

Music in Mind

Submission date 18/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 31/10/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

16 years

Sex

All

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**

United Kingdom

Northern Ireland

Study participating centre
Queen's University Belfast
Belfast
United Kingdom
BT9 5BN

Sponsor information

Organisation
Queen's University Belfast (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

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?
Results article	results	01/05/2017		Yes	No
Protocol article	protocol	01/10/2012		Yes	No