligible to participate. Participants will undergo block randomization (4 participants; 2 per arm) to the meditation or usual care arm on an ongoing basis. This will enable timely access to the intervention and its potential benefits. Participants randomized to the treatment arm will be taught an evidence-based meditation technique by trained instructors at Prasanna Wellness over the span of two online sessions (60 minutes each). Patients in the usual care arm will continue as per the standard of care. Data will be collected online via questionnaires using Research Electronic Data Capture (REDCAP) for encrypted data entry. Personal identifying information for all participants will be collected in a separate set of REDCAP questionnaires from those that will be used to collect study data. Furthermore, personal identifying information will be stored on a local computer in the principal investigator's (PI) office at St. Joseph's Health Care London (SJHC).

## Inclusion and Exclusion Criteria

Patients from the Ivey Eye Institute, SJHC will be recruited in person, based on the inclusion and exclusion criteria below.

### Inclusion Criteria

1. Patients diagnosed with glaucoma.
2. Older adults (age $\geq$ 75 years old).

3. Being able to provide valid informed consent to participate in the research study.
4. Written and oral fluency in English.
5. Not having a significant self-reported or physician-diagnosed mental health disorder.
6. Ability to independently access a computer.
7. Ability to sit comfortably for 30–35 minutes, ability to hear well enough to follow verbal instructions with their eyes closed, and good overall physical health.
8. Willing to dedicate approximately 30–35 minutes per day to practice meditation at home.

### Exclusion Criteria

1. Inability to provide informed consent.
2. Communication barriers or limited written or oral fluency in English that prevents them from completing the questionnaires.
3. Self-reported substance abuse or dependence within the past 3 months.
4. Acutely unstable medical illnesses such as delirium or acute cerebrovascular or cardiovascular events within the past 6 months.
5. Irreversible vision loss that prevents them from completing the questionnaires.
6. Participating in similar studies involving meditation.

## Questionnaires and Scales

The 12-Item Short Form Survey (SF-12) is measures self-reported health among a wide range of patient populations irrespective of age, treatment status, or disease.[35] The SF-12 consists of the following 8 domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. Furthermore, the SF-12 is comprised of 12 items in total. The SF-12 generally takes 2–3 minutes to complete, however, in a pilot study, 81% of participants completed the questionnaire within 2 minutes.[36] Domain-specific scores are standardized to a scale from 0 to 100 where higher scores represent better health. Results can be summarised using the physical component summary (PCS) score and the mental component summary (MCS) score. Physical functioning, role physical, bodily pain, and general health skills are weighted the most when calculating the PCS score. In contrast, vitality, social functioning, role emotional, and mental health scales are weighted the most when calculating the MCS score. Weights are derived via factor analysis using a sample of the country's general population.[37] Due to its widespread applicability and minimal respondent burden, the SF-12 will be used in the current study to assess self-reported health.

The Hospital Anxiety and Depression Scale – Anxiety subscale (HADS-A) is a self-report questionnaire consisting of 7 items that measure anxiety symptoms. The HADS-A takes about 2 to 5 minutes to complete. Each item is scored from 0–3 with total scores ranging from 0 to 21. Higher scores represent higher levels of anxiety.[38] A HADS-A score ≥8 has a sensitivity of 0.9 and specificity of 0.79 for identifying patients with anxiety.[39] Previously, the HADS-A has been used in study investigating the impact of low vision on the quality of life, depression, anxiety, and social support.[40] The HADS-A also demonstrated adequate internal consistency (Cronbach's alpha = 0.87) among older adults.[41]

The Center for Epidemiologic Studies – Depression scale (CES-D) is a brief self-report scale that measures self-reported depression symptoms within the past week. The scale takes approximately ten minutes to complete. The CES-D includes 6 scales and 20 items. Each scale captures a different facet of depression and includes depressed mood, feelings of guilt and worthlessness, feelings of helplessness and hopelessness, psychomotor retardation, loss of appetite, and sleep disturbance. Possible CES-D scores range from 0 to 60, with higher scores indicating an increased presence of depressive symptomatology. A CES-D score ≥16 has high sensitivity and specificity rates for identifying subjects with depressive disorder.[42] The CES-D has demonstrated high reliability (Cronbach's alpha = 0.90) and construct validity among older adults.[43]

The Pittsburgh Sleep Quality Index (PSQI) measures self-reported sleep quality over a 1-month time interval. The questionnaire consists of 19 items to form 7 components that produce 1 global score. In total, the questionnaire takes about 5–10 minutes to complete.[44] Higher PSQI scores indicate poorer sleep quality.[45] A PSQI score >5 demonstrated

sensitivity and specificity rates of 89.6% and 86.5%, respectively, for identifying individuals with sleep disorder.[44] The PSQI has demonstrated high test-retest reliability and good validity.[46]

The following metrics will be collected to assess feasibility:[36,47] number of potential participants approached in-person, consented, and enrolled online, online rate of retention, rate of adherence to protocol, completeness of final data for analysis, and quality of all collected data. When combined with our anticipated quantitative outcomes, including QOL, depression, anxiety, and sleep quality, we hope to show that meditation can be further assessed in a subsequent larger RCT study and that the protocol would work as intended.

### Anticipated Challenges

Although meditation has been shown to be effective among a wide range of patient populations, the effectiveness of online meditation is yet to be determined. The current study will also collect patient data including sensitive information such as mental health status and suicidal intent. In consideration of these risks, it is important to have measures in place to enforce ethical clinical research. This includes documentation of protocols to address potential adverse events occurring during the conduct of the study. In addition, research team members must be trained on the study protocol to ensure protocol adherence and study replicability. Research team members will also be trained on good practice when using REDCAP to collect and store patient information. These measures are discussed in further detail in the sections below.

## Data Fidelity and Management

### Training of Research Assistants

The Site Readiness Checklist (Supplementary File 1) ensures team readiness in terms of training completion and documentation. The research assistants (RA) will follow this checklist to complete all hospital and Lawson Research Institute (LRI) required training, and their training will be documented. The Study-specific Protocol training by the PI includes training the RAs on administration of the health-related quality of life measures.

The REDCAP quiz (Supplementary File 2) will be used to assess RA comprehension of REDCAP standard practices. The Site Readiness Checklist will also include a prompt for Post-training REDCAP evaluation. The results of this quiz will be documented and signed by both the PI and the RA (Supplementary File 3).

Role Assignments will be implemented to ensure that the RAs have a clear understanding of their roles and responsibilities. The Site Readiness Checklist will include a prompt for Role Assignments.

RAs will undergo thorough training on each questionnaire's content, purpose, administration, and scoring. RAs will observe experienced assessors and practice administering assessments under supervision. Training will emphasize the importance of maintaining neutrality and avoiding any cues that might influence participants' responses.

From the monitoring and quality control perspective, data entered into the study database will be regularly checked by the monitor for accuracy and completeness. If there are any significant, recurring, or systemic issues identified by the monitor, they will be communicated immediately to the study coordinator to ensure compliance. The study coordinator will communicate these issues immediately to the PI to secure compliance. The PI will ensure that corrective measures are put in place to address these issues and prevent them from recurring. Please refer to *Monitoring Plan* (Supplementary File 4) for further details on the monitoring procedures. RAs will maintain detailed assessment log in the Progress Notes, including participant ID, date and time of assessment, and assessor initials.

### Day-to-Day Management of the Study

The PI will oversee the coordination and monitoring of the overall study. The RAs will be delegated tasks related to patient recruitment in accordance with the *Recruitment and Retention Plan* (Supplementary File 5), as well as data collection, documentation, and storage in accordance with the *Data Management Plan* (Supplementary File 6), and participant communications following approved email and telephone scripts (Supplementary File 7). The Site Readiness Checklist will also include a prompt for Regular Monitoring and Oversight to facilitate and document day-to-day management of the study.

Weekly meetings will be conducted to (a) monitor adherence to the *Recruitment and Retention Plan*, (b) revisit Screening Logs, Progress Notes, and Eligibility Checklists of the participants recruited within that week for verification and documentation, (c) ensure blinding is maintained, and (d) verify REDCAP data fields for completeness and accuracy. Meeting notes will be collected and stored on a Microsoft Excel version 16.100 (Microsoft Corporation, Redmond, WA, USA) spreadsheet that will be saved on a password-protected and encrypted Microsoft OneDrive version 25.137.0715.0001 (Microsoft Corporation, Redmond, WA, USA) folder (Supplementary File 8).

# Recruitment and Study Procedures

## Recruitment and Data Collection

Dr. Hutnik, Dr. Tingey, and Dr. McIlraith at Ivey Eye Institute will identify potential study participants and ask if they are interested in participating. If the patient expresses interest, the physician will introduce them to the on-site RA and share the patient's medical records with them. The patient medical records will be used for pre-screening to verify age and glaucoma status eligibility by the RA. If the potential participant satisfies the age criteria and has a confirmed diagnosis of glaucoma, they are deemed eligible for recruitment into the study. If either criterion is not met, the individual is excluded from further consideration. While no formal questionnaire or instrument is used, the outcome of the pre-screening process will be documented in the QAEP Pre-screening Log to maintain a clear and auditable record of eligibility determinations. The eligibility outcome is documented using a Yes/No format, if the answer is No, the specific reason for ineligibility is recorded in the log. This documentation is minimal and does not involve data collection. The RA will use a standardized recruitment script (Supplementary File 9) during their interaction with the patient.

Potential participants will be given with an electronic Letter of Information (LOI) and Consent Form on a password-protected encrypted electronic tablet. The RA will briefly describe the study to them and answer any questions. The LOI will contain the contact information of the study investigators and the study description. After obtaining informed consent, the RA will conduct screening to determine the eligibility of the patient. If the patient meets the screening criteria, the RA will collect their contact information via REDCAP.

Subsequently, the participant will be invited to complete the demographic questionnaire and the study questionnaires (SF-12, CES-D, HADS-A, and PSQI) on-site, with assistance from the RA, if needed. If participants do not have time to complete the questionnaires on-site, a REDCAP link will be sent to their email within 24 hours for them to complete the questionnaires at their convenience. If the baseline questionnaires are not completed within a week, the participant will be contacted via telephone using an approved script (Supplementary File 7) up to 2 times within the span of two weeks before the participant will be considered lost to follow-up. If requested, the REDCAP link for the baseline questionnaires will be re-sent using an approved email script (Supplementary File 7).

To mitigate selection bias and adhere to the intention-to-treat principle, participants will be randomized to the intervention or control arm as they are recruited. The participants will be randomized in a 1:1 ratio via block randomization in blocks of 4 using the built-in randomization module in REDCAP to randomly generate an allocation table. This allocation table will be hidden from the PI and the team members performing data analysis. Consenting participants will receive a thank you letter (Supplementary File 10) upon completion of the final week questionnaire. For a visual representation of the patient flow, please see Supplementary File 11.

A REDCAP link for week 1, week 3, week 6, and week 12 study questionnaires will be sent to the participants at each respective timepoint by email to be completed at their convenience. If participants do not complete the follow-up questionnaires, they will be contacted via telephone up to 2 times within the span of 5 days before their data for that measurement timepoint will be considered missing. If requested, the REDCAP link for week 1, week 3, week 6, and week 12 questionnaires will be re-sent via email. Please refer to *Recruitment Retention Plan* (Supplementary File 5) for more details regarding patient follow-up procedures for data collection. For participants in the intervention arm, feedback forms will be sent after each weekly follow-up session to evaluate their personal experiences with the meditation sessions. In addition, participants in the intervention arm will receive a REDCAP link to complete a brief questionnaire regarding feasibility metrics at the end of week 12.

If the participant presents with severe depression (CES-D ≥ 24), an automated alert will be sent to the PI via REDCAP. The PI will be required to refer the participant to a mental health provider for further screening for the presence of imminent suicidality and safety within 48 hours of receiving the alert. The mental health provider will assess the participant for suicidal intent. In the rare event of an imminent risk, participants will be referred to the Centralized Emergency Psychiatry Service (CEPS) at Victoria Hospital.

### Intervention Administration

Participants randomized to the intervention arm will undergo a 12-week meditation program. The meditation intervention will be delivered virtually via Microsoft Teams version 25198.1109 (Microsoft Corporation, Redmond, WA, USA). Although participants will be given the option to remain de-identified during these meetings, they will be encouraged to turn on their camera and display a pseudonym if they are comfortable doing so. Participants will attend two virtual sessions (60 minutes each) where they will learn an evidence-based meditation-technique[48,49] taught by a trained and experienced instructor from Prasanna Wellness, a non-profit service organization. On day 1, participants will learn about meditation and undergo a guided meditation. On day 2, participants will undergo a guided meditation and participate in a discussion on what constitutes correct and incorrect meditation. More specifically, participants will learn how to respond to experiences that arise in meditation, discuss what enhances or detracts from effective meditation, and review methods for meditating at home. They will also be encouraged to practice at home on a regular basis for as much or as little time as they would like. Participants will complete 60-minute weekly follow-up sessions with an instructor which will consist of 33 minutes of guided meditation followed by a group-based discussion.

To ensure the intervention is delivered as outlined in the protocol, a research coordinator will be present at both initial and follow-up sessions. This coordinator will monitor the meditation sessions and administer feedback forms after each session. They will report any protocol deviations or concerning feedback to the PI. Furthermore, any indications of serious mental health concerns will be reported immediately to the PI for clinical assessment and management. Throughout the initial and follow-up sessions, Prasanna staff will consistently remind participants that breaks are available at their discretion.

### Comparator Administration

Participants randomized to the usual care arm will continue to receive their normal glaucoma treatment. Following the end of the 12-week study period, these participants will be offered the option to participate in the meditation program at no financial cost to them, however, no data will be collected.

## Statistical Analysis and Sample Size

### Data Storage

Data from REDCAP will be imported as a password-protected and encrypted spreadsheet onto a password-protected computer in the PI's office at St. Joseph's Hospital. In order to protect participant confidentiality, the data will be de-identified. The master list including identifying data will be stored in a password-protected and encrypted spreadsheet on a password-protected computer in the PI's office.

### Data Analysis

Feasibility outcome measures, such as recruitment rate and retention rates, will be analyzed. Adherence to protocol will be assessed to examine the degree to which participants followed the study protocol. Data completeness will be evaluated to report the proportion of complete data collected from participants. Participant feedback forms will be used to gather insights into participant experience. Resource utilization will be evaluated to determine the resources required to conduct the study, including time, personnel, and materials. Intervention fidelity will measure the extent to which the intervention was delivered as intended. Descriptive statistics will be gathered to analyze secondary outcomes such as health-related quality of life, depression, anxiety, and sleep quality. A repeated measures analysis of variance will be used to examine the differences in questionnaire scores both over time and between groups. Participants will not be excluded from the main analysis due to low adherence—however, secondary analyses will be conducted to factor in the proportion of

follow-up sessions attended and adherence to daily practice. STATA version 14.0 (StataCorp LP, College Station, TX, USA) will be used to conduct all statistical analyses.

Based on the pragmatics of recruitment and the necessity for examining feasibility, 50 participants per arm are typically enough for pilot studies.[50,51] In a study population of this size, the t-distribution approximates the normal distribution which enables meaningful interpretations of descriptive sample-based statistics such as means and standard deviations.[52] Considering this, 50 participants will be assigned to each arm.

# Potential Risks/Adverse Events

## Risks and Safety of Participants

Participants will maintain their standard medical care as prescribed by their physician. No additional medical treatments are incorporated into this study protocol. Rarely, participants with very difficult childhood experiences or with a history of psychosis (eg hearing voices, having severe fears) could experience difficult emotions with even brief meditation. Furthermore, other studies have found that the most common adverse events were anxiety, depression, cognitive anomalies, gastrointestinal problems, and suicidal behavior. However, it is important to recognize that none of these studies' populations included glaucoma patients and none of these studies considered guided meditation. To mitigate these potential side effects, Prasanna staff will instruct the participants to take a break from participating in the intervention if necessary. Participants will be encouraged to return to the intervention when they are comfortable doing so. If a participant would like to voice any concerns, they can do so via a de-identified feedback form that will be sent to participants at the end of every session. These feedback forms will be forwarded to the principal investigator. Furthermore, a research coordinator will be present in the Microsoft Teams meetings and report any noteworthy concerns to the principal investigator.

There are no additional risks caused by virtually learning meditation other than common side effects such as boredom. However, these side effects have mostly been observed among experience meditation practitioners. Furthermore, previous studies have safely administered meditation to older adults.[23,24] Therefore, we anticipate no significant risks with the intervention in the proposed sample population.

There are no direct risks associated with completing the questionnaires, however, there may be certain items that prompt participants to recollect potentially uncomfortable memories.

## Privacy, Confidentiality, and Data Protection

Data will be de-identified to protect participant confidentiality. The master list with identifying data will be stored in a password-protected and encrypted spreadsheet on a password-protected local computer in PI's office at St. Joseph's Hospital.

It is anticipated that the questionnaire data collection and analysis will be concluded within an 18-month period. Following study completion, the data will be retained for no longer than 15 years before being destroyed. A hospital destruction procedure will be followed. The local computer in PI's office will be wiped and formatted to ensure proper destruction. The files stored in the Microsoft OneDrive folder will be deleted and be permanently destroyed within 30 days as per Microsoft's Data Handling policy.

# Discussion and Conclusion

There is a substantial literature demonstrating a wide range of improvements of mindfulness practices on diverse groups of eye disease patients. In a systematic review and meta-analysis, relaxation techniques such as meditation, visual imagery, autogenic relaxation exercises, and ocular relaxation exercises were associated with improvements in quality of life among eye disease patients.[48,52] In addition, meditation was shown to enhance brain oxygenation among glaucoma patients.[53] Dada et al demonstrated beneficial effects of meditation on trabecular meshwork and intraocular pressure among glaucoma patients.[31] Furthermore, an improvement in optic disc perfusion due to mindfulness-based stress reduction was observed in eye disease patients.[32] In a randomized control trial, mindfulness-based stress reduction resulted in an improvement in best corrected visual acuity compared to control among patients with acute central serous chorioretinopathy.[54]

Given its promise as a treatment modality, meditation may be useful in mitigating the negative mental health consequences that are commonly observed among glaucoma patients. Since online meditation in particular is group-

based and scalable, it may be provided across large geographical regions. Lastly, if subsequent large-scale studies confirm the benefits of online meditation, it may be integrated into the standard of care for glaucoma patients.

## Abbreviations

QOL, quality of life; CES-D, Center for Epidemiologic Studies – Depression scale; HADS-A, Hospital Anxiety and Depression Scale – Anxiety subscale; PSQI, Pittsburgh Sleep Quality Index; SF-12, 12-Item Short Form Survey; PCS, physical component summary; MCS, mental component summary; REDCAP, Research Electronic Data Capture; SJHC, St. Joseph's Health Care London; RA, research assistant; PI, principal investigator; GCP, Good Clinical Practice; CEPS, Centralized Emergency Psychiatry Service; RCT, randomized controlled trial.

## Funding

Glaucoma Research Society of Canada (R-17-463).

## Disclosure

The author(s) report no conflicts of interest in this work.

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