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**DR FERESHTEH POURKAZEMI**

*Lecturer*

*Faculty of Health Sciences*

*Discipline of Physiotherapy*

Rm O221, 75 East Street

Faculty of Health Sciences

The University of Sydney

NSW 2141 AUSTRALIA

Telephone: +61 2 9351 9207

Email: [fereshteh.pourkazemi@sydney.edu.au](mailto:fereshteh.pourkazemi@sydney.edu.au)

Web: <http://www.sydney.edu.au/>

## Study Protocol

### Title

Paint the pain: Investigating the biopsychosocial impacts of a guided self-reflective visual art creation program on individuals living with chronic pain- a pilot randomised controlled trial

### Short Title

Paint the pain pilot study

### Protocol Number

### Project Sponsor

The University of Sydney

### Coordinating Principal Investigator/ Principal Investigator

Dr Fereshteh Pourkazemi

### Associate Investigator(s)

*(if required by institution)*

Dr Claire Hooker, Dr Marnee McKay, Dr Roxanna Pebdani, Dr Bernadette Brady, Dr Amy Jo Vassallo, Prof James Elliott, Dr Stephen Gibson, Ms Michelle Cook, Dr Alison Evans, Dr Tania Gardner, Dr Niamh Moloney, Dr Clair Hebron, and Assoc Prof Michael Thacker

### Location *(where CPI/PI will recruit)*

(Royal Prince Alfred Hospital)

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## Scientific Title

Paint the pain: Investigating the biopsychosocial impacts of a guided self-reflective visual art creation program on individuals living with chronic pain- a pilot randomised controlled trial

## Simplified Title

Paint the pain

## Investigators

- Dr Fereshteh Pourkazemi Dr Claire Hooker, Dr Marnee McKay, Dr Roxanna Pebdani, Dr Bernadette Brady, Dr Amy Jo Vassallo, Prof James Elliott, Dr Stephen Gibson, Ms Michelle Cook, Dr Alison Evans, Dr Tania Gardner, Dr Niamh Moloney, Dr Clair Hebron, and Assoc Prof Michael Thacker
- Research Assistant: Mr Christopher Burgess
- HRD students (Honours): Miss Jasmine Lou, Mr Eric Ju

## Aim

To investigate the physiological, psychological and social impacts of visual arts creation in individuals living with chronic pain

## Hypothesis

Creation of visual art produces physiological, psychological and social benefits for individuals living with chronic pain.

## Sub-hypotheses

1. That the intervention will have a priming effect on clinically guided pain management which will follow this project. The clinical process involves a lot of reflection on the circumstances that impact on participants' pain, and we hypothesise that some of this reflective work will begin through the process of visual art creation.
2. That participants will describe visual art creation as beneficial in one or more dimensions of the 'CHIME' framework –Connectedness, Hope, Identity, Meaning in life and Empowerment (Jensen, 2018; Piat, Seida, & Sabetti, 2017).

## Background

People living with chronic pain experience a multitude of feelings including anxiety, anger, depression, shame, self-loss, identity disruption, and isolation, all of which heighten their distress. A recent study showed that the median waiting time to be admitted to a publicly funded pain management service is 150 days in Australia. That is 5 months of waiting in pain, demonstrating pain management services are currently unable to meet service requirements adequately. Therefore, while current pain services deliver pain interventions, there is a need for programs targeting the distress and isolation associated with waiting in pain, and community options for support and social engagement of individuals with chronic pain, for the long-term.

Creation of visual arts is amongst the highest of human cognitive achievements. Visual arts convey emotions, concepts, ideas, cultural differences and overcomes language limitations. Studies investigating the impacts of visual arts on psychosocial and physiological effects in different clinical populations have demonstrated that the application of arts is associated with effects on well-being such as improvements in overall health, loneliness, self-awareness (Geue et al., 2010) and morale (Cohen et al., 2006), and clinical benefits of reduced healthcare utilisation. Further, physiological benefits include improvements in heart rate, blood pressure (Leckey, 2011), and cortisol levels in clinical populations (Clow A, 2006). Finally, at the neural level, visual art production has been observed to enhance functional connectivity of the default mode network in the brain (Bolwerk, Mack-Andrick, Lang, Dorfler, & Maihofner, 2014). This network is associated with cognitive processes such as self-examination, reflection, prospection, autobiographic memory, and understanding of the emotional states and intentions of others (Gusnard, Akbudak, Shulman, & Raichle, 2001; Raichle, 2010).

Despite the potential benefits for individuals with chronic disability, there is limited information on the impacts of visual arts on patients with chronic pain (Kirkham, Smith, & Havsteen-Franklin, 2015; Mische Lawson et al., 2012). Using art therapeutically, as well as a 'primer' for patients on waiting lists for pain management programs, is a novel means of providing them with an outlet for their pain-related distress, anxiety and feelings of social isolation. At the same time, art can provide a means to boost the therapeutic alliance and support patients to communicate their pain and re-establish connections with their community. In addition, this project proposes to explore how visual arts can be used as a medium to help develop the therapeutic alliance by enabling people in pain to express and communicate their pain experience during the therapeutic encounter.

Therefore, this pilot study aims to investigate a) the physiological, psychological and social impacts of visual arts creation in participants with chronic musculoskeletal pain and b) To evaluate how creation of visual arts can be used as a medium to enable people in pain to express and communicate their pain experience during a therapeutic encounter.

# Research Plan

## Study Type

A pilot randomised controlled trial

## Setting/Location

This project will be run in partnership with the Prince Alfred Hospital (RPAH) Pain clinic as the recruitment site and the Art Gallery of NSW (AGNSW) as the intervention site.

## Duration of Study

One year

## Methods

### *Study Population*

Patients (>18yrs) with chronic musculoskeletal pain (persistent pain >3 months) and on the waiting list of the pain management program at RPAH pain clinic will be the population of interest.

### *Recruitment*

Participants will be recruited from the waiting list of the pain management program at the RPAH Pain Management Clinic. RPAH Pain Management Clinic routinely delivers a one-day introductory program (STEPS), once a month for patients waiting to commence a pain management program. At the end of the STEPs session, information regarding the “Paint the Pain” project will be provided to patients by a research assistant and an artist from the AGNSW. Patients who are interested to receive further information will be asked to provide their contact details (email and phone number) and will be contacted by our research assistant.

All prospective participants will be provided with the ethically approved participant information sheet and given ample time to read and ask any questions they have about participation. The project research assistant will also contact participants by phone/email to provide detailed information about the project, research process, and participation requirements and answer any questions they may have and check their eligibility against the inclusion criteria.

The details of our recruitment strategy are provided in Appendix 1.

### *Key inclusion criteria*

Individuals above the age of 18, who have been diagnosed with chronic musculoskeletal pain, whose pain has been stable over the past 3 months will be included in this study.

### *Key Exclusion Criteria*

Individuals who have started any new pain-related medications within 3 months prior to recruitment will be excluded from the study.

### *Consent*

To be included in the study, each participant will need to provide written informed consent. Participation will be voluntary, and participants can withdraw at any time. signing the consent form, they will be randomised to either the intervention group or control group.

### *Randomisation*

The Participant Information Statement and Consent form will be emailed to participants who meet the inclusion criteria. The project research assistant will then contact participants by phone to provide detailed information about the project, research process, and participation requirements and answer any questions they may have.

People who agree to participate by signing the consent form will be randomised to either the intervention group or control group. Our randomisation approach will be impacted by the number of participants recruited from the STEPs Program.

- If we are successful in recruiting 20 patients after attending one of the monthly STEPs programs, participants will be randomly allocated by the research team to either intervention or control group, using a computer-generated sequence and a 1:1 allocation ratio.
- If we are not successful in recruiting 20 patients from one STEPs program, we aim to use the quasi-randomisation approach. That is, the first group of participants recruited from the first STEPs program will be allocated to the intervention group and participants recruited from the next STEPs program will be allocated to the control group.

This approach will not extend the waiting time of patients to receive their pain assessment and treatment, should we not succeed in recruiting 20 participants via the first STEPs program.

Participants will be notified by phone/email of their group and intervention participants will be notified about their first session of art observation and creation at the Art Gallery of NSW.

### *Study Procedure*

After receiving consent, participants will be randomised into an intervention or a control group. The intervention group will undergo a five sessions of art intervention. The assessments will take place in both groups at baseline, at post intervention (at conclusion of 5 sessions), 3 months, 6 months and 12 months' time points. In addition, several measurements will be

collected throughout the intervention sessions including saliva samples, pain behaviour using a pain diary, and heart rate using a mobile app. For the control group, the treatment will be as usual (they will be on the waitlist to receive their pain treatment), and they will be offered two tickets to visit the art gallery and art creation tool kit, once the study is concluded.

### *Study intervention*

Participants randomised/allocated to the art intervention group will be asked to attend five sessions of art observation and creation at the Art Gallery of NSW (3hrs per session, 1 session per week) for over five weeks. To monitor adherence, participants will be contacted by our research assistant two days prior to the session and will be sent a text message requesting to confirm their attendance 24 hours prior to the session.

The first hour of the session, will be allocated to observation and discussion of 3 art works at the art gallery of NSW. This session will be guided by two artists at the gallery.

The second hour of the session is allocated to creation of the art works guided by an artist, and two researchers experienced in the field of arts and health, and a rehabilitation counselling researcher. During these sessions, participants will be guided to explore and communicate their pain experiences through the creation of visual artworks including each individual's pain and its impact on their well-being, personal and social life. Participants may also depict their 'ideal' self and life if they could 'tame' their pain. Participants will be guided to share and discuss these art creations and experiences with family, others with chronic pain, and with community members. The themes for the five art making sessions will be decided upon iteratively by the research team from the following list:

1. Express your pain in paint. Explore any of its dimensions.
2. Paint yourself with your pain in your present life.
3. Paint the self you hope to be/ you could be in relation to moving beyond pain /taming pain
4. Paint all the places the pain has come from or are connected with
5. What do you need most in order to live with pain?
6. Paint your future self and how you would like to live
7. Paint what is meaningfully connected to your pain – in any way.

The final hour of the art-making sessions will be a group discussion and reflection on the art creation process, effectively a group interview, conducted jointly by team members, a rehabilitation counsellor and a qualitative arts and health researcher. This group interview is similar to a 'focus group' and is understood partly as 'action research' in which reflections prompted by the discussion may influence their experiences in the subsequent session.

### *Control group*

Participants randomised to the control group can continue with usual medical care while on the waiting list to receive their multidisciplinary pain management program at the RPAH Pain Management Clinic. At the conclusion of this study, participants in this group will be provided with an art making kit and tickets to the AGNSW, as compensation for their time and participation in the project.

### *Endpoints/Outcome Measurements*

#### *Quantitative Approach*

To assess patient demographics and pain-related medical history, we will seek participants' permission to access the results of their ePPOC<sup>1</sup> questionnaires (electronic Persistent Pain Outcomes Collaboration, Appendix 2). These questionnaires are required as part of admission to the pain management programs in Australia. After gaining informed consent, previously completed ePPOC questionnaires will be accessed and recorded. We briefly provide information on the items extracted from ePPOC data. For detailed information, please refer to Appendix 2. We will extract the following items from ePPOC questionnaires:

1. Patient demographic information:

In ePPOC analysis and reporting, patient information defines the patient population and contextualises the patient outcomes. We will record: sex, age, height (cm), weight (kg), postcode, and country of birth.

2. Pain History:

- *Episode information:* An episode is defined as a continuous period of care for a patient in one pain management service. Under this definition, a patient may have more than one episode. For example, a patient may receive treatment for pain at more than one pain management service or be re-referred to a service following completion of a previous episode. There should however, be only one active episode at any one time for a patient at a pain management service.

The information collected at the episode level reflects the circumstances at the beginning of the episode. We will record Patients' referral date for the current pain episode, episode start date, episode start mode (how the episode began), cause of pain, pain duration (the length of time for which the patients' pain has been present, comorbidities (comorbid conditions the patient has at the start of the episode of care).

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<sup>1</sup> ePPOC is a program which aims to help improve services and outcomes for individuals experiencing chronic pain through benchmarking of care and treatment.



- *Pathway information:* The “Pathway” describes the type of treatment the patient receives/has received during the episode of care. Pathways generally begin after education/orientation programs and appointments designed to assess the patient and determine the most appropriate treatment pathway. There are four primary pathways:
  - Pathway 1 Group pain management program(s) (PMP)
  - Pathway 2 Individual appointments with clinicians (e.g. medical, nursing and allied health practitioners)
  - Pathway 3 Concurrent pathways where group programs and individual appointments are provided at the same time
  - Pathway 4 One-off interventions, where it is not expected that any further intervention will be provided. These might include a procedural intervention with no further individual appointments planned, or a single appointment with a medical specialist.
  
- *Service information:* Service information describes the service events (also known as occasions of service) a patient receives during an episode of care. These include individual appointments with a physiotherapist (or nurse, psychologist, specialist), multidisciplinary assessments and discussions, pain management programs, procedures, education/orientation programs. This information is collected to understand what treatments the patient is receiving while enrolled in our study.
  
- *Health service utilisation* in the last three months (medical, allied health, emergency services and diagnostic tests)
  
- Work status and productivity measured on a 0-10 rating scale

### 3. Patient reported outcome measures:

As part of ePPOC, standardised patient questionnaires are completed by the patient in ‘referral’ and ‘follow-up’ questionnaires at:

- initial referral to the pain management service;
- the beginning and end of each pathway within an episode; and
- follow-up three to six months after the end of the episode.

While we will use the recorded data from ePPOC, we will also assess and record following outcome measures at commencement and at the end of our art intervention in both groups. Patient reported outcome measures are:

- *Pain description:* Patient is asked to choose or describe the following items:
  - Frequency of their pain (e.g., always present, occasionally present, etc).

- Pain site: report of where on a body map the patient feels pain.
  - Pain severity: The patient is asked to rate the intensity of their pain at its worst in the last week, at its least in the last week, on average, and right now. For each of the four questions above, the patient rates their pain on a scale of 0 to 10, where 0 = 'No pain' and 10 = 'Pain as bad as you can imagine'.
  - Rating of their change-overall (on a scale of -3 to 3 where -3 is 'very much worse', 0 is 'unchanged' and '3' is 'very much better'.)
  - Rating of their change-physical abilities (on a scale of -3 to 3 where -3 is 'very much worse', 0 is 'unchanged' and '3' is 'very much better'.)
  - Pain interference: The patient is asked to rate how much their pain has interfered with the following in the past week: general activity, mood, walking ability, normal work (both outside the home and housework), relations with other people, sleep, enjoyment of life. For each of the seven questions above, the patient rates their pain on a scale of 0 to 10, where 0 = 'Does not interfere' and 10 = 'Completely interferes'. An average rating of pain interference is calculated by summing the scores for the seven questions above, divided by the number of questions the patient completed. If more than one number has been circled for a question, use the highest score.
- *Depression, Anxiety, Stress Scale 21 (DASS21)*: The DASS is a set of three self-report scales designed to measure the negative emotional states of depression, anxiety and stress. ePPOC uses the short version of the DASS, the DASS21. The patient is asked to read the 21 statements and indicate how much the statement applied to them over the past week. For each of the statements, the patient indicates how much the statement applied to them according to the following scale:
- 0 – did not apply to me at all;
  - 1 – applied to me to some degree, or some of the time;
  - 2 – applied to me to a considerable degree, or a good part of the time; and
  - 3 – applied to me very much, or most of the time.
- For details on how to measure and interpret the final score, please refer to Appendix 2, Pages 26-27
- *Pain Self-Efficacy Questionnaire (PSEQ)*: The PSEQ is a measure of how confident a patient is that he or she can do a range of activities despite their pain. The patient is asked to read the 10 statements and rate how confident they are that they can do the tasks at present.

For each of the statements, the patient indicates on a scale of 0 to 6 how confident they are, where 0 = "Not at all confident" and 6 = "Completely confident". The sum of scores for all items provides a total score. Higher scores indicate higher levels of self-efficacy.

For details on how to measure and interpret the final score, please refer to Appendix 2, Page 28.

- *Pain catastrophising scale (PCS)*: The PCS is a measure of an individual's thoughts and feelings relating to their pain. The scale includes three sub scales measuring the dimensions of Rumination, Magnification and Helplessness.

The patient is asked to read 13 statements describing different thoughts and feelings that may be associated with pain and indicate the degree to which they have these thoughts and feelings when they are experiencing pain. For each of the statements, the patient indicates the degree to which they have these thoughts and feelings, according to the following scale:

- 0 - Not at all
- 1 - To a slight degree
- 2 - To a moderate degree
- 3 - To a great degree
- 4 - All the time

Total and subscales are calculated by summing the scores for the relevant items. For details on how to measure and interpret the total and subscale scores, please refer to Appendix 2, Pages 29-30.

- *Medications related information*: Records whether the patient is taking medications, based on the response provided in the Medication Use section of the ePPOC questionnaires.

#### 4. Saliva Cortisol Level:

Cortisol is the stress hormone biomarker used routinely in the monitoring of psychological and certain aspects of physiological well-being. The ability to monitor stress in a quick and easy non-invasive manner is possible by administering a saliva test. Saliva Cortisol level will be assessed using the IPRO Cortisol LFD. The IPRO Cortisol LFD is a non-invasive, quick and quantitative method of assessment that requires no laboratory equipment. The component parts required for a test are: an IPRO LFD Reader; an IPRO Oral Fluid Collector (OFC) swab; an IPRO OFC Buffer and an IPRO LFD cassette. The Cortisol can be gained within 12-13 minutes from giving the subject an IPRO OFC swab. One of the advantages of salivary Cortisol is that it represents the unbound "free" and thus biologically active component of this stress hormone.

In the intervention group, participants' saliva samples will be collected before, during and after each art intervention session, at specific time points (3 samples over each session, for each participant). Our trained research assistant will read and record the saliva Cortisol levels after collection of saliva.

In the control group, saliva Cortisol level will be once at baseline and once within five weeks. We intend to collect Saliva samples from the control group at a specific time point that matches the time point of intervention group during the day, after art intervention. The specific time points will be finalised once the art sessions are confirmed with the Art Gallery.

#### 5. Heart Rate

Participants' heart rate will be monitored and recorded at the same time as the collection of saliva samples. To record the heart rate, the Instant Heart Rate mobile application will be used. The application uses mobile phone's camera flash to measure heart rate in seconds. Participants place the tip of their index finger over the camera and wait for Instant Heart Rate to detect colour changes in the fingertip each time the heart beats.

#### 6. A self-reported journal:

Participants in both groups will be provided with a journal to document any changes or improvements regarding their mood, activities, medications, healthcare visits, pain behaviour or intensity over five weeks. This Journal is provided in Appendix 3 (My Pain Diary).

#### *Qualitative Approach*

In this pilot study we will undertake exploratory, open ended qualitative research that seeks to understand the social, psychological and experiential dimensions of visual arts creation in individuals with chronic pain. As this is a pilot, exploratory study, our approach will not be guided by commitments to any particular methodology. Rather we will take a broadly constructivist and interpretive approach to the collection and analysis of data. We characterise our approach as constructivist because the team is interested in how participants construct and reconstruct their sense of identity through the process of visual art creation, and how they present and understand their experiences. We also characterise our approach as interpretive because the researchers will be constantly interpreting the data as we encounter it, triangulating analysis from our different disciplinary backgrounds and perspectives.

#### Process:

1. The final hour of each session will be allocated to a group discussion and reflection on the art creation process, effectively a group interview, conducted jointly by team members Dr Roxanna Pebdani, a rehabilitation counsellor, and Dr Claire Hooker, a qualitative health researcher. This group interview is similar to a 'focus group' and is understood partly as

'action research' in which reflections prompted by the discussion may influence their experiences in the subsequent session.

2. It is expected that after two hours of art making, the participants will stand back from their works and have a 1 hour 'focus group' / reflective session. However, we think it is important to collect data during the entire 3-hour session, as it is possible that there will not be such a clear disjunction between the art making and the reflection, with the former going for longer and the latter occurring throughout. Because the art creation process values unpredicted emergences, the research design is somewhat flexible, and the team has created processes of iterative discussion and triangulation in order to preserve rigour and simultaneously be responsive to participants' developing experiences.
3. The entire 3-hour session will be recorded. The facilitator will wear a lapel microphone for this purpose and a Phillips digital audio recorder with four boundary microphones which will be used to record conversations between the facilitators and participants.

Group Interviews: Question route:

The question route for the group interviews will be open-ended as this is appropriate for an exploratory pilot study. However, we will use a loose structure to the group interviews. Each interview is anticipated to begin with a free association in which participants step back from the artwork they have created and write down as many terms as they can think of that relate to their art work

The question route will explore:

- How did you experience today's session?
  - How did you feel at the beginning?
  - Did your feelings or experience change over the session?
  - What are 3 words that describe your experience in this session?
- What were you thinking about when you began your painting?
- How does your pain, and your painting, look when you step back from it?
- Did the painting change as it developed?
- Did your understanding of yourself or of your pain change as you painted?
- Is painting or creative art making something you'd like to continue more in the future?

*Confounders*

- Socialisation, discussion of the art works and exposure to other art works at the gallery have the potential to improve the outcome measures. These experiences are all included in the art creation process and cannot be separated.

- Other treatments undertaken as part of routine medical care. We will collect information weekly to monitor if our participants have changed their medications or seen another healthcare provider.

#### *Statistical Considerations/Data analysis (Quantitative)*

Statistical support will be sought from the Faculty of Health Sciences Biostatistician (Prof Deborah Black). Descriptive statistics will be used to describe the population, patient-reported outcome measures and physiological outcome measures. Data will be assessed for normality. Generalized linear models will be used to compare the mean change in outcomes (continuous variables) from baseline to each time point between the intervention and control groups. This will provide effect estimates and 95% confidence intervals for any difference between the intervention and control group.

#### *Statistical Considerations/Data analysis (Qualitative)*

All 3-hour art making sessions, including the concluding hour of group discussion, will be audio recorded and the audio recordings transcribed. Analysis will be conducted by the research team and led by Claire Hooker, Fereshteh Pourkazemi and Roxanna Pebdani, with input from Clair Hebron and pain clinician Dr Bernadette Brady. Analysis will be iterative and interpretive, with the analysis team using processes of close coding, memoing, and building categories and themes, triangulating findings constructed following the first art making session through initial independent analysis and iteratively building an analytic framework through comparison and discussion across the team after each subsequent session.

Data will be stored on the University of Sydney Research Data Store, a password protected data storage facility that is compliant with all security and ethics requirements.

#### Ethical Considerations

Whilst all care will be taken to maintain participant privacy and confidentiality there is always a risk participating in group discussions that someone may repeat things said in a confidential group meeting. To mitigate this risk, all participants will be reminded every session to maintain confidentiality and complaints or concerns raised by individual participants will be managed by the program coordinator. While the control group will not receive an art intervention, they will be provided with art materials and two tickets to the AGNSW. Since this is a pilot study, they will be informed of future studies which they may wish to volunteer for.

#### Safety Considerations

A potential risk of any intervention that promotes self-exploration of mind-body interactions is an exacerbation of symptoms of pain and/or psychological distress. All participants will be informed of the potential for symptom exacerbation prior to commencing the intervention. Should any participant experience an adverse response to art therapy, their medical practitioner and other

providers involved in their management will be informed and they will be supported to access appropriate medical /psychological care as necessary.

### Investigator obligations

- Data safety
- Reporting of adverse events
- Copyright of art works at the gallery

### Funding

This study is funded by the University of Sydney Industry and Community Engagement Seed Fund (2018-19).

### Conflict of Interest

None

### **Outcomes**

We hypothesise that this research will produce 5 outcomes:

1. Whether making visual art produces physiological benefits on the stress responses (measured via cortisol levels and heart rate) for individuals with chronic pain, as suggested in other preliminary studies
2. Whether making visual art produces improves any of the patient's reported outcome measures (e.g., pain, mood, pain catastrophizing, self-efficacy).
3. Whether art-making is otherwise experienced as beneficial by individuals with chronic pain and identify why or why not through interviews and qualitative analyses.
4. Our research will provide information important to our partner, the AGNSW, by investigating how the art gallery can provide unique, high-value services in facilitating art experiences for individuals with chronic pain, an extensive and highly significant population where programming would sit in parallel to, and build from, that developed for individuals with dementia, people with autism, and people with disabilities.
5. The exhibition of works will enable the AGNSW to play a role in building new community-based knowledge and concepts of illness experience, and to explore and examine different aesthetic registers in the consequent artistic output.

From the results of this pilot study we will be able to identify primary and secondary outcome measures and sample sizes for future studies.

### **Significance**

The benefits of this project are significant because it provides a unique opportunity for:

- Individuals with chronic pain to engage in a creative activity and to express their health condition to clinicians and their wider community
- Australians to understand the experience of people living with chronic pain, one of the highly prevalent health conditions in Australia and worldwide (via the exhibition of artworks).

This project uses the international language of visual arts as a platform to engage and educate the individuals with chronic pain and a wider community (by exhibiting created art works) aiming to overcome any language barriers in the multicultural and ethnically diverse community of NSW. During this project, the Art Gallery of NSW is engaged, providing access to a wider community to observe the art works. This will lead to increased public awareness, empathy and engagement of people with chronic pain with their society, leading to multitude of positive impacts including improved patient, carer and healthcare provider experience.

Engagement of artists with the healthcare services will create and provide important information to policy makers demonstrating how the application of arts and employment of artists in the healthcare systems can provide unique, high-value services reducing the cost of healthcare system in the long term.

Fostering collaborations across research/educational organisations and the art and health sectors within Australia and internationally is another significant benefit of this project. By providing training for the arts and healthcare students with an innovative multidisciplinary project-based collaboration and education, the future generations of healthcare and arts leaders will be inspired.



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