#### Title:

Feasibility and Acceptability of Integrative Therapy for Managementof Symptomsin Persons With Pulmonary Hypertension

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#### **Session Title:**

Rising Stars of Research and Scholarship Invited Student Poster Session 1

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#### References

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#### **Abstract Summary:**

Participants will be able to identify process of determining feasibility and acceptability of an Urban Zen Integrative Therapy for symptom management. This proposal describes ways to maximize intervention fidelity and minimize common threats to internal validity of study design such as intervention dose delivery as well as participants' dose receipt.

Learning Activity:

Learning Objective #1 (Content #1)- The learner will be able to identify outcome measures indicative of feasibility and acceptability of a behavioral intervention to manage symptoms.	Content #1 - Feasibility Testing: To describe feasibility of a 6-week UZIT intervention in community-dwelling adults with PH. Feasibility will be determined by: 1) Recruitment rate (>40% recruited from those approached), 2) Enrollment rate (>2/month), 3) Home practice (>1 per week), 4) Retention rate (>70% of participants remaining at study completion).
Learning Objective # 1 (Content #2)	Content # 2 -Acceptability Testing: To describe acceptability testing of UZIT among community-dwelling adults with PH for symptom management. Acceptability will be determined by: 1) Participants' evaluation of the UZIT program, 2) Session completion rate (at least 5 of 6 sessions), 3) Participants' preference of the UZIT program components.
Learning Objective # 2 (Content #1) - The learner will be able to identify strategies in maximizing intervention fidelity of a behavioral intervention using the UZIT intervention as an exemplar.	Content #1 - Intervention delivery consistency: 1) Research intervention implementation protocol, 2) Interventionists' competency training check-list, 3) Quality audits of intervention delivery, and 4) Monitoring of consistent deliver.
Learning Objective #2 (Content #2)	Content # 2 - Intervention Dose Consistency: 1) Conduct quality audit of intervention delivery throughout the study by review of 50% video recording. This will begin by quality assurance review of the first 30 recordings, which is 25% of the total 120 video tapes. Additionally, we will conduct real-time observation of dose delivery during each session via field observation method. Additionally, we will establish plan for retraining of interventionists if/when intervention drift is observed.

# **Abstract Text:**

## Background:

Persons with the life-limiting cardiopulmonary disease face many symptom management challenges. Pulmonary Hypertension (PH) is one such progressive and debilitating chronic condition and serves as an excellent model for symptom management intervention development and testing. High mean pulmonary pressure characteristic of PH and the medications used to treat the disease lead to distressing symptoms such as chest pain, anxiety, nausea, insomnia, dyspnea, dizziness, and fatigue. Increased symptom burden can impair patients' ability to manage and adhere to medical treatments leading to reduced quality of life. Integrative approaches to symptom management are urgently needed. Many integrative health

approaches have shown benefit in symptom alleviation in chronic conditions such as cancer and heart disease and may have therapeutic benefits in severe cardiopulmonary conditions such as PH. A patient-centered, pragmatic integrative approach to symptom treatment can provide holistic management without added side effects. The **purpose** of this mixed-methods pilot study is to determine the feasibility, acceptability, and preliminary efficacy of a 6-week integrative therapy program, Urban Zen Integrative Therapy (UZIT) among community-dwelling adults with PH.

#### Methods:

The presentation will describe methods of determining the feasibility of a 6-week UZIT intervention in community-dwelling adults with PH. Feasibility will be determined by 1) Recruitment rate (>40% recruited from those approached), 2) Enrollment rate (>two /month), 3) Home practice (> 1/week), and 4) retention rate (>70% of participants remaining at study completion).

The presentation will describe methods of determining the acceptability of UZIT among community-dwelling adults with PH for symptom management. Acceptability will be determined by 1) Participants' evaluation of the UZIT program (composite mean System Usability Scale score > 5, scale 1-7), 2) Session completion rate (at least 5 of 6 sessions [83% attendance] by the participants retained at the study end), and 3) An exploratory sub-aim (Aim 2-A) is to determine what components of the UZIT program are preferred by adults with PH.

The presentation will describe strategies in maximizing intervention fidelity of a UZIT intervention that will include: consistency of intervention delivery and intervention dose. To strengthen the study design, we will address: 1) research intervention protocol, 2) interventionists' competency training, 3) quality audit, and 4) research process evaluation.

The study will enroll a single cohort of 20 patients with PH at The Ohio State University Wexner Medical Center PH outpatient clinics who are willing to participate in 6 weekly-60-minutes sessions of UZIT. The UZIT intervention will include four integrative modalities: essential oil, gentle body movement/restorative pose, body-awareness meditation, and Reiki. A trained UZIT therapist will provide treatments tailored to patients' symptoms and physical capability, within the bounds of the research protocol. Qualitative and quantitative data will be used to assess the feasibility and acceptability of the UZIT intervention. Field notes, semi-structured interviews, and daily symptom diaries will provide a qualitative description of symptoms and UZIT acceptability and constant comparison. Intervention sessions will be remotely video recorded and examined for fidelity.

### Discussion:

Implementation of behavioral intervention is challenged by many threats to study's internal validity. Furthermore, mind-body integrative therapy with multi-modal components (UZIT) adds complexity to the scientific testing standards. Measuring ways to assure that the intervention is feasible and acceptable to participants and that the intervention delivery dose is consistent will optimize scientific rigor. In preparation for future efficacy testing of this intervention, these basic requirements proposed in this preliminary testing detailing the design and implementation of UZIT research for symptom management in cardiopulmonary illness is necessary. If feasible and acceptable to cardiopulmonary patients, this intervention has the potential to mitigate the bothersome symptoms inherent in life-limiting, cardiopulmonary diseases and improve patients' quality of life. This presentation will use the exemplar of UZIT integrative therapy for symptom management in patients with pulmonary hypertension.