This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY

Sound and Vision: A collaboration between service-users, artists and the public to explore the lived experience of hallucinations

SHORT STUDY TITLE / ACRONYM

Sound and Vision

PROTOCOL VERSION NUMBER AND DATE

Version 1.2 16 September 2020

RESEARCH REFERENCE NUMBERS

IRAS Number: 269849

SPONSORS Number: Generated by the Sponsor. Enter if applicable

FUNDERS Number: N/A
SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator: 

Signature: 

Name: (please print): John Suckling 

Date: 18/2/2020
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## KEY STUDY CONTACTS

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<th>Phone</th>
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<tr>
<td>Chief Investigator</td>
<td>John Suckling</td>
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<td>Study Co-ordinator</td>
<td>Colleen Rollins</td>
<td>Department of Psychiatry, University of Cambridge, Herchel Smith Building, Robinson Way, Cambridge, CB2 0SZ.</td>
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<td>Key Protocol Contributors</td>
<td>Emilio Fernandez-Egea</td>
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# STUDY SUMMARY

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<th>Study Title</th>
<th>Sound and Vision: A collaboration between service-users, artists and the public to explore the lived experience of hallucinations</th>
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<td></td>
<td>Patients with Parkinson’s disease (N=6)</td>
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<td>Planned Study Period</td>
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<td>Research Question/Aim(s)</td>
<td>To promote the public understanding of mental health-related experiences through the artistic expression of the hallucinatory experience.</td>
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# FUNDING AND SUPPORT IN KIND

<table>
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<tr>
<th>FUNDER(S)</th>
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<td>Isaac Newton Trust</td>
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</table>
KEY WORDS:

hallucinations, psychotic disorders, neurodegenerative disorders, public engagement, artistic expression
STUDY FLOW CHART

1. Invitation to take part at scheduled clinic appointment
2. 2-4 days
3. Invitation to receive study information
4. At least 48 hours
5. Information Sheet sent
6. Invitation to appointment
7. Informed consent
8. First appointment with artist
   Second appointment arranged
9. Second discussion with artist
10. Artwork sent to participant

Key

- In clinic
- Via preferred method of communication
STUDY PROTOCOL

Sound and Vision: A collaboration between service-users, artists and the public to explore the lived experience of hallucinations

1 BACKGROUND

Hallucinations involve perceptions of stimuli that do not exist in the physical world, such as hearing voices or seeing visions. Hallucinations occur not only in schizophrenia, but are experienced by people with other psychiatric disorders, neurological and neurodegenerative conditions, and among the general population. But what is it like to experience hallucinations? And is the experience of hallucinations the same for patients with different disorders, and people without a diagnosis? There is strong historical and anecdotal evidence that suggests that the quality of hallucinations is in fact very different, and we have recently shown that the brain imaging evidence points towards entirely separate brain mechanisms for the experience of hallucinations in schizophrenia and neurodegenerative disorders such as Parkinson’s and Alzheimer’s disease. It is therefore possible, perhaps likely, that the lived experience of hallucinations is an indicator of the specific brain mechanisms involved, and may be used in a way that moves us closer to treatments that are tailored to individual patients. By exploring the plurality of hallucinations and their ubiquity in health and disease, we can reduce the fear and stigma of these experiences that challenge our perception of reality.

This project will pair local artists with patients who have hallucinations to create art pieces that represent their hallucinatory experiences. Patients with diagnoses of a psychotic disorder (N=6), for example schizophrenia, and with a diagnosis of a neurodegenerative disorder (N=6), for example Parkinson’s disease, will be invited to take part by their clinician when they attend their respective NHS clinics for continuing care. Subsequently, they will be contacted by their preferred means of communication, and if they remain interested in taking part an appointment will be made at a convenient time. Patients will meet with artists, with a member of the study team present, on two occasions who will then develop the piece, which may be a painting, drawing, or other media that the artist and service-user jointly select. Discussions will be audio recorded, with specific consent. Appointments will take place in a private room at the usual NHS clinics attended by the participants so that support is available for participants, if required.

Completed artworks will be the centrepiece for an exhibition at UK science festivals and a digital (online) presentation. The exhibition will be accompanied by researchers explaining the brain science of hallucinations, consented, anonymised recordings of patients and artists describing their experience with hallucinations and the process of developing the artworks, booklets cataloguing the exhibition, and art materials available for artistic expression of their own experiences. We will encourage the public to share their own experiences through completing anonymous online questionnaires giving us a platform to begin to improve our understanding of the diversity of hallucination-like experiences in the general population.

Our objectives are to engage the public in an appreciation of the experience of hallucinations and their prevalence across many common mental health and neurodegenerative disorders, as well as an experience many people will share without ever being diagnosed.

2 RATIONALE

Hallucinations involve perceptions of stimuli that do not exist in the physical world, such as hearing voices or seeing visions. Although hallucinations are often distressing, they may also be benign or
Sound and Vision

contribute to meaningful personal experiences, and are important phenomena in probing our perception of the external world. Hallucinations are considered a core symptom of schizophrenia, but commonly occur in other psychiatric disorders, neurological, and neurodegenerative conditions, as well as among individuals with no history of mental illness (Woods et al., 2015). Although of high prevalence, it remains unclear whether the quality of hallucinations in different disorders are similar (Llorca et al., 2016), and whether they are supported by common or distinct brain substrates. A recent, quantitative summary and meta-analysis of the extant literature by our group (Rollins et al., 2018) discovered non-overlapping patterns of grey matter change associated with hallucinations in psychiatric illness (predominantly schizophrenia) and neurodegenerative diseases (predominantly PD and AD) that are not adequately explained by differences in the primary modality of the hallucinations or age of the patients. Advances in neuroimaging technology have given insights into the brain structures and functions that are associated with hallucinations, but our understanding of why people experience hallucinations remains an active and fertile area of research.

An influential model of auditory hallucinations is the inner speech model, which proposes their origins in the misattribution of inner speech to a non-self source. Alternative models posit the causal agent to be memory-related processes, spontaneous activation in auditory and related memory areas, inappropriate proximal salience, skewed balance of top-down/bottom-up control dynamics between secondary sensory cortices and frontal regions or of inhibition/excitation at the physiological level, or the mismatch between processes comparing predictive representations of the external world to sensory evidence. While these models attempt to explain auditory hallucinations in schizophrenia and non-clinical populations, a separate array of models have been proposed for visual hallucinations in neurodegenerative disorders. Auditory and visual hallucination models overlap in alluding to deficits in reality monitoring, memory, salience, inhibition, and excitation. Additionally, hallucinations have been subcategorized by different neurocognitive mechanisms, or by differential contributions of a range of pharmacological systems. Whilst these models can generate refutable hypotheses, they do not in general include the quality of the lived experience. Understanding the subjective experience of hallucinations can guide research on the brain mechanisms of hallucinations, potentially optimizing treatment strategies, and contributing to the development of theoretical accounts of hallucinations.

References


3 RESEARCH QUESTION/AIM(S)

3.1 Objectives

To create an exhibition of artworks depicting the experience of hallucinations to promote the public understanding of mental health related experiences, specifically hallucinations and to record the public’s own experiences of hallucination by standardised questionnaire.

3.2 Outcome

Protocol v1.2
Sound and Vision

Original art pieces depicting the lived experience of hallucinations will be the centre-piece of an exhibition that will be displayed at science festivals across the UK, and as a permanent on-line exhibition. The exhibition will offer an immersive environment by providing a number of activities to engage attendees and convey the objectives of the project and its underlying research.

The exhibition will promote participation in completing on-line standardised questionnaires on the experience of hallucinations.

4 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

Service-users will be invited to participate when attending the Cambridgeshire and Peterborough Foundation NHS Trust Clozapine Clinic (patients with a diagnosis of a psychotic disorder, N=6), and the Cambridge Parkinson’s Disease Research Clinic, University of Cambridge or Cambridge University Hospitals NHS Trust Memory Clinic (patients with a diagnosis of a neurodegenerative disorder, N=6). Clinicians in the clinics with responsibility for their medical care will initially approach potential participants to ask if they would be interested in taking part in the study. Should that be the case, then a member of the study team will make contact with the participant using their preferred method of communication, and provide them with a Participant Information Sheet, if required. After at least 48 hours, potential participants will be re-contacted to see if they would like to participate, and if so then an appointment will be made with an artist from the local area who is a member of the study team. Each artist will be paired with two participants: one with a diagnosis of a psychotic disorder and one with a diagnosis of a neurodegenerative disease, to balance artistic styles between artworks arising from the participant groups.

Appointments will take place at the NHS clinic they attend for their clinical care, and from where they were recruited, or on-line using videoconferencing software. At the appointment, a member of the study team will give the participant an opportunity to clarify any queries and then obtain written informed consent. The study team member will be present during the discussion between the participant and the artist to ensure there is support available for service-users, if required. Additional support from clinicians in the clinic or on-line will be available, if required. During the appointment, the participant will describe their experience of hallucinations and the artist will have the opportunity to ask questions. Subsequently, the artist will produce drafts of the art piece. A second appointment will be arranged between participant and artist at the same venue or on-line and with the same support available to discuss the artist’s ideas, and any modifications to be made such that the participant feels it is an accurate representation of their experience. At both appointments, audio recordings will be made of the discussions on an encrypted device, and then transferred onto secure data hosting at the University of Cambridge at the earliest opportunity. At the final appointment, both artist and participant will be asked for their reflections on developing the art piece. Appointments will last no longer than one hour. The artists will then produce the final pieces, which will be photographed and sent to the participant for comment.

Participants will be remunerated £20 for each appointment with the artist; that is, £40 in total. This will be given to participants at the end of the second appointment. Travel costs for participants to the appointments will be reimbursed. They will also receive a high quality digital image of their artwork.

Artworks will be two-dimensional paintings, drawings, or other media that the artist and participant jointly select, meeting specific physical criteria (between 297x420mm and 594x841mm, weight < 3kg, and created with a robust medium).

Final art pieces will be displayed as part of an exhibition, where the public will be encouraged to engage with the experience of hallucinations. Visual content analysis (Bell, 2001) will find common...
iconographic elements which will form the basis of developing an overall narrative for exhibition visitors displayed with a description of the purpose of the exhibition, the historical background, and ongoing research. Additionally, experts in hallucination research will provide short presentations on current knowledge and will be available to answer questions. Textual content analysis (Hsieh & Shannon, 2005) of the audio recordings of the discussions will identify emerging themes and specific objects, animals or people that are present in the hallucinations. These will be organised to demonstrate any common structures observed across the participants and will add to overall narrative development. Based on this qualitative analysis, short audio recordings (consented and anonymised) of participants speaking about their experiences with hallucinations, extracted from the discussions, will be available to listen at the exhibition. A summary of the information will be provided in booklets cataloging the artworks. Art materials will be available for attendees to draw depictions of their own hallucination-like experiences. A key element to this project is the collection of anonymous data from a large sample of the general population of their experiences of hallucinations recorded using an online, composite of standardized instruments (Multi-Modality Unusual Sensory Experiences Questionnaire and University of Miami Parkinson's disease Hallucinations Questionnaire) that will record the modalities, severity, frequency and content of the lived experience. On the online questionnaire, we will also ask for feedback to assess the impact the exhibition has had on perceptions of hallucinations and mental health, and to further improve the exhibition. Study information and consent portals will preface participation in the on-line questionnaire. Analysis of on-line free text and image contributions will be undertaken using textual and visual content analysis, and compared to the similar analysis of the hallucinatory experiences of participants (above). A comparison will also be made of qualitative categories and themes with sub-scale ratings of the standardized instruments.

We expect that those attending the exhibition will indicate a greater understanding of the experience of hallucinations, the scientific research that is being undertaken, and a reduction in the stigma of mental illness. Combined responses to the questionnaires will inform future research by generating quantitative and qualitative data on the phenomenology of hallucinations in the general population, an area under-reported in the extant literature. Clustering algorithms, such as latent class analysis, will be used to indicate subgroups of experience informing interpretation of future research. We will summarize the results of the on-line questionnaire, illustrated by content generated by the public, in peer-reviewed publications.

References

Bell, P. Content analysis of visual images. In T. van Leeuwen & C. Jewitt (Eds.), Handbook of visual analysis 2001;10-34. London: Sage.


5 STUDY SETTING

Participants with a diagnosis of a psychotic disorder will be recruited from the Clozapine Clinic (Cambridge and Peterborough NHS Trust, Huntingdon and Cambridge), a clinic for people diagnosed with treatment resistant schizophrenia, likely to still experience chronic and enduring psychotic symptoms, including hallucinations. Appointments will take place here in a private room for consenting and discussions with the artist.

Participants with a diagnosis of a neurodegenerative disease will be recruited from Cambridge Parkinson's Disease Research Clinic (University of Cambridge) and The Cambridge Memory Clinic (Cambridge University Hospitals, Cambridge) both providing assessment and management for a wide
range of memory and cognitive disorders. Appointments will take place here in a private room for consenting and discussions with the artist, or on-line using teleconferencing software.

6 SAMPLE AND RECRUITMENT

6.1 Eligibility Criteria

6.1.1 Inclusion criteria

- Patients with a diagnosis of a psychotic disorder (for example, schizophrenia) who are currently experiencing hallucinations as one of the symptoms of their disorder and are attending the Clozapine Clinic, Cambridge.
- Patients with a diagnosis of a neurodegenerative disorder (for example, Parkinson’s disease) who are currently experiencing hallucinations as one of the symptoms of their disorder and are attending The Memory Clinic, Cambridge.
- The ability to read and understand English.
- The general public who wish to complete the on-line questionnaire and feedback.

6.1.2 Exclusion criteria

- Patients under 18 years.
- Anyone considered unsuitable for participation by their responsible clinician; for example, those who may lack capacity to consent, even temporally.

6.2 Sampling

6.2.1 Size of sample

A maximum of six (N=6) patients with a diagnosis of a psychotic disorder and six (N=6) patients with a neurodegenerative disorder will be recruited. The sample size is limited by logistic constraints. No formal between-group statistical comparison will be undertaken.

The online questionnaire will be open for the duration of the study to facilitate the greatest possible participation from the general public.

6.3 Recruitment

6.3.1 Sample identification

Participants recruited from participating NHS clinics will be identified by their responsible clinician who will ask them if they are willing to discuss participation with a member of the study team. This will take place at a scheduled clinic appointment for ongoing care. The name of the potential participant and the preferred method of contact will be recorded. Shortly thereafter, a member of the study team will contact them to verbally explain the study and ask if they remain interested in participation. If they are undecided, permission will be requested to re-contact them at a later date. If they are interested, the Participant Information Sheet (v1.1) will be sent to the potential participant. Posters raising aware of the study may be displayed in the clinics.

Individuals attending the Cambridge Parkinson's Disease Research Clinic, University of Cambridge are asked for their consent to be contacted about other research projects relevant to Parkinson's
Sound and Vision

disease (Cambridgeshire 3 Research Ethics committee; Ref 08/H0306/26), and only those who have consented will be approached for this study. Potential participants with a confirmed diagnosis of Parkinson’s disease and appropriate demographic and clinical characteristics will be identified from the Research Clinic database by the clinical team and sent a Participant Information Sheet (v1.2) by post together with a reply slip to express their interest in the study and to confirm that they are happy to be contacted by the study team.

Subsequent appointments for consent and discussions with the artist will take place in the NHS clinics they were recruited from in a private room, or on-line using videoconferencing software, at times that are convenient for the participant.

Following informed consent, the discussions between participant and artist will be audio recorded, which may contain identifiable details.

Reasonable travel expenses for the appointments will be available. Participants will receive £40 remuneration on completion of the appointments.

Anyone with internet access will be able to access the online questionnaire. There will be no remuneration for participation.

6.3.2 Consent

The clinical team responsible for the patient’s care will ask them if they would be interested in participation. If they agree verbally or by returning the reply slip, the potential participant will indicate their preferred method of communication.

At least 48 hours later, the participant will be re-contacted and if they wish to take part, an appointment arranged at a convenient time and date at least 48 hours later. Contact details of the study team will be included in the Participant Information Sheet should the potential participation have any questions or comments.

At the appointment, they will be met by a member for the study team. In a private room or on-line, the potential participant will have the opportunity to ask questions. Once these have been satisfactorily answered, written informed consent will be obtained. Specific informed consent will be obtained for the audio recordings; agreement to this aspect of the project is not an eligibility criterion.

Members of the public completing the online questionnaire will be greeted by a portal carrying information on the study, followed by a consent page that will require a box to be ticked to confirm that they are over 18 years and have read the study information.

7 ETHICAL AND REGULATORY CONSIDERATIONS

Artists will be briefed in advance of meeting patients on mental health in general, and psychiatric and neurodegenerative disorders specifically. Artists will have Visitor’s Agreements with the University of Cambridge so that they are covered by public liability insurance. Artists will complete Good Clinical Practice (GCP) training and have Research Passports that are required by University of Cambridge policy. Guidelines will be given to artists to maintain the anonymity of the participant and any individuals that are part of the hallucinatory content that will be represented in the art piece.
Prior to the first meeting with the artist, a study team member will ensure the participant is aware and comfortable with the outline of the meetings, and what will be the areas of discussion; namely, their personal experience of hallucinations. During the meeting, a member of the study team will be present to ensure the welfare of the participant. Appointments take place in a private room in the NHS clinic they normally attend to both provide familiar surroundings (patients at these clinics have regular appointments) and so that clinical support is available, if needed, or on-line using videoconferencing software.

All personally identifiable information, including audio recordings of the meetings with artists, will be recorded on an encrypted mobile device before being transferred to University of Cambridge secure data storage at the earliest opportunity.

Participants will have the opportunity to comment on final art piece prior to exhibition.

Participants can withdraw at any time without explanation and without any bearing on their continued care.

7.1 Assessment and management of risk

There is a risk that participants will become unhappy when discussing their hallucinatory experience with the artist. In mitigation, the artists will be briefed of this possibility, a member of the study team will be present to provide immediate support, and clinical support can be obtained if that were to become necessary as appointments will be at the NHS clinic they normally attend, or they can be put in contact with a member of their clinical team.

Members of the general public completing the online questionnaire and feedback on the exhibition may become unhappy when reflecting on their hallucinatory experiences. In mitigation, the website will contain links on online information (for example, from mental health charities), national support groups, and advice to see their family doctor if necessary.

7.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a UK Health Departments Research Ethics Service NHS REC for the study protocol, informed consent forms, and other relevant documents e.g. advertisements.

Substantial amendments that require review by NHS REC will not be implemented until that review is in place.

All correspondence with the REC will be retained.

The Chief Investigator will produce the annual reports as required.

If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance
Before any clinic enrolls patients into the study, the Chief Investigator or designee will ensure that appropriate approvals from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

**Amendments**

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor will submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. The sponsor has the responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

If applicable, other specialist review bodies will be notified about substantial amendments in case the amendment affects their opinion of the study.

Amendments will be notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated using the preferred method of contact to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site.

The amendment history will be tracked using a single, central information system to store and identify the most recent protocol version, and hardcopy within the Study Master File.

**7.3 Peer review**

**7.4 Patient & Public Involvement**

Discussions on the protocol with service-users were arranged through the Research & Development office, Cambridgeshire and Peterborough NHS Trust and through discussion with members of the Peterborough Hearing Voices Group. The protocol was reviewed by two volunteers from Parkinson’s UK. Comments received are incorporated into this protocol.

The primary objective of this project it to increase the public understanding of hallucinations by providing a platform to those who experience them, and opening the debate on the prevalence of hallucinations across the wider population. Final art pieces will be displayed as part of an exhibition and online, where the public will be encouraged to engage with the experience of hallucinations by completing an anonymous questionnaire. Attendees will also have the opportunity to complete an online questionnaire and give feedback on the exhibition. This will be used to further improve the presentation of the art pieces.

**7.5 Protocol compliance**

Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.
7.6 Data protection and patient confidentiality

The Data Custodian is the Chief Investigator.

Collection of identifiable information will be minimal; only the name and preferred method of communication will be recorded in a secure information system in accordance with Data Protection Policy of the Clinical School, University of Cambridge (https://www.medschl.cam.ac.uk/research/information-governance/sdhs-security-policy/). Only study team members with direct contact with participants will have access to this information. Consented audio recordings of discussions between participant and artist may contain identifiable information and will therefore also be secured stored under the same policy. Any use of extracts from these recordings will only be undertaken after anonymization.

Participants will be referred to by a code in all open correspondence between team members. The table linking participant’s identifiable data to their code will be securely stored.

All identifiable information will be deleted at the end of the study. Encrypted local documents will be deleted from study devices using appropriate data destruction software.

Long-term data storage and back-up of anonymous data will be on secure systems operated by the University of Cambridge. Both are secure access systems and are backed up automatically.

7.7 Indemnity

The University of Cambridge will provide public liability insurance for harm to participants arising from the design, management, or conduct of the research.

7.8 Access to the final study dataset

Final art pieces will be publically exhibited and displayed online.

On completion of the study and associated exhibitions, artworks will be auctioned and any funds raised donated to a charitable organisation.

The online questionnaire data will be made publically available through University of Cambridge resources in support of peer-reviewed publications.

8 DISSEMINATION POLICY

8.1 Dissemination policy

The study protocol will be published in an appropriate peer-reviewed journal.

The online questionnaire data will be published in peer-reviewed journals. The article without journal typesetting will be made available via the online display of the art pieces and in accordance with Open Access policy of the University of Cambridge (https://www.openaccess.cam.ac.uk/cambridge-open-access-policy).

Organisations funding the study will be acknowledged in publications, but will not review any documents prior to submission for peer-review.
Participants will be notified of the online display of artworks and of the dates and locations of the exhibitions. These communications will cease at the end of the study when identifiable data is deleted.

8.2 Authorship eligibility guidelines and any intended use of professional writers

The final study report will be authored by the Chief Investigator with agreement on content from all study team members.

Criteria for individually named authors on peer-review articles will conform to The International Committee of Medical Journal Editors criteria for manuscripts submitted for publication.