Title

Older people's participation and engagement in falls prevention interventions: Comparing rates and settings

1. Rationale

Falls among older people is a priority public health issue: they account for over 50% of injury-related hospital admissions and 40% of all injury deaths in those aged 65+ [1]. The Cochrane systematic reviews of randomised controlled trials (RCTs) found evidence for the prevention of both falls and risk of falls from exercise and home safety interventions in the community but have yet to find conclusive evidence for interventions in institutions [2,3]. Two articles were recently published that supplemented the Cochrane systematic reviews by reporting older people's participation in the RCTs and engagement with the falls prevention interventions [4,5]. These supplementary reviews demonstrated that achieving high uptake among older people and sustaining their participation remains a challenge on which rely the success of fall prevention interventions. In using data from these supplementary reviews, the current article facilitates accurate interpretation of the existing evidence-base and planning of future RCTs by drawing two important distinctions. First, new data is presented to make the distinction between acceptance and recruitment rates, i.e. those willing to participate in the RCTs versus those willing and included. Second, new data from RCTs conducted in institutions is presented to distinguish between data from nursing care facilities and hospitals, as they require different falls prevention strategies given the different needs of inpatients and residents respectively.

2. Method

The two Cochrane reviews of the effectiveness of fall prevention interventions had as the primary outcome the rate of falls and the number of participants sustaining at least one fall [6,7]. For the supplementary reviews we included all single interventions and separately all multifactorial interventions based on individual falls risk assessment [4,5]. For single interventions we followed the classification developed by the Prevention of Falls Network Europe [for full list see [6,8]: Exercise, medication (Vitamin D and / or calcium supplementation), environmental / assistive technology (home adaptations and provision of aids), surgery, interventions to increase knowledge, psychological (cognitive behavioural therapy to reduce fear of falling), and fluid / nutrition therapy. The two supplementary reviews had four main outcomes:

1. Recruitment rates - proportion of participants invited to participate who enrolled into the study, which were distinguished from those who refused, did not respond, or who were willing but excluded (volunteered but did not meet the study inclusion criteria).

For the current article, we also calculated acceptance rates; the proportion of older people who volunteered to participate in the RCTs (inclusion rate plus rate of those willing but excluded by the trial criteria).

2. Attrition rates - number of participants lost at 12-month follow-up due to mortality or other reasons.
3. Adherence rates - level of engagement with the intervention (e.g. for exercise interventions this could be the number of classes attended).
4. Moderator analyses - studies that reported adherence data were searched for whether they also tested if participants' adherence had an influence on trial outcomes.

Data was stored and analysed using Excel 2007 and SPSS 19.0. For each intervention type, we performed descriptive statistics on the outcome measures by generating percentages for each paper and then calculating the average percentage. Medians and ranges / interquartile ranges

are reported because the distributions of the data for the measures of interest were substantially skewed.

3. Results

For Tables 1-6 please see Appendix 1, located with Appendixes 2 and 3, in the online supplementary material.

3.1. Recruitment vs. acceptance rates

Table 1 shows the recruitment and acceptance rates for RCTs conducted in community settings. The median recruitment rate was = 41.3% (22.0-63.5%, n = 78), and when added with the rates of those willing but excluded (median = 19.0%, 13.5–48.0%, n = 63), the resultant median acceptance rate was = 70.7% (64.2–81.7%, n = 78). The median recruitment rate in institutional settings was = 48.5% (38.9-84.5%, n = 25), and when added with the rates of those willing but excluded (median = 42.3%, 27.4–60.2%, n = 15), the resultant median acceptance rate was = 88.7% (81.2–95.4%, n = 25) (see Table 2).

The above contrast in recruitment and acceptance rates has an impact on estimating the overall rates of older people's participation and engagement in the fall prevention RCTs. For community settings at 12 months, given an attrition rate of 10%, and adherence rate of 80%, the overall rate of uptake and adherence by older people is estimated at 28.8% and 50.4% when using the recruitment (40%) and acceptance rates (70%) respectively. For institutional settings at 12 months, given an attrition rate of 15%, and adherence rate of 80%, the overall rate of uptake and adherence by older people is estimated at 34.0% and 61.2% when using the recruitment (50%) and acceptance rates (90%) respectively.

3.2. Nursing care facilities vs. hospitals

Forty-one studies were conducted in nursing care facilities (n=30) and hospitals (n=11). For attrition at 12 months, all 11 studies reported in the original review were from nursing care facilities, as were all 6 studies that tested whether or not adherence acted as a moderator on the effectiveness of the intervention on trial outcomes [4].

Recruitment. Rates of recruitment into trials are presented in Tables 3 and 4 for nursing care facilities and hospitals respectively. In nursing care facilities, studies varied in the number of older people invited (487 - 1061, median = 655, n = 19) and subsequent rates of participation (38.9 – 84.5%, median = 53.2%, n = 19). In hospitals, a similar pattern emerged in terms of the number of older people invited (127 - 1040, median = 696, n = 6) and subsequent rates of participation (39.8 – 60.2%, median = 48.5%, n = 6). In nursing care facilities, of those that did not take up the intervention, the median refusal rate was 5.0% (4.6 – 15.6%, n = 12) and the median rate of those willing to take part but excluded was 39.5% (30.2 – 60.2%, n = 10). In hospitals, similarly, of those that did not take up the intervention, the median refusal rate was 7.4% (2.4 – 19.2%, n = 5) and the median rate of those willing to take part but excluded was 45.1% (22.5 – 52.6%, n = 5). Only one study conducted in nursing care facilities reported data on the proportion of older people who did not respond to a study invitation, with a non-response rate of 63.6% [9]. Acceptance rates are shown against recruitment rates in Tables 5 and 6 for nursing care facilities and hospitals respectively. For nursing care facilities, the median acceptance rate was 85.0% (70.9 – 95.4%, n = 19), and for hospitals, the median acceptance rate was 93.9% (91.9 – 96.9%, n = 6).

Adherence. Twenty-one studies reported adherence data; 17 were from nursing care facilities and 4 from hospitals. The original appendix providing detailed notes on this adherence

data has been separated by study setting (see Appendixes 2 and 3). In the original review article [4], medication (vitamin D and / or calcium supplementation) interventions conducted in both settings were reported: a hospital study reported an average adherence rate of 88% [10], whereas a nursing care facility study reported that 68% of participants achieved an adherence rate of 76-100% [11]. The remaining adherence data was from nursing care facilities, which was high for exercise (89% for physical therapy and 72% - 88% for group-based), and heterogeneous for multifactorial interventions (ranged from 11% for attending 60+/88 of exercise classes to 93% for use / repairs of aids).

4. Discussion

The above results suggest that the difference between rates of recruitment and acceptance are substantial (30-40%), highlighting the impact of exclusion criteria on recruitment within fall prevention trials. While some level of exclusion is required in order to maintain safety to participants and to target interventions effectively, the validity of trial results will be compromised if only select and unrepresentative samples are recruited. Indeed, many older people have cognitive impairment and multimorbidities who require intervention despite challenges to uptake and adherence [12,13]. Hence, despite advances in knowledge as to the causes of falls and prevention strategies, a central challenge remains to effectively implement the evidence into practice [14-16].

Very similar average recruitment and acceptance rates were found between nursing care facility residents and hospital inpatients. However, only a quarter of studies in institutional settings were conducted in hospitals, and while fall prevention policies in hospitals have improved within recent years, further research and improvements are required [17]. Future research is required on attrition rates and whether adherence moderates the effectiveness of interventions on trial outcomes, of which we identified data from only 12 and 6 trials in nursing care facilities respectively. Future studies could also test simple strategies such as assistance with transport to increase adherence to interventions [18].

The above findings facilitate accurate interpretation of the current evidence-base on fall prevention RCTs by highlighting the important distinction between rates of recruitment and acceptance, and by providing separate data from nursing care facilities and hospitals. However, a consensus remains desirable on how to define successful engagement with trials and successful uptake and adherence to trial interventions.

Conflicts of interest

The authors declare that they have no conflicts of interest concerning this article.

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