The effect of an Iyengar yoga-based exercise programme versus a seated yoga relaxation programme on falls in people aged 60 years and older (SAGE): a pragmatic, two-arm, parallel randomised controlled trial

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Summary

Background Exercises targeting balance and strength are proven to prevent falls. Yoga is growing in popularity and can improve balance and mobility in older adults, but its effects on falls have not been rigorously tested. In this study, we aimed to compare the effects of Iyengar yoga-based exercise and seated relaxation yoga on the rate of falls among older adults.

Methods This pragmatic, two-arm, parallel randomised controlled trial recruited Australian community-dwelling people aged 60 years and older who were not currently practising yoga and who lived independently. Participants were randomly assigned (1:1) to the intervention (Iyengar yoga-based exercise) or control (seated relaxation yoga) group using a computer-generated sequence. Participants and yoga instructors were unmasked, but research staff verifying falls data and assessing goal attainment were masked to group allocation. Intervention participants received 80 supervised, 1-h, twice-weekly yoga classes over 12 months, and were encouraged to undertake unsupervised practice on 2 additional days per week. Control participants attended two 1-h supervised workshops focused on seated breathing and stretching. Most classes were held online due to the COVID-19 pandemic. The primary outcome was fall rate per year. Secondary outcomes were mental wellbeing, physical activity, quality of life, balance self-confidence, physical function, sleep quality, pain, and goal attainment, all assessed in the intention-to-treat population. The study protocol was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619001183178).

Findings Between Oct 3, 2019, and Oct 28, 2021, 2182 older adults expressed their interest in participating, 810 were assessed for eligibility, 110 were excluded, and 700 were randomly assigned to either the Iyengar yoga exercise programme or the control group (seated yoga relaxation programme; 350 participants per group). The mean age of participants was 67 years (SD 5·2), and 570 (81%) were female and 130 (19%) were male. Six intervention participants reported musculoskeletal-related adverse events associated with the yoga programme, and no serious adverse events occurred. Contrary to expectations, there was a higher fall rate in the intervention group than in the control group (0·87 *vs* 0·64 falls per person-year; incidence rate ratio 1·33 [95% CI 1·01–1·75; p=0·044]). The intervention improved the number of hours per week of planned physical activity (mean difference 0·96 h per week [95% CI 0·43–1·49]; p<0·0001), self-reported balance confidence (mean difference 2·94 [0·60–5·28]; p=0·014), and goal attainment (mean difference 0·60 [0·26–0·94]; p=0·0006). No significant between-group differences were identified for other secondary outcomes.

Interpretation This Iyengar yoga-based programme should not be recommended for fall prevention in its current form. Modified programmes with dynamic balance and fall prevention strategies warrant investigation.

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Introduction

An alarming 37·3 million falls lead to injuries that require medical attention globally each year.[1] Approximately one in three community-dwelling people aged 65 years or older experience a fall each year, with about 5% of these falls resulting in fractures.[1] Many falls lead to subsequent morbidity, disability, and permanent residential care.[2] Therefore, strategies to prevent falls can have substantial personal, population health, and economic effects.

Much previous evidence has suggested that exercise can prevent falls.[3,4] A Cochrane systematic review of 108 randomised trials found that structured exercise can reduce fall rates by up to 34% in community-dwelling older people.[4] Additionally, a complementary review showed that

Research in context

Evidence before this study

It is well established that exercise can prevent falls, particularly exercises targeting balance. Yoga is popular among older people and can improve balance and mobility outcomes in this population. However, there are few large randomised controlled trials that specifically investigate the effect of yoga on falls. We searched PubMed between database inception and Aug 31, 2024, using the search terms "yoga" AND "falls" AND "clinical trials or randomised controlled trials" without language restrictions. The search returned 31 articles. After reviewing abstracts, we identified three randomised controlled trials investigating the effect of yoga on falls. Some of these trials were inadequately powered (<40 participants) and involved relatively short interventions (8, 12, and 14 weeks). The results of these trials showed no between-group difference in falls when compared with modified yoga Asana, Hatha, or chair-based yoga to home relaxation or usual care.

Added value of this study

To the best of our knowledge, this is the largest rigorous clinical trial investigating the effect of yoga on falls, and its findings showed that an Iyengar yoga-based exercise programme resulted in substantially more falls when compared with seated relaxation yoga. This programme effectively improved participation in planned exercise, balance self-confidence, and goal attainment.

Implications of all the available evidence

Our study does not support recommending this Iyengar yoga-based exercise programme as a fall prevention intervention for people aged 60 years and older. As the programme was primarily delivered online and was based on the Iyengar style, further research into different yoga types and delivery modes (including in-person) is warranted.

providing a high dose of training, and exercises that strongly challenge balance is more effective than lower-dose or less challenging exercise programmes in preventing falls.[5] However, reviews of exercise for fall prevention have not identified any trials evaluating the effect of yoga-based exercise on falls.[4]

Yoga is a popular mind–body exercise among middle and older age groups[6] that promotes physical and mental health. Several studies have found yoga has health benefits relating to hypertension,[7] chronic back pain and disability,[8] general health status,[9,10] mental wellbeing, and quality of life.[11,12] Yoga is well received by older people compared with other types of exercise and can be tailored for individuals with a range of functional abilities and clinical conditions.[13,14]

To see the study details on the **Open Science Framework** see https://osf.io/h5wer

There is also evidence that yoga can address some fall risk factors. Previous research shows that well designed yoga-based exercise is safe and substantially improves balance and mobility.[11,12,15] Based on these findings, yoga has been recommended as a fall prevention activity for older adults in exercise prescription guidelines.[16,17] However, no randomised controlled trials have been large enough to evaluate the effect of yoga on falls using rigorous research methods.

To fill this research gap, we conducted a randomised controlled trial to determine whether a 40-week, twice-weekly, supervised yoga exercise programme based on Iyengar style (the Successful Ageing [SAGE] yoga programme) could reduce falls over 12 months compared with a seated, unsupervised yoga relaxation programme in community-dwelling adults aged 60 years and older. We also aimed to measure the effectiveness of our Iyengar yoga-based exercise programme on mental wellbeing, physical activity, health-related quality of life, balance confidence, physical function, pain, goal attainment, and sleep.

Methods

Study design

We conducted a pragmatic, two-arm, parallel randomised controlled trial over 12 months. The study is reported according to the Consolidated Standards of Reporting Trials statement for randomised controlled trials[18] and with reference to the Template for Intervention Description and Replication checklist.[19] The trial protocol[20] and subsequent amendments were approved by the Human Research Ethics Committee at the University of Sydney as study sponsor (2019/604). The protocol was prospectively registered in the Australian and New Zealand Clinical Trials Registry (ACTRN12619001183178). The statistical analysis plan was registered on the Open Science Framework before commencing data analysis. A formal Data Safety Monitoring Board was not convened, as the intervention was considered low risk. Instead, adverse events were monitored by the trial management team and reviewed regularly by the chief investigator.

Participants

We initially recruited participants for face-to-face yoga classes in metropolitan Sydney, Australia, from Sept 23, 2019, to Feb 21, 2020. However, due to the COVID-19 pandemic, we transitioned to online classes on March 25, 2020. This transition expanded our recruitment to New South Wales beyond metropolitan Sydney and other states including Queensland, Victoria, and South Australia. Community-based recruitment was through advertisements in local newspapers, community centres, social media, online newsletters, and community organisations such as Men's Sheds, Rotary, and Probus.

To be eligible for the study, participants needed to be 60 years or older, live independently, not have participated in weekly yoga during the past year, and be able to travel to an intervention location for face-to-face classes (pre-pandemic enrolments only) or to access online classes via the internet. People were excluded if they were unable to leave the house without physical assistance from another person, had a diagnosis of dementia or a cognitive impairment assessed by a Memory Impairment Screen (score <5), insufficient English language ability to fully participate in the programme, a progressive neurological disease, or a medical condition precluding exercise participation. All participants provided written informed consent.

Randomisation and masking

After completion of baseline measures, participants were randomly assigned (1:1) to either the Iyengar yoga-based exercise programme or a seated yoga relaxation programme, using a computer-generated random allocation sequence uploaded to a REDCap database with randomly permuted block sizes of two and four. A researcher not involved with recruitment prepared the randomisation schedule, which was concealed from the research staff. Spouses or partners were assigned to the same group to avoid contamination (n=25 pairs). Due to the nature of the intervention, participants and those delivering the intervention could not be masked to group assignment. Outcome assessments were not masked because they were self-reported measures. However, research staff who assessed goal attainment and followed up on reported falls and missing data were masked to group allocation.

Procedures

Baseline information was collected electronically via REDCap and included demographic data (age, sex [self-reported; options: male, female, other], living arrangement, work status, education level, country of birth, and language spoken at home), anthropometric data (BMI), and health-related characteristics (number of medications, number and type of medical conditions, walking aid use, history of falls in the past year, self-rated balance, and self-rated fear of falling). Ethnicity data were not collected, country of birth and language spoken at home are used as proxy measures for cultural and linguistic diversity. Secondary outcome measures collected at baseline included mental wellbeing, physical activity, health-related quality of life, balance confidence, physical function, pain, and sleep. Individual mobility-related goals were also set at baseline. Participants allocated to the intervention received supervised instruction under a yoga-based exercise programme over 12 months. Our intervention (subsequently referred to as the SAGE yoga programme) was based on an Iyengar yoga programme designed for a previous pilot randomised controlled trial[15] that demonstrated significant improvements in balance and mobility.

The Iyengar style of yoga was chosen for its focus on holding static postures for longer durations, in contrast to the rapid flow movements typical of other yoga styles, such as Vinyasa. The Iyengar style incorporates props such as blocks, straps, chairs, and bolsters, providing support for the body in challenging poses, making it easier for older adults to practise. Yoga postures were adapted to accommodate individuals with varying levels of functional ability, prioritising participant safety. As participant skills and self-confidence developed, the balance demands for each pose gradually increased over the study period.[15] The SAGE yoga programme specifically emphasised standing postures, including tree pose, warrior pose, and side angle pose (appendix pp 3–18).

See Online for appendix

The SAGE yoga programme was led by qualified yoga instructors with between 12 years and 29 years of teaching experience, including experience in working with older people, and who specialised in the Iyengar style of yoga. The yoga instructors were trained by research investigators to deliver the SAGE yoga programme and followed a written protocol to ensure consistency of delivery between instructors.

The programme was initially intended to be delivered in person in yoga studios in Sydney, NSW, Australia. However, 4 months after the first class began (March, 2020), the SAGE yoga programme transitioned to be online via Zoom due to the COVID-19 pandemic. Our research team assisted participants with technology setup as required. Online participants were encouraged to keep their cameras on during classes for observation and feedback purposes. They were also offered a one-on-one online meeting with their instructor to discuss health concerns before the classes commenced. To foster social connection, each online yoga class had a dedicated WhatsApp instant messaging application group.

Participants were invited to attend 80 free, supervised, 1-h classes held twice weekly over 12 months. They were encouraged to do an additional 20-min unsupervised yoga routine aligned with class content at least twice a week, using a booklet that detailed the yoga postures. The intervention goal was to achieve a weekly exercise dosage, aligning with both physical activity guidelines and fall prevention recommendations that emphasise the importance of ongoing high-dose exercise that challenges balance to prevent falls.[5,21] The classes involved ten to 20 participants per group. Yoga instructors kept class attendance records to monitor adherence to the supervised SAGE yoga sessions, but unsupervised yoga sessions were not monitored.

Participants allocated to the control group were instructed in a seated yoga relaxation programme. The control participants were invited to two 1-h in-person or online workshops taught by the same yoga instructors who delivered the SAGE yoga programme. The seated yoga relaxation programme focused on stretching exercises for the lower back, hips, neck, shoulders, and chest, along with breathing and relaxation techniques. Participants could practise these exercises independently at home at their own discretion and were provided with a printed manual to guide them. The seated yoga relaxation programme was chosen as the control group activity as it was considered to have minimal effect on falls since it involved seated stretching and relaxation activities (appendix p 19).

Intervention participants completed a post-intervention survey measuring: (1) perceived programme benefit for physical health, wellbeing and balance or risk of falls (scored out of 10, with higher scores indicating increased benefit);[22,23] (2) satisfaction with programme features (ie, programme content, yoga instructors, yoga class facilities or Zoom; scored out of 10, with higher scores indicating greater satisfaction); (3) physical ability to take part in the programme (scored out of 10, with higher scores indicating greater ability); and (4) proportion of participants who would recommend the programme to others and would like to continue participation. Qualitative interviews using a realist evaluation approach were conducted with a purposive sample of participants and focus groups were held with the yoga instructors, with the findings published elsewhere.[22–24]

Outcomes

The primary outcome was the rate of falls in the 12 months after randomisation, assessed in the intention-to-treat population (table 1). Falls were recorded through monthly calendars completed online or on paper over 12 months. Staff who were masked to group allocation followed up unreturned calendars and reviewed reported falls to collect additional details, including injuries. Secondary outcomes included mental wellbeing,[26] physical activity,[27] quality of life,[28] balance self-confidence,[29] physical function,[30] sleep quality,[31] pain, and goal attainment,[32] assessed using validated questionnaires in the intention-to-treat population. Goal attainment was assessed at 12 months via telephone by a masked physiotherapist, based on two mobility-related goals set by participants at baseline. All other secondary outcomes were measured at baseline and 12 months via REDCap.

Statistical analysis

Full details of the sample size calculation are published elsewhere.[20] In summary, we initially determined that 560 participants (280 per group) were necessary to achieve 80% statistical power, enabling us to detect a 30% relative reduction in fall rates between groups, using a 5% significance level with a two-sided test. This sample size also allowed us to identify differences of 10–15% between groups for secondary outcome measures while considering potential overdispersion of the primary outcome. However, since the sample rate of falls was lower than what we had originally estimated and due to the possibility of a lower intervention intensity due to online delivery of the programme, we decided to re-calculate the sample size based on rate of falls across data collected from the first 100 participants in our sample. To account for a potential 20% loss to follow-up, the new sample size was determined to be 700 participants (350 per group). An average follow-up period of 11 months (rather than the planned 12 months) was used in these calculations to account for loss to follow-up.

For the **statistical analysis plan** see https://osf.io/h5wer

We followed a predefined statistical analysis plan with the following amendments. The original statistical analysis plan specified mixed effects models for both primary and secondary analyses. However, fixed-effect regression models were used instead as they provided a better fit to the data and were more interpretable. For the primary outcome, a negative binomial regression model was used to estimate the between-group ratio of fall rates at 12 months. For the continuously scored secondary outcome measures, generalised linear models adjusted for baseline values were used to assess the effect of group allocation. Data were presented as means with SDs, or effect estimates (hazard ratios, rate ratios, or incidence rate ratios) with 95% CIs, as appropriate. We used an intention-to-treat approach. Although not prespecified in the statistical analysis plan, we conducted an exploratory time-to-event analysis. A Cox proportional hazards model was used to estimate the hazard ratio (HR) for time to first fall between groups and Kaplan–Meier curves showed the probability of remaining fall-free over 12 months for the intervention and control groups. This approach was included to provide additional insight into intervention effects and is reported in the appendix (pp 23). Furthermore, although an economic analysis was initially planned and outlined in the study protocol and statistical analysis plan, this analysis was not conducted. This decision was based on the trial findings, as a cost-effectiveness analysis would not provide additional value in the context of the primary trial outcomes.

Planned subgroup analyses assessed whether the effects of the intervention varied according to baseline self-reported balance ability, history of falls, and baseline physical activity status. We dichotomised history of falls into no falls versus one or more fall in the past year. We also categorised baseline physical activity status by dividing the sample into equal thirds based on the mean of total physical activity score from the Incidental and Planned Exercise Questionnaire (IPEQ): less than 20 h per week, 20–35 h, and more than 35 h per week of physical activity. The total physical activity was calculated by summing hours per week spent in various activities, such as incidental and planned physical activity, regular and planned walking, and sports. Finally, we categorised the self-reported balance ability into two categories: poor or fair versus good, very good, or excellent. All statistical analyses were conducted using Stata/BE (version 18).

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Oct 3, 2019 and Oct 28, 2021, 2182 older adults expressed their interest in the study and, of these, the first 810 individuals who could be contacted by telephone or email were assessed for eligibility as we met our recruitment target. After excluding 110 ineligible participants (69 were not eligible, 41 were eligible but chose not to proceed), 700 were enrolled and 350 (50%) were randomly assigned

	Measurement
Primary outcome	
Falls	Monthly calendars collected over 12 months; falls were defined as "an unexpected event in which the participant comes to rest on the ground, floor, or lower level, as a result of a loss of balance".[25]
Secondary outcomes	
Mental wellbeing	Warwick-Edinburgh Mental Well-being Scale is a 14-item scale, with total scores ranging from 14 to 70. A higher score indicates a higher level of wellbeing.
Physical activity	IPEQ assessed the frequency and duration of planned and incidental physical activity, yielding continuous scores in min per week. Higher scores reflect greater amounts of physical activity.
Quality of life	EQ-5D-5L questionnaire generated a health utility score (–0·68 to 1·00; higher scores indicate better health-related quality of life) and a visual analogue scale score (0–100; higher scores indicate better self-rated health).
Balance self-confidence	Activity-specific Balance Confidence Scale–simplified scores range from 0 to 100, with higher scores indicating greater confidence in performing daily activities without losing balance.
Physical function	Late Life Function and Disability Instrument scores range from 0 to 100, with higher scores indicating better physical function and less disability.
Sleep quality	Pittsburgh Sleep Quality Index scores range from 0 to 21, with higher scores indicating poorer sleep quality.
Pain	Assessed using three questions: (1) Are you currently troubled by pain or discomfort, either all the time or on and off? (2) Have you had this pain or discomfort for more than 3 months? (3) Does this pain affect your daily activities? Responses for all questions were based on a 5-point Likert scale: 1=not at all, 2=a little bit, 3=moderately, 4=quite a lot, 5=extremely
Goal attainment	Goal Attainment Scale, which rates progress on a 5-point scale from –2 (much worse than baseline) to +2 (much better than expected); participants set two mobility-related goals at baseline, and each goal was scored at 12 months; the two scores were summed to create a continuous variable ranging from –4 to +4; example goals included improving the ability to get up from the floor, using stairs with greater confidence, or enhancing balance.

IPEQ=Incidental and Planned Exercise Questionnaire.

Table 1: **Study outcomes and measures**

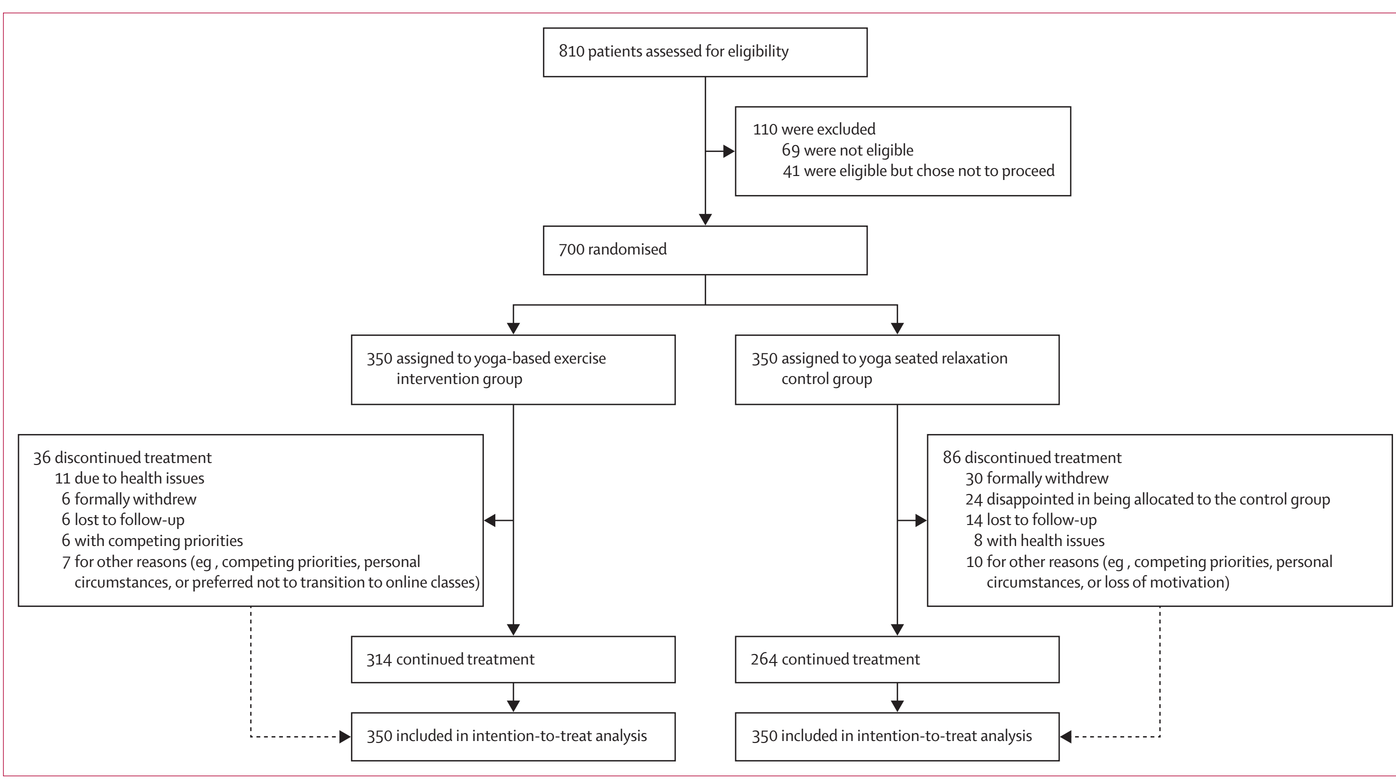

Figure 1: **Trial profile**

to the intervention (Iyengar yoga exercise programme) and 350 (50%) to the control (seated yoga relaxation programme; figure 1). More participants in the control group withdrew from the study than the intervention group (86 [25%] of 350 *vs* 36 [10%] of 350). The main reasons for withdrawal were not wanting to be allocated to the control

	Control group (n =350)	Intervention group (n=350)
Age (years)	66·5 (5·2)	66·8 (5·3)
Age group		
60–69	264 (75%)	252 (72%)
70–79	79 (23%)	93 (27%)
80 or older	7 (2%)	5 (1%)
Sex		
Female*	291 (83%)	279 (80%)
Male	59 (17%)	71 (20%)
Living alone	78 (22%)	90 (26%)
Language other than English spoken at home†	19 (5%)	23 (7%)
Born outside of Australia†	126 (36%)	145 (41%)
Low education attainment‡	92 (26%)	78 (22%)
Total number of medications	1·7 (1·7)	1·7 (1·7)
Medical conditions		
Total number of medical conditions	1·5 (1·4)	1·7 (1·5)
Number of participants with one medical condition	87 (25%)	98 (28%)
Number of participants with two or three medical conditions	113 (32%)	117 (33%)
Number of participants with four or more medical conditions	52 (15%)	45 (13%)
Walking aid use	5 (1%)	8 (2%)
Fallen in the past year	116 (33%)	113 (32%)
Self-rated balance fair or poor	83 (24%)	95 (27%)
Self-rated fear of falling more than moderate	70 (20%)	76 (22%)
EQ-5D-5L VAS	80·2 (12·2)	79·0 (12·9)
Self-reported physical activity (h per week)§	29·9 (15·8)	30·1 (16·8)

Data are mean (SD) or n (%). IPEQ=Incidental and Planned Exercise Questionnaire. VAS=visual analogue scale. *Sex options were male, female, other. †Ethnicity data were not collected; country of birth and language spoken at home are used as proxy measures for cultural and linguistic diversity. ‡Participants with a trade certificate, secondary school completion, or below. §IPEQ-based measure, derived by summing h per week spent in incidental activity, planned and usual walking activity, or planned activity and sports.

Table 2: **Baseline characteristics**

group and personal reasons (eg, competing priorities or family health issues). The mean age of the 700 participants was 67 years (SD 5·2), 570 (81%) were female, 130 (19%) were male, and 229 (33%) reported a history of falls in the past year at baseline. Characteristics were well balanced across the groups, and participants were similar in all measures (table 2; appendix p 20).

The intervention was delivered through 26 yoga classes, with an average of 14 participants per class. Participants randomly assigned to the intervention group attended an average of 55 (69%) of 80 supervised yoga sessions. 250 (71%) of 350 attended at least 50% of the sessions, and 207 (59%) attended at least 75% of the sessions. We did not monitor control group adherence. 46 participants from four classes started the programme in a studio setting before the COVID-19 lockdown came into effect. Three participants chose not to continue with the programme in an online format and of the remaining 43 participants who transitioned to online classes, 39 completed the full programme. Six intervention participants reported adverse events associated with the yoga programme: muscle strain (n=2), a knee ligament strain (n=1), an increase in hip discomfort (n=1), knee pain (n=1), and an increase in pre-existing neck pain (n=1). No serious adverse events were reported.

Of 700 randomised participants, 649 (93%) provided at least one fall diary, contributing to estimating fall incidence rates and the incidence rate ratios (IRRs), and 517 (74%) participants completed all monthly fall calendars. During the 12-month study period, participants experienced a total of 440 falls, of which 147 (33%) caused injury (ie, cuts, grazes, dislocation, sprain, fracture, or traumatic brain injury). Of the 700 participants, 245 (35%) experienced at least one fall and 99 (14%) experienced an injurious fall. The primary outcome analysis showed that the intervention group had a significantly higher 12-month incidence of falls than the control group (IRR 1·33 [95% CI 1·01–1·75]; p=0·044 table 3). The proportion of intervention and control participants experiencing at least one injurious fall was similar between the groups (15% of intervention participants *vs* 13% of control participants; RR 1·04 [95% CI 0·73 –1·50]; p=0·82). Although consistent with the direction of the primary analysis, the post-hoc exploratory analysis of time to first fall did not show a significant difference between groups (HR 1·24 [95% CI 0·96–1·60]; p=0·096). Kaplan–Meier curves comparing the probability of remaining fall-free between the intervention and control groups are shown in the appendix (p 23).

The secondary outcomes analyses indicated that, compared with the control group, the intervention significantly increased the number of hours per week of planned physical activity (ie, total hours per week spent in planned structured exercise; mean difference 0·96 h per week, [95% CI 0·43–1·49]; p<0·0001), self-reported balance confidence (mean difference 2·94 [0·60–5·28]; p=0·014), and had better goal attainment (mean difference 0·60 [0·26–0·94]; p=0·0006) at 12 months after randomisation. There were no significant differences between the intervention and control groups in other secondary outcomes (ie, mental wellbeing, health-related quality of life, total walking activity and overall activity, physical function, pain and discomfort lasting more than 3 months and affecting daily activities, or sleep) at 12 months (appendix pp 21–22).

The pre-planned subgroup analysis suggested a higher rate of falls in participants who had not fallen within the pre-intervention year; had high levels of physical activity; and self-reported good, very good, or excellent balance at baseline (figure 2). However, the interaction term was only significant for participants who reported high levels (>35 h per week) of total physical activity (ie, a combination of hours per week spent in various physical activities; p for interaction=0·0009). The intervention appeared to have reduced falls in the least physically active participants (IRR 0·61 [95% CI 0·37–1·01]), although the effect was not statistically significant (p=0·05).

In terms of process evaluation, 268 (77%) of 350 participants completed a survey regarding their impressions of the intervention. The survey used a 0–10 scale, where 0 indicated “not at all” and 10 indicated “extremely” (eg, extremely beneficial, extremely satisfied, extremely able). The mean rating of programme benefits was 8·4 (SD 2·1) out

	Control group (n=350)	Intervention group (n=350)	IRR or RR (95% CI)	p value
Number of participants who contributed falls data*	309 (88%)	340 (97%)	..	..
Number of person-years of follow-up†	256	317	..	..
Number of falls reported	164	276	..	..
Participants having one or more falls	102/350 (29%)	143/350 (41%)	RR 1·27 (1·04–1·55)	0·020
Participants with one fall	67/350 (19%)	86/350 (25%)	..	..
Participants with two or three falls	28/350 (8%)	48/350 (14%)	..	..
Participants with four or more falls	7/350 (2%)	9/350 (3%)	..	..
Falls, rate per person-year‡	0·64	0·87	IRR 1·33 (1·01–1·75)	0·044
Participants with one or more injurious fall	46/350 (13%)	53/350 (15%)	RR 1·04 (0·73–1·50)	0·82
Injurious falls, rate per person-year§	0·19	0·18	IRR 0·94 (0·64 to 1·38)	0·75

Data are n (%) or N/N (%), unless otherwise indicated. IRR=incidence rate ratio. RR=rate ratio. *Participants who provided at least one fall calendar. †Total time at risk contributed by all participants from randomisation until end of follow-up, loss to follow-up, or death. ‡Rate calculated as the total number of falls reported divided by months of follow-up. §An injurious fall was considered injurious if it resulted in cuts, grazes, dislocation, sprain, fracture, or traumatic brain injury.

Table 3: Fall outcomes at 12 months

of 10 for physical health, 8·1 (2·1) for mental health, and 8·3 (2·1) for balance or risk of falls. Overall, participants were satisfied with the programme, especially with the programme content (mean 8·8 [SD 1·7] out of 10) and yoga instructors (9·2 [1·6] out of 10). Participants viewed the yoga programme as enjoyable but challenging, and suitable for older people without previous yoga experience. Support, encouragement, professionalism, and tailoring of yoga poses to an individual's needs were the main comments associated with satisfaction with the instructors. Participants rated their physical ability to take part in the yoga programme as good (8·3 [SD 1·8] out of 10). Overall, 250 (93%) of the 268 participants who completed the survey would recommend the programme to others, and 194 (72%) stated they intended to continue participation in yoga after trial completion.

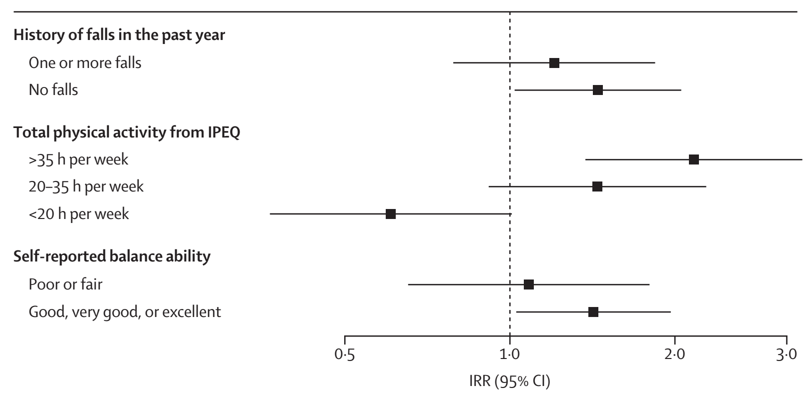

Figure 2: **Effects of intervention by subgroups categorised by history of falls, physical activity, and self-reported balance at baseline**
Data are IRR (95% CI). IRR=incidence rate ratio. IPEQ=Incidental and Planned Exercise Questionnaire.

Discussion

The SAGE yoga programme was delivered by experienced, specially trained yoga instructors, mostly through live online sessions. We found moderate adherence rates among participants, despite the lengthy 40-week intervention period and the challenges and uncertainty posed by the COVID-19 pandemic. Unexpectedly, in this trial, participants undertaking the SAGE yoga programme (intervention group) had substantially more falls than participants assigned to the yoga relaxation programme (control group). The two groups did not differ significantly in the rate of injurious falls. Exploratory prespecified subgroup analyses suggested larger (more harmful) effects of the intervention on fall rates in participants with no history of falls; high physical activity; and good, very good, or excellent self-reported balance ability. The SAGE yoga programme increased overall planned physical activity, improved balance confidence, and promoted better mobility goal attainment. No significant differences were found for other secondary outcomes, including total physical activity. Participants reported enjoying the intervention and perceiving physical and mental health improvements. Our study demonstrates the importance of conducting well designed trials with adequate statistical power to comprehensively investigate the effectiveness of a specific type of physical activity for preventing falls and how we can improve on current practice models. Below, we integrate our findings with the broader fall prevention literature and discuss how our unexpected outcomes might inform future research and practice.

The large sample of community-dwelling older people (n=700) and long follow-up (12 months) make this study the first robustly conducted trial designed to evaluate the effect of yoga on falls. Only one recently published yoga[33] trial involving a large sample of older people (n=454) exists with which to compare our results. This trial investigated the effect of chair-based yoga on falls in older people with multiple long-term conditions as a secondary outcome and found a higher incidence of falls in the intervention group than in the control group. Although the between-group difference was not statistically significant (IRR 1·38 [95% CI 0·95–2·01]; p=0·09), the IRR point estimate was similar to that of our study (IRR 1·33 [1·01–1·75]; p=0·04). The significant between-group difference observed in our trial could be attributed to the larger sample size, which provided more statistical power to detect differences between groups. Two previous trials also investigated the effect of yoga on falls in older people and reported no significant fall reduction compared with usual care or home relaxation exercises.[34,35] However, they used small samples (n=33 and n=38 participants) and a short intervention (8 weeks and 14 weeks). The limited research on yoga's effect on falls might be due to the complexity of conducting studies in the fall prevention area, which requires large sample sizes (at least 500 participants for sufficient power), extended data collection periods, and managing a population prone to dropouts.[36]

Our unexpected finding of a significant increase in falls in the intervention group contradicts our hypothesis, based on previous systematic reviews, that yoga would reduce falls.[11,12] We offer several possible explanations for this counterintuitive outcome. First, the improved mobility goal attainment and confidence in balance might have encouraged participants to engage in a wider range of physical activities and at greater intensity, potentially exposing them to higher fall-risk situations. A previous study linked behavioural risk to future falls, with higher fall rates observed in individuals who overestimated their physical abilities and took undue risks.[37] This observation might also help explain our subgroup analysis finding that participants with no history of falls and higher levels of physical activity had higher fall rates than their less active counterparts after the intervention. To help participants safely manage increased physical activity, future iterations of the programme might need to include discussion and education about safe mobility. Second, intervention participants had greater mobility goal attainment, greater planned physical activity (perhaps because of the time spent undertaking yoga), and modestly enhanced balance confidence, without an obvious increase in physical function (eg, Late Life Function and Disability Instrument scores unchanged). Participants might have felt more confident and motivated to be active, but could have lacked the increased physical capacity needed to prevent or recover from a fall. It is also possible that the predominantly online delivery mode of the SAGE programme prioritised safety over introducing more physically challenging exercises, facilitating this disconnect. The process evaluation identified that some participants exerted less effort in online classes due to reduced instructor oversight, and instructors noted slower progress, with some balance postures not achieved.[22,24] Future research should investigate the effect of in-person yoga on falls and include objective measures of balance and physical function. Third, the SAGE yoga programme's foundation in the Iyengar style, emphasising static postures, differs from most successful fall prevention interventions that have targeted dynamic balance and functional activities, and included fall prevention advice.[38–40] Fourth, while we chose an active control involving seated stretching and relaxation techniques with the expectation of minimal impact on fall risk, participation in the yoga relaxation programme might have influenced the control group's physical function parameters. Previous systematic reviews indicate that a stretching control group might improve balance and knee strength.[41] Therefore, we might have inadvertently reduced the potential for added benefit in the intervention compared with the control group.

The strengths of this study are that it is a large and appropriately powered, pragmatic trial testing the effect of a yoga-based programme on falls. We incorporated broad inclusion criteria, a robust randomised controlled design with a prospectively registered protocol, a relatively long intervention (12 months), and the recommended method for collecting fall data.[25] We used methods designed to reduce risk of bias, such as a concealed random allocation, masked research staff to collect details about reported falls, an intention-to-treat approach, a prospectively registered statistical analysis plan, and prespecified subgroup analyses. We achieved an outstanding recruitment rate due to the high level of interest in the study, recruiting 700 participants in approximately 2 years during a global pandemic. We had to turn away 1372 potential participants after reaching our recruitment goal, demonstrating the popularity of yoga among older people.

Our study had several limitations. Although we followed the recommended procedure of monthly calendars for collecting the falls data,[25] this method relies on self-report, which is prone to recall and response bias.[42] Another limitation is that due to the nature of physical activity trials, masking of participants and intervention providers was not possible, potentially introducing bias by expectation and affecting participants' behaviour and responses to subjective outcome measures.[43] However, research staff who collected fall details and followed up on missing data were masked to group allocation. Although our recruitment covered a range of rural and urban areas of Australia and applied few exclusion criteria, resulting in access to a generally representative community-dwelling older population, our participants had no English difficulties, were relatively young (mean age 67 [SD 5·2]), highly educated, more physically active, and generally in better health than the broader population, which potentially affects generalisability. More targeted recruitment strategies are needed to reach a more diverse and representative population. Another limitation is that adherence to the unsupervised yoga sessions was not monitored, which might have influenced the total intervention dose received. Adherence in the control group was also not tracked. However, because the control workshops focused solely on breathing and seated exercises, any variation in adherence is unlikely to have meaningfully affected the primary outcome of falls. Awareness of group allocation also introduced potential for reporting and performance bias[44]—issues common in exercise-based trials where participant masking is not feasible. Control group participants, aware they were not receiving the yoga intervention and receiving only two workshops and less interaction, might have been less engaged and thus under-reported falls or other outcomes. Moreover, although instructed not to participate in yoga classes during the trial, some control participants might have done so, thereby affecting the trial outcomes. These factors reflect the inherent challenges in delivering and evaluating exercise-based interventions in a real-world setting. A further limitation is that the IPEQ questionnaire does not differentiate between types of planned physical activity, such as yoga classes delivered as part of the intervention and other forms of planned exercise. As such, the observed increase in planned physical activity is likely to reflect participants' attendance at the yoga classes, rather than engagement in additional new activities. Finally, we did not use objective measures of balance or physical function, limiting the reliability of assessments of the effect of these indicators. However, there is no basis for assuming that there would be any systematic difference in the subjective assessment obtained between intervention and control groups.

In conclusion, our findings do not support recommending this Iyengar yoga-based programme to prevent falls in its current form. However, the adherence to the intervention was moderate, and there was a high level of interest in the study. These encouraging rates show that yoga is an enjoyable and appealing intervention among older people. Therefore, it is worth investigating the effect of different types of yoga that include more dynamic balance and the effect of including additional fall prevention advice. Further research investigating face-to-face yoga and including an objective measure of balance and physical function is needed.

Contributors

AT and CS were responsible for the conception of the study. AT, CS, SRL, AB, ACG, and KJA contributed to the design of the study. JSO was the trial manager, and GCC, SC, CAW, WSK, LMNP, and GW contributed to the data collection and management. AH and HG contributed to the study process evaluation design and analysis. MT contributed to data analysis, and MT, AT, JSO and CS contributed to interpreting the data. JSO drafted the manuscript and prepared the tables and supplementary tables 1–3 in the appendix. All authors critically revised the manuscript for important intellectual content. JSO and AT accessed and verified the underlying data. All authors had full access to the data in the study and accept responsibility for the decision to submit for publication.

Declaration of interests

CS declares funding for other studies from the Australian Medical Research Future Fund to the University of Sydney; royalties or licences from the Cambridge University Press for a book on falls; and is an executive member of the Fall Prevention Society of Australia. AH declares funding for other studies from the Australian Medical Research Future Fund to the University of Sydney. HG declares funding for other studies from the Australian Medical Research Future Fund and Physiotherapy Research Foundation to the University of Sydney. AT declares funding for other studies from the Australian Medical Research Future Fund and the National Health and Medical Research Council of Australia to the University of Sydney. All other authors declare no competing interests.

Data sharing

Data are available upon reasonable request. De-identified participant data underlying main results can be accessed by researchers who provide a methodological proposal directed to the principal investigator AT. (anne.tiedemann@sydney.edu.au). Approval for data access will be granted on a case-by-case basis at the discretion of the principal investigator. The data will be accessible from the date of this Article's publication and will be available for a period of 5 years thereafter. The study protocol and the statistical analysis plan are available.

For the **statistical analysis** please see https://osf.io/h5wer

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References

1 World Health Organization. Step safely: strategies for preventing and managing falls across the life-course. Geneva: World Health Organization, 2021.

2 James SL, Lucchesi LR, Bisignano C, et al. The global burden of falls: global, regional and national estimates of morbidity and mortality from the Global Burden of Disease Study 2017. *Inj Prev* 2020; **26** (suppl 1): i3–11.

3 Montero-Odasso M, van der Velde N, Martin FC, et al. World guidelines for falls prevention and management for older adults: a global initiative. *Age Ageing* 2022; **51:** afac205.

4 Sherrington C, Fairhall NJ, Wallbank GK, et al. Exercise for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2019; **1:** CD012424.

5 Sherrington C, Michaleff ZA, Fairhall N, et al. Exercise to prevent falls in older adults: an updated systematic review and meta-analysis. *Br J Sports Med* 2017; **51:** 1750–58.

6 Wang CC, Li K, Choudhury A, Gaylord S. Trends in Yoga, Tai Chi, and Qigong use among US adults, 2002–2017. *Am J Public Health* 2019; **109:** 755–61.

7 Yang K. A review of yoga programs for four leading risk factors of chronic diseases. *Evid Based Complement Alternat Med* 2007; **4:** 487–91.

8 Saper RB, Sherman KJ, Delitto A, et al. Yoga vs physical therapy vs education for chronic low back pain in predominantly minority populations: study protocol for a randomized controlled trial. *Trials* 2014; **15:** 67.

9 Roland KP, Jakobi JM, Jones GR. Does yoga engender fitness in older adults? A critical review. *J Aging Phys Act* 2011; **19:** 62–79.

10 Patel NK, Newstead AH, Ferrer RL. The effects of yoga on physical functioning and health related quality of life in older adults: a systematic review and meta-analysis. *J Altern Complement Med* 2012; **18:** 902–17.

11 Tulloch A, Bombell H, Dean C, Tiedemann A. Yoga-based exercise improves health-related quality of life and mental well-being in older people: a systematic review of randomised controlled trials. *Age Ageing* 2018; **47:** 537–44.

12 Youkhana S, Dean CM, Wolff M, Sherrington C, Tiedemann A. Yoga-based exercise improves balance and mobility in people aged 60 and over: a systematic review and meta-analysis. *Age Ageing* 2016; **45:** 21–29.

13 Tiedemann A, O'Rourke S, Sherrington C. Is a yoga-based program with potential to decrease falls perceived to be acceptable to community-dwelling people older than 60? *Public Health Res Pract* 2018; **28:** 28011801.

14 Birdee GS, Legedza AT, Saper RB, Bertisch SM, Eisenberg DM, Phillips RS. Characteristics of yoga users: results of a national survey. *J Gen Intern Med* 2008; **23:** 1653–58.

15 Tiedemann A, O'Rourke S, Sesto R, Sherrington C. A 12-week Iyengar yoga program improved balance and mobility in older community-dwelling people: a pilot randomized controlled trial. *J Gerontol A Biol Sci Med Sci* 2013; **68:** 1068–75.

16 Garber CE, Blissmer B, Deschenes MR, et al. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sports Exerc* 2011; **43:** 1334–59.

17 Farag I, Howard K, Ferreira ML, Sherrington C. Economic modelling of a public health programme for fall prevention. *Age Ageing* 2015; **44:** 409–14.

18 Schulz KF, Altman DG, Moher D, and the CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010; **340:** c332.

19 Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014; **348:** g1687.

20 Oliveira JS, Sherrington C, Lord S, et al. Yoga-based exercise to prevent falls in community-dwelling people aged 60 years and over: study protocol for the Successful AGEing (SAGE) yoga randomised controlled trial. *BMJ Open Sport Exerc Med* 2020; **6:** e000878.

21 Bull FC, Al-Ansari SS, Biddle S, et al. World Health Organization 2020 guidelines on physical activity and sedentary behaviour. *Br J Sports Med* 2020; **54:** 1451–62.

22 Haynes A, Gilchrist H, Oliveira JS, et al. What helps older people persevere with yoga classes? A realist process evaluation of a COVID-19-affected yoga program for fall prevention. *BMC Public Health* 2022; **22:** 463.

23 Haynes A, Gilchrist H, Oliveira JS, Sherrington C, Tiedemann A. "I wouldn't have joined if it wasn't online": understanding older people's engagement with teleyoga classes for fall prevention. *BMC Complement Med Ther* 2022; **22:** 283.

24 Gilchrist H, Haynes A, Oliveira JS, et al. ''My words become my hands'': Yoga instructors' experiences of adapting teleyoga in the SAGE fall prevention trial-A qualitative analysis. *Digit Health* 2023; **9:** 20552076231185273.

25 Lamb SE, Jørstad-Stein EC, Hauer K, Becker C. Development of a common outcome data set for fall injury prevention trials: the Prevention of Falls Network Europe consensus. *J Am Geriatr Soc* 2005; **53:** 1618–22.

26 Tennant R, Hiller L, Fishwick R, et al. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. *Health Qual Life Outcomes* 2007; **5:** 63.

27 Delbaere K, Hauer K, Lord SR. Evaluation of the incidental and planned activity questionnaire (IPEQ) for older people. *Br J Sports Med* 2010; **44:** 1029–34.

28 Oppe M, Devlin NJ, van Hout B, Krabbe PF, de Charro F. A program of methodological research to arrive at the new international EQ-5D-5L valuation protocol. *Value Health* 2014; **17:** 445–53.

29 Filiatrault J, Gauvin L, Fournier M, et al. Evidence of the psychometric qualities of a simplified version of the Activities-specific Balance Confidence scale for community-dwelling seniors. *Arch Phys Med Rehabil* 2007; **88:** 664–72.

30 Haley SM, Jette AM, Coster WJ, et al. Late Life Function and Disability Instrument: II. Development and evaluation of the function component. *J Gerontol A Biol Sci Med Sci* 2002; **57:** M217–22.

31 Buysse DJ, Reynolds CF 3rd, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res* 1989; **28:** 193–213.

32 Kolip P, Schaefer I. Goal attainment scaling as a tool to enhance quality in community-based health promotion. *Int J Public Health* 2013; **58:** 633–36.

33 Tew G, Wiley L, Ward L, et al. Effectiveness and cost-effectiveness of offering a chair-based yoga programme in addition to usual care in older adults with multiple long-term conditions: a pragmatic, parallel group, open label, randomised controlled trial. *NIHR Open Res* 2024; **3:** 52.

34 Saravanakumar P, Higgins IJ, van der Riet PJ, Marquez J, Sibbritt D. The influence of tai chi and yoga on balance and falls in a residential care setting: a randomised controlled trial. *Contemp Nurse* 2014; **48:** 76–87.

35 Hamrick I, Mross P, Christopher N, Smith PD. Yoga's effect on falls in rural, older adults. *Complement Ther Med* 2017; **35:** 57–63.

36 Tew GA, Ward L, Hewitt C, Tiedemann A. Does yoga reduce the risk of falls in older people? *BMJ* 2020; **370:** m3246.

37 Butler AA, Lord SR, Taylor JL, Fitzpatrick RC. Ability versus hazard: risk-taking and falls in older people. *J Gerontol A Biol Sci Med Sci* 2015; **70:** 628–34.

38 Clemson L, Cumming RG, Kendig H, Swann M, Heard R, Taylor K. The effectiveness of a community-based program for reducing the incidence of falls in the elderly: a randomized trial. *J Am Geriatr Soc* 2004; **52:** 1487–94.

39 Clemson L, Fiatarone Singh MA, Bundy A, et al. Integration of balance and strength training into daily life activity to reduce rate of falls in older people (the LiFE study): randomised parallel trial. *BMJ* 2012; **345:** e4547.

40 Campbell AJ, Robertson MC, Gardner MM, Norton RN, Tilyard MW, Buchner DM. Randomised controlled trial of a general practice programme of home based exercise to prevent falls in elderly women. *BMJ* 1997; **315:** 1065–69.

41 Sanchez-Lastra MA, Molina AJ, Martin V, Fernández-Villa T, Cancela JM, Ayan C. Is stretching exercise an adequate control group in clinical trials aimed at improving physical fitness and function of older adults? A systematic review and meta-analysis. *J Aging Phys Act* 2020; **28:** 889–910.

42 Prince SA, Adamo KB, Hamel ME, Hardt J, Connor Gorber S, Tremblay M. A comparison of direct versus self-report measures for assessing physical activity in adults: a systematic review. *Int J Behav Nutr Phys Act* 2008; **5:** 56.

43 Karanicolas PJ, Farrokhyar F, Bhandari M. Practical tips for surgical research: blinding: who, what, when, why, how? *Can J Surg* 2010; **53:** 345–48.

44 Forbes D. Blinding: an essential component in decreasing risk of bias in experimental designs. *Evid Based Nurs* 2013; **16:** 70–71.