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Review Article

Critical Appraisal on Randomized Factorial Trial of Falls Prevention Among Older People Living in Their Own Homes

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Abstract: Objective To test the effectiveness of, and explore interactions between, three interventions to prevent falls among older people. Design a randomized controlled trial with a full factorial design. Setting Urban community in Melbourne, Australia. Participants1090 aged 70 years and over and living at home. Most were Australian born and rated their health as good to excellent; just over half lived alone. Interventions Three interventions (group based exercise, home hazard management, and vision improvement) delivered to eight groups defined by the presence or absence of each intervention. Main outcome measure Time to first fall ascertained by an 18 month falls calendar and analyzed with survival analysis techniques. Changes to targeted risk factors were assessed by using measures of quadriceps strength, balance, vision, and number of hazards in the home. Results the rate ratio for exercise was 0.82 (95% confidence interval 0.70 to 0.97, P=0.02), and a significant effect (P < 0.05) was observed for the combinations of interventions that involved exercise. Balance measures improved significantly among the exercise group. Neither home hazard management nor treatment of poor vision showed a significant effect. The strongest effect was observed for all three interventions combined (rate ratio 0.67 (0.51 to 0.88, P=0.004)), producing an estimated 14.0% reduction in the annual fall rate. The number of people needed to be treated to prevent one fall a year ranged from 32 for home hazard management to 7 for all three interventions combined. Conclusions group based exercise was the most potent single intervention tested, and the reduction in falls among this group seems to have been associated with improved balance. Falls were further reduced by the addition of home hazard management or reduce division management, or both of these. Cost effectiveness is yet to be examined. These findings are most applicable to Australian born adults aged 70-84 years living at home who rate their health as good.

Keywords: Critical Appraisal, Falls Prevention, Older People, Own Homes

1. Introduction

The prevention of falls among older people living in their own homes is an established priority in many countries. The focus of falls prevention research has most recently been on testing interventions. Randomized trials of single interventions among older people living at home have shown that exercise, medication reduction, support services arranged by trained volunteers, and home modifications arranged by occupational therapists are all effective interventions trials of multiple interventions among older people living at home have also shown reductions in the risk of falling. 1 None of the designs of these trials, except one, 2 permitted examination of the effects of each component separately or of any interactive effect between components. The main aim of this randomized controlled trial was to test the effectiveness of, and to explore any interactions between, three interventions to reduce falls among older people.

2. Methods

Setting and subjects the study was conducted in the City of Whitehorse, mainly middle class area of Melbourne, the second largest city in Australia. Potential participants were people aged 70 years and over living in their own home.

2.1. Design

The targeted risk factors were strength, balance, poor vision,

and presence of home hazards. The selection of the first three risk factors was justified by strong research evidence and their being amenable to intervention through local government. The wide spread existence of home hazard modification programmes base justified inclusion of the fourth. A full factorial design was used, with eight distinct groups defined according to the presence or absence of each of the three interventions (figure 1). Seven groups received at least on intervention; the eighth received no intervention until after the study had ended. Participants were randomly assigned by an "adaptive biased coin" technique, rather than simple equiprobable randomization, to ensure balance of group.

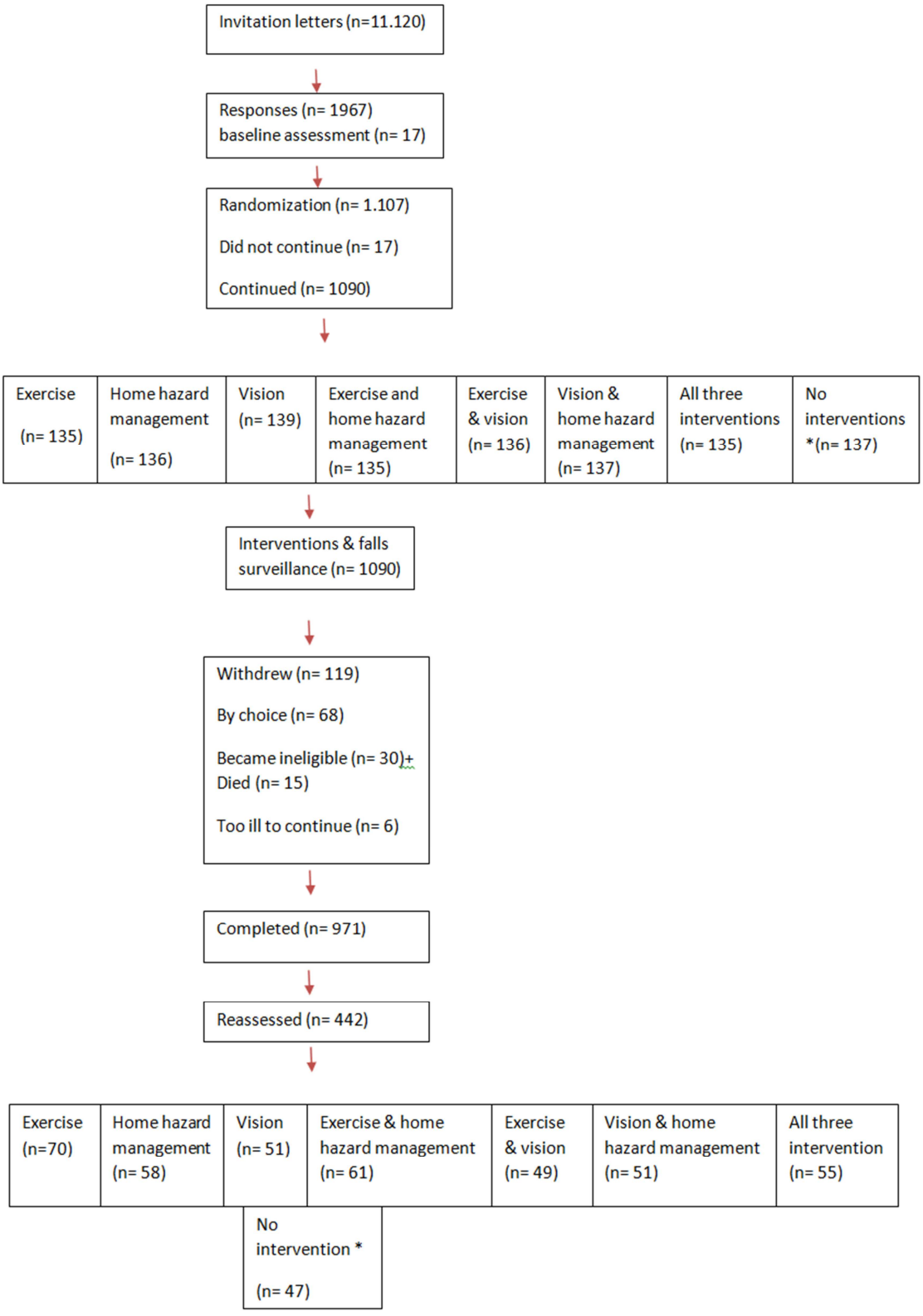

Figure 1. *Flow chart showing stages in study protocol and numbers of participants.*

2.2. Inclusion and Exclusion criteria

Participants had to be living in their own home or apartment or leasing similar accommodation and allowed to make modifications. Potential participants were excluded if they did not expect to remain in the area for two years (except for short absences); had par-ticipated in regular to moderate physical activity with a balance improvement component in the previous two months; could not walk 10-20 metres without rest, help, or having angina; had severe respiratory or cardiac disease; had a psychiatric illness prohibiting participation; had dysphasia; had had recent major home modifications; had an education and language adjusted score > 4 on the short portable mental status questionnaire 5; or did not have the approval of their general practitioner.

2.3. Sample Size

To detect a 25% relative reduction (or more) in the annual fall rate, with 5% significance level and power of80%, 914 individuals were needed. 6A 25% reduction was considered achievable on the basis of other multifactorial studies7and would be of public health significance. The calculation assumed a nonintervention annual rate of 35 falls per 100 people and a “main effects” two group comparison for each intervention. Allowing for a 20% dropout rate, 1143 subjects were needed.

2.4. Recruitment

We sent invitation letters and made follow up telephone calls to 11 120 people aged 70 years and over and registered on the Australian electoral roll for the area (96% of eligible voters in this age group areregistered8). All Australian citizens aged over 18 years and “of sound mind” are required by law to be registered on the electoral roll. The electoral roll therefore includes almost all older people, some of whom would not be eligible according to our inclusion an exclusion criteria. We could not estimate the eligible number owing to the nature of these criteria. Local publicity and recruitment by general practitioners supported the main strategy. When compared with data from the national census and health survey for Australians aged over 70living at home, the study group differed as follows: a higher proportion (46.0%v42.8%) were aged 70-74years and a lower proportion (7.3%v9.8%) aged over85 years old; a higher proportion (77.3%v66.7%) were Australian born; a higher proportion (53.8%v32.7%) were living alone; and a lower proportion (46.8%v52.3%) were married. Study participants rated their health status considerably higher (very good to excellent, 62.6%v30.7%), and a higher proportion (13.8%v9.0%) reported taking antidepressant and hypnotic medication. Assessment Participants received a home visit by a trained assessor, who was initially blinded to group assignment. After informed consent was obtained, a baseline questionnaire was completed covering demographic characteristics; ability to perform basic activities and instrumental (more complex) activities of daily living; use of support services; social outings and interests; the modified falls efficacy scale 10; self rated health; and fall sand medical history. Current prescription and over the counter drugs were recorded from containers at the participants' homes. The targeted risk factors were assessed by using the methods outlined in table 1. Participants were then assigned (by computer generated randomization) to an intervention group by an independent third party via telephone. After 18 months, the risk factor assessments were repeated in a proportion of participants (n=442) randomly selected by an assessor blinded to the intervention group (we used only a proportion of the participants because resources to reassess the whole study group were not available and this assessment was of secondary importance to the study's main goal) Strength and balance were also measured at the final exercise class of the first 177 participants to complete the 15 week program me, 79 of whom were among the442 subsequently selected for final reassessment

How did the prevention of fall for Elderly trail selected and allocate subjects

Selection:-

Volunteers were recruited by sending invitation letters and made follow up telephone calls to 11 120 people aged 70 years and those Continued (n=1090).

Inclusion:-

Participants had to be living in their own home or similar apartment or accommodation

Exclusion:-

Potential participants were excluded if they did not expect to remain in the area for two years (except for short absences) and nother relevant factors.

Allocation:-

Participants were randomly assigned by an “adaptive biased coin” technique, Then were assigned (by computer generated randomization).

Characteristics of study groups

1. Mean (SD) age (years) 76.1 (5.0) 75.4-76.5 (4.7-5.5) 75.9 (4.9)
2. No (%) of women 652 (59.8) 77-93 (55.4-68.4) 261 (59.0)
3. No (%) of participants living alone 586 (53.8) 68-83 (50.0-61.0) 230 (52.0)
4. No (%) of participants who had a fall in past month 69 (6.3) 5-11 (3.7-8.1) 31 (7.0)
5. Mean (SD) score for activities of daily living‡ 5.3 (1.1) 5.2-5.4 (0.92-1.2) 5.3 (1.1)

Were the groups similar at the start of the trial?

1. At the start:-Randomization (n= 1107), did not continue (n=17), continued (n=1090)
2. At the end: - Reassessed (n= 442)

Did the prevention of fall for Elderly trail treat subjects equally?

1. All Volunteers were recruited by sending letter invitation.
2. All Volunteers made follow up by telephone calls
3. All Australian citizens aged over 18 years and “of sound mind” are required by law to be registered on the

electoral roll

4. All Volunteers were randomly assigned by an "adaptive biased coin" technique
5. were then assigned (by computer generated randomization)
6. The study was conducted mainly in middle class area

Did the elderly person trial follow up all the subjects?

Follow up of subjects

1. 1107 subjects were randomized
2. 17Did not continue
3. 1090Continued
4. 1090 were falls surveillance
5. 119 were Withdrawn,
6. 68By choice.
7. 30 were Became ineligible.
8. 15 were Died.
9. 6 were Too ill to continue.
10. 971 were Completed
11. 442 were Reassessed as follow:-.

a. first 177 participants to complete the 15 week program me,
b. 79 of whom were among the 442subsequently selected for final reassessment

*How important were the losses? Were they equally distributed?

Invitation letters (n= 11 120), Responses (n= 1967) Baseline assessment (n=1107), Randomisation (n= 1107), Did not continue (n=17) Continued (n=1090

*Was the outcome measurement accurate?

These results show a statistically significant effect benefit ($P < 0.05$) for all interventions together.

*How did the prevention trail for the elderly eliminate measurement bias?

Subjects

1. Participants were randomly assigned by an "adaptive biased coin" technique, rather than simple randomization, to ensure balance of group number
2. 'Although the Participant were selected randomly they aware of the treatment' (i.e. not blinded) 442 and of the subsequently selection for final reassessment.

Outcome assessors

Most Participants, did not continue, Withdrew, By choice, Became ineligible and died

*Was a standardized measurement strategy used for all volunteers?

Measurements were carried out using the same procedures for all volunteers

*Did the prevention of fall for Elderly trail use a placebo?

The control group receive a placebo treatment in form of combinations of interventions that involved exercise, home hazard management, and treatment of poor vision.

*What were the results of the falls prevention among older people trial?

1. The reduction in falls among older people group (95% C I 0.67 (0.51 to 0.88)----14.0 (3.7 to 22.6)
2. P-value 0.004.
3. NNT= 7
4. The results are statistically significant because CI values do not overlap.

Summary of critical appraisal trial of prevention fall among Elderly

Internal validity

1. In the falls prevention among older people trial, the invitation by Letters and follow up by telephone calls.
2. Subjects were initially selected / allocated ("adaptive biased coin" technique), on volunteer basis. Inclusion/exclusion criteria ensured that the recruited subjects were, representative of the population of interest (1090 aged 50 years and over, and living at home by economy median class).
3. Onceal located to groups, all subjects were treated equally in the trial and there were only a few losses to follow up
4. Either due to all ocation bias (women were dominant (652) or other factors, there was statistically significant difference in sex ratio between the groups
5. The trial was single blinded (they were assessed by receiving a home visit by a trained assessor, who was initially blinded to group assignment.).
6. The groups were well matched for other factors
7. Outcomes were measured using the same methodology for both groups.
8. The control group did not receive a placebo treatment.
9. The sample size calculation assumed that annual rate of 35 falls per 100 people allowing for a 20%dropout rate, so1143 subjects were needed, to continue the research..
10. After 18 months, the risk factor assessments were repeated in a proportion of participants (n=442), randomly selected by an assessor blinded to the, intervention group (double blinded) so the possibility of differences in self report-ing bias may exists.

3. Results

1. The rate ratio for exercise was 0.82 (95%confidence interval 0.70 to 0.97, P=0.02),
2. And significant effect ($P < 0.05$) was observed for the combinations of interventions that involved exercise. Balance measures improved significantly among the exercise group.
3. interventions combined (rate ratio 0.67 (0.51 to 0.88, P=0.004)), producing an estimated 14.0% reduction in the annual fall rate
4. The number of people needed to be treated to prevent one fall a year ranged from 32for home hazard management to 7 for all three interventions combined. NNT=32
5. The results showed that there is statistically significant because of a large difference between the treated and control groups and CI values do not overlap

4. Discussion

This trial examined the individual contribution of, and

interaction between, three interventions to reduce falls. However, no interactive effect of the interventions on falls outcome was observed; rather, the intervention were additive. A study of withdrawal from psychotropic drug treatment combined with exercise also found no interactive effect. Unlike most previous studies of exercise among unselected older people living in their own homes, these results show that a supervised exercise pro-gramme for this group for one hour a week for 15weeks, supplemented with home exercise for up to 12 months, can reduce falls. The reduction occurred despite relatively poor compliance with the home exercise sessions, which were intended to be daily, but in fact were performed twice weekly on average. This is the shortest programme of the lowest intensity shown to reduce falls. Other successful trials of exercise alone have ranged from group classes twice a week for 15weeks (supplemented with daily exercise) to home based sessions three times a week for two years.

There was a greater reduction in falls in the programmes with more intense exercise regimes. The reduction in falls among participants receiving the exercise intervention was associated with improved balance, most prominent on completion of the exercise programme. However, the falls reduction in this group may also have been mediated via social interaction or behavioral change, or both of these, as a result of heightened awareness engendered during the classes. The limited effect of the other two interventions of alls outcome may be partly related to insufficient intensity of the interventions. The modifications of home hazards may not have been large enough, or may have been of the wrong type, to have affected falls outcome. Certainly, home modifications facilitated by occupational therapists have been shown to reduce the risk of falling among older people with a falls history who live at home .The relatively low numbers of participants who received vision improvement treatment, and the marginal improvement in visual acuity among the non-intervention group, may explain the limited effect on falls outcome among this intervention group. The population studied may already have had many visua problems addressed in the free public health care system, since 48% of the intervention group did not require referral. Furthermore, study participants may have been alerted to the potential benefits of the inter-ventions. This would be more likely to influence the results for vision and home hazard management than for exercise, which would have been difficult to replicate without detailed instructions. As the participants were not blinded to group assignment, the possibility of differences in self report-ing bias exists. Participants in the intervention groups may have under-reported falls, and those receiving amore intense intervention, such as the group based exercise programme, may have been even more inclined to under-report. The observed changes in some targeted risk factors supports the conclusion, however, that at least some of the falls reduction was mediated by the interventions. As the participants differed somewhat from the general older population living at home, the findings are most applicable to older adults living at home with similar characteristics—namely, Australian people living at home who are aged over 85, in poorer health, or from non-English speaking backgrounds. The combined effect of all three interventions pro-duced the largest outcome observed. However, the results for the single and dual intervention groups indicate that the exercise programme made the major contribution.

5. Conclusion

1. While the results show a successful interventions (Home hazard management, vision screening, and exercise programme). which will provide important information on which to base resource allocation for the prevention of falls among older people living at home, so the relative importance of the different strategies is unknown.

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