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The Gentle Years Yoga Trial

Submission date
18/03/2019

Recruitment status
No longer recruiting

Registration date
18/03/2019

Overall study status
Completed

Last Edited
30/06/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Multimorbidity is common in older adults and is associated with high levels of illness burden and healthcare expenditure. The evidence base for how best to manage older adults with multimorbidity is weak. Yoga might be a useful intervention, because it is low-cost, simple, and can address several health conditions simultaneously. Gentle Years Yoga (GYY) is a yoga programme that was developed for older adults with chronic conditions. A pilot trial of GYY demonstrated feasibility and encouraging preliminary data. The current full-scale trial aims to answer the following research question: What is the clinical and cost-effectiveness of the GYY programme plus usual care versus usual care only in community-dwelling older adults with multimorbidity?

Who can participate?
Eligible participants will be aged 65 years or over, community-dwelling, and with multimorbidity, defined as having two or more chronic conditions from a predefined list.

What does the study involve?
We will conduct a multi-site, two-arm, parallel-group, individually-randomised controlled trial with an internal pilot phase and nested process and economic evaluations. We aim to recruit 586 participants primarily via mail-out from general practices. Eligible participants will be aged 65 years or over, community-dwelling, and have multimorbidity, defined as having two or more chronic conditions from a predefined list. Participants will be randomly allocated to receive usual care and the offer of a 12-week Gentle Years Yoga (GYY) programme (n=293) or usual care alone (n=293). The GYY programme will involve weekly group-based sessions and self-managed yoga practice on most days. The group-based sessions will be delivered in non-medical community-based facilities in at least 12 areas across England, Wales and Scotland.
Outcome data will be collected at baseline, and 3, 6 and 12 months post-randomisation using postal questionnaires. If a participant is unable to complete the questionnaire or there are missing data, this may be collected by a researcher over the phone. The primary effectiveness endpoint will be the overall difference in quality of life over 12 months measured using the EQ-5D-5L. Secondary outcome measures will include depression, anxiety, health-related quality of life, falls incidence, loneliness, adverse events, and healthcare resource use. Socio-demographic data will be collected at screening and baseline. Preferences and beliefs for the yoga

programme and usual care will be collected at baseline and at 12 months. Intervention adherence will be assessed using class registers. A subset of participants and yoga teachers will be interviewed to inform intervention implementation.

What are the possible benefits and risks of participating?
Previous studies have shown that yoga programmes can benefit many different aspects of physical, mental and social wellbeing. However, as this is the first detailed investigation of the GYY programme in older people with multimorbidity, we cannot guarantee any specific treatment benefits. If enough people take part in this study, the information we get should help clarify the role of yoga as a routine treatment for this patient group.

The yoga exercises carry a very small risk of injury (for example, mild muscle strain), but this risk will be minimised by participants being carefully monitored by experienced yoga teachers who have been trained to teach the programme.

Where is the study run from?
Northumbria University is the Sponsor for this study based in the United Kingdom. The Chief Investigator is based at Northumbria University, and the process evaluation will be lead from here. Northumbria University has delegated responsibilities for the day-to-day management of the study to York Trials Unit at the University of York.
Potential participants will be identified primarily via GP database screening at GP practices located close to where the yoga classes are due to be held. The yoga courses will be delivered either face-to-face in a non-medical community-based facility (e.g. yoga studio, community hall, leisure centre), or online via video conferencing during the period of social distancing restrictions resulting from the COVID-19 pandemic. We plan to run classes in 12 parts of the UK, with one Scottish site, two Welsh sites, and nine English sites. The following CRN regions will be involved:
- NHS Research Scotland Primary Care Network
- Health and Care Research Wales
- NIHR CRN: Thames Valley and South Midlands
- NIHR CRN: East Midlands
- NIHR CRN: West Midlands
- NIHR CRN: Eastern
- NIHR CRN: Yorkshire and Humber
- NIHR CRN: North West Coast
- NIHR CRN: North Thames
- NIHR CRN: West of England
- NIHR CRN: Kent, Surrey and Sussex

When is the study starting and how long is it expected to run for?
January 2019 to September 2022

Who is funding the study?
National Institute for Health Research, Health Technology Assessment Programme, ref 17/94/36 (UK)

Who is the main contact?
Dr Garry Tew, garry.tew@northumbria.ac.uk

Study website
https://www.york.ac.uk/healthsciences/research/trials/research/trials/gyy-trial/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
255698

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS: 40392; IRAS: 255698

Study information

Scientific Title
Individually randomised controlled multi-centre trial to determine the clinical and cost effectiveness of an adapted yoga programme for older adults with multimorbidity, including an embedded process evaluation

Study objectives
The Gentle Years Yoga programme plus usual care will improve the health-related quality of life of community-dwelling older adults with multimorbidity relative to usual care only

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 24/04/2019, North East - York Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; Tel: +44 (0)207 1048091; Email: nrescommittee.northeast-york@nhs.net), ref: 19/NE/0072

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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
Two or more chronic health conditions in people aged over 65 years

Interventions
After baseline assessment, participants will be randomly allocated to receive either usual care and the offer of a 12-week British Wheel of Yoga Gentle Years Yoga (GYY) programme or usual care alone. The GYY programme will involve weekly group-based, supervised yoga sessions and self-managed yoga practice on most days. Usual care will comprise unrestricted care from primary, secondary, community and social services. After randomisation, all participants will be followed-up for 12 months.

Details of the randomisation process: Participants will have indicated (in the screening questionnaire) their preference and availability for a particular course of Gentle Years Yoga. Once a sufficient number (ideally ≥20) of recruited participants have stated their availability for a particular class they will be randomised collectively using a bespoke randomisation database, which will be managed by York Trial Unit. Varying allocation ratios will be used to ensure that (no more than) 15 participants are allocated to the intervention group in any one randomisation wave. Ideally, 30 participants will be randomised 1:1 in each wave (15 to the intervention group, and 15 to control). Classes for which fewer than 30 participants express availability will have an allocation ratio favouring the intervention group; conversely, classes for which more than 30 participants express availability will have an allocation ratio favouring the control group.

Intervention Type
Behavioural

Primary outcome measure

Health-related quality of life as measured by the EQ-5D-5L utility score assessed at baseline, and 3, 6 and 12 months after randomisation, and the primary endpoint will be the overall difference over the 12 months.

Secondary outcome measures
1. Health-related quality of life measured using the EQ-5D-5L utility score at each of the individual time points (3, 6, and 12 months)
2. Depression measured using the PHQ-8 at 3, 6, 12 months and overall
3. Anxiety measured using the GAD-7 at 3, 6, 12 months and overall
4. Health-related quality of life measured using the PROMIS-29 at 3, 6, 12 months and overall
5. Loneliness measured using the UCLA 3-Item Loneliness Scale and a direct loneliness question from the English Longitudinal Study of Ageing at 3, 6, 12 months and overall
6. Incidence of falls over the 12 months of follow-up, assessed using a question on the number of falls experienced at 3, 6 and 12 months
7. Incidence of adverse events over the 12 months of follow-up
8. Healthcare resource use (including prescriptions) over the 12 months of follow-up, assessed via self-report questionnaire at 3, 6 and 12 months

Overall study start date
01/01/2019

Completion date
09/09/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/01/2021:

1. Aged 65 years or older
2. Community-dwelling (including sheltered housing living with support)
3. Have two or more chronic health conditions from the following list:
3.1 Arthritis: including osteoarthritis, rheumatoid arthritis, and history of shoulder, hip or knee arthroplasty for arthritis
3.2 Asthma or chronic obstructive pulmonary disease (COPD)
3.3 Atrial fibrillation
3.4 A diagnosis of cancer within the last 5 years
3.5 Cardiovascular disease: including coronary heart disease (includes angina or history of heart attack, bypass surgery or angioplasty), hypertension, heart failure, peripheral arterial disease
3.5 Chronic kidney disease (CKD)
3.6 Dementia (only if patients have capacity to provide written informed consent)
3.7 Depression or anxiety
3.8 Diabetes
3.9 Epilepsy
3.10 Fibromyalgia
3.11 Multiple sclerosis
3.12 Osteoporosis or osteopenia
3.13 Parkinson’s disease

3.14 Sensory conditions: including hearing loss, macular degeneration, cataracts, glaucoma
3.15 Stroke within last 5 years
3.16 Bowel problems: including IBS, diverticulitis, inflammatory bowel disease

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Previous inclusion criteria:

1. Aged 65 years and over (on date of invitation to participate)
2. Community-dwelling (including sheltered living with support),
3. Have two or more chronic conditions from the following list:
3.1 Arthritis: including osteoarthritis, rheumatoid arthritis, and history of shoulder, hip or knee arthroplasty for arthritis
3.2 Asthma or chronic obstructive pulmonary disease (COPD)
3.3 Atrial fibrillation
3.4 A diagnosis of cancer within the last 5 years
3.5 Cardiovascular disease: including coronary heart disease (includes angina or history of heart attack, bypass surgery or angioplasty), hypertension, heart failure, peripheral arterial disease
3.5 Chronic kidney disease
3.6 Dementia (only if capacity to provide written informed consent)
3.7 Depression or anxiety
3.8 Diabetes
3.9 Epilepsy
3.10 Fibromyalgia
3.11 Multiple sclerosis
3.12 Osteoporosis or osteopenia
3.13 Parkinson's disease
3.14 Sensory conditions: including hearing loss, macular degeneration, glaucoma
3.15 Stroke
3.16 Bowel conditions: including IBS, diverticulitis, inflammatory bowel disease

Participant type(s)
Patient

Age group
Adult

Lower age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 586; UK Sample Size: 586

Total final enrolment
454

Key exclusion criteria
Current exclusion criteria as of 08/01/2021:

1. Inability to attend one of the yoga courses on offer
2. Attended yoga classes twice a month or more in in the previous 6 months
3. Contraindication to yoga participation (as identified by the patient's GP)
4. Severe mental health problem (Schizophrenia, bipolar affective disorder or other psychotic illness)
5. Learning disability
6. Unable to read or speak English
7. Unable to provide consent
8. Unable to complete and return a valid baseline questionnaire
9. No more than one patient per household
10. Currently enrolled in another research study for which concurrent participation is deemed inappropriate (by GP or clinical co-investigator)

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Previous exclusion criteria:

1. Baseline questionnaire not returned
2. Inability to attend one of the yoga courses on offer
3. Performance of yoga in the previous 6 months (defined as twice per month or more)
4. Contraindication to participation (as identified by the patient's GP)
5. Severe mental health problem (Schizophrenia, bipolar affective disorder or other psychotic illness)
6. Learning disability
7. Unable to read or speak English
8. Unable to provide written informed consent
9. Currently enrolled in another clinical trial where concurrent participation is deemed inappropriate
10. No more than one participant per household may take part

Date of first enrolment
01/07/2019

Date of final enrolment
01/10/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of York
York Trials Unit
Heslington

York
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YO10 5DD

Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/049e6bc10

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The research findings will be written up in journal publications and evidence briefings, and presented at various forums and conferences.

Intention to publish date
09/09/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. When there is a request to use the GYY Trial data from external researchers this will be notified to the Trial Management Group and the Sponsor. The external request must include the provision of a pre-defined protocol that specifies what data are required and how it will be used and describe how the data will be securely stored. The external researchers should also sign a confidentiality agreement that will include: 1) the data are used only for the reasons specified in the request; 2) they will not share the data with any other third party not included in the request; 3) declare the intent to publish the findings in a relevant peer-reviewed journal; and 4) agree to notify the Chief Investigator of any pending publications so that both the GYY Trial Team are aware of this and the output can be notified to the NIHR. When the Trial Management Group agrees to an external request for data the approval for this will be confirmed with the NIHR Programme Manager. The release of any data will be provided in an anonymised format and securely transferred to the requester. Finally, external data requests will only be considered once the main results paper has been published.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/04/2021	14/04/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article		11/10/2023	16/10/2023	Yes	No
Results article		01/09/2024	12/09/2024	Yes	No
Other publications	Process evaluation	17/03/2025	18/03/2025	Yes	No
Other publications	teaching insights for optimising participant safety and inclusion from the process evaluation	27/06/2025	30/06/2025	Yes	No