Effectiveness of the Chaos Falls Clinic in preventing falls and injuries of home-dwelling older adults: A randomised controlled trial

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ABSTRACT

Background: Falls and related injuries are a major public health concern in elderly people. Multifactorial interventions may result in significant reduction in falls but their effectiveness in prevention of fall-induced injuries at centre-based falls clinics is unclear. This study assessed the effectiveness of the multifactorial Chaos Clinic Falls Prevention Programme on rate of falls and related injuries of home-dwelling older adults.

Methods: This study was a pragmatic, randomised controlled trial concentrating on high risk individuals and their individual risk factors of falling. Home-dwelling elderly people aged 70 years or more were recruited to the Chaos falls clinics in the cities of Lappeenranta and Tampere in Finland between January 2005 and June 2009. 1314 participants with high-risk for falling and fall-induced injuries and fractures were randomised into intervention group (n = 661) and control group (n = 653). A multifactorial, individualized 12-month falls prevention programme concentrating on strength and balance training, medical review and referrals, medication review, proper nutrition (calcium, vitamin D), and home hazard assessment and modification was carried out in the intervention group. The main outcome measures were rates of falls, fallers, and fall-induced injuries.

Results: During the one-year follow-up, 608 falls occurred in the intervention group and 825 falls in the control group. The rate of falls was significantly lower in the intervention group (95 falls per 100 person-years) than in the controls (131 falls per 100 person-years), the incidence rate ratio (IRR) being 0.72 (95% confidence interval (CI) 0.61–0.86, p < 0.001, NNT 3). In the intervention group 296 participants fell at least once. In the controls the corresponding number was 349. The hazard ratio (HR) of fallers in the intervention group compared with the control group was 0.78 (95% CI 0.67–0.91, p = 0.001, NNT 6). The number of fall-induced injuries in the intervention group was 351 with the corresponding rate (per 100 person-years) of 55. In the control group, these figures were higher, 468 and 75. The IRR of fall-induced injuries in the intervention group compared with the control group was 0.74 (95% CI 0.61–0.89, p = 0.002, NNT 5).

Conclusions: The multifactorial Chaos Clinic Falls Prevention Programme is effective in preventing falls of older adults. The programme reduces the rate of falls and related injuries by almost 30%.

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Introduction

Falls and related injuries are a major public health concern in elderly people. Around 30% of home-dwelling people aged 65 years or older fall every year, and about half of those who fall do so repeatedly.1–6 Falls often lead to pain, functional limitations and excess health-care costs and are an independent predictor of nursing home admission.7 In Finland, annually more than 10,000 older people die due to a fall-induced injury. This is four times more than the annual number of traffic fatalities.8 Since falling is the main risk factor for fractures and other injuries in elderly people and since many of the risk factors for falls and serious injuries caused by falls are similar and correctable, fall prevention is essential in the planning of effective injury

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Falls clinics are one approach by which older people with increased risk for falls and injuries could be managed multifactorially.\(^{16}\) A falls clinic is an outpatient clinic where fall-prone older adults’ individual risk factors for falls and fall-induced injuries are first carefully assessed and then interventions and treatments are implemented as appropriate by a nurse, physiotherapist and physician. The first descriptive reports on falls clinics are from late 1980s,\(^{20}\) but as far as we know there is no randomised controlled study concerning the true effectiveness of the falls clinic approach. Thus, the purpose of the current study was to assess the effect of a multifactorial Chaos Clinic Falls Prevention Programme on rate of falls and related injuries of home-dwelling older adults.

**Methods**

**Setting and participants**

Two similar falls prevention clinics entitled the Chaos Clinics were situated in the cities of Tampere and Lappeenranta in Finland. In Tampere, the Chaos Clinic was a part of the city’s communal health services, while in Lappeenranta it was a part of the services of a private Lappeenranta Service Centre Foundation. Both clinics had three health care professionals: a nurse, a physiotherapist and a physician (general practitioner). The participants were recruited between January 2005 and June 2009 and they were inhabitants of these two cities.

The outcomes of the study were rate of falls, fallers and fall-related injuries (fractures). An a priori sample size calculation, based on the rarest outcome rate (ie, fracture rate) of 10\% in the control group, a 30\% reduction in the proportion of fractures in the intervention group, 80\% power, and a significance level of 4.5\%, indicated that we needed 3200 participants (1600 per group).

The trial is registered with the Current Controlled Trials Registry, ISRCTN48015966, and was approved by the ethics committee of Pirkanmaa Hospital District in November 18, 2003. The reference number (ETL-code) is R03161. All the participants in this study gave informed written consent before taking part.

**Participant eligibility**

Home-dwelling persons aged 70 years or more with increased risk for falling and fall-induced injuries were eligible and belonged to the target group. Primarily, such individuals were guided to the Chaos Clinic by the regional health care professionals (physicians, nurses, physical therapists) but relatives and older adults by themselves could also contact the Clinic for assessment of eligibility. The main inclusion criterion was age 70 years or more. In addition, the person had to have at least one of the following independent risk factors for falls and injuries: balance, mobility and everyday function, 3 or more falls during the last 12 months, a previous fracture after the age 50, an osteoporotic fracture (hip fracture) in a close relative (mother or father), osteoporosis (diagnosed or a strong clinical suspicion such as thoracic kyphosis), low body weight (BMI < 19), and sickness or illness essentially increasing the risk for osteoporosis, falls and fractures.

The exclusion criteria were: inability to give informed consent (for example, because of severe dementia or handicap), disabilities or illnesses preventing physical activity and training, inability to move (bedridden individuals), and terminal illness (predicted lifetime less than 12 months).

**Baseline assessment of intrinsic and extrinsic risk factors of falls**

At the Chaos Clinic, all the participants first provided signed informed consent. Then they were interviewed and went through a careful and comprehensive medical examination to find out the individual risk factors for falls and injuries. A nurse took care of the interview and basic body measures, a physiotherapist tested mobility, balance and strength, and a physician performed the medical check-up.

**Interview and baseline measurements**

At the first visit at the Chaos Clinic all the participants had one hour meeting with a nurse who interviewed background details (type of residence, activities of daily living, functional ability, exercise, fear of falling, medical conditions, medications, living arrangements, previous falls and injuries, and nutrition), assessed cognitive status by the Mini-Mental State Examination (MMSE)\(^{21,22}\) and depressive symptoms by the Geriatric Depression Scale (GDS-15).\(^{23}\) measured height, weight, blood pressure, and pulse rate in rest, and, made an orthostatic test (postural blood pressure).\(^{3}\)

**Physical functioning assessment**

During the first visit at Chaos Clinic, all the participants also had one-hour assessment by a physiotherapist. The assessments included tests for balance, walking speed, muscle activity and strength, and reaction time. Short Physical Performance Battery (SPPB)\(^{24}\) and Timed Up and Go-test (TUG)\(^{25,26}\) were used to measure mobility, balance, walking speed and ability to rise from a chair.

Reaction time was measured with computer-based eye-hand reaction test where a button was pressed after a light stimulus, and reaction time was calculated from the stimulus.\(^{27}\)

The isometric quadriceps strength was measured in the sitting position with a custom-made dynamometer.\(^{28}\) Grip strength was measured from both hands by Jamar hand dynamometer.\(^{29,30}\)

**Medical examination**

The medical examination was made by the Chaos Clinic physician. The cardiovascular assessment included heart auscultation, palpating peripheral pulses at rest, and checking peripheral swelling in the ankles. Evaluation of the results of the above noted blood pressure measurement and orthostatic test was also a part of the examination. The respiratory system was examined by auscultation.

Assessment of the musculoskeletal system included measurement of the active and passive ranges of motion of the joints, spine flexibility, and participant’s ability to walk by heels and toes. A short neurological examination assessed cerebral nerves, reflexes, sensation, and coordination. Participants’ visual acuity was tested by the Snellen eye chart and low contrast visual acuity test chart.\(^{31}\) Also the red reflection and field of vision (finger perimetry) were tested.

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Randomisation and masking

After the baseline assessments, all participants were randomised sequentially to one of two study groups (intervention, control) by sealed opaque envelopes. This was done by the Chaos Clinic’s physician. Group allocation remained fully concealed until opening of the envelope.

Randomisation was stratified by gender (men, women), age group (70–79 years, 80 years and over) and study clinic (Tampere, Lappeenranta). Within each of these eight strata, randomly varying block size of 6, 8, 10, or 12 was used to ensure the equality of group sizes. The randomisation schedule for each stratum was generated by a statistician who was not a part of the research team.

After randomisation the necessary preventive intervention measures were initiated in the intervention group. Because of the nature of the intervention it was not possible to blind the participants or the Chaos Clinic professionals. Researchers were blinded to group allocation.

Intervention

The control group received a general injury prevention brochure of the Finnish Prevention of Home Accidents Campaign (Kotitapaturma, www.kotitapaturma.fi/?p=1670). Additionally, participants in the intervention group received all the below-mentioned individually tailored preventive measures judged necessary at the baseline assessment.

Execution of the intervention measures was supervised by the personnel of the Chaos Clinic.

Improvement of functional ability

Strength and balance training. All participants who got less than 8 points from the SPPB test battery24 received individually tailored strength and balance home-training programme or they were referred to group training supervised by a professional exercise leader. The strengthening programme consisted a combination of exercises for hip abductors and adductors, knee extensors and flexor and ankle dorsiflexors and plantarflexors. The balance programme included exercises for both static and dynamic balance, such as one-leg stance, tandem-stance, tandem-walk and weight shifting to different directions. Many of the exercises were strength–balance combination trainings, such as half-squat, heel walking, toe walking, sit-to-stand and step-on-a-stair.

Hip protectors and mobility assistive devices. Use of hip protectors was recommended to all high-risk participants with at least 2 inclusion criteria, especially if they were 80 years of age or older. Similarly, wintertime use of anti-slip shoe devices was advised. Participants were also advised to use the assistive device, such as a cane or walker, if the measured time in TUG-test was more than 20 s.

General physical activity and exercise

Advice to increase general physical activity according to the participant’s functional ability was given by the Chaos Clinic physiotherapist – both orally and by a written physical activity prescription. In addition, the participants received a written home exercise brochure with schematic drawings of balance and low extremity muscle strength training, followed by those of flexibility and endurance training.

Nutrition advice

Guidance for proper nutrition concentrated on information about healthy diet and adequate calcium (1000–1500 mg per day) and vitamin D (600–800 IU per day) intake. If necessary, supplements were recommended and prescribed.

Medical review and referrals

The participants were referred to their personal primary care physician for diagnosis and treatment if untreated illnesses or symptoms increasing the risk of falling were found in the medical examination. A referral to optician or ophthalmologist was made if the distance visual acuity was less than 10/20 (Snellen Chart) with or without glasses in the better eye, or less than 6/20 in the poorer eye, or if there was a clear difference in vision between eyes (anisometropia). Similarly, participants with untreated cataract were recommended to contact ophthalmologist for expedited cataract surgery.

Medication review

Special attention was paid to medications that were known to increase the risk of falling, especially psychotropic drugs.37 Reduction of these medications was recommended and redundant psychotropic medications were withdrawn.

Alcohol and smoking

If necessary, reduction in alcohol consumption was advised, as well as request to stop smoking.

Home hazard assessment and modification

A one-hour, structured home visit was carried out by the physiotherapist or the nurse to assess hazards related to safety at home and its environment. This extrinsic risk factor survey was carried out according to the structured checklist made by the Finnish Prevention of Home Accidents Campaign (www.kotitapaturma.fi/?p=1302). After the assessment, instructions to reduce and modify the home hazards were given. The home visit also served for reviewing and reinforcing the earlier given nutritional and home exercise advice.

Follow-up

All the participants in both groups were followed for 12 months or until they either withdrew from the study or died. The Chaos Clinic professionals (who were not blinded to group allocation, as noted above) recorded the number of falls and fall-related injuries in three months intervals, by phone interview at 3 and 9 months, and at the follow-up visit at the Clinic at 6 and 12 months. A fall was defined as “an unexpected event in which the participant comes to rest on the ground, floor, or lower level” in.38,39 Injuries were verified from the medical records of the participants. In the intervention group, adherence to the given fall and fracture preventive measures was checked at each contact and booster interventions and recommendations were given if necessary.

Statistical analysis

The data was analysed on an intention-to-treat basis, using the data for all randomised participants. Follow-up time for falls, fallers and fall-induced injuries were calculated from the day of randomisation to the end of the study period (12 months) or until participants died or withdrew the study.

In the intervention group and control group, incidence rates of falls, fallers and fall-induced injuries (with their 95% confidence intervals (CIs)) were calculated per 100 person-years. The between-groups differences in rate of falls and rate of fall-induced
injuries were analysed with negative binomial regression analysis. The Cox proportional hazards regression model was used in analysing the difference in the rate of fallers. In this analysis, the follow-up was ended to the first fall.

Results

Between January 2005 and June 2009, 1601 elderly people were registered to the two Chaos Clinics and 1314 of them were randomised: 661 to intervention group and 653 to control group. The slight difference in the number of participants between groups was a result of the randomisation procedure (described in Methods section). The participants in the intervention and control groups had similar baseline characteristics (Table 1). Fig. 1 shows the trial profile through the study. 169 persons (12.9%) withdrew from the study. The total follow-up time of the participants was 1269 person-years (PY) (intervention group 640 PYs, control group 629 PYs).

Adherence

After the baseline assessments, the median number of the fall and injury prevention interventions and recommendations was 5 (range 0–9) in the intervention group. Five most common interventions and recommendations were exercise prescription, home hazard assessment and modification, medical review and referrals, nutrition advice, and medication review (Table 2). Adherence to these interventions and recommendations ranged from 31% to 89%. The median number of booster interventions and recommendations at 6 months was 3 (range 0–7). Three most common were exercise prescription, medical review and referrals, and nutrition advice. Adherence to these booster interventions and recommendations ranged from 73% to 82% (Table 2).

Rate of falls

During the one-year follow-up, 608 falls occurred in the intervention group and 825 falls in the control group. The rate of falls was significantly lower in the intervention group (95 falls per 100 person-years) than in the controls (131 falls per 100 person-years). (incidence rate ratio [IRR] 0.72; 95% CI, 0.61–0.86; p < .001), (Table 3). The number needed to treat (NNT) to prevent one fall was 3.

Rate of fallers

Of the 661 participants in the intervention group, 296 fell during the follow-up at least once. In the control group (n = 653), the corresponding number was 349. The rates of fallers (per 100 person-years) were 63 and 81, respectively. The hazard ratio (HR) of fallers in the intervention group compared with the control group was 0.78 (95% CI, 0.67–0.91; p = .001; NNT 6) (Table 3).

Rate of fall-induced injuries

The number of fall-induced injuries in the intervention group during the one-year follow-up was 351 with the corresponding rate (per 100 person-years) of 55. In the control group, these figures were higher, 468 and 75. The incidence rate ratio (IRR) of fall-induced injuries in the intervention group compared with the control group was 0.74 (95% CI, 0.61–0.89; p = .002; NNT 5) (Table 3). The injury category distribution did not show between-groups difference and was as following: 595 (73%) soft tissue bruises and contusions, 120 (15%) wounds and lacerations, 75 (9%) bone fractures, 18 (2%) joint distortions and dislocations, 5 (1%) head injuries other than fractures, and 6 (1%) other injuries.

The number of fractures was lower in the intervention group than in the control group although the difference was not statistically significant. The total number of fractures was 33 in the intervention group and 42 in the control group. The IRR of fractures in the intervention vs control group was 0.77 (95% CI, 0.48–1.23; p = .276) (Table 3). The fracture distribution did not show between-groups difference and was as following: wrist 20 (27%), hip 9 (12%), proximal humerus 9 (12%), rib 9 (12%), vertebra 9 (12%), pelvis 5 (7%), hand 5 (7%), foot 3 (4%), ankle 2 (3%), elbow 2 (3%), and other 2 (3%).

Discussion

This study showed that a multifactorial centre-based Chaos Clinic Falls Prevention Programme was effective in preventing falls and fall-induced injuries of home-dwelling older adults. The programme reduced the rate of falls and related injuries by almost 30%. The numbers needed to treat to prevent one fall and fall-induced injury were low, 3 and 5, respectively. This result is encouraging since the ultimate aim of falls prevention is to decrease the number of fall-induced injuries.

Previous research has indicated that multifactorial interventions can result in significant reduction in falls of older people, but, as noted previously, there has been lack of evidence of their...
effectiveness in preventing fall-induced injuries and fractures. The lack of evidence has concerned especially falls clinics in which home-dwelling high-risk individuals are assessed and managed. As such, a falls clinic approach sounds reasonable, because current falls prevention recommendations emphasize that direct interventions – performed by the health professionals who did the assessment – must follow the multifactorial fall risk assessment. The exact reasons for the reduced risk of falls and injuries in our multifactorial study are difficult to assess. Because each intervention group participant received an average 5 interventions or recommendations, the relative importance of each single

**Table 2**
Fall and injury prevention interventions and recommendations for the intervention group (n=661) at baseline and at the 6-month follow-up visit. Adherence to each intervention or recommendation was assessed at 6 months and 12 months.

<table>
<thead>
<tr>
<th>Intervention/recommendation at baseline</th>
<th>Adherence at 6 months</th>
<th>Booster intervention/recommendation at 6 months</th>
<th>Adherence at 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>n (%)</td>
<td>n</td>
</tr>
<tr>
<td>Exercise prescription&lt;sup&gt;a&lt;/sup&gt;</td>
<td>649</td>
<td>535 (82)</td>
<td>384</td>
</tr>
<tr>
<td>Home hazard assessment and modification</td>
<td>549</td>
<td>171 (31)</td>
<td>144</td>
</tr>
<tr>
<td>Medical review and referrals</td>
<td>488</td>
<td>410 (84)</td>
<td>332</td>
</tr>
<tr>
<td>Nutrition advice&lt;sup&gt;b&lt;/sup&gt;</td>
<td>475</td>
<td>425 (89)</td>
<td>322</td>
</tr>
<tr>
<td>Medication review</td>
<td>309</td>
<td>228 (74)</td>
<td>156</td>
</tr>
<tr>
<td>Hip protectors</td>
<td>285</td>
<td>40 (14)</td>
<td>186</td>
</tr>
<tr>
<td>Improvement of functional ability&lt;sup&gt;c&lt;/sup&gt;</td>
<td>200</td>
<td>102 (51)</td>
<td>133</td>
</tr>
<tr>
<td>Cessation of smoking</td>
<td>26</td>
<td>7 (27)</td>
<td>19</td>
</tr>
<tr>
<td>Reduction of alcohol use</td>
<td>12</td>
<td>2 (17)</td>
<td>6</td>
</tr>
</tbody>
</table>

<sup>a</sup> Home exercise programme with advice to increase general physical activity.

<sup>b</sup> Promotion of healthy diet including adequate calcium (1000–1500mg per day) and vitamin D (600–800IU per day) intake.

<sup>c</sup> Specific balance and strength training including assessment and recommendation of mobility assistive devices if necessary (canes, walkers, and anti-slip shoe devices).
intervention remained unknown. On the other hand, the Chaos Clinic Falls Prevention Programme included many single components (multicomponent exercise training, medication review and reduction, adequate calcium and vitamin D intake, home hazard assessment and modification, hip protectors, referral to cataract surgery) whose ability in falls and injury prevention is evidence based. 

Recently Hill et al. reported preliminary evidence of beneficial effect of falls clinic approach but the study was neither randomised nor controlled. Other recent studies focusing on effectiveness of multifactorial interventions have not been true falls clinic evaluations (assessment of the performance of an established falls clinic), or have concentrated on secondary prevention only (all subjects fallen at least once before enrolment).

Our study has several strengths. Firstly, this study is, as far as we know, the first randomised controlled trial assessing the effectiveness of a falls clinics approach in prevention of falls and related injuries by simultaneously concentrating on many individual intrinsic and extrinsic risk factors of falls. Secondly, this study took into account all high-risk home-dwelling elderly persons, not only those who had already had falls or injuries. In other words, the study concentrated on both primary and secondary prevention of falls. Thirdly, the drop out percentage of the participants was only 12.9% despite the fact that these persons were 70 years old or older and in high risk for falls and related injuries. This tells about excellent suitability of the Chaos Clinic approach for clinical practice. Fourthly, all the participants were followed by intention-to-treat basis as long they were involved in the study and so they were included in the analyses for the period they participated. Finally, the adherence to the top three interventions and recommendations (exercise prescription, medical review and referrals, and nutrition advice) was very good with 73–89% of the participants following the given interventions and recommendations throughout the study. In many other multifactorial trials, less intense implementation and lower adherence to the fall-prevention measures may have limited the effectiveness of the intervention.

The study also has some limitations. Firstly, although all the high-risk elderly people in the Chaos Clinic communities (Lappeenranta and Tampere) had possibility to take part into the study it was not possible catch them all and inform them about the clinic. The regional health care professionals could find only those persons who already had contacted Finnish health care system for some reason. Secondly, adherence to the given interventions and recommendations could be recorded at general level only. This was due to the study protocol according to which the participants were contacted in three-month intervals. Thirdly, the study was not large enough to show statistically significant difference in the number of fractures between the groups, although the finding was similarly beneficial as in the number of all fall-induced injuries (Table 3). The reason for not reaching the originally planned sample size of 3200 participants was that due to financial limitations (grant under-funding) only two Chaos falls clinics (instead of the planned six) could be realized. Fourthly, our non-blinded falls follow-up procedure in three months intervals was sub-optimal when the currently recommended procedure is weekly or monthly calendars. On the other hand, use of fall diaries increases workload of the personnel considerably and the risk for contamination bias of the controls (i.e., the controls start to act as the intervention persons due to continuous reminding of their fall risk), the facts we wanted to avoid in this pragmatic trial. Finally, cost calculations were not built in the study, so it was not possible to assess the cost-effectiveness of the Chaos Clinic Falls Prevention Programme. Further studies are needed to address this issue.

In conclusion, a multifactorial centre-based Chaos Clinic Falls Prevention Programme is effective in preventing falls and fall-induced injuries of high-risk older adults living at home. The rate of falls and related injuries can be reduced by almost 30%. Such clinics are relatively easy and quick to establish although proper education of the staff is needed before initiation. Although the results are very promising further research is needed to compare different types of falls prevention protocols with each other and to assess the costs per prevented injury.

**Conflict of interest**

The authors have no conflicts of interest to declare.

**Author contributions**

All authors contributed to the study design; acquisition, analysis and interpretation of the data; and the preparation of the manuscript.

**Role of funding source**

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These organisations had no role in the design and conduct of the study, in the collection, analysis, and interpretation of the data, or in the preparation, review, or approval of the manuscript.

**Additional contributions**

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**Table 3**

Falls, fallers, fall-induced injuries and fractures by treatment group over the 12-month follow-up period.

<table>
<thead>
<tr>
<th>Intervention group (n=661)</th>
<th>Control group (n=653)</th>
<th>Fall or injury risk ratio (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Falls</td>
<td>608</td>
<td>825</td>
<td>0.72 (0.61–0.86)*</td>
</tr>
<tr>
<td>Fallers*</td>
<td>206</td>
<td>349</td>
<td>0.78 (0.67–0.91)*</td>
</tr>
<tr>
<td>Fall-induced injuries</td>
<td>351</td>
<td>468</td>
<td>0.74 (0.61–0.89)*</td>
</tr>
<tr>
<td>Fractures</td>
<td>33</td>
<td>42</td>
<td>0.77 (0.48–1.23)*</td>
</tr>
</tbody>
</table>

* Incidence rate ratio.

| Hazard ratio. |

| Participants fallen at least once during the follow-up. |
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