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Yoga and cardiovascular health trial

Submission date
12/12/2017

Recruitment status
No longer recruiting

Registration date
05/03/2018

Overall study status
Completed

Last Edited
20/01/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Cardiac rehabilitation programmes aim to help patients to recover after a heart attack by improving physical fitness, reducing stress levels and encouraging positive lifestyle changes (such as healthy eating, smoking cessation and increasing physical activity). Yoga is also known to help improve physical fitness, reduce stress and bring about positive lifestyle changes. Many people believe that yoga directly improves heart health but there is no convincing evidence of this. The aim of this study is to compare a standard cardiac rehabilitation programme with a programme of yoga training in addition to the usual cardiac rehabilitation programme to find out whether yoga has an additional beneficial effect on the heart and blood vessels and if so, the ways in which it does so.

Who can participate?
Patients aged 35-80 referred to cardiac rehabilitation programmes after angioplasty, coronary artery bypass grafting or medical management as treatment for an acute coronary syndrome

What does the study involve?
Participants are randomly allocated to receive either usual care or to attend a programme of yoga classes plus usual care. The yoga intervention is delivered on a bi-weekly group session basis for 12 weeks alongside the usual cardiac rehabilitation programme. There are 24 yoga classes in total, of which each participant is required to attend a minimum of 18. Participants' partners are invited to take part in each session. The yoga session is designed and conducted by a teacher certified in yoga and cardiac rehabilitation, and includes exercises in deep relaxation, stretching, breathing, healing imagery and a healthy diet. Gentle exercises are practiced and a prescription of exercises is provided to be performed regularly at home. Each session lasts about 75 minutes, divided into three equal parts (yogic poses, breathing exercises and meditations, education and discussion). Participants' heart function and blood pressure are measured at the start of the study and after 3 months.

What are the possible benefits and risks of participating?
There are no known direct benefits of taking part in the study, although participants in the yoga group may experience greater improvements in heart health compared to usual care only. There are no known risks involved in taking part in the study, although participants in the yoga group may find that it is more time consuming and physically demanding, given that they are offered both yoga and usual cardiac rehabilitation care.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
June 2012 to August 2014

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
1. Dr Therese Tillin (public)
2. Prof. Nish Chaturvedi (scientific)

Study website
n/a

Contact information

Type(s)
Public

Contact name
Dr Therese Tillin

ORCID ID
http://orcid.org/0000-0003-1590-9826

Contact details
MRC Unit for Lifelong and Healthy Ageing at UCL
33 Bedford Place
London
United Kingdom
WC1B 5JU

Type(s)
Scientific

Contact name
Prof Nish Chaturvedi

ORCID ID
http://orcid.org/0000-0002-6211-2775

Contact details
MRC Unit for Lifelong and Healthy Ageing at UCL
33 Bedford Place
London
United Kingdom
WC1B 5JU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01597960

Secondary identifying numbers
Yoga-CaRe Programme

Study information

Scientific Title
Yoga And Cardiovascular Health Trial (YACHT): a randomised controlled trial

Acronym
YACHT

Study objectives
The trialists hypothesised that yoga would be associated with improvements in measures of cardiovascular risk both acutely and chronically.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee, Camberwell St Giles, 17/05/2012, ref: 12/LO/16956

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Referred to cardiac rehabilitation programmes post- angioplasty, coronary artery bypass grafting or prescribed medical management only as treatment for an acute coronary syndrome

Interventions

The acute study compared cardiovascular measures pre and post the first bout of yoga in participants randomised to the yoga arm only, the chronic study compared cardiovascular measures at 3 months between two groups randomised either to usual care or to a programme of yoga classes plus usual care. Participants were randomly allocated by an independent researcher using a standard computer algorithm, stratified by ethnicity, gender, 5 year age group and rehabilitation programme. Participants were recruited from four hospitals in west and north-west London.

The yoga intervention was delivered on a bi-weekly group session basis for 12 weeks alongside the usual cardiac rehabilitation programme. There were 24 yoga classes in total, of which each participant was required to attend a minimum of 18. Participants' partners were invited to take part in each session. The yoga session was designed and conducted by a teacher certified in yoga and cardiac rehabilitation, and included exercises in deep relaxation, stretching, breathing, healing imagery and a healthy diet. Gentle exercises were practiced and a prescription of exercises provided to be performed regularly at home. Each session lasted approximately 75 minutes, divided into three equal parts (yogic poses, breathing exercises and meditations, education and discussion), Individuals randomized to the yoga arm had their standard cardiac rehabilitation delivered at a separate time to those randomized to usual cardiac rehabilitation alone, (although delivered by the same team), to reduce risks of contamination.

Intervention Type

Behavioural

Primary outcome measure

Acute study:
Brachial blood pressure recovery after the Dundee 3-minute step test, measured on the day of the first yoga session, before and after the first yoga session. For each set of readings, blood pressure and heart rate are measured using an OMRON oscillometric device before the step test, immediately after the step test and then at 3 minutes after the step test

Chronic study:
1. Left ventricular diastolic function, measured using echocardiography at baseline and at three months follow-up. The ratio of early filling to early myocardial velocity (E/e') is used to estimate left ventricular diastolic function
2. 24 hour ambulatory blood pressure, measured using a Mobilograph oscillometric cuff-based device at baseline and at three months follow-up

Secondary outcome measures

Acute study:
1. Salivary cortisol as a measure of the hypothalamic-pituitary axis, measured from consecutive saliva samples taken by the participant using the Salivette self collection system on 5 occasions on the day of the first yoga session
2. Salivary alpha amylase as a measure of autonomic function measured from consecutive saliva samples taken by the participant using the Salivette system on 5 occasions on the day of the first yoga session

Chronic study:
1. Brachial blood pressure recovery after the Dundee 3-minute step test, measured at baseline and at three months follow-up. For each set of readings, blood pressure and heart rate are measured using an OMRON oscillometric device before the step test, immediately after the step test and then at 3 minutes after the step test
2. Resting blood pressure, measured using a Pulsecor (applanation tonometry) device at baseline and three months follow-up
3. Central blood pressure, measured using a Pulsecor device at baseline and three months follow-up
4. Pulse wave velocity, measured using a Vicorder oscillometric device at baseline and three months follow-up
5. Salivary cortisol as a measure of the hypothalamic-pituitary axis, measured from consecutive saliva samples taken by the participant using the Salivette system on 5 occasions on one day at baseline and on one day at three months follow-up
6. Glucose, total and LDL cholesterol, measured from venous blood samples at baseline and three months follow-up
7. Anthropometric measures to assess obesity at baseline and three months follow-up
8. Body fat percent, measured using a Tanita bioimpedance device at baseline and three months follow-up
9. Autonomic function: heart rate variability and baroreflex sensitivity measured at baseline and three months follow-up. Beat to beat arterial BP was recorded non-invasively using a Finometer (FMS Amsterdam, Netherlands), and the ECG was monitored using a 3 lead ECG. Signals were post processed as described in detail previously (Bathula R, Hughes AD, Panerai R, et al (Diabetologia 2010, Oct;53(10):2120-8))
10. Salivary alpha amylase as a measure of autonomic function, measured from consecutive saliva samples taken by the participant using the Salivette system on 5 occasions on one day at baseline and on one day at three months follow-up
11. Carotid intima-media thickness, measured using ultrasound at baseline and three months follow-up
12. Health behaviours, measured using self-report questionnaire at baseline and three months follow-up
13. Physical activity, self reported using the IPAQ long questionnaire at baseline and three months follow-up
14. Self-rated health, measured using the EuroQoL 5-item questionnaire and VAS scale at baseline and three months follow-up
15. Perceived stress level, measured using Cohen’s perceived stress questionnaire at baseline and three months follow-up

Overall study start date
01/06/2012

Completion date
01/08/2014

Eligibility

Key inclusion criteria
1. Referred to cardiac rehabilitation programmes post- angioplasty, coronary artery bypass grafting or prescribed medical management only as treatment for an acute coronary syndrome
2. Age 35-80

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Total final enrolment
80

Key exclusion criteria
1. Co-morbid disease or mobility limitations that would preclude participation in cardiac rehabilitation, yoga or study investigations
2. Unable to understand either English or Punjabi

Date of first enrolment
03/10/2012

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
International Centre for Circulatory Health
59-61 North Wharf Road
London
United Kingdom
W2 1LA

Sponsor information

Organisation
Imperial College London

Sponsor details
Kensington
London
England
United Kingdom
SW7 2AZ

Sponsor type
University/education

Website
www.icl.ac.uk/clinicalresearchgovernanceoffice

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists intend to submit a main manuscript to a quality peer reviewed journal (likely starting with the BMJ) in spring 2018. This will include the primary and secondary endpoint results. Further study of mechanisms and further publication are not currently planned.

Intention to publish date

31/05/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made publically available because the small numbers of participants and the non-blinded nature of the intervention mean that there is a substantial possibility that individual participants may be identifiable within the dataset, despite efforts to pseudonymise data as far as possible. However, the trialists encourage applications for access to the data by other researchers, which will be dealt with on a case by case basis by the study PI and CoIs. The data will be held by the YACHT study PI, Professor Sanjay Kinra (London School of Hygiene and Tropical Medicine) and by the CoIs responsible for the running and analysis of the study (Professor Alun Hughes, UCL, Professor Nish Chaturvedi, UCL).

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/11/2019	20/01/2022	Yes	No
HRA research summary			28/06/2023	No	No