ISRCTN15932647 https://doi.org/10.1186/ISRCTN15932647

iStoppFalls information and communication technologies (ICT) based system to predict and prevent falls

Submission date
30/01/2014

Recruitment status
No longer recruiting

Registration date
10/02/2014

Overall study status
Completed

Last Edited
15/02/2016

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
The purpose of the iStoppFalls study is to develop, implement and evaluate innovative information and communication technologies (ICT)-based technologies. This programme can easily be integrated into the daily life of older people living at home. iStoppFalls will develop unobtrusive technological solutions for continuous monitoring and prevention of fall risk factors, which are required to coach people in tailored individualized prevention programs, including exercise and education. The emphasis is not on laboratory research but on active implementation of successful fall prevention strategies in the daily life of older people in their own home. The aims of the study are to help to reduce the risk of falls, and thus to improve quality of life of older adults living at home. In addition, an assessment of fall risk is developed and implemented. Therefore, iStoppFalls will offer improved fall prediction and prevention measures, and thus provide a better assessment of fall risks for the elderly living at home.

Who can participate?
Men and women aged 65 and over who are able to stand and walk without a walking aid and who have an internet connection.

What does the study involve?
Participants will initially be expected to complete a pre-assessment test in the lab, whereby they will be required to complete both physical and cognitive measurements. Participants will then start the study and complete the in-built instruments every two weeks. Participants will be randomly allocated to either the intervention group or the control group. The control group will be asked to conduct their regular activities during the course of the study. The intervention group will receive an ICT system comprising of the PC and the Microsoft Kinect console to conduct the iStoppFalls programme on their own home television. The programme comprises exergames with strength and balance exercises. Participants will be advised to carry out a minimum of three sessions on each mode of exergame with 60 minutes on each session. The intensity will be increased individually and progressively by increasing sets and weights in the strength exercises and by increasing difficulty in the balance games. These methods will also minimize the risk of over-or under-exertion. In order to avoid falls during the exercise the

participants are able to hold onto one or two chairs. Participants wear the Senior Mobility Monitor (SMM) throughout the exergames and will be advised to wear it the whole day for mobility monitoring and analysis. Both the intervention and control groups will receive educational material. This includes information about fall risk (e.g., general health, falls, fear of falling, eating, medication, environment, emergency plan, exercise, checklists and quiz). After 8 weeks and 4 months the participants will be reassessed in the lab.

What are the possible benefits and risks of participating?
The possible benefits for participating in the study are:
Undertaking regular exercise regimens at home to reduce the individual risk of falling via strength and balance exercises.
Learning about individual fall risk via laboratory assessment, tracing regularly their improvements via system assessment and learning about health and falls via reading the educational material
Receiving feedback about their activity profile based on data collected from the SMM
Participants will be engaging in an innovative form of exercise via technology, which it could be a new experience for them, thus resulting in learning new skills and knowledge about digital game technology (this itself has the potential for the participants to take-up digital games as a means of a hobby).
There are no side effects to the treatment received during the study.

Where is the study run from?
The study is conducted across in Australia and two European sites: Cologne, Germany and Valencia, Spain. The lead centre in Europe is the German Sport University Cologne, Germany.

When is the study starting and how long is it expected to run for?
The study started in January 2014 and will run until August 2014. The study recruitment will last for about 3 months.

Who is funding the study?
European Commission - Collaborative project

Who is the main contact?
Dr Sabine Eichberg
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Study website
http://www.istoppfalls.eu

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
287361

Study information

Scientific Title
iStoppFalls ICT based system to predict and prevent falls: a randomized single-blind controlled trial

Acronym
ISF

Study objectives
The objectives of the study are:
1. To determine the effects of the intervention on falls risk and factors of falls
2. To improve quality of life for the elderly living at home
3. To evaluate feasibility and adherence to the programme

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committees, German Sport University Cologne, Germany, 24/09/2013
Ethics Committee, Universitat Politècnica de Valencia, Spain, 25/11/2011
Ethics Committee, University of New South Wales, Sydney, Australia, 19/12/2013

Study design
Multi-centre randomized single-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Falls and fall risk

Interventions
The treatment will last four months with a follow-up of two months.
The intervention group will receive an ICT system comprising of the PC, a set top box (STB), a Microsoft Kinect console, an Senior Mobility Monitor (SMM), and a Tablet to conduct the iStoppFalls programme on their own home television. The programme comprises exergames with strength and balance exercises. The Otago exercise programme was adapted for the strength training. The exergames for balance include three games which focus on stepping /walking, leaning and knee bending, as well as additional cognitive components for the dual task paradigm. Participants will be advised to carry out a minimum of three sessions each strength and balance exergame with 60 minutes per session. The intensity will be increased individually and progressively by increasing sets and weights in the strength exercises and by increasing difficulty in the balance games. These methods will also minimize the risk of over-/under-exertion. In order to avoid falls during the exercise the participants are able to hold onto one or two chairs. Participants wearing the SMM throughout the exergames and will be advised to wear it the whole day for mobility monitoring and analysis.
Both the intervention and control groups will receive educational material. This includes information about fall risk (e.g., general health, falls, fear of falling, eating, medication, environment, emergency plan, exercise, checklists and quiz).

The control group will undergo no exercise programme, but will be asked to conduct their regular activities during the course of the study.

Joint/secondary sponsor details:
1. Sabine Eichberg, Institute of Movement and Sport Gerontology, German Sport University Cologne
2. Helios DeRosario, Instituto De Biomecanica De Valencia, Spain
3. Mario Drobics, Austrian Institute of Technology, Austria
4. Janneke Annegarn, Philips Research Europe, Netherlands
5. Nico Kaartinen, Kaasa Solution GmBH, Germany
6. Kim Delbaere, Neuroscience Research Australia, Australia

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Reduction of fall risk by Short-form Physiological Profile Assessment (PPA; Lord, Menz, & Tiedemann, 2003), which includes five validated measures of physiological falls risk (visual contrast sensitivity, postural sway, quadriceps strength, reaction time and lower limb

proprioception).
2. Improvement of quality of life by 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0; http://www.who.int/classifications/icf/whodasii/en/) and by European Quality of Life-5 Dimensions (EQ-5D; http://www.euroqol.org/).
3. Provide an improved fall prediction and prevention assessment with balance, sit-to-stand from the Short Physical Performance Battery (SPPB; Guralnik et al. 1994) and reaction tests adapting for the iStoppFalls system.
4. Improve the prediction of falls (sensitivity, specificity, positive predictive value [PPV], negative predictive value [NPV] and total predictive accuracy [TPA]) based on algorithms and modeling. The risk assessment includes general questions (e.g., age, gender), fall-specific questionnaires (e. g., previous falls, medication) and physical tests (e.g., reaction time, balance).
5. Daily life mobility trend and risk indicator by a biomechanical model of exercises and movements based on the kinematics of the population.

Measured at baseline, mid-assessment after 2 months, post-assessment after 4 months, and 2 months follow-up.

Secondary outcome measures
1. History of falls by questionnaire and monthly falls calendar.
2. Gait velocity by 4 m walking from the SPPB (Guralnik et al. 1994), and 10 m walking in participants' habitual speed with 2 m for acceleration and deceleration.
3. Muscle strength and power of the lower extremities by sit-to-stand test from the SPPB (Guralnik et al. 1994) and the adaptation for the iStoppFalls system.
4. Functional mobility by Timed up and go test (TUG; Podsiadlo & Richardson, 1991).
5. Reaction time: hand and stepping choice reaction time adapted for the iStoppFalls system.
6. Balance by Maximal Balance Range (MBR; Lord et al., 1996), coordinated stability (CoStab; Lord et al., 1996), adapted balance tests (bipedal, semi-tandem, near tandem, tandem stance) from the SPPB (Guralnik et al. 1994) for the iStoppFalls system.
7. Cognitive functions which include general fluid function by Digit-Symbol-Coding (WAIS-III; Wechsler, 1997), divided and switched attention by Trail Making Test parts A and B Test (TMT A+B; Reitan, 1958) and by Attention Network Test (ANT) on PEBL, inhibition by the Victoria Stroop Test on PEBL, memory and working memory by digits forward and backward (WAIS-III; Wechsler, 1997).
8. Dual task costs by 10 walk + counting backwards by 3, sway + counting backwards by 3, sway + digit forward span.
9. Self-efficacy and fear of falling by Shortened Iconographical-Falls Efficacy Scale (Icon-FES; Delbaere, Smith, & Lord; http://www.neura.edu.au/sites/neura.edu.au/files/page-downloads /Icon-FES_10item.pdf)
10. Daily life activity profile by SMM.
11. Daily life movement quality indicator by SMM.

Measured at baseline, mid-assessment after 2 months, post-assessment after 4 months, and 2 months follow-up.

Overall study start date
02/01/2014

Completion date
15/08/2014

Eligibility

Key inclusion criteria
1. Men and women, aged 65+ years
2. Participants must be able to understand, read and speak German or Spanish, respectively
3. Not cognitively impaired
4. Are able to walk without walking aid
5. Television with HDMI
6. Internet access at home

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
100 participants in Europe, 60 participants in Australia

Key exclusion criteria
1. Acute coronary heart disease
2. Pulmonary embolism ≤6 months
3. Acute infections
4. Severe visual impairment
5. Psychiatric disorders
6. Untreated hypertension
7. Uncontrolled hypertension
8. Myocarditis
9. Bypass surgery ≤6 months
10. Participants with active implants (e.g., implantable defibrillators and pacemakers)
11. Severe neurological disorders: M. Parkinson, dementia, multiple sclerosis
12. Drug or alcohol dependence
13. Large abdominal aortic aneurysm
14. Uncontrolled metabolic diseases
15. Stroke
16. Acute cancer
17. Unstable cardiac disease
18. Arrhythmia
19. Chronic heart failure
20. Pulmonary embolism
21. Pneumonia
22. Chronic obstructive pulmonary disease (COPD)
23. Insufficient visual acuity
24. Insufficient visual aid
25. Colour blindness
26. Insufficient auditory acuity
27. Insufficient auditory aid
28. Valvular defect
29. Severe motor impairment

30. Anaemia
31. Renal insufficiency
32. Intermittent claudication
33. Osteoporosis
34. Inoperable enlarging aortic aneurysm
35. Malignant ventricular arrhythmia related to exertion
36. Severe aortic stenosis
37. End stage congestive heart failure
38. Other rapidly terminal illness
39. Severe behavioural agitation in response to exercise
40. Unstable angina
41. Uncontrolled cardiac failure
42. Severe aortic stenosis
43. Uncontrolled hypertension or grade 3 (severe) hypertension (e.g., blood pressure 180 mmHg [systolic] or 110 mmHg [diastolic])
44. Symptomatic hypotension <90/60 mmHg
45. Acute infection or fever, or feeling unwell (including, but not limited to, acute myocarditis or pericarditis)
46. Resting tachycardia or arrhythmias
47. Diabetes with poor blood glucose control (e.g., blood glucose level <6 mmol/L or >15 mmol/L

Date of first enrolment
02/01/2014

Date of final enrolment
15/08/2014

Locations

Countries of recruitment
Australia

Germany

Spain

Study participating centre
Am Sportpark Muengersdorf 6
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Sponsor information

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University/education

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ROR
https://ror.org/02azyry73

Funder(s)

Funder type
Government

Funder Name
European Commission - Collaborative project, Project number: 287361,ref: FP7-ICT-2011-7

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?
Protocol article	protocol	20/08/2014		Yes	No
Results article	results	27/11/2015		Yes	No