BMJ Open

Yoga therapy on elderly patients with fear of fall: an open-label randomised controlled trial (YOFEAR trial)

Kritartha Kashyap,[1] Minakshi Dhar ,[1,2] Khushboo Bisht ,[3] Yogesh Bahurupi ,[4] Monika Pathania[1]

To cite: Kashyap K, Dhar M, Bisht K, *et al*. Yoga therapy on elderly patients with fear of fall: an open-label randomised controlled trial (YOFEAR trial). *BMJ Open* 2023;**13**:e070540. doi:10.1136/bmjopen-2022-070540

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-070540).

Received 25 November 2022
Accepted 26 September 2023

[1]Geriatric Medicine, All India Institute of Medical Sciences, Rishikesh, Uttarakhand, India
[2]Internal Medicine, All India Institute of Medical Sciences, Rishikesh, Uttarakhand, India
[3]Clinical Pharmacology, All India Institute of Medical Sciences, Rishikesh, Uttarakhand, India
[4]Community & Family Medicine, All India Institute of Medical Sciences, Rishikesh, Uttarakhand, India

Correspondence to
Dr Minakshi Dhar;
minakshi.dhar@rediffmail.com

ABSTRACT

Introduction Fear of fall is experienced by the elderly irrespective of the presence or absence of history of fall. Falls contribute to injuries that culminate in hospitalisation that incur unwarranted medical expenses. Yoga is unique to Indian cultural practices, with a potential to enhance proprioception. It increases self-body awareness, ultimately improving the balancing capacity of older adults. Thus, the objective of this study is to compare the effect of yoga therapy in the study and control groups at 12 weeks from the baseline.

Methods and analysis This study is designed as an open-label, randomised controlled trial (1:1) with a sample size of 62 elderly patients more than or equal to 60 years of age. Participation of either sex, male or female with a fear of fall will be considered. Two randomised groups of 31 participants each will receive standard therapy for their primary diseases as per the local, national or international guidelines. However, participants in the intervention arm will receive additional structured yoga therapy sessions. The primary objective of this study is to assess and compare the change in fear of fall score of participants in each group using Falls Efficacy Scale (FES) and Berg Balance Scale (BBS) at 12 weeks versus baseline. The secondary endpoint will assess the change in the quality of life of participants at 3 months compared with the baseline.

Data will be gathered, entered into Microsoft Excel and further analysed by R software (V.4.3.0). Changes in FES-Intervention and BBS of two groups will be compared either by Student's t-test for parametric data or Mann-Whitney U test for non-parametric data. Statistical significance will be considered if $p<0.05$ at 95% confidence level.

Ethics and dissemination Ethical approval for this study protocol (version 1.0, 22 April 2022) was obtained from the institute ethics committee (AIIMS/IEC/22/195).

Trial registration number CTRI/2022/06/043287.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This randomised controlled trial included block randomisation, which was not adopted in any previous trials.
⇒ As yoga is a common cultural practice in India, and now accepted worldwide as well, a better adherence to study protocol could be reassured during the study.
⇒ Adherence was monitored during sessions at centre as well as remotely through zoom platform or video calls.
⇒ Bias may be higher as this is an open-label study.
⇒ A smaller sample size may limit generalisability of results.

INTRODUCTION

Fear of fall (FoF) is a great trepidation confronted by geriatric population.[1] The incidence of fall increases with age, as mentioned in the WHO global report on falls prevention in older age.[2] Geriatric population is defined as a population aged 60 years and above.[3] Biological ageing is a result of accumulation of a wide variety of molecular and cellular damage products, which lead to a gradual decrease in physical and mental capacity. Balance disorders in the elderly are most commonly due to multifactorial conditions, which may include age-related or disease-related decline in the balance system.[4]

There exists a high correlation between balance deficit and the incidence of falls, better the physical strength, less the incidence of falls.[5] Kellogg International Working Group defined falls in the elderly as 'a person coming to rest inadvertently on the ground or other lower level not as consequences of the following: sustaining a violent blow, loss of consciousness, sudden onset of paralysis or an epileptic seizure.[6] 'FoF' is defined as a disabling symptom of impaired mobility among frail older people and is common in community-dwelling older adults.[7] FoF has been identified as one of the greatest fears experienced by the elderly.[1] Fall-related injuries are a major cause of mortality and morbidity globally; it is estimated that 75% of fall injuries occur in low-income and middle-income countries.[8] Previous investigations have identified falls in older people in India as a major public health issue; however, interventional studies to prevent falls have

been neglected until.[8 9] As falls are associated with high mortality and morbidity that incurs a higher cost of medical interventions, FoF in the elderly population should be regarded as a serious health issue. Interventions to prevent the incidence of falls must be designed and implemented. One such interventional technique is yoga.

With the increasingly prevalent sedentary lifestyle and comorbidities in the elderly population, the importance of physical activities, such as yoga, is gaining more attention. Needless to say, physical activities contribute to many health benefits, and therefore, significantly delay typical physiological changes associated with ageing.[10 11] Schmid *et al* in a pilot study done on a retirement community found that FoF decreased by 6%, static balance increased by 4% (p=0.045) and lower-body flexibility increased by 34% after a 12-week yoga intervention therapy, indicating that yoga may be a promising intervention to manage FoF and improve balance, thereby reducing fall risk for older adults.[12] Nick *et al* reported that significant changes were found in both variables in the study (p<0.0001), that is, in balance and FoF. Mean differences before and after the intervention for the BBS (Bergs Balance Scale) for yoga and control groups were 10.19 and −1.16, respectively.[13] The study concluded that yoga is a potential intervention to reduce fear of falling and improve balance in older adults.

Yoga techniques, apart from having roots in traditional Indian culture, are a system for developing physical and mental along with spiritual well-being through stretching of all muscle groups for strength, flexibility and physical balance. It is more therapeutic than traditional exercise because it involves active involvement between mind and body. Yoga practice is associated with increased muscle strength, flexibility, range of motion and cardiopulmonary endurance. By working on body awareness and proprioception an improvement in balance can be achieved in older adults. For these reasons and owing to a higher cultural acceptance, yoga will prove to be a crucial fall prevention strategy in the elderly population.[14 15]

Thus, due to the lack of studies deciphering the effect of yoga on balance disorders, many of those being a pilot study, we planned a parallel arm (1:1), open-label, randomised controlled trial (RCT) to generate stronger evidence.[16–20]

The purpose of this study is to compare the effect of 12 weeks yoga intervention therapy on Falls Efficacy Scale (FES-I) and Berg Balance Scale (BBS) scores in the yoga intervention group versus the control group.

Aim

To compare the effect of yoga therapy in the elderly patients with FoF by assessing FES-I and BBS.

Primary objectives

- To compare the effect of yoga intervention therapy in the elderly with FoF at 12 weeks from baseline between the study group and control group assessed by FES-I and BBS.

Secondary objectives

- To compare the effect of yoga intervention therapy on quality of life at 12 weeks.

This study is designed as an open-label, parallel arm, randomised trial with a 1:1 allocation ratio (figure 1).

Study setting

The centre for this study will be the outpatient geriatric clinic in the Department of Geriatric Medicine of All India Institute of Medical Sciences, Rishikesh.

Study duration

This study will be conducted over a period of 18 months.

ELIGIBILITY CRITERIA

Inclusion criteria

- Patients of age 60 years and above.
- Patients with moderate to high concerns of FoF as per FES-I scale.
- Patients with Activities of Daily living score of 6 as per Katz ADL scale.

Exclusion criteria

- Patients with ulcers, gangrene, burns over the foot.
- Patients with musculoskeletal deformities.
- Patients with cognitive impairment with Hindi Mental State Examination (HMSE) score <19.
- Patients with known psychiatric disorders and who are under current treatment for the same conditions (antidepressants, antipsychotics) for more than 3 months.
- Patients with moderate to severe hearing impairment.
- Patients with visual acuity less than 6/60 with correction.

Study sample size

The sample size was calculated using G power software, with effect size 0.8; alpha error was kept at 0.05; power of 0.80; allocation ratio 1:1. The sample size was calculated as 52 with 26 subjects on each arm. Effect size was kept at 0.8 to get a large effect size since according to the values, putting in the formula gives a total sample size of 52. For the study purpose, we kept the attrition rate at 20% according to which the total sample size was 62 with 31 participants on each arm.

Study recruitment

Patient visiting OPD will be screened for eligibility criteria and will be recruited in the study after obtaining written informed consent. Probability sampling will be done by using simple random sampling method. The enrolment of the study will start from 24 May 2023 and the proposed last date of the study is 24 August 2023.

Randomisation

Computer-generated random allocation sequence will be generated using randomisation.com. Block

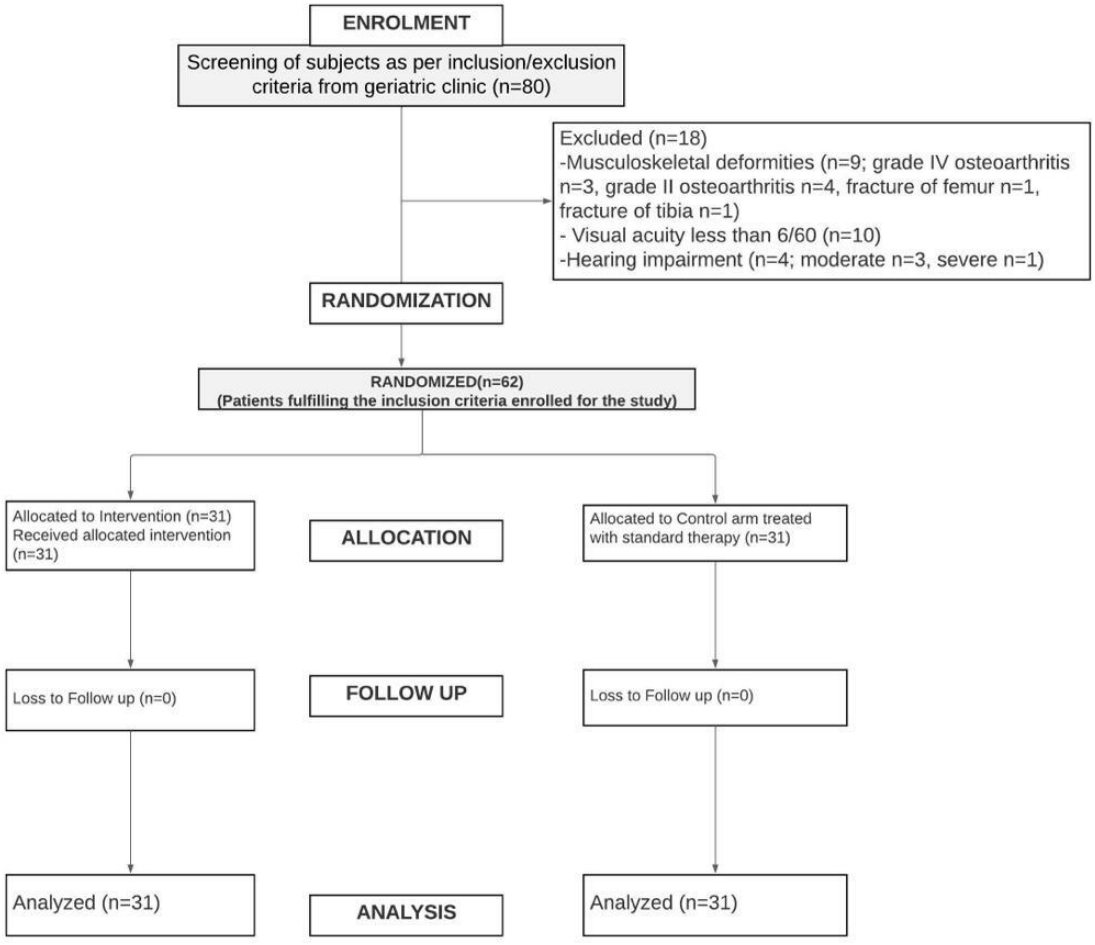

Figure 1 Study CONSORT diagram.
CONSORT - Consolidated Standards of Reporting Trials

randomisation with block size 4 will be done by one of the Co-PI, YB.[21] Sequentially numbered opaque scaled envelopes will be done for allocation concealment. Enrolment of patient and assigning the participants to the intervention will be done by MP.

As depicted in table 1, participants in arm 'A' will be receiving a 12-week yoga therapy as an add-on intervention to the standard therapy of their primary disease as per the respective guidelines.

YOGA INTERVENTION TECHNIQUE

A qualified yoga teacher, Miss Beena who has received a diploma and master's degree in Yogic Science, will conduct 30 min yoga intervention sessions twice a week for 12 weeks in the dedicated area. Each session will consist of not more than five participants. Also, each session will be built on tasks introduced during previous sessions. Yoga postures will be completed with participants in both sitting and standing postures, with meditation and yoga nidra at the end in supine position (online supplemental table S1). The yoga intervention will be focused on balance and postures as well as improving confidence in movement by building strength in arms, legs and feet to help prevent the fall episodes. The classes will emphasise breathing throughout all postures. Study participants will be encouraged to discuss complications or issues with the yoga instructor to allow for appropriate modifications. They will be advised to practise the yoga postures on a daily basis for 30 min at home. Participants will be followed up weekly basis during the intervention

Table 1 Treatment arms of the study

Treatment arm	Intervention
A	The 12-week yoga intervention therapy. (This will be used as an add-on intervention to standard therapy).
B	Standard therapy (recommended therapy of underlying primary disease as per the respective guidelines. Eg, a patient with stage I hypertension will receive any one of the recommended first-line antihypertensive agent as per standard treatment guidelines by Indian Council of Medical Research.)

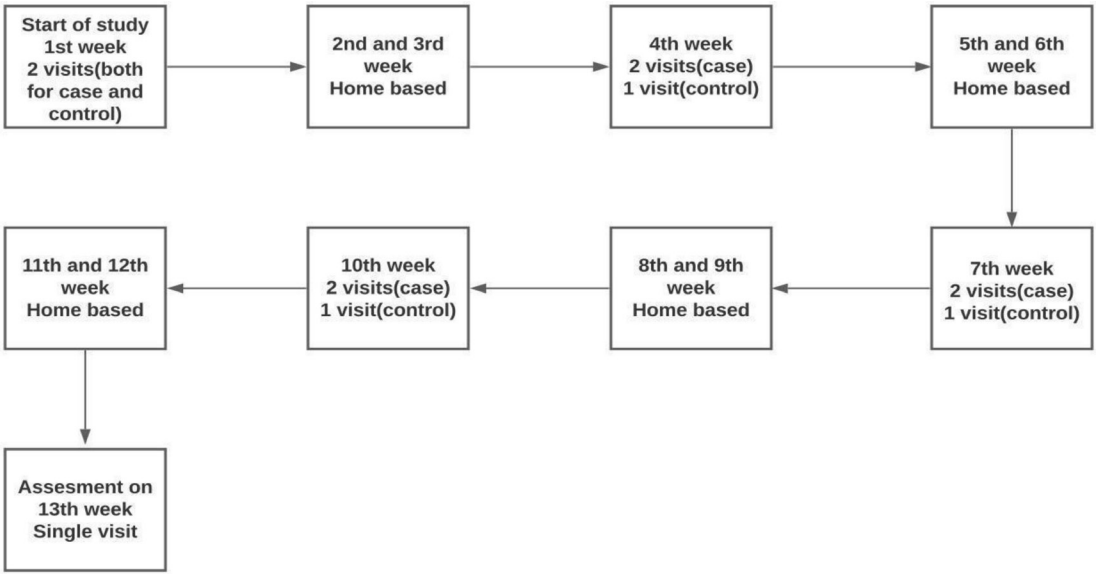

Figure 2 Follow-up visit plan for both Intervention and control group.

period of 3 months by phone contact to ensure proper adherence to the intervention. Follow-up plan is shown in figure 2. Caregivers of participants or participants well equipped with technical knowledge will be asked to send a recorded video of the participant's yoga sessions at home on a daily basis to the instructor.

Total visits for case group: 9 visits per participant for case group

Total visits for control group: 5 visits per participant for control group

Choice of comparators

The control group will consist of participants with a fear of falling who will receive treatment in accordance with the prevailing standard of care therapy for their underlying conditions, following the established guidelines specific to each condition.

Intervention modification

Any participant receiving the trial intervention who experiences hospitalisation or death for any reason will be withdrawn from the trial. A comprehensive analysis of the event will be conducted for each discontinued case at the conclusion of the study.

Intervention adherence

Participants will be followed up on a weekly basis during the intervention period of 3 months by phone contact/zoom meeting (based on the feasibility) to ensure proper adherence to the intervention. Caregivers of participants or participants well equipped with technical knowledge will be asked to send a recorded video of participant's yoga sessions at home on a daily basis to the instructor.

Endpoints

Primary endpoint

At the end of 3 months, see changes in FoF and Berg balance score.

Secondary endpoint

Improvement in quality of life after 3 months of yoga therapy.

Data collection

Data collection using Performa after written informed consent; evaluation for all the patients will be as follows:

- Katz ADL.
- FES I.
- BBS HMSE.
- Short Form (SF) 12 (SF-12) for quality of life—A performed proforma (online supplemental table S2) will be used to collect the patient demographic data and scores of various scales to be used along with a detailed consent form explaining the study aims, objectives, methodology, conflicts and benefits of the particular intervention.
- All patients will undergo baseline laboratory investigations, which will include complete blood count, kidney function test, liver function test, glycosylated haemoglobin; thyroid-stimulating hormone, triiodothyronine, ECG, FES-I, BBS, SF-12 and same will be repeated at 12 weeks except chest X-ray, echocardiography and ECG.
- Cognitive status assessment: The MMSE (Mini Mental State Examination) is a globally used instrument for cognitive screening, which nevertheless has a bias with respect to education and language. The Indo-U.S. Cross-National Epidemiology Study developed a modified version of MMSE, the HMSE, to counter this bias in India among rural and illiterate elderly. The cut-off score for possible cognitive impairment in HMSE is 19 or below. It is an excellent tool to assess cognitive ability; it encompasses the assessment of various dimensions that reflect the cognitive abilities of a person apart from being easily understood by most of the local population.

- Assessment of FoF: FES-I is a 16-item questionnaire, either self-administered or administered through interview, which asks the respondents to rate their level of confidence in performing daily life activities, rating each item on a 4-point scale with one indicating 'extreme confidence' and four indicating 'no confidence at all'. The FES-I assesses 'concern' about falling, closely related to fear and also socially acceptable by older adults. It has been developed to modify a previously existing scale FES, to maximise its suitability of usage in different languages and cultural contexts and to make it more approachable for translation. Studies have shown that FES-I is likely to perform better than FES in detecting concerns related to balance or fall.[22] A study done by Kempen *et al* has shown that the FES-I has good internal and test–retest reliability in community-dwelling older people.[23]
- Balance assessment: BBS was developed in 1989 to provide clinicians with a standardised measurement tool to assess balance in the elderly individuals. The BBS is a 14-item scale that challenges individuals balance in a variety of functional positions, ranging from sitting to standing and static and dynamic.[24] It is a 14-item list with each item consisting of 5-point ordinal scale ranging from 0 to 4, with 0 indicating the lowest level of function and four the highest. A score of 56 generally indicates functional balance while a score less than 45, indicates they may be at a greater risk of falling. Studies of various elderly populations have shown high intrarater and inter-rater reliability. Content and criterion-related validity has been supported by moderate to high correlations between BBS scores and other functional measurements in older adults with functional disability.[24]
- Assessment of quality of life: The SF-12 is a self-reported outcome measure assessing the impact of health on everyday life, often used as a tool for quality-of-life measurement. It is a shortened version of SF-36, producing similar results for physical and mental health scores with far less respondent burden.[25] It uses the same eight domains as SF-36 to assess the physical and mental health of the individual. It summarises two components, namely Mental Component Score-12 and Physical Component Score-12. Studies have shown that when compared with SF-36, in various patient groups, the score in SF-12 recorded the same level of health and change over time. Although it is not available for free due to a scoring programme, it can be used in research by a specific online calculator (https://orthotoolkit.com).
- Functional status assessment: ADL will be assessed by Katz ADL, a scale widely used that assesses six primary and psychological functions: bathing, dressing, going to the toilet, transferring, feeding and continence. It was originally designed to monitor the prognosis and treatment in chronically ill elderly patients, now being used to evaluate functional ability in older adults in various settings.[26] It scores each of the activities in 0 or 1, 1 meaning they are independent and 0 meaning they need assistance or supervision in performing the task.

We will then randomise the participants into equal groups of cases and control each comprising 30 participants. The case group will be then subjected for a 12-week yoga intervention programme by a trained personal and then assessed after 3 months to evaluate the effect of yoga therapy on their complaints by analysing the data collected and compared with the control group for the same.

Data sharing statement

The information gathered throughout the trial will be securely stored in an encrypted computer system, with exclusive access granted to the authors involved in this study. As our institute lacks a dedicated data and security management board and considering the purely academic nature of the study, without any involvement of external industry conflicts, the authors will personally oversee the adherence to top-tier protocols for data quality. This oversight encompasses data collection, secure storage and meticulous analysis. Furthermore, a comprehensive registry will be maintained, documenting individual information of cases that might have discontinued therapy due to reasons such as loss to follow-up, hospitalisation or unfortunate demise.

Patient and public involvement

Individuals identified with a fear of falling during our departmental screenings will receive detailed information about the study's design, intervention and expected outcomes. Prior to their participation in the study, written informed consent will be obtained from them.

Statistical analysis

The data will be extracted, followed by tabulation in an Excel sheet. All the analyses will be done with the help of R software. Based on the nature and distribution of variables, appropriate tests of significance will be applied. Changes in FES-I and BBS of two groups will be compared either by Student's t-test for parametric data or Mann-Whitney U test for non-parametric data. The statistical significance will be defined as $p<0.05$ and taking confidence level as 95%. Data will be analysed as per-protocol and intention-to-treat method. Also, age-adjusted and sex-adjusted analyses will be performed using linear multiple regression.

Confidentiality of data and data access

The principal investigator will ensure the confidentiality of source data and documents. Patient information will be strictly confidential and used solely for the purpose of this study. Patient identities will be safeguarded at all times. In the event of a study-related inspection, the institutional ethics committee (IEC) will be granted access to the data, subject to approval from the authors and explicit mention of the inspection in the final publication draft.

Dissemination policy

The findings and interpretations, encompassing a thorough exploration of strengths, weaknesses, limitations, adverse incidents and avenues for future research, will be openly accessible to both scholars and the general public through publication in a research journal. The aim is to ensure unrestricted access to this publication, maximising its utility for broader societal advantages and future investigations.[21]

Ethical clearance

This study has received clearance from the institutional ethics committee (IEC) through letter no AIIMS/IEC/22/195, dated 22 April 2022. The research involving human participants has been approved by the IEC of All India Institute of Medical Sciences, Rishikesh (EC/NEW/Inst/2020/1046CDSCO, ECR/736/Inst/UK/2015/RR-21). It adheres to the ethical principles outlined in the Declaration of Helsinki, 1964 (updated 2013), and International Conference on Harmonisation-Good Clinical Practice. Online supplemental material containing study data will be provided, and individual patient data can be accessed on request through correspondence with the authors. Participants will be screened only after providing informed consent. Any protocol amendments will be communicated to the ethics committee. The trial is registered under the number CTRI/2022/06/043287, institutional ethics committee approval letter number is AIIMS/IEC/22/195, dated 22 April 2022. KK will obtain a written informed consent from each study participant (online supplemental table S3). Patient information sheet (Annexure-VI/VII) will be used to provide information about the study and study procedure in the local language. For illiterate study participants, consent will be read to the patient in his/her language to their satisfaction in the presence of an impartial witness. Modifications and deviations in the study protocol will be intimated to the institutional ethics committee registered under DHR (EC/NEW/Inst/2020/1046) and CDSCO (ECR/736/Inst/UK/2015/RR-21).

Patient safety

Any adverse events identified throughout the study will be promptly reported to the IEC. If a participant sustains an injury during the study, they will receive free medical treatment for as long as necessary or until it is determined that the injury is unrelated to the study intervention, whichever comes first. In the event of an emergency during a home yoga session, participants will be instructed to seek further care or treatment at the hospital's emergency services.

Competing interest

All investigators declare no conflict of interest. The study will have no involvement with any organisation or entity with any financial interest. This is not industry sponsored. This study will not use any sponsored professional writers. The results will not be scrutinised by any external source before publication.

DISCUSSION

This research will be an interventional investigation conducted at a specialised medical facility in the northern region of India. The study will concentrate on individuals experiencing a fear of falling, adhering to established protocols while incorporating yoga therapy. Yoga therapy, recognised and accessible, is anticipated to enhance compliance owing to its cultural resonance. The initiative aims to augment existing insights into enhancing balance issues among the elderly and alleviating their FoF by integrating yoga therapy alongside conventional treatments for their underlying conditions.

Effect of yoga therapy has also been evaluated to see improvement in spine flexibility among the elderly population, which on long term can prevent the fall or FoF and the possible complications. Grabara and Szopa, on one such study, found a statistically significant increase of spine flexibility in the three planes before and after the yoga classes in all of the studied women with the mean values of the recorded improvement ranging from 6.9° to 12.5°.[27] In a review article by Woodyard, it showed that yogic practices enhance muscular strength and body flexibility, promote and improve respiratory and cardiovascular function, promote recovery from and treatment of addiction, reduce stress, anxiety, depression, and chronic pain, improve sleep patterns, and enhance overall well-being and quality of life.[28]

Patel *et al*, in an RCT based study evaluating the impact of yoga in the geriatric population and their balance control, concluded that statistically significant results were obtained in balance measured by Timed Up and Go test ($p<0.05$) and Modified Clinical Test of Sensory Interaction on Balance ($p<0.05$) among the subjects in yoga therapy group to those who were not given any intervention.[29]

Yoga exercises thus as complementary therapy are thought to be more therapeutic than traditional exercise and almost as effective as the balance control exercises taught in clinical practice, because it involves active engagement between mind and body. Its practice has shown a significantly increased muscle strength, flexibility, range of motion and cardiopulmonary endurance by focusing on increasing body awareness and proprioception, which will lead to improvement of balance in older adults and a better quality of life. Balance or fall problems in the elderly population have always been a field of concern when it comes to comprehensive geriatric care, however, often due to associated multimorbidities, it leads to high-cost intervention and management, and because of this it often gets neglected leading to further deterioration of functional status of the elderly population. Owing to such concerns, our study aims to educate and focus on yoga exercises as an effective mean to mitigate balance problems and fear of falling in the

elderly group through a more culturally acceptable form, involving their psychosocial, emotional and physical functioning and to improve their quality of life, which in recent past is the prime aim of elderly care among geriatricians.

Contributors MD conceptualised the idea, finalised the draft, planned the methodology; KK prepared the manuscript, will perform data collection; KB prepared and edited the final draft; MP will randomise and allocate participants to study groups and YB will perform statistical analysis.

Funding Mind-body medicine fellowship grant aid was provided by Central Council for Research in Yoga and Naturopathy-Collaborative Center for Mind Body Intervention through Yoga (CCRYN-CCMBIY). They can be contacted at ayush@aiimsrishikesh.edu.in through electronic mail.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Minakshi Dhar http://orcid.org/0000-0001-6336-5179
Khushboo Bisht http://orcid.org/0000-0001-9945-3752
Yogesh Bahurupi http://orcid.org/0000-0003-2433-1624

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Table S1: Yoga postures and Breathing exercises planned for the study

YOGA POSTURE AND BREATHING EXERCISES
Asana practices : with support of chair , will be individualised based on patient comfortability (10 minutes) ● Shoulder rotation; Mani bandh (10 cycles) ● Gentle neck stretches, movement of fingers, wrists, elbows, shoulders, toes, ankles, knees (same stretches completed in all sessions) (10 cycles) ● Simhasana (10 cycles) ● Bhujangasana (10 cycles) ● Uttanasana (10 cycles) ● Surya namaskaram (3 cycles) ● Gomukhasana (10 cycles)
Pranayama practices : (10 minutes) ● Anulom Vilom (10 cycles) ● Bhramari (10 cycles) ● Bhastrika (20 cycles x 3 reps) ● Breathing exercises (chest and abdominal exercises) (10 cycles)
Meditation: ● Yoga Nidra meditation on floor (10 minutes)

Table S2: Patient Proforma

NAME:	**STUDY NO.:**
UHID:	**AGE/SEX :**
ADDRESS:	**CONTACT NO.:**
CO-MORBIDITIES:	

TYPE 2 DM	**HYPERTENSION**
COPD	**CHRONIC KIDNEY DISEASE**
CAD	**HYPOTHYROIDISM**
TUBERCULOSIS	**ANY OTHER:**
HMSE SCORE:	
FES SCORE : (AT BASELINE)	
BERG BALANCE SCALE: (AT BASELINE)	
SF-12 SCORE : (AT BASELINE)	
ADL SCORE:	
FES SCORE : (AFTER THREE MONTHS)	
BERG BALANCE SCALE: (AFTER THREE MONTHS)	
SF-12 SCORE : (AFTER THREE MONTHS)	
DM-Diabetes Mellitus; COPD-Chronic Obstructive Pulmonary Disease; CAD-Coronary Artery Disease; HMSE-Hindi Mental State Examination; FES-Falls Efficacy Scale, SF-12-12 item Short Form Survey	

Table S3: Participant Informed Consent Form

PARTICIPANT INFORMED CONSENT FORM (PICF)

Participant identification number for this study: _____

Title of project: "**Yoga therapy on elderly patients with fear of fall – An open label randomized controlled trial (YOFEAR trial)**"

Name of the participant:

Age:

Gender:

UHID no:

Address:

1. I confirm that I have read and understand the parent information sheet of the above study and was given an opportunity to ask questions.

2. I understand that participation of my patient in this study is voluntary and that I am free to withdraw my patient from this study at any time, without giving any reason, without my patient's medical care or legal right being affected.

3. I understand that sections of any of my patient's medical notes may be looked at by responsible persons from All India Institute of Medical Sciences, Rishikesh Independent Ethics Committees /Institutional Review Boards and Regulatory authorities. I authorize these persons to directly avail my original medical records of my patient for the purpose verification of study procedures and / or data without violating my confidentiality.

4. I understand that the patient's investigators of this study, the ethics committee and the regulatory authority will not need my permission to look at my patient's health records both in respect of my current participation in the study and further prospective research that may be conducted in relation to it, even if I withdraw my patient from the study. However, I understand that my patient's identity will not be revealed in any information given to third party or published.

5. I agree not to restrict the use of any data or result arising from this study provided such a use is only for scientific purpose(s).

6. I have been given adequate time to consider my decision and have been given a copy of the subject information sheet and a copy of the informed consent form.

7. I agree to have my Patient take part in this study.

Participant Name: _____

- Parent/Guardian: _____

- Parent/Guardian: Name: _____ Date: Place:
- Signature/ Thumb impression _____