



## Intervention fidelity monitoring of Urban Zen Integrative Therapy (UZIT) for persons with pulmonary hypertension

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### ABSTRACT

**Background:** Systematic and consistent dose delivery is critical in intervention research. Few studies testing complementary health approach (CHA) interventions describe intervention fidelity monitoring (IFM) and measurement.

**Objective:** To describe methodological processes in establishing and measuring consistent dose, delivery, and duration of a multi-component CHA intervention.

**Methods:** Adults with pulmonary hypertension received six weekly, 1-hour Urban Zen Integrative Therapy (UZIT) sessions. A total of 78 sessions were delivered and 33% of these sessions were audited. Intervention dose (time allocated to each component), intervention consistency (protocol adherence audits), and intervention delivery (performance and sequence of components) were captured using remote video observation and review of the recorded video. IFM audits were performed at the beginning ( $n = 16$ ), middle ( $n = 5$ ), and end ( $n = 5$ ) of the study.

**Results:** UZIT interventionists adhered to the intervention protocol (99.3%) throughout the study period. Interventionists delivered UZIT components within the prescribed timeframe: 1) *Beginning*: gentle body movement ( $18.9 \pm 5.8$  min.), restorative pose with guided body awareness meditation ( $21.3 \pm 2.7$  min.), and Reiki ( $22.8 \pm 3.1$  min.); 2) *Middle*: gentle body movement ( $15.9 \pm 1.5$  min.), pose/body awareness meditation ( $30.1 \pm 6.5$  min.), and Reiki ( $30.1 \pm 7.0$  min.); 3) *End*: gentle body movement ( $18.1 \pm 3.6$  min.), pose/body awareness meditation ( $35.3 \pm 6.4$  min.), and Reiki ( $34.5 \pm 7.0$  min.). Essential oil inhalation was delivered during UZIT sessions 100% of the time. Interventionists adhered to treatment delivery behaviors throughout the study period: beginning (98.86%), middle (100%), and end (100%).

**Discussion:** In this pilot study, we demonstrated that the dose, consistency, and delivery of multi-component CHA therapy can be standardized and monitored to ensure intervention fidelity.

### 1. Introduction

Optimizing the scientific rigor of research can be viewed broadly as ensuring fidelity to all standard operating procedures throughout the conduct of the study,<sup>1</sup> as well as guaranteeing the intervention fidelity. Intervention fidelity is defined as the degree to which the intervention implementation process is an effective realization of the intervention as planned.<sup>2,3</sup> Intervention fidelity monitoring (IFM) is a methodological process of measuring and documenting that the intervention implementation is carried out consistently across interventionists as well as throughout the study period. Although critically important, little evidence is available to guide researchers on how best to monitor and accomplish intervention fidelity for complementary health approach

(CHA) interventions with multiple components. Measuring and documenting intervention fidelity is extremely important in determining the internal and external validity of CHA research.<sup>1,4</sup>

CHA refers to practices and products of non-mainstream origin, whereas integrative health refers to incorporating complementary approaches into conventional health care.<sup>5</sup> While complementary and integrative are similar and often used interchangeably, a clear distinction must be made between complementary/integrative and alternative. Complementary and integrative both mean that treatments are used along with conventional medicine. Alternative means that treatments are used *instead of* conventional medicine.<sup>6</sup> Older publications on this topic often used complementary and alternative medicine (CAM). However, the terminology accepted by the National Center of

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Complementary and Integrative Health (NCCIH) is CHA, which is synonymous with integrative therapy.

Consistent delivery of CHAs is particularly important in clinical trials involving multiple sites and/or interventions where people (interventionists) and process (standard operating procedure) may differ or drift.<sup>7</sup> Clinical trials employing behavioral interventions delivered by a trained interventionist must adhere to the consistent application of the critical ingredients of the intervention. Behavioral intervention research, therefore, is vulnerable to threats to the internal validity of the study such as inconsistent delivery of the intervention by an interventionist over the course of a study and inconsistent delivery between multiple interventionists.

Systematic evaluation of intervention fidelity is often difficult, particularly for complex interventions.<sup>2,8,9</sup> Song et al. acknowledged that evaluating the intervention fidelity of complex interventions is challenging due to their dynamic and highly individualized nature. Intervention research using CHAs raises additional, unique challenges of ensuring that the intervention is applied in the same dose with the same delivery method. While we can measure most CHA interventions, the key ingredient of some CHA interventions (such as Reiki) is more difficult to identify, define and objectively measure. Additionally, some CHA interventions (such as reflexology) require an elaborate confirmation method of treatment delivery that necessitates expert validation. Little evidence exists regarding the best practice for implementing, monitoring, and documenting intervention fidelity of multi-component CHA.

This manuscript describes the IFM protocol and results from a study using a multi-component complementary therapy: Urban Zen Integrative Therapy (UZIT). We will describe: 1) the state of the science of intervention fidelity for CHAs in general and combination therapies in particular, 2) an overview of the study: *Feasibility and Acceptability of an Integrative Therapy (UZIT) for Symptom Management in Persons with Pulmonary Hypertension*, 3) the IFM protocol from this study, and 4) the IFM audit results.

### 1.1. State of the science of intervention fidelity for CHAs

The National Institutes of Health Behavior Change Consortium (BCC) recommended guidelines for enhancing treatment fidelity for behavioral health research that include: study design, provider training, treatment delivery, treatment receipt, and treatment enactment.<sup>1</sup> Other models of intervention fidelity target treatment dosing, interventionists' consistency, in addition to intervention delivery, receipt, and enactment.<sup>10</sup> A systematic review evaluating the use of BCC fidelity strategies in behavioral health research conducted within a ten-year period (1990–2000) revealed that 54% of published studies did not report using any of the BCC recommendations and only 15.5% of the studies adhered to the BCC treatment fidelity strategies.<sup>11,12</sup>

To address the difficulty of interpreting results of studies on the impact of yoga, researchers proposed standardized delivery of yoga therapy according to the frequency and duration of delivery as well as the content of yoga class.<sup>13</sup> In mindfulness-based-stress-reduction (MBSR) clinical trials, there is a published standardized protocol for intervention dosing and delivery.<sup>14</sup> However, researchers often made modifications pertinent to their populations of interest with respect to the content, the duration of MBSR delivery, or both.<sup>15–19</sup> While these studies addressed treatment dose (e.g. duration and frequency of MBSR, home practice time, class attendance) and treatment delivery (e.g. training level of MBSR therapist) were reported, treatment consistency (such as specific behavioral checks confirming that all components of treatment dose were the same) was not provided. While single-component CHA research testing efficacy of integrative therapy utilized at least one aspect of intervention fidelity as recommended, no study adhered to all five components of intervention fidelity monitoring.<sup>10</sup>

We completed a search of the literature using the search string (“intervention fidelity” OR “fidelity monitoring”) AND (complementary

OR integrative OR non-pharmacologic) across three electronic databases; Scopus, Embase, and PubMed. Several studies involving single component CHAs mentioned intervention fidelity. Three studies involved multi-component interventions and assessed intervention fidelity, however, these were all training interventions that involved teaching and/or checklists but did not involve CHAs.<sup>20–22</sup> Several articles detailed why intervention fidelity matters in CHA research. These articles pointed out that intervention fidelity matters but either that there is no comprehensive guide<sup>23</sup> or proposed conceptual frameworks for IFM.<sup>10,24</sup>

### 1.2. Description of the Urban Zen Integrative Therapy (UZIT) Intervention

UZIT was created by combining several integrative approaches: 1) essential oils, 2) gentle body movements, 3) restorative yoga pose, 4) body-awareness meditation, and 5) Reiki therapy.<sup>25</sup> UZIT is currently being used as an accepted part of care for hospitalized patients in parts of the US where UZIT training takes place, and is complementary to self-care practices among healthcare professionals and participants living in these communities. The UZIT clinical protocol is designed to address the classic symptoms associated with chronic illness: pain, anxiety, nausea, insomnia, constipation, and exhaustion. Some components of UZIT may be delivered simultaneously within a session customized to the patient's primary symptom complaint and clinical illness. For example, while the patient inhales the scent of essential oil drops from a cotton pad, they practice awareness in recognizing body sensations through relaxation and calmness. Gentle body movement is often practiced in coordination with mindful breathing techniques, which facilitates awareness of body sensation during gentle stretching exercises. Restorative yoga poses (such as side-lying child's pose and supported relaxation pose) are used to enhance relaxation and release tension. Simultaneous application of Reiki and body-awareness meditation by the UZIT therapist allows for a more in-depth relaxation. A certified UZIT therapist provides each session in a synergistic, collaborative, and personalized manner tailoring to the participant's primary symptom recognition and physical condition.

UZIT was designed by a caregiver as an efficient, and practical self-care practice for nurses and other healthcare providers.<sup>26</sup> UZIT clinical sessions have been expanded to include patients in hospitals and clinics on an as-needed basis.<sup>25</sup> While anecdotal observation indicates symptom intensity change from before to after a UZIT session, the absence of rigorous studies and intervention fidelity measurement raises questions about how exactly the intervention is measured. Clinical studies documenting the effectiveness of UZIT are confined to quasi-experimental designs with no documentation of intervention fidelity.<sup>25,27</sup> There has been very little research on UZIT, so intervention fidelity is vital to both fully describing the intervention and to assuring consistency in treatment across studies.

### 1.3. Feasibility and acceptability of UZIT for symptom management in persons with pulmonary hypertension

The fidelity monitoring procedure described in this paper was carried out in our clinical study testing the feasibility and acceptability of UZIT for symptom management in persons with pulmonary hypertension. The intervention consists of six 60-minute UZIT sessions applied weekly within a six- to eight-week time frame. Our UZIT research protocol is prescriptive and detailed with an emphasis on the five-point plan proposed by The Treatment Fidelity Workgroup on the UZIT components of dose, consistency, delivery, receipt, and enactment.<sup>10</sup>

### 1.4. Intervention fidelity protocol

#### 1.4.1. UZIT dose

UZIT intervention timing, duration, and the interval between sessions should be based on pilot work, existing literature, and expert

recommendation.<sup>10,28</sup> Intervention timing refers to the number of sessions within the program. Intervention duration is the amount of time within a session, and time between sessions refers to the number of days between each session. A literature review of behavioral intervention research using mind-body interventions such as yoga therapy and/or MBSR revealed that 6–12 weekly sessions with each session being 30–90 minutes in length are common.<sup>29,30</sup> A typical UZIT program delivered to healthcare professionals, such as one provided at a large urban hospital,<sup>31</sup> is comprised of six weekly sessions where participants have the opportunity to practice new and learned techniques and ask questions related to home practice. Due to the absence of published report specific to the recommended UZIT dose testing for symptom management in pH patient population, we established our intervention dose based on published mind-body interventions and UZIT expert recommendation.

#### 1.4.2. UZIT delivery

To ensure the precise delivery of the UZIT intervention, we developed a standardized UZIT protocol, training, and quality process audit to ensure adherence to the research protocol for intervention consistency. We recruited UZIT therapists with extensive clinical experience. All certified UZIT therapists complete a 12-month training program consisting of 12 full day trainings over three weekends throughout the year, personal practice of a minimum of 20 sessions using UZIT techniques with friends and family, a minimum of 50 supervised clinical hours in a hospital or other clinical setting and a final clinical evaluation session with UZIT instructors.

#### 1.4.3. Interventionist study training

We recruited certified UZIT therapists who were also registered nurses (RNs) to be our interventionists. Due to the level of acuity of our research participants (e.g., adults with confirmed pulmonary hypertension), we required that UZIT therapists have recent experience working with patients either in a hospital or clinic setting. Because of the limited physical capability of our study participants (New York Heart Association Functional Classification II and III), monitoring of participants during the intervention was necessary for patient safety.

Once study interventionists were recruited to deliver the intervention, they received training using structured content on the research process, the UZIT intervention study protocol, and the potential adverse events to monitor specific to pulmonary hypertension. Interventionists received didactic and simulated practical training, including return demonstration of techniques, before they were approved to deliver the UZIT intervention. The training followed a written UZIT research protocol that describes specific behaviors to demonstrate and the minimum amount of time required for each UZIT component delivery. Interventionists had sufficient opportunity to ask clarifying questions about the written protocol. Each interventionist performed a session on a volunteer patient while the Principal Investigator (PI) evaluated behaviors and gave feedback according to the competency checklist (Table 1). Interventionists who had not delivered the intervention for more than one month were required to review the protocol with the study PI and to be reevaluated in the protocol so that there were no lapses in the delivery of study intervention.

## 2. Methods

Each UZIT session was video-recorded and the live video feed was monitored by the study PI from a separate room via a remote connection. Through the real-time observation of interventionists' behavior via the remote view video recording/monitoring system, we minimized the Hawthorne effect, which could potentially alter behaviors. Importantly, we recorded 100% of UZIT sessions, so an observation effect would be consistent throughout the study. To evaluate whether the interventionists adhered to the research protocol, we conducted quality audits of 33% (1/3) of all video-recorded participant sessions using an

investigator-developed tool, the Intervention Fidelity Monitoring Audit (Table 1), to assess interventionist behavior compliance. To capture UZIT components accurately and efficiently (while some components may be applied simultaneously), we recorded the exact start and end time of each component.

One-on-one summary of individual performance was verbally communicated to each interventionist. For example, at the end of one session, the study PI provided direct feedback to an interventionist who did not deliver Reiki from head to toe as observed and captured in the video recording. This failure to follow the research protocol was immediately remedied, leading our overall rate of adherence to be above 85% during the beginning phase of the study, and we were able to obtain 100% adherence for the remainder of the study. Another situation was promptly identified when the interventionist did not provide body awareness meditation and Reiki for at least 20 min. Based on the IFM, the study PI was able to have a meaningful discussion with the interventionist which led to the constructive behavior change. Subsequently, the interventionist suggested a strategy for self-improvement by making a mental note of body awareness meditation and Reiki start and stop time on her wristwatch rather relying on the wall clock (which was difficult to see depending on her positioning during the treatment).

## 3. Results

A total of 26 session audits from two interventionists were completed: 16 during the initiation of study, five during the middle of the study, and five during the end of the study. The audits for the middle and the end cohorts were randomly selected from stratified samples of all recorded session according to time period of UZIT intervention delivery (completed from June 2017 to May 2018). Since interventionists did not provide an equal number of UZIT sessions, we conducted intervention fidelity audits in the same proportion as their actual delivery. Recorded sessions were randomly selected from the video recordings of both interventionists. With the additional ten stratified randomly selected video recordings, the total number of sessions evaluated for consistency comprised of the total 26 out of 78 sessions (33.3%).

Our intervention fidelity auditing process adequately addressed the uneven numbers of UZIT sessions provided by both therapists. The ratios of sessions audited to sessions delivered were similar for both interventionist #1 and interventionist #2. Interventionist #1 provided the majority of UZIT sessions (59 of the total 78 sessions; 75.6%) compared to interventionist #2 (19 of the total 78 sessions; 24.4%). Out of 26 UZIT sessions audited, 19 (73.1%) for interventionist #1, and 7 (26.9%) for interventionist #2.

Interventionists adhered to the delivery of each component of UZIT with 99.3% compliance overall. Essential oil selection and application were completed at the beginning of all sessions audited and proper procedural steps of selecting and administering appropriate essential oil specific to symptom complaint was audited as part of IFM (Table 1). Table 2 lists the range, minimum, maximum, mean and standard deviation for each UZIT component within each cohort. Two areas that did not meet our protocol early in the study included body awareness meditation (93.8% compliance) and Reiki application in a head to toe fashion (87.5% compliance) (Table 1). Both areas were discussed and corrected with the therapist immediately after the session.

We conducted five additional audits during the middle and five at end of the study (Table 1). Appropriate essential oil selection and application were performed at the beginning of all sessions as described previously. Interventionists delivered UZIT components within the prescribed sequence and time frame. Interventionists demonstrated a high level of treatment fidelity throughout the study periods: beginning, middle, and end (98.86%, 100%, and 100%, respectively). Table 2 shows the duration of each UZIT component treatment according to the three study phases. UZIT intervention time across sessions show an

**Table 1**  
UZIT Intervention Fidelity Monitoring (IFM) Audit.

Component	Beginning Cohort (n = 16)	Middle Cohort (n = 5)	End Cohort (n = 5)
1. Introduced self to begin therapeutic relationship	16	5	5
2. Explained the overall plan of the UZIT session	16	5	5
3. Explained rationales for each essential oil use	16	5	5
4. Suggested appropriate essential oil based on symptom	16	5	5
5. Administered one to three drops of essential oil in a cotton pad and placed one inch from the nose	16	5	5
6. Explained and demonstrated each mindful movement	16	5	5
7. Guided in the performance of at least six gentle movements	16	5	5
8. Guided six gentle movements <u>for at least 10 minutes</u>	16	5	5
9. Instructed participant mindful breathing technique	16	5	5
10. Provide positive encouragement and constructive feedback to participant	16	5	5
11. Explained and demonstrated restorative position	16	5	5
12. Guided in the performance of at least one restorative pose	16	5	5
13. Guided one restorative pose for at <u>least 20 minutes</u> (included five minutes time for positioning)	16	5	5
14. Explained the process of body-awareness meditation	16	5	5
15. Performed body-awareness meditation <u>for at least 20 minutes</u> (including five minutes time for positioning)	15 (93.8%) <sup>a</sup>	5	5
16. Assisted and adjusted participant's pose to comfortable position	16	5	5
17. Evaluated participant's comfort level by asking	16	5	5
18. Administered Reiki in a systematic manner (head to toe)	14 (87.5%) <sup>b,c</sup>	5	5
19. Administered Reiki <u>for at least 20 minutes</u> (including five minutes time for positioning)	15 (93.8%) <sup>a</sup>	5	5
20. Guided participant to change position slowly	16	5	5
21. Gave participant specific instruction for home practice	16	5	5
22. Reminded patient to document in home diary	16	5	5
<b>Intervention procedure adherence (correct behavior/opportunities)</b>	<b>348/352 = 98.86%</b>	<b>100%</b>	<b>100%</b>
<b>Total number of opportunities</b>	<b>16 × 22 = 352</b>	<b>5 × 22 = 110</b>	<b>5 × 22 = 110</b>
<b>Overall Intervention procedure adherence</b>	<b>568/572 = 99.3%</b>		

<sup>a</sup> protocol deviation of UZIT session #1.

<sup>b</sup> protocol deviation of UZIT session #2.

<sup>c</sup> protocol deviation of UZIT session #3.

increased duration toward the end of the study, particularly, in body awareness and Reiki applications. Further analysis also indicates that there is variability between interventionists. Interventionist #1 was more consistent with her delivery time than interventionist #2 in that her intervention time variability across sessions was generally within 20%. Interventionist #2, however, varied her delivery time in the middle and at the end phases. These audit results indicated that our interventionists delivered UZIT intervention with good fidelity to the research protocol. Our IFM goal was achieved in the sense that we completed the UZIT IFM audits for intervention dose, consistency, and delivery in at least 25% of all UZIT sessions (78 total sessions) spanning the study period of 10 months as recommended.<sup>9</sup>

#### 4. Discussion

To our knowledge, we are the first to report and evaluate the use of an intervention fidelity tool designed to monitor the fidelity of multi-

component CHA interventions. Our approach was successful for monitoring the consistency of delivery within and across interventionists as well as the frequency and duration at which each component of the CHA was delivered. While we carefully stayed within the lower bound of UZIT component delivery, we did not establish upper bound of dose delivery in our protocol which led to the trend in longer duration, particularly when our participants had higher illness severity. This systematic approach to monitoring intervention fidelity provided a mechanism to review performance and provide feedback to the interventionist with the goal of optimizing delivery and impact of the intervention.

Due to the multi-component nature of the intervention and the fact the some of the UZIT components were applied simultaneously, we recommend the use of an intervention protocol, checklist, and a remote data-capturing system to enhance data collection accuracy, timeliness, and efficiency. Audit data obtained from both sources increased data accuracy and decreased human burden. More importantly,

**Table 2**  
Intervention Fidelity Monitoring (IFM) through the study period.

IFM Cohort (n = 26)	UZIT Component	Range	Min.	Max.	Mean (minutes)	Standard Deviation
Beginning Cohort (n = 16)	Gentle body movement	20	10	30	18.9	5.8
	Positioning <sup>#</sup>	11	4	15	7.5	3.1
	Body Awareness <sup>*</sup>	11	14	25	21.3	2.7
	Reiki <sup>**</sup>	13	19	32	22.8	3.1
Middle Cohort (n = 5)	Gentle body movement	3.7	13.7	17.4	15.9	1.5
	Positioning <sup>#</sup>	3.8	5.1	8.9	6.8	1.5
	Body Awareness <sup>*</sup>	15.5	21.9	37.4	30.1	6.5
	Reiki <sup>**</sup>	17.0	21.5	38.4	30.1	7.0
End Cohort (n = 5)	Gentle body movement	8.0	14.9	23.0	18.1	3.6
	Positioning <sup>#</sup>	4.8	6.4	11.2	9.0	1.9
	Body Awareness <sup>*</sup>	16.0	36.7	42.7	35.3	6.4
	Reiki <sup>**</sup>	16.0	26.7	42.7	34.5	7.0

<sup>#</sup> Amount of time to comfortable place patient in a restorative pose.

<sup>\*</sup> Duration of time for body awareness meditation while in pose.

<sup>\*\*</sup> Duration of time for Reiki while in pose.

documenting UZIT interventionists' performance in this manner provided objective data that facilitated constructive verbal feedback. Close monitoring, protocol adherence assurance, and continuous training were critical elements required in enhancing the internal validity of research study using multi-component CHA.

There were several lessons learned from this intervention fidelity monitoring process of a multi-component CHA. Conducting the IFM of multi-component integrative therapy such as UZIT was time-consuming and resource-intensive. In addition to the technological requirements, personnel who were trained in UZIT delivery in clinical practice as well as in the research protocol were also required. Our additional criteria for study interventionists to have a current registered nurse license with proficient nursing assessment skill provided us with only two qualified interventionists. The small number of interventionist is also another limitation in our study. Given the two major barriers stated above, conducting IFM at this intensive scale may be financially prohibitive in future research study designs. From this cost-benefit perspective, one question remains: What is the minimum IFM standard for multi-component CHAs such as UZIT? IFM guidelines for single integrative therapies (e.g. mind-body interventions, energy healing) can perhaps be better delineated in dose, delivery and consistency of the intervention. This study provides a framework for the process of IFM of a multi-component intervention, which may continue to evolve over time.

## 5. Conclusion

IFM of CHA research is essential, and critical when a multi-component CHA such as UZIT is investigated. More importantly, IFM should be established in an early phase pilot study to comprehensively address the preliminary value (efficacy) of a new intervention. We recommend that the processes for real-time monitoring and ongoing quality auditing be employed. By using this process of methodological rigor, systematic testing of CHA interventions will more likely yield meaningful outcomes.

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