Interactive group art therapy as an adjunctive treatment for people with schizophrenia

| Submission date 05/06/2006 | Recruitment status No longer recruiting | [X] Prospectively registered | | |
|-----------------------------------|--|------------------------------|--|--|
| | | [X] Protocol | | |
| Registration date 10/07/2006 | Overall study status Completed | Statistical analysis plan | | |
| | | [X] Results | | |
| Last Edited | Condition category | Individual participant data | | |
| 12/07/2016 | Mental and Behavioural Disorders | | | |

Plain English summary of protocol

Background and study aims

Schizophrenia is a severe mental illness that causes considerable distress and can damage other aspects of a person's life. People with schizophrenia often find it difficult to express themselves and their social functioning (their ability to look after themselves and get on with others) may also suffer. While medication can help to reduce these problems, many people continue to experience symptoms despite talking regular medication. Art therapy is a form of psychotherapy that may be particularly helpful for people who find it difficult to express themselves verbally. It is usually delivered in groups of up to eight people held weekly over a period of several months or years. Recent research has shown that group art therapy may improve the mental health of people with schizophrenia but studies have been too small to be sure whether it really makes a difference compared to other groups that are often used as part of the care that services usually provide. We would therefore like to carry out a larger study in which we examine the mental health, social functioning, and cost-effectiveness of art therapy for people with schizophrenia.

Who can participate?
Patients aged over 18 with schizophrenia

What does the study involve?

Participants are randomly allocated to receive either usual care, usual care plus a place in a weekly activity group, or usual care plus weekly group art therapy. Those allocated a place in the activity group or usual care are offered art therapy at the end of the study.

What are the possible benefits and risks of participating? This study will help us learn more about the forms of psychological intervention that help people with this important condition.

Where is the study run from? University College London (UK)

When is the study starting and how long is it expected to run for? November 2006 to October 2010 Who is funding the study? Health Technology Assessment Programme (UK)

Who is the main contact? Dr Helen Killaspy h.killaspy@medsch.ucl.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Helen Killaspy

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 04/39/04

Study information

Scientific Title

Interactive group art therapy as an adjunctive treatment for people with schizophrenia

Acronym

MATISSE

Study objectives

- 1. Among people with schizophrenia, adjunctive interactive group art therapy is associated with improved global functioning at 24 months compared to attention control treatment or standard care alone.
- 2. In the treatment of people with schizophrenia in secondary care settings, adjunctive

interactive group art therapy is more cost-effective than attention control treatment or standard care alone.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/043904 Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/51092/PRO-04-39-04.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 1 Research Ethics Committee (formerly Huntingdon Research Ethics Committee), 08/09/2006, ref: 06/Q0104/82

Study design

Three-arm parallel non-blinded randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

The trial has three arms. As well as the intervention group (group art therapy) there are two other arms: attention control and treatment as usual. The attention control includes activity groups which will function in terms of structure, number of facilitators and number of participants in a similar manner to the group art therapy i.e. they will run weekly for 90 minutes with eight members and two facilitators. They will involve any activity with the exception of anything that uses art or art materials e.g. outings, current affairs discussion, newspaper groups, games etc. The treatment-as-usual arm will have no specific intervention.

Intervention Type

Behavioural

Primary outcome measure

Global functioning assessed using the Global Assessment of Functioning Scale

Secondary outcome measures

- 1. Symptoms assessed using the Positive and Negative Syndrome Scale
- 2. Medication concordance will be assessed using the Morisky Scale
- 3. Quality of life will be assessed using Euroqol EQ-5D
- 4. Service costs will be assessed using the Client Service Receipt Inventory
- 5. Social function using the Social Function Schedule
- 6. Wellbeing will be assessed using the Psychological General Well Being Index
- 7. Satisfaction with services will be assessed using the Client Satisfaction Questionnaire
- 8. Engagement with services will be assessed using the Service Engagement Scale
- 9. Occupational and housing status
- 10. Adverse events

Overall study start date

01/11/2006

Completion date

31/10/2010

Eligibility

Key inclusion criteria

All those treated by secondary mental health services in the four study centres who are aged over 18 years and have a clinical diagnosis of schizophrenia, confirmed by an examination of case notes using operationalised criteria (OPCRIT), will be eligible to take part in the study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

376

Key exclusion criteria

- 1. Patients who are unwilling to provide written informed consent
- 2. Patients who speak insufficient English and are not able to complete baseline assessment
- 3. Have severe cognitive impairment
- 4. Are already receiving art therapy or any other art therapies (music therapy, drama therapy, or dance/ movement therapy)

Date of first enrolment

01/11/2006

Date of final enrolment

31/10/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University College London

London United Kingdom NW3 2PF

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

South Kensington Campus London United Kingdom SW7 2AZ

Sponsor type

Government

Website

http://www3.imperial.ac.uk/

ROR

https://ror.org/041kmwe10

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 27/08/2010 | | Yes | No |
| Results article | results | 28/02/2012 | | Yes | No |
| Results article | results | 01/08/2012 | | Yes | No |