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How does training in mindfulness meditation effect the brain structure and cognition?

Submission date	Recruitment status	[ ] Prospectively registered
23/11/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/05/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/05/2011	Other	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
25931/26960

Study information

Scientific Title
A randomised controlled trial using MRI scans and cognitive testing to determine the effect of meditation on brain structure and cognition

Study objectives
We will examine whether there is a causal relationship between meditation practice and the brain anatomy as well as number of physiological and cognitive parameters.
We are testing multiple hypotheses of training novices for 6 weeks, however our main hypotheses are:
1. Signifigant pre-frontal (IFG) and insular cortex density increase for meditation group (MG) measured by MRI.
2. Significant decrease in default mode network connectivity, correlated with increased insular density and improved self-regulation (stop accuracy) and error awareness
3. Signifigantly increased emotional stroop effect, with greater insula response to emotional distractors yet increased stroop accuracy

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Local Ethics Committee on clinical research approved on the 23rd of August 2010 (ref: 25931 /26960)

Study design
Single centre randomised wait list controlled 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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Meditation practice

Interventions
1. We studied normal subjects with no prior meditation, or related training undergoing intensive meditation training based on a set of breathing exercises and mindfulness techniques
2. We included 60 university students of which 30 randomly chosen subjects will practice daily 20 minutes for 6 weeks
3. The other 30 subjects (will be the waitlist for meditation training) will act as a control group to

check for i.e. training effects in the cognitive tests by being a reading group with same frequency of training and focusing on the narrative content only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Pre-frontal (IFG) and insular cortex density measured by MRI at baseline and 6 weeks

Secondary outcome measures
Measured at baseline and 6 weeks:
1. Default-mode network connectivity
2. Stop accuracy and error awareness
3. Emotional stroop

Overall study start date
03/12/2010

Completion date
01/03/2011

Eligibility

Key inclusion criteria
1. Either sex, aged 18-40 years, ethnic Danes
2. Right handed
3. Health subjects with no history of neurological disorders, psychological and/or psychiatric, cardiovascular or respiratory diseases, brain injury, cancer, addiction to drugs/alcohol, severe impediment to limb movement, hearing and vision
4. Normal MRI brain scan

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Both

Target number of participants

60

Key exclusion criteria
1. Frequent diving, high altitude climbing or flying or other activities related to the respiratory system
2. Recent biofeedback training, hypnosis and acupuncture (due to the possible modulating of the vagal output)

Date of first enrolment
03/12/2010

Date of final enrolment
01/03/2011

Locations

Countries of recruitment
Denmark

Study participating centre
Center for Functionally Integrative Neuroscience
Aarhus
Denmark
8000

Sponsor information

Organisation
Aarhus University (Denmark)

Sponsor details
Center for Functionally Integrative Neuroscience
Norrebrogade 44
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8000

Sponsor type
University/education

ROR
https://ror.org/01aj84f44

Funder(s)

Funder type
Government

Funder Name
Ministry of Health (Denmark)

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