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A pilot study to evaluate the effect of TWO kinds of MEditation programs on Hwa-byung patients

Submission date
02/06/2012

Recruitment status
No longer recruiting

Registration date
21/06/2012

Overall study status
Completed

Last Edited
29/09/2014

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hwa-byung is a Korean culture-bound syndrome, known as anger syndrome. Angry feelings should be vented properly, but blocked feelings accumulating in the patients mind become injurious emotions. These blocked emotions, such as stress, angeror anxiety, cause hwa-byung. Hwa-byung has various symptoms, including 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, palpitations, pounding heart, respiratory stuffiness/oppression, masses in the epigastrium or chest, dry mouth, insomnia, and lack of appetite. Metta is usually translated in English as loving-kindness. It means love, not limited to the specific one, but expanded to all independent of all self-interest. It includes friendship, non-violence, and a strong wish for the happiness of others. Metta meditation is a kind of sitting or walking meditation, based on Buddhist practice. It consists of loving-kindness meditation, comparison meditation, and compassionate mind training. The aim of this study is to evaluate the effect of two kinds of meditation programs on Hwa-byung patients.

Who can participate?
Men and women between 20 and 65 years of age who have been diagnosed as Hwa-byung can participate in this trial.

What does the study involve?
Participants will be randomly allocated to Metta meditation or basic meditation. Participants will have eight one-hour sessions of meditations, one session per one week for eight weeks in total. The metta meditation in this study will be a sitting form. At the beginning, participants will take a few minutes to quiet mind and body. Next, he/she will recite some phrases to himself/herself. There are no physical activities during the session.

What are the possible benefits and risks of participating?
The investigators hope that metta meditation may improve the participants symptoms, but they cannot guarantee the effectiveness. There are no financial benefits for the participants. Metta meditation does not involve physical activity so the risks of participating will be few.

When is study starting and how long is it expected to run for?
The study starts in March 2012 and will end in December 2012.

Who is funding the study?
Korea Health Industry Development Institute (Republic of Korea).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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134-727

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CCRG_2011_Meditation

Study information

Scientific Title
A randomized controlled, open-labelled, single-center, 8-week pilot study to assess the effectiveness of TWO kinds of MEditation programs on the emotions of Hwa-byung patients

Acronym
TwoMe

Study objectives
The primary aim of this study is to evaluate the effect of two kinds of meditation programs on Hwa-byung patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB of Kyung Hee University Gangdong, 01/02/2012, ref: KHNMC-OH-IRB 2011-011

Study design
Randomized double-blind parallel-group 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Hwa-byung (anger syndrome)

Interventions
1. Metta meditation or basic meditation
2. Treatment: one session/week
3. Duration: 8 weeks
4. Followed up for 4 weeks

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Hwa-byung symptoms scale at baseline (before the treatment) and post treatment (after eight sessions of treatment).

Secondary outcome measures
1. State-Trait Anger Expression Inventory (STAXI) (only 20 items in state anger and trait anger)
2. Hospital Anxiety and Depression Scale of Korea (HAD)
3. Korean version of Mindfulness Attention Awareness Scale (K-MAAS)

4. Korean version of Difficulties in Emotion Regulation Scale (K-DERS)
5. Self-Compassion Scale (SCS)
6. Acceptance and Action Questionnaire (AAQ)

Measured at baseline (before the treatment) and post treatment (after eight sessions of treatment).

Overall study start date
01/02/2012

Completion date
01/09/2012

Eligibility

Key inclusion criteria
1. Male or female from 20 to 65 years old
2. Diagnosed as hwa-byung using hwa-byung SCID (Structured Clinical Interview for DSM-W)
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
40 (metta meditation 20, basic meditation 20)

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

Date of first enrolment
01/02/2012

Date of final enrolment

01/09/2012

Locations

Countries of recruitment
Korea, South

Study participating centre
Kyung Hee University Gangdong Oriental Medical Center
Seoul
Korea, South
134-727

Sponsor information

Organisation
Korea Health Industry Development Institute (Korea, South)

Sponsor details
643 Yeonje-ri
Gangoe-myeon
Cheongwon-gun
Chuncheongbukdo
Korea, South
363-951

Sponsor type
Industry

Website
http://www.khidi.or.kr/eng/index.jsp

ROR
https://ror.org/00fdzyk40

Funder(s)

Funder type
Research organisation

Funder Name
Korea Health Industry Development Institute (Korea)

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