TITLE: Testing an Arts-based Program to Reduce Nurse Stigma Towards Perinatal Substance Use

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BACKGROUND AND AIMS

Between 2010 and 2017, perinatal opioid use (POU) at time of delivery significantly increased from 3.5 to 8.2 per 1000 hospital deliveries.[17] POU results in numerous negative outcomes for infants, including neonatal opioid withdrawal syndrome (NOWS), which is a drug withdrawal syndrome following birth associated with symptoms such as low birthweight, respiratory distress, feeding difficulties, poor weight gain, inconsolability, seizures, prolonged hospital stays, and separation of infant from their mother.[20-27,41-42] Recent studies support prioritization of maternally-provided care (e.g., breastfeeding, skin-to-skin), demonstrating increased maternal presence at infant bedsides (rooming-in) and involvement in infant care improves infant outcomes, including decreased symptom severity and reduction in pharmacologic treatment (83.3% to 14.3%), length of pharmacologic treatment and hospital stay (25 to 8 days), and costs.[43-51] However, these care approaches are not well implemented and vary widely,[43-44] partially due to stigmatizing attitudes of nurses who regularly care for and interact with these mothers and infants.

In a multisite study, over half of registered nurses (RNs) had heightened stigmatizing attitudes toward POU and NOWS with little variation across hospitals (48.8-58%).[1]Most RNs believed these mothers are manipulative and unreliable (81%) and responsible for the damage done to their infants (69%). The majority felt mothers were guilty of child abuse (64%) and should go to jail (61%). These negative attitudes can impede engagement of mothers as primary caregivers to the infants,[4] leading to decreased breastfeeding rates, heightened severity of infant withdrawal, prolonged hospital stays, and increased likelihood of maternal-infant separation (e.g., decreased maternal visits to hospitalized infant; loss of custody).[43-51,61] Addressing RN attitudes toward POU and NOWS can improve maternal engagement and infant health outcomes.

The relationships among art and health behaviors and outcomes are well established.[38-39] For example, art therapy has demonstrated effectiveness in improving attention, pleasure, social behavior, self-esteem, and neuropsychiatric symptoms in patients with Alzheimer's disease and/or other dementias.[37] For patients with mental illness and substance use disorders, art therapy improves self-confidence, sociability, and well-being.[40] Narrative and creative writing and storytelling improves pain, fatigue, immune system function, interpersonal relationships, attitudes/feelings, and perspective taking while additionally reducing health services utilization and stigmatizing and judgmental attitudes and actions.[31,38] Art interventions are novel and highly effective in changing human psychology and behaviors but are overtly underutilized in clinical education.[31,38] George et al. used creative storytelling to effectively improve clinician attitudes toward a stigmatized patient population: persons with dementia.[36] Thus, there is precedent for using art pedagogy to improve clinician attitudes toward stigmatized populations.

ArtSpective targets and improves RN attitudes toward POU and NOWS as an arts-based intervention delivered asynchronously. It has been adapted from and is informed by preliminary work of the research team.[1,4,53,60] ArtSpective facilitates perspective taking exercises using curated paintings and photographs and narrative storytelling. Perspective taking is described as taking the point of view of another person within the other's context.[62] For example, a nurse is engaging in perspective taking when he/she understands a mother's experience and perspective of POU and NOWS. It is not applying one own's point of view to the context of another's experience (eg, nurse applies own perspective to the mother's experience). Taking the viewpoint of someone in distress (eg, mother affected by POU) is considered necessary for taking actions and exerting behaviors to alleviate that distress and improve outcomes (eg, breastfeeding; skin-to-skin care; understanding how social determinants of health lead to maternal absence at infant bedsides).[62] ArtSpective facilitates perspective taking to improve RN stigmatizing attitudes toward POU and NOWS, leading to improved engagement of mothers in providing recommended NOWS care and ultimately aims at improving maternal and infant health outcomes.

In 2020, ArtSpective was pilot tested using a pre-post design and sample of senior undergraduate and graduate nursing students (N=11) interested in maternal-infant health.[30] A significant improvement in self-reported attitudes toward POU and NOWS (t= 4.11, p=.002; Cohen's d= .633) was observed. Despite these early signals of efficacy and feasibility, ArtSpective's previous delivery format (synchronous group intervention facilitated live through video conference) was neither scalable nor sustainable. Since, ArtSpective has been adapted to a fully asynchronous and digital product that improve scalability and sustainability. Feasibility of this adapted version needs to be rigorously evaluated as well as the direction, magnitude, and sustainability of its effect on RN attitudes toward POU and NOWS.
The ArtSpective digital platform consists of a 30-minute web-based session that RNs can complete asynchronously. The program is self-paced and synchronous. Modules (see table below) are based on five learning objectives and core competencies developed

by PI Shuman and Co-Is Rubyan and Boyd, with input from the U-M Museum of Art.[30] Once RNs have completed pre-course tasks, modules will open sequentially. Each module will consist of interactive elements (eg, videos, text-entry, animated graphics, select from a list) and will remain locked until the previous module is completed to ensure a high-fidelity user experience. At the conclusion of the intervention, RNs will receive a downloadable certificate of completion with facts about POU and NOWS, and the strategies (actions) they can take to improve engagement of mothers in care of infants with NOWS.

ArtSpective Components (Adapted version)		
Component	**Objective**	**Summary of Content**
Pre-course Tasks	Create username and password; complete pre-intervention questionnaire	Create login credentials; complete demographics; complete Modified Attitudes About Pregnancy Scale
Module 1	Understand one's own perspective of POU and NOWS	Select art; read directions; write a creative narrative from their own perspective.
Module 2	Understand POU and NOWS from the mother's perspective	Select new art; read directions; write a creative narrative from the mother's perspective.
Module 3	Compare perspectives	Watch 1 short, animated video discussing the importance of perspective taking in everyday life
Module 4	Describe experiences and trajectories of mothers and infants affected by POU	Navigate through a series of short clinical vignettes presenting hypothetical stories about POU and NOWS. Watch a short, animated video about strategies to decrease stigma towards POU and NOWS
Post-course Tasks	Complete post survey; Obtain certificate of completion	Post survey includes Modified Attitudes About Drug Use in Pregnancy, Abbreviated Acceptability Rating Profile; and Satisfaction questions; Downloadable certificate and personalized report

Accordingly, specific aim is to: Test the feasibility of the adapted ArtSpective intervention, including acceptability, adaptation, study logistics, and practicality.

THEORETICAL MODEL & ADAPTATION FRAMEWORK

Our study and the ArtSpective intervention are informed by Corrigan's model of stigma[63] and the Emancipatory Theory of Compassion.[64] Substance use disorder is among the most highly stigmatizing conditions and leads to discriminatory actions against vulnerable individuals.[65] In healthcare, stigma and discriminatory actions are considerable barriers to health-seeking behaviors and engagement in healthcare.[65-66] For NOWS treatment, maternal engagement in infant care is recommended because it improves infant outcomes. However, stigmatizing attitudes of RNs can result in discriminatory actions against mothers (eg, failure of RNs to engage mothers or provide opportunities for mothers to provide in infant care) and maternal absence at infant bedsides in an effort to avoid suffering from stigmatizing attitudes and discriminatory actions.[65-66] In the nursing discipline, compassion (wanting others to be free of suffering) is a necessary component of emancipatory practice which recognizes the effect of power relations on suffering.[67] The Emancipatory Theory of Compassion emphasizes relationships among nurses and patients within the broader context of health care delivery, health policy, and social justice issues including biases and judgments toward POU.[64] Its main assertion is that RNs must decrease patient, community, and population suffering through sharing power, increasing compassion, and enhancing the voice and agency of others. ArtSpective improves RN attitudes toward POU and NOWS and encourages maternal agency in providing care to infants.[30] By addressing stigmatizing attitudes which disrupt compassionate practice and praxis, RNs will be better prepared to engage mothers in infant care, empower mothers to participate as members of the care team, and improve implementation of evidence-based maternal-infant dyadic NOWS care and related outcomes (eg, length of stay; bonding; withdrawal severity; treatment adherence, relapse prevention).[65,66,30]

Adaptation Framework

We will apply the ADAPT-ITT model, originally used for adapting HIV interventions, but has demonstrated utility for other health interventions.[97] The model and will guide testing of an asynchronous web-based version of ArtSpective that is intended to be both scalable and sustainable. The research team has developed ArtSpective as an asynchronous, interactive, web-based tool. ArtSpective is now ready to be tested using a pilot cluster randomized trial among perinatal nurses. The ADAPT-ITT model consists of eight phases: 1) Assessment, 2) Decision, 3) Adaptation, 4) Production, 5) Topical expert review, 6) Integration, 7) Training, and 8) Testing.[97] Our team has already completed Phases 1-7. For this study, we will utilize phase 8 as a guide.

METHODS

STUDY DESIGN

We are conducting a pilot experimental study using two matched hospitals to examine feasibility. We will recruit 150 participants, 75 participants from each hospital, which is a sample size powered for a pilot experimental trial examining feasibility.[102-103] One recruitment site will be randomly selected to receive the educational intervention first (Site A), while the other site will serve as a control site (Site B) during phase 1 (month 1). In phase 2 (month 2), participants from Site A will be invited to complete a follow up survey while participants from Site B will be invited to complete the educational intervention. In phase 3, 10 participants from Site A will be randomly selected to complete interviews while the others complete follow up surveys. Participants from Site B will also complete follow up surveys in phase 3 (month 3).

We are following Bowen et al.'s suggestions for conducting feasibility studies and assess feasibility on the following dimensions: acceptability, demand, adaptation, and practicality.[104] Each of these will be examined by nursing unit, years of perinatal nursing experience, race/ethnicity, and age.

VARIABLES AND INSTRUMENTS

Acceptability: Acceptability is defined as participants' perceptions of ArtSpective's appropriateness and satisfaction with it.[104] We will evaluate acceptability using a modified version of the 8-item Abbreviated Acceptability Rating Profile.[105] Participants rate the extent to which they agree with each item on a 5-point Likert scale (e.g., "This program is a good way to develop compassion for women and infants affected by substance use" and "I would recommend this program to others"). We will also include items used in our preliminary work including perspectives on logistics (eg, length of the program), delivery format (eg, web-based), perceived effectiveness (eg, "Because of this program, I have more compassion toward mothers and infants affected by perinatal substance use") and free-text items (eg, "What was the most beneficial part?").[30] These items will be included on the experimental arm's baseline (post-intervention) and 1-2 month following surveys and asked *after* completing the M-AADUP scale.[52-53] Using a semi-structured interview guide, we will conduct 10 in-depth interviews (30 minutes) with participants randomly selected from the experimental arm instead of completing 2-month follow-up surveys. Participants will be asked about their attitudes about various components of the intervention: look (graphics, colors, artwork), intervention flow, appropriateness of content, ease of use, time to complete, and the completion certificate and personalized report card.

Adaptation: Adaptation is defined as the extent to which ArtSpective performs when adapted to a new platform and audience. Using a checklist to assess our ability to perform on the key core-components[106] of the original intervention using the online platform. The key components necessary to successfully adapt the intervention are to provide participants opportunity for 1) choosing artwork to engage with, 2) performing narrative writing, and 3) identifying key lessons learned. *Practicality:* Practicality is defined as the extent to which ArtSpective is carried out using existing means and resources and without requiring outside intervention.[104] We will monitor fidelity (completing ArtSpective as intended) and length (time to complete ArtSpective). We will collect data including the number of log-ons, pages visited, and time spent on each page. *Study Logistics:* We will monitor the rate of uptake, time to recruit 75 participants in each arm, and retention rate (from completion to 1 and 2 months later) to inform the development of a future efficacy trial. *Cost*: Although we are not conducting a formal cost analysis, to explore practicality, we will monitor costs of intervention development, implementation, and sustainability of the intervention on a web-based platform (eg, hosting, maintenance).

Stigmatizing attitudes of RNs toward POU and NOWS. Although not powered to detect change, we will also measure stigmatizing attitudes among RNs: this information, which will show the prevalence and potential direction of effect, is needed to inform the power of a future efficacy trial. We will collect data on RN stigma toward POU and NOWS using the modified Attitudes About Drug Use in Pregnancy (M-AADUP) scale.[52-53] The original scale has demonstrated validity and reliability and has been updated and revised (with permission) by PI Shuman and Co-I Boyd.[53] The modified scale has demonstrated internal consistency reliability in our previous studies (Cronbach's $\alpha = .92\text{-}.96$).[1,30,53] The modified version has 22 items, and participants rate their agreement with each statement on a 1-5 Likert scale, where lower scores indicate more stigmatizing attitudes. A total scale score is calculated by summing values for all items and dividing by the total number of items. Participants in the experimental arm will complete the M-AADUP at baseline (both pre- and post-intervention) and at 1 and 2 months later. Participants from the control arm will complete it at baseline, immediately preceding and following the intervention, and 1 month following completion of the intervention.

***Demographic information*:** Participants will also provide demographic information (at baseline) including age in years, race/ethnicity, primary unit, average number of hours worked each week, shift type (days, evening, nights, rotate), years of experience working in perinatal health, and highest education level. We will also collect demographic data which may be moderators including personal or familial history of substance use disorder (using the family history section of the Renard Diagnostic Interview[107-108]), whether a parent ("I am a mother/father"), and approximate number of mothers/infants with POU or NOWS cared for in the last year (adapted from Shuman et al[1]).

STUDY PROCEDURES

Consent

After obtaining IRB approval and registering the clinical trial with clinicaltrials.gov, we will begin study activities. All participants will consent to participate prior to participation. Prior to participation, participants will be informed of the study purpose and their involvement in a study information/informed consent document sent with the recruitment email.

Data Collection

We are using recordings from videoconference and Qualtrics, a web-based survey application, to collect data. While completing the intervention, survey question and demographic questions are embedded in the platform. Zoom, Qualtrics, and ArtSpective platform are password protected and data is only available to research team members. Data from recordings will be transcribed verbatim prior to analysis.

Randomization

Participants will be randomized by site. One site will be randomized to the experimental arm (Site A) and the other will serve as the control (Site B) during phase 1. During phase 3, we will randomly select 10 individuals from Site A to participate in interviews rather than completing a follow up survey. Random selection will be done using site/participant IDs and the "sample()" function in R.

DATA ANALYSIS

Demographic data from Qualtrics will be migrated from Qualtrics via a comma separated values document, which can be used for data cleaning and analysis. Audio recordings from Zoom sessions (Phase 3 interviews) will be transcribed verbatim and analyzed using an iterative process and the constant comparative method.[98-100] Member checking will contribute to credibility through validation of the research findings by participants.[100] A codebook will be developed after repeated high-level reading of the transcripts. Using NVivo software,[101] data will be coded and grouped into categories to facilitate abstraction and concept analysis. The written field notes will be analyzed using content analysis to locate statements where RNs and experts referred to navigational issues, missing content, or visual flaws. The statements will be organized into categories and lists that refer to elements of the intervention design, such as format, content, style, and setting, to make the necessary modifications. These methods will help identify and analyze RNs' thought processes to see how they: 1) relate to the content, 2) interpret the content, and 3) make meaning of the information, skills, and resources provided.

Two questions will be analyzed: feasibility and change in stigma. Feasibility of ArtSpective will be analyzed using univariate descriptive statistics (proportions, means, and ranges)[93] and by comparing differences by unit, years of experience, race/ethnicity, and age, using t-tests for continuous variables and test for the difference in proportion for binary variables.[109-110] The change in stigma score measured by the MAADUP will be analyzed at 2 points in time: 1) immediately following completion of ArtSpective, only within the experimental arm, and 2) at 3 months between the experimental and control arms. We will test the immediate change using a paired t-test[109] of the hypothesis that the change in score is different from zero within RNs who received the intervention. We will test the change at 3 months using an independent t-test of the hypothesis that the difference over time between the experimental group and the control group is non-zero.[109] In addition we will develop a regression model for the change in stigma score as a function of covariates such as unit, age, and race. An indicator variable for the experimental arm will be used to test the difference between the groups, controlling for the other covariates.[111] Stepwise selection will be used to identify variables that are most strongly and independently associated with the change in stigma scores.[111] For all hypothesis tests, we will report p-values and a threshold of .05 will be used to determine significance. We will also examine the difference in distribution of stigma score before and after the intervention using the Kolmogorov-Smirnov test.[112] This nonparametric test for distributions does not require assumptions about the shape of the underlying distributions. To visualize the test results, we will construct box plots of the attitude scores at each point of time by intervention group.

Power Calculation

As a pilot study, our power calculation focuses on only a few outcomes and leaves room for uncertainty in our assumptions. We based our sample size estimates on detecting a moderate effect size of 0.5[113] which we believe is a meaningful difference for these pilot data. Assuming 75 participants in each group, and test performed at alpha level of 5%, the between-group tests would have power of 86%, and the paired t-test for immediate change in stigma score would have power greater than 90%. The 3-month differences will be unpowered at a moderate effect size; however, these pilot data will provide us with an estimate of attrition. In addition, estimates of attrition, effect, and correlation will be needed to power a future multisite cluster-randomized study.

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