Chair-based yoga programme for older adults with multimorbidity: RCT with embedded economic and process evaluations

Garry Alan Tew,[1,2,3*] Laura Wiley,[2] Lesley Ward,[2,3] Jessica Grace Hugill-Jones,[2] Camila Sofia Maturana,[2] Caroline Marie Fairhurst,[2] Kerry Jane Bell,[2] Laura Bissell,[4] Alison Booth,[2] Jenny Howsam,[4] Valerie Mount,[5] Tim Rapley,[6] Sarah Jane Ronaldson,[2] Fiona Rose,[2] David John Torgerson,[2] David Yates[7] and Catherine Elizabeth Hewitt[2]

[1]Institute for Health and Care Improvement, York St John University, York, UK
[2]York Trials Unit, Department of Health Sciences, University of York, York, UK
[3]Department of Sport, Exercise and Rehabilitation, Northumbria University, Newcastle-upon-Tyne, UK
[4]British Wheel of Yoga Qualifications (BWYQ), Sleaford, Lincs, UK
[5]Member of the Public, York, UK
[6]Department of Social Work, Education and Community Well-being, Northumbria University, Newcastle-upon-Tyne, UK
[7]Department of Anaesthesia, York Hospitals NHS Foundation Trust, York, UK

[*]Corresponding author g.tew@yorksj.ac.uk

Published September 2024
DOI: 10.3310/KPGN4216

Scientific summary

Chair-based yoga programme for older adults with multimorbidity: RCT with embedded economic and process evaluations

Health Technology Assessment 2024; Vol. 28: No. 53
DOI: 10.3310/KPGN4216

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Multimorbidity, having two or more chronic health conditions, is a major challenge for older adults and increases healthcare utilisation and associated costs. Multimorbidity is associated with reduced health-related quality of life (HRQoL), impaired functional status, worse physical and mental health and premature death. In 2015, 54% of people aged 65 years and over in England had multimorbidity.

There has been limited exploration of the effectiveness of interventions to improve outcomes for people with multimorbidity. There is some evidence to suggest that yoga may help to prevent and treat various physical and mental illnesses and improve HRQoL. The available data offer support for the beneficial effects of yoga in older adults and for several chronic conditions. However, robust evidence of clinical and cost effectiveness is limited, and little research has specifically focused on older adults with multimorbidity.

The Gentle Years Yoga (GYY) programme was developed to cater specifically to the needs of older adults, including those with health conditions common to an older cohort such as osteoarthritis, hypertension and cognitive impairment. A pilot randomised trial of the GYY programme (n = 52 adults, mean age 75 years) demonstrated feasibility, with a potential for a clinically important benefit on health status [EuroQol-5 Dimensions, five-level version (EQ-5D-5L) utility index score] at 3 months after randomisation [mean difference 0.12, 95% confidence interval (CI) 0.03 to 0.21]. Consequently, we conducted this larger trial, as if shown to be clinically and cost-effective, GYY could be widely implemented, leading to improved outcomes for this population.

Objectives

The primary objective was to establish if the offer of a 12-week GYY programme in addition to usual care is more effective compared with usual care alone in improving HRQoL (EQ-5D-5L utility index score) over 12 months in people aged 65 years or over with multimorbidity.

Secondary objectives were to:

- explore the effect of the GYY programme on HRQoL, depression, anxiety, loneliness and incidence of falls
- explore the safety of the GYY programme in terms of the occurrence of adverse events
- assess the cost-effectiveness of the GYY programme
- undertake a qualitative process evaluation to explore the acceptability of the intervention and the experience of participants and teachers, explain the determinants of delivery and identify the optimal implementation strategies.

Methods

Design

This was a multisite, two-arm, parallel-group, superiority, individually randomised controlled trial comparing an experimental strategy of offering a 12-week GYY programme against a control strategy of no offer of GYY in community-dwelling people aged 65 years or over who had multimorbidity. Both trial arms continued with any usual care provided by primary, secondary, community and social services.

The study also included cost-effectiveness and qualitative process evaluations.

Setting

Participants were recruited from primary care general practices in the UK. General practices interested in taking part in the trial were identified with help from the NHS Clinical Research Networks and the Health and Care Research Wales Support and Delivery Centre. General practices were selected based on their proximity to yoga class venues and local transport routes.

The yoga courses were delivered either face-to-face in a yoga studio, community hall or leisure centre or online via video conferencing during periods of social distancing restrictions.

The trial's yoga consultants identified yoga teachers who were eligible and potentially interested in taking part in the trial. Yoga teachers needed to have completed the British Wheel of Yoga (BWY) Qualification Level 4 Teaching GYY and have valid BWY membership and insurance. For online courses, teachers also needed to be proficient in remote teaching.

Participant recruitment and consent

Patients were eligible to join the study if they were aged 65 years or older, community-dwelling and had two or more of the predefined chronic health conditions derived from the NHS Quality and Outcomes Framework. Exclusion criteria were: inability to attend one of the GYY courses on offer; yoga practice in the previous 6 months; contraindications to yoga participation; severe mental health problem; learning disability; or being unable to provide consent and/or return the baseline questionnaire. For online classes, ineligibility also included no internet access; inability to use the internet; no suitable device; insufficient space at home; and/or no sturdy chair for use during the classes.

Potential participants were identified by searching general practitioner (GP) electronic patient databases. Participating practices ran a custom-built search, based on predefined read codes, which identified patients with eligible health conditions.

Potentially eligible patients were sent a recruitment pack including an information sheet and, if interested, were invited to sign and return a consent form. After the research team checked their suitability for the trial with their GP, eligible patients were asked to provide baseline data on sociodemographic measures, primary and secondary outcome measures and preferences/beliefs for the treatments on offer in the trial. Participants indicated on the consent form if they also wanted to be considered to take part in the process evaluation interviews.

Intervention and comparison

Gentle Years Yoga is designed for older adults, including those with chronic conditions. Based on standard Hatha Yoga, it incorporates physical postures and transitions as well as breathing, concentration and relaxation activities. The aims of GYY are to improve muscle strength, flexibility, balance, mobility and mental and social well-being. Chairs are used for seated exercise and support when standing. The yoga practices are modified so individuals with varying medical conditions and functional abilities can participate safely. Props are used to modify some of the postures and concentration activities. The physical challenge of each posture can be progressed throughout the course as participants become more able and confident.

Participants randomised to the intervention were invited to take part in a free GYY course. Each course involved 12, 75-minute sessions of group-based yoga, usually delivered 1 week apart, either face to face or online. Each class included: 'housekeeping' activities (5 minutes); an introduction to the theme and practices of the class, basic breathing and focusing activities (5 minutes); an extended warmup/mobilisation and preparatory postures (30–35 minutes); focused postures and restorative activities (10–15 minutes); breathing exercises (5–10 minutes); and relaxation and concentration activities (5–10 minutes), followed by optional after-class social time (15–30 minutes).

Throughout the trial, both trial arms continued with any usual care provided by primary care, secondary care, community and social services.

Sample size

We proposed to randomise 586 participants in a 1 : 1 ratio to be able to detect a difference of 0.06 in EQ-5D-5L utility index score, assuming a standard deviation (SD) of 0.20, with 90% power, a two-sided alpha of 0.05 and 20% attrition. In October 2021, an interim calculation of the correlation between baseline and 12-month EQ-5D-5L utility index score indicated we would be able to detect a clinically important difference with close to or greater than 90% power with 454 participants, since the primary analysis adjusted for baseline score, which affords gains in power.

Randomisation

Participants were randomised via a central, computer-based randomisation system designed and managed by York Trials Unit (YTU), University of York. Randomisation was stratified by site using varying block sizes and allocation ratios. Blinding of participants or the yoga teachers was not possible.

Outcome measures

Outcomes were self-reported by the participant and collected using questionnaires at baseline and 3, 6 and 12 months after randomisation.

The primary outcome and end point was the EQ-5D-5L utility index score over the 12-month follow-up period. Utility index scores were calculated following current National Institute for Health and Care Excellence guidance.

Secondary outcomes were:

- EQ-5D-5L utility index score at 3, 6 and 12 months after randomisation
- EQ-5D-5L visual analogue scale (VAS) score at 3, 6 and 12 months and overall
- HRQoL at 3, 6 and 12 months and overall using PROMIS-29 (v2.1)
- depression severity at 3, 6 and 12 months and overall using the Patient Health Questionnaire-8 (PHQ-8)
- anxiety severity at 3, 6 and 12 months and overall using the Generalised Anxiety Disorder-7 (GAD-7)
- loneliness at 3, 6 and 12 months and overall. Questions used to capture loneliness were taken from the English Longitudinal Study of Ageing (ELSA), based on the University of California, Los Angeles 3-item (UCLA-3) loneliness scale and a direct question about how often the respondent felt lonely
- the incidence of falls, adverse events and healthcare resource use over 12 months.

Analysis

All analyses were conducted in Stata version 17 (StataCorp LP, College Station, TX, USA) following the principles of intention-to-treat using two-sided statistical tests at the 5% significance level. The primary outcome was analysed using a linear mixed model, including data at all available follow-up time points, adjusting for baseline EQ-5D-5L utility index score, time point, trial arm and an arm-by-time interaction as fixed effects. Participant (to account for the repeated measures) and site were included as random effects.

In sensitivity analyses, age, gender and adapted Bayliss (severity-adjusted count of health conditions) score were added as covariates to the primary analysis model, and the site was substituted for yoga teacher as a random effect.

Complier-average causal effect (CACE) analyses, using a two-stage instrumental variable regression approach with randomised group as the instrumental variable, were implemented to assess the impact of receiving GYY on the primary treatment estimate.

A subgroup analysis was conducted to assess for differential effects of the intervention based on mode of delivery (face to face or online).

The secondary outcomes of EQ-5D VAS, GAD-7, PHQ-8, T-scores from each of the seven subscales of the PROMIS-29 and the physical and mental health component scores and the global item score, UCLA-3 score and ELSA single-item direct loneliness question were analysed using the same methods as for the primary outcome, with baseline EQ-5D-5L utility index score swapped as a covariate for baseline value of the outcome.

The incidence of falls during the 12-month follow-up period was analysed using a mixed-effect negative binomial regression model, adjusting for the number of falls in the 3 months prior to baseline and site as a random effect.

Adverse events are summarised descriptively.

Economic analysis

The economic analysis assessed the relative cost-effectiveness of the GYY programme in addition to continued access to usual care compared with usual care alone. Costs and health outcomes were evaluated from the perspective of the NHS and Personal Social Services using a within-trial economic analysis and a cost–consequence analysis, both over a 12-month time horizon; hence, discounting was not required. Health outcomes were assessed in terms of quality-adjusted life-years (QALYs) using EQ-5D-5L data, with costs collected for healthcare resource use, medications and the intervention. Findings were presented in terms of the incremental cost-effectiveness ratio for the intervention versus usual care and net monetary benefit. The base-case analysis was undertaken on an intention-to-treat basis, with multiple imputation used to deal with missing data and sensitivity analyses conducted to explore uncertainty around the cost-effectiveness findings.

Process evaluation

The process evaluation was informed by qualitative interviews with trial participants, trial decliners, trial yoga teachers and stakeholders, as well as by observations of standardisation training sessions and yoga classes. Intervention fidelity was assessed by class observation and via interviews with teachers as part of the process evaluation.

Interviews were audio-recorded, transcribed verbatim and edited to ensure respondent anonymity. Data analysis was iterative throughout the trial and conducted according to standard procedures of qualitative analysis.

Results

Between July 2019 and August 2021, 13,070 invitation packs were sent to potentially eligible participants, of which 1297 responded. Of these, 454 (35.0%) participants were randomised: 240 to the intervention and 214 to usual care. The mean age of participants was 73.5 years (range 65–99); 60.6% were female, and participants had a median of three chronic conditions.

Among the intervention group, the mean number of GYY sessions attended was 8.8 (SD 3.7, median 10, range 0–12). Two hundred and twenty-two (92.5%) participants attended at least one session, and fifty-three (22.1%) attended all twelve. Eighty per cent (n = 192) attended at least three of the first six sessions and at least three other sessions. One participant in the usual care group was invited to attend classes in error; they attended eight sessions, including five of the first six.

The primary analysis included 422 participants with valid EQ-5D-5L data at baseline and at least one post-randomisation time point (intervention n = 227 of 240, 94.6%; usual care n = 195 of 214, 91.1%).

There was no statistically or clinically significant difference in the EQ-5D-5L utility index score over 12 months: the predicted mean score for the intervention group was 0.729 (95% CI 0.712 to 0.747) and for usual care was 0.710 (95% CI 0.691 to 0.729), with an adjusted mean difference of 0.020 favouring intervention (95% CI −0.006 to 0.045; $p = 0.14$). The sensitivity analyses produced very similar results. The CACE analyses, which considered compliance as attending (1) ≥ 1 GYY session and (2) ≥ 6 including 3 of the first 6, produced slightly greater, but not clinically relevant, treatment estimates (0.025, 95% CI −0.002 to 0.052; $p = 0.07$; and 0.029, 95% CI −0.002 to 0.059; $p = 0.06$, respectively).

There was no evidence of an interaction between trial arm and intended mode of delivery (interaction effect 0.007, 95% CI −0.042 to 0.057; $p = 0.77$).

No statistically significant differences were observed in secondary outcomes, except in the T-score for the pain interference subscale of the PROMIS-29 at 3 months (−1.44, 95% CI −2.63 to −0.26; $p = 0.02$) and over the 12 months (−1.14, 95% CI −2.24 to −0.04; $p = 0.04$), and in the global (pain intensity) PROMIS-29 item at 12 months (−0.45, 95% CI −0.83 to −0.08; $p = 0.02$) and over the 12 months (−0.32, 95% CI −0.61 to −0.04; $p = 0.03$), favouring intervention.

No serious, related adverse events were reported.

Economic evaluation

The base-case economic evaluation found that the intervention cost £80.85 more per participant (95% CI £76.73 to £84.97) than usual care, generated an additional 0.0178 QALYs per participant (95% CI 0.0175 to 0.0180) and had a 79% probability of being cost-effective at the willingness-to-pay threshold of £20,000 per QALY gained.

Process evaluation

Participants found both face-to-face and online courses acceptable. Participants were highly motivated; most viewed their health as good and engaged well with the GYY classes over time. The majority viewed GYY as a form of gentle exercise with mindful breathing. Some participants noted no or only a modest impact of GYY on their health or lifestyle, including physical, psychological and self-management benefits, while others described GYY as transformative, having substantial impacts and improvements on their physical health and emotional well-being.

Conclusions

The offer of a 12-week GYY programme was not associated with any statistically significant benefits in terms of HRQoL, mental health, loneliness or falls in older adults with multimorbidity. However, the intervention was safe, acceptable to most participants and highly valued by some. The economic evaluation suggests that the intervention could be cost-effective.

Trial registration

This trial is registered as ISRCTN13567538.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: 17/94/36) and is published in full in *Health Technology Assessment*; Vol. 28, No. 53. See the NIHR Funding and Awards website for further award information.

Health Technology Assessment

ISSN 2046-4924 (Online)

Impact factor: 3.6

A list of Journals Library editors can be found on the NIHR Journals Library website

Launched in 1997, *Health Technology Assessment* (HTA) has an impact factor of 3.6 and is ranked 32nd (out of 105 titles) in the 'Health Care Sciences & Services' category of the Clarivate 2022 Journal Citation Reports (Science Edition). It is also indexed by MEDLINE, CINAHL (EBSCO Information Services, Ipswich, MA, USA), EMBASE (Elsevier, Amsterdam, the Netherlands), NCBI Bookshelf, DOAJ, Europe PMC, the Cochrane Library (John Wiley & Sons, Inc., Hoboken, NJ, USA), INAHTA, the British Nursing Index (ProQuest LLC, Ann Arbor, MI, USA), Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and the Science Citation Index Expanded™ (Clarivate™, Philadelphia, PA, USA).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta.

Criteria for inclusion in the *Health Technology Assessment* journal
Manuscripts are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This article

The research reported in this issue of the journal was funded by the HTA programme as award number 17/94/36. The contractual start date was in January 2019. The draft manuscript began editorial review in January 2023 and was accepted for publication in August 2023. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

This article presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care.

This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).