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

¹² 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) Services)

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1.Introduction

vINCI project proposes a novel approach for providing personalized assistance services for patients in an IoT-based ecosystem. In this context, the 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.

The objective of this deliverable is to provide a description of the environment in which vINCI will be implemented and the behaviours / biomarkers to be monitored.

It will also present the recruitment methodology, how to select individuals to be participant of the pilots, as well as members of a control group.

In this document, a first study will be conducted on the participants (habits, cognitive status, biomarkers, etc.). The vINCI kits will be deployed in a real environment. A set of landmarks will be designed to re-test the performance and robustness of vINCI sets.

2.Use-case description

Following the patient monitoring and technology analysis, the following have been defined.

On an active screen tablet, seniors will be able to self-complete a questionnaire that assesses their QoL across multiple domains. The scoring algorithm will generate a direct feedback that will be visually displayed on the tablet's screen. If the senior's quality of life is optimal the received feedback will read: "Congratulations! Your quality of life is very good! You can take this test again after 6 months or any time your health status changes".

If their quality of life scores below the optimal level, evaluation of their psychological well-being and subjective and objective assessment of their physical activity level will be offered in a stepwise process.

Because mood disorders and also the user's mood at the time of completion can influence the QoL score, the next step will be the evaluation of psychological well-being. When the QoL and the psychological assessment results are sub-optimal, the user will be invited to further proceed with assessment of physical activity.

Specific parameters and assessment instruments have been documented and agreed.

The WHOQOL-BREF questionnaire of the World Health Organization is proposed to be used for the QoL measurement of older people [1].

The Dynamic Visual Analogue Mood Scales (D-VAMS) is proposed for psychiatric research of older people as brief measures of subjective distress (e.g. dysphoria, pain) [2].

The physical activity level will be subjectively evaluated with the International Physical Activity Questionnaire (IPAQ) [3].

The evaluation of the impact of technology on QoL will be carried out after the clinical validation is completed. The WHOQOL-Bref, the DVAMS mood scale and the IPAQ physical exercise questionnaires will be completed by participants before using the technology. Following the use of technology for a period of six months, the three above mentioned questionnaires will be completed again in order to identify any changes in the scores which can be linked with the use of technology.

The way to interpret the data entered by the patient will be established by clinical partners in the project. It's important that the entries make little use of visual texts, and we intend to use graphical items like smileys to map psychological data into the questionnaires.

After that, the patient will wear the CMD One smartwatch and the smart shoes. Within the house, the patient is being monitored by depth and stereo cameras. First, we start with algorithm to track the person while in-house, to monitor the activity level. Next, we aim to extend this research towards detecting also frailty problems, by asking the person to perform certain exercises and measuring mobility in arms and/or legs. Periodically, the person is also asked to fill in the D-VAMS and IPAQ questionnaires, to get his sense of activity/social levels.

The cameras, watch, shoes, questionnaires, all these elements serve to get data related to the patient.

2.1 The environment of each pilot in which VINCI will be implemented and the behaviours to be monitored

In **Romania**, to validate the vINCI technological construction for use with older people we will test the vINCI technology in clinical setting. The testing, herein named "The Pilot Study" will take place at the Geriatrics Clinical Ward of the National Institute of Gerontology and Geriatrics "Ana Aslan" (NIGG) Bucharest over a period of 4 months, from July to October 2019.

The main objectives of the Pilot Study are:

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

In **Cyprus**, potential participants will initially be evaluated on the basis of perceived Quality of Life (QoL). Those participants who will not reach the optimal level of Quality of Life (QoL) will be further evaluated on the basis of four sources, namely questionnaires, smart watch, smart shoes and depth cameras. The questionnaires (WHOQOL-Bref, IPAQ and DVAMS) will be filled in on tablets and will provide information about participants' perceived QoL, activity and mood. The remaining sources will generate information about actual activity, frequency, and quality of activity. Based on data from all these sources, feedback will be made available to the participants based on an algorithm. The feedback will aim to help participants improve their activity and, as a consequence, their perceived QoL, and it will be provided on tablets, in a written and spoken form.

2.2 Select individuals to be participant of the pilots, as well as members of a control group.

A first study about the participants (habits, cognitive state, biomarkers, etc.) was performed.

In **Romania**, the Pilot Study will enrol a suitable sample of a total of 30 persons 65 years of age and older. All consecutive patients 65 years of age and older admitted to NIGG - Geriatrics

Clinical Ward 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 ability to use a computer and digital skills, until the sample target number is reached. Selected participants will be alternatively included in the study and control group in equal numbers and matched for age, sex and living area (rural or urban).

In **Cyprus** 20 participants will be selected and separated into two groups in order to pilot the impact of vINCI technology on QoL (including mood and exercise); hence, WHOQOL-Bref, IPAQ and DMAS questionnaires will be used in combination with data provided by watch, shows and camera. Please see section 3.2. for more detail.

3. Pilot characterization

In the pilot, the patient is continuously monitored through smartwatch and smart shoes. Every day, the patient visits a specially designed room, where he / she carries out a series of activities in front of the camera. This is necessary for the assessment of the potential for the degradation of the subject's mobility capacity.

Each clinical investigation has an associated ICT algorithm describing the medical process. Clinical partners will define / explain the process, so that ICT partners can design and develop the associated programmable model.

At a time interval (days or months), the subject will re-complete the questionnaire regarding the perceived level of quality of life (through the mobile tablet) and will revisit the NIGG partner's clinical facilities in order to be investigated (ECG, psychometric investigations etc.). The data will be used to update the patient's profile.

As the patient is monitored, he / she will be monitored through smartwatch (the main tool for out-door situations). For in-door, the shoes will provide a view on the patient's physical activity level, recognizing conditions such as walking, running, sitting etc. On the server side, we will detect a "timeline" of different alternating states over a time interval (one day, one week). The evolution in time of patient-related conditions over the specified time interval can lead to the

recognition of conditions for the degradation of psychosocial status (and including age-related frailty).

As for the depth camera, we intend to get the patient perform a series of physical activities in front of the camera and to evaluate how they get to "correctly" perform those activities - the results will be associated with conditions related to frailty. A dedicated room will be set up for this purpose in the clinical pilot. In addition, we also intend to test our algorithms for detection of the level of activity (e.g., how long the subject stays in front of the TV).

The layout for the dedicated room will consist of installation on the ceiling of a depth camera for recognizing the type of activity (routing in the room and activity level) and another one in front of the subject (for recognition of his / hers posture when performing activities). In algorithms, we will describe what "ideally done" action means (what cannot happen at a certain age) and what "correctly" done motion means (according to the conditions associated with the person's age - appearance that will result in the patient's profile). Finally, the pilot has combined inputs and outputs of all these aspects; an illustration of the operation process can be seen in Figure 3.1.



Figure 3.1: An aggregated view of the processes being supplied, in an integrated manner, throughout the vINCI clinical support framework.

3.1 Description of Pilot from Romania

In Romania, at the National Institute of Gerontology and Geriatrics "Ana Aslan", a clinical validation study will be performed on a total number of 30 persons 65 years of age and older, who will agree to participate in the study and will sign the informed consent. On an active screen tablet, the selected seniors will be able to self-complete a questionnaire WHOQOL-BREF¹ (World Health Organization Quality of Life Instrument, Short Form) that assesses their quality of life (QoL) across multiple domains. If their quality of life scores below the optimal level, evaluation of their psychological well-being and subjective and objective assessment of their physical activity level will be offered in a stepwise process. Because mood disorders and also the user's mood at the time of completion can influence the QoL score, the next step will be evaluation of psychological well-being. When the QoL and the psychological assessment results are sub-optimal, the user will be invited to further proceed with assessment of physical activity. The WHOQOL-BREF questionnaire has been translated into Romanian. The short-form version of the World Health Organization's Quality of Life measurement tools (WHOQOL-BREF) is a 26-item questionnaire that assesses quality of life on physical, psychological, social, and environmental domains.

The physical activity level will be subjectively evaluated with the International Physical Activity Questionnaire (IPAQ3). Users will be able to complete the IPAQ on the tablet and receive a feedback with regard to their physical activity level and recommended subsequent actions. Sedentary behaviour will additionally be evaluated with the smart camera which will record time spent sitting. The feedback will be constructed on an algorithm based on current physical activity scientific guidelines with the aim of reaching the recommended targets. The physical activity will be objectively evaluated with the smart shoes which will measure the daily number of steps as well as a median gait speed. The gait speed is a simple yet very important parameter for early identification of functional decline. When the gait speed falls below a predefined value, the user will receive a specific feedback, also on the tablet screen.

¹ http://www.who.int/mental_health/media/en/76.pdf

The Dynamic Visual Analogue Mood Scales (D-VAMS) are based on the Circumplex Model of Affect, and consist of seven bipolar scales: Miserable-Satisfied, Sad-Happy, Distressed-Peaceful, Bored- Excited, Afraid-Calm, Angry-Peaceful and Sleepy-Alert. The scales comprise images of human faces whose expressions change according to the position of a slider. D-VAMS (or "Emotiscope") is a brief, nonverbal mood assessment instrument designed for stroke patients with communication difficulties due to aphasia. It consists of sliders controlling transitions between facial expressions on seven scales (see Figure 3.2).



Figure 3.2: E.g. of 'smiley' faces series ranging from glumness to happy [4]

The cameras, watch, shoes, questionnaires, all these serve to get data related to the patient. The smart shoes will be able to give a picture of the physical activity level of the patient, by recognizing different states, like standing, running, walking. As for the depth camera, we intend to put the patient perform specific physical activities in front of the camera and evaluate his ability to perform "correctly" those activities - could we associate again this with deterioration associated with fragility conditions (like he is unable to reach the hand perfectly horizontally - what does this tell us?; he is not able to completely perform squats - what does this tell us?). The depth camera may be used for different purposes, such as:

- Monitoring how much time the patient spends sitting on a sofa or chair (with the camera in a top-view configuration, installed on the ceiling);
- Evaluating the capability of the subject to perform some physical tasks (with the camera in front-view with respect to the subject).

The smart watch offers the possibility of identifying the user's exact location for the outdoor situation.

Questionnaires have been defined to be employed in the monitoring of conditions. Also, it was finalized the description of hardware to be used by the patients (and their separation into kits), and technology to collect the data technology to be developed together with the particular constraints and desires coming from the older adult. For all these aspects, the end-user has the final word, as we want technology to be developed together with the particular constraints and desires coming from the older adult. For this, we defined a set of questionnaires to be applied in focus groups with older adults in the two clinical pilots. Based on the findings (what the users say when presenting with the technology, even if by now some parts will be mockups) will influence the construction of all our interfaces with the real-world.

3.2 Description of Pilot from Cyprus

In **Cyprus** participants who stay in nursing homes or attend day centres will be invited to participate in the pilot. 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. Within these contexts we will randomly distribute the WHOQOL-Bref questionnaire to 50 potential participants who meet the following criteria: older than 65, do not have any limiting conditions or mental conditions. We will then select 20 potential participants who will have the lowest score in the QoL questionnaire, separate them into two groups and pilot the impact of vINCI technology on QoL (including mood and exercise); hence, WHOQOL-Bref, IPAQ and DMAS questionnaires will be used in combination with data provided by watch, shows and camera.

The pilot will take place in nursing homes or day centres for older people because these are more controlled environments and as a result participant will be monitored more closely. At the same time, it will be easier for the researcher to make period visits to ensure that the participants use the technology and complete the questionnaires properly.

Because the numbers are small, the impact on quality of life, exercise and mood will be measured on a pilot basis. Even in the case no significant differences are identified between the two groups, the pilot will give us insights about which areas in participants' life can potentially change because of the use of technology and set the parameters for a larger-scale research in the future.

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3.3 Description of Pilot from Slovenia

The Pilot in Slovenia is planned to be executed as a second step of the "proof of concept". It will enable to provide a new environment that will be able to identify not detected issues from the first pilots. Such an environment can identify some of issues that is hard to detect according to fix of the first issues

4. Recruitment strategy

vINCI technology is aimed to older adults aged 65+. In order to increase the acceptance rate, the main benefits of the technology will be presented to them - for this purpose, a brochure presentation was made at this stage.

Validation technology will be performed in clinical trials (one pilot will run in Romania and one in Cyprus). In order to maximise efficiency, clinical validation 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 validation, the other being used for a technological testing.

The group in Cyprus will include 20 elderly adults and it will contribute to the technical validation of the vINCI platform.

Two open-call validations, at least 30 in the group test in Romania (CMD) and 30 in the group test in Slovenia (Comtrade) will be deployed in controlled environments for real-life use cases involving older adults across Europe.

4.1 Recruitment Methodology

The group in **Romania** will include older people living in outpatient settings at the National Institute of Gerontology and Geriatrics "Ana Aslan" in Bucharest.

The selection will include people with a wide range of deficiencies associated with old age. In addition, we will consider a gender balance, social affiliation so as to obtain a statistical relevance of the technology validation results.

The group in Romania will include 30 elderly adults, whom we will equip with smartwatches. When they are in the outpatient clinic, they will also wear smart shoes, and they will be asked to use the room with depth cameras.

All consecutive patients 65 years of age and older admitted to NIGG - Geriatrics Clinical Ward 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. Selected participants will be alternatively included in the study and control group in equal numbers and matched for age, sex and living area (rural or urban).

A questionnaire recruitment form was defined to establish the target group of the study (see Annex 1). One of the skills to be verified by the elderly is related to digital skills. Digital skills include: basic digital skills definition includes: managing information, communicating, transacting, problem solving and creating.

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

According to Gallardo et al. (2015) [5], digital competence requires the presence of four literacies: a) information literacy, for managing digital information; b) computer literacy, for treating data in different formats; c) media literacy, for analysing and creating multimedia messages; and d) communication literacy, for participating in a safe, ethical and civic manner from a digital identity.

European Union (EU) projects define digital competence as follows [6]: digital competence is the set of knowledge, skills, attitudes (thus including abilities, strategies, values and awareness) that are required when using ICT and digital media to perform tasks; solve problems; communicate; manage information; collaborate; create and share content; and build knowledge effectively, efficiently, appropriately, critically, creatively, autonomously, flexibly, ethically, reflectively for work, leisure, participation, learning, socializing, consuming, and empowerment (see Figure 4.1).



Figure 4.1: DIGCOMP: a framework for developing and understanding digital competence in Europe [7]

The exclusion criteria will apply to both study and control groups and will be the following:

- any acute or subacute medical condition,
- any surgery in the last 3 months,
- neurocognitive disorder (Montreal Cognitive Assessment MoCA <26),
- depression or anxiety (Geriatric Depression Scale GDS ≥5),
- heart failure functional class NYHA III-IV,
- chronic or acute ischemic heart disease (on electrocardiogram),
- angina pectoris,
- uncontrolled high blood pressure (>160 mmHg systolic),
- heart arrhythmias (on electrocardiogram),
- peripheral arterial disease,
- vertigo,
- risk of falls (Tinetti Tool Score < 24),
- frailty syndrome (PRISMA $7 \ge 3$ "yes" answers),
- stroke,
- any terminal illness,
- any condition that might limit mobility (e.g. Parkinson's disease, severe arthritis),
- disability (ADL needs human help in one or more basic activities of daily living),

- visual impairment (best corrected visual acuity of worse than either 20/40 or 20/60).

Exclusion criteria will be documented by anamnesis and from patients' medical charts and documented medical history. Prior to study initialization, all seniors will sign the Informed Consent form. The persons who do not sign the Informed Consent will be excluded

The group in Cyprus will include 20 elderly adults (see Section 3.2).

List of figures

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Annex 1 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) <i>it is planned that this will not occur, but if it occurs it</i> <i>should be recorded</i>	□_1 Yes	2 No
Acute or subacute medical condition	□₁Yes	2 No
Surgery in the last 3 months	□₁Yes	2 No
Neurocognitive disorder (Montreal Cognitive Assessment MoCA <26)	□₁Yes	2 No
Depression or anxiety (Geriatric Depression Scale GDS ≥5)	□₁Yes	2 No
Heart failure functional class NYHA III-IV	□₁Yes	2 No
Chronic or acute ischaemic heart disease	□₁Yes	_2 No
Has disability Needs human help in one or more basic activities of daily living	□₁Yes	2 No
Angina pectoris	□₁Yes	2 No
Uncontrolled high blood pressure (>160 mmHg systolic)	□ ₁ Yes	2 No
Heart arrhythmias	□ ₁ Yes	2 No
Peripheral arterial disease	□₁Yes	2 No
Vertigo	□₁Yes	2 No
Risk of falls (Tinetti Tool Score < 24)	□₁Yes	2 No
Frailty syndrome (PRISMA 7 ≥ 3 "yes" answers)	□₁Yes	2 No
Stroke	□₁Yes	2 No
Terminal illness	₁ Yes	2 No

Any condition that might limit mobility	1 Yes	2 No
Visual impairment	□₁Yes	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 complete baseline questionnaires, pers	son is excluded from	m study.
Inability or unwillingness to fully comply with vINCI instructions or does not appropriately use vINCI items	₁ Yes	2 No
	describe reason	
If parson doos not fully comply with vINCL instructions or doos	not appropriately (Ico VINCL itom

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

vINCI Study in Romania: Flow-Chart part I



vINCI Study in Romania: Flow-Chart part II



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 or subacute 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
Chronic or acute ischaemic heart disease	□_1 Yes	2 No
Has disability	1 Yes	2 No
Needs human help in one or more basic activities of daily living		
Angina pectoris	1 Yes	2 No

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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
Stroke	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	

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.

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