Acronym:	vINCI
Name:	Clinically-validated INtegrated Support for Assistive Care and Lifestyle Improvement: the Human Link
Call:	AAL 2017 “AAL Packages / Integrated Solutions”
Contract nr:	AAL-2017-63-vINCI
Start date:	01 June 2018
Duration:	36 months

D4.4. Wellbeing and Smart Living Measurement Framework

Nature[1]: R

Dissemination level[2]: P

Due date: Month 12

Date of delivery: Month 12

Partners involved (leader in bold): ICI, **NIGG**, UNRF

Project Co-Funded by:

Project Partners:

[1] L = legal agreement, O = other, P = plan, PR = prototype, R = report, U = user scenario

[2] PU = Public, PP = Restricted to other programme participants (including the Commission Services), RE = Restricted to a group specified by the consortium (including the Commission Services), CO = Confidential, only for members of the consortium (including the Commission Services)

Partner list:

No.	Partner name	Short name	Org. type	Country
1	National Institute for Research and Development in Informatics	ICI	R&D	Romania
2	Marche Polytechnic University	MPU	R&D	Italy
3	University of Nicosia Research Foundation	UNRF	R&D	Cyprus
4	National Institute of Telecommunications	NIT	R&D	Poland
5	Connected Medical Devices	CMD	SME	Romania
6	Automa Srl	AUT	SME	Italy
7	Optima Molliter (former Salvatelli Srl)	SAL	SME	Italy
8	National Institute of Gerontology and Geriatrics "Ana Aslan"	NIGG	R&D	Romania
9	Comtrade Digital Services	CTR	Large enterprise	Slovenia

Revision History

Rev.	Date	Partner	Description	Name
1	26.05.2019	NIGG	Created the template, added the sections	Herghelegiu Anna Marie, Prada Gabriel Ioan, Draghici Rozeta
2	27.05.2019	NIGG	Added content at section 2.4.1 Pilot from Romania (NIGG Pilot)	Prada Gabriel Ioan, Draghici Rozeta
3	28.05.2019	NIGG, UNRF	Added content at section 2.4.2 Pilot from Cyprus (UNRF Pilot)	Costas S. Constantinou
4	26.06.2019	NIGG	Document finalized	Prada Gabriel Ioan, Herghelegiu Anna Marie, Draghici Rozeta, Rusu Alexandra

Table of Contents

1. Introduction

vINCI project proposes a novel approach for providing personalized assistance services for patients in an IoT-based ecosystem. In this context, challenges remain to develop technologies that meet the needs of older adults, accommodate their cognitive and perceptual declines, capitalize on their intact abilities, support them in performing everyday activities, and protect their privacy, independence and security. One of the challenges to the effective design of such technologies is the understanding of the conceptual model of the elderly. Traditional IT models are not sufficient to meet user requirements, in particular for elderly users but the vINCI technology could offer a feasible opportunity for seniors to independently evaluate their quality of life and health status and receive a direct feedback which would enable them to take appropriate measures to improve their health status and prevent future negative events.

For vINCI care, the patient profile will be the input to provide personalized support for daily /medical activities. The profile will be used as evidence to evaluate the impact of vINCI on the perceived Quality of Life (QoL) level, allowing a proper adjustment (if needed) of the intervention support provided by caregivers.

2. The vINCI Pilot Study

2.1 Concept

The vINCI modular technology comprises of different devices such as intelligent tablet (IT), smart insole (SI), smart watch (SW) and smart indepth camera (SC). Some people, especially seniors, might not be familiar with these devices. Many elderlies suffer from sensory deficits, mood disorders, neurocognitive disorders or various chronic conditions that might limit their movements. All of these factors have to be taken into account, therefore, the vINCI technology will be developed based on users' acceptability, preferences and suggestions collected during multiple stages of testing. To validate the vINCI technological construction for use in older people we will test the vINCI technology in clinical setting after the acceptability study is completed.

The vINCI Pilot Study has 2 parts: an acceptability and further development series of tests and the validation study.

2.2 Objectives

The main objectives of the Pilot Study are:

- assess acceptability and adapt the vINCI technology to the users' feedback and preferences
- identify user's socio-cultural and health related/medical profile
- field test and assess feasibility of the vINCI technology in clinical setting

As a secondary objective, we will be able to determine the level of computer literacy among seniors aged 65 and older as a preliminary analysis for a potential future research project on feasibility of vINCI technology in different target groups.

2.3 Testing Strategy

vINCI technology is aimed at older adults aged 65+. In order to increase the acceptance rate, the main benefits of the technology will be presented to each study subject. For this purpose, a written presentation of the protocol, in a language accessible to older people, will be given to each subject.

Validation technology will be performed in clinical settings, as follows: one pilot will run in Romania (NIGG Pilot) that will include 60 older adults (30 persons for test group and 30 persons for control group) and another one in Cyprus (UNRF Pilot) that will include 20 older adults. In order to maximise efficiency, clinical testing will take place in Romania, while Cyprus will focus on piloting the impact of technology on quality of life. Therefore, only the Romanian pilot will undergo a clinical testing, the other pilot being used for a technological testing. The group in Cyprus will contribute to the technical validation of the vINCI platform.

Before entering the Pilot Study, a total 140 patients will be screened using Recruitment Form and Digital Skills Questionnaire.

2.4 Description of pilots

2.4.1 Pilot from Romania (NIGG Pilot)

The Pilot Study will be performed on 60 persons 65 years of age and older, 30 for control group and 30 for test group.

All consecutive patients 65 years of age and older admitted to NIGG - Geriatrics and Gerontology Inpatients Department on referral from general practitioners or other specialist for various chronic or subacute conditions will be considered for inclusion in the Pilot Study and then evaluated against exclusion criteria. In the first 3 days of hospital admittance all patients will be screened for study inclusion against inclusion and exclusion criteria and for computer digital skills until the sample target number is reached for each part of the Pilot Study.

All potential participants will fill in a Digital Skills Questionnaire (DSQ) to evaluate their computer and technological literacy. Seniors who will score low on the DSQ will be excluded from inclusion in the study group.

Prior to study initialization, all seniors will sign the Informed Consent form. The persons who do not sign the Informed Consent will be excluded.

Exclusion criteria will be documented by medical examination, anamnesis and from patients' medical charts and documented medical history.

If person gives informed consent, person is included in study and continue with **Compliance Form.**

If person does not fully complete baseline questionnaires, person is excluded from study.

If person does not fully comply with vINCI instructions or does not appropriately use vINCI items, person is excluded from study.

The acceptability study and the validation study herein named "The vINCI Pilot Study" will take place at Geriatrics and Gerontology Inpatients Department of the National Institute of Gerontology and Geriatrics "Ana Aslan" (NIGG) Bucharest over a period of 18 months, from July 2019 to December 2020.

See Appendix 1 (Recruitment Form).

2.4.2 Pilot from Cyprus (UNRF Pilot)

Potential participants who stay in nursing homes or attend day centres will be invited to participate in the pilot in Cyprus. On this note and because the numbers are small, participants will be selected on the basis of convenient and random sampling. Sampling will be convenient because participants will be available at nursing homes or day centres. Potential participants who meet the following criteria: older than 65, if they meet the exclusion criteria as described earlier. 20 participants will be selected to participate in the pilot acceptability study in Cyprus. The procedure in Cyprus is the same as in Romania.

2.5 Data collection

The quality of life questionnaire will be the language version of the World Health Organization Quality of Life Instrument, Short Form (WHOQOL-BREF) [1,2]. We have a legal agreement between us and World Health Organization, granting us a licence to use the Licensed Materials subject to their terms and conditions. World Health Organization grants this licence to us based on the representation and warranties we made in the licence request we submitted through World Health Organization's online

platform. We received from them all three versions that we requested for WHOQOL-BREF: Romanian, Slovenian and Cypriot versions.

The physical activity level subjective evaluation will be performed with the International Physical Activity Questionnaire (IPAQ). IPAQ underwent a translation and cultural adaptation process for Romanian users taking into consideration the principle of conceptual equivalence, metric equivalence and linguistic equivalence [3,4]. Culturally relevant activities were identified and used as examples for applicable questionnaire items while the intensity of the physical activities (light, moderate, and vigorous) were retained [4]. The IPAQ questionnaire went through a back to back translation procedure and pilot testing. Examples of physical activities complied with the Compendium of Physical Activities where vigorous intensity activities are ≥ 6 METs and moderate intensity activities are 3-5.9 METs [5].

For all participants the following data will be collected at baseline:

- identification data: first name and surname, study type and number, contact details, department and room number, group allocation for the validation study
- socio-cultural data: date of birth, gender, formal education level (primary school, high school, college or university), living area (rural/urban), living arrangements (alone/with someone/nursing home), income (under or above medium monthly state pension)
- medical data: all documented diagnoses (documented medical history and new diagnoses during hospitalization)*
- presence of digital skills (DSQ)
- quality of life (WHOQOL-BREF)*
- physical activity level (IPAQ)*

Data marked with * will be recorded only for the validation study.

All participants in the acceptability study will receive a semi structured acceptability questionnaire adapted for each vINCI device and also an overall vINCI technology feedback questionnaire for self-completion. All acceptability and users feedback data will be recorded.

For all participants in the validation study the following data will be collected at follow-up:

- quality of life (WHOQOL-BREF)
- physical activity level (IPAQ)

Reasons for study attrition will also be recorded: death, worsening of health status during hospitalization, withdrawal of informed consent or misuse of any of the vINCI technological items.

3. Acceptability and technological revision study

The acceptability and technical revision and construction study will take place over a period of 12 months from July 2019 to June 2020. The vINCI technology has a modular construction therefore the acceptability of each device will be assessed and further technological adaptation and modification will be performed based on users' feedback in a step by step manner. After each device has completed the full development process, the acceptability of the entire vINCI technology will be assessed on a number of 10 senior users at the National Institute of Gerontology and Geriatrics "Ana Aslan", Bucharest and another 20 at the University of Nicosia Research Foundation. At this stage further modification and revision of the vINCI technology will be performed in collaboration with the technological partners and the medical and social teams.

To ensure that the vINCI smart devices are developed based on feedback received from culturally diverse users, the acceptability study will include a total number of 80 senior users in Romanian and Cypriot samples. The vINCI devices will be tested for acceptability on a number of 20 senior users each. Each vINCI device will be tested by 5 users at the NIGG and 15 at the University of Nicosia Research Foundation. To ensure consistency throughout the acceptability study and to coordinate with the validation study, the smart watch, smart shoes and smart in depth camera will be used by each participant for a period of 7 days. After this period, users will receive an acceptability questionnaire adapted for each vINCI device. These questionnaires will be constructed specifically for each device in a semi-structured model.

To avoid biased feedback and outcome due to previous usage of vINCI devices, different samples of seniors will be selected for each stage of the vINCI testing and validation. The users in each separate and consecutive SW, SS and SC test samples respectively, will be recruited over a period of 4 weeks. Each subject will wear the smart watch for 7 days and then will fill in the semi-structured acceptability questionnaire. Technological adaptation and revision of each smart device will take place during the following period and will be performed based on users' feedback and in close collaboration with the medical and social teams. There will be 2 distinctive test stages for each vINCI device and one for the entire vINCI instrument.

The users of the entire vINCI instrument will be recruited over a period of 8 weeks and each senior will use vINCI for 7 days. After 7 days they will receive the semi-structured acceptability questionnaire. This test will be followed by the final technical revision and adaptation performed based on users' feedback and in collaboration with the medical and social teams.

The Acceptability Questionnaires will address aspects related to usage of each particular vINCI devices in several questions with 5 options for answers and one or two open ended questions that will provide the user the opportunity to offer his/her own suggestions. The structured questions will enquire about how disagree/agree

with understanding how to use the device, how comfortable it was to wear the device, how useful the vINCI instrument is, etc. The options for each answer will be constructed on 5 levels of agreeing.

See Appendix 2 (Acceptability Questionnaires).

See Appendix 3 (Acceptability Study: Flow-Chart).

4. Acceptability and technological revision study

The Clinical Validation Study will take place at the National Institute of Gerontology and Geriatrics "Ana Aslan", Bucharest over a period of 6 months from August 2020 to December 2020. Statistical analysis and results discussion and interpretation along with formulation of the study conclusions will take place from January to March 2021 and will involve all consortium partners.

Eligible and selected participants in the study group will receive the vINCI technological items for testing for a period of 7 days (one week) while participants in the control group will receive usual care. Even though participants will self-complete the evaluation questionnaire, to ensure collection of unbiased data, two different investigators will monitor and assist the study and control group.

In the 3rd or 4th day of hospitalization patients in study group will begin testing of vINCI technology. No more than one patient per day will begin the testing process. Baseline assessment will take place in the course of one single day. Participants will receive the Informed Consent form for signing. Patients who sign the Informed Consent form will then receive instructions, clarifications and description on how to use the vINCI technological items: the tablet, the smart watch and the smart shoes. Participants will turn on and off, use, test the tablet and fill in the questionnaires and evaluation items on their own while help and assistance from the investigator will be readily available. Participants will receive the smart watch and smart shoes and instruction to wear them for a period of 7 days during hospitalization. After 7 days, participants in the study group will hand over the smart watch and smart shoes to the investigator, will use the tablet for self-completion of the questionnaires and evaluation items and will fill in the User Feedback questionnaire.

During the 3rd or 4th day of hospitalization, participants in the control group will receive the Informed Consent form for signing, the Quality of Life (QoL) and Physical Activity (PA) questionnaires in printed form for self-completion while assistance from the investigator will be readily available. Participants in the control group will receive the QoL and PA questionnaires results at baseline without any specific recommendation. After 7 days, participants in the control group will receive the same

Quality of Life and Physical Activity questionnaires for self-completion. To ensure compliance with ethical guidelines, at the end of the 7 days vINCI technology testing, the control subjects will be offered the same recommendations based on the assessment feedback as study subjects.

Selected participants will be alternatively included in the study and control group of the validation stage in equal numbers and matched for age, sex and living area (rural or urban).

See Appendix 4 (vINCI Validation Study: Flow-Chart).

5. vINCI feedback algorithm (tablet)

5.1 QoL scoring

The WHO QoL instrument is comprised of 4 domains [4] as follows:

1. Physical health Activities of daily living:

Dependence on medicinal substances and medical aids; Energy and fatigue; Mobility; Pain and discomfort; Sleep and rest; Work Capacity

2. Psychological Bodily image and appearance:

Negative feelings; Positive feelings; Self-esteem; Spirituality/ Religion/ Personal beliefs; Thinking, learning, memory and concentration

3. Social relationships Personal relationships:

Social support; Sexual activity

4. Environment Financial resources:

Freedom, physical safety and security; Health and social care: accessibility and quality; Home environment; Opportunities for acquiring new information and skills; Participation in and opportunities for recreation / leisure activities; Physical environment (pollution/ noise/ traffic/ climate); Transport.

To control for item order effects which could occur and change item meaning. The WHOQOL-BREF represents an agreed upon core set of international items. The four domain scores denote an individual's perception of quality of life in each particular domain. Domain scores are scaled in a positive direction (i.e. higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score. Where more than 20% of data is missing from an assessment, the assessment should be discarded [1,2].

There are 26 questions on the WHOQOL-BREF, each scored from 1-5, comprising 4 domains. The domain scores are not averages, they are the sum total score for each question within the domain. Multiplying the mean by 4 is used to transform the WHOQOL-BREF scores into the longer form WHOQOL-100. This is done in circumstances where researchers who use the WHOQOL-BREF want to easily compare their data. There are 3 questions negatively phrased and so are reversed scored when calculating the domain scores - a score of 5 becomes a 1 and vice versa, a score of 4 becomes a two and vice versa etc. This is performed on questions 3, 4, and 26. Correcting the reverse coded questions has to be done before calculating any domain scores [2].

This is an example of how the scores are calculated:

1. first calculate the raw score for the domain by summing all the values within the domain together (and accounting for any reverse coded items)

2. calculate the mean response for that domain

3. multiply the mean value by 4

4. subtract 4 from the result of previous step

5. apply the formula for conversion into percentiles.

For example, we have a Physical Health Domain raw score of 28 (step 1).

Step 2. That domain has 7 items, and so the mean response is 4.

Step 3. 4*4 = 16

Step 4. 16-4 = 12

Step 5. 12 * (100/16) = 75.

There are no set guidelines from the WHO about cut-off scores for identifying low/moderate/high categories on the domains. In order to achieve vINCI project's objectives we have to manage the WHO QoL scoring in such a way that would allow not only to identify specific domains and overall levels of quality of life for feedback construction but also to identify changes over time. There are no WHO QoL studies on samples of Romanian participants therefore we do not have comparable data bases for data analysis. The following values of scores were extracted from studies on different samples: score ≤ 45, low QOL; score 46 to 65, moderate QOL; and score > 65, relatively high QoL [6,7] and an QoL ≥ 60 cut-off point moderately sensitive for recognizing individuals with good/satisfactory QoL and a <60 cut-off optimum negative predictive value for screening older adults whose QoL was poor/unsatisfactory [8]. In our study we use the cut-off point of 60 points to formulate the feedback and recommendations for the user. A total score of at least 60 points identifies seniors with a good QoL and a score below 60 points signals impaired QoL. There is no information on scoring of individual domains of the WHOQOL-BREF nor

about their contribution and to the overall score in the literature. We propose to use the same 60th percentile for discrimination between satisfactory and unsatisfactory levels of QoL domains.

5.2 IPAQ scoring

IPAQ assesses physical activity undertaken across a comprehensive set of domains including:

a. leisure time physical activity

b. domestic and gardening (yard) activities

c. work-related physical activity

d. transport-related physical activity;

The IPAQ short form asks about three specific types of activity undertaken in the four domains introduced above. The specific types of activity that are assessed are walking, moderate-intensity activities and vigorous-intensity activities. The items in the short IPAQ form were structured to provide separate scores on walking, moderate-intensity and vigorous-intensity activity. Computation of the total score for the short form requires summation of the duration (in minutes) and frequency (days) of walking, moderate-intensity and vigorous-intensity activities. Domain specific estimates cannot be estimated.

For feedback and specific recommendations the following categories are used:

Category 1 Low

This is the lowest level of physical activity. Those individuals who not meet criteria for Categories 2 or 3 are considered to have a 'low' physical activity level.

Category 2 Moderate

The pattern of activity to be classified as 'moderate' is either of the following criteria:

a) 3 or more days of vigorous-intensity activity of at least 20 minutes per day

OR

b) 5 or more days of moderate-intensity activity and/or walking of at least 30 minutes per day

OR

c) 5 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum Total physical activity of at least 600 MET-minutes/week.

Individuals meeting at least one of the above criteria would be defined as accumulating a minimum level of activity and therefore be classified as 'moderate'.

Category 3 High

A separate category labelled 'high' can be computed to describe higher levels of participation.

The two criteria for classification as 'high' are:

a) vigorous-intensity activity on at least 3 days achieving a minimum Total physical activity of at least 1500 MET-minutes/week

OR

b) 7 or more days of any combination of walking, moderate-intensity or vigorous-intensity activities achieving a minimum Total physical activity of at least 3000 MET-minutes/week.

The IPAQ sitting question is an additional indicator variable of time spent in sedentary activity and is not included as part of any summary score of physical activity. Data on sitting will be reported as median values. To-date there are few data on sedentary (sitting) behaviours and no well-accepted thresholds for data presented as categorical levels.

The subjective PA levels depicted with the IPAQ instrument will be corroborated with the objective data on PA, number of steps per day monitored with the smart watch and smart shoes respectively and time spent sitting per day monitored with the smart cam. All objective measurements of PA will be integrated into the smart tablet software.

5.3 Recommendations algorithm

WHOQOL-BREF score ≥ 60: "Congratulations! The answers you provided to the test questions mean that your overall quality of life at the time you took this test was satisfactory!"

WHOQOL-BREF score < 60 + Physical health Activities of daily living score < 60th percentile: "The answers you provided to the test questions mean that your overall quality of life at the time you took this test was unsatisfactory. The most probable reason for this is that your physical health status is impaired. You are advised to contact your GP and discuss and address the issues related to your physical health."

WHOQOL-BREF score < 60 + Psychological Bodily image and appearance < 60th percentile:

"The answers you provided to the test questions mean that your overall quality of life at the time you took this test was unsatisfactory. The most probable reason for this is

that your psychological health status is impaired. You are advised to contact a psychologist and discuss and address the issues related to your emotional health. You are advised to take the physical activity test, follow the recommendations and retake this test after one week."

WHOQOL-BREF score < 60 + Social relationships Personal relationships < 60th percentile:

"The answers you provided to the test questions mean that your overall quality of life at the time you took this test was unsatisfactory. The most probable reason for this is that your social and personal relationships are disappointing. You are advised to contact a psychologist and discuss ways to improve your social and personal life. You are advised to take the physical activity test, follow the recommendations and retake this test after one week."

WHOQOL-BREF score < 60 + Environment Financial resources < 60th percentile:

"The answers you provided to the test questions mean that your overall quality of life at the time you took this test was unsatisfactory. The most probable reason for this is that environmental and financial factors are inadequate for you. You are advised to contact your local administration office and discuss ways to improve your situation and ways you can receive the necessary support."

Older adults should do at least 150 minutes of moderate-intensity aerobic physical activity throughout the week or do at least 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity.

Older persons should build up to at least 30 minutes of aerobic exercise daily [9,10]. For additional health benefits, older adults should increase their moderate-intensity aerobic physical activity to 300 minutes per week, or engage in 150 minutes of vigorous-intensity aerobic physical activity per week, or an equivalent combination of moderate-and vigorous-intensity activity [9,11]. Examples of aerobic exercise: moderate intensity: - brisk walking, swimming, dancing, cycling at normal speed; vigorous intensity: - jogging, cycling at high speed [12]. Muscle-strengthening activities, involving major muscle groups, should be done on 2 or more days a week. Strength training 2 to 3 days a week, with a day of rest between workouts, is recommended to maintain bone and muscle strength [9,12]. Patients undertaking a new exercise programme should be advised to seek medical advice if they have new or worsening exercise-related symptoms such as breathlessness or joint pains. When older adults cannot do the recommended amounts of physical activity due to health

conditions, they should be as physically active as their abilities and conditions allow and should be enrolled in specific individualized physical activities programmes.

IPAQ Category High: “Congratulations! Your physical activity levels are good, keep being active!”

IPAQ Category Moderate:” Your physical activity level could be improved. You are advised to spend more time being active and doing your favourite activities in the garden, cycling, swimming, dancing or brisk walking. You are advised to gradually spend up to at least 30 minutes daily brisk walking or cycling or swimming and perform resistance training exercises at least 3 days per week. You are advised to contact your GP and discuss your health status and specific physical activities recommended for you.”

IPAQ Category Low:” You are not active enough. Sedentary lifestyle and suboptimal physical activity levels are risk factors for many diseases such as heart problems, diabetes, memory loss, bone and joints weakness, sleep disorders. You are advised to gradually spend up to at least 30 minutes daily brisk walking or cycling or swimming and perform resistance training exercises at least 3 days per week. You are advised to contact your GP and discuss your health problems that might prevent you from being physically active.”

All procedures and experimental protocols are in compliance with the European Communities Council Directive of 24 November 1986 (86/609/EEC) and research involving human subjects complies with the Declaration of Helsinki.

References

1. The WHOQOL group. Development of the WHO-QOL BREF quality of life assessment. Psychological Medicine, 1998, 28:551–558.

2. WHOQOL User manual. Geneva, World Health Organization,1998.

3. Geisinger KF. Cross-cultural normative assessment: Translation and adaptation issues influencing the normative interpretation of assessment instruments. Psychological Assessment 1994, 6, 304-312.

4. Sperber AD, Devellis RF, Boehlecke B. Cross-cultural translation: Methodology and validation. Journal of Cross-Cultural Psychology 1994, 25, 501-524.

5. Ainsworth BE, Haskell WL, Herrmann SD et al. 2011 Compendium of Physical Activities: a second update of codes and MET values. Med Sci Sports Exerc. 2011 Aug;43(8):1575-81.

6. Bani-Issa W. Evaluation of the health-related quality of life of Emirati people with diabetes: integration of sociodemographic and disease-related variables. Eastern Mediterranean Health J, 2011, 17(11):825- 830.

7. Fatma Ibrahim Abd El Latif et al. Physical and psychological health domains of quality of life in type 2 diabetic patients in relation to clinical factors of diabetes mellitus in Egypt. Int Res J Med Med Sci, 2016, Vol. 4(1), pp. 7-16.

8. Barbosa Silva PA. et al. Cut-off point for WHOQOLbref as a measure of quality of life of older adults. Rev Saúde Pública 2014;48(3):390-7.

9. Global recommendations on physical activity for health. World Health Organization 2010 http://www.who.int/dietphysicalactivity/pa/en/index.html.

10. Guidelines on Physical Activity for Older People (aged 65 years and over). Wellington: Ministry of Health 2013 www.health.govt.nz

11. Seguin RA, Epping JN, Bloch R, Nelson ME. Growing Stronger: Strength Training for Older Adults. Tufts University 2002.

12. Canadian Physical Activity Guidelines for Older Adults 65 years and older. Canadian Society for Exercise Physiology 2011.

Appendix 1 Recruitment Form

Recruitment form

Please complete one form for each consecutively admitted person aged 65 years and older

Date of recruitment (DD/MM/YY)	
Study Number	
Study Group	
First name	
Surname	
Date of birth (DD/MM/YY)	
Gender	☐ 1 female ☐ 2 male
DSQ score	

Please check for the following exclusion criteria in the order listed. If one of the answers is "Yes", stop with checking the criteria and exclude the patient.

No check done for logistical reason (no capacity for recruitment of patients) *it is planned that this will not occur, but if it occurs it should be recorded*	☐ 1 Yes	☐ 2 No
Acute medical condition	☐ 1 Yes	☐ 2 No
Surgery in the last 3 months	☐ 1 Yes	☐ 2 No
Neurocognitive disorder (Montreal Cognitive Assessment MoCA <26)	☐ 1 Yes	☐ 2 No
Depression or anxiety (Geriatric Depression Scale GDS ≥5)	☐ 1 Yes	☐ 2 No
Heart failure functional class NYHA III-IV	☐ 1 Yes	☐ 2 No
Acute ischaemic heart disease	☐ 1 Yes	☐ 2 No
Has disability Needs human help in one or more basic activities of daily living	☐ 1 Yes	☐ 2 No
Angina pectoris	☐ 1 Yes	☐ 2 No
Uncontrolled high blood pressure (>160 mmHg systolic)	☐ 1 Yes	☐ 2 No

Heart arrhythmias	☐ 1 Yes	☐ 2 No
Peripheral arterial disease	☐ 1 Yes	☐ 2 No
Vertigo	☐ 1 Yes	☐ 2 No
Risk of falls (Tinetti Tool Score < 24)	☐ 1 Yes	☐ 2 No
Frailty syndrome (PRISMA 7 ≥ 3 “yes” answers)	☐ 1 Yes	☐ 2 No
Catchment area (Bucharest)	☐ 1 Yes	☐ 2 No
Terminal illness	☐ 1 Yes	☐ 2 No
Any condition that might limit mobility	☐ 1 Yes	☐ 2 No
Visual impairment	☐ 1 Yes	☐ 2 No
Low DSQ score	☐ 1 Yes	☐ 2 No

If all items are answered with NO, continue with informed consent

Person unwilling to give informed consent.	☐ 1 Yes	☐ 2 No

If person gives informed consent, person is included in study.

Person included in study, continue with WHOQOL-BREF and IPAQ baseline questionnaires in printed form for controls. Person included in study, continue with vINCI testing for study group.

Inability or unwillingness to fully complete any of the baseline questionnaire	☐ 1 Yes	☐ 2 No

If person does not fully completes baseline questionnaires, person is excluded from study.

Inability or unwillingness to fully comply with vINCI instructions or does not appropriately use vINCI items	☐ 1 Yes	☐ 2 No
	describe reason	

If person does not fully comply with vINCI instructions or does not appropriately use vINCI items, person is excluded from study.

Appendix 2 Acceptability Questionnaires

vINCI pilot study

Acceptability questionnaires

Introduction

This questionnaire has been constructed in order to collect feedback from vINCI technology users during a pilot study in Romania and Cyprus. Please fill in this questionnaire after you use each vINCI device for 7 days.

Smart watch

1. The instructions on how to use the smart watch were clear.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

2. I felt that smart watch was comfortable on my wrist during wearing it for 7 days.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

3. The smart watch was easy to use during wearing it for 7 days.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

4. The smart watch was useful during wearing it for 7 days.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

5. Considering everything, how would you rate the smart watch?

1	2	3	4	5
Very poor	Poor	Neither poor nor good	Good	Excellent

6. Considering your experience with the smart watch during the last 7 days, what has worked well with the use of this device?

7. Considering your experience with the smart watch during the last 7 days, what suggestions do you have to improve this device?

Smart shoes

1. The instructions on how to use the smart shoes were clear.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

2. I felt that smart shoes were comfortable on my feet during wearing them for 7 days.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

3. The smart shoes were easy to use during wearing them for 7 days.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

4. The smart shoes were useful during wearing them for 7 days.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

5. Considering everything, how would you rate the smart shoes?

1	2	3	4	5
Very poor	Poor	Neither poor nor good	Good	Excellent

6. Considering your experience with the smart shoes during the last 7 days, what has worked well with the use of this device?

7. Considering your experience with the smart shoes during the last 7 days, what suggestions do you have to improve this device?

Smart in-depth sensors (camera)

1. The instructions on how to use the smart camera were clear.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

2. I felt that smart camera was installed in a convenient area during using it for 7 days.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

3. The smart camera was easy to use during the last 7 days.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

4. The smart camera was useful during the last 7 days.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

5. Considering everything, how would you rate the smart camera?

1	2	3	4	5
Very poor	Poor	Neither poor nor good	Good	Excellent

6. Considering your experience with the smart camera during the last 7 days, what has worked well with the use of this device?

7. Considering your experience with the smart camera during the last 7 days, what suggestions do you have to improve this device?

vINCI technology

Considering all vINCI devices and the tablet (questionnaires, feedback), please answer the following statements/ questions:

1. The instructions on how to use the vINCI technology were clear.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

2. The vINCI technology was easy to use during the last for 7 days.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

3. The vINCI technology was useful during the last 7 days.

1	2	3	4	5
Definitely disagree	Mostly disagree	Neither agree nor disagree	Mostly agree	Definitely agree

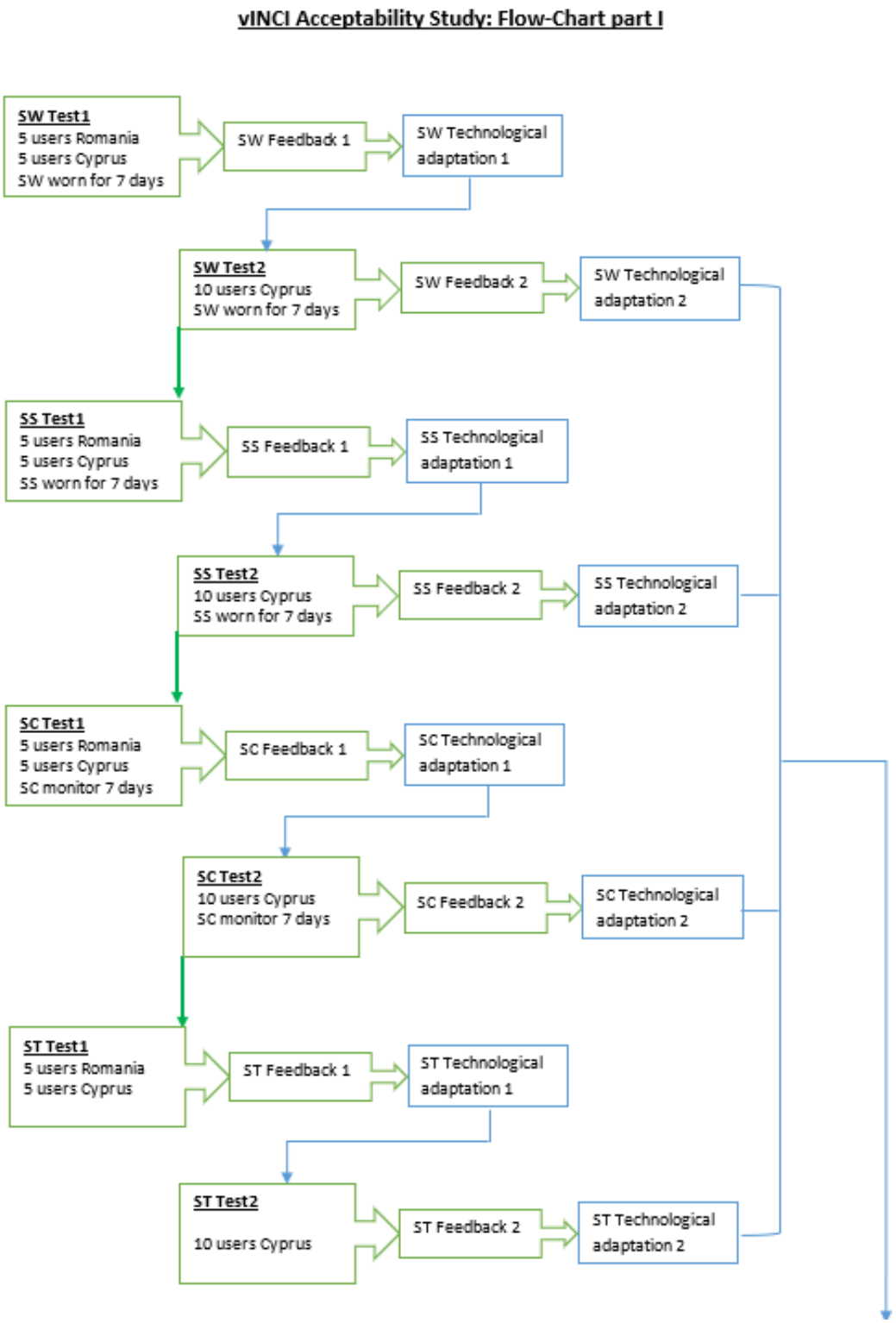
4. Considering everything, how would you rate the vINCI technology?

1	2	3	4	5
Very poor	Poor	Neither poor nor good	Good	Excellent

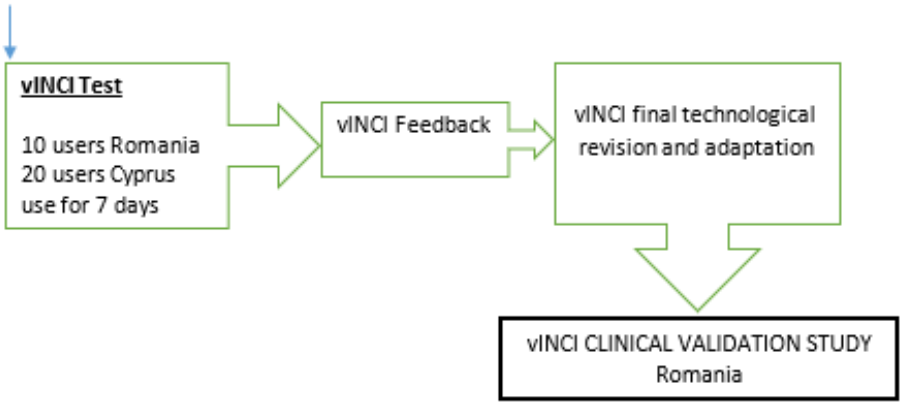
5. Considering your experience with the vINCI technology during the last 7 days, what has worked well?

6. Considering your experience with the vINCI technology during the last 7 days, what suggestions do you have to improve this technology?

Appendix 3 Acceptability Study: Flow-Chart

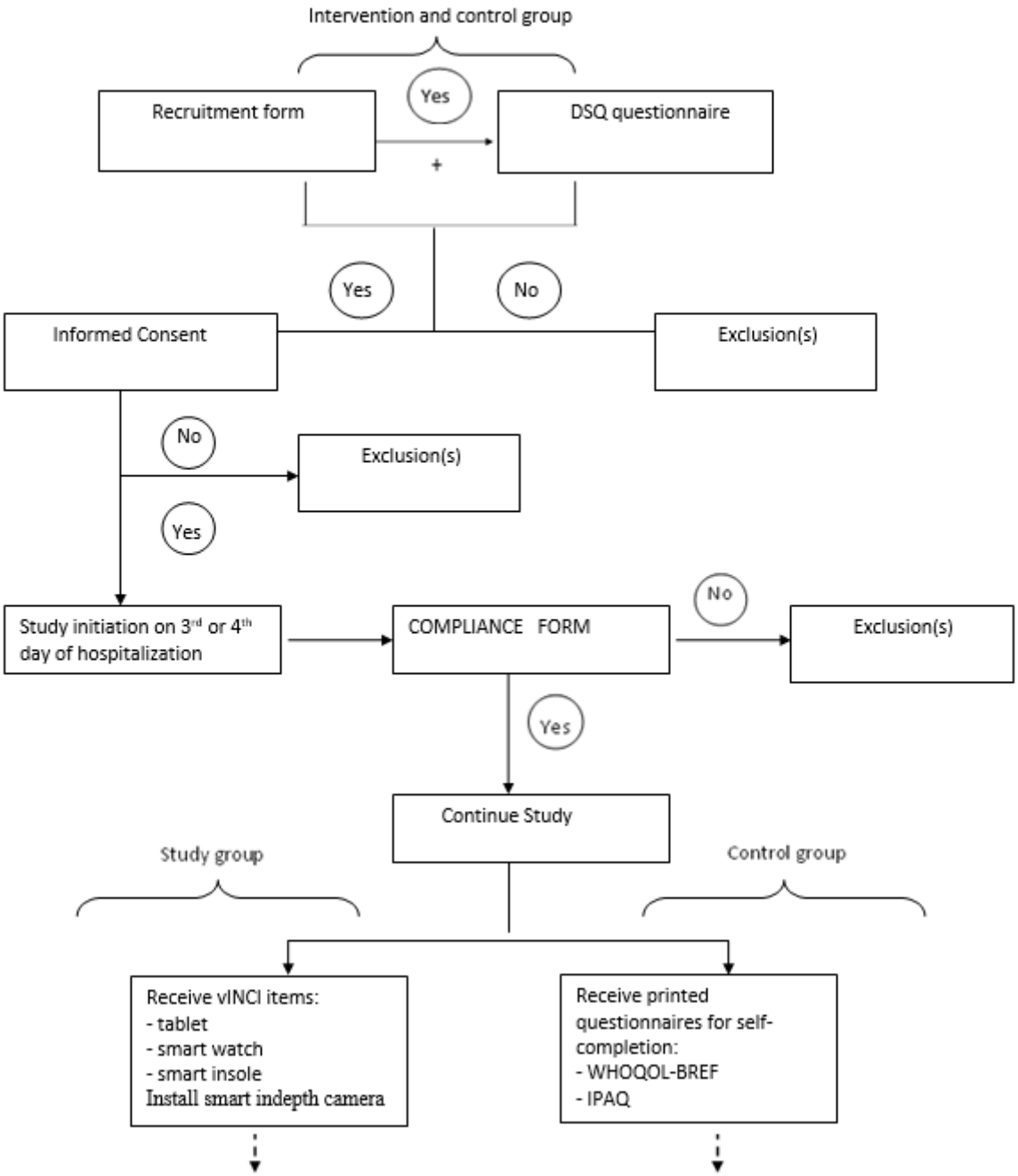


vINCI Acceptability Study: Flow-Chart part II



Appendix 4 vINCI Validation Study: Flow-Chart

vINCI Validation Study in Romania: Flow-Chart part I



vINCI Study in Romania: Flow-Chart part II