Early risk detection and prevention in ageing people by self-administered ICT-supported assessment and a behavioural change intervention delivered by use of smartphones and smartwatches

PreventIT

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Content

Abstract

This deliverable reports on the results that have been obtained so far, half-way through the PreventIT project, in the form of a white paper that covers the development of i) the content and behavioural change strategy of the lifestyle-integrated intervention, ii) tools for risk screening and profiling, iii) the back-end and front-end technology of the mHealth system under development in PreventIT, the so-called iPAS, and iv) intervention outcomes regarding functional performance and behavioural complexity. It also reports on two pilot studies that tested the two intervention arms on a sample from the target population of young older adults, and on the feasibility study that is in progress. The deliverable is part of Work Package 8 on Dissemination and exploitation. The objectives of WP8 are to i) disseminate evidence for the benefit of risk reduction interventions to older people, carers, and health care services, ii) to enhance the outreach of PreventIT at local, national, European, and international levels to help raise awareness for active, healthy ageing and promote personalised ICT-based interventions, and iii) to identify exploitable project results and develop and implement a business plan for marketable products and services.

The white paper will be made available on the project website www.preventit.eu and distributed to academic and professional communities, public administrations and local authorities, and user groups.

Glossary

aLiFE: The adapted LiFE programme. Adaption of the individually targeted LiFE programme to fit the needs and preferences of young older adults;

App: Mobile phone application;

eLiFE: Enhanced adapted LiFE programme, individually targeted by phenotype, including self-administered assessment, and feedback and motivational messages and delivered on smartphone and smartwatch interfaces;

HAPA: Health action process approach;

ICT: Information and communication technology;

iPAS: Personalised self-administered mHealth system for the consumer market for early identification of risk for age-related functional decline and with an individually targeted behavioural change intervention, that will be developed in PreventIT;

LiFE/oLiFE: The original lifestyle-integrated functional exercise programme for older adults, a non-traditional exercise programme with individualised balance and strengthening movements embedded within everyday activities, so that the exercises can be performed multiple times during the day;

mHealth system: The delivery of health care services via mobile communication devices;

PA: Physical activity;

RCT: Randomised controlled trial.

1. Introduction

PreventIT is a collaborative, European Commission funded research project with nine partners – two of which are SME's – from six European countries. The overall aim of the project is to meet challenges and barriers related to today's health services, and enable active and healthy ageing for an increasing ageing population by developing a proof of concept, unobtrusive mHealth system for the consumer market with young older adults as the target group. PreventIT focuses on self-assessment and self-intervention by use of smartphones/watches that implement new versions of an effective behaviour change programme with exercises integrated in daily life. Such a system will reduce risk related to ageing and empower people to take control of their own health, and thereby improve quality of life and reduce pressure on carers and the health care system. This white paper provides an overview over the project so far.

1.1 PreventIT at a glance

Lifestyle, disease and biology put older adults at risk of functional decline, leading to falls, cognitive impairment, frailty, and negative consequences for quality of life. PreventIT develops and tests an ICT based mHealth System (iPAS) for the consumer market, that enables early identification of risk of age-related functional decline and engenders behavioural change in young older adults in order to adopt a healthy, active lifestyle. We use an integrated system of a smartphone/watch as frontend technology and a protected cloud-based solution for handling of personal data as backend technology. We have also developed online instruments for risk-screening, complexity metrics, motivation for behavioural change, and a method to personalise exercise by phenotype, based on currently available large epidemiological studies. The ICT based intervention is delivered on a smartphone/watch with exercise integrated in daily life and tight coupling to a behaviour change programme. We developed the interventions and assessed them through two pilot studies. At the time of writing this white paper, we are in the process of evaluating the role of technology and behavioural change theories in risk prevention by performing a multi-national feasibility RCT to compare with the same intervention without use of technology and with practice as usual. Usability and feasibility are in focus, and ageing people are included in all phases of the project. Furthermore, we will assess the feasibility of collecting cost-effectiveness data to develop health economic models. At the end of the project, all assessment and intervention components will be integrated into a personalised self-administered activity system (iPAS), designed to empower ageing people to control their own health and function.

During and after the study, data is stored on protected servers at NTNU prepared specifically for the PreventIT project.

1.2 The building blocks of the iPAS

The iPAS that we are developing in PreventIT consists of many building blocks that will be further described in the sections below. The intervention itself is based on the LiFE programme (see section 2.1), which is a non-traditional exercise programme with individualised balance and strengthening movements embedded within everyday activities. Originally developed for older adults of 75+ years at risk of falls, we adjusted the programme to make it appropriately challenging for the younger target group of PreventIT, 60+ years young older adults early after retirement (aLiFE, see section 2.2). Furthermore, to maximise uptake and enhance behavioural change in everyday life, we developed a motivational strategy that is firmly grounded in behavioural change theory (section 2.3).

In order to identify young older adults at risk of future functional decline, we developed a risk screening tool (section 3.1) as well as further ICT-based tools to personalise the intervention to each user's needs and preferences (section 3.2). Together, these systems allowed us to transform the paper-based aLiFE intervention to an ICT-based intervention, eLiFE (section 4.1), consisting of smartphone and smartwatch as front-end technology (section 4.2). Behind the scenes, the smartwatch and smartphone are linked together and communicate with an in-house server, collecting information and sending motivational messages and feedback in return to the user (section 4.3). Collecting and sharing information at this scale necessitates an explicit data privacy and security strategy for the entire system that is in line with both national and EU regulations. This strategy in PreventIT is described in section 4.4.

Developing our mHealth system for young older adults of 60+ requires active involvement of the intended end user. Both aLiFE and eLiFE were tested in smaller groups of young older adults to inform the design of the different tools and interfaces and guide further development (section 5). At the first release of this white paper, we are in the process of testing the feasibility and usability of the paper-based aLiFE and ICT-based eLiFE interventions against a control group that receives current international recommendations regarding physical activity. The study protocol is briefly described in section 6.1, and the primary outcome measures on functional performance and behavioural complexity in sections 6.2 and 6.3, respectively. The white paper ends with conclusions regarding PreventIT so far and remaining work during the second half of the project.

2. Developing the intervention

2.1 The underpinning LiFE concept

The LiFE programme is a relatively new intervention approach for older adults, with small bits of exercises or activities integrated in daily life.[1] It incorporates behavioural change techniques and habit formation theory, including situational and environmental cues, planning, visualisation, repetition and re-enforcement. The participants identify daily routines so that LiFE activities can be planned. Activities can be performed indoors and outdoors. Exercises are tailored for each individual based on the LiFE Assessment Tool that is designed to give therapists indications of the participants' abilities in tasks specific to the LiFE programme, and thereby choose the appropriate level for each individual. The programme focuses on challenging balance and muscle strengthening activities in older adults. Activities are introduced gradually, initially in the same context to develop habits, and are connected with specific situations or environmental cues to strengthen behavioural change. Participants are taught the principles of upgrading their activities and encouraged to actively contribute to planning new activities that will challenge their balance and strength. The overall goal of the intervention is to find as many opportunities as possible throughout the day to embed the LiFE activities. See Figure 1 below for an illustration of the concepts underpinning LiFE. The programme has shown positive effects on physical function and disability, as assessed with the Late Life Function and Disability Index (LLFDI)[2], and better adherence rates than standard home exercise programme when used in a sample of older people with a mean age of 83 years.[3]

2.2 Adapting LiFE to young older adults: aLiFE

As the original LiFE intervention (oLiFE) was developed for older adults at risk of falls, we needed to adapt the intervention so that it would be appropriate for young older adults and have a broader focus than falls. This so-called aLiFE was developed within the PreventIT consortium during several workshops involving experts in the areas of exercise science, human movement science, psychology, occupational therapy, physical therapy, gerontology, geriatric medicine, and end users. The starting point for the aLiFE development was the original LiFE (oLiFE) programme. The oLiFE programme has a specific focus on preventing falls by introducing basic functional

[1] Clemson L et al. LiFE Pilot Study: A randomised trial of balance and strength training embedded in daily life activity to reduce falls in older adults. Aust Occup Ther J. 2010;57(1):42-50.
[2] Sayers S, Jette A, Haley S, Heeren T, Guralnik J, Fielding R. Validation of the Late-Life Function and Disability Instrument (LLFDI). Journal of the American Geriatrics Society. 2004;52:1-6.
[3] Clemson L et al. Integration of balance and strength training into daily life activity to reduce rate of falls in older people (the LiFE study): randomised parallel trial. *BMJ* 2012;345:e4547.

exercises for improving balance and strength. In contrast, the focus of aLiFE is to prevent general functional decline and improve physical fitness in young older adults.

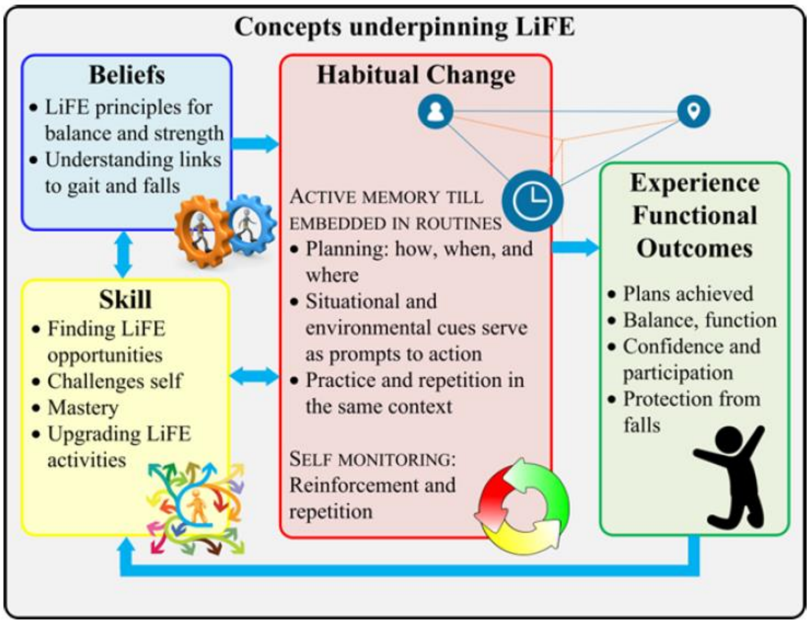

Figure 1: Theoretical underpinnings of the LiFE concept.[4]

In order to adapt oLiFE to the target population of young older adults, the activity framework and the behavioural change framework of the LiFE programme were adapted and extended as outlined in Table 1 below. In brief, adaptation of the activity framework included increasing the task challenge and intensity of the oLiFE balance and strength activities, and adding new strength and balance activities including challenging agility activities. Furthermore, a structured concept for increasing PA and reducing sedentary behaviour, which is lacking in oLiFE, was specifically developed for aLiFE.

Table 1: Differences between original LiFE (oLiFE) and adapted LiFE (aLiFE).

Aspect	**oLiFE**	**aLiFE**
Aim of the programme	Prevent falls	Prevent functional decline
Target group	75 years and older	60-70 years
Activity framework		
Static balance tasks	+++	+++
Dynamic balance tasks	+	+++
Agility tasks	-	+++
Sensorimotor tasks	+	+++
Dual-tasks	+	+++
Basic muscle strengthening tasks	+++	+++

[4] Clemson L et al. LiFE Pilot Study: A randomised trial of balance and strength training embedded in daily life activity to reduce falls in older adults. Aust Occup Ther J. 2010;57(1):42-50.

Challenging muscle strengthening tasks	+	+++
Physical activities	+	+++
Behavioural change framework		
Goal setting	+	+++
Planning	+++	+++
Activities into daily routine	+++	+++
Situational, environmental cues	+++	+++
Practice and repetition	+++	+++
Self-monitoring	+++	+++
Social interaction	-	++
Real time feedback	-	-
HAPA Model	-	++

2.3 Developing the motivational strategy

As stated above, the original LiFE programme included some behaviour change techniques and use of habit formation theory. Within the PreventIT project, we have further developed the behavioural change concept so that every element of the aLiFE and eLiFE is mapped to behaviour change theory and techniques. We used behaviour change theory to capture what works, and does not work, in our interventions. The LiFE programme uses action planning in order to make the performance of strength, balance and physical activities routine in everyday life. It is an intervention that has been shown to be effective[5], so we have further theorised it to understand how it is successful. We identified a social cognitive model, the health action process approach (HAPA)[6] that complemented and enhanced the original LiFE concept and mapped the interventions to this particular model. The model used helps us to understand behaviour change over time, from the initial expectations that we have, to developing an intention to change our behaviour, and making plans to turn that intention into action.[5]

In addition to the underpinning theory, we identified 25 different behaviour change techniques that are used within aLiFE and eLiFE. These include, but are not limited to, providing information about consequences of behaviour; goal setting; action planning at different points of the intervention; providing instruction and feedback; and reviewing progress. We have developed

[5] Clemson L et al. Integration of balance and strength training into daily life activity to reduce rate of falls in older people (the LiFE study): randomised parallel trial. *BMJ* 2012;345:e4547.
[6] HAPA: Health Action Process Approach, see Schwarzer R. Modeling health behavior change: How to predict and modify the adoption and maintenance of health behaviors. *Applied Psychology*, 2008; 57: 1-29.

assessment tools and feedback mechanisms to help us understand which of these elements contribute to behavioural change.

Using the theoretical model and the behaviour change techniques enabled us to enhance aLiFE for delivery through a smartphone application. The goal setting and action planning elements of the intervention are operationalised through consecutive screens within the App, resulting in a summary of planned activities. Each day, the user is prompted to carry out their planned activities and is asked to provide feedback on whether they have done what they planned to do. They receive personalised messages, depending on the activities that they have selected and planned. A proportion of these messages are related to the specific long-term goal that the user has set for her/himself. More than 1300 motivational messages have been written for real-time, personalised feedback within the application. These have all been translated into the three languages of the intervention sites (Dutch, German, and Norwegian), with a proportion being back-translated for validity. Each of these messages has been mapped to constructs of the behaviour change model (e.g. outcome expectations, action planning) and to behaviour change techniques. All of the messages are written in positive language, to encourage the user to engage with the interventions.

3. Developing screening and profiling tools

3.1 Screening the risk for future functional decline

We developed a risk screening tool within PreventIT that aims to predict functional decline in young older adults of 60-70 years of age. We pooled the data of nearly 800 participants from two large, ongoing cohort studies on older people: the InCHIANTI study from Italy[7] and the Longitudinal Aging Study Amsterdam (LASA) from the Netherlands.[8]

To assess development of functional decline, we analysed responses of people over a time span of 9 years on whether they could perform several activities of daily living independently: standing up, dressing oneself, taking the stairs, walking a longer distance outside, using public transportation, and cutting their own toenails. Using the statistical technique of latent class growth modelling, a technique used to identify subgroups (so-called classes) in a larger population, we identified three

[7] See: http://inchiantistudy.net/wp/
[8] See: http://www.lasa-vu.nl/index.htm

distinct subgroups showing different trajectories of functional decline over 9 years: a subgroup showing no/little decline, a subgroup showing intermediate decline, and a subgroup already starting with functional limitations and showing severe decline (see Figure 2).

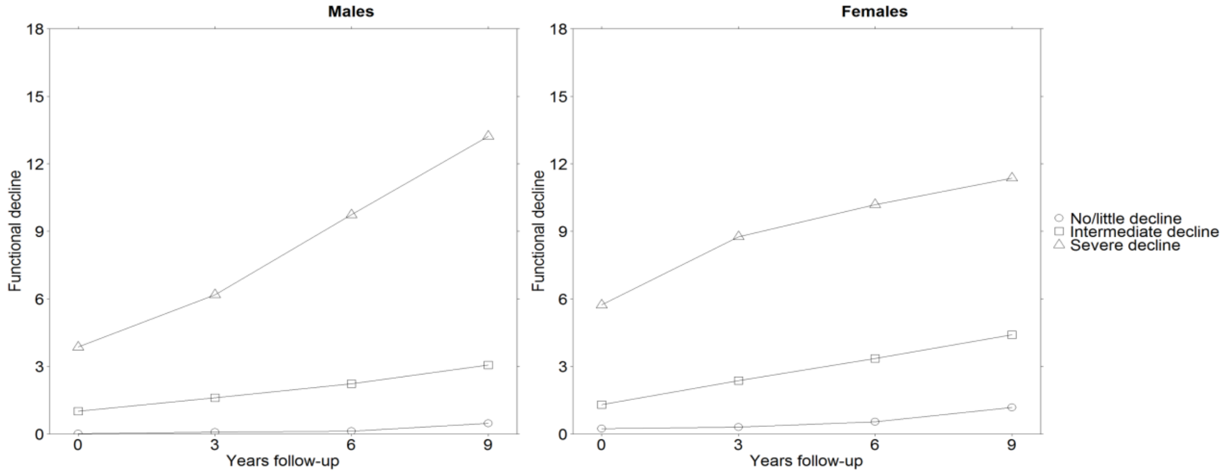

Figure 2: Identified trajectories of functional decline over 9 years in men and women aged 60-70 years.

Using regression models we identified variables at baseline that could predict a person's risk for being in the less favourable subgroups of intermediate or severe decline. A higher age, inability to perform a tandem stance for 10 seconds, lower handgrip strength, lower gait speed, lower levels of physical activity, fear of falling, and lower cognitive status were predictive of developing intermediate or severe functional decline in the next 9 years. Additional predictors for men were depressive symptoms, less than 8 years education, cardiovascular disease, and arthritis. For women, additional predictors were living alone, worse economic satisfaction, using more than 3 prescribed medications, and higher BMI.

We translated those results into a web-based application, in which baseline values on the predictors were entered and the computer automatically estimated a person's risk. This web-based risk screening tool is currently being tested with data collected during the feasibility randomised trial (section 6).

3.2 Personalising the intervention

We also developed a profiling tool to be able to personalise the intervention to individual end users. This tool is part of the iPAS application on the smartphones and uses different sources of information to rank all activities from the aLiFE programme in a personalised order for someone using the PreventIT application (see Figure 3 for an overview).

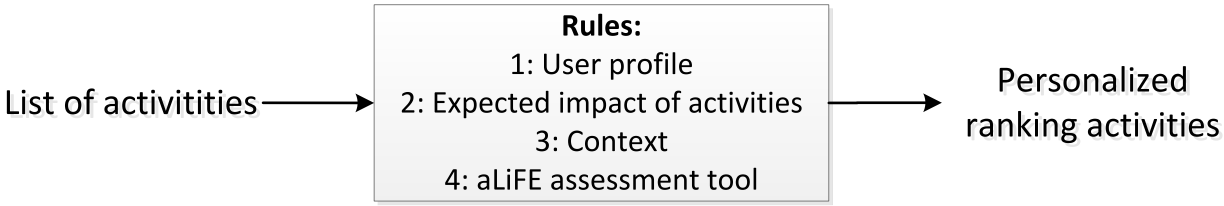

Figure 3: Profiling for personalisation of activities for the intervention, based on a combination of rules on four sources of information.

The activities from the aLiFE programme are divided into 3 domains that are specific for improvement of balance, strength, and physical activity, respectively. Using the results from different tests for balance (one leg, tandem stance), strength (handgrip strength, chair rises), and physical activity (step count per day, minutes vigorous activity per week) at the start of the programme, each person is given a personal score in the ***user profile***. The scores are based on cut-off values in a population of 60-70 year old people (using data from the ActiFE-ULM[9], InCHIANTI[10] and LASA[11] cohort studies) and indicate which domain(s) should be prioritised for that person.

For all activities in the aLiFE programme, we estimated their ***expected impact*** on each domain of the intervention (balance, strength, physical activity). For example, a tandem stance is expected to mostly impact the balance domain, while a one-legged squad is expected to impact both balance and strength. Furthermore, activities with a high expected impact on the domains of priority from the user profile were ranked higher in the personalized ranking of activities.

The ***context*** of an individual may influence whether he or she likes to do, or is able to do, certain activities from the aLiFE programme. With a specific option in the iPAS system, someone can indicate that he or she does not like to perform a specific activity, moving it to the bottom of the personalised rank list.

Finally, the ***aLiFE assessment tool*** assesses the starting levels for all activities (from very easy using hand support, to difficult performing dual tasks). This was used to define the starting levels of the activities ranked in the profiling tool. The result of the profiling tool is a personalised rank list of activities that help a user to choose those activities that benefit him or her the most. The tool will

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[9] Denkinger MD, Franke S, Rapp K, et al. Accelerometer-based physical activity in a large observational cohort - study protocol and design of the activity and function of the elderly in Ulm (ActiFE Ulm) study. BMC Geriatrics. 2010;10:50.

[10] See: http://inchiantistudy.net/wp/

[11] See: http://www.lasa-vu.nl/index.htm

be further developed using the results from the ongoing trial, as well as input from the participants in the eLiFE intervention arm.

4. ICT system development and implementation

4.1 Bringing it all together: eLiFE

PreventIT combines the LiFE concept, behavioural change theories, and ICT technology to develop a unique intervention, the eLiFE (enhanced adapted LiFE).

The eLiFE intervention programme uses ICT to personalise and enhance behavioural change during the intervention by providing motivational messages, reminders, guidance, and feedback on behaviour. The eLiFE programme is integrated into the iPAS (a personalised, self-administered mHealth system) which is a system designed for the consumer market for early identification of risk for age-related functional decline and for the delivery of an individually targeted behavioural change intervention.

The iPAS hardware architecture is composed of three main components: the system backend, a smartphone (Figure 4) and a smartwatch (Figure 5); apps and services continuously record the user's physical activity with sensor fusion algorithms. The system provides a personalised list of suggested activities from the eLiFE intervention programme and allows managing and self-reporting on selected activities.

Figure 4: The smartphone user interface sends the user a personalised list of suggested activities together with instructional videos and pictures.

Figure 5: The smartwatch is connected with the smartphone and tracks the user's physical activity by means of sensor fusion algorithms.

Not only can the PreventIT approach create new opportunities for healthy behaviour (healthy ageing), it also takes a substantial step in the direction of individual empowerment. In the iPAS, the user can select one or more long term goals grouped in four categories (Activity, Daily Life, Health Life, and Well Being) and preferred activities from a list that is personalised on the basis of the expected benefit of the specific activity on the specific user profile. The motivational strategy is then tailored to the individual needs, choices, behaviour, and preferences.

4.2 Front-end technology

In the iPAS system, the frontend application is the app that the user interacts with (Figure 6). An age-friendly user interface is the result of several iterations among Consortium partners and between Consortium partners, Advisory Board, and end users following the principles of user-centred design.

The application is multi-lingual and automatically selects the smartphone default language, if implemented, or English if a specific language is not available. In addition to English, three languages have been implemented in the app: Norwegian, German, and Dutch.

Figure 6: Smartphone screen with PreventIT app icon.

On the "Messages" screen, the user receives a daily personalised motivational message and is asked to report on selected activities. The "Activities" screen (Figure 7) shows the list of suggested activities. Each activity has up to 4 difficulty levels; the user can progress and unlock new difficulty

levels by achieving the daily goals on balance, strength, and physical activity. The “Stats” screen shows the daily achievements with three progression bars on the three domains of the intervention and two gauges show information on sedentary behaviour.

The fourth tab is the “History” screen (Figure 8) where the user can display the daily, weekly, and monthly statistics regarding goal tracking, walking behaviour, and sedentary behaviour. The app also includes a “virtual trainer” that provides information on the eLiFe concept, its benefits, and how to properly and safely perform the proposed activities.

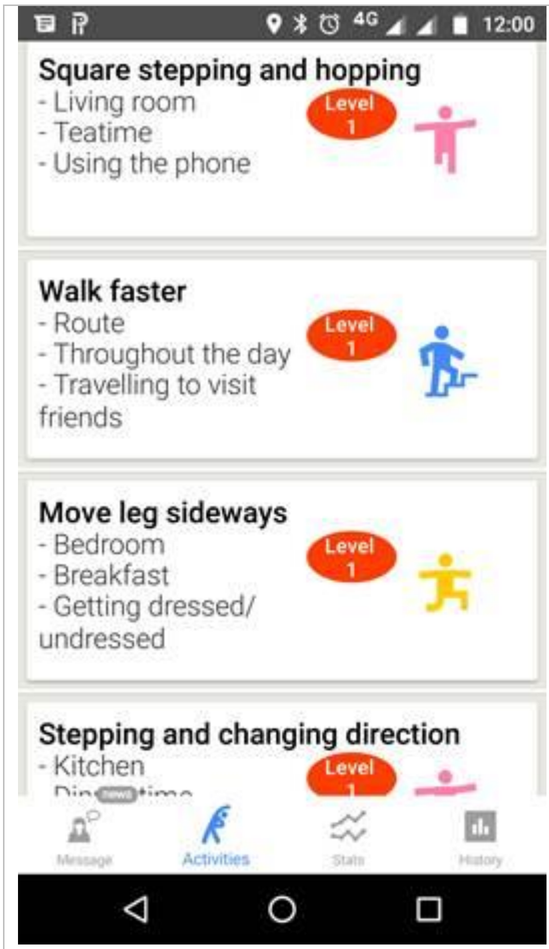

Figure 7: Activity screen of the iPAS user interface.

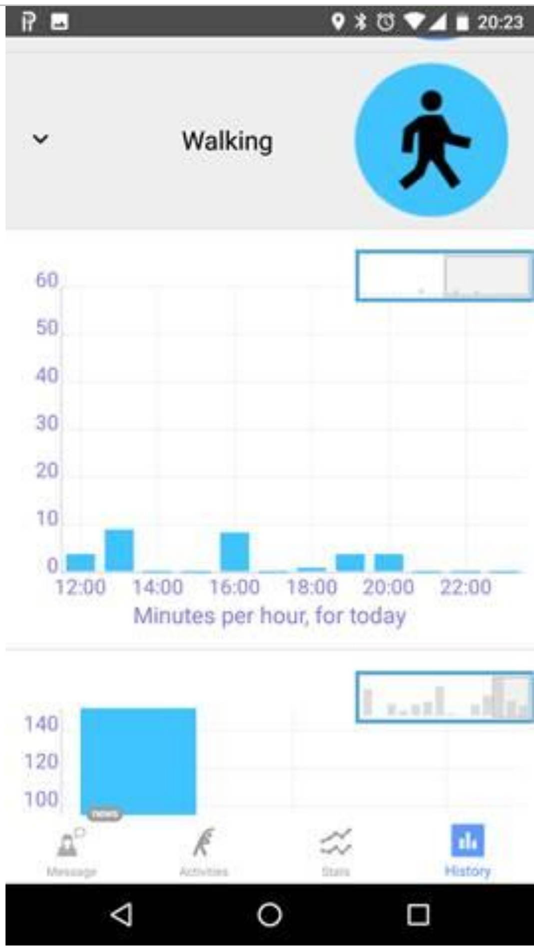

Figure 8: History screen of the iPAS user interface.

4.3 Back-end technology

Following a privacy and security by design approach[12], the PreventIT Consortium developed the iPAS backend technology on a secure NTNU server where services and software components are hosted. The iPAS system is configured to authenticate on this in-house server.

[12] Hes R. & Borking J. (eds.) (2000). Privacy-Enhancing Technologies: The Path to Anonymity -- Revised Edition. Registratiekamer.

Data collected and processed by the smartphone and the smartwatch are regularly synchronised with the system backend, which also contains all videos and pictures used in the description of the activities. A software component running on the system backend implements the PreventIT profiling tool and is used for personalising the list of suggested activities.

The profiling tool takes as an input the data collected during the baseline assessment about the domains of strength, balance, physical activity, fall risk, cognition, social interaction, and mood, in addition to the user's feedback on selected activities and the data from the activity monitoring. Activities are then ranked on the basis of the resulting expected benefit and presented to the user. The same seven domains are also used by the risk screen tool that implements the PreventIT prediction model for functional decline. Figure 9 shows how the different system components are linked together to form the iPAS.

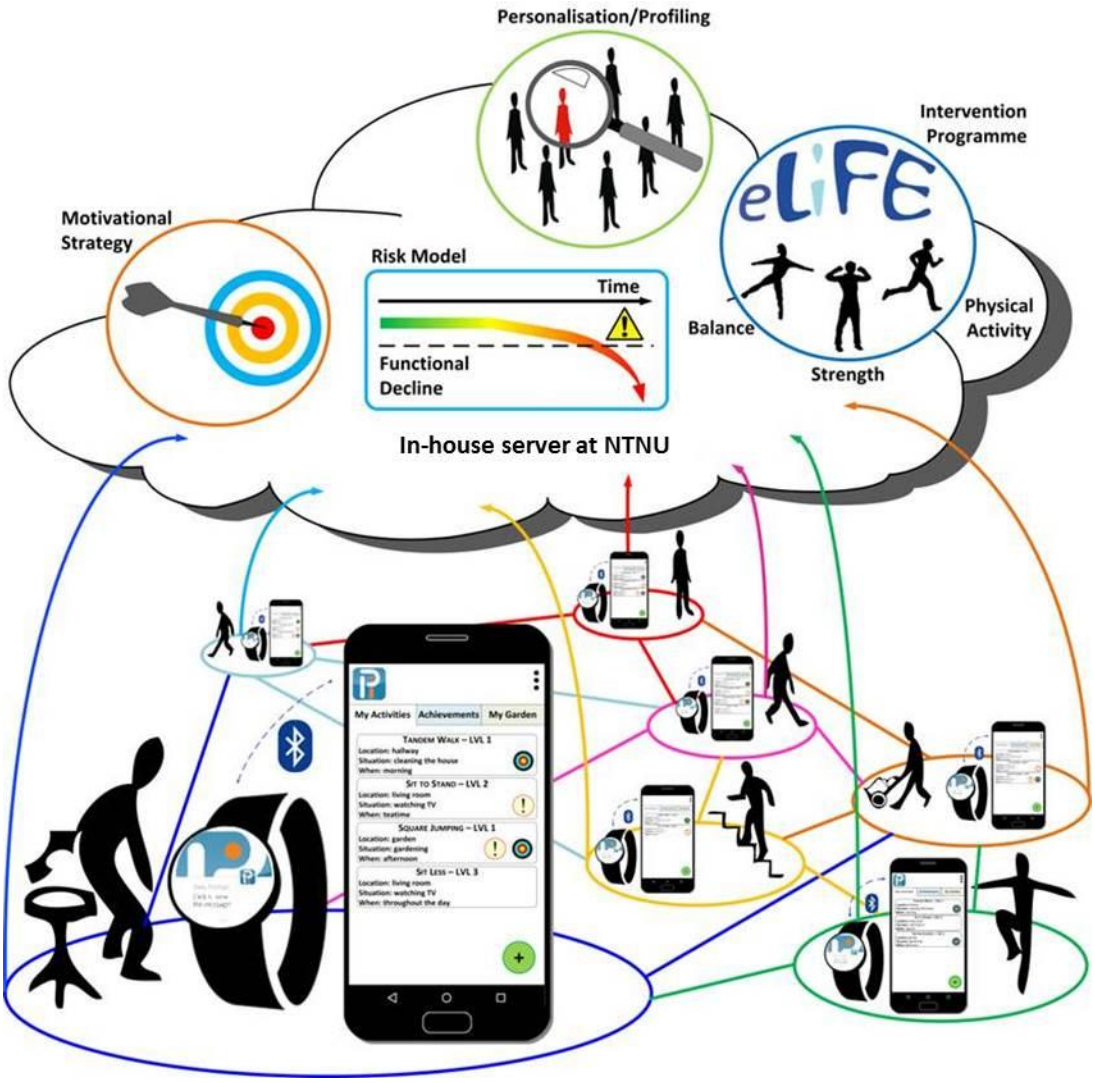

Figure 9: Illustration of how the technological components are linked together and communicate in the ICT-based intervention eLiFE.

4.4 Security and privacy issues

The PreventIT project collects personal and sensitive information from participants. Therefore, it is of paramount importance to assure security and privacy, particularly regarding data acquisition, data transmission, cloud processing, smartphone storage, and data sharing.

The first step in the PreventIT project has been the identification of all the physical and software components of the mHealth system, all the possible sources of information, and the flow of information. Subsequently, applicable laws regarding privacy and security have been analysed and a list of requirements was produced. We identified a group of privacy requirements derived from current European legislation, pending General Data Protection Regulation (GDPR), interpretations of the European legislation by bodies such as the European Data Protection Supervisor (EDPS), and the Article 29 Working Party (Art. 29 WP).

In PreventIT, a Privacy by Design methodology and Privacy by Default approach have been adopted. Privacy by Design is a term that refers to requirements and measures that should be taken into account during the design of ICT based applications and their entire life cycle, in order to ensure proper respect for personal data. Privacy by default requires that, wherever the user has a choice with respect to the processing of his or her data but does not take any action to express a preference, the app developer by default has pre-selected the least privacy invasive and compliant choice. Put more simply, privacy by default means that the strictest privacy settings automatically apply when a customer acquires a new product or service.

To allow access to PreventIT servers to authorised users only, and to ensure that each user only accesses his/her own information, a security mechanism has been implemented that is composed of three main elements:

- The smartphone app has been signed and only signed apps can communicate with the backend;
- Google federated authentication method is used;
- Each smartphone has a unique ID. At the first authentication, the ID is linked to the smartphone IMEI code so that no other phone can use that ID.

All data transmitted between the smartphones are encrypted and data on the backend servers are encrypted.

5. User involvement in the development process

We used ISO standard 9241-210 on user-centred development of products[13] to guide development of the technology in PreventIT. This includes iterative development and involves end-users in all phases of the design and development cycles. For the development of the aLiFE and eLiFE intervention as well as the technology tools, end users were involved in all developmental phases through usability studies, pilot studies, interviews, and the currently ongoing feasibility RCT. Our first technology prototypes were developed based on user involvement with older adults in a previous project (FARSEEING)[14], in particular, the need for clear screens, simple navigation, sufficient challenge, and clear progression. User feedback from the actual target group has been essential in developing an acceptable intervention for the 60-70 years age group, and for the appropriate delivery of motivational messages through the app. Below, more details are provided about end user involvement through two PreventIT pilot studies.

5.1 Testing aLiFE

The aLiFE programme was tested in the target population of young older adults in a pilot study from May to July 2016 at three clinical sites (Amsterdam, The Netherlands; Trondheim, Norway; Stuttgart, Germany). The aLiFE pilot study was registered in an international trial registry (ISRCTN BioMedCentral).[15] In brief, the pilot study consisted of a 4-week one-group, pre-posttest intervention study with 30 participants (10 participants at each study site). The study aimed to evaluate the feasibility of the new aLiFE programme in the target group of young community-dwelling men and women aged 60 to 70 years. Exclusion criteria for participants were inability to walk 500 meters without aids, cognitive impairment (Montreal Cognitive Assessment, MOCA <24 points), existence of severe diseases where exercise is contraindicated, and attending organised exercise classes more than twice a week and/or exercising more than 2 hours on their own each week. The aLiFE intervention programme was delivered by trained aLiFE instructors during 4 home visits. The primary outcome measure was the feasibility of aLiFE as defined by: 1) willingness to participate, 2) adherence, 3) possible harm, and 4) acceptability (rating of helpfulness, safety, level of difficulty, and adaptability). Furthermore, we explicitly aimed to obtain the participants' views on: 1) planning and engaging in aLiFE activities, 2) the aLiFE manual, 3) support from the instructors, and 4) their ideas for improving the programme using semi-structured interviews.

[13] See: https://www.iso.org/standard/52075.html
[14] See: http://farseeingresearch.eu/
[15] See: http://www.isrctn.com/ISRCTN37750605

Thirty one participants were successfully included into the intervention study. The willingness to participate was high, over 70% of the 119 persons contacted; just over 25% of those willing to participate were eligible and included in the study. One person dropped out after the baseline assessment because the content of the intervention did not match with his/her individual goal, namely improving upper extremity strength, all others completed the intervention. The mean age of the aLiFE pilot participants was 67 ± 2.4 (61-70) years which represents the PreventIT target population. Overall, acceptance of the aLiFE programme was high based on the ratings of the participants. Sixty percent of the participants liked the aLiFE programme, another 20% stated that they liked it very much. All except one participant (97%) would recommend the aLiFE programme to a friend. Perceived level of difficulty of aLiFE activities ranged from slightly difficult to easy, suggesting that task demands of recommended activities were successfully adapted to the target population of young older adults. Following the pilot study and with the user feedback received during the focus groups, a final aLiFE manual was developed and made available in four languages (English, German, Dutch, and Norwegian).

5.2 Testing eLiFE

As described above, the eLiFE programme is an enhanced lifestyle-integrated behavioural change activity programme specifically developed for young older adults. It is delivered through an Information and Communication Technology (ICT) platform consisting of a smartphone and smartwatch (frontend) and a cloud-based server system for managing data (backend), the iPAS. Four main components were included in the application (App): 1) eLiFE tools for tailoring the intervention, 2) a virtual trainer with background instructions on the programme and the app, 3) an activity presentation for setting up a personalised, lifestyle-integrated activity schedule, and 4) eLiFE behavioural change module. The tailoring of the intervention was performed by the eLiFE instructor with the help of the web-based PreventIT profiling tool using normative data from a reference population for personalisation of the eLiFE programme as well as through the use of the eLiFE Assessment Tool. Participants could select strength, balance, and PA activities from the eLiFE activity catalogue. The behavioural change module comprised goal setting, setting up a lifestyle-integrated activity plan, documenting adherence, feedback on behaviour, and supporting motivation. Furthermore, it offered the opportunity for social interaction with other app users in the form of group chat in the *Slack* app.

The eLiFE programme was evaluated in a 4-week one-group, pre-post test pilot intervention study with 15 participants (5 at each site). The feasibility, usability, and acceptability of the eLiFE system

were tested in the target group of community-dwelling young older adults aged 60-70 years old. Exclusion criteria were similar to the aLiFE pilot study described above. In eLiFE as well, participants received 4 home visits. Outcome measures were 1) willingness to participate, 2) adherence, 3) satisfaction with technology, and 4) handling of the iPAS system. In addition, we asked for participants' views on 1) planning and engaging in eLiFE activities, 2) the eLiFE ICT-based iPAS system, 3) motivation and behavioural change, and 4) suggested improvements of the programme and app. The mean age of the 15 included participants was 67±2.7 years, 66% (n=10) were female. The majority of participants liked the prototype application, as indicated by a median score of 6 out of 7. Furthermore, the app was considered easy to navigate and integrate into everyday life. However, the frequency of usage varied greatly between participants although after four weeks, more participants reported using the system frequently than at the beginning. The majority of participants reported that they benefitted from the technology, that it improved their physical well-being, and that the effort of using the technology was worthwhile. Although participants' views varied on whether they found the technology comfortable to wear, the majority felt comfortable wearing the technology visibly around others. The motivational elements that were tested in the eLiFE pilot were received positively by the participants, although more variation in response messages and less frequent prompts were requested. Following this second pilot study and with the user feedback received during the focus groups, the eLiFE app, tools, and interfaces were updated and made available in four languages (English, German, Dutch, and Norwegian).

6. Testing the interventions and iPAS

6.1 Testing the feasibility and usability of the iPAS

At the moment of writing the first release of this white paper, a feasibility RCT is in progress at the same three clinical sites as the pilot studies: Trondheim (Norway), Amsterdam (the Netherlands), and Stuttgart (Germany). In this RCT, we test the feasibility of performing the aLiFE and eLiFE integrated life-style interventions versus a control group who receives international recommendations on PA only.[16] The aim is to include 60 participants at each site.

[16] World Health Organization. Global recommendations on physical activity for health. 2011.

We started recruiting potential participants from national registries in March, and screened them using a three step process that included a telephone assessment, risk screening, and medical assessment. After a baseline assessment participants are randomised into one of the three arms and followed for 6 months with one of the two active interventions or "usual care" (international PA recommendations), followed by a post-test, a 6 month follow-up period without any active intervention, and a 12 month follow-up assessment. Figure 10 presents the flow of participants from recruitment until randomisation.

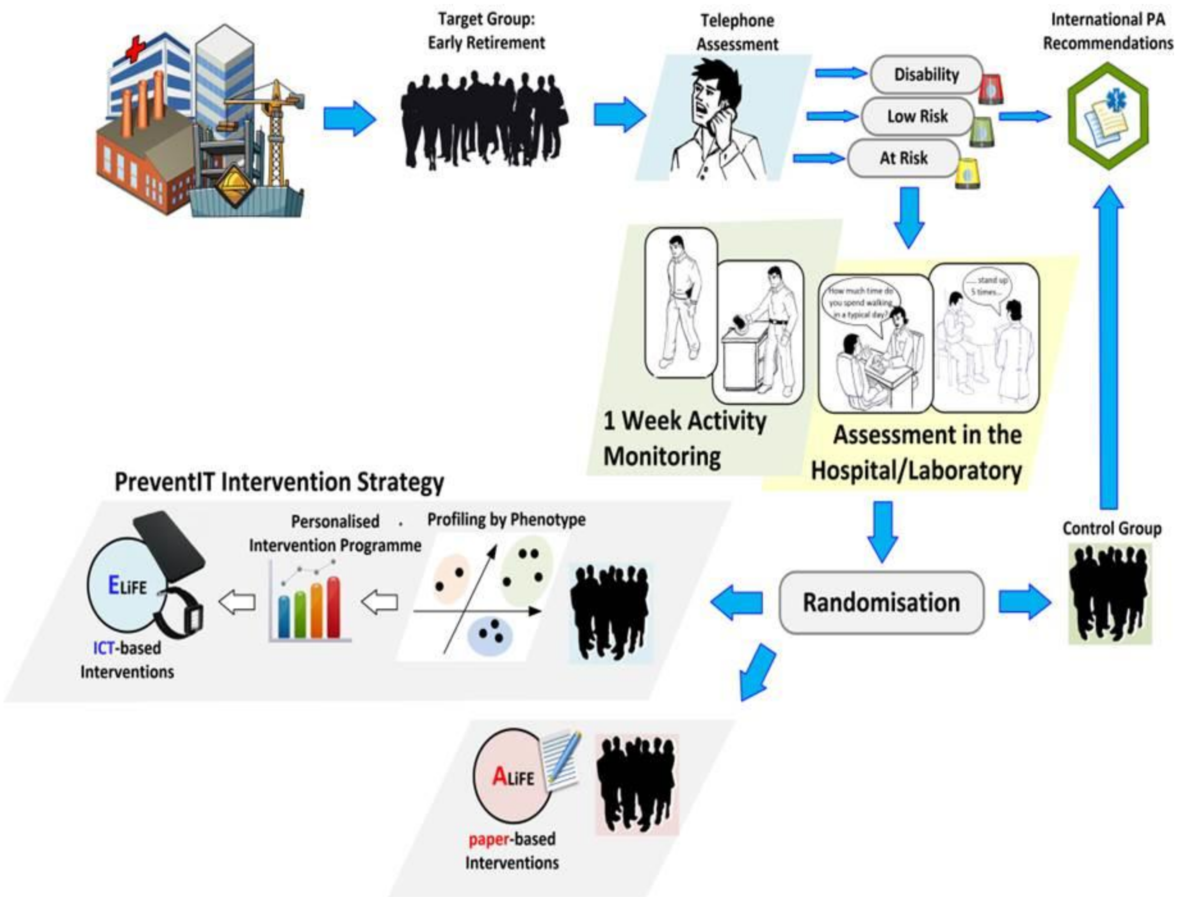

Figure 10: Study flow in the PreventIT feasibility RCT that compares aLiFE, eLiFE, and practice as usual (control group).

As described above, both aLiFE and eLiFE intervention arms are based on the aLiFE concept where balance, strength, and physical activity activities are developed to fit the needs of young older adults. Both intervention arms are taught to the participants by an instructor during home visits and phone calls during the 6 months intervention period. The aLiFE participants are taught the programme by the instructor and use of the paper-based aLiFE manual, while the eLiFE participants are taught how to use the ICT-based system, the iPAS, to learn the intervention programme.

6.2 Intervention outcomes: functional ability

One of the aims of the PreventIT feasibility study is to inform the design of a future definitive trial on prevention of functional loss. Therefore, the main intervention outcome focuses on function and disability as measured by the Late-Life Function and Disability Instrument (LLFDI),[17] which was included in the original LiFE study as well.[18] In addition, we collect information on a broad spectre of secondary outcomes. We use activity monitors for collecting objective measures of physical activity, performance-based tests of gait speed, hand grip strength, higher level balance and strength, static balance, functional muscle strength, and cognitive function. We also use self-administered tests where an app on the smart phones collects data during testing, and questionnaires to collect information about mood and self-efficacy. Finally, we collect information about adherence and usability of the interventions, and will evaluate the estimated cost-effectiveness of the trial using a microeconomic simulation model.

6.3 Intervention outcomes: behavioural complexity

A second main intervention outcome is more experimental and focuses on a comprehensive assessment and modelling of the richness, or complexity, of behavioural patterns in everyday life. In order to be able to capture this, a behavioural complexity model should reflect the multidimensional nature of daily behaviour, its dynamic changes, and the interaction among different dimensions. PreventIT aims to intervene on the lifestyle domains of physical activity, sleep, and social participation. To evaluate the outcome of RCT, the behavioural complexity is to be used to assess the effectiveness of intervention as well as to identify a behavioural pattern underlying healthy ageing.

In the first half of the PreventIT project, a first complexity metric was established that focuses on patterns of physical activity or physical behaviour. The physical complexity metric is a comprehensive score that evaluates the dynamic change of multiple aspects including type, duration, and intensity of physical activities in a continuous time sequence. The left panels in Figure 11 illustrate two color-coded time sequences (so-called barcodes) embedding multidimensional features of physical activity. The person represented in the top barcode is less active (cold colours) and has less variation in behaviour compared to the person represented in the bottom barcode who is more active (warmer colours) and has more variation in behaviour.

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[17] Sayers S, Jette A, Haley S, Heeren T, Guralnik J, Fielding R. Validation of the Late-Life Function and Disability Instrument (LLFDI). Journal of the American Geriatrics Society. 2004;52:1-6.

[18] Clemson L et al. LiFE Pilot Study: A randomised trial of balance and strength training embedded in daily life activity to reduce falls in older adults. Aust Occup Ther J. 2010;57(1):42-50.

The right panel indicates how the complexity metric that evaluates the dynamic change in the time sequence changes with age and disease. The barcode is an innovative way to visualise the rich features of physical activity performed with respect to their distribution in time. The derived score has good sensitivity to detect behaviour change induced by for example breaking up sedentary periods (see Figure 12), which is one of the healthy lifestyles the eLiFE intervention aims to promote.

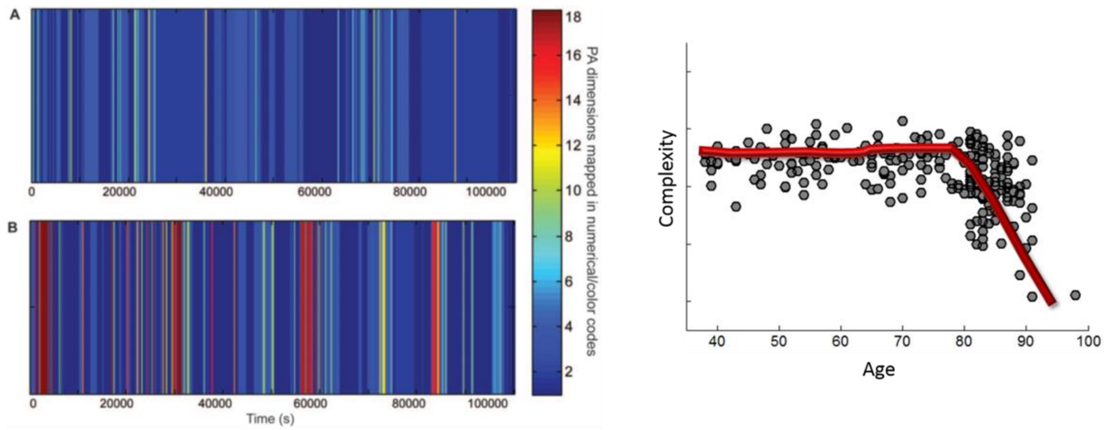

Figure 11: (a) color-coded time sequence describing multiple features of physical activity. (b) comprehensive score evaluating the dynamic change in the time sequence.

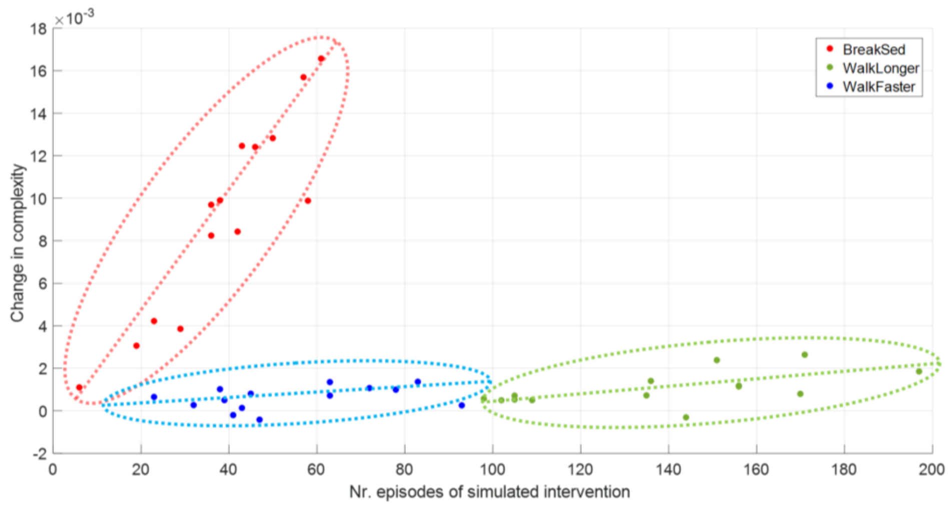

Figure 12: Associations between number of intervention episodes and changes in complexity.

In the second half of the project, the physical complexity metric is to be further developed to have improved sensitivity to other healthy lifestyle changes. Meanwhile, a behaviour complexity model will be developed to incorporate the additional aspects of sleep and social participation. At the end of the PreventIT project, we aim to be able to define a behavioural pattern of healthy ageing.

7. Conclusions and remaining work

The first half of the PreventIT project has resulted in the development of two lifestyle-integrated exercise intervention programmes to prevent functional decline in young older adults: the paper-based aLiFE and the app-based eLiFE. An explicit motivational strategy was developed to support behavioural change towards a more active, healthy lifestyle. In addition, several tools were developed to screen the risk for future functional decline, personalise the intervention to individual users, and assess behavioural complexity. End users were involved in all stages of development and provided invaluable feedback on appropriate exercises, delivery of motivational messages, and the app-interface. The remaining work in the second half of the PreventIT project will be dominated by the ongoing feasibility trial and subsequent data analyses to inform the next generation of PreventIT tools, the development of unsupervised self-tests, and version 2.0 of the iPAS. We will conduct focus groups and interviews at the end of the intervention that will give us insight in the users' experience of taking part in the interventions, which will complement the data collected on changes in balance, strength, physical activity, and sedentary behaviour. Furthermore, we will investigate users' motivation and its relationship with engagement, adherence, and activity levels. Based on the collection of health economics data, we will develop a health economics model and perform a sensitivity analysis of differences in potential costs of the intervention arms depending on variables such as age, living arrangements, education, gender, socio-economic status, and previous physical activity behaviour. Finally, marketable products and services resulting from the PreventIT project will be identified and a business plan for their exploitation will be developed.

8. PreventIT project themes and contact information

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