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The effect of oriental medicine music therapy on "hwa-byung" patients

Submission date	Recruitment status	[_] Prospectively registered
27/07/2011	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/09/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/09/2016	Mental and Behavioural Disorders	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hwa-byung is a Korean syndrome, also known as anger syndrome. Angry feelings should be vented properly, but blocked feelings are accumulated in the patient's mind. These blocked emotions cause hwa-byung. The most common feelings causing hwa-byung are vexation, mortification, regret or feeling victimized or otherwise mistreated. The source of the stress is feeling like they are victims in their daily life. It is usually associated with a stressful relationship, especially between a housewife and her mother-in-law and/or husband. Most hwa-byung patients are middle-aged or older women. Hwa-byung includes various symptoms, especially a sensation of heat in the body (including hot flushes, redness of the face, and sensitivity to hot environments), a feeling of tension in the chest, palpitation/heart-pounding, respiratory stuffiness/oppression, dry mouth, insomnia and anorexia. Oriental Medicine Music Therapy is a kind of performance that goes beyond listening to the music. During the treatment session, participants create sounds with their own voice or musical instruments like drums, maracas, hand-bells, etc. These performances can relax the hwa-byung patient's mind and body, reducing symptoms of hwa-byung. The aim of this study is to assess the effect of Oriental Medicine Music Therapy on hwa-byung patients.

Who can participate?
People aged over 20 diagnosed with hwa-byung

What does the study involve?
Participants are randomly allocated to receive either Oriental Medicine Music Therapy or placebo (dummy) music therapy. Participants receive the treatment two times per week for 4 weeks. That makes a total of eight sessions. A series of questionnaires is given before the first treatment and the last treatment. After the treatment phase, participants are followed up for 4 weeks.

What are the possible benefits and risks of participating?
This study hopes to demonstrate the effectiveness of Oriental Medicine Music Therapy and help patients find relief from their symptoms. There are no anticipated medical risks or potential

drawbacks to patients. The participants receive Oriental Medicine Music Therapy for free. If the participants receiving placebo music therapy want to have Oriental Medicine Music Therapy session, it will be given for free after the study. All laboratory test fees are waived.

Where is the study run from?
Hwa-byung Stress Clinic at Gangdong Kyung Hee University (South Korea)

When is the study starting and how long is it expected to run for?
April 2011 to December 2012

Who is funding the study?
Korean Health Industry Development Institute (KHIDI) (South Korea)

Who is the main contact?
Dr Ko Seoung-Gyu

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CCRG_2011_Music

Study information

Scientific Title
The effect of Oriental medicine Music THerapy on "hwa-byung" patients: a randomized double-blind parallel-group trial

Acronym
MuTH

Study objectives
Oriental medicine music therapy will be more effective than placebo music therapy: Improved State-Trait Anxiety Inventory (STAI) score.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB of Kyung Hee University Gangdong, 01/04/2011, ref: KHNMC-OH-IRB 2010-014

Study design
Randomized double-blind parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Hwa-byung (anger syndrome)

Interventions
1. Oriental medicine music therapy (active music therapy) and placebo music therapy
2. Treatment: 2 sessions/week
3. Duration: 4 weeks
4. Followed up for 4 weeks

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
State-Trait Anxiety Inventory (STAI), measured at Visit 2 (Day 1, their first treatment session), Visit 9 (Day 25, their last treatment session), and Visit 10 (Day 53, the follow-up)

Secondary outcome measures
1. Hwa-byung scale
2. The Center for Epidemiologic Studies Depression Scale (CES-D)
3. State-Trait Anger Expression Inventory (STAXI)
4. Hwa-byung primary symptoms Visual Analogue Scale (VAS)
5. World Health Organization Quality of Life (WHOQOL-BREF)
6. Salivary cortisol
Measured at Visit 2 (Day 1, their first treatment session), Visit 9 (Day 25, their last treatment session), and Visit 10 (Day 53, the follow-up).

Overall study start date
06/04/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Male or female over 20
2. Diagnosed as hwa-byung using hwa-byung Structured Clinical Interview (SCID) for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)
3. Written informed consent form taken
4. Has no problems with communication (reading, writing, listening, speaking, etc.)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
48 (Oriental Medicine Music Therapy 24, Placebo Music Therapy 24)

Key exclusion criteria
1. In need of regular medication or psychotherapy
2. Has a severe neuro- or psychiatric disorder
3. Has a history of major neuro-psychiatric disorder (autism, learning disorder, mental retardation etc.)
3. Had a change in medication of anti-depressant or barbiturate in the past one month
4. Seriously irritable patient
5. Participated in any other clinical trial in the past 1 month from the screening day
6. Had a regular mind-body relaxation training in the past 1 year, music therapy, qigong, yoga, and meditation
7. Cannot understand written informed consent form or follow this study
8. Mental retardation and mental or emotional problems.

Date of first enrolment
06/04/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Korea, South

Study participating centre
Kyung Hee University
Seoul
Korea, South
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Sponsor information

Organisation
Korea Health Industry Development Institute (Korea, South)

Sponsor details
643 Yeonje-ri
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Sponsor type
Industry

Website
http://www.khidi.or.kr/

ROR
https://ror.org/00fdzyk40

Funder(s)

Funder type
Industry

Funder Name
Korea Health Industry Development Institute (Korea, South)

Alternative Name(s)
KHIDI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Korea, South

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	11/09/2012		Yes	No