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REACH

## Deliverable D27: Formalised results of pretesting I and II activities (associated with tasks T 6.3 and T6.4)

**Abstract:** In this deliverable, we present, structure and interpret the formalised results of all testing activities that have been carried out thus far in REACH. We first (Chapter 2) introduce the detailed testing strategy of REACH, which details and brings forward previously described conceptual provisions (see Deliverables D4, D9 and D29) and responds to previous reviewer comments (R5 and R6, second review, November 2017; aiming at the improved emphasis of geriatric and medical aspects and their normalisation across Touchpoints and project activities). In response to the reviewers' comments, REACH re-aligned some of its resources and formed a medical/geriatric task force (SK, HUG, DTU, TUM), which analyses and streamlines testing activities across Touchpoints, clarifies the common goals and measures, and works towards a normalisation of study designs and tools used across the project. We outline in this context the overall hypothesis for the REACH system along with four well-defined sub-hypotheses for each Touchpoint. Based on this, in Chapter 3, we present our methodological approach with regard to testing in REACH and provide an overview and a classification system for all testing activities carried out. Accordingly, in Chapter 4, we present the results (documentation of the carried out testing activities), and in Chapter 5, we interpret the testing results. Chapter 6 summarises the state of play regarding testing in REACH and outlines the next steps and upcoming activities. The Appendix contains the full trial reports sorted according to a variety of items.

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**Tasks of the involved partners with respect to the deliverable (and respective tasks) presented in this report:**

Partner	Short task description
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CU	<ul style="list-style-type: none"> <li>• Support with the definition of overall strategy for testing and deliverable</li> <li>• Contribution to testing activities in Touchpoint 4</li> </ul>
Arjo	<ul style="list-style-type: none"> <li>• Contribution to the design and carrying out of testing activities in the context of Touchpoint 2</li> </ul>
Philips	<ul style="list-style-type: none"> <li>• Contribution to the design and carrying out of testing activities in the context of Touchpoints 2 and 4</li> </ul>
ZZ	<ul style="list-style-type: none"> <li>• Contribution to the design and carrying out of testing activities in the context of Touchpoints 1 and 3</li> </ul>
SK	<ul style="list-style-type: none"> <li>• Lead of the geriatric/medical task force</li> <li>• Task 6.1: Test standardisation (compilation of test activities, definition of assessments and medical outcomes, database, mini-protocol)</li> <li>• Task 6.3: Pre-testing in TUM Lab (br<sup>2</sup>)</li> <li>• Task 6.4: Design of test scenario and ethics application for Al-reh Medical devices and REACH Bed System</li> <li>• Task 6.5: Design of REACH Bed System components</li> </ul>
HUG	<ul style="list-style-type: none"> <li>• Member of the geriatric/medical task force</li> </ul>
TUM	<ul style="list-style-type: none"> <li>• Revision, strategy and structure</li> <li>• Support with integration of individual parts of the deliverable</li> <li>• Situation of the deliverable in the overall context of REACH and the REACH system architecture.</li> </ul>

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## Key expressions

### Abbreviations for partners:

**AH:** ArjoHuntleigh

**AM:** Alreh Medical

**CU:** University of Copenhagen

**DTU:** Technical University of Denmark

**EPFL:** École Polytechnique Fédérale de Lausanne, Switzerland

**FIAIS:** Fraunhofer IAIS

**HUG:** Hôpitaux Universitaires de Genève

**PSS:** Product Service System

**SC:** SmartCardia

**SK:** Schön Klinik

**TU/e:** Eindhoven University of Technology

**TUM:** Technical University of Munich

**ZZ:** ZuidZorg

**6mwt:** 6-minute walking test

**AD:** Alzheimer's Disease

**ADL:** Activities of Daily Living.

**ADL-run:** Changing ADL-activities in logical order

**ATZ:** Alzheimer Therapy Centre at SK

**BBS:** Berg Balance Score

**Behaviour change:** The change of one or more parameters, such as the activity levels, which characterise human behaviour.

**BMI:** Body Mass Index

**CACHET:** Copenhagen Center for Health Technology (<http://www.cachet.dk/>) managed from DTU and including CPH

**CARP:** CACHET Platform (CARP) for data management of sensing data

**CIP:** Critical Illness Neuropathy

**CPH:** University of Copenhagen

**CS:** 30 seconds chair stand test

**D:** Deliverable report.

**Drill run:** Repeated sequence of an activity (with or without modifications)

**End user:** There are two primary end users, patients and elderly citizens receiving care and their professional care givers. Family and friends are, by voluntary

invitation from the elderly, secondary users. REACH has a greater focus on patients and care-receiving citizens than on caregiver users.

**Engine:** The REACH Engine describes the analytics infrastructure of the REACH system, and serves as a back-end system for the Touchpoints. The Engine monitors the incoming data streams from the different Touchpoints, analyses them and takes actions if needed. Its two main components will be Subsystem 1 (*Analysis & Planning*) and Subsystem 2 (*Motivation & Intervention*).

**GDPR:** General Data Protection Regulation (fully enforced throughout the European Union in May 2018)

**HSDP:** HealthSuite Digital Platform - Philips vision of connected health.

**ICF:** International Classification of Functioning, Disability and Health

**Intervention/Treatment:** Action designed to bring about a change in a process or an individual.

**MFAS:** Musculoskeletal Function Assessment Scale (assessment for motor function)

**ML:** Machine Learning: The study and development of algorithms by computers to effectively perform a specific task without using explicit instructions

**MMSE:** MiniMental State Examination (questionnaire for mental status and dementia)

**MoCA:** Montreal Cognitive Assessment

**PAM:** Physical Activity Monitor

**PD:** Parkinson's Disease

**PSD:** Persuasive System Design Strategies

**RCT:** Randomised Controlled Trials

**Response:** a behaviour change that happened as a result to some intervention.

**SF-36:** Short Form Survey questionnaire to assess health status

**SMI:** Sensing-Monitoring-Intervention - the approach by REACH to monitor and analyse user behaviours in order to plan and implement interventions

**SMI:** Sensing-Monitoring-Intervention, key dimensions of REACH guiding medical hypotheses and testing as well as REACH technical development

**SPPB:** Short Physical Performance Battery

**T:** Task defined in the project proposal.

**TAM:** Technology Acceptance Model

**TAP:** Neuropsychological test-battery to assess alertness

**Touchpoints/Engine concept:** Structures the envisioned REACH product-service-system architecture into manageable research and development clusters.

**TP:** Touchpoints - the “Touchpoints” will act as “graspable” front ends towards the end users (elderly). The Touchpoints will serve as data gathering devices as well as mediator of services and interventions coordinated by the Engine towards the end user. Each Touchpoint is modular and made up of several subsystems which allow for the system to adapt both for a certain person or setting as well as over time.

**Use case setting:** Use case setting refers to the four solution operators and this report calls them the use case setting since they reflect concrete application scenarios.

**WP:** Work package defined in the project proposal.

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# 1 Background and summary of tasks and activities related to T6.3 + T6.4/ D7

In this chapter, we provide the backdrop for the work presented in this deliverable. We show the work presented is situated in the overall context of REACH, systematically continues previous achievements, reacts to important reviewer comments and paves the way for the upcoming project activities.

REACH is aiming to be a Sensing-Monitoring-Intervention (SMI) tool and consequently the testing goals are specified as target conditions which could be influenced by SMI actions. Additional and as preliminary work, the definitions of the components, actors and users of the system have to be confirmed with systematic testing. The most used assessments addressed medical (motor and cognitive) conditions, motivational aspects, feasibility parameter and technical requirements. Testing strategies were designed with respect to the age of REACH's core users (65+) and in compliance with ethical and legal standards and regulations.

## 1.1 Deliverable and related tasks in the larger context of REACH and the Touchpoints and Engine concept

REACH engages elderly people systematically in a variety of environments and contexts in target-oriented physical activity, exercise, and rehabilitation to counteract inactivity and sedentary behavior and their negative consequences. REACH goes its own way by developing value proposition and user acceptance around its digital-technological core and shared elements strictly through case sensitive adaptation and insertion into the ecosystem of a specific country, use case setting and/or individual user's needs. In this section, we describe the coordinated interrelations between REACH's value proposition, the Touchpoints and Engine concept (high level system architecture), the REACH toolkit (practical, low-level implementation process for a series of "raw elements"), and the demonstration of the exemplary adaptation and integration of essential REACH elements towards four (initial) use case settings through four (initial) Touchpoints.

### 1.1.1 REACH's value proposition

REACH targets the elderly who are at risk of inactivity and sedentary behavior and covers; in a highly dynamic and digitalized manner, the whole life cycle of early intervention (sensing, monitoring/analytics, intervention) to engage the elderly systematically in target-oriented physical activity, exercise, and rehabilitation. The goal of the interventions, techniques, products, services, and programs developed by REACH, is to improve the health outcomes of the elderly target population, i.e. to improve their classification according to the ICF (including better ability to perform ADLs, better grip strength), empower them for seamless and unrestricted participation in their communities, and thus ultimately increase their Healthy Life Years.

Compared to many other solutions on the market, REACH does this in a much subtler and more "nudging" manner by putting behavior design, adaptation to the ecosystems of a specific use case setting (e.g. by combining it in a case sensitive manner with

aspects such as nutrition, social activities, etc.), and digitally enabled and personalized just-in-time interventions at the center of its solutions. Thereby, REACH intentionally is not only rooted in the digital world, but exploits the interplay of the physical world (built care environment, highly function-oriented furniture, activation and exercise devices, mobility solutions), cutting edge digital applications (wearable and ambient sensors, various Machine Learning approaches, user profiling, etc.), and digitally informed; but selectively and efficiently provided, human services (e.g. human sports coaches, care givers, etc.).

Through the target-oriented and systematic engagement of the elderly in physical activity, exercise, and rehabilitation, REACH develops its value proposition's core dimensions: 1) prevention (of functional and cognitive decline), 2) engagement and empowerment (allowing better health outcomes with lower staff efforts), and 3) increased safety (during physical activity and throughout daily life; also as a bi-product of REACH's monitoring capability). However, REACH also creates value for the enterprises delivering its key components (data based insights and foresights) and for the health care system as a whole (better health outcomes at a lower cost). As such, REACH is of interest for elderly end-users, care and health providers, and payers (municipalities, insurances, etc.) alike.

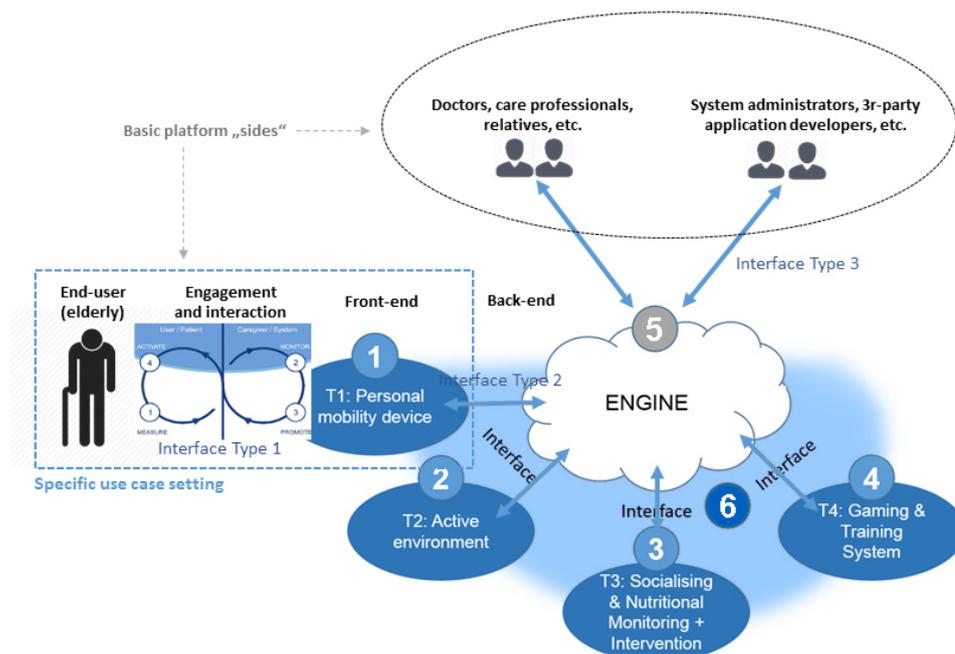


Figure 1-1 REACH Touchpoints and Engine concept

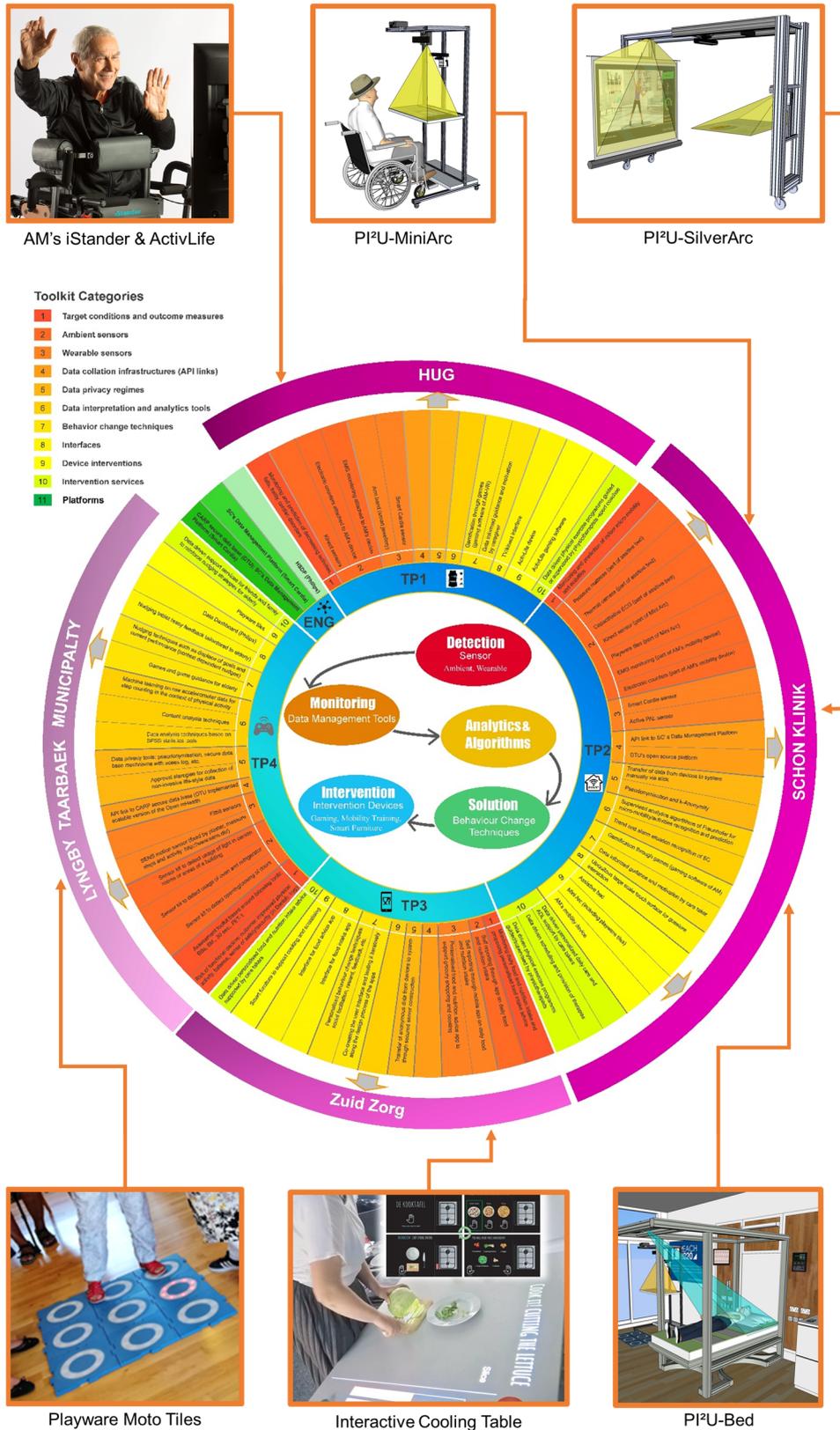


Figure 1-2 The REACH Toolkit Wheel

### 1.1.2 *The Touchpoints and Engine concept*

The REACH “Touchpoints and Engine concept” is the high-level description of REACH system architecture (see **Figure 1-1**). It guides the detailed structures of the REACH system architecture and its subsystems. With the “Touchpoints and Engine concept”, REACH’s so-called product-service-system architecture is divided into a set of manageable research and development clusters: four clusters of “Touchpoints (TPs)” that represent tangible connections between users (seniors, informal/formal caregivers, or physicians etc.) and the REACH system; one “Engine” cluster which encompasses a digital toolkit (analytics and ML-elements, data transformation and platform solutions, privacy and security tools, software applications, etc.); and one “Interface” cluster which is composed of a set of elements that allow Touchpoints to connect/interact with each other, engine elements, or the user. Each cluster is associated with a dedicated and independent development team that comes from the project consortium members.

### 1.1.3 *REACH: a toolkit of elements*

The REACH toolkit guides the practical, low-level implementation of REACH. The toolkit comprises a series of partially independent components or “raw elements” developed by the partners, which can be classified into 11 categories (sensors, analytics and ML-tools, devices, smart furniture, exercise and behaviour change schematics, human-machine-interfaces, data storage platforms etc.). During its first phase, REACH developed a methodological framework (Sensing-Monitoring-Intervention/SMI work flow) for the use case specific combination and integration of these elements.

Initial explorative testing, in combination with the long experience of key partners in the field of user experience and acceptability design, generated the insight that the value and acceptance of digital elements (value proposition, medical impact, acceptability, etc.) for elderly people specifically in the European context cannot be created by a monolithic, one-size fits all structure (e.g. products and services of large American or Chinese technology companies), nor by the creation of very large and highly integrated big data lakes (Fitbit, Tencent, etc.).

Rather, REACH takes advantage of the creation of solutions made by a combination of its elements (e.g., sensing, monitoring and rehabilitation/exercise configuration) that can be iteratively adapted to the individual users. REACH also considers (in light of both the GDPR and assessment of user acceptance) how to implement trusted small to medium sized data collection and processing solutions that are generated through local instantiations of either Philips’ HSDP (representing a proprietary B-to-B solution especially suited to medically oriented contexts) or DTU’s CARP (representing an open platform solution based on the Open mHealth architecture and suitable for also life-style-oriented contexts and especially mobile devices).

### 1.1.4 *The Touchpoints and their adaptation to a set of initial use case settings*

The REACH toolkit approach guides a practical tailoring of solutions that create a real value for end-users, care providers, and payers alike. It does so through the combination, integration/cross integration, and adaptation/re-design of its elements towards the different contexts of different countries, different payment and reimbursement structures (e.g., insurance or tax-based), specific use case settings and processes, and most importantly individual end-user needs and capabilities. REACH has combined

and iteratively tested and adapted (and continues to do so) in each of the four Touchpoints a selected set of “raw elements” towards a specific use case setting (SK/Schön Klinik, HUG/Geneva Hospital, ZZ/ZuidZorg, Lyngby/Lyngby Municipality). In this context, REACH also demonstrates its superior ability to integrate (e.g. integration of Touchpoints 2 and 4 with CARP), cross-integrate (e.g. Touchpoint 2 works both with HSDP and CARP), share and interchange its elements (e.g. several Touchpoints share standard elements that were to a certain extent adapted to the use case setting), and co-create (REACH considers the ability to identify, add, and design/develop new case specific elements for each use case setting as essential to achieve valuable and acceptable solutions).

In the following, we give an overview of the solutions and the overall scenarios (setting, target group and geriatric/medical goal, composition, proof of concept and testing) we developed for each use case setting based on the REACH toolkit and the above outlined capabilities of the REACH consortium.

#### 1.1.4.1 ***Proof of concept and testing Touchpoint 1***

- **Setting**: Touchpoint 1 draws on elements of the REACH toolkit to develop customized early intervention elements for independent but supported living solutions such as elderly residential solutions, activity and day care centers for the elderly, and linked physical therapy practices. The early detection and prevention scenario can be outlined as follows: 1) All elderly people enrolled in the target setting are equipped with a wearable activity monitor (e.g. a Modus Health Step-Watch 4) to screen the elderly regarding signs of inactivity and the risk of falls and frailty, 2) based on the monitored activity levels, semi-personalized activation or rehabilitation is provided with the ActiveLife device in a highly gamified manner using an optimized user experience to motivate and empower the elderly to perform as much self-training as possible, 3) the training in the ActiveLife device allows for further in-depth monitoring through a set of stationary sensors which are located in and on the device to analyze, assess, and continuously monitor the detailed functional ability and its change over time.
- 
- **Target group and geriatric/medical goal**: Touchpoint 1 focuses on an elderly target group who are not in hospital and is too weak to exercise; this also includes elderly people in elderly residential solutions and acre homes who are mentally able to engage in gaming. The medical mission of the system is to a) prevent falls and frailty, and at the same time b) empower elderly people towards more independence and self-training.
  - **Composition**: The early activation setting of Touchpoint 1 consists of a set of key components. This includes partly supervised training in a mechanical device that ensures that the elderly can conduct safe training (i.e. no risk of falls or injuries during training) with significantly more engagement than with conventional human-

based training facilities (e.g. services provided by a physical therapist). The system consists of a modular mechanical setting (ActiveLife device, monitor stilt with Kinect sensor, etc.), a sensing and data gathering sub-system (collects data during training and during daily life through a wearable sensor, Kinect sensors, step counters, and an on-device EMG sensor), software and algorithms (gaming software, algorithms to intelligently select, modulate, and personalize the training based on sensor data analysis), and novel training schematics (modular training procedures enriched by behavior change techniques that engage the elderly and prevent falling). Touchpoint 1 allows an easy and fast deployment of a medical grade training setting that allows user experience induced self-training (and associated personnel savings) and at the same time, improves the health outcomes of the target population.

- **Proof of concept and testing:** As in TP1, the users are mostly living at home but have some health constraints or are at risk of mental, physical or cognitive decline, the testing is focused on mobilisation and motivation in activity centres, day care centres, and at home. The testing is centred around Alreh Medical training devices which generates an overlap between TP1 and TP2. Due to these commonalities, neurological patients in the rehabilitation setting are also subjects in TP1 testing. The overall goal is to prevent adverse events during activation and enable the users to enhance their abilities. The testing started with usability and feasibility tests with healthy seniors and evolved to the integration of patients. Whether the skills acquired in the training are persistent and transferrable to daily life situations, increases the autonomy, and prevent adverse events, will be subject of future testing with larger sample sizes.

**Trial 10 (ActivLife Test):** In 2017 ZuidZorg, together with TU/e, started their first ActivLife testing with 48 participants consisting of elderly people living at home and visiting the ZZ meet and greet centre. The core research question was: Is the motivation to do more Physical Activity the same for seniors after using activLife at activity centre or exercising at home following the advice from physiotherapists?

**Table 1-1 Treatment and assessment plan for ActivLife group in trial 10**

Active Life Group	Assessments	Baseline	Intervention with Active Life (8 weeks)	Post study
	Age, gender, BMI, TFI	×		
	Stage of change questionnaire	×		×
	Tilburg Frailty Indicator	×		
	Strength test	×		×
	Mobee Fitness measurement	×		×
	Barriers to Being Active	×		×
	Active life exercise data		×	
	Rating of perceived Exertion (weekly, after each exercise)		×	
	Intrinsic Motivation Inventory (weekly)		×	

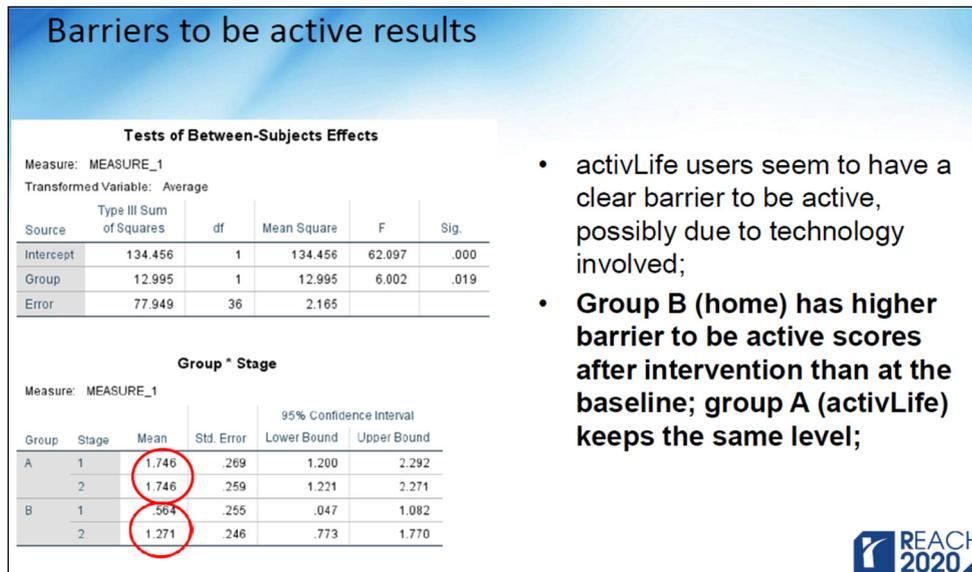


Figure 1-3 Results in trial 10: Barriers to be active

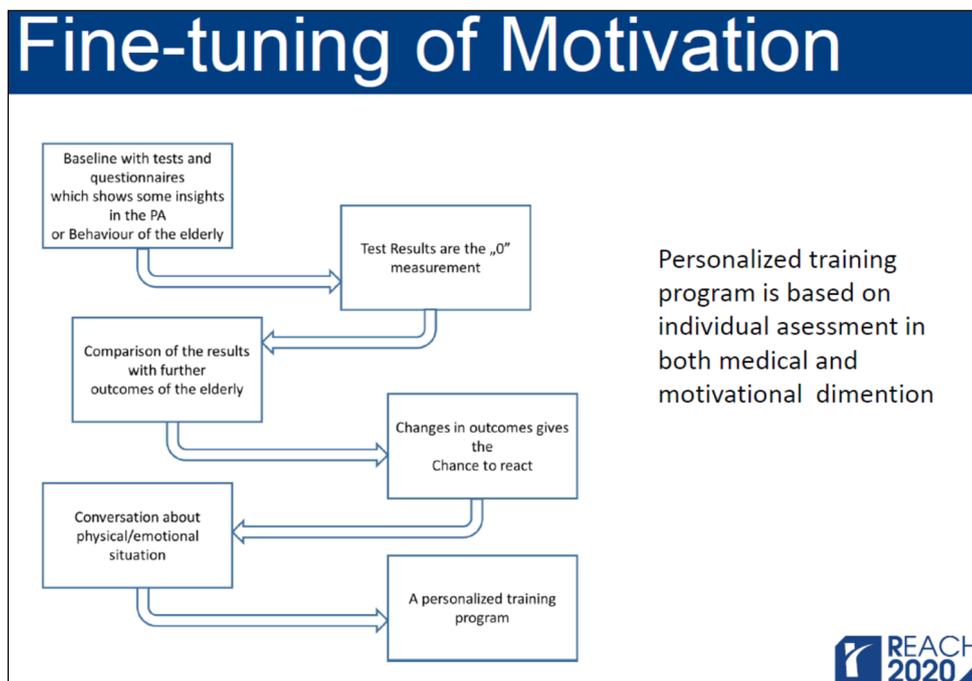


Figure 1-4 Motivation roadmap toward personalised training in trial 10

One interesting outcome of the trial was the core-role of the sport coach to foster motivation. The participants came from a rather physically active group with comparable TFI (**Gobbens et al., 2010**) stage of change measurement and hand grip test results (**Allen & Barnett, 2011**) (indicator for frailty). ActivLife training seems to have a clear contribution to the 4-stage balance skill. Both interventions contributed to the 30 second chair stand results. ActivLife training apparently does not sufficiently contribute to an enhancement in the Tinetti Balance Scale (**Tinetti et al., 1994**). The activLife device seems to generate a clear barrier to be active, possibly due to the technology involved. Exercise alone at home apparently has a higher barrier to be active than exercise together with a sport coach.

### Trial 17 (HUG ActivLife and Fitbit HR)

In 2017 10 patients, all satisfying the REACH target population characteristics (five using the Alreh equipment and five using standard equipment), and five healthy adults (using the Alreh equipment only) were included into the trial.

The following hypotheses were evaluated:

1. *iStander active device is safe to be used by elderly.*
2. *iStander active has a good functionality for the elderly in the rehabilitation setting.*
3. *Neuroforma gaming system (Software) is an engaging tool for the elderly in the rehabilitation setting.*
4. *Neuroforma interface is easy to use.*
5. *Fitbit HR sensor is a comfortable, easy to use, and valuable HR sensor.*

Care-givers and patients appreciated the ease and comfort of use. The use of Fitbit also promoted the patients' sense of empowerment. However, the wrist-band was reported as difficult to adapt to. Participants suggested as an improvement the additional function of an alert in case of exceeding the maximum heart rate or in the occurrence of cardiac rhythm disturbances.

Trial 21(A personal mobility device for elderly physical rehabilitation: a study of acceptance and efficiency):

46 planned

The RCT will start in 2019 in HUG, 46 participants are planned to be included with an intervention period of six weeks.

The following hypotheses will be tested:

1. *rehabilitation using the mobility equipment is as effective as the standard care*
2. *the usage of the mobility equipment will improve clinical outcomes such as physical strength, balance and risk of falls*
3. *the use of the REACH concept adds value to the continuity of patient care, specifically in terms of engagement and motivation to be more active during the hospital stay and when returning home*

**Table 1-2 Overview of trials that belong to TP1**

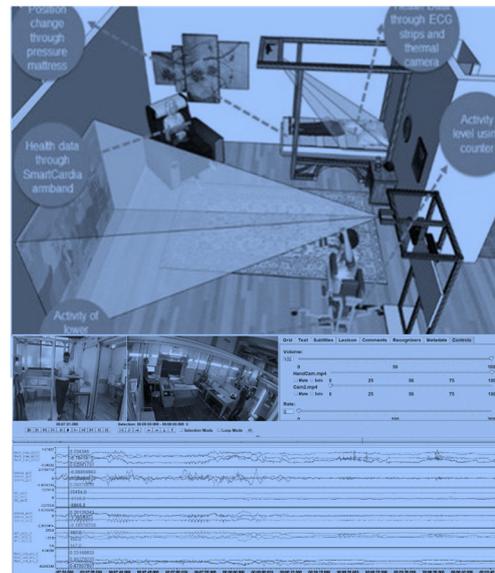
#		Title		Hypothesis	
10	1	ActivLife Test	motivation, activity centre, RCT	<ol style="list-style-type: none"> <li>1. H1: The motivation to do more PA is the same for seniors after using ActivLife and those after following the advice of physiotherapists.</li> <li>2. H2: Seniors remain at the same stage of change after using ActivLife.</li> <li>3. H3: Seniors remain in the same stage of change after following the advice of physiotherapists.</li> <li>4. H4: The physical conditions (in terms of strength) remain unchanged for seniors after using ActivLife and those after following the advice of physiotherapists.</li> <li>5. H5: The level of exertion of ActivLife exercise is the same as that of the exercise advised by the physiotherapists.</li> </ol>	Finished

Deliverable D27: Formalised results of pretesting I and II activities

				6. H6: The strength measurement is the same as the Mobee Fitness measurement.	
17	1	HUG early testing	Alreh Medical, elderly, safe standing, gaming platform,	<ol style="list-style-type: none"> <li>1. iStander active device is a safe solution for the elderly.</li> <li>2. iStander active has a good functionality for the elderly rehabilitation</li> <li>3. Neuroforma gaming system is engaging tool for elderly rehabilitation.</li> <li>4. Neuroforma interface is easy to use.</li> <li>5. Fitbit HR sensor is comfortable, easy to use and valuable HR sensor.</li> </ol>	Finished
21	1	A personal mobility device for elderly physical rehabilitation: a study of acceptance and efficiency	Rehabilitation; Serious games; Wearable Electronic Devices	<ol style="list-style-type: none"> <li>6. Rehabilitation using the mobility equipment is as effective as the standard care</li> <li>7. The usage of the mobility equipment will improve clinical outcomes such as physical strength, balance and risk of falls.</li> <li>8. The use of the REACH concept adds value to the continuity of patient care, specifically in terms of engagement and motivation to be more active during the hospital stay and after returning home.</li> </ol>	Ongoing

### 1.1.4.2 Proof of concept and testing Touchpoint 2

- **Setting:** In Touchpoint 2, based on the REACH toolkit, a fully-fledged activation care (and patient) room is developed. For the development, a patient room at Schön Klinik (rehabilitation clinic) is used as the lead use case setting initial scenario. The room is developed based strictly on modular principles (physical modularity, modularity on sensors and algorithms level, etc.) so that from this initial room, dedicated, adapted versions of care homes and home care environments can be generated.



- **Target group and geriatric/medical goal:** For the SK use case setting, the goal is to speed up the rehabilitation process and reduce the re-admission rate, increase the user experience (i.e. the fun-factor of physical ADL-focused exercise/training and rehabilitation, including motivational factors, and thus increase adherence to therapies/trainings and medical outcomes), and increase patient-empowerment (which is expected to lead to better ability for self-training, which will ultimately save care personnel costs).
- **Composition:** The patient room is comprised of the following key components. First, a modular physical-mechanical care/patient room environment is equipped in a minimally invasive manner with a set of smart and functional REACH furniture elements (PI<sup>2</sup>Us: Bed “activation cockpit”, MiniArc, SilverArc, ActiveLife/iStander). The furniture elements include a variety of novel features for “early” physical and cognitive activation, training, and rehabilitation. Second, a set of ambient and wearable sensors (which can be plugged into both the CARP and HSDP) were tailored to the use case specific application of Machine Learning (ML; supervised learning). The ambient sensors are embedded into the PI<sup>2</sup>Us Third, a ML based Human Activity Recognition chain was developed which allows for predicting human activities (in particular, ADLs such as sleeping, waking up, moving from one location to another, going to the toilet, teeth brushing, drinking, etc.) in order to a) detect early deviations from normal routines, b) inform sophisticated interventions and training in the patient room, and c) increase safety. Fourth, the output of the sensing and ML components coordinates a set of dynamic and just-in-time activation elements (in-room ADL-focused physical training, in-room mobility-integrated training, physical and cognitive stimulation through games). In the context of the development and provision of those activation regiments, the Touchpoint cross-employs and tests selected behavior change techniques that were developed in Touchpoints 1 and 3. Fifth, a novel room management GUI (to be used by both care personnel and elderly patients) was developed. It employs gesture control and can be projected dynamically onto any surface within the patient room.
- **Proof of concept and testing:** In the beginning, the main goals of the testing were to evaluate and validate the sensors and the environmental equipment to estimate

the suitability for further testing and – finally – for the integration into the REACH system. Another aim was the design of processes which are essential for the detection and classification of the users' health status. During the development of the trials and with enhanced involvement of the technical partners (TUM, IAIS) an additional important aspect was integrated: The suitability of the generated data for the algorithm design process. To process the data generated in the measurement sessions, the technical partner developed an annotation strategy based upon the concept of the "Opportunity data collection experiment" from **Roggen et al., 2010**:

- 1) **Level I:** Highest activity level
- 2) **Level II:** A decomposition of high-level activities into simpler activities. On this level, the activities are not temporal ordered and depend on the execution sequence of the test subject.
- 3) **Level III:** Logical, physiological and spatial limitations determine the order of activities in this level. This includes modes of locomotion and manipulative gestures.
- 4) **Level IV:** Comprises the atomic gestures forming the manipulative gestures of level III.

**Figure 1-5 Decomposition of human activities in human activity recognition, levels**

- High-level activities (e.g. *preparing breakfast, relaxing, cleaning up, etc.*)
- Mid-level activities (e.g. *slicing bread, open drawer, etc.*)
- Low-level activities (e.g. *moving bread, reach glass, etc.*)
- Locomotion activities (e.g. *walking, standing, sitting, etc.*)

**Figure 1-6 Decomposition of human activities in human activity recognition, level specifications**

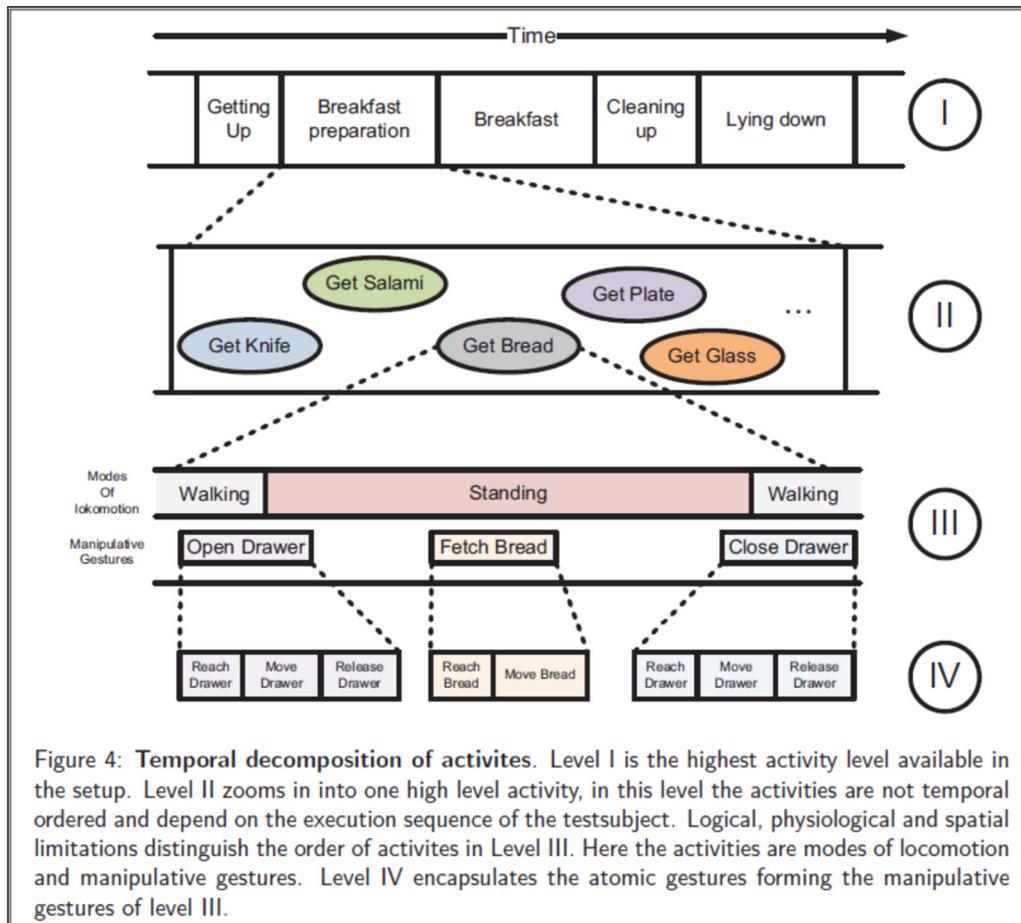


Figure 1-7 Sub-categorisation of activity “Breakfast preparation” (Roggen et al., 2010)

This leads to fundamental considerations regarding data quality, data protection, ethics and legal issues. Due to the commencement of the GDPR General Data Protection Regulation in May 2018, an in-depth analysis of the impacts of data handling and processing in the project had to be developed, together with the technical partners, Ethics Committees, Data Protection Officers and specialised lawyers. Central elements of the discussion were data transfer, data storage, data sharing of pseudonymised and personal data, allocation of responsibilities, automatic information processing, and compliance with user rights. Further iterations during the advanced testing phases: user had to perform more complex action processes, the test environment changed from single system elements to combined system modules and additional to healthy subjects, patients had also been involved. The inclusion of patients guided the researchers to a concentration on medical outcomes. SK consulted the other use cases to discuss superordinate assessments and generally accepted medical outcomes (see also section 2).

At the beginning, the reliability of the sensors was tested (trials 11, 12, 23). As Smart Cardia (SC) is a project partner, TP2 decided to concentrate on this sensor. In trials 11 and 12, initiated by the manufacturer, the accuracy of the measurement of vital signs of the SC sensor compared to ICU monitors was evaluated. The results showed that SC sensors could measure the vital signs at the same accuracy as the ICU monitor under different activity conditions, and also meet the accuracy of ICU monitors for vital signs monitoring, at ISO standards (95% agreement). In trial 23 (SC sensors compared to standard Holter system at SK, 7 healthy subjects

with different activity levels) an analysis was not possible because raw data was not available.

Trial 13, the coffee demonstrator experiment, was performed at FIAIS to evaluate time series motifs and pattern recognition. The data were analysed from two different perspectives: 1. Whether coffee drinking events might elevate (or decrease) the mean HR of a subject temporarily. This could be seen as shifts of the HR levels. 2. Whether caffeine consumption could result in more complex patterns of the time series. For example, caffeine could cause an instantaneous peak in the HR, before the HR starts to decrease again until it finally reaches the level from before. Patterns of this kind should be reflected in time series motifs centred around coffee drinking moments. To assess both hypotheses, a change points analysis was performed. No contradictory behaviours of the HR after coffee consumption was found. Change points analysis suggested that coffee drinking had no systematic effect on the heart rate levels. This preceding investigation was important to learn how measurements with sensors and analysis have to be performed to allow pattern recognition. In 2017, HUG and EPFL performed a cohort study with 20 healthy participants to evaluate the adoption potential of simple and manageable technology fostering behaviour change in the elderly. Sensors were Fitbit Charge 2, Fitbit Aria and Withings Body Cardio. The assessments were number of steps and qualitative interviews.

#### Trial 19: Activity detection with close-to-body and ambient sensors - Generation of data sets for empirical validation with neurological patients

In October 2018, SK, together with the technical partners TUM and FIAIS, performed a 5-day data collection and annotation workshop. The testing was a pre-trial with healthy subjects for trial 15 with patients at SK. The aim of the workshop was to clearly define the setting for measurements with patients and obtain data of healthy subjects as a baseline dataset. In addition to these aims, resource requirements, handling of the sensor set, the timing for the runs and synchronising procedure and the roadmap for the data annotation (with ELAN) were evaluated. The protocol followed key-items of activities of daily living (ADLs) (**Mahoney, 1965**). All participants underwent the same protocol.

ADL RUN	
<p><b>Start of session</b></p> <ol style="list-style-type: none"> <li>1. Check all equipment, wait for okay of technical assistants</li> <li>2. Hold up sheet of paper with session identifier into the cameras. (Note: has to do this in the bathroom, too).</li> <li>3. Perform synchronization procedure</li> </ol>	
<p><b>Morning phase (at bed place)</b></p> <ol style="list-style-type: none"> <li>4. Go to the bed</li> <li>5. Get into the bed               <ol style="list-style-type: none"> <li>a. Lay down</li> <li>b. Mimick sleeping (each position at least 10 seconds)                   <ol style="list-style-type: none"> <li>i. Lay on your left body side</li> <li>ii. Lay on your back</li> <li>iii. Lay on your right body side</li> <li>iv. Turn from your right to your left body side</li> </ol> </li> <li>c. Wake up</li> <li>d. Sit up in the bed (inside the bed)</li> <li>e. Grasp the smartphone</li> <li>f. Write a short text message</li> <li>g. Make a short telephone call</li> <li>h. Put the smartphone by side</li> <li>i. Stand up from bed</li> </ol> </li> <li>6. Take on pants</li> <li>7. Take on shoes</li> </ol>	
<p><b>Morning phase (at the bathroom)</b></p> <ol style="list-style-type: none"> <li>8. Go to the bathroom</li> <li>9. Enter the bathroom and Perform synchronization procedure</li> <li>10. Execute the following activities (free choice of execution)               <ol style="list-style-type: none"> <li>a. Wash the hands at the sink</li> <li>b. Dry your hands with a towel</li> <li>c. Brush the teeth</li> <li>d. Brush the hair</li> <li>e. Sit on toilet (open, sit down, stand up, and close)</li> </ol> </li> <li>11. Perform synchronization procedure and leave the bathroom</li> </ol>	
<p><b>Contemplation phase (at the table)</b></p> <ol style="list-style-type: none"> <li>12. Go to the table               <ol style="list-style-type: none"> <li>a. Choose a chair and approach it</li> </ol> </li> <li>13. Taking a chair for sitting down               <ol style="list-style-type: none"> <li>a. Move the chair in order to be able to sit down</li> <li>b. Sit down naturally</li> </ol> </li> <li>14. Drinking I (vary hands)               <ol style="list-style-type: none"> <li>a. Take the glass of water</li> <li>b. Take a sip</li> <li>c. Put the glass back to the table</li> </ol> </li> </ol>	
<ol style="list-style-type: none"> <li>15. Writing down some notes or draw any sketch               <ol style="list-style-type: none"> <li>a. Take a pencil and the college block</li> <li>b. Think for a little while</li> <li>c. Note down some thoughts or draw</li> <li>d. Place back pencil and college block to their origins</li> </ol> </li> <li>16. Relaxing for a few seconds               <ol style="list-style-type: none"> <li>a. Get yourself into some comfortable position</li> </ol> </li> </ol>	
<p><b>Someone at the door</b></p> <ol style="list-style-type: none"> <li>17. Someone knocks on the door</li> <li>18. Go and open the door</li> <li>19. Take tray with food</li> <li>20. Carry tray to the table (Note: Instructor holds door open to stop automatic closing)</li> <li>21. Return to the door</li> <li>22. Take plate with cookies</li> <li>23. Close the door</li> <li>24. Carry cookies to the cupboard and place there</li> </ol>	
<p><b>Eating, drinking and taking a pill</b></p> <ol style="list-style-type: none"> <li>25. Return to the table</li> <li>26. Choose a chair and approach it</li> <li>27. Taking a chair for sitting down               <ol style="list-style-type: none"> <li>a. Move the chair in order to be able to sit down</li> <li>b. Sit down naturally</li> </ol> </li> <li>28. Eat with dish, fork and knife</li> <li>29. Taking a pill               <ol style="list-style-type: none"> <li>a. Take the pillbox</li> <li>b. Open the pillbox</li> <li>c. Take one pill out of the box</li> <li>d. Eat the pill</li> </ol> </li> <li>30. Drinking II (left and right hand allowed)               <ol style="list-style-type: none"> <li>a. Take the glass of water</li> <li>b. Hold the glass for a certain time while looking through the windows</li> <li>c. Take a sip or tow</li> <li>d. Place back the glass to the table</li> </ol> </li> </ol>	
<p><b>Having a cookie and a drink</b></p> <ol style="list-style-type: none"> <li>31. Stand up from the table and take the glass with you</li> <li>32. Go to the cupboard</li> <li>33. Keep the glass in your hand</li> <li>34. Eat a cookie while standing</li> <li>35. Drinking III (while standing, left and right hand allowed)               <ol style="list-style-type: none"> <li>a. Take a sip or tow</li> </ol> </li> <li>36. Put glass onto the cupboard to have your hands free</li> </ol>	
<p><b>Session closing</b></p> <ol style="list-style-type: none"> <li>37. Perform synchronization procedure to finish the session</li> </ol>	

Figure 1-8 Measurement protocol with Activities of Daily Living (ADL) for healthy subjects and patients in neurological rehabilitation (Trial 19)

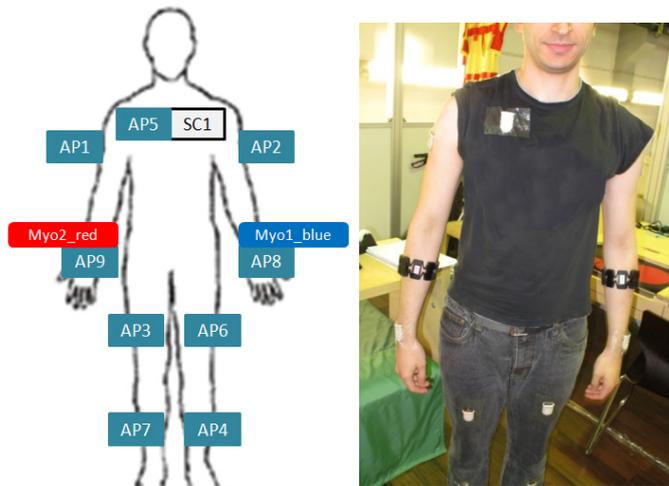


Figure 1-9 Wearables for Trial 19

n	Wearables
9	ActivPAL™ (AP1-9)
1	SmartCardia (SC1)
2	MyoArmband (Myo1_blue, Myo2_red)



Figure 1-10 Set-up scenario for ADL-run at TUM (trial 19)

Patients' information for the creation of algorithms can be generated from a wide variety of data generated with sensors on and around the patient. Patients with the following diagnoses will be included: Stroke, Alzheimer's Disease (AD), Parkinson's Disease (PD) and Critical Illness Polyneuropathy (CIP).

Similar to the previous laboratory testing at TUM, we will use wearable sensors (nine activPAL™, one SmartCardia, two Myo-Armbands) and ambient sensors (one pressure mattress BPMS™, four wall-mounted and one hand camera) to create a heterogeneous sensor system for the recognition of patients' daily activities, e.g., sleeping, sitting, standing, walking, eating. SK permanently has all sensors available. All measurements will be performed in a dedicated patient room reserved for this purpose. The appointments can be adapted to the therapy plan accordingly and to the patients' needs, so that there is no limitation regarding the ongoing therapies.

The primary outcome parameter will be retrieved from the hospital information system (body characteristics, diagnoses, physical and cognitive status). Technical affinity will be assessed with a questionnaire. The questionnaires will be filled in by the patients before and after the examination. After application of the sensors, all patients will undergo two different inspections: the measurement during activities of daily living in logical order (ADL runs) and repeated sequences (Drill runs). The patients will be instructed by an experienced researcher (scientific staff 1, SKBA) and filmed by another member of the research team (scientific staff 2, SKBA) with a hand-held camera. The observer (scientific staff 3, SKBA) prepares the requisites, observes the events during the runs, controls the sequence in the intended order and notes any deviations. All members of the research team will focus on the patients' wellbeing.

To synchronise all sensor data, a unique and identifiable "time stamp" is required, which is induced with a synchronisation gesture. At the beginning and at the end of each ADL run, as well as after changing rooms (from the living area to the bathroom), the synchronisation gesture is performed clearly in front of a wall camera. In the drill-run sessions, a synchronisation process is performed after every second drill-run. In

our pre-test, the synchronisation procedure was adapted and optimised, as a short interim evaluation of the data showed that the originally planned synchronisation movement was not displayed in all sensor data. The sequence will always be identical. The figure below shows the data flow: Immediately after the runs, all personal data will be pseudonymised form SKBA and given to the project partners TUM and FIAIS to start the data processing.

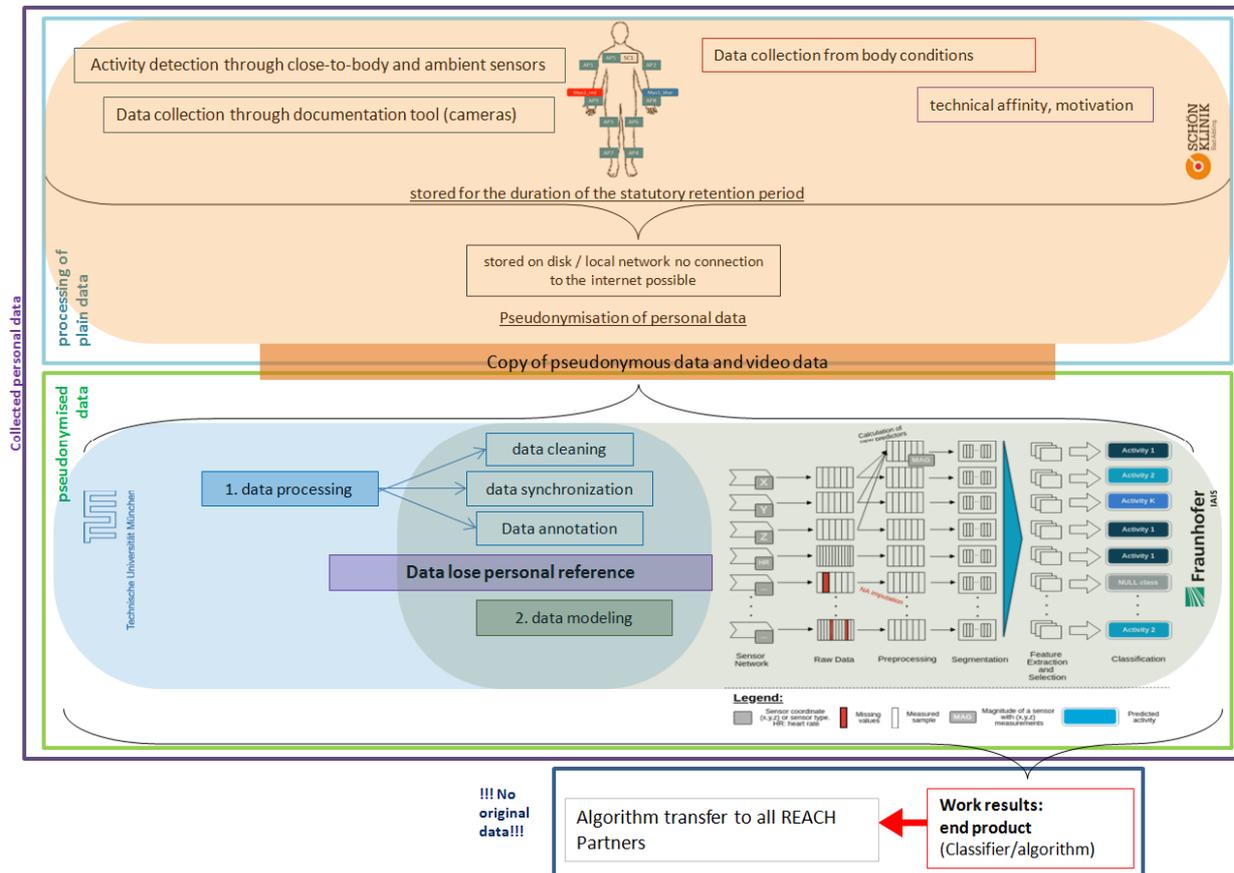


Figure 1-11 Data flow of sensor testing in SK

Currently, SK is working on the ethics proposal and preparation of the patient room.

Trial 20: The transfer and training device activLife used with neurological patients. Feasibility und usability trial at SK

The aim of this trial is to investigate the feasibility and suitability, and the effect of the transfer aid and training device *activLife* with neurological patients. *activLife* will be used as a transfer aid to support the patient to move from seating to standing position. It is important to evaluate if this device can be used in everyday clinical practice and after discharge for the benefit of neurological patients. The reduction of therapeutic activities after hospital discharge often leads to a decline in the acquired functions and thus a worsening of the general state of health. An intensive preparation for a high-frequency training starting during hospitalisation could attenuate this negative effect.

The study is designed in two parts (see protocol scheme):

1. **feasibility study** (period A.1 and B) and
2. **application observation** (period A.2 and C).

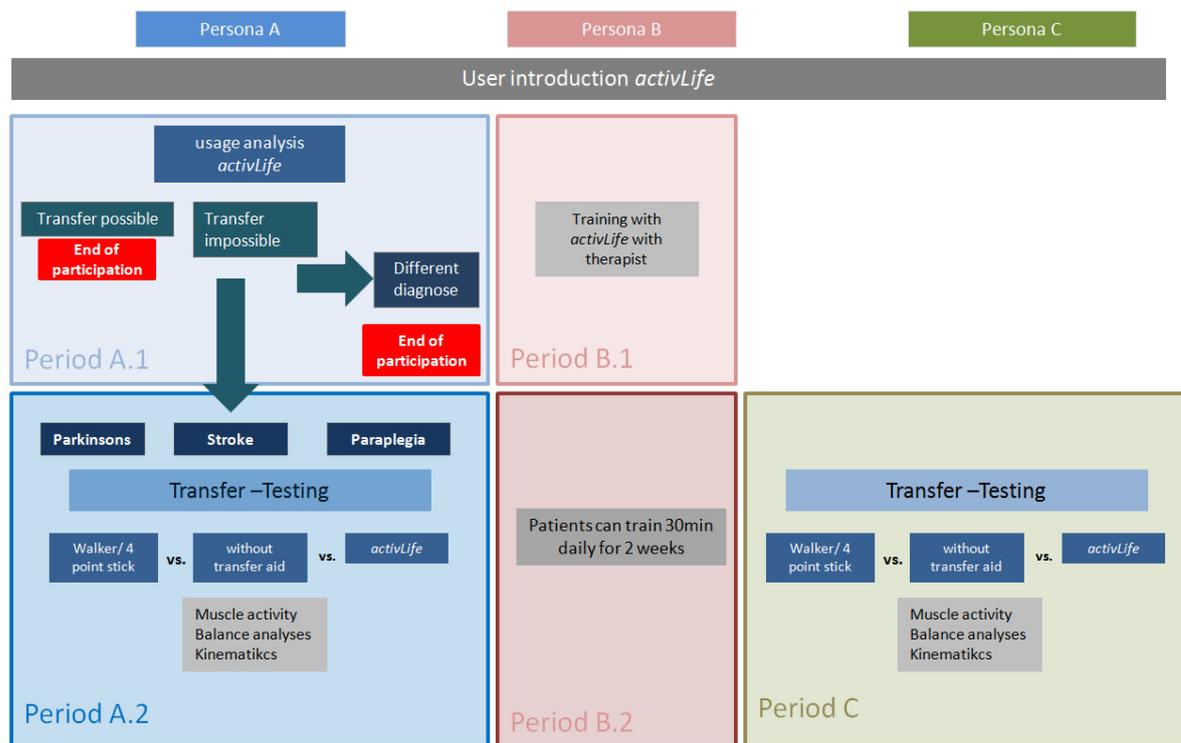


Figure 1-12 Protocol schematic for activLife testing with neurological patients at SK

The main objectives of this study are to investigate which requirements a neurological patient must fulfil in order to use the device, the integration potential into hospital therapy routine and the motivation of patients to continue using the activLife after discharge. The requirements a patient has to fulfil in order to train with the device successfully is of great relevance for the establishment of indications for home application and independent therapy. Additionally, the feasibility of the additional therapy based on the software VAST.Rehab in the hospital routine of the Alzheimer Therapy Centre (ATZ) will be evaluated. It is important to analyse to what extent patients with Alzheimer's Disease supported by their caregivers can use this training option.

To describe the functional status of the patient, some tests will be performed in addition to the inclusion criteria: Berg Balance Skala (BBS; (**Berg et al., 1995; Stevenson, 2001; Scherfer et al., 2006**)), 5x Sit-to-Stand Test (5XSST; **Bohannon, RW. 2006**), Motor Function Assessment Skala (MFA; **Freivogel et al. 1990**), Montreal Cognitive Assessment (**Nasredinne et al., 2004**), Hand grip strength test (**Allen & Barnett, 2011**), Intrinsic Motivation Inventory (**Ryan et al., 1982**), Capture the attention and technical affinity. All patients will undergo this first part of the study.

As a secondary study objective, intervention effects are evaluated in a clinical application observation. It is important to find out what differences exists during the sit-to-stand transfer in activLife compared to getting up and sitting down with or without different aids for the transfer (rollator or 4-point stick). All participants who are able to stand up in the activLife device will be included in this second period and will perform the same examination conditions of period 2. Differences in the respective transfer

conditions will be documented. The muscle activity in the thigh (EMG), the weight distribution via the pressure measuring platform zebris and kinematics analysis via Simi Motion® during the transfer are observed. In total, 40 patients are planned to perform those transmission sequences. Currently, SK is working on the ethics proposal.

**Table 1-3 Overview of trial that belongs to TP1**

		Title	Keywords	Hypothesis	
11	2	SmartCardia - Healthy Volunteer Testing	Wearable sensor; vital signs; validation against monitors; activity	Measurements with SmartCardia sensors (applied at chest and upper arm) during different activity levels and postures are reliable. Heart rate, respiration rate, blood pressure, oxygen saturation, blood pressure variations, skin temperature, activity and posture.	Finished
12	2	SmartCardia - Patient testing at CardioCentro Lugano	Vital signs; wearable; patient testing	To validate the parameters from the wearable against ICU monitor devices for vital signs measurement.	Finished
13	2	Coffee Demonstrator Experiment	Time series analysis, time series clustering, pattern detection, change point detection	We analysed the data from two different perspectives. On the one hand, coffee drinking events might elevate (or decrease) the mean HR of a subject temporarily. This could be seen as shifts of the HR levels. On the other hand, the effect of caffeine consumption on the subject's HR could result in more complicated patterns of the time series. For example, caffeine could cause an instantaneous peak in the HR, before the HR starts to decrease again until it finally reaches the level from before. Patterns of this kind should be reflected in time series motifs centred around coffee drinking moments. To assess both hypotheses, i.e. HR mean shifts and conserved time series motifs, we performed a change points analysis.	Finished
14	2	Opportunities and challenges for self-monitoring technologies for healthy aging: An in-situ study	Health; behaviour change; activity monitoring; qualitative studies; older adults; physical activity	Senior individuals are ready and willing to accept such technology to manage their health, considering some challenges. Senior individuals will change their behaviour and will sustain the device usage at the end of the study.	Finished
15	2	Activity recognition with wearables and ambient sensors - gathering of data sets for the empirical validation with neurological patients	Sensors; neurology; activity recognition; data sets; machine learning; algorithm	Explorative trial: With the sensor set used in the trial valid algorithms for activity detection can be generated, suitable for neurological patients and healthy subjects.	Ongoing
19	2	Data Collection and Annotation Workshop Touchpoint 2	Data Collection, Data Annotation, Ambient Sensing, Wearable Sensing, Monitoring, Targeting Specific Activities (Eating, Drinking and etc.)	Collection of data to monitor activities of daily living (ADL) at home, such as eating, drinking, activity (sleep, walking and etc) and hygienic aspects.	Finished
20	2	The Transfer and Training Device activLife with neurological patients. Feasibility and Usability Study	Activity, neurology, sit-to-stand, transfer, mobility, training	Explorative trial: with the sensors used in that trial, a valid feedback is given during the three different transfer methods. The activity and kinematic detection can be used to show if the activLife is suitable as a transfer-support and muscular training in the field of neurological rehabilitation. Moreover, a patient group with Alzheimer's disease and their relatives will test the implementation of the device with its Software.	Ongoing

*Deliverable D27: Formalised results of pretesting I and II activities*

23	2	Feasibility study - SmartCardia sensors with standard Holter system and activePal sensors	ECG, motion data, posture	ECG and motion data from SmartCardia are consistent with the ECG data from the standard Holter system and the motion data from the activePal sensors	Finished
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### 1.1.4.3 **Proof of concept and testing Touchpoint 3**

- **Setting:** In Touchpoint 3, based on the REACH toolkit, a process-based system is co-created with elderly residents who are enrolled in a community and activation center for elderly people (ZuidZorg). The system administers target-oriented physical activation and training (i.e. targeted at training of functions needed to perform ADLs independently) to independently-living elderly people through ICT and technology-based stimulation and ethically viable shaping of social behaviors and community activities (including cooking and nutrition).



- **Target group and geriatric/medical goal:** Touchpoint 3 identifies elderly people at risk of physical inactivity and the loss of function through the enrollment in an elderly activity center (ZuidZorg). Elderly people who are at risk are then equipped with a set of sensing elements (apps and sensors) which allow a data- and ML- based facilitation and modulation of social activities that are inherently integrated into daily life. The elements are designed as systematic, target-oriented physical and cognitive training with the goal of keeping the elderly in a healthy and independent condition for longer.
- **Composition:** The system consists of the following key components. First, a selected set of the use case design-adapted (i.e. from the standard designs available in the REACH toolkit) smart furniture elements (PI<sup>2</sup>Us: smart table Kooktafel, SilverArc, and ActiveLife) serve in a minimally invasive manner (i.e. without the need to intrude into the built structure of the environment) as physical elements that carry and deploy parts of the needed functionality. Second, the elderly people are equipped with a FitBit Flex 2 sensor plus in a case sensitive manner with a set of mobile phone applications (Apps: HealthyTogether for monitoring activity, Mirana Bot for food intake monitoring, and SMAAK concept social eating platform). Third, two tools for interpretation of health and lifestyle are developed and tested in parallel: Philip's data dashboard and a ML-based system. Philip's data dashboard was developed for the Touchpoint as a decision support system that guides the development and administering of personalized interventions (activity program, social program, training session, food, recipes, etc.) by a human person. The ML-based system uses supervised learning to profile users in an automated manner and predict which interventions will work best for them. Fourth, informed by and linked to these two data interpretation tools is a set of personalized intervention components (e.g. personalized food recipes which can be cooked and are guided by the smart table Kooktafel, gamified social activities, and physical training).
- **Proof of concept and testing:** Target users of TP3 are elderly residents who are visiting activity centres and are at risk of physical, mental and cognitive decline due to inactivity, malnutrition and social challenges (integration and isolation). A central and unique focus in TP3 is on eating habits, nutritional status and dietary requirements. The planned interventions addressing nutrition are far beyond usual dietary recommendations, they

include support for persons with oral impairments and dysphagia in need of specialised food and integrate additional health and lifestyle data to generate a holistic user model. Strategies to foster behaviour change are also within the scope of the test plan. To support the testing activities in TP3, Philips created the research dashboard. This innovation allows visualisation and comparison of scientific data and expedites the analyses. Furthermore, a permanent communication between sensors and the dashboard is planned to allow researchers a close monitoring of the state of the sensors without unnecessary obtrusive contact with the participants.

One important trial is planned to start in 2019: The testing of the MiranaBot, an app where a conversational agent is integrated with a hybrid user interface to promote healthy eating. The app gathers data on the user's eating habits and nutritional intake and provides personalised variety feedback, nutritional assistance and goal setting (for more details, see deliverable D18). A preliminary work for its development was the collection of data from Biozoon regarding the eating habits of elderly and dysphagia patients. The aim of the data collection was to enlighten the researchers on the relationship between eating habits and the participants' mood and its influence of the motivation to eat.

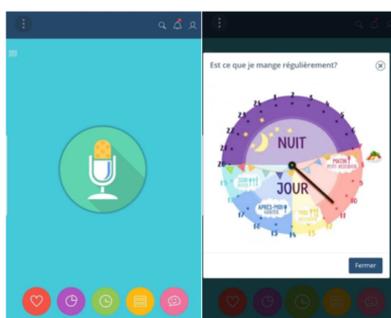


Figure 1-13 Mirana Bot Interfaces



Figure 1-14 Mirana: Visual feedback "Variety"

Two trials in TP3 concentrated on persuasive strategies and behaviour change regarding physical activity. One investigated the influence of self- and peer-awareness strategies on the number of steps performed by seniors with high or low self-efficacy. The other evaluated which persuasive strategies best addresses the motivation of older adults to increase their level of physical activity:

(Trial 16: Towards personalised persuasive strategies for active ageing)

Previously performed scientific evaluations were focused on persuasive system design strategies (PSD) to motivate seniors to adopt a more active lifestyle.

Increasing physical activity is important to promote independent living among seniors due to its impact in preventing chronic diseases and long-term care. Smart wearable technologies have been already developed to support citizens to be more physically active. However, the impact of these wearable technologies on seniors still requires more research. This project examined 12 student team design concepts which aim to add values to one existing wearable product by redesigning the accompanying application to suit an elderly user group using the PSD principles. By clustering the resulting re-design concepts, themes were identified which suggested values suitable for an elderly user group that aim to stimulate a more active lifestyle. Furthermore, common persuasive principles applied to redesign concepts in each value theme were defined so as to create design guidelines for active ageing lifestyle.

To compare and analyse these concepts, the general quality of each concept was examined in a user evaluation. Only concepts with sufficient quality will be included in further analysis. We identified which persuasive principles were used most frequently in design concepts in each value theme. The three most common persuasive principles used throughout each value theme suggested are listed in the table below associated with Value themes and Combined persuasive principle strategies. The Value themes are from both extrinsic and intrinsic points of view. Social fitness, Improved care and Prize are related to extrinsic motivation while Self-awareness and Fun are related to intrinsic motivation. This consolidated view of the most frequently recurring persuasive principle combinations suggests that certain combinations merit further investigation. For example, personalisation and suggestion were found to be the most frequently used principles for both intrinsic and extrinsic motivation. These observations suggest further evaluating these recurring persuasive principle combinations as design strategies to motivate senior citizens to adopt a more physically active lifestyle.

The suggested design strategies and Value themes require further investigation. Due to the limited number of student projects, it remains difficult to confidently draw design strategies from Value themes. It also remains unclear how many of the principles should be combined to gain the desired result. However, we suggest that a combination of several principles can enrich the system while isolating combinations of only two principles in further testing might allow the researcher to find more direct links between value creation and persuasive principle application. We suggest further research should test the above identified design strategies by applying them to a concept design for senior users intended to motivate them to engage in more physical activities before drawing any formal conclusions.

Although the obtained results helped us to focus on the potentially relevant persuasive strategies, they failed to help us address the varying needs among the targeted senior population. To further investigate how persuasive design strategies can be applied to motivate a senior target group to move more, these separate elements could be combined to create profiles of target users depending on their Regulatory Focus, current stage of change and background in

physical activities. The next step is to evaluate the identified strategies applied in a design intending to stimulate a more active lifestyle.

**Table 1-4 Identified strategies applied in a design intending to stimulate a more active lifestyle**

Value Clusters: proposed strategies	Combined Persuasive Categories	Combined Strategies
Social Fitness	Primary task support and Social support	Social-facilitation, self-monitoring, tunnelling, personalisation, suggestions
Improved care	Primary task support and credibility support	Expertise, suggestions, reward, authority
Prize	Primary task support and dialogue support	Tunnelling, personalization, suggestion
Self-awareness	Primary task support and dialogues support	Self-monitoring, personalization, expertise, real-world feel, suggestions, goal setting, social facilitation
Fun	Primary task support and dialogues support	Tunnelling, personalization

(Trial 18: Eindhoven Continued testing)

This trial aims to enlighten personalisation strategies to foster positive change in behaviour. Personalising motivation strategies have the potential to motivate seniors to engage in more physical activity; however, it remains unclear how to personalise strategies toward behaviour change. Self-reflection and social engagement have been shown to have potential. Test group A's intervention was an application using self-reflection strategies to motivate behaviour change (more physical activity) while group B's intervention was a similar application which used social reflection strategies to motivate behaviour change (more physical activity). Intervention was applied for a duration of four weeks. Contextual, psychological and self-reported behavioural factors were collected about participants via a questionnaire which was given three times: 1) before the baseline, 2) after the baseline before the intervention and 3) after the intervention. Behavioural data, in terms of physical activity, was also measured throughout the baseline and the intervention period via a Fitbit Flex. Research results are currently being evaluated and will be made available in the next revision of this deliverable.

**Table 1-5 Overview of trials that belong to TP3**

		Title	Keywords	Hypothesis	
1	3	Mirana: A conversational agent with a hybrid user interface to promote healthy eating	health; behaviour change; nutrition; obese; diabetes	<ol style="list-style-type: none"> <li>1. "Mirana" app is able to assess the user's nutrition habits as efficiently as or better than a health professional.</li> <li>2. "Mirana" is able to identify key food items that need to be reduced as efficiently as a health professional.</li> <li>3. Patient is more motivated and engaged to change their behaviour with the support of "Mirana" app.</li> </ol>	Future
16	3	Towards personalised persuasive strategies for active ageing	active ageing, behaviour change, persuasive strategies, personalisation, physical activity	Which persuasive strategies are preferred to motivate older adults to enhance activity level?	Finished
18	3	REACH Eindhoven Continued testing	active ageing; personalising behaviour change; motivation; technology acceptance	<ol style="list-style-type: none"> <li>1. H1: There is no correlation between the number of times seniors open the application and the number of steps seniors take.</li> </ol>	Finished

				<ol style="list-style-type: none"> <li>2. H2: There is no correlation between the number of calls made by seniors and the number of steps seniors taken.</li> <li>3. H3: Self-awareness motivates seniors to take the same number of steps as the measured baseline.</li> <li>4. H4: Peer-awareness motivates seniors to take the same number of steps as the measured baseline.</li> <li>5. H5: The relative difference in steps taken by seniors with high self-efficacy is the same as those taken by seniors with low self-efficacy when using peer-awareness strategy</li> <li>6. H6: The relative difference in steps taken by seniors with high self-efficacy is the same as those taken by seniors with low self-efficacy when using self-awareness strategy</li> <li>7. H7: The relative difference in steps taken by seniors with a promotion regulatory focus is the same as those taken by seniors with a prevention regulatory focus when using peer-awareness strategy</li> <li>8. H8: The relative difference in steps taken by seniors with a promotion regulatory focus is the same as those taken by seniors with a prevention regulatory focus when using self-awareness strategy</li> </ol>	
22	3	Questionnaire for the investigation of motivational aspects for food intake by elderly people / [...] by dysphagia patients	Dysphagia, pureed food, motivational aspects to eat, effects on appetite and mood	Current situations (living in a nursing home, dependency on others while eating, dependency of pureed food ...) have influence on the mood of elderly people and in the context of their motivation to eat.	Finished

#### 1.1.4.4 **Proof of concept and testing Touchpoint 4**

- Touchpoint 4 draws on elements of REACH toolkit to co-create active environments that encourage older adults towards an active lifestyle. The system administers the engagement environment of Playware tiles and fitness trackers at its centre, complemented by optional solutions drawn from the other Touchpoints (e.g., ActivLife)
- Target group and geriatric/medical goal:  
In Touchpoint 4, the goals are to motivate older adults e.g. through gamification and motivational strategies to become more physically active and improve their physical and functional ability. The aim of the interventions is to show that systematic interaction and exercising with the components of active environment (e.g. feedback on physical activity, playful exercise) can improve the health conditions of the elderly users (e.g. improved walking speed and improved balance) and social life of older adults (e.g. more visits to friends, leisure activities, shops, etc.).
- Composition: The system consists of a set of key components. First, at its core is the modular mechanical setting of Playware tiles which can optionally be combined with PI<sup>2</sup>Us (e.g. the PI<sup>2</sup>U-MiniArc). Second, monitoring of the elderly is performed through wearables (SENS motion, focus on steps), and through the activity and game performance on the Playware tiles (ambient sensor). In the next step, the system also foresees the interlinking with a set of smart home sensors (simple but effective ambient sensors to detect presence in certain rooms, such as infrared photo sensors and light barriers). Third, the Touchpoint employs ML for early detection (on device ML for accurate steps recognition for elderly + trends prediction) + device (playware) integrated functional assessment. DTU's CARP platform serves for this Touchpoint as the data collection and processing infrastructure. Fourth, the touchpoint works with a set of engagement techniques that are intended to nudge elderly people into more physical activity and community participation. Fifth, as with Touchpoint 3, Philip's data dashboard serves as a means for care givers to interpret physical activity data and trends at the point of care as the basis for additional data induced human interventions.
- Proof of concept and testing: Touchpoint 4 is focusing on enhancing physical activity, motivation, engagement and user acceptance as these topics are highly related with gamification and motivational feedback. Due to the integrative structure of the interventions, socialising is also a part of the trials.



The following graphic shows the test environment in the TP4:

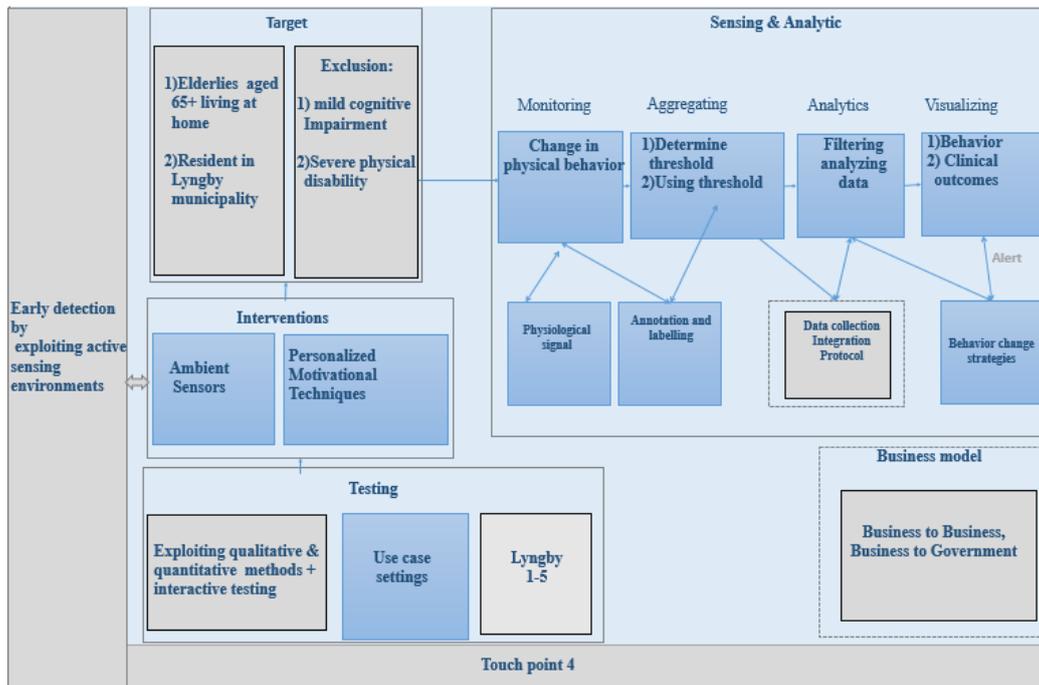


Figure 1-15 Test environment in TP4

This graphic shows the information flow from the sensors to the recipients which are supposed to take action:

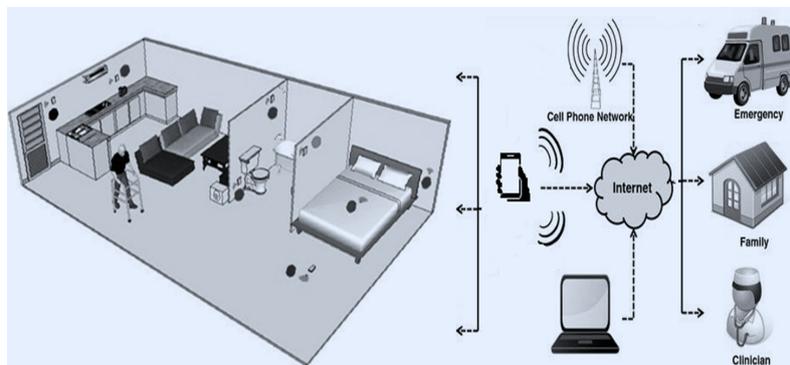


Figure 1-16 The integrated environment receiving signals from Ambient and motion sensors



Figure 1-17 TP 4 test scenario: Participant secured by two students playing colour-race with Mototiles

The trials performed follow a clear development from feasibility to RC trials, examining short and long-term effects and verification of the external validity. The outcomes are highly relevant to select the best practice for fostering physical activity, selecting reliable sensors, acceptance of smart home equipment, prediction of activities, prediction of changes in behaviour and assessing health status.

#### Trials at the University of Copenhagen

The reliability of four physical activity monitors (PAM) was compared regarding step counting with older adults with and without walking aid. The outcome showed that hip-worn PAMs have moderate reliability in all participants, whereas the wrist-worn PAMs could not fulfil the requirements for reliability. This outcome is very important for further tests because it provides excellent guidance for the selection of sensors. Second, a randomised controlled trial is planned to be performed in 2019. The trial aims to investigate the effect of bi-weekly motivational interviews. The outcome of this study contributes in identifying best practice strategies to increase physical activity level among older adults.

#### Lyngby trials

First, through cross over design trials (Lyngby 1), the effect of providing daily physical activity level were tested. Comparing daily average steps from the period where the elderly people were blind to feedback with the second period where they got feedback about activity level; there is no significant increase in the objective measure in term of numbers of steps. That means that providing feedback have no influence on the number of steps. However, our study shows that participants become more conscious of the behaviour. Comparing objective measures (activity level measured by Fitbit) with subjective measures (self-rated physical activity level) shows that providing feedback increases this awareness. It is thus possible that participants may have become more aware of their activity level which resulted in them becoming more conscious about the behaviour and therefore most participants rated their activity level lower. Hence, they misperceived their activity level by underestimating the intensity of their activities during the trials. This outcome contributes to identifying best practice strategies to increase physical activity level among older adults.

Second, a feasibility study (Lyngby 2) was conducted from April-July 2017 in preparation of the planned Lyngby 3 trial to investigate the logistics of recording simultaneously physical activity via Fitbit tracker, Sens tracker and play/exercise via Moto tiles.

The Berg Balance Score and the CS test shows the most promising results, while also TUG (**Podsiadlo and Richardson, 1991**) and 6MWT (**Enright et al., 1998**) show improvements worth further investigations of the effect of playful exercise on physical activity level (Lyngby 3 trial).

Third, an RCT (Lyngby 3) was conducted from March-June 2018 to investigate the effect of playful exercise on physical activity level. The outcome shows that the intervention group changes averaged 5.0 on the BBS (**Berg et al., 1995; Stevenson, 2001; Scherfer et al., 2006**). However, the difference between mean changes control vs. intervention group is not significant at alpha = 0.05 level,  $p = 0.11$ . Similarly, we see no significant difference between control and intervention groups in CS (**Rikli et al., 1999**) and 6MWT (**Enright et al., 1998**). The training on the MOTO tiles created a playful atmosphere, which improved motivation compared with standard rehabilitation training and exercise. This outcome is very important, and contributes in identifying best practice strategies to increase physical activity level among older adults.

Fourth, a validation study (Lyngby 4) was conducted to validate algorithms for counting steps of slow walkers with machine learning techniques on raw data from 3-axis accelerometers. The study is not yet completed. Data will be analysed with machine learning algorithms, using the observed number of steps as supervised training, in order to identify different clusters. Comparisons will be made across relatively slow and relatively fast walkers, both with and without walking aids. The most general hypothesis to be tested is a single algorithm using data from position X to predict, with a given level of reliability, the number of steps for all participants (e.g., the number of steps produced by the algorithm with a deviation of less than 5% for at least 95% of the users). Currently, activity trackers are designed for young adults and seem to be unreliable for counting steps of slow walkers or persons with walking aids or gait limitations. The outcomes of this study ensure a convenient and easy way to estimate the changes in physical activity of older adults, who walks with or without a walking /rollator; i.e., the vast majority of elderly citizens.

Fifth, a feasibility study (Lyngby 5) is planned to be conducted in 2019. The study aims to monitor older adult's daily activity throughout the day by in-home sensors. We want to detect changes in performance, behaviour and habits by analysing patterns for deviation from baseline data. This study provides evidence about the positive and negative impacts related to smart home technologies. Furthermore, it sheds light on the capability and consequences of smart home implementation in a real setting.

## DTU- Electro

A validation study (Body & Brain Test with the Moto Tiles) was conducted to test the reliability of the Moto Tile timing of the chosen balance tests. Normative game scores at different ages were calculated. The outcomes of the study are based on findings correlating game scores and standardised balance tests. Early detection and filtering of age-related diseases are complex processes and require professional and extensive analyses. By designing a Moto Tile game session, the examination process can be made interesting, easier to perform and more economical.

**Table 1-6 Overview of trials belonging to TP4**

		Title	Keywords	Hypothesis	
2	4	Criterion validity for step counting in four consumer-grade physical activity monitors among 103 older adults with and without rollators	Validity: physical activity monitors: walking: technology:	Bilateral counts from the same model measured on the left and the right side of the body have good agreement, and we expected all PAMs, no matter the placement, to have moderate criterion validity for all participants, good criterion validity for participants walking without a rollator and poor criterion validity for participants walking with a rollator.	Finished
3	4	The MIPAM trial: A 12-week intervention with motivational interviewing and physical activity monitoring, to enhance the daily amount of physical activity in community dwelling older adults – a randomised controlled trial	Physical activity monitoring: older adults: walking: wearables: motivational interview: behavioural change strategies	Motivational interviewing will enhance the effect from physical activity monitoring and consumer available monitors.	Future
4	4	Lyngby 2: Feasibility study conducted in preparation of the Lyngby 3 trial	Playware, behaviour change, gaming, elderly, exercise, physical activity, postural control	<ol style="list-style-type: none"> <li>Primary hypothesis: Physical exercise during a 9-week period with older (65+) citizens: <ul style="list-style-type: none"> <li>Improves physical and functional abilities</li> <li>Is accompanied by changes in physical activities outside exercise sessions</li> </ul> </li> <li>Secondary hypotheses: <ul style="list-style-type: none"> <li>Activity tracking is perceived by elderly citizens as an acceptable monitoring technology used by care providers</li> <li>Training on Moto tiles is adhered to and is perceived as acceptable by users over a 9-week period</li> <li>Changes in performance on MOTO tiles over time correlates with changes in balance and functional measures</li> </ul> </li> </ol>	Finished
5	4	Lyngby 3: The effect of playware technologies on physical activity	Gaming; Physical activity; Functional ability	<ol style="list-style-type: none"> <li>12 weeks of playful physical exercise improves physical and functional abilities.</li> <li>It is accompanied by changes in physical activities outside exercise sessions.</li> </ol>	Finished
6	4	Lyngby 1: Effect of daily feedback on older adults' physical activity level	Physical activity monitoring; Sensors; wearables; behaviour change;	<ol style="list-style-type: none"> <li>Receiving feedback on physical activity level increases activity.</li> <li>24/7 monitoring for 8 weeks generates concerns about privacy.</li> </ol>	Finished

Deliverable D27: Formalised results of pretesting I and II activities

			Effect of feedback; activity tracking		
7	4	Playful Body and Brain Test with the Moto Tiles	Playware; balance test; cognitive test ; fall risk	Calculation of a normative Moto Tiles game score for different age groups can be calculated with a bid data approach. There is a correlation between Moto Tiles game score and standard tests (Timed-Up-and-Go, Sit-to-Stand).	Finished
8	4	Lyngby 4: Developing a reliable technique for automatic counting of steps of older adults – a validation study	Accelerometer; pedometer; validation; physical activity; step count; algorithm	Algorithms can be developed and validated with machine learning techniques based on raw data from 3-axis accelerometers.	Ongoing
9	4	Lyngby 5 Trial: Test/demonstration of smart home technologies in a naturalistic environment	Smart Home, age at place	<ol style="list-style-type: none"> <li>1. Primary hypothesis: <ul style="list-style-type: none"> <li>• Determine potential problems occurring related to smart homes and potential positive and negative outcomes after the implementation of smart home technologies.</li> </ul> </li> <li>2. Secondary hypotheses: <ul style="list-style-type: none"> <li>• Acceptability of interior sensors by elderly citizens.</li> <li>• Acceptability of 24/7 monitoring by elderly citizens.</li> </ul> </li> </ol>	Ongoing

## 1.2 Coordinating and integrating Role of WP6 in REACH

REACH WP6 is concerned with key integration and verification/validation tasks (interpreted in a broader sense) along the REACH-adapted trajectories of a V-model approach (see, **Deliverable T6.1/D25**). As such, WP6 covers tasks related to a) subsequent system architecture coordination and iterative refinement, b) subsequent integration (including linked tasks such as modularization, standardization, and cross-integration), c) subsequent testing (exploration, usability, verification/ validation, etc.; including the generation of medical evidence regarding the impact of REACH's solutions), and subsequent system optimization.

In this context, WP6 was concerned up until now with the refinement of the Touchpoints and Engine concept (high-level system architecture, see **Figure 1-2**), the development of the REACH toolkit (practical low-level system implementation approach; see **Figure 1-3**), and the integration of REACH solutions into the "ecosystem" of each use case setting through Touchpoints in a system-of-systems approach (i.e. the insertion and adaptation of REACH systems/sub-systems into the four use case settings' existing systems; see **Section 1.1.4**).

As a continuation of **WP1**, **WP6** coordinates and verifies/validates the interplay of REACH's key system components. The case specific combination and integration of REACH's system components is guided by the previously developed REACH Sensing-Monitoring-Intervention work flow (REACH SMI-flow, see **Periodic Report No 1**). The SMI-flow provides cross-WP work flow schematics for setting specific co-adaptation and integration of the REACH system elements: early intervention goals (**WP6**), sensing elements (**WP2**), data collection and machine learning elements (**WP3**), motivation and intervention elements (**WP4**), smart furniture elements (**WP5**), personalization and acceptability schematics (**WP7**), and modular business model elements (**WP8**).

## 1.3 The Deliverable/ task in the context of WP6

The mission of this deliverable is to summarize the testing activities carried out thus far (primarily trial phases 1-3 and plans for trial phase 4; see **Table 1-7** for an overview of REACH's four trial phases), explain the underlying testing rationale and goals (testing covered a well-coordinated range of activities across the TPs ranging from usability/acceptability-oriented testing to tests designed to provide initial medical evidence for the impact of the developed solutions), and interpret its results. In order to attune this with the scope and resources available for REACH (it is impractical to test each Touchpoint with regard to its entire subsequent chain of early detection, motivational techniques, and provided interventions) as part of the initial project phase (see **Deliverables T1.4/D4** and **T6.1/D25**), the overall "testing system" was broken up into manageable "testing instances" (see **Table 1-8**).

**Table 1-7 The four major trial phases of REACH.**

Nature of trial phase	Trial phase	Locations	Description
	Test Period 1: Early testing (M1 - M24)	HUG, ZZ, Lyngby, SK	Qualitative testing of early mock-ups of sensors/equipment to develop requirements regarding acceptability, usability, early detection, and intervention regimes.
	Test Period 2: Pre-testing 1 (end of year 2)	Academic labs of TUM, TU/e, EPFL, and DTU	Testing in labs of academic partners, simulating various care environments.
	Test Period 3: Pre-testing 2 (year 3)	HUG, SK, ZZ, and Lyngby	Evaluate some selected SMI features in real world environments.
	Test Period 4: Continued testing and optimization (year 4)	Unstructured, real-world environments: Lyngby (lead) + HUG, SK, Tu/e/ZZ	Evaluate some selected SMI in real world environments – duration ranging from several hours up to eight weeks.

**Table 1-8 Concept for decomposition of testing approach**

Touchpoint		Testing Instances		
Name	Topic	Sensing and Early Detection	Motivational Techniques	Programmed Interventions
TP1 Personal Mobility Device	Frailty and risk of falls	Case specific hypotheses and study designs.	Case specific hypotheses and study designs.	Case specific hypotheses and study designs.
TP2 Active Environment	Mobility and rehabilitation	Case specific hypotheses and study designs.	Case specific hypotheses and study designs.	Case specific hypotheses and study designs.
TP3 Socializing and Nutrition	Social interaction and nutrition	Case specific hypotheses and study designs.	Case specific hypotheses and study designs.	Case specific hypotheses and study designs.
TP4 Gaming and Training	General physical and cognitive ability	Case specific hypotheses and study designs.	Case specific hypotheses and study designs.	Case specific hypotheses and study designs.
Engine related elements	Machine learning	Case specific hypotheses and study designs.	Case specific hypotheses and study designs.	Case specific hypotheses and study designs.

In this context, a key objective of REACH is to utilize in each Touchpoint a combination of wearable ambient sensors in combination with sophisticated analytics methods to detect the onset and changes of physical inactivity as early as possible. These methods form the basis for effective, personalized interventions that engage the elderly and increase their physical activity in a target-oriented manner to achieve its use-case-specific geriatric/medical goals. As such, REACH defined five early warning and detection dimensions in the 4 Touchpoints: one-off alarm (e.g. detection of sudden deviations such as a fall)

- 1) detection of short-term activities and patterns (over minutes and hours, capturing critical deviations from expected behaviour patterns such as skipping a visit to the toilet; long-lasting immobility).

- 2) long-term patterns (over days and weeks) including deviation from expected rehabilitation plan and its expected behaviours
- 3) device integrated automatic early assessment (e.g. device generated indicators from exercise sessions such as the capture by Playware Tiles of changes in physical ability, equivalent to a 6-minute walk test)

#### **1.4 Overview of contents presented in this Deliverable**

In this deliverable, we first (**Chapter 2**) introduce the detailed testing strategy of REACH, which detailed and took forward the above outlined conceptual provisions and responded to previous key reviewers' comments (R5 and R6, second review, November 2017) aimed at the improved emphasis of geriatric and medical aspects and their normalisation across Touchpoints and project activities. In reaction to these reviewer comments, REACH re-aligned some of its resources and formed a medical/geriatric task force (SK, HUG, DTU), which analyses and streamlines testing activities across TPs, clarified the common goals and measures and worked towards a normalisation of study design and tools used across the consortium. Based on this, in **Chapter 3**, we present our methodological approach with regard to testing and provide an overview and classification of all testing activities carried out in REACH. Accordingly, in **Chapter 4**, we present the results (documentation of the carried out testing activities), and in **Chapter 5**, we interpret the testing results. **Chapter 6** summarises the state of play regarding testing in REACH and outlines the next steps and upcoming activities. The **Appendix** contains the full trial reports sorted according to a variety of items.

## 2 Introduction - detailed testing strategy and medical goals, overall hypothesis, sub-hypotheses

In REACH, the concept of systematic, technology-based, and community-integrated, physical activation is the central target condition and theme cross testing instances (sensing and early detection, motivation and engagement, programmed exercises and interventions) and cross Touchpoints. Physical activity/inactivity is seen as a “primary” target condition impacting a broad array of “related” conditions that significantly determine health, functional ability, and independence of elderly people.

Multi-disciplinary testing was performed starting with explorative trials to test the sensors and equipment, developing into testing of (sub)systems and integration of technical aspects. This “hardware” based testing was accompanied by trials evaluating acceptance and motivational aspects. All partners developed expertise regarding ethical and data protection aspects and interchanged respective information.

### 2.1 The REACH target condition: physical activity

Specifically, REACH administered systematic, technology-based, and community-integrated physical activation enables:

- a) Increase of functional ability (in terms of ADLs, mobility, balance, walking speed, grip strength, etc.)
- b) increase of cardiac health and reduce risk of chronic diseases (e.g. cardiovascular diseases, diabetes, etc.) and mortality
- c) cognitive fitness and social participation (self-efficacy, less loneliness, etc.)
- d) general resilience (e.g. ability to regain health after hospital admission) and safety

The concept of systematic physical activation matters and is able to make a difference across the whole care continuum (early/late stages, levels and types of care, etc.) as well as in almost every community or use case setting in which elderly people in Europe may live. Through this broad impact, REACH contributes in a pro-active and preventative manner to both a) a healthier and more independent population of elderly in Europe and to b) the reduction of care, health care, and social cost associated with an ageing population.

In this context, the following challenges were addressed in the hypotheses of the trials:

- How reliable are the most likely sensor candidates and how may measurement data from the sensors become integrated into REACH?
- Are REACH components safe to users?
- Are REACH components/ approaches equal/ superior to standard interventions?
- What kinds of feedback/ system output/ support are motivating for the users?
- What kinds of motivational strategy work best for different users?
- Is there evidence that a REACH intervention will be accompanied by an enhanced level of physical activity outside of the intervention sessions?

- Is there evidence that REACH based intervention will improve the physical and functional ability (such as balance) of users?
- Which skills must users have to be able to use the REACH system?
- What kind of methods and data do we need to generate reliable algorithms?
- Will elderly users accept that their privacy is reduced when their activity is being watched over by care providers via sensors?
- How can we evaluate and identify evidence of potential and real medical gains to users of the REACH system?

To reflect the broad applicability of REACH's core concept of systematic physical activation, we demonstrated the integration of REACH toolkit elements into the ecosystems of a variety of country and care contexts (use case settings) through the REACH Touchpoints. As such, we developed both an overall REACH system level hypothesis as well as a sub-hypothesis for each Touchpoint.

## 2.2 Medical/geriatric goals and hypothesis for overall system and Touchpoints

### 1. Overall hypothesis for the REACH system and toolkit:

- The **REACH system** enables to early detect critical changes in physical activity of older adults (short-term and long-term changes), improve physical and functional ability of older adult users, strengthen their autonomy and capacity for independent living, by motivating them to improve (and maintain) physical and social-cognitive status and supporting a healthier life-style.

### 2. Sub-hypothesis for each Touchpoint:

- **TP1:** The REACH system enables older persons to prolong their time living independently through cost efficient, highly engaging, and safe community-integrated exercise technology. Specifically, the REACH system increases and maintains cardiopulmonary health (aerobic fitness), balance (and reduce risk of falls through target-oriented muscle strengthening activity), and cognitive fitness.
- **TP2:** The REACH system enables patients to reduce the duration of their hospitalisation, reduce decline after discharge, reduce risk of readmission, and be able to perform their ADL with reduced support from professional caregivers.
- **TP3:** The REACH system enables the elderly persons to improve their nutritional intake and their level of physical activity through social engagement and community participation.
- **TP4:** The REACH system enables early detection of critical changes in physical activity of older adults, either short-term or long-term changes, and supports increased physical activity through individualised motivational strategies and playful social or solitary activities.

## 2.3 Categories of Early Detection (CEDs)

The evaluations of these hypotheses are highly dependent on early detection of decline (sensing), measurement of relevant parameters (monitoring), and personalized feedback to prevent further decline or critical events (intervention). These core elements of the analyses are in turn based on the validity of the algorithms and the pre-determined thresholds.

In this context REACH has defined 4 core **Categories of Early Detection (CEDs)** which it is considering cross sectionally in all four Touchpoints:

- **CED1:** Sudden unexpected critical change in activity (e.g. a fall, not getting out of bed in the morning)
- **CED2:** Shorter-term unexpected deviation (skipping visits to kitchen/toilet, remaining for hours in bathroom, etc.)
- **CED3:** Longer-term changing trends of personalised activity (getting up later and later, increasingly frequent visits to bathroom, remaining indoors all day/for consecutive days, etc.)
- **CED3:** Deviations from expected patterns of activity during rehabilitation (e.g. after hospitalisation and subsequent expected recovery at home)

## 2.4 Roadmap for and standardisation of testing cross Touchpoints

In order to develop a holistic REACH concept which generates quantifiable values, it is necessary to follow a standardised and yet adaptable roadmap covering testing and outcomes of all use cases and touchpoints. REACH is intended to influence physiological processes and the physical, mental and cognitive status of its users. Therefore, the impact has to be measured in medical outcomes which in turn directly affects the selection of the assessments (see chapter 3 and 4).

The value of the system itself and its impact can only be assessed with comparable data over all test scenarios on a European level. Therefore, the changes induced by the REACH system (based on the outcomes of each of the trials) will be translated into and measured by using relevant units, e. g., cost savings, steps per day, independence level (**European Commission: MAFEIP**) in a next step.

To standardise the assessments and introduce medical outcome parameters, SK consulted all use case settings and Touchpoints (May 2018 Lyngby/ DTU, August 2018 HUG and ZZ/ TU/e). During the meetings, critical aspects were discussed, e. g., clinically relevant changes, the documentation of concomitant medication, differences between symptoms and diagnoses, translation from conditions into medical terms. Also, chances and obstacles regarding the implementation of the trials are considered important for all trial partners.

DTU together with SK designed a common database to collect key data of all experimental REACH trials. This has facilitated comparison across trials, providing a basis for analysis and identifying commonalities and differences in terms of test objectives,

methods, materials, demographics and outcomes, benefitting overview and each of the consortium members (see **Appendix 1 and 2**). In addition, this overview serves to inform further system development/optimisation as well as the design of the final studies of the project.

In this context, a special focus was set on the selection, specification, and use of assessments, able to optimally capture the target conditions. The individual characteristics of the Touchpoints (and use case settings and their related environmental circumstances) have to be taken into consideration (e. g., an elderly person in a rehabilitation facility may only have limited ADL capabilities, and physical performance of bedridden patients cannot be tested for balance, etc.). As such, superordinate assessments to understand and classify the health status/ behaviour patterns of the user over all trials were defined, e. g. hand grip strength for frailty (**Allen & Barnett, 2011**), 6m-walking test for mobility (**Enright et al., 1998**), BBS (**Berg et al., 1995; Stevenson, 2001; Scherfer et al., 2006**) for risk of falling (see **Chapter 3**).

### 3 Methodology – Overview and classification of all testing activities carried out in REACH

The complexity of the overall REACH goal/hypothesis can't be tested in one single activity. The complexity of the REACH project requires a subdivision of the overall goal in single sub-goals which can then be tested in separate testing activities. In the framework of REACH, 23 testing activities (trials, studies) have been performed. These testing activities can be classified according to different relevant aspects. Classifications can, for example, be performed to illustrate the assignment to the different touchpoints or different testing instances (see **Figure 3-1** on the next page).

A classification of the testing activities can also be performed to highlight a methodological aspect of the trial, i.e., the type of trials. The description of the trial type includes, on the one hand, the level of evidence that has been reached by means of the study design and, on the other hand, includes a description of the trial content, i.e. whether the trial has a validation, exploration, or feasibility character to address the REACH system. To increase the clarity for the level-of-evidence classification, the trials were categorised into three different subgroups, i.e., reviews/ randomised controlled trials (RCTs), observational/ non-randomised experimental trials, and case series/ single case trials. From the 23 trials that have been performed, six are classified with the highest level of evidence, 13 are observational or non-randomised experimental trials and four are case reports or case series.

In validation studies the extent to which a concept, conclusion or measurement is well-founded is investigated and likely corresponds accurately to the real world based on probability. Exploratory trials are linked to real world activities and problems. They gather preliminary information that help to define problems and suggest hypotheses. In feasibility studies, the practicality of the proposed testing activity or system is evaluated. Separating the REACH trials into these three categories, six can be categorized as validation, one as exploratory and seven as feasibility trials.

The attribution of each trial to one of the four REACH Touchpoints (TP) is another piece of important information to highlight, showing that each touchpoint is addressed adequately in the testing activities. A detailed description is listed under the respective subheadings. Overall, a total of eight studies have been performed addressing both **TP2** and **TP4**, four have been performed indicating **TP3** and three can be categorised under **TP1**.

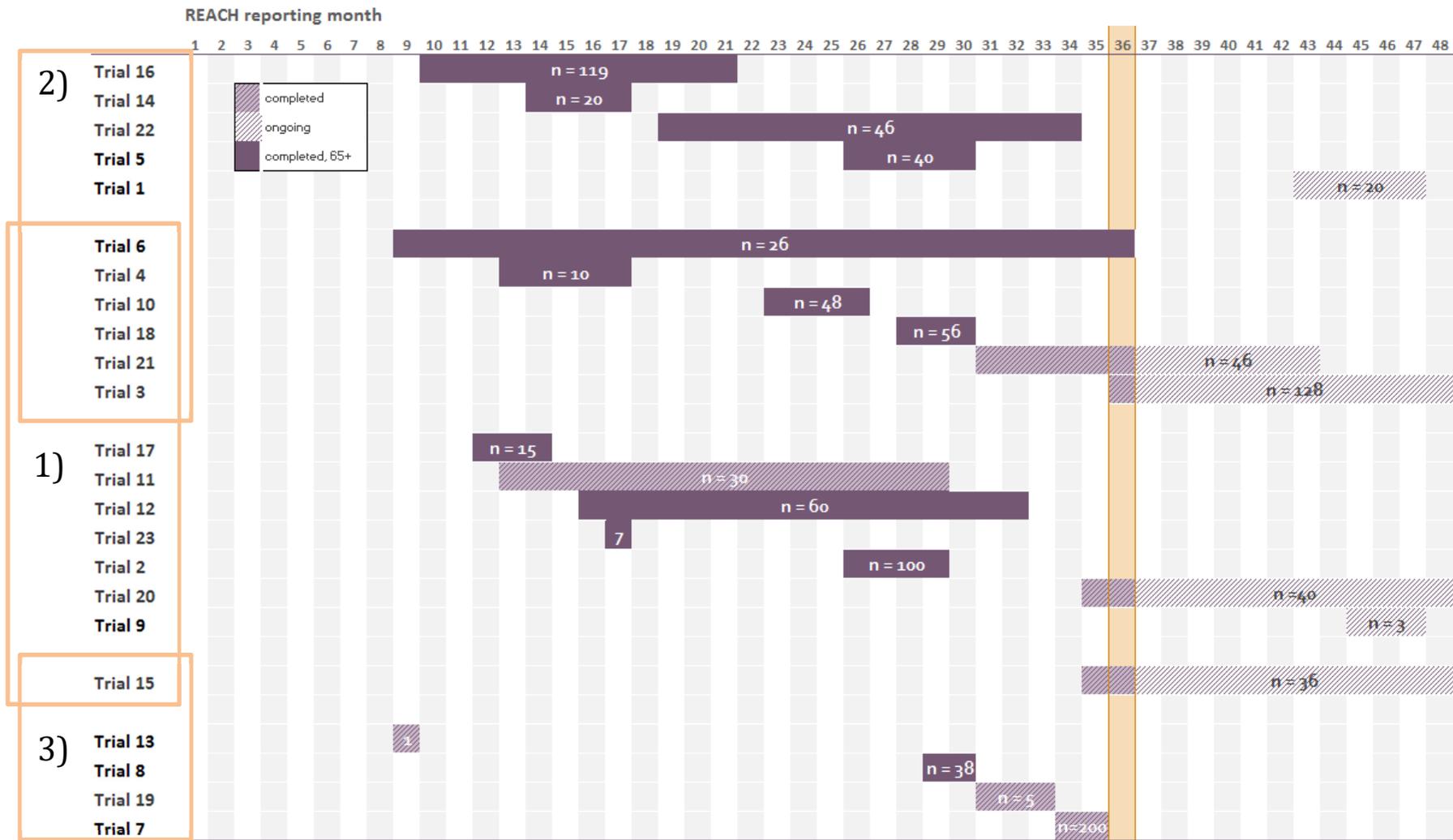
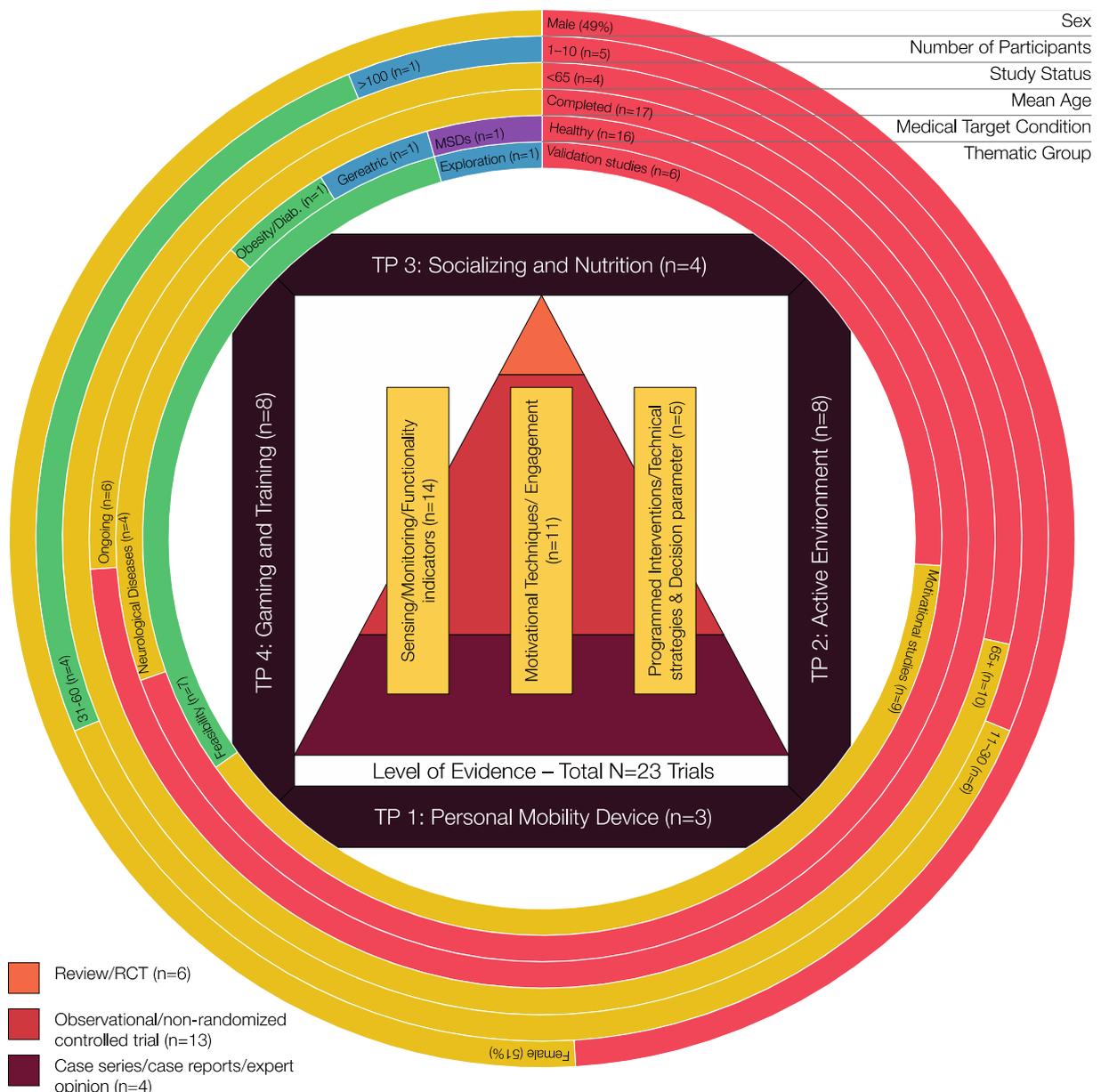


Figure 3-1 Timeline for all testing activities (trials) performed within REACH. The order of the testing activities shows the affiliation of each trial to one of the 3 system instances: 1) Sensing and Early Detection, 2) Motivational Techniques, and 3) Programmed Interventions. The dark purple bars present those trials that have been performed for the REACH target population (age 65+), and the light purple indicate those performed with younger adults. Ongoing trials are those on the right of the current reporting month 36.

A graphical overview of the above stated aspects on methodological classifications is given in **Figure 3-2**. In addition, the figure also highlights the information on methodological aspects like

- the age group addressed in the specific trials, whether it is the REACH focus group of adults 65+ (n=10) or younger (n=4);
- the proportion of female and male participants in the completed trials, showing a nearly equal number for both sexes, i.e., 49% of participants were male and 51% female; or
- the medical condition investigated within the trials, whether healthy subjects, patients with diabetes, orthopaedic, and neurological diseases were included.



**Figure 3-2 Overview of all testing activities (trials) performed within REACH. Descriptive analyses for several classification aspects are displayed, including the allocation of each trial to one of the touchpoints, the level of evidence or the system instances. Accordingly, micro-methodological decisions fundamental to the REACH overall goal are highlighted in the rings which is the age of the investigated participants, the proportion of female and male participants and the medical target condition that was addressed.**

## 4 Results - Documentation of the carried-out testing activities and their outcomes

A total of 23 respondents are collected via survey monkey which reflected the structured protocol outlined in Chapter 3. Overall, all 23 testing instances aim to solve the problems of caring for the ageing European population.

Based on the purpose of each testing instances, we have divided the 23 testing instances into 4 thematic groups:

1. Validation studies (*Analytics/ Software and Algorithms + clinical validity*)
2. Motivational studies (activation + socialising and nutritional interventions)
3. Feasibility (*functionality, safety and feasibility assessment*)
4. Exploration (e.g. nutritional)

For each Touchpoint, separate testing instances were created and each of these testing instances represents a separate trial with its own aim, outcome measures and an in-stance specific trial design. Overall, the aims of all 23 testing instances is to develop sensing monitoring intervention systems that can be place in various care settings and living environments of older adults. An overview of 23 multidisciplinary testing in-stances are summarised and key points and outcomes were extracted (see **Table 4-1** each testing and its' results ).

As it is described in **Table 4-1** each testing and its' results the testing instances uses different strategies (e.g. 1) set of sensors to detect health status and behaviour pattern, 2) motivational strategies and set of customised products and services with overall aim of promoting physical activity and 3) validation and safety assessment tests to improve the quality of available devices).

Table 4-1 Each testing and its' results

#	Trials	Aims	Study design	Results
1	<b>Mirana Bot</b>	Health behaviour change/ acceptance and adoption of the personalised and timely recommendation given by the conversational agent.	Crossover trial	No results available yet
2	<b>CPH 1-Criterion validity</b>	Comparison of wearables	Validation	All hip-worn PAMs fulfilled the a priori hypothesised moderate criterion validity evaluating all participants. The hip-worn Garmin Vivofit 3 fulfilled the a priori hypothesised criterion validities evaluating all participants, participants with rollator and participants without rollators. None of the wrist-worn PAMs fulfilled the a priori hypothesised criterion validity for any of the three participant groups.
3	<b>CPH 2 -The MIPAM trial</b>	Effect of bi-weekly motivational interviews	RCT	No results available yet
4	<b>Lyngby 2</b>	Test of Moto Tiles and sensors	Pilot-feasibility	Timed up and go: A mean improvement of 1.43 seconds in the test from pre-to post testing. The improvement is between -0.16 and 3.02 seconds. 6MWT: A mean difference of -33.3 meters, in the test from pre-to post testing.

#	Trials	Aims	Study design	Results
				The 95% confidence interval shows that the improvement is between -68.8 and 2.23 meters. Chair stand test: A mean difference of -1.44 stands in the test from pre-to post testing. The 95% confidence interval shows that the improvement is between -2.54 and -0.35 stands. Bergs balance scale: A mean difference of -11.22 points in the test from pre-to post testing. The 95% confidence interval shows that the improvement is between -17.42 and -5.03 point.
5	<b>Lyngby 3</b>	Effect of training with moto tiles (gaming)	RCT	Both groups had an increase in their BBS. Training group: increase of 5,0 points; Control group increase of 2,1 points in their BBS (p=0,11; anova). 30 second chair stand test, both groups had a decrease in number of stands; Training group -1.3 stands, control group -1.4 stands, p = 0.96. 6mwt: 14 people in each group. Training group: mean increase of 19 meters; control group 5 meters p = 0.75
6	<b>Lyngby 1</b>	Effect of providing daily feedback on physical activity level	Crossover trial	Difference between time participants received feedback on steps and the time with no feedback: The mean difference between the two conditions of trials is 181,18 with a standard deviation of 1093,25 and 95% confidence intervals of -303,54 to 665,90 steps. P=.44 indicates no statistically significant mean difference between the mean of two related groups.
7	<b>Body &amp; Brain Test with the Moto Tiles</b>	Validate the reliability of the Moto Tile timing of the chosen balance tests	Validation	No results available yet
8	<b>Lyngby 4</b>	Validate the reliability of the developed for algorithms for sens sensor	Validation	No results available yet
9	<b>Lyngby 5</b>	Likelihood and acceptability of smart homes	Pilot-feasibility	No results available yet
10	<b>activLife Test</b>	The effect of activLife	Pilot-feasibility	Active life training seems to have a clear contribution to the 4-stage balance skill. Both interventions contribute to the 30 second chair stand results activLife training apparently does not sufficiently contribute to Tinette Balance skill.
11	<b>Smart Cardia 1 - Healthy Volunteer Testing</b>	Validate the smart cardia wearable sensors for safety, usability	Pilot study; validity/ feasibility study	Smart Cardia sensors could measure the vital signs with the same accuracy as the ICU monitor under different activity conditions.
12	<b>Smart Cardia - CardioCentro Lugano</b>	Validate the smart cardia wearable sensors for safety, usability	Pilot study; validity/ feasibility study	Smart Cardia sensors meet the accuracy of ICU monitors for vital signs monitoring, at ISO standards (95% confidence level).
13	<b>Coffee Demonstrator</b>	The effect of coffee	Explorative	Coffee drinking had no systematic effect on the heart rate levels.

#	Trials	Aims	Study design	Results
14	<b>Geneva: In-situ study</b>	Motivation to behaviour change	Cohort study	Identified opportunities and challenges for older adults to adopt sensors and application for health / potential of acceptance and adoption of simple and manageable technology for behaviour change.
15	<b>Schön Klinik 2-Activity recognition</b>	Generating and collecting health data to support the development of machine learning algorithms for Reach Engine	Pilot-feasibility	No results available yet
16	<b>TU/e 1- Personalised persuasive strategies</b>	Strategies to increase activity level	Pilot feasibility	Analysed the persuasive strategies used and identified different value propositions each student concept used. "Value cluster"; Social Fitness, Improved Care, Prize, Self-awareness and Fun.
17	<b>HUG early testing</b>	Safety and functionality assessment of iStander mobility	Pilot: Safety, validity and functionality	Care-givers and patients appreciated the ease and comfort of use. The use of Fitbit also promoted patient empowerment. However, the wrist-band was reported as difficult to adapt. A suggested improvement was the addition of an alert in case of high or irregular heart rate.
18	<b>REACH Eindhoven Continued testing</b>	The effect of personalised motivational strategies	Feasibility	No results available yet
19	<b>Workshop Touchpoint 2</b>	Data collection through a workshop to support machine learning algorithms	Non-randomised	Initial Data Collection for the Machine Learning Algorithms, Properly Synchronising and Annotating Data, Setting the initial stepping stone for the ethics application at SK, trial sensor integration and implementation at br2
20	<b>activLife 2- The Transfer- and Training Device</b>	Test of activLife with neurological patients	Pilot study; usability/ feasibility study	No results available yet
21	<b>Geneva 2 - Personal mobility device</b>	Gamification (Kinect)	RCT	No results available yet
22	<b>ZZ; Lyngby; BZN- Motivational aspects for food intake</b>	Influence of food intake on older adults' mood	Explorative	Social context has a strong influence on the eating behaviour. Texture modified food (smoothfood) is able to be a motivational aspect to eating behaviour of elderly people
23	<b>Schön Klinik 1 - SmartCardia &amp; standard Holter system</b>	Evaluating the functionality of smart cardia sensors by comparing with ECG and motion data	Pilot: Feasibility and usability	No results available yet

To ensure the quality of charts and tables, we decided to use short titles for each testing instance. **Table 4-2** is an overview of the testing instances' original title (from survey monkey) and short title specified by us.

**Table 4-2 an overview of the original titles of trials and their short titles**

#	Original titles	Short titles
1	Mirana: A conversational agent with a hybrid user interface to promote healthy eating	Mirana BUTT
2	Criterion validity for step counting in four consumer-grade physical activity monitors among 103 older adults with and without rollators	CPH 1 – Criterion validity
3	The MIPAM trial: A 12-week intervention with motivational interviewing and physical activity monitoring, to enhance the daily amount of physical activity in community dwelling older adults – a randomised controlled trial	CPH 2 –The MIPAM trial
4	Lyngby 2: Feasibility study conducted in preparation of the planned Lyngby	Lyngby 2
5	Lyngby 3: The effect of playware technologies on physical activity	Lyngby 3
6	Lyngby 1: Effect of daily feedback on older adults' physical activity level	Lyngby 1
7	Playful Body and Brain Test with the Moto Tiles	Playful Body and Brain Test
8	Lyngby 4: Developing a reliable technique for automatic counting of steps of older adults – a validation study	Lyngby 4
9	Lyngby 5 Trial: Test of smart home technologies	Lyngby 5
10	ActivLife Test	activLife Test
11	SmartCardia – Healthy Volunteer Testing	SmartCardia 1 – Healthy Volunteer Testing
12	SmartCardia – Patient testing at CardioCentro Lugano	SmartCardia – CardioCentro Lugano
13	Coffee Demonstrator	Coffee Demonstrator
14	Opportunities and challenges for self-monitoring technologies for healthy ageing: An in-situ study	Geneva: In-situ study
15	Activity recognition with wearables and ambient sensors - gathering of data sets for the empirical validation with neurological patients	Schön Klinik 2 – Activity recognition
16	Towards personalised persuasive strategies for active ageing	TU/e 1- Towards personalised persuasive strategies
17	HUG early testing	HUG early testing
18	REACH Eindhoven Continued testing	REACH Eindhoven Continued testing
19	Data Collection and Annotation Workshop Touchpoint 2	Workshop Touchpoint 2
20	The Transfer- and Training Device activLife with neurological patients. Feasibility und Usability Study	activLife 2 – The Transfer- und Training Device
21	A personal mobility device for elderly physical rehabilitation: a study of acceptance and efficiency	Geneva 2 – A personal mobility device
22	Questionnaire for the investigation of motivational aspects for food intake by elderly people / [...] by dysphagia patients	ZZ; Lyngby; BZN- Motivational aspects for food intake
23	Feasibility study - SmartCardia sensors with standard Holter system and activePal sensors	Schön Klinik 1 – SmartCardia, standard Holter system

The requested structured protocols are included in full length in the Appendix of this Deliverable (see **Appendix 2**)

## 5 Discussion - Interpretation of the testing results and outcomes

In this chapter, we discuss and interpret the results and outcomes of the 23 testing instances. First, we discuss these testing instances results based on techniques for implementing the REACH objective. Next, we present descriptive analysis of testing instances. Due to the ageing societies in Europe and the limited resources in the health care system, the goals of the REACH project are highly relevant to support the elderly citizens in living at home independently for as long as possible, enhancing their health status and avoid institutionalisation. The goals of the testing strategy were selected to scientifically prove the validity, feasibility and acceptability of the system components, to choose the most effective motivation methods, overcome technical obstacles, support the design of REACH devices and protect patients' rights.

In the chapter "Introduction", the scientific questions were listed and the hypothesis of each TP was defined. The testing activities addressed these scientific questions and laid the groundwork for ongoing testing with more complex system components. An important achievement was that technical partners have to be included at the very beginning (trial design phase) to ensure data quality and usability for algorithm development.

Furthermore, the acceptance of elderly citizens regarding technological equipment has to be set into the focus of the testing. Although most trials focused on validity and users' perspective, a development to RCTs to evaluate impact has to be performed in the future.

Taken altogether, the testing actions already performed contributed to a user-centred development of devices and, based on the existing outcomes, allows an even more focused testing which addresses the core issues. The future testing activities will also strictly follow this roadmap.

### 5.1 Comparison and discussion

The questionnaires were developed and carried out in order to provide insights into each testing instance and its outcomes. As mentioned earlier, the 23 testing instances are categorised into four thematic groups. The following section is a comparison of each thematic group.

#### 5.1.1 Validation studies (Analytics/ Software and Algorithms + clinical validity)

Six out of 23 trials are categorised as validation studies (see **Figure 5-1**). The main objective of validation studies is to test the clinical validation of personal mobility and wearable devices. Each trial aims to test and analyse the needs and direction for further improvement of a specific device. These trials belong to **TP2** (Active environment) and **TP4** (Gaming & training) (see also **Figure 5-2**). The data focus is mostly on accurately measuring heart rate, activity level or numbers of steps. The sample size of validation studies varies from seven to 200 participants [min age 4 and max age 94] (see **Figure 5-4**). Overall, the mean age is 72 (see **Figure 5-5**). Five out of the above-

mentioned studies' data collection process is completed but two of out the five are still working on analysing the results. One is planned to be conducted in 2019 (see also **Table 5-1**). The inclusion criteria were identical for two trials; the participating criteria was community-dwelling (living at home). However, four trials involved younger participants too. The health/ ambulatory status criteria for validation of smart cardia sensors were different; they included patients suffering from CVD with an emphasis on Cardiovascular diseases and Patients with Minor Hemodynamic Instability after Cardiac Surgery or after Invasive Cardiac Intervention

#### 5.1.2 *Motivational studies (activation + socialising and Nutritional interventions)*

Nine of the 23 trials are categorised as motivational studies, since the focus of the trials is on behaviour change strategies to promote healthy ageing (see **Figure 5-1****Fehler! Verweisquelle konnte nicht gefunden werden.**) e.g. strategies to motivate older adults to become physically active. The motivational strategies correspond to providing feedback and gaming. Five out of nine above-mentioned trials are completed, versus four of the trials that are planned to be completed in 2019. The sample size varies from 18 to 60 participants [min age 47 and max age 94] (see **Figure 5-4**). The mean age of the completed trials is between 84 and 88 and one of the trials have younger participants with a mean age of 64.4 (see **Figure 5-5**). The study designs vary from RCT to cross over and feasibility studies. Three of the trials correspond to **TP4** (Gaming & Training), four of trials correspond to **TP3** (Socialising & Nutritional Intervention), one to **TP2** (Active Environment) and one to **TP1** (Personal Mobility Device) (see also **Figure 5-2**). The inclusion criteria were identical in almost all of the nine trials.

#### 5.1.3 *Feasibility (functionality, safety and feasibility assessment)*

Seven out of 23 trials are categorised as usability and Safety assessment trials (see **Figure 5-1**). The main objective of feasibility studies is to evaluate the logistic, functionality, usability and safety of the devices. The testing of the equipment is conducted to analysis the needs and direction for further development of the devices so that it can be an accurate and efficient tool for promoting daily physical activity. All trials are designed as pilot feasibility studies. Two of the trials belong to **TP4** (Gaming & Training), three are associated with **TP2** (Active Environment) and two to **TP1** (Personal Mobility Device) (see also **Figure 5-2**). The inclusion criteria were identical for almost all of the trials. Five of the studies have already been conducted and two are planned to be conducted in 2019 (see also **Table 5-1**). The data collection is based on the activity of daily living; hereby the data focus is on number of steps, and heart rate pressure data video recordings and interviews.

#### 5.1.4 *Exploration (Nutritional)*

One out of the 23 trails is categorised as an exploration study (see **Figure 5-1**). The researcher wanted to explore the effect of coffee on heart rate by collecting movement data and heart rate via Fitbit tracker. The sample was based on one-person aged 38. The study corresponds to **TP2** (Active environment) (see also **Figure 5-2**). The study is completed, and it appears that coffee had no effect on heart rate level.

### The proportion trials divided into themes

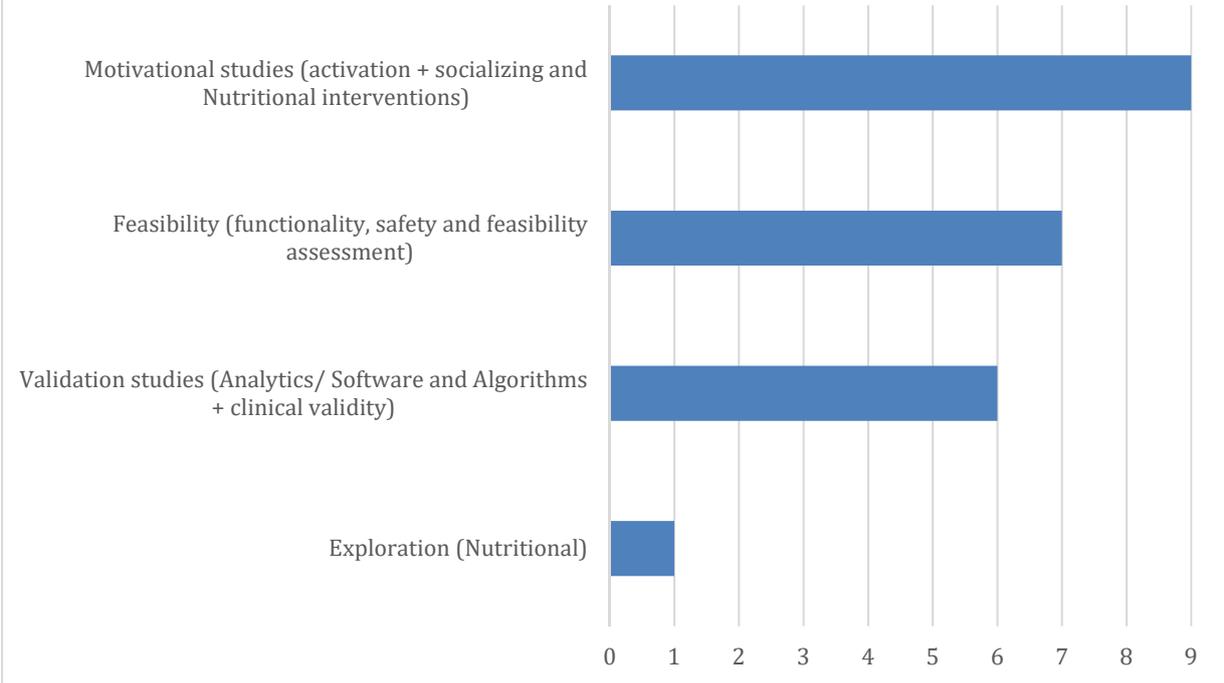


Figure 5-1 The proportion trials divided into themes

### The distribution of 23 trials across touchpoints

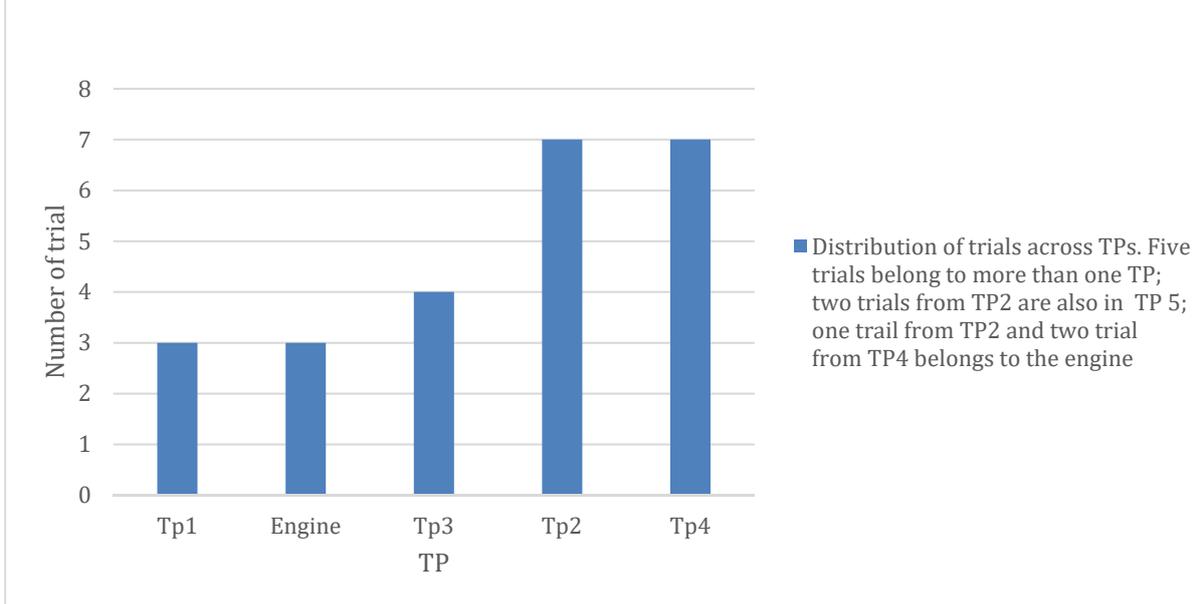


Figure 5-2 The distribution of 23 trials across touchpoints

Table 5-1 The proportion of completed trials vs "planned to perform"

	Number of trials	%
Completed	17	73,95 %
Planned to perform in 2019	6	26,1 %

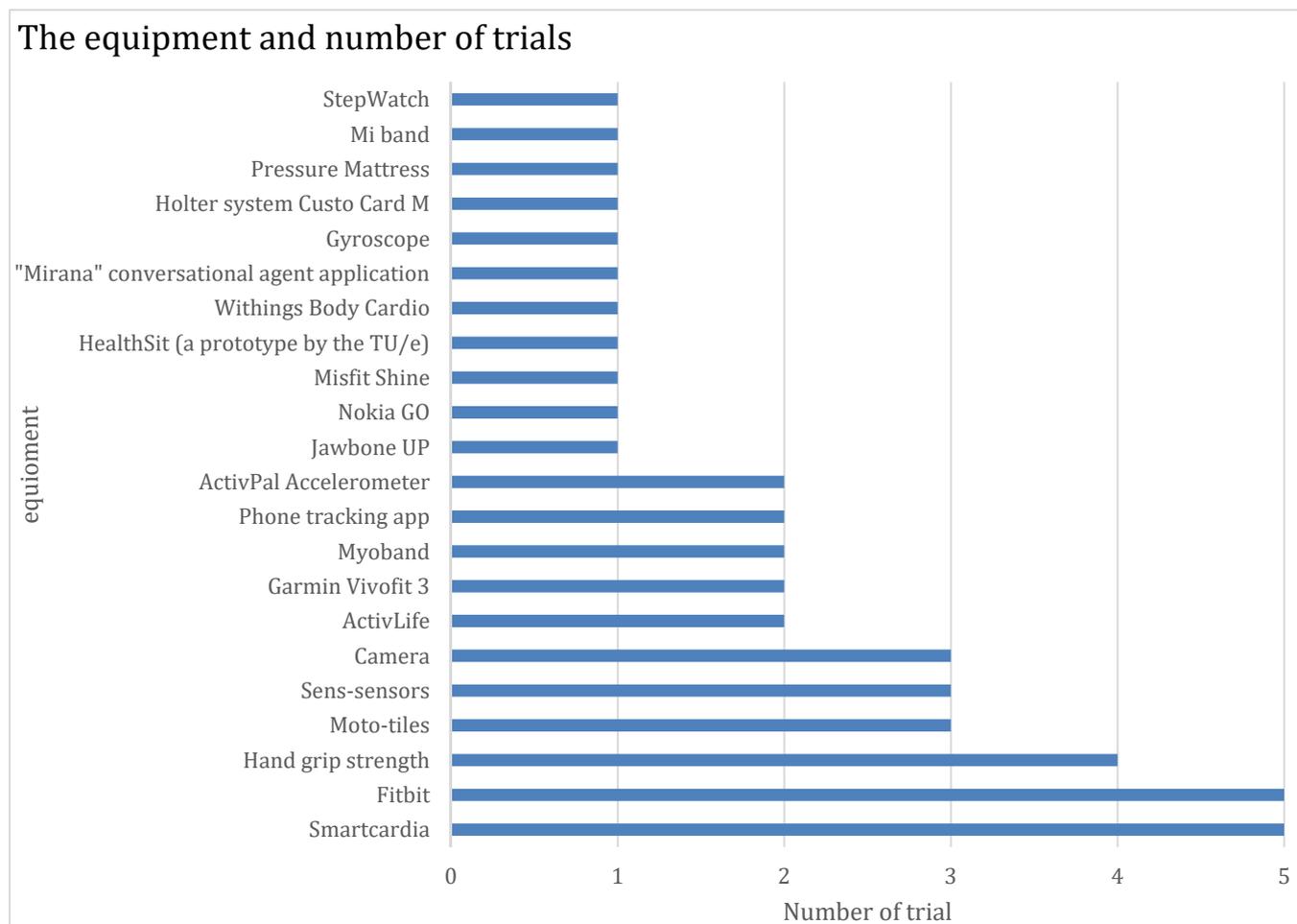


Figure 5-3 The equipment and number of trials

Table 5-2 Trials based on power analysis

	Number of trials	%
Yes	8	34,78 %
No	15	65,22 %

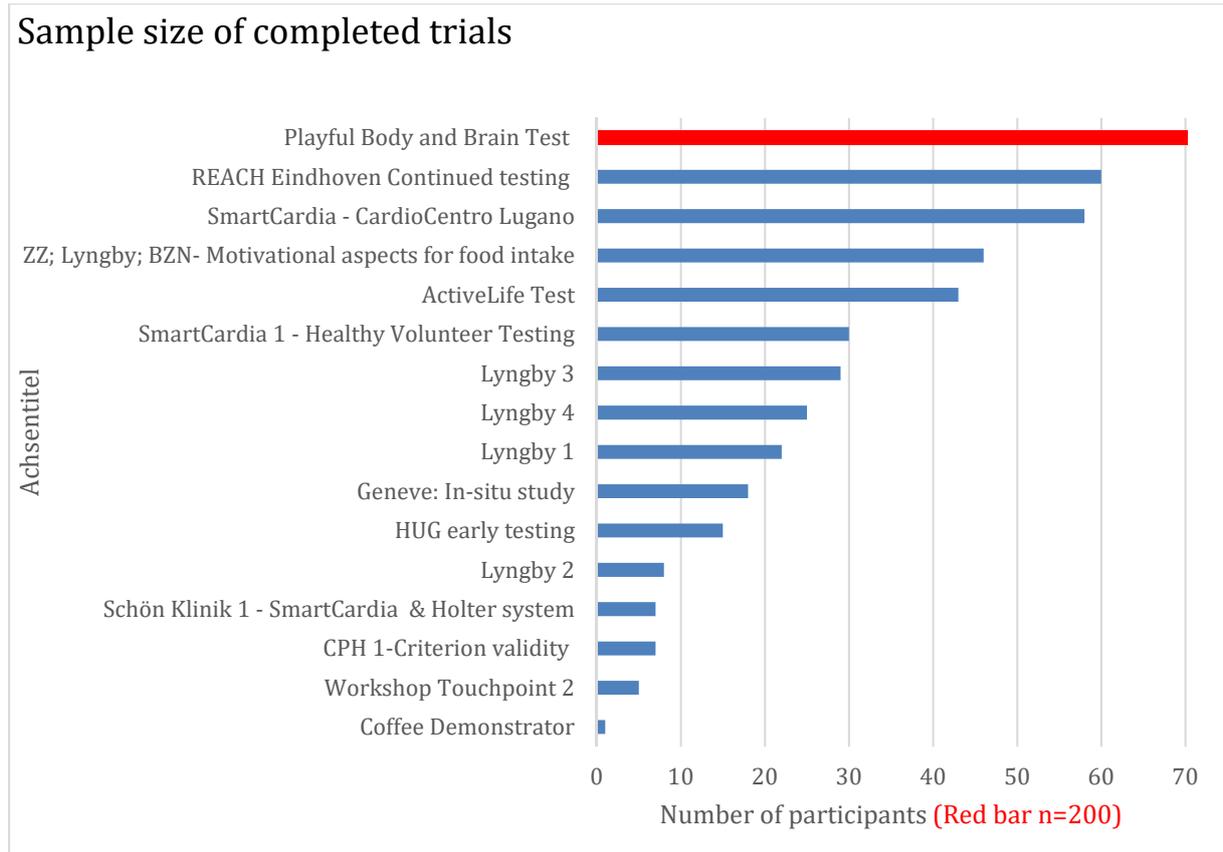


Figure 5-4 Sample size of completed trials

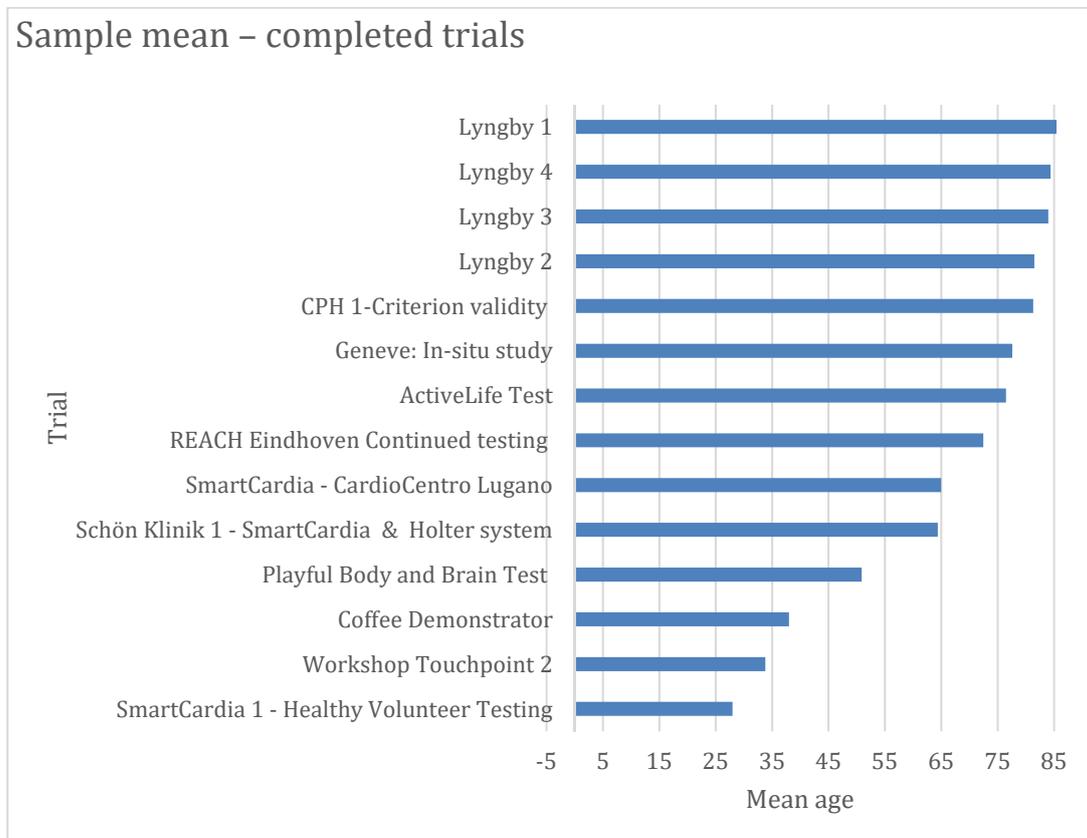
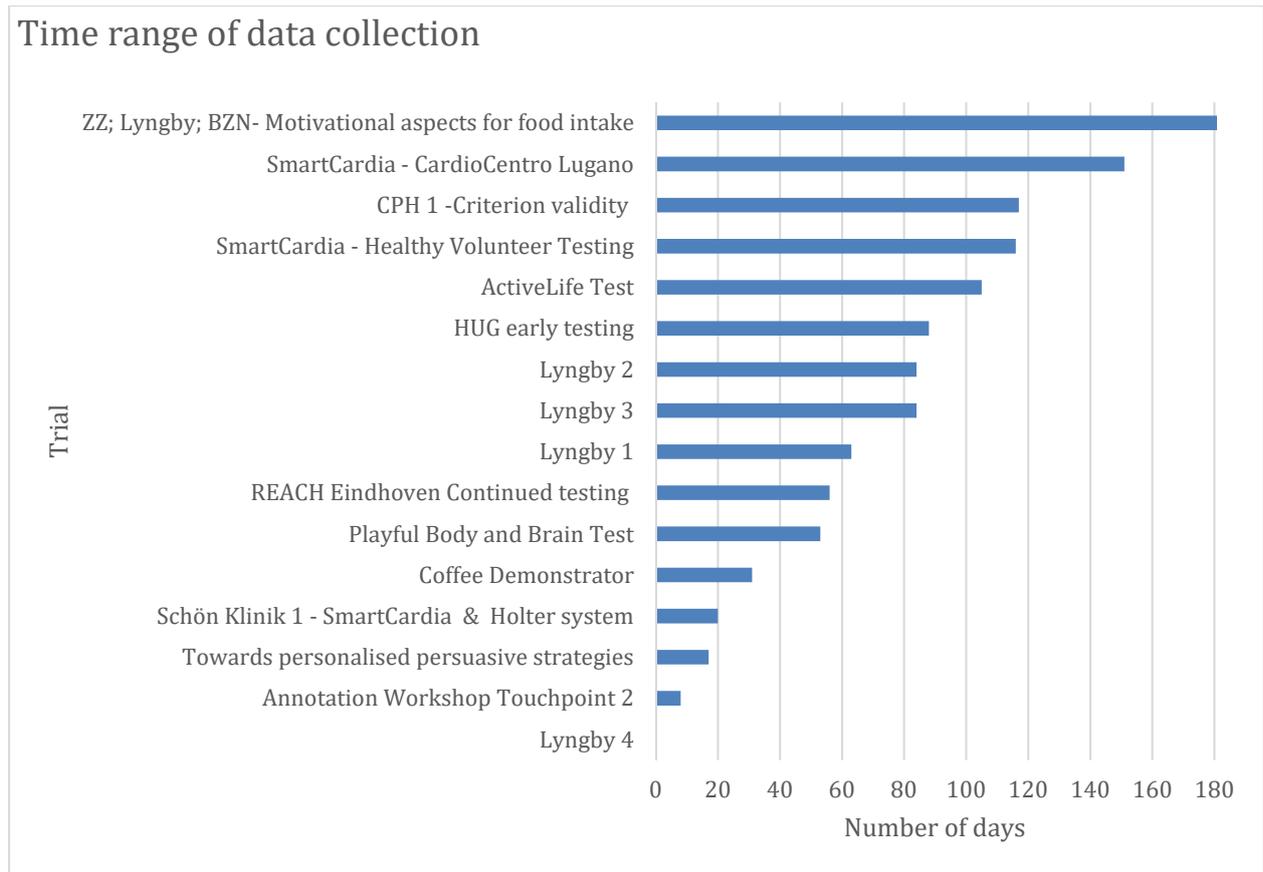
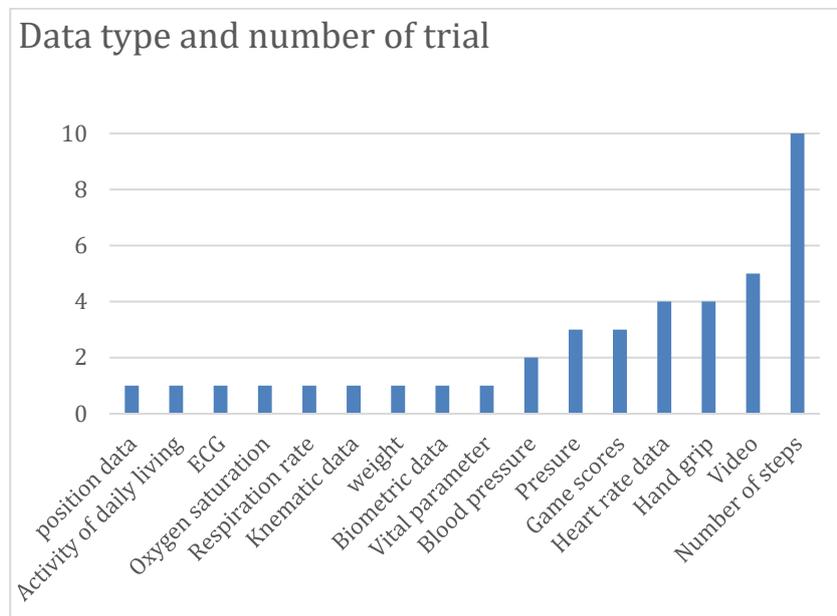


Figure 5-5 Sample mean – completed trials



**Figure 5-6 Time range of data collection**

Data collection: This chart is based on the answers for Q15: Time range of data collection period: Start: Begin data collection End. (The intervention times are unknown)



**Figure 5-7 Data type and number of trials**

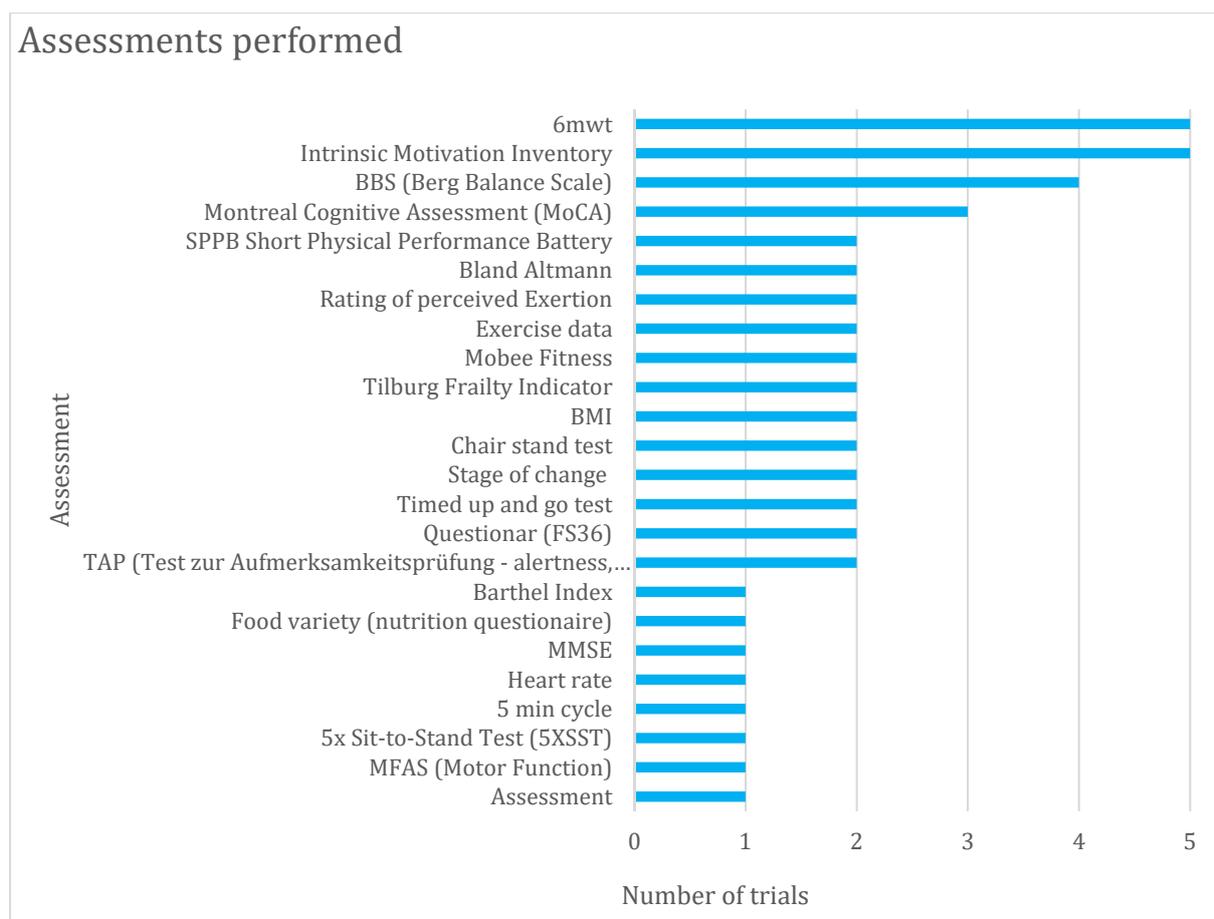


Figure 5-8 Assessments performed

## 5.2 Strengths and weaknesses of the results

Due to the complex environment of the REACH testing, multiple factors influence the results, both positive and negative, that have to be considered.

For all REACH testing sites, the first and utmost concern was the protection of the wellbeing and rights of the participants. When required by law, ethical approval was obtained and participants gave written informed consent for the participation. In trials with personalised and pseudonymised data, all participants signed a data protection approval. Trials were performed in conformity with GDPR and ethical regulations.

The REACH system is designed to fit in several different settings (use cases) which leads to a high level of complexity. Use case specific requirements and specific characteristics could in its variety not be covered by central testing. Due to decentralised trial centres, the system components and methods were tested in real environment settings. The test results are highly specific for the respective use cases, but also have general validity for the REACH system. The cooperation and data exchange between the test partners is intense and continuous.

Most trials included participants who fulfil the criteria of the intended end-users as defined in deliverable 1 (see chapter 3). The decision to include younger participants was triggered by ethical considerations. Some strenuous procedures should be tested in

younger adults to estimate the real burden and feasibility without involvement of the more vulnerable elderly or patients.

Motivation and acceptance were central research subjects. Therefore, the results are not only focused on physical outcomes, but they also aim to enlighten the impact on the overall quality of life. The data obtained are useful to define the target user group more precisely. The results were influenced by the limitations which occurred during the testing. In the following table, these events, as considered by the trial experts, are listed together with proposed solutions for the upcoming testing:

**Table 5-3 Listed limitations results and proposed solutions for the upcoming testing**

Limitation(s)	Effect(s)	Possible solution(s)
Unreliable sensor - Incorrect algorithm design - Synchronisation problems - Unreliable measurements - Unstable power supply	Missing data/ data loss/ limited sensor selection	Extensive evaluation of sensors/ contact to other institutions which already have experience with the sensors/ literature research
Access to (raw) data denied by manufacturer	Missing data/ limited sensor selection	Contract with manufacturer before sensor selection
Data protection issues - Data flow not transparent - Data storage/ processing outside EU	Ethical denial of trial/ non-compliance with GDPR/ risk of infringement	Extensive evaluation of data flow process/ contact to manufacturer/ involvement of data protection specialists
Exclusion of participating centres	Reduced sample size/ tedious recruiting/ prolonged duration	Thorough check of possible test sites before start of trial
Overly strict in- and exclusion criteria	Reduced sample size/ tedious recruiting/ prolonged duration	1. Realistic calculation of available participants based on existing data in combination with prognostic factors. 2. Application of in- and exclusion criteria and, if necessary, adaptation on existing profiles of participants
Challenging test procedures - Completion of patient logs - Complex questionnaires - Strenuous test scenarios	Drop-outs/ overstrained participants/ reduced sample size/ tedious recruitment/ prolonged duration	Consideration of physical, cognitive, and mental limitations of REACH users 65+/ patients
Bias in self-reported outcome measurements	Invalid data/ data conflicts	Consideration of deviation/ objective monitoring
Ceiling/ ground effects	Reduced sensitivity to change	Verification of which assessment is appropriate for participants
Level of staff experience	Unreliable data/ dissatisfaction on side of participants/ protocol deviations	Exact instructions, extensive training of study staff with quality control, provide in-depth information about strategies and methods

Apart from the above listed restrictions, excellent results with meaningful data had been obtained from the REACH testing partners (see outcome part in **Appendix 2**).

## 6 Summary and Conclusion - Lessons learned, next steps, exploitation opportunities, project impact

In REACH, our goal is to improve some aspect of the user's wellbeing by triggering an external event (intervention) which is suitable to have positive causal impact on the patient. The intervention has to be personalised to be effective because REACH users have diverse requirements, are varying in health status and live in different environments. Those interventions will be generated based on outcome data from trials. Therefore, during the design phase, the targeted condition has to be taken into account. Guidance on how to perform experimental designs with focus on data quality is shown in D6 (pgs. 99 et sq.).

Another important goal in our project is to generate two kinds of datasets, the first to generate algorithms which can be applied to REACH users, the second to train the algorithms and enhance and refine the interventions with machine learning methods (Roggen et al., 2010). The technical approach will develop from gathering data sets allowing machine learning in proof of concept trials regarding recognition validity, system generated interventions and impact values. During the ongoing testing activities, an extension of the data base to stabilise algorithm structures and system outcomes is planned.

Since the first period of testing activities has been performed with focus on feasibility, reliability, sensor-selection, motivation and engagement, and acceptability, the shift now turns to collecting data for the algorithm design. The technical partners participated already in the past but will have a more central role in the future testing to secure high-quality data and give guidelines to the test partners. As an example, FIAIS designed (as part of **Deliverables D9 and D11 on data analytics and Machine Learning**) a simple and universally applicable checklist about important questions before start of the design process:

Designing a use case requires the answer to the following questions:

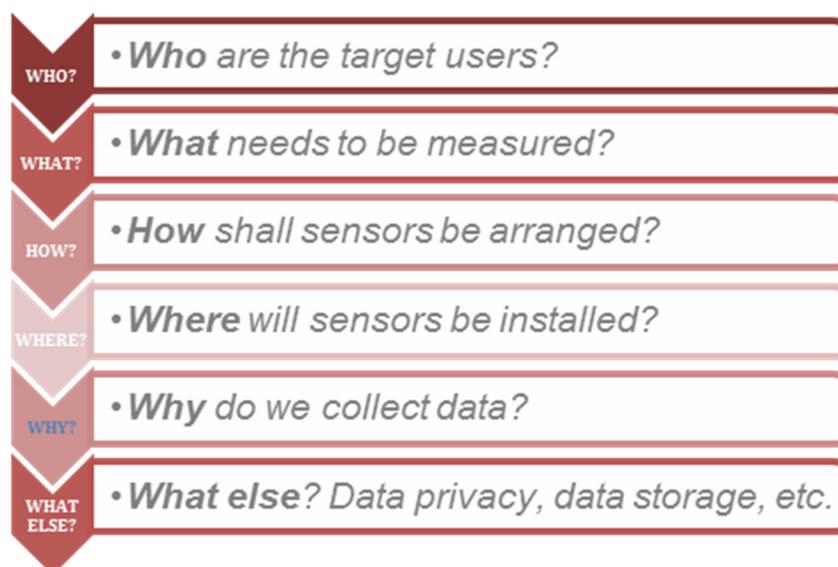


Figure 6-1 Checklist designed by FIAIS (see Deliverables D9 and D11)

Additional to trial 19, at SK, a two-day workshop in December 2018 was held to transfer technical expertise to all test partners. During those two days at TUM, FIAIS and EPFL, fundamental knowledge was provided to the test partners regarding data analysis and machine learning methods. The knowledge transfer between use cases and technical partners will ensure user-centricity and technical excellence and guarantee the highest data quality.

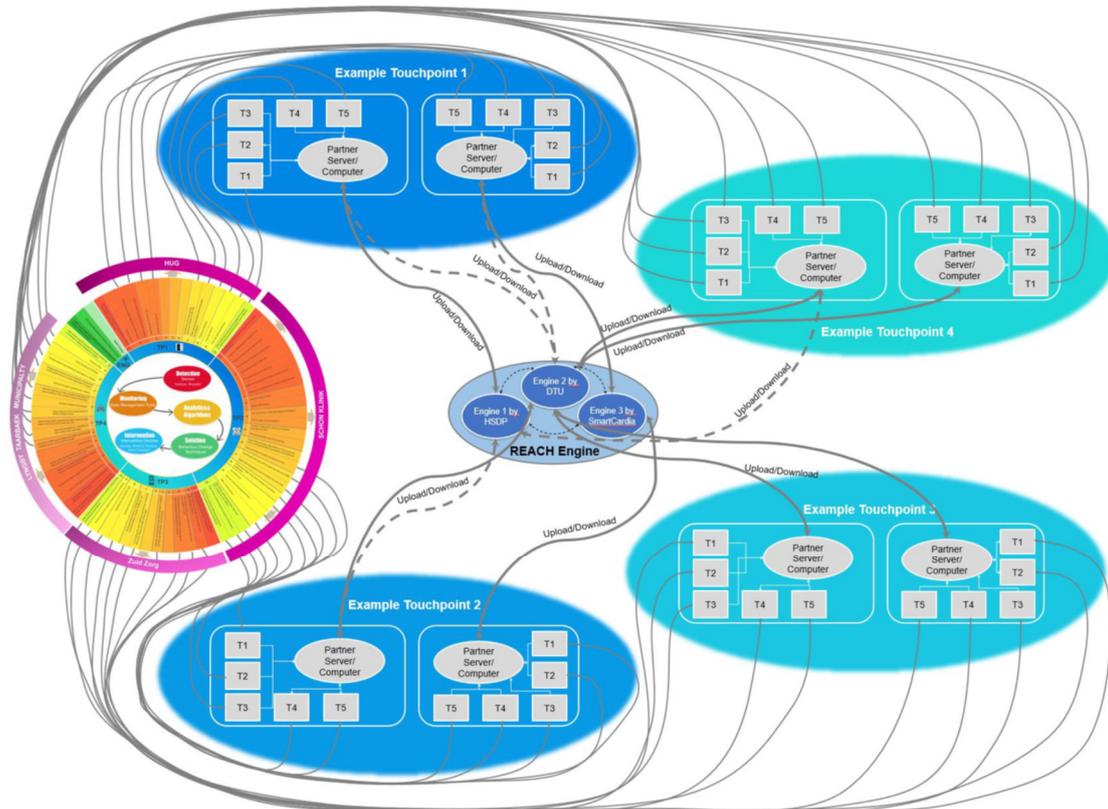


Figure 6-2 Detailed Toolkit-Engine relation (Source: TUM, Data Analytics Workshop Dec 2018)

Impact on project and system: The impact of the testing on the consortium is an intensive information exchange between technical, scientific, medical and commercial partners. The non-technical partners have had to learn what kind and quality of data is needed to qualify as a dataset for algorithm designing and what possibilities and boundaries are given in the respective machine learning methods. In return, the technical partners have to learn about the limits and preferences of the end users. This happened, for example, during the set-up of the test scenario and the testing on healthy subjects at TUM. The impacts on the system are a better understanding of which sensors or sensor classes and equipment are suitable for use in the REACH system, which data meets the quality requirements and what kind of adaptations have to be made to soft- and hardware to create a seamless system.

Another development associated with the trials is the design of the equipment to allow unobtrusive implementation of sensors. Central parts of the REACH system will be the PI<sup>2</sup>U-Bed, the PI<sup>2</sup>U-MiniArc, the PI<sup>2</sup>U-SilverArc and the PI<sup>2</sup>U-Stander, which are under development at TUM together with SK. In the TUM laboratory, the design of the components will be adopted according to the requirements generated at SK. Prototypes of the modified system components will be evaluated by SK. Several meetings with

physicians, therapists, caregiver, manufacturers, technicians and hygiene experts were held to define the requirements.



Figure 6-3 Alreh Medical iStander together with prototype of PI2U-SilverArc



Figure 6-4 Arjo Combilizer: Testing for usability at TUM

The technical partners, together with the use cases, defined the requirements to meet the user needs and ensure their acceptance (e. g., Lyngby 5 trial: Test of smart home technologies). The adaptive capacity regarding usability in different use cases is a central target in the development process and calls for close collaboration within the developer, technicians, manufacturer and use cases.

In the future, more complex component combinations will be tested. At the beginning, the focus is to gather data for the algorithm design, and afterwards to measure the

impact of REACH interventions together with the above mentioned REACH specific hard- and software.

In the upcoming testing activities/studies, the partner will:

1. evaluate whether the tests can be designed as a continuation of an already performed test
2. use assessments out of the REACH assessment toolbox
3. use already existing data to enrich/ complete them
4. check whether the data allows processing in the Engine
5. and check for redundancies.

Today, an estimation of long-term effects and impact on the health status in larger populations is not possible. For a reliable prognosis, larger sample sizes, long-term data and outcomes of trials performed are needed (e. g., testing of Mirana app to support a healthy diet). These trials are either planned, ongoing or under analysis. In one of the next revisions of this deliverable, the transfer of outcomes into healthcare expenditures, length and number of hospitalisations readmission will be made.

The 23 testing instances conducted/created are multi-disciplinary researches that evolved iteratively during the project's duration. This deliverable gave an overview of the scientific-medical/geriatric achievements of the REACH project so far.

- The described results indicate the requirements and strategies to achieve REACH's overall aim
- The similarities and results indicated the shared challenges and potential across different use cases
- Use cases presents a deeper understanding of strategies and challenges faced by each use case
- 23 testing instances are multi-disciplinary (the work covers the aim and requirements of multiple TPs)
- The testing instances have several limitations: 1) sample size 2) accuracy of device 3) loss of data.

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# Appendix 1: Trial reports

# #1

**COMPLETE**

**Collector:** Third collection (Email)  
**Started:** Monday, December 10, 2018 11:24:49 AM  
**Last Modified:** Monday, December 10, 2018 3:00:19 PM  
**Time Spent:** 03:35:29  
**Email:** BSchaepers@schoen-klinik.de  
**IP Address:** 217.89.104.182

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Page 1

## Q1 Title and acronym:

Feasibility study - SmartCardia sensors with standard Holter system and activePal sensors

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**ECG, motion data, posture**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Feasibility and usability study to evaluate the functionalities of the SmartCardia sensor and to compare the ECG and motion data of the SC sensors to other sensors. 7 healthy subjects performed the TuG test, 6 min walking test, and 5 min training with an cycle ergometer while wearing all sensor systems. Additional to ECG and motion data gender, age, height, weight, and pigmentary phototype were collected.

---

## Q4 Protocol

Inclusion:

**7 healthy subjects**

Exclusion:

**Age < 60 years, non-ambulatory**

Medical target conditions (when relevant):

**N/A**

---

## Q5 Background for the trial:

We wanted to compare the data recorded with SmartCardia sensors vs. data from a standard Holter system and activePal sensors

---

## Q6 Aim/purpose of the trial:

The aim of the trial was to evaluate the usability of the SmartCardia sensors for further testing in the REACH projects with neurological patients

---

**Q7 Hypotheses of the trial:**

ECG and motion data from SmartCardia are consistent with the ECG data from the standard Holter system and the motion data from the activePal sensors

**Q8 Risks and biases of the trial:**

**Respondent skipped this question**

**Q9 Ethics approval and data protection:** (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001**,  
(if applicable):

Data protection approval date **01/01/2001**  
(if applicable):

**Q10 Comments on Ethics / Data protection approval (if any)**

No ethic's approval needed, only healthy subjects were included. Data protection approval was obtained from every participant before performing any study activity.

**Q11 Participating centers, institutions or companies:**Name/ short name (address only in case center is not REACH partner) separated by semicolons

Schön Klinik Bad Aibling, SmartCardia

**Q12 Key Investigator(s):**First name, second name of each of the key persons involved

Names separated by semicolons:

**Barbara Schäpers, Carmen Krewer**

**Q13 Corresponding REACH parts:**

TP2	<b>X</b>
TP5	<b>X</b>

**Q14 Time range of the study phase:**Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)

Start date study phase: **01/06/2017**,  
End date study phase: **29/06/2017**

**Q15 Time range of data collection period:**Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)

Start date study phase: **09/06/2017**,  
End date study phase: **22/06/2017**

**Q16 Protocol deviations/amendments:**Describe major deviations from planned study

Patient 1: Holter system failed to record data

Patient 3: SmartCardia sensors failed to record data

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	7
Actual number recruitment - female:	3
Actual number recruitment - male:	4
Actual number completed study - female:	3
Actual number completed study - male:	4

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	64,4
Median age:	64
Min. age:	60
Max. age:	69

---

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:	<b>Only healthy subjects were included</b>
Health / ambulatory status:	<b>Ambulatory without restriction</b>

---

**Q20** Number of participants:Planned number based on power analysis? **No**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	<b>SmartCardia (sensors and app), activePal, camera, Holter system Custo Card M</b>
Types of data collected, resolution:	<b>ECG, position data</b>
Data resolution (e.g. steps/hour; time to completion)	<b>ca. 10 min data recording</b>

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength..); comparators (what was the intervention compared to, if relevant)

Assessment measures:	<b>Timed up and go test, 6 min walking test, 5 min cycle ergometer training</b>
Comparators:	<b>none, all participants performed the same assessments</b>

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

No results available because SmartCardia data were not available

---

**Q24** Problems, limitations, other factors, key lessons:E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

Comparison of data could not be performed because raw SmartCardia data were not available.

---

## #2

**COMPLETE**

**Collector:** First collection (Email)  
**Started:** Monday, December 10, 2018 11:29:47 AM  
**Last Modified:** Monday, December 10, 2018 3:10:50 PM  
**Time Spent:** 03:41:02  
**Email:** Schwarze@biozoon.de  
**IP Address:** 80.245.135.226

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Page 1

### Q1 Title and acronym:

Questionnaire for the investigation of motivational aspects for food intake by elderly people / [...] by dysphagia patients

---

### Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Dysphagia, pureed food, motivational aspects to eat, effects on appetite and mood**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Two separated questionnaires (normal eating elderly & dysphagia patients) in three different countries (Denmark, The Netherlands, Germany). Both subdivided in demographic data & overview and Food & Eating

---

### Q4 Protocol

**Inclusion:** **for the second group: swallowing and/or mastication problems**

**Exclusion:** **0**

**Medical target conditions (when relevant):** **Malnutrition, Dysphagia**

---

### Q5 Background for the trial:

The change in the usual life-style changes the motivation to eat. Consequences are malnutrition. Biozoon is "fighting" against both in their task, developing personalized recipes together with motivational aspects while eating. Therefore it was necessary to receive answers about motivational/demotivational aspects and eating behaviour.

---

### Q6 Aim/purpose of the trial:

Investigation of motivational aspects for food intake by elderly people and elderly suffering from dysphagia

---

**Q7** Hypotheses of the trial:

Current situations (living in a nursing home, dependency on others while eating, dependency of pureed food,..) have influence on elderly's mood and in context on their motivation to eat.

**Q8** Risks and biases of the trial:

**Respondent skipped this question**

**Q9** Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001**,  
(if applicable):

Data protection approval date **01/01/2001**  
(if applicable):

**Q10** Comments on Ethics / Data protection approval (if any)

**Respondent skipped this question**

**Q11** Participating centers, institutions or companies: Name/ short name (address only in case center is not REACH partner) separated by semicolons

ZZ; Lyngby; BZN

**Q12** Key Investigator(s): First name, second name of each of the key persons involved

Names separated by semicolons:

**Jakob Sylvest Nielsen (Lyngby); Hubert Cornelis (ZZ);  
Alexandru Rusu, Sarah Engelhardt, Ann-Kristin  
Schwarze (BZN)**

**Q13** Corresponding REACH parts:

TP3

**ZZ; Lyngby; BZN**

**Q14** Time range of the study phase: Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted (if no dates write 01/01/2001)

Start date study phase: **31/08/2017**,  
End date study phase: **30/11/2018**

**Q15** Time range of data collection period: Start: Begin data collection End: Data collection finished (if no dates write 01/01/2001)

Start date study phase: **01/10/2017**,  
End date study phase: **31/03/2018**

**Q16** Protocol deviations/amendments: Describe major deviations from planned study

none

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	46
Actual number recruitment - female:	29
Actual number recruitment - male:	17
Actual number completed study - female:	29
Actual number completed study - male:	17

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	80+
Median age:	0
Min. age:	60
Max. age:	80+

---

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:	<b>one interviewed group was able to eat "normal" food, the other group had to eat pureed food due to mastication problems.</b>
----------------------	---

---

**Q20** Number of participants:Planned number based on power analysis? **No**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	0
Types of data collected, resolution:	0
Data resolution (e.g. steps/hour; time to completion)	0

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures:	0
Comparators:	0

---

**Q23 Results:** Write summary bullets only, and leave data details in report on Projectplace

- The research revealed the strong influence that the social context has on the eating behaviour. - It has been shown the importance of enhancing the meals in order to avoid malnutrition. - The study confirmed the influence that the meal's sensory aspects have on food acceptance as well as their relation with aging. - The research resulted the strongly negative connection between suffering from eating difficulties (swallowing disorders) and psychological factors. - It has turned out that texture modified food (smoothfood) is able to be a motivational aspect to eating behaviour of elderly.

---

**Q24 Problems, limitations, other factors, key lessons:** E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

not every elderly, who is normally exactly in our target group, is able to answer questionnaires due to physical and/or psychological conditions (e.g. they are confused or are not able to talk clear anymore)

---

# #3

**COMPLETE**

**Collector:** Second collection (Email)  
**Started:** Monday, December 10, 2018 3:25:38 PM  
**Last Modified:** Monday, December 10, 2018 4:13:59 PM  
**Time Spent:** 00:48:20  
**Email:** MiranaMichelle.Randriambelonoro@hcuge.ch  
**IP Address:** 129.194.108.138

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Page 1

## Q1 Title and acronym:

A personal mobility device for elderly physical rehabilitation: a study of acceptance and efficiency

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Rehabilitation; Serious games; Wearable Electronic Devices**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Randomized Clinical Trial with 46 patients during 6 weeks.

---

## Q4 Protocol

Inclusion:

**Seniors (65+) hospitalized in one of the involved sites at the Geneva University Hospital, with musculoskeletal issues (fracture, prosthesis, falls and low back pain), a minimal level of independence and strength (FIM  $\geq$  4 for the items regarding mobility and locomotion), and minimal level of cognitive ability (MMSE  $\geq$  24). They should be able to interact with the equipment and be hospitalized at least 3 weeks at one of the hospitals.**

Exclusion:

**Patients that are considered too weak to interact with the de-vice and that are hospitalized less than 3 weeks.**

Medical target conditions (when relevant):

**Musculoskeletal issues (fracture, prosthesis, falls and low back pain)**

---

**Q5 Background for the trial:**

In 2015, musculoskeletal disorders such as low back pain, fractures, prosthesis and falls were identified as the most common cause for hospitalisation in Switzerland. During hospitalisation, patients with musculoskeletal issues follow rehabilitation therapy to regain their body functions and perform daily tasks independantly such as walking, eating, bathing or moving from a wheelchair to a bed. The hospital-to-home transition is increasingly recognized as a critical period in the patient care, during which different incidents can occur and induce frequent re-hospitalization. There is therefore a growing interest in strengthening the physical and functional capacities of hospitalized elderly patients to prevent re-hospitalization. Researchers have extensively studied the use of computer-aided physical rehabilitation to promote physical activity. Serious games coupled with monitoring devices such as Kinect have shown to positively impact patient's motivation to do rehabilitation exercices. Whether such devices would be as efficient as the standard care in the hospital and engage the elderly to remain active after discharge is still understudied.

**Q6 Aim/purpose of the trial:**

The main objective of the study is to investigate whether rehabilitation using the mobility equipment is as effective as the standard care; secondly, to determine if there is an improvement in clinical outcomes such as physical strength, balance, and risk of falls after using the mobility equipment; and third, to establish whether the use of the REACH concept adds value to the continuity of patient care, specifically in terms of engagement and motivation to be more active during the hospital stay and when returning home.

**Q7 Hypotheses of the trial:**

- rehabilitation using the mobility equipment is as effective as the standard care
- the usage of the mobility equipment will improve clinical outcomes such as physical strength, balance, and risk of falls
- the use of the REACH concept adds value to the continuity of patient care, specifically in terms of engagement and motivation to be more active during the hospital stay and when returning home

**Q8 Risks and biases of the trial:**

**Respondent skipped this question**

**Q9 Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".**

Ethics Committee reply date **31/10/2018**,  
(if applicable):  
Data protection approval date **01/01/2001**  
(if applicable):

**Q10 Comments on Ethics / Data protection approval (if any)**

**Respondent skipped this question**

**Q11 Participating centers, institutions or companies:Name/ short name (address only in case center is not REACH partner) separated by semicolons**

- University Hospital of Geneva (HUG)
- Alreh Medical

**Q12** Key Investigator(s):First name, second name of each of the key persons involved

Names separated by semicolons:

**Mirana Randriambelonoro; Christophe Graf; Caroline Perrin; Dominika Kozak**

**Q13** Corresponding REACH parts:

TP1

**Personal Mobility Device**

**Q14** Time range of the study phase:Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)

Start date study phase: **05/08/2018**  
End date study phase: **31/08/2019**

**Q15** Time range of data collection period:Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)

Start date study phase: **01/02/2019**  
End date study phase: **31/07/2019**

**Q16** Protocol deviations/amendments:Describe major deviations from planned study

No deviations. We just added the handgrip strength test.

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>46</b>
Actual number recruitment - female:	<b>0</b>
Actual number recruitment - male:	<b>0</b>
Actual number completed study - female:	<b>0</b>
Actual number completed study - male:	<b>0</b>

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>0</b>
Median age:	<b>0</b>
Min. age:	<b>0</b>
Max. age:	<b>0</b>

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:

**Musculoskeletal issues (fracture, prosthesis, falls and low back pain)**

Health / ambulatory status:

**Hospitalized**

**Q20** Number of participants:Planned number based on power analysis? **Yes**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	<b>ActiveLife + Stepwatch sensors</b>
Types of data collected, resolution:	<b>Interview data + steps</b>
Data resolution (e.g. steps/hour; time to completion)	<b>steps/second or steps/minutes</b>

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength..); comparators (what was the intervention compared to, if relevant)

Assessment measures:	<b>SPPB, MMSE, Hand grip strength</b>
Comparators:	<b>Standard care (actual equipment or no equipment at all)</b>

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

- To be filled later (study not started yet)

---

**Q24** Problems, limitations, other factors, key lessons:E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

- To be filled later (study not started yet)

---

## #4

COMPLETE

**Collector:** Second collection (Email)  
**Started:** Monday, December 10, 2018 2:29:24 PM  
**Last Modified:** Monday, December 10, 2018 4:59:39 PM  
**Time Spent:** 02:30:15  
**Email:** BSchaepers@schoen-klinik.de  
**IP Address:** 217.89.104.182

---

Page 1

### Q1 Title and acronym:

The Transfer- und Training Device activLife with neurological patients. Feasibility und Usability Study

---

### Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**activity, neurology, sit-to-stand, transfer, mobility, training**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Pilot study; usability/ feasibility study; monitoring project. Subjects will be measured with multiple sensors during 3 different sit-to-stand-transfer methods in a controlled environment: Transfer with activLife device, with and without transfer aid. Neurological patients and healthy subjects will be included.

---

#### Q4 Protocol

Inclusion:	<b>Inpatients at Schön Klinik Bad Aibling (SKBA) with diagnose: TBI, stroke (ischemic or hemorrhagic), hypoxia, critical illness polyneuropathy (CIP) or myopathy (CIM), Alzheimer's disease (• MMSE ≥18), Parkinson's disease, or paraplegia and healthy subjects:</b> • Age ≥ 65 years • Mobility factors that make the patient suitable for the transfer-training-groups at SKBA: MFAS point 11:0, BBS: tasc 1,4,6: > 2points, FAC <2; • device-specific: <120kg, 150-190cm
Exclusion:	<b>Exclusion factors for the participating the transfer-group: pain during transmission, acut and painful shoulder-hand-syndrom. contractions and</b>
Medical target conditions (when relevant):	<b>mobilisations status, balance, hand grip strength, cognitive function, motivation</b>
Protocol link (eg. Projectplace link):	<b><a href="https://service.projectplace.com/#project/1203354283/documents/840802189/953288637">https://service.projectplace.com/#project/1203354283/documents/840802189/953288637</a></b>

---

#### Q5 Background for the trial:

In the course of the REACH Project the Project Partner Alreh developed the transfer- and training device activLife with it's Training-Software VAST.rehab. In the Schön Klinik Bad Aibling we have the possibility to test this decive with neurological patients (one group with motoric deficits (Persona A) and one group with cognitive deficits (Persona B) together with their relatives) and healthy subjects over the age of 65.

It is important to monitor the applicability of this device in the neurological field. Recent studies showed that sit-to-stand training has a positive effect to the health and reduces the risk of fall.

---

#### Q6 Aim/purpose of the trial:

The aim of the trial is to get data from the transfer strategies of neurological patients with motoric and cognitive disabilities, and healthy subjects to show the applicability of the activLife in neurological patients to help to development of the implementation of the transfer device in the REACH system .

---

#### Q7 Hypotheses of the trial:

Explorative trial: with the sensors used in that trial a valid Feedback is given during the three different transfer methods. The activity and kinematic detection can be used to show if the activLife is suitable as a transfer-support and muscular training in the field of neurological rehabilitation. Moreover a patient group with Alzheimer's disease and their relatives, will test the implementation of the device with it's Software.

---

#### Q8 Risks and biases of the trial:

In this trial the patients will not be exposed to additional risks beyond clinical Routine. To prevent falls the patients will be secured by trained employees. Furthermore the activLife device and ist Software VAST.rehab are CE-certified. The data protection takes place according to the GDPR.

---

**Q9** Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001**,  
(if applicable):  
Data protection approval date **01/01/2001**  
(if applicable):

**Q10** Comments on Ethics / Data protection approval (if any)

**Respondent skipped this question**

**Q11** Participating centers, institutions or companies: Name/ short name (address only in case center is not REACH partner) separated by semicolons

SKBA

**Q12** Key Investigator(s): First name, second name of each of the key persons involved

Names separated by semicolons:

**Dr. Friedemann Mueller, Barbara Schaeppers, Dr. Carmen Krewer, Martina Steinboeck, Prof. Eberhard Koenig, Melanie Medenilla**

**Q13** Corresponding REACH parts:

TP2

**X**

**Q14** Time range of the study phase: Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted (if no dates write 01/01/2001)

Start date study phase: **30/12/2018**,  
End date study phase: **31/01/2020**

**Q15** Time range of data collection period: Start: Begin data collection End: Data collection finished (if no dates write 01/01/2001)

Start date study phase: **06/01/2019**,  
End date study phase: **31/10/2019**

**Q16** Protocol deviations/amendments: Describe major deviations from planned study

The Project didn't start yet.

**Q17** Number of participants: (if not yet started write "0" in the "actual number" fields)

Planned by protocol:

**min. 40 neurological patients: (n=10 stroke, n=10 SCI, n=10 Parkinson, n=Alzheimer's) 10 healthy subjects**

Actual number recruitment - female:

**0**

Actual number recruitment - male:

**0**

Actual number completed study - female:

**0**

Actual number completed study - male:

**0**

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age: 0  
Median age: 0  
Min. age: 65  
Max. age: 0

---

**Q19** Medical conditions(fill out when relevant / applicable) Respondent skipped this question

---

**Q20** Number of participants:Planned number based on power analysis? No

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment: iPhone tracking app, EMG-sensors, Simi Motion, zebris-plate  
Types of data collected, resolution: Movement /knematic data, film recordings, distribution of pressure data, motivation

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures: BBS (Berg Balance Scale), MFAS (Motor Function Assessment Skala), 5x Sit-to-Stand Test (5XSST), Hand grip strength, IMI (Intrinsic Motivation Inventory), Montreal Cognitive Assessment (MoCA), TAP (Test zur Aufmerksamkeitsprüfung - alertness, awareness), Questionnaires: affinity towards technology (TA-EG), System-Usability-Skala (SUS), • NASA Task Load Index (NASA-TLX; Usability),  
Comparators: None

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

Not yet applicable

---

**Q24** Problems, limitations, other factors, key lessons:E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

Ethics vote applied

---

## #5

**COMPLETE**

**Collector:** First collection (Email)  
**Started:** Thursday, December 06, 2018 10:09:23 AM  
**Last Modified:** Tuesday, December 11, 2018 1:35:27 PM  
**Time Spent:** Over a day  
**Email:** amir.kabouteh@br2.ar.tum.de  
**IP Address:** 129.187.114.225

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Page 1

### Q1 Title and acronym:

Data Collection and Annotation Workshop Touchpoint 2

---

### Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Data Collection, Data Annotation, Ambient Sensing, Wearable Sensing, Monitoring, Targeting Specific Activities (Eating, Drinking and etc.)**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

non-randomised trial

---

### Q4 Protocol

Inclusion:

**Activity monitoring, data collection, sensor integration and implementation, protocol and procedure definition and declaration**

Exclusion:

**none**

Medical target conditions (when relevant):

**none**

Protocol link (eg. Projectplace link):

**[https://service.projectplace.com/pp/pp.cgi/0/316508877?op=meeting&open\\_win=1](https://service.projectplace.com/pp/pp.cgi/0/316508877?op=meeting&open_win=1)**

---

### Q5 Background for the trial:

In order to support machine learning algorithm development at FIAIS and ethics application submission at SK, there was a need for a workshop to collect sufficient amount of data and to clearly define the procedures and methodologies for data collection and running the trial. Data should be collected in a way to make sure it is possible to annotate the data with ELAN. The annotated data will be used for generating the classifiers and the classifiers will support developing machine learning algorithms.

---

**Q6** Aim/purpose of the trial:

Initial Data Collection for the Machine Learning Algorithms  
Recognition of specific activities by data pattern  
Properly Synchronizing and Annotating Data  
Setting the initial step stone for the ethics application at SK  
Trial for sensor integration and implementation at br2

---

**Q7** Hypotheses of the trial:

Collection data to monitor activities of daily living (ADL) at home, such as eating, drinking, activity (sleep, walking and etc) and hygienic aspects.

---

**Q8** Risks and biases of the trial:

The main risks were minor skin rashes due to the frequent change of the sensors.

---

**Q9** Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001** ,

(if applicable):

Data protection approval date **01/01/2001**

(if applicable):

---

**Q10** Comments on Ethics / Data protection approval (if any)

No ethic's approval necessary, only healthy subjects were included. Data protection approval was obtained from every participant before performing any study activity.

---

**Q11** Participating centers, institutions or companies:Name/ short name (address only in case center is not REACH partner) separated by semicolons

TU München, FIAIS, SKBA

---

**Q12** Key Investigator(s):First name, second name of each of the key persons involved

Names separated by semicolons:

**Sebastian Konietzny, Joerg Guettler, Barbara Schaeppers, Amir Kabouteh, Karolina Klockmann**

---

**Q13** Corresponding REACH parts:

TP1	<b>none</b>
TP2	<b>FIAIS, SK, TUM</b>
TP3	<b>none</b>
TP4	<b>none</b>
TP5	<b>none</b>
Engine	<b>none</b>

---

**Q14** Time range of the study phase:Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)

Start date study phase:	<b>01/08/2018</b>	,
End date study phase:	<b>22/10/2018</b>	

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**Q15** Time range of data collection period:Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)

Start date study phase:	<b>05/10/2018</b>	,
End date study phase:	<b>11/10/2018</b>	

---

**Q16** Protocol deviations/amendments:Describe major deviations from planned study

none

---

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>5</b>
Actual number recruitment - female:	<b>3</b>
Actual number recruitment - male:	<b>2</b>
Actual number completed study - female:	<b>3</b>
Actual number completed study - male:	<b>2</b>

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>33.8</b>
Median age:	<b>30</b>
Min. age:	<b>24</b>
Max. age:	<b>55</b>

---

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:	<b>Only healthy subjects were included</b>
Health / ambulatory status:	<b>Ambulatory</b>

**Q20** Number of participants:Planned number based on power analysis? **No**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:

**ActivPal Accelerometer, SmartCardia, Mobile Phone Accelerometer and Gyroscope, Camera, Pressure Mattress, Myo Band**

Types of data collected, resolution:

**Video, Text file, Acceleration Data, Pressure Data, EMG Data**

Data resolution (e.g. steps/hour; time to completion)

**10 Frames Per Second of Pressure, 4K Video**

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures:

**Activities of daily living**

Comparators:

**none**

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

Initial Data Collection for the Machine Learning Algorithms, Properly Synchronizing and Annotating Data, Setting the initial step stone for the ethics application at SK, trial sensor integration and implementation at br2

---

**Q24** Problems, limitations, other factors, key lessons:E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

Procedures (e. g., sensor handling, sequence order...) were analysed to optimise the time sequences and organisational processes and enhance the data quality to allow annotation and prepare the protocol for the measurements in SKBA.

---

## #6

**COMPLETE**

**Collector:** First collection (Email)  
**Started:** Tuesday, December 11, 2018 1:09:36 PM  
**Last Modified:** Tuesday, December 11, 2018 6:49:30 PM  
**Time Spent:** 05:39:54  
**Email:** C.A.L.Valk@tue.nl  
**IP Address:** 86.92.183.161

---

Page 1

### Q1 Title and acronym:

REACH Eindhoven Continued testing

---

### Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**active ageing; personalising behaviour change; motivation; technology acceptance**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Within-participant A and B test comparing baseline (4 weeks) to intervention (4weeks). Test group A's intervention was an application using self-reflection strategies to motivate behavior change (more physical activity) while group B's intervention was a similar application which using social reflection strategies to motivate behavior change (more physical activity). Contextual, phycological, and self-reported behavioral factors were collected about participants via a questionnaire which was given three times: 1) before the baseline, 2) after the baseline before the intervention and 3) after the intervention. Behavioral data, in terms of physical activity, was also measured throughout the baseline and the intervention period via a Fitbit Flex.

---

### Q4 Protocol

**Inclusion:** participant of the senior community centre  
**Exclusion:** not enough measured activity data collected  
**Medical target conditions (when relevant):** none  
**Protocol link (eg. Projectplace link):** dont have one yet

---

### Q5 Background for the trial:

Personalizing motivation strategies has potential to motivate seniors to engage in more physical activity, however it remains unclear how to personalize strategies toward behavior change. Self-reflection and social engagement have been shown to have potential. In this trial we build off of REACH early testing in Eindhoven.

---

**Q6** Aim/purpose of the trial:

Thus we would like to test what personal factors people have in common who respond similarly to the intervention strategies.

---

**Q7** Hypotheses of the trial:

The related hypotheses are

H10: There is no correlation between the number of times seniors open the application and the number of steps seniors take.

H20: There is no correlation between the number of calls made by seniors and the number of steps seniors taken.

H30: Self-awareness motivates seniors to take the same number of steps as the measured baseline.

H40: Peer-awareness motivates seniors to take the same number of steps as the measured baseline.

H50: The relative difference in steps taken by seniors with high self-efficacy is the same as those taken by seniors with low self-efficacy when using peer-awareness strategy

H60: The relative difference in steps taken by seniors with high self-efficacy is the same as those taken by seniors with low self-efficacy when using self-awareness strategy

H70: The relative difference in steps taken by seniors with a promotion regulatory focus is the same as those taken by seniors with a prevention regulatory focus when using peer-awareness strategy

H80: The relative difference in steps taken by seniors with a promotion regulatory focus is the same as those taken by seniors with a prevention regulatory focus when using self-awareness strategy

---

**Q8** Risks and biases of the trial:

Respondent skipped this question

---

**Q9** Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001** ,

(if applicable):

Data protection approval date **01/01/2001**

(if applicable):

---

**Q10** Comments on Ethics / Data protection approval (if any)

Due to our close partnership we talked to the test bed responsible party and knowledgeable people at the TU/e to approve our protocol

---

**Q11** Participating centers, institutions or companies: Name/ short name (address only in case center is not REACH partner) separated by semicolons

Vrienden van de Thuis Zorg (REACH partner test bed in Eindhoven), TU/e, Philips and EPFL

---

**Q12** Key Investigator(s): First name, second name of each of the key persons involved

Names separated by semicolons:

**carlijn, valk; yuan, lu; hubert, cornelis: peter, lovei; yaliang, chuang;**

---

**Q13** Corresponding REACH parts:

TP3	TU/e, Vrienden van de Thuiszorg, Philips, EPFL
Engine	EPFL

<b>Q14</b> Time range of the study phase:Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)	Start date study phase:	<b>22/05/2018</b>	,
	End date study phase:	<b>20/07/2018</b>	

<b>Q15</b> Time range of data collection period:Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)	Start date study phase:	<b>23/05/2018</b>	,
	End date study phase:	<b>20/07/2018</b>	

**Q16** Protocol deviations/amendments:Describe major deviations from planned study

Originally we had hoped to test the social reflection intervention with one group of participants collaborating with peers and the other group collaborating intergenerationally. However, we were unable to recruit enough people for the intergenerational group, thus we tested with the self-reflection group and the peer to peer social group.

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>56</b>
Actual number recruitment - female:	<b>?</b>
Actual number recruitment - male:	<b>?</b>
Actual number completed study - female:	<b>45</b>
Actual number completed study - male:	<b>15</b>

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>72.47</b>
Median age:	<b>73</b>
Min. age:	<b>47</b>
Max. age:	<b>90</b>

**Q19** Medical conditions(fill out when relevant / applicable)

Health / ambulatory status:	<b>Tilburg frailty index</b>
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<b>Q20</b> Number of participants:Planned number based on power analysis?	<b>No</b>
---	-----------

**Q21** Sensors and equipment used: E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour, time to completion...)

Sensors/equipment:

**Fitbit flex 2 and Mi A1 phone**

Types of data collected, resolution:

**physical activity**

Data resolution (e.g. steps/hour; time to completion)

**steps/day**

---

**Q22** Assessments performed: E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures:

**stage of change, self efficacy**

---

**Q23** Results: Write summary bullets only, and leave data details in report on Projectplace

working on further analysis now

---

**Q24** Problems, limitations, other factors, key lessons: E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

continued monitoring is important to prevent data loss.

---

# #7

COMPLETE

**Collector:** Second collection (Email)  
**Started:** Wednesday, December 12, 2018 3:57:18 PM  
**Last Modified:** Wednesday, December 12, 2018 4:40:26 PM  
**Time Spent:** 00:43:08  
**Email:** dominika.kozak@alreh.pl  
**IP Address:** 89.70.113.178

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Page 1

**Q1 Title and acronym:**

HUG early testing

---

**Q2 Keywords (min. 3; max. 8):**

List keywords, separated by semicolon:

**Alreh Medical, elderly, safe standing, gaming platform,**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

This study aims at assessing the safety, validity and functionality of an innovative rehabilitation equipment produced by Alreh Medical, the iStander activ, associated with its software, Neuroforma, as well as a commercially available sensor produced by Fitbit, the Fitbit Charge 2. Patients hospitalized in the Geneva Geriatric Division and healthy controls matching our inclusion criteria were recruited by care-givers and the research team, respectively. Patients were randomly assigned to train their transfers with the iStander activ and its associated-software, neuroforma (n=5), or according to the Standard Medical Care (SMC, n=5) during 4 consecutive days over 30 minutes. Healthy controls (n=5) trained their transfers using the iStander activ and Neuroforma. Exercises were performed under monitoring by the Fitbit Charge 2 device. Safety was assessed by free reporting of any adverse events by patients or care-givers. Functionality was assessed by the NASA Task-Load Index (NTLI) jointly filled in by patients and care-givers at day 4. Care-givers and patients were also invited to freely comment on the devices. Finally, a comparison of heart rate values measured by the Fitbit device and heart rate values measured by care-givers assessed the validity of the Fitbit Charge 2 as an heart rate measurement tool. This study was approved by the Geneva Canton Ethics Body (Commission Cantonale d'Ethique de la Recherche) under the number 2016-01957.

---

#### Q4 Protocol

Inclusion:	<b>those of the REACH HUG use-case: age over 65 years old, and hospitalized at the Geneva geriatric Hospital (Hôpital des Trois Chênes), and planned discharged with the help of the Geneva Institution of home care (Institution Genevoise de Maintien à Domicile, IMAD), and a Mini-Mental State Examination (MMSE) 20= 4 for the items regarding mobility and locomotion) and a minimal level of cognitive ability (MMSE&gt;=27) to be able to interact with the equipment AND hospitalized at least 3 weeks at one of the hospitals.</b>
Exclusion:	<b>Patients too weak to interact with the equipment and staying less than 3 weeks at the hospital.</b>
Protocol link (eg. Projectplace link):	<b><a href="https://service.projectplace.com/#project/1203354283/documents/993594569/993634307">https://service.projectplace.com/#project/1203354283/documents/993594569/993634307</a></b>

---

#### Q5 Background for the trial:

The REACH project was created to solve the problems of caring for the ageing European population. The system supporting active ageing for both ageing people and carers is to be the result of the project works.

Activities in the REACH project were divided into thematic sections - hereinafter referred to as the Touchpoint Clusters.

The main objective of Touchpoint Cluster 1 is to create tools for preventive monitoring, intervention strategy as well as to allow an earlier return of the conditions of hospital care for much more favourable conditions. Within this cluster, a personal mobility device will be created. Early testing of the equipment, which is the main subject of this work was to analysis the needs and direction of the development of the device so that it is the best tool for an earlier daily physical activity. Activities within Cluster 1 also apply to the motivation of a senior for daily exercises. The role of gamification and the use of multimedia tools to stimulate both the physical and cognitive functions of the elderly is not without significance. It is known that the combination of these two forms of exercises during one training will provide the best therapeutic effects.

The mobility device, created within the project, optimally follows (and can modularly be adapted to) the person throughout the patient journey through different care stages.

---

#### Q6 Aim/purpose of the trial:

The main aim of the study was to assess the safety and functionality of the innovative iStander mobility solution for the elderly, and the ability to use the Fitbit Charge sensor as a HR monitoring tool.

Endpoints

The endpoints were the safety of the iStander and the fitbit Charge 2, the functionality of the iStander, its associated software and the standard medical care, as well as the validity of the heart-rate measurement by the Fitbit Charge.

---

#### Q7 Hypotheses of the trial:

1. istander active device is a safe solution for the elderly.
  2. iStander active has a good functionality for the elderly rehabilitation
  3. Neuroforma gaming system is engaging tool for elderly rehabilitation.
  4. Neuroforma interface is easy to use.
  5. Fitbit HR sensor is comfortable, easy to use and valuable HR sensor.
-

**Q8 Risks and biases of the trial:**

The main risks to which patients will be exposed will be:

- Risk of injury due to Alreh/Smartcardia/Fitbit device malfunction. This risk appears extremely low because of the nature of the products (rehabilitation equipment, sensor), the fact that they have achieved European certification (except for the Smartcardia device for which it is an ongoing procedure) and because exercises will be performed under the careful supervision of occupational and physical therapists. Moreover, the study will be immediately stopped in case of an injury and the CCER will be immediately informed.
- One may argue that the transfer training with the Alreh device may be less efficient than the standard medical care that may use different equipment. Occupational therapists will evaluate if this is indeed the case for every patients and will complement patient training with the standard medical care in that case.
- Of note, there will be no access to non-anonymized personal medical data by the research team (with the exception of care givers bound by medical confidentiality) because of the study design. All data will be collected in an anonymized form.

In return, collected data will be extremely useful for the improvement of devices that will be used in the REACH project.

**Q9 Ethics approval and data protection:** (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001**

(if applicable):

Data protection approval date **01/01/2001**

(if applicable):

**Q10 Comments on Ethics / Data protection approval (if any)**

This study was approved by the Geneva Canton Ethics Body (Commission Cantonale d'Ethique de la Recherche) under the number 2016-01957.

**Q11 Participating centers, institutions or companies:**Name/ short name (address only in case center is not REACH partner) separated by semicolons

HUG,

**Q12 Key Investigator(s):**First name, second name of each of the key persons involved

Names separated by semicolons:

**Dominika Kozak, Simon Burgermeister, Jean De Buretel De Chasseyd, Adrien Naef, Alexandre Maringue, Damien Dietrich**

**Q13 Corresponding REACH parts:**

TP1

**HUG**

**Q14 Time range of the study phase:**Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)

Start date study phase:

**01/01/2017**

End date study phase:

**31/03/2017**

**Q15** Time range of data collection period:Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)

Start date study phase: **05/01/2017**  
End date study phase: **31/03/2017**

**Q16** Protocol deviations/amendments:Describe major deviations from planned study

no major deviations were observed

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:

**15 participants, including 10 patients satisfying the REACH target population inclusion/exclusion criteria (5 using the Alreh equipment and 5 using standard equipment) and 5 healthy adults (using the Alreh equipment only)**

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:

**Basic demographic and medical information of participants are depicted in Figure 1. The mean age was 79.8 years in the SMC patient group and 89.6 years in the iStander activ patient group with a male to female ratio of 3/2 and 4/1 respectively.The healthy control group had a mean age of 42.4 years with a slight predominance of woman.**

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:

**The total number of active pathologies highlights the net predominance of cardio-vascular diseases in both groups. Osteoarticular and endocrine diseases were also frequently encountered, with osteoarticular diseases being overrepresented in the SMC patient group. The causes of hospitalization were diverse in both groups**

**Q20** Number of participants:Planned number based on power analysis?

**No**

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:

**Fitbit**

Types of data collected, resolution:

**HR,**

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures:

**MMSE, Nasa task Load Index, MSC, NTLI scale,**

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

Care-givers and patients appreciated the ease and comfort of use. The use of Fitbit also promoted patient empowerment. However, the wrist-band was reported as difficult to adapt. A suggested improvement was the addition of an alert in case of high or irregular heart rate.

---

**Q24** Problems, limitations, other factors, key lessons:E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

ethics registration

---

## #8

**COMPLETE**

**Collector:** Second collection (Email)  
**Started:** Thursday, December 13, 2018 10:07:35 AM  
**Last Modified:** Thursday, December 13, 2018 11:13:07 AM  
**Time Spent:** 01:05:32  
**Email:** C.A.L.Valk@tue.nl  
**IP Address:** 86.92.183.161

---

Page 1

### Q1 Title and acronym:

Towards personalised persuasive strategies for active ageing

---

### Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**active ageing, behaviour change, persuasive strategies, personalisation, physical activity**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

We analyzed the design outcomes of 12 student projects, who each followed a user-centered, iterative design process, according to Persuasive Systems Design framework (Oinas-Kukkonen, 2009). The students were given the assignment to redesign an application to motivate older adults to engage in more physical activity. From this investigation, five main persuasive strategies were identified which likely will be valuable in motivating older adults for physical activity.

---

### Q4 Protocol

Inclusion:

**Students in our course**

Exclusion:

**We would have excluded concepts which were insufficient quality, such as the students not passing the course, but all concepts deemed sufficiently similar in quality to be acceptable to include in our analysis.**

Medical target conditions (when relevant):

**none**

Protocol link (eg. Projectplace link):

**Gerontechnology REACH special issue**

---

### Q5 Background for the trial:

It is widely accepted how important physical activity is to the health and independence of older adults, however, many older adults lead a sedentary lifestyle, sitting for long periods of time.

---

**Q6** Aim/purpose of the trial:

In order to motivate these older adults to increase their level of physical activity we aim to identify which persuasive strategies best address this user group.

**Q7** Hypotheses of the trial:

This was an explorative study but the hypotheses we were testing is which themes would be used to motivate older adults to move more.

**Q8** Risks and biases of the trial:

There is a risk that because this is student work they might not have the design insight to really connect the preferred persuasive strategies for their user. However, they were guided by coaches and a panel of external people evaluated the student concepts on perceived quality.

**Q9** Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001** ,  
(if applicable):  
Data protection approval date **01/01/2001**  
(if applicable):

**Q10** Comments on Ethics / Data protection approval (if any)

**Respondent skipped this question**

**Q11** Participating centers, institutions or companies: Name/ short name (address only in case center is not REACH partner) separated by semicolons

TU/e

**Q12** Key Investigator(s): First name, second name of each of the key persons involved

Names separated by semicolons:

**Carlijn, Valk; Yuan, Lu;**

**Q13** Corresponding REACH parts:

TP3

**TU/e**

**Q14** Time range of the study phase: Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted (if no dates write 01/01/2001)

Start date study phase: **16/11/2016** ,  
End date study phase: **26/10/2017**

**Q15** Time range of data collection period: Start: Begin data collection End: Data collection finished (if no dates write 01/01/2001)

Start date study phase: **16/11/2016** ,  
End date study phase: **01/12/2016**

**Q16** Protocol deviations/amendments:Describe major deviations from planned study

There were no major deviations from the planned study except that our editors asked us to do one more focus group to asses the quality of the student work, by a panel of people who were not involved in giving and grading the course, which was done as proposed.

---

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>There were 119 students enrolled in the class and we analysed the results of 12 groups each of which had (I believe) 5,6 or 7 team members depending on the group.</b>
Actual number recruitment - female:	?
Actual number recruitment - male:	?
Actual number completed study - female:	?
Actual number completed study - male:	?

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>0</b>
Median age:	<b>0</b>
Min. age:	<b>0</b>
Max. age:	<b>0</b>

---

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:	<b>NA</b>
Health / ambulatory status:	<b>older adults students worked with were community dwelling seniors</b>

---

**Q20** Number of participants:Planned number based on power analysis? **No**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	<b>Mi band and HealthSit (a prototype by the TU/e)</b>
Types of data collected, resolution:	<b>Project reports and prototype videos</b>
Data resolution (e.g. steps/hour; time to completion)	<b>one final report and prototype video per group</b>

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength..); comparators (what was the intervention compared to, if relevant)

Assessment measures:

NA

Comparators:

NA

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

We analysed the persuasive strategies used and from this also identified different value propositions each student concept used. These values and persuasive strategies were distilled into five "value cluster" with proposed strategies on how to achieve these. The value clusters are Social Fitness, Improved Care, Prize, Self-awareness and Fun. For more please see table 9 in the Gerontechnology paper

---

**Q24** Problems, limitations, other factors, key lessons:E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

This was an explorative study so more research is required.

---

## #9

**COMPLETE**

**Collector:** First collection (Email)  
**Started:** Thursday, December 13, 2018 2:38:13 PM  
**Last Modified:** Thursday, December 13, 2018 2:51:53 PM  
**Time Spent:** 00:13:40  
**Email:** BSchaepers@schoen-klinik.de  
**IP Address:** 2.108.90.82

---

Page 1

### Q1 Title and acronym:

Activity recognition with wearables and ambient sensors - gathering of data sets for the empirical validation with neurological patients

---

### Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Sensors; neurology; activity recognition; data sets;  
machine learning; algorithm**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Pilot study; usability/ feasibility study

Subjects will be measured with multiple sensors in a controlled environment (apartment and bathroom) during activities of daily living (ADL). Patients and healthy subjects will be included.

---

#### Q4 Protocol

Inclusion:

**Patients and healthy subjects: • Age  $\geq$  65 years • Ambulatory with and without walking aids • Speech comprehension Patients: • Inpatients at Schön Klinik Bad Aibling with one of the following diagnoses: TBI, stroke (ischemic or hemorrhagic), hypoxia, critical illness polyneuropathy (CIP) or myopathy (CIM), Alzheimer's disease, Parkinson's disease, incomplete paraplegia. • Full Barthel score without items 5, 6, 10 (fecal and urinary incontinence, stair climbing) • Bogenhausener Dysphagia Score  $\geq$ 6 (BODS 1 and BODS2)**

Exclusion:

**Instable cardiac arrhythmia; cardiac pacemaker; continous oxygen supply; uncontrolled medical conditions: cardiovascular diseases, rheumatoid arthritis, acute cancer, joint deformation caused by arthritis, kidney disorders, pulmonary or cardiovascular conditions in the final stage, uncontrolled epilepsy); acute alcohol or drug abuse**

Medical target conditions (when relevant):

**ADL, ambulatory status, balance, hand grip strength, cognitive function, motivation**

Protocol link (eg. Projectplace link):

**<https://service.projectplace.com/pp/pp.cgi/r945597971>**

---

#### Q5 Background for the trial:

To validate the recommendations of the REACH system an exact pattern recognition and reliable classification strategy has to be integrated. The detection of activity pattern is based on data from wearables and ambient sensors, complemented with additional data, e. g., biometric data, medication, medical records. All data will be collected, interpreted, and classified at an central memory unit (engine). A first step to create algorithms is to generate data in a controlled environment which allow the recognition of certain activities. First data sets were generated on healthy subjects at the TU München. In an identical setting at SKBA data from neurological patients will be collected to specify the characteristics and variations. REACH should be able to recognize pattern and based on machine learning autonomously create proposed solutions. Multi sensor networks allow the precise recognition of the environment and the persons involved. Resource intensive activities could be transformed in automated processes resulting in savings into the health care system.

---

#### Q6 Aim/purpose of the trial:

The aim of the trial is to generate data sets from neurological patients and healthy subjects to support the development of machine learning algorithms for the REACH system for activity recognition.

---

#### Q7 Hypotheses of the trial:

Explorative trial: With the sensor set used in the trial valid algorithms for activity detection can be generated, suitable for neurological patients and healthy subjects .

---

**Q8** Risks and biases of the trial:

In this trial the patients will not be exposed to additional risks beyond clinical routine. To prevent falls the patients will be secured by trained employees. Sensors directly attached to the skin may cause mild pressure marks or rashes. In case of exhaustion the measurements will be paused due to the requirements of the participants.

**Q9** Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001** ,  
(if applicable):  
Data protection approval date **01/01/2001**  
(if applicable):

**Q10** Comments on Ethics / Data protection approval (if any)

**Respondent skipped this question**

**Q11** Participating centers, institutions or companies: Name/ short name (address only in case center is not REACH partner) separated by semicolons

SKBA, TUM, IAIS

**Q12** Key Investigator(s): First name, second name of each of the key persons involved

Names separated by semicolons:

**Dr. Friedemann Mueller, Barbara Schaeppers, Dr. Carmen Krewer, Martina Steinboeck, Prof. Eberhard Koenig, Melanie Medenilla**

**Q13** Corresponding REACH parts:

TP2	<b>x</b>
TP5	<b>x</b>
Engine	<b>x</b>

**Q14** Time range of the study phase: Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted (if no dates write 01/01/2001)

Start date study phase: **01/12/2018** ,  
End date study phase: **31/01/2020**

**Q15** Time range of data collection period: Start: Begin data collection End: Data collection finished (if no dates write 01/01/2001)

Start date study phase: **06/01/2019** ,  
End date study phase: **31/08/2019**

**Q16** Protocol deviations/amendments: Describe major deviations from planned study

Project not started yet

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>max. 18 patients and 18 healthy subjects</b>
Actual number recruitment - female:	<b>0</b>
Actual number recruitment - male:	<b>0</b>
Actual number completed study - female:	<b>0</b>
Actual number completed study - male:	<b>0</b>

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>0</b>
Median age:	<b>0</b>
Min. age:	<b>65</b>
Max. age:	<b>0</b>

---

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:	<b>Neurological Diseases</b>
Health / ambulatory status:	<b>Ambulatory with or without walking aids</b>

---

**Q20** Number of participants:Planned number based on power analysis? **No**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	<b>Myoband, SmartCardia, activePal, cameras, iPhone tracking app</b>
Types of data collected, resolution:	<b>Movement data, film recordings, vital parameter, biometric data, ADL data</b>
Data resolution (e.g. steps/hour; time to completion)	<b>none</b>

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength..); comparators (what was the intervention compared to, if relevant)

Assessment measures:	<b>Barthel Index, SPPB Short Physical Performance Battery Protocol, Hand grip strength, MOCA, IMI Intrinsic Motivation Inventory</b>
Comparators:	<b>None</b>

---

**Q23 Results:** Write summary bullets only, and leave data details in report on Projectplace

None

---

**Q24 Problems, limitations, other factors, key lessons:** E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

Ethics vote applied

---

# #10

**COMPLETE**

**Collector:** First collection (Email)  
**Started:** Thursday, December 13, 2018 3:19:26 PM  
**Last Modified:** Thursday, December 13, 2018 4:01:20 PM  
**Time Spent:** 00:41:53  
**Email:** mirana.randriambelonoro@etu.unige.ch  
**IP Address:** 178.198.101.65

---

Page 1

## Q1 Title and acronym:

Opportunities and challenges for self-monitoring technologies for healthy aging: An in-situ study

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Health; behavior change; activity monitoring; qualitative studies; older adults; physical activity**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Cohort study (qualitative study) with 20 participants during 6 weeks at their home.

---

## Q4 Protocol

**Inclusion:** 65+ years old, living at home, and in need of occasional help for their daily activities.

**Exclusion:** Elderly who are not able to interact with the device.

**Medical target conditions (when relevant):** Not relevant

---

## Q5 Background for the trial:

Faced with the constant growth of aging population, the need to promote an environment for healthy aging is expanding. Although maintaining healthy behavior has been shown to be highly beneficial for older adults' health and wellbeing, the challenge remains in motivating the adoption and the long-term engagement in such behavior. There are opportunities for emerging technology to increase older adults' engagement in being physically active and managing their health. Within the European REACH (Responsive Engagement of the Elderly promoting Activity and Customized Healthcare) project, the goal is to learn the older adults' behavior by collecting physical activity and health related data in order to provide personalized health recommendation to them. For this purpose, we conducted an ethnographic study for data collection to get insights on older adults' readiness, willingness, and challenges to adopt pervasive sensors and applications for healthy ageing.

---

**Q6 Aim/purpose of the trial:**

The goal of this ethnographic study is three folded: First, we will obtain insights on older adults' attitudes towards increasing physical activity as well as their readiness towards tracking technologies. Second, we will identify senior's potential behavior changes as well as their usage intention. Third, we will shed light on the opportunities and barriers for them to be monitored and try to understand how they would integrate the system in their daily life.

**Q7 Hypotheses of the trial:**

Senior individuals are ready and willing to accept such technology to manage their health, considering some challenges. Senior individuals will change their behavior and will sustain the device usage at the end of the study.

**Q8 Risks and biases of the trial:**

**Respondent skipped this question**

**Q9 Ethics approval and data protection:** (if you have no dates yet, please enter "01/01/2001").

Ethics Committee reply date **01/01/2001**,  
(if applicable):  
Data protection approval date **01/01/2001**  
(if applicable):

**Q10 Comments on Ethics / Data protection approval (if any)**

We did not need ethical committee approval for this study.

**Q11 Participating centers, institutions or companies:**Name/ short name (address only in case center is not REACH partner) separated by semicolons

HUG  
EPFL

**Q12 Key Investigator(s):**First name, second name of each of the key persons involved

Names separated by semicolons:

**Mirana Randriambelonoro; Pearl Pu**

**Q13 Corresponding REACH parts:**

TP2

**Touchpoint 2 (sensing)**

**Q14 Time range of the study phase:**Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)

Start date study phase: **01/03/2017**,  
End date study phase: **30/06/2017**

**Q15 Time range of data collection period:**Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)

Start date study phase: **01/03/2017**,  
End date study phase: **30/06/2017**

**Q16** Protocol deviations/amendments:Describe major deviations from planned study

No deviation

---

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>20</b>
Actual number recruitment - female:	<b>13</b>
Actual number recruitment - male:	<b>7</b>
Actual number completed study - female:	<b>12</b>
Actual number completed study - male:	<b>6</b>

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>77.6</b>
Median age:	<b>77</b>
Min. age:	<b>65</b>
Max. age:	<b>89</b>

---

**Q19** Medical conditions(fill out when relevant / applicable)

**Respondent skipped this question**

---

**Q20** Number of participants:Planned number based on power analysis?

**No**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	<b>Fitbit Charge 2, Fitbit Aria or Withings Body Cardio</b>
Types of data collected, resolution:	<b>Interview data + steps + weight</b>
Data resolution (e.g. steps/hour; time to completion)	<b>steps/minutes</b>

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures:	<b>Qualitative interview / Number of steps</b>
Comparators:	<b>No comparator</b>

---

**Q23 Results:** Write summary bullets only, and leave data details in report on Projectplace

- we identified opportunities and challenges for the older adults to adopt sensors and application for health / potential of acceptance and adoption of simple and manageable technology for behavior change.

---

**Q24 Problems, limitations, other factors, key lessons:** E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

The recruitment was tedious in the beginning.

---

# #11

**COMPLETE**

**Collector:** First collection (Email)  
**Started:** Tuesday, December 18, 2018 2:38:52 PM  
**Last Modified:** Tuesday, December 18, 2018 3:13:09 PM  
**Time Spent:** 00:34:17  
**Email:** Sebastian.Konietzny@iais.fraunhofer.de  
**IP Address:** 129.26.67.33

---

Page 1

## Q1 Title and acronym:

Coffee Demonstrator Experiment

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**time series analysis, time series clustering, pattern detection, change point detection**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

For this test, I myself (Dr. Sebastian Konietzny) represented the test subject.

---

## Q4 Protocol

Inclusion: **none**  
Exclusion: **none**  
Medical target conditions (when relevant): **none**  
Protocol link (eg. Projectplace link): **<https://service.projectplace.com/pp/pp.cgi/r1077731542>**

---

## Q5 Background for the trial:

We designed an experiment, called the Coffee Demonstrator, to continuously track the heart rate data of a test user over one month by means of a Fitbit Surge smartwatch. Our goal was to analyze the collected sensor data time series, and to test whether it will be possible to predict moments of coffee drinking from that data. An essential part of the data collection process was the manual logging of coffee drinking moments done by the test user. The resulting data logs thus provided ground-of-truth labels for the later analysis.

---

**Q6** Aim/purpose of the trial:

Search for heart rate patterns that are indicative/predictive for coffee consumption moments.

---

**Q7** Hypotheses of the trial:

We analyzed the data from two different perspectives. On the one hand, coffee drinking events might elevate (or decrease) the mean HR of a subject temporarily. This could be seen as shifts of the HR levels. On the other hand, the effect of caffeine consumption on the subject's HR could result in more complicated patterns of the time series. For example, caffeine could cause an instantaneous peak in the HR, before the HR starts to decrease again until it finally reaches the level from before. Patterns of this kind should be reflected in time series motifs centered around coffee drinking moments. To assess both hypotheses, i.e. HR mean shifts and conserved time series motifs, we performed a change points analysis.

---

**Q8** Risks and biases of the trial:

There were no risks when collecting the data.

---

**Q9** Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001**,  
(if applicable):

Data protection approval date **01/01/2001**  
(if applicable):

---

**Q10** Comments on Ethics / Data protection approval (if any)

Since I collected my own data and there were no third persons involved, this does not apply.

---

**Q11** Participating centers, institutions or companies: Name/ short name (address only in case center is not REACH partner) separated by semicolons

Dr. Sebastian Konietzny, Fraunhofer IAIS, Sankt Augustin, Germany

---

**Q12** Key Investigator(s): First name, second name of each of the key persons involved

Names separated by semicolons:

**Dr. Sebastian Konietzny**

---

**Q13** Corresponding REACH parts:

TP2

**Analyses of time series from wearable devices.**

---

**Q14** Time range of the study phase: Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted (if no dates write 01/01/2001)

Start date study phase: **01/01/2001**,  
End date study phase: **01/01/2001**

---

**Q15** Time range of data collection period: Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001) Start date study phase: **01/01/2001** , End date study phase: **01/01/2001**

---

**Q16** Protocol deviations/amendments: Describe major deviations from planned study

none

---

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>1</b>
Actual number recruitment - female:	<b>0</b>
Actual number recruitment - male:	<b>1</b>
Actual number completed study - female:	<b>0</b>
Actual number completed study - male:	<b>1</b>

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>38</b>
Median age:	<b>38</b>
Min. age:	<b>38</b>
Max. age:	<b>38</b>

---

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:	<b>none</b>
Health / ambulatory status:	<b>healthy subject</b>

---

**Q20** Number of participants:Planned number based on power analysis? **No**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	<b>Fitbit Surge</b>
Types of data collected, resolution:	<b>heart rate data</b>
Data resolution (e.g. steps/hour; time to completion)	<b>sampling frequency varied between 1-3 seconds</b>

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures: **none**

Comparators: **none**

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

We found contradictory behaviors of the HR after coffee consumption. Change points analysis suggested that coffee drinking had no systematic effect on the heart rate levels. This is in line with a related study by [Green et al., 1996], which concluded that caffeine affects blood pressure, but not heart rate.

---

**Q24** Problems, limitations, other factors, key lessons:E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

- The lack of information provided by the sensor manufacturer represents also an obstacle for the experiment.
  - Our experiment showed that even young healthy adults tend to forget making manual loggings of events after some time. Elderly people, as in the typical REACH settings, will likely not be able to log data thoroughly themselves.
-

# #12

COMPLETE

**Collector:** Second collection (Email)  
**Started:** Wednesday, December 19, 2018 6:28:03 PM  
**Last Modified:** Wednesday, December 19, 2018 6:59:16 PM  
**Time Spent:** 00:31:12  
**Email:** srinivasan.murali@smartcardia.com  
**IP Address:** 157.50.60.76

---

Page 1

## Q1 Title and acronym:

SmartCardia - Patient testing at CardioCentro Lugano

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Vital signs; wearable; patient testing**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

In this study, we aimed at assessing the safety, validity and satisfaction of the innovative equipment produced by SmartCardia SA (an EPFL start-up). All the evaluations have been performed with Golden Standard ICU existing monitoring system of CardioCentro to allow a proper validation of SmartWearable device.

The following primary, secondary endpoints will be used for the study design:

Primary outcome measures:

- Data Collection of continuous Vital Signs and Physiological Parameters recorded with standard monitor. ECG, HRV, SPO2, Skin Temperature, Blood Pressure Trends, Pulse Rate, Posture and Activity
- Continuous SmartWearable measure of the following parameters
  - Heart rate and heart rate variability of the ICU patients
  - Blood pressure based on Pulse Transit Time (PTT)
  - Oxygen saturation
  - Skin temperature
- Benchmark the vital parameters obtained by the SmartCardia device
- Comparison of the accuracy and efficacy, between SmartWearable vs. Golden Standard monitoring system of CardioCentro ICU.

Secondary endpoints

- Algorithmic Predictive Validity
- Algorithmic Predictive Accuracy
- Algorithmic Predictive Efficacy

Total Enrollment 60 patients

---

#### Q4 Protocol

Inclusion:	<b>The duration of the Study was 39 weeks and the targeted population (patients suffering from CVD with an emphasis on Cardiovascular Patients with Minor Hemodynamic Instability after Cardiac Surgery or after Invasive Cardiac Intervention) have reached the number 60 (details on the diagnosis and reason of admission are depicted in table 2). The Safety, Efficacy, Validity,. Accuracy and Sensitivity of the SmartWearable has being tested in a cross over comparison with the existing ICU Dräger - Healthcare Monitoring System of the Hospital as well as with the fully CE certified (and with FDA Clearance) Medical Devices, tracing the same vital parameters.</b>
Exclusion:	<b>Pacemaker, IVD implant patients</b>
Medical target conditions (when relevant):	<b>Cardiac ICU monitoring</b>

---

#### Q5 Background for the trial:

Title of Study: Clinical Validation Study for Algorithmic Evaluation & SmartCardia device(s) / "SmartWearable" for Accuracy / Safety and Efficacy vs. the Golden Standard Monitoring ICU System

Study Design: Assessing the safety, validity and satisfaction of the innovative equipment

Purpose: To investigate the safety and efficacy and accuracy of SmartWearable vs. the Golden Standard Monitoring ICU System

Patient Population:.

Study Duration: Total duration of the use of the SmartWearable device for each subject is continuous monitoring of 24 hrs.

Study Status: Enrollment: Completed in 31.03.2018

Completion of data collection and analysis: 31.08.2018

Study Sites: Fondazione Cardiocentro Lugano

---

#### Q6 Aim/purpose of the trial:

In the Department of Cardiovascular Medicine of CardioCentro University Hospital of Lugano, under the supervision of Professor Med. Dr. Tiziano Cassina, M.D., Ph.D. the Director of Cardiac ICU, as a Principal Clinician Investigator and PD Med. Dr. Enrico Ferrari, M.D., Ph.D. from the Department of Cardiac Surgery, as the Co-Clinical Investigator. The duration of the Study was 39 weeks and the targeted population (patients suffering from CVD with an emphasis on Cardiovascular Patients with Minor Hemodynamic Instability after Cardiac Surgery or after Invasive Cardiac Intervention) have reached the number 60 (details on the diagnosis and reason of admission are depicted in table 2). The Safety, Efficacy, Validity,. Accuracy and Sensitivity of the SmartWearable has being tested in a cross over comparison with the existing ICU Dräger - Healthcare Monitoring System of the Hospital as well as with the fully CE certified (and with FDA Clearance) Medical Devices, tracing the same vital parameters.

---

#### Q7 Hypotheses of the trial:

To validate the parameters from the wearable against ICU monitor devices for vital signs measurement.

---

#### Q8 Risks and biases of the trial:

**Respondent skipped this question**

---

**Q9** Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **17/05/2017**  
(if applicable):  
Data protection approval date **01/01/2001**  
(if applicable):

**Q10** Comments on Ethics / Data protection approval (if any)

Canton Ticino Ethics Approval and Cardiocentro approval

**Q11** Participating centers, institutions or companies: Name/ short name (address only in case center is not REACH partner) separated by semicolons

CardioCentro Lugano, Switzerland

**Q12** Key Investigator(s): First name, second name of each of the key persons involved

Names separated by semicolons:

**Prof. Tiziano Cassina; Dr. Petros Malitas**

**Q13** Corresponding REACH parts:

TP2

**Q14** Time range of the study phase: Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted (if no dates write 01/01/2001)

Start date study phase: **17/05/2017**  
End date study phase: **30/09/2018**

**Q15** Time range of data collection period: Start: Begin data collection End: Data collection finished (if no dates write 01/01/2001)

Start date study phase: **01/11/2017**  
End date study phase: **30/03/2018**

**Q16** Protocol deviations/amendments: Describe major deviations from planned study

None

**Q17** Number of participants: (if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>60</b>
Actual number recruitment - female:	<b>17</b>
Actual number recruitment - male:	<b>43</b>
Actual number completed study - female:	<b>16</b>
Actual number completed study - male:	<b>42</b>

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>65</b>
Median age:	<b>65</b>
Min. age:	<b>30</b>
Max. age:	<b>89</b>

---

**Q19** Medical conditions(fill out when relevant / applicable) **Respondent skipped this question**

---

**Q20** Number of participants:Planned number based on power analysis? **Yes**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	<b>SmartCardia</b>
Data resolution (e.g. steps/hour; time to completion)	<b>Heart rate, respiration rate, activity, posture every minute</b>

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength..); comparators (what was the intervention compared to, if relevant)

Assessment measures:	<b>Bland Altman plot analysis</b>
Comparators:	<b>ICU monitor: Drager monitor</b>

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

SmartCardia sensors meet the accuracy of ICU monitors for vital signs monitoring, at ISO standards (95% agreement)

---

**Q24** Problems, limitations, other factors, key lessons:E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

Additional data analysis of patient condition prediction under progress

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# #13

**COMPLETE**

**Collector:** First collection (Email)  
**Started:** Wednesday, December 19, 2018 7:01:21 PM  
**Last Modified:** Wednesday, December 19, 2018 7:11:57 PM  
**Time Spent:** 00:10:35  
**Email:** srinivasan.murali@smartcardia.com  
**IP Address:** 103.204.158.99

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Page 1

## Q1 Title and acronym:

SmartCardia - Healthy Volunteer Testing

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Wearable sensor; vital signs; validation against monitors; activity**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

This is a 30 healthy subject trial in which the smartcardia wearable sensors were tested against medically approved monitor (EDAN ICU monitor that measures the ECG, SpO2 and skin temperature using cable sensors).

---

## Q4 Protocol

**Inclusion:** Healthy volunteers  
**Exclusion:** People with cardiovascular or other medical conditions, patients under medications  
**Medical target conditions (when relevant):** None  
**Protocol link (eg. Projectplace link):** None

---

## Q5 Background for the trial:

The study took place at the SmartCardia office at EPFL innovation park. The ethical committee of the Canton of Vaud was obtained for it.

---

## Q6 Aim/purpose of the trial:

In this protocol, the goal is to measure the vital signs in healthy subjects and validate it for accuracy under different conditions, such as different activities and postures.

---

**Q7** Hypotheses of the trial:

The hypothesis is that SmartCardia wearable sensors at different body locations (such as chest and upper arm) can measure important vitals, such as the heart rate, respiration rate, blood pressure, oxygen saturation, blood pressure variations, skin temperature, activity and posture.

**Q8** Risks and biases of the trial:

None

**Q9** Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/02/2017**,  
(if applicable):

Data protection approval date **01/01/2001**  
(if applicable):

**Q10** Comments on Ethics / Data protection approval (if any)

Ethics approval of Canton of Vaud

**Q11** Participating centers, institutions or companies: Name/ short name (address only in case center is not REACH partner) separated by semicolons

Self-study performed by SmartCardia

**Q12** Key Investigator(s): First name, second name of each of the key persons involved

Names separated by semicolons:

**Srinivasan Murali; Petros Malitas**

**Q13** Corresponding REACH parts:

TP2

**x**

**Q14** Time range of the study phase: Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted (if no dates write 01/01/2001)

Start date study phase: **01/02/2017**,

End date study phase: **30/06/2018**

**Q15** Time range of data collection period: Start: Begin data collection End: Data collection finished (if no dates write 01/01/2001)

Start date study phase: **08/02/2017**,

End date study phase: **23/05/2017**

**Q16** Protocol deviations/amendments: Describe major deviations from planned study

None

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>30</b>
Actual number recruitment - female:	<b>5</b>
Actual number recruitment - male:	<b>25</b>
Actual number completed study - female:	<b>5</b>
Actual number completed study - male:	<b>25</b>

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>28</b>
Median age:	<b>28</b>
Min. age:	<b>20</b>
Max. age:	<b>45</b>

---

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:	<b>None</b>
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---

**Q20** Number of participants:Planned number based on power analysis? **Yes**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	<b>SmartCardia</b>
Types of data collected, resolution:	<b>Per minute heart rate, oxygen saturation; every 15 minutes activity, posture and blood pressure</b>

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures:	<b>Bland Altmann</b>
Comparators:	<b>EDAN ICU monitor</b>

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

SmartCardia sensors could measure the vital signs at the same accuracy as the ICU monitor under different activity conditions

---

**Q24** Problems, limitations, other factors, key lessons: E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

The results were sufficient to perform patient testing in hospitals in further trials

---

# #14

**COMPLETE**

**Collector:** Third collection (Email)  
**Started:** Wednesday, December 19, 2018 7:28:49 PM  
**Last Modified:** Wednesday, December 19, 2018 8:30:48 PM  
**Time Spent:** 01:01:58  
**Email:** Y.Lu@tue.nl  
**IP Address:** 80.56.44.206

---

Page 1

## Q1 Title and acronym:

ActiveLife Test

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**motivation, activity center, RCT**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Study flow, test setting and design are provided in the file in project place  
<https://service.projectplace.com/#project/1203354283/documents/840801989>

---

## Q4 Protocol

Inclusion:

**Both groups were recruited from the guests of Ontmoet en Groet center. Group 1: 21, 11 females and 10 males, with an averaged age of 78.05 Group 2: 22, 8 females and 14 males, with an averaged age of 75.82**

Exclusion:

**people who cannot independently visit the center**

Protocol link (eg. Projectplace link):

**<https://service.projectplace.com/#project/1203354283/documents/840801989>**

---

## Q5 Background for the trial:

ActiveLife is to be tested for a longer period of time as an intervention to compared to physiotherapist's advice on regular sport activities.

---

## Q6 Aim/purpose of the trial:

Main purpose: Is the motivation to do more Physical Activity the same for seniors after :

1)using activLife at activity center?

2)exercising at home following the advices from physiotherapists ?

---

**Q7 Hypotheses of the trial:**

H10: The motivation to do more PA is the same for seniors after using Active Life and those after following the advices from physiotherapists.

H20: Seniors remains in the same stage of change after using Active Life.

H30: Seniors remains in the same stage of change after following the advices from physiotherapists

H40: The physical conditions (in terms of strength) remain unchanged for seniors after using Active Life and those after following advices from physiotherapists.

H50: The level of exertion of Active Life exercise is the same as that of the exercise advised from the physiotherapists.

H60: The strength measurement is the same as the Mobee Fitness measurement.

**Q8 Risks and biases of the trial:**

risks: participants may fall out of the test due to personal health conditions

bias: participants may be already very active before joining the test

**Q9 Ethics approval and data protection:** (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001**,  
(if applicable):

Data protection approval date **01/01/2001**  
(if applicable):

**Q10 Comments on Ethics / Data protection approval** (if any)

**Respondent skipped this question**

**Q11 Participating centers, institutions or companies:**Name/ short name (address only in case center is not REACH partner) separated by semicolons

ZZ ontmoet en groet center

**Q12 Key Investigator(s):**First name, second name of each of the key persons involved

Names separated by semicolons:

**Dominika Kozak, Hubert Cornelis, Athena Chen, Yuan Lu**

**Q13 Corresponding REACH parts:**

TP1

**ActiveLife**

**Q14 Time range of the study phase:**Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)

Start date study phase: **19/12/2017**,

End date study phase: **31/03/2018**

**Q15** Time range of data collection period:Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)

Start date study phase:	<b>19/12/2017</b>	,
End date study phase:	<b>31/03/2018</b>	

**Q16** Protocol deviations/amendments:Describe major deviations from planned study

everything went as planned

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>48</b>
Actual number recruitment - female:	<b>19</b>
Actual number recruitment - male:	<b>24</b>
Actual number completed study - female:	<b>19</b>
Actual number completed study - male:	<b>24</b>

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age: **76.5**

**Q19** Medical conditions(fill out when relevant / applicable)

Health / ambulatory status: **living independently, participate in vitality square, ontmoet en groet plein**

**Q20** Number of participants:Planned number based on power analysis? **No**

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment: **ActiveLife**

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures: **Age, gender, BMI, Stage of change questionnaire, Tilburg Frailty Indicator, Strength test, Mobeefitness measurement, Barriers to Being Active, Active life exercise data, Rating of perceived Exertion (weekly, after each exercise), Intrinsic Motivation Inventory (weekly)**

**Q23 Results:** Write summary bullets only, and leave data details in report on Projectplace

The test participants come from a rather physical active group with comparable TFI, stage of change measurement, an hand grip test results (frailty). Active life training seems to have a clear contribution to the 4-stage balance skill Both interventions contribute to the 30 sec chair stand results Active Life training apparently do not sufficiently contribute to Tinette Balance skill Active Life training seems to have a clear barrier to be active, possibly due to technology involved; Exercise alone at home apparently has a higher barrier to be active than exercise together with a sport coach. Mobee measures apparently different skills (walking) than balance

---

**Q24 Problems, limitations, other factors, key lessons:** E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

no

---

# #15

**COMPLETE**

**Collector:** Flfth collection (Email)  
**Started:** Tuesday, December 25, 2018 12:34:31 PM  
**Last Modified:** Tuesday, December 25, 2018 12:48:16 PM  
**Time Spent:** 00:13:44  
**Email:** HUMEHRA@DTU.DK  
**IP Address:** 85.24.243.65

---

Page 1

## Q1 Title and acronym:

Lyngby 5 Trial: Test of smart home technologies

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Smart Home, age at place**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Test Design: Feasibility study: collecting in-home activity data by sensors mounted in walls, furniture, and daily objects.

---

## Q4 Protocol

Inclusion:

**Inclusion criteria: We want to include two or three older adults, who are living independent living independently at their own home and are responsible for their daily tasks themselves**

Exclusion:

**N/A**

Medical target conditions (when relevant):

**N/A**

Protocol link (eg. Projectplace link):

**N/A**

---

## Q5 Background for the trial:

Background: Smart homes seems to be a promising approach in helping older adults to stay safe and independent in their own home. However, there are lack of evidence about the positive and negative outcomes of smart home technologies. This study aims to measuring the ability and likelihood of smart home in real setting.

---

**Q6 Aim/purpose of the trial:**

Aims: Study aims to monitor older adult's daily activity throughout the day in an unobtrusive way. We want to detect changing capabilities and changing stages of behavior change by looking for patterns and recognizing deviations from normal patterns.

**Q7 Hypotheses of the trial:**

Purpose: Primary purpose is to emphasize potential problems that could occur related to implementation of smart homes and to determine potential positive and negative outcomes of smart home technologies.

Secondary:

- Whether interior sensors is perceived by elderly citizens as an acceptable smart home technology
- Whether elderly citizens accepts 24/7 monitoring

**Q8 Risks and biases of the trial:**

**Respondent skipped this question**

**Q9 Ethics approval and data protection:** (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001**,  
(if applicable):

Data protection approval date **01/01/2001**  
(if applicable):

**Q10 Comments on Ethics / Data protection approval (if any)**

**Respondent skipped this question**

**Q11 Participating centers, institutions or companies:**Name/ short name (address only in case center is not REACH partner) separated by semicolons

Not yet fixed

**Q12 Key Investigator(s):**First name, second name of each of the key persons involved

Names separated by semicolons:

**Henning Boje Andersen, Hemant Ghyvat, Humira Ehrari**

**Q13 Corresponding REACH parts:**

TP4

**x**

**Q14 Time range of the study phase:**Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)

Start date study phase: **01/01/2001**,  
End date study phase: **01/01/2001**

**Q15 Time range of data collection period:**Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)

Start date study phase: **01/01/2001**,  
End date study phase: **01/01/2001**

**Q16** Protocol deviations/amendments: Describe major deviations from planned study

the study is not yet completed

---

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol: **3**

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Min. age: **65**

---

**Q19** Medical conditions(fill out when relevant / applicable) **Respondent skipped this question**

---

**Q20** Number of participants:Planned number based on power analysis? **No**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:

**Materials and data collection: We want to collect raw data from 2-3 homes with different indoor sensors, mounted in walls, furniture, and daily objects to deduce older adults' daily activities. Monitoring may detect when a person falls, opens the refrigerator, opens a door, etc.**

Types of data collected, resolution:

**The smart home will be used to generate behavior pattern recognition and anomaly detection based on real time sensor activation. The system aims to work as alarms and personal emergency response system to detect acute events, monitor chronic risks and adverse events**

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength..); comparators (what was the intervention compared to, if relevant)

Assessment measures: **N/A**

---

**Q23 Results:** Write summary bullets only, and leave data details in report on Projectplace

Data analysis: we want to apply annotation techniques to detect anomalies in data. Machine learning techniques to detect critical deviation from normal activity pattern. The data collected will be transmitted to a database. Based on predefined parameters, an alert will be generated locally at the person's home or through telephone or internet messaging. Results: The smart home will be used to generate behavior pattern recognition and anomaly detection based on real time sensor activation. The system aims to work as alarms and personal emergency response system to detect acute events, monitor chronic risks and adverse events

---

**Q24 Problems, limitations, other factors, key lessons:** E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

no yet discovered any

---

# #16

**COMPLETE**

**Collector:** Second collection (Email)  
**Started:** Friday, December 07, 2018 12:49:10 PM  
**Last Modified:** Wednesday, January 09, 2019 10:03:27 AM  
**Time Spent:** Over a month  
**Email:** HUMEHRA@DTU.DK  
**IP Address:** 192.38.90.68

---

Page 1

## Q1 Title and acronym:

Lyngby 4: Developing a reliable technique for automatic counting of steps of older adults – a validation study

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Accelerometer; pedometer; validation; physical activity; step count; algorithm**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Test design as planned This validation study was planned to use data collected from activity assessment of Lyngby 3 supplemented with additional walking data. A test of balance and functional ability of a group of 25 older adults, involving for each participant a 6-minute walk test, was carried out as planned in June/July 2018. About half of the elderly participants used a rollator regularly. according to the plan, we collected data from five sensors and a video-based observational counting of steps. Each Participant walked 6 min for each of three different walking trials: 1) a 6 min walk at self-selected pace (natural speed of the participants – half indoors, half outdoor walks 2) a 6 min walk outdoors at fastest pace 3) a 6 min walk indoors at fastest pace

---

## Q4 Protocol

**Inclusion:** Citizens aged 65+ at Lyngby activity center

**Exclusion:** Inability to maintain a standing position either alone or with the use of support; - Strongly reduced mobility due to illness (arthritis, inflammation/ phlebitis...)

**Medical target conditions (when relevant):** none

**Protocol link (eg. Projectplace link):** none

---

**Q5 Background for the trial:**

A primary factor in measuring functional mobility is the assessment of gait performance. However, the performance of accelerometer-based algorithms for step detection at low walking speeds is still deficient which limits their use in patients or elderly populations with gait impairment walking at low speeds.

---

**Q6 Aim/purpose of the trial:**

Our study aimed to develop and validate algorithms for counting steps of elderly slow/anomaly walkers with machine learning techniques using raw data from 3-axis accelerometers. The study is exploratory and will ascertain the degree to which a single algorithm using data from position X can reliably predict number of steps for "most" participants (e.g., number of steps produced by the algorithm by a deviation of less than 5% for at least 95% of the users).

---

**Q7 Hypotheses of the trial:**

described as Aim

---

**Q8 Risks and biases of the trial:**

none

---

**Q9 Ethics approval and data protection:** (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001**,  
(if applicable):

Data protection approval date **01/01/2001**  
(if applicable):

---

**Q10 Comments on Ethics / Data protection approval (if any)**

**Respondent skipped this question**

---

**Q11 Participating centers, institutions or companies:**Name/ short name (address only in case center is not REACH partner) separated by semicolons

institution1 Activity center in Lyngby Bredebovej 1;  
institution2 Activity center in Virum Snnepmarken 1;  
Sens Innovation ApS Ole Maaløes Vej 3, 2200  
Frederiksberg

---

**Q12** Key Investigator(s):First name, second name of each of the key persons involved

Names separated by semicolons:

**Henning Boje Andersen; Humira Ehrari**

---

**Q13** Corresponding REACH parts:

TP4 **x**

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**Q14** Time range of the study phase:Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)

Start date study phase: **01/01/2001**

---

**Q15** Time range of data collection period:Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)

Start date study phase: **01/06/2018**  
End date study phase: **15/07/2018**

---

**Q16** Protocol deviations/amendments:Describe major deviations from planned study

none

---

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol: **38**

Actual number completed study - female: **18**

Actual number completed study - male: **7**

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age: **84,4**

Median age: **81**

Min. age: **67**

Max. age: **94**

---

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information: **none**

Health / ambulatory status: **none**

---

**Q20** Number of participants:Planned number based on power analysis? **No**

---

**Q21** Sensors and equipment used: E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour, time to completion...)

Sensors/equipment:

**SENS-motion 3-axis sensors mounted on 5 body positions**

Types of data collected, resolution:

**Numbers of steps,**

---

**Q22** Assessments performed: E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures:

**6 min walk test**

Comparators:

**none**

---

**Q23** Results: Write summary bullets only, and leave data details in report on Projectplace

the study is not yet complete, so we do not have any results yet.

---

**Q24** Problems, limitations, other factors, key lessons: E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

No problem discovered yet.

---

# #17

**COMPLETE**

**Collector:** First collection (Email)  
**Started:** Wednesday, January 09, 2019 1:58:30 PM  
**Last Modified:** Wednesday, January 09, 2019 2:03:16 PM  
**Time Spent:** 00:04:46  
**Email:** b33liu@gmail.com  
**IP Address:** 113.118.224.20

---

Page 1

## Q1 Title and acronym:

Playful Body and Brain Test with the Moto Tiles

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Playware; balance test; cognitive test ;fall risk**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

The study consists of two parts. The first part includes three standardized balance tests. Participants are timed by both stopwatch and the Moto Tiles. The second part includes four Moto Tile games. Participants play the four games in sequence and the scores are collected.

---

## Q4 Protocol

Inclusion:	<b>All people aged over 4 years old</b>
Exclusion:	<b>Color Blindness</b>
Medical target conditions (when relevant):	<b>N/A</b>
Protocol link (eg. Projectplace link):	<b>N/A</b>

---

## Q5 Background for the trial:

Ordinary early detection and filtering of some age-related diseases require completed and professional examination. By designing a special Moto Tile game session, the examination process can be turned interesting and simple.

---

## Q6 Aim/purpose of the trial:

Validate the reliability of the Moto Tile timing of the chosen balance tests. Calculate normative game scores at different ages. Find correlation between game scores and standardized balance tests.

---

**Q7 Hypotheses of the trial:**

A big data approach can be applied to create a normative Moto Tiles game score for a given age. There is correlation between Moto Tiles game score and standard tests such as Time-Up-and-Go and Chair-to-Stand.

**Q8 Risks and biases of the trial:**

The obtained normative scores might be influenced by the overall physical and cognitive ability of the people at the test site.

**Q9 Ethics approval and data protection:** (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001**,  
(if applicable):

Data protection approval date **01/01/2001**  
(if applicable):

**Q10 Comments on Ethics / Data protection approval (if any)**

**Respondent skipped this question**

**Q11 Participating centers, institutions or companies:**Name/ short name (address only in case center is not REACH partner) separated by semicolons

Dagcentret Tvaerbommenn, Dagcenter Vennerslund, Daghjemmet Blaaklokkevej, Betaniahjemmet, Hilleroed Sundhedscentret, Omsorgscentret Toftehoejen, Lyngby Idaetsby, Det Kongelige Bibliotek, Technical University of Denmark.

**Q12 Key Investigator(s):**First name, second name of each of the key persons involved

Names separated by semicolons:

**Yanxin Liu; Henrik Hautop Lund**

**Q13 Corresponding REACH parts:**

TP4

**Playware-based Stationary and ambulant systems that enforce intervention regiments**

**Q14 Time range of the study phase:**Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)

Start date study phase: **01/01/2001**,  
End date study phase: **01/01/2001**

**Q15 Time range of data collection period:**Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)

Start date study phase: **01/11/2018**,  
End date study phase: **22/12/2018**

**Q16 Protocol deviations/amendments:**Describe major deviations from planned study

N/A

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>200</b>
Actual number recruitment - female:	<b>114</b>
Actual number recruitment - male:	<b>89</b>
Actual number completed study - female:	<b>114</b>
Actual number completed study - male:	<b>89</b>

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>50.9</b>
Median age:	<b>48</b>
Min. age:	<b>4</b>
Max. age:	<b>97</b>

---

**Q19** Medical conditions(fill out when relevant / applicable)

**Respondent skipped this question**

---

**Q20** Number of participants:Planned number based on power analysis? **No**

---

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	<b>The Moto Tiles</b>
Types of data collected, resolution:	<b>Scores</b>
Data resolution (e.g. steps/hour; time to completion)	<b>integer scores (number of detected steps)</b>

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength..); comparators (what was the intervention compared to, if relevant)

Assessment measures:	<b>N/A</b>
Comparators:	<b>N/A</b>

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

Normative scores of different ages are calculated by polynomial fitting.

---

**Q24** Problems, limitations, other factors, key lessons: E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

The constructed model may be refined by collecting more data for the training. Samples of children and teenagers are relatively less than other age groups.

---

# #18

**COMPLETE**

**Collector:** Third collection (Email)  
**Started:** Friday, December 07, 2018 1:04:07 PM  
**Last Modified:** Thursday, January 10, 2019 11:24:45 AM  
**Time Spent:** Over a month  
**Email:** HUMEHRA@DTU.DK  
**IP Address:** 192.38.90.68

---

Page 1

## Q1 Title and acronym:

Lyngby 1: Effect of daily feedback on older adults' physical activity level

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Physical activity monitoring; Sensors; wearables; behaviour change; Effect of feedback; activity tracking**

---

## Q3 Test Design as planned: Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

This randomized control trial started over 9 weeks. N=26 aged 65+ has been randomly assigned to monitor vital signs such as heart rate, daily steps, sleep hours and etc. by using Fitbit charge HR. All participant was asked to wear the Fitbit tracker for 5 days to assess baseline physical activity level. After successfully completing the baseline measurement and signing the informed consent, participants were randomized into two groups to perform the trial. Group A received 4 weeks feedback on sleep, group B received 4 weeks feedback on steps. Depending on which group the participant belongs to, the participant was asked to rate how active they were yesterday or how they slept last night. Participants were asked to rate their activity level in 3 categories, less active than I am used to, moderate (as I am used to), high active than I am used to. After 4 weeks the groups shifted e.g. group A started receiving feedback on steps group B started receiving feedback on sleep.

---

## Q4 Protocol

**Inclusion:** Citizens aged 65+ at Lyngby activity center.

**Exclusion:** Inability to maintain a standing position either alone or with the use of support; - Strongly reduced mobility due to illness (arthritis, inflammation/ phlebitis...)

**Medical target conditions (when relevant):** none

**Protocol link (eg. Projectplace link):** none

---

**Q5 Background for the trial:**

Evidence from epidemiological and clinical studies shows that one of the most important approaches to improve the quality of life and healthy aging is to encourage daily physical activity among older adults. However, there is lack of evidence on the effect of feedback on older adults physical activity level.

**Q6 Aim/purpose of the trial:**

The study aims to determine the effect of providing daily feedback on physical activity level and assess awareness of physical activity, based on self-rated and objective physical activity measures

**Q7 Hypotheses of the trial:**

Through the study we tested two hypothesis 1) Receiving feedback on physical activity level would increase activity 2) 24/7 monitoring of 8 weeks leads to concerns about privacy

**Q8 Risks and biases of the trial:**

None

**Q9 Ethics approval and data protection:** (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **01/01/2001**,  
(if applicable):

Data protection approval date **03/01/2017**  
(if applicable):

**Q10 Comments on Ethics / Data protection approval (if any)**

None

**Q11 Participating centers, institutions or companies:**Name/ short name (address only in case center is not REACH partner) separated by semicolons

institution 1 Activity center in Lyngby Bredebovej 1;  
institution 2 Activity center in Virum Snnepmarken 1

**Q12 Key Investigator(s):**First name, second name of each of the key persons involved

Names separated by semicolons:

**Henning Boje Andersen; Humira Ehrari**

**Q13 Corresponding REACH parts:**

TP4	x
Engine	x

**Q14** Time range of the study phase:Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001) Start date study phase: **31/07/2016** , End date study phase: **01/01/2001**

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**Q15** Time range of data collection period:Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001) Start date study phase: **30/10/2016** , End date study phase: **31/01/2019**

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**Q16** Protocol deviations/amendments:Describe major deviations from planned study

no deviations

---

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>26</b>
Actual number recruitment - female:	<b>21</b>
Actual number recruitment - male:	<b>5</b>
Actual number completed study - female:	<b>18</b>
Actual number completed study - male:	<b>4</b>

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>88</b>
Median age:	<b>88</b>
Min. age:	<b>73</b>
Max. age:	<b>94</b>

---

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:	<b>none</b>
Health / ambulatory status:	<b>none</b>

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**Q20** Number of participants:Planned number based on power analysis? **Yes**

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**Q21** Sensors and equipment used: E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour, time to completion...)

Sensors/equipment:	<b>Fitbit Charge HR and Smartphones to transmit Fitbit data</b>
Types of data collected, resolution:	<b>physical activity in terms of numbers of steps and sleeping hours</b>
Data resolution (e.g. steps/hour; time to completion)	<b>Automatic measurement (continuously)</b>

---

**Q22** Assessments performed: E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures:	<b>Self-assessment (at home by patient)</b>
Comparators:	<b>None</b>

---

**Q23** Results: Write summary bullets only, and leave data details in report on Projectplace

Difference between time participants received feedback on steps and the time with no feedback: The mean difference between the two conditions of trails is 181,18 with a standard deviation of 1093,25 and 95% confidence intervals of -303,54 to 665,90 steps.  $P=.44$  indicates no statistically significant mean difference between the mean of two related groups.

---

**Q24** Problems, limitations, other factors, key lessons: E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

During the trials we discovered, that raw data gathered from Fitbit has a certain degree of erroneous, redundant information that caused by discharged batteries, and sync problems and the design of the fitbit algorithm. To compensate for these effects, a data cleaning process was conducted, where only samples with complete outcome data were included in the analyses. To ensure complete outcome data, all steps measures were compared with heart rate data. Days within more than 4 hours of missing data were excluded from the analysis.

---

# #19

**COMPLETE**

**Collector:** Fourth collection (Email)  
**Started:** Friday, December 07, 2018 1:12:50 PM  
**Last Modified:** Thursday, January 10, 2019 11:26:27 AM  
**Time Spent:** Over a month  
**Email:** HUMEHRA@DTU.DK  
**IP Address:** 192.38.90.68

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Page 1

## Q1 Title and acronym:

Lyngby 3: The effect of playware technologies on physical activity

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Gaming; Physical activity; Functional ability**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

This randomized control trial was designed as a 24 weeks trial. The initial plane was to balance randomized a sample of 40 older adults aged 65+ into two groups; an intervention and a control group. The intervention run for 12 weeks, hence each participant was engaged in 16 sessions, each of approx.12 minutes per training day.

The intervention was divided into teams of 4 or 5 people. Each team was engage in 1 hour of playful activity session twice a week at a municipal center. Each session was led by Moto play master and each team member was engage in 12 minutes of activity divided into 2 minute exercises.

Randomization was balanced so that the two groups had approximately the same distribution of daily physical activity (indicated by the 5-day pre-training measure of daily number of steps and postural control measures) and age.

During the trial all participants wore a sensor (SENS motion sensor under a patch on their thigh 10 cm above their knee. There were no training planned for control group at the first 12 weeks of the trial. Control group particioants were engaged in their normal physical and social activities, similar to those of the intervention group.

As it is illustrated in the figure bellow, the initial plan was to conduct 4 balance measuring rounds.

---

## Q4 Protocol

Inclusion:	<b>Citizens aged 65+ at Lyngby activity center</b>
Exclusion:	<b>Inability to maintain a standing position either alone or with the use of support; - Strongly reduced mobility due to illness (arthritis, inflammation/ phlebitis...)</b>
Medical target conditions (when relevant):	<b>none</b>
Protocol link (eg. Projectplace link):	<b>none</b>

---

**Q5 Background for the trial:**

Evidence from epidemiological and clinical studies shows that one of the most important approaches to improve the quality of life and healthy aging is to encourage daily physical activity among older adults. However, motivation to engage in physical activity is often low in old age. A potential method to increase physical activity may be the use of playware technologies such as moto tiles.

**Q6 Aim/purpose of the trial:**

This study aim to investigate the potential of moto tiles in motivating older adults to become physically active. Hence, we examine what extent playful physical exercise during a 12 week period by of older (65+) citizens improves physical and functional abilities and to what extent it is accompanied by changes in physical activities outside exercise sessions.

**Q7 Hypotheses of the trial:**

- 1) 12 weeks of playful physical exercise improves physical and functional abilities.
- 2) It is accompanied by changes in physical activities outside exercise sessions.

**Q8 Risks and biases of the trial:**

none

**Q9 Ethics approval and data protection:** (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **30/08/2017**  
(if applicable):  
Data protection approval date **18/01/2018**  
(if applicable):

**Q10 Comments on Ethics / Data protection approval (if any)**

**Respondent skipped this question**

**Q11 Participating centers, institutions or companies:**Name/ short name (address only in case center is not REACH partner) separated by semicolons

institution1 Activity center in Lyngby Bredebovej 1;  
Institution 2 Activity center in Lyngby/Virum  
Snnepmarken 1; Sens Innovation ApS Ole Maaløes Vej  
3, 2200 Frederiksberg

**Q12 Key Investigator(s):**First name, second name of each of the key persons involved

Names separated by semicolons:

**Henning Boje Andersen; Humira Ehrari**

**Q13 Corresponding REACH parts:**

TP4

**x**

**Q14** Time range of the study phase:Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001) Start date study phase: **01/01/2001** , End date study phase: **01/01/2001**

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**Q15** Time range of data collection period:Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001) Start date study phase: **01/03/2018** , End date study phase: **01/07/2018**

---

**Q16** Protocol deviations/amendments:Describe major deviations from planned study

After completing the first 12 weeks of the trial, we got quit a lot of useful data and on the basis of the obtained data, we decided to cancel the second part of the study and change it to RCT. Likewise there were major deviations in sample size. We did not succeed in recruiting 40 older adults. The trial was started with 38 and ended up with only 29 participants.

---

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>40</b>
Actual number completed study - female:	<b>22</b>
Actual number completed study - male:	<b>7</b>

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>84</b>
Median age:	<b>85,5</b>
Min. age:	<b>67</b>
Max. age:	<b>94</b>

---

**Q19** Medical conditions(fill out when relevant / applicable) Respondent skipped this question

---

**Q20** Number of participants:Planned number based on power analysis? **Yes**

---

**Q21** Sensors and equipment used: E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour, time to completion...)

Sensors/equipment:

**The actual physical activity level was monitored by sens-motion sensors. Fitbit were used to assist 5-day pre-training measure of daily number of steps. Moto tiles were used during exercise sessions**

Types of data collected, resolution:

**Activity level in terms of numbers of steps & postural control level**

Data resolution (e.g. steps/hour; time to completion)

**24h /7w**

---

**Q22** Assessments performed: E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength..); comparators (what was the intervention compared to, if relevant)

Assessment measures:

**Bergs Balance scale; Chair stand test; 6 min walk test**

Comparators:

**None**

---

**Q23** Results: Write summary bullets only, and leave data details in report on Projectplace

Both groups had an increase in their BBS. Training group: increase of 5,0 points; Control group increase of 2,1 points in their BBS (p=0,11; anova). 30 sec chair stand test, both groups had a decreased in numbers of stands; Training group -1.3 stands, control group -1,4 stands, p = 0.96. 6mwt: 14 people in each group. Training group: mean increase of 19 meters; control group 5 meters p = 0.75

---

**Q24** Problems, limitations, other factors, key lessons: E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

Our initial plan was to recruit 40 participants from 3 activity centers. But after being around in 5 activity centers, 3 activity centers were excluded. We recruited 2X18 participant from two activity centers.

## #20

COMPLETE

**Collector:** First collection (Email)  
**Started:** Thursday, December 06, 2018 1:48:01 PM  
**Last Modified:** Thursday, January 10, 2019 11:29:05 AM  
**Time Spent:** Over a month  
**Email:** HUMEHRA@DTU.DK  
**IP Address:** 192.38.90.68

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Page 1

### Q1 Title and acronym:

Lyngby 2: Feasibility study conducted in preparation of the planned Lyngby

---

### Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Playware, behaviour change, gaming, elderly, exercise, physical activity, postural control**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

The Lyngby 2 trial was a feasibility study conducted from April-July 2017 in preparation of the planned Lyngby 3 trial. The study involved 9 elderly participants engaging in playful exercise and from whom movement tracking data were collected throughout the day over 8 week

Participants are divided into two teams of 5 persons. Each team is engaged in 1 hour of playful activity session twice a week at a municipal center. For each session, led by Moto play master, each team member is engaged in 12 minutes of activity divided into 2-minute exercises.

The experiment run for 8 weeks, so each participant has 16 sessions. During the test participants wear two types of activity trackers: Sens patch and Fitbit Charge HR that measure physical activity (steps: per minute/hour/day), sleep durations and heart rate. Tracking data will be uploaded from the trackers to a smartphone in participants' home. Data upload will be monitored at DTU and if the data connection is lost, the analysis team will make a phone call and, if accepted, a visit to re-establish data collection. They participated in training on the Moto tiles for eight weeks. The Moto tiles are tiles that light up and react when pressed, they allow for making a different kind of games that require the user to use the body and mind to complete.

---

### Q4 Protocol

**Inclusion:** - Citizens aged 65+ at Lyngby activity center.

**Exclusion:** - Inability to maintain a standing position either alone or with the use of support; - Strongly reduced mobility due to illness (arthritis, inflammation/ phlebitis...)

**Protocol link (eg. Projectplace link):** none

---

**Q5 Background for the trial:**

Lyngby 2 trial was conducted in preparation of the planned Lyngby 3 trial

---

**Q6 Aim/purpose of the trial:**

Feasibility study wrt. logistics of recording simultaneously physical activity via Fitbit tracker, Sens tracker and (during play/exercise sessions) Moto tiles

---

**Q7 Hypotheses of the trial:**

The primary purpose is to examine to what extent playful physical exercise during a 9-week period by of older (65+) citizens:

- Improves physical and functional abilities
- Is accompanied by changes in physical activities outside exercise sessions

A secondary purpose is to determine:

- Whether activity tracking is perceived by elderly citizens as an acceptable monitoring technology used by care providers
  - Whether training on Moto tiles is adhered to and is perceived as acceptable by users over a 9-week period
  - Changes in performance on MOTO tiles over time correlate with changes in balance and functional measures
- 

**Q8 Risks and biases of the trial:**

**Respondent skipped this question**

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**Q9 Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".**

Ethics Committee reply date **01/01/2001**,  
(if applicable):  
Data protection approval date **03/05/2017**  
(if applicable):

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**Q10 Comments on Ethics / Data protection approval (if any)**

**Respondent skipped this question**

---

**Q11 Participating centers, institutions or companies:Name/ short name (address only in case center is not REACH partner) separated by semicolons**

Institution  
Activity center in Lyngby  
Bredebovej 1

Brane ApS  
Stumpedyssevej 9  
DK-2970 Hørsholm  
Denmark

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**Q12 Key Investigator(s):First name, second name of each of the key persons involved**

Names separated by semicolons:

**Henning Boje Andersen Humira Ehrari Jari due Jensen**

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**Q13** Corresponding REACH parts:

TP4 x

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**Q14** Time range of the study phase: Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001) Start date study phase: **01/02/2017** , End date study phase: **30/06/2017**

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**Q15** Time range of data collection period: Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001) Start date study phase: **03/04/2017** , End date study phase: **30/06/2017**

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**Q16** Protocol deviations/amendments: Describe major deviations from planned study

NONE

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**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol: **10**  
Actual number recruitment - female: **6**  
Actual number recruitment - male: **4**  
Actual number completed study - female: **5**  
Actual number completed study - male: **3**

---

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age: **81,5**  
Median age: **81,5**  
Min. age: **66**  
Max. age: **93**

---

**Q19** Medical conditions(fill out when relevant / applicable) Respondent skipped this question

---

**Q20** Number of participants:Planned number based on power analysis? **Yes**

---

**Q21** Sensors and equipment used: E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour, time to completion...)

Sensors/equipment:

**Fitbit Charge HR for Pre-test screening; SENS-motion 3 axes sensors mounted on thigh 5-10 cm above knee & waist; Moto tiles for light exercise**

Types of data collected, resolution:

**Activity level in terms of numbers of steps, postural control level**

Data resolution (e.g. steps/hour; time to completion)

**24h /7w**

---

**Q22** Assessments performed: E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures:

**- Chair Stand; Timed Up and Go; Bergs Balance Score; 6 Minutes Walking Test; Questionar (FS36)**

---

**Q23** Results: Write summary bullets only, and leave data details in report on Projectplace

Timed up and go: A mean improvement of 1.43 seconds in the test from pre-to post testing. The improvement is between -0.16 and 3.02 seconds. 6MWT: A mean difference of -33.3 meter, in the test from pre-to post testing. The 95% confidence interval shows that the improvement is between -68.8 and 2.23 meters. Chair stand test: A mean difference of -1.44 stands in the test from pre-to post testing. The 95% confidence interval shows that the improvement is between -2.54 and -0.35 stands. Bergs balance scale: A mean difference of -11.22 points in the test from pre-to post testing. The 95% confidence interval shows that the improvement is between -17.42 and -5.03 point.

---

**Q24** Problems, limitations, other factors, key lessons: E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

NONE

# #21

**COMPLETE**

**Collector:** Third collection (Email)  
**Started:** Thursday, January 10, 2019 9:16:45 PM  
**Last Modified:** Thursday, January 10, 2019 9:33:37 PM  
**Time Spent:** 00:16:51  
**Email:** rala@sund.ku.dk  
**IP Address:** 85.24.5.16

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Page 1

## Q1 Title and acronym:

The MIPAM trial: A 12-week intervention with motivational interviewing and physical activity monitoring, to enhance the daily amount of physical activity in community dwelling older adults – a randomized controlled trial

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**physical activity monitoring: older adults: walking: wearables: motivational interview: behavioural change strategies**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

A parallel group randomized controlled trial with a superiority research question. Participants will be randomized into the intervention group or the control group and receive the 12-week intervention. The intervention will consist of bi-weekly (5 in total) motivational interviews related to the objectively measured physical activity using a social cognitive theory-based conversation guide.

---

## Q4 Protocol

Inclusion:

**A. Status as community-dwelling (living at home and not in a nursing home). B. Age above 70 years C. Willing to participate and owns a smartphone with an internet connection at home. D. Ability to walk independently on their own with or without assistive devices.**

Exclusion:

**A. Major cognitive impairment (dementia or Alzheimer's disease). B. Major mobility impairment from disease (sclerosis, parkinson's disease and similar). C. Life threatening cancer (active treatment).**

Medical target conditions (when relevant):

**None**

Protocol link (eg. Projectplace link):

**None**

---

**Q5 Background for the trial:**

In several RCTs and in a systematic review with a meta-analysis, physical activity monitors have been reported to effectively enhance the daily amount of physical activity in older adults. Some evidence suggests that increased feedback and focus on social barriers to physical activity might increase the effect.

---

**Q6 Aim/purpose of the trial:**

The aim of this study is to investigate if bi-weekly motivational telephone interviews as a add-on intervention to the use of consumer-grade physical activity monitors is superior to the use of consumer-grade physical activity monitors alone.

---

**Q7 Hypotheses of the trial:**

That motivational interviewing will enhance the effect from physical activity monitoring and consumer available monitors.

---

**Q8 Risks and biases of the trial:**

Limited criterion validity in the trackers, social desirability bias in self reported outcome measures and other types of over reporting.

---

**Q9 Ethics approval and data protection:** (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **09/10/2018** ,

(if applicable):

Data protection approval date **18/12/2018**

(if applicable):

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**Q10 Comments on Ethics / Data protection approval (if any)**

NA

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**Q11 Participating centers, institutions or companies:**Name/ short name (address only in case center is not REACH partner) separated by semicolons

Municipality of Copenhagen

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**Q12 Key Investigator(s):**First name, second name of each of the key persons involved

Names separated by semicolons:

**Rasmus Tolstrup Larsen and Professor Henning Langberg**

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**Q13 Corresponding REACH parts:**

TP4

**Henning Boje Andersen**

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**Q14** Time range of the study phase:Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001) Start date study phase: **01/03/2019** , End date study phase: **01/03/2020**

**Q15** Time range of data collection period:Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001) Start date study phase: **01/03/2019** , End date study phase: **01/03/2020**

**Q16** Protocol deviations/amendments:Describe major deviations from planned study

The study has not started yet

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>128</b>
Actual number recruitment - female:	<b>0</b>
Actual number recruitment - male:	<b>0</b>
Actual number completed study - female:	<b>0</b>
Actual number completed study - male:	<b>0</b>

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>0</b>
Median age:	<b>0</b>
Min. age:	<b>0</b>
Max. age:	<b>0</b>

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:	<b>NA</b>
Health / ambulatory status:	<b>NA</b>

**Q20** Number of participants:Planned number based on power analysis? **Yes**

**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	<b>Garmin Vivofit 3</b>
Types of data collected, resolution:	<b>Step counts</b>
Data resolution (e.g. steps/hour; time to completion)	<b>Steps/day</b>

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures: **NA**

Comparators: **NA**

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

NA

---

**Q24** Problems, limitations, other factors, key lessons:E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

Secondary outcome measures include

HRQoL (EQ5D)

Self-efficacy for exercise scale

Outcome Expectancy for Exercise

Self reported physical activity (IPAQ and Nordic PAQ)

Loneliness Scale

---

## #22

COMPLETE

**Collector:** Fourth collection (Email)  
**Started:** Friday, January 11, 2019 6:49:52 AM  
**Last Modified:** Friday, January 11, 2019 7:27:43 AM  
**Time Spent:** 00:37:50  
**Email:** rala@sund.ku.dk  
**IP Address:** 85.24.5.16

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Page 1

### Q1 Title and acronym:

Criterion validity for step counting in four consumer-grade physical activity monitors among 103 older adults with and without rollators

---

### Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**Validity: physical activity monitors: walking: technology:**

---

**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Participants performed self-paced walking for six minutes while two physiotherapists counted the steps with a click-counter. The participants were fitted with 16 monitors, four devices located bilaterally on both hips and wrists. Physical activity monitors were eligible for inclusion in this study if; 1) they were able to be fastened at the hip as well as on the wrist, 2) they were simple in function and design so they could be handled without flair for technical devices, 3) they only included step-counting as outcome measure and 4) they operated with a button cell battery. Interclass correlation coefficients (2,1). A priory, we expected all monitors to have at least moderate criterion validity for all participants, a good criterion validity for participants walking without a rollator and a poor criterion validity for participants walking with a rollator.

---

### Q4 Protocol

Inclusion:

**Participants were eligible to participate if they were above 65 years of age, community-dwelling, living at home and able to walk independently with or without a rollator.**

Exclusion:

**Exclusion criteria included major cognitive impairment such as dementia or Alzheimer's disease, and major mobility issues from stroke, Parkinson's disease, Multiple Sclerosis or similar diseases affecting the mobility.**

Medical target conditions (when relevant):

**None**

---

**Q5** Background for the trial:

Few studies have investigated the measurement properties of consumer-grade physical activity monitors in older adults.

**Q6** Aim/purpose of the trial:

We investigated the criterion validity of consumer-grade physical activity monitors in older adults and whether the measurement properties differed between older adults with and without rollators and if body placement of the same type of monitor affected the results.

**Q7** Hypotheses of the trial:

A priori, we expected bilateral counts from the same model measured on the left and the right side of the body to have good agreement and we expected all PAMs, no matter the placement, to have at least moderate criterion validity for all participants, a good criterion validity for participants walking without a rollator and a poor criterion validity for participants walking with a rollator.

**Q8** Risks and biases of the trial:

Respondent skipped this question

**Q9** Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date **27/10/2017**,  
(if applicable):  
Data protection approval date **01/01/2001**  
(if applicable):

**Q10** Comments on Ethics / Data protection approval (if any)

We did not collect any person data.

**Q11** Participating centers, institutions or companies: Name/ short name (address only in case center is not REACH partner) separated by semicolons

Municipality of Copenhagen

**Q12** Key Investigator(s): First name, second name of each of the key persons involved

Names separated by semicolons:

**Rasmus Tolstrup Larsen: Henning Langberg**

**Q13** Corresponding REACH parts:

TP4

**Henning Boje Andersen**

**Q14** Time range of the study phase: Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted (if no dates write 01/01/2001)

Start date study phase: **01/03/2018**,  
End date study phase: **06/25/0018**

**Q15** Time range of data collection period: Start: Begin data collection End: Data collection finished (if no dates write 01/01/2001) Start date study phase: **01/03/2018** , End date study phase: **06/25/0018**

**Q16** Protocol deviations/amendments: Describe major deviations from planned study

The Nokia GO monitor were not used as planned as it was not able to synchronise between study participants.

**Q17** Number of participants: (if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<b>100</b>
Actual number recruitment - female:	<b>0</b>
Actual number recruitment - male:	<b>0</b>
Actual number completed study - female:	<b>68</b>
Actual number completed study - male:	<b>35</b>

**Q18** Age of participants: (if not yet started, write "0"; provide either mean or median or both)

Mean age:	<b>81.3</b>
Median age:	<b>0</b>
Min. age:	<b>63</b>
Max. age:	<b>97</b>

**Q19** Medical conditions (fill out when relevant / applicable)

Medical information:	<b>None</b>
Health / ambulatory status:	<b>103</b>

**Q20** Number of participants: Planned number based on power analysis? **Yes**

**Q21** Sensors and equipment used: E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect... Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:	<b>Garmin Vivofit 3: Jawbone UP: Nokia GO: Misfit Shine</b>
Types of data collected, resolution:	<b>Steps</b>
Data resolution (e.g. steps/hour; time to completion)	<b>Steps in six minutes</b>

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures: **None**

Comparators: **None**

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

Four physical activity monitors were included in this study; Misfit Shine, Nokia GO, Jawbone UP and Garmin Vivofit 3. A total of 103 older adults participated and for each monitor, a total of 206 measures were available. All hip-worn PAMs fulfilled the a priori hypothesized moderate criterion validity evaluating all participants. The hip-worn Garmin Vivofit 3 fulfilled the a priori hypothesized criterion validities evaluating all participants, participants with rollator and participants without rollators. None of the wrist-worn PAMs fulfilled the a priori hypothesized criterion validity for any of the three participant groups.

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**Q24** Problems, limitations, other factors, key lessons:E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

Wrist-worn monitors cannot measure number of steps in a population of older adults using rollators. The hip-worn PAMs were not significantly different in terms of measurement error or criterion validity, but overall the Garmin Vivofit 3 seems to be the best performing device of the four.

---

# #23

**COMPLETE**

**Collector:** Third collection (Email)  
**Started:** Friday, January 11, 2019 2:26:07 PM  
**Last Modified:** Friday, January 11, 2019 2:40:42 PM  
**Time Spent:** 00:14:35  
**Email:** MiranaMichelle.Randriambelonoro@hcuge.ch  
**IP Address:** 178.198.101.65

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Page 1

## Q1 Title and acronym:

Mirana: A conversational agent with a hybrid user interface to promote healthy eating

---

## Q2 Keywords (min. 3; max. 8):

List keywords, separated by semicolon:

**health; behavior change; nutrition; obese; diabetes**

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**Q3 Test Design as planned:** Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Cross over trial with 20 participants during 8 weeks at their home.

---

## Q4 Protocol

Inclusion:

**Overweight, obese and diabetic patients (BMI $\geq$ 27) treated at the therapeutical education department of HUG and going there for a consultation once a month; having a smartphone or a computer and an access to internet.**

Exclusion:

**Patients with specific diet due to his/her medical condition; patients who are not able to interact with the intervention technology.**

Medical target conditions (when relevant):

**Obese and diabetes**

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**Q5 Background for the trial:**

Every year, 41 million people die due to noncommunicable diseases (NCDs), which represents 71% of all the deaths in the world [1]. Among the main risk factors of non-communicable diseases are lifestyle habits that we can influence such as smoking, unhealthy eating or lack of physical exercise. However, although engaging in healthy behaviors has been shown to be very beneficial to health and well-being, the main challenge remains in the motivation for adoption and the long-term commitment to such behavior. Food recommender systems have received increasing attention to help people adopt healthier eating behavior. These systems focus on suggesting proper food items based on individuals' preferences and health conditions [2]. Nevertheless, despite the extensive research and the large number of existing nutrition applications, food recommender systems are still facing many challenges in terms of nutrition habits tracking and delivery of the proper recommendations [3]. People find it often difficult and time consuming to enter manually their food everyday in the system. Many studies are also facing the uncertainty of the information given by the users as they may not know or tend to forget what they have eaten which makes it more challenging for the system to recommend the correct food item. Additionally, many studies have shown that the recommendation is not necessarily followed by a change in the behavior [4]. There is still a lack of understanding in how to incorporate efficiently behavior change techniques into a food recommender system. On the other side, with the recent development in natural language understanding, conversational agent has gained popularity over the past three years. In the nutrition domain, it allows to collect user data in an easy and user-friendly manner. Researchers at MIT developed a Web-based prototype of a speech-controlled nutrition-logging system which convert the entry spoken by the users into calories intake [5]. Researchers at the University of Applied Sciences in Western Switzerland worked on a chatbot that help people reduce their meat and increase fruits and vegetables consumption [6]. Users were able to set nutrition goals themselves and had a follow-up with the system every day. Although, only 11% could reach their objectives, more than half of the participants showed positive changes in their nutrition habits. Here, we developed a conversational agent called "Mirana", where the goal is to help the user to be aware of their eating habits in terms of variety and regularity. Rather than focusing of food quantity and nutritional value, the system targets the variety of the individuals' diet.

**Q6 Aim/purpose of the trial:**

The goal of the study is first, to understand the efficiency of a conversational agent in detecting the user's nutrition habits and identifying a key food item that needs to be reduced compared to a health professional. Second, to test the adoption and the acceptance of the personalized and timely recommendation given by the conversational agent.

**Q7 Hypotheses of the trial:**

"Mirana" is able to assess the user's nutrition habits as efficiently and even better than a health professional.  
"Mirana" is able to identify a key food items that needs to be reduced as efficiently as a health professional.  
Patient is more motivated and engaged to change their behavior with the help of the conversational agent.

**Q8 Risks and biases of the trial:**

**Respondent skipped this question**

**Q9 Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".**

Ethics Committee reply date **01/01/2001**  
(if applicable):  
Data protection approval date **01/01/2001**  
(if applicable):

**Q10 Comments on Ethics / Data protection approval (if any)**

**Respondent skipped this question**

**Q11** Participating centers, institutions or companies:Name/ short name (address only in case center is not REACH partner) separated by semicolons

HUG

**Q12** Key Investigator(s):First name, second name of each of the key persons involved

Names separated by semicolons:

**Mirana Randriambelonoro; Antoine Geissbuhler; Dimitri Konstantas; Alain Golay; Aude Daccord**

**Q13** Corresponding REACH parts:

TP3

**Socializing and Nutrition**

**Q14** Time range of the study phase:Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)

Start date study phase:

**01/01/2001**

End date study phase:

**01/01/2001**

**Q15** Time range of data collection period:Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)

Start date study phase:

**01/01/2001**

End date study phase:

**01/01/2001**

**Q16** Protocol deviations/amendments:Describe major deviations from planned study

Not applicable yet.

**Q17** Number of participants:(if not yet started write "0" in the "actual number" fields)

Planned by protocol:

**20**

Actual number recruitment - female:

**0**

Actual number recruitment - male:

**0**

Actual number completed study - female:

**0**

Actual number completed study - male:

**0**

**Q18** Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Mean age:

**0**

Median age:

**0**

Min. age:

**0**

Max. age:

**0**

**Q19** Medical conditions(fill out when relevant / applicable)

Medical information:

**Obese and diabete**

---

**Q20** Number of participants:Planned number based on power analysis? **No**

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**Q21** Sensors and equipment used:E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:

**"Mirana" conversational agent application**

Types of data collected, resolution:

**Interview data + food logging**

Data resolution (e.g. steps/hour; time to completion)

**3 interviews and food logging everyday**

---

**Q22** Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength.); comparators (what was the intervention compared to, if relevant)

Assessment measures:

**Qualitative interview / Food variety (nutrition questionnaire)**

Comparators:

**Standard care (manual food logging) with no assistance from the conversational agent**

---

**Q23** Results:Write summary bullets only, and leave data details in report on Projectplace

Not applicable yet.

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**Q24** Problems, limitations, other factors, key lessons:E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

Not applicable yet.

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# Appendix 2: Trial reports sorted by item

## Q1 Title and acronym:

Answered: 23 Skipped: 0

#	RESPONSES	DATE
1	Mirana: A conversational agent with a hybrid user interface to promote healthy eating	1/11/2019 2:40 PM
2	Criterion validity for step counting in four consumer-grade physical activity monitors among 103 older adults with and without rollators	1/11/2019 7:27 AM
3	The MIPAM trial: A 12-week intervention with motivational interviewing and physical activity monitoring, to enhance the daily amount of physical activity in community dwelling older adults – a randomized controlled trial	1/10/2019 9:33 PM
4	Lyngby 2: Feasibility study conducted in preparation of the planned Lyngby	1/10/2019 11:29 AM
5	Lyngby 3: The effect of playware technologies on physical activity	1/10/2019 11:26 AM
6	Lyngby 1: Effect of daily feedback on older adults' physical activity level	1/10/2019 11:24 AM
7	Playful Body and Brain Test with the Moto Tiles	1/9/2019 2:03 PM
8	Lyngby 4: Developing a reliable technique for automatic counting of steps of older adults – a validation study	1/9/2019 10:03 AM
9	Lyngby 5 Trial: Test of smart home technologies	12/25/2018 12:48 PM
10	ActiveLife Test	12/19/2018 8:30 PM
11	SmartCardia - Healthy Volunteer Testing	12/19/2018 7:11 PM
12	SmartCardia - Patient testing at CardioCentro Lugano	12/19/2018 6:59 PM
13	Coffee Demonstrator Experiment	12/18/2018 3:13 PM
14	Opportunities and challenges for self-monitoring technologies for healthy aging: An in-situ study	12/13/2018 4:01 PM
15	Activity recognition with wearables and ambient sensors - gathering of data sets for the empirical validation with neurological patients	12/13/2018 2:51 PM
16	Towards personalised persuasive strategies for active ageing	12/13/2018 11:13 AM
17	HUG early testing	12/12/2018 4:40 PM
18	REACH Eindhoven Continued testing	12/11/2018 6:49 PM
19	Data Collection and Annotation Workshop Touchpoint 2	12/11/2018 1:35 PM
20	The Transfer- und Training Device activLife with neurological patients. Feasibility und Usability Study	12/10/2018 4:59 PM
21	A personal mobility device for elderly physical rehabilitation: a study of acceptance and efficiency	12/10/2018 4:13 PM
22	Questionnaire for the investigation of motivational aspects for food intake by elderly people / [...] by dysphagia patients	12/10/2018 3:10 PM
23	Feasibility study - SmartCardia sensors with standard Holter system and activePal sensors	12/10/2018 3:00 PM

## Q2 Keywords (min. 3; max. 8):

Answered: 23 Skipped: 0

ANSWER CHOICES		RESPONSES
List keywords, separated by semicolon:		100.00% 23
#	LIST KEYWORDS, SEPARATED BY SEMICOLON:	DATE
1	health; behavior change; nutrition; obese; diabetes	1/11/2019 2:40 PM
2	Validity: physical activity monitors: walking: technology:	1/11/2019 7:27 AM
3	physical activity monitoring: older adults: walking: wearables: motivational interview: behavioural change strategies	1/10/2019 9:33 PM
4	Playware, behaviour change, gaming, elderly, exercise, physical activity, postural control	1/10/2019 11:29 AM
5	Gaming; Physical activity; Functional ability	1/10/2019 11:26 AM
6	Physical activity monitoring; Sensors; wearables; behaviour change; Effect of feedback; activity tracking	1/10/2019 11:24 AM
7	Playware; balance test; cognitive test ;fall risk	1/9/2019 2:03 PM
8	Accelerometer; pedometer; validation; physical activity; step count; algorithm	1/9/2019 10:03 AM
9	Smart Home, age at place	12/25/2018 12:48 PM
10	motivation, activity center, RCT	12/19/2018 8:30 PM
11	Wearable sensor; vital signs; validation against monitors; activity	12/19/2018 7:11 PM
12	Vital signs; wearable; patient testing	12/19/2018 6:59 PM
13	time series analysis, time series clustering, pattern detection, change point detection	12/18/2018 3:13 PM
14	Health; behavior change; activity monitoring; qualitative studies; older adults; physical activity	12/13/2018 4:01 PM
15	Sensors; neurology; activity recognition; data sets; machine learning; algorithm	12/13/2018 2:51 PM
16	active ageing, behaviour change, persuasive strategies, personalisation, physical activity	12/13/2018 11:13 AM
17	Alreh Medical, elderly, safe standing, gaming platform,	12/12/2018 4:40 PM
18	active ageing; personalising behaviour change; motivation; technology acceptance	12/11/2018 6:49 PM
19	Data Collection, Data Annotation, Ambient Sensing, Wearable Sensing, Monitoring, Targeting Specific Activities (Eating, Drinking and etc.)	12/11/2018 1:35 PM
20	activity, neurology, sit-to-stand, transfer, mobility, training	12/10/2018 4:59 PM
21	Rehabilitation; Serious games; Wearable Electronic Devices	12/10/2018 4:13 PM
22	Dysphagia, pureed food, motivational aspects to eat, effects on appetite and mood	12/10/2018 3:10 PM
23	ECG, motion data, posture	12/10/2018 3:00 PM

### Q3 Test Design as planned: Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

Answered: 23 Skipped: 0

#	RESPONSES	DATE
1	Cross over trial with 20 participants during 8 weeks at their home.	1/11/2019 2:40 PM
2	Participants performed self-paced walking for six minutes while two physiotherapists counted the steps with a click-counter. The participants were fitted with 16 monitors, four devices located bilaterally on both hips and wrists. Physical activity monitors were eligible for inclusion in this study if; 1) they were able to be fastened at the hip as well as on the wrist, 2) they were simple in function and design so they could be handled without flair for technical devices, 3) they only included step-counting as outcome measure and 4) they operated with a button cell battery. Interclass correlation coefficients (2,1). A priori, we expected all monitors to have at least moderate criterion validity for all participants, a good criterion validity for participants walking without a rollator and a poor criterion validity for participants walking with a rollator.	1/11/2019 7:27 AM
3	A parallel group randomized controlled trial with a superiority research question. Participants will be randomized into the intervention group or the control group and receive the 12-week intervention. The intervention will consist of bi-weekly (5 in total) motivational interviews related to the objectively measured physical activity using a social cognitive theory-based conversation guide.	1/10/2019 9:33 PM
4	The Lyngby 2 trial was a feasibility study conducted from April-July 2017 in preparation of the planned Lyngby 3 trial. The study involved 9 elderly participants engaging in playful exercise and from whom movement tracking data were collected throughout the day over 8 week Participants are divided into two teams of 5 persons. Each team is engaged in 1 hour of playful activity session twice a week at a municipal center. For each session, led by Moto play master, each team member is engaged in 12 minutes of activity divided into 2-minute exercises. The experiment run for 8 weeks, so each participant has 16 sessions. During the test participants wear two types of activity trackers: Sens patch and Fitbit Charge HR that measure physical activity (steps: per minute/hour/day), sleep durations and heart rate. Tracking data will be uploaded from the trackers to a smartphone in participants' home. Data upload will be monitored at DTU and if the data connection is lost, the analysis team will make a phone call and, if accepted, a visit to re-establish data collection. They participated is training on the Moto tiles for eight weeks. The Moto tiles are tiles that light up and react when pressed, they allow for making a different kind of games that require the user to use the body and mind to complete.	1/10/2019 11:29 AM
5	This randomized control trial was designed as a 24 weeks trial. The initial plane was to balance randomized a sample of 40 older adults aged 65+ into two groups; an intervention and a control group. The intervention run for 12 weeks, hence each participant was engaged in 16 sessions, each of approx.12 minutes per training day. The intervention was divided into teams of 4 or 5 people. Each team was engage in 1 hour of playful activity session twice a week at a municipal center. Each session was led by Moto play master and each team member was engage in 12 minutes of activity divided into 2 minute exercises. Randomization was balanced so that the two groups had approximately the same distribution of daily physical activity (indicated by the 5-day pre-training measure of daily number of steps and postural control measures) and age. During the trial all participants wore a sensor (SENS motion sensor under a patch on their thigh 10 cm above their knee. There were no training planned for control group at the first 12 weeks of the trial. Control group particioants were engaged in their normal physical and social activities, similar to those of the intervention group. As it is illustrated in the figure bellow, the initial plan was to conduct 4 balance measuring rounds.	1/10/2019 11:26 AM

6	This randomized control trial starded over 9 weeks. N=26 aged 65+ has been randomly assigned to monitor vital signs such as heart rate, daily steps, sleep hours and etc. by using Fitbit charge HR. All participant was asked to wear the Fitbit tracker for 5 days to assess baseline physical activity level. After successfully completing the baseline measurement and signing the informed consent, participants were randomized into two groups to perform the trial. Group A received 4 weeks feedback on sleep, group B received 4 weeks feedback on steps. Depending on which group the participant belongs to, the participant was asked to rate how active they were yesterday or how they slept last night. Participants were asked to rate their activity level in 3 categories, less active than I am used to, moderate (as I am used to), high active than I am used to. After 4 weeks the groups shifted e.g. group A started receiving feedback on steps group B started receiving feedback on sleep.	1/10/2019 11:24 AM
7	The study consists of two parts. The first part includes three standardized balance tests. Participants are timed by both stopwatch and the Moto Tiles. The second part includes four Moto Tile games. Participants play the four games in sequence and the scores are collected.	1/9/2019 2:03 PM
8	Test design as planned This validation study was planned to use data collected from activity assessment of Lyngby 3 supplemented with additional walking data. A test of balance and functional ability of a group of 25 older adults, involving for each participant a 6- minute walk test, was carried out as planned in June/July 2018. About half of the elderly participants used a rollator regularly. according to the plan, we collected data from five sensors and a video-based observational counting of steps. Each Participant walked 6 min for each of three different walking trials: 1) a 6 min walk at self-selected pace (natural speed of the participants – half indoors, half outdoor walks 2) a 6 min walk outdoors at fastest pace 3) a 6 min walk indoors at fastest pace	1/9/2019 10:03 AM
9	Test Design: Feasibility study: collecting in-home activity data by sensors mounted in walls, furniture, and daily objects.	12/25/2018 12:48 PM
10	Study flow, test setting and design are provided in the file in project place <a href="https://service.projectplace.com/#project/1203354283/documents/840801989">https://service.projectplace.com/#project/1203354283/documents/840801989</a>	12/19/2018 8:30 PM
11	This is a 30 healthy subject trial in which the smartcardia wearable sensors were tested against medically approved monitor (EDAN ICU monitor that measures the ECG, SpO2 and skin temperature using cable sensors).	12/19/2018 7:11 PM
12	In this study, we aimed at assessing the safety, validity and satisfaction of the innovative equipment produced by SmartCardia SA (an EPFL start-up). All the evaluations have bee performed with Golden Standard ICU existing monitoring system of Cardiocentro to allow a proper validation of SmartWearable device. The following primary, secondary endpoints will be used for the study design: Primary outcome measures: • Data Collection of continuous Vital Signs and Physiological Parameters recorded with standard monitor. ECG, HRV, SPO2, Skin Temperature, Blood Pressure Trends, Pulse Rate, Posture and Activity • Continuous SmartWearable measure of the following parameters - Heart rate and heart rate variability of the ICU patients - Blood pressure based on Pulse Transit Time (PTT) - Oxygen saturation - Skin temperature • Benchmark the vital parameters obtained by the SmartCardia device • Comparison of the accuracy and efficacy, between SmartWearable vs. Golden Standard monitoring system of Cardiocentro ICU. Secondary endpoints • Algorithmic Predictive Validity • Algorithmic Predictive Accuracy • Algorithmic Predictive Efficacy Total Enrollment 60 patients	12/19/2018 6:59 PM
13	For this test, I myself (Dr. Sebastian Konietzny) represented the test subject.	12/18/2018 3:13 PM
14	Cohort study (qualitative study) with 20 participants during 6 weeks at their home.	12/13/2018 4:01 PM
15	Pilot study; usability/ feasibility study Subjects will be measured with multiple sensors in a controlled environment (apartment and bathroom) during activities of daily living (ADL). Patients and healthy subjects will be included.	12/13/2018 2:51 PM
16	We analyzed the design outcomes of 12 student projects, who each followed a user-centered, iterative design process, according to Persuasive Systems Design framework (Oinas-Kukkonen, 2009). The students were given the assignment to redesign an application to motivate older adults to engage in more physical activity. From this investigation, five main persuasive strategies were identified which likely will be valuable in motivating older adults for physical activity.	12/13/2018 11:13 AM

17	<p>This study aims at assessing the safety, validity and functionality of an innovative rehabilitation equipment produced by Alreh Medical, the iStander activ, associated with its software, Neuroforma, as well as a commercially available sensor produced by Fitbit, the Fitbit Charge 2. Patients hospitalized in the Geneva Geriatric Division and healthy controls matching our inclusion criteria were recruited by care-givers and the research team, respectively. Patients were randomly assigned to train their transfers with the iStander activ and its associated-software, neuroforma (n=5), or according to the Standard Medical Care (SMC, n=5) during 4 consecutive days over 30 minutes. Healthy controls (n=5) trained their transfers using the iStander activ and Neuroforma. Exercises were performed under monitoring by the Fitbit Charge 2 device. Safety was assessed by free reporting of any adverse events by patients or care-givers. Functionality was assessed by the NASA Task-Load Index (NTLI) jointly filled in by patients and care-givers at day 4. Care-givers and patients were also invited to freely comment on the devices. Finally, a comparison of heart rate values measured by the Fitbit device and heart rate values measured by care-givers assessed the validity of the Fitbit Charge 2 as an heart rate measurement tool. This study was approved by the Geneva Canton Ethics Body (Commission Cantonale d’Ethique de la Recherche) under the number 2016-01957.</p>	12/12/2018 4:40 PM
18	<p>Within-participant A and B test comparing baseline (4 weeks) to intervention (4weeks). Test group A's intervention was an application using self-reflection strategies to motivate behavior change (more physical activity) while group B's intervention was a similar application which using social reflection strategies to motivate behavior change (more physical activity). Contextual, phycological, and self-reported behavioral factors were collected about participants via a questionnaire which was given three times: 1) before the baseline, 2) after the baseline before the intervention and 3) after the intervention. Behavioral data, in terms of physical activity, was also measured throughout the baseline and the intervention period via a Fitbit Flex.</p>	12/11/2018 6:49 PM
19	<p>non-randomised trial</p>	12/11/2018 1:35 PM
20	<p>Pilot study; usability/ feasibility study; monitoring project. Subjects will be measured with multiple sensors during 3 differnet sit-to-stand-transfer methods in a controlled environment: Transfer with activLife device, with and without transfer aid. Neurological patients and healthy subjects will be included.</p>	12/10/2018 4:59 PM
21	<p>Randomized Clinical Trial with 46 patients during 6 weeks.</p>	12/10/2018 4:13 PM
22	<p>Two separated questionnaires (normal eating elderly &amp; dysphagia patients) in three different countries (Denmark, The Netherlands, Germany). Both subdivided in demographic data &amp; overview and Food &amp; Eating</p>	12/10/2018 3:10 PM
23	<p>Feasibility and usability study to evaluate the functionalities of the SmartCardia sensor and to compare the ECG and motion data of the SC sensors to other sensors.7 healthy subjects performed the TuG test, 6 min walking test, and 5 min training with an cycle ergometer while wearing all sensor systems. Additional to ECG and motion data gender, age, height, weight, and pigmentary phototype were collected.</p>	12/10/2018 3:00 PM

## Q4 Protocol

Answered: 23 Skipped: 0

ANSWER CHOICES	RESPONSES	
Inclusion:	100.00%	23
Exclusion:	100.00%	23
Medical target conditions (when relevant):	86.96%	20
Protocol link (eg. Projectplace link):	69.57%	16

#	INCLUSION:	DATE
1	Overweight, obese and diabetic patients (BMI>=27) treated at the therapeutical education department of HUG and going there for a consultation once a month; having a smartphone or a computer and an access to internet.	1/11/2019 2:40 PM
2	Participants were eligible to participate if they were above 65 years of age, community-dwelling, living at home and able to walk independently with or without a rollator.	1/11/2019 7:27 AM
3	A. Status as community-dwelling (living at home and not in a nursing home). B. Age above 70 years C. Willing to participate and owns a smartphone with an internet connection at home. D. Ability to walk independently on their own with or without assistive devices.	1/10/2019 9:33 PM
4	- Citizens aged 65+ at Lyngby activity center.	1/10/2019 11:29 AM
5	Citizens aged 65+ at Lyngby activity center	1/10/2019 11:26 AM
6	Citizens aged 65+ at Lyngby activity center.	1/10/2019 11:24 AM
7	All people aged over 4 years old	1/9/2019 2:03 PM
8	Citizens aged 65+ at Lyngby activity center	1/9/2019 10:03 AM
9	Inclusion criteria: We want to include two or three older adults, who are living independent living independently at their own home and are responsible for their daily tasks themselves	12/25/2018 12:48 PM
10	Both groups were recruited from the guests of Ontmoet en Groet center. Group 1: 21, 11 females and 10 males, with an averaged age of 78.05 Group 2: 22, 8 females and 14 males, with an averaged age of 75.82	12/19/2018 8:30 PM
11	Healthy volunteers	12/19/2018 7:11 PM
12	The duration of the Study was 39 weeks and the targeted population (patients suffering from CVD with an emphasis on Cardiovascular Patients with Minor Hemodynamic Instability after Cardiac Surgery or after Invasive Cardiac Intervention) have reached the number 60 (details on the diagnosis and reason of admission are depicted in table 2). The Safety, Efficacy, Validity, Accuracy and Sensitivity of the SmartWearable has being tested in a cross over comparison with the existing ICU Dräger - Healthcare Monitoring System of the Hospital as well as with the fully CE certified (and with FDA Clearance) Medical Devices, tracing the same vital parameters.	12/19/2018 6:59 PM
13	none	12/18/2018 3:13 PM
14	65+ years old, living at home, and in need of occasional help for their daily activities.	12/13/2018 4:01 PM
15	Patients and healthy subjects: • Age ≥ 65 years • Ambulatory with and without walking aids • Speech comprehension Patients: • Inpatients at Schön Klinik Bad Aibling with one of the following diagnoses: TBI, stroke (ischemic or hemorrhagic), hypoxia, critical illness polyneuropathy (CIP) or myopathy (CIM), Alzheimer's disease, Parkinson's disease, incomplete paraplegia. • Full Barthel score without items 5, 6, 10 (fecal and urinary incontinence, stair climbing) • Bogenhausener Dysphagia Score ≥6 (BODS 1 and BODS2)	12/13/2018 2:51 PM
16	Students in our course	12/13/2018 11:13 AM

17	those of the REACH HUG use-case: age over 65 years old, and hospitalized at the Geneva geriatric Hospital (Hôpital des Trois Chênes), and planned discharged with the help of the Geneva Institution of home care (Institution Genevoise de Maintien à Domicile, IMAD), and a Mini-Mental State Examination (MMSE) 20= 4 for the items regarding mobility and locomotion) and a minimal level of cognitive ability (MMSE>=27) to be able to interact with the equipment AND hospitalized at least 3 weeks at one of the hospitals.	12/12/2018 4:40 PM
18	participant of the senior community centre	12/11/2018 6:49 PM
19	Activity monitoring, data collection, sensor integration and implementation, protocol and procedure definition and declaration	12/11/2018 1:35 PM
20	Inpatients at Schön Klinik Bad Aibling (SKBA) with diagnose: TBI, stroke (ischemic or hemorrhagic), hypoxia, critical illness polyneuropathy (CIP) or myopathy (CIM), Alzheimer's disease (• MMSE ≥18), Parkinson's disease, or paraplegia and healthy subjects: • Age ≥ 65 years • Mobility factors that make the patient suitable for the transfer-training-groups at SKBA: MFAS point 11:0, BBS: tasc 1,4,6: > 2points, FAC <2; • device-specific: <120kg, 150-190cm	12/10/2018 4:59 PM
21	Seniors (65+) hospitalized in one of the involved sites at the Geneva University Hospital, with musculoskeletal issues (fracture, prosthesis, falls and low back pain), a minimal level of independence and strength (FIM >= 4 for the items regarding mobility and locomotion), and minimal level of cognitive ability (MMSE>=24). They should be able to interact with the equipment and be hospitalized at least 3 weeks at one of the hospitals.	12/10/2018 4:13 PM
22	for the second group: swallowing and/or mastication problems	12/10/2018 3:10 PM
23	7 healthy subjects	12/10/2018 3:00 PM
<b>#</b>	<b>EXCLUSION:</b>	<b>DATE</b>
1	Patients with specific diet due to his/her medical condition; patients who are not able to interact with the intervention technology.	1/11/2019 2:40 PM
2	Exclusion criteria included major cognitive impairment such as dementia or Alzheimer's disease, and major mobility issues from stroke, Parkinson's disease, Multiple Sclerosis or similar diseases affecting the mobility.	1/11/2019 7:27 AM
3	A. Major cognitive impairment (dementia or Alzheimer's disease). B. Major mobility impairment from disease (sclerosis, parkinson's disease and similar). C. Life threatening cancer (active treatment).	1/10/2019 9:33 PM
4	- Inability to maintain a standing position either alone or with the use of support; - Strongly reduced mobility due to illness (arthritis, inflammation/ phlebitis...)	1/10/2019 11:29 AM
5	Inability to maintain a standing position either alone or with the use of support; - Strongly reduced mobility due to illness (arthritis, inflammation/ phlebitis...)	1/10/2019 11:26 AM
6	Inability to maintain a standing position either alone or with the use of support; - Strongly reduced mobility due to illness (arthritis, inflammation/ phlebitis...)	1/10/2019 11:24 AM
7	Color Blindness	1/9/2019 2:03 PM
8	Inability to maintain a standing position either alone or with the use of support; - Strongly reduced mobility due to illness (arthritis, inflammation/ phlebitis...)	1/9/2019 10:03 AM
9	N/A	12/25/2018 12:48 PM
10	people who cannot independently visit the center	12/19/2018 8:30 PM
11	People with cardiovascular or other medical conditions, patients under medications	12/19/2018 7:11 PM
12	Pacemaker, IVD implant patients	12/19/2018 6:59 PM
13	none	12/18/2018 3:13 PM
14	Elderly who are not able to interact with the device.	12/13/2018 4:01 PM
15	Instable cardiac arrhythmia; cardiac pacemaker; continous oxygen supply; uncontrolled medical conditions: cardiovascular diseases, rheumatoid arthritis, acute cancer, joint deformation caused by arthritis, kidney disorders, pulmonary or cardiovascular conditions in the final stage, uncontrolled epilepsy); acute alcohol or drug abuse	12/13/2018 2:51 PM

16	We would have excluded concepts which were insufficient quality, such as the students not passing the course, but all concepts deemed sufficiently similar in quality to be acceptable to include in our analysis.	12/13/2018 11:13 AM
17	Patients too weak to interact with the equipment and staying less than 3 weeks at the hospital.	12/12/2018 4:40 PM
18	not enough measured activity data collected	12/11/2018 6:49 PM
19	none	12/11/2018 1:35 PM
20	Exclusion factors for the participating the tranfer-group: pain during transmission, acut and painful shoulder-hand-syndrom. contractions and	12/10/2018 4:59 PM
21	Patients that are considered too weak to interact with the de-vice and that are hospitalized less than 3 weeks.	12/10/2018 4:13 PM
22	0	12/10/2018 3:10 PM
23	Age < 60 years, non-ambulatory	12/10/2018 3:00 PM
<b>#</b>	<b>MEDICAL TARGET CONDITIONS (WHEN RELEVANT):</b>	<b>DATE</b>
1	Obese and diabetes	1/11/2019 2:40 PM
2	None	1/11/2019 7:27 AM
3	None	1/10/2019 9:33 PM
4	none	1/10/2019 11:26 AM
5	none	1/10/2019 11:24 AM
6	N/A	1/9/2019 2:03 PM
7	none	1/9/2019 10:03 AM
8	N/A	12/25/2018 12:48 PM
9	None	12/19/2018 7:11 PM
10	Cardiac ICU monitoring	12/19/2018 6:59 PM
11	none	12/18/2018 3:13 PM
12	Not relevant	12/13/2018 4:01 PM
13	ADL, ambulatory status, balance, hand grip strength, cognitive function, motivation	12/13/2018 2:51 PM
14	none	12/13/2018 11:13 AM
15	none	12/11/2018 6:49 PM
16	none	12/11/2018 1:35 PM
17	mobilisations status, balance, hand grip strength, cognitive function, motivation	12/10/2018 4:59 PM
18	Musculoskeletal issues (fracture, prosthesis, falls and low back pain)	12/10/2018 4:13 PM
19	Malnutrition, Dysphagia	12/10/2018 3:10 PM
20	N/A	12/10/2018 3:00 PM
<b>#</b>	<b>PROTOCOL LINK (EG. PROJECTPLACE LINK):</b>	<b>DATE</b>
1	None	1/10/2019 9:33 PM
2	none	1/10/2019 11:29 AM
3	none	1/10/2019 11:26 AM
4	none	1/10/2019 11:24 AM
5	N/A	1/9/2019 2:03 PM
6	none	1/9/2019 10:03 AM
7	N/A	12/25/2018 12:48 PM
8	<a href="https://service.projectplace.com/#project/1203354283/documents/840801989">https://service.projectplace.com/#project/1203354283/documents/840801989</a>	12/19/2018 8:30 PM

9	None	12/19/2018 7:11 PM
10	<a href="https://service.projectplace.com/pp/pp.cgi/r1077731542">https://service.projectplace.com/pp/pp.cgi/r1077731542</a>	12/18/2018 3:13 PM
11	<a href="https://service.projectplace.com/pp/pp.cgi/r945597971">https://service.projectplace.com/pp/pp.cgi/r945597971</a>	12/13/2018 2:51 PM
12	Gerontechnology REACH special issue	12/13/2018 11:13 AM
13	<a href="https://service.projectplace.com/#project/1203354283/documents/993594569/993634307">https://service.projectplace.com/#project/1203354283/documents/993594569/993634307</a>	12/12/2018 4:40 PM
14	dont have one yet	12/11/2018 6:49 PM
15	<a href="https://service.projectplace.com/pp/pp.cgi/0/316508877?op=meeting&amp;open_win=1">https://service.projectplace.com/pp/pp.cgi/0/316508877?op=meeting&amp;open_win=1</a>	12/11/2018 1:35 PM
16	<a href="https://service.projectplace.com/#project/1203354283/documents/840802189/953288637">https://service.projectplace.com/#project/1203354283/documents/840802189/953288637</a>	12/10/2018 4:59 PM

## Q5 Background for the trial:

Answered: 23 Skipped: 0

#	RESPONSES	DATE
1	<p>Every year, 41 million people die due to noncommunicable diseases (NCDs), which represents 71% of all the deaths in the world [1]. Among the main risk factors of non-communicable diseases are lifestyle habits that we can influence such as smoking, unhealthy eating or lack of physical exercise. However, although engaging in healthy behaviors has been shown to be very beneficial to health and well-being, the main challenge remains in the motivation for adoption and the long-term commitment to such behavior. Food recommender systems have received increasing attention to help people adopt healthier eating behavior. These systems focus on suggesting proper food items based on individuals' preferences and health conditions [2]. Nevertheless, despite the extensive research and the large number of existing nutrition applications, food recommender systems are still facing many challenges in terms of nutrition habits tracking and delivery of the proper recommendations [3]. People find it often difficult and time consuming to enter manually their food everyday in the system. Many studies are also facing the uncertainty of the information given by the users as they may not know or tend to forget what they have eaten which makes it more challenging for the system to recommend the correct food item. Additionally, many studies have shown that the recommendation is not necessarily followed by a change in the behavior [4]. There is still a lack of understanding in how to incorporate efficiently behavior change techniques into a food recommender system. On the other side, with the recent development in natural language understanding, conversational agent has gained popularity over the past three years. In the nutrition domain, it allows to collect user data in an easy and user-friendly manner. Researchers at MIT developed a Web-based prototype of a speech-controlled nutrition-logging system which convert the entry spoken by the users into calories intake [5]. Researchers at the University of Applied Sciences in Western Switzerland worked on a chatbot that help people reduce their meat and increase fruits and vegetables consumption [6]. Users were able to set nutrition goals themselves and had a follow-up with the system every day. Although, only 11% could reach their objectives, more than half of the participants showed positive changes in their nutrition habits. Here, we developed a conversational agent called "Mirana", where the goal is to help the user to be aware of their eating habits in terms of variety and regularity. Rather than focusing of food quantity and nutritional value, the system targets the variety of the individuals' diet.</p>	1/11/2019 2:40 PM
2	<p>Few studies have investigated the measurement properties of consumer-grade physical activity monitors in older adults.</p>	1/11/2019 7:27 AM
3	<p>In several RCTs and in a systematic review with a meta-analysis, physical activity monitors have been reported to effectively enhance the daily amount of physical activity in older adults. Some evidence suggests that increased feedback and focus on social barriers to physical activity might increase the effect.</p>	1/10/2019 9:33 PM
4	<p>Lyngby 2 trial was conducted in preparation of the planned Lyngby 3 trial</p>	1/10/2019 11:29 AM
5	<p>Evidence from epidemiological and clinical studies shows that one of the most important approaches to improve the quality of life and healthy aging is to encourage daily physical activity among older adults. However, motivation to engage in physical activity is often low in old age. A potential method to increase physical activity may be the use of playware technologies such as moto tiles.</p>	1/10/2019 11:26 AM
6	<p>Evidence from epidemiological and clinical studies shows that one of the most important approaches to improve the quality of life and healthy aging is to encourage daily physical activity among older adults. However, there is lack of evidence on the effect of feedback on older adults physical activity level.</p>	1/10/2019 11:24 AM
7	<p>Ordinary early detection and filtering of some age-related diseases require complected and professional examination. By designing a special Moto Tile game session, the examination process can be turned interesting and simple.</p>	1/9/2019 2:03 PM

8	A primary factor in measuring functional mobility is the assessment of gait performance. However, the performance of accelerometer-based algorithms for step detection at low walking speeds is still deficient which limits their use in patients or elderly populations with gait impairment walking at low speeds.	1/9/2019 10:03 AM
9	Background: Smart homes seems to be a promising approach in helping older adults to stay safe and independent in their own home. However, there are lack of evidence about the positive and negative outcomes of smart home technologies. This study aims to measuring the ability and likelihood of smart home in real setting.	12/25/2018 12:48 PM
10	ActiveLife is to be tested for a longer period of time as an intervention to compared to physiotherapist's advice on regular sport activities.	12/19/2018 8:30 PM
11	The study took place at the SmartCardia office at EPFL innovation park. The ethical committee of the Canton of Vaud was obtained for it.	12/19/2018 7:11 PM
12	Title of Study: Clinical Validation Study for Algorithmic Evaluation & SmartCardia device(s) / "SmartWearable" for Accuracy / Safety and Efficacy vs. the Golden Standard Monitoring ICU System Study Design: Assessing the safety, validity and satisfaction of the innovative equipment Purpose: To investigate the safety and efficacy and accuracy of SmartWearable vs. the Golden Standard Monitoring ICU System Patient Population:. Study Duration: Total duration of the use of the SmartWearable device for each subject is continuous monitoring of 24 hrs. Study Status: Enrollment: Completed in 31.03.2018 Completion of data collection and analysis: 31.08.2018 Study Sites: Fondazione Cardiocentro Lugano	12/19/2018 6:59 PM
13	We designed an experiment, called the Coffee Demonstrator, to continuously track the heart rate data of a test user over one month by means of a Fitbit Surge smartwatch. Our goal was to analyze the collected sensor data time series, and to test whether it will be possible to predict moments of coffee drinking from that data. An essential part of the data collection process was the manual logging of coffee drinking moments done by the test user. The resulting data logs thus provided ground-of-truth labels for the later analysis.	12/18/2018 3:13 PM
14	Faced with the constant growth of aging population, the need to promote an environment for healthy aging is expanding. Although maintaining healthy behavior has been shown to be highly beneficial for older adults' health and wellbeing, the challenge remains in motivating the adoption and the long-term engagement in such behavior. There are opportunities for emerging technology to increase older adults' engagement in being physically active and managing their health. Within the European REACH (Responsive Engagement of the Elderly promoting Activity and Customized Healthcare) project, the goal is to learn the older adults' behavior by collecting physical activity and health related data in order to provide personalized health recommendation to them. For this purpose, we conducted an ethnographic study for data collection to get insights on older adults' readiness, willingness, and challenges to adopt pervasive sensors and applications for healthy ageing.	12/13/2018 4:01 PM
15	To validate the recommendations of the REACH system an exact pattern recognition and reliable classification strategy has to be integrated. The detection of activity pattern is based on data from wearables and ambient sensors, complemented with additional data, e. g., biometric data, medication, medical records. All data will be collected, interpreted, and classified at an central memory unit (engine). A first step to create algorithms is to generate data in a controlled environment which allow the recognition of certain activities. First data sets were generated on healthy subjects at the TU München. In an identical setting at SKBA data from neurological patients will be collected to specify the characteristics and variations. REACH should be able to recognize pattern and based on machine learning autonomously create proposed solutions. Multi sensor networks allow the precise recognition of the environment and the persons involved. Resource intensive activities could be transformed in automated processes resulting in savings into the health care system.	12/13/2018 2:51 PM
16	It is widely accepted how important physical activity is to the health and independence of older adults, however, many older adults lead a sedentary lifestyle, sitting for long periods of time.	12/13/2018 11:13 AM

17	The REACH project was created to solve the problems of caring for the ageing European population. The system supporting active ageing for both ageing people and carers is to be the result of the project works. Activities in the REACH project were divided into thematic sections - hereinafter referred to as the Touchpoint Clusters. The main objective of Touchpoint Cluster 1 is to create tools for preventive monitoring, intervention strategy as well as to allow an earlier return of the conditions of hospital care for much more favourable conditions. Within this cluster, a personal mobility device will be created. Early testing of the equipment, which is the main subject of this work was to analysis the needs and direction of the development of the device so that it is the best tool for an earlier daily physical activity. Activities within Cluster 1 also apply to the motivation of a senior for daily exercises. The role of gamification and the use of multimedia tools to stimulate both the physical and cognitive functions of the elderly is not without significance. It is known that the combination of these two forms of exercises during one training will provide the best therapeutic effects. The mobility device, created within the project, optimally follows (and can modularly be adapted to) the person throughout the patient journey through different care stages.	12/12/2018 4:40 PM
18	Personalizing motivation strategies has potential to motivate seniors to engage in more physical activity, however it remains unclear how to personalize strategies toward behavior change. Self-reflection and social engagement have been shown to have potential. In this trial we build off of REACH early testing in Eindhoven.	12/11/2018 6:49 PM
19	In order to support machine learning algorithm development at FIAIS and ethics application submission at SK, there was a need for a workshop to collect sufficient amount of data and to clearly define the procedures and methodologies for data collection and running the trial. Data should be collected in a way to make sure it is possible to annotate the data with ELAN. The annotated data will be used for generating the classifiers and the classifiers will support developing machine learning algorithms.	12/11/2018 1:35 PM
20	In the course of the REACH Project the Project Partner Alreh developed the transfer- and training device activLife with it's Training-Software VAST.rehab. In the Schön Klinik Bad Aibling we have the possibility to test this decive with neurological patients (one group with motoric deficits (Persona A) and one group with cognitive deficits (Persona B) together with their relatives) and healthy subjects over the age of 65. It is important to monitor the applicability of this device in the neurological field. Recent studies showed that sit-to-stand training has a positive effect to the health and reduces the risk of fall.	12/10/2018 4:59 PM
21	In 2015, musculoskeletal disorders such as low back pain, fractures, prosthesis and falls were identified as the most common cause for hospitalisation in Switzerland. During hospitalisation, patients with musculoskeletal issues follow rehabilitation therapy to regain their body functions and perform daily tasks independantly such as walking, eating, bathing or moving from a wheelchair to a bed. The hospital-to-home transition is increasingly recognized as a critical period in the patient care, during which different incidents can occur and induce frequent re-hospitalization. There is therefore a growing interest in strengthening the physical and functional capacities of hospitalized elderly patients to prevent re-hospitalization. Researchers have extensively studied the use of computer-aided physical rehabilitation to promote physical activity. Serious games coupled with monitoring devices such as Kinect have shown to positively impact patient's motivation to do rehabilitation exercices. Whether such devices would be as efficient as the standard care in the hospital and engage the elderly to remain active after discharge is still understudied.	12/10/2018 4:13 PM
22	The change in the usual life-style changes the motivation to eat. Consequences are malnutrition. Biozoon is "fighting" against both in their task, developing personalized recipes together with motivational aspects while eating. Therefore it was necessary to receive answers about motivational/demotivational aspects and eating behaviour.	12/10/2018 3:10 PM
23	We wanted to compare the data recorded with SmartCardia sensors vs. data from a standard Holter system and activePal sensors	12/10/2018 3:00 PM

## Q6 Aim/purpose of the trial:

Answered: 23 Skipped: 0

#	RESPONSES	DATE
1	The goal of the study is first, to understand the efficiency of a conversational agent in detecting the user's nutrition habits and identifying a key food item that needs to be reduced compared to a health professional. Second, to test the adoption and the acceptance of the personalized and timely recommendation given by the conversational agent.	1/11/2019 2:40 PM
2	We investigated the criterion validity of consumer-grade physical activity monitors in older adults and whether the measurement properties differed between older adults with and without rollators and if body placement of the same type of monitor affected the results.	1/11/2019 7:27 AM
3	The aim of this study is to investigate if bi-weekly motivational telephone interviews as a add-on intervention to the use of consumer-grade physical activity monitors is superior to the use of consumer-grade physical activity monitors alone.	1/10/2019 9:33 PM
4	Feasibility study wrt. logistics of recording simultaneously physical activity via Fitbit tracker, Sens tracker and (during play/exercise sessions) Moto tiles	1/10/2019 11:29 AM
5	This study aim to investigate the potential of moto tiles in motivating older adults to become physically active. Hence, we examine what extent playful physical exercise during a 12 week period by of older (65+) citizens improves physical and functional abilities and to what extent it is accompanied by changes in physical activities outside exercise sessions.	1/10/2019 11:26 AM
6	The study aims to determine the effect of providing daily feedback on physical activity level and assess awareness of physical activity, based on self-rated and objective physical activity measures	1/10/2019 11:24 AM
7	Validate the reliability of the Moto Tile timing of the chosen balance tests. Calculate normative game scores at different ages. Find correlation between game scores and standardized balance tests.	1/9/2019 2:03 PM
8	Our study aimed to develop and validate algorithms for counting steps of elderly slow/anomaly walkers with machine learning techniques using raw data from 3-axis accelerometers. The study is exploratory and will ascertain the degree to which a single algorithm using data from position X can reliably predict number of steps for "most" participants (e.g., number of steps produced by the algorithm by a deviation of less than 5% for at least 95% of the users).	1/9/2019 10:03 AM
9	Aims: Study aims to monitor older adult's daily activity throughout the day in an unobtrusive way. We want to detect changing capabilities and changing stages of behavior change by looking for patterns and recognizing deviations from normal patterns.	12/25/2018 12:48 PM
10	Main purpose: Is the motivation to do more Physical Activity the same for seniors after : 1)using activLife at activity center? 2)exercising at home following the advices from physiotherapists ?	12/19/2018 8:30 PM
11	In this protocol, the goal is to measure the vital signs in healthy subjects and validate it for accuracy under different conditions, such as different activities and postures.	12/19/2018 7:11 PM
12	In the Department of Cardiovascular Medicine of CardioCentro University Hospital of Lugano, under the supervision of Professor Med. Dr. Tiziano Cassina, M.D., Ph.D. the Director of Cardiac ICU, as a Principal Clinicapl Investigator and PD Med. Dr. Enrico Ferrari, M.D., Ph.D. from the Department of Cardiac Surgery, as the Co-Clinical Investigator. The duration of the Study was 39 weeks and the targeted population (patients suffering from CVD with an emphasis on Cardiovascular Patients with Minor Hemodynamic Instability after Cardiac Surgery or after Invasive Cardiac Intervention) have reached the number 60 (details on the diagnosis and reason of admission are depicted in table 2). The Safety, Efficacy, Validity,. Accuracy and Sensitivity of the SmartWearable has being tested in a cross over comparison with the existing ICU Dräger - Healthcare Monitoring System of the Hospital as well as with the fully CE certified (and with FDA Clearance) Medical Devices, tracing the same vital parameters.	12/19/2018 6:59 PM
13	Search for heart rate patterns that are indicative/predictive for coffee consumption moments.	12/18/2018 3:13 PM

14	The goal of this ethnographic study is three folded: First, we will obtain insights on older adults' attitudes towards increasing physical activity as well as their readiness towards tracking technologies. Second, we will identify senior's potential behavior changes as well as their usage intention. Third, we will shed light on the opportunities and barriers for them to be monitored and try to understand how they would integrate the system in their daily life.	12/13/2018 4:01 PM
15	The aim of the trial is to generate data sets from neurological patients and healthy subjects to support the development of machine learning algorithms for the REACH system for activity recognition.	12/13/2018 2:51 PM
16	In order to motivate these older adults to increase their level of physical activity we aim to identify which persuasive strategies best address this user group.	12/13/2018 11:13 AM
17	The main aim of the study was to assess the safety and functionality of the innovative iStander mobility solution for the elderly, and the ability to use the Fitbit Charge sensor as a HR monitoring tool. Endpoints The endpoints were the safety of the iStander and the fitbit Charge 2, the functionality of the iStander, its associated software and the standard medical care, as well as the validity of the heart-rate measurement by the Fitbit Charge.	12/12/2018 4:40 PM
18	Thus we would like to test what personal factors people have in common who respond similarly to the intervention strategies.	12/11/2018 6:49 PM
19	Initial Data Collection for the Machine Learning Algorithms Recognition of specific activities by data pattern Properly Synchronizing and Annotating Data Setting the initial step stone for the ethics application at SK Trial for sensor integration and implementation at br2	12/11/2018 1:35 PM
20	The aim of the trial is to get data from the transfer strategies of neurological patients with motoric and cognitive disabilities, and healthy subjects to show the applicability of the activLife in neurological patients to help to development of the implementation of the transfer device in the REACH system .	12/10/2018 4:59 PM
21	The main objective of the study is to investigate whether rehabilitation using the mobility equipment is as effective as the standard care; secondly, to determine if there is an improvement in clinical outcomes such as physical strength, balance, and risk of falls after using the mobility equipment; and third, to establish whether the use of the REACH concept adds value to the continuity of patient care, specifically in terms of engagement and motivation to be more active during the hospital stay and when returning home.	12/10/2018 4:13 PM
22	Investigation of motivational aspects for food intake by elderly people and elderly suffering from dysphagia	12/10/2018 3:10 PM
23	The aim of the trial was to evaluate the usability of the SmartCardia sensors for further testing in the REACH projects with neurological patients	12/10/2018 3:00 PM

## Q7 Hypotheses of the trial:

Answered: 23 Skipped: 0

#	RESPONSES	DATE
1	"Mirana" is able to assess the user's nutrition habits as efficiently and even better than a health professional. "Mirana" is able to identify a key food items that needs to be reduced as efficiently as a health professional. Patient is more motivated and engaged to change their behavior with the help of the conversational agent.	1/11/2019 2:40 PM
2	A priory, we expected bilateral counts from the same model measured on the left and the right side of the body to have good agreement and we expected all PAMs, no matter the placement, to have at least moderate criterion validity for all participants, a good criterion validity for participants walking without a rollator and a poor criterion validity for participants walking with a rollator.	1/11/2019 7:27 AM
3	That motivational interviewing will enhance the effect from physical activity monitoring and consumer available monitors.	1/10/2019 9:33 PM
4	The primary purpose is to examine to what extent playful physical exercise during a 9-week period by of older (65+) citizens: • Improves physical and functional abilities • Is accompanied by changes in physical activities outside exercise sessions A secondary purpose is to determine: • Whether activity tracking is perceived by elderly citizens as an acceptable monitoring technology used by care providers • Whether training on Moto tiles is adhered to and is perceived as acceptable by users over a 9-week period • Changes in performance on MOTO tiles over time correlate with changes in balance and functional measures	1/10/2019 11:29 AM
5	1) 12 weeks of playful physical exercise improves physical and functional abilities. 2) It is accompanied by changes in physical activities outside exercise sessions.	1/10/2019 11:26 AM
6	Through the study we tested two hypothesis 1) Receiving feedback on physical activity level would increase activity 2) 24/7 monitoring of 8 weeks leads to concerns about privacy	1/10/2019 11:24 AM
7	A big data approach can be applied to create a normative Moto Tiles game score for a given age. There is correlation between Moto Tiles game score and standard tests such as Time-Up-and-Go and Chair-to-Stand.	1/9/2019 2:03 PM
8	described as Aim	1/9/2019 10:03 AM
9	Purpose: Primary purpose is to emphasize potential problems that could occur related to implementation of smart homes and to determine potential positive and negative outcomes of smart home technologies. Secondary: - Whether interior sensors is perceived by elderly citizens as an acceptable smart home technology - Whether elderly citizens accepts 24/7 monitoring	12/25/2018 12:48 PM
10	H10: The motivation to do more PA is the same for seniors after using Active Life and those after following the advices from physiotherapists. H20: Seniors remains in the same stage of change after using Active Life. H30: Seniors remains in the same stage of change after following the advices from physiotherapists H40: The physical conditions (in terms of strength) remain unchanged for seniors after using Active Life and those after following advices from physiotherapists. H50: The level of exertion of Active Life exercise is the same as that of the exercise advised from the physiotherapists. H60: The strength measurement is the same as the Mobee Fitness measurement.	12/19/2018 8:30 PM
11	The hypothesis is that SmartCardia wearable sensors at different body locations (such as chest and upper arm) can measure important vitals, such as the heart rate, respiration rate, blood pressure, oxygen saturation, blood pressure variations, skin temperature, activity and posture.	12/19/2018 7:11 PM
12	To validate the parameters from the wearable against ICU monitor devices for vital signs measurement.	12/19/2018 6:59 PM

13	We analyzed the data from two different perspectives. On the one hand, coffee drinking events might elevate (or decrease) the mean HR of a subject temporarily. This could be seen as shifts of the HR levels. On the other hand, the effect of caffeine consumption on the subject's HR could result in more complicated patterns of the time series. For example, caffeine could cause an instantaneous peak in the HR, before the HR starts to decrease again until it finally reaches the level from before. Patterns of this kind should be reflected in time series motifs centered around coffee drinking moments. To assess both hypotheses, i.e. HR mean shifts and conserved time series motifs, we performed a change points analysis.	12/18/2018 3:13 PM
14	Senior individuals are ready and willing to accept such technology to manage their health, considering some challenges. Senior individuals will change their behavior and will sustain the device usage at the end of the study.	12/13/2018 4:01 PM
15	Explorative trial: With the sensor set used in the trial valid algorithms for activity detection can be generated, suitable for neurological patients and healthy subjects .	12/13/2018 2:51 PM
16	This was an explorative study but the hypotheses we were testing is which themes would be used to motivate older adults to move more.	12/13/2018 11:13 AM
17	1. iStander active device is a safe solution for the elderly. 2. iStander active has a good functionality for the elderly rehabilitation 3. Neuroforma gaming system is engaging tool for elderly rehabilitation. 4. Neuroforma interface is easy to use. 5. Fitbit HR sensor is comfortable, easy to use and valuable HR sensor.	12/12/2018 4:40 PM
18	The related hypotheses are H10: There is no correlation between the number of times seniors open the application and the number of steps seniors take. H20: There is no correlation between the number of calls made by seniors and the number of steps seniors taken. H30: Self-awareness motivates seniors to take the same number of steps as the measured baseline. H40: Peer-awareness motivates seniors to take the same number of steps as the measured baseline. H50: The relative difference in steps taken by seniors with high self-efficacy is the same as those taken by seniors with low self-efficacy when using peer-awareness strategy H60: The relative difference in steps taken by seniors with high self-efficacy is the same as those taken by seniors with low self-efficacy when using self-awareness strategy H70: The relative difference in steps taken by seniors with a promotion regulatory focus is the same as those taken by seniors with a prevention regulatory focus when using peer-awareness strategy H80: The relative difference in steps taken by seniors with a promotion regulatory focus is the same as those taken by seniors with a prevention regulatory focus when using self-awareness strategy	12/11/2018 6:49 PM
19	Collection data to monitor activities of daily living (ADL) at home, such as eating, drinking, activity (sleep, walking and etc) and hygienic aspects.	12/11/2018 1:35 PM
20	Explorative trial: with the sensors used in that trial a valid Feedback is given during the three different transfer methods. The activity and kinematic detection can be used to show if the activLife is suitable as a transfer-support and muscular training in the field of neurological rehabilitation. Moreover a patient group with Alzheimer's disease and their relatives, will test the implementation of the device with it's Software.	12/10/2018 4:59 PM
21	- rehabilitation using the mobility equipment is as effective as the standard care - the usage of the mobility equipment will improve clinical outcomes such as physical strength, balance, and risk of falls - the use of the REACH concept adds value to the continuity of patient care, specifically in terms of engagement and motivation to be more active during the hospital stay and when returning home	12/10/2018 4:13 PM
22	Current situations (living in a nursing home, dependency on others while eating, dependency of pureed food,...) have influence on elderly's mood and in context on their motivation to eat.	12/10/2018 3:10 PM
23	ECG and motion data from SmartCardia are consistent with the ECG data from the standard Holter system and the motion data from the activePal sensors	12/10/2018 3:00 PM

## Q8 Risks and biases of the trial:

Answered: 13 Skipped: 10

#	RESPONSES	DATE
1	Limited criterion validity in the trackers, social desirability bias in self reported outcome measures and other types of over reporting.	1/10/2019 9:33 PM
2	none	1/10/2019 11:26 AM
3	None	1/10/2019 11:24 AM
4	The obtained normative scores might be influenced by the overall physical and cognitive ability of the people at the test site.	1/9/2019 2:03 PM
5	none	1/9/2019 10:03 AM
6	risks: participants may fall out of the test due to personal health conditions bias: participants may be already very active before joining the test	12/19/2018 8:30 PM
7	None	12/19/2018 7:11 PM
8	There were no risks when collecting the data.	12/18/2018 3:13 PM
9	In this trial the patients will not be exposed to additional risks beyond clinical routine. To prevent falls the patients will be secured by trained employees. Sensors directly attached to the skin may cause mild pressure marks or rashes. In case of exhaustion the measurements will be paused due to the requirements of the participants.	12/13/2018 2:51 PM
10	There is a risk that because this is student work they might not have the design insight to really connect the preferred persuasive strategies for their user. However, they were guided by coaches and a panel of external people evaluated the student concepts on perceived quality.	12/13/2018 11:13 AM
11	The main risks to which patients will be exposed will be: • Risk of injury due to Alreh/Smartcardia/Fitbit device malfunction. This risk appears extremely low because of the nature of the products (rehabilitation equipment, sensor), the fact that they have achieved European certification (except for the Smartcardia device for which it is an ongoing procedure) and because exercises will be performed under the careful supervision of occupational and physical therapists. Moreover, the study will be immediately stopped in case of an injury and the CCER will be immediately informed. • One may argue that the transfer training with the Alreh device may be less efficient than the standard medical care that may use different equipment. Occupational therapists will evaluate if this is indeed the case for every patients and will complement patient training with the standard medical care in that case. • Of note, there will be no access to non-anonymized personal medical data by the research team (with the exception of care givers bound by medical confidentiality) because of the study design. All data will be collected in an anonymized form. In return, collected data will be extremely useful for the improvement of devices that will be used in the REACH project.	12/12/2018 4:40 PM
12	The main risks were minor skin rashes due to the frequent change of the sensors.	12/11/2018 1:35 PM
13	In this trial the patients will not be exposed to additional risks beyond clinical Routine. To prevent falls the patients will be secured by trained employees. Furthermore the activLife device and ist Software VAST.rehab are CE-certified. The data protection takes place according to the GDPR.	12/10/2018 4:59 PM

## Q9 Ethics approval and data protection: (if you have no dates yet, please enter "01/01/2001".

Answered: 23 Skipped: 0

ANSWER CHOICES	RESPONSES
Ethics Committee reply date (if applicable):	100.00% 23
Data protection approval date (if applicable):	100.00% 23

#	ETHICS COMMITTEE REPLY DATE (IF APPLICABLE):	DATE
1	01/01/2001	1/11/2019 2:40 PM
2	27/10/2017	1/11/2019 7:27 AM
3	09/10/2018	1/10/2019 9:33 PM
4	01/01/2001	1/10/2019 11:29 AM
5	30/08/2017	1/10/2019 11:26 AM
6	01/01/2001	1/10/2019 11:24 AM
7	01/01/2001	1/9/2019 2:03 PM
8	01/01/2001	1/9/2019 10:03 AM
9	01/01/2001	12/25/2018 12:48 PM
10	01/01/2001	12/19/2018 8:30 PM
11	01/02/2017	12/19/2018 7:11 PM
12	17/05/2017	12/19/2018 6:59 PM
13	01/01/2001	12/18/2018 3:13 PM
14	01/01/2001	12/13/2018 4:01 PM
15	01/01/2001	12/13/2018 2:51 PM
16	01/01/2001	12/13/2018 11:13 AM
17	01/01/2001	12/12/2018 4:40 PM
18	01/01/2001	12/11/2018 6:49 PM
19	01/01/2001	12/11/2018 1:35 PM
20	01/01/2001	12/10/2018 4:59 PM
21	31/10/2018	12/10/2018 4:13 PM
22	01/01/2001	12/10/2018 3:10 PM
23	01/01/2001	12/10/2018 3:00 PM

#	DATA PROTECTION APPROVAL DATE (IF APPLICABLE):	DATE
1	01/01/2001	1/11/2019 2:40 PM
2	01/01/2001	1/11/2019 7:27 AM
3	18/12/2018	1/10/2019 9:33 PM
4	03/05/2017	1/10/2019 11:29 AM
5	18/01/2018	1/10/2019 11:26 AM
6	03/01/2017	1/10/2019 11:24 AM

7	01/01/2001	1/9/2019 2:03 PM
8	01/01/2001	1/9/2019 10:03 AM
9	01/01/2001	12/25/2018 12:48 PM
10	01/01/2001	12/19/2018 8:30 PM
11	01/01/2001	12/19/2018 7:11 PM
12	01/01/2001	12/19/2018 6:59 PM
13	01/01/2001	12/18/2018 3:13 PM
14	01/01/2001	12/13/2018 4:01 PM
15	01/01/2001	12/13/2018 2:51 PM
16	01/01/2001	12/13/2018 11:13 AM
17	01/01/2001	12/12/2018 4:40 PM
18	01/01/2001	12/11/2018 6:49 PM
19	01/01/2001	12/11/2018 1:35 PM
20	01/01/2001	12/10/2018 4:59 PM
21	01/01/2001	12/10/2018 4:13 PM
22	01/01/2001	12/10/2018 3:10 PM
23	01/01/2001	12/10/2018 3:00 PM

## Q10 Comments on Ethics / Data protection approval (if any)

Answered: 11 Skipped: 12

#	RESPONSES	DATE
1	We did not collect any person data.	1/11/2019 7:27 AM
2	NA	1/10/2019 9:33 PM
3	None	1/10/2019 11:24 AM
4	Ethics approval of Canton of Vaud	12/19/2018 7:11 PM
5	Canton Ticino Ethics Approval and Cardiocentro approval	12/19/2018 6:59 PM
6	Since I collected my own data and there were no third persons involved, this does not apply.	12/18/2018 3:13 PM
7	We did not need ethical committee approval for this study.	12/13/2018 4:01 PM
8	This study was approved by the Geneva Canton Ethics Body (Commission Cantonale d'Ethique de la Recherche) under the number 2016-01957.	12/12/2018 4:40 PM
9	Due to our close partnership we talked to the test bed responsible party and knowledgeable people at the TU/e to approve our protocol	12/11/2018 6:49 PM
10	No ethic's approval necessary, only healthy subjects were included. Data protection approval was obtained from every participant before performing any study activity.	12/11/2018 1:35 PM
11	No ethic's approval needed, only healthy subjects were included. Data protection approval was obtained from every participant before performing any study activity.	12/10/2018 3:00 PM

## Q11 Participating centers, institutions or companies:Name/ short name (address only in case center is not REACH partner) separated by semicolons

Answered: 23 Skipped: 0

#	RESPONSES	DATE
1	HUG	1/11/2019 2:40 PM
2	Municipality of Copenhagen	1/11/2019 7:27 AM
3	Municipality of Copenhagen	1/10/2019 9:33 PM
4	Institution Activity center in Lyngby Bredebovej 1 Brane ApS Stumpedyssevej 9 DK-2970 Hørsholm Denmark	1/10/2019 11:29 AM
5	institution1 Activity center in Lyngby Bredebovej 1; Institution 2 Activity center in Lyngby/Virum Snnepmarken 1; Sens Innovation ApS Ole Maaløes Vej 3, 2200 Frederiksberg	1/10/2019 11:26 AM
6	institution 1 Activity center in Lyngby Bredebovej 1; institution 2 Activity center in Virum Snnepmarken 1	1/10/2019 11:24 AM
7	Dagcentret Tvaerbommenn, Dagcenter Vennerlund, Daghemmet Blaaklokkevej, Betaniahemmet, Hilleroed Sundhedscentret, Omsorgscentret Toftehoejen, Lyngby Idrætsby, Det Kongelige Bibliotek, Technical University of Denmark.	1/9/2019 2:03 PM
8	institution1 Activity center in Lyngby Bredebovej 1; institution2 Activity center in Virum Snnepmarken 1; Sens Innovation ApS Ole Maaløes Vej 3, 2200 Frederiksberg	1/9/2019 10:03 AM
9	Not yet fixed	12/25/2018 12:48 PM
10	ZZ ontmoet en groet center	12/19/2018 8:30 PM
11	Self-study performed by SmartCardia	12/19/2018 7:11 PM
12	CardioCentro Lugano, Switzerland	12/19/2018 6:59 PM
13	Dr. Sebastian Konietzny, Fraunhofer IAIS, Sankt Augustin, Germany	12/18/2018 3:13 PM
14	HUG EPFL	12/13/2018 4:01 PM
15	SKBA, TUM, IAIS	12/13/2018 2:51 PM
16	TU/e	12/13/2018 11:13 AM
17	HUG,	12/12/2018 4:40 PM
18	Vrienden van de Thuis Zorg (REACH partner test bed in Eindhoven), TU/e, Philips and EPFL	12/11/2018 6:49 PM
19	TU München, FIAIS, SKBA	12/11/2018 1:35 PM
20	SKBA	12/10/2018 4:59 PM
21	- University Hospital of Geneva (HUG) - Alreh Medical	12/10/2018 4:13 PM
22	ZZ; Lyngby; BZN	12/10/2018 3:10 PM
23	Schön Klinik Bad Aibling, SmartCardia	12/10/2018 3:00 PM

## Q12 Key Investigator(s):First name, second name of each of the key persons involved

Answered: 23 Skipped: 0

ANSWER CHOICES	RESPONSES
Names separated by semicolons:	100.00% 23

#	NAMES SEPARATED BY SEMICOLONS:	DATE
1	Mlrana Randriambelonoro; Antoine Geissbuhler; Dimitri Konstantas; Alain Golay; Aude Daccord	1/11/2019 2:40 PM
2	Rasmus Tolstrup Larsen: Henning Langberg	1/11/2019 7:27 AM
3	Rasmus Tolstrup Larsen and Professor Henning Langberg	1/10/2019 9:33 PM
4	Henning Boje Andersen Humira Ehrari Jari due Jensen	1/10/2019 11:29 AM
5	Henning Boje Andersen; Humira Ehrari	1/10/2019 11:26 AM
6	Henning Boje Andersen; Humira Ehrari	1/10/2019 11:24 AM
7	Yanxin Liu; Henrik Hautop Lund	1/9/2019 2:03 PM
8	Henning Boje Andersen; Humira Ehrari	1/9/2019 10:03 AM
9	Henning Boje Andersen, Hemant Ghyvat, Humira Ehrari	12/25/2018 12:48 PM
10	Dominika Kozak, Hubert Cornelis, Athena Chen, Yuan Lu	12/19/2018 8:30 PM
11	Srinivasan Murali; Petros Malitas	12/19/2018 7:11 PM
12	Prof. Tiziano Cassina; Dr. Petros Malitas	12/19/2018 6:59 PM
13	Dr. Sebastian Konietzny	12/18/2018 3:13 PM
14	Mirana Randriambelonoro; Pearl Pu	12/13/2018 4:01 PM
15	Dr. Friedemann Mueller, Barbara Schaeppers, Dr. Carmen Krewer, Martina Steinboeck, Prof. Eberhard Koenig, Melanie Medenilla	12/13/2018 2:51 PM
16	Carlijn,Valk;Yuan,Lu;	12/13/2018 11:13 AM
17	Dominika Kozak,Simon Burgermeister, Jean De Buretel De Chasseyd, Adrien Naef, Alexandre Maringue, Damien Dietrich	12/12/2018 4:40 PM
18	carlijn,valk;yuan,lu;hubert,cornelis:peter,lovei;yaliang,chuang;	12/11/2018 6:49 PM
19	Sebastian Konietzny, Joerg Guettler, Barbara Schaeppers, Amir Kabouteh, Karolina Klockmann	12/11/2018 1:35 PM
20	Dr. Friedemann Mueller, Barbara Schaeppers, Dr. Carmen Krewer, Martina Steinboeck, Prof. Eberhard Koenig, Melanie Medenilla	12/10/2018 4:59 PM
21	Mirana Randriambelonoro; Christophe Graf; Caroline Perrin; Dominika Kozak	12/10/2018 4:13 PM
22	Jakob Sylvest Nielsen (Lyngby); Hubert Cornelis (ZZ); Alexandru Rusu, Sarah Engelhardt, Ann-Kristin Schwarze (BZN)	12/10/2018 3:10 PM
23	Barbara Schäppers, Carmen Krewer	12/10/2018 3:00 PM

## Q13 Corresponding REACH parts:

Answered: 23 Skipped: 0

ANSWER CHOICES	RESPONSES	
TP1	17.39%	4
TP2	34.78%	8
TP3	21.74%	5
TP4	39.13%	9
TP5	13.04%	3
Engine	17.39%	4

#	TP1	DATE
1	ActiveLife	12/19/2018 8:30 PM
2	HUG	12/12/2018 4:40 PM
3	none	12/11/2018 1:35 PM
4	Personal Mobility Device	12/10/2018 4:13 PM

#	TP2	DATE
1	x	12/19/2018 7:11 PM
2	X	12/19/2018 6:59 PM
3	Analyses of time series from wearable devices.	12/18/2018 3:13 PM
4	Touchpoint 2 (sensing)	12/13/2018 4:01 PM
5	x	12/13/2018 2:51 PM
6	FIAIS, SK, TUM	12/11/2018 1:35 PM
7	X	12/10/2018 4:59 PM
8	X	12/10/2018 3:00 PM

#	TP3	DATE
1	Socializing and Nutrition	1/11/2019 2:40 PM
2	TU/e	12/13/2018 11:13 AM
3	TU/e, Vrienden van de Thuiszorg, Philips, EPFL	12/11/2018 6:49 PM
4	none	12/11/2018 1:35 PM
5	ZZ; Lyngby; BZN	12/10/2018 3:10 PM

#	TP4	DATE
1	Henning Boje Andersen	1/11/2019 7:27 AM
2	Henning Boje Andersen	1/10/2019 9:33 PM
3	x	1/10/2019 11:29 AM
4	x	1/10/2019 11:26 AM
5	x	1/10/2019 11:24 AM
6	Playware-based Stationary and ambulant systems that enforce intervention regiments	1/9/2019 2:03 PM
7	x	1/9/2019 10:03 AM

8	x	12/25/2018 12:48 PM
9	none	12/11/2018 1:35 PM
#	TP5	DATE
1	x	12/13/2018 2:51 PM
2	none	12/11/2018 1:35 PM
3	X	12/10/2018 3:00 PM
#	ENGINE	DATE
1	x	1/10/2019 11:24 AM
2	x	12/13/2018 2:51 PM
3	EPFL	12/11/2018 6:49 PM
4	none	12/11/2018 1:35 PM

## Q14 Time range of the study phase:Start: Ethics Committee application / protocol finished End: Results paper/ poster... submitted(if no dates write 01/01/2001)

Answered: 23 Skipped: 0

ANSWER CHOICES	RESPONSES
Start date study phase:	100.00% 23
End date study phase:	95.65% 22

#	START DATE STUDY PHASE:	DATE
1	01/01/2001	1/11/2019 2:40 PM
2	01/03/2018	1/11/2019 7:27 AM
3	01/03/2019	1/10/2019 9:33 PM
4	01/02/2017	1/10/2019 11:29 AM
5	01/01/2001	1/10/2019 11:26 AM
6	31/07/2016	1/10/2019 11:24 AM
7	01/01/2001	1/9/2019 2:03 PM
8	01/01/2001	1/9/2019 10:03 AM
9	01/01/2001	12/25/2018 12:48 PM
10	19/12/2017	12/19/2018 8:30 PM
11	01/02/2017	12/19/2018 7:11 PM
12	17/05/2017	12/19/2018 6:59 PM
13	01/01/2001	12/18/2018 3:13 PM
14	01/03/2017	12/13/2018 4:01 PM
15	01/12/2018	12/13/2018 2:51 PM
16	16/11/2016	12/13/2018 11:13 AM
17	01/01/2017	12/12/2018 4:40 PM
18	22/05/2018	12/11/2018 6:49 PM
19	01/08/2018	12/11/2018 1:35 PM
20	30/12/2018	12/10/2018 4:59 PM
21	05/08/2018	12/10/2018 4:13 PM
22	31/08/2017	12/10/2018 3:10 PM
23	01/06/2017	12/10/2018 3:00 PM
#	END DATE STUDY PHASE:	DATE
1	01/01/2001	1/11/2019 2:40 PM
2	06/25/0018	1/11/2019 7:27 AM
3	01/03/2020	1/10/2019 9:33 PM
4	30/06/2017	1/10/2019 11:29 AM
5	01/01/2001	1/10/2019 11:26 AM

6	01/01/2001	1/10/2019 11:24 AM
7	01/01/2001	1/9/2019 2:03 PM
8	01/01/2001	12/25/2018 12:48 PM
9	31/03/2018	12/19/2018 8:30 PM
10	30/06/2018	12/19/2018 7:11 PM
11	30/09/2018	12/19/2018 6:59 PM
12	01/01/2001	12/18/2018 3:13 PM
13	30/06/2017	12/13/2018 4:01 PM
14	31/01/2020	12/13/2018 2:51 PM
15	26/10/2017	12/13/2018 11:13 AM
16	31/03/2017	12/12/2018 4:40 PM
17	20/07/2018	12/11/2018 6:49 PM
18	22/10/2018	12/11/2018 1:35 PM
19	31/01/2020	12/10/2018 4:59 PM
20	31/08/2019	12/10/2018 4:13 PM
21	30/11/2018	12/10/2018 3:10 PM
22	29/06/2017	12/10/2018 3:00 PM

## Q15 Time range of data collection period:Start: Begin data collection End: Data collection finished(if no dates write 01/01/2001)

Answered: 23 Skipped: 0

ANSWER CHOICES	RESPONSES
Start date study phase:	100.00% 23
End date study phase:	100.00% 23

#	START DATE STUDY PHASE:	DATE
1	01/01/2001	1/11/2019 2:40 PM
2	01/03/2018	1/11/2019 7:27 AM
3	01/03/2019	1/10/2019 9:33 PM
4	03/04/2017	1/10/2019 11:29 AM
5	01/03/2018	1/10/2019 11:26 AM
6	30/10/2016	1/10/2019 11:24 AM
7	01/11/2018	1/9/2019 2:03 PM
8	01/06/2018	1/9/2019 10:03 AM
9	01/01/2001	12/25/2018 12:48 PM
10	19/12/2017	12/19/2018 8:30 PM
11	08/02/2017	12/19/2018 7:11 PM
12	01/11/2017	12/19/2018 6:59 PM
13	01/01/2001	12/18/2018 3:13 PM
14	01/03/2017	12/13/2018 4:01 PM
15	06/01/2019	12/13/2018 2:51 PM
16	16/11/2016	12/13/2018 11:13 AM
17	05/01/2017	12/12/2018 4:40 PM
18	23/05/2018	12/11/2018 6:49 PM
19	05/10/2018	12/11/2018 1:35 PM
20	06/01/2019	12/10/2018 4:59 PM
21	01/02/2019	12/10/2018 4:13 PM
22	01/10/2017	12/10/2018 3:10 PM
23	09/06/2017	12/10/2018 3:00 PM
#	END DATE STUDY PHASE:	DATE
1	01/01/2001	1/11/2019 2:40 PM
2	06/25/0018	1/11/2019 7:27 AM
3	01/03/2020	1/10/2019 9:33 PM
4	30/06/2017	1/10/2019 11:29 AM
5	01/07/2018	1/10/2019 11:26 AM
6	31/01/2019	1/10/2019 11:24 AM

7	22/12/2018	1/9/2019 2:03 PM
8	15/07/2018	1/9/2019 10:03 AM
9	01/01/2001	12/25/2018 12:48 PM
10	31/03/2018	12/19/2018 8:30 PM
11	23/05/2017	12/19/2018 7:11 PM
12	30/03/2018	12/19/2018 6:59 PM
13	01/01/2001	12/18/2018 3:13 PM
14	30/06/2017	12/13/2018 4:01 PM
15	31/08/2019	12/13/2018 2:51 PM
16	01/12/2016	12/13/2018 11:13 AM
17	31/03/2017	12/12/2018 4:40 PM
18	20/07/2018	12/11/2018 6:49 PM
19	11/10/2018	12/11/2018 1:35 PM
20	31/10/2019	12/10/2018 4:59 PM
21	31/07/2019	12/10/2018 4:13 PM
22	31/03/2018	12/10/2018 3:10 PM
23	22/06/2017	12/10/2018 3:00 PM

## Q16 Protocol deviations/amendments: Describe major deviations from planned study

Answered: 23 Skipped: 0

#	RESPONSES	DATE
1	Not applicable yet.	1/11/2019 2:40 PM
2	The Nokia GO monitor were not used as planned as it was not able to synchronise between study participants.	1/11/2019 7:27 AM
3	The study has not started yet	1/10/2019 9:33 PM
4	NONE	1/10/2019 11:29 AM
5	After completing the first 12 weeks of the trial, we got quit a lot of useful data and on the basis of the obtained data, we decided to cancel the second part of the study and change it to RCT. Likewise there were major deviations in sample size. We did not succeed in recruiting 40 older adults. The trial was started with 38 and ended up with only 29 participants.	1/10/2019 11:26 AM
6	no deviations	1/10/2019 11:24 AM
7	N/A	1/9/2019 2:03 PM
8	none	1/9/2019 10:03 AM
9	the study is not yet completed	12/25/2018 12:48 PM
10	everything went as planned	12/19/2018 8:30 PM
11	None	12/19/2018 7:11 PM
12	None	12/19/2018 6:59 PM
13	none	12/18/2018 3:13 PM
14	No deviation	12/13/2018 4:01 PM
15	Project not started yet	12/13/2018 2:51 PM
16	There were no major deviations from the planned study except that our editors asked us to do one more focus group to asses the quality of the student work, by a panel of people who were not involved in giving and grading the course, which was done as proposed.	12/13/2018 11:13 AM
17	no major deviations were observed	12/12/2018 4:40 PM
18	Originally we had hoped to test the social reflection intervention with one group of participants collaborating with peers and the other group collaborating intergenerationally. However, we were unable to recruit enough people for the intergenerational group, thus we tested with the self-reflection group and the peer to peer social group.	12/11/2018 6:49 PM
19	none	12/11/2018 1:35 PM
20	The Project didn't start yet.	12/10/2018 4:59 PM
21	No deviations. We just added the handgrip strength test.	12/10/2018 4:13 PM
22	none	12/10/2018 3:10 PM
23	Patient 1: Holter system failed to record data Patient 3: SmartCardia sensors failed to record data	12/10/2018 3:00 PM

## Q17 Number of participants:(if not yet started write "0" in the "actual number" fields)

Answered: 23 Skipped: 0

ANSWER CHOICES	RESPONSES
Planned by protocol:	100.00% 23
Actual number recruitment - female:	82.61% 19
Actual number recruitment - male:	82.61% 19
Actual number completed study - female:	91.30% 21
Actual number completed study - male:	91.30% 21

#	PLANNED BY PROTOCOL:	DATE
1	20	1/11/2019 2:40 PM
2	100	1/11/2019 7:27 AM
3	128	1/10/2019 9:33 PM
4	10	1/10/2019 11:29 AM
5	40	1/10/2019 11:26 AM
6	26	1/10/2019 11:24 AM
7	200	1/9/2019 2:03 PM
8	38	1/9/2019 10:03 AM
9	3	12/25/2018 12:48 PM
10	48	12/19/2018 8:30 PM
11	30	12/19/2018 7:11 PM
12	60	12/19/2018 6:59 PM
13	1	12/18/2018 3:13 PM
14	20	12/13/2018 4:01 PM
15	max. 18 patients and 18 healthy subjects	12/13/2018 2:51 PM
16	There were 119 students enrolled in the class and we analysed the results of 12 groups each of which had (I believe) 5,6 or 7 team members depending on the group.	12/13/2018 11:13 AM
17	15 participants, including 10 patients satisfying the REACH target population inclusion/exclusion criteria (5 using the Alreh equipment and 5 using standard equipment) and 5 healthy adults (using the Alreh equipment only)	12/12/2018 4:40 PM
18	56	12/11/2018 6:49 PM
19	5	12/11/2018 1:35 PM
20	min. 40 neurological patients: (n=10 stroke, n=10 SCI, n=10 Parkinson, n=Alzheimer's) 10 healthy subjects	12/10/2018 4:59 PM
21	46	12/10/2018 4:13 PM
22	46	12/10/2018 3:10 PM
23	7	12/10/2018 3:00 PM
#	ACTUAL NUMBER RECRUITMENT - FEMALE:	DATE

1	0	1/11/2019 2:40 PM
2	0	1/11/2019 7:27 AM
3	0	1/10/2019 9:33 PM
4	6	1/10/2019 11:29 AM
5	21	1/10/2019 11:24 AM
6	114	1/9/2019 2:03 PM
7	19	12/19/2018 8:30 PM
8	5	12/19/2018 7:11 PM
9	17	12/19/2018 6:59 PM
10	0	12/18/2018 3:13 PM
11	13	12/13/2018 4:01 PM
12	0	12/13/2018 2:51 PM
13	?	12/13/2018 11:13 AM
14	?	12/11/2018 6:49 PM
15	3	12/11/2018 1:35 PM
16	0	12/10/2018 4:59 PM
17	0	12/10/2018 4:13 PM
18	29	12/10/2018 3:10 PM
19	3	12/10/2018 3:00 PM

#	ACTUAL NUMBER RECRUITMENT - MALE:	DATE
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1	0	1/11/2019 2:40 PM
2	0	1/11/2019 7:27 AM
3	0	1/10/2019 9:33 PM
4	4	1/10/2019 11:29 AM
5	5	1/10/2019 11:24 AM
6	89	1/9/2019 2:03 PM
7	24	12/19/2018 8:30 PM
8	25	12/19/2018 7:11 PM
9	43	12/19/2018 6:59 PM
10	1	12/18/2018 3:13 PM
11	7	12/13/2018 4:01 PM
12	0	12/13/2018 2:51 PM
13	?	12/13/2018 11:13 AM
14	?	12/11/2018 6:49 PM
15	2	12/11/2018 1:35 PM
16	0	12/10/2018 4:59 PM
17	0	12/10/2018 4:13 PM
18	17	12/10/2018 3:10 PM
19	4	12/10/2018 3:00 PM

#	ACTUAL NUMBER COMPLETED STUDY - FEMALE:	DATE
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1	0	1/11/2019 2:40 PM
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2	68	1/11/2019 7:27 AM
3	0	1/10/2019 9:33 PM
4	5	1/10/2019 11:29 AM
5	22	1/10/2019 11:26 AM
6	18	1/10/2019 11:24 AM
7	114	1/9/2019 2:03 PM
8	18	1/9/2019 10:03 AM
9	19	12/19/2018 8:30 PM
10	5	12/19/2018 7:11 PM
11	16	12/19/2018 6:59 PM
12	0	12/18/2018 3:13 PM
13	12	12/13/2018 4:01 PM
14	0	12/13/2018 2:51 PM
15	?	12/13/2018 11:13 AM
16	45	12/11/2018 6:49 PM
17	3	12/11/2018 1:35 PM
18	0	12/10/2018 4:59 PM
19	0	12/10/2018 4:13 PM
20	29	12/10/2018 3:10 PM
21	3	12/10/2018 3:00 PM
#	ACTUAL NUMBER COMPLETED STUDY - MALE:	DATE
1	0	1/11/2019 2:40 PM
2	35	1/11/2019 7:27 AM
3	0	1/10/2019 9:33 PM
4	3	1/10/2019 11:29 AM
5	7	1/10/2019 11:26 AM
6	4	1/10/2019 11:24 AM
7	89	1/9/2019 2:03 PM
8	7	1/9/2019 10:03 AM
9	24	12/19/2018 8:30 PM
10	25	12/19/2018 7:11 PM
11	42	12/19/2018 6:59 PM
12	1	12/18/2018 3:13 PM
13	6	12/13/2018 4:01 PM
14	0	12/13/2018 2:51 PM
15	?	12/13/2018 11:13 AM
16	15	12/11/2018 6:49 PM
17	2	12/11/2018 1:35 PM
18	0	12/10/2018 4:59 PM
19	0	12/10/2018 4:13 PM
20	17	12/10/2018 3:10 PM



## Q18 Age of participants:(if not yet started, write "0"; provide either mean or median or both)

Answered: 23 Skipped: 0

ANSWER CHOICES	RESPONSES	
Mean age:	95.65%	22
Median age:	86.96%	20
Min. age:	91.30%	21
Max. age:	86.96%	20

#	MEAN AGE:	DATE
1	0	1/11/2019 2:40 PM
2	81.3	1/11/2019 7:27 AM
3	0	1/10/2019 9:33 PM
4	81,5	1/10/2019 11:29 AM
5	84	1/10/2019 11:26 AM
6	88	1/10/2019 11:24 AM
7	50.9	1/9/2019 2:03 PM
8	84,4	1/9/2019 10:03 AM
9	76.5	12/19/2018 8:30 PM
10	28	12/19/2018 7:11 PM
11	65	12/19/2018 6:59 PM
12	38	12/18/2018 3:13 PM
13	77.6	12/13/2018 4:01 PM
14	0	12/13/2018 2:51 PM
15	0	12/13/2018 11:13 AM
16	Basic demographic and medical information of participants are depicted in Figure 1. The mean age was 79.8 years in the SMC patient group and 89.6 years in the iStander activ patient group with a male to female ratio of 3/2 and 4/1 respectively. The healthy control group had a mean age of 42.4 years with a slight predominance of woman.	12/12/2018 4:40 PM
17	72.47	12/11/2018 6:49 PM
18	33.8	12/11/2018 1:35 PM
19	0	12/10/2018 4:59 PM
20	0	12/10/2018 4:13 PM
21	80+	12/10/2018 3:10 PM
22	64,4	12/10/2018 3:00 PM
#	MEDIAN AGE:	DATE
1	0	1/11/2019 2:40 PM
2	0	1/11/2019 7:27 AM
3	0	1/10/2019 9:33 PM

4	81,5	1/10/2019 11:29 AM
5	85,5	1/10/2019 11:26 AM
6	88	1/10/2019 11:24 AM
7	48	1/9/2019 2:03 PM
8	81	1/9/2019 10:03 AM
9	28	12/19/2018 7:11 PM
10	65	12/19/2018 6:59 PM
11	38	12/18/2018 3:13 PM
12	77	12/13/2018 4:01 PM
13	0	12/13/2018 2:51 PM
14	0	12/13/2018 11:13 AM
15	73	12/11/2018 6:49 PM
16	30	12/11/2018 1:35 PM
17	0	12/10/2018 4:59 PM
18	0	12/10/2018 4:13 PM
19	0	12/10/2018 3:10 PM
20	64	12/10/2018 3:00 PM

#	MIN. AGE:	DATE
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1	0	1/11/2019 2:40 PM
2	63	1/11/2019 7:27 AM
3	0	1/10/2019 9:33 PM
4	66	1/10/2019 11:29 AM
5	67	1/10/2019 11:26 AM
6	73	1/10/2019 11:24 AM
7	4	1/9/2019 2:03 PM
8	67	1/9/2019 10:03 AM
9	65	12/25/2018 12:48 PM
10	20	12/19/2018 7:11 PM
11	30	12/19/2018 6:59 PM
12	38	12/18/2018 3:13 PM
13	65	12/13/2018 4:01 PM
14	65	12/13/2018 2:51 PM
15	0	12/13/2018 11:13 AM
16	47	12/11/2018 6:49 PM
17	24	12/11/2018 1:35 PM
18	65	12/10/2018 4:59 PM
19	0	12/10/2018 4:13 PM
20	60	12/10/2018 3:10 PM
21	60	12/10/2018 3:00 PM

#	MAX. AGE:	DATE
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1	0	1/11/2019 2:40 PM
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2	97	1/11/2019 7:27 AM
3	0	1/10/2019 9:33 PM
4	93	1/10/2019 11:29 AM
5	94	1/10/2019 11:26 AM
6	94	1/10/2019 11:24 AM
7	97	1/9/2019 2:03 PM
8	94	1/9/2019 10:03 AM
9	45	12/19/2018 7:11 PM
10	89	12/19/2018 6:59 PM
11	38	12/18/2018 3:13 PM
12	89	12/13/2018 4:01 PM
13	0	12/13/2018 2:51 PM
14	0	12/13/2018 11:13 AM
15	90	12/11/2018 6:49 PM
16	55	12/11/2018 1:35 PM
17	0	12/10/2018 4:59 PM
18	0	12/10/2018 4:13 PM
19	80+	12/10/2018 3:10 PM
20	69	12/10/2018 3:00 PM

## Q19 Medical conditions(fill out when relevant / applicable)

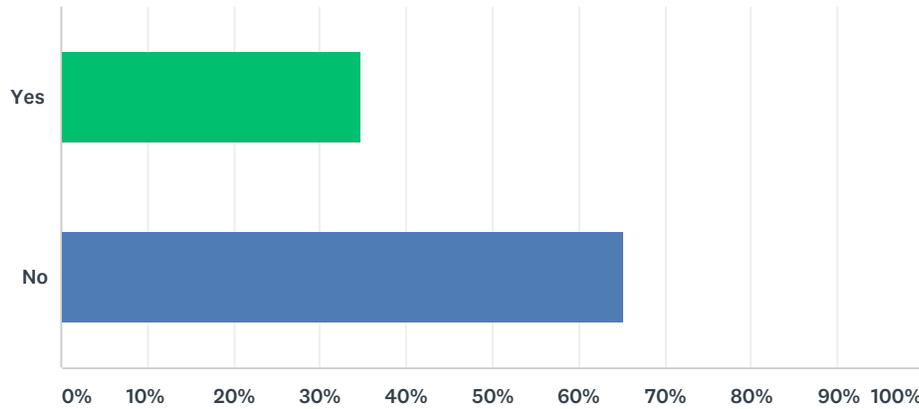
Answered: 16 Skipped: 7

ANSWER CHOICES	RESPONSES	
Medical information:	87.50%	14
Health / ambulatory status:	75.00%	12

#	MEDICAL INFORMATION:	DATE
1	Obese and diabete	1/11/2019 2:40 PM
2	None	1/11/2019 7:27 AM
3	NA	1/10/2019 9:33 PM
4	none	1/10/2019 11:24 AM
5	none	1/9/2019 10:03 AM
6	None	12/19/2018 7:11 PM
7	none	12/18/2018 3:13 PM
8	Neurological Diseases	12/13/2018 2:51 PM
9	NA	12/13/2018 11:13 AM
10	The total number of active pathologies highlights the net predominance of cardio-vascular diseases in both groups. Osteoarticular and endocrine diseases were also frequently encountered, with osteoarticular diseases being overrepresented in the SMC patient group. The causes of hospitalization were diverse in both groups	12/12/2018 4:40 PM
11	Only healthy subjects were included	12/11/2018 1:35 PM
12	Musculoskeletal issues (fracture, prosthesis, falls and low back pain)	12/10/2018 4:13 PM
13	one interviewed group was able to eat "normal" food, the other group had to eat pureed food due to mastication problems.	12/10/2018 3:10 PM
14	Only healthy subjects were included	12/10/2018 3:00 PM
#	HEALTH / AMBULATORY STATUS:	DATE
1	103	1/11/2019 7:27 AM
2	NA	1/10/2019 9:33 PM
3	none	1/10/2019 11:24 AM
4	none	1/9/2019 10:03 AM
5	living independently, participate in vitality square, ontmoet en groet plein	12/19/2018 8:30 PM
6	healthy subject	12/18/2018 3:13 PM
7	Ambulatory with or without walking aids	12/13/2018 2:51 PM
8	older adults students worked with were community dwelling seniors	12/13/2018 11:13 AM
9	Tilburg frailty index	12/11/2018 6:49 PM
10	Ambulatory	12/11/2018 1:35 PM
11	Hospitalized	12/10/2018 4:13 PM
12	Ambulatory without restriction	12/10/2018 3:00 PM

## Q20 Number of participants:Planned number based on power analysis?

Answered: 23 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	34.78%	8
No	65.22%	15
Total Respondents: 23		

**Q21 Sensors and equipment used: E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...). Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)**

Answered: 23 Skipped: 0

ANSWER CHOICES	RESPONSES
Sensors/equipment:	100.00% 23
Types of data collected, resolution:	91.30% 21
Data resolution (e.g. steps/hour; time to completion)	73.91% 17

#	SENSORS/EQUIPMENT:	DATE
1	"Mirana" conversational agent application	1/11/2019 2:40 PM
2	Garmin Vivofit 3: Jawbone UP: Nokia GO: Misfit Shine	1/11/2019 7:27 AM
3	Garmin Vivofit 3	1/10/2019 9:33 PM
4	Fitbit Charge HR for Pre-test screening; SENS-motion 3 axes sensors mounted on thigh 5-10 cm above knee & waist; Moto tiles for light exercise	1/10/2019 11:29 AM
5	The actual physical activity level was monitored by sens-motion sensors. Fitbit were used to assist 5-day pre-training measure of daily number of steps. Moto tiles were used during exercise sessions	1/10/2019 11:26 AM
6	Fitbit Charge HR and Smartphones to transmit Fitbit data	1/10/2019 11:24 AM
7	The Moto Tiles	1/9/2019 2:03 PM
8	SENS-motion 3-axis sensors mounted on 5 body positions	1/9/2019 10:03 AM
9	Materials and data collection: We want to collect raw data from 2-3 homes with different indoor sensors, mounted in walls, furniture, and daily objects to deduce older adults' daily activities. Monitoring may detect when a person falls, opens the refrigerator, opens a door, etc.	12/25/2018 12:48 PM
10	ActiveLife	12/19/2018 8:30 PM
11	SmartCardia	12/19/2018 7:11 PM
12	SmartCardia	12/19/2018 6:59 PM
13	Fitbit Surge	12/18/2018 3:13 PM
14	Fitbit Charge 2, Fitbit Aria or Withings Body Cardio	12/13/2018 4:01 PM
15	Myoband, SmartCardia, activePal, cameras, iPhone tracking app	12/13/2018 2:51 PM
16	Mi band and HealthSit (a prototype by the TU/e)	12/13/2018 11:13 AM
17	Fitbit	12/12/2018 4:40 PM
18	Fitbit flex 2 and Mi A1 phone	12/11/2018 6:49 PM
19	ActivPal Accelerometer, SmartCardia, Mobile Phone Accelerometer and Gyroscope, Camera, Pressure Mattress, Myo Band	12/11/2018 1:35 PM
20	iPhone tracking app, EMG-sensors, Simi Motion, zebris-plate	12/10/2018 4:59 PM
21	ActiveLife + Stepwatch sensors	12/10/2018 4:13 PM
22	0	12/10/2018 3:10 PM
23	SmartCardia (sensors and app), activePal, camera, Holter system Custo Card M	12/10/2018 3:00 PM

#	TYPES OF DATA COLLECTED, RESOLUTION:	DATE
1	Interview data + food logging	1/11/2019 2:40 PM
2	Steps	1/11/2019 7:27 AM
3	Step counts	1/10/2019 9:33 PM
4	Activity level in terms of numbers of steps. postural control level	1/10/2019 11:29 AM
5	Activity level in terms of numbers of steps & postural control level	1/10/2019 11:26 AM
6	physical activity in terms of numbers of steps and sleeping hours	1/10/2019 11:24 AM
7	Scores	1/9/2019 2:03 PM
8	Numbers of steps,	1/9/2019 10:03 AM
9	The smart home will be used to generate behavior pattern recognition and anomaly detection based on real time sensor activation. The system aims to work as alarms and personal emergency response system to detect acute events, monitor chronic risks and adverse events	12/25/2018 12:48 PM
10	Per minute heart rate, oxygen saturation; every 15 minutes activity, posture and blood pressure	12/19/2018 7:11 PM
11	heart rate data	12/18/2018 3:13 PM
12	Interview data + steps + weight	12/13/2018 4:01 PM
13	Movement data, film recordings, vital parameter, biometric data, ADL data	12/13/2018 2:51 PM
14	Project reports and prototype videos	12/13/2018 11:13 AM
15	HR,	12/12/2018 4:40 PM
16	physical activity	12/11/2018 6:49 PM
17	Video, Text file, Acceleration Data, Pressure Data, EMG Data	12/11/2018 1:35 PM
18	Movement /knematic data, film recordings, distribution of pressure data, motivation	12/10/2018 4:59 PM
19	Interview data + steps	12/10/2018 4:13 PM
20	0	12/10/2018 3:10 PM
21	ECG, position data	12/10/2018 3:00 PM
#	DATA RESOLUTION (E.G. STEPS/HOUR; TIME TO COMPLETION)	DATE
1	3 interviews and food logging everyday	1/11/2019 2:40 PM
2	Steps in six minutes	1/11/2019 7:27 AM
3	Steps/day	1/10/2019 9:33 PM
4	24h /7w	1/10/2019 11:29 AM
5	24h /7w	1/10/2019 11:26 AM
6	Automatic measurement (continuously)	1/10/2019 11:24 AM
7	integer scores (number of detected steps)	1/9/2019 2:03 PM
8	Heart rate, respiration rate, activity, posture every minute	12/19/2018 6:59 PM
9	sampling frequency varied between 1-3 seconds	12/18/2018 3:13 PM
10	steps/minutes	12/13/2018 4:01 PM
11	none	12/13/2018 2:51 PM
12	one final report and prototype video per group	12/13/2018 11:13 AM
13	steps/day	12/11/2018 6:49 PM
14	10 Frames Per Second of Pressure, 4K Video	12/11/2018 1:35 PM
15	steps/second or steps/minutes	12/10/2018 4:13 PM
16	0	12/10/2018 3:10 PM
17	ca. 10 min data recording	12/10/2018 3:00 PM

## Q22 Assessments performed:E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength..); comparators (what was the intervention compared to, if relevant)

Answered: 23 Skipped: 0

ANSWER CHOICES	RESPONSES	
Assessment measures:	100.00%	23
Comparators:	78.26%	18

#	ASSESSMENT MEASURES:	DATE
1	Qualitative interview / Food variety (nutrition questionnaire)	1/11/2019 2:40 PM
2	None	1/11/2019 7:27 AM
3	NA	1/10/2019 9:33 PM
4	- Chair Stand; Timed Up and Go; Bergs Balance Score; 6 Minutes Walking Test; Questionar (FS36)	1/10/2019 11:29 AM
5	Bergs Balance scale; Chair stand test; 6 min walk test	1/10/2019 11:26 AM
6	Self-assessment (at home by patient)	1/10/2019 11:24 AM
7	N/A	1/9/2019 2:03 PM
8	6 min walk test	1/9/2019 10:03 AM
9	N/A	12/25/2018 12:48 PM
10	Age, gender, BMI, Stage of change questionnaire, Tilburg Frailty Indicator, Strength test, Mobee Fitness measurement, Barriers to Being Active, Active life exercise data, Rating of perceived Exertion (weekly, after each exercise), Intrinsic Motivation Inventory (weekly)	12/19/2018 8:30 PM
11	Bland Altman	12/19/2018 7:11 PM
12	Bland Altman plot analysis	12/19/2018 6:59 PM
13	none	12/18/2018 3:13 PM
14	Qualitative interview / Number of steps	12/13/2018 4:01 PM
15	Barthel Index, SPPB Short Physical Performance Battery Protocol, Hand grip strength, MOCA, IMI Intrinsic Motivation Inventory	12/13/2018 2:51 PM
16	NA	12/13/2018 11:13 AM
17	MMSE, Nasa task Load Index, MSC, NTLI scale,	12/12/2018 4:40 PM
18	stage of change, self efficacy	12/11/2018 6:49 PM
19	Activities of daily living	12/11/2018 1:35 PM
20	BBS (Berg Balance Scale), MFAS (Motor Function Assessment Skala), 5x Sit-to-Stand Test (5XSST), Hand grip strength, IMI (Intrinsic Motivation Inventory), Montreal Cognitive Assessment (MoCA), TAP (Test zur Aufmerksamkeitsprüfung - alertness, awareness), Questionnaires: affinity towards technology (TA-EG), System-Usability-Skala (SUS), • NASA Task Load Index (NASA-TLX; Usability),	12/10/2018 4:59 PM
21	SPPB, MMSE, Hand grip strength	12/10/2018 4:13 PM
22	0	12/10/2018 3:10 PM
23	Timed up and go test, 6 min walking test, 5 min cycle ergometer training	12/10/2018 3:00 PM
#	COMPARATORS:	DATE

1	Standard care (manual food logging) with no assistance from the conversational agent	1/11/2019 2:40 PM
2	None	1/11/2019 7:27 AM
3	NA	1/10/2019 9:33 PM
4	None	1/10/2019 11:26 AM
5	None	1/10/2019 11:24 AM
6	N/A	1/9/2019 2:03 PM
7	none	1/9/2019 10:03 AM
8	EDAN ICU monitor	12/19/2018 7:11 PM
9	ICU monitor: Drager monitor	12/19/2018 6:59 PM
10	none	12/18/2018 3:13 PM
11	No comparator	12/13/2018 4:01 PM
12	None	12/13/2018 2:51 PM
13	NA	12/13/2018 11:13 AM
14	none	12/11/2018 1:35 PM
15	None	12/10/2018 4:59 PM
16	Standard care (actual equipment or no equipment at all)	12/10/2018 4:13 PM
17	0	12/10/2018 3:10 PM
18	none, all participants performed the same assessments	12/10/2018 3:00 PM

## Q23 Results: Write summary bullets only, and leave data details in report on Projectplace

Answered: 23 Skipped: 0

#	RESPONSES	DATE
1	Not applicable yet.	1/11/2019 2:40 PM
2	Four physical activity monitors were included in this study; Misfit Shine, Nokia GO, Jawbone UP and Garmin Vivofit 3. A total of 103 older adults participated and for each monitor, a total of 206 measures were available. All hip-worn PAMs fulfilled the a priori hypothesized moderate criterion validity evaluating all participants. The hip-worn Garmin Vivofit 3 fulfilled the a priori hypothesized criterion validities evaluating all participants, participants with rollator and participants without rollators. None of the wrist-worn PAMs fulfilled the a priori hypothesized criterion validity for any of the three participant groups.	1/11/2019 7:27 AM
3	NA	1/10/2019 9:33 PM
4	Timed up and go: A mean improvement of 1.43 seconds in the test from pre-to post testing. The improvement is between -0.16 and 3.02 seconds. 6MWT: A mean difference of -33.3 meter, in the test from pre-to post testing. The 95% confidence interval shows that the improvement is between -68.8 and 2.23 meters. Chair stand test: A mean difference of -1.44 stands in the test from pre-to post testing. The 95% confidence interval shows that the improvement is between -2.54 and -0.35 stands. Bergs balance scale: A mean difference of -11.22 points in the test from pre-to post testing. The 95% confidence interval shows that the improvement is between -17.42 and -5.03 point.	1/10/2019 11:29 AM
5	Both groups had an increase in their BBS. Training group: increase of 5,0 points; Control group increase of 2,1 points in their BBS ( $p=0,11$ ; anova). 30 sec chair stand test, both groups had a decreased in numbers of stands; Training group -1.3 stands, control group -1,4 stands, $p = 0.96$ . 6mwt: 14 people in each group. Training group: mean increase of 19 meters; control group 5 meters $p = 0.75$	1/10/2019 11:26 AM
6	Difference between time participants received feedback on steps and the time with no feedback: The mean difference between the two conditions of trails is 181,18 with a standard deviation of 1093,25 and 95% confidence intervals of -303,54 to 665,90 steps. $P=.44$ indicates no statistically significant mean difference between the mean of two related groups.	1/10/2019 11:24 AM
7	Normative scores of different ages are calculated by polynomial fitting.	1/9/2019 2:03 PM
8	the study is not yet complete, so we do not have any results yet.	1/9/2019 10:03 AM
9	Data analysis: we want to apply annotation techniques to detect anomalies in data. Machine learning techniques to detect critical deviation from normal activity pattern. The data collected will be transmitted to a database. Based on predefined parameters, an alert will be generated locally at the person's home or through telephone or internet messaging. Results: The smart home will be used to generate behavior pattern recognition and anomaly detection based on real time sensor activation. The system aims to work as alarms and personal emergency response system to detect acute events, monitor chronic risks and adverse events	12/25/2018 12:48 PM
10	The test participants come from a rather physical active group with comparable TFI, stage of change measurement, an hand grip test results (frailty). Active life training seems to have a clear contribution to the 4-stage balance skill Both interventions contribute to the 30 sec chair stand results Active Life training apparently do not sufficiently contribute to Tinette Balance skill Active Life training seems to have a clear barrier to be active, possibly due to technology involved; Exercise alone at home apparently has a higher barrier to be active than exercise together with a sport coach. Mobee measures apparently different skills (walking) than balance	12/19/2018 8:30 PM
11	SmartCardia sensors could measure the vital signs at the same accuracy as the ICU monitor under different activity conditions	12/19/2018 7:11 PM
12	SmartCardia sensors meet the accuracy of ICU monitors for vital signs monitoring, at ISO standards (95% agreement)	12/19/2018 6:59 PM

13	We found contradictory behaviors of the HR after coffee consumption. Change points analysis suggested that coffee drinking had no systematic effect on the heart rate levels. This is in line with a related study by [Green et al., 1996], which concluded that caffeine affects blood pressure, but not heart rate.	12/18/2018 3:13 PM
14	- we identified opportunities and challenges for the older adults to adopt sensors and application for health / potential of acceptance and adoption of simple and manageable technology for behavior change.	12/13/2018 4:01 PM
15	None	12/13/2018 2:51 PM
16	We analysed the persuasive strategies used and from this also identified different value propositions each student concept used. These values and persuasive strategies were distilled into five "value cluster" with proposed strategies on how to achieve these. The value clusters are Social Fitness, Improved Care, Prize, Self-awareness and Fun. For more please see table 9 in the Gerontechnology paper	12/13/2018 11:13 AM
17	Care-givers and patients appreciated the ease and comfort of use. The use of Fitbit also promoted patient empowerment. However, the wrist-band was reported as difficult to adapt. A suggested improvement was the addition of an alert in case of high or irregular heart rate.	12/12/2018 4:40 PM
18	working on further analysis now	12/11/2018 6:49 PM
19	Initial Data Collection for the Machine Learning Algorithms, Properly Synchronizing and Annotating Data, Setting the initial step stone for the ethics application at SK, trial sensor integration and implementation at br2	12/11/2018 1:35 PM
20	Not yet applicable	12/10/2018 4:59 PM
21	- To be filled later (study not started yet)	12/10/2018 4:13 PM
22	- The research revealed the strong influence that the social context has on the eating behaviour. - It has been shown the importance of enhancing the meals in order to avoid malnutrition. - The study confirmed the influence that the meal's sensory aspects have on food acceptance as well as their relation with aging. - The research resulted the strongly negative connection between suffering from eating difficulties (swallowing disorders) and psychological factors. - It has turned out that texture modified food (smoothfood) is able to be a motivational aspect to eating behaviour of elderly.	12/10/2018 3:10 PM
23	No results available because SmartCardia data were not available	12/10/2018 3:00 PM

## Q24 Problems, limitations, other factors, key lessons: E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...

Answered: 23 Skipped: 0

#	RESPONSES	DATE
1	Not applicable yet.	1/11/2019 2:40 PM
2	Wrist-worn monitors cannot measure number of steps in a population of older adults using rollators. The hip-worn PAMs were not significantly different in terms of measurement error or criterion validity, but overall the Garmin Vivofit 3 seems to be the best performing device of the four.	1/11/2019 7:27 AM
3	Secondary outcome measures include HRQoL (EQ5D) Self-efficacy for exercise scale Outcome Expectancy for Exercise Self reported physical activity (IPAQ and Nordic PAQ) Loneliness Scale	1/10/2019 9:33 PM
4	NONE	1/10/2019 11:29 AM
5	Our initial plan was to recruit 40 participants from 3 activity centers. But after being around in 5 activity centers, 3 activity centers were excluded. We recruited 2X18 participant from two activity centers.	1/10/2019 11:26 AM
6	During the trials we discovered, that raw data gathered from Fitbit has a certain degree of erroneous, redundant information that caused by discharged batteries, and sync problems and the design of the fitbit algorithm. To compensate for these effects, a data cleaning process was conducted, where only samples with complete outcome data were included in the analyses. To ensure complete outcome data, all steps measures were compared with heart rate data. Days within more than 4 hours of missing data were excluded from the analysis.	1/10/2019 11:24 AM
7	The constructed model may be refined by collecting more data for the training. Samples of children and teenagers are relatively less than other age groups.	1/9/2019 2:03 PM
8	No problem discovered yet.	1/9/2019 10:03 AM
9	no yet discovered any	12/25/2018 12:48 PM
10	no	12/19/2018 8:30 PM
11	The results were sufficient to perform patient testing in hospitals in further trials	12/19/2018 7:11 PM
12	Additional data analysis of patient condition prediction under progress	12/19/2018 6:59 PM
13	- The lack of information provided by the sensor manufacturer represents also an obstacle for the experiment. - Our experiment showed that even young healthy adults tend to forget making manual loggings of events after some time. Elderly people, as in the typical REACH settings, will likely not be able to log data thoroughly themselves.	12/18/2018 3:13 PM
14	The recruitment was tedious in the beginning.	12/13/2018 4:01 PM
15	Ethics vote applied	12/13/2018 2:51 PM
16	This was an explorative study so more research is required.	12/13/2018 11:13 AM
17	ethics registration	12/12/2018 4:40 PM
18	continued monitoring is important to prevent data loss.	12/11/2018 6:49 PM
19	Procedures (e. g., sensor handling, sequence order...) were analysed to optimise the time sequences and organisational processes and enhance the data quality to allow annotation and prepare the protocol for the measurements in SKBA.	12/11/2018 1:35 PM
20	Ethics vote applied	12/10/2018 4:59 PM
21	- To be filled later (study not started yet)	12/10/2018 4:13 PM

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22	not every elderly, who is normally exactly in our target group, is able to answer questionnaires due to physical and/or psychological conditions (e.g. they are confused or are not able to talk clear anymore)	12/10/2018 3:10 PM
23	Comparison of data could not be performed because raw SmartCardia data were not available.	12/10/2018 3:00 PM

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# Appendix 3: Trial report items



## REACH Trial Report Questionnaire

This questionnaire is designed to collect summary data of all REACH trials. Please input your data by December 10

**\* 1. Title and acronym:**

**\* 2. Keywords (min. 3; max. 8):**

List keywords, separated  
by semicolon:

**\* 3. Test Design as planned:**

Short description of methods, study flow, test setting, and design, (e.g. RCT, non-randomised trial, cohort, case-control, case-series...). Include number + duration of exposure/training times per individual.

**\* 4. Protocol**

Inclusion:

Exclusion:

Medical target conditions  
(when relevant):

Protocol link (eg.  
Projectplace link):

**\* 5. Background for the trial:**

**\* 6. Aim/purpose of the trial:**

**\* 7. Hypotheses of the trial:**

**8. Risks and biases of the trial:**

**\* 9. Ethics approval and data protection:**

(if you have no dates yet, please enter "01/01/2001".

Ethics Committee reply date (if applicable):

DD/MM/YYYY

Data protection approval date (if applicable):

DD/MM/YYYY

**10. Comments on Ethics / Data protection approval (if any)**

**\* 11. Participating centers, institutions or companies:**

Name/ short name (address only in case center is not REACH partner) separated by semicolons

**\* 12. Key Investigator(s):**

First name, second name of each of the key persons involved

Names separated by  
semicolons:

**\* 13. Corresponding REACH parts:**

TP1

TP2

TP3

TP4

TP5

Engine

**\* 14. Time range of the study phase:**

Start: Ethics Committee application / protocol finished

End: Results paper/ poster... submitted

(if no dates write 01/01/2001)

Start date study phase:

DD/MM/YYYY

End date study phase:

DD/MM/YYYY

**\* 15. Time range of data collection period:**

Start: Begin data collection  
End: Data collection finished  
(if no dates write 01/01/2001)

Start date study phase:

End date study phase:

**\* 16. Protocol deviations/amendments:**

Describe major deviations from planned study

**\* 17. Number of participants:**

(if not yet started write "0" in the "actual number" fields)

Planned by protocol:	<input type="text"/>
Actual number recruitment - female:	<input type="text"/>
Actual number recruitment - male:	<input type="text"/>
Actual number completed study - female:	<input type="text"/>
Actual number completed study - male:	<input type="text"/>

**\* 18. Age of participants:**

(if not yet started, write "0"; provide either mean or median or both)

Mean age:	<input type="text"/>
Median age:	<input type="text"/>
Min. age:	<input type="text"/>
Max. age:	<input type="text"/>

**19. Medical conditions**

(fill out when relevant / applicable)

Medical information:	<input type="text"/>
Health / ambulatory status:	<input type="text"/>

**\* 20. Number of participants:**

Planned number based on power analysis?

Yes  No

**\* 21. Sensors and equipment used:**

E. g., Fitbit, Myoband, SmartCardia, Moto Tiles, ActiveLife, Kinect...).

Please provide a short description of the kind of data that has been collected with the sensors, including resolution (e.g., steps per hour. time to completion...)

Sensors/equipment:

Types of data collected, resolution:

Data resolution (e.g. steps/hour; time to completion)

**\* 22. Assessments performed:**

E.g. Berg Balance Scale, MMSE, MOCA, Hand grip strength..);

comparators (what was the intervention compared to, if relevant)

Assessment measures:

Comparators:

**\* 23. Results:**

Write summary bullets only, and leave data details in report on Projectplace

**\* 24. Problems, limitations, other factors, key lessons:**

E.g. ethics registration, risk-benefit analysis, recruitment, equipment, publication, poster, additional analysis, other reports...