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Effectiveness of mind-body meditation approach on improvement of mental and physical health of people with cardiovascular disease and risk factors

Submission date
04/08/2013

Recruitment status
No longer recruiting

Registration date
09/08/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are interested in finding out about what affects peoples health. We know from previous studies that taking part in certain leisure activities, such as Taichi, singing, playing a musical instrument or dancing, may help people feel better, but there are many things we still dont know, for example what kind of people benefit from what activities. In this study we want to see if we can find out more about this.

Who can participate?
People who are 35 years or above and who live in the participating area can participate in the study. People should have responded to the preliminary information about the project.

What does the study involve?
Participants will be randomly allocated to one of two groups: the intervention or the control group. If you belong to the intervention group, you will be asked to complete and return a questionnaire asking for a few personal details. You will then be invited to participate in a Taichi group. The Taichi group will meet weekly for 24 weeks. During this time we will ask you to fill in three short questionnaires about your health and return them to us by post in a pre-paid envelope. We will also measure your height, weight, blood pressure and blood cholesterol and sugar level. We will ask you to do this at the start of the research, then 6 months later (at the end of the Taichi group sessions) and a further 6 months after that. We may also ask if we can talk to you on the telephone or at a place convenient to you around the third time you fill in the questionnaires. This will allow you to tell us about your health in your own words and what you think about any activities you have taken part in. This will be tape recorded only if you agree and the tapes will be erased following transcription of your comments. After the final questionnaires have been completed, everyone will be able to join a Taichi group if they wish. If you belong to the control group, you will be given a booklet that contains advice about healthy eating and support.

What are the possible benefits and risks of participating?
The research will help us to understand whether particular activities help people with heart diseases feel better and to know who benefits the most. This means that in future, individuals can be referred by professionals to the right sort of activities to help improve their health. There are no risks of participating in the project.

Where is the study run from?
The study will be conducted in Fangshan District, Beijing, Changshu City, and SooChow City, in China; In Australia study sites, this will include Brisbane, Gold Coast, and Ipswich in Queensland.

When is the study starting and how long is it expected to run for?
The study started in October 2012 and it is expected to run for 18 months until April 2014.

Who is funding the study?
This study is funded by Griffith University in Australia, Jiangsu Provincial Center for Disease Control and Prevention, Nanjing, China; Changshu Center for Disease Control and Prevention, Changshu, China; and Fangshan District Center for Disease Control and Prevention, Beijing, China.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Effectiveness of mind-body meditation approach on improvement of mental and physical health of people with cardiovascular disease and risk factors: a randomised controlled trial

Study objectives
The hypotheses of this study are:
1. Intervention programs using mind-body meditative approach, will result in greater improvement than usual care in symptoms of cardiovascular disease, perceptions of illness, exercise tolerance, quality of life and reductions to readmission to hospital.
2. The interventions are feasible to implement for patients with cardiovascular diseases.
3. The interventions are a cost-effective use of health care resources.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Griffith University Human Ethics Committee, Australia
2. Gold Coast Health District Human Ethics Committee, Australia.
3. China Beijing Fangshan CDC and Changshu CDC research boards have approved the study protocol.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Primary health care and secondary prevention

Interventions
Participants wil be randomized to: intervention (n=750) and control (n=750). Participants in all intervention and control groups will attend community centres in China and Gold Coast in

Australia. This will be arranged with China Fangshan District Center for Disease Control and Prevention and Changshu Center for Disease Control and Prevention, and Gold Coast Hospital Program Team leader.

Group 1: The therapeutic singing intervention: Singing groups will be facilitated by skilled and experienced vocal training musicians. The facilitators recruited will undergo a five-day training course and will meet regularly throughout the project to ensure a standardized and consistent approach. The singing program will take place in the sing group in each research site over two twelve-week blocks. The group will come together at the end of each
block for a choral workshop and performance event. Each session will last about 120 minutes, with 30 minutes break for socialising during the singing session. Sessions will commence with 30 minutes of relaxation, posture, breathing and vocal exercises followed by 30 minutes of singing, 30 minutes socialising, then 30 minutes singing. A wide repertoire of familiar and new songs will be available in a high quality song book. Participants will also steer the musical direction of their group according to their interests. Keeping the programme fresh, enjoyable, stimulating and challenging is essential for a
project planned to run over one year. Songs will be taught by ear and will be sung without accompaniment. Participants will also receive specially prepared CDs of exercises and songs to practice at home at the start of each block of sessions. A partner, friend or family member of the person with CVD recruited into the singing groups may also attend the groups to provide support.
Group 2: Therapeutic Taichi: TC groups will be led by skilled and qualified TC instructor. The TC program will take place in the two groups in each site over two twelve-week blocks. Each session will last for 90 minutes with 30 minutes break for socialising. The principles of TC will be used in the management of hypertension, functional status, quality of life and cholesterol levels. These interventions conform to approaches adopted in other studies (13, 23, 24).
Group 3: Dancing. The same procedure as the Taichi Group
Group 4: Music instrument. The same procedure as the Tai Chi group.
Control group: The booklet Secondary Prevention Program: A National Heart Foundation of Australia will be used to inform participants in Australia of key risk factors and to guide the secondary prevention protocols for the control group. The main sections are: a) Medications b) Smoking c) Exercise d) Healthy eating e) Stress and f) Community support. A translation of the booklet (with permission from NHFA) will be used for Chinese sites. Participants at target sites will receive booklets from practitioners who will discuss the contents with them and use the booklet to guide them.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary outcome measures will be recorded by the research coordinator. These measurements will be taken at three points: Baseline, 6 months after intervention, one year after intervention.
1. Current medications names and dose.
2. Blood pressure
3. Total serum cholesterol (TC), HDL-C and LDL-C levels
4. Height in cm/weight in kg/BMI/waist circumference in cm/waist hip ratio

5. Number of patients surviving during the study period
6. Number of hospital readmissions during the 12 months after entry to the program
7. Number of days spent in hospital during the 12 months after entry to the program

Secondary outcome measures
Secondary outcome measures: The following measurements will be collected at baseline and at the final therapeutic singing and TC class, after 6 months of intervention, and follow up 3 months after interventions finish.
1. Exercise capacity as measured by the 6 minute walking test where patients walk at maximum effort and speed for 6 minutes. This test is of use with all ages, particularly older cardiac patients. It is reliable, especially in patients with heart failure.
2. Symptoms assessment: Minnesota Living with Heart Failure Questionnaire (LIhFE). The LihFE is a valid, reliable and responsive instrument of 21 items, and suitable for both asymptomatic and symptomatic CVD patients.
3. Quality of Life after Myocardial Infarction Questionnaire (QLMI), The QLMI contains subscales measuring physical symptoms and restrictions (the Limitations domain) and emotional function, confidence and self-esteem (the Emotions domain). It is reported to be a valid, reliable and responsive specific HRQL instrument. Developed in Canada, it has recently been modified and validated for use in Australia as the MacNew Quality of Life after MI Questionnaire.
4. EQ-5D: a 5-item health status questionnaire which provides health utility scores, widely used in health economic assessments of health interventions.

Overall study start date
01/09/2012

Completion date
01/03/2014

Eligibility

Key inclusion criteria
People who aged 35 and more, and with one of the following risk factors: obesity, metabolic syndrome, hypertension, abnormal cholesterol and fasting glucose.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2500

Key exclusion criteria
People with severe neurological impairments, psychosis, severe cardiovascular disease including heart failure and stroke will be excluded.

Date of first enrolment
01/09/2012

Date of final enrolment
01/03/2014

Locations

Countries of recruitment
Australia

China

Study participating centre
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Sponsor information

Organisation
Griffith University (Australia)

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Sponsor type
University/education

ROR
https://ror.org/02sc3r913

Funder(s)

Funder type
Government

Funder Name
Changshu Centre for Disease Control (CDC) and Fangshan District CDC (China)

Funder Name
Griffith University (Australia)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Australia

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?
Results article	results	01/10/2015	17/12/2020	Yes	No