# Effects of a One-Year Home-Based Case Management Intervention on Falls in Older People: A Randomized Controlled Trial

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# Effects of a One-Year Home-Based Case Management Intervention on Falls in Older People: A Randomized Controlled Trial

**Ulrika Olsson Möller, Jimmie Kristensson, Patrik Midlöv, Charlotte Ekdahl, and Ulf Jakobsson**

***Objectives:*** To investigate the effects of a home-based one-year case management intervention in older people with functional dependency and repeated contact with the health care services on self-reported falls and self-reported injurious falls. ***Methods:*** The study was a randomized controlled trial with repeated follow-ups. The sample ($n$ = 153) was consecutively and randomly assigned to the intervention group ($n$ = 80, mean age = 81.4 [*SD* 5.9]) or control group ($n$ = 73, mean age = 81.6 [*SD* 6.8]). The intervention group received a case management intervention which comprised monthly home visits during 12 months by nurses and physiotherapists employing a multifactorial preventive approach. ***Results:*** In the intervention group, 96 falls occurred during the intervention period compared with 85 falls in the control group ($p$ = .900). There were 40 and 38 injurious falls ($p$ = .669) in the intervention and control groups, respectively. ***Conclusions:*** This home-based case management intervention was not able to prevent falls or injurious falls.

***Keywords:*** aged, accidental falls, case management, health promotion, randomized controlled trial

The severity of associated outcomes for the individual after a fall, such as fractures and disability, as well as high health care costs for society (World Health Organization [WHO], 2007), make fall prevention interventions essential. The majority of costs for fall injuries concern older people living at home (National Board of Health and Welfare, 2011). About 35% of people aged 65 years and older fall each year and the rate increases with age (WHO, 2007). About 20% of the falls require medical attention (Tinetti et al., 1994) and about 5% result in a fracture (Stel, Smit, Pluijm, & Lips, 2004). Other negative consequences such as disability and fear of falling (Stel et al., 2004) increase the risk of a reduced activity level and reduced participation. A fall has been defined as ‘‘an unexpected event in which the participants come to rest on the ground, floor or lower level’’ (Lamb, Jorstad-Stein, Hauer, Becker, & Prevention of Falls Network Europe and Outcomes Consensus Group, 2005).

The risk of falling increases with age (WHO, 2007). In Sweden, as well as in other European countries, it is increasingly common for older people to receive health care and social services at home instead of in nursing homes (National Board of Health and Welfare, 2012; WHO, 2012). With a greater number of older people at high risk of falling while living at home, home-based fall prevention interventions are essential.

A recent Cochrane review stated that fall preventive interventions that include several different components such as group exercise, home-based exercise, and home safety assessment reduce the risk of falling in older people (Gillespie et al., 2012). Randomized controlled trials of different home-based interventions aimed at preventing falls in older people with a risk of falls have, however, shown divergent results (Campbell et al., 1997; Ciaschini et al., 2009; de Vries et al., 2010; Latham et al., 2003; Nikolaus & Bach, 2003; Tinetti et al., 1994; van Haastregt et al., 2000). Three studies with multifactorial interventions and one study with high-intensity training showed no effect (Ciaschini et al., 2009; de Vries et al., 2010; Latham et al., 2003; van Haastregt et al., 2000) while other multifactorial studies have shown effects with a reduction in falls (Campbell et al., 1997; Nikolaus & Bach, 2003; Tinetti et al., 1994). The diversity in the results indicates a need to further explore the effects of home-based fall prevention interventions. Case management is a care model that has been applied in various settings (Cooper & Deborah, 2006). According to the Case Management Society of America (2010) case management is defined as “ …a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual’s and family’s comprehensive health needs through communication and available resources to promote quality, cost-effective outcomes”. A review by You, Dunt, Doyle, and Hsueh (2012) described that case management interventions have been implemented in community-aged care in developed countries in recent years to meet the comprehensive needs of older people. These interventions may include home visits that involve identification of risk factors through comprehensive geriatric assessment, providing information to the elderly individuals and their caregivers, and referral to different care providers, thereby coordinating care over a longer period of time (Hallberg & Kristensson, 2004). The review by You et al. (2012) concluded that case management has shown positive effects such as improved client psychological health or well-being and reduced unmet service needs, but inconclusive results for other outcomes such as physical and cognitive functioning. However, the multifactorial approach in case management studies may have the potential to prevent falls. To our knowledge no study has investigated the effects of a prolonged home-based case management intervention on falls.

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## Aim

To investigate the effects of a home-based one-year case management intervention in older people with functional dependency and repeated contact with health care services on self-reported falls and self-reported injurious falls.

## Method

### Design

The study was a randomized controlled trial (RCT) (Kristensson, Ekwall, Jakobsson, Midlöv, & Hallberg, 2010). Briefly, this RCT was designed according to the framework for complex interventions by the Medical Research Council (2008). The trial started in 2006 with the aim to evaluate the effects of a home-based health care model using case managers (CMs). The hypothesis for the main trial was that CMs for frail older people may decrease health care consumption and have a positive effect on life satisfaction and related variables. Power calculations were conducted in June 2009 ($n$ = 63; alpha = .05; power 0.80; two-tailed test) for various mean differences in outcome measures life satisfaction (measured with the instrument LSIZ) (Neugarten, Havighurst, & Tobin, 1961), depressive symptoms (measured with the GDS-20) (Gottfries, Noltorp, & Norgaard, 1997), and health care consumption. A difference in mean values of 2 in the LSIZ (*SD* 4.8) showed that the sample size needed to be $n$ = 92/group. The figures for GDS-20 (*SD* 3.4) were $n$ = 46/group for a mean difference of 2. For health care consumption the figures were $n$ = 70/group for inpatient care (*SD* 2.1), for a mean difference of 1, and $n$ = 76/group for visits with primary care physicians (*SD* 5.5), for a mean difference of 2.5.

### Sample

The study was conducted in a medium-sized municipality in southern Sweden, with approximately 30,000 inhabitants living in both urban and rural areas. The inclusion criteria were: aged 65 years or older, resident in the study municipality, need of help with at least two activities of daily living, admitted to hospital at least twice or have had at least four outpatient contacts during the previous 12 months. The participants had to be able to communicate verbally and to have no cognitive impairments (i.e., a score of ≥ 25 in Mini Mental State Examination [MMSE] (Folstein, Folstein, & McHugh, 1975). The sample was recruited through the municipal home care organization ($n$ = 13), from three primary care centers in the municipality ($n$ = 117), three clinics at a nearby university hospital ($n$ = 20), or by own referral ($n$ = 3). At the hospital, the case managers screened, recruited, and informed potential participants. In primary and municipal care, staff asked potential participants if the research team was allowed to contact them to provide more information. A screening procedure was also used in primary care. All those 65 years or older with four or more visits in primary care were contacted by mail or telephone with information about the study. Those contacted by mail got a reply form and were asked if they agreed to allow the research team to contact them to give additional information. Between 2006 and 2010, 1,079 people were assessed for eligibility. Out of these, 571 did not respond to the screening based invitation, 231 did not meet the inclusion criteria, 71 declined participation, 28 were unreachable due to missing contact information, 18 declined participation due to being too tired or sick, and 7 died before randomization. In total 153 participants were consecutively randomized by using sealed envelopes containing information about group allocation to the intervention group (IG; $n$ = 80) or a control group (CG; $n$ = 73) (Figure 1).

### Intervention

The intervention started in 2006 with two nurses working as CMs. The intervention comprised four dimensions: (1) Case management tasks (e.g., assessment, planning, evaluation, advocacy, home visits, and care coordination). (2) General information (e.g., exercise, nutrition, social activities, the health system, and more). 3) Specific information (e.g., the participant's individual needs, medication, and more). The intervention always included an evaluation of prescribed medications. One of the physicians involved in the project was contacted if any problems with the medication were detected. (4) Safety and continuity (the case managers were contactable by phone during office hours) (Kristensson et al., 2010).

The CM performed at least one home visit per month during 12 months. During the visit an assessment with the Minimum Data Set for Home Care (MDS-HC; Landi et al., 2000) was made. One aspect of the intervention was fall prevention. After the pilot study, the intervention was expanded in 2008 by also employing two physiotherapists (PTs). The main reasons for this were that a low degree of physical activity and falls were seen as problems. Sixty-one of the 80 participants in the IG therefore received home visits from both a PT and nurse (Figure 1). The PTs worked together with the nurses, but focused mainly on fall prevention and support for physical exercise. Initially an assessment including the Berg Balance Scale (Berg, Wood-Dauphineé, Williams, & Gayton, 1989), General Motor Function assessment scale (Åberg, Lindmark, & Lithell, 2003), Fukuda Stepping test (Fukuda, 1959), and of deep sensibility in the lower extremities (Kristinsdottir, Jarnlo, & Magnusson, 1997) was conducted to assess physical function. The instruments were chosen to obtain an estimation of general physical ability and to examine various risk factors for falls involved in human postural control. They were also chosen because they could be performed at the participants' homes. The results of the assessment, together with the information collected in MDS-HC (Landi et al., 2000), helped to create an individual nonsupervised home exercise program that was prescribed in consultation with the participant. Because of the variability in the participant's functional ability, the intensity, frequency, and duration of the individual exercise programs varied, but always included components of leg muscle strength and balance. Efforts were made to continuously, (i.e., at least once a month) support and motivate the participants to be physically active and to evaluate and modify the home exercise program if needed. The intervention also included information about fall prevention and referral to a physician, PT, or occupational therapist in primary or community health care was made when needed. A brief standardized home safety checklist (only available in Swedish) was used to assess environmental risk factors for falls and corrections were made when needed. During the 12-month intervention the PTs performed visits (mean = 10.4) and telephone calls (mean = 0.8) and the nurses performed an average of 11.1 home visits and 1.9 telephone calls for those completing the intervention. For drop-outs (Figure 1), the mean number of PT visits and telephone calls were 2.5 and 1.0, respectively, and the mean number of nurse visits and telephone calls were 3.7 and 1.0. The CMs and PTs documented the intervention and were supported by two primary care physicians who were part of the project group.

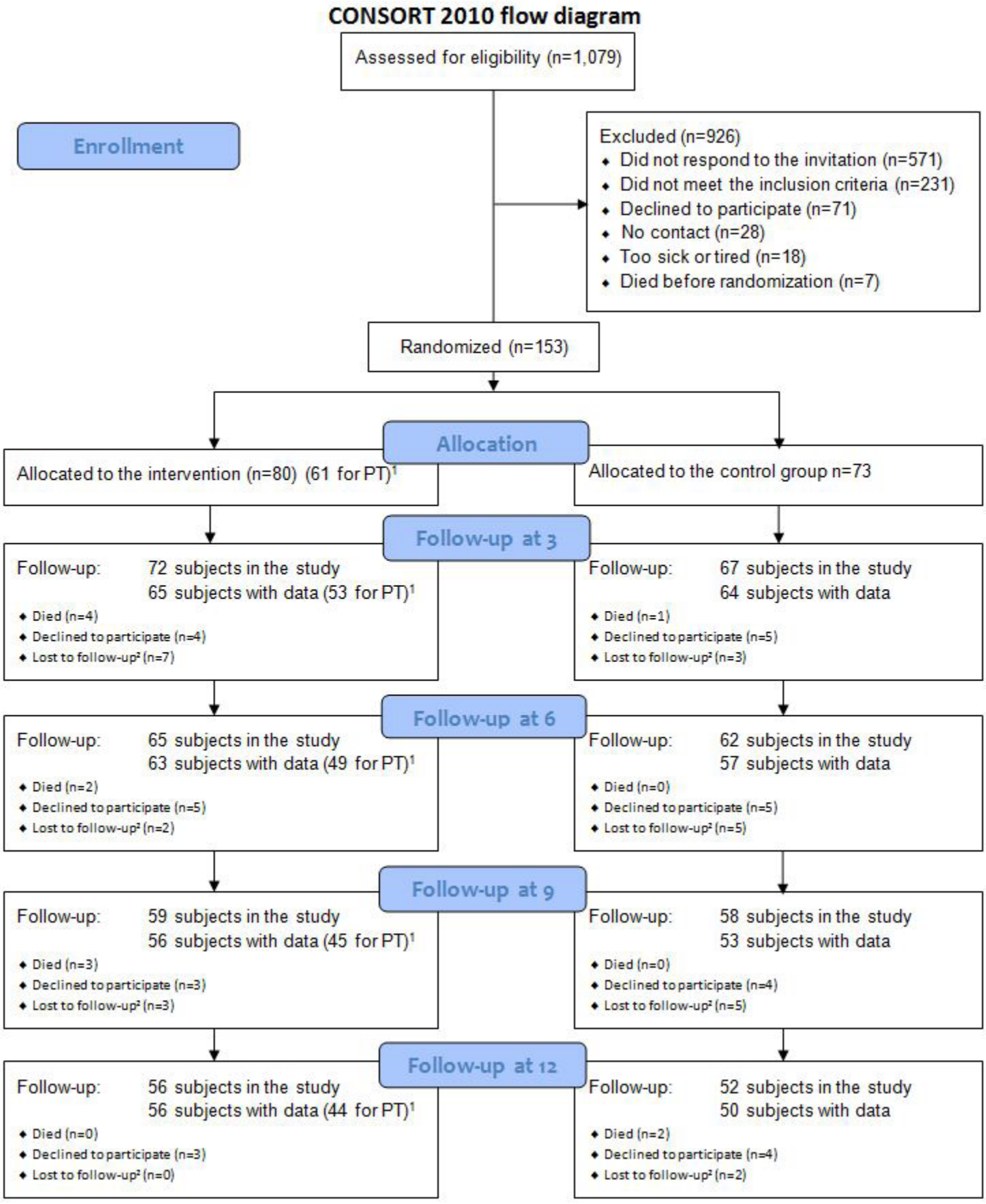


**Figure 1** — CONSORT flow diagram of participants in the trial. [1]The number in the brackets is the number of subjects who received intervention from nurse and physiotherapists. [2]Lost to follow-up because the participant was hospitalized, too sick, or too tired to perform the data collection.

### Data Collection and Measurements

Data were collected by the research team by means of personal interviews using an extensive structured questionnaire (Kristensson et al., 2010) and examinations in the participants' homes. The data collection was carried out independently of the case managers. It was not blinded due to the nature of the intervention.

Data were collected at baseline (i.e., before the intervention started) and then at 3, 6, 9, and 12 months (i.e., during the intervention). If the follow-up was delayed more than five weeks, it was not carried out. Self-reported falls in the past three months (yes/no) was used as the primary outcome in this study. When there was a positive response, further questions regarding number of falls, injurious falls (based on the question: Did you hurt yourself? yes/no), type of injury, and falls resulting in medical care (yes/no) were asked. Assessments including the Downton Fall Risk Index (DFRI; Downton, 1993), the Activities of Daily Living (ADL) staircase (Sonn & Åsberg, 1991) and the Timed Up & Go (TUG; Podsiadlo & Richardson, 1991) were included as additional measures. TUG was performed in the participants' homes and was only used for data collection from 2008, meaning that 85 participants had baseline TUG data (IG, $n = 46$; CG, $n = 39$).

### Data Analysis

Descriptive and analytic statistics were used to compare the IG and CG at baseline and after 3, 6, 9, and 12 months within the intervention. The main outcomes in terms of participants with at least one fall, number of participants with injurious falls, number of participants with falls resulting in medical care, as well as total number of falls, total injurious falls, and total falls resulting in medical care were summarized from the data collections at 3, 6, 9, and 12 months. To strengthen the study's internal validity, complete case analyses, as well as analyses according to the intention-to-treat principle using last observation carried forward as the imputation technique (LOCF; Polit & Gillespie, 2010), were performed in participants with at least one fall, DFRI, ADL staircase, and TUG. Pearson's chi-square test, the Mann-Whitney *U* test, and Student's *t* test were used to compare the groups. *P* values ≤ .05 were considered to be statistically significant. Statistical analyses were conducted using the software program SPSS 19.0 (IBM, Armonk, New York).

## Ethical Considerations

The Regional Ethics Review Board in Lund approved the study (approval nos. LU 342/2006 and 499/2008) and informed written consent was obtained from all participants. The study was registered at ClinicalTrials.gov (no. NCT01829594).

## Results

The mean age at baseline in the total sample ($n = 153$) was 81.5 years (*SD* 6.4); 66.7% of the participants were female and 24.8% reported a fall in the past 3 months. No significant differences between the IG and CG were reported at baseline (Table 1). In the IG, 20% of participants had suffered a fall in the past 3 months, 77% had a risk of falling (i.e., a score of ≥ 3 on the DFRI) and the mean TUG result was 15.4 s. In the CG, 30% of participants had suffered a fall in the past 3 months, 85% had a risk of falling, and the mean TUG result was 16.3 s. Both groups scored a median of two points on the ADL staircase and had a median of 11 health complaints. About one-third of participants in both groups used community elderly care (Table 1).

**Table 1 Baseline Characteristics of the Intervention Group (IG) and Control Group (CG)**

| | IG ($n = 80$) | CG ($n = 73$) | *p* value |
|---|---|---|---|
| Age, mean (*SD*) | 81.4 (5.9) | 81.6 (6.8) | .795[d] |
| Women, *n* (%) | 52 (65.0) | 50 (68.5) | .647[e] |
| Community elderly care, *n* (%) | 30 (37.5) | 24 (32.9) | .550[e] |
| Number of health complaints, median (q1-q3) | 11 (7–15) | 11 (8–15) | .655[f] |
| Fall in the last 3 months, *n* (%) | 16 (20.0) | 22 (30.1) | .147[e] |
| Fall injuries in the last 3 months, *n* (%) | 11 (13.8) | 15 (20.5) | .263[e] |
| Fall injuries requiring medical care in the last 3 months, *n* (%) | 7 (8.8) | 5 (6.8) | .662[e] |
| ADL staircase score,[1] median (q1-q3) | 2 (1–3) | 2 (1–3) | .831[f] |
| IADL,[1] median (q1-q3) | 2 (1–3) | 2 (1–3) | .651[f] |
| PADL,[1] median (q1–q3) | 0 (0–0.8) | 0 (0–0.5) | .881[e] |
| Downton Fall Risk Index[2] ≥ 3, *n* (%) | 59 (76.6) | 62 (84.9) | .198[e] |
| Timed Up & Go,[3] sec, mean (*SD*)[e] | 15.4 (6.8)[a] | 16.3 (5.5)[c] | .468[d] |
| Dizziness, *n* (%) | 38 (47.5) | 41 (56.2) | .284[e] |
| Vision impairment, *n* (%) | 24 (30.0) | 19 (26.0) | .585[e] |
| Walking aids, *n* (%) | 57 (71.2)[b] | 54 (74.0)[b] | .492[e] |
| Fear of falling, *n* (%) | 47 (60.3) | 47 (65.3) | .525[e] |
| Fatigue, *n* (%) | 45 (56.3) | 41 (56.2) | .991[e] |

[1]Sonn & Åsberg, 1991.
[2]Downton, 1993.
[3]Podsiadlo & Richardson, 1991.
[a] $n = 46$ [d] Student's *t* test
[b] $n = 67$ [e] Pearson's chi-square test
[c] $n = 38$ [f] Mann-Whitney *U* test

Figure 2 shows the percentage of participants reporting a fall at each data collection time point. The values ranged from 20–36%. No statistically significant differences were found between the groups at any time point (3 months, $p = .864$; 6 months, $p = .641$; 9 months, $p = .218$; and 12 months, $p = .174$). The results remained nonsignificant after imputation. Table 2 shows the number of falls during the 12-month follow-up period (3 months, $p = .616$; 6 months, $p = .989$; 9 months, $p = .073$; and 12 months, $p = .706$). Thirty percent of the participants in the IG and 16.5% in the CG reported one fall and 24% of the participants in the IG and 31.5% in the CG reported at least two falls (nonsignificant).

No significant differences were found between the groups in self-reported falls, injurious falls, and falls resulting in medical care (Table 3). About 50% of the participants in both groups had experienced at least one fall (Table 3), of which 68% and 77% were injurious, respectively. There were 96 falls in the IG and 85 in the CG, and about 45% of these falls resulted in an injury. The injuries consisted mainly of wounds, bruises, and pain. Six falls led to fractures: five in the IG (facial, wrist, rib, hip, toes) and one in the CG (pelvis plus rib).

In the 12-month follow-up assessment, when analyzing complete cases, no statistically significant differences were found in

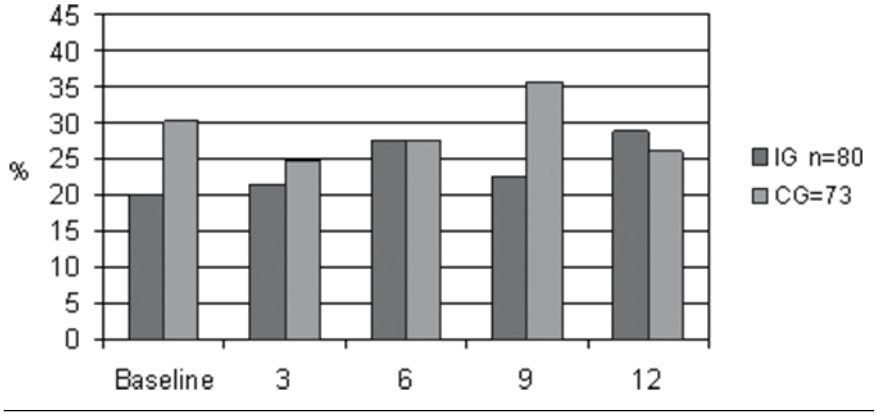


**Figure 2** — Participants (%) reporting a fall in the past 3 months in the intervention group (IG) and control group (CG) at baseline, 3, 6, 9, and 12-month follow-ups.

**Table 2 Number (%) of Participants in the Intervention Group (IG) and Control Group (CG) Who Fell During Intervention**

| | Total Sample (*n* = 153) | |
|---|---|---|
| | IG (*n* = 80) | CG (*n* = 73) |
| Number of Falls | *n* (%) | *n* (%) |
| 0 | 37 (46) | 38 (52) |
| 1 | 24 (30) | 12 (16.5) |
| 2 | 6 (7.5) | 12 (16.5) |
| 3 | 3 (4) | 5 (7) |
| ≥ 4 | 10 (12.5) | 6 (8) |

**Table 3 Numbers of Participants with Falls, Injurious Falls, and Falls Requiring Medical Care in the Intervention Group (IG) and Control Group (CG) During the 12-month Follow-up Period**

| | IG (*n* = 80) | CG (*n* = 73) | *p* value |
|---|---|---|---|
| Participants with falls, *n* (%) | 44 (55.0)[a] | 35 (47.9)[a] | .248[b] |
| Participants with fall injuries, *n* (%) | 30 (68.2) | 27 (77.1) | .338[b] |
| Participants with fall injuries requiring medical care, *n* (%) | 15 (50.0)[a] | 9 (33.3)[a] | .402[b] |
| Number of falls (falls per person) | 96 (1.20) | 85 (1.16) | .900[c] |
| Number of fall injuries, *n* (%) | 40 (41.7) | 38 (44.7) | .669[c] |
| Number of fall injuries requiring medical care, *n* (%) | 19 (47.5) | 15 (39.5) | .151[c] |

[a]Item response rate: 88.8%–91.8%.
[b]Pearson's chi-square test.
[c]Student's *t* test.

DFRI (≥ 3 points: IG = 90.7%, CG = 88.0%, $p$ = .650) or ADL (median [q1–q3]: IG = 28[1–3], CG = 2[1–3.35], $p$ = .297), but in TUG (mean [*SD*]: IG = 18.1 [9.3], CG = 13.8 [3.8], $p$ = .009).

No significant results were shown after imputation for DFRI (≥ 3 points: IG = 85.7%, CG = 86.3%, $p$ = .918), ADL (median [q1–q3]: IG = 2[1–3.35], CG = 2[1–3.5], $p$ = .423), or TUG (mean [SD]: IG = 17.5 [9.0], CG = 15.1 [4.6], $p$ = .096). No significant differences were found between the groups when analyzing the subsample containing those participants ($n$ = 61 in the intervention group [Figure 1]) that received the expanded intervention with PTs in any of the outcomes.

The participants in the IG and the CG that dropped out during the 12-month follow-up period did not report any statistically significant differences in baseline characteristics: age ($p$ = .892), gender ($p$ = .172), falls in the past 3 months ($p$ = .680), or risk of future falls (DFRI; $p$ = .936).

## Discussion

This one-year case management intervention did not show any significant effects on self-reported falls or injurious falls during the 12-month follow-up period (Table 3). In addition, there were no differences between the groups in risk of future falls (DFRI), ADL capacity, or functional ability (TUG). There may be several explanations as to why this case management intervention had no effect. One explanation that has been mentioned in other studies (de Vries et al., 2010) is that currently, preventing falls is usually an integrated part of health care and social services for older people. This may have affected the number of falls in the CG, in which all participants had repeated health care contacts and 33% of participants received community elderly care. This is underpinned by the fact that the number of falls reported in each group (Figure 2) can be considered quite low (20–36%) given the inclusion criteria and baseline characteristics of the participants in this study. In addition, the number of falls did not increase during the 12-month follow up in either of the groups. Another explanation may be that the case management intervention partly consisted of assessment, information, and referrals. Other home-based interventions that comprised assessment, recommendations, and referral did not show any effect (Ciaschini et al., 2009; de Vries et al., 2010; van Haastregt et al., 2000). However, the intervention in the current study also included fall prevention tactics such as a home hazard assessment and a home exercise program. Two home-based studies with home exercise programs have shown positive effects on falls (Campbell et al., 1997; Tinetti et al., 1994). In the present study, an individualized self-training exercise program was prescribed but due to the heterogeneity of the participants, the type and intensity of the exercise program varied substantially. For instance, for participants in the IG, both the DFRI and the ADL staircase scores ranged from 2–7, the number of health complaints ranged from 1–22, and TUG results ranged from 5.6–36.4 s. Although this intervention included physical exercise, an important aspect of fall prevention interventions (Gillespie et al., 2012), with an individually prescribed program and monthly follow-ups, the participants performed the exercise without supervision by a CM or PT. To increase ADL performance in older people and thereby decrease the risk of falls, the exercise ought to be of high intensity (Daniels, van Rossum, de Witte, Kempen, & van den Heuvel, 2008). This may be difficult to achieve by self-training in older people with several health complaints and reduced physical function. It may also be difficult to provide frail older persons with home exercises (for instance, regarding balance), that are challenging enough without risking injuries when self-training.

Several systematic reviews have concluded that exercise in older people has positive effects in moderate frail individuals and in facility-based group exercise programs (Chin A Paw, van Uffelen, Riphagen, & van Mechelen, 2008; Daniels et al., 2008). Studies of older people in special accommodations have shown that high-intensity group exercise has positive effects on physical function and fall rates (Jensen, Lundin-Olsson, Nyberg, & Gustafson, 2002; Madureira et al., 2007). This may indicate that group training may be more effective at increasing physical function and reducing falls in frail older people.

The inconclusive results of home-based fall prevention interventions and exercise in frail older people indicate that further home-based studies to prevent falls need to be conducted. Future studies may focus on the type, intensity, and frequency of the physical exercise program, but also the type and frequency of supervision and the most favorable location to optimize exercise in frail older people.

### Study Limitations

The aspects described above are possible clinical explanations for the nonsignificant findings, but methodological factors may also have influenced the results. Experimental studies can be assessed in terms of internal-, external-, construct-, and statistical conclusion validity (Kazdin, 2003). In this study, internal validity was foremost about establishing equivalent groups and treating (with exception of the intervention) and measuring the groups identically (Kazdin, 2003). Threats in terms of selection bias, testing, and instrumentation has to be considered as small since the randomization created similar groups. However, the population comprised persons with functional limitations and repeated health care contacts. Fall risk was not an inclusion criteria and this may have affected the results since fall preventive interventions may be more beneficial for those at risk (Chang et al., 2004). In addition, data were self-reported which might have caused recall bias. The randomization of the participants and the nonsignificant differences at baseline however argues against the latter. Nevertheless, the use of a fall calendar instead of personal interviews every third month might have reduced this risk.

Construct validity refers to the content of the intervention and aspects that may explain causality (Kazdin, 2003). The intervention was complex since it was multidimensional, and to a great extent, individually tailored (Medical Research Council, 2008). The intervention was based on a personal relationship and needed to be, since frail, older people are known to have a complex situation. This makes it difficult to document, reproduce, and pinpoint active ingredients, which may be potential reasons for the nonsignificant findings. Adherence with the intervention was not measured and the extent to which the intervention was implemented (i.e., the amount of exercise actually performed) is unknown, which is a weakness. Because this multicomponent intervention contained several elements, fall prevention interventions were sometimes implemented a few months into the intervention, which may have affected the outcome.

Sample characteristics and features related to study context are potential threats to external validity in experimental studies (Kazdin, 2003). This study was conducted in the Swedish health system and thus, generalizations to other systems have to be done with caution.

One potential threat to statistical conclusion validity is the risk for type II error. Power was not calculated on fall, but on health care consumption, depressive symptoms, and life satisfaction. Health care consumption data are known to often be skewed (Kristensson, Hallberg, & Jakobsson, 2007; Condelius, Edberg, Jakobsson, & Hallberg, 2008) and thus, demand quite a large sample. However, the results have to be interpreted with this in mind.

## Conclusions

This home-based one-year case management intervention with monthly home visits by nurses and physiotherapists was not able to prevent self-reported falls or injurious falls. Further home-based studies of frail older people to prevent falls needs to be conducted.

### Acknowledgments

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