



BMJ Open Study protocol for yoga-based lifestyle intervention for healthy ageing phenotype in the older adults (yHAP): a two-armed, waitlist randomised controlled trial with multiple primary outcomes

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ABSTRACT

Introduction The conceptualisation of healthy ageing phenotype (HAP) and the availability of a tentative panel for HAP biomarkers raise the need to test the efficacy of potential interventions to promote health in older adults. This study protocol reports the methodology for a 24-week programme to explore the holistic influence of the yoga-based intervention on the (bio)markers of HAP.

Methods and analysis The study is a two-armed, randomised waitlist controlled trial with blinded outcome assessors and multiple primary outcomes. We aim to recruit 250 subjects, aged 60–80 years from the residential communities and old age clubs in Bangalore city, India, who will undergo randomisation into intervention or control arms (1:1). The intervention will include a yoga-based programme tailored for the older adults, 1 hour per day for 6 days a week, spread for 24 weeks. Data would be collected at the baseline and post-intervention, the 24th week. The multiple primary outcomes of the study are the (bio)markers of HAP: glycated haemoglobin, low-density lipoprotein cholesterol (LDL-C), systolic blood pressure, and forced expiratory volume in 1 s for physiological and metabolic health; Digit Symbol Substitution Test, Trail Making Tests A and B for cognition; hand grip strength and gait speed for physical capability; loneliness for social well-being and WHO Quality of Life Instrument-Short Form for quality of life. The secondary outcomes include inflammatory markers, tumour necrosis factor-alpha receptor II, C reactive protein, interleukin 6 and serum Klotho levels. Analyses will be by intention-to-treat and the holistic impact of yoga on HAP will be assessed using global statistical test.

Ethics and dissemination The study is approved by the Institutional Ethics Committee of Swami Vivekananda Yoga Anusandhana Samsthana University, Bangalore (ID: RES/IEC-SVYASA/143/2019). Written informed consent will be obtained from each participant prior to inclusion. Results will be available through research articles and conferences.

Trial registration number CTRI/2021/02/031373.

Strengths and limitations of this study

- First yoga-based randomised controlled trial on multiple potential (bio)markers of physiological and psychological integrity.
- Free-of-charge and customised, yoga-based intervention with minimal reported adverse events.
- Expected health benefits on several physiological and mental aspects of the participants.
- If found effective, the findings of the trial will lead to a paradigm shift from individual management/prevention of age-associated medical conditions to a holistic approach towards ageing per se.
- Generalisability of the intervention findings might be restricted to healthy older adults only.

INTRODUCTION

The swift demographic transition of an ageing population does not only indicate extended life expectancy but is also associated with an increased risk of ageing-associated diseases and disabilities.^{1–6} It has been estimated that there would be a worldwide increase in the number of individuals aged ≥60 years by 500 million (from 900 million in 2015 to 1400 million by 2030).² The advancing knowledge of the ageing trajectories has led the scientific and clinical fraternity to put forth the feasibility of holistic, multi-disciplinary lifestyle-based interventional strategies to promote biological resilience and reverse the course of deflection from pathological trajectories at early time points in the lifespan.^{6–11} These strategies seem to overcome the barriers posed by the long lifespan and the extended time course for the symptomatic manifestation of ageing-related

health decline in humans, against the clinical translation of preclinical evidence on the modifiability of biological ageing.^{7–9} This recent quest has led to the conceptualisation of the healthy ageing phenotype (HAP), defined as the condition of being alive while having preserved functioning metabolic, hormonal and neuroendocrine control systems.⁸ Hence, adopting the concept of the HAP, Lara *et al* proposed a comprehensive panel of (bio) markers to measure the influence of lifestyle-based interventions on HAP.⁵ They reported several distinct domains of HAP: cognition, physiological and metabolic health, physical strength or capability, psychological and social well-being, and the corresponding tools to measure the same.⁵ The selection of these biomarkers was guided by their expected correlation with ageing and the related phenotypes (such as morbidity, mortality, quality of life (QoL), health span), and amenability to modification by lifestyle interventions.⁵ Lifestyle, in particular physical activity, has been considered as a driver for a healthy and long life for older people. Despite the growing evidence on the efficacy of physical activity, the participation of older adults in physical activities remains poor.¹² Approximately 30%–60% of adults aged ≥ 60 years across the WHO regions do not meet the recommended activity level 4, that is, ≥ 150 min of moderate-intensity or 75 min of vigorous-intensity aerobic physical activity (or an equivalent combination) per week.¹³ There is an immediate need to test the efficacy of potential interventions against the multiple outcomes (markers) proposed to measure the HAP and establish a proof of principle to enable the extension of the study outcomes at large community-based settings to promote healthy ageing and reduce the health burden imposed by ageing population.^{5 8–11}

Yoga is an ancient Indian holistic mind–body discipline, classified as complementary medicine by the National Institutes of Health.¹⁴ Over the years, yoga-based lifestyle interventions have been associated with several health-related benefits in community settings. Several of these benefits have also been reported in the older adults, particularly balance and mobility, cardiac health, respiratory function, cognition, sleep quality and QoL.^{15–18} These findings indicate key intersections with the domains of HAP. The easy deployment of yoga-based interventions (YBIs) in community settings, cost-effectiveness, rising popularity and measurability across various health domains strengthen their potency as geriatric interventions. However, there are distinct perception-related and culture-related barriers recognised towards participation in yoga across older adults.^{15 19} The public awareness and perception of yoga for geriatric health need extend beyond fitness and flexibility, to other health outcomes, such as physiological, metabolic, cognitive and social well-being. This notion indicates an unmet need of capturing the comprehensive influence of the health-related benefits of yoga in exploratory but well-designed trials in the older adults. Though few of the recent trials have reported study protocols on yoga and healthy ageing, they have primarily focused on the subjective well-being

of the older individuals.^{9 10} We hereby report the study protocol of a 24-week yoga-based lifestyle intervention programme in a cohort of inactive older subjects towards comprehensive enhancement of HAP, measured with multiple primary outcomes using a waitlist randomised controlled design.

METHOD AND ANALYSIS

Study design

The present study, yoga for the HAP (yHAP), is a two-armed, randomised waitlist controlled trial with blinded outcome assessors and multiple primary outcomes. The yHAP aims at facilitating healthy ageing in the older adults with yoga as a lifestyle intervention, with a holistic influence on distinct domains of health, that is, physiological and metabolic health, cognitive function, physical capability, and psychological and social well-being.⁵ The protocol was drafted following CONSORT (Consolidated Standards of Reporting Trials)²⁰ (figure 1). The study participants would be older Indian citizens aged 60–80 years, recruited from the residential communities and old age clubs of Bangalore city, India. Recruitment has started on 19 February 2021 through the distribution of pamphlets and door-to-door visits in the vicinity of the intervention facility. We aim to complete the data collection by March 2022. We want to ensure diversity and a heterogeneous representation of lifestyle disorders, diabetes, hypertension and obesity in the study cohort; hence, participants will be recruited through purposive sampling.^{21 22} Detailed study information will be provided to all individuals while screening. Interested individuals will be further screened for variables including age, lifestyle disorders, chronic ailments, mobility restrictions and prevalent cognitive impairment based on Mini-Mental Status Examination.²³ Individuals not fitting into the eligibility criteria will be excluded from participation (the inclusion and exclusion criteria have been mentioned separately in table 1). Written informed consent would be obtained from voluntary participants, and they will receive home visits for data collection. Data collection will be conducted in different phases with an enrolment of 15–20 participants at each phase; the process would be repeated until the final number of 250 is achieved. Assessments will be performed at baseline and after the 24th week post-intervention (see figure 1, participant flow chart based on the CONSORT guidelines for transparent reporting of trials). To obtain sufficient numbers of participants from each community association and minimise loss to follow-up, we will involve community heads (CHs) for different communities. These CHs will monitor, supervise and encourage the participants, and hence, their involvement is critical. Researchers, together with the clinical staff, will set up schedules to ensure the availability of all participants during data collection or supervision. Venipuncture will be done post a minimum of 8-hour fasting, and blood samples will be collected in EDTA tubes.

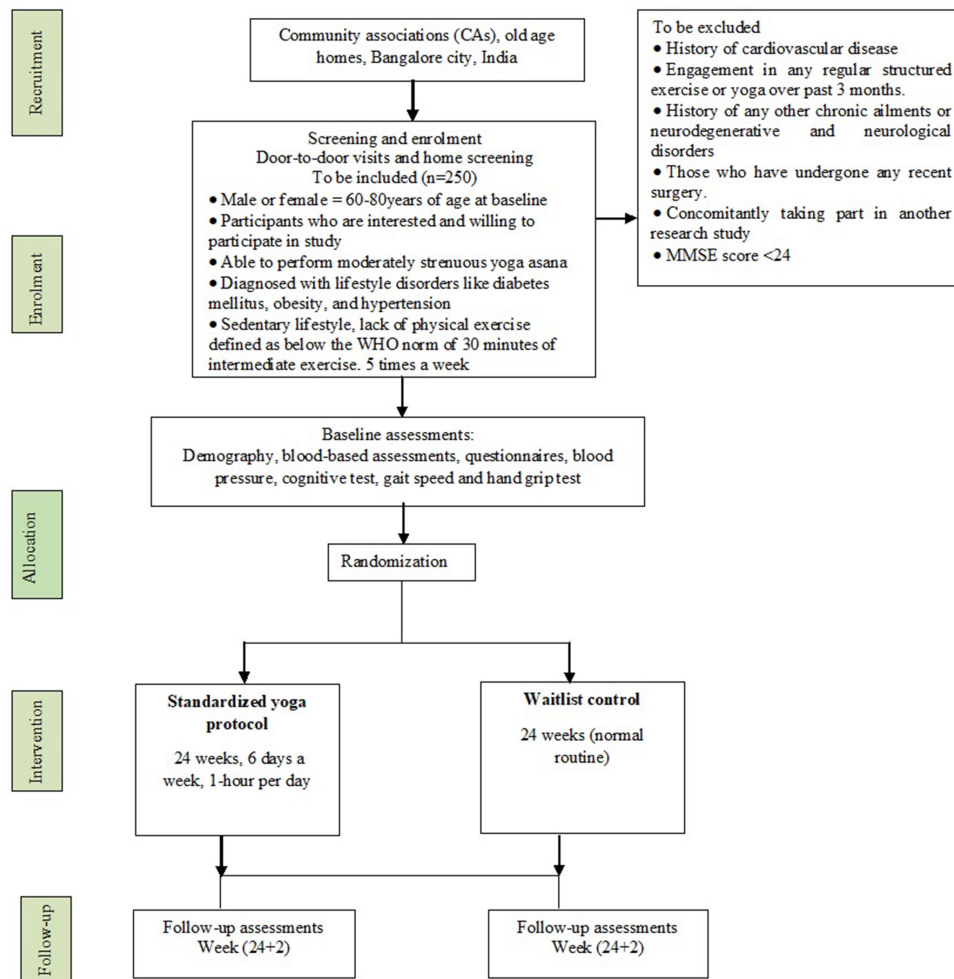


Figure 1 Participant flow chart for parallel design, based on the Consolidated Standards of Reporting Trials guidelines for transparent reporting of trials. MMSE, Mini-Mental Status Examination.

Randomisation and blinding

An external statistician who is not directly involved in implementation of the intervention will randomise the participants during the baseline visit in a 1:1 ratio ($n=125$, each arm) using a sequence randomiser. Only one eligible member from each household would be

randomly selected to avoid any clustering effect (within-family correlations). The allocation sequences will be sealed, and immediately after baseline assessments, the participants will be informed about the further process. Owing to the nature of the intervention, complete double blinding is not possible. However, to reduce the detection

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> ▶ Age ≥ 60–80 years ▶ Both the genders ▶ Interested and willing to participate in study ▶ Able to perform moderately strenuous yoga asanas ▶ Diagnosed with lifestyle disorders like diabetes mellitus, obesity and hypertension ▶ Signed informed consent by the parent/legally acceptable representative and assent by the patient appropriate to the patient's age, including willingness to participate in the study ▶ Sedentary lifestyle, lack of physical exercise defined as below the WHO norm of 30 min of intermediate exercise, 5 times a week 	<ul style="list-style-type: none"> ▶ Engagement in any regular structured exercise or yoga over past 3 months ▶ History of any other chronic ailments like cancer, chronic kidney disease or neurodegenerative and neurological disorders like stroke, major depressive disorder, psychosis, anxiety disorder, severe hearing and visual impairments ▶ Those who have undergone any recent surgery ▶ Concomitantly taking part in another research study ▶ Mini-Mental Status Examination score <24 for prevalent cognitive impairment

bias, investigators involved in the evaluation of outcome measures would be blinded for the randomisation groups.

Interventions

The yHAP is a multifactorial intervention, aimed at improving the outcomes across different dimensions of ageing to be assessed through HAP markers. Details of the intervention are given in the online supplemental table 1. Yoga sessions will include physical activity, relaxation, regulated breathing, dietetic advice and counselling on philosophical aspects and social support (described as a sangha in ancient literature).²⁴ Dietetic advice is drafted based on the ancient yoga-based concepts aligned with the research-based evidence for healthy nutrition aspects in the older adults.^{25–28} Participants will be advised to consume a diet that includes sprouted whole grains, fresh fruits, land and sea vegetables, pure fruit juices, nut and seed milk and cheese, legumes, nuts, seeds, sprouted seeds, honey and herbal teas (please see online supplemental table for details). The integrated multifactorial approach of yHAP is derived from the principles of ancient texts which emphasise that yoga should promote holistic health.^{29–31} The intervention will be given 1 hour per day for 6 days a week, spread for 24 weeks, interrupted by weekend breaks of 1 day. yHAP will be delivered by certified and experienced yoga instructors who would be trained for the intervention. Participants will be advised to practise the same on their own on the off-days. The course will be given to a group of 15–20 patients at a time. The yHAP will be uniform throughout the study to avoid the risk of intervention variability. Daily attendance will be taken for the participants. Those who will not attend the sessions would be contacted personally by the research team to understand the reason for their absence and cut

out any adverse effects of the intervention. Personal time with the trainer will be given separately throughout the intervention phase to all the participants, to make them understand the practices more clearly.

Waitlist group

For the inactive control group, we chose a waitlist design as we deemed it as an ethically appropriate alternative to provide needed care to the inactive older adults following the trial. While recruitment, they will be instructed to continue their daily activities (without engaging in regular structured exercise). After the completion of the 24-week study, these participants will receive the same yoga-based lifestyle intervention given to the intervention group post their data collection and a secondary within-group analysis will be conducted including these participants.

Measures to maintain adherence

Yoga classes will be given free of charge and will be conducted near the radius of 1 km, instructions will be made simple and less demanding; cognitive–motivational factors such as self-efficacy and health beliefs will also be included in theory-based motivations to maintain adherence to the intervention.³²

Study outcomes

The panel of (bio)markers considered for the present trial (table 2) is primarily influenced by the insights presented by Lara *et al*,⁵ for the measurement of the HAP in lifestyle-based intervention studies. However, given the complexity in statistical analysis owing to multiplicity, we have selected few tools deemed as most relevant under each domain. Further, based on the mechanistic and epidemiological correlates with the process of

Table 2 Primary outcome panel—HAP domains and the respective tools/assessments included

Domains	Tools adopted from the panel proposed by Lara <i>et al</i> ⁵
Physiological and metabolic health	
Cardiovascular health metric	Glycated haemoglobin Plasma concentrations of cholesterol fractions (LDL-C) Arterial systolic blood pressure (mm Hg)
Lung function	Forced expiratory volume
Cognitive function	
Processing speed	Digit Symbol Substitution Test ⁴⁰
Executive function	Trail Making Tests A and B ⁴¹
Physical capability	
Strength	Hand grip strength
Locomotion	Gait speed ⁴²
Psychological well-being	
Quality of life	WHOQOL-Bref ⁴³
Social well-being	University of California, Los Angeles Loneliness Scale ⁴⁴

As mentioned above, we have included five domains of HAP under the primary outcomes of the study: physiological and metabolic health, cognitive function, physical capability, psychological well-being and social well-being.

HAP, healthy ageing phenotype; LDL-C, low-density lipoprotein cholesterol; WHOQOL-Bref, WHO Quality of Life Instrument-Short Form.

Table 3 Secondary outcome panel

Adiposity	Body mass index (kg/m ²)
Auxiliary blood biochemistry	Complete haemogram Differential count Blood urea (kidney function marker) Serum creatinine (kidney function)
Inflammatory markers (IL-6, TNF-alpha and CRP)	A composite score for inflammaging would be created for the three markers CRP, IL-6 and TNF-alpha; for each inflammatory marker, a z-score will be calculated ($z = (x - \bar{x})/SD$ where x is an individual marker value, \bar{x} is the mean marker value, and SD is the SD of marker values). Further, a composite z-score will be calculated for inflammaging using the individual z-scores, (ie, z-score (inflammaging)=average (z-CRP, z-IL-6, z-TNF-alpha)). Cut-offs will be defined based on the 50th percentile of the population distribution of the composite z-score.
Systemic integrity	Z-score will be calculated for the physiological serum Klotho concentrations. Scoring will be based on baseline z-score distribution and appropriate quantiles will be generated, highest quantile will be assigned the highest score and lowest will be assigned a score of 0.
Frailty Index for Elderly (FIFE)	FIFE is a 10-item assessment instrument with scores ranging from 0 to 10. A score of 0 indicates no frailty; a score of 1–3 indicates frailty risk; and a score of 4 or greater indicates frailty. ⁴⁵
Cardiovascular function	None=1, 1 factor=0.75, 2 factors=0.5, 3 factors=0.25, 4 factors=0

CRP, C reactive protein; IL-6, interleukin 6; TNF, tumour necrosis factor.

biological ageing, we included a few additional secondary biomarkers in the panel (table 3) such as Klotho and the inflammatory cytokines (tumour necrosis factor-alpha, C reactive protein and interleukin 6).^{7 33 34} Over the last 20 years, Klotho has emerged as a biomarker for healthy ageing,³⁴ as an integrator of organ systems, making it both a promising tool for advancing our understanding of the biology of ageing and an intriguing target for interventional studies.

The secondary outcomes would be evaluated as the difference between baseline and follow-up values at the 24th week of the 10 individual markers related to physiological and metabolic health: low-density lipoprotein cholesterol (LDL-C), body mass index, systolic blood pressure, forced expiratory volume in 1s; cognition—Digit Symbol Substitution Test, Trail Making Tests A and B; physical capability gait speed and hand grip strength; social-well being loneliness and quality of life—WHO Quality of Life Instrument-Short Form. Further, all the secondary variables will also be assessed, as the panel presented in table 3.

Assessments

The schedule of enrolment, interventions and assessments, according to Standard Protocol Items: Recommendations for Interventional Trials 2013 guidelines, has been reported in table 4. The baseline assessment will be performed by trained research assistants before randomisation. The assessment covers demographic characteristics and collection of primary and secondary outcomes including anthropometric measurements, questionnaires, and functional ability tests of physical health and cognition. The detailed methods of assessments are given in online supplemental appendix 1. Participants

will receive a prior appointment in Sri Jayadeva Institute of Cardiovascular Sciences and Research for Biological Sampling and will receive a scheduled time for follow-up.

Data will be managed by the principal investigator and study coordinator and they will be responsible for maintaining the confidentiality of data. Information of participants will be collected through study proforma and collected information will be transferred to Excel sheet. Each participant will be given a unique code for confidentiality, and the data will be transferred for further statistical analysis.

Statistical analyses

Sample size

Since we aim to capture a holistic effect of YBI across the multiple domains of HAP, we propose to use the global statistical test (GST) to assess the efficacy of the intervention.^{35 36} However, in view of non-availability of preliminary data, unknown nature of correlations among the outcome variables and their distribution, we prefer to choose a sample size of $n_1 - n_2 = 100$, which is in line with the adequate sample size proposed for 10 multiple outcomes (K), under the simulations reported for sample size calculations with computation of the global treatment effect under various possible settings by Huang *et al.*³⁵ Further, since the reported efficiency of GST to summarise a treatment's merit is not compromised with small sample sizes, we could avoid the risk of being underpowered.³⁷ Further, keeping in view of the attrition rate of 25% over 6 months, we derived a sample size of $n = 250$ for the present study. We will compare the baseline characteristics of this sample with the intention-to-treat population (all randomised subjects). Baseline characteristics of participants will be summarised using mean and SD or

Table 4 Schedule of enrolment, interventions and assessments, according to SPIRIT 2013⁴³ guidelines

Study period		Enrolment	Baseline	Intervention	Endpoint
Time points		Week-1	Week 0	Week 1–24	Week 24+2
Eligibility screening		x			
Informed consent		x			
Allocation		x			
Intervention				x	
Yoga				x	
Waitlist			x		x
Assessments	Methods				
Demographics	Study proforma	x	x		
Cardiovascular and metabolic function	Systolic blood pressure Blood lipid—LDL-C Haemoglobin	x	x		x
Lung function	Forced expiratory volume 1	x	x		x
Body composition	Body mass index	x	x		x
Physiological function (biomarkers)	Serum Klotho levels, an anti-ageing protein	x	x		x
	Markers of inflammaging, IL-6, TNF-alpha, CRP	x	x		x
	Complete haemogram	x	x		x
	Differential count	x	x		x
	Blood urea (auxiliary kidney function marker)	x	x		x
	Serum creatinine (kidney function)	x	x		x
Strength	Hand grip strength	x	x		x
Locomotion	Gait speed	x	x		x
Frailty	Frailty Index for Elderly	x	x		x
Processing speed	Digit Symbol Substitution Task	x	x		x
Executive function	Trail Making Tests A and B	x	x		x
Psychological well-being	WHOQOL-Bref	x	x		x

CRP, C reactive protein; IL-6, interleukin 6; LDL-C, low-density lipoprotein cholesterol; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials; TNF, tumour necrosis factor; WHOQOL-Bref, WHO Quality of Life Instrument-Short Form.

median and IQR for continuous variables and frequency and percentage for categorical variables. The analyses will observe intention-to-treat, that is, participants will be analysed according to the group to which they were allocated. Missing data will be replaced using multiple imputation methods. Sensitivity analyses will be performed. Log binomial models will be estimated by generalised estimating equations. Mixed-effects linear regression models will be used. We will include outcomes at baseline and 12 weeks, and include all participants with outcomes data available. All analyses will be performed in IBM SPSS, V.26 and in R (V.76). We will employ a statistical threshold of $\alpha=0.05$.

Patient and public involvement

Participants in the study are not involved in the development of this trial protocol as the study consists of a

non-clinical sample. Study participants will be involved only at the time of recruitment and once they meet the eligibility criteria, research assistants will explain the whole trial and their role in the study and clarify their queries if any informed consent will be obtained. The intervention will be free of cost and there would not be any burden to participate in research. Results of biomarkers and phenotypic markers will be offered to individual participants on completion of follow-up data collection.

Assessment of harms

All eligible candidates will be screened by trained research assistants to eliminate those with health-related problems that might disturb their participation or increase their physical activity. Participants will be instructed to inform the study coordinator of any

experienced adverse events throughout the study and there will be a personal meeting with a trainer after each session to eliminate the harm if any. Decision of the participant in the discontinuation of the study will be taken by the principal investigator.

Ethics and dissemination

The study will be conducted in accordance with the protocol, and in accordance with the requirement from the institution's ethical committee. The study is approved by the Institutional Ethics Committee of Swami Vivekananda Yoga Anusandhana Samsthana University, Bangalore (RES/IEC-SVYASA/143/2019). The study is also registered in Clinical Trials Registry India. Primary results and datasets will be available from the corresponding author on reasonable request. The results of the study will be publicly available in scientific media through research articles and conferences.

Consent to participate

Every potential participant will be informed about the study aims and procedures by a research assistant prior to participation, verbally and in writing. Confidentiality, voluntariness and freedom to withdraw from the study at any point will be stated. Written informed consent will be obtained from all participants by a research assistant.

Confidentiality

Study participants will be allocated unique study IDs at inclusion. Data will be coded and stored in the participant proforma and will be converted in Microsoft Excel 2013. Collected data will be handled only by the principal investigator. Trial randomisation codes will also be maintained confidential.

Data statement

As the paper relates to a study protocol, data sharing is not applicable as no datasets generated and/or analysed for this study. However, after completion of the study, individual participant data that underlie the results will be reported in a peer-reviewed publication after de-identification in the form of an appendix. Hence, we feel that data sharing statement will be applicable in the manuscript that will arise from the proposed study. We plan to share the study protocol along with the main manuscript. Researchers who provide a methodologically sound proposal would be able to view the files, proposals should be directed to email of the corresponding author. The third-party website will be provided in the main manuscript. The data will be available to achieve aims in the approved proposal and for individual participant data meta-analysis.

DISCUSSION

The present trial would be a pioneer yoga-based lifestyle trial envisaged to understand the measurable impact of

the YBI on HAP. The major strength of this trial is the comprehensive approach including assessments on the key domains of HAP, which are carefully selected, aligning with the requisite of harnessing age-associated clinical comorbid events. Tracking of clinically morbid events would otherwise require longer follow-ups and was deemed to be not feasible.⁵ Though a few recent trial protocols have included the multidimensional outcomes of yoga intervention on health in older individuals, they have included single primary outcome measures, implicitly prioritising subjective well-being over the other dimensions of health.^{9 10} Analysis of multiple primary outcomes is associated with concerns related to the multiplicity aspect, in particular, due to unknown correlations between the study outcomes.^{35 36} Towards the same, we propose to implement the GST, first proposed by Huang *et al* and further extended by others, that seems to provide a useful solution to assess the global impact of multidimensional interventions with multiple primary outcomes.³⁵ GST could provide us an overall test of multiple outcomes, with separate reports of individual outcomes with an adaptation of the Bonferroni procedure.³⁶ There are several statistical advantages associated with the use of GST. The interpretation of GST has been reported to be unaffected by the outcomes of individual items, even if they fail to achieve significance. Further, GST offers a solution to combine outcomes to demonstrate efficacy using fewer subjects, the sample size would also not be a limiting factor to establish the efficacy of the intervention.

The selected panel of primary outcomes adopted from Lara *et al*⁵ aligns with the requisite of GST of a careful selection of the essential outcomes used to address the efficacy of an intervention.³⁷ We hypothesise that the trial findings will enhance the interpretability of findings across different clinical trials with varied interventions.⁵ Additionally, we have incorporated a few more cardinal biomarkers including Klotho and inflammatory markers for the secondary outcomes. Despite being reported to be the drivers of biological ageing rather than just indicators,^{7 33 34} these markers have not been systematically explored before for geriatric trials on healthy ageing using the YBI. Hence, the outcomes on these markers will pave the foundation for the development of yoga-based therapeutic strategies to counteract age-related declines. Overall, the proposed trial will be one of the few preliminary steps for the foundation of large clinical trials and could provide a concept of proof that biological ageing could be targeted through interventions in humans.

The study design could be limited by waitlist controlled design, as these studies report an inflated effect size due to the inclusion of inactive controls.³⁸ However, our primary aim is to establish the efficacy of yoga on multiple outcomes compared with an inactive lifestyle. Yoga has been reported to be as effective as stretching-strengthening exercises in improving functional fitness in older adults,³⁹ with small-to-moderate

effects on several aspects of health. Hence, we did not include an active control group, assuming a small effect size in a study with multiple outcomes, and a chance of missing the overall effect of the intervention. However, for future intervention studies, we propose the inclusion of an active control group to derive conclusions concerning the effectiveness of yoga compared with different exercise programmes. We also anticipate challenges during data collection of the trial in the community setting. Due to a lack of social support, there is likely reduced participation in geriatric clinical studies. Refusal to participate may also be due to caste, gender, religion and other social attributes. To address these challenges, data collectors will be trained and retrained on how to build rapport with participants and maintain privacy and confidentiality. Further, as yoga being a popular healthcare strategy in India, there could be a motivational bias for participation that could further influence the generalisability of the findings. Despite an increasing trend observed in older adult participation in yoga/pilates in western countries, yoga participation rates remain low.¹⁹ The findings of this trial could lead to the effective implementation of global health policies promoting yoga-based physical activity for enhancing healthy ageing in inactive older individuals.

Contributors The study design and concept were conceived by VM and NKM. ASn will conduct screening, data collection and analysis. VM and ASn prepared the first draft of the manuscript. RN, RM, ASI, KSR and NHR provided edits and critiqued the manuscript for intellectual content.

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