

# Group art therapy as an adjunctive treatment for people with schizophrenia: a randomised controlled trial (MATISSE)

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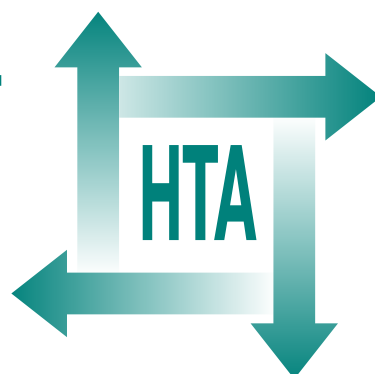


## Executive summary

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# Executive summary

## Background

Although pharmacotherapy can reduce the symptoms of schizophrenia, many people with this condition continue to experience poor mental health and social functioning. It has been argued that creative therapies could provide a complementary approach to improving mental health through helping people to express themselves, and develop self-awareness and insight. Group art therapy has been widely used as an adjunctive treatment for people with schizophrenia, but there have been few attempts to examine its clinical effects and cost-effectiveness has not been examined.

## Objectives

We undertook a pragmatic, randomised controlled trial (RCT), which was designed to achieve the following objectives:

- compare the effects of referral to group art therapy plus standard care with referral to an active control group plus standard care or to standard care alone on the mental health and global functioning of people with schizophrenia
- examine the impact of referral to weekly group art therapy on well-being, health-related quality of life (HRQoL) and satisfaction with care over a 24-month period
- examine whether or not any benefits associated with art therapy exceeded those associated with an active control group
- compare the costs and cost-effectiveness of group art therapy, active control treatment and standard care over a 2-year period.

## Methods

The study was a single-blind, parallel-group RCT of referral to group art therapy plus standard care, referral to an activity group plus standard care or standard care alone. Participants were randomised via an independent and remote telephone randomisation service using permuted blocks, stratified by site. The block size was randomly assigned between 3 and 6. Each participant within the block was randomly assigned to one of the three treatments in proportion to the size of the block. Participants and clinical staff were aware of to which arm of the trial participants were allocated, but all interviews were conducted by researchers masked to allocation status. Art therapy and activity groups were run on a weekly basis by a lead therapist and a co-facilitator and were made available to participants for an average of 12 months.

## Participants

Study participants were recruited from inpatient and community-based mental health and social care services at four centres in England and Northern Ireland. Participants were aged 18 years or over and had a clinical diagnosis of schizophrenia, confirmed by an examination of case notes using operationalised criteria. To take part in the study, potential participants had to be willing to take part in groups and to provide written informed consent. We excluded those with severe cognitive impairment, those who were unable to speak sufficient English to complete the baseline (BSL) assessment and those who were already attending art or other creative therapies.

### **Main outcome measures**

The primary outcomes for the study were global functioning [measured using the Global Assessment of Functioning Scale (GAF)] and symptoms of schizophrenia [measured using the Positive and Negative Syndrome Scale (PANSS)], assessed at 24 months. Secondary outcomes were global functioning and mental health symptoms measured at 12 months, as well as levels of group attendance, social functioning [measured using the Social Function Questionnaire (SFQ)], concordance with prescribed medication (measured using the Morisky Scale), satisfaction with care (measured using the Client Satisfaction Questionnaire), mental well-being (measured using the General Well-Being Scale), HRQoL [measured using the five-item EuroQol scale 'European Quality of Life-5 Dimensions' (EQ-5D)] and resource use (measured using a modified version of the Adult Service Use Schedule), assessed at 12 and 24 months after randomisation.

### **Study procedures**

Health- and social-care professionals, working on inpatient units or in community teams, day centres and rehabilitation and residential units, identified potential participants. Researchers and clinical studies officers of the UK Mental Health Research Network met those who had given verbal consent to be approached about the study, assessed eligibility, provided written and verbal information, and obtained written consent. Following completion of the BSL assessments, participants were then randomised. Participants, their key worker and their general practitioner were notified of allocation status by an independent administrator. The administrator simultaneously informed local art therapists or activity group facilitators of the participants' allocation status, so that arrangements could be made for the participants to receive their allocated intervention. Researchers involved in collecting follow-up data remained masked.

Those randomised to group art therapy were offered weekly sessions of 90 minutes' duration for an average of 12 months. Art therapy was conducted in keeping with recommendations of the British Association of Art Therapists. Control groups also took place on a weekly basis and were made available to participants for an average of 12 months. All lead facilitators had previous experience of working with people with psychosis in groups and all art therapy and activity groups were co-facilitated by another member of staff or volunteer. During the treatment phase of the trial, art therapists and activity group facilitators received local monthly group supervision from senior practitioners with relevant expertise who were not involved in delivering either intervention. Supervision sessions were audio-recorded and recordings reviewed by a senior member of the study team who provided feedback to supervisors regarding adherence to agreed guidelines about the delivery of both interventions. Standard care involved follow-up from secondary-care mental health services, care co-ordination, pharmacotherapy and the option of referral to other services. No restrictions were imposed on referral to other services, apart from arts therapies, which participants agreed not to use until the final follow-up assessment had been completed.

### **Statistical methods**

We calculated that, using a 5% significance level and a design effect of 2.22 (intraclass correlation coefficient = 0.175), we needed data on 300 patients to have 80% power to detect a clinically relevant improvement in GAF score of six points [standard deviation (SD) = 10] between treatments. In anticipation of a 20% dropout rate, we planned to recruit 376 participants.

All primary statistical analyses were conducted using the intention-to-treat principle. Differences in mean score between those randomised to each of the three arms of the trial were examined using analysis of covariance, adjusting for BSL value of the outcome, site, sex and age. A secondary analysis was performed using a multilevel model in order to take into account the clustering effect of the site. In another secondary analysis, we examined the impact of the uptake of the interventions on our primary outcomes using two-stage least squares estimates.

The health economic evaluation was conducted from a broad perspective, covering all health and social services received and productivity losses. Cost-effectiveness was assessed in terms of functioning using the GAF and quality-adjusted life-years using the EQ-5D measure of HRQoL. The cost-effectiveness and cost-utility of the art therapy intervention were explored through the calculation of incremental cost-effectiveness ratios – the difference in mean costs divided by the difference in mean effects. To explore the uncertainty that exists around the estimates of mean costs and effects as a result of sampling variation and uncertainty regarding the maximum cost-effectiveness ratio that a decision-maker would consider acceptable, cost-effectiveness acceptability curves are presented by plotting these probabilities for a range of possible values of the ceiling ratio.

## Results

Four hundred and seventeen participants were recruited to the trial between February 2007 and August 2008, of whom 140 were allocated to group art therapy, 140 were allocated to the activity group and 137 to standard care. Participants had a mean age of 41 years (SD = 12 years) and two-thirds ( $n = 279$ , 67%) were male. Eighty-six (61%) of those randomised to art therapy and 73 (52%) of those randomised to activity control groups attended at least one group. The median delay between randomisation and attending the first group was 61 days for art therapy and 61.5 days for an activity group. Forty-four (31%) of those randomised to group art therapy and 30 (21%) of those randomised to activity groups attended 10 or more groups. The number of participants per art therapy group ranged from zero to six (mean attendance = 2.4, SD = 1.1). The number of participants per activity group ranged from zero to nine (mean attendance = 2.1, SD = 0.9).

No differences in primary outcomes were found between trial arms. The adjusted mean difference between those randomised to art therapy and standard care alone was  $-0.9$  on the GAF Scale [95% confidence interval (CI) =  $-3.8$  to  $2.1$ ,  $p = 0.57$ ] and  $0.7$  on the PANSS Scale (95% CI =  $-3.1$  to  $4.6$ ,  $p = 0.71$ ). The adjusted mean difference between those randomised to art therapy and activity groups was  $-1.1$  on the GAF Scale (95% CI =  $-4.0$  to  $1.8$ ,  $p = 0.47$ ) and  $3.1$  on the PANSS Scale (95% CI =  $-0.7$  to  $6.9$ ,  $p = 0.11$ ). Differences in secondary outcomes at 12 and 24 months were not found, except that those who were referred to an activity group had fewer positive symptoms of schizophrenia at 24 months compared with those randomised to group art therapy. Instrumental variables analysis indicated that attendance at art therapy groups was not associated with improvements in global functioning or symptoms of schizophrenia.

The mean cost per participant over 24 months was £36,238 for those randomised to group art therapy, £43,795 for those randomised to activity groups and £37,447 for those who received standard care. Although the additional cost of the art and activity group interventions was small compared with the total cost of care provided, we did not find evidence to support the cost-effective use of referring people with schizophrenia to group art therapy.

## Conclusions

Levels of attendance at both art therapy and activity groups were low and this may have had an effect on their impact. However, we found no evidence that group art therapy, as delivered in this trial, improves global functioning or health outcomes of people with established schizophrenia or that it constitutes a cost-effective use of resources.

### **Implications for health care**

Although we cannot rule out the possibility that group art therapy benefits a minority of people who are highly motivated to use this treatment, our findings do not provide evidence to support the view that group art therapy leads to improved patient outcomes when offered to most people with schizophrenia.

### **Recommendations for research**

1. Data from exploratory trials of other creative therapies, including music therapy and body movement therapy, have shown promising results and randomised trials examining the clinical effectiveness and cost-effectiveness of offering these interventions to people with schizophrenia should be conducted.
2. Group art therapy has been used as an adjunctive treatment for people with a range of other mental disorders and the impact art therapy for people with these other disorders is also required.
3. The impact of adjunctive art therapy for inpatients with acute psychosis should be evaluated.
4. The impact of adjunctive art therapy and for those with recent-onset schizophrenia should be evaluated.

### **Trial registration**

This trial is registered as ISRCTN 46150447.

### **Funding**

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### **Publication**

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# NIHR Health Technology Assessment programme

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 04/39/04. The contractual start date was in November 2006. The draft report began editorial review in December 2010 and was accepted for publication in June 2011. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

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