Arts-based Social Prescribing for Mental Health in Adults with Psychiatric Diagnoses. (AoP-II)

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Study Protocol

Organization's Unique Protocol ID: AoP-II

Brief Title: Arts-based Social Prescribing for Mental Health

Acronym: AoP-II

Study Type: Interventional

Official Title: Arts-based Social Prescribing for Mental Health in Adults With Psychiatric Diagnoses

Record Verification Date: August 2025

Study Start Date: September 2025, Anticipated

Primary Completion Date: January 2026, Anticipated

Study Completion Date: January 2026, Anticipated

Sponsors and Collaborators

Responsible Party, by Official Title: Sponsor

Name of the Sponsor: University Mental Health Research Institute, Athens, Greece

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Board Status: Submitted, approved

Approval Number: UMHRI session 7/15-10-2024

Board Name: Institutional Review Board; Epitropi Vioithikis kai Deontologias) of the UMHRI

Board Affiliation: UMHRI

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Study Description

Brief Summary

This is a parallel-group randomised-controlled trial aiming to assess the effect of exposure to the arts on mental health and wellbeing of community dwelling recipients of mental health care. The trial constitutes a comparison of two arms: An Art Intervention arm, hereby the Active Group (AG), versus a waitlist control arm (WL).

Detailed description

Design:

This is a randomised controlled trial with two arms: art intervention (any of the arts interventions, see below), which is hereby called Active Group (AG) vs waitlist control (WL). This is a new RCT that is based on a previous RCT performed in 2024 (NCT06361667). This trial has been approved by the Institutional Ethics Committee (Institutional Review Board; Epitropi Vioithikis kai Deontologias) of the UMHRI in Greece (UMHRI session 7/15-10-2024).

This trial will be conducted as part of the novel Arts on Prescription initiative of the Hellenic Ministry of Culture in Greece and at several Ministry-of-Culture-approved Organisations from the field of arts and culture. The University Mental Health, Neurosciences and Precision Medicine Research Institute 'COSTAS STEFANIS' (UMHRI) was commissioned by the Ministry of Culture to organize and conduct the RCT. In the beginning, an open invitation to institutions of culture and mental health has been sent. Cultural organizations presented their action plans for interventional courses. After quality control by the UMHRI and the Ministry of Culture. the following cultural organizations provided approved action plans: National Gallery - Alexandros Soutsos Museum, National Museum of Contemporary Art Athens, Athens Concert Hall Organization, Greek National Opera, Athens Conservatoire, Michael Cacoyannis Foundation, Stavros Niarchos Foundation Cultural Center (SNFCC), Nikolaos and Dolly Goulandris Foundation - Museum of Cycladic Art, Galilee Palliative Care Centre of the Holy Metropolis of Mesogaia and Lavreotiki, Archaeological Museum of Thessaloniki, Thessaloniki Concert Hall Organization, Metropolitan Organisation of Museums of Visual Arts of Thessaloniki (MOMus)", Kazantzakis Museum, Paul and Alexandra Canellopoulos Museum, National School of Dance (KSOT), Municipal Regional Theatre of Ioannina, National Theatre of Northern Greece, Drama International Short Film Festival (DISFF) Cultural Organization, and Heraklion Archaeological Museum.

AG consists of art intervention sessions that have been *a priori* developed by each cultural organization, specific to the field of each cultural organization (i.e., theatre, dance, visual arts, music, cinema). The intervention sessions have been elaborated and enhanced based on the previous experience of the NCT06361667 trial; specifically, the differences versus the NCT06361667 trial are the following: i. all Cultural Organizations are offering weekly sessions and there is no variability in the total number of sessions provided, ii. a larger sample is included in this trial to improve the precision of estimates and be able to detect smaller effect sizes (given the potential scalability and public health relevance of

the intervention, and iii. this trial includes Cultural Organizations and therefore patients beyond the metropolitan areas of Athens and Thessaloniki.

Participants will be randomly allocated to AG or WL for 12 weeks; that marks the end of the trial period. After completion of the 12-week trial, people who were included in the WL will have the opportunity to receive art on prescription by the Cultural Organizations the participated in the trial, should they wish to take this up.

Randomisation will be performed separately in each Cultural Organization and will be carried out using a computer-generated list provided centrally by SIBA Soft (Athens, Greece), an independent software and project management company.

Frequency of Measurement:

Data will be collected at baseline, including gender, age, educational level, marital status, socioeconomic characteristics, and mental health conditions. The primary and the secondary outcomes will be measured at time points:

- T0: (before the randomisation; and after informed consent and patient's sociodemographic data)
- T1: 6 weeks (after the start of the intervention for the AG group or the entry into the study for the WL group)
- T2: 12 weeks (after the start of the intervention for the AG group or the entry into the study for the WL group)

Interventional Model Description:

The duration of the RCT will be 12 weeks. The AG group will engage in different art forms (theatre, dance, visual arts, music, and cinema), whereas the WL group will remain in the waiting list.

The AG intervention will consist of sessions and/or performances in one of the five art forms: theatre, dance, visual arts, music and cinema. The number of sessions/performances will be 12 for all art forms over the duration of the trial, based on the specific features of each Cultural Organization.

The intervention activities in the AG group have been organized by each site and approved by the UMHRI and the Hellenic Ministry of Culture creating a space for 8-16 participants per activity.

The intervention consists of weekly visits over three months, featuring a guided tour followed by an art activity. All activities will include a discussion group, fostering reflection and connection, and each session will last approximately 1.5 to 2 hours. UMHRI and Ministry of Culture-approved, experienced professionals from the fields of mental health and arts, will lead the intervention sessions ensuring the safety and support of participants.

Statistical analysis model and sample size calculation

The standard practice for RCTs will be followed and a linear mixed effects model will be applied, with random intercepts to estimate the effects of treatment, time, with interaction terms for treatment (AG treatment) and time (6 and 12 weeks). The inference of interest for the study concerns the interaction term at week 12.

Assuming correlation coefficients equal to $r_{\_0\_6\_weeks} = 0.71$, $r_{\_0\_12\_weeks} = 0.65$ and $r_{\_6\_12\_weeks} = 0.69$ for the 0-6, 0-12 and 6-12 week intercorrelations, respectively, in the primary outcome values (PHQ-9), with a standard deviation of 5.60 at week 12 (numbers drawn from the results of the NCT06361667 trial) and a Cohen's d for the interaction term that is equal to 0.258 at week 12 for PHQ-9, at a type I error set at 5%, 205 participants per intervention arm would be needed for the achievement of 80% statistical power; importantly, assuming an anticipated 20% loss at follow-up rate, the total number required is 410/0.8, yielding 512 participants (256 participants by treatment arm). The power calculation was performed using the GLIMMPSE online statistical software (https://glimmpse.samplesizeshop.org/)

Sensitivity analyses will be carried out, including site as a fixed/random effects factor in the models. In case of missing longitudinal data, sensitivity analyses will be performed using maximum likelihood / Last Observation Carried Forward (LOCF) approaches.

Conditions

Mental Health Issue; Anxiety Disorders; Affective Disorders; Affective Disorders, Psychotic; Psychotic disorder; Adjustment Disorder; Autism Spectrum Disorder; Mild Cognitive Impairment; Depression Disorders; Schizophrenia Disorders

Keywords

Mental Health Issue; Anxiety Disorders; Affective Disorders; Affective Psychotic Disorders; Psychotic disorders; Adjustment Disorders; Autism Spectrum Disorders; Mild Cognitive Impairment; Depression; Schizophrenia; Non-affective psychotic disorders; Psychological and behavioural factors associated with disorders or diseases classified elsewhere (ICD-10 diagnosis code F54

Primary Purpose: Other

Study Phase: N/A

Interventional Study Model: Parallel

Number of Arms: 2

Masking: None (Open Label)

Allocation: Randomized

Enrollment – Number of Participants: 512

Type: Anticipated

Arms and Interventions

Arms	Intervention
Arm Title: Active Group (AG) Arm Type: Experimental Arm Description: This arm will receive the arts intervention (any of the arts interventions).	Intervention Type: Other Intervention Name: Art Prescription Other Intervention Names: Arts (theatre, dance, visual arts, music or cinema). Intervention Description: Any of the art interventions (theatre, dance, visual arts, music or cinema)
Arm Title: Waiting list Control (WL) Arm Type: No intervention Arm Description: This arm will remain in the waiting list during the 12-week period	No intervention

Primary Outcome Measure

Outcome Measure	Measure Description	Time Frame
The Patient Health Questionnaire-9 (PHQ-9)	The Patient Health Questionnaire-9 (PHQ-9) is a questionnaire which measures depression and grade severity of symptoms in general medical and mental health settings using nine DSM-5 criteria for major depression within the last two weeks. PHQ-9 was constructed in 2001 and has been validated in Greek in 2011, using a four-point Likert-type scale. After summing all responses (0=not at all, 3=nearly every day), scores range from 0 to 27, with higher levels indicating increased	From enrollment to the end of intervention at 12 weeks

Outcome Measure	Measure Description	Time Frame
	symptom severity (0-4 no to minimal; 5-9 mild; 10-14 moderate; 15-19 moderately severe; 20-27 severe). The reliability of the PHQ-9 was excellent, with a Cronbach's alpha of 0.89 in the PHQ Primary Care Study and 0.82 in the Greek validation study.	

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Generalised Anxiety Disorder Assessment (GAD-7)	The Generalised Anxiety Disorder Assessment (GAD-7) is provided to screen symptom severity for the four most common anxiety disorders (generalized anxiety disorder, panic disorder, social phobia and posttraumatic stress disorder). GAD-7 was constructed in 2006 and was validated in Greek in 2022. It consists of 7 items. The GAD-7 score is computed by assigning scores of 0, 1, 2, and 3, to the response categories of 'not at all', 'several days', 'more than half the days', and 'nearly every day', respectively, and summing together the scores for the seven questions (scores range from 0 to 21). Higher levels indicate increased anxiety. There are cut-offs for severity of anxiety as: (i) score 0-4: Minimal Anxiety; (ii) score 5-9: Mild Anxiety; (iii) score 10-14: Moderate Anxiety; (iv) score greater than 15: Severe Anxiety. The internal consistency of the GAD-7 has been excellent.	From enrollment to the end of intervention at 12 weeks
The Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)	The Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS). This tool was developed in 2007, in order to measure mental wellbeing in the general population. It consists of 14 items responding using a 5-point Likert scale from 1 (never) to 5 (all the time). The overall score is calculated by summing the responses for every item without reversing none. The minimum overall score ranges from 14 to 70. Higher scores indicate increased mental wellbeing. The scale has been widely used	From enrollment to the end of intervention at 12 weeks

Outcome Measure	Measure Description	Time Frame
	nationally and internationally for monitoring, evaluating projects and programmes and investigating the determinants of mental wellbeing. An efficient internal consistency was proven using Cronbach's alpha score which was 0.89 for the student sample and 0.91 for the general population sample. Also, test-retest reliability at one week was high (0.83). The Greek validation study showed acceptable internal consistency (Cronbach's alpha score 0.90).	
UCLA 3-item Loneliness Scale	The Revised UCLA Loneliness Scale-20 (UCLA-20) is a questionnaire which measures level of psychological loneliness experienced by a person. UCLA-20 was constructed in 1980 and was validated in Greek in 1992. The internal reliability of the UCLA-20 was excellent, with a Cronbach's alpha of 0.94 in the original study and and 0.89 in the Greek validation study. In 2004, this long scale was shortened to 3 questions (UCLA 3-item Loneliness Scale) in order to be used in large surveys. It is using a 3-point Likert-type scale (hard ever, some of the time, often). The scores can be added together to give a range of scores from 3 to 9. Higher scores mean most lonely (worse outcome).	From enrollment to the end of intervention at 12 weeks

Eligibility

Accepts Healthy Volunteers: No

Sex/Gender: All

Gender Based: No

Age Limits

Minimum Age: 18 years

Maximum Age: No Limit

Eligibility Criteria

Description

The study will be advertised to public and private mental health professionals across Greece, including those in public hospitals, day care centres, and non-governmental and non-profit organisations. Clinicians will then refer potential participants to the study.

Inclusion Criteria:

- Recipients of mental health care in the community, or private practice with an F-category ICD-10 diagnosis referred to the trial by their mental healthcare provider
- Age range: >=18 years
- Being able to communicate effectively in order to provide answers to questionnaires that he/she/they will be asked to complete
- Being able to participate in the activity alone (unaccompanied, without a carer)
- Being able to answer the questionnaires
- Having legal capacity to consent

Exclusion Criteria:

- Current substance abuse dependence,
- Current condition posing clinical risks (e.g. acute psychosis)
- Patients that are not compliant in following their medication plans,
- Patients that are not able attend due to severe physical, cognitive or other impairments
- Patients not "affiliated" with a mental health professional therapist.

Contacts and Locations

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Investigators

- Principal Investigator: Prof. Nikos Stefanis, MD, PhD, FRANZCP, The University Mental Health, Neurosciences and Precision Medicine Research Institute 'COSTAS STEFANIS' (UMHRI)

References

Anderson LR, Malikiosi-Loizos M. Reliability data for a Greek translation of the revised UCLA Loneliness Scale: Comparisons with data from the USA. Psychological Reports 1992;71: 665-666.

Carey EG, Isobel Ridler I, Ford TJ, Stringaris A. Editorial Perspective: When is a 'small effect' actually large and impactful? Journal of Child Psychology and Psychiatry 2023;64(11):1643–1647

Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606–613

Hughes ME, Waite LJ, Hawkley LC, Cacioppo JT. A Short Scale for Measuring Loneliness in Large Surveys: Results From Two Population-Based Studies. Res Aging. 2004;26(6):655-672.

Hyphantis T, Kotsis K, Voulgari PV, Tsifetaki N, Creed F, Drosos AA. Diagnostic accuracy, internal consistency, and convergent validity of the Greek version of the patient health questionnaire 9 in diagnosing depression in rheumatologic disorders. Arthritis Care Res (Hoboken). 2011 Sep;63(9):1313-21

Russel D, Peplau LA, Cutrona CE. (1980). The Revised UCLA Loneliness Scale: Concurrent and discriminant validity evidence, Journal of Personality and Social Psychology, 39, 472-480.

Spitzer RL, Kroenke K, Williams JB, et al; A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006 May 22;166(10):1092-7.

Vogazianos P, Motrico E, Domínguez-Salas S, Christoforou A, Hadjigeorgiou E. Validation of the generalized anxiety disorder screener (GAD-7) in Cypriot pregnant and postpartum women. BMC Pregnancy Childbirth. 2022 Nov 15;22(1):841.