Health, demographic change and wellbeing

Personalising health and care: Advancing active and healthy ageing

H2020-PHC-19-2014

Research and Innovation Action

ACANTO

GA 643644

Deliverable 8.2:

Clinical Validation Plan

Deliverable due date: 04.2017	**Actual submission date: 27/04/2017**
Start date of project: February 1, 2015	**Duration: 42 months**
Lead beneficiary for this deliverable: SERMAS	**Revision: 1.0**
Authors: Rodrigo Pérez-Rodríguez (SERMAS), Pedro A. Moreno-Sánchez (SERMAS), Myriam Valdés-Aragonés (SERMAS), Andrew McNeill (UNAN)	
Internal reviewer: Ivo Ramos (ATOS)	

The research leading to these results has received funding from the European Union's H2020 Research and Innovation Programme - Societal Challenge 1 (DG CONNECT/H) under grant agreement n°643644

Dissemination Level		
PU	Public	**X**
CO	Confidential, only for members of the consortium (including the Commission Services)	

Contents

1 EXECUTIVE SUMMARY 4

2 INTRODUCTION 5

3 DESIGN OF THE EXPERIMENTAL VALIDATION 6

3.1 .....CLINICAL TRIAL 6

3.1.1 Design of the trial protocol 6

3.1.1.1 Objectives 6

3.1.1.2 Participants 6

3.1.1.3 Protocol 7

3.1.2 Management plan 13

3.1.3 Data Management plan 15

3.1.3.1 eCRF 15

3.1.3.2 Data collection methods 17

3.1.3.3 Data validation 17

3.1.3.4 Security aspects 17

3.1.4 Plan for statistical analysis 17

3.2 .....SOCIAL TRIAL

.....17

3.2.1 Potential intersection of clinical and social 17

3.2.2 A social intervention 18

3.2.3 Design of the trial protocol 18

3.2.3.1 Objectives 19

3.2.3.2 Participants 21

3.2.3.3 Equipment/Resources 21

3.2.3.4 Protocol 22

3.2.4 Management plan 26

3.2.5 Data Management plan 27

3.2.6 Plan for statistical analysis 27

4 ETHICAL APPROVAL 28

4.1.1 Clinical trial 28

4.1.2 Social trial 28

5 REGULATORY APPLICATION 29

6 INSURANCE FOR THE TRIALS 30

7 BIBLIOGRAPHY 31

8 ANNEX I: PATIENT INFORMATION SHEET 1

9 ANNEX II: INFORMED CONSENT 3

10 ANNEX III: WALKER INFORMATION FOR GOVERNMENTAL APPROVAL..... 4

1 Executive Summary

This document describes the experimental validation of the FriWalk device carried out in the ACANTO project. The validation comprises two scenarios proposed to validate the FriWalk: the clinical scenario and social scenario.

The main content of the document is aimed at describing the design of the validation, where the design of the trial protocol is specified as well as the management plan and the statistical analysis plan. Besides, the patient information sheet and the informed consent are included as part of the ethical approval of the validation for both scenarios.

In particular, for the clinical scenario, two additional sections are described: the regulatory application of the FriWalk and the insurance for the trials.

2 Introduction

ACANTO is a research project aimed to increase the number of older adults who engage in a regular and sustained physical activity. This result is sought by developing a robotic friend that supports the execution of everyday activities that entail a controlled physical effort in public spaces and an intelligent system that produces activity recommendation considering the habit and the preference of the user observed through the robot. Main and specific objectives of the project are detailed below:

- Development of a robotic friend (FriWalk). The FriWalk will offer direct support to the user activities and collect analytics on her/his behaviours.
- Development of a recommendation system for user activities. The recommendation system will rely on a social network created using physical information for users' profilse (the CPSN)
- Development of a cloud of supporting service in the environment. Most of the ability of the FriWalk to offer advanced functionalities in spite of its low cost lies in its reliance to external services that augment its sensing range and its computation abilities

The aim of the pilots conducted in ACANTO project is to evaluate the clinical validity of the robotic system for rehabilitation and diagnostic tool, and assess its impact in enhancing social inclusion of the older population that benefit of using a walker.

In particular, the clinical pilot pursues the following primary goals:

- Mitigate functional deterioration while hospitalization, by performing physical exercise with the FriWalk.
- Recover functional performance earlier after hospitalization.
- Validate FriWalk as a tool for measuring SPPB and gait speed (6m).

For those purposes, a clinical validation plan is stablished which comprises a set of phases detailed in section 3.1.1.3. In case of validation the FriWalk as a therapeutic tool, the patients' selection will be made within 48 hours of initial hospital admission in the Geriatric Acute Care Unit, and in the Orthogeriatrics. Next the participants will sign the inform consent and later they will be assigned by using a randomization process to the control group or to the intervention group. Patients in the intervention group, who are hospitalized in Geriatric Acute Care or in Orthogeriatrics Unit, will dispose of the FriWalk to perform the prescribed rehabilitation exercises. For both groups, data will be collected in five different moments; at patients' admission, at discharge, one month, three and six months after discharge. Regarding the validation as a diagnostic tool, the selected patients will be those who were previously selected for therapeutic validation in Acute Care Geriatrics Unit. Patients will have to perform the Short Physical Performance Battery (SPPB) and the gait speed (6 meters). Then, we will compare data acquired by FriWalk and data acquired by a traditional method.

On the other hand, the social pilot is intended to increase both (1) *social involvement* and (2) *physical activity* of the users. To achieve these targets, a pair of use cases is defined respectively: one by using the social network, and other by using the FriWalk. Therefore, several variables will be measured: performance expectancy, effort expectancy, attitude towards the system, social influence, facilitating conditions, self-efficacy, anxiety, intention to use the system, perceived and actual social involvement, number of steps taken, well-being, perceived sleep quality, fear of falling.

3 Design of the experimental validation

3.1 Clinical trial

3.1.1 Design of the trial protocol

3.1.1.1 Objectives

Primary endpoints:

- Mitigate functional deterioration while hospitalization, by performing physical exercise with the FriWalk.
- Recover functional performance earlier after hospitalization.
- Validate FriWalk as a tool for measuring SPPB and gait speed (6m).

Secondary endpoints:

- To increase physical activity during hospitalization in Geriatric Acute Care and Orthogeriatric Units.
- Evaluate the influence of FriWalk in the onset of delirium during hospitalization.
- Evaluate the influence of FriWalk in the cognitive performance of the patients.
- Evaluate the influence of FriWalk in the affective sphere of the patients.
- Evaluate the influence of FriWalk in the quality of life of the patients.
- Evaluate the influence of FriWalk in the number of falls after discharge.
- Evaluate the influence of FriWalk in mortality.
- Evaluate the influence of FriWalk in the consumption of health resources after discharge.
- Evaluate FriWalk in terms of usability, satisfaction and acceptability.

3.1.1.2 Participants

The FriWalk validation as a therapeutic tool will be carried out in two different and independent clinical scenarios (two settings), one of them will be Geriatric Acute Care Unit and the other will be Orthogeriatrics Unit. We will select patients over 75 years old in both scenarios. For the validation of the FriWalk as a diagnostic tool, we will recruit patients over 75 years old only in Geriatric Acute Care Unit.

As it is a novel technological tool in the care model of elderly patients, we do not have previous data to evaluate the effect of an intelligent walker in the clinical scenarios. Therefore, we will develop a pilot in which we will include all patients who meet the eligibility criteria and sign the informed consent for a stipulated time of one year.

INCLUSION AND EXCLUSION CRITERIA:

A. GERIATRIC ACUTE CARE UNIT:

- Inclusion criteria:
  - Patients' ≥ 75 years old.
  - Supervision during hospitalization by caregivers or family.
  - Ability to walk with or without aid prior to hospitalization.

- Exclusion criteria:
  - ≥ 48h of stay in the hospital.
  - Inability to understand and use the FriWalk.
  - Illness that impedes carrying out the prescribed therapy.

        - Acute myocardial infarction in the last 3 months.
        - Instable cardiovascular disease.
        - Terminal illness.
        - Other pathologies involving clinical instability.
    - Functional impairment established (Barthel Index < 40).
    - Precedent of alcohol and/or drug abuse.
    - Psychiatric disorders (Schizophrenia and psychotics disorders.
    - Participation in any other clinical study.

B. ORTHOGERIATRICS UNIT:

- Inclusion criteria:
    - Patients' ≥ 75 years old.
    - Hip fracture surgery with permission to stand during hospitalisation.
    - Supervision during hospitalization by caregivers or family.
    - Ability to walk with or without aid prior to hospitalization.

- Exclusion criteria:
    - ≥ 48h after surgery intervention.
    - Inability to understand and use the FriWalk.
    - Illness that impedes carrying out the prescribed therapy.
        - Acute myocardial infarction in the last 3 months.
        - Instable cardiovascular disease.
        - Terminal illness.
        - Other pathologies involving clinical instability.
    - Functional impairment established (Barthel Index < 40).
    - History of alcohol and/or drug abuse.
    - Psychiatric disorders (Schizophrenia and psychotics disorders.
    - Participation in any other clinical study.

3.1.1.3 Protocol

This is a prospective, randomized and blind pilot study.

The FriWalk validation as a therapeutic tool will be carried out in two clinical scenarios, one of them in geriatric acute care and the other in Orthogeriatrics Unit, because people usually use the walker in these units. On the other hand, the FriWalk validation as a diagnostic tool (SPPB and gait speed) will be carried out in Acute Care Geriatrics Unit, in those patients who have been recruited to FriWalk validation as a therapeutic tool.

The duration of the pilot will be one year, we will have two FriWalk during pilot. Recruitment time will be six months from the start of the pilot study.

Regarding the number of patients who will participate in the study, as FriWalk is a new technologic tool, which going to be included in model care in elderly people, we do not have previous data to evaluate the effect of the walker in clinical scenario. Hence, correct sample size cannot be calculated. So, we propose developing a pilot study in which all patients who meet inclusion and exclusion criteria and sign the inform consent will be included. The pilot study will last a year.

Patients' evaluations, in therapeutic tool scenario, will be carried out during hospitalization (in admission and discharge), one month after discharge, three months after discharge and six months after discharge. The last evaluation will be done by phone. A block randomization will be performed to ensure a balance between the control group and the intervention group in each setting. The block size is 4 (2 for control group and 2 for intervention group). In order to perform the randomization, we will always need that one of the FriWalk is free.

In the FriWalk validation as a diagnostic tool, the tests will be performed once there will not be a further follow-up.

In table 1 we will find described the professionals that participate in the pilot study as well as their responsibilities.

Table 1. Professionals.

PROFESSIONALS.	
RESPONSABLE:	**COMPETENCES:**
Clinical researcher.	- Pre-screening and screening phases: check that patients meet inclusion and exclusion criteria. Give information to patients and caregivers about the pilot study and provide informed consent. - The clinical researcher will carry out the evaluations during hospitalization, in discharge, and afterwards (one month after discharge and three months after discharge). - Validation of the FriWalk as a diagnostic tool.
Physician.	- Pre-screening phase: the physician along with the clinical researcher will made a pre-selection of patients that could be participants in the pilot study.
Technical support.	- The technical support will develop training sessions about walker use. In addition, the walker maintenance will be carried out.
Occupational Therapist.	- Exercises prescription. - Validation of the FriWalk as diagnostic tool in Geriatrics Acute Care Unit.
FIB-HUG Professionals.	- They will perform the analysis data.

A. VALIDATION OF THE FRIWALK AS A THERAPEUTIC TOOL:

Patients' selection will be made within 48 hours of initial hospital admission in the Geriatric Acute Care Unit, and in the Orthogeriatrics Unit after the stand permission by traumatology. These patients will be identified in both units through the admission list. Then physician and clinical researcher will check those participants who fulfil the inclusion and exclusion criteria. Next the participants will sign the informed consent and later the will be assigned by using a randomization process (through the www.randomizerd.org tool) to the control group or to the intervention group.

- **Control group**: the participants will receive the usual intervention, including rehabilitation programs if the participants need it during hospitalization.
- **Intervention group**: the participants will receive the usual intervention, including rehabilitation programs if the participants need it. In addition, we will provide them with the FriWalk as well as the exercises recommendations which prescribed by their physician and the Occupational Therapist.

Patients in the intervention group, who are hospitalized in Geriatric Acute Care or in Orthogeriatrics Unit, will dispose of the FriWalk at the time they have received authorization for walking by their doctor in Acute Care Unit, or for standing in Orthogeriatrics Unit until their discharge respectively.

The evaluations will be the same in both groups. When clinical researcher detects any alterations in the tests or questionnaires which might condition the patient's clinical management, the physician will be informed to take the appropriate measurements.

For both groups, data will be collected in five different moments; when patients' admission, at discharge, one month, three and six months after discharge.

In table 2 is describe pilot study in Geriatric Acute Care Unit and Orthogeriatrics Unit.

Table 2. Pilot study phases as therapeutic tool.

PHASE I: PRE-SCREENING.	
RESPONSABLE:	**DESCRIPTION:**
Clinical researcher. Physician.	Clinical researcher and physician will make an initial selection based on admission list (Orthogeriatrics Unit and Geriatrics Acute Care Unit). They will have to check that patients meet the inclusion and exclusion criteria a priori.
PHASE II: SCREENING AND RECRUIMENT.	
RESPONSABLE:	**DESCRIPTION:**
Clinical researcher.	Over pre-selected patients will be carried out different actions: - Patients meet inclusion and exclusion criteria. - Provide information about pilot study. - If patients agree to participate in pilot study, informed consent will be provided and if they agree, then they will sign it.
PHASE III: RANDOMIZATION.	
RESPONSABLE:	**DESCRIPTION:**
Person who does not participate in pilot study.	If patients agree to participate in the pilot study and sign the informed consent, they will be randomized and consequently assigned to control group or intervention group.
PHASE IV: FIRST VISIT (ADMISSION).	
RESPONSABLE:	**DESCRIPTION:**
Clinical researcher. Occupational Therapist.	Clinical researcher will carry out a patient examination composed of different tests and evaluations. - Demographic and clinical data. - Gait speed in 6 meters (Graham et al. 2008). - SPPB (Short Physical Performance Battery) (Freiberger et al. 2012). - Barthel Índex (Barthel and Mahoney 1965). - Lawton and Brody (Lawton and Brody 1969). - Confussion Assesment Method (Vasunilashorn et al. 2016). - Semantic and Phonologic fluency (Mirra et al. 1991). - MMSE (Folstein, Folstein, and McHugh 1975). - Clock Drawing Test (Shulman 2000).

	- Yesavage (Greenberg 2012). - EuroQL-5D (Group 1990). - Visual Analogue Scale for pain (only in Orthogeriatric Unit). Occupational Therapist will prescribe the physical exercises that patients should do.
PHASE V: TRAINING.	
RESPONSABLE:	**DESCRIPTION:**
Technical support.	After randomization, patients assigned to the intervention group, as well as their family and caregivers, will receive a training session about how to use the system.
PHASE VI: FOLLOW-UP.	
RESPONSABLE:	**DESCRIPTION:**
Technical support. Physician. Occupational Therapist.	During hospitalization, the technical support team will visit patient if he will need help for using the FriWalk. The physician and the Occupational Therapist will do the clinical follow-up.
PASE VII: DISCHARGE.	
RESPONSABLE:	**DESCRIPCIÓN:**
Clinical researcher.	New evaluation will be carried out at discharge moment with different tests and evaluations from admission. - Demographic and clinical data. - Gait speed (6 meters). - SPPB (Short Physical Performance Battery). - Barthel Índex. - Lawton and Brody. - Confusion Assessment Method. - Semantic and Phonologic fluency. - MMSE. - Clock Drawing Test. - Yesavage. - EuroQL-5D. - Visual Analogue Scale for pain (only in Orthogeriatric Unit). - Length of admission. - Adherence to treatment. We obtain this information by the FriWalk in the intervention group, and by questionnaires in the control group. - Assistant level at discharge. - System _Usability Test (intervention group).Satisfaction and acceptability (intervention group).
PHASE VIII: VISIT 1 MONTH AFTER DISCHARGE.	
RESPONSABLE:	**DESCRIPTION:**
Clinical researcher.	New evaluation will be carried out one month after discharge. Different test will be performed. - Demographic and clinical data. - Gait speed (6 meters). - SPPB (Short Physical Performance Battery).

	- Barthel Índex. - Lawton and Brody. - Confusion Assessment Method. - Semantic and Phonologic fluency. - MMSE. - Clock Drawing Test. - Yesavage. - EuroQL-5D. - Visual Analogue Scale for pain (only in Orthogeriatric Unit). - New admissions. - Emergency visits. - Admission days in Emergency. - Primary care visits - Falls. - Mortality. - Assistance level at month 1.
PHASE IX: VISIT 3 MONTHS AFTER DISCHARGE.	
RESPONSABLE:	**DESCRIPTION:**
Clinical researcher.	Last evaluation will be carried out. - Demographic and clinical data. - Gait speed (6 meters). - SPPB (Short Physical Performance Battery). - Barthel Índex. - Lawton and Brody. - Confusion Assessment Method. - Semantic and Phonologic fluency. - MMSE. - Clock Drawing Test. - Yesavage. - EuroQL-5D. - Visual Analogue Scale for pain (only in Orthogeriatric Unit). - New admissions. - Emergency visits. - Admission days in Emergency. - Primary care visits - Falls. - Mortality. - Assistance level at month 1.
PHASE X: TELEPHON EVALUATION, 6 MONTHS AFTER DISCHARGE.	
RESPONSABLE:	**DESCRIPTION:**
Clinical researcher.	We will make a call, 6 months after discharge: - Barthel Índex. - EuroQL. - Mortality. - Assistance level at month 1.
PHASE XI: DATA ANALYSIS.	
RESPONSABLE:	**DESCRIPTION**:
FIB-HUG professionals.	At the end of the study, data analysis will be carried out using the information stored during the pilot study. Then, conclusions will be drawn about the use of the walker.

B. VALIDATION OF THE FRIWALK AS A DIAGNOSTIC TOOL.

Patients selected to validate the FriWalk as a diagnostic tool will be those who have been selected for therapeutic validation in Acute Care Geriatrics Unit setting.
Patients will have to perform the Short Physical Performance Battery (SPPB) and the gait speed (6 meters). Then, we will compare data acquired by FriWalk and data acquired by a traditional method.
Table 3 describes the pilot study in Acute Care Geriatrics Unit as a diagnostic tool.

Table 3. Pilot Study phases as diagnostic tool.

PHASE I: PRE-SCREENING.	
RESPONSABLE:	**DESCRIPTION:**
Clinical researcher. Occupational Therapist.	Initially, clinical researcher and occupational therapist will make an initial selection among patients who have been admitted in Acute Care Geriatrics Units. These patients must meet a priori the inclusion and exclusion criteria.
FASE II: SCREENING AND RECRUIMENT.	
RESPONSABLE:	**DESCRIPTION:**
Clinical researcher. Occupational Therapist.	Different actions will be carried out in selected patients. - Check inclusion and exclusion criteria. - Provide information about the study. - If patients agree, the informed consent will be provided and if they agree they will have to sign it.
PHASE III: SPPB.	
RESPONSABLE:	**DESCRIPTION:**
Clinical researcher. Technical support. Occupational Therapist.	SPPB will be performed in Acute Care Geriatrics Unit. Clinical researcher will use the FriWalk and Occupational Therapist will measure this test by using a traditional method.
PHASE IV: GAIT SPEED.	
RESPONSABLE:	**DESCRIPTION:**
Clinical researcher. Technical support. Occupational Therapist.	Gait speed in 6 meters will be performed in Acute Care Geriatrics Unit. Clinical researcher will use the FriWalk to measure gait speed and Occupational Therapist will do it through traditional method.
PHASE V: FEEDBACK COLLECTION OF PHYSICIANS.	
RESPONSABLE.	**DESCRIPTION.**
Clinical researcher.	Three test will be realized: - System Usability test. - Acceptability and satisfaction test.
PHASE VI: DATA ANALYSIS.	
RESPONSABLE:	**DESCRIPTION:**
FIB-HUG personal.	At the end of the study, data collected will be analysed. Then, conclusions will be drawn about the use of the Walker as a diagnostic tool.

3.1.2 Management plan

The clinical trial will start in September 2017, and will last for 12 months.

This clinical study will be carried out coherently with the Guideline for Good Clinical Practice (GGCP) (CPMP/ICH/135/95) and the current Spanish legislation (RD 1090/2015).

An exhaustive study of the risks and possible inconveniences has been carried out, taking into account that participants' rights, safety and wellbeing prevail over the science. After this analysis, it has been reached the conclusion that the experiment is clearly more beneficial than inconvenient for the subjects that will participate.

The clinical researcher will be responsible of supervising and monitoring the clinical experiment, guaranteeing that it is developed, archived and published according to the protocol defined in the aforementioned normative and legislation. The following activities will be carried out:

a) Verify that the rights and wellbeing of the participants are constantly protected.
b) Check that the data obtained during the clinical study are accurate, complete and verifiable.
c) Guarantee that the experiment is being developed according to the defined clinical protocol, its amendments and prevailing normative and legislation.

It is necessary to highlight the points below:

d) The clinical study will be only carried out with the pertinent approval of Clinical Ethics Committee (CEC).
e) All participants must have freely signed the informed consent prior to participating (potential participants will not be coerced; also, an adapted language will be used for doubts solving). In case the informed consent is modified, a new approval from the CEC will be necessary.
f) In case the informed consent needs to be signed by a legal guardian, the actual participant will be also informed.
g) A qualified healthcare professional will be responsible for the medical care received by the participants and clinical decisions taken.
h) The scientific team will be only composed by qualified and experienced personnel.
i) All the information produced during the clinical study will be registered, handled and archived in such a way that it is possible to communicate, interpret and verify in an accurate way.
j) Any modification in the electronic Case Report Form (eCRF) will be dated and explained without hiding the original data.
k) All documentation produced during the trial will be available at all time to the Clinical Research Assistant (CRA), auditor and CEC.
l) Confidentiality and privacy will be protected at all time. Spanish prevailing law will apply (LOPD 15/1999).
m) The clinical trial protocol has been designed to guarantee the quality of the experiment to be carried out.
n) Neither severe deviations nor protocol modifications will be made without the permission of the sponsor and the pertinent approval of the CEC. A severe modification is that one that may affect:
o) The safety and physical integrity of the participants.
p) The scientific validity of the study.

q) The principal investigator will provide the CEC with a finalization report at the end of the study. If the CEC requires one or more mid-term reports, they will be also provided.

r) Any adverse event will be communicated to the CEC.

s) It the clinical study ends earlier than expected or it is cancelled for any reason, the principal investigator will consequently inform the participants and the CEC.

It is not possible to have a totally risk free environment. Many decisions involve managing risks according to the project's assessment of what constitutes an acceptable level of risk and its judgments about the costs and benefits of particular courses of action.

Risk management involves establishing an appropriate governance infrastructure and culture and applying logical and sympathetic methods for establishing the context, identification, analysis, treatment, monitoring and communication of risks.

Table 4 the risk action plan for the current clinical trial. The main objectives are:

- To ensure that the major risks faced by the project are identified, understood and appropriately managed.
- To ensure that the planning and management processes focus on areas where risk management is needed.
- To create an environment where the consortium staff take responsibility for identifying and managing risk.

Table 4. Risk Action Plan.

Risk	Description	Likelihood	Threat	Strategy
1	Not achieving of the challenging scientific objectives	Rare	Major	This risk will be minimized by assessing continuously the project progress and at specific decision points deciding on potential fall-back strategies. At each point, a decision has to be made whether the applied approach will guarantee the achievements of the final targets or not. If not, a fall-back strategy will be applied
2	Delay in starting the study	Possible	Significant	In case the start of the study is postponed, an extension of the study lifetime will be requested
3	The FriWalk breaks down during the development of the trial	Unlikely	Significant	There will be a minimum of 2 FriWalks in the clinical dependencies during the clinical study. If one breaks down, the local technical team will try to fix it with remote support from the walker developers; in case it is not possible, and depending on the actual damage, technology specialist will come to the site to restore the walker into operation.
4	A patient gets injured while using FriWalk	Unlikely	Major	Although it is very unlikely, a patient can fall down and get injured while using FriWalk. In that case, as the study will be carried out within Hospital dependencies, the patient will receive immediate clinical assistance. The insurance will economically cover with the expenses.

5	The number of participants is not enough to guarantee strong scientific results	Possible	Major	A weekly estimation of participants recruited will be set. If the number of participants is not achieved, the recruitment activities will be reinforced. If a severe deviation occurs, an extension of the study lifetime will be requested
6	Problems related to the consortium communication during the study	Unlikely	Significant	Potentiate team building among members and increase face to face or teleconference communications when possible. Gather all points of view and intervention of the project coordinator to solve the problem in case it is needed
7	Problems in the management of the project	Possible	Significant	A close follow up of project activities will be carried out. Periodic meetings and reports are scheduled
8	Problems in the dissemination of results	Possible	Significant	The dissemination activities will be planned from the onset of the clinical study. Periodic reviews are scheduled

3.1.3 Data Management plan

3.1.3.1 eCRF

The eCRF will be designed to store every data obtained by the researchers. One eCRF will be created per participant, by complying the national data protection law. Any clarification, correction or change made in the eCRF will be performed by the sponsor or its representative. The clinical researcher will be responsible of fulfilling correctly the eCRF according to the protocol requirements.

The eCRF will comprise the information contained in Table 5.

Table 5. Information in the eCRF.

Test/questionnaire	Short description
Demographic	Information related to participants' age, gender, technology literacy, etc. will be collected
Consumption of healthcare resources	The consumption of healthcare resources after the intervention will be explored.
Barthel index	Index that evaluates the basic daily activities. It comprises a series of questions. The final result ranges from 0 to 100.
Lawton & Brody index	Index that evaluates the instrumental daily activities. It comprises a series of questions. The final result ranges from 0 to 8.
Short Physical Performance Battery	This test evaluates the physical performance throughout 3 specific tests: balance (both feet, semi-tandem and tandem), gait speed in 4 meters and standing-up from a chair. Time used in completing each activity is evaluated. This test ranges from 0 to 12.
Gait speed	For this test, the patient has to walk 6 m at normal speed. Time is evaluated.
Confusion Assessment Method	This test is administered to evaluate delirium by means of a set of Yes/No questions.
Minimental State Examination	This test evaluates the cognitive performance of the patient by analysing the answers provided to a series of questions. Final score ranges from 0 to 30.
Clock Drawing Test	By means of this test, cognitive impairment is explored by analysing motor skills, attention, understanding and numerical

	knowledge. The patient is asked to draw a clock (a circle with the corresponding 12 hours) and indicate a given hour.
Verbal fluency	Semantic fluency is explored by asking the patient to enumerate as many animals as he/she can in 1 minute time. Phonologic fluency is analysed by requiring the patient to say as many names (no proper names) as he/she can starting with letter 'p' in 1 minute time; the test is administered again but this time with letter 'm'. The final score for both semantic and phonologic fluency is the number of valid words the patient was able to say.
Geriatric Depression Test	This test is applied to explore if a given patient is suffering from depression. It consists in a set of 15 to Yes/No questions; a final score higher than 5 points may indicate depression; if it is higher or equal to 10 indicates depression with more accuracy.
EuroQoL-5D	This questionnaire is administered to evaluate the quality of life of the participants. It comprises 5 items: mobility, personal care, daily activities, pain and anxiety/depression.
Analogue Visual Scale for pain	This scale allows measuring intensity of pain. It consists on a 10cm line in which edges extreme expressions of pain are shown (no pain at all in the left hand-side, the unbearable pain on the right hand-side). Pain intensity is expressed in cm or mm.
Adherence to treatment	To evaluate if patients have committed to the prescribed therapy, a set of questions will be asked.
System Usability Test	This scale is administered to evaluate the usability of the system after being used. The final score ranges from 0 to 100.
Satisfaction	A questionnaire will be applied to evaluate patients' satisfaction after having used FriWalk.
Acceptability	Acceptability of FriWalk will be evaluated throughout a specific questionnaire.

The eCRF service will have, in general, the following functionalities:

- Access control by user roles: clinical researcher, CRA, administrator.
- Real-time verification of consistency in the input data.
- Security guaranteed by SSL-encrypted communications.
- Auditable activity log. All changes will be registered in such a way that the historic value of every field will be maintained. The author, date, time and reason of all changes will be indicated.

The service architecture will be based in a client-server paradigm. The client will consist in the following sections:

- Login: that will allow the start a session by introducing username and password. Depending on the user roles, different options will be available.
- Configuration: only available for the administrator. This section will allow the user to configure technical aspects of the service (URL, etc.).
- Administration: only available for the administrator. Assignation of a participant to a group.
- Form: available for the clinical researcher to upload information related to the development of the study.

The server:

- MySQL database where all the information will be stored.
- REST service.

- Privilege management.
- Data export service.

3.1.3.2 Data collection methods

Data will be collected and uploaded intro de eCRF manually.

3.1.3.3 Data validation

As stated in the general description of the eCRF service, data consistency will be checked for all inputs where verification is feasible (i.e. age of the patient given the date of birth).

3.1.3.4 Security aspects

To protect security and privacy all connections between client and server will be encrypted using SSL protocol.

Besides, only granted researchers will have access to the collected clinical information that will be anonymized prior to being uploaded. Access to information will be managed by the server by means of user privileges.

To avoid issues related to privacy, data will be treated in such a way that it will be impossible to identify the individual patient who owns them.

3.1.4 Plan for statistical analysis

Data will be analysed using statistical information management software. Statistical descriptors will be gathered with a confidence interval of 95%. Tests' results obtained will be analysed considering primary and secondary objectives as well as research hypothesis. The statistical significance level will be established in 0.05. The feasibility of each scale employed will be tested taking into account patients' observations and number of excluded cases due to value loss. The percentage of participants with maximum and minimum theoretical levels will be calculated to estimate range of each scale.

3.2 Social trial

3.2.1 Potential intersection of clinical and social

People who are in the process of recovery, after having left the hospital, benefit from social support (Chronister et al. 2008; Mutran et al. 1995). This social support can be especially effective when those who are in the group have experienced the same problem (Reblin and Uchino 2008; Ussher et al. 2006; Woodgate, Brawley, and Shields 2007) and are thus in a position to encourage one another, model recovery for one another, and provide advice for one another. While the cited studies do not refer directly to rehabilitation after falls, the mechanisms by which peer support groups differ from other forms of support (information, acceptance, and sense of community) seem plausible mechanisms by which a falls-rehabilitation support group might benefit members. The ACANTO system can offer a means of facilitating such contact between users after leaving the hospital. Because the system records details about the mobility state of the user, it can use this to match participants based on similar characteristics. The social network can then convey recommendations to the users about others that they can meet with. Venues for meeting can be proposed that host FriWalk devices where users can meet together and obtain the social support they need by meeting other similar users, and obtain the physical support they need to navigate the venue that they visit.

For practical reasons, we will not test this intersection of clinical and social uses. There are several reasons for this: (1) The clinical testing of the FriWalk will be conducted in Spain, and UNAN do not have sufficient

Spanish language skills to work effectively with that population. (2) Even if testing was conducted in Spain, it would require an additional sample separate from those currently associated with the clinical testing in order to avoid conflating the effects of the two interventions. (3) If testing were conducted in the UK, the extensive preparation and delay in gaining ethical approval to work with a clinical population (via the NHS) renders the task infeasible. For these and other reasons, we decided not to explore the "bridging" scenario, even though it holds strong potential on theoretical grounds. Nevertheless, we believe that if we test the social scenario and demonstrate its effectiveness, the joint findings of both the clinical intervention and the social intervention will show that the middle ground, the intersection between the two, is an effective and plausible way of combining the benefits of the ACANTO system. Thus, not testing the intersectional scenario is not an exclusion of an important test, but testing the system at the two ends of the spectrum (the clinical and social ends) shows that if both ends of the spectrum are successful, the intersection can be assumed to some extent.

3.2.2 A social intervention

The social intervention will therefore focus on the social use of the walker in a non-clinical setting. As mentioned previously, there are two components: the FriWalk and the social network. The social network is the means by which the recommender system provides recommendations to users. The FriWalk provides the means of providing physical support for users, as well as providing an enhanced experience for the user. In the social intervention, we aim to test both components of the system. Both components are expected to have benefits on the users and testing of both components can be associated with measurable outcomes. In the sections below, we outline the specific objectives, measures and design of studies to test the system.

3.2.3 Design of the trial protocol

Firstly, a brief summary of the intervention will be helpful. There are two strands of the intervention: (1) testing of the social network and recommender system, and (2) testing of the FriWalk in a social context.

Testing the social network and recommendation system

The first part of the intervention, testing the social network and recommendation system, will involve recruiting a group of older adults to use the FriTab which contains the CPSN API installed. The CPSN will be populated with various events and participants will be asked to rate the quality of the recommendations. There will also be an event organised by the experimenters via the system to test how well it brings together people who have similar interests. We will test whether participants who use the social network and engage in the recommended activities are consequently more socially and physically active as a result of taking part (longitudinal comparison) and compared to a control group who do not take part (between-groups comparison).

Testing the FriWalk

The second part of the intervention will involve testing the FriWalk. To do this, an experimenter will set up a group activity via CPSN API for the FriTab (visiting the museum) to which numerous participants will be invited. Participants will receive a guided tour of the museum with the assistance of the FriWalk and the

activity will be repeated on several occasions. We expect that this experience of using the FriWalk will reduce fear of falling while at the museum, will enhance the experience of visiting the museum, and will encourage bonding between the participants. These effects will be stronger for those using the FriWalk compared to those who (a) do not use the FriWalk in the museum, and (b) who do not attend the event.

3.2.3.1 Objectives

Broadly speaking, there are two objectives for both the CPSN and the FriWalk. The use of both should increase both (1) *social involvement* and (2) *physical activity*. There are several other objectives listed below, and the two key objectives are broken down into more detail below.

Controlled factors

While there are clear objectives around what we want the system to achieve, these will be affected by several interacting variables such as the user's perception of the system's ease-of-use, their enjoyment of the system and their sense of the usefulness of the system. These variables are drawn from the Unified Theory of Acceptance and Use of Technology (UTAUT) (Morris, Hall, Davis, Davis, & Walton, 2003) and we expect that a user's perception of the system's ease-of-use (for example) will affect the benefits that they gain from using it; if they find it hard to use they are less likely to adopt recommendations or find it helpful. These control variables apply both to the FriTab API and to the FriWalk (i.e. two sets of questions). While we treat them as control variables, we also expect to see some changes in the levels of enjoyment and sense of usefulness. Increasing use should, hopefully, increase these levels. The variables we will measure are:

1. Performance expectancy – Perception of the extent to which the system will be/is useful.
2. Effort expectancy – Perception of the extent to which the system will be/is easy to use.
3. Attitude towards the system – positive or negative view of the system.
4. Social influence - Perception of the extent to which other people like or dislike the system.
5. Facilitating conditions – Perception of the extent to which someone helps in getting used to the system.
6. Self-efficacy - Perception of the extent to which the user can use the system by themselves (aided or unaided).
7. Anxiety - Perception of the extent to which the system makes one feel anxious when using it (e.g. fear of making mistakes).
8. Intention to use the system – The extent to which the user says they would use the system again. This is a clear outcome measure that expresses overall intention to use the system.

Outcome measures (social network)

There are several general objectives and accompanying specific objectives.

Firstly, for the testing of the *CPSN*:

1. Social involvement
    a. Perceived social involvement: this should increase as a result of using the system, but will interact with the user's extent of use of the system. The more they use it, the more

benefits they will receive. Those who do not engage much with the system are not expected to show benefits.

b. Actual social involvement: by using participant diaries, we will show the effect of using the social network on actual involvement.

c. Quality of recommendations: the more that a user discloses to the system, the greater the quality of the recommendations.

d. Turnout to event: users who are more engaged with the system and who perceived higher quality of recommendations will be more likely to attend an event to which they are invited. This event will be organised by the experimenters and numerous people will be invited.

e. Liking of the participants: At the event, liking for each other will be greater depending on the number of similar interests as recorded by the system compared to groups whose members have been randomly selected (similarity-attraction hypothesis; Byrne, 1972).

2. Physical activity
    a. Number of steps taken: as a result of being more socially involved and attending an event, participants should show an increased number of steps compared to their own pattern of activities in a similar period without the intervention. They will also show more steps compared to a control group who do not take part in the intervention.
3. General well-being
    a. Well-being: as a result of having more physical activity, users should show increased levels of subjective well-being (Netz et al. 2005).
    b. Perceived sleep quality: this should increase as a result of having more physical activity. We know that sleep quality is affected by physical activity (King et al. 1997; Sherrill, Kotchou, and Quan 1998) and that sleep is linked to poor health outcomes (Strine and Chapman 2005). Therefore, it is an important finding if physical activity can increase sleep quality through use of the ACANTO system.

Outcome measures (FriWalk)

Then for the testing of the *FriWalk*. We intend to organise several events where users will come to a museum to test the FriWalk devices. It will involve an administrator/experimenter setting up an event and inviting users to come to the event. Users may be selected based on their stated interests (e.g. history) and may be matched based on their performance abilities (e.g. speed of walking). The experimenter will collaborate with a museum to arrange the event. UNAN has numerous museums that may be available for collaboration (e.g. Centre for Life, The Great North Museum, the Discovery Museum, or Segedunum Roman Fort).

The outcome measures are:

1. Physical activity
    a. Step count: there should be an increased number of steps as a result of taking part in the activity
2. Psychological confidence
    a. Fear of falling: Reduced fear of falling when using the device. This will be measured at baseline (T 1.2.4 questionnaires).

   b. Less anxiety about going out to attend an event where the FriWalk will be used
3. Social and emotional bonding
   a. Sense of common identity: Social bonding/sense of shared identity as "FriWalk user group"
   b. Increased perceived wellbeing as a result of shared identity (C. Haslam, Cruwys, and Haslam 2014; S. A. Haslam et al. 2009)
4. Improved ability to use the museum
   a. Time taken to find facilities: it should be quicker for users who are unfamiliar with the environment to find facilities when they have the FriWalk.
5. Improved sleep quality
   a. Subjective sleep quality: this should increase as a result of increase physical activity (see above (3b) for the rationale).

3.2.3.2 Participants

Participants will be a non-clinical sample from the UK. Some of these participants will be from the 1.2.4 longitudinal tracking task and others will be new participants recruited from the North-East of England (predominantly Newcastle-Gateshead). Further details of numbers are provided in the next section (Protocol).

The criteria for inclusion in the testing is that the participant must be able to provide consent for taking part (thus ruling out serious cognitive impairments) and must be able to get to the location where testing will take place (thus ruling out certain serious physical impairments). There are no other exclusion criteria.

3.2.3.3 Equipment/Resources

To complete the intervention, a number of requirements are stated below. Some of these requirements are essential, while others are desirable. Contingency plans are discussed in the section dealing with risk management, below.

Table 6. Requirements for intervention study

Requirement	**Priority**	**Description**	**Responsibility**
3-4 FriWalk devices	Essential	These devices should be available by September 2017.	UNITN
FriWalk navigation system	Essential	The FriWalk devices should be able to navigate several routes in a designated museum environment.	UNITN
FriWalk user interface for older adults	Important	An appropriate user interface for older adults to enable them to use the system.	UNITN

CPSN recommendation system	Essential	System should be able to recommend activities to users.	ATOS + UNITN
FriTab user interface for older adults	Important	While an interface is available for the social network system, the FriTab version for older adults is important to encourage their use.	UNITN
Access to user data	Important	Experimenters should be able to access data from participating users' profiles in order to assess what recommendations they have seen, what they have accepted, and what they have liked.	ATOS

3.2.3.4 Protocol

There are two use cases matching the testing of the two different aspects of the system: the CPSN and the FriWalk itself. These are described below.

Use case 1: Using the social network

George is an elderly man who lives alone. While he sometimes finds out what is going on in the area, he would like to know about more events. When he is offered a chance to use the ACANTO CPSN, he is eager to try it. He enters his details into the FriTab API and will be presented with some recommendations. He finds one that he likes and decides to try it. The next day, he attends the recommended activity. His step counter records his physical activity and it can be seen that his physical activity has increased. At the event, he also meets several people and feels more socially involved as a result.

Use case 2: Using the FriWalk

Sandra is an elderly lady who lives alone. She has some difficulties with walking after having a fall several months ago. One day, she is invited to attend a session at the museum where she will use the FriWalk to get a guided tour. She decides that she will attend because the subject of the tour matches her interests. At the museum, she meets several other people who have come for the tour. A guide shows them how to use the FriWalk and they have a chance to ask any questions. After seeing how her FriWalk works, Sandra sets off with some other users. They take a tour about "The history of the North-East of England" and the FriWalk shows them where to go. At one point, Sandra decides that she needs to use the toilet. She presses a button requesting guidance to the toilet and the FriWalk shows her where to go. After returning from the toilet, the FriWalk guides her back to the group. At the end of the tour, Sandra is impressed with the system and decides to come back and try it again. She enjoyed using it and appreciated the interaction with other people in the group as they explored the features of the system.

Recruitment process (social network study)

Participants will be recruited from several sources: some participants are already engaged with longitudinal tracking for the ACANTO project, while others will be recruited fresh.

- 15 participants will be recruited from existing participants (i.e. longitudinal tracking, Task 1.2.4).
- 15 participants will be recruited from outside existing participants.
- 15 participants will be selected as controls (they will not use the social network).

Recruitment process (FriWalk study)

- 10 participants will be used to test the FriWalk to tour the museum.
- 10 participants will be used to have a non-FriWalk based museum tour.
- 10 participants will be selected as a control group (no tour, no FriWalk).

Scales

The objectives listed above provide the conceptual variables that need to be measured. What follows is how we propose to measure them.

Control variables

Each of the control variables are taken from the UTAUT scale (Morris et al. 2003) and the items will be adaptations (for the ACANTO system) of these items. In the case of the social network testing, we will also ask about their engagement with the system to control for participants who were less interested in the system.

Table 7. Social network testing

Variable	**Scale/measure**
Perceived social involvement	Three items asking about the extent of perceived social involvement, its quality, and its enjoyability.
Actual social involvement	In participant diaries, participants will list who they met during the day from outside the people who live in their home (1 item). This should be corroborated with data from the social network system.
Quality of recommendations	Several items asking about the personal relevance of the recommendations, the liking of the recommendations, and the ability to do the recommendations.
Turnout to experimenter-organised event	Number of people who attend event (recorded by experimenter)
Liking of participants for one another	Several items asking to what extent they perceive others in the group as similar and the extent to which they like them.
Physical activity	Number of steps taken as measured by step counters
Well-being	Personal wellbeing index (International Wellbeing Group 2013)
Perceived sleep quality	Pittsburgh Sleep Quality Index (Buysse et al. 1989)

Table 8. FriWalk testing

Variable	**Scale/measure**
Physical activity	Steps from step counters
Fear of falling	Falls Efficacy Scale International Short form (Kempen et al. 2008)
Anxiety about attending event	Several items asking extent to which the user feels anxious about attending events outside the home (baseline) and the extent to which they feel anxious attending events where a FriWalk is available. Anxiety will be asked with reference to (a) finding their way around the environment and (b) having physical support.
Sense of common identity	Two items adapted from Drury, Cocking, & Reicher, (2009) asking about a sense of unity within groups.
Well-being	Personal wellbeing index (International Wellbeing Group 2013)
Time taken to find facilities	Comparison of time taken between participants who do not use the FriWalk to find facilities and those who do use it (given unfamiliarity with the environment).
Sleep quality	Pittsburgh Sleep Quality Index (Buysse et al. 1989)
Willingness to return	Several items asking about whether the participant would come back to the museum for a similar tour using the FriWalk.

Phases

The following is a brief outline of the phases involved in collecting data for the social network trial.

Table 9. Phases of social network study

Phase 1: Ethics and Recruitment	
Ethical approval	Ethical approval forms should be completed and approved
Recruitment	Recruitment of 30 participants and invitation to try the system.
Phase 2: Pilot study	
Seeding system with recommendations	Experimenters will add activities to the system from the surrounding area and will tag these appropriately.
Checking system	Experimenters and some participants will check that the system is working properly.
Phase 3: Testing	
Initial workshop	Participants will be invited to a workshop where the system will be explained to them and where they will enter their data. At this initial session, participants will be given a diary to complete during the next 2 weeks. The

	diary will contain questions about their social involvement. They will also be given step counters and will also be asked to complete a short questionnaire for baseline measurement. For practical purposes, this workshop may be split into two or three workshops (given participant availability).
Using the network	Participants will use the FriTab API for a period of 2 weeks.
Control group	An additional 15 participants (control group) will be asked to complete diaries and carry step counters for 2 weeks.
Test event	To test the system, the experimenters will run an interactive workshop and will advertise it via the ACANTO social network. The topic of this workshop is to be decided, but it may be something like, "A guide to smartphones for the older user." The activity will be tagged with relevant tags (e.g. "technology", "internet") and users who express these interests should receive a recommendation for the workshop. Turnout will be monitored at the event and liking for others in the group will be assessed.
Return and debrief	After the 2 weeks, all participants will return and be debriefed on the purpose of the study. Additional measures will be taken via a short questionnaire (to see changes from the questionnaire administered at the start of the study).

Table 10. Phases of FriWalk study

Phase 1: Ethics, recruitment and collaboration	
Ethics	Ensure ethical approval is obtained from UNAN ethics procedure
Recruitment	Recruit interested participants to take part in the FriWalk trial.
Collaboration	Collaboration with museums to implement FriWalk devices in the environment.
Phase 2: Pilot testing	
Testing at UNAN	Devices will be set up on UNAN premises and participants will be invited to try out the devices. Data will be collected about users' average walking pace to assist with matching participants for the museum trial.
Baseline tracking	Participants will be given diaries and step counters to monitor their baseline activity.
Phase 3: Museum testing	
Museum tour start	Participants will be invited to a tour of a museum where they will be given a FriWalk. Approximately 4 participants will be in each group, assuming that 4 FriWalk devices will be available. Each group will be tested on separate days. Some of these events may be advertised via the social network system. Participants may be matched based on their average walking pace or ability.

Pre-tour questionnaire	Questionnaires will be completed before the tour.
Tour	The tour will involve a programmed route during which the FriWalk will guide the user around the museum. An experimenter will accompany the participants.
Post-tour questionnaire	After the tour, a questionnaire will be completed to ask about the experience.
Control group	A tour will be arranged without the FriWalk and will act as a control group. Questionnaires will be completed before and after.
Second control group	Participants in the no-tour, no-FriWalk group will attend the university to provide answers to a questionnaire.

3.2.4 Management plan

Milestones

MS1	User interfaces implemented for FriWalk and social network
MS2	Ethical approval granted
MS3	Collaboration with museums finalised
MS4	Walkers shipped to UK
MS5	Implementation of system in museum environment
MS6	Completed workshop via FriTab API
MS7	Completed social network testing
MS8	Completed tour testing
MS9	Data analysis
MS10	Post-trial presentation and discussion with participants

Risk management

There are some risks associated with the proposed plan and most of these are consistent with the risks identified in the clinical testing. However, some unique risks are identified below.

Table 11. Risk management

Risk	Description	Likelihood	Threat	Strategy
1	Not receiving user interfaces designed for older adults	Possible	Low	If user interfaces designed for older adults specifically are not implemented, we will have to use whatever interfaces are available. These may not be very user-friendly but we will endeavour to explain them as much as possible to users and familiarise them with the UIs. We will also provide as much assistance as necessary and let them know that we are available to help.

2	Museums do not agree to collaborate	Unlikely	Significant	If no museums agree to collaborate (although some have agreed in principle) or they restrict the collaboration in some way, we may have to use facilities at UNAN to provide a "mock" museum or something similar.
3	Insufficient activities are available for participants via the social network	Unlikely	Major	Experimenters will design activities and actively seek out collaborators to provide activities.

3.2.5 Data Management plan

Data will be collected from the social network system, from questionnaires and from the FriWalk sensors. These data will be stored in an Access database to facilitate matching of participant data and easy retrieval. It will be available to partners in the project but will not be made open access due to the project-specific nature of the data. However, the data will be available on request to enable scrutiny.

3.2.6 Plan for statistical analysis

A variety of statistical methods will be used to analyse the data. Regression analysis will be used to model the effects of using the social network system (acceptance of recommendations) on outcome measures such as social and physical activity. This will allow other measures such as attitudes to the system or engagement with the system to be controlled for.

ANOVA (analysis of variance) tests will be used to assess differences between groups in the CPSN (social network users vs. non-users and pre-trial vs. post-trial) and in the FriWalk testing (experimental groups vs control groups). These will also allow for the testing of interaction effects to see whether the use of the walker interacts with other measures (e.g. fear of falling or frailty) on the effects of the intervention (such as increased confidence or increased physical activity).

4 Ethical approval

4.1.1 Clinical trial

The clinical protocol previously described has been submitted to the local ethical committee. Annex I and Annex II contain the patient information sheet and the informed consent to be signed in the original language (Spanish).

4.1.2 Social trial

An ethics approval document will be submitted to UNAN ethics reviewers. No additional approval is needed for the trial of the social network and FriWalk in the social testing. Ethical approval typically takes around 2 weeks. This procedure will also ensure that adequate insurance is in place, although this is known to be covered by the university (UNAN).

5 Regulatory application

In Spain, it is mandatory to get the approval of the National Agency of Drugs and Health Products (*Agencia Española de Medicamentos y Productos Sanitarios* - AEMPS) to carry out clinical studies using medical devices. Therefore, a set of documents (clinical trial description, researcher and sponsor identification, and description of the product) have been submitted to this regulatory institution. Annex III contains the submitted document describing the technological aspects of the device.

6 Insurance for the trials

An insurance will be hired by SERMAS prior to the execution of the clinical study.

7 Bibliography

Barthel, Dorothea, and Florence Mahoney. 1965. "Baltimore City Medical Society Functional Evaluation : The Barthel Index." *Maryland State Medical Journal* 14: 56–61.

Buysse, Daniel J. et al. 1989. "The Pittsburgh Sleep Quality Index: A New Instrument for Psychiatric Practice and Research." *Psychiatry Research* 28(2): 193–213.

Chronister, Julie, Chih Chin Chou, Michael Frain, and Elizabeth da Silva Cardoso. 2008. "The Relationship between Social Support and Rehabilitation Related Outcomes: A Meta-Analysis." *The Journal of Rehabilitation* 74(2): 16–27.

Drury, John, Chris Cocking, and Stephen D. Reicher. 2009. "The Nature of Collective Resilience: Survivor Reactions to the 2005 London Bombings." *International Journal of Mass Emergencies and Disasters* 27(1): 66–95.

Folstein, Marshal F., Susan E. Folstein, and Paul R. McHugh. 1975. "A Practical State Method for." *Journal of psychiatric research* 12(3): 189–98.

Freiberger, Ellen et al. 2012. "Performance-Based Physical Function in Older Community-Dwelling Persons: A Systematic Review of Instruments." *Age and Ageing* 41(6): 712–21.

Graham, James E. et al. 2008. "Relationship Between Test Methodology and Mean Velocity in Timed Walk Tests: A Review." *Archives of Physical Medicine and Rehabilitation* 89(5): 865–72.

Greenberg, S. a. 2012. "The Geriatric Depression Scale (GDS)." *Best Practices in Nursing Care to Older Adults* 4(4): 1–2.

Group, The Euroqol group. 1990. "EuroQol - a New Facility for the Measurement of Health-Related Quality of Life." *Health policy* 16(3): 199–208.

Haslam, Catherine, Tegan Cruwys, and S. Alexander Haslam. 2014. "'The We's Have It': Evidence for the Distinctive Benefits of Group Engagement in Enhancing Cognitive Health in Aging." *Social Science and Medicine* 120: 57–66.

Haslam, S. Alexander, Jolanda Jetten, Tom Postmes, and Catherine Haslam. 2009. "Social Identity, Health and Well-Being: An Emerging Agenda for Applied Psychology." *Applied Psychology* 58(1): 1–23.

International Wellbeing Group. 2013. *Personal Wellbeing Index: 5th Edition*. Melbourne: Australian Centre on Quality of Life, Deakin University.

Kempen, Gertrudis I J M et al. 2008. "The Short FES-I: A Shortened Version of the Falls Efficacy Scale-International to Assess Fear of Falling." *Age and Ageing* 37(1): 45–50.

King, A C et al. 1997. "Moderate-Intensity Exercise and Self-Rated Quality of Sleep in Older Adults. A Randomized Controlled Trial." *JAMA* 277(1): 32–37.

Lawton, M Powell, and Elaine M Brody. 1969. "Assessment of Older People : Self-Maintaining and Instrumental Activities of Daily Living 1."

Mirra, SS, A Heyman, D McKeel, and SM Sumi. 1991. "The Consortium to Establish a Registry for Alzheimer's Disease (CREAD). Part II. Standardization of the Neuropathologic Assessment of Alzheimer's Disease." *Neurology* 46(1): 142–45. http://www.neurology.org/content/41/4/479.short.

Morris, Michael G et al. 2003. "User Acceptance of Information Technology: Toward a Unified View." *MIS Quarterly* 27(3): 425–78.

Mutran, E J, D C Reitzes, J Mossey, and M E Fernandez. 1995. "Social Support, Depression, and Recovery

of Walking Ability Following Hip Fracture Surgery." *The journals of gerontology. Series B, Psychological sciences and social sciences* 50(6): S354-61.

Netz, Yael, Meng-Jia M.-J. Wu, Betsy Jane Becker, and Gershon Tenenbaum. 2005. "Physical Activity and Psychological Well-Being in Advanced Age: A Meta-Analysis of Intervention Studies." *Psychology and aging* 20(2): 272–84.

Reblin, M, and B N Uchino. 2008. "Social and Emotional Support and It's Implication for Health." *Current Opinion in Psychiatry* 21(2): 201–5.

Sherrill, Duane L, Kimberly Kotchou, and Stuart F Quan. 1998. "Association of Physical Activity and Human Sleep Disorders." *Archives of internal medicine* 158(17): 1894–98.

Shulman, Kenneth I. 2000. "Clock Drawing: Is It the Ideal Cognitive Screening Test?" *International Journal of Geriatric Psychiatry* 15(March): 548–61.

Strine, Tara W., and Daniel P. Chapman. 2005. "Associations of Frequent Sleep Insufficiency with Health-Related Quality of Life and Health Behaviors." *Sleep Medicine* 6(1): 23–27.

Ussher, Jane, Laura Kirsten, Phyllis Butow, and Mirjana Sandoval. 2006. "What Do Cancer Support Groups Provide Which Other Supportive Relationships Do Not? The Experience of Peer Support Groups for People with Cancer." *Social Science and Medicine* 62(10): 2565–76.

Vasunilashorn, Sarinnapha M. et al. 2016. "Derivation and Validation of a Severity Scoring Method for the 3-Minute Diagnostic Interview for Confusion Assessment Method--Defined Delirium." *Journal of the American Geriatrics Society* 64(8): 1684–89.

Woodgate, Jennifer, Lawrence R. Brawley, and Christopher A. Shields. 2007. "Social Support in Cardiac Rehabilitation Exercise Maintenance: Associations with Self-Efficacy and Health-Related Quality of Life." *Journal of Applied Social Psychology* 37(5): 1041–59.

8 Annex I: Patient information sheet

Título del estudio: Validación clínica del Andador inteligente ACANTO.
Promotor: Fundación para la Investigación Biomédica – Hospital Universitario de Getafe.
Investigador Principal: Rodriguez-Mañas, Leocadio. MD, PhD.
Centro: Hospital Universitario de Getafe.

INTRODUCCIÓN

El proyecto de investigación ACANTO tiene como objetivo fundamental ayudar a personas mayores con problemas funcionales a mejorar su rendimiento físico y mejorar su independencia y funcionalidad, evitando el deterioro durante la hospitalización. Para ello, el proyecto propone el desarrollo de un andador inteligente que se comunica con usted a través de una pantalla, a través de la que recibirá recomendaciones de ejercicios previamente prescritos por su médico. Además de estas recomendaciones, el andador también puede utilizarse como herramienta diagnóstica midiendo tanto la velocidad de la marcha, como el SPPB. Esta herramienta puede ser clave en la prevención del deterioro funcional durante la hospitalización y ayudar en la rehabilitación tras fractura de cadera.

PARTICIPACIÓN VOLUNTARIA

Debe saber que su participación en este estudio es voluntaria y que puede decidir no participar o cambiar su decisión y retirar el consentimiento en cualquier momento, sin que por ello se altere la relación con su médico ni se produzca perjuicio alguno en su tratamiento.

DESCRIPCIÓN GENERAL DEL ESTUDIO

El estudio que se le está proponiendo, es la validación de una herramienta que ayuda al diagnóstico y permite evaluar el rendimiento físico de los pacientes.

La selección de los pacientes para la validación del andador inteligente como herramienta diagnóstica, se realizará con pacientes que estén recibiendo terapia en el hospital de día y que cumplan los criterios de inclusión y de exclusión.

A los pacientes se les realizará tanto el Short Physical Performance Battery (SPPB) y la velocidad de la marcha en 6 metros. Posteriormente se compararán las medidas realizadas con el andador inteligente y las realizadas mediante el método tradicional por el terapeuta ocupacional.

POSIBLES RIESGOS

El andador inteligente conlleva mínimos riesgos, ya que ha pasado todos los controles de seguridad y su utilización ha sido aprobada por la Agencia Española de Medicamentos y Productos Sanitarios. Por otro lado, el uso del andador, se encuentra en un ambiente clínico controlado y supervisado.

CONFIDENCIALIDAD

El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los sujetos participantes se ajustará a lo dispuesto en la Ley Orgánica 15/1999 de protección de datos de carácter personal. De acuerdo a lo que establece la legislación mencionada, usted puede ejercer los derechos de acceso, modificación, oposición y cancelación de datos, para lo cual deberá dirigirse a su médico del estudio.

Los datos recogidos para el estudio estarán identificados mediante un código y solo los investigadores del estudio podrán relacionar dichos datos con usted. Por lo tanto, su identidad no será revelada a persona alguna salvo excepciones como en el caso de urgencia médica o requerimiento legal.

El acceso a su información personal quedará restringido a los investigadores del estudio y/o colaboradores, al Comité Ético de Investigación Clínica y al personal autorizado por el promotor, cuando lo precisen, para comprobar los datos y procedimientos del estudio, pero siempre manteniendo la confidencialidad de los mismos de acuerdo a la legislación vigente.

COMPENSACIÓN ECONÓMICA

Este proyecto no conlleva ningún beneficio económico ni para usted ni para los investigadores. El promotor del estudio es el responsable de gestionar la financiación del mismo.

La participación en el estudio no le supondrá ningún gasto añadido.

OTRA INFORMACIÓN RELEVANTE

Si usted decide retirar el consentimiento para participar en este estudio, ningún dato nuevo será añadido a la base de datos y, puede exigir la destrucción de toda la documentación identificable previamente retenida para evitar la realización de nuevos análisis.

También debe saber que puede ser excluido del estudio si el promotor o los investigadores del estudio lo consideran oportuno, ya sea por motivos de seguridad, o por considerar que no está cumpliendo con los procedimientos establecidos. En cualquiera de los casos, usted recibirá una explicación adecuada del motivo que ha ocasionado su retirada del estudio.

Si precisa de mayor información sobre este estudio puede contactar con el investigador principal del proyecto ACANTO, el Dr. Leocadio Rodríguez Mañas, Jefe del Servicio de Geriatría del Hospital Universitario de Getafe (Tel. 91 683 93 60 ext. 6412).

9 Annex II: Informed consent

Proyecto ACANTO

VALIDACIÓN CLÍNICA DE UN ANDADOR INTELIGENTE: ACANTO.

Investigador Principal: Dr. Leocadio Rodríguez Mañas

Promotor: Fundación para la Investigación Biomédica – Hospital Universitario de Getafe

Yo (Nombre y apellidos), ...

He leído la hoja de información que se me ha entregado.

He podido hacer preguntas sobre el estudio.

He recibido suficiente información sobre el estudio.

He hablado con (Nombre del investigador) .....

Comprendo que mi participación es voluntaria.

Comprendo que puedo retirarme del estudio:

Cuando quiera.

Sin tener que dar explicaciones.

Sin que esto repercuta en mis cuidados médicos.

Presto libremente mi conformidad para participar en el estudio.

Fecha: **Firma del participante**

10 Annex III: Walker information for governmental approval

10.1 Production identification data

- Commercial name: FriWalk.
- Model or number of model: The system is a derivative of Trionic Rollator Walker 12er, article number 24 – 00 – 001.
- Classification: biomedical assistive device.

10.2 Overview

The FriWalk is a robotic walking assistance derived from a standard commercial walker (the Trionic Rollator Walker 12e)[1], The walker is equipped with a number of sensors, mechatronic devices and computing boards, which are explicitly designed for rehabilitation, diagnostic activities and navigation assistance. The most important abilities of the walker when used for clinical applications can be summarised as follows:

- Doctors can exploit the sensing ability of the walker in order to gather information about patients' stability, strength and mobility (e.g., the SPPB test).
- The FriWalk can instruct the patients about the correct way to carry out physical exercise,
- The FriWalk can give real--time feedback to the user on the proper execution of the exercise, correcting errors when needed;
- The FriWalk can collect emotional information through the patients' facial expression to detect weariness and pain;
- the FriWalk can collect analytic data on the patients' performance during the exercise.
- The FriWalk can support the patients during their navigation of complex environment (e.g., the hospital's hallways, or gardens), showing them the shortest path.
- The FriWalk can guide the patients using a number of solutions (e.g., motorised wheels or haptic interface) and can stimulate them to walk with a specified pace.
- The FriWalk can detect unusual patterns (e.g., acceleration peaks) and block the wheels to prevent falls.

This device looks no different from a classic walker, since it is based on four wheels to improve stability and better support the user's weight. However, it's sensing and computing abilities

[1] http://trionicwalker.com

Figure 1: the FriWalk

allow it to gather information from the environment, localize itself and generate paths that can be followed with safety by the user.

As it is possible to from Figure 1, the walker has four wheels to maximise stability and offer physical support to the user.

The most important devices mounted on the walker are the following:

- two brushless motors mounted on the rear wheel. Each motor is endowed with a reduction gearbox and with an incremental encoder and is controlled by an electronic driver (LitePro). The rear mors enable autonomous motion for the device. They are also used for guidance purposes for emergency manoeuvres and as brakes to halt the device.
- two brushless motors (DF45-Nanotec) mounted on the front wheels (not visible in the figure) , reduction gearbox, absolute encoders and a driver (LitePro). These components are used to guide the user along a specified path. The guidance solutions obtainable with the front wheels are smoother and better modulated than the ones obtained with the back wheels, which are arguably better suited for emergency turns.
- a box, which contains all the control components and the batteries;
- a tablet, to provide a graphical user interface to let the person directly interact with the robot;
- a pair of resistive contact sensors mounted inside the grips to detect when the user is holding them.
- one version of the device has also force sensors mounted in the two handles, which can be used to detect tangential and vertical force;
- a PlayStationEye camera used to identify QR landmarks in the environment used for localisation;
- an OrbeccAstra RGBD sensor looking at the feet of the user to perform gait analysis (mounted underneath the box containing the control components).
- an PlayStationEye RGBD sensor looking at the user to perform face recognition;
- an AsusXtionProLive RBG and depth sensor looking ahead to detect the presence of other users and walkers in the surroundings.
- a set of haptic bracelets and anklets to convey guidance signals and regulate the user's walking speed

- an Inertial Measurement Unit (IMU) used to detect if the vehicle is moving uphill or downhill.

10.3 Operating Principles

The operating principles thought for this device are, essentially, two. In particular:

- mobile sensor platform: thanks to its autonomous navigation and its sensing abilities this device can be exploited as a mobile sensor platform. It can follow the users and interact with them during the rehabilitation exercises; The device is equipped with cameras, RGBD sensors and force sensors to collect and record all the information required by doctors; the information is processed on board and can be stored locally or on a remote disk (as far as a wifi infrastructure is available). The collected data can be visualised using external tools.
- assistive guidance support: thanks to its steering and sensing abilities, the user can exploit this platform to move more confidentially alone. Thanks to a vision system installed on the device, the robot is able to detect unexpected and moving obstacles, helping the user avoid dangerous situations. The robot has long range planning abilities (i.e., it can find a path to a desired location) and short range planning abilities (i.e., it can modify the trajectory the robot is moving on to avoid obstacles). A combination of front and rear actuators can be used to guide the user or to halt the walker for emergency stops.

The diagram showing the different components of the FriWalk is shown in Figure 2, where it is possible to appreciate the interconnection of the different elements.

10.4 Main components of the systems

The architecture is organised in two layers: the mechatronic layer and the cognitive layer. The mechatronic layer is organised around a Controller Area Network (CAN) infrastructure and is compounded of a number of nodes used to operate the different mechatronic components. Noteworthy are: 1. the different drivers for the brushless motors on the front and on the rear side of the vehicle (denoted as Back Left Noder, Back Right Node, etc.). Such drivers are “intelligent components” able to implement position, velocity or torque feedback control loops. Directly connected to the drivers is an enable signal coming from the mechanical brakes of the device: whenever the user pulls the handle of the brakes, the disable signal to the driver causes an immediate disconnection of all the motors.
The cognitive layer comprises a number of computing units (boxes) devoted to heavy data processing activities. In particular,

- NUC 1: is a Next Unit of Computing and is used to:
  - detect and interpret the QR landmarks for localisation;
  - manage the RGBD sensor looking at the user used for emotion recognition;
  - execute the reactive (short range) planning algorithms
  - host the software infrastructure used for the web based graphical interface;
- NUC 2: is a Next Unit of Computing and is used to:

- perform gait analysis using the data collected from the RGBS sensor
- detect human target and other walkers in the surroundings.

The two boxes are connected through an high speed switched Ethernet link.
The cognitive and the mechatronic layers are connected to each other by an embedded board (a Beaglebone) that acts as gateway. This board can also be used to implement control and estimation tasks requiring a moderate computation load (in particular guidance algorithms and localisation).

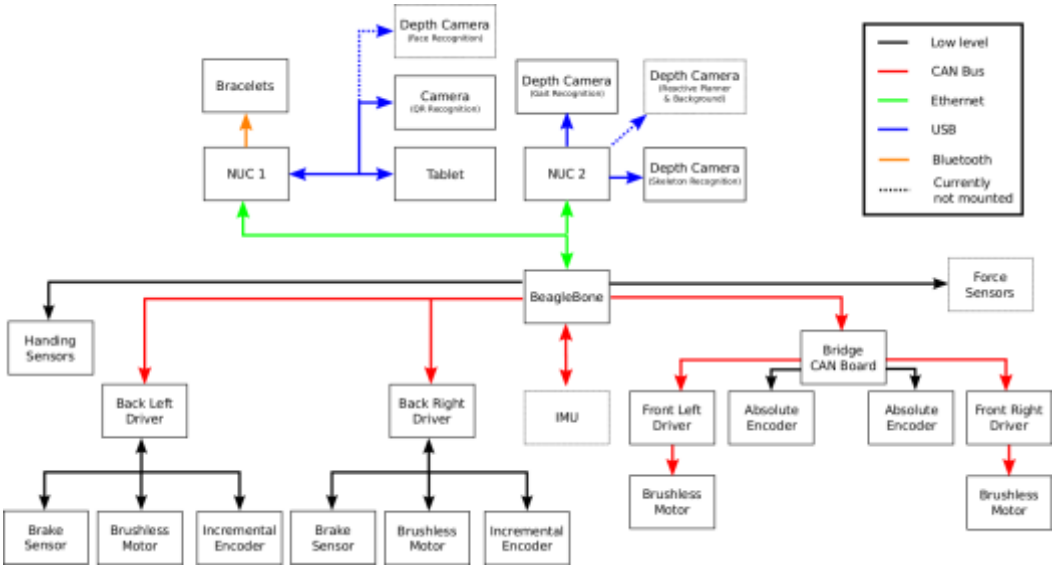

Figure 2: Diagram of the main electronic and mechanical components

In order to reduce the traffic on the CAN bus, the device also mounts a Bridge CAN bus to filter the messages from and to the drivers on the front motors. Grip and Force sensors are directly connected to the board.

10.5 Different functionality from similar devices

Identification of any features that make the device different from similar one that is CE marked.

The FriWalk is based on a the TRIONIC Rollator Walker 12er walking device, which is a CE marked device. The different functionalities of the FriWalk related to sensing, planning and actuation are not obviously present in the original system.
The only commercial device we know of is LEA produced by Robot Care Systems[2]. THis device can apparently be used for therapeutic purposes (i.e., to guide the users and to measure the force they use to push forward and other parameters). The main additional features of the FriWalk that are not present in LEA are the following:

- The FriWalk offers a plethora of difference guidance solutions, using front wheels, rear wheels, haptic devices and combinations thereof.
- The FriWalk embeds both a long range and a short range planner
- The FriWalk has sensors to detect the surrounding environment (e.g., in order to navigate), the users (e.g., in order to detect if they are doing the exercise properly and their stress conditions), and their walking patterns and gaits. This allows a fine grained diagnosis of the users' current conditions and of their evolution.
- The FriWalk embeds software to implement diagnostic and therapeutic activities specified by means of a protocol defined with the geriatricians.

10.6 Feature details

Details of any feature of the product that either is new or has not been tested yet, including, when applicable, functionalities and principles of operation.

The ACANTO project plans to use the FriWalk in a number of clinical activities, which have been defined with the staff of the hospital of Getafe. For each diagnostic and therapeutic activity, we have defined a protocol, consisting of actions, which are executed in sequence until the activity ends or a fatal anomaly is detected (e.g., the user refusing to go on). The FriWalk offers a SdK with a library of predefined actions (such as "say …. to the speakers", "write …. on the tablet", "wait for the user to hold the grips", "move from X to Y", etc.) which can be aggregated together to form tasks.
Each task is a sequential composition of actions. Actions are of two types: elementary and composite actions. Elementary actions are atomic and have to be executed in sequence. Composite actions are aggregates of elementary actions that can be executed in parallel (e.g., guiding the user from x to y while monitoring that no obstacles are on the way).

[2] http://www.robotcaresystems.com/en/waarom/

The protocol can immediately be translated into a task or a sequence of tasks, while the use of C++ metaprogramming secures a correct by construction combination of actions (see Section 11).
The different clinical activities we identified are of two types: diagnostic and therapeutic activities.
At the beginning of each activity a special protocol is applied to ensure that the attention of the user is focused on the exercise (typically the user is required to hold the grips). A preliminary phase is devoted to delivering the instruction for the activities. The user receives a complete description of the different phases using pictograms and recorded voice instructions. Voice instructions and signals are also delivered during the execution of the exercise. The volume and the type of signals is tunable to the patient specific needs and is stored into her/his profile for future executions. The robot also stores a map of the operating environment. Some of the tests could be executed only in a specific set of "certified" places, where the environment conditions allow us to carry out the test successfully. In this case, the robot could check automatically if it is in one of the certified areas.
The clinical activities are planned with the FriWalk (and not yet tested on real users at the moment of this writing) are described in a specific document. We report here a short summary
In the following we report a small description.

10.7 Diagnostic Activities

The diagnostic activity programmed in the FriWalk is the so-called SPBB test, which is quite popular amongst the geriatricians to assess the general conditions of the patient and the risk of falls or of other traumatic events.
The activity is illustrated in Figure 3.

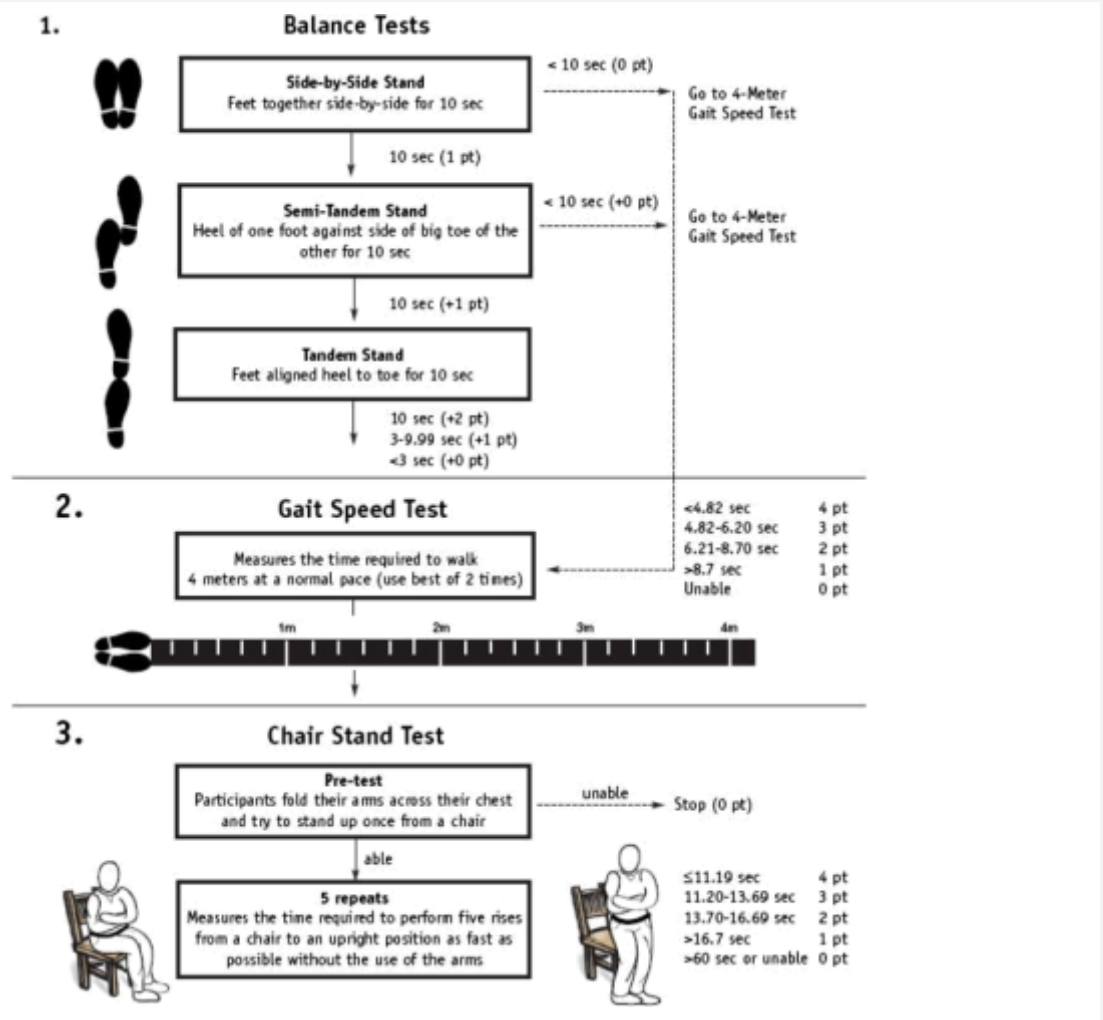

Figure 3: The different phases of the SPBB test

organised in three tasks

- **balance test**: in this test the FriWalk is positioned in front of the user to take measurement and offer support in case of balance loss. The task is required to keep the feet in a well specified position without holding the grips of the FriWalk. The gait sensor gather the information about the feet posture and analyses the test performance. If the feet have moved or the user touches the grips, then the test fails. If the tests for all the positions are satisfied, then the balance test is passed;
- **gait speed test**: for this test we have two cases:
  - **user able to walk**: in this scenario the robot is behind the user, so that the user is not influenced by its presence. At a certain time the loudspeaker on the walker tells the user the user to start walking, and the gait components detect the movements and collect information about the walk. The robot follows the human keeping the optimal distance. When a certain number of meters have been traveled, then the test finishes and the user stops;
  - **user in need of the walker**: this test is performed with the user in combination with the walker. As soon as the walker is aligned with a corridor, the walker actuates the front motors in order to force the person to follow a straight trajectory. The user starts walking and gait sensor gathers

all the information needed for doctors. When a certain number of meters are traveled the test finishes;

- **stand up test**: for this scenario a chair is required behind the user. The robot is positioned (autonomously or manually) in the optimal position to analyze the user posture. The person stands up and sits down on the chair repetitively, meanwhile the skeleton sensing reconstruct the posture of the user in order to gather the information required by the doctors;

10.8 Therapeutic Activities

Therapeutic activities are of two types: orthogeriatric activities and Therapeutic activities.

10.8.1 Orthogeriatric activities

Orthogeriatric activities are executed in the hospital (e.g., while the patient is healing from a trauma). For all orthogeriatric activities, the patient receives an invitation on the tablet, which can be accepted only if a caregiver is available for a direct supervision (the caregiver can be a paramedic, a relative or a close friend of the patient). If a caregiver is not available, either the exercise is simply skipped or it is prohibited to execute the exercise alone because being too dangerous. In the latter case, a mechanism of authorization/confirmation by the caregiver is adopted. The orthogeriatric activities supported by the FriWalk are the following:

- walk x minutes / one hour: in this scenario the walker reminds and invites the user to take a walk. The user exploits the robot as a standard walker to move wherever he wants, meanwhile sensors gather information about the distance covered by the user and the time of the walk;
- isometric/isotonic exercise: the walker is positioned in the environment for the correct detection of the user. The user is required to perform specific isometric exercises while the skeleton sense his/her performance.

10.8.2 Therapeutic Activities

Therapeutic activities are executed in a protected residence. In this case the user is allowed to make a personal use of the walker (at least for some time), without the constant supervision of a care-giver (although one should always be in easy reach). The activities designed for the FriWalk are the following:

- **walk certain X metres/day at a velocity V**: the robot, periodically, reminds the user about the distance and the velocity that the user has to walk today. The user exploits the robot as a standard walker while the sensors gather the desired information. Meanwhile, the graphical user interface shows the total distance to be walked, the traveled and pending distance and a speedometer; while the user walks the FriWalk activates environment monitoring and obstacle avoidance.
- **standing on one leg**: the robot, periodically, reminds the user about the exercise that he/she has to perform. So that, the user performs the test, meanwhile the skeleton sensor gather information about the user performance; this information is consolidated within the user's profile and periodically reviewed by the physicians.
- **standing on the tiptoes**: the robot, periodically, reminds the user about the exercise that he/she has to perform. In this case the gait components analyses the user during its exercise and evaluate the user performances.

Figure 4: DALi's cWalker.

10.9 Summary of experience

At the moment of the writing, the FriWalk has been integrated and tested in the laboratories of the University of Trento by a team of technicians and PhD students. However, the ACANTO research project (www-ict-acanto.eu) sponsoring the development of the FriWalk is a follow up of a previous FP7 project called DALi (www.ict-dali.eu), which led to the development of a different robotic walker called cWalker [1] (see Figure 4). The FriWalk is significantly different from the cWalker. It has a superior mechanics and adopts a number of novel solutions. However, we could say that the FriWalk evolves the idea of the cWalker and takes it to the limits of the current robotic technology. Therefore, several solutions of the FriWalk take their natural inspiration from the preliminary work developed on the cWalker. In particular the following fearures of the CWalker have been acquired as background material for ACANTO and are being developed in the FriWalk:

1. Long range and short range planning [2]
2. Localisation techniques based on the combination of odometry, inertial sensors and QR readings [3]
3. Guidance technology based on motorised front wheels and on the brakes [4]
4. Use of haptic bracelets for guidance.

The guidance and the navigation solutions have been tested on a number of users (at 20 older adults recruited in Ciudad Real, Spain and just as many in Trento, Italy) during the DALi project. The outcome of the experimentation reveal an initial reluctance in the initial approach toward the device, deriving from the possible stigma that its use could generate. This consideration is hardly applicable to the FriWalk clinical application, for which the user are in a hospital on in a protected residence and are somewhat in the right mindset for the use of medical devices.

From the technical point of view, the DALi experimentation was afflicted by a long sequence of electrical failures and software fault. This lead us to the conclusion that any experimentation of this kind requires a very reliable platform. Thereby, the greatest share of our effort have been toward the radical improvement of the mechanical and the electronic design. The adoption of a correct-by-construction paradigm (based on template metaprogramming) enables us to remove most of the programming errors in the software during the compilation phase. The resulting software architecture is robust and dependable.

Finally, our experience with the users has revealed that: 1. guidance using brakes is normally annoying and imprecise and its use should be restricted to emergency manoeuvres, 2. the guidance through the front steering wheels is generally well received by the user, but it can also be perceived as intrusive, 3. the guidance using bracelets is generally appreciated but, since the ultimate decision on which direction to take is left to the user, it should be complemented by other mechanism that come into play when an uncooperative user meets potentially dangerous situations. The lessons learned have been translated into the design of the FriWalk. Some of the key improvements being:

- adopting more powerful (brushless motors) in place of the stepper motors for the front wheels; this solution enables more sophisticated guidance solutions that strike a good trade-off between safety and comfort;
- replacing the rear brakes with brushless motors with a 1 to 40 reduction; the braking functionality has been preserved but the use of motors allows the system to move autonomously (which is required by some of the clinical applications) and to adopt much softer guidance mechanisms modulating the velocity of the wheels than allowed by outright stopping the wheel;
- the use of force and contact sensors allows the FriWalk to estimate the force and the torques exerted by the user and adjust the guidance decisions accordingly.

In addition, the general improvement of the system's mechanical and electrical components and the adoption of a software architecture will permit the autonomous use of the FriWalk without direct supervision of technicians for long periods of time.

10.10 Risk analysis

Risk analysis, including the identification of hazards, risks associated with the manufacture (consider those factors related with the selection of the product, materials, software, etc.) and risks related with the actual use of the product along with a description of the actions taken with the aim to minimizing or even eliminating the identified risks.

Risk	Mitigation Action	Severity	Likelihood to Happen	Detectability	Risk #
The FriWalk moves out of control running over the user or by-standers	Presence of passive devices to switch off the machine (lanyard, switches)	7	2	2	28
The user dresses or shoelaces catch on the mechanical mechanisms of the front or rear motors causing a fall	Plexiglass cover on mechanical parts	5	1	2	10
Electrical shock	Internal Cabling. Insulation of the batteries.	3	2	3	18
Injuries caused by tips, sharp edges, or hot surfaces	High quality of the frame. Rounded edges for the carters.	2	2	2	8

Leakage of corrosive fluids from the batteries	Triple mechanical barrier between the batteries and the environment.	8	1	5	40
Explosion or meltdown of the lithium batteries	State of the art protection mechanisms in the devices. Extensive testing.	8	0.5	5	20

The different risks are listed in the following UNE-14971 compliant table and described in detail in the text below. In the table Severity, Likelihood and Detectability are numbers chosen in the range 0 (non existent) – 10 (critical).

Risk 1: the FriWalk moves out of control running over the user or by-standers

Since the FriWalk is capable of autonomous motion, one of the main risk that is potentially harmful for the user is related to a severe software failure, which could make the robot move unpredictably. The FriWalk could in this case on its own alone, running over the user or causing her/him to lose her/his balance. Similarly, the robot could crash against other patients or bystanders or cause material damage. In order to minimize/eliminate the identified risk, to preserve user safety, we installed two devices:

- a safety lanyard which connects the user's chest with the robot. If the distance between the user and the robot exceeds the lanyard length, than the power supply is immediately and automatically detached;

- a safety switch mounted in the two bars of the seat. In this way, if the FriWalk goes backwards, as soon as the seat comes into contact with the user legs the power supply is immediately and automatically disconnected.

We point out that both mechanisms operate directly on the power switches; therefore they do not need any software signal to be activated.

Finally, the use of correct-by-construction programming mechanisms, of well tested versions of the Linux Kernel and of well known computing devices (adopted and supported by a large community) mitigates the risk of a severe software failure.

Risk 2: the user dresses or shoelaces catch on the mechanical mechanisms of the front or rear motors causing a fall

The tyres are connected with the motors by means of a gear system on the rear and a pulley–belt system on the front. In order to minimize the risk of entanglement (but also of small injuries, bruises or bunts), all the moving parts (like gears, pulley and belts) have been covered with a thick plexiglass case so that the user cannot come in direct contact with them.

Risk 3: Electrical shock

Regarding the electrical risk, since there are lead battery inside the box (which could electrocute the user in case of shortcuts), we designed an insulation system to avoid direct contacts of batteries with the walker frame. Moreover, all the wires are cabled

inside the walker frame in order to minimize the possibility of direct contact with the user's body. The electrical circuits respects the requirement of the current regulations (in particular as regards the adoption of high quality connectors).

Risk 4: Injuries caused by tips, sharp edges, or hot surfaces

The walker is a derivative of the a high quality commercial walker, which is carefully designed and manufactured to avoid injuries and accidents of the kind. The additional components are packed within plexiglass cases or aluminium boxes. All the edges are rounded and the gap between the hot part (motors) inside the case are sufficient to avoid contacts with hot parts.

Risk 5: Leakage of corrosive fluids from the batteries

The lead batteries are protected by a pair of fuses to prevent short circuits that could determine overheating and meltdown of the lead batteries. Besides, the batteries we selected are based on a acid lead gel (which does not easily leak out) and are endowed with a thick plastic cover that contains the lead core. Finally, a third barrier is the aluminium box that contains the batteries .

Risk 6: explosion or meltdown of the lithium batteries

The batteries used for power supply of the electronic components contain state-the-art protection circuits. We have tested them for several hundred of hours of operating time and no important problem emerged.

10.11 Summary of preclinical trial

Summary and analysis of any preclinical trial carried out (including experimental data), in- cluding the results, mechanical trials, electrical trials, software validation, safety trials and any other relevant trial. In this point it is necessary to indicate those technical standards or internal manufacturer procedures that have been followed.

However, preliminary tests have been conducted on a low fi prototype derived from DALi's cWalker with the medical staff with the purpose of identifying requirements Preclinical trials have not been conducted on the FriWalk as yet.

However, preliminary tests have been conducted on a low-fi prototype derived from DALi's cWalker with the medical staff with the purpose of identifying requirements and define application scenarios. Many of the design choices reported about above derive from this experience.

More in detail, the experience with the user collected with the low-fi prototype have been translated into design guidelines concerning a number of different points. The most important are listed next.

Guideline n. 1: selection of the device platform

For the DALi project, the device was developed with a clear goal in mind: demonstrate that the solutions could be viable using low cost hardware solution. This philosophy lead

us to the adoption of a very low cost mechanical platform (one that is possible to buy for less than 150 Euros). While the goals of the DALi project have been met, we encountered the following problems: 1. The platform did not lend itself to the easy integration of mechatronic devices and of the cabling, 2. The presence of mechanical backlashes significantly exacerbated the difficulty of implementing guidance algorithms, 3. The stigma deriving from using a bad looking device could potentially discourage its use in public spaces.

For these reasons, we have decided to ***improve the quality of the platform*** because the benefit could be worth the price, and elected the TRIONIC platform mentioned above.

Guideline n. 2: electrical design

Among the problems encountered with the use of DALi device, there were occasional disconnections of the cables, shunts (which several times caused components failure) and electric shocks. Such problems determined frequent slow-down in the experimental work agenda and were a constant cause for concerns when we involved older adults in the user validation.

In view of these experience, we decided to use the ***maximum care in the quality of the connector, in the cabling and in the insulation of the batteries***.

Guideline n. 3: replacing brakes with motors

DALi's cWalker had a couple of electromagnetic brakes applied on the rear wheels instead of the motors. This choice was determined by the following considerations: 1. The cost and the complexity of the control electronic for a brake is way lower than the one required by a motor, 2. Having a passive device (i.e., a device incapable of autonomous motion) is arguably safer than having an active device.

The changed context of the ACANTO project forced us to consider other requirements such as the ability of the walker to follow the user for the SPBB test. What is more, we have developed a control approach named "simulated passivity" in which the rear motors can be actuated to steer the vehicle without any apparent change in the forward velocity (which could endanger the user). On the other hand, the combination of gearbox and brushless motors produces, when required, a behaviour very similar to a braking action.

With these considerations in mind, we decided ***that the use of rear motors instead of brakes had a clear potential to improve the flexibility of the device without sacrificing safety.***

Guideline n. 4: adoption of a structured testing procedure for software

In the DALi project the integration of the different components was carried out in the very last months of the project. The foreseeable result was an evident lack of robustness in the behaviour of the product, which generated frequent bugs very hard to identify causing delays in the project.

This experience spurred us into the ***adoption of a formalised testing procedure***, in which each component is first tested in isolation and only after this test is passed is the integration completed and the system tested as a whole.

This policy, in combination with the development of a well-founded software architecture, has lead us to a drastic reduction in the number of bugs encountered during the "user validation" phase. The integration testing phase is currently under way for all the clinical applications.

Guideline n. 5: Design of robust software architecture

In a complex project like ACANTO, one of the critical and potentially most error prone activity is the integration of the different components (which come from different research groups). As observed in Section 7.4, in the DALi project this activity gave rise to frequent problems (i.e., bugs very difficult to identify).

In order to alleviate the problem, we have designed a very robust software architecture based on the widespread adoption of the zeroMQ middleware and of the template metaprogramming paradigm, which drastically reduces the probability of "trivial" programming errors detecting them during the compilation phase of the application.

7.6 Guideline n. 6: Test the applications with PhD students and intact users before moving to the validation with actual users.

Our experience with DALi revealed that the validation with realistic users (i.e., older adults with degrading abilities) could be quite demanding both from the physical and from the psychological point of view. For this reason, our current ethical guidelines require that for any experimentation activity that the ***very same protocol that will be used for older adults is first administered to a good number of younger and physically intact users*** (e.g., PhD students and technical stuff). The level of physical and psychological test is tentatively evaluated during this phase to fine tune such parameters as the duration of the exercise or the number of repetitions.

10.12 Materials in contact and justification

Description of the materials in direct contact with the user's body. Material selection justification and applicable standards.

Figure 5 - The grips

The material in most direct contact with the user is the rubber of the grips (see Figure 5). In the original device the grips are anatomic and slip free. The brake handles are all aluminum.
A resistive contact is buried inside the grips (see Figure 6).

Figure 6: resistive contact sensor

Occasional contacts are obviously possible with the frame of the walker, which has been left unchanged from the original walker. The frame is aluminum made and its CE certification comes from the original producer. The same consideration apply to the seat, made of water repellent 600D polyester tissue (which is also unchanged from the original device)
All the additional components that have been mounted on the FriWalk (e.g., the flanges to host the motors or the boc containing the control logic) are aluminum made. The justification of such a choice is to have a light and stainless robot, preventing any rust formation that could cause tetanus infections. The only mechanical components that are made of steel are the gears, since they have to transmit high torques. Anyway, since every transmission system is covered by a case, the user cannot come into direct contact with any of these components.
Finally, the cases of the mechanical systems are made of plexiglass (5mm and 3mm thick). The cases have rounded edges and corners and are strong enough to withstand crashes of medium intensity.

10.13 Biological safety

The external surfaces of the FriWalk which could come into direct contact with microorganisms (viruses and bacteria) carried by body fluids are made of one of the following materials:

- Rubber (grips and tyres)
- aluminum (frame, box for control logic)
- plexiglass (the case)
- plastic (cameras, wheel rims)
- steel (gears)
- polyester (seat)
- touch screen of the table used to control the functionalities of the system

All these surfaces can be treated with standard bleach to remove possible contaminations and guarantee appropriate hygiene levels. Attention must be paid to the choice of disinfectant used to treat the rubber grips and the aluminum frame for possible corrosion and degradation of the treated surfaces, but the situation is no different from the one faced to treat standard devices (such as wheelchairs and walkers). The back wheels are easy to detach to sanitise/sterilise the gears when needed.
The most remarkable risks are related to possible infiltration of body fluids or of contaminated liquids internal parts of the robots, from which they could not easily be removed. In particular, we envisage two possible risks. In particular, we envisage two possible risks, which are summarised in the following UNE-14971 compliant table and described below.

Risk	Mitigation Action	Severity	Likelihood to Happen	Detectability	Risk #
Contaminated fluid penetrates into the cables running inside the FriWalk's frame	Holes sealed by waterproof silicone paste.	9	0.5	5	22.5
Contaminated fluid penetrates into the motor cases	Either seal the ventilation slit or apply disposable cover	6	1	1	6

Risk 1: contaminated fluid penetrates into the cables running inside the FriWalk's frame

There are six possible holes in which the different wires, twisted together and protected by a sheath, enter into (or exit from) the frame. Each of this hole could be potentially vulnerable to a possible infiltration of contaminated fluid. To mitigate the risk, each of the holes is sealed by waterproof silicone paste. The sheath of the twisted cable offers and additional protection.

Risk 2: contaminated fluid penetrates into the motor cases

This is the most important vulnerability of the system to biological hazard because of the presence of ventilation slits back and in the front sides of the cases. The slits are very narrow (3 millimetres each) and are present on the case to prevent overheating of the mechanical elements and of the motors in case of long uses of the vehicle. Still, their

presence could potentially determine infiltration in case of direct flow of body fluids (e.g., due to an intense bleeding). Our possible countermeasures are the following:

1. seal the slits whenever the device is subject to a high risk of contamination
2. apply disposable cover (e.g., similar to the polypropylene shoe covers or surgical mask normally used in clinical environments).

The first strategy is applicable when the device is used for relatively short time. Our preliminary experiences reveal that no real overheating problem occurs for less than 15 minutes of continuous use of the device (e.g., a rather long walk in the hospital) even with sealed slits. The second strategy requires the adoption of a tissue cover that permits a reasonable level of airflow shielding the system from the most common risks of fluid penetration (e.g., a few drops of blood or other body fluids).

In the unfortunate event of a contamination, it is still possible to sterilise the system, but this requires the intervention of a technician to preserve the integrity of the electrical connections and cannot be made by paramedic staff without a specific training.

10.14 Design drawings and circuitry diagrams

Design drawings and circuitry diagrams (including materials and biomaterials) along with the required explanations necessary for the understanding of the pictures/diagrams.

10.15 Design drawings

As described in the previous sections the *FriWalk* is based on a classic walker with a mechatronic modification both at the front and at the rear.

10.15.1 Rear design

The overall mounting configuration is visible in Figure 7. As it is possible to appreciate from this figure the mechatronic elements installed on the walker and described in the first section have been covered by:

- a fender: which aim is to protect the user from the gear rotation;
- a cater: a cover made of several layers in order to protect all the mechatronic components installed on the rear wheel. Moreover it preserves the grease. Lubricating is fundamental in this type of mechanical coupling mainly to reduce friction and to avoid wearing.

Both elements are made of plexiglass.

Figure 7: Acanto FriWalk rear overview.

A better overview of the rear covers is reported in Figure 8 where it is possible to see how they are mounted together.

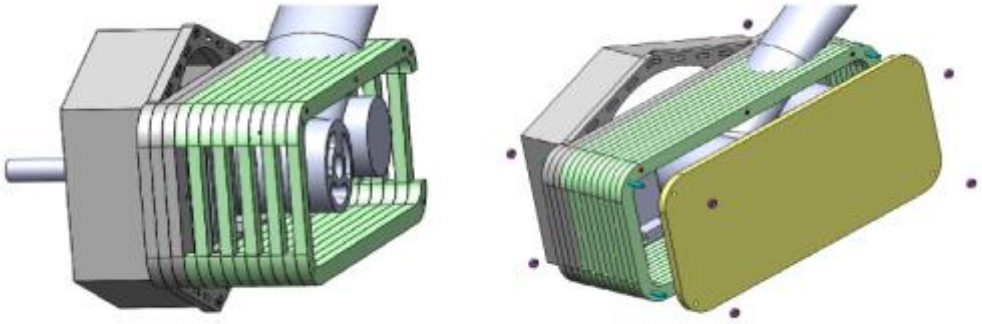

Figure 8: Rear covers.

For what concern the actuation of the rear wheel, the design drawing of the gearbox is shown in Figure 9 where:

- red flange: is the flange directly mounted on the walker loam by means of two bolts;
- orange flange: is the flange used to support the motor;
- green and cyan gears: gears of the gearbox;
- yellow shaft: element which hosts the external pinion which is coupled with the gear mounted on the wheel of the walker (see Figure 10). Moreover, this shaft hosts the incremental encoder which is used for the localization of the robot.

The motor is connected with the driver by means of direct wires, which are hosts inside the carter, while the power is supplied by wires plugged inside the loam of the walker. Thanks to this configuration the user is not allowed to touch, also accidentally, the wires.

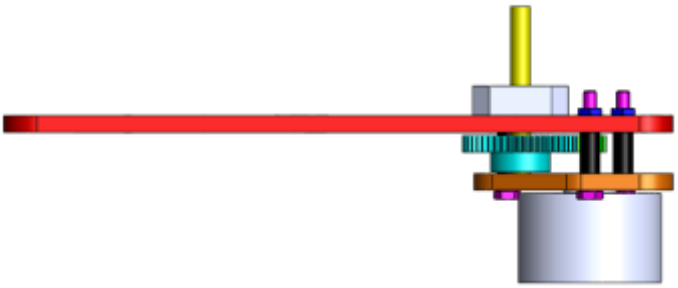

Figure 9: Rear gearbox.

Figure 10: Rear mechanical coupling.

10.15.2 Front design

The actuation of the front wheel is guaranteed thanks to a pulley-belt system, where the original pulley present on the fork of the walker has been preserved. The overall front configuration is reported in Figure 11 where, also in this case, it is possible to notice that a coverage made of plexiglass has been mounted around the actuation system. This coverage is based on three different parts:

- encoder carter: protection of the absolute encoder mounted to measure the absolute rotation of the fork;
- motor carter: protection installed around the motor to protect the user from electrical hazards;
- belt carter: lower guard mounted to isolate the belt transmission. At the same time, the pulley is completely covered, so that the pinching hazard has been reduced to the maximum.

Even from Figure 11 it is possible to notice that, starting from the original walker frame, two flanges have been added in order to host the gearmotor. In particular we have:

- motor flange: horizontal flange on which the gearmotor is mounted;
- lateral flange: is coupled with the loam by means of one bolt. This flange (as visible from Figure 12) is characterized by two slots, which are used to let the motor flange slide to tighten the belt.

As done for the rear actuation system, also for the front the power wires comes from the inside of the frame, while the connection between the motor and its driver is protected by means of the motor carter.

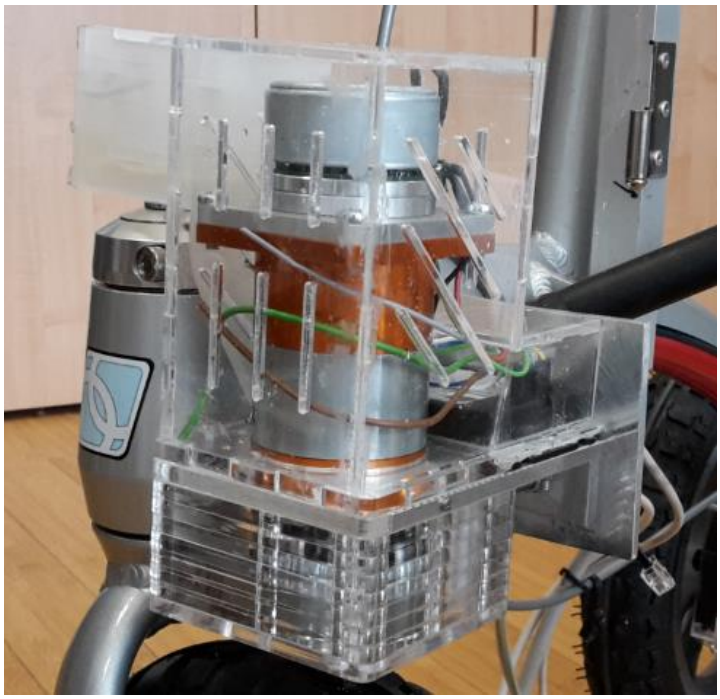

Figure 11: Front actuation overview.

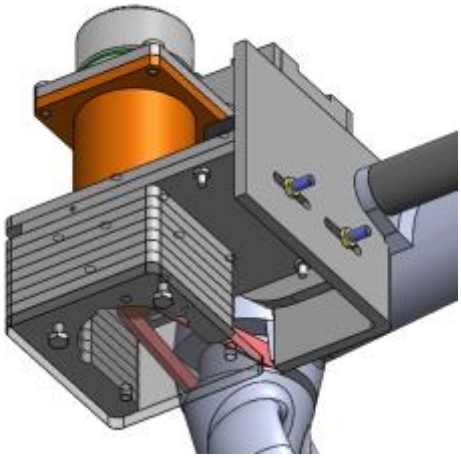

Figure 12: Front actuation coupling system.

10.15.3 Box design

FriWalk is equipped with a box containing all the electronic (described deeply in section 10.3), the batteries and the intelligence (BeagleBone Black and Nuc). This box is connected with the motors, drivers and sensors thanks to four connectors attached on the bottom of the box:

- two connectors (with 4 poles each) are dedicated to transport the power (motor and drivers) for the right and left section of the walker;
- two connector (with 16 poles each) are dedicated to the connection of all the sensors (front encoders, grip sensors and of the can bus) for the right and left section of the walker.

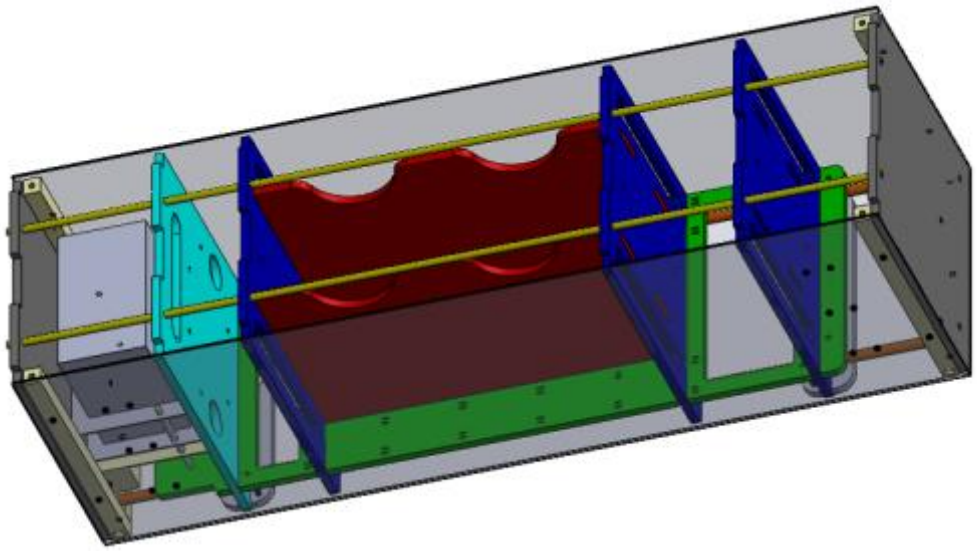

Figure 13: Box design.

Figure 13 shows the final design of the box of the *FriWalk*. This box is based, basically, on:

- an external U-shaped structure of aluminium;
- an internal layer-structure of plexiglass. These layers are highlighted in Figure 13 with different colours and, in particular:
  - gray left layer: on this layer there are mounted all the components dedicated to the interaction with the users, i.e.: general button (to switch on the entire system) and the charging plug;
  - light cyan layer: on this layer (on the left part) there are mounted the BeagleBone Black and the bridge can board;
  - red layers: there are used to contain the lead batteries, separating them from the lithium ones. More precisely, the lead batteries are located between the two red layers, while the lithium batteries are hosted between the red layer and the lateral wall of the box;
  - blue layers: the first and the second blue layers, starting from the right, are used to host the Nucs;
  - gray right layer: on this layer there are mounted all the components dedicated to the connection of the box with external sensors, i.e.: gait and depth cameras. Moreover, on this layer there are collocated two fans for the ventilation of the box;
  - green layer: base of the inner structure;
  - bottom grey layers: there are two layers collocated bottom the base layer which aim is to host the connectors for the connection of the box with the outside;
- bottom orange bars: these bars are collocated on the bottom of the structure to increase the stiffness of the plexiglass structure;
- top yellow bars: these are threaded bars which are necessary to limit the flexibility of the vertical plexiglass layers. With these elements the fragility of the entire inner structure is limited at the maximum.

For what concern the mounting system of this box on the *FriWalk* Figure 14 shows the adopted solution. As it is possible to appreciate from the figure, on the rear alluminium wall of the box there are mounted 4 hinges dedicated to the anchor of the box.

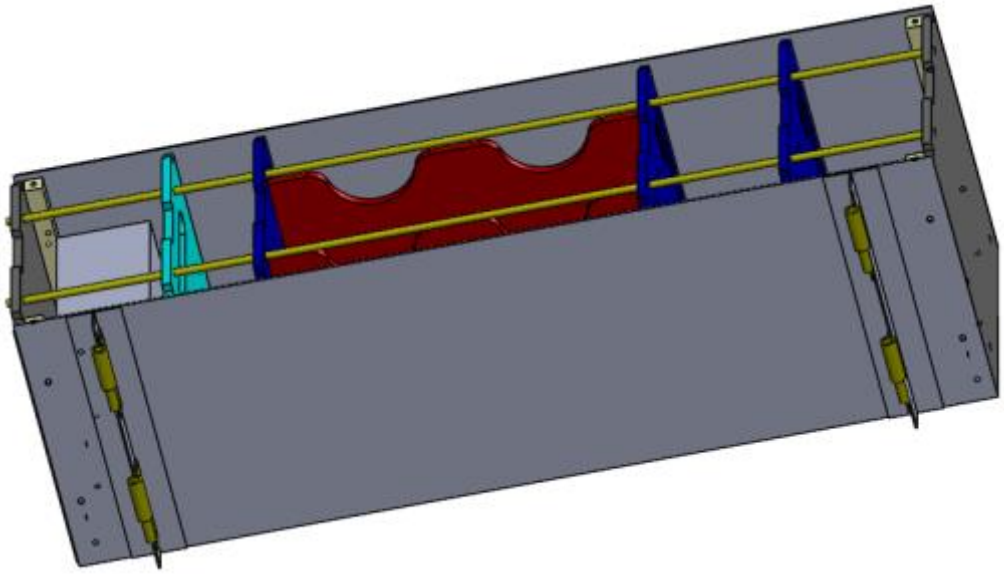

Figure 14: Placement of the hinges on the box.

10.15.4 Box connection to the walker frame

From Figure 14 we showed how the “male” parts of the hinges are collocated on the box. For what concern the mounting solution of the “female” parts of the hinges on the walker frame it is possible to look at Figure 15, which emphasizes the box support.

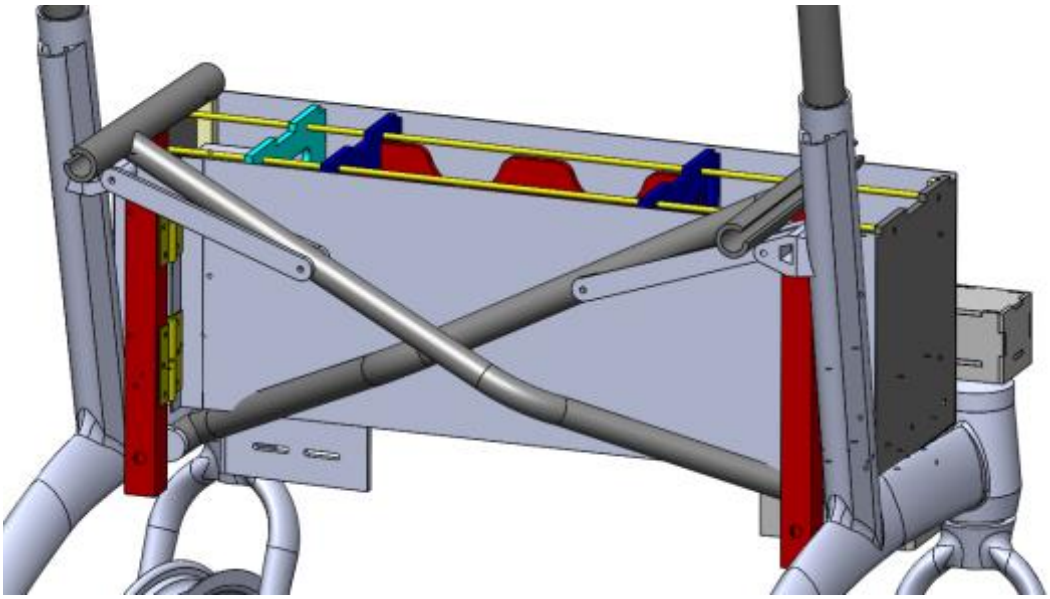

Figure 15: Placement of the hinges on the bo**x**

This box support is based, basically, on:

●two vertical squared bars (red elements in Figure 15), which are connected with the walker frame by means of two bolts each, and hosts the "female" of the hinges;
●two spacers each (which are not visible from Figure 15) which aim is to keep the vertical squared bars at the desired distance from the walker.

10.16 Circuitry diagrams

FriWalk is equipped with an electrical circuit made of three circuits, dedicated to the management of the power supply of all mechatronic and electronic components, included the batteries. This circuit is basically made of three sections, which are connected together:

- charging circuit: responsible of the charging of the lead batteries;
- sensing circuit: which checks the correct operation of the power supply circuit and collects inputs from the user;
- power supply circuit: activates and deactivates the supply to all system components.

All these circuits are under the control of an ST, which is a microcontroller interfaced with a development board. Moreover, all these circuits, because of encumbrance, are splitted over three boards mounted one over each other:

- relay board;
- charging board;
- sensing and microcontroller board.

10.16.1 Relay board

The schematic circuit of the *relay board* is reported in Figure 16. This board activates the relay according to the instruction coming from the microcontroller. As soon as the microcontroller sends the information to excitate a relay coil, the corresponding output is activated, turning on the desired mechatronic component.
This circuit is responsible of the motors and of the logic power supply. Moreover it hosts a reed relay, which is a component attached to a lanyard emergency strip, so that, as soon as the strip is pulled, an information is sent to the microcontroller, which switches off the power system, but preserves the logic section. The reason of such a choice is due to let the user know if the strip has been pulled, so that the graphical user interface has to interact directly with the user in this emergency situation. At the same time, the motors have to be switched off.

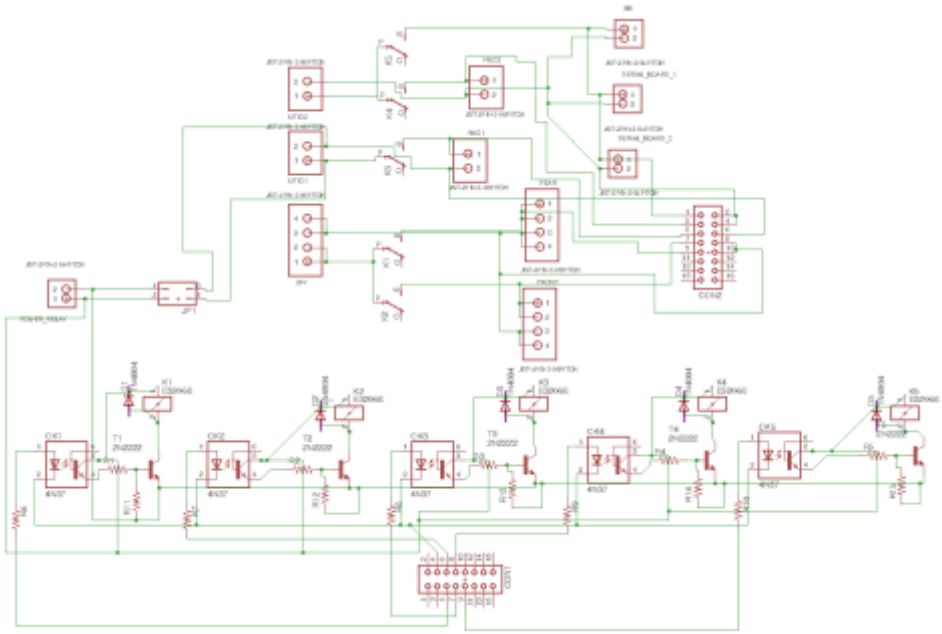

Figure 16: Relay board schematic circuit

The *relay board* derived from the electrical circuit reported in Figure 16 is reported in Figure 17.

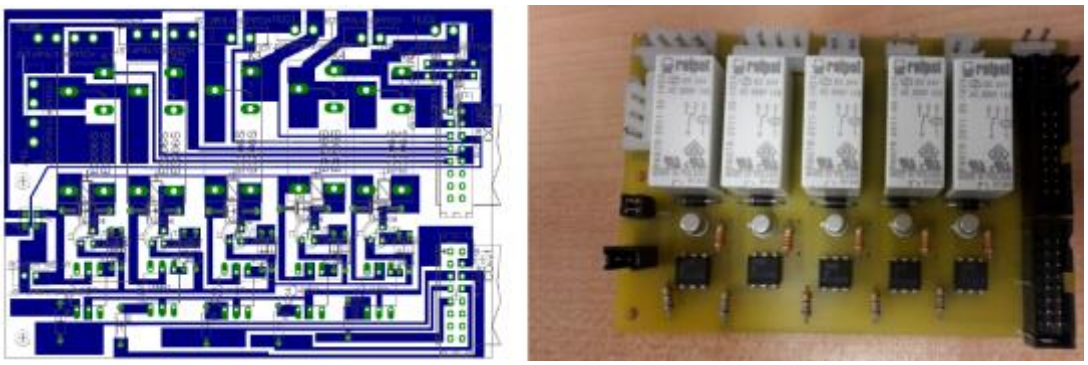

Figure 17: Relay board

10.16.2 Charging board

The schematic circuit of the *charging board* is reported in Figure 18. This section of the circuit provides the power from the two lead batteries. During charging phase, the battery are connected in parallel, in order that they can be recharged independently (12V DC). During the common phase, the battery are connected in series, in order that they supply the correct desired voltage (24V DC). As soon as one both the two charger (CH1 and CH2) is connected to the box, that the circuit automatically switches from the series configuration to the parallel configuration thanks to one relay.

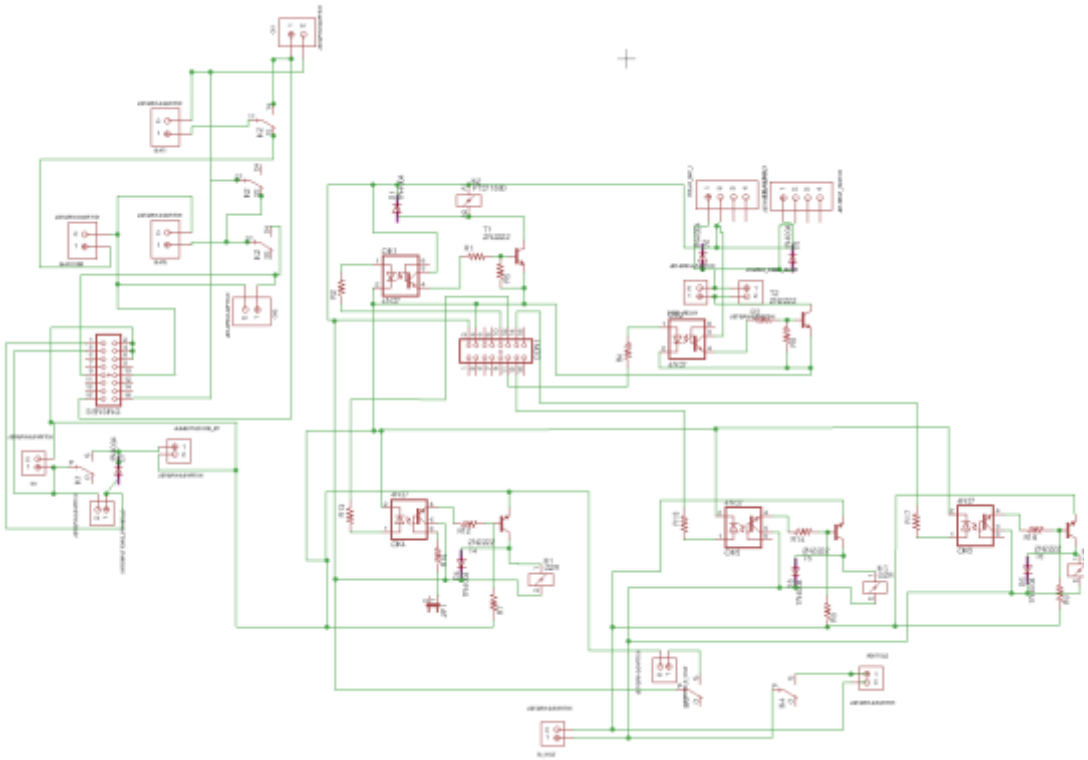

Figure 18: Charging board schematic circuit

The *charging board* derived from the electrical circuit reported in Figure 18 is reported in Figure 19.

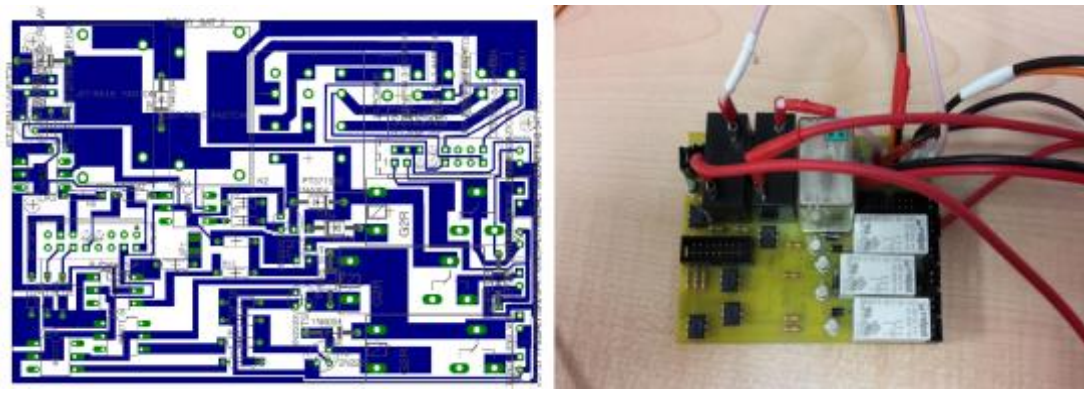

Figure 19: Charging board

10.16.3 Sensing and microcontroller board

The schematic circuit of the *sensing board* is reported in Figure 20. This board hosts the microcontroller, which is the brain of the power supply of all components and manages the inputs coming from the user. This circuit is equipped also with 5 leds, which gives direct information about the status of the different mechatronic components.

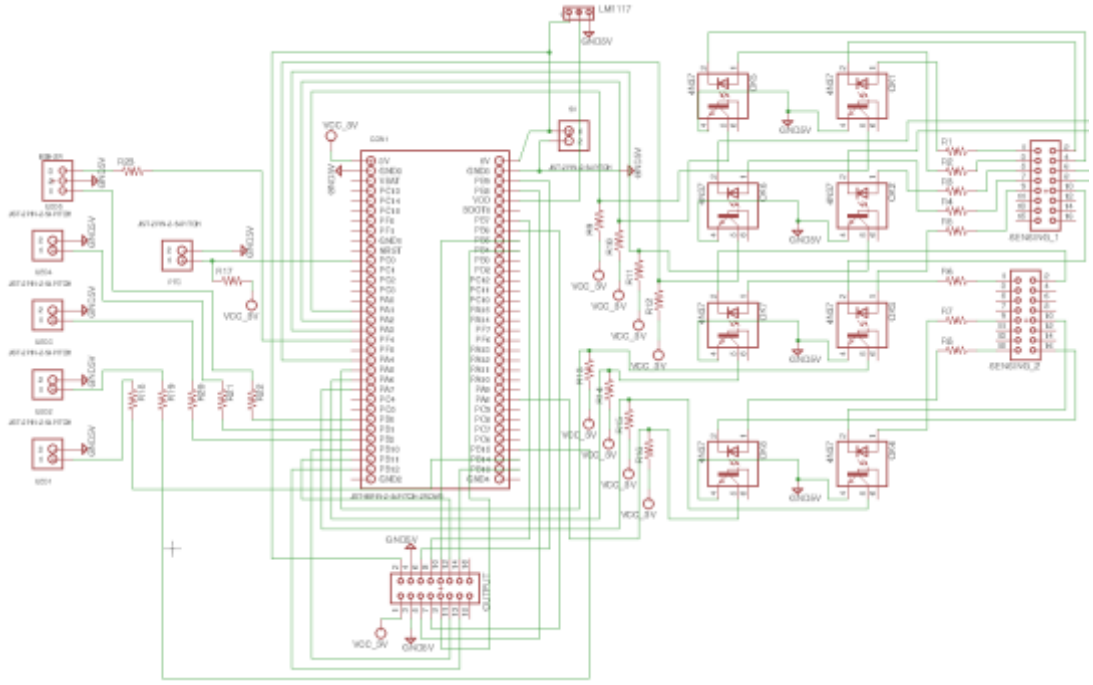

Figure 20: Sensing and microcontroller schematic circuit

The *sensing and microcontroller board* derived from the electrical circuit reported in Figure 20 is reported in Figure 21.

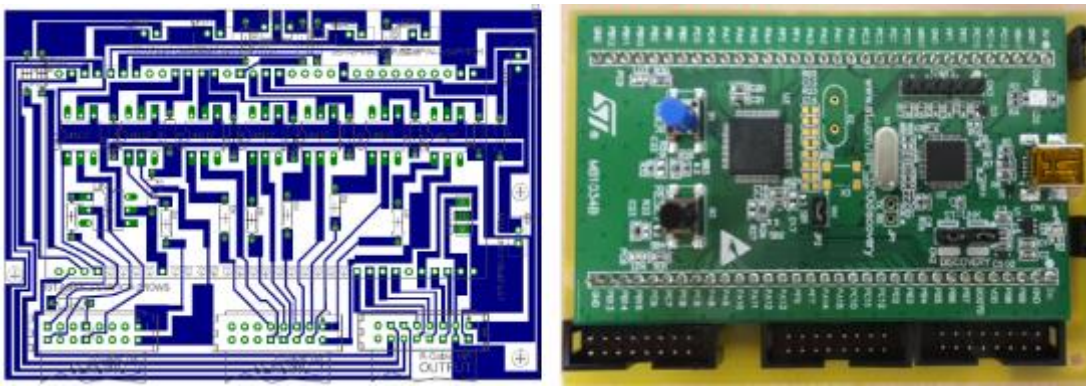

Figure 21: Sensing and microcontroller board

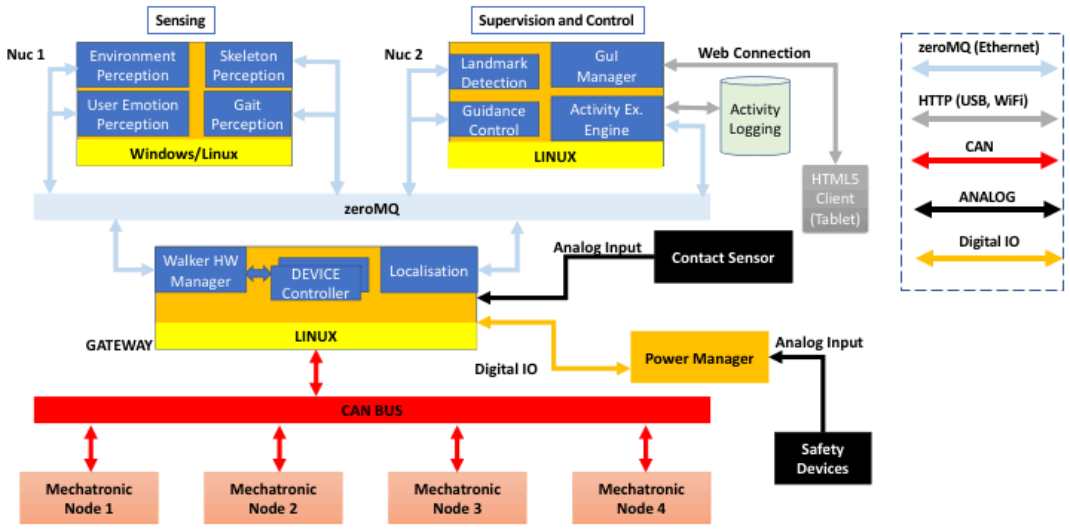

Figure 21: Outline for the HW/SW architecture

10.17 Software description and constraint logic

An outline of the software description is presented in Figure 21. As evident from the scheme, we have a first mechatronic layer interconnected by a CAN connection where all the different control boards are connected. The protocol used to establish a proper coordination between the different nodes is CAN Open. The cognitive components (deployed on the NUC nodes) are interconnected through a zeroMQ bus. A description of the various components is offered next.

10.18 Mechatronic nodes

At the moment of this writing the mechatronic nodes are essentially the drivers used to control the motors. They are operated by the firmware shipped with the device by the manufacturer.
Appropriate CAN messages are used to choose the appropriate settings of the driver during the FriWalk setup. Such configuration messages are generated by a Windows GUI.
The drivers offer a wide range of possible execution modes. In the FriWalk we use the following ones:

- velocity control: the driver closes the loop at low level using the information from the encoder. The loop is closed with a very high frequency tracking the velocity set points encoded in a CAN packet. The guidance controller can generate packets with sampling period of 10ms without saturating the bandwidth of the CAN bus;
- torque/position control: the driver closes the loop receiving either current or position setpoint. The driver implements position control using the hall sensor, which are relative. Therefore an external loop is required to read the absolute sensors and carry out corrections as needed.

In the future, we plan to integrate an Inertial Measurement Unit (IMU), which is implemented using an Arm7 microcontroller, programmed directly by the FriWalk development team.

10.19 Gateway

The gateway node has two main roles:

- carrying messages back and forth between the CAN bus and the zeroMQ (over ethernet) bus used for the communication within the cognitive layer;
- implementing low level control algorithm for the control of the walker hardware (mechanics and electronic components).

The control of the low level functionalities is implemented by a C++ software consisting of several modules. Each module controls a different aspect of the hardware and is interfaced to the low level devices by means of a device controller. The different devices are:

- the mechatronic nodes (interfaced through a CAN bus)
- the grip sensors (connected to the gateway through an analog link)
- the power controller (connected through a digital IO link)

For the mechatronic nodes, the device controller consists of three components: a streamer, a monitor and a listener.

The streamer sends high priority messages and waits until an ACK is received. If an ACK is not received within a time-out, the message is re-transmitted.

The monitor periodically sends diagnostic messages (to find if the nodes are still alive). Such messages are *best effort* (i.e., no ACK is required for each of them).

The listener receives messages from the CAN, which can be of various nature. The ACK to the diagnostic messages are noted; if no ACK has been received for a long time the state of the node is marked as "possibly faulty" and specific control are taken (e.g., a high priority message is sent to verify if the node is actually faulty). Other messages have to do with the data generated by the mechatronic nodes, such as the number of ticks of the encoder or the readings of the IMU. The walker hardware manager wraps such messages into data packets (JSON) and transmits them to cognitive layer through the zeroMQ middleware. This middleware operates with a publisher/subscriber mechanism and the possible subscribers are within the cognitive layer.

An example subscriber is the localisation module, which subscribes to the encoder readings, to the IMU and to the landmark readings. The module implements an Extended Kalman Filter (EKF) [3] which fuses these different layers of information together to produce a localisation accuracy within tens of centimetres. Such data is propagated on to the zeroMQ bus; therefore the localisation module is both a consumer and a producer. The picture reflects the current implementation, in which the localisation module is deployed inside the gateway. However, the use of the middleware allows us to relocate the module to any of the computing nodes (e.g., NUC1 or NUC2) if required by the application.

The safety devices (safety lanyard, and safety bar to prevent the system from running backward over the user) are connected to a microcontroller. When an emergency situation occurs (lanyard stripped off, or safety bar pushed), the motors are immediately powered off. Moreover, a digital signal is generated for the gateway. The Walker Hardware Manager sends a shutdown messages to the NUCs through the zeroMQ bus. As soon as an ack is received, the gateway is powered off.

10.20 Sensing

A number of modules are used to sense the environment in the surroundings (e.g., to detect obstacles on the path), the user facial expression (e.g., to detect pain and stress), the user's skeleton reconstruction and the user's gait.

All these different components are written in C++ and are interfaced to the zeroMQ communication facility. As we said for the localisation module, the use of this abstraction layer allows us to relocate the modules to any computing unit. The current implementation is reflected in the figure, in which the most important sensing components are deployed onto a dedicated and Windows Operated core I7 NUC. This choice is determined by the need for computing power and by the sharing of common sources of information (the cameras). Other mapping options if a real convenience is found (e.g., for some versions of the walker, we could just need some of the modules use just a single NUC to reduce costs and power consumption.
An appropriate protocol has been specified to define the exact format of each JSON packets exchanged. A (non exhaustive) list of some of the most important packets are detailed in the following table.

Message	**Producer**	**Consumer**	**Usage**
User standup sitdown	Skeleton Reconstruction	Activity Execution Engine, GUI, Logger	SPPB test
Leg up/down	Skeleton Reconstruction	Activity Execution Engine, GUI, Logger	Orthogeriatric and Therapeutic Exercises
Step done	Gait analysis	Activity Execution Engine, GUI, Logger	SPPB Test, Orthogeriatric and Therapeutic Exercises
Obstacle Position	Environment Perception	Activity Execution Engine, Guidance Control	Any kind of activity that involves moving in human populated areas
Emotion	Emotion Perception	Activity Execution Engine, Logging	Any activity
Landmark detected	Landmark Detection	Activity Execution Engine, Localisation	Any activity that involves moving
Position	Localisation	Activity Execution, Guidance Control, Logging, GUI manager	Any activity that involves moving

The landmark detector senses the presence of QR or barcodes landmarks deployed in the environment at known position. Strictly speaking a sensing module, but for the sake of convenience in the current implementation it is deployed in a different NUC.

10.21 Supervision and Control

Supervision and control of the walker operations is implemented by a group of three modules:

1. Guidance control,
2. Activity Execution Engine,
3. GUI manager,

In addition an activity logger is used to store the relevant data into the database containing the user's profile.

10.21.1 Guidance Control

The guidance control module contains a set of c++ classes used to: 1. generate motion plan to reach a destination from a start point, 2. update the motion plan reactively based on the situation on the ground, 3. guide the user along the plan.
The motion plan is generated using algorithms that account for the dynamics of the vehicle, for the presence of static obstacles and for the user comfort. A comprehensive description of our motion planning solution can be found in a conference paper [5]. The motion planner is normally invoked at the beginning of a motion (other calls are possible in emergency situations).
The reactive planner utilises information on the presence of human obstacles along the way. For each human, it makes a prediction on the future possible positions using a derivative of the social force model [6] and computes the probability of a collision. If such a probability remains below a bound, the FriWalk stays on the course. Otherwise a modification of the plan is attempted that reduces the probability of collisions to an acceptable bounds. The reactive planning is executed periodically and is a subscriber of the localisation and environment detection modules.
The guidance algorithms properly said are used to follow the path and are of different type. Some of them use the rear brakes (see [4] for details), other use the front steering wheels, the haptic bracelets or combinations of haptics information and braking.The selection of which algorithm to use can made when the activity is specified, along with the selection of parameters to use. Parameters can also be fine tuned on the specific users using the GUI. Notably, each guide has an implicit virtual corridor, within which she/he is left free to move without any intervention of the guidance system. The width of this corridor is typically a configurable parameter.

10.21.2 Activity Execution Engine

The activity execution engine is a module that takes as input an activity, and orchestrates its execution managing possible exceptions or problems.
An activity is a collection of tasks (for instance the SPPB tests consists of a sequence of three tasks: balance tests, gait speed tests, chair stand test).
Tasks are executed sequentially (with the execution of a task subject to the successful completion of the one preceding it in the sequence). A task is modeled as a sequence of actions. Actions can be simple (e.g., "send the text … to the loudspeakers") or composite (e.g., "show instruction on screen" + "count repetition of an exercise"). An action is associated with a terminating event (e.g., "user presses ok on the tablet"). A composite actions is completed when either when all the events terminating the different actions have occurred (AND composition) or when any of the event terminating one action is completed

(OR composition). For any action, be it simple or composite, it is possible to identify asynchronous termination events, i.e., events associated to anomalies or faults (e.g., the user is experiencing pain and expresses her willingness to quit).
Simple actions are parametric. In particular it is possible to have input parameters, output parameters, and execution parameters. For instance a motion action can have as input parameters: initial location, desired target location. Output of the action could the actual final position. A possible execution parameter is the map of the environment.
Actions are also associated with a list of mutually exclusive resources that they use to accomplish their goal (e.g., the rear motors).
The programming technique used for the action management is based on template metaprogramming. Essentially, an action is a template class and its parameters are the parameters of the action, the termination events and the asynchronous termination events. By using this technique, a task is specified as an hard-coded sequence of actions which is interpreted by the compiler and generated. This allows us to do a number of checks during the compilation phase and generate a correct by construction code. The software is consequently relieved of the burden of such tests during its execution maintaining very high level of safety. A tiny sample of the possible tests that can be done in this way is in the following list:

- consistency of measurement units when connecting two actions (i.e., if an action produces metres and another action expects centimetres the compilation fails);
- two subsequent motion actions use the same map of the environment;
- when a composite actions is created, it never happens that two concurrent actions use the same exclusive resource;
- the events both for the correct termination of an action and for its asynchronous termination are correctly bound to an event generator, which creates events of compatible type.

10.21.3 GUI management

The GUI is based on web technology. In practice the GUI is a website that is accessible on an appropriate port. The front end is compounded of a set of JavaScript programs and of CSS files that allow to adapt the appearance of the interface to the terminal used (PC, tablet, smartphones). The contents of the GUI are generated dynamically by a set of Java programs that have access to the zeroMQ bus and maintain an updated representation of the state of the FriWalk. The access to the zeroMQ bus is bidirectional. Therefore, the GUI can also generate commands that the back end wraps into JSON packets transmitted over the zeroMQ link and received by the modules that need them (e.g., Activity Execution Engine, Guidance Control, etc.). Most of the modules expose a number of configurable parameters, which can be set using the JSON packets.
Different interfaces are available for three classes of users:

1. patients,
2. caregivers (doctors and physicians)
3. technicians.

Patients are the end users and receive both visual and audio messages for the execution of their activities. For navigation task, they can use a navigator interface showing their position on the map and the next turn to make; they also have shortcut buttons for tasks such as: “take me to the closest toilet”, or “take me back to my room”.
Caregivers have an interface to select the patient, the exercises programme, the duration of each exercise, etc. They also have a quick access to the result of a test, the trajectory followed, the duration etc. The most important data are logged on a database within the user’s profile (as a future development such data could be consolidated into the user’s mobility record).

Technicians have access to a number of configuration parameters for the walker and they can easily perform diagnostic activity (e.g., to see if the different devices are working properly, if the localisation produces correct results, etc). Such data are extremely useful during the development of the different features of the walker and during its maintenance.

10.21.4 Software Quality Control

Quality control for the software is enforced in five different ways:

1. The most important modules written in C++ (i.e., the Guidance Control, and the Activity Execution) are written using the metaprogramming approach described in Section 11.4.2. This technology allows us to solve many of the possible programming error during the compilation phase;
2. Unit testing: each delivered software component comes along with a number of test cases to identify the most common sources of bugs;
3. Integration Testing: all the operation scenarios have been extensively tested in realistic conditions, simulating a range of possible problems;
4. fault injection: some of the most dangerous scenarios in which one of the components goes offline (e.g., due to a power failure or to a battery exhaustion) have been simulated by turning off the component. This is possible because a software controlled relay is used to power up all the hardware units, thus enabling a selective power down of the the different computers. As a result of these checks, we have implemented a whole range of periodic diagnostic monitoring activity, such as an heart-beat signal exchanges between the different units to figure out that they are alive.
5. logging mode: each component of the control logic can be set to operated in logging mode and produce a number of logs that can be analysed post-mortem in case of run-time problems that were not discovered during the testing phase.

10.22 Manufacturing conditions

Identification of the required specific manufacturing conditions and how they have been ful- filled.

The device has to be mounted with proper care and constant quality checks have to be made on the following aspects. A checklist of the most important quality checks is as follows

- absence of rust on the gears
- precision of the mechanical couplings
- absence of defects and robustness of the plexiglass covers
- correct insulations of the cablings and soundness of the connections
- absence of sharp edges and corners of the cases.

The device has to pass a number of integration tests both on the hardware and on the software components.

To prevent biological hazard proper hygienic conditions have to be guaranteed during the mounting phases of the device.

10.23 Technical standards

Technical standards that have been totally or partially applied. In the latter case, description of the adopted solutions to fulfill the standards.

At the moment of the writing the FriWalk is a research prototype that has not yet reached a sufficient maturity level to require a formal compliance with any standard. In view of a possible commercial exploitation of the product the following standard turn out to be relevant:

- EN 12183 for manual wheelchairs
- EN 12184 for electric wheelchairs and scoot mobiles
- ISO 7176-series - the internationally accepted series of standards that describe the various testing methods wheelchairs and scoot mobiles
- IEC 60601-1: general safety for medical electrical devices
- EN 12182: technical aids for disabled persons.

The FriWalk development aims at satisfy all the requirements of the relevant standard, but since different changes could be required as a result of the user validation no formal steps toward securing compliance has been taken just yet. We foresee this as a necessary step in the event of a successful experimentation.

10.24 Instruction for use and product labeling

Except for the components specifically developed for the project (e.g., the cases and the electrical circuits) all the components we used are CE labeled.
The product has been developed with usability as our polar star. The re-charging procedure for the batteries is very simple and so is the procedure for turning on/off the device. All these procedures are documented in a 5 pages quick start guide.
The use of the different functionalities of the project requires the interaction with a graphical user interface executed in the robot's tablet. The different interfaces are self explanatory and have been developed with a close collaboration between doctors, physicians and developers. Every page of the interface proposes a multi-lingual help button. From the patient's perspective the different exercises are supported by a combination of vocal instructions and text instructions on the screen.

10.25 Current regulatory situation of the product

Information related to the current regulatory situation of the product.

The prototype used in the ACANTO experimentation has at the moment of the moment of this writing has reached the Technology Readiness Level (TRL) 4: technology validated in lab. The initial ambition of the project is to reach TRL 5: technology validated in relevant environment. The compliance with relevant standard is presumably required from TRL8: system complete and qualified, which means that the product is essentially market ready. The transition from a research prototype to a full fledged product requires some additional steps, the most important being a successful clinical validation and the definition of a clear route to the product's exploitation.

10.26 Bibliography

[1] Luigi Palopoli, et al.: "Navigation assistance and guidance of older adults across complex public spaces: the DALi approach". **Intelligent Service Robotics** 8(2): 77-92 (2015)
[2] Colombo, Alessio, et al. "Efficient customisable dynamic motion planning for assistive robots in complex human environments." **Journal of Ambient Intelligence and Smart Environments** 7.5 (2015): 617-633

[3] Nazemzadeh, P.; Moro, F.; Fontanelli, D.; Macii, D.; Palopoli, L., "Indoor Positioning of a Robotic Walking Assistant for Large Public Environments," in **Instrumentation and Measurement, IEEE Transactions on** , vol.64, no.11, pp.2965-2976, Nov. 2015
[4] Daniele Fontanelli et al., "A passive guidance system for a robotic walking assistant using brakes", **Proceeding of 54th Control Decision Conference**, Osaka, Japan, December, 2015
[5] Paolo Bevilacqua, Marco Frego, Enrico Bertolazzi, Daniele Fontanelli, Luigi Palopoli, Francesco Biral: "Path planning maximising human comfort for assistive robots". **CCA 2016:** 1421-1427
[6] Francesco Farina, Daniele Fontanelli, Andrea Garulli, Antonio Giannitrapani, Domenico Prattichizzo: "When Helbing meets Laumond: The Headed Social Force Model". **CDC 2016**: 3548-3553