NIHR HTA Programme

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The NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), based at the University of Southampton, manages evaluation research programmes and activities for the NIHR

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Protocol
Art Therapy
NIHR Health Technology Assessment 12/27/16

1. Title

Systematic review and cost effectiveness modelling of the clinical and cost-effectiveness of art therapy among people with non-psychotic mental disorders.

2. Project Team

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3. Brief project description

A systematic review, evidence synthesis and meta-analysis of quantitative and qualitative studies examining the clinical and/or cost-effectiveness of art therapy for non-psychotic mental health disorders.

3.1. Aims and objectives

i. To determine the relative clinical efficacy of art therapy compared with currently used packages of care for people with non-psychotic mental disorders. A full systematic review of the literature will be undertaken to provide evidence on efficacy.
ii. To provide a detailed user perspective on the acceptability and relative benefits and potential harms of art therapy, a second systematic review will be undertaken on the available qualitative research literature.
iii. To undertake a full synthesis of available evidence and generate probability distributions for uncertain parameters for use in an economic model.
iv. To undertake a full economic analysis. This will include a systematic review of published economic evaluations in the area and identification of other evidence needed to populate an economic model.

Cost effectiveness will be assessed in terms of the incremental cost per quality adjusted life year (QALY) gained from a probabilistic analyses. Uncertainty in the most cost-effective treatment will be illustrated using cost-effectiveness acceptability curves.

v. To determine the value of collecting further data on all or some of the input parameters, an expected value of information analysis will be performed.

4. Methods

4.1 Search strategy

A comprehensive and exhaustive literature search will be conducted to identify all relevant national and international studies of art therapy. The aims of the search strategy are to:

i. Use major health-related, and health economic electronic bibliographic databases;
ii. Consult via the internet with key health service organisations and guideline producing bodies;
iii. Consult national and international experts in research and clinical practice (both referring to and practising art therapy);
iv. Use patient and public involvement in a project advisory/steering group comprising the project team; and referring psychiatrists;
v. Search the UK Clinical Research Network Portfolio Database; archive of National Research Register, Current Controlled Trials (and its links: Clinical Trials.gov; HSRProj; and Index to Theses) to identify ongoing/recently completed research;
vi. Use existing systematic reviews to identify relevant studies;
vii. Identify Grey literature;
viii. Examine reference lists of included studies for further relevant references and, if appropriate, use the citation facility in Web of Science to search for specific papers/authors;
ix. Not restrict searches by language or date.

4.2 Inclusion/Exclusion Criteria

Studies examining art therapy as might be delivered in the NHS for non-psychotic mental health conditions will be included in the review. The inclusion/exclusion criteria are as follows:

Included interventions	Excluded interventions
Art therapy as might be delivered in the NHS	Art therapy combined with any other therapy (creative therapy= art and music therapy) Art therapy delivered by non-art therapists Accelerated Resolution Therapy (ART) Anti-retroviral therapy (ART) 'The Arts in Health' Movement

Included populations	Excluded populations
Adults or children Any non-psychotic mental health disorder including depression, anxiety, mood disorders, OCD, PTSD, fear of childbirth, cancer patients, stroke, dementia	Any psychotic mental illness, People without mental health problems

Included studies	Excluded studies
Randomised Controlled Trials	Non controlled studies including case series,

Controlled studies	cohort and retrospective studies

Setting: Any, although community is the main setting of interest.

4.3 Study selection

The aims of the process of study selection are to:

i. Use a three-line strategy to identify studies using wide ranging, multi-disciplinary databases, with sifting to examine title and abstract, then article full-text;
ii. Use complementary strategies of citation tracking, citation pearl growing to identify relevant related articles;
iii. Target Dissertation Abstracts and Index to Theses for qualitative research reports;
iv. Identify "sibling studies", e.g. process evaluations; and identify mixed methods studies blending quantitative and qualitative research within a common context to maximise external validity and;
v. Track studies through citation linkage from included Randomised Controlled Trials (RCTs) and follow-up of principal investigator web sites;
vi. Decisions on the final composition of included studies, assessed from a hard copy of the item, will be made by two reviewers with advice from clinical experts. The decisions will be coded and recorded on the Reference Manager database by the Project Manager. Data extraction will be undertaken independently, with discrepancies being discussed by the systematic reviewers. Those that cannot be resolved at this stage will be referred to the rest of the project team.

4.4 Sifting

i. Each study fitting the review criteria identified by the searches will be obtained.
ii. One assessor will assess the studies identified for inclusion according to specified inclusion criteria, focusing on the rigour and relevance of the study to the review questions.
iii. A second assessor will independently assess a sample comprising 20% of all identified studies. Sampling will be applied to ensure consistency across the major parameters of the studies (e.g. control/comparator; range of art therapy interventions). The second reviewer will also assess any studies whose inclusion status is ambiguous.
iv. Agreement on inclusion will be calculated using the kappa statistic. The full text of all studies of possible relevance will be obtained for assessment.
v. The opinion of a third reviewer will be sought if there is any disagreement regarding the quality of a trial.
vi. Where data are missing, reviewers will attempt to contact the author/s at their last known address.

4.5 Data extraction

The outcomes of interest for clinical effectiveness are:

1. Changes to mental health;

   Psychological symptoms (e.g., BDI, CORE, SDQ for children); quality of life; well-being; cost-effectiveness. Where possible, findings will be analysed by health condition, severity and duration, and whether the therapy was delivered by a trained art therapist.

2. Patient acceptability of treatment.

The review will also assess the quality of the quantitative and qualitative studies. Qualitative meta-synthesis will provide added value to the quantitative analysis by indicating patient issues around the acceptability of art therapy as a treatment for non-psychotic mental disorders. Data will be extracted using a standardised data extraction tool and double checked by a second reviewer.

A standard quality checklist will be used to appraise each included article (CRD report 4). Data on the quality and results of these studies will be summarised in tables of included studies.

Heterogeneity among the results will be explored. Where high levels of heterogeneity are found, sensitivity analyses will be used. A priori subgroup analyses will estimate the effect of intervention type (e.g. psychosocial and psychological), mode of intervention (e.g. group based vs. individual), onset of intervention (e.g. first-line psychotherapeutic intervention vs. last in a series of psychotherapeutic interventions), and sample selection criteria (e.g. patients with specific risk factors vs. general population). Other sources of heterogeneity may include: occupational and social functioning; social support; and the use of different rating scales.

4.6 Evidence Synthesis

a) Quantitative evidence synthesis

We will use network meta-analysis to allow a comprehensive synthesis and comparison of the relative effects of each intervention to a reference intervention (to be defined). The output from the network meta-analysis will include:

- Point estimates and 95% credible intervals for the relative effect of each intervention to a reference intervention
- A ranking of the interventions and an assessment of the probability that each intervention is the best
- A joint probability distribution for the effect of each intervention to represent uncertainty about uncertain inputs in the economic model

The model for the data will be a random effects model that acknowledges that each study is estimating a related but not identical intervention effect.

b) Qualitative evidence synthesis

We will include qualitative research which:

i. Examines patient acceptability from reports by people who have received art therapy interventions;
ii. Examines how patient acceptability may affect clinical effectiveness using data within trial reports or process evaluations and;
iii. Reports the acceptability of interventions to health care practitioners with data from separately conceived research or within trial reports.

Combining the quantitative and qualitative data

Methodological work to date has been unable to establish the superiority of conducting the qualitative and quantitative synthesis in parallel, or of conducting quantitative followed by qualitative, qualitative followed by quantitative or some more iterative approach. Our choice of method of combining data will therefore be determined by the needs of this particular review where the quantitative data is the main focus and the qualitative data is used for its explanatory potential in. We shall therefore use methods similar to those

described by Noyes (2008) to explore an effectiveness review in the light of supporting qualitative research data.

Variables initially identified from the meta-analysis will be explored qualitatively in an attempt to identify key moderating variables which may explain differences in the effect size of individual studies.

4.7 Cost-effectiveness modelling

i. Where appropriate, clinical effectiveness estimates will be obtained by meta-analysis of available evidence, and network meta-analyses, with the cost per QALY as the final outcome.
ii. Analysis will be conducted in accordance with the NICE reference case (NICE guidelines).
iii. Net benefit analysis will be used to identify the most cost-effective option at varying thresholds of willingness to pay.
iv. The optimal strategy at the threshold currently used by NICE for decision-making will be presented as the optimal strategy for the NHS.
v. The time frame for the model will be the lifetime of the patients, but sensitivity analysis will be used to explore uncertainty in estimates of long-term costs.
vi. The methodology used in the decision analytic model will be dependent on the data that are available and the number of health states that are necessary to incorporate, with the most appropriate technique selected.

5. Expected outputs

i. The project is registered on the PROSPERO international register of systematic reviews (registration no. CRD42013003957).
ii. We plan to disseminate findings in high profile journals; at national and international conferences; and to guideline development bodies.
iii. We aim to feed the results into curricula for professional education.
iv. If necessary, recommendations for the direction of future trials in art therapy will be made.

6. Approval by ethics committees

As the project is a synthesis of existing evidence and does not require primary data collection, no ethical approval is required.

7. Plain English abstract

Mental health problems account for almost half of all ill health in people under 65. The majority of these mental health problems are non-psychotic. This includes depression, anxiety, obsessive compulsive disorder, eating disorders and phobias. Despite the high prevalence of mental ill health disorders, only one quarter of people of those with mental health problems are in treatment. Currently The National Institute of Health and Clinical Excellence (NICE) recommend cognitive behavioural therapy (CBT) for most non-psychotic mental disorders and currently only recommend arts therapies for schizophrenia. However for some people, art therapies may provide more profound and long-lasting healing than more standard forms of treatment for mental health problems, such as CBT. This may be because they provide an alternative means of expression and release from trauma to talking therapies. Art therapy involves using painting, clay work and other creative, visual art as a form of non-verbal expression in a therapeutic setting. There is a small body of evidence to support the claim that art therapy is effective in treating a variety of symptoms, age groups, and disorders however to date there has not been a systematic review of the clinical and cost-effectiveness of art therapy in the NHS for non-psychotic mental disorders. This project aims to evaluate the current evidence

for art therapy in comparison with other packages of care for people with non-psychotic mental disorders in order to inform guidance for future use of art therapy in the NHS.