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The Chaos Clinic for prevention of falls and related injuries: a randomised, controlled trial

Submission date	Recruitment status
09/05/2007	No longer recruiting
Registration date	**Overall study status**
08/06/2007	Completed
Last Edited	**Condition category**
10/06/2021	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
128

Study information

Scientific Title

The Chaos Clinic for prevention of falls and related injuries: a randomised, controlled trial

Acronym
KAAOS (Kaatumis-ja osteoporoosiklinikka [The Chaos Clinic])

Study objectives
Falls are the most common accidents in elderly people. Around 30% of people aged 65 years or older living in the community fall every year. In Finland, annually more than 1000 people die after a fall-induced injury. This is three times more than the number of victims in traffic accidents. The number of hip fractures has increased over threefold during last three decades and the same trend can be seen in the number and incidence of many other osteoporotic fractures, too. If preventive measures are not urgently adopted these numbers will continue to rise.

Falls and fractures have several independent risk factors and many studies have shown that it is difficult to prevent these accidents by concentrating only to one or few of these factors (single-intervention strategy). In this study, the main purpose is to prevent falls and fall-related injuries (fractures) by concentrating to high-risk individuals and by intervening all the individual risk factors at the same time (multi-factorial preventive approach).

At the Chaos Clinic, the elderly participants are first interviewed and examined very carefully and comprehensively to find out the individual risk factors for falls and injuries. There are three professionals at the Chaos Clinic: a nurse who takes care of the interview, a physical therapist who do the tests of mobility, balance and strength, and a physician who do the medical check-up.

The effectiveness of the Chaos Clinic will be studied in this randomised controlled trial. The project will continue for many years finally aiming to answer the following questions:
1. Can the Chaos Clinic decrease falls and fall-related injuries among home-dwelling fall-prone elderly people, and if so, how well and what kind of injuries (fractures) can be prevented?
2. Does the clinic show positive effects in the mobility, function, activities of daily living, or quality of life of the target population?
3. If effective, what is the cost-effectiveness of the Chaos Clinic system?

Our hypothesis is that the older adults who belong to the Chaos Clinic falls prevention program (intervention group) will have 30% less falls and fall-related injuries than participants in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study has been approved by the ethics committee of Pirkanmaa Hospital District on the 18th November 2003 (ref [ETL-code]: R03161).

Study design
This is a pragmatic, randomised controlled study.

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Falls and related injuries

Interventions
So far, the Chaos Clinic study has been a national trial only. Currently (year 2007), Finland has two Chaos Clinics (Tampere and Lappeenranta) and negotiations to start the clinic action in other places (or countries) as well are very lively. Since the Clinics are in every aspect identical, new clinics can be included in the trial.

The Clinic has a multidisciplinary approach to evaluate and treat individual intrinsic and extrinsic risk factors for falls and fall-induced injuries such as fractures. Home-dwelling elderly people with a high-risk for falling are first interviewed and examined at the Chaos Clinic by a physiotherapist, nurse and physician. After comprehensive and individual assessment of the risk factors for falling, the participants are randomised to the intervention group and control group. Thereafter, the personnel of the Chaos Clinic decide, on individual basis, the preventive measures needed and supervise their execution in the intervention group. The other half of the participants or the control group receives general injury prevention guidelines only.

Control:
The control group receives general injury prevention guidelines in the form of a brochure made by the Finnish Campaign called Prevention of Home Accidents (Kotitapaturmien ehkäisykampanja).

Intervention:
In addition, the participants in study group receive all the individual preventive measures judged necessary at the baseline assessment. The personnel of the Chaos Clinic supervise the execution of the intervention measures. These measures include:
1. General guidance for physical activity (physical activity prescription)
2. Guidance for adequate nutrition (calcium and vitamin D supplementation)
3. Individually tailored or group training of strength and balance (led by a professional exercise leader)
4. Treatment of illnesses increasing the risk of falling
5. Review of medications (withdrawal of redundant psychotropic medication)
6. Alcohol use reduction, if necessary
7. Request to stop smoking, if necessary
8. Recommendation for the use of hip protectors, if necessary
9. Specific treatment of osteoporosis, if necessary
10. Home hazard assessment and modification

In both groups, the number of falls and fall-related injuries are recorded for 12 months, by phone interview at 3 and 9 months, and, at a follow-up visit at 6 and 12 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Falls and fall-related injuries, especially fractures. These will be measured every three months i. e. by phone calls at 3 and 9 months, and on follow-up visits at 6 and 12 months from the beginning.

Secondary outcome measures
1. Mobility, function, and activities of daily living (Guralnik-test, Timed Up and Go [TUG]-test, and tests for reaction time, balance, and muscle strength)
2. Ability for everyday exercise
3. Fear of falling
4. Occurrence of depression (the 15-item Geriatric Depression Scale [GDS-15])
5. Cognitive functioning (Mini Mental State Examination [MMSE]-test)
6. It is also possible to assess the so called Fracture Index (an index showing the individual risk for fracture) from the data

The secondary outcomes will be measured every six months ie. on follow-up visits at 6 and 12 months from the beginning.

Overall study start date
17/01/2005

Completion date
31/12/2010

Eligibility

Key inclusion criteria
All home-dwelling persons aged 70 years or more with high-risk for falling and fall-induced injuries and fractures are eligible and belong to the target group. Primarily, such individuals are guided to the Chaos Clinic by the regional health care professionals (physicians, nurses, physical therapists) but relatives and older adults by themselves can also contact the Clinic for assessment of the eligibility.

Inclusion criteria
Age: 70 years or more, with at least one of the following criteria:
a. Problems in mobility and everyday function
b. Three or more falls in the last 12 months
c. Previous fracture after the age 50
d. Osteoporotic fracture (hip fracture) in a close relative (mother or dad)
e. Osteoporosis; clinically proved or strong suspicion
f. Low body weight (Body Mass Index [BMI] less than 19)
g. Sickness/illness essentially increasing the risk for osteoporosis, falls or fractures

Participant type(s)

Patient

Age group
Senior

Sex
Both

Target number of participants
1600 participants per group (i.e. 3200 participants)

Total final enrolment
1314

Key exclusion criteria
Person's inability to give informed consent (for example, because of dementia or handicap) is a contraindication to be included in the study. Other exclusion criteria are:
1. Disabilities or illnesses preventing physical activity and training
2. Inability to move (bedridden individuals)
3. Terminal illness (predicted lifetime less than 12 months)

Date of first enrolment
17/01/2005

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Finland

Study participating centre
The UKK Institute
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Sponsor information

Organisation
The Urho Kaleva Kekkonen (UKK) Institute for Health Promotion Research (Finland)

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Sponsor type
Research organisation

Website
http://www.ukkinstituutti.fi/en/

ROR
https://ror.org/05ydecq02

Funder(s)

Funder type
Research organisation

Funder Name
This study is partly internally funded by the principal research organisation, the Urho Kaleva Kekkonen (UKK) Institute for Health Promotion Research (Finland).

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Funder Name
City of Tampere (Finland)

Funder Name
State Provincial Office of Southern Finland (Finland)

Funder Name
City of Lappeenranta (Finland)

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Alternative Name(s)
Juho Vainio Foundation, Reppy Institute

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Finland

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2014	10/06/2021	Yes	No