

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

<b>Submission date</b> 02/06/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/06/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/09/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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, anger or 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?  
Dr Jong-Woo Kim  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Jong-Woo Kim

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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 MEdition 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