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Music in Mind

Submission date	Recruitment status	[_] Prospectively registered
18/10/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 4, 6th October 2010

Study information

Scientific Title
A randomised controlled trial measuring the effects of music therapy on the communicative skills of children and adolescents with behavioural and emotional problems and/or pervasive developmental disorders

Acronym
MiM

Study objectives
The null hypothesis for this research is that music therapy in addition to standard care will not lead to an improvement in communicative and interactional skills compared to standard care alone, as measured one week after completion of the music therapy course.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Office for Research Ethics Committees Northern Ireland (ORECNI) HSC REC1, 14/10/2010, ref: 10/NIR01/52

Study design
Multicentre single-blind 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Social, emotional or behavioural difficulties in paediatrics

Interventions
Participants will be randomly assigned to two groups. The interventions will be provided and monitored for 12 weeks.

1. Control group:
Clients assigned to the control group will receive standard care only, which will consist of psychiatric counselling and/or medication. The dose and frequency of standard care will be as deemed appropriate by the CAMHS professional in charge of their treatment.

2. Experimental group:
In addition to the standard care described above, clients assigned to the experimental group will receive psychodynamic improvisational music therapy in an individual setting. Music therapy will be conducted for 30 minutes once a week. A total of 12 sessions will be offered, with the aim of completing at least 10 sessions. In line with the intention-to-treat principle, clients who attend fewer sessions will not be excluded from data analysis.

The model of music therapy delivered will be the Alvin model of 'Free Improvisation' (Bruscia 1987). This is the model that is currently adopted by the Northern Ireland Music Therapy Trust in its work with young people with mental health difficulties. The music therapist(s) involved have been professionally trained in its use.

As with the control group, the dose and frequency of standard care will be as deemed appropriate by the CAMHS professional in charge of their treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The effect of music therapy upon communicative and interactional skills one week after completion of the music therapy course (parental and self report)

Secondary outcome measures
1. The effect of music therapy upon communicative and interactional skills 13 weeks after completion of the music therapy course (parental and self report)
2. The effect of music therapy upon self esteem one week and 13 weeks after completion of the music therapy course (self report)
3. The effect of music therapy upon social functioning one week and 13 weeks after completion of the music therapy course (parental report)
4. The effect of music therapy upon depression one week and 13 weeks after completion of the music therapy course (self report)
5. The effect of music therapy upon family functioning one week and 13 weeks after completion of the music therapy course (parental report)
6. The cost-effectiveness of music therapy

Overall study start date
01/08/2010

Completion date
28/02/2014

Eligibility

Key inclusion criteria
1. Young people aged between 8 and 16 years old, either sex
2. Working diagnosis within the ambit of the International Classification of Diseases, version 10 (ICD-10) of Mental and Behavioural Disorders (F00 - F99) as assessed within the Trust and/or by the Child and Adolescent Mental Health Services (CAMHS) professional in charge of their care.

This includes disorders falling within the following classifications:
2.1. Mood (affective) disorders (F30 - F39), e.g., depression
2.2. Neurotic, stress related and somatoform disorders (F40 - 48), e.g., anxiety disorders, obsessive compulsive disorder and posttraumatic stress disorder
2.3. Disorders of psychological development (F80 - F89), e.g., pervasive developmental disorder (autism spectrum disorders)
2.4. Behavioural and emotional disorders with onset usually occurring in childhood and adolescence (F90 - 98), e.g., hyperkinetic disorders and conduct disorders
3. Recruited from the CAMH Service of the Belfast Health and Social Care Trust, Northern Ireland
4. Musical skills are not required. Prior musical skills will not lead to exclusion from the study.
5. The young person and their parent/guardian (who will also be asked to participate in the research) must freely consent to participation following receipt of information about the trial

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Chronic and severe substance abuse: problems related to addiction lie outside the aims of this study. Moreover, substance abuse is likely to compromise concentration during sessions, and commitment to completing the therapeutic regime.
2. Psychosis: a secondary diagnosis of psychosis would presume a requirement for care additional to standard care
3. Repeated suicidal behaviour: a history of suicidal behaviour would presume a requirement for care additional to standard care
4. Incapacity to complete self-administered questionnaires with assistance from researcher: patients who, due to a learning disability as identified in a statement of educational needs, or who are unable to adequately understand written or verbal English, are deemed incapable of completing the self-reporting tests will not be included in the study
5. Receiving any other treatments or therapies outside of standard care which may interfere with Music in Mind. Patients who are in receipt of another creative therapy.
6. Inability to attend music therapy sessions at a Tier 3 facility: if circumstances of the client or parent/guardian are such that they will be unable to attend for trial visits or music therapy sessions (if randomised to treatment group) they will be excluded from the trial
7. Previously involved in Music in Mind. Young people who have previously been randomised for participation in Music in Mind are not eligible to be recruited at a later stage.
8. Non-consent: participants who decide not to consent, or whose parents/guardians decide not

to consent will be excluded from the trial. These will be assured that this decision will have no implications for the care that they receive. The provision of music therapy in addition to standard care will be available to them if a clinical decision is made that this is appropriate.

Date of first enrolment
01/08/2010

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Queen's University Belfast
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BT9 5BN

Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.qub.ac.uk/

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Charity

Funder Name
Big Lottery Fund (ref: C984A1530)

Alternative Name(s)
BIG

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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	01/10/2012		Yes	No
Results article	results	01/05/2017		Yes	No