## #205

**PART I:**

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| **Name of Schulich faculty member who will supervise the project** | Monali Malvankar |
| **Supervisor's Schulich, Western, Hospital or Lawson Email** | mmalvan@uwo.ca |
| **Schulich Department** | Ophthalmology |

**PART II - Project Description**

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| **Title of Project** | Impact of Breathing Followed by Meditation on Improving Quality of Life in Glaucoma Patients: An Electronic Feasibility Study |

**Background**

Glaucoma is a chronic disease that causes loss of vision and potentially blindness as a result of optic nerve damage, often due to increased intraocular pressure. Glaucoma is currently the leading cause of irreversible blindness worldwide. In 2020, 4.1 million and 3.6 million adults over the age of 50 suffered from mild to severe glaucoma-induced visual impairment and blindness, respectively. However, these figures are likely underestimated since glaucoma can remain asymptomatic until later stages in disease progression. The relaxation response evoked by mind-body interventions, such as breathing exercises and meditation, is known to reduce stress and improve quality of life (QOL). In a recent study, mindfulness-based meditation was found to reduce intraocular pressure and improve QOL in patients with glaucoma.

A feasibility study will be conducted using a mixed-method design to assess the feasibility of the online delivery of an intervention titled Breathing Exercises followed by Meditation for potentially enhancing the QOL and mental health of glaucoma patients. Upon recruitment, participants will undergo blocked randomization to either the intervention arm or the usual care arm. Participants in each arm will complete online questionnaires at baseline and weeks 1, 3, 6, and 12 to collect data on health-related quality of life (HRQOL), depression symptoms, anxiety, and sleep quality using REDCap, an electronic data capturing system provided by Lawson Health Research Institute (LHRI). Our study can help assess the feasibility of conducting a study on breathing exercises followed by meditation to assess its effects in a sample of patients with glaucoma.

**Hypothesis**

Primary objectives: To assess the feasibility of conducting an online study of the breathing exercise followed by meditation intervention in a sample of glaucoma patients.

Primary hypothesis: It will be feasible to assess the effects of breathing exercise followed by meditation in a sample of glaucoma patients.

Secondary objectives: To assess the benefits of breathing exercise followed by meditation in enhancing QOL, sleep quality, and reducing depression and anxiety when compared to controls.

Secondary hypothesis: Glaucoma patients will experience enhanced QOL, reduced depression and anxiety, and improved sleep quality by participating in the intervention.

**Proposed Methodology**

A masked, 12-week RCT will be conducted. Fifty patients with a diagnosis of mild glaucoma aged 40-65 will be eligible to participate. Participants will undergo block randomization (10 participants; five per arm) to either the intervention arm or the usual care arm on a rolling basis. For intervention arm participants, breathing exercise followed by meditation will be delivered virtually via the hospital-approved Microsoft Teams platform in addition to usual care. Through this platform, patients will be taught an evidence-based breathing exercise followed by a meditation technique. For usual care arm participants, usual care will be continued.

Data analysis

mixed model with the score as the dependent variable, and demographic variables as covariates. The univariate and bivariate analysis will be performed for each independent variable against the dependent variable to elicit the impact of each co-variate on the pattern of preference-based HRQoL, depression, anxiety, and sleep quality without adjusting for the effect of other variables. A repeated measures analysis of variance will be used to examine the differences in questionnaire scores both over time and between intervention groups. Participants will not be excluded from the main analysis due to low adherence—however, we do plan on conducting secondary analyses while factoring in the proportion of follow-up sessions attended and adherence to daily practice. Models will be deemed statistically significant if they are associated with a significant F value ($p < 0.01$) and if they explain over 15% variability of the dependent variable. Only those independent variables that are statistically significantly associated with the score ($p < 0.05$) will be used for model construction. STATA 17.0 will be used to run all statistical analyses.

**Expected Outcomes**

Primary Outcomes

Assess the feasibility of conducting an online feasibility study on Breathing Exercise Followed by Meditation in a sample of patients with glaucoma.

Secondary Outcomes

Health-Related Quality of Life
Improvement in Health-Related Quality of Life (HRQOL) score as measured by the 12-item Short Form questionnaire (SF-12).

Depression
Depressive symptoms as measured by in Center for Epidemiologic Studies – Depression (CES-D) scores (< 16).

Anxiety
Anxiety symptoms as measured by the Hospital Anxiety and Depression Scale – Anxiety subscale (HADS-A) scores

Sleep Quality
Sleep quality is measured by a reduction in Pittsburgh Sleep Quality Index (PSQI) scores (≤ 5).

**Research Environment – Description of the number of research personnel, primary location of research, size of lab, etc**

The Ivey Eye Institute at St. Joseph's Hospital (SJHC), London, ON has state-of-the-art research facilities that include office space (approximately 5 students office space, 2nd floor, B-zone, SJHC), lab space, and library collection including access to various databases, conference proceedings, and grey literature. Further, clinical research at the Ivey Eye Institute provides patients with access to cutting-edge clinical trials for a number of conditions.

**Names and titles of other individuals who will be involved with the research project?**

A research coordinator will be involved who will help coordinate the overall project. PI (Dr. Malvankar) will meet the team every week for an update and will also oversee the activities of the project.

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| **Can this project be done remotely?** | No |
| **Duration of Project** | Two Summers |

**Expected Objectives/Accomplishments for Student for Year 1?**

Student for year 1 will be expected to interview participants at baseline, interview participants over the phone for follow-up data, enter collected data in a secured Excel sheet, keep track of participants recruited and to be recruited, clean the excel data sheet, call participants to gather missing data if any.

**Expected Objectives/Accomplishments for Student for Year 2?**

Student for year 2 will be expected to clean data sheets, conduct statistical analysis, report writing, and manuscript submission.

**PART III - Certifications**

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| **If the project will require any certification approvals from one or more of the following offices, please check the appropriate box below.** | - Human Ethics |
| **Human Ethics: If you have the protocol information, please enter it below (or enter the status of the approval).** | Approved; REDA #: 12010 WREM #: 122096 LORA #: 7998<br>ClinicalTrials.gov identifier: NCT 05960513 |

**Note: certification approval should be obtained prior to the start of the summer. Projects without this approval will not be a priority for funding.**