Title: Assessing the Efficacy of Self-Driven Repetitive Artmaking Practice

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Title: Assessing the Efficacy of Self-Driven Repetitive Artmaking Practice on Pain and Mood States for Patients with Chronic Pain, Opioid Use Disorder, and Opioid Misuse

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1. SPECIFIC AIMS

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The proposed pilot study is an exploratory implementation and mixed methods evaluation of self-guided repetitive art-making to assess the impact of this artistic practice on 1) self-reported pain levels, 2) self-reported mood states including anxiety and depression, and 3) self-reported feelings of connection for patients living with chronic pain and opioid use disorder (OUD) or documented misuse of opioids. A secondary research focus will be to assess whether viewing art made by patients with chronic pain and OUD/opioid misuse diminishes stigma towards these populations for the broader population.

Aim 1 (Acceptability): Develop three (3) self-guided repetitive artmaking kits for patients with chronic pain and OUD/opioid misuse to use on their own, with instructions in English and Spanish, and train the patients on the use of these artmaking kits through three (3) in-person workshops in English and Spanish. *Hypothesis 1: Simple art kits that offer repetitive artmaking practices will be acceptable for and interesting to patients with chronic pain and OUD/opioid misuse.* Acceptability will be measured by whether patients complete the pre- and post-survey and/or whether they report to the Study Coordinator during monthly check-ins that they have engaged with the art kit(s). At least 80% of patients will report using an art kit on their own (via self-report on surveys, to be supplemented by Study Coordinator text check-ins and storytelling data for patients who participate in the final showcase event). We will ask brief questions at the workshops to assess patients' previous experience with art and openness to mindfulness activities, along with a brief demographic questionnaire, to provide a baseline.

Aim 2 (Efficacy): Evaluate whether the self-guided repetitive artmaking kits significantly impact patients' self-reported experiences of pain, mood (inclusive of depression and anxiety), and social isolation. *Hypothesis 2: Repetitive artmaking will reduce experiences of pain for patients with both chronic pain and OUD/opioid misuse.* Acceptance criteria: Significant pain reduction during artmaking practice as captured using the first three questions of the BPI Reduced Minus Peg Questions 8-item questionnaire (attached) – questions one and two will be only asked in the pre-survey as these questions ask about pain over the last week and will therefore not change before and after a solo artmaking experience. We also propose to have patients complete the 6-item Pain Catastrophizing Questionnaire (attached) during the in-person workshop to gain an understanding about patients' experiences of pain. This data will be supplemented with qualitative data from the meaning making session and storytelling content, for those who participate. *Hypothesis 3: Repetitive artmaking will reduce depression and anxiety and improve mood for patients with chronic pain and OUD/opioid misuse.* Significance improvements in mood (anxiety and depression) during artmaking practice as captured using single survey questions asking patients to rate their current experiences of anxiety and depression. This data will be supplemented with qualitative data from the meaning making session and storytelling content, for those who participate. *Hypothesis 4: Supporting patients with chronic pain and OUD/opioid misuse in making art will result in higher ratings of social connectivity.* Significant improvement in social connectivity during artmaking practice as captured using the IOS-CC (attached). *Hypothesis 5: Repetitive artmaking will reduce opioid misuse in patients.* Any reduction in non-prescribed opioid use as captured by a question asking patients if they have used non-prescribed opioids in the past 24 hours (modified from the Addiction Severity Index question about recent opioid use) as both a measure of opioid use in connection with artmaking and we will be evaluating patients' opioid use over the course of the study, and a question asking patients to share how high they are at the time of the survey (from the Modified DFAQ-CU Inventory but focusing on opioids not cannabis). This

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data will be supplemented with qualitative data from the meaning making session and storytelling content, for those who participate.

Aim 3 (Community Intervention): Prepare an exhibit of art made by patients and stories of their experiences and evaluate whether this exhibit impacts stigma regarding chronic pain and opioid use in the broader population (audience). *Hypothesis 6: Laypersons viewing photographs of the art paired with patients' descriptions of their art and the artmaking process, will lessen stigma towards people with chronic pain and OUD/opioid misuse.* Laypersons who view the exhibit and who complete a retroactive pre-post survey will self-report lessened stigma towards persons with chronic pain and OUD/opioid misuse through positive appraisal of the artists.

2. SIGNIFICANCE

Chronic pain is extremely prevalent in the United States with approximately 20-21% or over 50 million adults reporting pain most or every day.[1,2] Chronic pain can result in depression,[3,4] anxiety,[5] and isolation,[6,7] among other negative affective outcomes.[8] Many people who experience chronic pain have at some point in their medical journey been prescribed opioids,[9] and many more have been found to misuse/overuse these pain medications: as of 2019, 6-7 million adolescent and adult Americans were diagnosed with OUD[10] and, based on the 2021 National Survey on Drug Use and Health, 9.2 million people reported misusing opioids in the past year.[11] The cost of opioid misuse and OUD is estimated at $11 billion in annual hospital costs[12] and totals an estimated $1.02 trillion when including loss or reduced quality of life.[13] It is therefore clear that solutions – and particularly low-cost solutions – to chronic pain are needed that can support patients with chronic pain and OUD/opioid misuse in managing their pain.

Art therapy is well-regarded as a cost-effective tool to minimize pain in individuals experiencing chronic pain.[14-16] Practices that incorporate art into psychotherapy can support patients' self-understanding of their experience through full mind-body intervention.[17,18] Outcomes of art therapy practice with patients experiencing chronic pain include: changes in physical symptoms,[19-22] changes in psychological symptoms,[23-28] and changes to social interactions such as increased socialization,[29] new relationships,[30] and improved communication.[31] Specifically, the use of artistic practice as distraction from pain is useful for mitigating pain.[32-34] Art therapy has been used in clinical settings to treat substance use disorders including OUD for 70 years with demonstrated success particularly in supporting detox and helping patients understand their relationship to substances.[35-40] However, there remains a dearth of literature on treatment outside clinical treatment settings or to assess the utility of art therapy in mitigating the experience of chronic pain in patients with OUD.[41]

Since self-management is understood to be critical to chronic pain treatment,[42,43] art-based solutions that allow patients to self-manage their symptoms outside of the clinical context are of particular interest. For instance, mandala creation, which is repetitive and can promote mindfulness, is often used in art therapy and in one study was shown to mitigate pain and anxiety in pediatric patients experiencing procedures that caused acute pain.[44] However art therapy is overwhelmingly offered in formal contexts with professional art therapists, and does not often provide options that patients can use on their own, away from clinical settings.

3. RESEARCH DESIGN AND METHODS

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Overview:

The proposed pilot is an exploratory evaluation of whether repetitive artmaking in home environments is acceptable for chronic pain self-management in individuals with OUD/opioid misuse, and whether self-driven repetitive artmaking can offer respite from pain, depression, and anxiety, and improve social connectivity. The study will recruit approximately 40 individuals living with chronic pain with an OUD diagnosis or opioid misuse from a Montefiore-led methadone clinic, 1250 Waters Place. The Principal Investigators (PIs) will collaborate with an Art Therapist to develop three (3) simple art kits. Patients will participate in an in-person art workshop, to be held in English with the support of a Spanish translator, and complete pre- and post-surveys assessing in-the-moment pain, anxiety, depression, and social connectivity. Patients will be given all three (3) kits to take home and offered financial incentives to complete the same pre- and post-surveys and art kits at home up to four (4) times within a four-month period to assess real-world adoptability and efficacy. The art kits will not include any visible information about Montefiore or the study in the front of the packets; paper versions of the survey will be enclosed within the kits, to support confidentiality. All patients will be invited to a virtual meaning making group to capture qualitative feedback. The study staff will not share the names of patients with anyone outside the core research team – the co-PIs, Study Coordinator, Patient Advocate, Biostatistician, Art Therapist, and Photographer and Exhibit Coordinator. All patients will be invited to have their art photographed and share their experience of the artmaking process and how it relates to their chronic pain and opioid use. Photographs and stories will be shared on the Montefiore campus as an art exhibit, and the layperson audience will be surveyed to assess any resultant alteration in feelings of stigma toward the population of those living with chronic pain and OUD/opioid misuse. Patients who share their artwork will be able to decide if they want their name (or a portion of their name) or a pseudonym to be included in the exhibit alongside their artwork, or if they would like to maintain anonymity.

Implementation:

In-Person Workshop: Kathryn Sclavi, an Art Therapist, will lead three (3) two-hour in-person workshops at 1250 Waters Place, with all patients required to attend one (1) in-person workshop as part of this study. Spanish translation will be available at all workshops. The purpose of these workshops are twofold: they will gather patient characteristic data (demographics, Pain Catastrophizing Survey, questions on experience with art and openness to mindfulness) and orient patients to the use of the art kits available to them to take and use at home. The art therapist will develop three (3) repetitive artmaking kit options and will develop enough for patients to leave the workshop with one of each kit. Preliminary options include mandala painting and macramé, with the final kits to be developed during the planning phase in partnership with the IMPOWR-ME Community Leadership Board. As previously stated, the art kits will be compiled to minimize visual identification from others that they are part of a research study, with all survey materials asking sensitive questions buried in the middle of the packet. At the start of the in-person workshop, the PI will orient patients to the pilot goals and activities, answer all questions, collect consent forms, and provide the link to the pre-survey assessing pain and mood as well as paper versions of the survey. Ms. Sclavi will provide an engaging overview of the three available kits, and patients will select a kit to try for the in-person workshop. Dr. Seham and the Study Coordinator will be present to provide Spanish translation and explanation as necessary. The last 15 minutes of the workshop will be saved for patients to complete the post-survey on pain and

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mood and to remind patients that they will be compensated for using the art kits at home up to four (4) times if they complete pre- and post-surveys. Finally, patients will be informed that they will be invited to bring their artistic outputs to be photographed by a professional photographer (Megan Ghiroli) at the end of the four-month period and to share their experiences of making the art, so that they can share what they have made with the broader community. It will be made it clear that displaying their art and sharing their experiences is not mandatory, that patients do not need to decide during the workshop if they will want to share their artwork, and that they will be able to use full, part, or none of their name in the event.

At-Home Artmaking: Patients will be invited to take home all three (3) art kits at the end of the in-person workshop, each of which will allow them to make multiple versions of the type of art in question (aka materials for multiple mandalas). Each kit will include multiple copies of the pre- and post-survey assessing pain and mood and a reminder to complete the pre- and post-survey when doing the kits to receive an incentive of $20 compensation for up to four (4) times within a four-month period (the end date will be included in the art kits). Communication from the Survey Coordinator will also include the links to the pre- and post-surveys. The instructions will prompt patients to complete the survey immediately before starting the art kit and immediately after concluding. Patients will further be prompted to include a photo of their art in the post-survey if they are using the online survey system, or they can text their photo to the Study Coordinator if they have phone-based photography capacity. All instructions will be in English and Spanish. This implementation process is designed to assess real-world use of the art kits.

Data Collection:

Event	Data Collection Method	Measures to be Collected
In-Person Workshop	Patients complete online pre- and post-survey via a QR code or paper form	• Questions 1-3 of the BPI Reduced Minus Peg Questions (pre) and question 3 of the BPI Reduced Minus Peg Questions (post) • Pain Catastrophizing Questionnaire • Single question asking about current level of depression • Single question asking about current level of anxiety • IOS-CC • Questions asking about current and recent unprescribed opioid use (pre) and level of highness in the moment (pre, post) • Single question asking about experience with art • Single question asking about openness to mindfulness activities
At-Home Artistic Practice #1	Patients complete paper pre- and post-survey	• Questions 1-3 of the BPI Reduced Minus Peg Questions (pre) and

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At-Home Artistic Practice #2 At-Home Artistic Practice #3 At-Home Artistic Practice #4		question 3 of the BPI Reduced Minus Peg Questions (post) • Single question asking about current level of depression • Single question asking about current level of anxiety • IOS-CC • Questions asking about current and recent unprescribed opioid use (pre) and level of highness in the moment (pre, post)
Check-in Texts & Calls	The Study Coordinator will text all patients one (1) month after the in-person workshop and every one (1) month thereafter for a total of four (4) connection points to assess any barriers to at-home engagement; for those patients who do not respond to texts, the Study Coordinator will complete phone calls and document in Redcap	• Question asking whether patients used the art kits in the past month • Documentation of any barriers • Brief qualitative data
Meaning Making Session	All patients will be invited to join a two-hour virtual meaning making session	• Rich qualitative data of their experience of the art kits and solo repetitive artmaking
Exhibit	Exhibit viewers (laypersons) will complete an online post-survey via QR code that captures reactions before/after viewing the exhibit	• Short set of stigma questions to be developed

Most data will be collected online, via an online survey that automatically populates into a password protected spreadsheet. The Patient Advocate or Study Coordinator will collect all paper surveys during routine treatment at 1250 Waters Place and provide them to the Study Coordinator, who will clean and manually input the data.

Data Analysis:

Analysis will be conducted through a mixed-methods approach. Quantitative analysis to test hypotheses 2-5 will be led by Chenshu Zhang, Biostatistician, who will report changes from pre- and post-surveys on all the measures provided to patients and exhibit viewers. For bivariate analyses, he will used paired t-tests. For multivariate analyses, he will employ control variables from baseline, such as demographic variables, and conduct linear regressions. Qualitative analysis to test hypotheses 1-5 will be led by the co-PI, who will code all qualitative data collected from patients (open-ended questions in all surveys, transcript from the meaning making session) to

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surface themes that can provide phenomenological or experiential data. Drs. Zhang and the co-PIs will collaborate to develop a final report that includes both quantitative and qualitative data.

4. STUDY POPULATION

Individuals will be eligible to participate in the pilot study if they:

1. Experience chronic pain
2. Have received medication for OUD in the past 30 days
3. Are aged 18 or older
4. Are fluent in English and/or Spanish

Eligibility screening to be led by the Study Coordinator will include:

1. Chronic pain screening via the first three questions of the BPI Reduced Minus Peg Questions 8-item questionnaire
2. OUD/opioid misuse assessment via the Modified Addiction Severity Index question about recent opioid use

Patients will be enrolled into the study until a total of approximately 40 have completed the in-person art workshops; due to the nature of this community and the high level of attrition, we plan to over-enroll the workshops and as a result may have more than 40 participations at the conclusion.

5. PARTICIPANT RECRUITMENT

Patients will be recruited by the Study Coordinator and Patient Advocate from 1250 Waters Place. Patient Advocates have existing trusted relationships with clients at this methadone clinic site. The Study Coordinator will coordinate with the Patient Advocate's existing schedule to they can collaborate on talking to patients, sharing information about the study, and in the case of the Study Coordinator, assessing eligibility. Information about the study will additionally be shared in the form of flyers posted around the recruitment site, and the co-PIs will present to all staff during scheduled staff meetings to orient the staff to the project and request direct referrals.

6. INFORMED CONSENT

Informed consent will be conducted by the Study Coordinator as follows: all potential patients will complete a brief oral consent and then complete the eligibility screener. This process can take place in-person in a private room at 1250 Waters Place or over the phone in the case of patients who wish to be screened at a time of their choosing as opposed to when they encounter the study team. If eligible, the Study Coordinator will explain the study and any risks and benefits, and obtain written informed consent.

<u>Remuneration:</u>

Patients will receive $50 for participating in the in-person workshop and will be incentivized to use the art kits at home and complete pre- and post-testing for up to four times with $20 each time. Further, all patients will be invited to participate in a meaning making session to capture qualitative feedback on the feasibility of the project; if they attend, they will be compensated $50 for their participation. Patients will be compensated through a Clincard in their name. These cards include no information that link them to the study or indicate that this compensation is related to a study.

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7. RISK/BENEFIT TO PARTICIPANTS

The study protocol asks that patients reflect on their levels of pain, depression, anxiety, and social connection and as such could bring these experiences to the forefront of patients' minds during study activities and result in discomfort. There is also a small risk of loss of confidentiality, as patients will be recruited in a community setting – the 1250 Waters Place methadone clinic. To address confidentiality, we will remove any names used in the meaning making session during the transcription process and will enclose all written information about the study that is included in the art kits so that they are not immediately viewable by third parties. Audio recording of the meaning making session will be stored in a password protected folder on a password protected computer and destroyed once it has been transcribed. Patients will further be informed that they can refuse to answer any question if it makes them uncomfortable, and will be reminded that their participation is wholly voluntary.

Patients participating in groups and home practice may benefit from potential improvements in pain, OUD, and mental health symptoms. They will derive no specific benefits from completing questionnaires and participating in qualitative interviews.

8. DATA QUALITY CONTROL AND DATABASE MANAGEMENT

To protect confidentiality, each patient will be assigned an alphanumeric ID. The spreadsheet listing patient names and their associated ID, along with workshop attendance forms which will also include patient names, will be saved in a password protected folder separate from all other materials. During the data cleaning process of the pre- and post-surveys from both the workshops and the at-home data collection, the Study Coordinator will replace patient names with their respective ID. The audio recording of the meaning making session will be stored in a password protected folder on a password protected computer and destroyed once the session has been transcribed. All names and other identifying elements will be removed from the meaning making data during the transcription process.

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ATTACHMENTS
Please find attached:

- The BPI Reduced Minus Peg Questions Questionnaire
- Pain Catastrophizing Questionnaire
- IOS-CC
- Addiction Severity Index
- Modified DFAQ-CU Inventory