



Grant Agreement n. 215493

SMILING PROJECT

"Self Mobility Improvement of eLderly by counteractING falls" Information and Communication Technologies Instrument: Collaborative Project

Smiling Publishable Summary Report

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(2007-2013) Dissemination Level		
PU	Public	Х
РР	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services).	
СО	Confidential, only for members of the consortium (including the Commission Services)	

Executive summary

This document has the aim to provide information about the project context, objectives and results. It will be published in the project web-site (<u>www.smilingproject.eu</u>) and it will target the wider society. This document is the result of the reviewers request made during the Final Review Meeting, held in Ancon on 14th February 2011. The document is public and doesn't include any confidential information.

Project context and objectives

Mobility means freedom, flexibility and autonomy to all people, especially for older ones. Mobility is a key element to enhance independence and social participation through relevant daily activities, such as keeping up relationships with family and friends, leisure time activities, access to health care or reaching everyday facilities (i.e. food store, ...) and contributes to life satisfaction and subjective well-being. Unfortunately, aging is characterized by functional changes in the sensory, neurological and musculoskeletal systems, affecting motor tasks including gait and postural balance, with the consequence of **risk of falling**. Current data show that 33% of people aged over 65 years has a higher risk of falling or have experienced falling. These falls cause physical injury, emotional trauma and mobility avoidance. Beside severe social consequences, there are significant financial impacts on health care system. The most effective way to counteract falls is to improve movement capabilities, by training and rehabilitation programs.

SMILING project moves in such a direction by merging innovative theories in walking and balance training with state-of-the-art ICT technologies to implement an effective, cheap and easy to use solution to be widely spread in health centres, fitness clubs and rehabilitation environments. The SMILING project plans to diminish age related impairments through the interference of diminished neural plasticity that limits walking ability and by continuing these functional improvements into real life situations. The scientific idea of the project is based on the Chaos theory and Dynamic system theory statements, applied to the training of rehabilitation in the older population. The approach is intended to challenge older people to solve new motor problems in real time by inducing changeable environments that need active response and problem solving.

The overall objectives are:

- to develop and construct an advanced prototype of a wearable non-invasive computerized miniature system for mechanical chaotic perturbations of gait pattern in order to counteract and prevent tendencies to fall;
- to develop perturbation algorithms fitted to suit individual user's specific needs;
- to test both the technological solution and the developed perturbation algorithms in real conditions of use;
- to implement a system for training to be spread in rehabilitation, health care and fitness centres for a reorganization of the rehabilitation process in ageing.

The SMILING project (Self Mobility Improvement of eLderly by counteractING falls, GA n.215493) is funded under FP7, "ICT and Ageing" with a contribution from the EC of \in 2.250.000. The project lasted 36 months, from January 1st, 2008 to December 31st 2010.



The partners of the project are: Italian National Research Institute on Aging - INRCA (IT, Coordinator), University of Strathclyde (UK), Technical University of Kosice (SK), Step of Mind (IL), Alma Mater Studiorum - Università di Bologna (IT), Stichting Imec (NL), Ab.Acus (IT), École

Polytechnique Fédérale de Lausanne (CH), Centre Hospitalier Universitarie Vaudois (CH), Mishan (IL), and Geriatric Center Kosice (SK).

Work performed and results achieved

The important role of physical-activity-based interventions to improve function has been previously widely demonstrated in older people with and without age-related pathology. The aim of the SMILING project was to apply training regimes to institute new learning processes to counteract falling in elderly persons. The SMILING system challenges elderly users to solve new motor problems in real time by introducing variable environments that need active response and problem solving. Flexibility is a key factor in adapting to the unexpected changes of the environment, such as an uneven terrain, whilst stability allows reaction to any external perturbation.

The rationale of the SMILING system lies in adopting a new approach in neuro-motor rehabilitation that employs exercise programmes to both recover and improve neural plasticity in a natural way. The project built on the primary concept that perturbation of walking would help users acquire improved ability to cope with the challenges encountered in daily living that constitute some of the main causes of falls in the elderly population. Variable environments induced by perturbations weaken stiff motor behaviour, induces flexibility and thus enables effective training and improvement in mobility. The SMILING training programmes are characterised by sensory, cognitive, and motor tasks that can challenge brain functions in extensive training schedules. Skills are practised over multiple cycles in real life environments to ensure motor learning is developed and transferred to everyday life activities. The SMILING solution provides a changeable yet safe environment that needs an active problem solving response by the user.

The SMILING system has been tested by a group of older people who had a falling experience and need a rehabilitation programme. Acceptance by the users, reliability and ease of use are mandatory specifications of the project were the key factors of the test. The validation of the system was strictly monitored by clinical and rehabilitation professionals and was performed according to the national ethical rules.

Technical challenge (the SMILING system)

The main technical challenge was the development of a wearable non-invasive computer-controlled system that applies chaotic perturbations to the lower extremities during walking through small alterations of the height and slope of weight-bearing surfaces. The SMILING system in its present format is a complete system for walking assessment and training and it consists of four main modules: i) a motorized pair of shoes, ii) a user friendly portable control unit, iii) a set of PC based algorithms for ad hoc perturbation generation, iv) a complete facility for walking assessment.

The motorised shoes provide perturbation of walking in successive strides, to change the user's perception of the ground's surface at each foot contact. Each motorised shoe has four actuators, two in the forefoot and two in the heel, which are able to change their height independently up to 25 mm in order to provide different inclinations of the support surface at each step.

Movement of the four actuators is done in a very short time, which is the time the foot is off the ground during the swing phase of walking.

Each shoe is equipped with dedicated electronics (micro-controller, sensors and wireless communication capabilities) to provide for different functions.

The sensors are part of a wireless unit (named "S-Sense") placed on the back of the shoe to transmit data about the foot's position to the motor control unit (MCU) that controls the motors.

Dedicated software has been designed to speed up this event recognition and start the motors.

High level control function of the shoes is managed by means of a dedicated user control unit (UCU) worn by the subject performing the walking trials. Ad hoc tailored perturbation patterns are downloaded to the shoe before starting any training tasks to drive the motors to provide the expected functional perturbations. The unit has the facilities to start and stop training through verbal commands to the user and attendant. It also downloads the required perturbation patterns to the shoes and collects data from the shoe sensors to evaluate walking features.



The mechanical structure of the motorised SMILING shoe



The manufactured results

The SMILING User Control Unit

During walking, the user wears the shoes and the UCU and activates autonomously the perturbation session. For each foreseen walking task, the control unit supplies the main instructions and monitors the user's performance. At the end of the complete walking session, the UCU evaluates the acquired walking data and supplies a performance indication.

After the initial test application with elderly people, attention was paid to a simple interface characterised by only two buttons easily identifiable by colour coding and position. Audio messages are played and they are available in multiple languages.

Because of the various walking capabilities and anthropometric features, the SMILING perturbations need to be tailored for each subject.

According to the SMILING shoe design, perturbations may be any sequence of foot inclinations (both in the frontal and sagittal plane).

Geometrical parameters of the shoe (lateral distance between the actuators, relationship between motor rotations and height change) are fixed by the manufacturing constraints while the shoe length may be varied according to the subject's foot characteristics.

Gait analysis is a key add-on to the SMILING system. The assessment of any modification in the walking features of a subject both wearing and not wearing the SMILING shoes is a definite requirement to tailor perturbation sessions and to complete training programmes.

The computed gait parameters are used by the operator (e.g. clinicians, physiotherapist) in charge of the SMILING system setup to select the most suitable training exercises for the specific user.

Scientific and Technological Results

The system was tested in a group of 97 elderly people who had a history of falling or were considered at risk of falling by clinical assessment. Tests were conducted in four countries (Israel, Italy, Slovakia and Switzerland) in a study that used a cross-over design comparing training periods with SMILING versus wooden dummy shoes of same size, weight and shape. After the initial assessment at baseline, subjects were assigned to two groups:

• **GROUP A** (47 subjects): 4 weeks of training using the SMILING shoes including perturbation followed by 4 weeks of training with dummy shoes without perturbations.

• **GROUP B** (50 subjects): 4 weeks of training with dummy shoes without perturbations followed by 4 weeks of training using the SMILING shoes with perturbations.

In both groups, subjects were mostly women, with a mean age of 74 years; almost half of them living alone; mainly with a low/medium educational level and only a few of them are still working.

The primary outcome of the SMILING study was walking speed, while the secondary ones were gait parameters and other functional tests. In fact, age-related declines in both gait speed and gait stability have been associated with increased fall risk in older adults.

Other outcomes are the Tinnetti Performance Oriented Mobility Assessment Tool (POMA) aimed to assess the mobility problems of the subjects: higher scores of the POMA test indicate better gait and balance. If gait stability is fundamental for the prevention of falls, then it is important to improve narrow base walking. Results for all subjects over the entire trial showed significant increases in distance walked during 6 minutes walking (6MWD) tests, POMA balance, trial time average under dual task in narrow base tests and also decrease in double support time. However, there were no significant differences when comparing training periods using SMILING vs dummy shoes. Trends were noticed in walking speed that constituted the study's primary outcomes and approached the minimal clinically important difference in gait speed for the group A.

The 6MWD increased after each of the two periods. These results indicate improvement in the subjects' cardio-vascular fitness that may be explained by intensive exercising with additional weight. Several hypotheses were generated to explain the lack of observed effects of smiling training on the primary and secondary outcomes, including a decreased statistical power due to the attrition, the heterogeneity of the enrolled population, the limited sensitivity to change of the outcome measures used, the limited intensity and duration of the smiling training , as well as the competing effect of strength training due to the dummy shoes' weight. This latter factor might have made it more difficult to detect the specific effect of the smiling perturbations on gait speed, an outcome that appears, in retrospect, too rough and insufficiently sensitive. Future studies would have three primary areas of focus: (i) significant improvement of the system in terms of integrity & reliability; (ii) reduction in shoe weight and size; (iii) improved heterogeneity in the trial population. In addition, future trials would be performed according to the randomized controlled study protocol and would include more sensitive outcome measures that might focus on finer tests (e.g. verbal fluency at dual task, energy cost of walking, etc.).

Satisfaction and acceptance of the device by the final users were evaluated, measuring the level of satisfaction with the prototype, the feelings of competence and efficacy, the willingness to try out new technologies and the feelings of emotional health and happiness.

As regard satisfaction with the SMILING system, high values were registered in each country; another important result is the high level of adaptability, confirming that older people, if adequately prepared, can be willing to try out new technologies.

Further results are that a longer treatment is better than a shorter one in terms of device satisfaction and adaptability. This outcome is enforced distinguishing by the two groups (A and B), given that the average impact for the group A was higher both in the first than in the second training period.

The SMILING trials were the first ever conducted in the application of chaos theory for walking training and it is inevitable that many lessons have been learnt. Considerable knowledge and knowhow has been accumulated that can be used for future improvements.

Conclusions, impact and future plans

The SMILING training approach has been oriented to have a meaningful impact on the organization of elderly rehabilitation processes, keeping in account novel principles of neuro-rehabilitation and focusing on enhancing mobility. Therefore SMILING is expected to contribute strongly to a new organization of training and rehabilitation programmes to overcome the limitations of traditional rehabilitation paradigms. Health centres, fitness clubs, geriatric centres, sheltered houses, rehabilitation centres and institutions involved in elderly assistance and care are considered the target market of the SMILING system.

Falls-prevention programmes that are perceived to impact negatively on self-image are likely to be unattractive while those, which are viewed as improving skills or characteristics valued by older people, are likely to be more popular.

Indeed, the SMILING system applies novel approaches such as adoption of self-learning (and adapting systems) schema because the system's behaviour adapt itself in response to the walking performance of the user. Moreover, the feedback of the users that used the system during the trials was very positive, and they confirmed to have acquired a greater confidence and a greater awareness of their walking pattern, in particular for what concerns the wrongly or risky behaviours.

Further development of the system to provide walking training and rehabilitation using the application of chaos theory in motor learning and recovery is the primary goal.

In addition to the original SMILING concept, applications in other research and training areas are a possibility such as virtual reality and basic motor & neuro-physiological sciences.

The five possible products deriving from the SMILING project are:

1. The Hospital Fall Prevention system:

The complete SMILING system may be used in protected environment such as hospitals or rehabilitation centres to supply different training programmes according to the patients' needs and therapeutic programmes. Within this environment, the shoes for the application of perturbations and gait analysis for monitoring the therapy are needed.

2. The Home Fall Prevention system:

A wider application of the system outside clinics and hospitals can be envisaged for use in other areas such as fitness centres or private homes. It would use reduced features of the original SMILING system, for instance pre-defined perturbation patterns and training programmes.

3. The Motion Lab Research system:

The SMILING system is suitable for adaptation for research environments. It is flexible and this feature is also a key issue in a system aimed at providing a wide set of perturbations during walking. The system allows the recording of complete gait analysis data during training performance and it is an interesting tool for research on the mechanisms of the human neuromuscular system supplying balance perturbation during walking.

4. The Virtual Reality Lab system:

The capability to perturb walking by simulating an unexpected terrain is a feature that is interesting for virtual reality application. No systems exist with the same features as SMILING allowing a change of the environment to cause different proprioceptive experiences.

5. The Gait/Motion Analysis system:

The SMILING system component aimed at the monitoring of the training, namely the gait analysis system, is adequate for exploitation as it is, independently by the main system. It configures itself as a multipurpose motion analysis system comprising two instrumented units to be used for walking, running and other sport analysis which may be interesting for evaluation of motion.

Address of the project public website, as well as relevant contact details

Project website: <u>www.smilingproject.eu</u>

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