

Meditation for school children

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|----------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| Submission date 04/07/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 12/07/2016 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 11/07/2016 | Condition category 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

Childhood is considered by many to be a time of happiness and being carefree, without the stress of bills to pay or job to keep. However, even very young children can have worries and may experience stress to some degree. This can be due to the demands of school or social activities, extracurricular activities and feeling worried about world events that they see on the news. Sahaja Yoga Meditation is a technique that can lead to better health and sense of well-being. It is said to help decrease stress and anxiety, strengthen the immune system and improve concentration, amongst other things. This study aims to provide children with meditation skills to better equip them to cope with stress and manage their emotions both at school and at home.

Who can participate?

Primary school aged children

What does the study involve?

Children are placed into one of three groups. Those in group 1 are taught Sahaja Yoga Meditation via face-to-face instruction in 20 minute sessions three times a week. Those in group 2 are taught Sahaja Yoga Meditation via video instruction in 5-10 minute sessions, 3-5 days a week. Those in group 3 are not taught Sahaja Yoga Meditation. The mental health of all children taking part is assessed by questionnaire at the start of the study and after 30 weeks.

What are the possible benefits and risks of participating?

The possible benefits of this study are that the child will learn a simple skill of reducing stress and improving emotional well-being that they can use regularly or at times when they are experiencing difficulty. It is hoped that by using this skill their long term risk of developing a mental health problem will be reduced. The researchers do not foresee any risks associated with taking part.

Where is the study run from?

Two primary schools in Australia.

When is the study starting and how long is it expected to run for?

October 2011 to December 2016

Who is funding the study?
Sydney University (Australia)

Who is the main contact?
Dr Ramesh Manocha

Contact information

Type(s)
Public

Contact name
Dr Ramesh Manocha

Contact details
88 Wentworth Road
Burwood
Australia
2134

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Assessment of meditation for enhancement of mental health and well-being of school aged children

Study objectives
Regular meditation delivered within the school environment enhances mental health and well-being of school aged children

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sydney University Human Research Ethics Committee, 28/10/2011, ref: 14118

Study design
Multi-centre non-randomised interventional trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

General well-being and mental health risk

Interventions

In this study, primary school children will participate in a controlled trial. They will be placed into one of three groups:

1. Face to face meditation instruction, based on sahaja yoga, delivered in class time (three times per week for ~20 minutes each time)
2. Video meditation instruction, based on sahaja yoga delivered in class time (three to five times per week for ~5-10 minutes each time)
3. No treatment (control)

Mental health will be assessed at baseline and after 30 weeks using the Strengths and Difficulties Questionnaire. The duration will be determined by each participating school, aiming for a minimum of one semester. Follow-up assessment is not anticipated due to practical challenges.

Intervention Type

Behavioural

Primary outcome measure

Changes in mental health, assessed using the Strengths and Difficulties Questionnaire at baseline and after 30 weeks

Secondary outcome measures

1. Drop out rates
2. Qualitative feedback regarding acceptability and feasibility of the intervention

Overall study start date

28/10/2011

Completion date

31/12/2016

Eligibility

Key inclusion criteria

Primary school aged children

Participant type(s)

Healthy volunteer

Age group

Child

Sex

Both

Target number of participants

200

Key exclusion criteria

1. No current/ previous history severe mental illness/disability
2. No condition that may prevent comprehension and engagement with behavioural intervention being studied

Date of first enrolment

28/10/2011

Date of final enrolment

31/12/2016

Locations**Countries of recruitment**

Australia

Study participating centre

Ashfield Primary School

Sydney

Australia

2131

Study participating centre

Toorak Primary School

Melbourne

Australia

3142

Sponsor information

Organisation

Department of Psychiatry, Sydney University

Sponsor details

Northern Clinical School
Royal North Shore Hospital
St Lenoards
Australia
2065

Sponsor type

University/education

ROR

<https://ror.org/0384j8v12>

Funder(s)**Funder type**

University/education

Funder Name

Sydney University

Results and Publications**Publication and dissemination plan**

Peer-reviewed journals

Intention to publish date

01/01/2016

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Stored in repository